MIZUHO

MES-CK07-952-03EN-0

PREPARED:(2023-04-17) (Version 1)

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

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

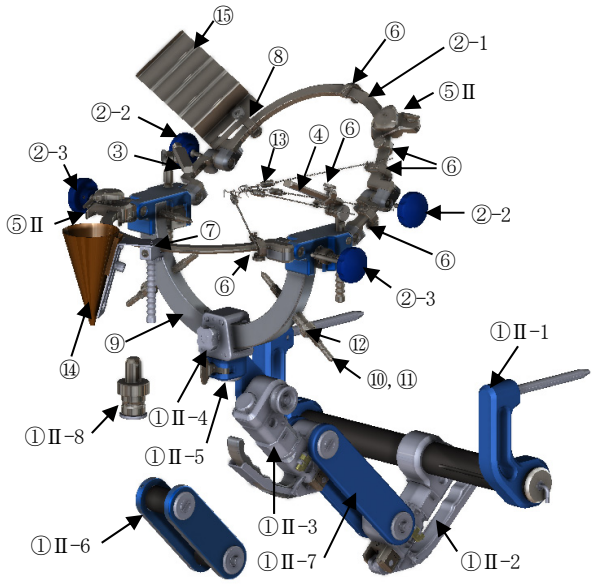
When the device is used on a patient with, or suspected of having CJD or vCJD, make sure to adhere to the most recent and updated restrictions available in each country and/or region for its reuse. Be cautious of the possibility of secondary infection. Refer to www.a-k-i.org or AAMI Standard ST79 for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

2. While placing the patient's head in the head frame and adjusting the head position in order to secure the skull bone, ensure that the patient's respiratory tract is unobstructed and the carotid artery is not twisted. When securing the skull bone, do not apply excessive clamping force.
3. Retracting the scalp:
   Do not excessively recline the frame too much to avoid applying any pressure onto the optic nerve. When retracting the scalp with the scalp hook retractor, do not recline the upper frame of the basal frame too much to avoid applying any pressure onto the optic nerve. Failure to follow recommendations may result in patient injury, reduced vision or loss of sight.
4. Possibility of penetration and depression in the skull bone
   Hardness of skull bone is different with each person. Be careful when inserting a screw pin (head pin), not to insert beyond necessity to prevent skull crack, skull depression, skull penetration and skin laceration. Because the skull temporal bone (the temple area) is thin and insertion could cause skull crack, skull depression, skull penetration and skin laceration, avoid inserting a screw pin to the skull temporal bone. The shock may cause epidural hematoma or cerebral contusion.

Contraindication/Prohibition

1. 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.
2. Use for intended purpose only
   Use devices for their intended purposes only. Incorrect use could cause this product to break.
3. Do not tighten levers of Flexible Clamp A II and Flexible Clamp B II without being assembled. Failure to do so may permanently deform the product causing it to become unusable.
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.

Specifications



No.		Code No.	Product Description
①II		07-952-03	Flexible Base Unit II
	-1	—	Bracket Bar
	-2	—	Flexible Clamp A II
	-3	—	Flexible Clamp B II
	-4	—	Compact Head Holder II
	-5	—	Head Holder Base II
	-6	—	120 mm Arm
	-7	—	180 mm Arm
	-8	—	Conversion Adapter II
		07-983-02	Frame Unit
②	-1	—	Frame
	-2	—	Short Handle
	-3	—	Long Handle
③		07-983-03	Hand Rest R
④		07-983-04	Hand Rest L
⑤II		07-983-15	Retractor Slide Adjustor II
⑥		07-983-06	Spring Hook Adjustor
⑦		07-983-07	Sub Hole Attachment
⑧		07-983-08	Cotton Plate Adjustor
⑨		07-951-11	Smart Fix C Holder
⑩		07-951-33	Smart Fix Head Pin Standard
⑪		07-951-34	Smart Fix Head Pin Long
⑫		07-951-15	Smart Fix Stopper Sleeve

⑬	07-954-00MM	Spring Scalp Hook Retractors, SUS
⑭	07-981-06	Instrument Receptacle
⑮	07-981-07	Cotton Plate

Material: Stainless steel, aluminum alloy, resin, titanium alloy

Intended purpose

This product is a surgery device to hold the skull in order to fix the head and neck at the specific position during operation. It is usually used for a neurosurgical procedure.

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, refer to the related instruction for use (Multi-purpose Head Frame, Head Pin, and Spring Scalp Hook Retractors). Before using this product, inspect, wash, and sterilize in accordance with these instructions.

Outline of use:

- Remove the head board from the operation table, and attach and fix the (optional) Table Attachment to the table with screws.

●Release or fix the Flexible Base Unit II according to the following procedure. (Fig.1-4)

(1) Release

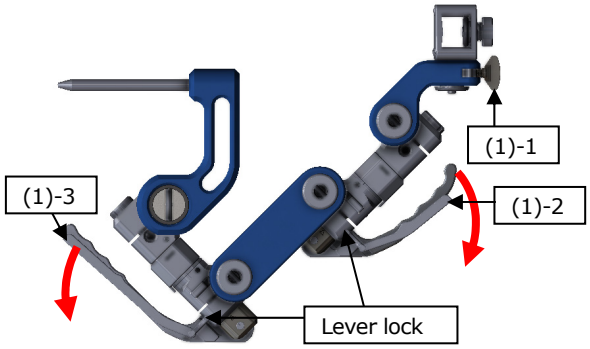


Fig.1

(1)-1 Turn the knob on the Head Holder Base II to release the Holder.

(1)-2 Grasp the lever on the operator's side, make sure the lever lock is released and pull the lever to release the fixation.

(1)-3 Grasp the lever on the operation table side, make sure the lever lock is released, and pull the lever to release the fixation.

＜Releasing the Rotating Part of the Flexible Clamp＞

Release the rotating part if necessary.

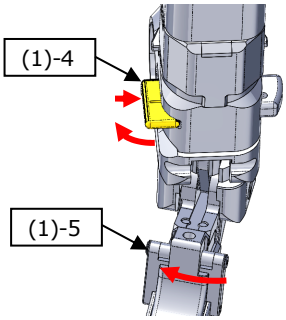


Fig.2

(1)-4 Raise the yellow flap and insert it into the Main Unit.

(1)-5 Rotate the lever to your left when facing the Main Unit.

*Do not push in the flap of (1)-4 or apply excessive pressure to the lever. Doing so could deform the equipment so it can't be fixed.

(2) Fixation

＜Fixation of rotating part of the Flexible Clamp＞

After releasing the rotating part, perform the fixing operation (2)-1 and (2)-2.

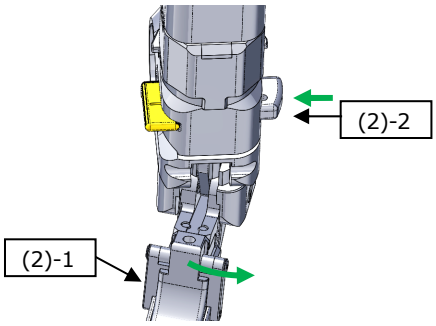


Fig.3

(2)-1 Move the lever to its original position (parallel to the Main Unit).

(2)-2 Push in the protrusion on the opposite side of the flap.

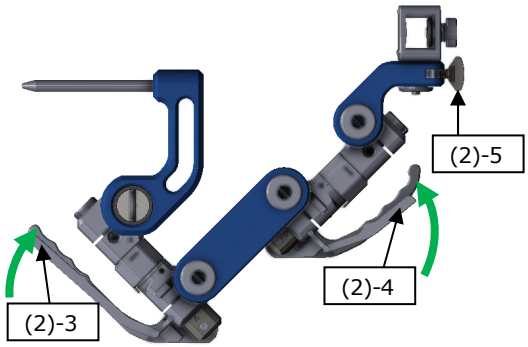


Fig.4

(2)-3 Push in the lever on the operation table side to fix it.

(2)-4 Push in the lever on the operator's side to fix it.

(2)-5 Turn the knob of the Head Holder Base II to fix the Holder.

●Attach the Head Holder to the Table Attachment, and fix each joint to position the Head Holder perpendicularly and both ends horizontally to the floor. Please make sure to confirm that each joint is firmly fixed/adjusted.

●Determine the optimum patient head position for the access path after craniotomy, and fix the patient's head with dedicated head pins

●To fix the head, follow the procedures from (1) to (3) below. (Also see Fig.5-7.)

(1) Fix the head provisionally with sterilized head pins while an assistant holds the patient's head. (Fig.5-1) There are individual differences in hardness of patient's skulls. Upon provisional fixing, fix the head with utmost care by examining the position of the head pin tip. Make sure that the patient's head moves around the head pin as a center axis under the provisional fixing condition as the arrow "A" below shows. (Fig.5-2)

(1)-1 If the patient's head does not move around the head pin as the center axis as the arrow "A" (Fig.5-2), the

head pin may have been tightened too much. Loosen the head pin until the patient's head will move around the head pin as the center axis.

(1)-2 If the skull is unstable and the patient's head moves up and down, gradually tighten the head pin until the patient's head does not move up and down and will move around the head pin as the center axis as shown below.

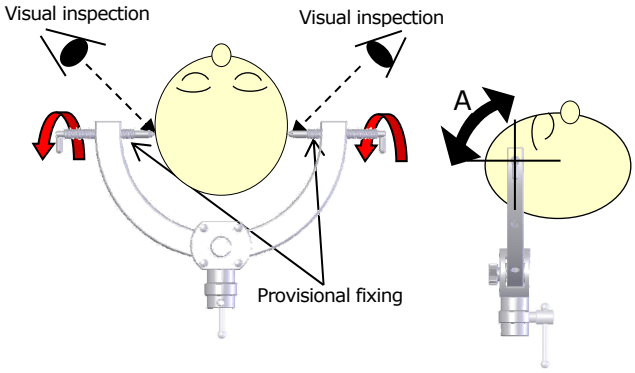


Fig.5-1 Fig.5-2

(2) Insert the head pins into two places while examining the head pin tip in order to stop the patient's head from moving around the head pins as the center axis (arrow "A" Fig.5-2) and tighten them to the extent that they can hold the patient's head.

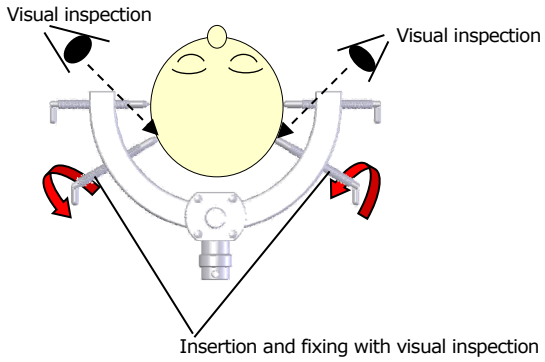


Fig.6

(3) Finally turn the head pins 1/4 to 1/2 rotation which were provisionally fixed to tighten them further (Fig.7). Excessive tightening by the head pin may result in making cracks, depression, or penetration in the skull or laceration of the skin. Be sure to tighten the head pin with utmost care.

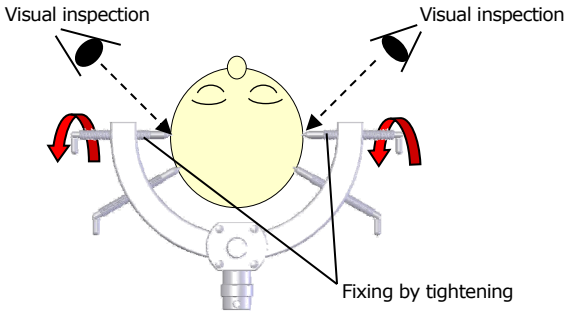


Fig.7

- As with the progress of the operation, attach the basal frame, slide adjuster, and brain spatula to the product.

Warning/Caution

1. Fundamental precautions

・Prior to use, ensure you sufficiently understand the Instruction for Use of Head Pin. Use the product according to the Instruction for Use while being attentive to the safety of the patient. [Lowering of holding force, rattling, injury, penetration, or laceration could occur.]

・When retracting the scalp with the scalp hook retractor, do not secure the ball chain by winding it around and applying tension to the mounting bracket of the spring hook adjuster.
[The ball chain may break due to the bending load. (Fig.8)]

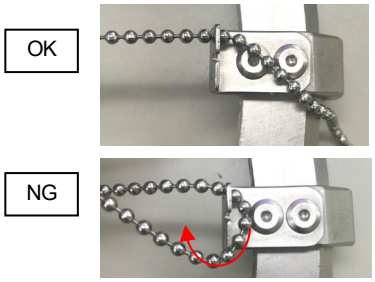


Fig.8

・When retracting the scalp with the scalp hook retractor, select the indent in the mounting bracket that is appropriate for the retraction direction, and insert the ball chain completely into the indent to secure it.
[Retracting in the wrong direction will apply a force that may pull the ball chain out of the indent and that may result in the ball chain slipping out of the mounting bracket. [Fig.9]]

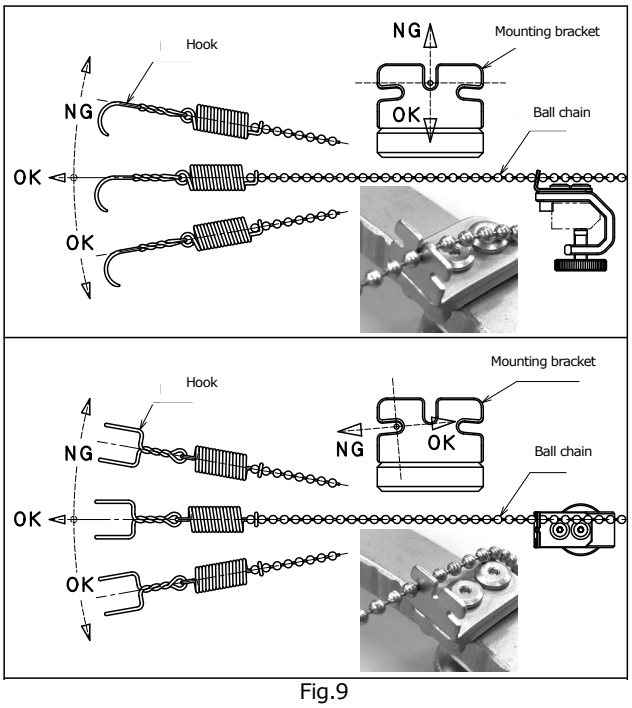


Fig.9

・When fixing the Flexible Clamp II, first make sure that there are no hands, fingers, or cords at the base of the joint. [Hands, fingers, or cords may be caught.]

・When loosening the clamp screw of the Compact Head Holder II, stop if you feel resistance to the operation (Fig. 10). The clamp screw is processed to prevent the part from coming off, but if the clamp screw is too loose, it may not operate properly due to sticking of the screw part, or

the part may fall off due to damage to the processed part.

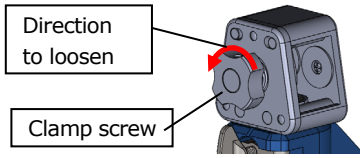


Fig.10

2. Defect/Adverse event

Defect

- Lowering of holding force
- Rattling
- Breakage
- Crack
- Deformation
- Deterioration

Adverse events

- Injury
- Penetration
- Laceration
- Contamination

3. Other cautions.

(1) Prior to installation, remove the head board of the operating table. This product cannot be used with the head board attached to the operating table.

(2) 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

(3) Before fixing the skull, make sure that all the joints are securely fixed.

(4) Upon fixing the head pins, do not adjust the bottom and top side, but the intermediate portion of the skull.

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

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 soft nylon brush or a low pressure water jet for cleaning.

(1)-5 To avoid damage, do not use a metal brush, coarse polishing agents, or apply excessive force when handling the device.

(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)
Cleaning with an ultrasonic cleaning machine or a jet cleaning is acceptable for the following products. However Thermal Disinfection cannot be used for the following products. As such, any cleaning program for the following products should exclude the Thermal Disinfection process

Code No.	Product Description
07-952-03	Flexible Base Unit II
07-983-02	Frame Unit
07-951-11	Smart Fix C Holder

(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 Lubricate as described the attached lubricant application manual for Flexible Base Unit II.

(4)-3 Either soak the Retractor Slide Adjustor II in a water-based, anticorrosive lubricant or apply the lubricant to the parts indicated by the arrows in the following fig (Fig.11), and then disinfect the product. [Insufficient lubricant can cause sticking problems.]
Apply about 0.06 to 0.10 ml of lubricant (equivalent to one drop) to each place.

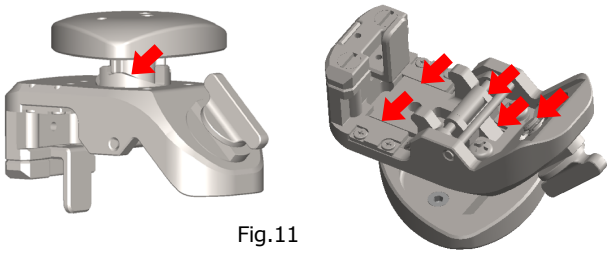


Fig.11

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
①II -1	Bracket Bar	Yes	No
①II -2	Flexible Clamp A II	Yes	No
①II -3	Flexible Clamp B II	Yes	No
①II -4	Compact Head Holder II	Yes	No
①II -5	Head Holder Base II	Yes	No
①II -6	120 mm Arm	Yes	No
①II -7	180 mm Arm	Yes	No
①II -8	Conversion Adapter II	Yes	No
②-1	Frame	Yes	No
②-2	Short Handle	Yes	No
②-3	Long Handle	Yes	No
③	Hand Rest R	Yes	Yes
④	Hand Rest L	Yes	Yes
⑤II	Retractor Slide Adjustor II	Yes	Yes
⑥	Spring Hook Adjustor	Yes	Yes
⑦	Sub Hole Attachment	Yes	Yes
⑧	Cotton Plate Adjustor	Yes	Yes

Yes: Applicable No: Not applicable

Table 2: Applicable Disinfectant

		Disinfectant	
		Iodine	Alcohol
①II -1	Bracket Bar	No	Yes
①II -2	Flexible Clamp A II	No	Yes
①II -3	Flexible Clamp B II	No	Yes
①II -4	Compact Head Holder II	No	Yes
①II -5	Head Holder Base II	No	Yes
①II -6	120 mm Arm	No	Yes
①II -7	180 mm Arm	No	Yes
①II -8	Conversion Adapter II	No	Yes
②-1	Frame	No	Yes
②-2	Short Handle	No	Yes
②-3	Long Handle	No	Yes
③	Hand Rest R	No	Yes
④	Hand Rest L	No	Yes
⑤II	Retractor Slide Adjustor II	No	Yes
⑥	Spring Hook Adjustor	No	Yes
⑦	Sub Hole Attachment	No	Yes
⑧	Cotton Plate Adjustor	No	Yes

Yes: Applicable No: Not applicable

Table 3: Applicable Sterilization Method

		Sterilization		
		Steam	EOG	Low temperature hydrogen peroxide gas plasma
①II -1	Bracket Bar	Yes	Yes	No
①II -2	Flexible Clamp A II	Yes	Yes	No
①II -3	Flexible Clamp B II	Yes	Yes	No
①II -4	Compact Head Holder II	Yes	Yes	No
①II -5	Head Holder Base II	Yes	Yes	No
①II -6	120 mm Arm	Yes	Yes	No
①II -7	180 mm Arm	Yes	Yes	No
①II -8	Conversion Adapter II	Yes	Yes	No
②-1	Frame	Yes	Yes	No
②-2	Short Handle	Yes	Yes	No
②-3	Long Handle	Yes	Yes	No
③	Hand Rest R	Yes	Yes	Yes
④	Hand Rest L	Yes	Yes	Yes
⑤II	Retractor Slide Adjustor II	Yes	Yes	Yes
⑥	Spring Hook Adjustor	Yes	Yes	Yes
⑦	Sub Hole Attachment	Yes	Yes	Yes
⑧	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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