

Instruction for Use

- 1 [Family name] Orthodontic Pliers
- 2 [Manufacturer] YDM CORPORATION
- 3 [Model No and Device trade name]



ModelNo.	Device trade name	UDI-DI	Maximum cutting and bending capacities
22001	Adams Pliers Universal T/C	4963931220014	
22102	Orthodontic Pliers Band Contouring ND-202L	4963931221028	-
22104	Orthodontic Pliers Band Margin ND-204	4963931221042	-
22133	Orthodontic Pliers Band Removing ND-303	4963931221332	-
22141	Orthodontic Pliers Peeso ND-401	4963931221417	.040"
22142	Orthodontic Pliers Young ND-402	4963931221424	.040"
22143	Orthodontic Pliers Tweed Arch ND-403	4963931221431	.022"-.028"
22145	Orthodontic Pliers Tweed Loop Forming ND-405	4963931221455	.022"-.028"
22147	Orthodontic Pliers Three Jaw ND-407	4963931221479	.036"
22149	Orthodontic Pliers Bird Beak ND-409	4963931221493	.036"
22152	Orthodontic Pliers How ND-502L	4963931221523	-
22154	Orthodontic Pliers Utility ND-504	4963931221547	-
22155	Orthodontic Pliers How ND-502S	4963931221554	-
22159	Orthodontic Pliers Kim T/C ND-419	4963931221592	.016"-.022"(Bend)/.020"(Cut)
22160	Orthodontic Pliers Light Wire Cutter T/C ND-420	4963931221608	.020"(Bend/Cut)
22210	Orthodontic Pliers for Aligner Tear Drop	4963931222100	-
22211	Orthodontic Pliers for Aligner Vertical	4963931222117	-
22212	Orthodontic Pliers for Aligner Horizontal	4963931222124	-
22213	Orthodontic Pliers for Aligner Hole Punch	4963931222131	-
22506	Tying Pliers YS-506	4963931225064	-
22507	Tying Pliers YS-507	4963931225071	-
22508	Tying Pliers YS-508	4963931225088	-
22509	Module Pliers Str.	4963931225095	-
22510	Module Pliers Cvd.	4963931225101	-
22511	Module Pliers with Groove Str.	4963931225118	-
22513	Module Pliers Mosquito Str.	4963931225132	-
22514	Module Pliers Mosquito Cvd.	4963931225149	-
22551	Separator YS-551	4963931225514	-
22601	Wire Cutter YS-601	4963931226016	.032"
22602	Wire Cutter YS-602 KI	4963931226023	.045"
22603	Wire Cutter YS-603 Standard	4963931226030	.048"
22606	Pin & Ligature Cutter ND-605 with Hard Material	4963931226061	.012"
22607	Pin & Ligature Cutter ND-605B T/C	4963931226078	.014"
22610	Distal End Cutter ND-606S T/C	4963931226108	.022"-.028"
22611	Distal End Cutter ND-606LT/C	4963931226115	.022"-.028"
27410	Ortho.Pliers EVER Classic 410 Band Contouring	4963931274109	-
27411	Ortho.Pliers EVER Classic 411 Band Margin	4963931274116	-
27412	Ortho.Pliers EVER Classic 412 Band Removing	4963931274123	-
27413	Ortho.Pliers EVER C. 413 Bracket Removing T/C	4963931274130	-
27414	Ortho.Pliers EVER Classic 414 Young	4963931274147	.040"
27415	Ortho.Pliers EVER Classic 415 Tweed Arch	4963931274154	.022 x .028"
27416	Ortho.Pliers EVER C. 416 Tweed Loop Forming	4963931274161	.022 x .028"
27417	Ortho.Pliers EVER Classic 417 Three Jaw	4963931274178	.036"
27418	Ortho.Pliers EVER Classic 418 Bird Beak	4963931274185	.036"
27419	Ortho.Pliers EVER C. 419 Nance Closing Loop	4963931274192	.022"
27420	Ortho.Pliers EVER Classic 420 How	4963931274208	-
27421	Ortho.Pliers EVER Classic 421 Weingart	4963931274215	-
27422	Ortho.Pliers EVER Classic 422 Utility	4963931274222	-

27423	Ortho.Pliers EVER Classic 423 Kim T/C	4963931274239	.016"-.022"(Bend)/.020"(Cut)
27424	Ortho.Pliers EVER Classic 424 Light Wire T/C	4963931274246	.020"(Bend/Cut)
27425	Ortho.Pliers EVER Classic 425 Crimping	4963931274253	-
27426	Ortho.Pliers EVER C.426 Lingual Hollow Chop	4963931274260	.022 x .028"
27427	Ortho.Pliers EVER Classic 427 Torquing M	4963931274277	.022 x .028"
27428	Ortho.Pliers EVER Classic 428 Torquing F	4963931274284	.022 x .028"
27440	Ortho.Pliers EVER Fine 440 Utility	4963931274406	-
27441	Ortho.Pliers EVER Fine 441 Weingart	4963931274413	-
27442	Ortho.Pliers EVER Fine 442 How	4963931274420	-
27443	Ortho.Pliers EVER Fine 443 Band Removing	4963931274437	-
27444	Ortho.Pliers EVER F.444 Bracket Removing T/C	4963931274444	-
27445	Ortho.Pliers EVER Fine 445 Step 1/2mm	4963931274451	.022 x .028"
27446	Ortho.Pliers EVER Fine 446 Step 3/4mm	4963931274468	.022 x .028"
27447	Ortho.Pliers EVER Fine 447 Step 1mm	4963931274475	.022 x .028"
27448	Ortho.Pliers EVER Fine 448 Tear Drop	4963931274482	-
27449	Ortho.Pliers EVER Fine 449 Vertical	4963931274499	-
27450	Ortho.Pliers EVER Fine 450 Horizontal	4963931274505	-
27451	Ortho.Pliers EVER Fine 451 Hole Punch	4963931274512	-
27452	Ortho.Pliers EVER Fine 452 Light Wire T/C	4963931274529	.020"(Bend/Cut)
27453	Ortho.Pliers EVER Fine 453 Kim T/C	4963931274536	.016"-.022"(Bend)/.020"(Cut)
27454	Ortho.Pliers EVER Fine 454 Young	4963931274543	.040"
27455	Ortho.Pliers EVER Fine 455 Tweed Arch	4963931274550	.022 x .028"
27456	Ortho.Pliers EVER Fine 456 Tweed Loop Forming	4963931274567	.022 x .028"
27457	Ortho.Pliers EVER Fine 457 Three Jaw	4963931274574	.036"
27458	Ortho.Pliers EVER Fine 458 Bird Beak	4963931274581	.036"
27459	Ortho.Pliers EVER F. 459 Nance Closing Loop	4963931274598	.022"
27460	Ortho.Pliers EVER Fine 460 Band Removing L	4963931274604	-
27461	Ortho.Pliers EVER Fine 461 Cinch Back	4963931274611	.020"/.016"-016"
27462	Ortho.Pliers EVER Fine 462 Lingual Utility	4963931274628	-
27463	Ortho.Pliers EVER F.463 Round Former 1.0	4963931274635	-
27464	Ortho.Pliers EVER F.464 Round Former 2.0 SM	4963931274642	-
27465	Ortho.Pliers EVER Fine Key Punch 465	4963931274659	-
27550	Orthodontic Pliers Crimping Ortolan	4963931275502	-
27551	ROMAN 1 Circle Cutter SMOOTH	4963931275519	-
27552	ROMAN 2 Horizontal Box SMOOTH	4963931275526	-
27553	ROMAN 3 Vertical Box SMOOTH	4963931275533	-
27554	ROMAN 4 Pearl Dot SMOOTH	4963931275540	-
27555	ROMAN 5 Keyhole Cutter SMOOTH	4963931275557	-
27556	Angle Fluted Bird Beak Pliers	4963931275564	.036"
27601	Pin&Ligature Cutter EVER F.601 Angle 40	4963931276011	.012"
27602	Pin&Ligature Cutter EVER F.602 Reverse 40	4963931276028	.012"
27603	Pin&Ligature Cutter EVER F.603 Angle 50	4963931276035	.012"
27604	Pin&Ligature Cutter EVER F.604 Reverse 50	4963931276042	.012"
27605	Pin&Ligature Cutter EVER F.605 with Hard MATL	4963931276059	.012"
27606	Distal End Cutter EVER Fine 606S T/C	4963931276066	.022"-.028"
27607	Distal End Cutter EVER Fine 606L T/C	4963931276073	.022"-.028"
27615	Pin&Ligature Cutter EVER C.615 with Hard MATL	4963931276158	.014"
27934	Convertible Cap Removing Pliers ND-934	4963931279340	-
27935	Convertible Cap Removing Pliers ND-934 Blade	4963931279357	-

4 [The device's intended purpose]

The intended medical indication is to use to hold or to fix or to remove small objects or to bend or to cut metal strips or wire or to cut out or make dents in several places on the resin orthodontic appliance.

5 [The performance characteristics of the device]

<Overview>

This device is small pincers with variously shaped jaws depending on the purpose.

<Material>

Stainless steel

6 [How to use]

ModelNo.	Device trade name	How to use
22001	Adams Pliers Universal T/C	Hold,bend clasp wire to make retainer.
22102	Orthodontic Pliers Band Contouring ND-202L	Hold,bend edge of band to fit shape of teeth.
22104	Orthodontic Pliers Band Margin ND-204	Hold,bend edge of band to fit shape of teeth.
22133	Orthodontic Pliers Band Removing ND-303	Fit edge of band,occlusal side of teeth and remove band
22141	Orthodontic Pliers Peeso ND-401	Hold,bend archwire to apply torque,step.
22142	Orthodontic Pliers Young ND-402	Hold,bend archwire to make a roop.
22143	Orthodontic Pliers Tweed Arch ND-403	Hold,bend archwire to apply torque,step.
22145	Orthodontic Pliers Tweed Loop Forming ND-405	Hold,bend archwire to make a roop.
22147	Orthodontic Pliers Three Jaw ND-407	Hold,bend archwire to make a v shape.
22149	Orthodontic Pliers Bird Beak ND-409	Hold,bend archwire to make a roop.
22152	Orthodontic Pliers How ND-502L	Hold,tie ligature wire.
22154	Orthodontic Pliers Utility ND-504	Hold archwire and insert into braces,buccal tube.
22155	Orthodontic Pliers How ND-502S	Hold,tie ligature wire.
22159	Orthodontic Pliers Kim T/C ND-419	Hold,bend archwire to make a roop.
22160	Orthodontic Pliers Light Wire Cutter T/C ND-420	Hold,bend archwire to make a roop.
22210	Orthodontic Pliers for Aligner Tear Drop	Hold,apply additional funtion on aligner.
22211	Orthodontic Pliers for Aligner Vertical	Hold,apply additional funtion on aligner.
22212	Orthodontic Pliers for Aligner Horizontal	Hold,apply additional funtion on aligner.
22213	Orthodontic Pliers for Aligner Hole Punch	Hold,apply additional funtion on aligner.
22506	Tying Pliers YS-506	Hold,tie ligature wire.
22507	Tying Pliers YS-507	Hold,tie ligature wire.
22508	Tying Pliers YS-508	Hold,tie ligature wire.
22509	Module Pliers Str.	Hold erastic module and put on braces.
22510	Module Pliers Cvd.	Hold erastic module and put on braces.
22511	Module Pliers with Groove Str.	Hold erastic module and put on braces.
22513	Module Pliers Mosquito Str.	Hold erastic module and put on braces.
22514	Module Pliers Mosquito Cvd.	Hold erastic module and put on braces.
22551	Separator YS-551	Spread separating module and insert inter teeth.
22601	Wire Cutter YS-601	Hold,cut wire.
22602	Wire Cutter YS-602 KI	Hold,cut wire.
22603	Wire Cutter YS-603 Standard	Hold,cut wire.
22606	Pin & Ligature Cutter ND-605 with Hard Material	Hold,cut excess ligature wire.
22607	Pin & Ligature Cutter ND-605B T/C	Hold,cut excess ligature wire.
22610	Distal End Cutter ND-606S T/C	Hold,cut excess archwire.
22611	Distal End Cutter ND-606LT/C	Hold,cut excess archwire.
27410	Ortho.Pliers EVER Classic 410 Band Contouring	Hold,bend edge of band to fit shape of teeth.
27411	Ortho.Pliers EVER Classic 411 Band Margin	Hold,bend edge of band to fit shape of teeth.
27412	Ortho.Pliers EVER Classic 412 Band Removing	Fit edge of band,occlusal side of teeth and remove band
27413	Ortho.Pliers EVER C. 413 Bracket Removing T/C	Hold,remove braces.
27414	Ortho.Pliers EVER Classic 414 Young	Hold,bend archwire to make a roop.
27415	Ortho.Pliers EVER Classic 415 Tweed Arch	Hold,bend archwire to apply torque,step.
27416	Ortho.Pliers EVER C. 416 Tweed Loop Forming	Hold,bend archwire to make a roop.
27417	Ortho.Pliers EVER Classic 417 Three Jaw	Hold,bend archwire to make a v shape.
27418	Ortho.Pliers EVER Classic 418 Bird Beak	Hold,bend archwire to make a roop.
27419	Ortho.Pliers EVER C. 419 Nance Closing Loop	Hold,bend archwire to make a roop.
27420	Ortho.Pliers EVER Classic 420 How	Hold,tie ligature wire.
27421	Ortho.Pliers EVER Classic 421 Weingart	Hold archwire and insert into braces,buccal tube.
27422	Ortho.Pliers EVER Classic 422 Utility	Hold archwire and insert into braces,buccal tube.
27423	Ortho.Pliers EVER Classic 423 Kim T/C	Hold,bend archwire to make a roop.
27424	Ortho.Pliers EVER Classic 424 Light Wire T/C	Hold,bend archwire to make a roop.
27425	Ortho.Pliers EVER Classic 425 Crimping	Hold,apply crimpable hook on archwire.
27426	Ortho.Pliers EVER C.426 Lingual Hollow Chop	Hold,bend archwire to apply curve.
27427	Ortho.Pliers EVER Classic 427 Torquing M	Hold archwire with "27428",rotate to apply torque on archwire.
27428	Ortho.Pliers EVER Classic 428 Torquing F	Hold archwire with "27427",rotate to apply torque on archwire.
27440	Ortho.Pliers EVER Fine 440 Utility	Hold archwire and insert into braces,buccal tube.
27441	Ortho.Pliers EVER Fine 441 Weingart	Hold archwire and insert into braces,buccal tube.
27442	Ortho.Pliers EVER Fine 442 How	Hold,tie ligature wire.
27443	Ortho.Pliers EVER Fine 443 Band Removing	Fit edge of band,occlusal side of teeth and remove band
27444	Ortho.Pliers EVER F.444 Bracket Removing T/C	Hold,remove braces.
27445	Ortho.Pliers EVER Fine 445 Step 1/2mm	Hold,bend archwire to apply step.
27446	Ortho.Pliers EVER Fine 446 Step 3/4mm	Hold,bend archwire to apply step.
27447	Ortho.Pliers EVER Fine 447 Step 1mm	Hold,bend archwire to apply step.
27448	Ortho.Pliers EVER Fine 448 Tear Drop	Hold,apply additional funtion on aligner.
27449	Ortho.Pliers EVER Fine 449 Vertical	Hold,apply additional funtion on aligner.

27450	Ortho.Pliers EVER Fine 450 Horizontal	Hold,apply additional funtion on aligner.
27451	Ortho.Pliers EVER Fine 451 Hole Punch	Hold,apply additional funtion on aligner.
27452	Ortho.Pliers EVER Fine 452 Light Wire T/C	Hold,bend archwire to make a roop.
27453	Ortho.Pliers EVER Fine 453 Kim T/C	Hold,bend archwire to make a roop.
27454	Ortho.Pliers EVER Fine 454 Young	Hold,bend archwire to make a roop.
27455	Ortho.Pliers EVER Fine 455 Tweed Arch	Hold,bend archwire to apply torque,step.
27456	Ortho.Pliers EVER Fine 456 Tweed Loop Forming	Hold,bend archwire to make a roop.
27457	Ortho.Pliers EVER Fine 457 Three Jaw	Hold,bend archwire to make a v shape.
27458	Ortho.Pliers EVER Fine 458 Bird Beak	Hold,bend archwire to make a roop.
27459	Ortho.Pliers EVER F. 459 Nance Closing Loop	Hold,bend archwire to make a roop.
27460	Ortho.Pliers EVER Fine 460 Band Removing L	Fit edge of band,occcusal side of teeth and remove band
27461	Ortho.Pliers EVER Fine 461 Cinch Back	Hold,bend end of archwire.
27462	Ortho.Pliers EVER Fine 462 Lingual Utility	Hold archwire and insert into braces,buccal tube.
27463	Ortho.Pliers EVER F.463 Round Former 1.0	Hold,apply additional funtion on aligner.
27464	Ortho.Pliers EVER F.464 Round Former 2.0 SM	Hold,apply additional funtion on aligner.
27465	Ortho.Pliers EVER Fine Key Punch 465	Hold,apply additional funtion on aligner.
27550	Orthodontic Pliers Crimping Ortolan	Hold,apply crimpable hook on archwire.
27551	ROMAN 1 Circle Cutter SMOOTH	Hold,apply additional funtion on aligner.
27552	ROMAN 2 Horizontal Box SMOOTH	Hold,apply additional funtion on aligner.
27553	ROMAN 3 Vertical Box SMOOTH	Hold,apply additional funtion on aligner.
27554	ROMAN 4 Pearl Dot SMOOTH	Hold,apply additional funtion on aligner.
27555	ROMAN 5 Keyhole Cutter SMOOTH	Hold,apply additional funtion on aligner.
27556	Angle Fluted Bird Beak Pliers	Hold,bend end of archwire.
27601	Pin&Ligature Cutter EVER F.601 Angle 40	Hold,cut excess ligature wire.
27602	Pin&Ligature Cutter EVER F.602 Reverse 40	Hold,cut excess ligature wire.
27603	Pin&Ligature Cutter EVER F.603 Angle 50	Hold,cut excess ligature wire.
27604	Pin&Ligature Cutter EVER F.604 Reverse 50	Hold,cut excess ligature wire.
27605	Pin&Ligature Cutter EVER F.605 with Hard MATL	Hold,cut excess ligature wire.
27606	Distal End Cutter EVER Fine 606S T/C	Hold,cut excess archwire.
27607	Distal End Cutter EVER Fine 606L T/C	Hold,cut excess archwire.
27615	Pin&Ligature Cutter EVER C.615 with Hard MATL	Hold,cut excess ligature wire.
27722	Wire Cutter Heavy Duty	Cut wire.
27934	Convertible Cap Removing Pliers ND-934	Hold,remove cap of convertible tube.
27935	Convertible Cap Removing Pliers ND-934 Blade	Key part of "27934"

7 [General precautions and prohibition]

- 1) The use of the product is strictly limited to dental treatments.
Precautions must be followed to ensure the appropriate use of the instruments
- 2) Do not use the instruments for anything other than its intended use.
- 3) Clean, lubricate and sterilize before using instructed by IFU.
- 4) Do not use the instruments for patients who have a disease of hypersensitivity symptoms such as rash and dermatitis or allergic symptoms.
- 5) Do not change the design or remodel the instruments
- 6) Do not drop the instruments. Avoid any strong impact on the instruments.
- 7) When disposing of the instruments, follow the instructions detailed in appropriate national regulations.
- 8) Do not heat the instruments.
- 9) If chemicals adhere to the instruments, wipe it off immediately to avoid corrosion.
- 10) In bending the wire with this instruments, hold the wire with pliers and bend it with your finge to avoid damage to the pliers.
- 11) Stainless steel is more resistant to rust than iron, however it may corrode due to method of use and environment like temperature,humidity.

8 [Limitations on processing]

Stop using the instruments immediately if you find out deterioration or something strange.

9 [Initial treatment at the point of use]

Clean, lubricate and sterilize before using as IFU instructed.

10 [Preparation before cleaning]

See next section.

11 [The process of cleaning and sterilization/disinfection]

1) General cautions

a) In case of maintenance of instruments, please refer to the "The Fundamental Guide Book for Cleaning and Sterilizing Instruments" published by our company or the item of "maintenance" on our website (http://www.ydm.co.jp/en-new/pdf/The_process_of_cleaning_and_sterilizing.pdf).

b) The instruments contaminated with blood, body fluid, tissue fragments, chemicals, etc. shall be cleaned and sterilized immediately in compliance with following method in order to prevent the contaminants from drying out and sticking.

Contaminants attached to the instruments for a long time become difficult to be removed.

2) Procedure

a) Open the joint.

b) Clean the instruments with a cleaning agent in the method of i) or ii).

i) Use an ultrasonic cleaner with medical rust preventive detergent for 5 minutes.

ii) Immerse in a cleaner with a rust preventive detergent for medical use for 15 minutes.

c) Wash off dirt and cleaner adhered to the instruments with running water.

(If soap components remain on the surface of instruments, it cause rust, stains.)

d) Dry the instruments. (Remaining moisture may cause rust, reduce sterilization effect)

e) Add anti-rust lubricant such as "instrument oil" to the joint.

* Do not open or close until anti-rust lubricant is added. (Opening and closing without oil will cause galling)

f) Sterilize with using an autoclave sterilizer.

Conditions: 134°C to 138°C, 3 minutes to 3.5 minutes

* To prevent scratches because of contact with other instruments, put them in a sterilized pack or case.

g) After use, clean immediately according to b) above.

3) Cautions of cleaning and sterilization/disinfection

a) Do not use the following chemicals as they may cause metal corrosion.

sodium hypochlorite, benzalkonium chloride, chlorhexidine gluconate, tincture of iodine, Iodoform and peracetic acid may corrode metal.

b) Do not use chemical autoclave on the instruments, which may cause corrosion.

c) Do not perform plasma sterilization as it may affect the material.

d) Do not use household cleaning agents as it's not suitable with remove protein on the surface of instruments.

e) Wire brush and steel wool may cause damage instruments.

f) Do not use Super Acidic Water as it may cause corrosion.

Purified water (no impurities) is recommended for rinsing.

Tap water contains chlorine, which may corrode the metal.

g) When using a washer-disinfector, the stucked dirt or cleaning solution may not be completely removed if water saving or a time saving program is used. Be sure to refer to the manufacturer's instruction manual, etc. to ensure rinsing and to remove dirt.

h) Note the following when handling autoclave sterilizers.

i) The autoclave sterilizer may be contaminated in the cabinet depending on the usage status and period. If dirt remain autoclave sterilizer they may stick to the instruments.

We recommend cleaning according to instruction manual of the sterilizer.

Then inside of the chamber does not become dirty. In particular, the rubber seal on the chamber lid and air filter shall be replaced in a certain of period.

ii) Use purified water as much as possible. When tap water may cause of corrosion due to the influence of chlorine ions.

iii) Pay attention to the drying temperature inside autoclave sterilizer.

iv) Do not place this instruments near the heater. (It may be higher than the indicated temperature)

v) If cleaning and rinsing are not complete inside autoclave sterilizer, or moisture remains autoclave sterilizer chamber, it may cause of burn on the surface of the instruments.

i) After washing and sterilization, remove the water adhering to the instrument and dry it completely

12 [Maintenance, Inspection and Testing]

After cleaning and sterilization, check the following before use.

1) Check that there is no dirt, damage, cracks, scratches or corrosion on the inside of the joint and the joint.

2) Check for abnormal movement of the joint.

13 [Storage]

- 1) Store in a clean place free from dust, avoid high temperature, humidity.
- 2) To prevent galvanic current due to metal potential difference, do not store with instruments made of different materials.
- 3) Note the following in order to prevent rust stains.
 - a) Do not store with rusted instruments.
 - b) Do not store with chemicals.
 - c) Pay attention to rust inside sterilizers and storages.

14 [Disposal considerations]

Dental specialists and / or orthodontists are responsible for disposal in accordance with relevant applicable law. YDM CORPORATION doesn't take responsibility for disclaims caused by improper disposal personal injury.

15 [Additional information]

<Breakage or Sharpening>

In case of breakage of instruments, please report to dealer from which you purchased in format prepared by YDM CORPORATION named "Claim Report".

In case of sharpening of cutters, we will do with a certain of charges.

16 [Manufacturer contact]



YDM CORPORATION

28 Imaizumi, Higashi-Matsuyama-shi,

Saitama 355-0042, Japan

TEL: 81-3-3828-3161 FAX: 81-3-3827-8991

URL: <http://www.ydm.co.jp/> E-mail: ydm@ydm.co.jp

17 [Notice to the user and/or patient]

Any serious incident that has occurred in relation to the instruments should be reported to the YDM CORPORATION.

18 [Additional information]

In case of defect of device, please report to dealer from which you purchased in format prepared by YDM Corporation named "Claim Report".

19 [Description of symbols]



Medical device



Manufacturere



Lot number



Notice

The instructions provided above have been validated by the manufacturer of the medical device as being capable of preparing a medical device for reuse. It remains the responsibility of the processor to ensure that the processing, as actually performed using equipment, materials and personnel in the processing facility, achieves the desired result. This requires verification and/or validation and routine monitoring of the process.

Ver.01 23th June, 2021

Ver.02 24th August, 2022

Ver.03 6th July, 2023

- 1 [Familiename] Orthodontische Zangen
- 2 [Hersteller] YDM CORPORATION
- 3 [ModellNr. und Handelsname]



ModellNr.	Handelsname	UDI-DI	Maximale Schneid- und Biegefähigkeit
22001	Adams Pliers Universal T/C	4963931220014	
22102	Orthodontic Pliers Band Contouring ND-202L	4963931221028	-
22104	Orthodontic Pliers Band Margin ND-204	4963931221042	-
22133	Orthodontic Pliers Band Removing ND-303	4963931221332	-
22141	Orthodontic Pliers Peeso ND-401	4963931221417	,040"
22142	Orthodontic Pliers Young ND-402	4963931221424	,040"
22143	Orthodontic Pliers Tweed Arch ND-403	4963931221431	,022"- ,028"
22145	Orthodontic Pliers Tweed Loop Forming ND-405	4963931221455	,022"- ,028"
22147	Orthodontic Pliers Three Jaw ND-407	4963931221479	,036"
22149	Orthodontic Pliers Bird Beak ND-409	4963931221493	,036"
22152	Orthodontic Pliers How ND-502L	4963931221523	-
22154	Orthodontic Pliers Utility ND-504	4963931221547	-
22155	Orthodontic Pliers How ND-502S	4963931221554	-
22159	Orthodontic Pliers Kim T/C ND-419	4963931221592	,016"- ,022"(Bieg.)/ ,020"(Schneid.)
22160	Orthodontic Pliers Light Wire Cutter T/C ND-420	4963931221608	,020"(Bieg./Schneid.)
22210	Orthodontic Pliers for Aligner Tear Drop	4963931222100	-
22211	Orthodontic Pliers for Aligner Vertical	4963931222117	-
22212	Orthodontic Pliers for Aligner Horizontal	4963931222124	-
22213	Orthodontic Pliers for Aligner Hole Punch	4963931222131	-
22506	Tying Pliers YS-506	4963931225064	-
22507	Tying Pliers YS-507	4963931225071	-
22508	Tying Pliers YS-508	4963931225088	-
22509	Module Pliers Str.	4963931225095	-
22510	Module Pliers Cvd.	4963931225101	-
22511	Module Pliers with Groove Str.	4963931225118	-
22513	Module Pliers Mosquito Str.	4963931225132	-
22514	Module Pliers Mosquito Cvd.	4963931225149	-
22551	Separator YS-551	4963931225514	-
22601	Wire Cutter YS-601	4963931226016	,032"
22602	Wire Cutter YS-602 KI	4963931226023	,045"
22603	Wire Cutter YS-603 Standard	4963931226030	,048"
22606	Pin & Ligature Cutter ND-605 with Hard Material	4963931226061	,012"
22607	Pin & Ligature Cutter ND-605B T/C	4963931226078	,014"
22610	Distal End Cutter ND-606S T/C	4963931226108	,022"- ,028"
22611	Distal End Cutter ND-606LT/C	4963931226115	,022"- ,028"
27410	Ortho.Pliers EVER Classic 410 Band Contouring	4963931274109	-
27411	Ortho.Pliers EVER Classic 411 Band Margin	4963931274116	-
27412	Ortho.Pliers EVER Classic 412 Band Removing	4963931274123	-
27413	Ortho.Pliers EVER C. 413 Bracket Removing T/C	4963931274130	-
27414	Ortho.Pliers EVER Classic 414 Young	4963931274147	,040"
27415	Ortho.Pliers EVER Classic 415 Tweed Arch	4963931274154	,022 x ,028"
27416	Ortho.Pliers EVER C. 416 Tweed Loop Forming	4963931274161	,022 x ,028"
27417	Ortho.Pliers EVER Classic 417 Three Jaw	4963931274178	,036"
27418	Ortho.Pliers EVER Classic 418 Bird Beak	4963931274185	,036"
27419	Ortho.Pliers EVER C. 419 Nance Closing Loop	4963931274192	,022"
27420	Ortho.Pliers EVER Classic 420 How	4963931274208	-
27421	Ortho.Pliers EVER Classic 421 Weingart	4963931274215	-
27422	Ortho.Pliers EVER Classic 422 Utility	4963931274222	-
27423	Ortho.Pliers EVER Classic 423 Kim T/C	4963931274239	,016"- ,022"(Bieg.)/ ,020"(Schneid.)
27424	Ortho.Pliers EVER Classic 424 Light Wire T/C	4963931274246	,020"(Bieg./Schneid.)
27425	Ortho.Pliers EVER Classic 425 Crimping	4963931274253	-
27426	Ortho.Pliers EVER C.426 Lingual Hollow Chop	4963931274260	,022 x ,028"
27427	Ortho.Pliers EVER Classic 427 Torquing M	4963931274277	,022 x ,028"
27428	Ortho.Pliers EVER Classic 428 Torquing F	4963931274284	,022 x ,028"
27440	Ortho.Pliers EVER Fine 440 Utility	4963931274406	-
27441	Ortho.Pliers EVER Fine 441 Weingart	4963931274413	-
27442	Ortho.Pliers EVER Fine 442 How	4963931274420	-
27443	Ortho.Pliers EVER Fine 443 Band Removing	4963931274437	-
27444	Ortho.Pliers EVER F.444 Bracket Removing T/C	4963931274444	-

27445	Ortho.Pliers EVER Fine 445 Step 1/2mm	4963931274451	,022 x ,028"
27446	Ortho.Pliers EVER Fine 446 Step 3/4mm	4963931274468	,022 x ,028"
27447	Ortho.Pliers EVER Fine 447 Step 1mm	4963931274475	,022 x ,028"
27448	Ortho.Pliers EVER Fine 448 Tear Drop	4963931274482	-
27449	Ortho.Pliers EVER Fine 449 Vertical	4963931274499	-
27450	Ortho.Pliers EVER Fine 450 Horizontal	4963931274505	-
27451	Ortho.Pliers EVER Fine 451 Hole Punch	4963931274512	-
27452	Ortho.Pliers EVER Fine 452 Light Wire T/C	4963931274529	,020"(Bieg./Schneid.)
27453	Ortho.Pliers EVER Fine 453 Kim T/C	4963931274536	,016"-,022"(Bieg.),,020"(Schneid.)
27454	Ortho.Pliers EVER Fine 454 Young	4963931274543	,040"
27455	Ortho.Pliers EVER Fine 455 Tweed Arch	4963931274550	,022 x ,028"
27456	Ortho.Pliers EVER Fine 456 Tweed Loop Forming	4963931274567	,022 x ,028"
27457	Ortho.Pliers EVER Fine 457 Three Jaw	4963931274574	,036"
27458	Ortho.Pliers EVER Fine 458 Bird Beak	4963931274581	,036"
27459	Ortho.Pliers EVER F. 459 Nance Closing Loop	4963931274598	,022"
27460	Ortho.Pliers EVER Fine 460 Band Removing L	4963931274604	-
27461	Ortho.Pliers EVER Fine 461 Cinch Back	4963931274611	,020"/,016"-016"
27462	Ortho.Pliers EVER Fine 462 Lingual Utility	4963931274628	-
27463	Ortho.Pliers EVER F.463 Round Former 1.0	4963931274635	-
27464	Ortho.Pliers EVER F.464 Round Former 2.0 SM	4963931274642	-
27465	Ortho.Pliers EVER Fine Key Punch 465	4963931274659	-
27550	Orthodontic Pliers Crimping Ortolan	4963931275502	-
27551	ROMAN 1 Circle Cutter SMOOTH	4963931275519	-
27552	ROMAN 2 Horizontal Box SMOOTH	4963931275526	-
27553	ROMAN 3 Vertical Box SMOOTH	4963931275533	-
27554	ROMAN 4 Pearl Dot SMOOTH	4963931275540	-
27555	ROMAN 5 Keyhole Cutter SMOOTH	4963931275557	-
27556	Angle Fluted Bird Beak Pliers	4963931275564	,036"
27601	Pin&Ligature Cutter EVER F.601 Angle 40	4963931276011	,012"
27602	Pin&Ligature Cutter EVER F.602 Reverse 40	4963931276028	,012"
27603	Pin&Ligature Cutter EVER F.603 Angle 50	4963931276035	,012"
27604	Pin&Ligature Cutter EVER F.604 Reverse 50	4963931276042	,012"
27605	Pin&Ligature Cutter EVER F.605 with Hard MATL	4963931276059	,012"
27606	Distal End Cutter EVER Fine 606S T/C	4963931276066	,022"-,028"
27607	Distal End Cutter EVER Fine 606L T/C	4963931276073	,022"-,028"
27615	Pin&Ligature Cutter EVER C.615 with Hard MATL	4963931276158	,014"
27934	Convertible Cap Removing Pliers ND-934	4963931279340	-
27935	Convertible Cap Removing Pliers ND-934 Blade	4963931279357	-

4 [Verwendungszweck]

Die vorgesehene medizinische Indikation ist das Halten, Fixieren oder Entfernen kleiner Gegenstände und das Biegen oder Schneiden von Metallbändern oder Drähten oder das Ausschneiden oder Aussparen an verschiedenen Stellen der orthodontischen Vorrichtung aus Kunstharz.

5 [Leistungsmerkmale]

<Übersicht>

Dieses Gerät ist eine kleine Zange mit verschiedenen geformten Klemmbacken (abhängig von ihrem Verwendungszweck).

<Material>

Edelstahl

ModellNr.	Handelsname	Gebrauchshinweise
22001	Adams Pliers Universal T/C	Halten, Biegen von Klammern und Draht für Retainer.
22102	Orthodontic Pliers Band Contouring ND-202L	Halten, Biegen der Bandkante; passend auf Zahnform.
22104	Orthodontic Pliers Band Margin ND-204	Halten, Biegen der Bandkante; passend auf Zahnform.
22133	Orthodontic Pliers Band Removing ND-303	Anpassen der Bandkante, okklusale Seite und Entfernen v. Band.
22141	Orthodontic Pliers Peeso ND-401	Halten, Biegen d. Bogendrahts um Drehmoment zu erzeugen, Stufe.
22142	Orthodontic Pliers Young ND-402	Halten, Biegen d. Bogendrahts zur Schlaufe.
22143	Orthodontic Pliers Tweed Arch ND-403	Halten, Biegen d. Bogendrahts um Drehmoment zu erzeugen, Stufe.
22145	Orthodontic Pliers Tweed Loop Forming ND-405	Halten, Biegen d. Bogendrahts zur Schlaufe.
22147	Orthodontic Pliers Three Jaw ND-407	Halten, Biegen d. Bogendrahts zur V-Form.
22149	Orthodontic Pliers Bird Beak ND-409	Halten, Biegen d. Bogendrahts zur Schlaufe.
22152	Orthodontic Pliers How ND-502L	Halten, Festziehen des Ligaturendrahts.
22154	Orthodontic Pliers Utility ND-504	Halten d. Bogendrahts und Einführen in Spange, Bukkalröhrchen.
22155	Orthodontic Pliers How ND-502S	Halten, Festziehen des Ligaturendrahts.
22159	Orthodontic Pliers Kim T/C ND-419	Halten, Biegen d. Bogendrahts zur Schlaufe.
22160	Orthodontic Pliers Light Wire Cutter T/C ND-420	Halten, Biegen d. Bogendrahts zur Schlaufe.
22210	Orthodontic Pliers for Aligner Tear Drop	Halten, zusätzliche Funktionen an Aligner verbessern.
22211	Orthodontic Pliers for Aligner Vertical	Halten, zusätzliche Funktionen an Aligner verbessern.
22212	Orthodontic Pliers for Aligner Horizontal	Halten, zusätzliche Funktionen an Aligner verbessern.
22213	Orthodontic Pliers for Aligner Hole Punch	Halten, zusätzliche Funktionen an Aligner verbessern.
22506	Tying Pliers YS-506	Halten, Festziehen des Ligaturendrahts.
22507	Tying Pliers YS-507	Halten, Festziehen des Ligaturendrahts.
22508	Tying Pliers YS-508	Halten, Festziehen des Ligaturendrahts.
22509	Module Pliers Str.	Halten des elastischen Moduls und Einsetzen der Spange.
22510	Module Pliers Cvd.	Halten des elastischen Moduls und Einsetzen der Spange.
22511	Module Pliers with Groove Str.	Halten des elastischen Moduls und Einsetzen der Spange.
22513	Module Pliers Mosquito Str.	Halten des elastischen Moduls und Einsetzen der Spange.
22514	Module Pliers Mosquito Cvd.	Halten des elastischen Moduls und Einsetzen der Spange.
22551	Separator YS-551	Spreizen des Trennmoduls und Einsetzen zwischen Zähne.
22601	Wire Cutter YS-601	Halten, Schneiden von Draht.
22602	Wire Cutter YS-602 KI	Halten, Schneiden von Draht.
22603	Wire Cutter YS-603 Standard	Halten, Schneiden von Draht.
22606	Pin & Ligature Cutter ND-605 with Hard Material	Halten, Schneiden von überschüssigem Ligaturendraht.
22607	Pin & Ligature Cutter ND-605B T/C	Halten, Schneiden von überschüssigem Ligaturendraht.
22610	Distal End Cutter ND-606S T/C	Halten, Schneiden von überschüssigem Bogendraht.
22611	Distal End Cutter ND-606LT/C	Halten, Schneiden von überschüssigem Bogendraht.
27410	Ortho.Pliers EVER Classic 410 Band Contouring	Halten, Biegen der Bandkante; passend auf Zahnform.
27411	Ortho.Pliers EVER Classic 411 Band Margin	Halten, Biegen der Bandkante; passend auf Zahnform.
27412	Ortho.Pliers EVER Classic 412 Band Removing	Anpassen der Bandkante, okklusale Seite und Entfernen v. Band.
27413	Ortho.Pliers EVER C. 413 Bracket Removing T/C	Halten, Entfernen der Spange.
27414	Ortho.Pliers EVER Classic 414 Young	Halten, Biegen d. Bogendrahts zur Schlaufe.
27415	Ortho.Pliers EVER Classic 415 Tweed Arch	Halten, Biegen d. Bogendrahts um Drehmoment zu erzeugen, Stufe.
27416	Ortho.Pliers EVER C. 416 Tweed Loop Forming	Halten, Biegen d. Bogendrahts zur Schlaufe.
27417	Ortho.Pliers EVER Classic 417 Three Jaw	Halten, Biegen d. Bogendrahts zur V-Form.
27418	Ortho.Pliers EVER Classic 418 Bird Beak	Halten, Biegen d. Bogendrahts zur Schlaufe.
27419	Ortho.Pliers EVER C. 419 Nance Closing Loop	Halten, Biegen d. Bogendrahts zur Schlaufe.
27420	Ortho.Pliers EVER Classic 420 How	Halten, Festziehen des Ligaturendrahts.
27421	Ortho.Pliers EVER Classic 421 Weingart	Halten d. Bogendrahts und Einführen in Spange, Bukkalröhrchen.
27422	Ortho.Pliers EVER Classic 422 Utility	Halten d. Bogendrahts und Einführen in Spange, Bukkalröhrchen.
27423	Ortho.Pliers EVER Classic 423 Kim T/C	Halten, Biegen d. Bogendrahts zur Schlaufe.
27424	Ortho.Pliers EVER Classic 424 Light Wire T/C	Halten, Biegen d. Bogendrahts zur Schlaufe.
27425	Ortho.Pliers EVER Classic 425 Crimping	Halten, Anbringen des klemmbaren Hakens am Bogendraht.
27426	Ortho.Pliers EVER C.426 Lingual Hollow Chop	Halten, Biegen d. Bogendrahts um Rundung zu erzeugen.
27427	Ortho.Pliers EVER Classic 427 Torquing M	Halten d. Bogendrahts mit „27428“; Drehen, um Drehmoment auf Bogendraht zu erzeugen.
27428	Ortho.Pliers EVER Classic 428 Torquing F	Halten d. Bogendrahts mit „27427“; Drehen, um Drehmoment auf Bogendraht zu erzeugen.
27440	Ortho.Pliers EVER Fine 440 Utility	Halten d. Bogendrahts und Einführen in Spange, Bukkalröhrchen.
27441	Ortho.Pliers EVER Fine 441 Weingart	Halten d. Bogendrahts und Einführen in Spange, Bukkalröhrchen.
27442	Ortho.Pliers EVER Fine 442 How	Halten, Festziehen des Ligaturendrahts.
27443	Ortho.Pliers EVER Fine 443 Band Removing	Anpassen der Bandkante, okklusale Seite und Entfernen v. Band.
27444	Ortho.Pliers EVER F.444 Bracket Removing T/C	Halten, Entfernen der Spange.
27445	Ortho.Pliers EVER Fine 445 Step 1/2mm	Halten, Biegen d. Bogendrahts um Stufe zu erzeugen.
27446	Ortho.Pliers EVER Fine 446 Step 3/4mm	Halten, Biegen d. Bogendrahts um Stufe zu erzeugen.
27447	Ortho.Pliers EVER Fine 447 Step 1mm	Halten, Biegen d. Bogendrahts um Stufe zu erzeugen.
27448	Ortho.Pliers EVER Fine 448 Tear Drop	Halten, zusätzliche Funktionen an Aligner verbessern.
27449	Ortho.Pliers EVER Fine 449 Vertical	Halten, zusätzliche Funktionen an Aligner verbessern.

27450	Ortho.Pliers EVER Fine 450 Horizontal	Halten, zusätzliche Funktionen an Aligner verbessern.
27451	Ortho.Pliers EVER Fine 451 Hole Punch	Halten, zusätzliche Funktionen an Aligner verbessern.
27452	Ortho.Pliers EVER Fine 452 Light Wire T/C	Halten, Biegen d. Bogendrahts zur Schlaufe.
27453	Ortho.Pliers EVER Fine 453 Kim T/C	Halten, Biegen d. Bogendrahts zur Schlaufe.
27454	Ortho.Pliers EVER Fine 454 Young	Halten, Biegen d. Bogendrahts zur Schlaufe.
27455	Ortho.Pliers EVER Fine 455 Tweed Arch	Halten, Biegen d. Bogendrahts um Drehmoment zu erzeugen, Stufe.
27456	Ortho.Pliers EVER Fine 456 Tweed Loop Forming	Halten, Biegen d. Bogendrahts zur Schlaufe.
27457	Ortho.Pliers EVER Fine 457 Three Jaw	Halten, Biegen d. Bogendrahts zur V-Form.
27458	Ortho.Pliers EVER Fine 458 Bird Beak	Halten, Biegen d. Bogendrahts zur Schlaufe.
27459	Ortho.Pliers EVER F. 459 Nance Closing Loop	Halten, Biegen d. Bogendrahts zur Schlaufe.
27460	Ortho.Pliers EVER Fine 460 Band Removing L	Anpassen der Bandkante, okklusale Seite und Entfernen v. Band.
27461	Ortho.Pliers EVER Fine 461 Cinch Back	Halten, Biegen des Bogendrahtendes.
27462	Ortho.Pliers EVER Fine 462 Lingual Utility	Halten d. Bogendrahts und Einführen in Spange, Bukkalröhrchen.
27463	Ortho.Pliers EVER F.463 Round Former 1.0	Halten, zusätzliche Funktionen an Aligner verbessern.
27464	Ortho.Pliers EVER F.464 Round Former 2.0 SM	Halten, zusätzliche Funktionen an Aligner verbessern.
27465	Ortho.Pliers EVER Fine Key Punch 465	Halten, zusätzliche Funktionen an Aligner verbessern.
27550	Orthodontic Pliers Crimping Ortolan	Halten, Anbringen des klemmbaren Hakens am Bogendraht.
27551	ROMAN 1 Circle Cutter SMOOTH	Halten, zusätzliche Funktionen an Aligner verbessern.
27552	ROMAN 2 Horizontal Box SMOOTH	Halten, zusätzliche Funktionen an Aligner verbessern.
27553	ROMAN 3 Vertical Box SMOOTH	Halten, zusätzliche Funktionen an Aligner verbessern.
27554	ROMAN 4 Pearl Dot SMOOTH	Halten, zusätzliche Funktionen an Aligner verbessern.
27555	ROMAN 5 Keyhole Cutter SMOOTH	Halten, zusätzliche Funktionen an Aligner verbessern.
27556	Angle Fluted Bird Beak Pliers	Halten, Biegen des Bogendrahtendes.
27601	Pin&Ligature Cutter EVER F.601 Angle 40	Halten, Schneiden von überschüssigem Ligaturendraht.
27602	Pin&Ligature Cutter EVER F.602 Reverse 40	Halten, Schneiden von überschüssigem Ligaturendraht.
27603	Pin&Ligature Cutter EVER F.603 Angle 50	Halten, Schneiden von überschüssigem Ligaturendraht.
27604	Pin&Ligature Cutter EVER F.604 Reverse 50	Halten, Schneiden von überschüssigem Ligaturendraht.
27605	Pin&Ligature Cutter EVER F.605 with Hard MATL	Halten, Schneiden von überschüssigem Ligaturendraht.
27606	Distal End Cutter EVER Fine 606S T/C	Halten, Schneiden von überschüssigem Bogendraht.
27607	Distal End Cutter EVER Fine 606L T/C	Halten, Schneiden von überschüssigem Bogendraht.
27615	Pin&Ligature Cutter EVER C.615 with Hard MATL	Halten, Schneiden von überschüssigem Ligaturendraht.
27722	Wire Cutter Heavy Duty	Schneiden von Draht.
27934	Convertible Cap Removing Pliers ND-934	Halten, Entfernen von Kappe des konvertiblen Röhrchens.
27935	Convertible Cap Removing Pliers ND-934 Blade	Wichtiges Bestandteil von „27934“

7 [Allgemeine Vorsichtsmaßnahmen und Einschränkungen]

- 1) Die Verwendung des Produkts ist strikt auf zahnärztliche Behandlungen beschränkt.
Vorsichtsmaßnahmen müssen eingehalten werden, um die zweckmäßige Verwendung des Instruments sicherzustellen.
- 2) Verwenden Sie das Instrument ausschließlich für den vorgesehenen Zweck.
- 3) Vor Gebrauch wie durch die IFU angewiesen reinigen, schmieren und sterilisieren.
- 4) Verwenden Sie dieses Instrument nicht für Patienten mit hypersensitiven Reaktionen wie Ausschlag und Dermatitis oder allergischen Reaktionen.
- 5) Nehmen Sie keinerlei Änderungen an dem Instrument vor.
- 6) Lassen Sie das Instrument nicht fallen. Schützen Sie das Instrument vor starken Stößen.
- 7) Folgen Sie bei der Entsorgung des Instruments den in den jeweiligen landesspezifischen Bestimmungen vorgegebenen Hinweisen.
- 8) Erhitzen Sie das Instrument nicht.
- 9) Wischen Sie Chemikalien zur Vermeidung von Korrosion ggf. sofort vom Instrument ab.
- 10) Halten Sie beim Biegen von Draht mit diesem Instrument den Draht mit der Zange und biegen Sie ihn mit den Fingern, um die Zange nicht zu beschädigen.
- 11) Edelstahl ist widerstandsfähiger gegen Rost als Eisen. Abhängig von der Art der Nutzung und den Umgebungsbedingungen (Temperatur, Luftfeuchtigkeit) ist eine Korrosion trotzdem möglich.

8 [Einschränkungen der Nutzung]

Unterlassen Sie umgehend die Verwendung des Instruments, wenn es abgenutzt oder unerklärlich verändert ist.

9 [Erste Behandlung am Ort der Verwendung]

Vor Gebrauch, wie durch die IFU instruiert, reinigen, schmieren und sterilisieren.

10 [Vor der Reinigung]

Siehe nächster Abschnitt.

11 [Reinigung und Sterilisation/Desinfizierung]

1) Allgemeine Warnhinweise

a) Beachten Sie bei der Instandhaltung des Instruments die von unserem Unternehmen herausgegebene Anleitung „The Fundamental Guide Book for Cleaning and Sterilizing Instruments“ (Grundlegende Hinweise für die Reinigung und Sterilisation von Instrumenten) und die Hinweise unter Menüpunkt „Maintenance“ (Instandhaltung) auf unserer Website (Instandhaltung) auf unserer Website

(http://www.ydm.co.jp/en-new/pdf/The_process_of_cleaning_and_sterilizing.pdf).

b) Das mit Blut, Körperflüssigkeiten, Gewebefragmenten, Chemikalien usw. verunreinigte Instrument ist unverzüglich gemäß dem folgenden Verfahren zu reinigen und zu sterilisieren.

Verunreinigungen, die lange Zeit an den Instrumenten haften, lassen sich nur schwer entfernen.

2) Verfahren

a) Öffnen Sie das Gelenk.

b) Reinigen Sie das Instrument mit einem Reinigungsmittel gemäß Verfahren i) oder ii).

i) Verwendung eines Ultraschallreinigers mit medizinischem Reiniger (mit Rostschutzmittel) für 5 Minuten.

ii) In einen medizinischen Reiniger mit Rostschutz eintauchen und 15 Minuten einwirken lassen.

c) Schmutz und Reinigungsflüssigkeit unter fließendem Wasser vom Instrument abwaschen.

(Seifenrückstände können zu Rost, Flecken an der Oberfläche des Instruments führen.)

d) Instrument trocknen. (Restfeuchtigkeit kann Rost verursachen und die Sterilisationswirkung verringern)

e) Rostschutzschmierstoff wie „Instrument Oil“ am Gelenk auftragen.

* Nicht öffnen oder schließen, bis der Rostschutzschmierstoff aufgetragen wurde.

(Das Öffnen und Schließen ohne Schmierstoff verursacht Kaltverschweißung)

f) Sterilisation in einem Autoklav.

Einstellungen: 134°C bis 138°C, 3 bis 3,5 Minuten

* Um Kratzer durch den Kontakt mit anderen Instrumenten zu verhindern, wird empfohlen, diese in ein sterilisiertes Behältnis zu geben.

g) Nach der Verwendung unverzüglich gemäß (b) oben reinigen.

3) Warnhinweise zur Reinigung und Sterilisation/Desinfizierung

a) Verwenden Sie keine der folgenden Chemikalien, da diese Korrosion verursachen können.

Natriumhypochlorid, Benzalkoniumchlorid, Chlorhexidingluconat, Jodtinktur, Iodoform und Peressigsäure können Korrosion verursachen.

b) Instrument wegen Korrosionsgefahr nicht chemisch autoklavieren.

c) Zur Vermeidung von Materialschäden keine Plasmasterilisation durchführen.

d) Keine Haushaltsreiniger zur Entfernung von Proteinresten an der Oberfläche des Instruments verwenden.

e) Drahtbürsten und Stahlwolle können Beschädigungen am Instrument verursachen.

f) Wegen Korrosionsgefahr kein stark saures Wasser verwenden.

Stattdessen wird zum Abspülen die Verwendung von demineralisiertem Wasser (ohne Verunreinigungen) empfohlen. Chlorhaltiges Leitungswasser kann Metall korrodieren.

g) Bei Verwendung eines Thermodesinfektors werden anhaftende Verunreinigungen oder Reinigungslösungen im Wassereinsparungs- oder Schnellreinigungsprogramm möglicherweise nicht vollständig entfernt.

Beachten Sie dringend die Herstellerinformationen (z. B. Gebrauchsanleitung), um eine vollständige Entfernung von Verunreinigungen und das ordnungsgemäße Abspülen sicherzustellen.

h) Beachten Sie die folgenden Hinweise bei der Sterilisation mit einem Autoklav.

i) Der Druckbehälter des Autoklavs kann abhängig vom Verwendungszustand und der Nutzungsdauer kontaminiert sein.

Im Autoklav verbliebener Schmutz haftet möglicherweise am Instrument an.

Es empfiehlt sich, den Autoklav gemäß Betriebsanleitung zu reinigen.

So bleibt das Gerät innen sauber. Insbesondere ist die Gummidichtung an Deckel und Luftfilter regelmäßig auszutauschen.

ii) Verwenden Sie soweit möglich demineralisiertes Wasser. Chlorhaltiges Leitungswasser kann zu Korrosion führen.

iii) Achten Sie auf die Trocknungstemperatur im Autoklav.

iv) Instrument nicht in die Nähe von Heizgeräten legen. (Diese können wärmer als die angegebene Temperatur sein.)

v) Unvollständige Reinigung und Spülung im Autoklav oder Restfeuchte in der Sterilisationskammer können Verbrennungen an der Oberfläche des Instruments verursachen.

i) Entfernen Sie Wasser vom Instrument und trocknen Sie es nach der Reinigung und Sterilisation gründlich.

12 [Wartung, Inspektion und Prüfung]

Prüfen Sie das Instrument nach der Reinigung und Sterilisation wie folgt.

1) Prüfen Sie das Gelenk und dessen Innenseite und Außenseite auf Verunreinigungen, Beschädigungen, Risse, Kratzer und Korrosion.

2) Prüfen Sie das Gelenk auf abnormale Bewegungen.

13 [Aufbewahrung]

- 1) Bewahren Sie das Instrument an einem sauberen, staubfreien Ort, geschützt vor hohen Temperaturen und hoher Luftfeuchtigkeit auf.
- 2) Bewahren Sie keine Instrumente unterschiedlicher Materialien zusammen auf, um galvanischen Strom verursacht von der Potentialdifferenz von Metallen zu verhindern.
- 3) Hinweise zur Verhinderung von Rostflecken.
 - a) Nicht gemeinsam mit rostenden Instrumenten aufbewahren.
 - b) Nicht gemeinsam mit Chemikalien aufbewahren.
 - c) Achten Sie auf Rost in Autoklaven oder am Aufbewahrungsort.

14 [Hinweise zur Entsorgung]

Zahnärzte/Kieferorthopäden sind für die angemessene Entsorgung gemäß den geltenden Vorschriften verantwortlich. YDM CORPORATION haftet nicht für Sach- oder Personenschaden durch unsachgemäße Entsorgung.

15 [Zusätzliche Informationen]

<Bruchstellen oder Schleifen>

Wenden Sie sich bei Bruchstellen an Ihren Händler, über den Sie dieses Instrument bezogen haben.

Nutzen Sie dazu das Formular „Schadensmeldung“ von YDM CORPORATION.

Das Schleifen von Klingen wird von uns gegen eine festgelegte Gebühr durchgeführt.

16 [Kontaktinformationen des Herstellers]



YDM CORPORATION

28 Imaizumi, Higashi-Matsuyama-shi,

Saitama 355-0042, Japan

TEL.: 81-3-3828-3161

FAX: 81-3-3827-8991

URL: <http://www.ydm.co.jp/>

E-Mail: ydm@ydm.co.jp

17 [Hinweise für Benutzer/Patienten]

In Verbindung mit diesem Instrument aufgetretene, schwerwiegende Zwischenfälle, sind YDM CORPORATION zu melden.

18 [Zusätzliche Informationen]

Wenden Sie sich bei einem Defekt an Ihren Händler, über den Sie dieses Instrument bezogen haben.

Nutzen Sie dazu das Formular „Schadensmeldung“ von YDM Corporation.

19 [Erklärung der Symbole]



Medizinprodukt



Hersteller



Losnummer



Hinweis

Die oben genannten Hinweise wurden vom Hersteller des Medizinprodukts als geeignet erklärt, um ein Medizinprodukt für die Wiederverwendbarkeit aufzubereiten. Es liegt in der Verantwortung des Anwenders sicherzustellen, dass die tatsächlich mithilfe von Geräten und Materialien von Mitarbeitern in der Verarbeitungsanlage durchgeführte Aufbereitung das gewünschte Ergebnis erzielt. Dies erfordert eine Verifizierung bzw. Bewertung sowie regelmäßige Überwachung des Verfahrens.

Ver.01 23. Juni 2021

Ver.02 24. August 2022

Ver.03 6. Juli 2023

- 1 [Familiename] Orthodontische Zangen
- 2 [Hersteller] YDM CORPORATION
- 3 [ModellNr. und Handelsname]



ModellNr.	Handelsname	UDI-DI	Maximale Schneid- und Biegefähigkeit
22001	Adams Pliers Universal T/C	4963931220014	
22102	Orthodontic Pliers Band Contouring ND-202L	4963931221028	-
22104	Orthodontic Pliers Band Margin ND-204	4963931221042	-
22133	Orthodontic Pliers Band Removing ND-303	4963931221332	-
22141	Orthodontic Pliers Peeso ND-401	4963931221417	,040"
22142	Orthodontic Pliers Young ND-402	4963931221424	,040"
22143	Orthodontic Pliers Tweed Arch ND-403	4963931221431	,022"- ,028"
22145	Orthodontic Pliers Tweed Loop Forming ND-405	4963931221455	,022"- ,028"
22147	Orthodontic Pliers Three Jaw ND-407	4963931221479	,036"
22149	Orthodontic Pliers Bird Beak ND-409	4963931221493	,036"
22152	Orthodontic Pliers How ND-502L	4963931221523	-
22154	Orthodontic Pliers Utility ND-504	4963931221547	-
22155	Orthodontic Pliers How ND-502S	4963931221554	-
22159	Orthodontic Pliers Kim T/C ND-419	4963931221592	,016"- ,022"(Bieg.)/ ,020"(Schneid.)
22160	Orthodontic Pliers Light Wire Cutter T/C ND-420	4963931221608	,020"(Bieg./Schneid.)
22210	Orthodontic Pliers for Aligner Tear Drop	4963931222100	-
22211	Orthodontic Pliers for Aligner Vertical	4963931222117	-
22212	Orthodontic Pliers for Aligner Horizontal	4963931222124	-
22213	Orthodontic Pliers for Aligner Hole Punch	4963931222131	-
22506	Tying Pliers YS-506	4963931225064	-
22507	Tying Pliers YS-507	4963931225071	-
22508	Tying Pliers YS-508	4963931225088	-
22509	Module Pliers Str.	4963931225095	-
22510	Module Pliers Cvd.	4963931225101	-
22511	Module Pliers with Groove Str.	4963931225118	-
22513	Module Pliers Mosquito Str.	4963931225132	-
22514	Module Pliers Mosquito Cvd.	4963931225149	-
22551	Separator YS-551	4963931225514	-
22601	Wire Cutter YS-601	4963931226016	,032"
22602	Wire Cutter YS-602 KI	4963931226023	,045"
22603	Wire Cutter YS-603 Standard	4963931226030	,048"
22606	Pin & Ligature Cutter ND-605 with Hard Material	4963931226061	,012"
22607	Pin & Ligature Cutter ND-605B T/C	4963931226078	,014"
22610	Distal End Cutter ND-606S T/C	4963931226108	,022"- ,028"
22611	Distal End Cutter ND-606LT/C	4963931226115	,022"- ,028"
27410	Ortho.Pliers EVER Classic 410 Band Contouring	4963931274109	-
27411	Ortho.Pliers EVER Classic 411 Band Margin	4963931274116	-
27412	Ortho.Pliers EVER Classic 412 Band Removing	4963931274123	-
27413	Ortho.Pliers EVER C. 413 Bracket Removing T/C	4963931274130	-
27414	Ortho.Pliers EVER Classic 414 Young	4963931274147	,040"
27415	Ortho.Pliers EVER Classic 415 Tweed Arch	4963931274154	,022 x ,028"
27416	Ortho.Pliers EVER C. 416 Tweed Loop Forming	4963931274161	,022 x ,028"
27417	Ortho.Pliers EVER Classic 417 Three Jaw	4963931274178	,036"
27418	Ortho.Pliers EVER Classic 418 Bird Beak	4963931274185	,036"
27419	Ortho.Pliers EVER C. 419 Nance Closing Loop	4963931274192	,022"
27420	Ortho.Pliers EVER Classic 420 How	4963931274208	-
27421	Ortho.Pliers EVER Classic 421 Weingart	4963931274215	-
27422	Ortho.Pliers EVER Classic 422 Utility	4963931274222	-
27423	Ortho.Pliers EVER Classic 423 Kim T/C	4963931274239	,016"- ,022"(Bieg.)/ ,020"(Schneid.)
27424	Ortho.Pliers EVER Classic 424 Light Wire T/C	4963931274246	,020"(Bieg./Schneid.)
27425	Ortho.Pliers EVER Classic 425 Crimping	4963931274253	-
27426	Ortho.Pliers EVER C.426 Lingual Hollow Chop	4963931274260	,022 x ,028"
27427	Ortho.Pliers EVER Classic 427 Torquing M	4963931274277	,022 x ,028"
27428	Ortho.Pliers EVER Classic 428 Torquing F	4963931274284	,022 x ,028"
27440	Ortho.Pliers EVER Fine 440 Utility	4963931274406	-
27441	Ortho.Pliers EVER Fine 441 Weingart	4963931274413	-
27442	Ortho.Pliers EVER Fine 442 How	4963931274420	-
27443	Ortho.Pliers EVER Fine 443 Band Removing	4963931274437	-
27444	Ortho.Pliers EVER F.444 Bracket Removing T/C	4963931274444	-

27445	Ortho.Pliers EVER Fine 445 Step 1/2mm	4963931274451	,022 x ,028"
27446	Ortho.Pliers EVER Fine 446 Step 3/4mm	4963931274468	,022 x ,028"
27447	Ortho.Pliers EVER Fine 447 Step 1mm	4963931274475	,022 x ,028"
27448	Ortho.Pliers EVER Fine 448 Tear Drop	4963931274482	-
27449	Ortho.Pliers EVER Fine 449 Vertical	4963931274499	-
27450	Ortho.Pliers EVER Fine 450 Horizontal	4963931274505	-
27451	Ortho.Pliers EVER Fine 451 Hole Punch	4963931274512	-
27452	Ortho.Pliers EVER Fine 452 Light Wire T/C	4963931274529	,020"(Bieg./Schneid.)
27453	Ortho.Pliers EVER Fine 453 Kim T/C	4963931274536	,016"-,022"(Bieg.),,020"(Schneid.)
27454	Ortho.Pliers EVER Fine 454 Young	4963931274543	,040"
27455	Ortho.Pliers EVER Fine 455 Tweed Arch	4963931274550	,022 x ,028"
27456	Ortho.Pliers EVER Fine 456 Tweed Loop Forming	4963931274567	,022 x ,028"
27457	Ortho.Pliers EVER Fine 457 Three Jaw	4963931274574	,036"
27458	Ortho.Pliers EVER Fine 458 Bird Beak	4963931274581	,036"
27459	Ortho.Pliers EVER F. 459 Nance Closing Loop	4963931274598	,022"
27460	Ortho.Pliers EVER Fine 460 Band Removing L	4963931274604	-
27461	Ortho.Pliers EVER Fine 461 Cinch Back	4963931274611	,020"/,016"-016"
27462	Ortho.Pliers EVER Fine 462 Lingual Utility	4963931274628	-
27463	Ortho.Pliers EVER F.463 Round Former 1.0	4963931274635	-
27464	Ortho.Pliers EVER F.464 Round Former 2.0 SM	4963931274642	-
27465	Ortho.Pliers EVER Fine Key Punch 465	4963931274659	-
27550	Orthodontic Pliers Crimping Ortolan	4963931275502	-
27551	ROMAN 1 Circle Cutter SMOOTH	4963931275519	-
27552	ROMAN 2 Horizontal Box SMOOTH	4963931275526	-
27553	ROMAN 3 Vertical Box SMOOTH	4963931275533	-
27554	ROMAN 4 Pearl Dot SMOOTH	4963931275540	-
27555	ROMAN 5 Keyhole Cutter SMOOTH	4963931275557	-
27556	Angle Fluted Bird Beak Pliers	4963931275564	,036"
27601	Pin&Ligature Cutter EVER F.601 Angle 40	4963931276011	,012"
27602	Pin&Ligature Cutter EVER F.602 Reverse 40	4963931276028	,012"
27603	Pin&Ligature Cutter EVER F.603 Angle 50	4963931276035	,012"
27604	Pin&Ligature Cutter EVER F.604 Reverse 50	4963931276042	,012"
27605	Pin&Ligature Cutter EVER F.605 with Hard MATL	4963931276059	,012"
27606	Distal End Cutter EVER Fine 606S T/C	4963931276066	,022"-,028"
27607	Distal End Cutter EVER Fine 606L T/C	4963931276073	,022"-,028"
27615	Pin&Ligature Cutter EVER C.615 with Hard MATL	4963931276158	,014"
27934	Convertible Cap Removing Pliers ND-934	4963931279340	-
27935	Convertible Cap Removing Pliers ND-934 Blade	4963931279357	-

4 [Verwendungszweck]

Die vorgesehene medizinische Indikation ist das Halten, Fixieren oder Entfernen kleiner Gegenstände und das Biegen oder Schneiden von Metallbändern oder Drähten oder das Ausschneiden oder Aussparen an verschiedenen Stellen der orthodontischen Vorrichtung aus Kunstharz.

5 [Leistungsmerkmale des Geräts]

<Übersicht>

Dieses Gerät ist eine kleine Zange mit verschiedenen geformten Schnäbeln (abhängig von ihrem Verwendungszweck).

<Material>

Edelstahl

ModellNr.	Handelsname	Gebrauchshinweise
22001	Adams Pliers Universal T/C	Halten, Biegen von Klammern und Draht für Retainer.
22102	Orthodontic Pliers Band Contouring ND-202L	Halten, Biegen der Bandkante; passend auf Zahnform.
22104	Orthodontic Pliers Band Margin ND-204	Halten, Biegen der Bandkante; passend auf Zahnform.
22133	Orthodontic Pliers Band Removing ND-303	Anpassen der Bandkante, okklusale Seite und Entfernen v. Band.
22141	Orthodontic Pliers Peeso ND-401	Halten, Biegen d. Bogendrahts um Drehmoment zu erzeugen, Stufe.
22142	Orthodontic Pliers Young ND-402	Halten, Biegen d. Bogendrahts zur Schlaufe.
22143	Orthodontic Pliers Tweed Arch ND-403	Halten, Biegen d. Bogendrahts um Drehmoment zu erzeugen, Stufe.
22145	Orthodontic Pliers Tweed Loop Forming ND-405	Halten, Biegen d. Bogendrahts zur Schlaufe.
22147	Orthodontic Pliers Three Jaw ND-407	Halten, Biegen d. Bogendrahts in V-Form.
22149	Orthodontic Pliers Bird Beak ND-409	Halten, Biegen d. Bogendrahts zur Schlaufe.
22152	Orthodontic Pliers How ND-502L	Halten, festziehen des Ligaturendrahts.
22154	Orthodontic Pliers Utility ND-504	Halten d. Bogendrahts und einführen in Spange, Bukkalröhrchen.
22155	Orthodontic Pliers How ND-502S	Halten, festziehen des Ligaturendrahts.
22159	Orthodontic Pliers Kim T/C ND-419	Halten, Biegen d. Bogendrahts zur Schlaufe.
22160	Orthodontic Pliers Light Wire Cutter T/C ND-420	Halten, Biegen d. Bogendrahts zur Schlaufe.
22210	Orthodontic Pliers for Aligner Tear Drop	Halten, zusätzliche Funktionen an Aligner verbessern.
22211	Orthodontic Pliers for Aligner Vertical	Halten, zusätzliche Funktionen an Aligner verbessern.
22212	Orthodontic Pliers for Aligner Horizontal	Halten, zusätzliche Funktionen an Aligner verbessern.
22213	Orthodontic Pliers for Aligner Hole Punch	Halten, zusätzliche Funktionen an Aligner verbessern.
22506	Tying Pliers YS-506	Halten, festziehen des Ligaturendrahts.
22507	Tying Pliers YS-507	Halten, festziehen des Ligaturendrahts.
22508	Tying Pliers YS-508	Halten, festziehen des Ligaturendrahts.
22509	Module Pliers Str.	Halten des elastischen Moduls und einsetzen der Spange.
22510	Module Pliers Cvd.	Halten des elastischen Moduls und einsetzen der Spange.
22511	Module Pliers with Groove Str.	Halten des elastischen Moduls und einsetzen der Spange.
22513	Module Pliers Mosquito Str.	Halten des elastischen Moduls und einsetzen der Spange.
22514	Module Pliers Mosquito Cvd.	Halten des elastischen Moduls und einsetzen der Spange.
22551	Separator YS-551	Spreizen des Trennmoduls und einsetzen zwischen Zähne.
22601	Wire Cutter YS-601	Halten, Schneiden von Draht.
22602	Wire Cutter YS-602 KI	Halten, Schneiden von Draht.
22603	Wire Cutter YS-603 Standard	Halten, Schneiden von Draht.
22606	Pin & Ligature Cutter ND-605 with Hard Material	Halten, Schneiden von überschüssigem Ligaturendraht.
22607	Pin & Ligature Cutter ND-605B T/C	Halten, Schneiden von überschüssigem Ligaturendraht.
22610	Distal End Cutter ND-606S T/C	Halten, Schneiden von überschüssigem Bogendraht.
22611	Distal End Cutter ND-606LT/C	Halten, Schneiden von überschüssigem Bogendraht.
27410	Ortho.Pliers EVER Classic 410 Band Contouring	Halten, Biegen der Bandkante; passend auf Zahnform.
27411	Ortho.Pliers EVER Classic 411 Band Margin	Halten, Biegen der Bandkante; passend auf Zahnform.
27412	Ortho.Pliers EVER Classic 412 Band Removing	Anpassen der Bandkante, okklusale Seite und entfernen v. Band.
27413	Ortho.Pliers EVER C. 413 Bracket Removing T/C	Halten, entfernen der Spange.
27414	Ortho.Pliers EVER Classic 414 Young	Halten, Biegen d. Bogendrahts zur Schlaufe.
27415	Ortho.Pliers EVER Classic 415 Tweed Arch	Halten, Biegen d. Bogendrahts um Drehmoment zu erzeugen, Stufe.
27416	Ortho.Pliers EVER C. 416 Tweed Loop Forming	Halten, Biegen d. Bogendrahts zur Schlaufe.
27417	Ortho.Pliers EVER Classic 417 Three Jaw	Halten, Biegen d. Bogendrahts in V-Form.
27418	Ortho.Pliers EVER Classic 418 Bird Beak	Halten, Biegen d. Bogendrahts zur Schlaufe.
27419	Ortho.Pliers EVER C. 419 Nance Closing Loop	Halten, Biegen d. Bogendrahts zur Schlaufe.
27420	Ortho.Pliers EVER Classic 420 How	Halten, festziehen des Ligaturendrahts.
27421	Ortho.Pliers EVER Classic 421 Weingart	Halten d. Bogendrahts und einführen in Spange, Bukkalröhrchen.
27422	Ortho.Pliers EVER Classic 422 Utility	Halten d. Bogendrahts und einführen in Spange, Bukkalröhrchen.
27423	Ortho.Pliers EVER Classic 423 Kim T/C	Halten, Biegen d. Bogendrahts zur Schlaufe.
27424	Ortho.Pliers EVER Classic 424 Light Wire T/C	Halten, Biegen d. Bogendrahts zur Schlaufe.
27425	Ortho.Pliers EVER Classic 425 Crimping	Halten, anbringen des klemmbaren Hakens am Bogendraht.
27426	Ortho.Pliers EVER C.426 Lingual Hollow Chop	Halten, Biegen d. Bogendrahts um Rundung zu erzeugen.
27427	Ortho.Pliers EVER Classic 427 Torquing M	Halten d. Bogendrahts mit „27428“, Drehen um Drehmoment auf Bogendraht zu erzeugen.
27428	Ortho.Pliers EVER Classic 428 Torquing F	Halten d. Bogendrahts mit „27427“, Drehen um Drehmoment auf Bogendraht zu erzeugen.
27440	Ortho.Pliers EVER Fine 440 Utility	Halten d. Bogendrahts und einführen in Spange, Bukkalröhrchen.
27441	Ortho.Pliers EVER Fine 441 Weingart	Halten d. Bogendrahts und einführen in Spange, Bukkalröhrchen.
27442	Ortho.Pliers EVER Fine 442 How	Halten, festziehen des Ligaturendrahts.
27443	Ortho.Pliers EVER Fine 443 Band Removing	Anpassen der Bandkante, okklusale Seite und entfernen v. Band.
27444	Ortho.Pliers EVER F.444 Bracket Removing T/C	Halten, entfernen der Spange.
27445	Ortho.Pliers EVER Fine 445 Step 1/2mm	Halten, Biegen d. Bogendrahts um Stufe zu erzeugen.
27446	Ortho.Pliers EVER Fine 446 Step 3/4mm	Halten, Biegen d. Bogendrahts um Stufe zu erzeugen.
27447	Ortho.Pliers EVER Fine 447 Step 1mm	Halten, Biegen d. Bogendrahts um Stufe zu erzeugen.
27448	Ortho.Pliers EVER Fine 448 Tear Drop	Halten, zusätzliche Funktionen an Aligner verbessern.
27449	Ortho.Pliers EVER Fine 449 Vertical	Halten, zusätzliche Funktionen an Aligner verbessern.

27450	Ortho.Pliers EVER Fine 450 Horizontal	Halten, zusätzliche Funktionen an Aligner verbessern.
27451	Ortho.Pliers EVER Fine 451 Hole Punch	Halten, zusätzliche Funktionen an Aligner verbessern.
27452	Ortho.Pliers EVER Fine 452 Light Wire T/C	Halten, Biegen d. Bogendrahts zur Schlaufe.
27453	Ortho.Pliers EVER Fine 453 Kim T/C	Halten, Biegen d. Bogendrahts zur Schlaufe.
27454	Ortho.Pliers EVER Fine 454 Young	Halten, Biegen d. Bogendrahts zur Schlaufe.
27455	Ortho.Pliers EVER Fine 455 Tweed Arch	Halten, Biegen d. Bogendrahts um Drehmoment zu erzeugen, Stufe.
27456	Ortho.Pliers EVER Fine 456 Tweed Loop Forming	Halten, Biegen d. Bogendrahts zur Schlaufe.
27457	Ortho.Pliers EVER Fine 457 Three Jaw	Halten, Biegen d. Bogendrahts in V-Form.
27458	Ortho.Pliers EVER Fine 458 Bird Beak	Halten, Biegen d. Bogendrahts zur Schlaufe.
27459	Ortho.Pliers EVER F. 459 Nance Closing Loop	Halten, Biegen d. Bogendrahts zur Schlaufe.
27460	Ortho.Pliers EVER Fine 460 Band Removing L	Anpassen der Bandkante, okklusale Seite und entfernen v. Band.
27461	Ortho.Pliers EVER Fine 461 Cinch Back	Halten, Biegen des Bogendrahtendes.
27462	Ortho.Pliers EVER Fine 462 Lingual Utility	Halten d. Bogendrahts und einführen in Spange, Bukkalröhrchen.
27463	Ortho.Pliers EVER F.463 Round Former 1.0	Halten, zusätzliche Funktionen an Aligner verbessern.
27464	Ortho.Pliers EVER F.464 Round Former 2.0 SM	Halten, zusätzliche Funktionen an Aligner verbessern.
27465	Ortho.Pliers EVER Fine Key Punch 465	Halten, zusätzliche Funktionen an Aligner verbessern.
27550	Orthodontic Pliers Crimping Ortolan	Halten, anbringen des klemmbaren Hakens am Bogendraht.
27551	ROMAN 1 Circle Cutter SMOOTH	Halten, zusätzliche Funktionen an Aligner verbessern.
27552	ROMAN 2 Horizontal Box SMOOTH	Halten, zusätzliche Funktionen an Aligner verbessern.
27553	ROMAN 3 Vertical Box SMOOTH	Halten, zusätzliche Funktionen an Aligner verbessern.
27554	ROMAN 4 Pearl Dot SMOOTH	Halten, zusätzliche Funktionen an Aligner verbessern.
27555	ROMAN 5 Keyhole Cutter SMOOTH	Halten, zusätzliche Funktionen an Aligner verbessern.
27556	Angle Fluted Bird Beak Pliers	Halten, Biegen des Bogendrahtendes.
27601	Pin&Ligature Cutter EVER F.601 Angle 40	Halten, Schneiden von überschüssigem Ligaturendraht.
27602	Pin&Ligature Cutter EVER F.602 Reverse 40	Halten, Schneiden von überschüssigem Ligaturendraht.
27603	Pin&Ligature Cutter EVER F.603 Angle 50	Halten, Schneiden von überschüssigem Ligaturendraht.
27604	Pin&Ligature Cutter EVER F.604 Reverse 50	Halten, Schneiden von überschüssigem Ligaturendraht.
27605	Pin&Ligature Cutter EVER F.605 with Hard MATL	Halten, Schneiden von überschüssigem Ligaturendraht.
27606	Distal End Cutter EVER Fine 606S T/C	Halten, Schneiden von überschüssigem Bogendraht.
27607	Distal End Cutter EVER Fine 606L T/C	Halten, Schneiden von überschüssigem Bogendraht.
27615	Pin&Ligature Cutter EVER C.615 with Hard MATL	Halten, Schneiden von überschüssigem Ligaturendraht.
27722	Wire Cutter Heavy Duty	Schneiden von Draht.
27934	Convertible Cap Removing Pliers ND-934	Halten, Entfernen von Kappe des konvertiblen Röhrchens.
27935	Convertible Cap Removing Pliers ND-934 Blade	Wichtiges Bestandteil von „27934“

7 [Allgemeine Vorsichtsmaßnahmen und Einschränkungen]

- 1) Die Verwendung des Produkts ist strikt auf zahnärztliche Behandlungen beschränkt.
Vorsichtsmaßnahmen müssen eingehalten werden, um die zweckmäßige Verwendung des Instruments sicherzustellen.
- 2) Verwenden Sie das Instrument ausschließlich für den vorgesehenen Zweck.
- 3) Vor Gebrauch wie durch die IFU instruiert reinigen, schmieren und sterilisieren.
- 4) Verwenden Sie dieses Instrument nicht für Patienten mit Hypersensitivität wie Ausschlag und Dermatitis oder allergischen Reaktionen.
- 5) Nehmen Sie keine Änderungen an dem Instrument vor.
- 6) Lassen Sie das Instrument nicht fallen. Vermeiden Sie die Einwirkung starker Stöße auf das Instrument.
- 7) Folgen Sie bei der Entsorgung des Instruments den in den jeweiligen nationalen Bestimmungen vorgegebenen Hinweisen.
- 8) Erhitzen Sie das Instrument nicht.
- 9) Wischen Sie Chemikalien zur Vermeidung von Korrosion ggf. sofort vom Instrument ab.
- 10) Halten Sie beim Biegen von Draht mit diesem Instrument den Draht mit der Zange und biegen Sie ihn mit den Fingern, um die Zange nicht zu beschädigen.
- 11) Edelstahl ist widerstandsfähiger gegen Rost als Eisen. Abhängig von der Art der Nutzung und den Umgebungsbedingungen (Temperatur, Luftfeuchte) ist eine Korrosion trotzdem möglich.

8 [Einschränkungen der Nutzung]

Verwenden Sie das Instrument nicht weiter, wenn es abgenutzt oder verändert ist.

9 [Erste Behandlung am Ort der Verwendung]

Vor Gebrauch wie durch die IFU instruiert reinigen, schmieren und sterilisieren.

10 [Vor der Reinigung]

Siehe nächster Abschnitt.

11 [Reinigung und Sterilisierung/Desinfizierung]

1) Allgemeine Warnhinweise

- a) Beachten Sie bei der Instandhaltung des Instruments die von unserem Unternehmen herausgegebene Anleitung „The Fundamental Guide Book for Cleaning and Sterilizing Instruments“ (Grundlegende Hinweise für die Reinigung und Sterilisation von Instrumenten) und die Hinweise unter Menüpunkt „Maintenance“ (Instandhaltung) auf unserer Website (http://www.ydm.co.jp/en-new/pdf/The_process_of_cleaning_and_sterilizing.pdf).
- b) Das mit Blut, Körperflüssigkeiten, Gewebefragmenten, Chemikalien usw. verunreinigte Instrument ist unverzüglich gemäß dem folgenden Verfahren zu reinigen und zu sterilisieren.
Verunreinigungen, die lange Zeit an den Instrumenten haften, lassen sich nur schwer entfernen.

2) Verfahren

- a) Öffnen Sie das Gelenk.
- b) Reinigen Sie das Instrument mit einem Reinigungsmittel gemäß Verfahren i) oder ii).
 - i) Verwendung eines Ultraschallreinigers mit medizinischem Reiniger mit Rostschutz für 5 Minuten.
 - ii) In einen medizinischen Reiniger mit Rostschutz eintauchen und 15 Minuten einwirken lassen.
- c) Schmutz und Reinigungsflüssigkeit unter fließendem Wasser vom Instrument abwaschen.
(Seifenrückstände können zu Rost, Flecken an der Oberfläche des Instruments führen.)
- d) Instrument trocknen. (Restfeuchtigkeit kann Rost verursachen, die Sterilisationswirkung verringern)
- e) Rostschutzschmierstoff wie „Instrument Oil“ am Gelenk auftragen.
* Nicht öffnen oder schließen, bis der Rostschutzschmierstoff aufgetragen wurde.
(Das Öffnen und Schließen ohne Schmierstoff verursacht Fressen)

f) Sterilisation in einem Autoklav.

Einstellungen: 134°C bis 138°C, 3 bis 3,5 Minuten

- * Um Kratzer durch den Kontakt mit anderen Instrumenten zu verhindern, wird empfohlen, diese in ein sterilisiertes Behältnis zu geben.

g) Nach der Verwendung unverzüglich gemäß (b) oben reinigen.

3) Warnhinweise zur Reinigung und Sterilisierung/Desinfizierung

- a) Verwenden Sie keine der folgenden Chemikalien, da diese Korrosion verursachen können.

Natriumhypochlorid, Benzalkoniumchlorid, Chlorhexidingluconat, Jodtinktur, Iodoform und Peressigsäure können Korrosion verursachen.

- b) Instrument wegen Korrosionsgefahr nicht chemisch autoklavieren.

- c) Zur Vermeidung von Materialschäden keine Plasmasterilisation durchführen.

- d) Zur Entfernung von Proteinresten an der Oberfläche des Instruments sind Haushaltsreiniger ungeeignet.

- e) Drahtbürsten und Stahlwolle können Beschädigungen am Instrument verursachen.

- f) Wegen Korrosionsgefahr kein stark saures Wasser verwenden.

Stattdessen wird zum Abspülen die Verwendung von demineralisiertem Wasser (ohne Verunreinigungen) empfohlen.
Chlorhaltiges Leitungswasser kann Metall korrodieren.

- g) Beim Thermodesinfektor werden anhaftende Verunreinigungen oder Reinigungslösungen im Wassereinsparungs- oder Schnellreinigungsprogramm möglicherweise nicht vollständig entfernt. Beachten Sie dringend die Herstellerinformationen (z. B. Gebrauchsanleitung), um eine vollständige Entfernung von Verunreinigungen und das ordnungsgemäße Abspülen sicherzustellen.

- h) Beachten Sie die folgenden Hinweise bei der Sterilisation mit einem Autoklav.

- i) Der Druckbehälter des Autoklavs kann abhängig vom Verwendungszustand und der Nutzungsdauer kontaminiert sein.

Im Autoklav verbliebener Schmutz kann am Instrument anhaften.

Es empfiehlt sich, den Autoklav gemäß Betriebsanleitung zu reinigen.

So bleibt das Gerät innen sauber. Insbesondere ist die Gummidichtung an Deckel und Luftfilter regelmäßig auszutauschen.

- ii) Verwenden Sie soweit möglich demineralisiertes Wasser. Chlorhaltiges Leitungswasser kann zu Korrosion führen.

iii) Achten Sie auf die Trocknungstemperatur im Autoklav.

iv) Instrument nicht in die Nähe von Heizgeräten legen. (Diese können wärmer als die angegebene Temperatur sein.)

- v) Unvollständige Reinigung und Spülung im Autoklav oder Restfeuchte in der Sterilisationskammer können Verbrennungen an der Oberfläche des Instruments verursachen.

- i) Entfernen Sie Wasser vom Instrument und trocknen Sie es nach der Reinigung und Sterilisation gründlich.

12 [Wartung, Inspektion und Prüfung]

Überprüfen Sie das Instrument nach der Reinigung und Sterilisation wie folgt.

- 1) Überprüfen Sie das Gelenk und dessen Innenseite und Außenseite auf Verunreinigungen, Beschädigungen, Risse, Kratzer und Korrosion.

- 2) Überprüfen Sie das Gelenk auf abnormale Bewegungen.

13 [Aufbewahrung]

- 1) Bewahren Sie das Instrument an einem sauberen, staubfreien Ort, geschützt vor hohen Temperaturen und hoher Luftfeuchtigkeit auf.
- 2) Bewahren Sie keine Instrumente unterschiedlicher Materialien zusammen auf, um galvanischen Strom aufgrund der Potentialdifferenz von Metallen zu verhindern.
- 3) Hinweise zur Verhinderung von Rostflecken.
 - a) Nicht gemeinsam mit rostenden Instrumenten aufbewahren.
 - b) Nicht gemeinsam mit Chemikalien aufbewahren.
 - c) Achten Sie auf Rost in Autoklaven oder am Aufbewahrungsort.

14 [Hinweise zur Entsorgung]

Zahnärzte/Kieferorthopäden sind für die angemessene Entsorgung gemäß den geltenden Vorschriften verantwortlich. Von YDM CORPORATION wird nicht für Sach- oder Personenschaden durch unsachgemäße Entsorgung gehaftet.

15 [Zusätzliche Informationen]

<Bruchstellen oder Schleifen>

Wenden Sie sich bei Bruchstellen an Ihren Händler, über den Sie dieses Instrument bezogen haben. Nutzen Sie dazu das Formular „Schadensmeldung“ von YDM CORPORATION.

Das Schleifen von Klingen wird von uns gegen eine festgelegte Gebühr durchgeführt.

16 [Kontaktinformationen des Herstellers]



YDM CORPORATION

28 Imaizumi, Higashi-Matsuyama-shi,

Saitama 355-0042, Japan

TEL.: 81-3-3828-3161

FAX: 81-3-3827-8991

URL: <http://www.ydm.co.jp/>

E-Mail: ydm@ydm.co.jp

17 [Hinweise für Benutzer/Patienten]

In Verbindung mit diesem Instrument aufgetretene, schwerwiegende Zwischenfälle, sind YDM CORPORATION zu melden.

18 [Zusätzliche Informationen]

Wenden Sie sich bei einem Defekt des Geräts an Ihren Händler, über den Sie dieses Instrument bezogen haben.

Nutzen Sie dazu das Formular „Schadensmeldung“ von YDM Corporation.

19 [Erklärung der Symbole]



Medizinprodukt



Hersteller



Losnummer



Hinweis

Die oben genannten Hinweise wurden vom Hersteller des Medizinprodukts als geeignet erklärt, um ein Medizinprodukt für die Wiederverwendbarkeit aufzubereiten. Es liegt in der Verantwortung des Anwenders, sicherzustellen, dass die tatsächlich mithilfe von Geräten und Materialien von Mitarbeitern in der Verarbeitungsanlage durchgeführte Aufbereitung das gewünschte Ergebnis erzielt. Dies erfordert eine Verifizierung bzw. Bewertung sowie regelmäßige Überwachung des Verfahrens.

Ver.01 23. Juni 2021

Ver.02 24. August 2022

Ver.03 6. Juli 2023

- 1 [Nombre de la familia] Alicates para ortodoncia
- 2 [Fabricante] YDM CORPORATION
- 3 [N.º de modelo y nombre comercial del instrumento]



N.º modelo	Nombre comercial del instrumento	UDI-DI	Capacidad máxima de corte y doblamiento
22001	Adams Pliers Universal T/C	4963931220014	
22102	Orthodontic Pliers Band Contouring ND-202L	4963931221028	-
22104	Orthodontic Pliers Band Margin ND-204	4963931221042	-
22133	Orthodontic Pliers Band Removing ND-303	4963931221332	-
22141	Orthodontic Pliers Peeso ND-401	4963931221417	,040"
22142	Orthodontic Pliers Young ND-402	4963931221424	,040"
22143	Orthodontic Pliers Tweed Arch ND-403	4963931221431	,022"- ,028"
22145	Orthodontic Pliers Tweed Loop Forming ND-405	4963931221455	,022"- ,028"
22147	Orthodontic Pliers Three Jaw ND-407	4963931221479	,036"
22149	Orthodontic Pliers Bird Beak ND-409	4963931221493	,036"
22152	Orthodontic Pliers How ND-502L	4963931221523	-
22154	Orthodontic Pliers Utility ND-504	4963931221547	-
22155	Orthodontic Pliers How ND-502S	4963931221554	-
22159	Orthodontic Pliers Kim T/C ND-419	4963931221592	,016"- ,022"(doblamiento)/ ,020"(corte)
22160	Orthodontic Pliers Light Wire Cutter T/C ND-420	4963931221608	,020"(doblamiento/corte)
22210	Orthodontic Pliers for Aligner Tear Drop	4963931222100	-
22211	Orthodontic Pliers for Aligner Vertical	4963931222117	-
22212	Orthodontic Pliers for Aligner Horizontal	4963931222124	-
22213	Orthodontic Pliers for Aligner Hole Punch	4963931222131	-
22506	Tying Pliers YS-506	4963931225064	-
22507	Tying Pliers YS-507	4963931225071	-
22508	Tying Pliers YS-508	4963931225088	-
22509	Module Pliers Str.	4963931225095	-
22510	Module Pliers Cvd.	4963931225101	-
22511	Module Pliers with Groove Str.	4963931225118	-
22513	Module Pliers Mosquito Str.	4963931225132	-
22514	Module Pliers Mosquito Cvd.	4963931225149	-
22551	Separator YS-551	4963931225514	-
22601	Wire Cutter YS-601	4963931226016	,032"
22602	Wire Cutter YS-602 KI	4963931226023	,045"
22603	Wire Cutter YS-603 Standard	4963931226030	,048"
22606	Pin & Ligature Cutter ND-605 with Hard Material	4963931226061	,012"
22607	Pin & Ligature Cutter ND-605B T/C	4963931226078	,014"
22610	Distal End Cutter ND-606S T/C	4963931226108	,022"- ,028"
22611	Distal End Cutter ND-606LT/C	4963931226115	,022"- ,028"
27410	Ortho.Pliers EVER Classic 410 Band Contouring	4963931274109	-
27411	Ortho.Pliers EVER Classic 411 Band Margin	4963931274116	-
27412	Ortho.Pliers EVER Classic 412 Band Removing	4963931274123	-
27413	Ortho.Pliers EVER C. 413 Bracket Removing T/C	4963931274130	-
27414	Ortho.Pliers EVER Classic 414 Young	4963931274147	,040"
27415	Ortho.Pliers EVER Classic 415 Tweed Arch	4963931274154	,022 x ,028"
27416	Ortho.Pliers EVER C. 416 Tweed Loop Forming	4963931274161	,022 x ,028"
27417	Ortho.Pliers EVER Classic 417 Three Jaw	4963931274178	,036"
27418	Ortho.Pliers EVER Classic 418 Bird Beak	4963931274185	,036"
27419	Ortho.Pliers EVER C. 419 Nance Closing Loop	4963931274192	,022"
27420	Ortho.Pliers EVER Classic 420 How	4963931274208	-
27421	Ortho.Pliers EVER Classic 421 Weingart	4963931274215	-
27422	Ortho.Pliers EVER Classic 422 Utility	4963931274222	-
27423	Ortho.Pliers EVER Classic 423 Kim T/C	4963931274239	,016"- ,022"(doblamiento)/ ,020"(corte)
27424	Ortho.Pliers EVER Classic 424 Light Wire T/C	4963931274246	,020"(doblamiento/corte)
27425	Ortho.Pliers EVER Classic 425 Crimping	4963931274253	-
27426	Ortho.Pliers EVER C.426 Lingual Hollow Chop	4963931274260	,022 x ,028"
27427	Ortho.Pliers EVER Classic 427 Torquing M	4963931274277	,022 x ,028"
27428	Ortho.Pliers EVER Classic 428 Torquing F	4963931274284	,022 x ,028"
27440	Ortho.Pliers EVER Fine 440 Utility	4963931274406	-
27441	Ortho.Pliers EVER Fine 441 Weingart	4963931274413	-
27442	Ortho.Pliers EVER Fine 442 How	4963931274420	-
27443	Ortho.Pliers EVER Fine 443 Band Removing	4963931274437	-
27444	Ortho.Pliers EVER F.444 Bracket Removing T/C	4963931274444	-

27445	Ortho.Pliers EVER Fine 445 Step 1/2mm	4963931274451	,022 x ,028"
27446	Ortho.Pliers EVER Fine 446 Step 3/4mm	4963931274468	,022 x ,028"
27447	Ortho.Pliers EVER Fine 447 Step 1mm	4963931274475	,022 x ,028"
27448	Ortho.Pliers EVER Fine 448 Tear Drop	4963931274482	-
27449	Ortho.Pliers EVER Fine 449 Vertical	4963931274499	-
27450	Ortho.Pliers EVER Fine 450 Horizontal	4963931274505	-
27451	Ortho.Pliers EVER Fine 451 Hole Punch	4963931274512	-
27452	Ortho.Pliers EVER Fine 452 Light Wire T/C	4963931274529	,020"(doblamiento/corte)
27453	Ortho.Pliers EVER Fine 453 Kim T/C	4963931274536	,016"-,022"(doblamiento),,020"(corte)
27454	Ortho.Pliers EVER Fine 454 Young	4963931274543	,040"
27455	Ortho.Pliers EVER Fine 455 Tweed Arch	4963931274550	,022 x ,028"
27456	Ortho.Pliers EVER Fine 456 Tweed Loop Forming	4963931274567	,022 x ,028"
27457	Ortho.Pliers EVER Fine 457 Three Jaw	4963931274574	,036"
27458	Ortho.Pliers EVER Fine 458 Bird Beak	4963931274581	,036"
27459	Ortho.Pliers EVER F. 459 Nance Closing Loop	4963931274598	,022"
27460	Ortho.Pliers EVER Fine 460 Band Removing L	4963931274604	-
27461	Ortho.Pliers EVER Fine 461 Cinch Back	4963931274611	,020"/,016"-016"
27462	Ortho.Pliers EVER Fine 462 Lingual Utility	4963931274628	-
27463	Ortho.Pliers EVER F.463 Round Former 1.0	4963931274635	-
27464	Ortho.Pliers EVER F.464 Round Former 2.0 SM	4963931274642	-
27465	Ortho.Pliers EVER Fine Key Punch 465	4963931274659	-
27550	Orthodontic Pliers Crimping Ortolan	4963931275502	-
27551	ROMAN 1 Circle Cutter SMOOTH	4963931275519	-
27552	ROMAN 2 Horizontal Box SMOOTH	4963931275526	-
27553	ROMAN 3 Vertical Box SMOOTH	4963931275533	-
27554	ROMAN 4 Pearl Dot SMOOTH	4963931275540	-
27555	ROMAN 5 Keyhole Cutter SMOOTH	4963931275557	-
27556	Angle Fluted Bird Beak Pliers	4963931275564	,036"
27601	Pin&Ligature Cutter EVER F.601 Angle 40	4963931276011	,012"
27602	Pin&Ligature Cutter EVER F.602 Reverse 40	4963931276028	,012"
27603	Pin&Ligature Cutter EVER F.603 Angle 50	4963931276035	,012"
27604	Pin&Ligature Cutter EVER F.604 Reverse 50	4963931276042	,012"
27605	Pin&Ligature Cutter EVER F.605 with Hard MATL	4963931276059	,012"
27606	Distal End Cutter EVER Fine 606S T/C	4963931276066	,022"-,028"
27607	Distal End Cutter EVER Fine 606L T/C	4963931276073	,022"-,028"
27615	Pin&Ligature Cutter EVER C.615 with Hard MATL	4963931276158	,014"
27934	Convertible Cap Removing Pliers ND-934	4963931279340	-
27935	Convertible Cap Removing Pliers ND-934 Blade	4963931279357	-

4 [Uso indicado del instrumento]

Según la indicación médica prevista, el instrumento debe utilizarse para sujetar, fijar o retirar pequeños objetos, para doblar o cortar tiras metálicas o alambre o para cortar o realizar muescas en algunos puntos del aparato de ortodoncia de resina.

5 [Características de rendimiento del instrumento]

<Descripción general>

Este instrumento consta de unas pequeñas pinzas con bocas de distintas formas en función del uso.

<Material>

Acero inoxidable

N.º modelo	Nombre comercial del instrumento	Instrucciones de uso
22001	Adams Pliers Universal T/C	Sujetar, doblar el cierre de alambre para el retenedor.
22102	Orthodontic Pliers Band Contouring ND-202L	Sujetar, doblar el borde de la banda para ajustarse a la forma de los dientes.
22104	Orthodontic Pliers Band Margin ND-204	Sujetar, doblar el borde de la banda para ajustarse a la forma de los dientes.
22133	Orthodontic Pliers Band Removing ND-303	Ajustar el borde de la banda al lado oclusal de los dientes y retirar la banda.
22141	Orthodontic Pliers Peeso ND-401	Sujetar, doblar arco de alambre para aplicar par, escalonar.
22142	Orthodontic Pliers Young ND-402	Sujetar, doblar arco de alambre para formar un bucle.
22143	Orthodontic Pliers Tweed Arch ND-403	Sujetar, doblar arco de alambre para aplicar par, escalonar.
22145	Orthodontic Pliers Tweed Loop Forming ND-405	Sujetar, doblar arco de alambre para formar un bucle.
22147	Orthodontic Pliers Three Jaw ND-407	Sujetar, doblar arco de alambre para dar forma de v.
22149	Orthodontic Pliers Bird Beak ND-409	Sujetar, doblar arco de alambre para formar un bucle.
22152	Orthodontic Pliers How ND-502L	Sujetar, atar ligadura de alambre.
22154	Orthodontic Pliers Utility ND-504	Sujetar arco de alambre e insertarlo en aparatos, tubo bucal.
22155	Orthodontic Pliers How ND-502S	Sujetar, atar ligadura de alambre.
22159	Orthodontic Pliers Kim T/C ND-419	Sujetar, doblar arco de alambre para formar un bucle.
22160	Orthodontic Pliers Light Wire Cutter T/C ND-420	Sujetar, doblar arco de alambre para formar un bucle.
22210	Orthodontic Pliers for Aligner Tear Drop	Sujetar, aplicar una función adicional en el alineador.
22211	Orthodontic Pliers for Aligner Vertical	Sujetar, aplicar una función adicional en el alineador.
22212	Orthodontic Pliers for Aligner Horizontal	Sujetar, aplicar una función adicional en el alineador.
22213	Orthodontic Pliers for Aligner Hole Punch	Sujetar, aplicar una función adicional en el alineador.
22506	Tying Pliers YS-506	Sujetar, atar ligadura de alambre.
22507	Tying Pliers YS-507	Sujetar, atar ligadura de alambre.
22508	Tying Pliers YS-508	Sujetar, atar ligadura de alambre.
22509	Module Pliers Str.	Sujetar módulo elástico y colocar aparatos.
22510	Module Pliers Cvd.	Sujetar módulo elástico y colocar aparatos.
22511	Module Pliers with Groove Str.	Sujetar módulo elástico y colocar aparatos.
22513	Module Pliers Mosquito Str.	Sujetar módulo elástico y colocar aparatos.
22514	Module Pliers Mosquito Cvd.	Sujetar módulo elástico y colocar aparatos.
22551	Separator YS-551	Desplegar el módulo separador e insertarlo a nivel interdental.
22601	Wire Cutter YS-601	Sujetar, cortar alambre.
22602	Wire Cutter YS-602 KI	Sujetar, cortar alambre.
22603	Wire Cutter YS-603 Standard	Sujetar, cortar alambre.
22606	Pin & Ligature Cutter ND-605 with Hard Material	Sujetar, cortar ligadura de alambre sobrante.
22607	Pin & Ligature Cutter ND-605B T/C	Sujetar, cortar ligadura de alambre sobrante.
22610	Distal End Cutter ND-606S T/C	Sujetar, cortar arco de alambre sobrante.
22611	Distal End Cutter ND-606LT/C	Sujetar, cortar arco de alambre sobrante.
27410	Ortho.Pliers EVER Classic 410 Band Contouring	Sujetar, doblar el borde de la banda para ajustarse a la forma de los dientes.
27411	Ortho.Pliers EVER Classic 411 Band Margin	Sujetar, doblar el borde de la banda para ajustarse a la forma de los dientes.
27412	Ortho.Pliers EVER Classic 412 Band Removing	Ajustar el borde de la banda al lado oclusal de los dientes y retirar la banda.
27413	Ortho.Pliers EVER C. 413 Bracket Removing T/C	Sujetar, retirar aparatos.
27414	Ortho.Pliers EVER Classic 414 Young	Sujetar, doblar arco de alambre para formar un bucle.
27415	Ortho.Pliers EVER Classic 415 Tweed Arch	Sujetar, doblar arco de alambre para aplicar par, escalonar.
27416	Ortho.Pliers EVER C. 416 Tweed Loop Forming	Sujetar, doblar arco de alambre para formar un bucle.
27417	Ortho.Pliers EVER Classic 417 Three Jaw	Sujetar, doblar arco de alambre para dar forma de v.
27418	Ortho.Pliers EVER Classic 418 Bird Beak	Sujetar, doblar arco de alambre para formar un bucle.
27419	Ortho.Pliers EVER C. 419 Nance Closing Loop	Sujetar, doblar arco de alambre para formar un bucle.
27420	Ortho.Pliers EVER Classic 420 How	Sujetar, atar ligadura de alambre.
27421	Ortho.Pliers EVER Classic 421 Weingart	Sujetar arco de alambre e insertarlo en aparatos, tubo bucal.
27422	Ortho.Pliers EVER Classic 422 Utility	Sujetar arco de alambre e insertarlo en aparatos, tubo bucal.
27423	Ortho.Pliers EVER Classic 423 Kim T/C	Sujetar, doblar arco de alambre para formar un bucle.
27424	Ortho.Pliers EVER Classic 424 Light Wire T/C	Sujetar, doblar arco de alambre para formar un bucle.
27425	Ortho.Pliers EVER Classic 425 Crimping	Sujetar, aplicar gancho en arco de alambre.
27426	Ortho.Pliers EVER C.426 Lingual Hollow Chop	Sujetar, doblar arco de alambre para aplicar curva.
27427	Ortho.Pliers EVER Classic 427 Torquing M	Sujetar arco de alambre con "27428", rotar para aplicar par en arco de alambre.
27428	Ortho.Pliers EVER Classic 428 Torquing F	Sujetar arco de alambre con "27427", rotar para aplicar par en arco de alambre.
27440	Ortho.Pliers EVER Fine 440 Utility	Sujetar arco de alambre e insertarlo en aparatos, tubo bucal.
27441	Ortho.Pliers EVER Fine 441 Weingart	Sujetar arco de alambre e insertarlo en aparatos, tubo bucal.
27442	Ortho.Pliers EVER Fine 442 How	Sujetar, atar ligadura de alambre.
27443	Ortho.Pliers EVER Fine 443 Band Removing	Ajustar el borde de la banda al lado oclusal de los dientes y retirar la banda.
27444	Ortho.Pliers EVER F.444 Bracket Removing T/C	Sujetar, retirar aparatos.
27445	Ortho.Pliers EVER Fine 445 Step 1/2mm	Sujetar, doblar arco de alambre para aplicar paso.
27446	Ortho.Pliers EVER Fine 446 Step 3/4mm	Sujetar, doblar arco de alambre para aplicar paso.
27447	Ortho.Pliers EVER Fine 447 Step 1mm	Sujetar, doblar arco de alambre para aplicar paso.
27448	Ortho.Pliers EVER Fine 448 Tear Drop	Sujetar, aplicar una función adicional en el alineador.
27449	Ortho.Pliers EVER Fine 449 Vertical	Sujetar, aplicar una función adicional en el alineador.

27450	Ortho.Pliers EVER Fine 450 Horizontal	Sujetar, aplicar una función adicional en el alineador.
27451	Ortho.Pliers EVER Fine 451 Hole Punch	Sujetar, aplicar una función adicional en el alineador.
27452	Ortho.Pliers EVER Fine 452 Light Wire T/C	Sujetar, doblar arco de alambre para formar un bucle.
27453	Ortho.Pliers EVER Fine 453 Kim T/C	Sujetar, doblar arco de alambre para formar un bucle.
27454	Ortho.Pliers EVER Fine 454 Young	Sujetar, doblar arco de alambre para formar un bucle.
27455	Ortho.Pliers EVER Fine 455 Tweed Arch	Sujetar, doblar arco de alambre para aplicar par, escalonar.
27456	Ortho.Pliers EVER Fine 456 Tweed Loop Forming	Sujetar, doblar arco de alambre para formar un bucle.
27457	Ortho.Pliers EVER Fine 457 Three Jaw	Sujetar, doblar arco de alambre para dar forma de v.
27458	Ortho.Pliers EVER Fine 458 Bird Beak	Sujetar, doblar arco de alambre para formar un bucle.
27459	Ortho.Pliers EVER F. 459 Nance Closing Loop	Sujetar, doblar arco de alambre para formar un bucle.
27460	Ortho.Pliers EVER Fine 460 Band Removing L	Ajustar el borde de la banda al lado oclusal de los dientes y retirar la banda.
27461	Ortho.Pliers EVER Fine 461 Cinch Back	Sujetar, doblar el final del arco de alambre.
27462	Ortho.Pliers EVER Fine 462 Lingual Utility	Sujetar arco de alambre e insertarlo en aparatos, tubo bucal.
27463	Ortho.Pliers EVER F.463 Round Former 1.0	Sujetar, aplicar una función adicional en el alineador.
27464	Ortho.Pliers EVER F.464 Round Former 2.0 SM	Sujetar, aplicar una función adicional en el alineador.
27465	Ortho.Pliers EVER Fine Key Punch 465	Sujetar, aplicar una función adicional en el alineador.
27550	Orthodontic Pliers Crimping Ortolan	Sujetar, aplicar gancho en arco de alambre.
27551	ROMAN 1 Circle Cutter SMOOTH	Sujetar, aplicar una función adicional en el alineador.
27552	ROMAN 2 Horizontal Box SMOOTH	Sujetar, aplicar una función adicional en el alineador.
27553	ROMAN 3 Vertical Box SMOOTH	Sujetar, aplicar una función adicional en el alineador.
27554	ROMAN 4 Pearl Dot SMOOTH	Sujetar, aplicar una función adicional en el alineador.
27555	ROMAN 5 Keyhole Cutter SMOOTH	Sujetar, aplicar una función adicional en el alineador.
27556	Angle Fluted Bird Beak Pliers	Sujetar, doblar el final del arco de alambre.
27601	Pin&Ligature Cutter EVER F.601 Angle 40	Sujetar, cortar ligadura de alambre sobrante.
27602	Pin&Ligature Cutter EVER F.602 Reverse 40	Sujetar, cortar ligadura de alambre sobrante.
27603	Pin&Ligature Cutter EVER F.603 Angle 50	Sujetar, cortar ligadura de alambre sobrante.
27604	Pin&Ligature Cutter EVER F.604 Reverse 50	Sujetar, cortar ligadura de alambre sobrante.
27605	Pin&Ligature Cutter EVER F.605 with Hard MATL	Sujetar, cortar ligadura de alambre sobrante.
27606	Distal End Cutter EVER Fine 606S T/C	Sujetar, cortar arco de alambre sobrante.
27607	Distal End Cutter EVER Fine 606L T/C	Sujetar, cortar arco de alambre sobrante.
27615	Pin&Ligature Cutter EVER C.615 with Hard MATL	Sujetar, cortar ligadura de alambre sobrante.
27722	Wire Cutter Heavy Duty	Cortar alambre.
27934	Convertible Cap Removing Pliers ND-934	Sujetar, retirar tapa de tubo convertible.
27935	Convertible Cap Removing Pliers ND-934 Blade	Pieza clave de "27934"

7 [Precauciones generales y prohibiciones]

- 1) El uso del producto está estrictamente limitado a los tratamientos dentales.
Deben tomarse las precauciones correspondientes para garantizar el uso adecuado de los instrumentos.
- 2) No utilizar los instrumentos para un uso distinto del indicado.
- 3) Limpiar, lubricar y esterilizar antes de su uso tal como indica IFU.
- 4) No utilizar los instrumentos en pacientes que tienen una enfermedad con síntomas de hipersensibilidad como sarpullidos y dermatitis o síntomas de alergia.
- 5) No cambiar el diseño ni remodelar los instrumentos.
- 6) No dejar caer los instrumentos. Evitar golpes fuertes en los instrumentos.
- 7) Al desechar los instrumentos, seguir las instrucciones detalladas en las normativas nacionales correspondientes.
- 8) No calentar los instrumentos.
- 9) Si se adhieren sustancias químicas a los instrumentos, limpiarlos inmediatamente para evitar corrosión.
- 10) Al doblar el alambre con estos instrumentos, sujetar el alambre con los alicates y doblarlo con los dedos para evitar daños en los alicates.
- 11) El acero inoxidable es más resistente al óxido que el hierro. No obstante, puede corroerse debido al método de uso y a las condiciones ambientales como la temperatura o la humedad.

8 [Limitaciones en el uso]

Dejar de usar los instrumentos inmediatamente si se encuentra deterioro o algo extraño.

9 [Tratamiento inicial en el punto de uso]

Limpiar, lubricar y esterilizar antes de su uso tal como se indica en las instrucciones de uso.

10 [Preparación previa a la limpieza]

Consultar la siguiente sección.

11 [El proceso de limpieza y esterilización/desinfección]

1) Precauciones generales

- a) En el caso de mantenimiento de los instrumentos, consultar la "The Fundamental Guide Book for Cleaning and Sterilizing Instruments" (Guía fundamental para la limpieza y la esterilización de instrumentos) publicada por nuestra empresa o la sección de "mantenimiento" de nuestro sitio web (http://www.ydm.co.jp/en-new/pdf/The_process_of_cleaning_and_sterilizing.pdf).
- b) Si los instrumentos se han contaminado con sangre, fluidos corporales, fragmentos de tejido, sustancias químicas, etc., deben limpiarse y esterilizarse inmediatamente de conformidad con el método siguiente para evitar que los contaminantes se adhieran y se sequen.

Los contaminantes adheridos a los instrumentos durante mucho tiempo resultan difíciles de eliminar.

2) Procedimiento

- a) Abrir la junta.
 - b) Limpiar los instrumentos con un producto de limpieza según el método i) o ii).
 - i) Usar un limpiador ultrasónico con un detergente antióxido de uso sanitario durante 5 minutos.
 - ii) Sumergir en un detergente antióxido de uso sanitario durante 15 minutos.
 - c) Limpiar la suciedad y el limpiador adheridos al instrumento con agua corriente.
(Si los componentes del jabón siguen en la superficie de los instrumentos, pueden causar óxido, manchas.)
 - d) Secar los instrumentos. (La humedad puede provocar óxido, reducir el efecto de la esterilización)
 - e) Aplicar lubricante antióxido como, por ejemplo, "aceite para instrumentos" en la junta.
- * No abrir ni cerrar hasta que se haya aplicado el lubricante antióxido. (Si el instrumento se abre y cierra sin aceite, puede resultar dañado)
- f) Esterilizar con un autoclave.

Condiciones: De 134 °C a 138 °C, de 3 minutos a 3,5 minutos

* Para evitar rasguños por el contacto con otros instrumentos, introducir en un envase o una caja esterilizados.

g) Tras el uso, deben limpiarse inmediatamente según el apartado b) anterior.

3) Precauciones de limpieza y esterilización/desinfección

- a) No utilizar las sustancias químicas siguientes, ya que pueden corroer el metal:
hipoclorito sódico, cloruro de benzalconio, gluconato de clorhexidina, tintura de yodo, yodoformo y ácido peracético.
- b) No usar autoclave químico en los instrumentos, ya que puede ser corrosivo.
- c) No realizar la esterilización por plasma, ya que puede afectar al material.
- d) No usar agentes de limpieza domésticos, ya que no eliminan la proteína en la superficie de los instrumentos.
- e) El cepillo de alambre y la lana de acero pueden dañar los instrumentos.
- f) No utilizar agua superácida, ya que puede provocar corrosión.
Se recomienda utilizar agua depurada (sin impurezas) para el enjuague.
El agua del grifo contiene cloro, que puede corroer el metal.
- g) Cuando se esté usando una lavadora desinfectadora, la suciedad o la solución de limpieza puede que no se acabe de quitar si se usa un programa de ahorro de agua o tiempo. Consultar el manual de instrucciones del fabricante para garantizar un buen enjuague y eliminar la suciedad.
- h) Tener en cuenta lo siguiente al manipular los autoclaves.
 - i) La cabina del autoclave puede estar contaminada en función del estado y del período de uso. Si queda suciedad, el esterilizador autoclave puede adherirse a los instrumentos.
Recomendamos limpiar según el manual de instrucciones del esterilizador.
El interior de la cámara no se ensucia. En concreto, el sello de goma de la tapa de la cámara y el filtro de aire se deben colocar en un periodo determinado.
 - ii) Utilizar agua depurada en la medida de lo posible.
El agua del grifo puede provocar corrosión por la influencia de los iones de cloro.

iii) Controlar la temperatura de secado dentro del esterilizador autoclave.
 - iv) No colocar los instrumentos cerca del calentador. (Su temperatura puede ser superior a la indicada)
 - v) Si la limpieza y el enjuague no han finalizado dentro del esterilizador autoclave, o queda humedad dentro de la cámara del esterilizador autoclave, se puede quemar la superficie de los instrumentos
- i) Tras la limpieza y la esterilización, retirar el agua que se ha adherido al instrumento y secarlo por completo.

12 [Mantenimiento, inspección y pruebas]

Tras la limpieza y la esterilización, comprobar los siguientes puntos antes del uso.

- 1) Comprobar que no hay suciedad, daños, fisuras, rasguños ni corrosión en la parte interior o exterior de la junta.
- 2) Comprobar que la junta no presenta ningún movimiento anómalo.

13 [Almacenamiento]

- 1) Los instrumentos deben guardarse en un lugar limpio sin polvo, altas temperaturas ni humedad.
- 2) Para evitar la corriente galvánica debido a la diferencia de potencial de los metales, no guardar conjuntamente instrumentos de distintos materiales.
- 3) Para evitar las manchas de óxido, tener en cuenta lo siguiente:
 - a) No guardar los instrumentos con otros instrumentos oxidados.
 - b) No guardar los instrumentos con productos químicos.
 - c) Comprobar que no se oxiden los esterilizadores ni los lugares de almacenamiento.

14 [Consideraciones relativas a la retirada]

Los especialistas y/o ortodoncistas dentales son los responsables de la retirada de conformidad con la ley correspondiente. YDM CORPORATION no asume la responsabilidad por reclamaciones causadas por retirada indebida o lesiones personales.

15 [Información adicional]

<Rotura o afilado>

En caso de rotura de los instrumentos, informe al distribuidor en el que lo ha adquirido mediante el "Informe de reclamación" preparado por YDM CORPORATION.

En relación con el afilado de las cuchillas, podemos realizarlo con un coste determinado.

16 [Contacto del fabricante]



YDM CORPORATION

28 Imaizumi, Higashi-Matsuyama-shi,
Saitama 355-0042, Japan

TEL.: 81-3-3828-3161

FAX: 81-3-3827-8991

URL: <http://www.ydm.co.jp/>

E-mail: ydm@ydm.co.jp

17 [Aviso para el usuario o el paciente]

Cualquier acontecimiento grave que se haya producido en relación con los instrumentos se debe notificar a YDM CORPORATION.

18 [Información adicional]

En caso de defecto del producto, informe al distribuidor en el que lo ha adquirido mediante el "Informe de reclamación" preparado por YDM CORPORATION.

19 [Descripción de los símbolos]



Dispositivo médico



Fabricante



Número de lote



Aviso

Las presentes instrucciones han sido validadas por el fabricante del dispositivo médico, que es capaz de preparar un dispositivo médico para su reutilización. La persona encargada del proceso es la responsable de que este proceso, realizado mediante el equipo, los materiales y el personal de la instalación, logre el resultado deseado. Esto requiere una verificación o validación y supervisión de la rutina del proceso.

Ver. 01 23 de junio de 2021

Ver. 02 24 de agosto de 2022

Ver. 03 6 de julio, 2023

- 1 [Nom] Pincers orthodontiques
- 2 [Fabricant] YDM CORPORATION
- 3 [Numéro de modèle et dénomination commerciale du dispositif]



Numéro de modèle	Dénomination commerciale du dispositif	IUD-ID	Capacités de coupe et de courbure maximales
22001	Adams Pliers Universal T/C	4963931220014	
22102	Orthodontic Pliers Band Contouring ND-202L	4963931221028	-
22104	Orthodontic Pliers Band Margin ND-204	4963931221042	-
22133	Orthodontic Pliers Band Removing ND-303	4963931221332	-
22141	Orthodontic Pliers Peeso ND-401	4963931221417	,040"
22142	Orthodontic Pliers Young ND-402	4963931221424	,040"
22143	Orthodontic Pliers Tweed Arch ND-403	4963931221431	,022"- ,028"
22145	Orthodontic Pliers Tweed Loop Forming ND-405	4963931221455	,022"- ,028"
22147	Orthodontic Pliers Three Jaw ND-407	4963931221479	,036"
22149	Orthodontic Pliers Bird Beak ND-409	4963931221493	,036"
22152	Orthodontic Pliers How ND-502L	4963931221523	-
22154	Orthodontic Pliers Utility ND-504	4963931221547	-
22155	Orthodontic Pliers How ND-502S	4963931221554	-
22159	Orthodontic Pliers Kim T/C ND-419	4963931221592	,016"- ,022"(courber)/ ,020"(couper)
22160	Orthodontic Pliers Light Wire Cutter T/C ND-420	4963931221608	,020"(courber/couper)
22210	Orthodontic Pliers for Aligner Tear Drop	4963931222100	-
22211	Orthodontic Pliers for Aligner Vertical	4963931222117	-
22212	Orthodontic Pliers for Aligner Horizontal	4963931222124	-
22213	Orthodontic Pliers for Aligner Hole Punch	4963931222131	-
22506	Tying Pliers YS-506	4963931225064	-
22507	Tying Pliers YS-507	4963931225071	-
22508	Tying Pliers YS-508	4963931225088	-
22509	Module Pliers Str.	4963931225095	-
22510	Module Pliers Cvd.	4963931225101	-
22511	Module Pliers with Groove Str.	4963931225118	-
22513	Module Pliers Mosquito Str.	4963931225132	-
22514	Module Pliers Mosquito Cvd.	4963931225149	-
22551	Separator YS-551	4963931225514	-
22601	Wire Cutter YS-601	4963931226016	,032"
22602	Wire Cutter YS-602 KI	4963931226023	,045"
22603	Wire Cutter YS-603 Standard	4963931226030	,048"
22606	Pin & Ligature Cutter ND-605 with Hard Material	4963931226061	,012"
22607	Pin & Ligature Cutter ND-605B T/C	4963931226078	,014"
22610	Distal End Cutter ND-606S T/C	4963931226108	,022"- ,028"
22611	Distal End Cutter ND-606LT/C	4963931226115	,022"- ,028"
27410	Ortho.Pliers EVER Classic 410 Band Contouring	4963931274109	-
27411	Ortho.Pliers EVER Classic 411 Band Margin	4963931274116	-
27412	Ortho.Pliers EVER Classic 412 Band Removing	4963931274123	-
27413	Ortho.Pliers EVER C. 413 Bracket Removing T/C	4963931274130	-
27414	Ortho.Pliers EVER Classic 414 Young	4963931274147	,040"
27415	Ortho.Pliers EVER Classic 415 Tweed Arch	4963931274154	,022 x ,028"
27416	Ortho.Pliers EVER C. 416 Tweed Loop Forming	4963931274161	,022 x ,028"
27417	Ortho.Pliers EVER Classic 417 Three Jaw	4963931274178	,036"
27418	Ortho.Pliers EVER Classic 418 Bird Beak	4963931274185	,036"
27419	Ortho.Pliers EVER C. 419 Nance Closing Loop	4963931274192	,022"
27420	Ortho.Pliers EVER Classic 420 How	4963931274208	-
27421	Ortho.Pliers EVER Classic 421 Weingart	4963931274215	-
27422	Ortho.Pliers EVER Classic 422 Utility	4963931274222	-
27423	Ortho.Pliers EVER Classic 423 Kim T/C	4963931274239	,016"- ,022"(courber)/ ,020"(couper)
27424	Ortho.Pliers EVER Classic 424 Light Wire T/C	4963931274246	,020"(courber/couper)
27425	Ortho.Pliers EVER Classic 425 Crimping	4963931274253	-
27426	Ortho.Pliers EVER C.426 Lingual Hollow Chop	4963931274260	,022 x ,028"
27427	Ortho.Pliers EVER Classic 427 Torquing M	4963931274277	,022 x ,028"
27428	Ortho.Pliers EVER Classic 428 Torquing F	4963931274284	,022 x ,028"
27440	Ortho.Pliers EVER Fine 440 Utility	4963931274406	-
27441	Ortho.Pliers EVER Fine 441 Weingart	4963931274413	-
27442	Ortho.Pliers EVER Fine 442 How	4963931274420	-
27443	Ortho.Pliers EVER Fine 443 Band Removing	4963931274437	-
27444	Ortho.Pliers EVER F.444 Bracket Removing T/C	4963931274444	-

27445	Ortho.Pliers EVER Fine 445 Step 1/2mm	4963931274451	,022 x ,028"
27446	Ortho.Pliers EVER Fine 446 Step 3/4mm	4963931274468	,022 x ,028"
27447	Ortho.Pliers EVER Fine 447 Step 1mm	4963931274475	,022 x ,028"
27448	Ortho.Pliers EVER Fine 448 Tear Drop	4963931274482	-
27449	Ortho.Pliers EVER Fine 449 Vertical	4963931274499	-
27450	Ortho.Pliers EVER Fine 450 Horizontal	4963931274505	-
27451	Ortho.Pliers EVER Fine 451 Hole Punch	4963931274512	-
27452	Ortho.Pliers EVER Fine 452 Light Wire T/C	4963931274529	,020"(courber/couper)
27453	Ortho.Pliers EVER Fine 453 Kim T/C	4963931274536	,016"-,022"(courber)/,020"(couper)
27454	Ortho.Pliers EVER Fine 454 Young	4963931274543	,040"
27455	Ortho.Pliers EVER Fine 455 Tweed Arch	4963931274550	,022 x ,028"
27456	Ortho.Pliers EVER Fine 456 Tweed Loop Forming	4963931274567	,022 x ,028"
27457	Ortho.Pliers EVER Fine 457 Three Jaw	4963931274574	,036"
27458	Ortho.Pliers EVER Fine 458 Bird Beak	4963931274581	,036"
27459	Ortho.Pliers EVER F. 459 Nance Closing Loop	4963931274598	,022"
27460	Ortho.Pliers EVER Fine 460 Band Removing L	4963931274604	-
27461	Ortho.Pliers EVER Fine 461 Cinch Back	4963931274611	,020"/,016"-016"
27462	Ortho.Pliers EVER Fine 462 Lingual Utility	4963931274628	-
27463	Ortho.Pliers EVER F.463 Round Former 1.0	4963931274635	-
27464	Ortho.Pliers EVER F.464 Round Former 2.0 SM	4963931274642	-
27465	Ortho.Pliers EVER Fine Key Punch 465	4963931274659	-
27550	Orthodontic Pliers Crimping Ortolan	4963931275502	-
27551	ROMAN 1 Circle Cutter SMOOTH	4963931275519	-
27552	ROMAN 2 Horizontal Box SMOOTH	4963931275526	-
27553	ROMAN 3 Vertical Box SMOOTH	4963931275533	-
27554	ROMAN 4 Pearl Dot SMOOTH	4963931275540	-
27555	ROMAN 5 Keyhole Cutter SMOOTH	4963931275557	-
27556	Angle Fluted Bird Beak Pliers	4963931275564	,036"
27601	Pin&Ligature Cutter EVER F.601 Angle 40	4963931276011	,012"
27602	Pin&Ligature Cutter EVER F.602 Reverse 40	4963931276028	,012"
27603	Pin&Ligature Cutter EVER F.603 Angle 50	4963931276035	,012"
27604	Pin&Ligature Cutter EVER F.604 Reverse 50	4963931276042	,012"
27605	Pin&Ligature Cutter EVER F.605 with Hard MATL	4963931276059	,012"
27606	Distal End Cutter EVER Fine 606S T/C	4963931276066	,022"-,028"
27607	Distal End Cutter EVER Fine 606L T/C	4963931276073	,022"-,028"
27615	Pin&Ligature Cutter EVER C.615 with Hard MATL	4963931276158	,014"
27934	Convertible Cap Removing Pliers ND-934	4963931279340	-
27935	Convertible Cap Removing Pliers ND-934 Blade	4963931279357	-

4 [Objectif du dispositif]

L'indication médicale visée du dispositif est de maintenir, de fixer ou de retirer des objets de petite taille, ou de couper ou courber des bandes ou fils métalliques, ou d'exécuter des déformations à différents emplacements sur l'appareil orthodontique en résine.

5 [Caractéristiques d'exécution du dispositif]

<Synthèse>

Le dispositif est constitué de petites pinces et de mâchoires dont la forme varie en fonction du cas.

<Matériau>

Acier inoxydable

Numéro de modèle	Dénomination commerciale du dispositif	Utilisation
22001	Adams Pliers Universal T/C	Maintenir, courber le crochet pour créer la rétention.
22102	Orthodontic Pliers Band Contouring ND-202L	Maintenir, courber le bord de la bande pour épouser la forme de la dent.
22104	Orthodontic Pliers Band Margin ND-204	Maintenir, courber le bord de la bande pour épouser la forme de la dent.
22133	Orthodontic Pliers Band Removing ND-303	Ajuster le bord de la bande, côté occlusal de la dent et supprimer la bande
22141	Orthodontic Pliers Peeso ND-401	Maintenir, courber l'arc dentaire pour appliquer le couple, le niveau.
22142	Orthodontic Pliers Young ND-402	Maintenir, courber l'arc dentaire pour faire une boucle.
22143	Orthodontic Pliers Tweed Arch ND-403	Maintenir, courber l'arc dentaire pour appliquer le couple, le niveau.
22145	Orthodontic Pliers Tweed Loop Forming ND-405	Maintenir, courber l'arc dentaire pour faire une boucle.
22147	Orthodontic Pliers Three Jaw ND-407	Maintenir, courber l'arc dentaire pour faire un V.
22149	Orthodontic Pliers Bird Beak ND-409	Maintenir, courber l'arc dentaire pour faire une boucle.
22152	Orthodontic Pliers How ND-502L	Maintenir, ligaturer le fil.
22154	Orthodontic Pliers Utility ND-504	Maintenir l'arc dentaire et l'insérer dans le tube vestibulaire.
22155	Orthodontic Pliers How ND-502S	Maintenir, ligaturer le fil.
22159	Orthodontic Pliers Kim T/C ND-419	Maintenir, courber l'arc dentaire pour faire une boucle.
22160	Orthodontic Pliers Light Wire Cutter T/C ND-420	Maintenir, courber l'arc dentaire pour faire une boucle.
22210	Orthodontic Pliers for Aligner Tear Drop	Maintenir, appliquer la fonction supplémentaire sur l'aligneur.
22211	Orthodontic Pliers for Aligner Vertical	Maintenir, appliquer la fonction supplémentaire sur l'aligneur.
22212	Orthodontic Pliers for Aligner Horizontal	Maintenir, appliquer la fonction supplémentaire sur l'aligneur.
22213	Orthodontic Pliers for Aligner Hole Punch	Maintenir, appliquer la fonction supplémentaire sur l'aligneur.
22506	Tying Pliers YS-506	Maintenir, ligaturer le fil.
22507	Tying Pliers YS-507	Maintenir, ligaturer le fil.
22508	Tying Pliers YS-508	Maintenir, ligaturer le fil.
22509	Module Pliers Str.	Maintenir le module élastique et le placer sur l'arc.
22510	Module Pliers Cvd.	Maintenir le module élastique et le placer sur l'arc.
22511	Module Pliers with Groove Str.	Maintenir le module élastique et le placer sur l'arc.
22513	Module Pliers Mosquito Str.	Maintenir le module élastique et le placer sur l'arc.
22514	Module Pliers Mosquito Cvd.	Maintenir le module élastique et le placer sur l'arc.
22551	Separator YS-551	Étendre le module de séparation et l'insérer dans la dent.
22601	Wire Cutter YS-601	Maintenir, couper le fil.
22602	Wire Cutter YS-602 KI	Maintenir, couper le fil.
22603	Wire Cutter YS-603 Standard	Maintenir, couper le fil.
22606	Pin & Ligature Cutter ND-605 with Hard Material	Maintenir, couper le fil excédentaire.
22607	Pin & Ligature Cutter ND-605B T/C	Maintenir, couper le fil excédentaire.
22610	Distal End Cutter ND-606S T/C	Maintenir, couper l'arc excédentaire.
22611	Distal End Cutter ND-606LT/C	Maintenir, couper l'arc excédentaire.
27410	Ortho.Pliers EVER Classic 410 Band Contouring	Maintenir, courber le bord de la bande pour épouser la forme de la dent.
27411	Ortho.Pliers EVER Classic 411 Band Margin	Maintenir, courber le bord de la bande pour épouser la forme de la dent.
27412	Ortho.Pliers EVER Classic 412 Band Removing	Ajuster le bord de la bande, côté occlusal de la dent et supprimer la bande
27413	Ortho.Pliers EVER C. 413 Bracket Removing T/C	Maintenir, supprimer les arcs.
27414	Ortho.Pliers EVER Classic 414 Young	Maintenir, courber l'arc dentaire pour faire une boucle.
27415	Ortho.Pliers EVER Classic 415 Tweed Arch	Maintenir, courber l'arc dentaire pour appliquer le couple, le niveau.
27416	Ortho.Pliers EVER C. 416 Tweed Loop Forming	Maintenir, courber l'arc dentaire pour faire une boucle.
27417	Ortho.Pliers EVER Classic 417 Three Jaw	Maintenir, courber l'arc dentaire pour faire un V.
27418	Ortho.Pliers EVER Classic 418 Bird Beak	Maintenir, courber l'arc dentaire pour faire une boucle.
27419	Ortho.Pliers EVER C. 419 Nance Closing Loop	Maintenir, courber l'arc dentaire pour faire une boucle.
27420	Ortho.Pliers EVER Classic 420 How	Maintenir, ligaturer le fil.
27421	Ortho.Pliers EVER Classic 421 Weingart	Maintenir l'arc dentaire et l'insérer dans le tube vestibulaire.
27422	Ortho.Pliers EVER Classic 422 Utility	Maintenir l'arc dentaire et l'insérer dans le tube vestibulaire.
27423	Ortho.Pliers EVER Classic 423 Kim T/C	Maintenir, courber l'arc dentaire pour faire une boucle.
27424	Ortho.Pliers EVER Classic 424 Light Wire T/C	Maintenir, courber l'arc dentaire pour faire une boucle.
27425	Ortho.Pliers EVER Classic 425 Crimping	Maintenir, appliquer le crochet boule sur l'arc dentaire.
27426	Ortho.Pliers EVER C.426 Lingual Hollow Chop	Maintenir, courber l'arc dentaire pour appliquer la courbe.
27427	Ortho.Pliers EVER Classic 427 Torquing M	Maintenir l'arc dentaire sur « 27428 », pivoter pour appliquer le couple sur l'arc.
27428	Ortho.Pliers EVER Classic 428 Torquing F	Maintenir l'arc dentaire sur « 27427 », pivoter pour appliquer le couple sur l'arc.
27440	Ortho.Pliers EVER Fine 440 Utility	Maintenir l'arc dentaire et l'insérer dans le tube vestibulaire.
27441	Ortho.Pliers EVER Fine 441 Weingart	Maintenir l'arc dentaire et l'insérer dans le tube vestibulaire.
27442	Ortho.Pliers EVER Fine 442 How	Maintenir, ligaturer le fil.
27443	Ortho.Pliers EVER Fine 443 Band Removing	Ajuster le bord de la bande, côté occlusal de la dent et supprimer la bande
27444	Ortho.Pliers EVER F.444 Bracket Removing T/C	Maintenir, supprimer les arcs.
27445	Ortho.Pliers EVER Fine 445 Step 1/2mm	Maintenir, courber l'arc dentaire pour appliquer le niveau.
27446	Ortho.Pliers EVER Fine 446 Step 3/4mm	Maintenir, courber l'arc dentaire pour appliquer le niveau.
27447	Ortho.Pliers EVER Fine 447 Step 1mm	Maintenir, courber l'arc dentaire pour appliquer le niveau.
27448	Ortho.Pliers EVER Fine 448 Tear Drop	Maintenir, appliquer la fonction supplémentaire sur l'aligneur.
27449	Ortho.Pliers EVER Fine 449 Vertical	Maintenir, appliquer la fonction supplémentaire sur l'aligneur.

27450	Ortho.Pliers EVER Fine 450 Horizontal	Maintenir, appliquer la fonction supplémentaire sur l'aligneur.
27451	Ortho.Pliers EVER Fine 451 Hole Punch	Maintenir, appliquer la fonction supplémentaire sur l'aligneur.
27452	Ortho.Pliers EVER Fine 452 Light Wire T/C	Maintenir, courber l'arc dentaire pour faire une boucle.
27453	Ortho.Pliers EVER Fine 453 Kim T/C	Maintenir, courber l'arc dentaire pour faire une boucle.
27454	Ortho.Pliers EVER Fine 454 Young	Maintenir, courber l'arc dentaire pour faire une boucle.
27455	Ortho.Pliers EVER Fine 455 Tweed Arch	Maintenir, courber l'arc dentaire pour appliquer le couple, le niveau.
27456	Ortho.Pliers EVER Fine 456 Tweed Loop Forming	Maintenir, courber l'arc dentaire pour faire une boucle.
27457	Ortho.Pliers EVER Fine 457 Three Jaw	Maintenir, courber l'arc dentaire pour faire un V.
27458	Ortho.Pliers EVER Fine 458 Bird Beak	Maintenir, courber l'arc dentaire pour faire une boucle.
27459	Ortho.Pliers EVER F. 459 Nance Closing Loop	Maintenir, courber l'arc dentaire pour faire une boucle.
27460	Ortho.Pliers EVER Fine 460 Band Removing L	Ajuster le bord de la bande, côté occlusal de la dent et supprimer la bande
27461	Ortho.Pliers EVER Fine 461 Cinch Back	Maintenir, courber l'extrémité de l'arc dentaire.
27462	Ortho.Pliers EVER Fine 462 Lingual Utility	Maintenir l'arc dentaire et l'insérer dans le tube vestibulaire.
27463	Ortho.Pliers EVER F.463 Round Former 1.0	Maintenir, appliquer la fonction supplémentaire sur l'aligneur.
27464	Ortho.Pliers EVER F.464 Round Former 2.0 SM	Maintenir, appliquer la fonction supplémentaire sur l'aligneur.
27465	Ortho.Pliers EVER Fine Key Punch 465	Maintenir, appliquer la fonction supplémentaire sur l'aligneur.
27550	Orthodontic Pliers Crimping Ortolan	Maintenir, appliquer le crochet boule sur l'arc dentaire.
27551	ROMAN 1 Circle Cutter SMOOTH	Maintenir, appliquer la fonction supplémentaire sur l'aligneur.
27552	ROMAN 2 Horizontal Box SMOOTH	Maintenir, appliquer la fonction supplémentaire sur l'aligneur.
27553	ROMAN 3 Vertical Box SMOOTH	Maintenir, appliquer la fonction supplémentaire sur l'aligneur.
27554	ROMAN 4 Pearl Dot SMOOTH	Maintenir, appliquer la fonction supplémentaire sur l'aligneur.
27555	ROMAN 5 Keyhole Cutter SMOOTH	Maintenir, appliquer la fonction supplémentaire sur l'aligneur.
27556	Angle Fluted Bird Beak Pliers	Maintenir, courber l'extrémité de l'arc dentaire.
27601	Pin&Ligature Cutter EVER F.601 Angle 40	Maintenir, couper le fil excédentaire.
27602	Pin&Ligature Cutter EVER F.602 Reverse 40	Maintenir, couper le fil excédentaire.
27603	Pin&Ligature Cutter EVER F.603 Angle 50	Maintenir, couper le fil excédentaire.
27604	Pin&Ligature Cutter EVER F.604 Reverse 50	Maintenir, couper le fil excédentaire.
27605	Pin&Ligature Cutter EVER F.605 with Hard MATL	Maintenir, couper le fil excédentaire.
27606	Distal End Cutter EVER Fine 606S T/C	Maintenir, couper l'arc excédentaire.
27607	Distal End Cutter EVER Fine 606L T/C	Maintenir, couper l'arc excédentaire.
27615	Pin&Ligature Cutter EVER C.615 with Hard MATL	Maintenir, couper le fil excédentaire.
27722	Wire Cutter Heavy Duty	Couper le fil.
27934	Convertible Cap Removing Pliers ND-934	Maintenir, supprimer le couvercle du tube convertible.
27935	Convertible Cap Removing Pliers ND-934 Blade	Pièce principale de « 27934 »

7 [Précautions générales et interdiction]

- 1) L'utilisation du produit est strictement réservée aux soins dentaires.
Des précautions doivent être prises pour garantir une utilisation appropriée des instruments.
- 2) Ne pas utiliser les instruments à toute autre fin que celle prévue.
- 3) Nettoyer, lubrifier et stériliser le produit avant utilisation conformément aux instructions d'utilisation.
- 4) Ne pas utiliser les instruments pour des patients présentant des symptômes d'hypersensibilité comme une éruption cutanée, une dermatite ou des symptômes allergiques.
- 5) Ne pas modifier la conception des instruments, et ne pas altérer les modèles.
- 6) Ne pas faire tomber les instruments. Éviter tout impact important sur les instruments.
- 7) Lors de la mise au rebut des instruments, suivre les instructions détaillées dans les réglementations nationales appropriées.
- 8) Ne pas chauffer les instruments.
- 9) Si des substances chimiques entrent en contact avec les instruments, les nettoyer immédiatement pour éviter la corrosion.
- 10) Lors de la courbure du fil à l'aide de ces instruments, maintenir le fil avec les pinces et le courber avec vos doigts afin d'éviter tout dommage sur les pinces.
- 11) L'acier inoxydable est plus résistant à la rouille que le fer, mais il peut subir une corrosion suivant la méthode d'utilisation et l'environnement, comme la température ou l'humidité.

8 [Restrictions concernant l'utilisation]

Interrompre immédiatement l'utilisation des instruments si vous détectez des signes de détérioration ou quelque chose d'anormal.

9 [Traitement initial au point d'utilisation]

Nettoyer, lubrifier et stériliser avant utilisation conformément aux instructions d'utilisation.

10 [Préparation avant nettoyage]

Voir la section suivante.

11 [Processus de nettoyage et de stérilisation/désinfection]

1) Précautions

a) Pour la maintenance des instruments, se référer au « Fundamental Guide Book for Cleaning and Sterilizing Instruments » (Guide essentiel pour le nettoyage et la stérilisation d'instruments) publié par notre société, ou à la rubrique « Maintenance » sur notre site Web (http://www.ydm.co.jp/en-new/pdf/The_process_of_cleaning_and_sterilizing.pdf).

b) Les instruments en contact avec du sang, un fluide corporel, des fragments de tissus, ou des substances chimiques, etc. doivent être nettoyés et stérilisés immédiatement, en suivant la méthode suivante, afin d'éviter que les contaminants ne s'assèchent et ne collent.

Les contaminants attachés aux instruments pendant une longue période deviennent difficiles à éliminer.

2) Procédure

a) Ouvrir le joint.

b) Nettoyer les instruments à l'aide d'un agent nettoyant en utilisant la méthode i) ou ii).

i) Utiliser un nettoyeur à ultrasons avec un nettoyant antirouille à usage médical pendant 5 minutes.

ii) Immerger dans un nettoyeur avec un nettoyant antirouille à usage médical pendant 15 minutes.

c) Retirer la saleté et enlever le produit de nettoyage ayant adhéré aux instruments à l'eau courante.

(Si des composants de savon demeurent sur la surface des instruments, de la rouille et des taches peuvent apparaître.)

d) Sécher les instruments. (Les restes de moisissure peuvent entraîner l'apparition de rouille et réduire l'efficacité de la stérilisation)

e) Ajouter un lubrifiant antirouille, comme « l'huile pour instruments » au joint.

* Ne pas ouvrir ou fermer tant que le lubrifiant antirouille n'est pas appliqué.

(L'ouverture ou la fermeture sans huile peut entraîner un grippage)

f) Stériliser en utilisant la stérilisation autoclave.

Conditions : De 134°C à 138°C, de 3 minutes à 3,5 minutes.

* Pour éviter des éraflures causées par le contact avec d'autres instruments, les placer dans un emballage ou un étui stérilisé.

g) Après utilisation, nettoyer immédiatement conformément à la section b) ci-dessus.

3) Précautions de nettoyage et de stérilisation/désinfection

a) Ne pas utiliser les substances chimiques suivantes, car elles peuvent causer la corrosion du métal :

l'hypochlorite de sodium, le chlorure de benzalkonium, le digluconate de chlorhexidine, la teinture d'iode, l'iodoforme et l'acide peracétique peuvent entraîner la corrosion du métal.

b) Ne pas utiliser de chemiclave sur les instruments, car cela peut entraîner la corrosion.

c) Ne pas effectuer de stérilisation plasma, car cela risque d'endommager le matériau.

d) Ne pas utiliser des produits de nettoyage domestiques,

car ils ne conviennent pas pour éliminer les protéines présentes sur la surface des instruments.

e) Les brosses métalliques et la laine d'acier peuvent endommager les instruments.

f) Ne pas utiliser d'eau à haute teneur acide, car cela peut entraîner la corrosion.

Une eau purifiée (sans impuretés) est recommandée pour le rinçage.

L'eau du robinet contient du chlore, ce qui peut entraîner la corrosion du métal.

g) Lors de l'utilisation d'un appareil de désinfection, la saleté collée ou la solution de nettoyage peut ne pas être retirée totalement si un programme d'économie d'eau ou de gain de temps est utilisé. Bien s'assurer de se référer au manuel d'utilisation du fabricant pour garantir le rinçage et pour supprimer la saleté.

h) Tenir compte des remarques suivantes lors de l'utilisation de la stérilisation autoclave.

i) Le dispositif pour la stérilisation autoclave peut être contaminé en fonction du statut d'utilisation et de la période.

Si de la saleté est présente sur le dispositif pour la stérilisation autoclave, elle peut contaminer les instruments.

Nous recommandons d'effectuer le nettoyage selon les instructions du manuel du stérilisateur.

Ainsi, la saleté ne pénétrera pas à l'intérieur de la chambre. Plus particulièrement, le joint en caoutchouc du couvercle et le filtre à air de la chambre peuvent nécessiter un remplacement régulier.

ii) Utiliser une eau purifiée autant que possible. L'utilisation de l'eau du robinet peut entraîner la corrosion en raison de l'effet des ions de chlore.

iii) Prêter attention à la température de séchage dans le dispositif de stérilisation autoclave.

iv) Ne pas placer ces instruments près d'une source de chaleur. (La température indiquée ne doit pas être dépassée)

v) Si le nettoyage et le rinçage ne sont pas terminés à l'intérieur du dispositif de stérilisation autoclave,

ou si de la moisissure est présente dans la chambre du dispositif de stérilisation autoclave,

cela risque de provoquer des brûlures sur la surface des instruments.

i) Après lavage et stérilisation, retirer l'eau ayant adhéré à l'instrument et le sécher complètement

12 [Maintenance, inspection et test]

Après nettoyage et stérilisation, vérifier les éléments suivants avant toute utilisation.

1) Vérifier qu'il n'existe pas de saleté, de dommages, de fissures, d'éraflures ou de corrosion à l'intérieur et extérieur du joint.

2) Vérifier qu'il n'existe pas de mouvement anormal du joint.

13 [Stockage]

- 1) Stocker l'instrument dans un endroit propre sans saleté, éviter les températures élevées et l'humidité.
- 2) Pour éviter tout courant galvanique provoqué par la différence de potentiel des métaux, ne pas stocker avec des instruments composés de matériaux différents.
- 3) Tenir compte des instructions suivantes pour éviter les taches de rouille.
 - a) Ne pas stocker avec des instruments rouillés.
 - b) Ne pas stocker avec des produits chimiques.
 - c) Prêter attention à la rouille dans les stérilisateurs et les lieux de stockage.

14 [Remarques concernant la mise au rebut]

Les spécialistes dentaires et/ou les orthodontistes sont responsables de la mise au rebut, conformément au droit applicable. YDM CORPORATION n'assume aucune responsabilité pour les dommages causés par une mise au rebut inappropriée ou des préjudices corporels.

15 [Informations supplémentaires]

<Casse ou aiguisage>

En cas de casse des instruments, veuillez contacter le distributeur auprès duquel vous avez acheté l'équipement via le « Formulaire de réclamation » établi par YDM CORPORATION.

En cas de besoin d'aiguisage de vos lames, nous nous en chargerons moyennant une certaine somme d'argent.

16 [Contact du fabricant]



YDM CORPORATION

28 Imaizumi, Higashi-Matsuyama-shi,
Saitama 355-0042, Japan

TÉL : 81-3-3828-3161

FAX : 81-3-3827-8991

URL : <http://www.ydm.co.jp/>

E-mail : ydm@ydm.co.jp

17 [À l'attention de l'utilisateur et/ou du patient]

Tout incident grave en lien avec les instruments doit être signalé à YDM CORPORATION.

18 [Informations supplémentaires]

En cas de défaut du dispositif, contacter le distributeur auprès duquel vous avez acheté l'équipement via le « Formulaire de réclamation » établi par YDM CORPORATION.

19 [Description des symboles]



Dispositif médical



Fabricant



Numéro de lot



Avertissement

Les instructions établies ci-dessus ont été validées par le fabricant du dispositif médical comme étant aptes à préparer la réutilisation d'un dispositif médical. Il demeure de la responsabilité de l'utilisateur de garantir que le processus, exécuté en utilisant l'équipement, les matériaux, et avec le personnel médical dans le centre approprié, atteindra les résultats escomptés. Cela nécessite une vérification et/ou une validation et un système de suivi du processus.

Ver.01 23 juin 2021

Ver.02 24 août 2022

Ver.03 6 juillet 2023

- 1 [Denominazione della famiglia di prodotti] Pinze per ortodonzia
- 2 [Produttore] YDM CORPORATION
- 3 [Numero modello e denominazione commerciale del dispositivo]



Numeromodello	Denominazione commerciale del dispositivo	UDI-DI	Capacità massime di taglio e piega
22001	Adams Pliers Universal T/C	4963931220014	
22102	Orthodontic Pliers Band Contouring ND-202L	4963931221028	-
22104	Orthodontic Pliers Band Margin ND-204	4963931221042	-
22133	Orthodontic Pliers Band Removing ND-303	4963931221332	-
22141	Orthodontic Pliers Peeso ND-401	4963931221417	,040"
22142	Orthodontic Pliers Young ND-402	4963931221424	,040"
22143	Orthodontic Pliers Tweed Arch ND-403	4963931221431	,022"- ,028"
22145	Orthodontic Pliers Tweed Loop Forming ND-405	4963931221455	,022"- ,028"
22147	Orthodontic Pliers Three Jaw ND-407	4963931221479	,036"
22149	Orthodontic Pliers Bird Beak ND-409	4963931221493	,036"
22152	Orthodontic Pliers How ND-502L	4963931221523	-
22154	Orthodontic Pliers Utility ND-504	4963931221547	-
22155	Orthodontic Pliers How ND-502S	4963931221554	-
22159	Orthodontic Pliers Kim T/C ND-419	4963931221592	,016"- ,022"(piega)/ ,020"(taglio)
22160	Orthodontic Pliers Light Wire Cutter T/C ND-420	4963931221608	,020"(piega/taglio)
22210	Orthodontic Pliers for Aligner Tear Drop	4963931222100	-
22211	Orthodontic Pliers for Aligner Vertical	4963931222117	-
22212	Orthodontic Pliers for Aligner Horizontal	4963931222124	-
22213	Orthodontic Pliers for Aligner Hole Punch	4963931222131	-
22506	Tying Pliers YS-506	4963931225064	-
22507	Tying Pliers YS-507	4963931225071	-
22508	Tying Pliers YS-508	4963931225088	-
22509	Module Pliers Str.	4963931225095	-
22510	Module Pliers Cvd.	4963931225101	-
22511	Module Pliers with Groove Str.	4963931225118	-
22513	Module Pliers Mosquito Str.	4963931225132	-
22514	Module Pliers Mosquito Cvd.	4963931225149	-
22551	Separator YS-551	4963931225514	-
22601	Wire Cutter YS-601	4963931226016	,032"
22602	Wire Cutter YS-602 KI	4963931226023	,045"
22603	Wire Cutter YS-603 Standard	4963931226030	,048"
22606	Pin & Ligature Cutter ND-605 with Hard Material	4963931226061	,012"
22607	Pin & Ligature Cutter ND-605B T/C	4963931226078	,014"
22610	Distal End Cutter ND-606S T/C	4963931226108	,022"- ,028"
22611	Distal End Cutter ND-606LT/C	4963931226115	,022"- ,028"
27410	Ortho.Pliers EVER Classic 410 Band Contouring	4963931274109	-
27411	Ortho.Pliers EVER Classic 411 Band Margin	4963931274116	-
27412	Ortho.Pliers EVER Classic 412 Band Removing	4963931274123	-
27413	Ortho.Pliers EVER C. 413 Bracket Removing T/C	4963931274130	-
27414	Ortho.Pliers EVER Classic 414 Young	4963931274147	,040"
27415	Ortho.Pliers EVER Classic 415 Tweed Arch	4963931274154	,022 x ,028"
27416	Ortho.Pliers EVER C. 416 Tweed Loop Forming	4963931274161	,022 x ,028"
27417	Ortho.Pliers EVER Classic 417 Three Jaw	4963931274178	,036"
27418	Ortho.Pliers EVER Classic 418 Bird Beak	4963931274185	,036"
27419	Ortho.Pliers EVER C. 419 Nance Closing Loop	4963931274192	,022"
27420	Ortho.Pliers EVER Classic 420 How	4963931274208	-
27421	Ortho.Pliers EVER Classic 421 Weingart	4963931274215	-
27422	Ortho.Pliers EVER Classic 422 Utility	4963931274222	-
27423	Ortho.Pliers EVER Classic 423 Kim T/C	4963931274239	,016"- ,022"(piega)/ ,020"(taglio)
27424	Ortho.Pliers EVER Classic 424 Light Wire T/C	4963931274246	,020"(piega/taglio)
27425	Ortho.Pliers EVER Classic 425 Crimping	4963931274253	-
27426	Ortho.Pliers EVER C.426 Lingual Hollow Chop	4963931274260	,022 x ,028"
27427	Ortho.Pliers EVER Classic 427 Torquing M	4963931274277	,022 x ,028"
27428	Ortho.Pliers EVER Classic 428 Torquing F	4963931274284	,022 x ,028"
27440	Ortho.Pliers EVER Fine 440 Utility	4963931274406	-
27441	Ortho.Pliers EVER Fine 441 Weingart	4963931274413	-
27442	Ortho.Pliers EVER Fine 442 How	4963931274420	-
27443	Ortho.Pliers EVER Fine 443 Band Removing	4963931274437	-
27444	Ortho.Pliers EVER F.444 Bracket Removing T/C	4963931274444	-

27445	Ortho.Pliers EVER Fine 445 Step 1/2mm	4963931274451	,022 x ,028"
27446	Ortho.Pliers EVER Fine 446 Step 3/4mm	4963931274468	,022 x ,028"
27447	Ortho.Pliers EVER Fine 447 Step 1mm	4963931274475	,022 x ,028"
27448	Ortho.Pliers EVER Fine 448 Tear Drop	4963931274482	-
27449	Ortho.Pliers EVER Fine 449 Vertical	4963931274499	-
27450	Ortho.Pliers EVER Fine 450 Horizontal	4963931274505	-
27451	Ortho.Pliers EVER Fine 451 Hole Punch	4963931274512	-
27452	Ortho.Pliers EVER Fine 452 Light Wire T/C	4963931274529	,020"(piega/taglio)
27453	Ortho.Pliers EVER Fine 453 Kim T/C	4963931274536	,016"-,022"(piega)/,020"(taglio)
27454	Ortho.Pliers EVER Fine 454 Young	4963931274543	,040"
27455	Ortho.Pliers EVER Fine 455 Tweed Arch	4963931274550	,022 x ,028"
27456	Ortho.Pliers EVER Fine 456 Tweed Loop Forming	4963931274567	,022 x ,028"
27457	Ortho.Pliers EVER Fine 457 Three Jaw	4963931274574	,036"
27458	Ortho.Pliers EVER Fine 458 Bird Beak	4963931274581	,036"
27459	Ortho.Pliers EVER F. 459 Nance Closing Loop	4963931274598	,022"
27460	Ortho.Pliers EVER Fine 460 Band Removing L	4963931274604	-
27461	Ortho.Pliers EVER Fine 461 Cinch Back	4963931274611	,020"/,016"-016"
27462	Ortho.Pliers EVER Fine 462 Lingual Utility	4963931274628	-
27463	Ortho.Pliers EVER F.463 Round Former 1.0	4963931274635	-
27464	Ortho.Pliers EVER F.464 Round Former 2.0 SM	4963931274642	-
27465	Ortho.Pliers EVER Fine Key Punch 465	4963931274659	-
27550	Orthodontic Pliers Crimping Ortolan	4963931275502	-
27551	ROMAN 1 Circle Cutter SMOOTH	4963931275519	-
27552	ROMAN 2 Horizontal Box SMOOTH	4963931275526	-
27553	ROMAN 3 Vertical Box SMOOTH	4963931275533	-
27554	ROMAN 4 Pearl Dot SMOOTH	4963931275540	-
27555	ROMAN 5 Keyhole Cutter SMOOTH	4963931275557	-
27556	Angle Fluted Bird Beak Pliers	4963931275564	,036"
27601	Pin&Ligature Cutter EVER F.601 Angle 40	4963931276011	,012"
27602	Pin&Ligature Cutter EVER F.602 Reverse 40	4963931276028	,012"
27603	Pin&Ligature Cutter EVER F.603 Angle 50	4963931276035	,012"
27604	Pin&Ligature Cutter EVER F.604 Reverse 50	4963931276042	,012"
27605	Pin&Ligature Cutter EVER F.605 with Hard MATL	4963931276059	,012"
27606	Distal End Cutter EVER Fine 606S T/C	4963931276066	,022"-,028"
27607	Distal End Cutter EVER Fine 606L T/C	4963931276073	,022"-,028"
27615	Pin&Ligature Cutter EVER C.615 with Hard MATL	4963931276158	,014"
27934	Convertible Cap Removing Pliers ND-934	4963931279340	-
27935	Convertible Cap Removing Pliers ND-934 Blade	4963931279357	-

4 [Uso previsto del dispositivo]

Il dispositivo è previsto per l'uso al fine di afferrare, fissare o rimuovere oggetti di piccole dimensioni, piegare o tagliare strisce o fili di metallo, così come sagomare o praticare incisioni in diversi punti dell'apparecchio ortodontico in resina.

5 [Caratteristiche prestazionali del dispositivo]

<Panoramica>

Il dispositivo consiste in una piccola pinza con bracci di diversa forma a seconda dello scopo di utilizzo.

<Materiale>

Acciaio inossidabile

Numeromodello	Denominazione commerciale del dispositivo	Modalità d'uso
22001	Adams Pliers Universal T/C	Afferrare, piegare il filo del fermo per l'apparecchio di contenzione.
22102	Orthodontic Pliers Band Contouring ND-202L	Afferrare, piegare il bordo della striscia in base alla forma dei denti.
22104	Orthodontic Pliers Band Margin ND-204	Afferrare, piegare il bordo della striscia in base alla forma dei denti.
22133	Orthodontic Pliers Band Removing ND-303	Collocare il bordo della striscia, lato occlusale del dente, e rimuovere la striscia.
22141	Orthodontic Pliers Peeso ND-401	Afferrare, piegare l'arco ortodontico per applicare il torque, creare uno scalino.
22142	Orthodontic Pliers Young ND-402	Afferrare, piegare l'arco ortodontico per formare un cappio.
22143	Orthodontic Pliers Tweed Arch ND-403	Afferrare, piegare l'arco ortodontico per applicare il torque, creare uno scalino.
22145	Orthodontic Pliers Tweed Loop Forming ND-405	Afferrare, piegare l'arco ortodontico per formare un cappio.
22147	Orthodontic Pliers Three Jaw ND-407	Afferrare, piegare l'arco ortodontico per formare una forma a V.
22149	Orthodontic Pliers Bird Beak ND-409	Afferrare, piegare l'arco ortodontico per formare un cappio.
22152	Orthodontic Pliers How ND-502L	Afferrare, legare il filo per legatura.
22154	Orthodontic Pliers Utility ND-504	Afferrare l'arco ortodontico e inserirlo nell'apparecchio ortodontico, tubo buccale.
22155	Orthodontic Pliers How ND-502S	Afferrare, legare il filo per legatura.
22159	Orthodontic Pliers Kim T/C ND-419	Afferrare, piegare l'arco ortodontico per formare un cappio.
22160	Orthodontic Pliers Light Wire Cutter T/C ND-420	Afferrare, piegare l'arco ortodontico per formare un cappio.
22210	Orthodontic Pliers for Aligner Tear Drop	Afferrare, utilizzare l'allineatore per funzionalità aggiuntive.
22211	Orthodontic Pliers for Aligner Vertical	Afferrare, utilizzare l'allineatore per funzionalità aggiuntive.
22212	Orthodontic Pliers for Aligner Horizontal	Afferrare, utilizzare l'allineatore per funzionalità aggiuntive.
22213	Orthodontic Pliers for Aligner Hole Punch	Afferrare, utilizzare l'allineatore per funzionalità aggiuntive.
22506	Tying Pliers YS-506	Afferrare, legare il filo per legatura.
22507	Tying Pliers YS-507	Afferrare, legare il filo per legatura.
22508	Tying Pliers YS-508	Afferrare, legare il filo per legatura.
22509	Module Pliers Str.	Afferrare il modulo elastico e posizionarlo sull'apparecchio ortodontico.
22510	Module Pliers Cvd.	Afferrare il modulo elastico e posizionarlo sull'apparecchio ortodontico.
22511	Module Pliers with Groove Str.	Afferrare il modulo elastico e posizionarlo sull'apparecchio ortodontico.
22513	Module Pliers Mosquito Str.	Afferrare il modulo elastico e posizionarlo sull'apparecchio ortodontico.
22514	Module Pliers Mosquito Cvd.	Afferrare il modulo elastico e posizionarlo sull'apparecchio ortodontico.
22551	Separator YS-551	Divaricare il modulo di separazione e inserire i denti interni.
22601	Wire Cutter YS-601	Afferrare, tagliare il filo.
22602	Wire Cutter YS-602 KI	Afferrare, tagliare il filo.
22603	Wire Cutter YS-603 Standard	Afferrare, tagliare il filo.
22606	Pin & Ligature Cutter ND-605 with Hard Material	Afferrare, tagliare il filo per legatura in eccesso.
22607	Pin & Ligature Cutter ND-605B T/C	Afferrare, tagliare il filo per legatura in eccesso.
22610	Distal End Cutter ND-606S T/C	Afferrare, tagliare l'arco ortodontico in eccesso.
22611	Distal End Cutter ND-606LT/C	Afferrare, tagliare l'arco ortodontico in eccesso.
27410	Ortho.Pliers EVER Classic 410 Band Contouring	Afferrare, piegare il bordo della striscia in base alla forma dei denti.
27411	Ortho.Pliers EVER Classic 411 Band Margin	Afferrare, piegare il bordo della striscia in base alla forma dei denti.
27412	Ortho.Pliers EVER Classic 412 Band Removing	Collocare il bordo della striscia, lato occlusale del dente, e rimuovere la striscia.
27413	Ortho.Pliers EVER C. 413 Bracket Removing T/C	Afferrare, rimuovere l'apparecchio ortodontico.
27414	Ortho.Pliers EVER Classic 414 Young	Afferrare, piegare l'arco ortodontico per formare un cappio.
27415	Ortho.Pliers EVER Classic 415 Tweed Arch	Afferrare, piegare l'arco ortodontico per applicare il torque, creare uno scalino.
27416	Ortho.Pliers EVER C. 416 Tweed Loop Forming	Afferrare, piegare l'arco ortodontico per formare un cappio.
27417	Ortho.Pliers EVER Classic 417 Three Jaw	Afferrare, piegare l'arco ortodontico per formare una forma a V.
27418	Ortho.Pliers EVER Classic 418 Bird Beak	Afferrare, piegare l'arco ortodontico per formare un cappio.
27419	Ortho.Pliers EVER C. 419 Nance Closing Loop	Afferrare, piegare l'arco ortodontico per formare un cappio.
27420	Ortho.Pliers EVER Classic 420 How	Afferrare, legare il filo per legatura.
27421	Ortho.Pliers EVER Classic 421 Weingart	Afferrare l'arco ortodontico e inserirlo nell'apparecchio ortodontico, tubo buccale.
27422	Ortho.Pliers EVER Classic 422 Utility	Afferrare l'arco ortodontico e inserirlo nell'apparecchio ortodontico, tubo buccale.
27423	Ortho.Pliers EVER Classic 423 Kim T/C	Afferrare, piegare l'arco ortodontico per formare un cappio.
27424	Ortho.Pliers EVER Classic 424 Light Wire T/C	Afferrare, piegare l'arco ortodontico per formare un cappio.
27425	Ortho.Pliers EVER Classic 425 Crimping	Afferrare, applicare un gancio restringibile all'apparecchio ortodontico.
27426	Ortho.Pliers EVER C.426 Lingual Hollow Chop	Afferrare, piegare l'arco ortodontico per applicare una curvatura.
27427	Ortho.Pliers EVER Classic 427 Torquing M	Afferrare l'arco ortodontico con "27428", ruotare per applicare il torque all'arco ortodontico.
27428	Ortho.Pliers EVER Classic 428 Torquing F	Afferrare l'arco ortodontico con "27427", ruotare per applicare il torque all'arco ortodontico.
27440	Ortho.Pliers EVER Fine 440 Utility	Afferrare l'arco ortodontico e inserirlo nell'apparecchio ortodontico, tubo buccale.
27441	Ortho.Pliers EVER Fine 441 Weingart	Afferrare l'arco ortodontico e inserirlo nell'apparecchio ortodontico, tubo buccale.
27442	Ortho.Pliers EVER Fine 442 How	Afferrare, legare il filo per legatura.
27443	Ortho.Pliers EVER Fine 443 Band Removing	Collocare il bordo della striscia, lato occlusale del dente, e rimuovere la striscia.
27444	Ortho.Pliers EVER F.444 Bracket Removing T/C	Afferrare, rimuovere l'apparecchio ortodontico.
27445	Ortho.Pliers EVER Fine 445 Step 1/2mm	Afferrare, piegare l'arco ortodontico per applicare uno scalino.
27446	Ortho.Pliers EVER Fine 446 Step 3/4mm	Afferrare, piegare l'arco ortodontico per applicare uno scalino.
27447	Ortho.Pliers EVER Fine 447 Step 1mm	Afferrare, piegare l'arco ortodontico per applicare uno scalino.
27448	Ortho.Pliers EVER Fine 448 Tear Drop	Afferrare, utilizzare l'allineatore per funzionalità aggiuntive.
27449	Ortho.Pliers EVER Fine 449 Vertical	Afferrare, utilizzare l'allineatore per funzionalità aggiuntive.

27450	Ortho.Pliers EVER Fine 450 Horizontal	Afferrare, utilizzare l'allineatore per funzionalità aggiuntive.
27451	Ortho.Pliers EVER Fine 451 Hole Punch	Afferrare, utilizzare l'allineatore per funzionalità aggiuntive.
27452	Ortho.Pliers EVER Fine 452 Light Wire T/C	Afferrare, piegare l'arco ortodontico per formare un cappio.
27453	Ortho.Pliers EVER Fine 453 Kim T/C	Afferrare, piegare l'arco ortodontico per formare un cappio.
27454	Ortho.Pliers EVER Fine 454 Young	Afferrare, piegare l'arco ortodontico per formare un cappio.
27455	Ortho.Pliers EVER Fine 455 Tweed Arch	Afferrare, piegare l'arco ortodontico per applicare il torque, creare uno scalino.
27456	Ortho.Pliers EVER Fine 456 Tweed Loop Forming	Afferrare, piegare l'arco ortodontico per formare un cappio.
27457	Ortho.Pliers EVER Fine 457 Three Jaw	Afferrare, piegare l'arco ortodontico per formare una forma a V.
27458	Ortho.Pliers EVER Fine 458 Bird Beak	Afferrare, piegare l'arco ortodontico per formare un cappio.
27459	Ortho.Pliers EVER F. 459 Nance Closing Loop	Afferrare, piegare l'arco ortodontico per formare un cappio.
27460	Ortho.Pliers EVER Fine 460 Band Removing L	Collocare il bordo della striscia, lato occlusale del dente, e rimuovere la striscia.
27461	Ortho.Pliers EVER Fine 461 Cinch Back	Afferrare, piegare l'estremità dell'arco ortodontico.
27462	Ortho.Pliers EVER Fine 462 Lingual Utility	Afferrare l'arco ortodontico e inserirlo nell'apparecchio ortodontico, tubo buccale.
27463	Ortho.Pliers EVER F.463 Round Former 1.0	Afferrare, utilizzare l'allineatore per funzionalità aggiuntive.
27464	Ortho.Pliers EVER F.464 Round Former 2.0 SM	Afferrare, utilizzare l'allineatore per funzionalità aggiuntive.
27465	Ortho.Pliers EVER Fine Key Punch 465	Afferrare, utilizzare l'allineatore per funzionalità aggiuntive.
27550	Orthodontic Pliers Crimping Ortolan	Afferrare, applicare un gancio restringibile all'apparecchio ortodontico.
27551	ROMAN 1 Circle Cutter SMOOTH	Afferrare, utilizzare l'allineatore per funzionalità aggiuntive.
27552	ROMAN 2 Horizontal Box SMOOTH	Afferrare, utilizzare l'allineatore per funzionalità aggiuntive.
27553	ROMAN 3 Vertical Box SMOOTH	Afferrare, utilizzare l'allineatore per funzionalità aggiuntive.
27554	ROMAN 4 Pearl Dot SMOOTH	Afferrare, utilizzare l'allineatore per funzionalità aggiuntive.
27555	ROMAN 5 Keyhole Cutter SMOOTH	Afferrare, utilizzare l'allineatore per funzionalità aggiuntive.
27556	Angle Fluted Bird Beak Pliers	Afferrare, piegare l'estremità dell'arco ortodontico.
27601	Pin&Ligature Cutter EVER F.601 Angle 40	Afferrare, tagliare il filo per legatura in eccesso.
27602	Pin&Ligature Cutter EVER F.602 Reverse 40	Afferrare, tagliare il filo per legatura in eccesso.
27603	Pin&Ligature Cutter EVER F.603 Angle 50	Afferrare, tagliare il filo per legatura in eccesso.
27604	Pin&Ligature Cutter EVER F.604 Reverse 50	Afferrare, tagliare il filo per legatura in eccesso.
27605	Pin&Ligature Cutter EVER F.605 with Hard MATL	Afferrare, tagliare il filo per legatura in eccesso.
27606	Distal End Cutter EVER Fine 606S T/C	Afferrare, tagliare l'arco ortodontico in eccesso.
27607	Distal End Cutter EVER Fine 606L T/C	Afferrare, tagliare l'arco ortodontico in eccesso.
27615	Pin&Ligature Cutter EVER C.615 with Hard MATL	Afferrare, tagliare il filo per legatura in eccesso.
27722	Wire Cutter Heavy Duty	Tagliare il filo.
27934	Convertible Cap Removing Pliers ND-934	Afferrare, rimuovere il tappo del tubo convertibile.
27935	Convertible Cap Removing Pliers ND-934 Blade	Componente fondamentale di "27934"

7 [Precauzioni e divieti generali]

- 1) L'uso del prodotto è rigorosamente limitato all'ambito dei trattamenti odontoiatrici.
Devono essere seguite precauzioni volte a garantire l'uso appropriato degli strumenti.
- 2) Non utilizzare gli strumenti per finalità diverse dall'uso previsto.
- 3) Pulire, lubrificare e sterilizzare prima dell'uso, seguendo le istruzioni riportate nelle istruzioni per l'uso.
- 4) Non utilizzare gli strumenti per pazienti che presentano sintomi di ipersensibilità, quali eruzione cutanea o dermatite, o sintomi allergici.
- 5) Non modificare la struttura né rimodellare gli strumenti.
- 6) Non far cadere gli strumenti. Evitare di sottoporli a forti urti.
- 7) Per lo smaltimento degli strumenti seguire le indicazioni delle pertinenti normative nazionali.
- 8) Non scaldare gli strumenti.
- 9) Qualora gli strumenti venga a contatto con sostanze chimiche, rimuoverle immediatamente per evitare il pericolo di corrosione.
- 10) Per piegare un filo utilizzando gli strumenti, afferrarlo con le pinze e piegarlo con le dita per evitare di danneggiare le pinze.
- 11) Pur presentando una maggior resistenza rispetto al ferro, l'acciaio inossidabile può comunque essere soggetto a corrosione a causa della modalità d'uso e a condizioni ambientali, quali temperatura e umidità.

8 [Restrizioni all'utilizzo]

Interrompere immediatamente l'uso del prodotto in caso di segni di deterioramento o anomalie.

9 [Trattamento iniziale presso il punto di utilizzo]

Pulire, lubrificare e sterilizzare prima dell'uso, seguendo le istruzioni riportate nelle istruzioni per l'uso.

10 [Preparazione prima della pulizia]

Vedere la sezione successiva.

11 [Procedura di pulizia e sterilizzazione/disinfezione]

1) Precauzioni generali

a) Per la manutenzione degli strumenti consultare la "The Fundamental Guide Book for Cleaning and Sterilizing Instruments" (Guida fondamentale alla pulizia e sterilizzazione della strumentazione) pubblicata dalla nostra azienda o la voce "Manutenzione" del nostro sito web (http://www.ydm.co.jp/en-new/pdf/The_process_of_cleaning_and_sterilizing.pdf).

b) Se contaminati con sangue, liquidi corporei, frammenti di tessuto, sostanze chimiche e simili, gli strumenti devono essere immediatamente puliti e sterilizzati, seguendo la procedura, sotto descritta per impedire che gli agenti contaminanti si secchino e si attacchino.

Gli agenti contaminanti presenti sugli strumenti per lungo tempo possano diventare difficili da rimuovere.

2) Procedura

a) Aprire il giunto.

b) Pulire gli strumenti con un detergente, seguendo il metodo i) o ii).

i) Utilizzare un sistema di pulizia a ultrasuoni, effettuando un trattamento con detergente antiruggine durante 5 minuti.

ii) Immergere in detergente antiruggine per uso medico e lavare durante 15 minuti.

c) Rimuovere dagli strumenti le impurità e il detergente utilizzando acqua corrente.

(La presenza prolungata di componenti del detergente sulla superficie degli strumenti può causare ruggine e macchie.)

d) Asciugare gli strumenti. (L'umidità residua può essere causa di ruggine e ridurre l'effetto di sterilizzazione)

e) Applicare sul giunto un lubrificante antiruggine, come l'"olio per strumentazione".

* Non aprire o chiudere fino all'applicazione del lubrificante antiruggine. (In caso contrario il movimento sarà difficoltoso)

f) Sterilizzare in autoclave.

Condizioni: da 134 °C a 138 °C, tra 3 e 3,5 minuti

* Per impedire che possano verificarsi graffi per via del contatto con altri strumenti, riporre il dispositivo in una confezione o astuccio sterile.

g) Dopo l'uso pulire immediatamente come descritto al precedente punto b).

3) Precauzioni per pulizia e sterilizzazione/disinfezione

a) Non utilizzare i seguenti agenti chimici che possono causare corrosione del metallo.

Ipoclorito di sodio, cloruro di benzalconio, clorexidina gluconato, tintura di iodio, iodoform e acido peracetico possono corrodere il metallo.

b) Non usare l'autoclave chimica per pulire gli strumenti in quanto può causare corrosione.

c) Non eseguire sterilizzazione al plasma in quanto può influire sul materiale.

d) Non utilizzare detergenti domestici in quanto non sono idonei a rimuovere le proteine sulla superficie degli strumenti.

e) Spazzole di metallo e lana d'acciaio possono danneggiare gli strumenti.

f) Non utilizzare acqua super acida, in quanto può causare corrosione.

Per il risciacquo si raccomanda l'uso di acqua purificata (priva di impurità).

L'acqua del rubinetto contiene cloro che può corrodere il metallo.

g) Utilizzando un dispositivo quale una lava-disinfettatrice è possibile che i residui di impurità o soluzione detergente possano non venire completamente rimossi con un programma ridotto o eco. Consultare il manuale di istruzioni del produttore e documenti analoghi per garantire un adeguato risciacquo e la rimozione delle impurità.

h) Prendere nota di quanto segue quando si utilizzano autoclavi sterilizzatrici.

i) Il serbatoio dell'autoclave sterilizzatrice può essere soggetto a contaminazione, a seconda del periodo e del tipo di utilizzo.

Le eventuali impurità presenti nell'autoclave sterilizzatrice possono aderire agli strumenti.

Si raccomanda di effettuare le operazioni di pulizia in base al manuale di istruzioni della sterilizzatrice.

Ciò consentirà di evitare la penetrazione di impurità all'interno della camera. In particolare, è opportuno sostituire con una certa frequenza la guarnizione di gomma del coperchio della camera e il filtro dell'aria.

ii) Per quanto possibile fare uso di acqua purificata.

L'uso di acqua del rubinetto può causare corrosione per via dell'influenza degli ioni di cloro.

iii) Fare attenzione alla temperatura di asciugatura all'interno dell'autoclave sterilizzatrice.

iv) Non posizionare gli strumenti nei pressi di sorgenti di calore.

(In tal caso la temperatura potrebbe essere superiore a quella indicata)

v) Esiste il rischio di danneggiare la superficie degli strumenti in caso di procedura incompleta di pulizia o risciacquo o in presenza

i) A seguito di lavaggio e sterilizzazione, rimuovere l'acqua presente sullo strumento e far asciugare accuratamente

12 [Manutenzione, ispezione e controllo]

Dopo aver eseguito la pulizia e la sterilizzazione controllare quanto segue prima dell'uso.

1) Verificare l'assenza di impurità, danni, crepe, graffi o segni di corrosione all'interno e esterno del giunto.

2) Verificare che il giunto non presenti un movimento anomalo.

13 [Conservazione]

- 1) Conservare in un luogo pulito privo di polvere, evitando valori elevati di temperatura e umidità.
- 2) Per prevenire correnti galvaniche causate dalla differenza di potenziale, non conservare insieme a strumenti di materiali diversi.
- 3) Considerare quanto segue per prevenire la comparsa di ruggine.
 - a) Non conservare insieme a strumenti arrugginiti.
 - b) Non conservare insieme a sostanze chimiche.
 - c) Fare attenzione alla ruggine all'interno dei sistemi di sterilizzazione e di conservazione.

14 [Smaltimento]

Lo smaltimento nel rispetto delle pertinenti norme applicabili è di responsabilità dei professionisti dentali e/o degli ortodontisti. YDM CORPORATION declina qualsiasi responsabilità per danni causati da smaltimento non conforme alle prescrizioni e lesioni personali.

15 [Informazioni supplementari]

<Rottura o affilatura>

In caso di rottura degli strumenti, contattare il distributore da cui è stato acquistato utilizzando il modulo denominato "Segnalazione di guasto" predisposto da YDM CORPORATION.

Per quanto riguarda l'affilatura di strumenti di taglio, potremo occuparcene a fronte del pagamento di un determinato corrispettivo.

16 [Contatti del produttore]



YDM CORPORATION

28 Imaizumi, Higashi-Matsuyama-shi,

Saitama 355-0042, Japan

TEL: 81-3-3828-3161

FAX: 81-3-3827-8991

URL: <http://www.ydm.co.jp/>

E-mail: ydm@ydm.co.jp

17 [Comunicazione per l'utente e/o il paziente]

Eventuali incidenti gravi verificatisi in relazione agli strumenti devono essere segnalate a YDM CORPORATION.

18 [Informazioni supplementari]

In caso di vizio del dispositivo, contattare il distributore da cui è stato acquistato utilizzando il modulo denominato "Segnalazione di guasto" predisposto da YDM Corporation.

19 [Descrizione dei simboli]



Dispositivo medico



Produttore



Numero di lotto



Avviso

Il produttore del dispositivo ha verificato che le istruzioni sopra riportate consentono di preparare un dispositivo medico per il riutilizzo.

È di responsabilità dell'operatore garantire il raggiungimento del risultato desiderato dell'effettivo trattamento fornito utilizzando l'apparecchiatura, i materiali e il personale nella struttura di trattamento.

A tal fine sono necessari la verifica e/o convalida e il monitoraggio di routine del procedimento.

Ver. 01 23 giugno 2021

Ver. 02 24 agosto 2022

Ver. 03 6 luglio 2023

- 1 [Naam productfamilie] Orthodontische tang
- 2 [Fabrikant] YDM CORPORATION
- 3 [Modelnr. en handelsnaam van het instrument]



Modelnr.	Handelsnaam van instrument	UDI-DI	Maximale snijdiepte en buigvermogen
22001	Adams Pliers Universal T/C	4963931220014	
22102	Orthodontic Pliers Band Contouring ND-202L	4963931221028	-
22104	Orthodontic Pliers Band Margin ND-204	4963931221042	-
22133	Orthodontic Pliers Band Removing ND-303	4963931221332	-
22141	Orthodontic Pliers Peeso ND-401	4963931221417	,040"
22142	Orthodontic Pliers Young ND-402	4963931221424	,040"
22143	Orthodontic Pliers Tweed Arch ND-403	4963931221431	,022"- ,028"
22145	Orthodontic Pliers Tweed Loop Forming ND-405	4963931221455	,022"- ,028"
22147	Orthodontic Pliers Three Jaw ND-407	4963931221479	,036"
22149	Orthodontic Pliers Bird Beak ND-409	4963931221493	,036"
22152	Orthodontic Pliers How ND-502L	4963931221523	-
22154	Orthodontic Pliers Utility ND-504	4963931221547	-
22155	Orthodontic Pliers How ND-502S	4963931221554	-
22159	Orthodontic Pliers Kim T/C ND-419	4963931221592	,016"- ,022"(buigen)/ ,020"(snijden)
22160	Orthodontic Pliers Light Wire Cutter T/C ND-420	4963931221608	,020"(buigen/snijden)
22210	Orthodontic Pliers for Aligner Tear Drop	4963931222100	-
22211	Orthodontic Pliers for Aligner Vertical	4963931222117	-
22212	Orthodontic Pliers for Aligner Horizontal	4963931222124	-
22213	Orthodontic Pliers for Aligner Hole Punch	4963931222131	-
22506	Tying Pliers YS-506	4963931225064	-
22507	Tying Pliers YS-507	4963931225071	-
22508	Tying Pliers YS-508	4963931225088	-
22509	Module Pliers Str.	4963931225095	-
22510	Module Pliers Cvd.	4963931225101	-
22511	Module Pliers with Groove Str.	4963931225118	-
22513	Module Pliers Mosquito Str.	4963931225132	-
22514	Module Pliers Mosquito Cvd.	4963931225149	-
22551	Separator YS-551	4963931225514	-
22601	Wire Cutter YS-601	4963931226016	,032"
22602	Wire Cutter YS-602 KI	4963931226023	,045"
22603	Wire Cutter YS-603 Standard	4963931226030	,048"
22606	Pin & Ligature Cutter ND-605 with Hard Material	4963931226061	,012"
22607	Pin & Ligature Cutter ND-605B T/C	4963931226078	,014"
22610	Distal End Cutter ND-606S T/C	4963931226108	,022"- ,028"
22611	Distal End Cutter ND-606LT/C	4963931226115	,022"- ,028"
27410	Ortho.Pliers EVER Classic 410 Band Contouring	4963931274109	-
27411	Ortho.Pliers EVER Classic 411 Band Margin	4963931274116	-
27412	Ortho.Pliers EVER Classic 412 Band Removing	4963931274123	-
27413	Ortho.Pliers EVER C. 413 Bracket Removing T/C	4963931274130	-
27414	Ortho.Pliers EVER Classic 414 Young	4963931274147	,040"
27415	Ortho.Pliers EVER Classic 415 Tweed Arch	4963931274154	,022 x ,028"
27416	Ortho.Pliers EVER C. 416 Tweed Loop Forming	4963931274161	,022 x ,028"
27417	Ortho.Pliers EVER Classic 417 Three Jaw	4963931274178	,036"
27418	Ortho.Pliers EVER Classic 418 Bird Beak	4963931274185	,036"
27419	Ortho.Pliers EVER C. 419 Nance Closing Loop	4963931274192	,022"
27420	Ortho.Pliers EVER Classic 420 How	4963931274208	-
27421	Ortho.Pliers EVER Classic 421 Weingart	4963931274215	-
27422	Ortho.Pliers EVER Classic 422 Utility	4963931274222	-
27423	Ortho.Pliers EVER Classic 423 Kim T/C	4963931274239	,016"- ,022"(buigen)/ ,020"(snijden)
27424	Ortho.Pliers EVER Classic 424 Light Wire T/C	4963931274246	,020"(buigen/snijden)
27425	Ortho.Pliers EVER Classic 425 Crimping	4963931274253	-
27426	Ortho.Pliers EVER C.426 Lingual Hollow Chop	4963931274260	,022 x ,028"
27427	Ortho.Pliers EVER Classic 427 Torquing M	4963931274277	,022 x ,028"
27428	Ortho.Pliers EVER Classic 428 Torquing F	4963931274284	,022 x ,028"
27440	Ortho.Pliers EVER Fine 440 Utility	4963931274406	-
27441	Ortho.Pliers EVER Fine 441 Weingart	4963931274413	-
27442	Ortho.Pliers EVER Fine 442 How	4963931274420	-
27443	Ortho.Pliers EVER Fine 443 Band Removing	4963931274437	-
27444	Ortho.Pliers EVER F.444 Bracket Removing T/C	4963931274444	-

27445	Ortho.Pliers EVER Fine 445 Step 1/2mm	4963931274451	,022 x ,028"
27446	Ortho.Pliers EVER Fine 446 Step 3/4mm	4963931274468	,022 x ,028"
27447	Ortho.Pliers EVER Fine 447 Step 1mm	4963931274475	,022 x ,028"
27448	Ortho.Pliers EVER Fine 448 Tear Drop	4963931274482	-
27449	Ortho.Pliers EVER Fine 449 Vertical	4963931274499	-
27450	Ortho.Pliers EVER Fine 450 Horizontal	4963931274505	-
27451	Ortho.Pliers EVER Fine 451 Hole Punch	4963931274512	-
27452	Ortho.Pliers EVER Fine 452 Light Wire T/C	4963931274529	,020"(buigen/snijden)
27453	Ortho.Pliers EVER Fine 453 Kim T/C	4963931274536	,016"-,022"(buigen),,020"(snijden)
27454	Ortho.Pliers EVER Fine 454 Young	4963931274543	,040"
27455	Ortho.Pliers EVER Fine 455 Tweed Arch	4963931274550	,022 x ,028"
27456	Ortho.Pliers EVER Fine 456 Tweed Loop Forming	4963931274567	,022 x ,028"
27457	Ortho.Pliers EVER Fine 457 Three Jaw	4963931274574	,036"
27458	Ortho.Pliers EVER Fine 458 Bird Beak	4963931274581	,036"
27459	Ortho.Pliers EVER F. 459 Nance Closing Loop	4963931274598	,022"
27460	Ortho.Pliers EVER Fine 460 Band Removing L	4963931274604	-
27461	Ortho.Pliers EVER Fine 461 Cinch Back	4963931274611	,020"/,016"-016"
27462	Ortho.Pliers EVER Fine 462 Lingual Utility	4963931274628	-
27463	Ortho.Pliers EVER F.463 Round Former 1.0	4963931274635	-
27464	Ortho.Pliers EVER F.464 Round Former 2.0 SM	4963931274642	-
27465	Ortho.Pliers EVER Fine Key Punch 465	4963931274659	-
27550	Orthodontic Pliers Crimping Ortolan	4963931275502	-
27551	ROMAN 1 Circle Cutter SMOOTH	4963931275519	-
27552	ROMAN 2 Horizontal Box SMOOTH	4963931275526	-
27553	ROMAN 3 Vertical Box SMOOTH	4963931275533	-
27554	ROMAN 4 Pearl Dot SMOOTH	4963931275540	-
27555	ROMAN 5 Keyhole Cutter SMOOTH	4963931275557	-
27556	Angle Fluted Bird Beak Pliers	4963931275564	,036"
27601	Pin&Ligature Cutter EVER F.601 Angle 40	4963931276011	,012"
27602	Pin&Ligature Cutter EVER F.602 Reverse 40	4963931276028	,012"
27603	Pin&Ligature Cutter EVER F.603 Angle 50	4963931276035	,012"
27604	Pin&Ligature Cutter EVER F.604 Reverse 50	4963931276042	,012"
27605	Pin&Ligature Cutter EVER F.605 with Hard MATL	4963931276059	,012"
27606	Distal End Cutter EVER Fine 606S T/C	4963931276066	,022"-,028"
27607	Distal End Cutter EVER Fine 606L T/C	4963931276073	,022"-,028"
27615	Pin&Ligature Cutter EVER C.615 with Hard MATL	4963931276158	,014"
27934	Convertible Cap Removing Pliers ND-934	4963931279340	-
27935	Convertible Cap Removing Pliers ND-934 Blade	4963931279357	-

4 [Gebruiksdoel van het instrument]

Het instrument is medisch geïndiceerd voor gebruik bij het vasthouden, vastzetten of verwijderen van kleine voorwerpen, het buigen of doorsnijden van metaalstrips of -draad en het maken van kleine putjes in de harslaag van orthodontische voorzieningen.

5 [Prestatiekenmerken van het instrument]

<Overzicht>

Het instrument fungeert als een klein pincet met een bek waarvan de vorm varieert, afhankelijk van het gebruiksdoel.

<Materiaal>

Roestvrij staal

6 [Instructies voor het gebruik]

Modelnr.	Handelsnaam van instrument	Instructies voor het gebruik
22001	Adams Pliers Universal T/C	Pak en buig het klemdraad om te fixeren.
22102	Orthodontic Pliers Band Contouring ND-202L	Pak en buig de rand van het band om te laten aansluiten op de vorm van de tanden.
22104	Orthodontic Pliers Band Margin ND-204	Pak en buig de rand van het band om te laten aansluiten op de vorm van de tanden.
22133	Orthodontic Pliers Band Removing ND-303	Laat de rand van het band aansluiten, occlusale zijde van de tanden en verwijder het band
22141	Orthodontic Pliers Peeso ND-401	Pak en buig het buigdraad om aan te spannen, voor traprede-effect.
22142	Orthodontic Pliers Young ND-402	Pak en buig het buigdraad tot een lus.
22143	Orthodontic Pliers Tweed Arch ND-403	Pak en buig het buigdraad om aan te spannen, voor traprede-effect.
22145	Orthodontic Pliers Tweed Loop Forming ND-405	Pak en buig het buigdraad tot een lus.
22147	Orthodontic Pliers Three Jaw ND-407	Pak en buig het buigdraad tot een v-vorm.
22149	Orthodontic Pliers Bird Beak ND-409	Pak en buig het buigdraad tot een lus.
22152	Orthodontic Pliers How ND-502L	Pak het binddraad en knoop het vast.
22154	Orthodontic Pliers Utility ND-504	Pak het buigdraad en breng het aan in de beugel, buccale slotje.
22155	Orthodontic Pliers How ND-502S	Pak het binddraad en knoop het vast.
22159	Orthodontic Pliers Kim T/C ND-419	Pak en buig het buigdraad tot een lus.
22160	Orthodontic Pliers Light Wire Cutter T/C ND-420	Pak en buig het buigdraad tot een lus.
22210	Orthodontic Pliers for Aligner Tear Drop	Pak het uitlijninstrument en stel dit verder in werking.
22211	Orthodontic Pliers for Aligner Vertical	Pak het uitlijninstrument en stel dit verder in werking.
22212	Orthodontic Pliers for Aligner Horizontal	Pak het uitlijninstrument en stel dit verder in werking.
22213	Orthodontic Pliers for Aligner Hole Punch	Pak het uitlijninstrument en stel dit verder in werking.
22506	Tying Pliers YS-506	Pak het binddraad en knoop het vast.
22507	Tying Pliers YS-507	Pak het binddraad en knoop het vast.
22508	Tying Pliers YS-508	Pak het binddraad en knoop het vast.
22509	Module Pliers Str.	Pak de elastiekmodule en breng deze aan op de beugel.
22510	Module Pliers Cvd.	Pak de elastiekmodule en breng deze aan op de beugel.
22511	Module Pliers with Groove Str.	Pak de elastiekmodule en breng deze aan op de beugel.
22513	Module Pliers Mosquito Str.	Pak de elastiekmodule en breng deze aan op de beugel.
22514	Module Pliers Mosquito Cvd.	Pak de elastiekmodule en breng deze aan op de beugel.
22551	Separator YS-551	Spreid de scheidingsmodule en breng deze aan tussen de tanden.
22601	Wire Cutter YS-601	Pak het draad en snijd het door.
22602	Wire Cutter YS-602 KI	Pak het draad en snijd het door.
22603	Wire Cutter YS-603 Standard	Pak het draad en snijd het door.
22606	Pin & Ligature Cutter ND-605 with Hard Material	Pak eventueel overtollig binddraad en snijd het door.
22607	Pin & Ligature Cutter ND-605B T/C	Pak eventueel overtollig binddraad en snijd het door.
22610	Distal End Cutter ND-606S T/C	Pak eventueel overtollig buigdraad en snijd het door.
22611	Distal End Cutter ND-606LT/C	Pak eventueel overtollig buigdraad en snijd het door.
27410	Ortho.Pliers EVER Classic 410 Band Contouring	Pak en buig de rand van het band om te laten aansluiten op de vorm van de tanden.
27411	Ortho.Pliers EVER Classic 411 Band Margin	Pak en buig de rand van het band om te laten aansluiten op de vorm van de tanden.
27412	Ortho.Pliers EVER Classic 412 Band Removing	Laat de rand van het band aansluiten, occlusale zijde van de tanden en verwijder het band
27413	Ortho.Pliers EVER C. 413 Bracket Removing T/C	Pak de beugel en verwijder deze.
27414	Ortho.Pliers EVER Classic 414 Young	Pak en buig het buigdraad tot een lus.
27415	Ortho.Pliers EVER Classic 415 Tweed Arch	Pak en buig het buigdraad om aan te spannen, voor traprede-effect.
27416	Ortho.Pliers EVER C. 416 Tweed Loop Forming	Pak en buig het buigdraad tot een lus.
27417	Ortho.Pliers EVER Classic 417 Three Jaw	Pak en buig het buigdraad tot een v-vorm.
27418	Ortho.Pliers EVER Classic 418 Bird Beak	Pak en buig het buigdraad tot een lus.
27419	Ortho.Pliers EVER C. 419 Nance Closing Loop	Pak en buig het buigdraad tot een lus.
27420	Ortho.Pliers EVER Classic 420 How	Pak het binddraad en knoop het vast.
27421	Ortho.Pliers EVER Classic 421 Weingart	Pak het buigdraad en breng het aan in de beugel, buccale slotje.
27422	Ortho.Pliers EVER Classic 422 Utility	Pak het buigdraad en breng het aan in de beugel, buccale slotje.
27423	Ortho.Pliers EVER Classic 423 Kim T/C	Pak en buig het buigdraad tot een lus.
27424	Ortho.Pliers EVER Classic 424 Light Wire T/C	Pak en buig het buigdraad tot een lus.
27425	Ortho.Pliers EVER Classic 425 Crimping	Pak de krimphaak en breng deze aan op het buigdraad.
27426	Ortho.Pliers EVER C.426 Lingual Hollow Chop	Pak het buigdraad en buig dit in de gewenste curve.
27427	Ortho.Pliers EVER Classic 427 Torquing M	Pak het buigdraad met de "27428" en draai om het buigdraad te spannen.
27428	Ortho.Pliers EVER Classic 428 Torquing F	Pak het buigdraad met de "27427" en draai om het buigdraad te spannen.
27440	Ortho.Pliers EVER Fine 440 Utility	Pak het buigdraad en breng het aan in de beugel, buccale slotje.
27441	Ortho.Pliers EVER Fine 441 Weingart	Pak het buigdraad en breng het aan in de beugel, buccale slotje.
27442	Ortho.Pliers EVER Fine 442 How	Pak het binddraad en knoop het vast.
27443	Ortho.Pliers EVER Fine 443 Band Removing	Laat de rand van het band aansluiten, occlusale zijde van de tanden en verwijder het band
27444	Ortho.Pliers EVER F.444 Bracket Removing T/C	Pak de beugel en verwijder deze.
27445	Ortho.Pliers EVER Fine 445 Step 1/2mm	Pak het buigdraad en buig het voor een traprede-effect.
27446	Ortho.Pliers EVER Fine 446 Step 3/4mm	Pak het buigdraad en buig het voor een traprede-effect.
27447	Ortho.Pliers EVER Fine 447 Step 1mm	Pak het buigdraad en buig het voor een traprede-effect.
27448	Ortho.Pliers EVER Fine 448 Tear Drop	Pak het uitlijninstrument en stel dit verder in werking.
27449	Ortho.Pliers EVER Fine 449 Vertical	Pak het uitlijninstrument en stel dit verder in werking.

27450	Ortho.Pliers EVER Fine 450 Horizontal	Pak het uitlijninstrument en stel dit verder in werking.
27451	Ortho.Pliers EVER Fine 451 Hole Punch	Pak het uitlijninstrument en stel dit verder in werking.
27452	Ortho.Pliers EVER Fine 452 Light Wire T/C	Pak en buig het buigdraad tot een lus.
27453	Ortho.Pliers EVER Fine 453 Kim T/C	Pak en buig het buigdraad tot een lus.
27454	Ortho.Pliers EVER Fine 454 Young	Pak en buig het buigdraad tot een lus.
27455	Ortho.Pliers EVER Fine 455 Tweed Arch	Pak en buig het buigdraad om aan te spannen, voor traprede-effect.
27456	Ortho.Pliers EVER Fine 456 Tweed Loop Forming	Pak en buig het buigdraad tot een lus.
27457	Ortho.Pliers EVER Fine 457 Three Jaw	Pak en buig het buigdraad tot een v-vorm.
27458	Ortho.Pliers EVER Fine 458 Bird Beak	Pak en buig het buigdraad tot een lus.
27459	Ortho.Pliers EVER F. 459 Nance Closing Loop	Pak en buig het buigdraad tot een lus.
27460	Ortho.Pliers EVER Fine 460 Band Removing L	Laat de rand van het band aansluiten, occlusale zijde van de tanden en verwijder het band
27461	Ortho.Pliers EVER Fine 461 Cinch Back	Pak en buig het uiteinde van het buigdraad.
27462	Ortho.Pliers EVER Fine 462 Lingual Utility	Pak het buigdraad en breng het aan in de beugel, buccale slotje.
27463	Ortho.Pliers EVER F.463 Round Former 1.0	Pak het uitlijninstrument en stel dit verder in werking.
27464	Ortho.Pliers EVER F.464 Round Former 2.0 SM	Pak het uitlijninstrument en stel dit verder in werking.
27465	Ortho.Pliers EVER Fine Key Punch 465	Pak het uitlijninstrument en stel dit verder in werking.
27550	Orthodontic Pliers Crimping Ortolan	Pak de krimphaak en breng deze aan op het buigdraad.
27551	ROMAN 1 Circle Cutter SMOOTH	Pak het uitlijninstrument en stel dit verder in werking.
27552	ROMAN 2 Horizontal Box SMOOTH	Pak het uitlijninstrument en stel dit verder in werking.
27553	ROMAN 3 Vertical Box SMOOTH	Pak het uitlijninstrument en stel dit verder in werking.
27554	ROMAN 4 Pearl Dot SMOOTH	Pak het uitlijninstrument en stel dit verder in werking.
27555	ROMAN 5 Keyhole Cutter SMOOTH	Pak het uitlijninstrument en stel dit verder in werking.
27556	Angle Fluted Bird Beak Pliers	Pak en buig het uiteinde van het buigdraad.
27601	Pin&Ligature Cutter EVER F.601 Angle 40	Pak eventueel overtollig binddraad en snijd het door.
27602	Pin&Ligature Cutter EVER F.602 Reverse 40	Pak eventueel overtollig binddraad en snijd het door.
27603	Pin&Ligature Cutter EVER F.603 Angle 50	Pak eventueel overtollig binddraad en snijd het door.
27604	Pin&Ligature Cutter EVER F.604 Reverse 50	Pak eventueel overtollig binddraad en snijd het door.
27605	Pin&Ligature Cutter EVER F.605 with Hard MATL	Pak eventueel overtollig binddraad en snijd het door.
27606	Distal End Cutter EVER Fine 606S T/C	Pak eventueel overtollig buigdraad en snijd het door.
27607	Distal End Cutter EVER Fine 606L T/C	Pak eventueel overtollig buigdraad en snijd het door.
27615	Pin&Ligature Cutter EVER C.615 with Hard MATL	Pak eventueel overtollig binddraad en snijd het door.
27722	Wire Cutter Heavy Duty	Snijd het draad door.
27934	Convertible Cap Removing Pliers ND-934	Pak en verwijder het kapje van het convertible slotje.
27935	Convertible Cap Removing Pliers ND-934 Blade	Hoofdonderdeel van "27934"

7 [Algemene voorzorgsmaatregelen en beperkingen]

- 1) Het product dient uitsluitend voor gebruik bij gebitsbehandelingen.
Voor een correct gebruik van de instrumenten dienen de voorzorgsmaatregelen in acht te worden genomen.
- 2) Gebruik de instrumenten nergens anders voor dan het gebruiksdoel.
- 3) Reinig, smeer en steriliseer de instrumenten voorafgaand aan het gebruik en volgens de instructies in de gebruiksaanwijzing.
- 4) Gebruik de instrumenten niet bij patiënten met ziekteverschijnselen die duiden op een overgevoeligheid, zoals uitslag en dermatitis of symptomen van een allergie.
- 5) Er mogen geen wijzigingen worden aangebracht aan het ontwerp of model van de instrumenten.
- 6) Laat de instrumenten niet vallen. De instrumenten mogen niet worden blootgesteld aan hoge slagkrachten.
- 7) Volg voor het afvoeren van de instrumenten de gedetailleerde instructies in de desbetreffende nationale voorschriften.
- 8) Verhit de instrumenten niet.
- 9) Veeg chemische stoffen die zich aan de instrumenten hebben gehecht onmiddellijk weg om roestvorming te voorkomen.
- 10) Wanneer u het draad met deze instrumenten wilt buigen, houdt u het draad vast met de tang, waarna u het draad met uw vingers buigt. Zo voorkomt u dat de tang wordt beschadigd.
- 11) Hoewel roestvrij staal beter bestand is tegen roestvorming dan ijzer, kunnen factoren als de manier van gebruik en omgevingsfactoren zoals de temperatuur en vochtigheidsgraad, toch roestvorming in de hand werken.

8 [Beperkingen bij de verwerking]

Staak het gebruik van de instrumenten onmiddellijk wanneer u een beschadiging of iets anders afwijkends constateert.

9 [Eerste keer gebruiken in het doelgebied]

Reinig, smeer en steriliseer de instrumenten voorafgaand aan het gebruik volgens de instructies in de gebruiksaanwijzing.

10 [Voorbereiding voorafgaand aan het reinigen]

Zie de volgende paragraaf.

11 [Het proces van reinigen en steriliseren/desinfecteren]

1) Algemene voorzorgsmaatregelen

a) Raadpleeg voor onderhoud van de instrumenten het "The Fundamental Guide Book for Cleaning and Sterilizing Instruments" (basishandboek voor het reinigen en steriliseren van instrumenten) dat door ons bedrijf is uitgegeven of het onderdeel maintenance (onderhoud) op onze website

(http://www.ydm.co.jp/en-new/pdf/The_process_of_cleaning_and_sterilizing.pdf).

b) Indien een instrument is verontreinigd met bloed, lichaamsvocht, weefselresten, chemische stoffen en dergelijke, moet het onmiddellijk op de hier volgende wijze worden gesteriliseerd, om te voorkomen dat de verontreinigingen opdrogen en zich vasthechten.

Verontreinigingen die zich langdurig aan de instrumenten hebben vastgehecht, zijn moeilijker te verwijderen.

2) Procedure

a) Open het scharnier.

b) Reinig de instrumenten met een schoonmaakmiddel volgens methode i) of ii).

i) In een ultrasoon reinigingstoestel met een medisch antiroest-reinigingsmiddel gedurende 5 minuten.

ii) Ondergedompeld in een reinigingstoestel met antiroest-reinigingsmiddel voor medische doeleinden gedurende 15 minuten.

c) Was vuil en resten van het reinigingsmiddel van de instrumenten onder stromend water.

(Eventuele achtergebleven zeepresten op de instrumenten veroorzaken roest en vlekken).

d) Droog de instrumenten.

(Niet opgedroogde vloeistoffen kunnen roestvorming en een verminderd effect van de sterilisatie teweegbrengen)

e) Breng een antiroest-smeermiddel zoals "instrument oil" aan op het scharnier.

*Open of sluit het scharnier pas nadat het antiroest-smeermiddel is aangebracht (openen en sluiten zonder olie leidt tot stroefheid).

f) Steriliseer het instrument in een sterilisatie-autoclaaf.

Voorwaarden: 134 °C tot 138 °C, 3 tot 3,5 minuten

*Plaats instrumenten in een sterilisatieverpakking of -cassette om krassen door contact met andere instrumenten te voorkomen.

g) Reinig instrumenten na gebruik onmiddellijk zoals aangegeven bij b) hierboven.

3) Voorzorgsmaatregelen voor het reinigen en steriliseren/desinfecteren

a) De volgende chemische stoffen kunnen corrosie veroorzaken en mogen daarom niet worden gebruikt.

natriumhypochloriet, benzalkoniumchloride, chloorhexidinegluconaat, joodtinctuur, jodoform en perazijnzuur kunnen metaal laten corroderen.

b) Plaats de instrumenten niet in een chemische autoclaaf; dit kan corrosie veroorzaken.

c) Voer geen plasmasterilisatie uit. Dit kan het materiaal aantasten.

d) Gebruik geen huishoudelijke schoonmaakmiddelen; deze zijn niet geschikt om eiwitten van de instrumenten te verwijderen.

e) Staalborstels en staalwol kunnen instrumenten beschadigen.

f) Gebruik geen water met een hoge zuurgraad; dit kan corrosie veroorzaken.

Voor het spoelen wordt gezuiverd water (zonder onzuiverheden) aanbevolen.

Door het chloor dat aanwezig is in leidingwater kan metaal gaan corroderen.

g) Wanneer bij het gebruik van een reinigungsapparaat zoals een was-/desinfectietoestel een programma voor water- of tijdbesparing wordt gebruikt, worden vastgehechte resten van de reinigungsoplossing mogelijk niet volledig verwijderd.

voor water- of tijdbesparing wordt gebruikt, worden vastgehechte resten van de reinigungsoplossing mogelijk niet volledig verwijderd. Raadpleeg altijd de gebruiksaanwijzing van de fabrikant en dergelijke om zeker te zijn van de juiste methode voor het spoelen en het verwijderen van vuil.

h) Houd bij het gebruik van een sterilisatieautoclaaf rekening met het volgende.

i) De sterilisatieautoclaaf kan in de kast verontreinigd zijn, afhankelijk van de status en duur van het gebruik.

Achtergebleven vuil in de sterilisatieautoclaaf kan zich aan de instrumenten hechten.

We raden u aan de instrumenten te reinigen volgens de instructies in de handleiding van het sterilisatietoestel.

Op die manier houdt u de kamer vrij van vuil. Na een bepaalde tijdsduur moeten in elk geval de rubberen verzegeling van het deksel op de kamer en het luchtfilter worden vervangen.

ii) Gebruik waar mogelijk gezuiverd water. Leidingwater kan door de aanwezigheid van chloorionen corrosie veroorzaken.

iii) Houd rekening met de temperatuur voor drogen in de sterilisatieautoclaaf.

iv) Plaats de instrumenten niet in de buurt van een warmtebron

(deze kan een hogere temperatuur hebben dan wordt aangegeven).

v) Als het reinigungs- of spoelprogramma van de sterilisatieautoclaaf nog niet is voltooid,

of als de kamer van de sterilisatieautoclaaf nog water bevat, kunnen zich brandplekken vormen op de instrumenten.

i) Verwijder na het wassen en steriliseren al het water van het instrument en laat het goed drogen.

12 [Onderhoud, inspectie en testen]

Na het reinigen en steriliseren en voorafgaand aan het gebruik moet het volgende worden gecontroleerd.

1) Controleer of de binnen- of buitenzijde van het scharnier geen schade, barsten, krassen of corrosie vertoont.

2) Controleer of het scharnier normaal kan bewegen.

13 [Opslag]

- 1) Bewaar het instrument op een schone, stofvrije plaats waar de temperatuur en vochtigheidsgraad niet te hoog zijn.
- 2) Bewaar instrumenten van verschillende materialen niet bij elkaar om galvanische stroom als gevolg van potentiaalverschillen in de metalen te voorkomen.
- 3) Houd rekening met het volgende om roestvlekken te voorkomen.
 - a) Niet bewaren met roestige instrumenten.
 - b) Niet bewaren met chemische stoffen.
 - c) Let op eventuele roestvorming die zich in sterilisatietoestellen of opslagruimten heeft voorgedaan.

14 [Richtlijnen voor afvoer]

De tandheelkundig specialist en/of orthodontist is verantwoordelijk voor het juist afvoeren van het instrument in overeenstemming met de geldende wetgeving.

YDM CORPORATION wijst elke aansprakelijkheid voor lichamelijk letsel ten gevolge van een onjuiste wijze van afvoer af.

15 [Aanvullende informatie]

<Defecten en slijpen>

Als een instrument defect raakt, kunt u dit aan de dealer, waar u het instrument hebt gekocht,

melden via het door YDM CORPORATION samengestelde meldingsformulier genaamd "Claim Report".

Messen kunt u tegen betaling bij ons laten slijpen.

16 [Contactgegevens fabrikant]



YDM CORPORATION

28 Imaizumi, Higashi-Matsuyama-shi,

Saitama 355-0042, Japan

Tel: 81-3-3828-3161

Fax: 81-3-3827-8991

URL: <http://www.ydm.co.jp/>

E-mail: ydm@ydm.co.jp

17 [Ter kennisgeving aan de gebruiker en/of de patiënt]

Elk ernstig incident dat zich in verband met dit instrument heeft voorgedaan, dient te worden gemeld aan YDM CORPORATION.

18 [Aanvullende informatie]

Als het instrument defect raakt, kunt u dit aan de dealer, waar u het product hebt gekocht,

melden via het door YDM CORPORATION samengestelde meldingsformulier genaamd "Claim Report".

19 [Beschrijving van symbolen]



Medisch hulpmiddel



Fabrikant



Lotnummer



Kennisgeving

De fabrikant van het medische hulpmiddel heeft bevestigd dat de bovengenoemde instructies effectief zijn voor het geschikt maken voor hergebruik van een medisch hulpmiddel. Het blijft echter de verantwoordelijkheid van de gebruiker om ervoor te zorgen dat het verwerkingsproces, en de hierbij ingezette apparatuur, materialen en medewerkers in de verwerkingsfaciliteit, tot het gewenste resultaat leidt. Hiervoor is het noodzakelijk dat het proces wordt gecontroleerd en/of gevalideerd en op gezette tijden wordt nagelopen.

Ver.01 23 juni 2021

Ver.02 24 augustus 2022

Ver.03 6 juli 2023



- 1 [Nazwa rodziny produktów] Kleszcze ortodontyczne
- 2 [Producent] YDM CORPORATION
- 3 [Nr modelu i nazwa handlowa wyrobu]

Nr modelu	Nazwa handlowa wyrobu	UDI-DI	Maksymalne parametry cięcia i zginania
22001	Adams Pliers Universal T/C	4963931220014	
22102	Orthodontic Pliers Band Contouring ND-202L	4963931221028	-
22104	Orthodontic Pliers Band Margin ND-204	4963931221042	-
22133	Orthodontic Pliers Band Removing ND-303	4963931221332	-
22141	Orthodontic Pliers Peeso ND-401	4963931221417	,040"
22142	Orthodontic Pliers Young ND-402	4963931221424	,040"
22143	Orthodontic Pliers Tweed Arch ND-403	4963931221431	,022"- ,028"
22145	Orthodontic Pliers Tweed Loop Forming ND-405	4963931221455	,022"- ,028"
22147	Orthodontic Pliers Three Jaw ND-407	4963931221479	,036"
22149	Orthodontic Pliers Bird Beak ND-409	4963931221493	,036"
22152	Orthodontic Pliers How ND-502L	4963931221523	-
22154	Orthodontic Pliers Utility ND-504	4963931221547	-
22155	Orthodontic Pliers How ND-502S	4963931221554	-
22159	Orthodontic Pliers Kim T/C ND-419	4963931221592	,016"- ,022"(zginanie)/ ,020"(cięcie)
22160	Orthodontic Pliers Light Wire Cutter T/C ND-420	4963931221608	,020"(zginanie/cięcie)
22210	Orthodontic Pliers for Aligner Tear Drop	4963931222100	-
22211	Orthodontic Pliers for Aligner Vertical	4963931222117	-
22212	Orthodontic Pliers for Aligner Horizontal	4963931222124	-
22213	Orthodontic Pliers for Aligner Hole Punch	4963931222131	-
22506	Tying Pliers YS-506	4963931225064	-
22507	Tying Pliers YS-507	4963931225071	-
22508	Tying Pliers YS-508	4963931225088	-
22509	Module Pliers Str.	4963931225095	-
22510	Module Pliers Cvd.	4963931225101	-
22511	Module Pliers with Groove Str.	4963931225118	-
22513	Module Pliers Mosquito Str.	4963931225132	-
22514	Module Pliers Mosquito Cvd.	4963931225149	-
22551	Separator YS-551	4963931225514	-
22601	Wire Cutter YS-601	4963931226016	,032"
22602	Wire Cutter YS-602 KI	4963931226023	,045"
22603	Wire Cutter YS-603 Standard	4963931226030	,048"
22606	Pin & Ligature Cutter ND-605 with Hard Material	4963931226061	,012"
22607	Pin & Ligature Cutter ND-605B T/C	4963931226078	,014"
22610	Distal End Cutter ND-606S T/C	4963931226108	,022"- ,028"
22611	Distal End Cutter ND-606LT/C	4963931226115	,022"- ,028"
27410	Ortho.Pliers EVER Classic 410 Band Contouring	4963931274109	-
27411	Ortho.Pliers EVER Classic 411 Band Margin	4963931274116	-
27412	Ortho.Pliers EVER Classic 412 Band Removing	4963931274123	-
27413	Ortho.Pliers EVER C. 413 Bracket Removing T/C	4963931274130	-
27414	Ortho.Pliers EVER Classic 414 Young	4963931274147	,040"
27415	Ortho.Pliers EVER Classic 415 Tweed Arch	4963931274154	,022 x ,028"
27416	Ortho.Pliers EVER C. 416 Tweed Loop Forming	4963931274161	,022 x ,028"
27417	Ortho.Pliers EVER Classic 417 Three Jaw	4963931274178	,036"
27418	Ortho.Pliers EVER Classic 418 Bird Beak	4963931274185	,036"
27419	Ortho.Pliers EVER C. 419 Nance Closing Loop	4963931274192	,022"
27420	Ortho.Pliers EVER Classic 420 How	4963931274208	-
27421	Ortho.Pliers EVER Classic 421 Weingart	4963931274215	-
27422	Ortho.Pliers EVER Classic 422 Utility	4963931274222	-
27423	Ortho.Pliers EVER Classic 423 Kim T/C	4963931274239	,016"- ,022"(zginanie)/ ,020"(cięcie)
27424	Ortho.Pliers EVER Classic 424 Light Wire T/C	4963931274246	,020"(zginanie/cięcie)
27425	Ortho.Pliers EVER Classic 425 Crimping	4963931274253	-
27426	Ortho.Pliers EVER C.426 Lingual Hollow Chop	4963931274260	,022 x ,028"
27427	Ortho.Pliers EVER Classic 427 Torquing M	4963931274277	,022 x ,028"
27428	Ortho.Pliers EVER Classic 428 Torquing F	4963931274284	,022 x ,028"
27440	Ortho.Pliers EVER Fine 440 Utility	4963931274406	-
27441	Ortho.Pliers EVER Fine 441 Weingart	4963931274413	-
27442	Ortho.Pliers EVER Fine 442 How	4963931274420	-
27443	Ortho.Pliers EVER Fine 443 Band Removing	4963931274437	-
27444	Ortho.Pliers EVER F.444 Bracket Removing T/C	4963931274444	-

27445	Ortho.Pliers EVER Fine 445 Step 1/2mm	4963931274451	,022 x ,028"
27446	Ortho.Pliers EVER Fine 446 Step 3/4mm	4963931274468	,022 x ,028"
27447	Ortho.Pliers EVER Fine 447 Step 1mm	4963931274475	,022 x ,028"
27448	Ortho.Pliers EVER Fine 448 Tear Drop	4963931274482	-
27449	Ortho.Pliers EVER Fine 449 Vertical	4963931274499	-
27450	Ortho.Pliers EVER Fine 450 Horizontal	4963931274505	-
27451	Ortho.Pliers EVER Fine 451 Hole Punch	4963931274512	-
27452	Ortho.Pliers EVER Fine 452 Light Wire T/C	4963931274529	,020"(zginanie/cięcie)
27453	Ortho.Pliers EVER Fine 453 Kim T/C	4963931274536	,016"-,022"(zginanie)/,020"(cięcie)
27454	Ortho.Pliers EVER Fine 454 Young	4963931274543	,040"
27455	Ortho.Pliers EVER Fine 455 Tweed Arch	4963931274550	,022 x ,028"
27456	Ortho.Pliers EVER Fine 456 Tweed Loop Forming	4963931274567	,022 x ,028"
27457	Ortho.Pliers EVER Fine 457 Three Jaw	4963931274574	,036"
27458	Ortho.Pliers EVER Fine 458 Bird Beak	4963931274581	,036"
27459	Ortho.Pliers EVER F. 459 Nance Closing Loop	4963931274598	,022"
27460	Ortho.Pliers EVER Fine 460 Band Removing L	4963931274604	-
27461	Ortho.Pliers EVER Fine 461 Cinch Back	4963931274611	,020"/,016"-016"
27462	Ortho.Pliers EVER Fine 462 Lingual Utility	4963931274628	-
27463	Ortho.Pliers EVER F.463 Round Former 1.0	4963931274635	-
27464	Ortho.Pliers EVER F.464 Round Former 2.0 SM	4963931274642	-
27465	Ortho.Pliers EVER Fine Key Punch 465	4963931274659	-
27550	Orthodontic Pliers Crimping Ortolan	4963931275502	-
27551	ROMAN 1 Circle Cutter SMOOTH	4963931275519	-
27552	ROMAN 2 Horizontal Box SMOOTH	4963931275526	-
27553	ROMAN 3 Vertical Box SMOOTH	4963931275533	-
27554	ROMAN 4 Pearl Dot SMOOTH	4963931275540	-
27555	ROMAN 5 Keyhole Cutter SMOOTH	4963931275557	-
27556	Angle Fluted Bird Beak Pliers	4963931275564	,036"
27601	Pin&Ligature Cutter EVER F.601 Angle 40	4963931276011	,012"
27602	Pin&Ligature Cutter EVER F.602 Reverse 40	4963931276028	,012"
27603	Pin&Ligature Cutter EVER F.603 Angle 50	4963931276035	,012"
27604	Pin&Ligature Cutter EVER F.604 Reverse 50	4963931276042	,012"
27605	Pin&Ligature Cutter EVER F.605 with Hard MATL	4963931276059	,012"
27606	Distal End Cutter EVER Fine 606S T/C	4963931276066	,022"-,028"
27607	Distal End Cutter EVER Fine 606L T/C	4963931276073	,022"-,028"
27615	Pin&Ligature Cutter EVER C.615 with Hard MATL	4963931276158	,014"
27934	Convertible Cap Removing Pliers ND-934	4963931279340	-
27935	Convertible Cap Removing Pliers ND-934 Blade	4963931279357	-

4 [Przewidziane zastosowanie wyrobu]

Przewidzianym wskazaniem medycznym jest zastosowanie w celu przytrzymania, zamocowania lub usunięcia niewielkich przedmiotów, zginania lub cięcia metalowych taśm lub drutu, a także to wycinania lub tworzenia wgłębień w wielu miejscach na aparacie ortodontycznym wykonanym z żywicy.

5 [Właściwości eksploatacyjne wyrobu]

<Podsumowanie>

Niniejszy wyrób to niewielkie kleszcze z końcówkami o zróżnicowanym kształcie w zależności od docelowego zastosowania.

<Materiał>

Stal nierdzewna

Nr modelu	Nazwa handlowa wyrobu	Sposób użycia
22001	Adams Pliers Universal T/C	Przytrzymanie i zaginanie drutu protetycznego w celu utworzenia podparcia.
22102	Orthodontic Pliers Band Contouring ND-202L	Przytrzymywanie i zaginanie krawędzi taśmy, aby dopasować ją do kształtu zębów.
22104	Orthodontic Pliers Band Margin ND-204	Przytrzymywanie i zaginanie krawędzi taśmy, aby dopasować ją do kształtu zębów.
22133	Orthodontic Pliers Band Removing ND-303	Dopasowywanie krawędzi taśmy do powierzchni okluzyjnej zębów i usuwanie taśmy.
22141	Orthodontic Pliers Peeso ND-401	Przytrzymywanie i zaginanie drutu łukowego w celu nadania torcu, wykonywanie stopni.
22142	Orthodontic Pliers Young ND-402	Przytrzymywanie i zaginanie drutu łukowego w celu uzyskania pętli.
22143	Orthodontic Pliers Tweed Arch ND-403	Przytrzymywanie i zaginanie drutu łukowego w celu nadania torcu, wykonywanie stopni.
22145	Orthodontic Pliers Tweed Loop Forming ND-405	Przytrzymywanie i zaginanie drutu łukowego w celu uzyskania pętli.
22147	Orthodontic Pliers Three Jaw ND-407	Przytrzymywanie i zaginanie drutu łukowego w celu uzyskania kształtu litery V.
22149	Orthodontic Pliers Bird Beak ND-409	Przytrzymywanie i zaginanie drutu łukowego w celu uzyskania pętli.
22152	Orthodontic Pliers How ND-502L	Przytrzymywanie i wiązanie drutu ligaturowego.
22154	Orthodontic Pliers Utility ND-504	Przytrzymywanie drutu łukowego i wprowadzanie go do zamków i rurek policzkowych.
22155	Orthodontic Pliers How ND-502S	Przytrzymywanie i wiązanie drutu ligaturowego.
22159	Orthodontic Pliers Kim T/C ND-419	Przytrzymywanie i zaginanie drutu łukowego w celu uzyskania pętli.
22160	Orthodontic Pliers Light Wire Cutter T/C ND-420	Przytrzymywanie i zaginanie drutu łukowego w celu uzyskania pętli.
22210	Orthodontic Pliers for Aligner Tear Drop	Chwywanie, przytrzymywanie i dostosowywanie nakładek.
22211	Orthodontic Pliers for Aligner Vertical	Chwywanie, przytrzymywanie i dostosowywanie nakładek.
22212	Orthodontic Pliers for Aligner Horizontal	Chwywanie, przytrzymywanie i dostosowywanie nakładek.
22213	Orthodontic Pliers for Aligner Hole Punch	Chwywanie, przytrzymywanie i dostosowywanie nakładek.
22506	Tying Pliers YS-506	Przytrzymywanie i wiązanie drutu ligaturowego.
22507	Tying Pliers YS-507	Przytrzymywanie i wiązanie drutu ligaturowego.
22508	Tying Pliers YS-508	Przytrzymywanie i wiązanie drutu ligaturowego.
22509	Module Pliers Str.	Przytrzymywanie ligatur i zakładanie ich na zamki.
22510	Module Pliers Cvd.	Przytrzymywanie ligatur i zakładanie ich na zamki.
22511	Module Pliers with Groove Str.	Przytrzymywanie ligatur i zakładanie ich na zamki.
22513	Module Pliers Mosquito Str.	Przytrzymywanie ligatur i zakładanie ich na zamki.
22514	Module Pliers Mosquito Cvd.	Przytrzymywanie ligatur i zakładanie ich na zamki.
22551	Separator YS-551	Rozciąganie gumek separacyjnych i wprowadzanie ich między zęby.
22601	Wire Cutter YS-601	Przytrzymywanie i cięcie drutu.
22602	Wire Cutter YS-602 KI	Przytrzymywanie i cięcie drutu.
22603	Wire Cutter YS-603 Standard	Przytrzymywanie i cięcie drutu.
22606	Pin & Ligature Cutter ND-605 with Hard Material	Przytrzymywanie i odcinanie nadmiaru drutu ligaturowego.
22607	Pin & Ligature Cutter ND-605B T/C	Przytrzymywanie i odcinanie nadmiaru drutu ligaturowego.
22610	Distal End Cutter ND-606S T/C	Przytrzymywanie i odcinanie nadmiaru drutu łukowego.
22611	Distal End Cutter ND-606LT/C	Przytrzymywanie i odcinanie nadmiaru drutu łukowego.
27410	Ortho.Pliers EVER Classic 410 Band Contouring	Przytrzymywanie i zaginanie krawędzi taśmy, aby dopasować ją do kształtu zębów.
27411	Ortho.Pliers EVER Classic 411 Band Margin	Przytrzymywanie i zaginanie krawędzi taśmy, aby dopasować ją do kształtu zębów.
27412	Ortho.Pliers EVER Classic 412 Band Removing	Dopasowywanie krawędzi taśmy do powierzchni okluzyjnej zębów i usuwanie taśmy.
27413	Ortho.Pliers EVER C. 413 Bracket Removing T/C	Przytrzymywanie i zdejmowanie zamków.
27414	Ortho.Pliers EVER Classic 414 Young	Przytrzymywanie i zaginanie drutu łukowego w celu uzyskania pętli.
27415	Ortho.Pliers EVER Classic 415 Tweed Arch	Przytrzymywanie i zaginanie drutu łukowego w celu nadania torcu, wykonywanie stopni.
27416	Ortho.Pliers EVER C. 416 Tweed Loop Forming	Przytrzymywanie i zaginanie drutu łukowego w celu uzyskania pętli.
27417	Ortho.Pliers EVER Classic 417 Three Jaw	Przytrzymywanie i zaginanie drutu łukowego w celu uzyskania kształtu litery V.
27418	Ortho.Pliers EVER Classic 418 Bird Beak	Przytrzymywanie i zaginanie drutu łukowego w celu uzyskania pętli.
27419	Ortho.Pliers EVER C. 419 Nance Closing Loop	Przytrzymywanie i zaginanie drutu łukowego w celu uzyskania pętli.
27420	Ortho.Pliers EVER Classic 420 How	Przytrzymywanie i wiązanie drutu ligaturowego.
27421	Ortho.Pliers EVER Classic 421 Weingart	Przytrzymywanie drutu łukowego i wprowadzanie go do zamków i rurek policzkowych.
27422	Ortho.Pliers EVER Classic 422 Utility	Przytrzymywanie drutu łukowego i wprowadzanie go do zamków i rurek policzkowych.
27423	Ortho.Pliers EVER Classic 423 Kim T/C	Przytrzymywanie i zaginanie drutu łukowego w celu uzyskania pętli.
27424	Ortho.Pliers EVER Classic 424 Light Wire T/C	Przytrzymywanie i zaginanie drutu łukowego w celu uzyskania pętli.
27425	Ortho.Pliers EVER Classic 425 Crimping	Przytrzymywanie i zakładanie haczyków zaciskanych na łuk.
27426	Ortho.Pliers EVER C.426 Lingual Hollow Chop	Przytrzymywanie i zaginanie drutu łukowego w celu nadania krzywizny.
27427	Ortho.Pliers EVER Classic 427 Torquing M	Przytrzymywanie drutu łukowego za pomocą kleszczy 27428, obrót w celu nadania torcu na drucie łukowym.
27428	Ortho.Pliers EVER Classic 428 Torquing F	Przytrzymywanie drutu łukowego za pomocą kleszczy 27427, obrót w celu nadania torcu na drucie łukowym.
27440	Ortho.Pliers EVER Fine 440 Utility	Przytrzymywanie drutu łukowego i wprowadzanie go do zamków i rurek policzkowych.
27441	Ortho.Pliers EVER Fine 441 Weingart	Przytrzymywanie drutu łukowego i wprowadzanie go do zamków i rurek policzkowych.
27442	Ortho.Pliers EVER Fine 442 How	Przytrzymywanie i wiązanie drutu ligaturowego.
27443	Ortho.Pliers EVER Fine 443 Band Removing	Dopasowywanie krawędzi taśmy do powierzchni okluzyjnej zębów i usuwanie taśmy.
27444	Ortho.Pliers EVER F.444 Bracket Removing T/C	Przytrzymywanie i zdejmowanie zamków.
27445	Ortho.Pliers EVER Fine 445 Step 1/2mm	Przytrzymywanie i zaginanie drutu łukowego w celu wykonania stopni.
27446	Ortho.Pliers EVER Fine 446 Step 3/4mm	Przytrzymywanie i zaginanie drutu łukowego w celu wykonania stopni.
27447	Ortho.Pliers EVER Fine 447 Step 1mm	Przytrzymywanie i zaginanie drutu łukowego w celu wykonania stopni.
27448	Ortho.Pliers EVER Fine 448 Tear Drop	Chwywanie, przytrzymywanie i dostosowywanie nakładek.
27449	Ortho.Pliers EVER Fine 449 Vertical	Chwywanie, przytrzymywanie i dostosowywanie nakładek.

27450	Ortho.Pliers EVER Fine 450 Horizontal	Chwytywanie, przytrzymywanie i dostosowywanie nakładek.
27451	Ortho.Pliers EVER Fine 451 Hole Punch	Chwytywanie, przytrzymywanie i dostosowywanie nakładek.
27452	Ortho.Pliers EVER Fine 452 Light Wire T/C	Przytrzymywanie i zaginanie drutu łukowego w celu uzyskania pętli.
27453	Ortho.Pliers EVER Fine 453 Kim T/C	Przytrzymywanie i zaginanie drutu łukowego w celu uzyskania pętli.
27454	Ortho.Pliers EVER Fine 454 Young	Przytrzymywanie i zaginanie drutu łukowego w celu uzyskania pętli.
27455	Ortho.Pliers EVER Fine 455 Tweed Arch	Przytrzymywanie i zaginanie drutu łukowego w celu nadania toru, wykonywanie stopni.
27456	Ortho.Pliers EVER Fine 456 Tweed Loop Forming	Przytrzymywanie i zaginanie drutu łukowego w celu uzyskania pętli.
27457	Ortho.Pliers EVER Fine 457 Three Jaw	Przytrzymywanie i zaginanie drutu łukowego w celu uzyskania kształtu litery V.
27458	Ortho.Pliers EVER Fine 458 Bird Beak	Przytrzymywanie i zaginanie drutu łukowego w celu uzyskania pętli.
27459	Ortho.Pliers EVER F. 459 Nance Closing Loop	Przytrzymywanie i zaginanie drutu łukowego w celu uzyskania pętli.
27460	Ortho.Pliers EVER Fine 460 Band Removing L	Dopasowywanie krawędzi taśmy do powierzchni okluzyjnej zębów i usuwanie taśmy.
27461	Ortho.Pliers EVER Fine 461 Cinch Back	Przytrzymywanie, zaginanie końca drutu łukowego.
27462	Ortho.Pliers EVER Fine 462 Lingual Utility	Przytrzymywanie drutu łukowego i wprowadzanie go do zamków i rurek policzkowych.
27463	Ortho.Pliers EVER F.463 Round Former 1.0	Chwytywanie, przytrzymywanie i dostosowywanie nakładek.
27464	Ortho.Pliers EVER F.464 Round Former 2.0 SM	Chwytywanie, przytrzymywanie i dostosowywanie nakładek.
27465	Ortho.Pliers EVER Fine Key Punch 465	Chwytywanie, przytrzymywanie i dostosowywanie nakładek.
27550	Orthodontic Pliers Crimping Ortolan	Przytrzymywanie i zakładanie haczyków zaciskanych na łuk.
27551	ROMAN 1 Circle Cutter SMOOTH	Chwytywanie, przytrzymywanie i dostosowywanie nakładek.
27552	ROMAN 2 Horizontal Box SMOOTH	Chwytywanie, przytrzymywanie i dostosowywanie nakładek.
27553	ROMAN 3 Vertical Box SMOOTH	Chwytywanie, przytrzymywanie i dostosowywanie nakładek.
27554	ROMAN 4 Pearl Dot SMOOTH	Chwytywanie, przytrzymywanie i dostosowywanie nakładek.
27555	ROMAN 5 Keyhole Cutter SMOOTH	Chwytywanie, przytrzymywanie i dostosowywanie nakładek.
27556	Angle Fluted Bird Beak Pliers	Przytrzymywanie, zaginanie końca drutu łukowego.
27601	Pin&Ligature Cutter EVER F.601 Angle 40	Przytrzymywanie i odcinanie nadmiaru drutu ligaturowego.
27602	Pin&Ligature Cutter EVER F.602 Reverse 40	Przytrzymywanie i odcinanie nadmiaru drutu ligaturowego.
27603	Pin&Ligature Cutter EVER F.603 Angle 50	Przytrzymywanie i odcinanie nadmiaru drutu ligaturowego.
27604	Pin&Ligature Cutter EVER F.604 Reverse 50	Przytrzymywanie i odcinanie nadmiaru drutu ligaturowego.
27605	Pin&Ligature Cutter EVER F.605 with Hard MATL	Przytrzymywanie i odcinanie nadmiaru drutu ligaturowego.
27606	Distal End Cutter EVER Fine 606S T/C	Przytrzymywanie i odcinanie nadmiaru drutu łukowego.
27607	Distal End Cutter EVER Fine 606L T/C	Przytrzymywanie i odcinanie nadmiaru drutu łukowego.
27615	Pin&Ligature Cutter EVER C.615 with Hard MATL	Przytrzymywanie i odcinanie nadmiaru drutu ligaturowego.
27722	Wire Cutter Heavy Duty	Odcinanie drutu.
27934	Convertible Cap Removing Pliers ND-934	Przytrzymywanie, zdejmowanie nasadki z rurek odwracalnych.
27935	Convertible Cap Removing Pliers ND-934 Blade	Najważniejsza część kleszczy 27934

7 [Ogólne środki ostrożności i zakazy]

- 1) Stosowanie produktu jest ściśle ograniczone do zabiegów wykonywanych w ramach leczenia dentystycznego.
Należy przestrzegać środków ostrożności, aby zapewnić właściwe użytkowanie narzędzi.
- 2) Nie należy używać narzędzi do celów innych niż te, do których są przeznaczone.
- 3) Wyczyścić, nasmarować i wysterylizować przed użyciem zgodnie z instrukcją obsługi.
- 4) Nie używać narzędzi u pacjentów z objawami nadwrażliwości, takimi jak wysypka, zapalenie skóry lub objawy alergiczne.
- 5) Nie należy zmieniać konstrukcji ani przebudowywać narzędzi.
- 6) Nie upuszczać narzędzi. Unikać silnych uderzeń w narzędzia.
- 7) Podczas utylizacji narzędzi należy postępować zgodnie z instrukcjami określonymi w odpowiednich przepisach krajowych.
- 8) Nie podgrzewać narzędzi.
- 9) Jeśli do narzędzi przyłgną środki chemiczne, należy je natychmiast zetrzeć, aby uniknąć rozwoju korozji.
- 10) Podczas zaginania drutu za pomocą tych narzędzi należy przytrzymać drut kleszczami i zgiąć go palcem, aby uniknąć uszkodzenia kleszczy.
- 11) Stal nierdzewna jest bardziej odporna na rdzewienie niż żelazo, ale może korodować pod wpływem metody użytkowania oraz czynników środowiskowych takich jak temperatura czy wilgotność.

8 [Ograniczenia dotyczące przetwarzania]

Należy natychmiast zaprzestać używania narzędzi, jeśli widoczne jest pogorszenie stanu wyrobu lub coś nieoczekiwanego.

9 [Wstępna obróbka w miejscu użytkowania]

Wyczyścić, nasmarować i wysterylizować przed użyciem zgodnie z instrukcją obsługi.

10 [Przygotowanie przed czyszczeniem]

Patrz następny punkt.

11 [Proces czyszczenia i sterylizacji/dezynfekcji]

1) Przestrogi ogólne

- a) W przypadku konserwacji narzędzi należy zapoznać się z treścią „The Fundamental Guide Book for Cleaning and Sterilizing Instruments” (Podstawowego przewodnika czyszczenia i sterylizacji narzędzi) opublikowanego przez naszą firmę lub z zakładką „konserwacja” w naszej witrynie internetowej (http://www.ydm.co.jp/en-new/pdf/The_process_of_cleaning_and_sterilizing.pdf).
- b) Narzędzia zanieczyszczone krwią, płynami ustrojowymi, fragmentami tkanek, środkami chemicznymi, itp. powinny być natychmiast czyszczone i sterylizowane zgodnie z poniższą metodą, aby zapobiec przedostawaniu się zanieczyszczeń do ich wnętrza. Zanieczyszczenia pozostające na narzędziach przez długi czas są trudne do usunięcia.

2) Procedura

- a) Otworzyć przegub.
 - b) Wyczyścić narzędzia środkiem czyszczącym zgodnie z metodą i) lub ii).
 - i) Użyć myjki ultradźwiękowej z detergentem przeciwrdzewnym do użytku medycznego przez 5 minut.
 - ii) Zanurzyć w środku czyszczącym z detergentem przeciwrdzewnym do użytku medycznego na 15 minut.
 - c) Zmyć brud i środek czyszczący przylegający do narzędzi pod bieżącą wodą.
(Jeśli składniki mydła pozostaną na powierzchni narzędzi, spowoduje to powstanie rdzy, plam).
 - d) Wysuszyć narzędzia. (Pozostała wilgoć może powodować rdzę, osłabiać efekt sterylizacji)
 - e) Dodać do przegubu przeciwrdzewny środek smarujący (olej do narzędzi medycznych).
- * Nie otwierać ani nie zamykać przegubu przed dodaniem smaru przeciwrdzewnego.
(Otwieranie i zamykanie przegubu narzędzia bez oleju spowoduje zatarcie).

f) Sterylizować w autoklawie.

Warunki: 134°C do 138°C przez 3 minuty do 3,5 minuty.

* Aby zapobiec zarysowaniom spowodowanym kontaktem z innymi narzędziami, kleszcze należy umieścić w sterylizowanym opakowaniu lub etui.

g) Po użyciu natychmiast wyczyścić zgodnie z podpunktem b) powyżej.

3) Przestrogi dotyczące czyszczenia i sterylizacji/dezynfekcji

- a) Nie używać następujących środków chemicznych, ponieważ mogą powodować korozję metali: podchloryn sodu, chlorek benzalkoniowy, glukonian chlorheksydyny, jodyna. Jodoform i kwas nadoctowy mogą powodować korozję metalu.
- b) Nie używać autoklawu chemicznego do sterylizacji narzędzi, ponieważ może to powodować korozję.
- c) Nie wykonywać sterylizacji plazmowej, ponieważ może to wpływać na materiał, z którego wykonano narzędzia.
- d) Nie używać domowych środków czyszczących, ponieważ nie nadają się one do usuwania białek z powierzchni narzędzi.
- e) Szczotka druciana i wełna stalowa mogą uszkadzać narzędzia.
- f) Nie używać wody o bardzo kwaśnym odczynie, ponieważ może powodować korozję.
Do płukania zaleca się stosowanie wody oczyszczonej (bez zanieczyszczeń).
Woda z kranu zawiera chlor, który może powodować korozję metalu.
- g) W przypadku korzystania z myjni-dezynfektora uporczywe zabrudzenia lub roztwór czyszczący mogą nie zostać całkowicie usunięte, jeśli używany jest program oszczędzania wody lub czasu. Należy zapoznać się z instrukcją obsługi przygotowaną przez producenta, aby zagwarantować spłukanie i usunięcie zabrudzeń.
- h) Podczas obsługi autoklawów należy pamiętać o następujących kwestiach.
 - i) W zależności od statusu i okresu użytkowania komora autoklawu może być zanieczyszczona.
Zanieczyszczenia znajdujące się w autoklawie mogą przykleić się do narzędzi.
Zalecamy czyszczenie zgodnie z instrukcją obsługi sterylizatora.
Wówczas wnętrze komory nie ulegnie zanieczyszczeniu.
W szczególności należy co pewien czas wymieniać gumową uszczelkę na pokrywie komory oraz filtr powietrza.
 - ii) W miarę możliwości należy używać wody oczyszczonej.
Woda z kranu może powodować korozję ze względu na wpływ jonów chloru.
 - iii) Należy zwracać uwagę na temperaturę suszenia wewnątrz autoklawu.
 - iv) Nie umieszczać narzędzi w pobliżu grzejnika. (Temperatura może być wyższa niż wskazana).
 - v) Jeśli czyszczenie i płukanie nie zostaną zakończone wewnątrz autoklawu lub wilgoć pozostanie w komorze autoklawu, może to spowodować oparzenia na powierzchni narzędzi.
- i) Po umyciu i sterylizacji należy usunąć wodę przylegającą do narzędzia i całkowicie je wysuszyć.

12 [Konserwacja, kontrola i testy]

Po czyszczeniu i sterylizacji, przed użyciem należy sprawdzić następujące elementy.

- 1) Sprawdzić, czy wewnątrz i w przegubie nie ma brudu, uszkodzeń, pęknięć, zadrapań lub korozji.
- 2) Sprawdzić, czy przegub porusza się prawidłowo.

13 [Przechowywanie]

- 1) Przechowywać w czystym miejscu wolnym od kurzu, unikać wysokiej temperatury i wilgotności.
- 2) Aby zapobiec powstawaniu prądu galwanicznego spowodowanego różnicą potencjałów metali, nie należy przechowywać wyrobu razem z narzędziami wykonanymi z różnych materiałów.
- 3) Aby zapobiec powstawaniu plam rdzy, należy przestrzegać poniższych zaleceń.
 - a) Nie przechowywać razem z zardzewiałymi narzędziami.
 - b) Nie przechowywać razem ze środkami chemicznymi.
 - c) Należy zwracać uwagę na rdzę wewnątrz sterylizatorów i w magazynach.

14 [Postępowanie z odpadami]

Dentyści i (lub) ortodocci są odpowiedzialni za utylizację wyrobów zgodnie z obowiązującymi przepisami. YDM CORPORATION nie ponosi odpowiedzialności za szkody spowodowane niewłaściwym postępowaniem z odpadami.

15 [Informacje dodatkowe]

<Pęknięcie lub ostrzenie>

W przypadku pęknięcia wyrobu należy zgłosić się do sprzedawcy, u którego dokonano zakupu, wypełniając formularz „Zgłoszenie reklamacyjne” przygotowany przez YDM CORPORATION.

Ostrzeżenie noży jest dostępne za opłatą.

16 [Kontakt z producentem]



YDM CORPORATION

28 Imaizumi, Higashi-Matsuyama-shi,

Saitama 355-0042, Japan

TEL.: 81-3-3828-3161

FAKS: 81-3-3827-8991

URL: <http://www.ydm.co.jp/>

E-mail: ydm@ydm.co.jp

17 [Uwaga dla użytkownika i (lub) pacjenta]

Każdy poważny incydent, który miał miejsce w związku z używaniem narzędzia należy zgłosić do YDM CORPORATION.

18 [Informacje dodatkowe]

W przypadku wady produktu należy zgłosić się do dystrybutora, od którego produkt został zakupiony, za pomocą przygotowanego przez YDM Corporation formularza o nazwie „Zgłaszanie szkód”.

19 [Opis symboli]



Wyrób medyczny



Producent



Numer serii



Uwaga

Powyższe instrukcje zostały zatwierdzone przez producenta wyrobu medycznego. Pozwalają one przygotować wyrób medyczny do ponownego użycia. Osoba przeprowadzająca obróbkę ponosi odpowiedzialność za to, aby obróbka przeprowadzona za pomocą sprzętu i materiałów przez personel w miejscu obróbki osiągnęła zamierzony cel. W tym celu niezbędna jest weryfikacja i/lub zatwierdzenie procedury, a także jej rutynowe kontrolowanie.

Wer. 01 23 czerwca 2021 r.

Wer. 02 24 sierpnia 2022 r.

Wer. 03 6 lipca 2023 r.

- 1 [Nume de familie] Clește ortodontic
- 2 [Producător] YDM CORPORATION
- 3 [Nr. model și denumirea comercială a dispozitivului]



Nr.model	Denumirea comercială a dispozitivului	UDI-DI	Capacități maxime de tăiere și îndoire
22001	Adams Pliers Universal T/C	4963931220014	
22102	Orthodontic Pliers Band Contouring ND-202L	4963931221028	-
22104	Orthodontic Pliers Band Margin ND-204	4963931221042	-
22133	Orthodontic Pliers Band Removing ND-303	4963931221332	-
22141	Orthodontic Pliers Peeso ND-401	4963931221417	,040"
22142	Orthodontic Pliers Young ND-402	4963931221424	,040"
22143	Orthodontic Pliers Tweed Arch ND-403	4963931221431	,022"- ,028"
22145	Orthodontic Pliers Tweed Loop Forming ND-405	4963931221455	,022"- ,028"
22147	Orthodontic Pliers Three Jaw ND-407	4963931221479	,036"
22149	Orthodontic Pliers Bird Beak ND-409	4963931221493	,036"
22152	Orthodontic Pliers How ND-502L	4963931221523	-
22154	Orthodontic Pliers Utility ND-504	4963931221547	-
22155	Orthodontic Pliers How ND-502S	4963931221554	-
22159	Orthodontic Pliers Kim T/C ND-419	4963931221592	,016"- ,022"(Îndoire)/ ,020"(Tăiere)
22160	Orthodontic Pliers Light Wire Cutter T/C ND-420	4963931221608	,020"(Îndoire/Tăiere)
22210	Orthodontic Pliers for Aligner Tear Drop	4963931222100	-
22211	Orthodontic Pliers for Aligner Vertical	4963931222117	-
22212	Orthodontic Pliers for Aligner Horizontal	4963931222124	-
22213	Orthodontic Pliers for Aligner Hole Punch	4963931222131	-
22506	Tying Pliers YS-506	4963931225064	-
22507	Tying Pliers YS-507	4963931225071	-
22508	Tying Pliers YS-508	4963931225088	-
22509	Module Pliers Str.	4963931225095	-
22510	Module Pliers Cvd.	4963931225101	-
22511	Module Pliers with Groove Str.	4963931225118	-
22513	Module Pliers Mosquito Str.	4963931225132	-
22514	Module Pliers Mosquito Cvd.	4963931225149	-
22551	Separator YS-551	4963931225514	-
22601	Wire Cutter YS-601	4963931226016	,032"
22602	Wire Cutter YS-602 KI	4963931226023	,045"
22603	Wire Cutter YS-603 Standard	4963931226030	,048"
22606	Pin & Ligature Cutter ND-605 with Hard Material	4963931226061	,012"
22607	Pin & Ligature Cutter ND-605B T/C	4963931226078	,014"
22610	Distal End Cutter ND-606S T/C	4963931226108	,022"- ,028"
22611	Distal End Cutter ND-606LT/C	4963931226115	,022"- ,028"
27410	Ortho.Pliers EVER Classic 410 Band Contouring	4963931274109	-
27411	Ortho.Pliers EVER Classic 411 Band Margin	4963931274116	-
27412	Ortho.Pliers EVER Classic 412 Band Removing	4963931274123	-
27413	Ortho.Pliers EVER C. 413 Bracket Removing T/C	4963931274130	-
27414	Ortho.Pliers EVER Classic 414 Young	4963931274147	,040"
27415	Ortho.Pliers EVER Classic 415 Tweed Arch	4963931274154	,022 x ,028"
27416	Ortho.Pliers EVER C. 416 Tweed Loop Forming	4963931274161	,022 x ,028"
27417	Ortho.Pliers EVER Classic 417 Three Jaw	4963931274178	,036"
27418	Ortho.Pliers EVER Classic 418 Bird Beak	4963931274185	,036"
27419	Ortho.Pliers EVER C. 419 Nance Closing Loop	4963931274192	,022"
27420	Ortho.Pliers EVER Classic 420 How	4963931274208	-
27421	Ortho.Pliers EVER Classic 421 Weingart	4963931274215	-
27422	Ortho.Pliers EVER Classic 422 Utility	4963931274222	-
27423	Ortho.Pliers EVER Classic 423 Kim T/C	4963931274239	,016"- ,022"(Îndoire)/ ,020"(Tăiere)
27424	Ortho.Pliers EVER Classic 424 Light Wire T/C	4963931274246	,020"(Îndoire/Tăiere)
27425	Ortho.Pliers EVER Classic 425 Crimping	4963931274253	-
27426	Ortho.Pliers EVER C.426 Lingual Hollow Chop	4963931274260	,022 x ,028"
27427	Ortho.Pliers EVER Classic 427 Torquing M	4963931274277	,022 x ,028"
27428	Ortho.Pliers EVER Classic 428 Torquing F	4963931274284	,022 x ,028"
27440	Ortho.Pliers EVER Fine 440 Utility	4963931274406	-
27441	Ortho.Pliers EVER Fine 441 Weingart	4963931274413	-
27442	Ortho.Pliers EVER Fine 442 How	4963931274420	-
27443	Ortho.Pliers EVER Fine 443 Band Removing	4963931274437	-
27444	Ortho.Pliers EVER F.444 Bracket Removing T/C	4963931274444	-

27445	Ortho.Pliers EVER Fine 445 Step 1/2mm	4963931274451	,022 x ,028"
27446	Ortho.Pliers EVER Fine 446 Step 3/4mm	4963931274468	,022 x ,028"
27447	Ortho.Pliers EVER Fine 447 Step 1mm	4963931274475	,022 x ,028"
27448	Ortho.Pliers EVER Fine 448 Tear Drop	4963931274482	-
27449	Ortho.Pliers EVER Fine 449 Vertical	4963931274499	-
27450	Ortho.Pliers EVER Fine 450 Horizontal	4963931274505	-
27451	Ortho.Pliers EVER Fine 451 Hole Punch	4963931274512	-
27452	Ortho.Pliers EVER Fine 452 Light Wire T/C	4963931274529	,020"(Îndoire/Tăiere)
27453	Ortho.Pliers EVER Fine 453 Kim T/C	4963931274536	,016"-,022"(Îndoire)/,020"(Tăiere)
27454	Ortho.Pliers EVER Fine 454 Young	4963931274543	,040"
27455	Ortho.Pliers EVER Fine 455 Tweed Arch	4963931274550	,022 x ,028"
27456	Ortho.Pliers EVER Fine 456 Tweed Loop Forming	4963931274567	,022 x ,028"
27457	Ortho.Pliers EVER Fine 457 Three Jaw	4963931274574	,036"
27458	Ortho.Pliers EVER Fine 458 Bird Beak	4963931274581	,036"
27459	Ortho.Pliers EVER F. 459 Nance Closing Loop	4963931274598	,022"
27460	Ortho.Pliers EVER Fine 460 Band Removing L	4963931274604	-
27461	Ortho.Pliers EVER Fine 461 Cinch Back	4963931274611	,020"/,016"-016"
27462	Ortho.Pliers EVER Fine 462 Lingual Utility	4963931274628	-
27463	Ortho.Pliers EVER F.463 Round Former 1.0	4963931274635	-
27464	Ortho.Pliers EVER F.464 Round Former 2.0 SM	4963931274642	-
27465	Ortho.Pliers EVER Fine Key Punch 465	4963931274659	-
27550	Orthodontic Pliers Crimping Ortolan	4963931275502	-
27551	ROMAN 1 Circle Cutter SMOOTH	4963931275519	-
27552	ROMAN 2 Horizontal Box SMOOTH	4963931275526	-
27553	ROMAN 3 Vertical Box SMOOTH	4963931275533	-
27554	ROMAN 4 Pearl Dot SMOOTH	4963931275540	-
27555	ROMAN 5 Keyhole Cutter SMOOTH	4963931275557	-
27556	Angle Fluted Bird Beak Pliers	4963931275564	,036"
27601	Pin&Ligature Cutter EVER F.601 Angle 40	4963931276011	,012"
27602	Pin&Ligature Cutter EVER F.602 Reverse 40	4963931276028	,012"
27603	Pin&Ligature Cutter EVER F.603 Angle 50	4963931276035	,012"
27604	Pin&Ligature Cutter EVER F.604 Reverse 50	4963931276042	,012"
27605	Pin&Ligature Cutter EVER F.605 with Hard MATL	4963931276059	,012"
27606	Distal End Cutter EVER Fine 606S T/C	4963931276066	,022"-,028"
27607	Distal End Cutter EVER Fine 606L T/C	4963931276073	,022"-,028"
27615	Pin&Ligature Cutter EVER C.615 with Hard MATL	4963931276158	,014"
27934	Convertible Cap Removing Pliers ND-934	4963931279340	-
27935	Convertible Cap Removing Pliers ND-934 Blade	4963931279357	-

4 [Scopul prevăzut al dispozitivului]

Utilizarea medicală prevăzută este de a prinde, de a fixa sau de a îndepărta obiecte mici, de a îndoi sau de a tăia benzi sau sârme metalice, sau de a tăia sau de a face creștături pe aparatul ortodontic din rășină.

5 [Caracteristicile de performanță ale dispozitivului]

<Prezentare generală>

Acest dispozitiv este un mic clește cu fălci de diferite forme, în funcție de scopul utilizării.

<Material>

Oțel inoxidabil

Nr.model	Denumirea comercială a dispozitivului	Mod de utilizare
22001	Adams Pliers Universal T/C	Țineți, îndoiiți sârma de închidere pentru a realiza aparatul ortodontic.
22102	Orthodontic Pliers Band Contouring ND-202L	Țineți, îndoiiți marginea benzii pentru a o adapta la forma dinților.
22104	Orthodontic Pliers Band Margin ND-204	Țineți, îndoiiți marginea benzii pentru a o adapta la forma dinților.
22133	Orthodontic Pliers Band Removing ND-303	Potriviiți marginea benzii, marginea ocluzală a dinților și îndepărtați banda
22141	Orthodontic Pliers Peeso ND-401	Țineți, îndoiiți arcul metalic pentru a aplica un moment de torsiune, urcați o treaptă.
22142	Orthodontic Pliers Young ND-402	Țineți, îndoiiți arcul metalic pentru a realiza o buclă.
22143	Orthodontic Pliers Tweed Arch ND-403	Țineți, îndoiiți arcul metalic pentru a aplica un moment de torsiune, urcați o treaptă.
22145	Orthodontic Pliers Tweed Loop Forming ND-405	Țineți, îndoiiți arcul metalic pentru a realiza o buclă.
22147	Orthodontic Pliers Three Jaw ND-407	Țineți, îndoiiți arcul metalic pentru a realiza o formă de V.
22149	Orthodontic Pliers Bird Beak ND-409	Țineți, îndoiiți arcul metalic pentru a realiza o buclă.
22152	Orthodontic Pliers How ND-502L	Țineți, legați sârma de ligatură.
22154	Orthodontic Pliers Utility ND-504	Țineți arcul metalic și introduceți tubul bucal în aparatul dentar.
22155	Orthodontic Pliers How ND-502S	Țineți, legați sârma de ligatură.
22159	Orthodontic Pliers Kim T/C ND-419	Țineți, îndoiiți arcul metalic pentru a realiza o buclă.
22160	Orthodontic Pliers Light Wire Cutter T/C ND-420	Țineți, îndoiiți arcul metalic pentru a realiza o buclă.
22210	Orthodontic Pliers for Aligner Tear Drop	Țineți, luați pe aliniatorul și montați-l.
22211	Orthodontic Pliers for Aligner Vertical	Țineți, luați pe aliniatorul și montați-l.
22212	Orthodontic Pliers for Aligner Horizontal	Țineți, luați pe aliniatorul și montați-l.
22213	Orthodontic Pliers for Aligner Hole Punch	Țineți, luați pe aliniatorul și montați-l.
22506	Tying Pliers YS-506	Țineți, legați sârma de ligatură.
22507	Tying Pliers YS-507	Țineți, legați sârma de ligatură.
22508	Tying Pliers YS-508	Țineți, legați sârma de ligatură.
22509	Module Pliers Str.	Țineți modulul elastic și puneți-l pe aparatul dentar.
22510	Module Pliers Cvd.	Țineți modulul elastic și puneți-l pe aparatul dentar.
22511	Module Pliers with Groove Str.	Țineți modulul elastic și puneți-l pe aparatul dentar.
22513	Module Pliers Mosquito Str.	Țineți modulul elastic și puneți-l pe aparatul dentar.
22514	Module Pliers Mosquito Cvd.	Țineți modulul elastic și puneți-l pe aparatul dentar.
22551	Separator YS-551	Întindeți modulul de separare și introduceți-l între dinți.
22601	Wire Cutter YS-601	Țineți, tăiați sârma.
22602	Wire Cutter YS-602 KI	Țineți, tăiați sârma.
22603	Wire Cutter YS-603 Standard	Țineți, tăiați sârma.
22606	Pin & Ligature Cutter ND-605 with Hard Material	Țineți, tăiați excesul de sârmă de ligatură.
22607	Pin & Ligature Cutter ND-605B T/C	Țineți, tăiați excesul de sârmă de ligatură.
22610	Distal End Cutter ND-606S T/C	Țineți, tăiați excesul de arc metalic.
22611	Distal End Cutter ND-606LT/C	Țineți, tăiați excesul de arc metalic.
27410	Ortho.Pliers EVER Classic 410 Band Contouring	Țineți, îndoiiți marginea benzii pentru a o adapta la forma dinților.
27411	Ortho.Pliers EVER Classic 411 Band Margin	Țineți, îndoiiți marginea benzii pentru a o adapta la forma dinților.
27412	Ortho.Pliers EVER Classic 412 Band Removing	Potriviiți marginea benzii, marginea ocluzală a dinților și îndepărtați banda
27413	Ortho.Pliers EVER C. 413 Bracket Removing T/C	Țineți, îndepărtați aparatul dentar.
27414	Ortho.Pliers EVER Classic 414 Young	Țineți, îndoiiți arcul metalic pentru a realiza o buclă.
27415	Ortho.Pliers EVER Classic 415 Tweed Arch	Țineți, îndoiiți arcul metalic pentru a aplica un moment de torsiune, urcați o treaptă.
27416	Ortho.Pliers EVER C. 416 Tweed Loop Forming	Țineți, îndoiiți arcul metalic pentru a realiza o buclă.
27417	Ortho.Pliers EVER Classic 417 Three Jaw	Țineți, îndoiiți arcul metalic pentru a realiza o formă de V.
27418	Ortho.Pliers EVER Classic 418 Bird Beak	Țineți, îndoiiți arcul metalic pentru a realiza o buclă.
27419	Ortho.Pliers EVER C. 419 Nance Closing Loop	Țineți, îndoiiți arcul metalic pentru a realiza o buclă.
27420	Ortho.Pliers EVER Classic 420 How	Țineți, legați sârma de ligatură.
27421	Ortho.Pliers EVER Classic 421 Weingart	Țineți arcul metalic și introduceți tubul bucal în aparatul dentar.
27422	Ortho.Pliers EVER Classic 422 Utility	Țineți arcul metalic și introduceți tubul bucal în aparatul dentar.
27423	Ortho.Pliers EVER Classic 423 Kim T/C	Țineți, îndoiiți arcul metalic pentru a realiza o buclă.
27424	Ortho.Pliers EVER Classic 424 Light Wire T/C	Țineți, îndoiiți arcul metalic pentru a realiza o buclă.
27425	Ortho.Pliers EVER Classic 425 Crimping	Țineți, aplicați cârligul crimpabil pe arcul metalic.
27426	Ortho.Pliers EVER C.426 Lingual Hollow Chop	Țineți, îndoiiți arcul metalic pentru a aplica curba.
27427	Ortho.Pliers EVER Classic 427 Torquing M	Țineți arcul metalic cu „27428”, rotiți pentru a aplica un moment de torsiune pe arcul metalic.
27428	Ortho.Pliers EVER Classic 428 Torquing F	Țineți arcul metalic cu „27427”, rotiți pentru a aplica un moment de torsiune pe arcul metalic.
27440	Ortho.Pliers EVER Fine 440 Utility	Țineți arcul metalic și introduceți tubul bucal în aparatul dentar.
27441	Ortho.Pliers EVER Fine 441 Weingart	Țineți arcul metalic și introduceți tubul bucal în aparatul dentar.
27442	Ortho.Pliers EVER Fine 442 How	Țineți, legați sârma de ligatură.
27443	Ortho.Pliers EVER Fine 443 Band Removing	Potriviiți marginea benzii, marginea ocluzală a dinților și îndepărtați banda
27444	Ortho.Pliers EVER F.444 Bracket Removing T/C	Țineți, îndepărtați aparatul dentar.
27445	Ortho.Pliers EVER Fine 445 Step 1/2mm	Țineți, îndoiiți arcul metalic pentru a aplica un moment de torsiune, urcați o treaptă.
27446	Ortho.Pliers EVER Fine 446 Step 3/4mm	Țineți, îndoiiți arcul metalic pentru a aplica un moment de torsiune, urcați o treaptă.
27447	Ortho.Pliers EVER Fine 447 Step 1mm	Țineți, îndoiiți arcul metalic pentru a aplica un moment de torsiune, urcați o treaptă.
27448	Ortho.Pliers EVER Fine 448 Tear Drop	Țineți, luați pe aliniatorul și montați-l.
27449	Ortho.Pliers EVER Fine 449 Vertical	Țineți, luați pe aliniatorul și montați-l.

27450	Ortho.Pliers EVER Fine 450 Horizontal	Țineți, luați pe aliniatorul și montați-l.
27451	Ortho.Pliers EVER Fine 451 Hole Punch	Țineți, luați pe aliniatorul și montați-l.
27452	Ortho.Pliers EVER Fine 452 Light Wire T/C	Țineți, îndoiți arcul metalic pentru a realiza o buclă.
27453	Ortho.Pliers EVER Fine 453 Kim T/C	Țineți, îndoiți arcul metalic pentru a realiza o buclă.
27454	Ortho.Pliers EVER Fine 454 Young	Țineți, îndoiți arcul metalic pentru a realiza o buclă.
27455	Ortho.Pliers EVER Fine 455 Tweed Arch	Țineți, îndoiți arcul metalic pentru a aplica un moment de torsiune, urcați o treaptă.
27456	Ortho.Pliers EVER Fine 456 Tweed Loop Forming	Țineți, îndoiți arcul metalic pentru a realiza o buclă.
27457	Ortho.Pliers EVER Fine 457 Three Jaw	Țineți, îndoiți arcul metalic pentru a realiza o formă de V.
27458	Ortho.Pliers EVER Fine 458 Bird Beak	Țineți, îndoiți arcul metalic pentru a realiza o buclă.
27459	Ortho.Pliers EVER F. 459 Nance Closing Loop	Țineți, îndoiți arcul metalic pentru a realiza o buclă.
27460	Ortho.Pliers EVER Fine 460 Band Removing L	Potrivii marginea benzii, marginea ocluzală a dinților și îndepărtați banda
27461	Ortho.Pliers EVER Fine 461 Cinch Back	Țineți, îndoiți capătul arcului metalic.
27462	Ortho.Pliers EVER Fine 462 Lingual Utility	Țineți arcul metalic și introduceți tubul bucal în aparatul dentar.
27463	Ortho.Pliers EVER F.463 Round Former 1.0	Țineți, luați pe aliniatorul și montați-l.
27464	Ortho.Pliers EVER F.464 Round Former 2.0 SM	Țineți, luați pe aliniatorul și montați-l.
27465	Ortho.Pliers EVER Fine Key Punch 465	Țineți, luați pe aliniatorul și montați-l.
27550	Orthodontic Pliers Crimping Ortolan	Țineți, aplicați cârligul crimpabil pe arcul metalic.
27551	ROMAN 1 Circle Cutter SMOOTH	Țineți, luați pe aliniatorul și montați-l.
27552	ROMAN 2 Horizontal Box SMOOTH	Țineți, luați pe aliniatorul și montați-l.
27553	ROMAN 3 Vertical Box SMOOTH	Țineți, luați pe aliniatorul și montați-l.
27554	ROMAN 4 Pearl Dot SMOOTH	Țineți, luați pe aliniatorul și montați-l.
27555	ROMAN 5 Keyhole Cutter SMOOTH	Țineți, luați pe aliniatorul și montați-l.
27556	Angle Fluted Bird Beak Pliers	Țineți, îndoiți capătul arcului metalic.
27601	Pin&Ligature Cutter EVER F.601 Angle 40	Țineți, tăiați excesul de sârmă de ligatură.
27602	Pin&Ligature Cutter EVER F.602 Reverse 40	Țineți, tăiați excesul de sârmă de ligatură.
27603	Pin&Ligature Cutter EVER F.603 Angle 50	Țineți, tăiați excesul de sârmă de ligatură.
27604	Pin&Ligature Cutter EVER F.604 Reverse 50	Țineți, tăiați excesul de sârmă de ligatură.
27605	Pin&Ligature Cutter EVER F.605 with Hard MATL	Țineți, tăiați excesul de sârmă de ligatură.
27606	Distal End Cutter EVER Fine 606S T/C	Țineți, tăiați excesul de arc metalic.
27607	Distal End Cutter EVER Fine 606L T/C	Țineți, tăiați excesul de arc metalic.
27615	Pin&Ligature Cutter EVER C.615 with Hard MATL	Țineți, tăiați excesul de sârmă de ligatură.
27722	Wire Cutter Heavy Duty	Tăiați sârma.
27934	Convertible Cap Removing Pliers ND-934	Țineți, îndepărtați capacul tubului convertibil.
27935	Convertible Cap Removing Pliers ND-934 Blade	Partea esențială a „27934”

7 [Precauții generale și interdicții]

- 1) Utilizarea produsului este strict limitată la tratamentele stomatologice.
Respectați precauțiile pentru a asigura utilizarea adecvată a instrumentelor.
- 2) Nu folosiți instrumentele în alte scopuri decât cele pentru care au fost proiectate.
- 3) Curățați, lubrifiați și sterilizați înainte de utilizare, conform instrucțiunilor IFU.
- 4) Nu utilizați instrumentele la pacienții cu manifestări de hipersensibilitate precum erupții cutanate și dermatită sau simptome alergice.
- 5) Nu modificați designul și nu remodelați instrumentele.
- 6) Nu scăpați instrumentele. Evitați orice impact puternic asupra instrumentelor.
- 7) Atunci când aruncați instrumentele, urmați instrucțiunile detaliate în reglementările naționale corespunzătoare.
- 8) Nu încălziți instrumentele.
- 9) Dacă la instrumente aderă substanțe chimice, ștergeți-le imediat pentru a evita riscul de coroziune.
- 10) Atunci când îndoiți sârma utilizând acest instrument, țineți-o cu cleștele și îndoiți-o cu degetele pentru a evita deteriorarea cleștelui.
- 11) Oțelul inoxidabil este mai rezistent la rugină decât fierul, însă se poate coroda din cauza metodei de utilizare și a factorilor de mediu precum temperatura sau umiditatea.

8 [Limitări privind prelucrarea]

Încetați imediat utilizarea instrumentului dacă observați deteriorări sau ceva neobișnuit.

9 [Tratament inițial la punctul de utilizare]

Curățați, lubrifiați și sterilizați înainte de utilizare, conform instrucțiunilor IFU.

10 [Pregătire înainte de curățare]

A se vedea secțiunea următoare.

11 [Procesul de curățare și sterilizare/dezinfectare]

1) Atenționări generale

- a) pentru întreținerea instrumentelor, consultați „The Fundamental Guide Book for Cleaning and Sterilizing Instruments” (Ghidul fundamental pentru curățarea și sterilizarea instrumentelor) publicat de compania noastră sau secțiunea „Maintenance” (Întreținere) de pe site-ul nostru web (http://www.ydm.co.jp/en-new/pdf/The_process_of_cleaning_and_sterilizing.pdf).
- b) Instrumentele contaminate cu sânge, fluide corporale, fragmente de țesut, substanțe chimice etc. trebuie curățate și sterilizate imediat, în conformitate cu următoarea metodă, pentru a preveni uscarea și lipirea impurităților. Impuritățile lipite de instrumente pentru o perioadă lungă de timp devin greu de îndepărtat.

2) Procedura

- a) Deschideți îmbinarea.
 - b) Curățați instrumentele cu ajutorul unui agent de curățare prin metoda i) sau ii).
 - i) Utilizați un aparat de curățare cu ultrasunete cu un detergent medical de prevenire a ruginii timp de 5 minute.
 - ii) Scufundați într-o soluție de curățare cu detergent de prevenire a ruginii pentru uz medical timp de 15 minute.
 - c) Spălați cu apă curentă murdăria și lichidul de curățare care au aderat la instrumente. (În cazul în care rămân componente de săpun pe suprafața instrumentelor, acestea pot provoca rugină și pete.)
 - d) Uscați instrumentele. (Umezeala rămasă poate provoca rugină și reducerea efectului de sterilizare)
 - e) Adăugați în îmbinare lubrifiant anti-rugină, cum ar fi „ulei pentru instrumente”.
- * Nu deschideți sau închideți până când nu este adăugat lubrifiantul antirugină.
(Deschiderea și închiderea fără ulei va cauza tocirea instrumentului)
- f) Sterilizați folosind un sterilizator autoclav.

Condiții: 134°C până la 138°C, 3 minute până la 3,5 minute

- * Pentru a preveni zgârieturile provocate de contactul cu alte instrumente, se recomandă să le puneți într-un ambalaj sau cutie sterilizată.
- g) După utilizare, curățați imediat conform punctului b) de mai sus.

3) Atenționări privind curățarea și sterilizarea/dezinfectarea

- a) Nu utilizați următoarele substanțe chimice, deoarece acestea pot provoca corodarea metalelor. hipoclorit de sodiu, clorură de benzalconiu, gluconat de clorhexidină, tinctură de iod, iodoformul și acidul peracetic pot coroda metalul.
- b) Nu utilizați autoclavarea chimică, deoarece instrumentele se pot coroda.
- c) Nu efectuați sterilizarea cu plasmă, deoarece aceasta afectează materialul.
- d) Nu folosiți agenți de curățare de uz casnic, aceștia nefiind potriviți pentru a îndepărta proteinele de pe suprafața instrumentelor.
- e) Peria de sârmă și lâna de oțel pot provoca deteriorarea instrumentelor.
- f) Nu utilizați apă super acidă, deoarece astfel de agenți pot provoca coroziune. Pentru clătire, se recomandă apa purificată (fără impurități). Apa curentă conține clor, care poate coroda metalul.
- g) Atunci când folosiți un dispozitiv de spălare-dezinfectare, este posibil ca murdăria lipită sau soluția de curățare să nu fie îndepărtată complet dacă se utilizează un program de economisire a apei sau a timpului. Consultați manualul de instrucțiuni al producătorului etc. pentru a asigura clătirea și pentru a îndepărta murdăria.
- h) Rețineți următoarele atunci când manipulați sterilizatoarele autoclave.
 - i) Sterilizatorul autoclav se poate contamina în cabinet în funcție de starea și perioada de utilizare. Dacă rămâne murdărie în sterilizatorul autoclav, aceasta se poate lipi de instrumente. Recomandăm curățarea conform manualului de utilizare al sterilizatorului. Astfel, veți preveni murdărirea camerei acestuia. În special, garnitura de cauciuc de pe capacul camerei și filtrul de aer trebuie înlocuite la un anumit interval de timp.
 - ii) Utilizați apă purificată cât de mult posibil. Ionii de clor din apa curentă pot provoca coroziune.
 - iii) Fiți atenți la temperatura de uscare din interiorul sterilizatorului autoclav.
 - iv) Nu așezați instrumentele în apropierea încălzitorului. (Temperatura reală poate să fie mai mare decât cea indicată)
 - v) În cazul în care curățarea și clătirea nu sunt complete în interiorul sterilizatorului autoclav sau dacă în camera acestuia rămâne umezeală, pot apărea arsuri pe suprafața instrumentelor.
- i) După spălare și sterilizare, îndepărtați apa rămasă pe instrumente și uscați-l bine

12 [Întreținere, inspecție și testare]

După curățare și sterilizare, verificați următoarele înainte de utilizare.

- 1) Asigurați-vă că nu există murdărie, deteriorări, fisuri, zgârieturi sau coroziune nici pe interiorul și nici pe exteriorul îmbinării.
- 2) Verificați dacă există mișcări anormale ale îmbinării.

13 [Depozitare]

- 1) Depozitați într-un loc curat, ferit de praf, evitând temperaturile ridicate și umiditatea.
- 2) Pentru a preveni coroziunea galvanică datorată diferenței de potențial metalic, nu depozitați împreună instrumente din materiale diferite.
- 3) Pentru a preveni petele de rugină, țineți cont de următoarele.
 - a) Nu depozitați împreună cu instrumente ruginite.
 - b) Nu depozitați împreună cu substanțe chimice.
 - c) Aveți grijă la rugina produsă în interiorul sterilizatoarelor sau zonelor de depozitare.

14 [Aspecte privind eliminarea]

Specialiștii în stomatologie și/sau ortodonție sunt responsabili pentru eliminarea în conformitate cu legislația aplicabilă relevantă. YDM CORPORATION nu își asumă răspunderea pentru reclamații sau vătămări corporale cauzate de eliminarea necorespunzătoare.

15 [Informații suplimentare]

<Rupere sau ascuțire>

În caz de rupere a instrumentelor, vă rugăm să raportați distribuitorului de la care le-ați cumpărat în modelul de „Raport de reclamație” al YDM CORPORATION.

Pentru ascuțirea tășurilor, se vor aplica anumite taxe.

16 [Contact producător]



YDM CORPORATION

28 Imaizumi, Higashi-Matsuyama-shi,

Saitama 355-0042, Japan

TEL: 81-3-3828-3161

FAX: 81-3-3827-8991

URL: <http://www.ydm.co.jp/>

E-mail: ydm@ydm.co.jp

17 [Avis către utilizator și/sau pacient]

Orice incident grav care a avut loc în legătură cu dispozitivul trebuie raportat YDM Corporation.

18 [Informații suplimentare]

În caz de defectare a produsului, vă rugăm să raportați distribuitorului de la care ați cumpărat în modelul de „Raport de reclamație” al YDM CORPORATION.

19 [Descrierea simbolurilor]



Dispozitiv medical



Fabricant



Număr lot



Notă

Instrucțiunile furnizate mai sus au fost validate de către producătorul dispozitivului medical ca fiind capabile să pregătească un dispozitiv medical pentru reutilizare. Procesatorul are în continuare responsabilitatea de a se asigura că procesarea, așa cum este efectuată cu ajutorul echipamentelor, materialelor și personalului din unitatea de procesare, atinge rezultatul dorit. Acest lucru necesită verificarea și/sau validarea și monitorizarea de rutină a procesului.

Vers. 01 23 iunie 2021

Vers. 02 24 august 2022

Vers. 03 6 iulie 2023

- 1 [Trivialnamn] Ortodontisk tång
 2 [Tillverkare] YDM CORPORATION
 3 [Modellnummer och handelsnamn]



Modellnr	Handelsnamn	UDI-DI	Maximal klipp- och böjfunktion
22001	Adams Pliers Universal T/C	4963931220014	
22102	Orthodontic Pliers Band Contouring ND-202L	4963931221028	-
22104	Orthodontic Pliers Band Margin ND-204	4963931221042	-
22133	Orthodontic Pliers Band Removing ND-303	4963931221332	-
22141	Orthodontic Pliers Peeso ND-401	4963931221417	,040"
22142	Orthodontic Pliers Young ND-402	4963931221424	,040"
22143	Orthodontic Pliers Tweed Arch ND-403	4963931221431	,022"- ,028"
22145	Orthodontic Pliers Tweed Loop Forming ND-405	4963931221455	,022"- ,028"
22147	Orthodontic Pliers Three Jaw ND-407	4963931221479	,036"
22149	Orthodontic Pliers Bird Beak ND-409	4963931221493	,036"
22152	Orthodontic Pliers How ND-502L	4963931221523	-
22154	Orthodontic Pliers Utility ND-504	4963931221547	-
22155	Orthodontic Pliers How ND-502S	4963931221554	-
22159	Orthodontic Pliers Kim T/C ND-419	4963931221592	,016"- ,022"(böja), ,020"(klippa)
22160	Orthodontic Pliers Light Wire Cutter T/C ND-420	4963931221608	,020"(böja/klippa)
22210	Orthodontic Pliers for Aligner Tear Drop	4963931222100	-
22211	Orthodontic Pliers for Aligner Vertical	4963931222117	-
22212	Orthodontic Pliers for Aligner Horizontal	4963931222124	-
22213	Orthodontic Pliers for Aligner Hole Punch	4963931222131	-
22506	Tying Pliers YS-506	4963931225064	-
22507	Tying Pliers YS-507	4963931225071	-
22508	Tying Pliers YS-508	4963931225088	-
22509	Module Pliers Str.	4963931225095	-
22510	Module Pliers Cvd.	4963931225101	-
22511	Module Pliers with Groove Str.	4963931225118	-
22513	Module Pliers Mosquito Str.	4963931225132	-
22514	Module Pliers Mosquito Cvd.	4963931225149	-
22551	Separator YS-551	4963931225514	-
22601	Wire Cutter YS-601	4963931226016	,032"
22602	Wire Cutter YS-602 KI	4963931226023	,045"
22603	Wire Cutter YS-603 Standard	4963931226030	,048"
22606	Pin & Ligature Cutter ND-605 with Hard Material	4963931226061	,012"
22607	Pin & Ligature Cutter ND-605B T/C	4963931226078	,014"
22610	Distal End Cutter ND-606S T/C	4963931226108	,022"- ,028"
22611	Distal End Cutter ND-606LT/C	4963931226115	,022"- ,028"
27410	Ortho.Pliers EVER Classic 410 Band Contouring	4963931274109	-
27411	Ortho.Pliers EVER Classic 411 Band Margin	4963931274116	-
27412	Ortho.Pliers EVER Classic 412 Band Removing	4963931274123	-
27413	Ortho.Pliers EVER C. 413 Bracket Removing T/C	4963931274130	-
27414	Ortho.Pliers EVER Classic 414 Young	4963931274147	,040"
27415	Ortho.Pliers EVER Classic 415 Tweed Arch	4963931274154	,022 x ,028"
27416	Ortho.Pliers EVER C. 416 Tweed Loop Forming	4963931274161	,022 x ,028"
27417	Ortho.Pliers EVER Classic 417 Three Jaw	4963931274178	,036"
27418	Ortho.Pliers EVER Classic 418 Bird Beak	4963931274185	,036"
27419	Ortho.Pliers EVER C. 419 Nance Closing Loop	4963931274192	,022"
27420	Ortho.Pliers EVER Classic 420 How	4963931274208	-
27421	Ortho.Pliers EVER Classic 421 Weingart	4963931274215	-
27422	Ortho.Pliers EVER Classic 422 Utility	4963931274222	-
27423	Ortho.Pliers EVER Classic 423 Kim T/C	4963931274239	,016"- ,022"(böja), ,020"(klippa)
27424	Ortho.Pliers EVER Classic 424 Light Wire T/C	4963931274246	,020"(böja/klippa)
27425	Ortho.Pliers EVER Classic 425 Crimping	4963931274253	-
27426	Ortho.Pliers EVER C.426 Lingual Hollow Chop	4963931274260	,022 x ,028"
27427	Ortho.Pliers EVER Classic 427 Torquing M	4963931274277	,022 x ,028"
27428	Ortho.Pliers EVER Classic 428 Torquing F	4963931274284	,022 x ,028"
27440	Ortho.Pliers EVER Fine 440 Utility	4963931274406	-
27441	Ortho.Pliers EVER Fine 441 Weingart	4963931274413	-
27442	Ortho.Pliers EVER Fine 442 How	4963931274420	-
27443	Ortho.Pliers EVER Fine 443 Band Removing	4963931274437	-
27444	Ortho.Pliers EVER F.444 Bracket Removing T/C	4963931274444	-

27445	Ortho.Pliers EVER Fine 445 Step 1/2mm	4963931274451	,022 x ,028"
27446	Ortho.Pliers EVER Fine 446 Step 3/4mm	4963931274468	,022 x ,028"
27447	Ortho.Pliers EVER Fine 447 Step 1mm	4963931274475	,022 x ,028"
27448	Ortho.Pliers EVER Fine 448 Tear Drop	4963931274482	-
27449	Ortho.Pliers EVER Fine 449 Vertical	4963931274499	-
27450	Ortho.Pliers EVER Fine 450 Horizontal	4963931274505	-
27451	Ortho.Pliers EVER Fine 451 Hole Punch	4963931274512	-
27452	Ortho.Pliers EVER Fine 452 Light Wire T/C	4963931274529	,020"(böja/klippa)
27453	Ortho.Pliers EVER Fine 453 Kim T/C	4963931274536	,016"-,022"(böja)/,020"(klippa)
27454	Ortho.Pliers EVER Fine 454 Young	4963931274543	,040"
27455	Ortho.Pliers EVER Fine 455 Tweed Arch	4963931274550	,022 x ,028"
27456	Ortho.Pliers EVER Fine 456 Tweed Loop Forming	4963931274567	,022 x ,028"
27457	Ortho.Pliers EVER Fine 457 Three Jaw	4963931274574	,036"
27458	Ortho.Pliers EVER Fine 458 Bird Beak	4963931274581	,036"
27459	Ortho.Pliers EVER F. 459 Nance Closing Loop	4963931274598	,022"
27460	Ortho.Pliers EVER Fine 460 Band Removing L	4963931274604	-
27461	Ortho.Pliers EVER Fine 461 Cinch Back	4963931274611	,020"/,016"-016"
27462	Ortho.Pliers EVER Fine 462 Lingual Utility	4963931274628	-
27463	Ortho.Pliers EVER F.463 Round Former 1.0	4963931274635	-
27464	Ortho.Pliers EVER F.464 Round Former 2.0 SM	4963931274642	-
27465	Ortho.Pliers EVER Fine Key Punch 465	4963931274659	-
27550	Orthodontic Pliers Crimping Ortolan	4963931275502	-
27551	ROMAN 1 Circle Cutter SMOOTH	4963931275519	-
27552	ROMAN 2 Horizontal Box SMOOTH	4963931275526	-
27553	ROMAN 3 Vertical Box SMOOTH	4963931275533	-
27554	ROMAN 4 Pearl Dot SMOOTH	4963931275540	-
27555	ROMAN 5 Keyhole Cutter SMOOTH	4963931275557	-
27556	Angle Fluted Bird Beak Pliers	4963931275564	,036"
27601	Pin&Ligature Cutter EVER F.601 Angle 40	4963931276011	,012"
27602	Pin&Ligature Cutter EVER F.602 Reverse 40	4963931276028	,012"
27603	Pin&Ligature Cutter EVER F.603 Angle 50	4963931276035	,012"
27604	Pin&Ligature Cutter EVER F.604 Reverse 50	4963931276042	,012"
27605	Pin&Ligature Cutter EVER F.605 with Hard MATL	4963931276059	,012"
27606	Distal End Cutter EVER Fine 606S T/C	4963931276066	,022"-,028"
27607	Distal End Cutter EVER Fine 606L T/C	4963931276073	,022"-,028"
27615	Pin&Ligature Cutter EVER C.615 with Hard MATL	4963931276158	,014"
27934	Convertible Cap Removing Pliers ND-934	4963931279340	-
27935	Convertible Cap Removing Pliers ND-934 Blade	4963931279357	-

4 [Produktens avsedda användning]

Den avsedda medicinska användningen är att hålla i, fixera eller avlägsna mindre objekt, böja eller klippa av metallremsor eller -trå dar eller att skära ut eller göra fördjupningar i den ortodontiska hartsprodukten.

5 [Produktens prestandadata]

<Översikt>

Denna produkt är en liten tång med olikformade käftar beroende på avsedd användning.

<Material>

Rostfritt stål

6 [Anvisningar för användning]

Modellnr	Handelsnamn	Anvisningar för användning
22001	Adams Pliers Universal T/C	Håll i och böj låstråden för att skapa en retainer.
22102	Orthodontic Pliers Band Contouring ND-202L	Håll i och böj kanten på bandet efter tändernas form.
22104	Orthodontic Pliers Band Margin ND-204	Håll i och böj kanten på bandet efter tändernas form.
22133	Orthodontic Pliers Band Removing ND-303	Forma kanten på bandet efter tändernas ocklusala sida och avlägsna bandet.
22141	Orthodontic Pliers Peeso ND-401	Håll i och böj bågen, skapa vridmoment för att göra ett trappsteg.
22142	Orthodontic Pliers Young ND-402	Håll i och böj bågen för att skapa en ögla.
22143	Orthodontic Pliers Tweed Arch ND-403	Håll i och böj bågen, skapa vridmoment för att göra ett trappsteg.
22145	Orthodontic Pliers Tweed Loop Forming ND-405	Håll i och böj bågen för att skapa en ögla.
22147	Orthodontic Pliers Three Jaw ND-407	Håll i och böj bågen för att skapa en V-form.
22149	Orthodontic Pliers Bird Beak ND-409	Håll i och böj bågen för att skapa en ögla.
22152	Orthodontic Pliers How ND-502L	Håll i och knyt ligaturtråden.
22154	Orthodontic Pliers Utility ND-504	Håll i bågen och för in den i tandställningens buckala rör.
22155	Orthodontic Pliers How ND-502S	Håll i och knyt ligaturtråden.
22159	Orthodontic Pliers Kim T/C ND-419	Håll i och böj bågen för att skapa en ögla.
22160	Orthodontic Pliers Light Wire Cutter T/C ND-420	Håll i och böj bågen för att skapa en ögla.
22210	Orthodontic Pliers for Aligner Tear Drop	Håll i och utöka skenans funktion.
22211	Orthodontic Pliers for Aligner Vertical	Håll i och utöka skenans funktion.
22212	Orthodontic Pliers for Aligner Horizontal	Håll i och utöka skenans funktion.
22213	Orthodontic Pliers for Aligner Hole Punch	Håll i och utöka skenans funktion.
22506	Tying Pliers YS-506	Håll i och knyt ligaturtråden.
22507	Tying Pliers YS-507	Håll i och knyt ligaturtråden.
22508	Tying Pliers YS-508	Håll i och knyt ligaturtråden.
22509	Module Pliers Str.	Håll i den elastiska modulen och sätt på tandställningen.
22510	Module Pliers Cvd.	Håll i den elastiska modulen och sätt på tandställningen.
22511	Module Pliers with Groove Str.	Håll i den elastiska modulen och sätt på tandställningen.
22513	Module Pliers Mosquito Str.	Håll i den elastiska modulen och sätt på tandställningen.
22514	Module Pliers Mosquito Cvd.	Håll i den elastiska modulen och sätt på tandställningen.
22551	Separator YS-551	Bred ut separeringsmodulen och för in mellan tänder.
22601	Wire Cutter YS-601	Håll i och klipp av tråden.
22602	Wire Cutter YS-602 KI	Håll i och klipp av tråden.
22603	Wire Cutter YS-603 Standard	Håll i och klipp av tråden.
22606	Pin & Ligature Cutter ND-605 with Hard Material	Håll i och klipp av överflödig ligaturtråd.
22607	Pin & Ligature Cutter ND-605B T/C	Håll i och klipp av överflödig ligaturtråd.
22610	Distal End Cutter ND-606S T/C	Håll i och klipp av överflödig båge.
22611	Distal End Cutter ND-606LT/C	Håll i och klipp av överflödig båge.
27410	Ortho.Pliers EVER Classic 410 Band Contouring	Håll i och böj kanten på bandet efter tändernas form.
27411	Ortho.Pliers EVER Classic 411 Band Margin	Håll i och böj kanten på bandet efter tändernas form.
27412	Ortho.Pliers EVER Classic 412 Band Removing	Forma kanten på bandet efter tändernas ocklusala sida och avlägsna bandet.
27413	Ortho.Pliers EVER C. 413 Bracket Removing T/C	Håll i och ta loss tandställningen.
27414	Ortho.Pliers EVER Classic 414 Young	Håll i och böj bågen för att skapa en ögla.
27415	Ortho.Pliers EVER Classic 415 Tweed Arch	Håll i och böj bågen, skapa vridmoment för att göra ett trappsteg.
27416	Ortho.Pliers EVER C. 416 Tweed Loop Forming	Håll i och böj bågen för att skapa en ögla.
27417	Ortho.Pliers EVER Classic 417 Three Jaw	Håll i och böj bågen för att skapa en V-form.
27418	Ortho.Pliers EVER Classic 418 Bird Beak	Håll i och böj bågen för att skapa en ögla.
27419	Ortho.Pliers EVER C. 419 Nance Closing Loop	Håll i och böj bågen för att skapa en ögla.
27420	Ortho.Pliers EVER Classic 420 How	Håll i och knyt ligaturtråden.
27421	Ortho.Pliers EVER Classic 421 Weingart	Håll i bågen och för in den i tandställningens buckala rör.
27422	Ortho.Pliers EVER Classic 422 Utility	Håll i bågen och för in den i tandställningens buckala rör.
27423	Ortho.Pliers EVER Classic 423 Kim T/C	Håll i och böj bågen för att skapa en ögla.
27424	Ortho.Pliers EVER Classic 424 Light Wire T/C	Håll i och böj bågen för att skapa en ögla.
27425	Ortho.Pliers EVER Classic 425 Crimping	Håll i och applicera den krimpbara kroken på bågen.
27426	Ortho.Pliers EVER C.426 Lingual Hollow Chop	Håll i och böj bågen för att skapa en böj.
27427	Ortho.Pliers EVER Classic 427 Torquing M	Håll i bågen med "27428", rotera för att tillämpa vridmoment på bågen.
27428	Ortho.Pliers EVER Classic 428 Torquing F	Håll i bågen med "27427", rotera för att tillämpa vridmoment på bågen.
27440	Ortho.Pliers EVER Fine 440 Utility	Håll i bågen och för in den i tandställningens buckala rör.
27441	Ortho.Pliers EVER Fine 441 Weingart	Håll i bågen och för in den i tandställningens buckala rör.
27442	Ortho.Pliers EVER Fine 442 How	Håll i och knyt ligaturtråden.
27443	Ortho.Pliers EVER Fine 443 Band Removing	Forma kanten på bandet efter tändernas ocklusala sida och avlägsna bandet.
27444	Ortho.Pliers EVER F.444 Bracket Removing T/C	Håll i och ta loss tandställningen.
27445	Ortho.Pliers EVER Fine 445 Step 1/2mm	Håll i och böj bågen, skapa vridmoment för att göra ett trappsteg.
27446	Ortho.Pliers EVER Fine 446 Step 3/4mm	Håll i och böj bågen, skapa vridmoment för att göra ett trappsteg.
27447	Ortho.Pliers EVER Fine 447 Step 1mm	Håll i och böj bågen, skapa vridmoment för att göra ett trappsteg.
27448	Ortho.Pliers EVER Fine 448 Tear Drop	Håll i och utöka skenans funktion.
27449	Ortho.Pliers EVER Fine 449 Vertical	Håll i och utöka skenans funktion.

27450	Ortho.Pliers EVER Fine 450 Horizontal	Håll i och utöka skenans funktion.
27451	Ortho.Pliers EVER Fine 451 Hole Punch	Håll i och utöka skenans funktion.
27452	Ortho.Pliers EVER Fine 452 Light Wire T/C	Håll i och böj bågen för att skapa en ögla.
27453	Ortho.Pliers EVER Fine 453 Kim T/C	Håll i och böj bågen för att skapa en ögla.
27454	Ortho.Pliers EVER Fine 454 Young	Håll i och böj bågen för att skapa en ögla.
27455	Ortho.Pliers EVER Fine 455 Tweed Arch	Håll i och böj bågen, skapa vridmoment för att göra ett trappsteg.
27456	Ortho.Pliers EVER Fine 456 Tweed Loop Forming	Håll i och böj bågen för att skapa en ögla.
27457	Ortho.Pliers EVER Fine 457 Three Jaw	Håll i och böj bågen för att skapa en V-form.
27458	Ortho.Pliers EVER Fine 458 Bird Beak	Håll i och böj bågen för att skapa en ögla.
27459	Ortho.Pliers EVER F. 459 Nance Closing Loop	Håll i och böj bågen för att skapa en ögla.
27460	Ortho.Pliers EVER Fine 460 Band Removing L	Forma kanten på bandet efter tändernas ocklusala sida och avlägsna bandet.
27461	Ortho.Pliers EVER Fine 461 Cinch Back	Håll i och böj änden av bågen.
27462	Ortho.Pliers EVER Fine 462 Lingual Utility	Håll i bågen och för in den i tandställningens buckala rör.
27463	Ortho.Pliers EVER F.463 Round Former 1.0	Håll i och utöka skenans funktion.
27464	Ortho.Pliers EVER F.464 Round Former 2.0 SM	Håll i och utöka skenans funktion.
27465	Ortho.Pliers EVER Fine Key Punch 465	Håll i och utöka skenans funktion.
27550	Orthodontic Pliers Crimping Ortolan	Håll i och applicera den krimpbara kroken på bågen.
27551	ROMAN 1 Circle Cutter SMOOTH	Håll i och utöka skenans funktion.
27552	ROMAN 2 Horizontal Box SMOOTH	Håll i och utöka skenans funktion.
27553	ROMAN 3 Vertical Box SMOOTH	Håll i och utöka skenans funktion.
27554	ROMAN 4 Pearl Dot SMOOTH	Håll i och utöka skenans funktion.
27555	ROMAN 5 Keyhole Cutter SMOOTH	Håll i och utöka skenans funktion.
27556	Angle Fluted Bird Beak Pliers	Håll i och böj änden av bågen.
27601	Pin&Ligature Cutter EVER F.601 Angle 40	Håll i och klipp av överflödig ligaturtråd.
27602	Pin&Ligature Cutter EVER F.602 Reverse 40	Håll i och klipp av överflödig ligaturtråd.
27603	Pin&Ligature Cutter EVER F.603 Angle 50	Håll i och klipp av överflödig ligaturtråd.
27604	Pin&Ligature Cutter EVER F.604 Reverse 50	Håll i och klipp av överflödig ligaturtråd.
27605	Pin&Ligature Cutter EVER F.605 with Hard MATL	Håll i och klipp av överflödig ligaturtråd.
27606	Distal End Cutter EVER Fine 606S T/C	Håll i och klipp av överflödig båge.
27607	Distal End Cutter EVER Fine 606L T/C	Håll i och klipp av överflödig båge.
27615	Pin&Ligature Cutter EVER C.615 with Hard MATL	Håll i och klipp av överflödig ligaturtråd.
27722	Wire Cutter Heavy Duty	Klipp av tråden.
27934	Convertible Cap Removing Pliers ND-934	Håll i och ta loss locket på det konvertibla röret.
27935	Convertible Cap Removing Pliers ND-934 Blade	Viktig del av "27934"

7 [Allmänna försiktighetsåtgärder och förbud]

- 1) Användningen av produkten är strikt begränsad till dentala behandlingar.
Försiktighetsåtgärder måste vidtas för att säkerställa korrekt användning av instrumenten.
- 2) Använd inte instrumenten för något annat än vad de är avsedda för.
- 3) Rengör, smörj och sterilisera före användning enligt bruksanvisningen.
- 4) Använd inte instrumenten till patienter med överkänslighetssymtom som hudutslag och dermatit, eller allergiska symtom.
- 5) Ändra inte utformningen på eller modifiera instrumenten.
- 6) Tappa inte instrumenten. Undvik att utsätta instrumenten för kraftiga slag eller stötar.
- 7) Vid avyttring av instrumenten ska aktuella nationella föreskrifter följas.
- 8) Värm inte upp instrumenten.
- 9) Om kemikalier hamnar på instrumenten ska de omedelbart torkas av så att de inte orsakar korrosion.
- 10) Vid böjning av trådar med dessa instrument ska du hålla i tråden med tången och böja den med fingret så att tången inte skadas.
- 11) Rostfritt stål är mer motståndskraftigt mot rost än järn men det kan ändå rosta på grund av användningsmetod och miljöfaktorer som temperatur och fuktighet.

8 [Begränsning av bearbetning]

Sluta genast använda instrumenten om du märker någon försämring hos instrumentet eller om något verkar konstigt.

9 [Initial behandling på användningsplatsen]

Rengör, smörj och sterilisera före användning enligt bruksanvisningen.

10 [Förberedelser före rengöring]

Se nästa avsnitt.

11 [Procedur för rengöring och sterilisering/desinfektion]

1) Allmänna försiktighetsåtgärder

- a) Vid underhåll av instrumenten, läs "The Fundamental Guide Book for Cleaning and Sterilizing Instruments" (Grundläggande handbok för att rengöra och sterilisera instrument) som publicerats av vårt företag eller avsnittet om underhåll på vår webbplats (http://www.ydm.co.jp/en-new/pdf/The_process_of_cleaning_and_sterilizing.pdf).
- b) Om instrumenten har kontaminerats av blod, kroppsvätskor, vävnadsfragment, kemikalier osv. ska de rengöras och steriliseras omedelbart i enlighet med nedanstående metod för att förhindra att kontaminerande ämnen torkar in och fastnar. Om de kontaminerande ämnena får sitta kvar på instrumenten länge kan det bli svårt att avlägsna dem.

2) Procedur

- a) Öppna leden.
- b) Rengör instrumenten med ett rengöringsmedel enligt metod i) eller ii).
 - i) Använd en ultraljudsvätt med ett rostskyddande rengöringsmedel för medicinskt bruk i 5 minuter.
 - ii) Sänk ner instrumenten i ett bad med rostskyddande rengöringsmedel för medicinskt bruk i 15 minuter.
- c) Tvätta bort smuts och rengöringsmedel som fastnat på instrumenten med rinnande vatten.
(Om tvårester sitter kvar på instrumenten kan de orsaka rost och fläckar.)
- d) Torka instrumenten. (Fukt som finns kvar kan orsaka rost och en nedsatt steriliseringseffekt)
- e) Applicera rostskyddande smörjmedel, till exempel "instrumentolja" på leden.
* Öppna eller stäng inte leden förrän det rostskyddande smörjmedlet har applicerats.
(Om du öppnar och stänger utan smörjmedel nöts leden)
- f) Sterilisera med hjälp av autoklav.
Förhållanden: 134 °C till 138 °C, 3 minuter till 3,5 minuter
* För att förhindra repor vid kontakt med andra instrument bör de placeras i en steriliserad förpackning eller påse.
- g) Efter användning ska instrumenten omedelbart rengöras i enlighet med b) ovan.

3) Försiktighetsåtgärder vid rengöring och sterilisering/desinfektion

- a) Använd inte följande kemikalier, eftersom de kan få metallen att rosta:
natriumhypoklorit, bensalkoniumklorid, klorhexidylglukonat, jodlösning.
Jodoform och perättiksyra kan få metall att rosta.
- b) Använd inte kemisk autoklav på instrumenten, eftersom det kan orsaka korrosion.
- c) Plasmasterilisering får inte användas, eftersom det kan påverka materialet.
- d) Använd inte hushållsrengöringsmedel, eftersom de inte är lämpliga för att avlägsna protein från ytan på instrumenten.
- e) Metallborste och stålull kan skada instrumenten.
- f) Använd inte supersurt vatten eftersom det kan orsaka korrosion.
Renat vatten (inga orenheter) rekommenderas för sköljning.
Kranvatten innehåller klor, vilket kan få metallen att rosta.
- g) När en diskdesinfektor används kanske inte ingrodd smuts eller rengöringslösningen avlägsnas helt om vatten- eller tidsbesparande program används. Läs tillverkarens bruksanvisning för att säkerställa korrekt sköljning och avlägsnande av smuts.
- h) Tänk på nedanstående när du hanterar autoklaver.
 - i) Autoklavens kammare kan vara kontaminerad beroende på användningsstatus och tidsperiod.
Om smuts lämnas kvar i autoklaven kan den fastna på instrumenten.
Vi rekommenderar att autoklaven rengörs enligt dess bruksanvisning.
På så sätt hålls insidan av kammaren ren.
I synnerhet ska gummitätningen vid kammarens lucka och luftfiltret bytas ut efter en viss tid.
 - ii) Använd renat vatten i största möjliga utsträckning. Kranvatten kan orsaka korrosion på grund av kloridjoner.
 - iii) Var uppmärksam på torktemperaturen inuti autoklaven.
 - iv) Placera inte dessa instrument nära värmaren. (Temperaturen kan vara högre än vad som anges)
 - v) Om autoklavens insida inte rengörs och sköljs, eller om fukt finns kvar i autoklavens kammare, kan instrumentens utsida brännas.
- i) Efter rengöring och sterilisering ska resterande vatten avlägsnas från instrumentet och det ska torkas ordentligt.

12 [Underhåll, inspektion och testning]

Efter rengöring och sterilisering ska nedanstående kontrolleras före användning.

- 1) Kontrollera att det inte förekommer smuts, skador, sprickor, repor eller rost inuti eller utanpå leden.
- 2) Kontrollera att leden inte rör sig på onormalt sätt.

13 [Förvaring]

- 1) Förvara på en ren, dammfri plats. Undvik hög temperatur och luftfuktighet.
- 2) För att förhindra galvanisk korrosion på grund av potentialskillnad mellan metaller ska instrument av olika sorters metall inte förvaras tillsammans.
- 3) Observera nedanstående för att motverka rostfläckar.
 - a) Förvara inte tillsammans med rostiga instrument.
 - b) Förvara inte tillsammans med kemikalier.
 - c) Var uppmärksam på rost inuti sterilisatorer och förvaringsutrymmen.

14 [Kassering]

Tandvårdsspecialister och/eller tandreglerare ansvarar för att kassering sker i enlighet med relevant och gällande lagstiftning. YDM CORPORATION åtar sig inget ansvar för anspråk gällande personskador orsakade av felaktig kassering.

15 [Ytterligare information]

<Trasig produkt och vässning>

Om instrumenten skulle gå sönder ska du kontakta den återförsäljare som du köpte instrumenten av via ett formulär som YDM CORPORATION utfärdat och som kallas för "Claim Report" (Reklamationsrapport).

Om ett skärinstrument behöver vässas utför vi det mot en viss avgift.

16 [Tillverkarens kontaktuppgifter]



YDM CORPORATION

28 Imaizumi, Higashi-Matsuyama-shi,

Saitama 355-0042, Japan

TEL.: 81-3-3828-3161

FAX: 81-3-3827-8991

URL: <http://www.ydm.co.jp/>

E-post: ydm@ydm.co.jp

17 [Meddelande till användaren och/eller patienten]

Eventuella allvarliga incidenter som sker i samband med användning av instrumenten ska rapporteras till YDM CORPORATION.

18 [Ytterligare information]

Om produkten skulle vara defekt ska du kontakta den återförsäljare som du köpte produkten av via ett formulär som YDM Corporation har utfärdat som kallas för "Claim Report" (Reklamationsrapport).

19 [Beskrivning av symboler]



Medicinteknisk produkt

Tillverkare

Lotnummer

Meddelande

visningarna ovan har godkänts av tillverkaren av den medicintekniska produkten för att förbereda en medicinteknisk produkt för åeranvändning. Det är bearbetarens ansvar att säkerställa att bearbetningen, så som den utförs med hjälp av utrustning, material och personal på behandlingsinrättningen, uppnår önskat resultat. Detta kräver verifiering och/eller validering samt rutinmässig övervakning av proceduren.

Ver.01 23 juni 2021

Ver.02 24 augusti 2022

Ver.03 6 juli 2023

- 1 [Aile adı] Ortodontik Pens
 2 [Üretici] YDM CORPORATION
 3 [Model No ve Cihazın ticari adı]



ModelNo.	Cihazın ticari adı	UDI-DI	Maksimum kesme ve bükme kapasiteleri
22001	Adams Pliers Universal T/C	4963931220014	
22102	Orthodontic Pliers Band Contouring ND-202L	4963931221028	-
22104	Orthodontic Pliers Band Margin ND-204	4963931221042	-
22133	Orthodontic Pliers Band Removing ND-303	4963931221332	-
22141	Orthodontic Pliers Peeso ND-401	4963931221417	,040"
22142	Orthodontic Pliers Young ND-402	4963931221424	,040"
22143	Orthodontic Pliers Tweed Arch ND-403	4963931221431	,022"- ,028"
22145	Orthodontic Pliers Tweed Loop Forming ND-405	4963931221455	,022"- ,028"
22147	Orthodontic Pliers Three Jaw ND-407	4963931221479	,036"
22149	Orthodontic Pliers Bird Beak ND-409	4963931221493	,036"
22152	Orthodontic Pliers How ND-502L	4963931221523	-
22154	Orthodontic Pliers Utility ND-504	4963931221547	-
22155	Orthodontic Pliers How ND-502S	4963931221554	-
22159	Orthodontic Pliers Kim T/C ND-419	4963931221592	,016"- ,022"(Bükme)/ ,020"(Kesme)
22160	Orthodontic Pliers Light Wire Cutter T/C ND-420	4963931221608	,020"(Bükme/Kesme)
22210	Orthodontic Pliers for Aligner Tear Drop	4963931222100	-
22211	Orthodontic Pliers for Aligner Vertical	4963931222117	-
22212	Orthodontic Pliers for Aligner Horizontal	4963931222124	-
22213	Orthodontic Pliers for Aligner Hole Punch	4963931222131	-
22506	Tying Pliers YS-506	4963931225064	-
22507	Tying Pliers YS-507	4963931225071	-
22508	Tying Pliers YS-508	4963931225088	-
22509	Module Pliers Str.	4963931225095	-
22510	Module Pliers Cvd.	4963931225101	-
22511	Module Pliers with Groove Str.	4963931225118	-
22513	Module Pliers Mosquito Str.	4963931225132	-
22514	Module Pliers Mosquito Cvd.	4963931225149	-
22551	Separator YS-551	4963931225514	-
22601	Wire Cutter YS-601	4963931226016	,032"
22602	Wire Cutter YS-602 KI	4963931226023	,045"
22603	Wire Cutter YS-603 Standard	4963931226030	,048"
22606	Pin & Ligature Cutter ND-605 with Hard Material	4963931226061	,012"
22607	Pin & Ligature Cutter ND-605B T/C	4963931226078	,014"
22610	Distal End Cutter ND-606S T/C	4963931226108	,022"- ,028"
22611	Distal End Cutter ND-606LT/C	4963931226115	,022"- ,028"
27410	Ortho.Pliers EVER Classic 410 Band Contouring	4963931274109	-
27411	Ortho.Pliers EVER Classic 411 Band Margin	4963931274116	-
27412	Ortho.Pliers EVER Classic 412 Band Removing	4963931274123	-
27413	Ortho.Pliers EVER C. 413 Bracket Removing T/C	4963931274130	-
27414	Ortho.Pliers EVER Classic 414 Young	4963931274147	,040"
27415	Ortho.Pliers EVER Classic 415 Tweed Arch	4963931274154	,022 x ,028"
27416	Ortho.Pliers EVER C. 416 Tweed Loop Forming	4963931274161	,022 x ,028"
27417	Ortho.Pliers EVER Classic 417 Three Jaw	4963931274178	,036"
27418	Ortho.Pliers EVER Classic 418 Bird Beak	4963931274185	,036"
27419	Ortho.Pliers EVER C. 419 Nance Closing Loop	4963931274192	,022"
27420	Ortho.Pliers EVER Classic 420 How	4963931274208	-
27421	Ortho.Pliers EVER Classic 421 Weingart	4963931274215	-
27422	Ortho.Pliers EVER Classic 422 Utility	4963931274222	-
27423	Ortho.Pliers EVER Classic 423 Kim T/C	4963931274239	,016"- ,022"(Bükme)/ ,020"(Kesme)
27424	Ortho.Pliers EVER Classic 424 Light Wire T/C	4963931274246	,020"(Bükme/Kesme)
27425	Ortho.Pliers EVER Classic 425 Crimping	4963931274253	-
27426	Ortho.Pliers EVER C.426 Lingual Hollow Chop	4963931274260	,022 x ,028"
27427	Ortho.Pliers EVER Classic 427 Torquing M	4963931274277	,022 x ,028"
27428	Ortho.Pliers EVER Classic 428 Torquing F	4963931274284	,022 x ,028"
27440	Ortho.Pliers EVER Fine 440 Utility	4963931274406	-
27441	Ortho.Pliers EVER Fine 441 Weingart	4963931274413	-
27442	Ortho.Pliers EVER Fine 442 How	4963931274420	-
27443	Ortho.Pliers EVER Fine 443 Band Removing	4963931274437	-
27444	Ortho.Pliers EVER F.444 Bracket Removing T/C	4963931274444	-

27445	Ortho.Pliers EVER Fine 445 Step 1/2mm	4963931274451	,022 x ,028"
27446	Ortho.Pliers EVER Fine 446 Step 3/4mm	4963931274468	,022 x ,028"
27447	Ortho.Pliers EVER Fine 447 Step 1mm	4963931274475	,022 x ,028"
27448	Ortho.Pliers EVER Fine 448 Tear Drop	4963931274482	-
27449	Ortho.Pliers EVER Fine 449 Vertical	4963931274499	-
27450	Ortho.Pliers EVER Fine 450 Horizontal	4963931274505	-
27451	Ortho.Pliers EVER Fine 451 Hole Punch	4963931274512	-
27452	Ortho.Pliers EVER Fine 452 Light Wire T/C	4963931274529	,020"(Bükme/Kesme)
27453	Ortho.Pliers EVER Fine 453 Kim T/C	4963931274536	,016"-,022"(Bükme)/,020"(Kesme)
27454	Ortho.Pliers EVER Fine 454 Young	4963931274543	,040"
27455	Ortho.Pliers EVER Fine 455 Tweed Arch	4963931274550	,022 x ,028"
27456	Ortho.Pliers EVER Fine 456 Tweed Loop Forming	4963931274567	,022 x ,028"
27457	Ortho.Pliers EVER Fine 457 Three Jaw	4963931274574	,036"
27458	Ortho.Pliers EVER Fine 458 Bird Beak	4963931274581	,036"
27459	Ortho.Pliers EVER F. 459 Nance Closing Loop	4963931274598	,022"
27460	Ortho.Pliers EVER Fine 460 Band Removing L	4963931274604	-
27461	Ortho.Pliers EVER Fine 461 Cinch Back	4963931274611	,020"/,016"-016"
27462	Ortho.Pliers EVER Fine 462 Lingual Utility	4963931274628	-
27463	Ortho.Pliers EVER F.463 Round Former 1.0	4963931274635	-
27464	Ortho.Pliers EVER F.464 Round Former 2.0 SM	4963931274642	-
27465	Ortho.Pliers EVER Fine Key Punch 465	4963931274659	-
27550	Orthodontic Pliers Crimping Ortolan	4963931275502	-
27551	ROMAN 1 Circle Cutter SMOOTH	4963931275519	-
27552	ROMAN 2 Horizontal Box SMOOTH	4963931275526	-
27553	ROMAN 3 Vertical Box SMOOTH	4963931275533	-
27554	ROMAN 4 Pearl Dot SMOOTH	4963931275540	-
27555	ROMAN 5 Keyhole Cutter SMOOTH	4963931275557	-
27556	Angle Fluted Bird Beak Pliers	4963931275564	,036"
27601	Pin&Ligature Cutter EVER F.601 Angle 40	4963931276011	,012"
27602	Pin&Ligature Cutter EVER F.602 Reverse 40	4963931276028	,012"
27603	Pin&Ligature Cutter EVER F.603 Angle 50	4963931276035	,012"
27604	Pin&Ligature Cutter EVER F.604 Reverse 50	4963931276042	,012"
27605	Pin&Ligature Cutter EVER F.605 with Hard MATL	4963931276059	,012"
27606	Distal End Cutter EVER Fine 606S T/C	4963931276066	,022"-,028"
27607	Distal End Cutter EVER Fine 606L T/C	4963931276073	,022"-,028"
27615	Pin&Ligature Cutter EVER C.615 with Hard MATL	4963931276158	,014"
27934	Convertible Cap Removing Pliers ND-934	4963931279340	-
27935	Convertible Cap Removing Pliers ND-934 Blade	4963931279357	-

4 [Cihazın amaçlanan kullanımı]

Amaçlanan medikal kullanım endikasyonu küçük nesnelere tutmak, sabitlemek veya çıkarmak, metal şeritleri ya da telleri bükme veya kesme ya da reçine ortodontik araçlarda birden fazla yerde kesik veya oyuk açmaktır.

5 [Cihazın performans karakteristikleri]

<Genel Bakış>

Bu cihazlar, amaca bağlı olarak çeşitli şekillerde çenelere sahip küçük penslerdir.

<Materyal>

Paslanmaz çelik

ModelNo.	Cihazın ticari adı	Kullanımı
22001	Adams Pliers Universal T/C	Pekiştirme apareyi yapmak için kroşe telini tutma, bükme.
22102	Orthodontic Pliers Band Contouring ND-202L	Dişin şekline uyması için şeridin kenarını tutma, bükme.
22104	Orthodontic Pliers Band Margin ND-204	Dişin şekline uyması için şeridin kenarını tutma, bükme.
22133	Orthodontic Pliers Band Removing ND-303	Şeridin kenarını dişin oklüzal yüzüne uygun hale getirme ve şeridi çıkarma
22141	Orthodontic Pliers Peeso ND-401	Tork, adım uygulamak için ark telini tutma, bükme.
22142	Orthodontic Pliers Young ND-402	Halka haline getirmek için ark telini tutma, bükme.
22143	Orthodontic Pliers Tweed Arch ND-403	Tork, adım uygulamak için ark telini tutma, bükme.
22145	Orthodontic Pliers Tweed Loop Forming ND-405	Halka haline getirmek için ark telini tutma, bükme.
22147	Orthodontic Pliers Three Jaw ND-407	V şekline getirmek için ark telini tutma, bükme.
22149	Orthodontic Pliers Bird Beak ND-409	Halka haline getirmek için ark telini tutma, bükme.
22152	Orthodontic Pliers How ND-502L	Ligatür telini tutma, bağlama.
22154	Orthodontic Pliers Utility ND-504	Ark telini tutma ve diş tellerine, bukkal tüpe sokma.
22155	Orthodontic Pliers How ND-502S	Ligatür telini tutma, bağlama.
22159	Orthodontic Pliers Kim T/C ND-419	Halka haline getirmek için ark telini tutma, bükme.
22160	Orthodontic Pliers Light Wire Cutter T/C ND-420	Halka haline getirmek için ark telini tutma, bükme.
22210	Orthodontic Pliers for Aligner Tear Drop	Şeffaf apareyi tutma ve ek işlev uygulama.
22211	Orthodontic Pliers for Aligner Vertical	Şeffaf apareyi tutma ve ek işlev uygulama.
22212	Orthodontic Pliers for Aligner Horizontal	Şeffaf apareyi tutma ve ek işlev uygulama.
22213	Orthodontic Pliers for Aligner Hole Punch	Şeffaf apareyi tutma ve ek işlev uygulama.
22506	Tying Pliers YS-506	Ligatür telini tutma, bağlama.
22507	Tying Pliers YS-507	Ligatür telini tutma, bağlama.
22508	Tying Pliers YS-508	Ligatür telini tutma, bağlama.
22509	Module Pliers Str.	Elastik modülü tutma ve diş teline takma.
22510	Module Pliers Cvd.	Elastik modülü tutma ve diş teline takma.
22511	Module Pliers with Groove Str.	Elastik modülü tutma ve diş teline takma.
22513	Module Pliers Mosquito Str.	Elastik modülü tutma ve diş teline takma.
22514	Module Pliers Mosquito Cvd.	Elastik modülü tutma ve diş teline takma.
22551	Separator YS-551	Ayırma modülünü açma ve diş arasına yerleştirme.
22601	Wire Cutter YS-601	Teli tutma, kesme.
22602	Wire Cutter YS-602 KI	Teli tutma, kesme.
22603	Wire Cutter YS-603 Standard	Teli tutma, kesme.
22606	Pin & Ligature Cutter ND-605 with Hard Material	Fazla ligatür telini tutma, kesme.
22607	Pin & Ligature Cutter ND-605B T/C	Fazla ligatür telini tutma, kesme.
22610	Distal End Cutter ND-606S T/C	Fazla ark telini tutma, kesme.
22611	Distal End Cutter ND-606LT/C	Fazla ark telini tutma, kesme.
27410	Ortho.Pliers EVER Classic 410 Band Contouring	Dişin şekline uyması için şeridin kenarını tutma, bükme.
27411	Ortho.Pliers EVER Classic 411 Band Margin	Dişin şekline uyması için şeridin kenarını tutma, bükme.
27412	Ortho.Pliers EVER Classic 412 Band Removing	Şeridin kenarını dişin oklüzal yüzüne uygun hale getirme ve şeridi çıkarma
27413	Ortho.Pliers EVER C. 413 Bracket Removing T/C	Diş telini tutma, çıkarma.
27414	Ortho.Pliers EVER Classic 414 Young	Halka haline getirmek için ark telini tutma, bükme.
27415	Ortho.Pliers EVER Classic 415 Tweed Arch	Tork, adım uygulamak için ark telini tutma, bükme.
27416	Ortho.Pliers EVER C. 416 Tweed Loop Forming	Halka haline getirmek için ark telini tutma, bükme.
27417	Ortho.Pliers EVER Classic 417 Three Jaw	V şekline getirmek için ark telini tutma, bükme.
27418	Ortho.Pliers EVER Classic 418 Bird Beak	Halka haline getirmek için ark telini tutma, bükme.
27419	Ortho.Pliers EVER C. 419 Nance Closing Loop	Halka haline getirmek için ark telini tutma, bükme.
27420	Ortho.Pliers EVER Classic 420 How	Ligatür telini tutma, bağlama.
27421	Ortho.Pliers EVER Classic 421 Weingart	Ark telini tutma ve diş tellerine, bukkal tüpe sokma.
27422	Ortho.Pliers EVER Classic 422 Utility	Ark telini tutma ve diş tellerine, bukkal tüpe sokma.
27423	Ortho.Pliers EVER Classic 423 Kim T/C	Halka haline getirmek için ark telini tutma, bükme.
27424	Ortho.Pliers EVER Classic 424 Light Wire T/C	Halka haline getirmek için ark telini tutma, bükme.
27425	Ortho.Pliers EVER Classic 425 Crimping	Kıvrılabilir kancayı tutma, ark teline uygulama.
27426	Ortho.Pliers EVER C.426 Lingual Hollow Chop	Eğim uygulamak için ark telini tutma, bükme.
27427	Ortho.Pliers EVER Classic 427 Torquing M	Ark telini "27428" ile tutma, ark teline tork uygulamak için döndürme.
27428	Ortho.Pliers EVER Classic 428 Torquing F	Ark telini "27427" ile tutma, ark teline tork uygulamak için döndürme.
27440	Ortho.Pliers EVER Fine 440 Utility	Ark telini tutma ve diş tellerine, bukkal tüpe sokma.
27441	Ortho.Pliers EVER Fine 441 Weingart	Ark telini tutma ve diş tellerine, bukkal tüpe sokma.
27442	Ortho.Pliers EVER Fine 442 How	Ligatür telini tutma, bağlama.
27443	Ortho.Pliers EVER Fine 443 Band Removing	Şeridin kenarını dişin oklüzal yüzüne uygun hale getirme ve şeridi çıkarma
27444	Ortho.Pliers EVER F.444 Bracket Removing T/C	Diş telini tutma, çıkarma.
27445	Ortho.Pliers EVER Fine 445 Step 1/2mm	Adım uygulamak için ark telini tutma, bükme.
27446	Ortho.Pliers EVER Fine 446 Step 3/4mm	Adım uygulamak için ark telini tutma, bükme.
27447	Ortho.Pliers EVER Fine 447 Step 1mm	Adım uygulamak için ark telini tutma, bükme.
27448	Ortho.Pliers EVER Fine 448 Tear Drop	Şeffaf apareyi tutma ve ek işlev uygulama.
27449	Ortho.Pliers EVER Fine 449 Vertical	Şeffaf apareyi tutma ve ek işlev uygulama.

27450	Ortho.Pliers EVER Fine 450 Horizontal	Şeffaf apareyi tutma ve ek işlev uygulama.
27451	Ortho.Pliers EVER Fine 451 Hole Punch	Şeffaf apareyi tutma ve ek işlev uygulama.
27452	Ortho.Pliers EVER Fine 452 Light Wire T/C	Halka haline getirmek için ark telini tutma, bükme.
27453	Ortho.Pliers EVER Fine 453 Kim T/C	Halka haline getirmek için ark telini tutma, bükme.
27454	Ortho.Pliers EVER Fine 454 Young	Halka haline getirmek için ark telini tutma, bükme.
27455	Ortho.Pliers EVER Fine 455 Tweed Arch	Tork, adım uygulamak için ark telini tutma, bükme.
27456	Ortho.Pliers EVER Fine 456 Tweed Loop Forming	Halka haline getirmek için ark telini tutma, bükme.
27457	Ortho.Pliers EVER Fine 457 Three Jaw	V şekline getirmek için ark telini tutma, bükme.
27458	Ortho.Pliers EVER Fine 458 Bird Beak	Halka haline getirmek için ark telini tutma, bükme.
27459	Ortho.Pliers EVER F. 459 Nance Closing Loop	Halka haline getirmek için ark telini tutma, bükme.
27460	Ortho.Pliers EVER Fine 460 Band Removing L	Şeridin kenarını dişin oklüzal yüzüne uygun hale getirme ve şeridi çıkarma
27461	Ortho.Pliers EVER Fine 461 Cinch Back	Ark telinin ucunu tutma, bükme.
27462	Ortho.Pliers EVER Fine 462 Lingual Utility	Ark telini tutma ve diş tellerine, bukkal tüpe sokma.
27463	Ortho.Pliers EVER F.463 Round Former 1.0	Şeffaf apareyi tutma ve ek işlev uygulama.
27464	Ortho.Pliers EVER F.464 Round Former 2.0 SM	Şeffaf apareyi tutma ve ek işlev uygulama.
27465	Ortho.Pliers EVER Fine Key Punch 465	Şeffaf apareyi tutma ve ek işlev uygulama.
27550	Orthodontic Pliers Crimping Ortolan	Kıvrılabilir kancayı tutma, ark teline uygulama.
27551	ROMAN 1 Circle Cutter SMOOTH	Şeffaf apareyi tutma ve ek işlev uygulama.
27552	ROMAN 2 Horizontal Box SMOOTH	Şeffaf apareyi tutma ve ek işlev uygulama.
27553	ROMAN 3 Vertical Box SMOOTH	Şeffaf apareyi tutma ve ek işlev uygulama.
27554	ROMAN 4 Pearl Dot SMOOTH	Şeffaf apareyi tutma ve ek işlev uygulama.
27555	ROMAN 5 Keyhole Cutter SMOOTH	Şeffaf apareyi tutma ve ek işlev uygulama.
27556	Angle Fluted Bird Beak Pliers	Ark telinin ucunu tutma, bükme.
27601	Pin&Ligature Cutter EVER F.601 Angle 40	Fazla ligatür telini tutma, kesme.
27602	Pin&Ligature Cutter EVER F.602 Reverse 40	Fazla ligatür telini tutma, kesme.
27603	Pin&Ligature Cutter EVER F.603 Angle 50	Fazla ligatür telini tutma, kesme.
27604	Pin&Ligature Cutter EVER F.604 Reverse 50	Fazla ligatür telini tutma, kesme.
27605	Pin&Ligature Cutter EVER F.605 with Hard MATL	Fazla ligatür telini tutma, kesme.
27606	Distal End Cutter EVER Fine 606S T/C	Fazla ark telini tutma, kesme.
27607	Distal End Cutter EVER Fine 606L T/C	Fazla ark telini tutma, kesme.
27615	Pin&Ligature Cutter EVER C.615 with Hard MATL	Fazla ligatür telini tutma, kesme.
27722	Wire Cutter Heavy Duty	Teli kesme.
27934	Convertible Cap Removing Pliers ND-934	Dönüştürülebilir tüp kapağını tutma, çıkarma.
27935	Convertible Cap Removing Pliers ND-934 Blade	"27934" ürününün anahtar parçası

7 [Genel önlemler ve yasaklar]

1) Ürünün kullanımı yalnızca dental tedavilerle sınırlıdır.

Aletlerin doğru şekilde kullanılmasını sağlamak için önlemlerin uygulanması gerekir.

2) Aletleri amaçlanan kullanımları dışında hiçbir şey için kullanmayın.

3) Kullanmadan önce kullanım talimatlarında belirtilen şekilde temizleyin, yağlayın ve sterilize edin.

4) Döküntü ve dermatit gibi hipersensitivite semptomları veya alerjik semptomlar görülen hastalarda aletleri kullanmayın.

5) Aletlerin tasarımında veya biçiminde değişiklik yapmayın.

6) Aletleri yere düşürmeyin. Aletlerin sert darbeler almasını engelleyin.

7) Aletleri bertaraf ederken ilgili ulusal düzenlemelerde açıklanan talimatları uygulayın.

8) Aletleri ısıtmayın.

9) Aletlere kimyasallar yapışması halinde korozyonu önlemek için bu kimyasalları vakit kaybetmeden silin.

10) Bu aletlerle tel bükerken pensin hasar görmesini önlemek üzere teli pensle tutup parmağınızla bükün.

11) Paslanmaz çelik demire göre paslanmaya karşı daha dirençlidir ancak kullanım yöntemine ve sıcaklık ile nem gibi ortam koşulları na bağlı olarak korozyon gerçekleşebilir.

8 [Cihazın işlenmesiyle ilgili sınırlamalar]

Bozulma veya anormal bir durum fark ederseniz aletleri kullanmayı derhal bırakın.

9 [Kullanım noktasında yapılacak ilk işlem]

Kullanmadan önce kullanım talimatlarında belirtilen şekilde temizleyin, yağlayın ve sterilize edin.

10 [Temizlik öncesi hazırlık]

Bir sonraki bölüme bakın.

11 [Temizlik ve sterilizasyon/dezenfeksiyon işlemi]

1) Genel önlemler

a) Aletlerin bakımı yapılırken lütfen şirketimiz tarafından yayımlanan "The Fundamental Guide Book for Cleaning and Sterilizing Instruments"(Aletlerin Temizliği ve Sterilizasyonu İçin Temel Kılavuz Kitabı) belgesine veya web sitemizdeki "bakım" bölümüne (http://www.ydm.co.jp/en-new/pdf/The_process_of_cleaning_and_sterilizing.pdf) başvurun.

Kan, vücut sıvıları, doku parçaları, kimyasallar vs. ile kontamine olmuş aletler, kontaminantların kurumasını ve yapışmasını önlemek için aşağıda verilen yöntem kullanılarak derhal temizlenmeli ve sterilize edilmelidir.

Uzun süre boyunca aletlere yapışan kontaminantların çıkarılması zor olabilir.

2) Prosedür

a) Birleşme yerini açın.

b) Aletleri bir temizlik ajanıyla i) veya ii) yöntemini kullanarak temizleyin.

i) Tıbbi bir pas önleyici deterjan kullanarak 5 dakika süreyle ultrasonik temizlik yapın.

ii) 15 dakika süreyle tıbbi kullanıma yönelik pas önleyici deterjan içeren bir temizleyiciye daldırarak yıkayın.

c) Aletlere yapışan kirleri ve temizleyicileri akan su altında yıkayarak giderin.

(Aletlerin yüzeyinde sabun bileşenleri kalırsa bunlar paslanmaya ve lekeler neden olur.)

d) Aletleri kurutun. (Cihazın nemli kalması paslanmaya neden olabilir ve sterilizasyon etkisini azaltabilir)

e) "Alet yağı" gibi paslanma önleyici bir yağlama maddesi ile birleşme yerini yağlayın.

* Paslanma önleyici yağlama maddesi uygulanana kadar açmayın veya kapamayın.

(Ürünün yağ olmadan açılması ve kapatılması aşırı sürtünmeye neden olur.)

f) Otoklav sterilizatörünü kullanarak sterilizasyon yapın.

Koşullar: 134 °C ila 138 °C, 3 dakika ila 3,5 dakika

* Diğer aletlere temastan kaynaklanan çizilmeleri önlemek için, aletleri sterilize edilmiş bir ambalaja veya kaba koyun.

g) Kullanımdan sonra, yukarıdaki b) adımına göre derhal temizleyin.

3) Temizlik ve sterilizasyon/dezenfeksiyon önlemleri

a) Metal korozyonuna yol açabilecekleri için aşağıdaki kimyasalları kullanmayın.

Sodyum hipoklorit, benzalkonyum klorür, klorheksidin glukonat, tendüriyot, iyodoform ve perasetik asit metal korozyonuna neden olabilir.

b) Aletlerde korozyona neden olabilecek kimyasal otoklav kullanmayın.

c) Materyali etkileyeceği için plazma sterilizasyonu uygulamayın.

d) Aletlerin yüzeyindeki proteini gidermeye uygun olmadığından ev temizliği ajanları kullanmayın.

e) Tel fırça ve çelik yünü aletlerde hasara yol açabilir.

f) Korozyona neden olabileceğinden, Süper Asitli Su kullanmayın.

Durulama için saflaştırılmış su (safsızlık içermeyen) kullanılması önerilir.

Musluk suyu, metalde korozyona neden olabilecek klorür içerir.

g) Yıkayıcı-dezenfektör kullanılırken su veya zaman tasarrufu bir program uygulanırsa yapışmış kirler veya temizlik solüsyonu tamamen giderilemeyebilir. Durulama ve kirlerin giderilmesi işlemlerinin doğru gerçekleştirildiğinden emin olmak için üreticinin talimat kılavuzu vs. gibi kaynaklara başvurmayı ihmal etmeyin.

h) Otoklav sterilizatörlerini kullanırken aşağıdakilere dikkat edin.

i) Otoklav sterilizatörünün dolabı, kullanım durumuna ve süresine bağlı olarak kontamine olabilir.

Otoklav sterilizatöründe kirler kalırsa bunlar aletlere yapışabilir.

Sterilizatörün talimat kılavuzu uyarınca temizlenmesini öneririz.

Böylece haznenin içi kirlenmez. Özellikle hazne kapağının kauçuk contası ve hava filtresi belirli bir süre sonra değiştirilmelidir.

ii) Mümkün olduğu ölçüde saflaştırılmış su kullanın. Musluk suyu kullanıldığında klorür iyonlarının etkisiyle korozyona neden olabilir.

iii) Otoklav sterilizatörü içindeki kurutma sıcaklığına dikkat edin.

iv) Bu aletleri ısıtıcının yanına yerleştirmeyin. (Bu konumdaki sıcaklık belirtilenden daha yüksek olabilir)

v) Otoklav sterilizatörü içindeki temizlik ve durulama tamamlanmazsa veya otoklav sterilizatörü haznesinde nem kalırsa bu, aletlerin yüzeyinde yanıklara neden olabilir.

i) Yıkama ve sterilizasyondan sonra alete yapışan suyu giderin ve aleti iyice kurutun

12 [Bakım, İnceleme ve Test]

Temizlik ve sterilizasyonun ardından, aleti kullanmadan önce aşağıdakileri kontrol edin.

1) Birleşme yerinin iç tarafında ve üzerinde kir, hasar, çatlama, çizilme veya korozyon bulunmadığını kontrol edin.

2) Birleşme yerinin anormal şekilde hareket edip etmediğini kontrol edin.

13 [Saklama]

- 1) Temiz ve tozsuz bir yerde saklayın; yüksek sıcaklık ve nem olmamasına dikkat edin.
- 2) Metallerin potansiyel farklılığı nedeniyle oluşan galvanik akımı engellemek için, farklı materyallerden imal edilmiş aletlerle birlikte saklamayın.
- 3) Pas lekelerini önlemek için aşağıdakilere dikkat edin.
 - a) Paslanmış aletlerle birlikte saklamayın.
 - b) Kimyasallarla birlikte saklamayın.
 - c) Sterilizatörlerin ve saklama alanlarının içindeki paslanmalara dikkat edin.

14 [Bertarafıa ilgili konular]

Aletin yürürlükteki ilgili yasalara göre bertaraf edilmesinden dental uzmanlar ve/veya ortodontistler sorumludur. YDM CORPORATION, uygunsuz bertaraf işlemlerinden kaynaklanan kişisel yaralanmalarla ilgili taleplerde sorumluluk kabul etmez.

15 [Ek Bilgiler]

<Kırılma veya Bileme>

Aletlerin kırılması durumunda, lütfen CORPORATION tarafından hazırlanan "Talep Raporu" adlı form biçimini kullanarak ürünü satın aldığınız satıcı ile iletişimi kurun.

Kesicilerin bilenmesini istediğinizde, belirli bir ücret karşılığında bileme hizmeti sunuyoruz.

16 [Üretici iletişim bilgileri]



YDM CORPORATION

28 Imaizumi, Higashi-Matsuyama-shi,

Saitama 355-0042, Japan

TEL: 81-3-3828-3161

FAKS: 81-3-3827-8991

URL: <http://www.ydm.co.jp/>

E-posta: ydm@ydm.co.jp

17 [Kullanıcı ve/veya hasta bildirim]

Aletlerle bağlantılı olarak gerçekleşen her türlü ciddi olay YDM CORPORATION'a bildirilmelidir.

18 [Ek Bilgiler]

Ürün arızalarıyla ilgili olarak, lütfen YDM Corporation tarafından hazırlanan "Talep Raporu" adlı form formatını kullanarak ürünü satın aldığınız satıcı ile iletişimi kurun.

19 [Sembollerin açıklamaları]



Tıbbi cihaz



Üretici



Lot numarası



Dikkat

Yukarıda verilen talimatların tıbbi cihazın yeniden kullanıma hazırlanması için gerekli bilgileri sağladığı tıbbi cihaz üreticisi tarafından valide edilmiştir. İşleme tesisindeki ekipmanların, materyallerin ve personelin fiilen kullanıldığı işlemlerin amaçlanan sonucu sağlamasından işlemi gerçekleştiren kişi sorumludur. Bunun için işlemin doğrulanması ve/veya valide edilmesi ve rutin şekilde takibi gereklidir.

Ver.01 23 Haziran 2021

Ver.02 24 Ağustos 2022

Ver.03 6 Temmuz 2023

- 1 [Име на серията] ортодонтски клещи
 2 [Производител] YDM CORPORATION
 3 [№ на модела и търговско наименование на изделието]



Модел№	Търговско наименование на изделието	UDI-DI	Максимален капацитет на рязане и огъване
22001	Adams Pliers Universal T/C	4963931220014	
22102	Orthodontic Pliers Band Contouring ND-202L	4963931221028	-
22104	Orthodontic Pliers Band Margin ND-204	4963931221042	-
22133	Orthodontic Pliers Band Removing ND-303	4963931221332	-
22141	Orthodontic Pliers Peeso ND-401	4963931221417	,040"
22142	Orthodontic Pliers Young ND-402	4963931221424	,040"
22143	Orthodontic Pliers Tweed Arch ND-403	4963931221431	,022"- ,028"
22145	Orthodontic Pliers Tweed Loop Forming ND-405	4963931221455	,022"- ,028"
22147	Orthodontic Pliers Three Jaw ND-407	4963931221479	,036"
22149	Orthodontic Pliers Bird Beak ND-409	4963931221493	,036"
22152	Orthodontic Pliers How ND-502L	4963931221523	-
22154	Orthodontic Pliers Utility ND-504	4963931221547	-
22155	Orthodontic Pliers How ND-502S	4963931221554	-
22159	Orthodontic Pliers Kim T/C ND-419	4963931221592	,016"- ,022"(огъване)/ ,020"(рязане)
22160	Orthodontic Pliers Light Wire Cutter T/C ND-420	4963931221608	,020"(огъване/рязане)
22210	Orthodontic Pliers for Aligner Tear Drop	4963931222100	-
22211	Orthodontic Pliers for Aligner Vertical	4963931222117	-
22212	Orthodontic Pliers for Aligner Horizontal	4963931222124	-
22213	Orthodontic Pliers for Aligner Hole Punch	4963931222131	-
22506	Tying Pliers YS-506	4963931225064	-
22507	Tying Pliers YS-507	4963931225071	-
22508	Tying Pliers YS-508	4963931225088	-
22509	Module Pliers Str.	4963931225095	-
22510	Module Pliers Cvd.	4963931225101	-
22511	Module Pliers with Groove Str.	4963931225118	-
22513	Module Pliers Mosquito Str.	4963931225132	-
22514	Module Pliers Mosquito Cvd.	4963931225149	-
22551	Separator YS-551	4963931225514	-
22601	Wire Cutter YS-601	4963931226016	,032"
22602	Wire Cutter YS-602 KI	4963931226023	,045"
22603	Wire Cutter YS-603 Standard	4963931226030	,048"
22606	Pin & Ligature Cutter ND-605 with Hard Material	4963931226061	,012"
22607	Pin & Ligature Cutter ND-605B T/C	4963931226078	,014"
22610	Distal End Cutter ND-606S T/C	4963931226108	,022"- ,028"
22611	Distal End Cutter ND-606LT/C	4963931226115	,022"- ,028"
27410	Ortho.Pliers EVER Classic 410 Band Contouring	4963931274109	-
27411	Ortho.Pliers EVER Classic 411 Band Margin	4963931274116	-
27412	Ortho.Pliers EVER Classic 412 Band Removing	4963931274123	-
27413	Ortho.Pliers EVER C. 413 Bracket Removing T/C	4963931274130	-
27414	Ortho.Pliers EVER Classic 414 Young	4963931274147	,040"
27415	Ortho.Pliers EVER Classic 415 Tweed Arch	4963931274154	,022 x ,028"
27416	Ortho.Pliers EVER C. 416 Tweed Loop Forming	4963931274161	,022 x ,028"
27417	Ortho.Pliers EVER Classic 417 Three Jaw	4963931274178	,036"
27418	Ortho.Pliers EVER Classic 418 Bird Beak	4963931274185	,036"
27419	Ortho.Pliers EVER C. 419 Nance Closing Loop	4963931274192	,022"
27420	Ortho.Pliers EVER Classic 420 How	4963931274208	-
27421	Ortho.Pliers EVER Classic 421 Weingart	4963931274215	-
27422	Ortho.Pliers EVER Classic 422 Utility	4963931274222	-
27423	Ortho.Pliers EVER Classic 423 Kim T/C	4963931274239	,016"- ,022"(огъване)/ ,020"(рязане)
27424	Ortho.Pliers EVER Classic 424 Light Wire T/C	4963931274246	,020"(огъване/рязане)
27425	Ortho.Pliers EVER Classic 425 Crimping	4963931274253	-
27426	Ortho.Pliers EVER C.426 Lingual Hollow Chop	4963931274260	,022 x ,028"
27427	Ortho.Pliers EVER Classic 427 Torquing M	4963931274277	,022 x ,028"
27428	Ortho.Pliers EVER Classic 428 Torquing F	4963931274284	,022 x ,028"
27440	Ortho.Pliers EVER Fine 440 Utility	4963931274406	-
27441	Ortho.Pliers EVER Fine 441 Weingart	4963931274413	-
27442	Ortho.Pliers EVER Fine 442 How	4963931274420	-
27443	Ortho.Pliers EVER Fine 443 Band Removing	4963931274437	-
27444	Ortho.Pliers EVER F.444 Bracket Removing T/C	4963931274444	-

27445	Ortho.Pliers EVER Fine 445 Step 1/2mm	4963931274451	,022 x ,028"
27446	Ortho.Pliers EVER Fine 446 Step 3/4mm	4963931274468	,022 x ,028"
27447	Ortho.Pliers EVER Fine 447 Step 1mm	4963931274475	,022 x ,028"
27448	Ortho.Pliers EVER Fine 448 Tear Drop	4963931274482	-
27449	Ortho.Pliers EVER Fine 449 Vertical	4963931274499	-
27450	Ortho.Pliers EVER Fine 450 Horizontal	4963931274505	-
27451	Ortho.Pliers EVER Fine 451 Hole Punch	4963931274512	-
27452	Ortho.Pliers EVER Fine 452 Light Wire T/C	4963931274529	,020"(огъване/рязане)
27453	Ortho.Pliers EVER Fine 453 Kim T/C	4963931274536	,016"-,022"(огъване)/,020"(рязане)
27454	Ortho.Pliers EVER Fine 454 Young	4963931274543	,040"
27455	Ortho.Pliers EVER Fine 455 Tweed Arch	4963931274550	,022 x ,028"
27456	Ortho.Pliers EVER Fine 456 Tweed Loop Forming	4963931274567	,022 x ,028"
27457	Ortho.Pliers EVER Fine 457 Three Jaw	4963931274574	,036"
27458	Ortho.Pliers EVER Fine 458 Bird Beak	4963931274581	,036"
27459	Ortho.Pliers EVER F. 459 Nance Closing Loop	4963931274598	,022"
27460	Ortho.Pliers EVER Fine 460 Band Removing L	4963931274604	-
27461	Ortho.Pliers EVER Fine 461 Cinch Back	4963931274611	,020"/,016"-016"
27462	Ortho.Pliers EVER Fine 462 Lingual Utility	4963931274628	-
27463	Ortho.Pliers EVER F.463 Round Former 1.0	4963931274635	-
27464	Ortho.Pliers EVER F.464 Round Former 2.0 SM	4963931274642	-
27465	Ortho.Pliers EVER Fine Key Punch 465	4963931274659	-
27550	Orthodontic Pliers Crimping Ortolan	4963931275502	-
27551	ROMAN 1 Circle Cutter SMOOTH	4963931275519	-
27552	ROMAN 2 Horizontal Box SMOOTH	4963931275526	-
27553	ROMAN 3 Vertical Box SMOOTH	4963931275533	-
27554	ROMAN 4 Pearl Dot SMOOTH	4963931275540	-
27555	ROMAN 5 Keyhole Cutter SMOOTH	4963931275557	-
27556	Angle Fluted Bird Beak Pliers	4963931275564	,036"
27601	Pin&Ligature Cutter EVER F.601 Angle 40	4963931276011	,012"
27602	Pin&Ligature Cutter EVER F.602 Reverse 40	4963931276028	,012"
27603	Pin&Ligature Cutter EVER F.603 Angle 50	4963931276035	,012"
27604	Pin&Ligature Cutter EVER F.604 Reverse 50	4963931276042	,012"
27605	Pin&Ligature Cutter EVER F.605 with Hard MATL	4963931276059	,012"
27606	Distal End Cutter EVER Fine 606S T/C	4963931276066	,022"-,028"
27607	Distal End Cutter EVER Fine 606L T/C	4963931276073	,022"-,028"
27615	Pin&Ligature Cutter EVER C.615 with Hard MATL	4963931276158	,014"
27934	Convertible Cap Removing Pliers ND-934	4963931279340	-
27935	Convertible Cap Removing Pliers ND-934 Blade	4963931279357	-

4 [Предназначение на изделието]

Предназначеното медицинско показание е да се използва за придържане или за фиксиране, или за премахване на малки предмети, или за огъване, или за рязане на метални ивици или тел, или за изрязване или направа на вдлъбнатини на няколко места върху каучуковия ортодонтически апарат.

5 [Работни характеристики на изделието]

<Общ преглед>

Изделието представлява малка щипка с различна форма на челюстите в зависимост от предназначението.

<Материал>

Неръждаема стомана

Модел№	Търговско наименование на изделието	Начин на използване
22001	Adams Pliers Universal T/C	Задръжете и огънете телта за закопчаване, за да направите фиксатор.
22102	Orthodontic Pliers Band Contouring ND-202L	Задръжете и огънете ръба на лентата, за да се нагоди към формата на зъбите.
22104	Orthodontic Pliers Band Margin ND-204	Задръжете и огънете ръба на лентата, за да се нагоди към формата на зъбите.
22133	Orthodontic Pliers Band Removing ND-303	Поставете ръба на лентата към окузалната страна на зъбите и отстранете лентата
22141	Orthodontic Pliers Peeso ND-401	Задръжете и огънете арката, за да приложите въртящ момент, стъпка.
22142	Orthodontic Pliers Young ND-402	Задръжете и огънете арката, за да направите примка.
22143	Orthodontic Pliers Tweed Arch ND-403	Задръжете и огънете арката, за да приложите въртящ момент, стъпка.
22145	Orthodontic Pliers Tweed Loop Forming ND-405	Задръжете и огънете арката, за да направите примка.
22147	Orthodontic Pliers Three Jaw ND-407	Задръжете и огънете арката, за да направите v-образна форма.
22149	Orthodontic Pliers Bird Beak ND-409	Задръжете и огънете арката, за да направите примка.
22152	Orthodontic Pliers How ND-502L	Задръжете и завържете лигатурната тел.
22154	Orthodontic Pliers Utility ND-504	Задръжете телта и я поставете в брекети, букална тръба.
22155	Orthodontic Pliers How ND-502S	Задръжете и завържете лигатурната тел.
22159	Orthodontic Pliers Kim T/C ND-419	Задръжете и огънете арката, за да направите примка.
22160	Orthodontic Pliers Light Wire Cutter T/C ND-420	Задръжете и огънете арката, за да направите примка.
22210	Orthodontic Pliers for Aligner Tear Drop	Задръжете и приложете допълнителна функция върху подравнителя.
22211	Orthodontic Pliers for Aligner Vertical	Задръжете и приложете допълнителна функция върху подравнителя.
22212	Orthodontic Pliers for Aligner Horizontal	Задръжете и приложете допълнителна функция върху подравнителя.
22213	Orthodontic Pliers for Aligner Hole Punch	Задръжете и приложете допълнителна функция върху подравнителя.
22506	Tying Pliers YS-506	Задръжете и завържете лигатурната тел.
22507	Tying Pliers YS-507	Задръжете и завържете лигатурната тел.
22508	Tying Pliers YS-508	Задръжете и завържете лигатурната тел.
22509	Module Pliers Str.	Задръжете еластичния модул и го поставете в брекети.
22510	Module Pliers Cvd.	Задръжете еластичния модул и го поставете в брекети.
22511	Module Pliers with Groove Str.	Задръжете еластичния модул и го поставете в брекети.
22513	Module Pliers Mosquito Str.	Задръжете еластичния модул и го поставете в брекети.
22514	Module Pliers Mosquito Cvd.	Задръжете еластичния модул и го поставете в брекети.
22551	Separator YS-551	Разстелете разделителния модул и го поставете между зъбите.
22601	Wire Cutter YS-601	Задръжете и срежете телта.
22602	Wire Cutter YS-602 KI	Задръжете и срежете телта.
22603	Wire Cutter YS-603 Standard	Задръжете и срежете телта.
22606	Pin & Ligature Cutter ND-605 with Hard Material	Задръжете и срежете излишната тел.
22607	Pin & Ligature Cutter ND-605B T/C	Задръжете и срежете излишната тел.
22610	Distal End Cutter ND-606S T/C	Задръжете и срежете излишната част от арката.
22611	Distal End Cutter ND-606LT/C	Задръжете и срежете излишната част от арката.
27410	Ortho.Pliers EVER Classic 410 Band Contouring	Задръжете и огънете ръба на лентата, за да се нагоди към формата на зъбите.
27411	Ortho.Pliers EVER Classic 411 Band Margin	Задръжете и огънете ръба на лентата, за да се нагоди към формата на зъбите.
27412	Ortho.Pliers EVER Classic 412 Band Removing	Поставете ръба на лентата към окузалната страна на зъбите и отстранете лентата
27413	Ortho.Pliers EVER C. 413 Bracket Removing T/C	Задръжете и свалете брекетите.
27414	Ortho.Pliers EVER Classic 414 Young	Задръжете и огънете арката, за да направите примка.
27415	Ortho.Pliers EVER Classic 415 Tweed Arch	Задръжете и огънете арката, за да приложите въртящ момент, стъпка.
27416	Ortho.Pliers EVER C. 416 Tweed Loop Forming	Задръжете и огънете арката, за да направите примка.
27417	Ortho.Pliers EVER Classic 417 Three Jaw	Задръжете и огънете арката, за да направите v-образна форма.
27418	Ortho.Pliers EVER Classic 418 Bird Beak	Задръжете и огънете арката, за да направите примка.
27419	Ortho.Pliers EVER C. 419 Nance Closing Loop	Задръжете и огънете арката, за да направите примка.
27420	Ortho.Pliers EVER Classic 420 How	Задръжете и завържете лигатурната тел.
27421	Ortho.Pliers EVER Classic 421 Weingart	Задръжете телта и я поставете в брекети, букална тръба.
27422	Ortho.Pliers EVER Classic 422 Utility	Задръжете телта и я поставете в брекети, букална тръба.
27423	Ortho.Pliers EVER Classic 423 Kim T/C	Задръжете и огънете арката, за да направите примка.
27424	Ortho.Pliers EVER Classic 424 Light Wire T/C	Задръжете и огънете арката, за да направите примка.
27425	Ortho.Pliers EVER Classic 425 Crimping	Задръжете и приложете гофрирана кука върху арката.
27426	Ortho.Pliers EVER C.426 Lingual Hollow Chop	Задръжете и огънете арката, за да приложите крива.
27427	Ortho.Pliers EVER Classic 427 Torquing M	Задръжете арката с „27428“ и завъртете, за да приложите въртящ момент върху арката.
27428	Ortho.Pliers EVER Classic 428 Torquing F	Задръжете арката с „27427“ и завъртете, за да приложите въртящ момент върху арката.
27440	Ortho.Pliers EVER Fine 440 Utility	Задръжете телта и я поставете в брекети, букална тръба.
27441	Ortho.Pliers EVER Fine 441 Weingart	Задръжете телта и я поставете в брекети, букална тръба.
27442	Ortho.Pliers EVER Fine 442 How	Задръжете и завържете лигатурната тел.
27443	Ortho.Pliers EVER Fine 443 Band Removing	Поставете ръба на лентата към окузалната страна на зъбите и отстранете лентата
27444	Ortho.Pliers EVER F.444 Bracket Removing T/C	Задръжете и свалете брекетите.
27445	Ortho.Pliers EVER Fine 445 Step 1/2mm	Задръжете и огънете арката, за да приложите стъпка.
27446	Ortho.Pliers EVER Fine 446 Step 3/4mm	Задръжете и огънете арката, за да приложите стъпка.
27447	Ortho.Pliers EVER Fine 447 Step 1mm	Задръжете и огънете арката, за да приложите стъпка.
27448	Ortho.Pliers EVER Fine 448 Tear Drop	Задръжете и приложете допълнителна функция върху подравнителя.
27449	Ortho.Pliers EVER Fine 449 Vertical	Задръжете и приложете допълнителна функция върху подравнителя.

27450	Ortho.Pliers EVER Fine 450 Horizontal	Задръжте и приложете допълнителна функция върху подравнителя.
27451	Ortho.Pliers EVER Fine 451 Hole Punch	Задръжте и приложете допълнителна функция върху подравнителя.
27452	Ortho.Pliers EVER Fine 452 Light Wire T/C	Задръжте и огънете арката, за да направите примка.
27453	Ortho.Pliers EVER Fine 453 Kim T/C	Задръжте и огънете арката, за да направите примка.
27454	Ortho.Pliers EVER Fine 454 Young	Задръжте и огънете арката, за да направите примка.
27455	Ortho.Pliers EVER Fine 455 Tweed Arch	Задръжте и огънете арката, за да приложите въртящ момент, стъпка.
27456	Ortho.Pliers EVER Fine 456 Tweed Loop Forming	Задръжте и огънете арката, за да направите примка.
27457	Ortho.Pliers EVER Fine 457 Three Jaw	Задръжте и огънете арката, за да направите v-образна форма.
27458	Ortho.Pliers EVER Fine 458 Bird Beak	Задръжте и огънете арката, за да направите примка.
27459	Ortho.Pliers EVER F. 459 Nance Closing Loop	Задръжте и огънете арката, за да направите примка.
27460	Ortho.Pliers EVER Fine 460 Band Removing L	Поставете ръба на лентата към окузалната страна на зъбите и отстранете лентата
27461	Ortho.Pliers EVER Fine 461 Cinch Back	Задръжте и огънете края на арката.
27462	Ortho.Pliers EVER Fine 462 Lingual Utility	Задръжте телта и я поставете в брекети, букална тръба.
27463	Ortho.Pliers EVER F.463 Round Former 1.0	Задръжте и приложете допълнителна функция върху подравнителя.
27464	Ortho.Pliers EVER F.464 Round Former 2.0 SM	Задръжте и приложете допълнителна функция върху подравнителя.
27465	Ortho.Pliers EVER Fine Key Punch 465	Задръжте и приложете допълнителна функция върху подравнителя.
27550	Orthodontic Pliers Crimping Ortolan	Задръжте и приложете гофрирана кука върху арката.
27551	ROMAN 1 Circle Cutter SMOOTH	Задръжте и приложете допълнителна функция върху подравнителя.
27552	ROMAN 2 Horizontal Box SMOOTH	Задръжте и приложете допълнителна функция върху подравнителя.
27553	ROMAN 3 Vertical Box SMOOTH	Задръжте и приложете допълнителна функция върху подравнителя.
27554	ROMAN 4 Pearl Dot SMOOTH	Задръжте и приложете допълнителна функция върху подравнителя.
27555	ROMAN 5 Keyhole Cutter SMOOTH	Задръжте и приложете допълнителна функция върху подравнителя.
27556	Angle Fluted Bird Beak Pliers	Задръжте и огънете края на арката.
27601	Pin&Ligature Cutter EVER F.601 Angle 40	Задръжте и срежете излишната тел.
27602	Pin&Ligature Cutter EVER F.602 Reverse 40	Задръжте и срежете излишната тел.
27603	Pin&Ligature Cutter EVER F.603 Angle 50	Задръжте и срежете излишната тел.
27604	Pin&Ligature Cutter EVER F.604 Reverse 50	Задръжте и срежете излишната тел.
27605	Pin&Ligature Cutter EVER F.605 with Hard MATL	Задръжте и срежете излишната тел.
27606	Distal End Cutter EVER Fine 606S T/C	Задръжте и срежете излишната част от арката.
27607	Distal End Cutter EVER Fine 606L T/C	Задръжте и срежете излишната част от арката.
27615	Pin&Ligature Cutter EVER C.615 with Hard MATL	Задръжте и срежете излишната тел.
27722	Wire Cutter Heavy Duty	Срежете телта.
27934	Convertible Cap Removing Pliers ND-934	Задръжте и свалете капачката на огъващата се тръбичка.
27935	Convertible Cap Removing Pliers ND-934 Blade	Ключова част на „27934“

7 [Общи предпазни мерки и забрани]

- 1) Използването на изделието е строго ограничено до дентално лечение.
Трябва да се спазват предпазните мерки, за да се гарантира подходящата употреба на инструментите.
- 2) Не използвайте инструментите за друга цел, освен предназначението им.
- 3) Почистете, смажете и стерилизирайте преди употреба според инструкциите.
- 4) Не използвайте инструментите при пациенти, които имат симптоми на свръхчувствителност като обрив и дерматит или алергични симптоми.
- 5) Не променяйте дизайна и не ремоделирайте инструментите.
- 6) Не изпускайте инструментите. Избягвайте силен удар по инструментите.
- 7) Когато изхвърляте инструментите, спазвайте инструкциите, описани в съответните национални разпоредби.
- 8) Не нагрявайте инструментите.
- 9) Ако по инструментите полепнат химикали, веднага ги избършете, за да избегнете корозия.
- 10) При огъване на тел с тези инструменти дръжте телта с клещите и я огънете с пръст, за да избегнете повреда на клещите.
- 11) Неръждаемата стомана е по-устойчива на ръжда от желязото, но въпреки това може да ръждяса в резултат на начина на използване и условията на околната среда като температура, влажност.

8 [Ограничения за обработка]

Спрете използването на инструментите веднага, ако забележите износване или нещо странно.

9 [Първоначално третиране на мястото на използване]

Почистете, смажете и стерилизирайте преди употреба според инструкциите.

10 [Подготовка преди почистване]

Вижте следващия раздел.

11 [Процес на почистване и стерилизация/дезинфекция]

1) Общи предпазни мерки

- а) Относно поддръжката на инструментите вижте „The Fundamental Guide Book for Cleaning and Sterilizing Instruments“ (Фундаментално ръководство за почистване и стерилизиране на инструменти), публикувано от нашата компания или раздела „поддръжка“ на нашия уебсайт (http://www.ydm.co.jp/en-new/pdf/The_process_of_cleaning_and_sterilizing.pdf).
- б) Инструментите, замърсени с кръв, телесна течност, фрагменти от тъкан, химикали и т.н., трябва да се почистят и стерилизират незабавно в съответствие със следния метод, за да се предотврати замърсяване със. Замърсители, останали върху инструментите в продължение на дълъг период от време, стават трудни за почистване.

2) Процедура

- а) Отворете мястото на съединяване.
- б) Почистете инструментите с почистващото средство от метода i) или ii).
 - i) Използвайте ултразвуков почистващ апарат с медицински препарат за предотвратяване на ръжда за 5 минути.
 - ii) Потопете в почистващо средство с медицински препарат за предотвратяване на ръжда за 15 минути.
- в) Отмийте мръсотията и препарата, полепнал по инструментите, с течаща вода. (Ако по повърхността на инструментите остане сапун, той причинява ръжда, петна).
- г) Подсушете инструментите. (Останалата влага може да причини ръжда, да намали ефекта от стерилизацията).
- д) Добавете лубрикант срещу ръжда като „масло за инструменти“ на мястото на съединяване.
* Не отваряйте и не затваряйте преди добавянето на лубрикант срещу ръжда. (Отварянето и затварянето без масло ще предизвика повреда от изтъкване).
- е) Стерилизирайте в стерилизатор-автоклав.
Условия: от 134 °C до 138 °C, 3 до 3,5 минути
* За да предотвратите надраскване поради контакт с други инструменти, поставете ги в стерилизирана опаковка или кутия.
- ж) След употреба почистете незабавно според б) по-горе.

3) Предпазни мерки при почистване и стерилизация/дезинфекция

- а) Не използвайте следните химикали, тъй като могат да причинят корозия на метала.
натриев хипохлорит, бензалкониев хлорид, хлорхексидин глюконат, тинктура на йод
Йодоформ и пероцетна киселина могат да причинят корозия на метала.
 - б) Не използвайте химически автоклав за инструментите, защото може да причини корозия.
 - в) Не извършвайте плазмена стерилизация, тъй като може да засегне материала.
 - г) Не използвайте домакински почистващи препарати, тъй като те не са подходящи за премахване на протеини от повърхността на инструментите.
 - д) Телените четки и стоманената вълна може да повредят инструментите.
 - е) Не използвайте супер кисела вода, тъй като може да причини корозия.
За изплакване се препоръчва пречистена вода (без примеси).
Чешмяната вода съдържа хлор, който може да причини корозия на метала.
 - ж) Когато използвате машина за миене и дезинфекция, полепналата мръсотия или почистващ разтвор може да не бъде напълно отстранена, ако се използва програма за пестене на вода или за пестене на време.
Следвайте препоръките в ръководството с инструкции на производителя, за да гарантирате изплакването и отстраняването на мръсотията.
- з) Имайте предвид следното, когато работите със стерилизатори-автоклави.
- i) Отделението на стерилизатора-автоклав може да е замърсено в зависимост от състоянието и времето на употреба.
Ако в стерилизатора-автоклав остане мръсотия, тя може да полепне по инструментите.
Препоръчваме почистване според инструкциите в ръководството на стерилизатора.
Тогава вътрешната част на камерата не се замърсява. По-специално, гуменото уплътнение на капака на камерата и въздушният филтър трябва да се сменят през определен период от време.
 - ii) Използвайте пречистена вода възможно най-често.
Чешмяната вода може да причини корозия поради влиянието на хлорните йони.
 - iii) Обръщайте внимание на температурата на сушене вътре в стерилизатора-автоклав.
 - iv) Не поставяйте инструментите близо до нагревателя. (Той може да е с температура над посочената)
 - v) Ако почистването и изплакването не са извършени в стерилизатор-автоклав или в камерата на стерилизатора-автоклав остане влага, тя може да причини изгаряне на повърхността на инструментите.
- и) След измиване и стерилизация отстранете водата от инструментите и ги подсушете напълно

12 [Поддръжка, инспекция и тестване]

След почистване и стерилизация, проверете следното преди употреба.

- 1) Проверете да няма мръсотия, повреда, пукнатини, драскотини или корозия от вътрешната страна на мястото на съединяване и по мястото на съединяване.
- 2) Проверете дали мястото на съединяване се движи нормално.
не съхранявайте с инструменти, изработени от различни материали.

13 [Съхранение]

- 1) Съхранявайте на чисто място без мръсотия, избягвайте висока температура и влажност.
- 2) За да предотвратите галваничен ток, дължащ се на разлика в потенциала на метала, не съхранявайте с инструменти, изработени от различни материали.
- 3) Имайте предвид следното, за да предотвратите появата на петна от ръжда.
 - а) Не съхранявайте заедно с ръждясали инструменти.
 - б) Не съхранявайте заедно с химикали.
 - в) Обръщайте внимание има ли ръжда вътре в стерилизаторите и местата за съхранение.

14 [Съображения при изхвърляне]

Специалистите по дентална медицина и/или ортодонтите са отговорни за изхвърлянето в съответствие с приложимото законодателство.

YDM CORPORATION не поема отговорност за откази от отговорност, причинени от неправилно изхвърляне и телесна повреда.

15 [Допълнителна информация]

<Счупване или заточване>

В случай на счупване на инструментите, моля, съобщете на търговеца, от когото сте ги закупили, чрез изготвения от YDM CORPORATION формуляр, наречен „Доклад за рекламация“.

При нужда от заточване на остриетата ще направим това срещу определено заплащане.

16 [Контакт с производителя]



YDM CORPORATION

28 Imaizumi, Higashi-Matsuyama-shi,

Saitama 355-0042, Japan

ТЕЛ.: 81-3-3828-3161

ФАКС: 81-3-3827-8991

URL: <http://www.ydm.co.jp/>

Имейл: ydm@ydm.co.jp

17 [Бележка за потребителя и/или пациента]

За всеки сериозен инцидент, възникнал във връзка с инструментите, трябва да се съобщава на YDM CORPORATION.

18 [Допълнителна информация]

В случай на дефект на изделието, моля, съобщете на търговеца, от когото сте го закупили, чрез изготвения от YDM CORPORATION формуляр, наречен „Доклад за рекламация“.

19 [Описание на символите]



Медицинско изделие



Производител



Номер на партида



Бележка

Горепосочените инструкции са валидирани от производителя на медицинското изделие като в състояние да подготвят медицинско изделие за повторна употреба. Отговорност на потребителя е да гарантира, че обработката, каквато е действително извършена в помещението за обработка с помощта на оборудване, материали и персонал, постига желания резултат. Това изисква проверка и/или валидиране и рутинно наблюдение на процеса.

Версия 01 23 юни 2021 г.

Версия 02 24 август 2022 г.

Версия 03 6 юли 2023 г.

- 1 [Megnevezés] fogszabályozó fogó
- 2 [Gyártó] YDM CORPORATION
- 3 [Modellszám és eszköz kereskedelmi neve]



Modell-sz.	Eszköz kereskedelmi neve	UDI-DI	Maximális vágási és hajlítási képesség
22001	Adams Pliers Universal T/C	4963931220014	
22102	Orthodontic Pliers Band Contouring ND-202L	4963931221028	-
22104	Orthodontic Pliers Band Margin ND-204	4963931221042	-
22133	Orthodontic Pliers Band Removing ND-303	4963931221332	-
22141	Orthodontic Pliers Peeso ND-401	4963931221417	.040"
22142	Orthodontic Pliers Young ND-402	4963931221424	.040"
22143	Orthodontic Pliers Tweed Arch ND-403	4963931221431	.022"-.028"
22145	Orthodontic Pliers Tweed Loop Forming ND-405	4963931221455	.022"-.028"
22147	Orthodontic Pliers Three Jaw ND-407	4963931221479	.036"
22149	Orthodontic Pliers Bird Beak ND-409	4963931221493	.036"
22152	Orthodontic Pliers How ND-502L	4963931221523	-
22154	Orthodontic Pliers Utility ND-504	4963931221547	-
22155	Orthodontic Pliers How ND-502S	4963931221554	-
22159	Orthodontic Pliers Kim T/C ND-419	4963931221592	.016"-.022"(hajlítás)/.020"(vágás)
22160	Orthodontic Pliers Light Wire Cutter T/C ND-420	4963931221608	.020"(hajlítás/vágás)
22210	Orthodontic Pliers for Aligner Tear Drop	4963931222100	-
22211	Orthodontic Pliers for Aligner Vertical	4963931222117	-
22212	Orthodontic Pliers for Aligner Horizontal	4963931222124	-
22213	Orthodontic Pliers for Aligner Hole Punch	4963931222131	-
22506	Tying Pliers YS-506	4963931225064	-
22507	Tying Pliers YS-507	4963931225071	-
22508	Tying Pliers YS-508	4963931225088	-
22509	Module Pliers Str.	4963931225095	-
22510	Module Pliers Cvd.	4963931225101	-
22511	Module Pliers with Groove Str.	4963931225118	-
22513	Module Pliers Mosquito Str.	4963931225132	-
22514	Module Pliers Mosquito Cvd.	4963931225149	-
22551	Separator YS-551	4963931225514	-
22601	Wire Cutter YS-601	4963931226016	.032"
22602	Wire Cutter YS-602 KI	4963931226023	.045"
22603	Wire Cutter YS-603 Standard	4963931226030	.048"
22606	Pin & Ligature Cutter ND-605 with Hard Material	4963931226061	.012"
22607	Pin & Ligature Cutter ND-605B T/C	4963931226078	.014"
22610	Distal End Cutter ND-606S T/C	4963931226108	.022"-.028"
22611	Distal End Cutter ND-606LT/C	4963931226115	.022"-.028"
27410	Ortho.Pliers EVER Classic 410 Band Contouring	4963931274109	-
27411	Ortho.Pliers EVER Classic 411 Band Margin	4963931274116	-
27412	Ortho.Pliers EVER Classic 412 Band Removing	4963931274123	-
27413	Ortho.Pliers EVER C. 413 Bracket Removing T/C	4963931274130	-
27414	Ortho.Pliers EVER Classic 414 Young	4963931274147	.040"
27415	Ortho.Pliers EVER Classic 415 Tweed Arch	4963931274154	.022 x .028"
27416	Ortho.Pliers EVER C. 416 Tweed Loop Forming	4963931274161	.022 x .028"
27417	Ortho.Pliers EVER Classic 417 Three Jaw	4963931274178	.036"
27418	Ortho.Pliers EVER Classic 418 Bird Beak	4963931274185	.036"
27419	Ortho.Pliers EVER C. 419 Nance Closing Loop	4963931274192	.022"
27420	Ortho.Pliers EVER Classic 420 How	4963931274208	-
27421	Ortho.Pliers EVER Classic 421 Weingart	4963931274215	-
27422	Ortho.Pliers EVER Classic 422 Utility	4963931274222	-
27423	Ortho.Pliers EVER Classic 423 Kim T/C	4963931274239	.016"-.022"(hajlítás)/.020"(vágás)
27424	Ortho.Pliers EVER Classic 424 Light Wire T/C	4963931274246	.020"(hajlítás/vágás)
27425	Ortho.Pliers EVER Classic 425 Crimping	4963931274253	-
27426	Ortho.Pliers EVER C.426 Lingual Hollow Chop	4963931274260	.022 x .028"
27427	Ortho.Pliers EVER Classic 427 Torquing M	4963931274277	.022 x .028"
27428	Ortho.Pliers EVER Classic 428 Torquing F	4963931274284	.022 x .028"
27440	Ortho.Pliers EVER Fine 440 Utility	4963931274406	-
27441	Ortho.Pliers EVER Fine 441 Weingart	4963931274413	-
27442	Ortho.Pliers EVER Fine 442 How	4963931274420	-
27443	Ortho.Pliers EVER Fine 443 Band Removing	4963931274437	-
27444	Ortho.Pliers EVER F.444 Bracket Removing T/C	4963931274444	-

27445	Ortho.Pliers EVER Fine 445 Step 1/2mm	4963931274451	.022 x .028"
27446	Ortho.Pliers EVER Fine 446 Step 3/4mm	4963931274468	.022 x .028"
27447	Ortho.Pliers EVER Fine 447 Step 1mm	4963931274475	.022 x .028"
27448	Ortho.Pliers EVER Fine 448 Tear Drop	4963931274482	-
27449	Ortho.Pliers EVER Fine 449 Vertical	4963931274499	-
27450	Ortho.Pliers EVER Fine 450 Horizontal	4963931274505	-
27451	Ortho.Pliers EVER Fine 451 Hole Punch	4963931274512	-
27452	Ortho.Pliers EVER Fine 452 Light Wire T/C	4963931274529	.020"(hajlítás/vágás)
27453	Ortho.Pliers EVER Fine 453 Kim T/C	4963931274536	.016"-.022"(hajlítás)/.020"(vágás)
27454	Ortho.Pliers EVER Fine 454 Young	4963931274543	.040"
27455	Ortho.Pliers EVER Fine 455 Tweed Arch	4963931274550	.022 x .028"
27456	Ortho.Pliers EVER Fine 456 Tweed Loop Forming	4963931274567	.022 x .028"
27457	Ortho.Pliers EVER Fine 457 Three Jaw	4963931274574	.036"
27458	Ortho.Pliers EVER Fine 458 Bird Beak	4963931274581	.036"
27459	Ortho.Pliers EVER F. 459 Nance Closing Loop	4963931274598	.022"
27460	Ortho.Pliers EVER Fine 460 Band Removing L	4963931274604	-
27461	Ortho.Pliers EVER Fine 461 Cinch Back	4963931274611	.020"/.016"-016"
27462	Ortho.Pliers EVER Fine 462 Lingual Utility	4963931274628	-
27463	Ortho.Pliers EVER F.463 Round Former 1.0	4963931274635	-
27464	Ortho.Pliers EVER F.464 Round Former 2.0 SM	4963931274642	-
27465	Ortho.Pliers EVER Fine Key Punch 465	4963931274659	-
27550	Orthodontic Pliers Crimping Ortolan	4963931275502	-
27551	ROMAN 1 Circle Cutter SMOOTH	4963931275519	-
27552	ROMAN 2 Horizontal Box SMOOTH	4963931275526	-
27553	ROMAN 3 Vertical Box SMOOTH	4963931275533	-
27554	ROMAN 4 Pearl Dot SMOOTH	4963931275540	-
27555	ROMAN 5 Keyhole Cutter SMOOTH	4963931275557	-
27556	Angle Fluted Bird Beak Pliers	4963931275564	.036"
27601	Pin&Ligature Cutter EVER F.601 Angle 40	4963931276011	.012"
27602	Pin&Ligature Cutter EVER F.602 Reverse 40	4963931276028	.012"
27603	Pin&Ligature Cutter EVER F.603 Angle 50	4963931276035	.012"
27604	Pin&Ligature Cutter EVER F.604 Reverse 50	4963931276042	.012"
27605	Pin&Ligature Cutter EVER F.605 with Hard MATL	4963931276059	.012"
27606	Distal End Cutter EVER Fine 606S T/C	4963931276066	.022"-.028"
27607	Distal End Cutter EVER Fine 606L T/C	4963931276073	.022"-.028"
27615	Pin&Ligature Cutter EVER C.615 with Hard MATL	4963931276158	.014"
27934	Convertible Cap Removing Pliers ND-934	4963931279340	-
27935	Convertible Cap Removing Pliers ND-934 Blade	4963931279357	-

4 [Az eszköz rendeltetése]

Az eszköz orvosi rendeltetése kisebb tárgyak tartása, rögzítése vagy eltávolítása, valamint fémcsíkok vagy -drót hajlítása vagy vágása, illetve mélyedést készíteni a gyantából készült fogszabályozási eszközökön.

5 [Az eszköz teljesítményjellemzői]

<Áttekintés>

Az eszköz kis méretű fogó, a céltól függően különféle formájú pofával.

<Anyag>

Rozsdamentes acél

Modell-sz.	Eszköz kereskedelmi neve	Használat
22001	Adams Pliers Universal T/C	Fogszabályzó készítéséhez használt fűződrót tartásához, hajlításához.
22102	Orthodontic Pliers Band Contouring ND-202L	Szalagok széleinek tartása, hajlítása, hogy illeszkedjen a fogak alakjához.
22104	Orthodontic Pliers Band Margin ND-204	Szalagok széleinek tartása, hajlítása, hogy illeszkedjen a fogak alakjához.
22133	Orthodontic Pliers Band Removing ND-303	Szalagszél, fogak rágófelszín felőli oldalának illesztése, ív eltávolítása
22141	Orthodontic Pliers Peeso ND-401	Ív tartása, hajlítása nyomaték alkalmazásához.
22142	Orthodontic Pliers Young ND-402	Ív tartása, hajlítása hurok kialakításához.
22143	Orthodontic Pliers Tweed Arch ND-403	Ív tartása, hajlítása nyomaték alkalmazásához.
22145	Orthodontic Pliers Tweed Loop Forming ND-405	Ív tartása, hajlítása hurok kialakításához.
22147	Orthodontic Pliers Three Jaw ND-407	Ív tartása, hajlítása V forma kialakításához.
22149	Orthodontic Pliers Bird Beak ND-409	Ív tartása, hajlítása hurok kialakításához.
22152	Orthodontic Pliers How ND-502L	Ligatúra tartása, kötése.
22154	Orthodontic Pliers Utility ND-504	Ív tartása és behelyezése a fogszabályozóba, bukkális csőbe.
22155	Orthodontic Pliers How ND-502S	Ligatúra tartása, kötése.
22159	Orthodontic Pliers Kim T/C ND-419	Ív tartása, hajlítása hurok kialakításához.
22160	Orthodontic Pliers Light Wire Cutter T/C ND-420	Ív tartása, hajlítása hurok kialakításához.
22210	Orthodontic Pliers for Aligner Tear Drop	Tartás, további funkció a beállítón.
22211	Orthodontic Pliers for Aligner Vertical	Tartás, további funkció a beállítón.
22212	Orthodontic Pliers for Aligner Horizontal	Tartás, további funkció a beállítón.
22213	Orthodontic Pliers for Aligner Hole Punch	Tartás, további funkció a beállítón.
22506	Tying Pliers YS-506	Ligatúra tartása, kötése.
22507	Tying Pliers YS-507	Ligatúra tartása, kötése.
22508	Tying Pliers YS-508	Ligatúra tartása, kötése.
22509	Module Pliers Str.	Rugalmas modul tartása és felhelyezése a fogszabályozóra.
22510	Module Pliers Cvd.	Rugalmas modul tartása és felhelyezése a fogszabályozóra.
22511	Module Pliers with Groove Str.	Rugalmas modul tartása és felhelyezése a fogszabályozóra.
22513	Module Pliers Mosquito Str.	Rugalmas modul tartása és felhelyezése a fogszabályozóra.
22514	Module Pliers Mosquito Cvd.	Rugalmas modul tartása és felhelyezése a fogszabályozóra.
22551	Separator YS-551	Szeperáló modul nyitása és behelyezése a fogközbe.
22601	Wire Cutter YS-601	Drót tartása, vágása.
22602	Wire Cutter YS-602 KI	Drót tartása, vágása.
22603	Wire Cutter YS-603 Standard	Drót tartása, vágása.
22606	Pin & Ligature Cutter ND-605 with Hard Material	Felesleges ligatúra tartása, vágása.
22607	Pin & Ligature Cutter ND-605B T/C	Felesleges ligatúra tartása, vágása.
22610	Distal End Cutter ND-606S T/C	Felesleges ív tartása, vágása.
22611	Distal End Cutter ND-606LT/C	Felesleges ív tartása, vágása.
27410	Ortho.Pliers EVER Classic 410 Band Contouring	Szalagok széleinek tartása, hajlítása, hogy illeszkedjen a fogak alakjához.
27411	Ortho.Pliers EVER Classic 411 Band Margin	Szalagok széleinek tartása, hajlítása, hogy illeszkedjen a fogak alakjához.
27412	Ortho.Pliers EVER Classic 412 Band Removing	Szalagszél, fogak rágófelszín felőli oldalának illesztése, ív eltávolítása
27413	Ortho.Pliers EVER C. 413 Bracket Removing T/C	Fogszabályozó tartása, eltávolítása.
27414	Ortho.Pliers EVER Classic 414 Young	Ív tartása, hajlítása hurok kialakításához.
27415	Ortho.Pliers EVER Classic 415 Tweed Arch	Ív tartása, hajlítása nyomaték alkalmazásához.
27416	Ortho.Pliers EVER C. 416 Tweed Loop Forming	Ív tartása, hajlítása hurok kialakításához.
27417	Ortho.Pliers EVER Classic 417 Three Jaw	Ív tartása, hajlítása V forma kialakításához.
27418	Ortho.Pliers EVER Classic 418 Bird Beak	Ív tartása, hajlítása hurok kialakításához.
27419	Ortho.Pliers EVER C. 419 Nance Closing Loop	Ív tartása, hajlítása hurok kialakításához.
27420	Ortho.Pliers EVER Classic 420 How	Ligatúra tartása, kötése.
27421	Ortho.Pliers EVER Classic 421 Weingart	Ív tartása és behelyezése a fogszabályozóba, bukkális csőbe.
27422	Ortho.Pliers EVER Classic 422 Utility	Ív tartása és behelyezése a fogszabályozóba, bukkális csőbe.
27423	Ortho.Pliers EVER Classic 423 Kim T/C	Ív tartása, hajlítása hurok kialakításához.
27424	Ortho.Pliers EVER Classic 424 Light Wire T/C	Ív tartása, hajlítása hurok kialakításához.
27425	Ortho.Pliers EVER Classic 425 Crimping	Tartás, krimpelhető kampó felhelyezése az ívre.
27426	Ortho.Pliers EVER C.426 Lingual Hollow Chop	Ív tartása, hajlítása az ív felhelyezéséhez.
27427	Ortho.Pliers EVER Classic 427 Torquing M	Tartsa az ívet a „27428” eszközzel, forgassa nyomaték kifejtéséhez az ívre.
27428	Ortho.Pliers EVER Classic 428 Torquing F	Tartsa az ívet a „27427” eszközzel, forgassa nyomaték kifejtéséhez az ívre.
27440	Ortho.Pliers EVER Fine 440 Utility	Ív tartása és behelyezése a fogszabályozóba, bukkális csőbe.
27441	Ortho.Pliers EVER Fine 441 Weingart	Ív tartása és behelyezése a fogszabályozóba, bukkális csőbe.
27442	Ortho.Pliers EVER Fine 442 How	Ligatúra tartása, kötése.
27443	Ortho.Pliers EVER Fine 443 Band Removing	Szalagszél, fogak rágófelszín felőli oldalának illesztése, ív eltávolítása
27444	Ortho.Pliers EVER F.444 Bracket Removing T/C	Fogszabályozó tartása, eltávolítása.
27445	Ortho.Pliers EVER Fine 445 Step 1/2mm	Ív tartása, hajlítása a felhelyezéshez.
27446	Ortho.Pliers EVER Fine 446 Step 3/4mm	Ív tartása, hajlítása a felhelyezéshez.
27447	Ortho.Pliers EVER Fine 447 Step 1mm	Ív tartása, hajlítása a felhelyezéshez.
27448	Ortho.Pliers EVER Fine 448 Tear Drop	Tartás, további funkció a beállítón.
27449	Ortho.Pliers EVER Fine 449 Vertical	Tartás, további funkció a beállítón.

27450	Ortho.Pliers EVER Fine 450 Horizontal	Tartás, további funkció a beállítón.
27451	Ortho.Pliers EVER Fine 451 Hole Punch	Tartás, további funkció a beállítón.
27452	Ortho.Pliers EVER Fine 452 Light Wire T/C	Ív tartása, hajlítása hurok kialakításához.
27453	Ortho.Pliers EVER Fine 453 Kim T/C	Ív tartása, hajlítása hurok kialakításához.
27454	Ortho.Pliers EVER Fine 454 Young	Ív tartása, hajlítása hurok kialakításához.
27455	Ortho.Pliers EVER Fine 455 Tweed Arch	Ív tartása, hajlítása nyomaték alkalmazásához.
27456	Ortho.Pliers EVER Fine 456 Tweed Loop Forming	Ív tartása, hajlítása hurok kialakításához.
27457	Ortho.Pliers EVER Fine 457 Three Jaw	Ív tartása, hajlítása V forma kialakításához.
27458	Ortho.Pliers EVER Fine 458 Bird Beak	Ív tartása, hajlítása hurok kialakításához.
27459	Ortho.Pliers EVER F. 459 Nance Closing Loop	Ív tartása, hajlítása hurok kialakításához.
27460	Ortho.Pliers EVER Fine 460 Band Removing L	Szalagszél, fogak rágófelszín felőli oldalának illesztése, ív eltávolítása
27461	Ortho.Pliers EVER Fine 461 Cinch Back	Ívvég tartása, hajlítása.
27462	Ortho.Pliers EVER Fine 462 Lingual Utility	Ív tartása és behelyezése a fogszabályozóba, bukkális csőbe.
27463	Ortho.Pliers EVER F.463 Round Former 1.0	Tartás, további funkció a beállítón.
27464	Ortho.Pliers EVER F.464 Round Former 2.0 SM	Tartás, további funkció a beállítón.
27465	Ortho.Pliers EVER Fine Key Punch 465	Tartás, további funkció a beállítón.
27550	Orthodontic Pliers Crimping Ortolan	Tartás, krimpelhető kampó felhelyezése az ívre.
27551	ROMAN 1 Circle Cutter SMOOTH	Tartás, további funkció a beállítón.
27552	ROMAN 2 Horizontal Box SMOOTH	Tartás, további funkció a beállítón.
27553	ROMAN 3 Vertical Box SMOOTH	Tartás, további funkció a beállítón.
27554	ROMAN 4 Pearl Dot SMOOTH	Tartás, további funkció a beállítón.
27555	ROMAN 5 Keyhole Cutter SMOOTH	Tartás, további funkció a beállítón.
27556	Angle Fluted Bird Beak Pliers	Ívvég tartása, hajlítása.
27601	Pin&Ligature Cutter EVER F.601 Angle 40	Felesleges ligatúra tartása, vágása.
27602	Pin&Ligature Cutter EVER F.602 Reverse 40	Felesleges ligatúra tartása, vágása.
27603	Pin&Ligature Cutter EVER F.603 Angle 50	Felesleges ligatúra tartása, vágása.
27604	Pin&Ligature Cutter EVER F.604 Reverse 50	Felesleges ligatúra tartása, vágása.
27605	Pin&Ligature Cutter EVER F.605 with Hard MATL	Felesleges ligatúra tartása, vágása.
27606	Distal End Cutter EVER Fine 606S T/C	Felesleges ív tartása, vágása.
27607	Distal End Cutter EVER Fine 606L T/C	Felesleges ív tartása, vágása.
27615	Pin&Ligature Cutter EVER C.615 with Hard MATL	Felesleges ligatúra tartása, vágása.
27722	Wire Cutter Heavy Duty	Drót vágása.
27934	Convertible Cap Removing Pliers ND-934	Tartás, átalakítható tubus sapkájának eltávolítása.
27935	Convertible Cap Removing Pliers ND-934 Blade	A „27934” fontos része.

7 [Általános óvintézkedések és tiltások]

1) A termék kizárólag fogászati kezelésre használható.

Be kell tartani az óvintézkedéseket, hogy szavatolható legyen a műszerek megfelelő használata.

2) Ne használja műszereket rendeltetésüktől eltérő célokra.

3) Használat előtt a használati útmutató szerint tisztítsa, kenje és sterilizálja.

4) Ne használja a műszereket túlérzékenységgel rendelkező páciensekhez kiütésekhez, dermatitishoz hasonló vagy allergiás tünetekkel.

5) Ne alakítsa át vagy módosítsa a műszereket.

6) Ne ejtse le a műszereket. Kerülje a műszereket érő erős ütések.

7) A műszerek ártalmatlanításához kövesse a nemzeti előírások útmutatásait.

8) Ne melegítse fel a műszereket.

9) Ha vegyszerek tapadnak a műszerhez, azonnal törölje le, hogy elkerülje a korróziót.

10) Ha ezen műszerekkel hajt drótot, tartsa a drótot a fogóval, és hajtsa meg az ujjával, hogy elkerülje a fogó sérülését.

11) A rozsdamentes acél ellenállóbb a rozsdával szemben, mint a vas, azonban a használat módja és a környezet (pl. hőmérséklet, páratartalom) miatt korrodálódhat.

8 [Feldolgozás korlátai]

Azonnal hagyja abba a műszer használatát, ha kopást vagy bármi szokatlant észlel.

9 [Első kezelés a használat helyén]

Használat előtt a használati útmutató szerint tisztítsa, kenje és sterilizálja.

10 [Előkészítés tisztítás előtt]

Lásd következő szakasz.

11 [Tisztítás és sterilizálás/fertőtlenítés folyamata]

1) Általános óvintézkedések

- a) A műszerek karbantartásához lásd a vállalatunk által kiadott „The Fundamental Guide Book for Cleaning and Sterilizing Instruments” (Műszerek alapvető tisztítási és fertőtlenítési útmutatója), vagy a „karbantartás” részt weboldalunkon (http://www.ydm.co.jp/en-new/pdf/The_process_of_cleaning_and_sterilizing.pdf).
- b) A vérrel, testnedvekkel, szövetdarabokkal, vegyszerekkel stb. szennyezett műszereket azonnal meg kell tisztítani és fertőtleníteni kell az alábbi módszerrel, hogy megelőzze a szennyeződések rátapadását.
A műszerekhez hosszú ideig tapadó szennyeződések eltávolítása nehéz lehet.

2) Folyamat

- a) Nyissa ki a csuklót.
- b) Tisztítsa meg a műszert tisztítószerrel az i) vagy ii) módszer szerint.
 - i) Használjon ultrahangos tisztítót egészségügyi rozsdásodásgátló mosószerrel 5 percig.
 - ii) Merítse egészségügyi rozsdásodásgátló mosószerrel feltöltött tisztítóba 15 percre.
- c) Folyó vízben mossa le a műszerhez tapadt szennyeződést és mosószert.
(Ha szappanmaradványok maradnak a műszerek felületén, az rozsdásodást, foltokat okozhat.)
- d) Szárítsa meg a műszereket. (A fennmaradó nedvesség rozsdásodást, a sterilizáló hatás csökkenését okozhatja.)
- e) Vigyen fel rozsdásodásgátló kenőanyagot, például „műszerolajat” a csuklóra.
* Ne nyissa vagy zárja, amíg nem vitt fel rozsdásodásgátló kenőanyagot. (Az olaj nélküli nyitás vagy zárás kopáshoz vezet.)
- f) Sterilizálja sterilizáló autoklávval.

Körülmények: 134°C – 138°C, 3 – 3,5 perc

* A más műszerekkel való érintkezés okozta karcok elkerüléséhez helyezze azokat sterilizált tasakba vagy tokba.

g) Használat után azonnal tisztítsa meg a fenti b) alapján.

3) Tisztítás és sterilizálás/fertőtlenítés folyamatával kapcsolatos óvintézkedések

- a) Ne használja az alábbi vegyszereket, mert a fém korrózióját okozhatják:
nátrium-hipoklorit, benzalkónium-klorid, klórhexidin-glükonát, jódtinktúra, jodoform és perecetsav.
- b) Ne használjon vegyi autoklávot a műszerekhez, ami korróziót okozhat.
- c) Ne végezzen plazmasterilizálást, mert hatással lehet az anyagra.
- d) Ne használjon háztartási tisztítószereket, mert nem alkalmasak a műszer felületén lévő fehérje eltávolításához.

e) A drótkéfe és az acélgyapot a műszer sérülését okozhatja.

f) Ne használjon túl savas vizet, mert korróziót okozhat.

Tisztított vizet (szennyeződés nélkül) javasolunk az öblítéshez.

A csapvíz klórt tartalmaz, ami korrodálhatja a fémeket.

g) Mosó-fertőtlenítő használatakor a feltapadt szennyeződés vagy tisztító oldat nem mindig távolítható el víztakarékos vagy időtakarékos program használatára esetén. Mindig tartsa be a gyártó kezelési útmutatójának előírásait stb., hogy szavatolja a szennyeződések eltávolítását.

h) Autokláv sterilizáló kezelése esetén ügyeljen az alábbiakra.

i) Az autokláv sterilizáló szekrénye szennyezett lehet a felhasználási állapot és időtartam függvényében.

Ha szennyeződés marad az autokláv sterilizálóban, az rátapadhat a műszerre.

A sterilizáló kezelési útmutatójának megfelelően végzett tisztítást javasoljuk.

A kamra belseje nem lesz szennyezett. Különösen ügyeljen rá,

hogy a kamra fedelének és a légszűrő gumi tömítését bizonyos időnként cserélni kell.

ii) Lehetőleg tisztított vizet használjon. A csapvíz korróziót okozhat a benne lévő klóronok miatt.

iii) Ügyeljen az autokláv sterilizáló szárítási hőmérsékletére.

iv) Ne helyezze a műszert a fűtés közelébe. (Magasabb lehet a jelzett hőmérsékletnél.)

v) Ha a tisztítás és öblítés nem fejeződik be az autokláv sterilizálóban, vagy nedvesség marad az autokláv sterilizáló kamrájában, megéghet a műszer felszíne.

i) A mosást és sterilizálást követően távolítsa el a műszerhez tapadó vizet, és teljesen szárítsa meg.

12 [Karbantartás, vizsgálat és próba]

A tisztítást és sterilizálást követően, használat előtt ellenőrizze az alábbiakat.

- 1) Ellenőrizze, hogy nem tapasztal-e szennyeződést, sérülést, repedést, karcokat vagy korróziót a csukló belső részén és a csuklóban.
- 2) Ellenőrizze a csuklót rendellenes mozgás szempontjából.

13 [Tárolás]

- 1) Tiszta, portól mentes helyen tárolja, kerülje a magas hőmérsékletet és páratartalmat.
- 2) A fémek potenciálkülönbsége miatti galvánelem-képződés elkerülése érdekében ne tárolja együtt más anyagból tárolt műszerekkel.
- 3) A rozsdafoltok elkerülése érdekében ügyeljen az alábbiakra.
 - a) Ne tárolja rozsdás műszerekkel.
 - b) Ne tárolja vegyszerekkel.
 - c) Ügyeljen a sterilizáló és tárolóeszközök belsejében lévő rozsdára.

14 [Ártalmatlanítás]

A fogtechnikusok és/vagy fogorvosok felelősek a hatályos törvények szerinti ártalmatlanításért.
Az YDM CORPORATION nem vállal felelősséget a nem megfelelő ártalmatlanításból eredő személyi sérülésért.

15 [Kiegészítő információ]

<Törés vagy élezés>

A műszer törése esetén jelezze azt az YDM CORPORATION „Igénybejelentés” űrlapján a kereskedő felé, ahonnan azt vásárolta.
A vágószerszámok élezéséért díjat számítunk fel.

16 [Gyártó elérhetőségei]



YDM CORPORATION

28 Imaizumi, Higashi-Matsuyama-shi,
Saitama 355-0042, Japan

TEL: 81-3-3828-3161

FAX: 81-3-3827-8991

URL: <http://www.ydm.co.jp/>

E-mail: ydm@ydm.co.jp

17 [Megjegyzés a felhasználó és/vagy páciens számára]

A műszerekkel kapcsolatban előforduló minden súlyos incidenst jelezni kell az YDM CORPORATION felé.

18 [Kiegészítő információ]

A műszer hibája esetén jelezze azt az YDM CORPORATION „Igénybejelentés” űrlapján a kereskedő felé, ahonnan azt vásárolta.

19 [Szimbólummagyarázat]



Orvosi eszköz



Gyártó



Sarzsorszám



Megjegyzés

A fenti útmutatásokat az orvosi eszköz gyártója jóváhagyta, mint orvosi eszköz ismételt használatra történő felkészítésére alkalmas folyamat. A feldolgozó felelőssége azonban annak biztosítása, hogy a feldolgozás, ami ténylegesen történik az eszközzel, az anyagok és a feldolgozást végző személyzet elérje a kívánt végeredményt. Ehhez a folyamat jóváhagyására és/vagy hitelesítésére és rutinszerű ellenőrzésére van szükség.

1. ver.: 2021. június 23.

2. ver.: 2022. augusztus 24.

3. ver.: 2023. július 6.