MIZUHO

** MES-CK07-980-02EN-0

PREPARED: (2019-03-11) (Version 6)**
(2018-11-01) (Version 5) *

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

CE

Head Pin,
Spring Scalp Hook Retractor, SUS

CE 0123

Instruction for Use

Trade Name: 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 manufacturers 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

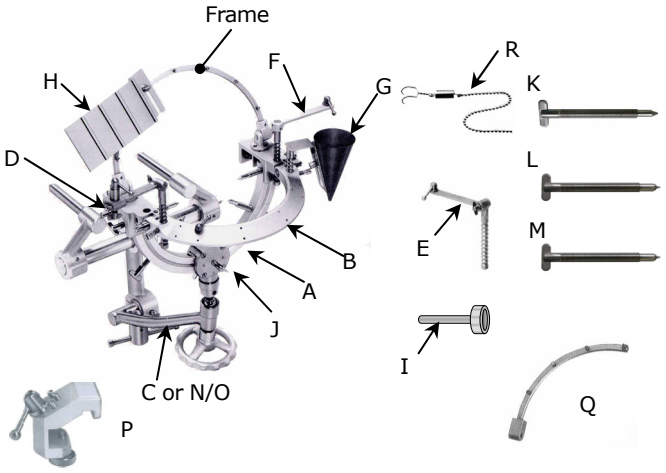
When the device is used on a patient with, or suspected of having CJD or vCJD, make sure to adhere to the most recent and updated restrictions available in each country and/or region for its reuse. Be cautious of the possibility of secondary infection. Refer to www.a-k-i.org or AAMI Standard ST79 for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

2. 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. 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 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 cracking of the skull, skull depression, skull penetration and skin laceration. Also, avoid inserting a head 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. Prohibition of use of chemicals
   Avoid exposing this product to chemicals. Doing so could damage this product due to corrosion.
3. 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.
4. 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.
5. 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.
6. Do not tighten the head arm base without the table attachment and Head Holder inserted and as shown. Failure to do so may permanently deform the product causing it to become unusable.

****Shape / Structure**



Material: stainless steel, aluminum alloy, plastic, titanium alloy

№	Code#	Description
A	07-951-00MM	Head holder
B	07-981-02	Basal frame/Semi-Circular Frame
C	07-952-00	Table attachment
D	07-981-09	Adjustable hand rest with slide
E	07-981-04	Adjustable hand rest with dome screw
F	07-981-03	Hand rest
G	07-981-06	Instrument receptacle
H	07-981-07	Cotton plate
I	(07-981-02)	Handle*
J	(07-951-00MM)	Box joint*
K	07-951-01MM	Head Pin, Standard, SUS*
L	07-951-02MM	Head Pin, Short Tip, for Adult, SUS*
M	07-951-03MM	Head Pin, Short Tip, for Pediatric, SUS*
N	07-952-05	Table attachment for 2080
O	07-952-06	Table attachment for 3080
P	07-955-01	Slide Adjustor For Retractor
Q	07-981-10	Quarter Frame
R	07-954-00MM	Spring Scalp Hook Retractors, SUS*

Handle (I) is included as part of Basal frame/Semi-Circular Frame (B).
Box joint (J) is included as part of Head holder (A).
Head pins (K, L, M) and Spring Scalp Hook Retractors (R) are sold separately.

Table attachments (N, O), Slide Adjustor (P) and Quarter Frame (Q) are optional accessories and sold separately.

Please refer to the instructions for use for (R) Spring Scalp Hook Retractors, SUS (CK07-954-00MMEN-0) and (K) (L) (M) Head pins (CK07-951-01MMEN-0) for details.

＊ 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.

＊ Instructions for Use

Before using this product, refer to the related instructions for use (Head Pin, Spring Scalp Hook Retractors). Before using this product, inspect, wash, and sterilize in accordance with these instructions.
Prior to use, refer to the maintenance and inspection section.

Outline of use:

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

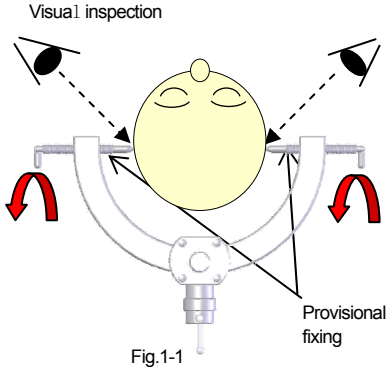


Fig.1-1

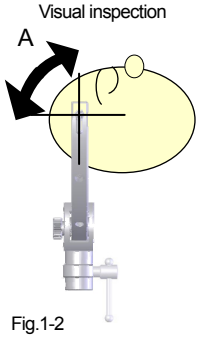


Fig.1-2

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.

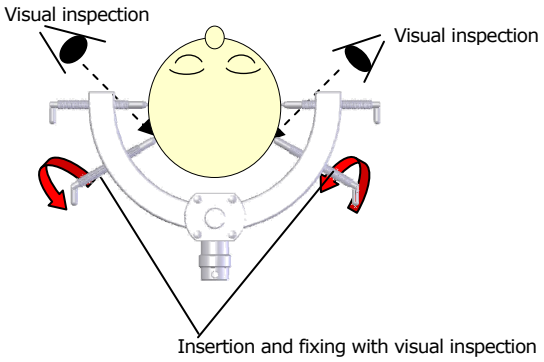


Fig.2

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

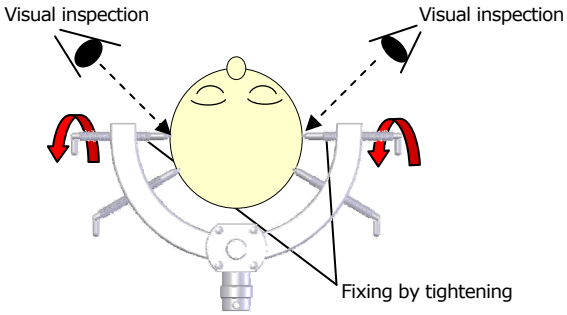


Fig.3

- As with the progress of the operation, attach the basal frame, slide adjuster, and brain spatula to the product.
- Wash, sterilize, and dry the product immediately after operation and store it in a proper place.

＊ CAUTIONS & WARNINGS

1. **WARNING**

Prior to use the device must be sterilized under the standard sterilization conditions 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
- Tips or pieces of head pins 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.

(2) Fit cranium adequately so not to excessively screw head pins as there is a possibility of cracking, depression, penetration or other damage to the skull bone.

(3) **WARNING:** 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. [Doing so may result in reduced vision or loss of sight.]

(4) **CAUTION**: Prior to use, also read these instructions and instructions for use for the Head Pin and Scalp Hook Retractors. 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 and/or injury to patient and/or healthcare worker.

4. Other cautions

(1) Before installing this product on an operating table, fully inspect for any damage, broken and/or failed or missing parts. 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) This device is only used for securing the head in neurosurgical procedures.

(6) ONLY use this product with recommended products.

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

(8) Only trained health professionals (doctor, nurse and so on) are allowed to use this product.

(9) 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

(10) Be sure to clean the device after use. When using a detergent upon cleaning, be sure to use a neutral detergent.

** 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 the following specified maintenance, inspection and proper storage requirements:

- Head Pin, Spring Scalp Hook Retractor, SUS: 1 year
- Other Components: 5 years

** 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 Only use distilled water or deionized water (reverse osmosis) to wash this product.

(1)-7 Only use fully deionized water (reverse osmosis) 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)

Note: Thermal Disinfection cannot be used for 07-952-00 Table Attachment

(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) Only use distilled or deionized water

Use distilled or deionized water to wash 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. Do not use without lubricant oil to sliding part, or galling could occur. After washing this product, apply a water-based anticorrosive lubricant prior to sterilization.

3. Sterilization

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

(2) Our recommended sterilization parameters are as follows.

Table 1: Applicable Detergent

		Detergent	
		neutral	alkaline
A	Head holder	Yes	No
B	Basal frame/Semi-Circular Frame	Yes	No
C	Table attachment	Yes	No
D	Adjustable hand rest with slide	Yes	Yes
E	Adjustable hand rest with dome screw	Yes	Yes
F	Hand rest	Yes	No
G	Instrument receptacle	Yes	No
H	Cotton plate	Yes	Yes
I	Handle	Yes	Yes
J	Box joint	Yes	No
K	Head Pin, Standard, SUS	Yes	Yes
L	Head Pin, Short Tip, for Adult, SUS	Yes	Yes
M	Head Pin, Short Tip, for Pediatric, SUS	Yes	Yes
N	Table attachment for 2080	Yes	No
O	Table attachment for 3080	Yes	No

P	Slide Adjustor For Retractor	Yes	No
Q	Quarter Frame	Yes	No
R	Spring Scalp Hook Retractors, SUS	Yes	No

** Yes: Applicable No: Not applicable

Table 2: Applicable disinfectant

		disinfectant	
		iodine	alcohol
A	Head holder	No	Yes
B	Basal frame/Semi-Circular Frame	No	Yes
C	Table attachment	No	Yes
D	Adjustable hand rest with slide	No	Yes
E	Adjustable hand rest with dome screw	No	Yes
F	Hand rest	No	Yes
G	Instrument receptacle	No	Yes
H	Cotton plate	No	Yes
I	Handle	No	Yes
J	Box joint	No	Yes
K	Head Pin, Standard, SUS	No	Yes
L	Head Pin, Short Tip, for Adult, SUS	No	Yes
M	Head Pin, Short Tip, for Pediatric, SUS	No	Yes
N	Table attachment for 2080	No	Yes
O	Table attachment for 3080	No	Yes
P	Slide Adjustor For Retractor	No	Yes
Q	Quarter Frame	No	Yes
R	Spring Scalp Hook Retractors, SUS	No	Yes

** Yes: Applicable No: Not applicable

Table 3: Applicable sterilization method

		Sterilization		
		Steam	EOG	low temperature hydrogen peroxide gas plasma
A	Head holder	Yes	Yes	No
B	Basal frame/Semi-Circular Frame	Yes	Yes	No
C	Table attachment	No	Yes	No
D	Adjustable hand rest with slide	Yes	Yes	Yes
E	Adjustable hand rest with dome screw	Yes	Yes	Yes
F	Hand rest	Yes	Yes	No
G	Instrument receptacle	Yes	Yes	Yes
H	Cotton plate	Yes	Yes	Yes
I	Handle	Yes	Yes	Yes
J	Box joint	Yes	Yes	Yes
K	Head Pin, Standard, SUS	Yes	Yes	Yes
L	Head Pin, Short Tip, for Adult, SUS	Yes	Yes	Yes
M	Head Pin, Short Tip, for Pediatric, SUS	Yes	Yes	Yes
N	Table attachment for 2080	Yes	Yes	No
O	Table attachment for 3080	Yes	Yes	No
P	Slide Adjustor For Retractor	Yes	Yes	No
Q	Quarter Frame	Yes	Yes	No
R	Spring Scalp Hook Retractors, SUS	Yes	Yes	No

** 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 / 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 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.

* **Matters related to warranty period**

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.

Name and address of manufacturer

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