MIZUHO

MES-CK07-983-02EN-0

PREPARED:(2024-10-03) (Version 6)

Be sure to read this instruction manual before using this product.
Keep this manual available for reference when needed.

CE

Instruction for Use

Trade Name: Multi-Purpose Head Frame II

Warning

1. Please read these instructions carefully prior to using this product. Product should be used according to these instructions and pay close attention to the safety of patients. Failure to follow manufacturer's recommendations may cause harm or injury to patient.

For the US market

Do not reuse the device when it is used on a patient with, or suspected of having Creutzfeldt-Jakob Disease (CJD) or variant CJD (vCJD).

For markets outside the US

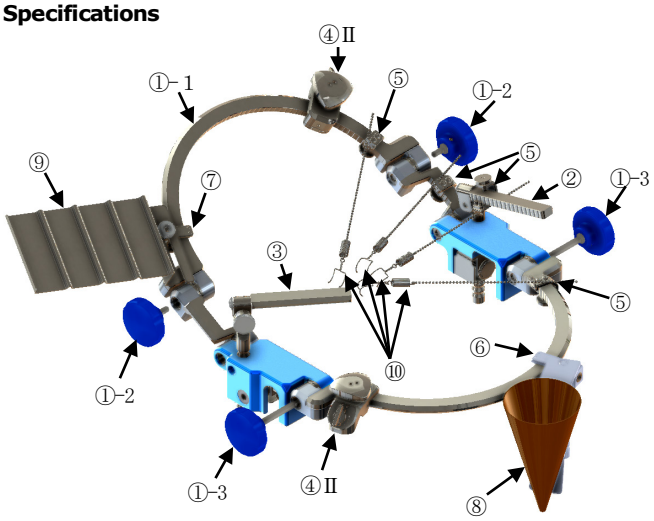
When the device is used on a patient with, or suspected of having CJD or vCJD, make sure to adhere to the most recent and updated restrictions available in each country and/or region for its reuse. Be cautious of the possibility of secondary infection. Refer to www.a-k-i.org or AAMI Standard ST79 for more information related to cleaning and sterilization.

2. Do not overtighten the head pin during cranial fixation.
When using head pins to fix the cranium, they should be properly fixed to avoid overtightening. Be especially careful when using for a child or osteoporotic patient [Possible cranial depression may occur.].
3. Ensure that there is no compression of the optic nerve during scalp traction due to overturning of the frame. When tractioning the scalp with the scalp traction fish hook, the upper part of the Frame Unit should not be overturned to avoid compression of the optic nerve [There is a possibility of a decrease in eyesight or blindness.].

Contraindication/Prohibition

1. Use for intended purpose only
Use devices for their intended purposes only. Incorrect use could cause this product to break.
2. Use with specified products only
Use this product only with products specified by Manufacturer. Other products than those specified by Manufacturer could be incompatible with this product due to differences in design and development policies.
3. Prohibition of use of chemicals
Avoid exposing this product to chemicals. Doing so could damage this product due to corrosion.
4. Prohibition of secondary processing of this product
Do not apply any secondary processing to this product, for example, do not apply impacts or vibration markings to the surface of this product. Doing so could break this product.
5. Prohibition of use of polishing powder and wire wool
When cleaning this product, do not attempt to polish its surfaces with rough polishing powder or wire wool. This could cause scratches on the surface of this product and result in rust or corrosion.
6. Prohibition of use of acid, and household detergents
Use only medical detergents to clean this product. Do not use any acid, or household detergent. Washing this product with an improper detergent could result in discoloration or corrosion

Specifications



Material: stainless steel, aluminum alloy, resin

No.	Code No.	Product Description
①	07-983-02	Frame Unit
①-1	—	Frame
①-2	—	Short Handle
①-3	—	Long Handle
②	07-983-03	Hand Rest R
③	07-983-04	Hand Rest L
＊④II	07-983-15	Retractor Slide Adjustor II
⑤	07-983-06	Spring Hook Adjustor
⑥	07-983-07	Sub Hole Attachment
⑦	07-983-08	Cotton Plate Adjustor
⑧	07-981-06	Instrument Receptacle
⑨	07-981-07	Cotton plate
＊⑩	07-954-00MM	Spring Scalp Hook Retractors, SUS
＊Not CE Marked		

Please refer to the instructions for use for ⑩ Spring Scalp Hook Retractors, SUS (CK07-954-00MMEN-0)

Intended purpose

This product is a surgical instrument that is used to secure a patient's skull bone so that the patient's cephalic and cervical regions are maintained in a specific, fixed position during an operation. This product is normally used in neurosurgical operations.

Intended user

This product is to be used by health care professionals, including but not limited to surgeons, nurses and biomedical technicians.

Instructions for Use

・Before using this product, inspect, wash, and sterilize in accordance with these instructions.

● Install and operate the Retractor Slide Adjustor II according to the following steps (Fig.1-1 to Fig.5-2).

(1) Installation of the Retractor Slide Adjustor II.

(1)-1 Rotate the fixing knob counterclockwise and stop the operation when you feel resistance (Fig.1-1).

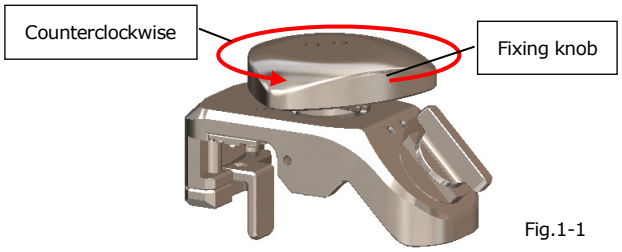


Fig.1-1

(1)-2 Push the dropout prevention stopper outward (Fig.1-2).

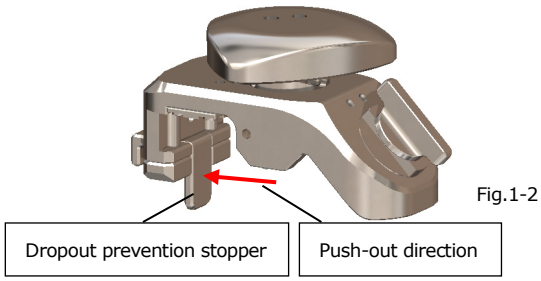


Fig.1-2

(1)-3 Install the Retractor Slide Adjustor II over the frame (Fig.1-3).

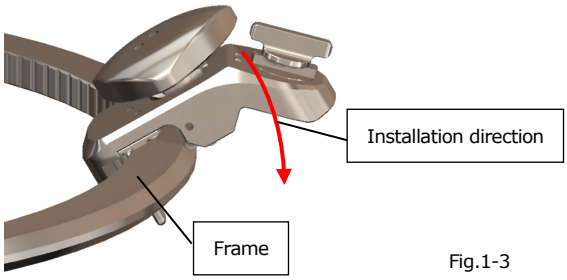


Fig.1-3

(1)-4 Push in and lock the dropout prevention stopper (Fig.1-4).

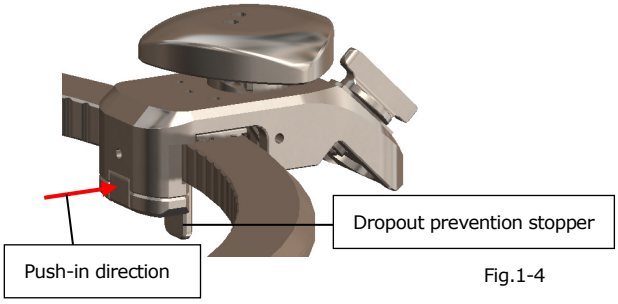


Fig.1-4

(2) Attachment of the brain spatula fixator

(2)-1 Position the protrusion of the brain spatula fixator attachment perpendicular to the frame (Fig.2-1).

(2)-2 Rotate the fixing knob clockwise to fix the fixator temporarily (Fig.2-1).

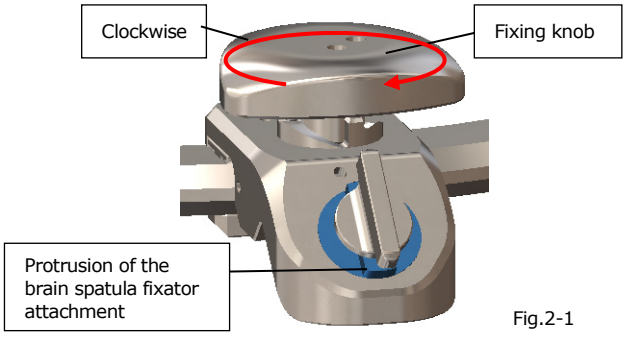


Fig.2-1

(2)-3 Rotate the brain spatula fixator attachment knob counterclockwise and stop the operation when you feel resistance (Fig.2-2). Excessive rotation may result in a loss of functionality.

(2)-4 Insert the brain spatula fixator into the protrusion (Fig.2-2).

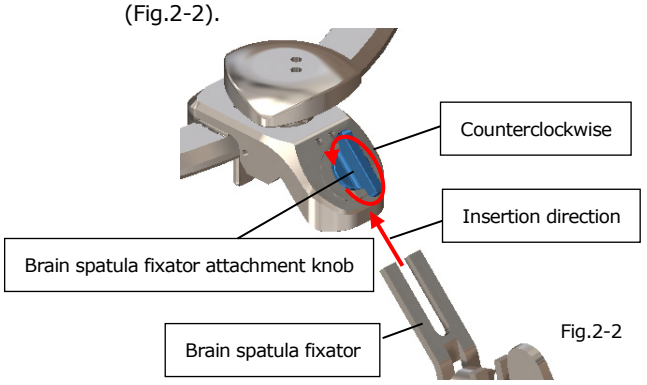


Fig.2-2

(2)-5 Rotate the brain spatula fixator attachment knob clockwise to fix the brain spatula fixator (Fig.2-3).

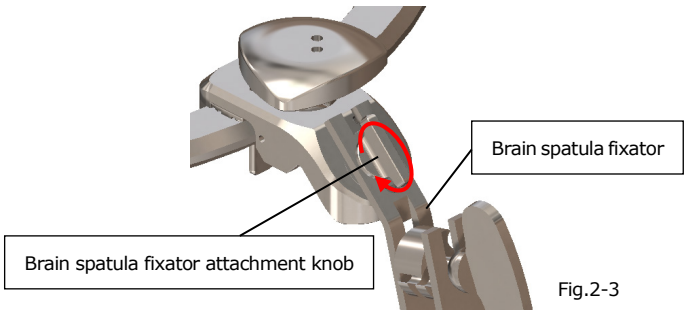


Fig.2-3

(3) Operation of the Retractor Slide Adjustor II

(3)-1 Rotate the fixing knob counterclockwise to loosen the fixation. At this point, hold the brain spatula fixator before loosening it (Fig.3-1).
Stop the operation when you feel resistance.

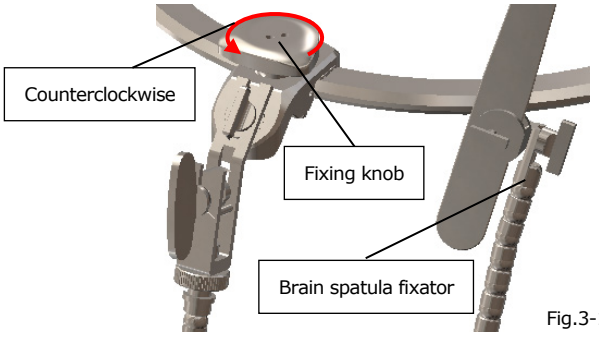


Fig.3-1

(3)-2 Move the Retractor Slide Adjustor II to the desired position (Fig.3-2).
You can adjust the position of the brain spatula fixator simultaneously when you move it.

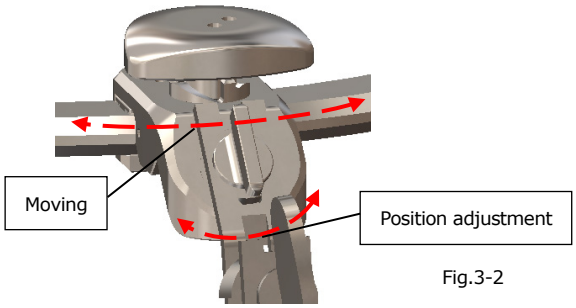


Fig.3-2

(3)-3 Rotate the fixing knob clockwise to fix it to the frame.
If the operation stops halfway and fails to fix, move and adjust the position of the brain spatula fixator again.

(3)-4 Confirm the fixation.

(4) Removal of the brain spatula fixator.

(4)-1 Rotate the brain spatula fixator attachment knob clockwise to fix it in place.

(4)-2 Rotate the brain spatula fixator attachment knob counterclockwise to release the fixation. Before loosening, hold the brain spatula fixator (Fig.4-1).

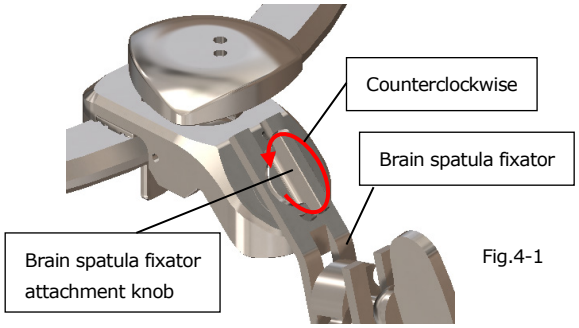


Fig.4-1

(4)-3 Remove the brain spatula fixator (Fig.4-2).

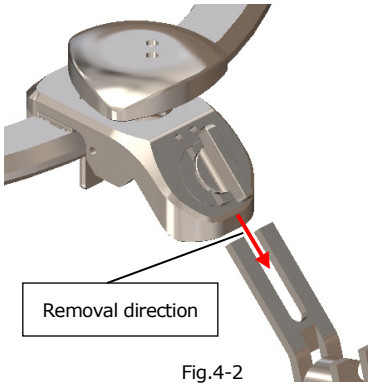


Fig.4-2

(5) Removal of the Retractor Slide Adjustor II

(5)-1 Push the dropout prevention stopper outward (Fig.5-1).

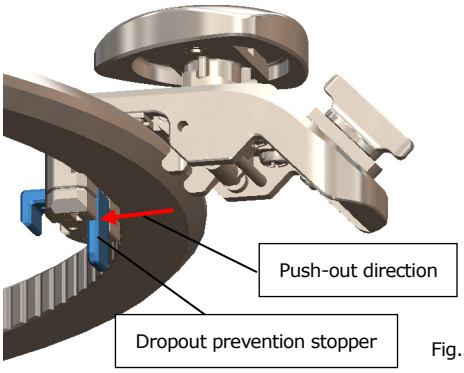


Fig.5-1

(5)-2 Rotate the fixing knob counterclockwise to release the fixation.
Stop when resistance is observed in the rotating operation.

(5)-3 Remove the Retractor Slide Adjustor II from the frame (Fig.5-2).

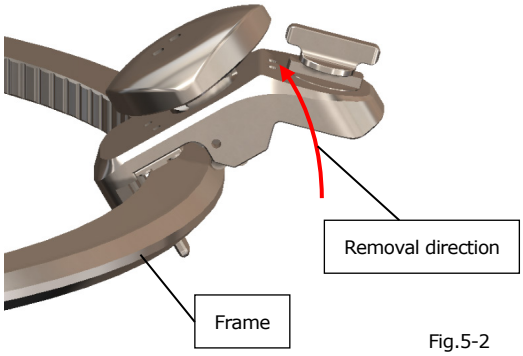
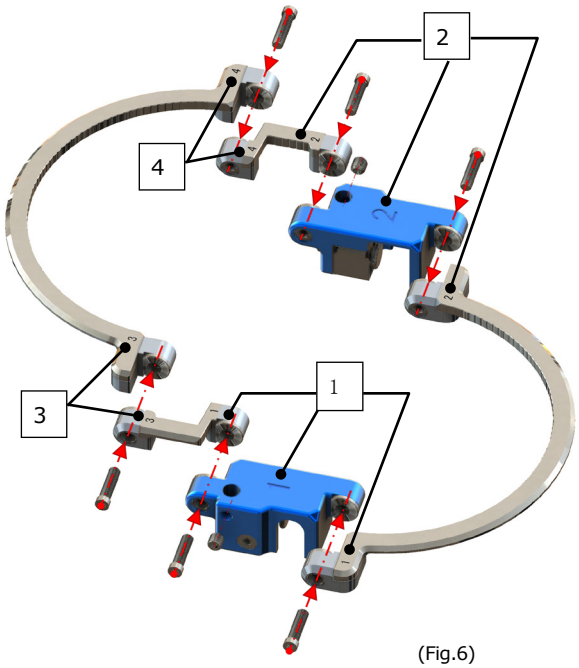
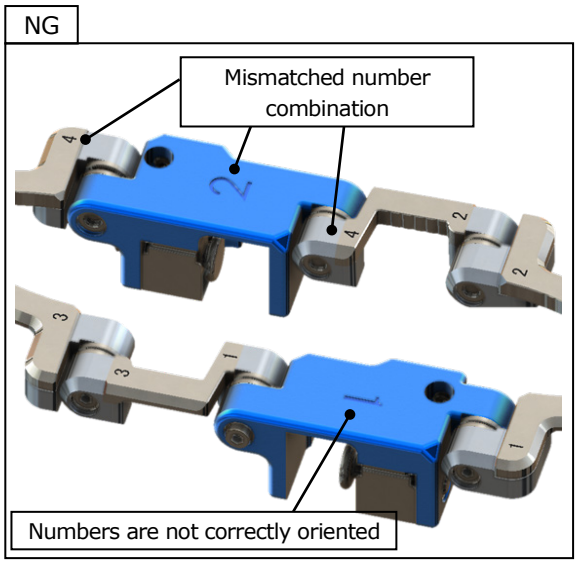


Fig.5-2

- The Frame Unit should be combined as shown in the figure so that the displayed numbers are correctly oriented, and the same numbers are assembled together by inserting the screws from the outside (outer circumference) to complete the assembly (Fig.6, Fig.7).



(Fig.6)

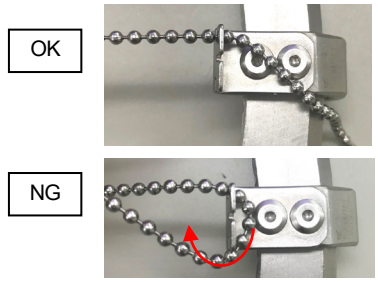


(Fig.7)

Warning/Caution

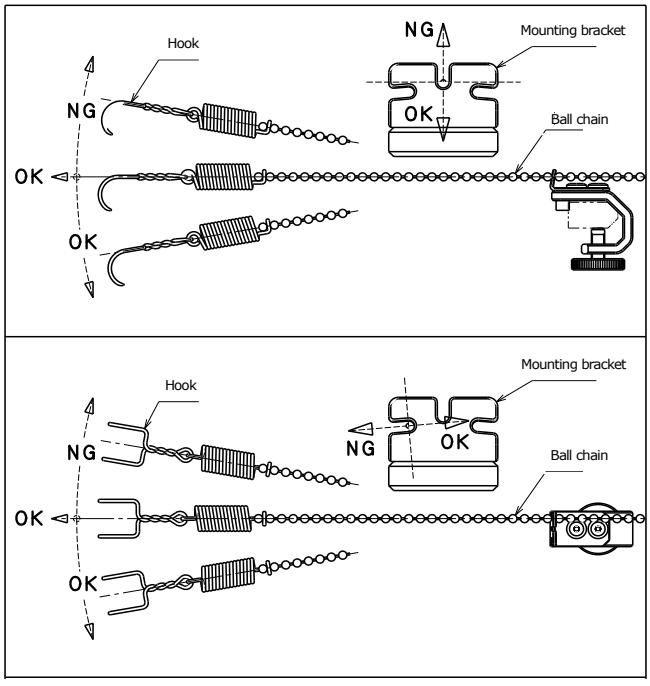
1. Important fundamental cautions

・When using the scalp traction fish hook, do not wrap or fix the ball chain around the spring hook adjustor attachment while applying tension [The ball chain may break because of the bending load (Fig. 8)].



(Fig.8)

・When tractioning the scalp with the fishhook, select the appropriate mounting bracket groove for the direction of traction and insert the ball chain deep into the groove to fix it in place [When tractioning in the NG direction, the ball chain may come out of the mounting bracket because of the force exerted to pull it out of the groove (Fig. 9)].



(Fig.9)

2. Defect/Adverse event

Defect

- lowering of holding force
- rattling
- breakage
- crack
- deformation
- deterioration

Adverse event

- serious health damage
- injury
- laceration
- contamination

3. Other cautions.

- Before using this product, inspect appearance and construction. Do not use if any deformation, crack or anything wrong in sliding motion is found during inspection. Failure to not follow recommendations may cause injury to patient

Storage/Life

1. Please store the device in normal ambient temperature areas. Do not store in areas of high humidity where the temperature may dramatically vary causing condensation. Be careful not to impact or vibrate (including while transporting) this product.
2. Service life of this product: 5 years
   (Subject to following manufacturer's specified maintenance, inspection and proper storage requirements.)

Maintenance/Inspection

<By the user>

1. Check prior to each use

(1) Conduct daily and pre-operation checks of this product to make sure that it functions properly.

2. Check after each use

(1) Immediately wash with clean water

(1)-1 If exposed to bleach or antiseptic solutions, immediately wash: Wash and rinse with clear water immediately and immerse in neutral enzyme detergent to remove any bleach or antiseptic solution, which may contain chlorine or iodine and can damage the instrument. Manually remove contaminated matter by hand or with an ultrasonic-cleaner.

(1)-2 Further remove any remaining contamination with a plastic brush.

(1)-3 Select a proper detergent for each decontamination method and maintain appropriate density and handling.

(1)-4 Use a soft towel, a plastic brush or a water jet for cleaning.

(1)-5 Avoid using metallic brushes or rough polishing agents, applying excessive force, dropping or bumping the device, etc.

(1)-6 Reverse osmosis water is recommended to wash this product.

(1)-7 Only use reverse osmosis water for the final rinse.

(1)-8 It is recommended to use a washer-disinfector for this device Thermal Disinfection can be used by following the manufacturer's defined parameters. Thermal Disinfection Band: 90-93 °C, 5-10 minutes (A0 value: 3000-12000) (reference EN ISO 15883-1)

(2) Fully dry this product immediately after washing it
Do not leave it wet for a longer time than necessary as residual water may damage the instrument.

(3) Use distilled water or reverse osmosis water
Use distilled water or reverse osmosis water to wash and sterilize this product. Residual chlorine and organic matters in tap water may cause stainings and/or rust and may damage the instrument.

(4) Use a water-based anticorrosive lubricant

(4)-1 Lubricating oil is completely removed by washing. After washing this product, apply a water-based, anticorrosive lubricant prior to sterilization. Do not use this product without applying anticorrosive lubricant on its sliding part. [Galling could occur.]

(4)-2 For the Retractor Slide Adjustor II, soak it in water-based lubricant and rust-preventive maintenance agent, or apply the lubricant to the arrowed part shown in Fig.10 before sterilizing the product [Insufficient lubrication may cause fixation failure.].
Appropriate application quantity for one place: 0.06 to 0.10 ml (equivalent to a water droplet)

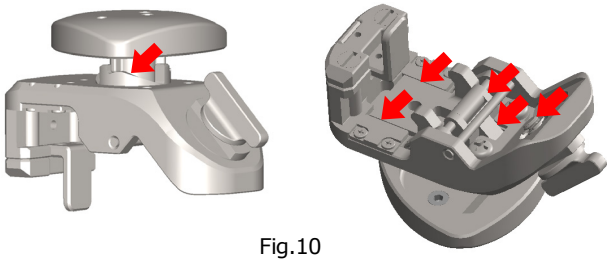


Fig.10

3. Sterilization
Device must be sterilized by users in accordance with validated sterilization procedures, such as an autoclave, that are regulated by medical organizations in each country or region.

Table 1: Applicable Detergent

		Detergent	
		Neutral	Alkaline
①-1	Frame	Yes	No
①-2	Short Handle	Yes	No
①-3	Long Handle	Yes	No
②	Hand Rest R	Yes	Yes
③	Hand Rest L	Yes	Yes
④II	Retractor Slide Adjustor II	Yes	Yes
⑤	Spring Hook Adjustor	Yes	Yes
⑥	Sub Hole Attachment	Yes	Yes
⑦	Cotton Plate Adjustor	Yes	Yes

Yes: Applicable No: Not applicable

Table 2: Applicable Disinfectant

		Disinfectant	
		Iodine	Alcohol
①-1	Frame	No	Yes
①-2	Short Handle	No	Yes
①-3	Long Handle	No	Yes
②	Hand Rest R	No	Yes
③	Hand Rest L	No	Yes
④II	Retractor Slide Adjustor II	No	Yes
⑤	Spring Hook Adjustor	No	Yes
⑥	Sub Hole Attachment	No	Yes
⑦	Cotton Plate Adjustor	No	Yes

Yes: Applicable No: Not applicable

Table 3: Applicable Sterilization Method

		Sterilization		
		Steam	EOG	Low temperature hydrogen peroxide gas plasma
①-1	Frame	Yes	Yes	No
①-2	Short Handle	Yes	Yes	No
①-3	Long Handle	Yes	Yes	No
②	Hand Rest R	Yes	Yes	Yes
③	Hand Rest L	Yes	Yes	Yes
④II	Retractor Slide Adjustor II	Yes	Yes	Yes
⑤	Spring Hook Adjustor	Yes	Yes	Yes
⑥	Sub Hole Attachment	Yes	Yes	Yes
⑦	Cotton Plate Adjustor	Yes	Yes	Yes

Yes: Applicable No: Not applicable

Sterilization of the device may be accomplished by steam.

The recommended sterilization parameters are as follows,

ISO/TS 17665-2	
Temp.	Minimum exposure time
121°C / 250°F*	15 Min
126°C / 259°F*	10 Min
134°C / 273°F*	3 Min

*According to the Guideline for Disinfection and Sterilization in Healthcare Facilities,2008 (Update: May 2019)

For the US market

FDA has not approved or cleared medical devices, including sterilizers, for the intended use of reducing the infectivity of TSE agents (i.e., prions).

For the markets outside the US

When the device is used on a patient with or suspected of having CJD or vCJD, make sure to adhere to the most recent and updated restrictions available in each country and/or region for its reuse.

Maintenance and check by agents

For safe use of this instrument, inspect device prior to and after each use. Alternative or no review and/or inspection may cause injury to the patient and/or healthcare worker and may decrease the performance and function of this device. Additionally, it is recommended to schedule a periodic inspection through your local distributor or the manufacturer.

Packing

1 piece per pack

Warranty

MIZUHO Corporation will repair defective parts of this product without charge for one year from the date of delivery/installment except for cases of damage caused by a third party's repair, act of nature, improper use or intentional damage. All other warranty terms and conditions are subject to regulations of MIZUHO Corporation.

Disposal

This device must be disposed of in accordance with local regulations.
Please contact your local distributor for proper disposal.

Notice

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority in which the user and/or patient is established.

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