MIZUHO

MES-CK07-986-00EN-0

PREPARED: (2020-11-11) (Version 10)

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

CE
CE 0123

Head Pin, Spring Hook

Instruction for Use

Trade Name: Radiolucent Multi-purpose Head Frame

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 the 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. When fixing the skull, excessively tightening the head pins may injure the patient and/or result in depression of the skull, possibility of penetration and depression in the skull bone.
3. Do not excessively recline the frame too much.

   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 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 head pin to the skull temporal bone. The shock may cause epidural hematoma or cerebral contusion.

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. Handle with care

   Handle this product with care, as it can be deformed or damaged. Rough handling could significantly reduce the service life of devices and appliances.
5. Prohibition of use of polishing powder and wire wool

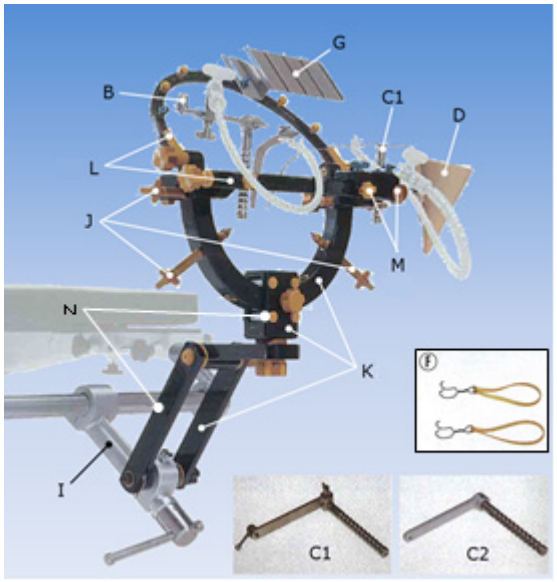
   When cleaning this product, do not attempt to polish its surfaces with rough polishing powder or wire wool. This could cause scratches on the surface of this product and result in rust or corrosion.
6. Prohibition of use of acid and household detergents

   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.
7. Do not tighten the Head Arm Base without inserting the Radiolucent Rotatable Head Holder as shown below. Failure to do so may permanently deform the product causing it to become unusable.

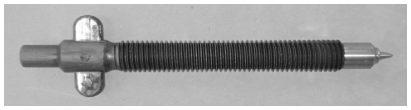
Symbol mark for labeling

MD : Medical Device

Specifications



J: 07-986-07



№	Code No.	Product Description
B	07-981-09	Adjustable Hand Rest with Slide
C1	07-981-04	Adjustable Hand Rest with Dome screw
C2	07-981-03	Hand Rest
D	07-981-06	Instrument Receptacle
F	07-985-15	Spring Hook, (Titanium) with Elastic band
G	07-981-07	Cotton Plate
I	07-952-01	Head Arm Base
	07-952-07	Head Arm Base, Pin dia. 19mm
	07-952-08	Head Arm Base, Pin dia. 16mm
J	07-986-07	Head Pin, (Radiolucent, Carbon 2)
K	07-986-04	Radiolucent Rotatable Head Holder
L	07-986-05	Radiolucent Basal Frame
M	07-986-06	Radiolucent Slide Adjuster
N	07-986-03	Radiolucent Head Frame Up Grade Kit

＜Set product＞

Code No.	Product Description
07-986-60	Radiolucent Head Frame Basic Set

＜07-986-60 : Set details＞

№	Code No.	Product Description	Qty
B	07-981-09	Adjustable Hand Rest with Slide	1
C1	07-981-04	Adjustable Hand Rest with Dome screw	1
C2	07-981-03	Hand Rest	1
D	07-981-06	Instrument Receptacle	1
G	07-981-07	Cotton Plate	1
K	07-986-04	Radiolucent Rotatable Head Holder	1
L	07-986-05	Radiolucent Basal Frame	1
M	07-986-06	Radiolucent Slide Adjuster	2

Please refer to the instruction for use for (F) Spring Hook (MES-CK07-985-05EN-0) and (J) Head pins (MES-CK07-986-07EN-0) for details.
Elastic bands for Spring Hook are consumption items.
Material: carbon fiber reinforced plastic, plastic, rubber, stainless steel, titanium alloy, aluminum alloy, polyester-based polyurethane

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 neurosurgical procedures.

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 (Head Pin, 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) Head Arm Base to the table with screws.
- Attach the Radiolucent Rotatable Head Holder to the Head Arm Base, and fix each joint to position the Radiolucent Rotatable 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. (Please refer to the figure below.)
- To fix the head, follow the procedures from 1 to 3 below. (Also see figures 1 to 3.)

1. Fix the head provisionally with sterilized head pins while an assistant holds the patient's head. (Figure 1-1) 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. (Figure 1-2)

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

(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.

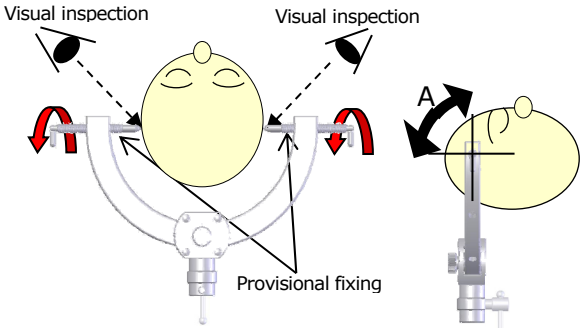


Fig.1-1 Fig.1-2

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" Figure 1-2) and tighten them to the extent that they can hold the patient's head.

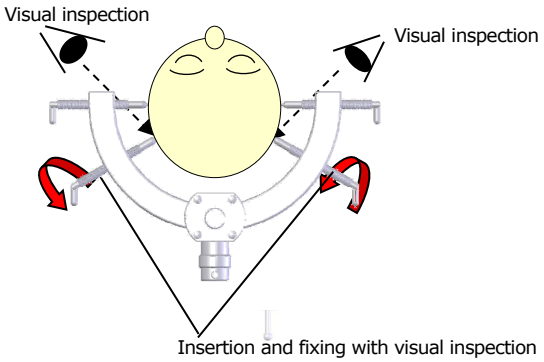


Fig.2

3. Finally turn the head pins 1/4 to 1/2 rotation which were provisionally fixed to tighten them further (Figure 3). 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

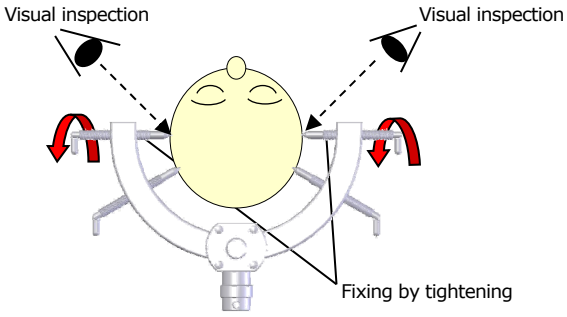


Fig.3

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

Warning/Caution

1. **WARNING**

Device must be sterilized by users in accordance with our recommended sterilization procedures or the validated sterilization conditions for which validity has been proven by medical organizations in each country or region.

2. Defect/Adverse event

Defect

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

Adverse events

- Cracking, depression, penetration, or other damage to skull
- Laceration or damage to the skin
- Epidural hematoma or cerebral contusion
- Broken pieces of metal from the damaged instrument left in the skull
- Contamination

3. Fundamental precautions

(1) Confirm that there is sufficient airway and no twisting of the patient's carotid when setting a head position for fixing cranium.

4. 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 fixing the skull, make sure that all the joints are securely fixed.

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

(4) During an operation, always monitor that there are no problems for the patient.

(5) Do not use iodine disinfectant for the device as it may cause permanent damage to the device.

(6) 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 follow recommendations may cause injury to the 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. Do not store on or near chemicals as the chemicals may cause damage to the device.

2. Service life

Subject to following manufacturer's specified maintenance, inspection and proper storage requirements:

- Head Pin, Spring Hook: 1 year
- Other components: 5 years

Maintenance/Inspection

1. Check prior to each use

(1) Operational and functional checks

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 clean 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 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 / 194.0-199.4°F, 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 at least.

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

Lubricating oil is completely removed by washing. After washing this product, apply a water-based, anticorrosive lubricant prior to sterilization.

3. Sterilization

Device must be sterilized by users in accordance with validated sterilization procedures that are regulated by medical organizations in each country or region.

Table 1: Applicable Detergent

		Detergent	
		neutral	alkaline
B	Adjustable Hand Rest with Slide	Yes	Yes
C1	Adjustable Hand Rest with Dome screw	Yes	Yes
C2	Hand Rest	Yes	No
D	Instrument Receptacle	Yes	No
F	Spring Hook, (Titanium)	Yes	No
	Elastic band	Yes	No
G	Cotton Plate	Yes	Yes
I	HEAD ARM BASE Head Arm Base, Pin dia. 19mm Head Arm Base, Pin dia. 16mm	Yes	No
J	Head Pin, (Radiolucent, Carbon 2)	Yes	No
K	Radiolucent Rotatable Head Holder	Yes	No
L	Radiolucent Basal Frame	Yes	No
M	Radiolucent Slide Adjuster	Yes	No
N	Radiolucent Head Frame Up Grade Kit	Yes	No

Yes: Applicable No: Not applicable

Table 2: Applicable disinfectant

		Disinfectant	
		iodine	alcohol
B	Adjustable Hand Rest with Slide	No	Yes
C1	Adjustable Hand Rest with Dome screw	No	Yes
C2	Hand Rest	No	Yes
D	Instrument Receptacle	No	Yes
F	Spring Hook, (Titanium)	No	Yes
	Elastic band	No	Yes
G	Cotton Plate	No	Yes
I	HEAD ARM BASE Head Arm Base, Pin dia. 19mm Head Arm Base, Pin dia. 16mm	No	Yes
J	Head Pin, (Radiolucent, Carbon 2)	No	Yes
K	Radiolucent Rotatable Head Holder	No	Yes
L	Radiolucent Basal Frame	No	Yes
M	Radiolucent Slide Adjuster	No	Yes
N	Radiolucent Head Frame Up Grade Kit	No	Yes

Yes: Applicable No: Not applicable

Table 3: Applicable sterilization method

		Sterilization		
		Steam	EOG	low temperature hydrogen peroxide gas plasma
B	Adjustable Hand Rest with Slide	Yes	Yes	Yes
C1	Adjustable Hand Rest with Dome screw	Yes	Yes	Yes
C2	Hand Rest	Yes	Yes	No
D	Instrument Receptacle	Yes	Yes	Yes
F	Spring Hook, (Titanium)	Yes	Yes	**Yes**
	Elastic band	No	Yes	No
G	Cotton Plate	Yes	Yes	Yes
I	HEAD ARM BASE Head Arm Base, Pin dia. 19mm Head Arm Base, Pin dia. 16mm	Yes	Yes	No
J	Head Pin, (Radiolucent, Carbon 2)	Yes	Yes	No
K	Radiolucent Rotatable Head Holder	Yes	Yes	No
L	Radiolucent Basal Frame	Yes	Yes	**Yes**
M	Radiolucent Slide Adjuster	Yes	Yes	**Yes**
N	Radiolucent Head Frame Up Grade Kit	Yes	Yes	No

Yes: Applicable

Yes: Applicable (Low temperature hydrogen peroxide gas plasma sterilization does not affect the characteristics of the product. However, it may discolor the surface of the product.)

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 / 249.8°F	15 Min
126°C / 258.8°F	10 Min
134°C / 273.2°F	3 Min

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 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 safety use of this instrument, conduct periodic checks by the manufacturer or the agent recognized by the manufacturer. Maintenance and check by other agents could cause the adverse events and the decrease of the performance and the function. To schedule the periodic check, contact 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.

Manufacturer

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