

Instructions for Use

Trade Name: MRI 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. Not doing so may give rise to serious problems or adverse events.

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 the market outside the US

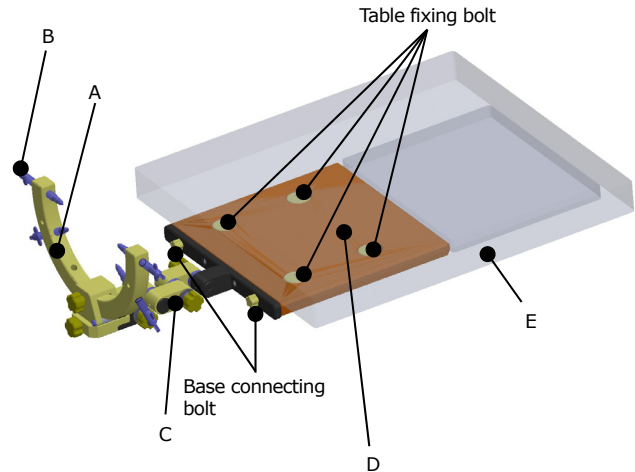
When the device is used on a patient with, or suspected of having CJD or vCJD, make sure to adhere to the most recent and updated restrictions available in each country and/or region for its reuse. Be cautious of the possibility of secondary infection. Refer to www.a-k-i.org or AAMI Standard ST79 for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

2. 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 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 alkaline, acid, and household detergents
Use only medical neutral detergents (pH 6 to 8) to clean this product. Do not use any alkaline, acid, or household detergent. Washing this product with an improper detergent could result in discoloration or corrosion.
7. Do not use low temperature hydrogen peroxide gas plasma sterilization.
This product is not suitable for sterilization with hydrogen peroxide low temperature gas plasma. It may discolor the surface of the product or affect the feature of the product.

Shape / Structure



Code No.	Product Description
A	07-988-51 MRI Head Arm HM
C	07-988-04 MRI Head Frame Arm with Joint
D	07-988-05 MRI Base Table 7300
E	07-988-06 MRI Pad for 7300 Head Frame

Material: glass-fiber reinforced resin, resin, titanium alloy



Code No.	Product Description
B	07-988-02 MRI Head Pin Ti
B	07-988-03 MRI Head Pin Ti 90mm

Material: titanium alloy

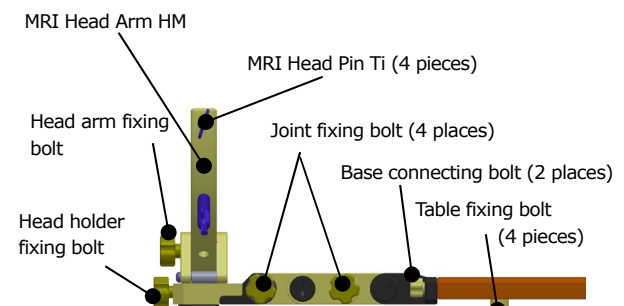
Please refer to the instructions for use for MRI Head pin Ti and MRI Head Pin Ti 90mm for details.

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

Outline of the operation method is as follows. Refer to the figure below for each part name.



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

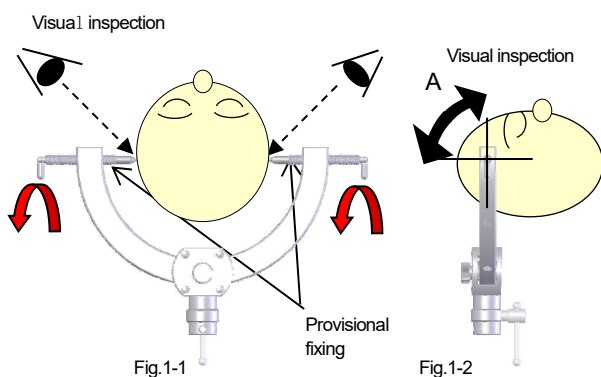
Outline of the operation method is as follows.

1. Align the screw hole of the top plate for the head of the dedicated operating table with the screw hole of the base table, and fix securely with table fixing bolts (4 pieces).
2. As for various MRI Head Frames, adjust and fix the positions of the sliding part and the joint by turning the head arm fixing bolt, joint fixing bolt, and head holder fixing bolt so that it becomes vertical against the floor surface with the both ends horizontal. As for compatible multipurpose head frame 7300, make sure that the two base connecting bolts are securely tightened.
3. Decide the head position at the position where the path to the affected part after opening the head is optimal, and fix the cranium with sterilized MRI Head Pin Ti. The pitch of this head pin is 1.75 mm/rotation.
4. If the MRI Head Pin Ti hits the table at the time of rotation, the rotation angle can be further enlarged by changing the head pin hitting the table to the MRI titanium head pin length 90 mm (MRI Head Pin Ti 90mm).
5. To fix the head, follow the procedures from 1 to 3 below (Figures 1 to 3)

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

(1)-1 If the patient's head does not move around the Ti head pin as the center axis as the arrow "A" (Figure 1-2), the Ti head pin may have been tightened too much. Loosen the Ti head pin until the patient's head will move around the Ti head pin as the center axis.

(1)-2 If the skull is fixed unstably and the patient's head moves up and down, **tighten the Ti head pin gradually by examining the position** until the patient's head does not move up and down and will move around the Ti head pin as the center axis.



- (2) Insert the Ti head pins into two places **while examining the Ti head pin tip** in order to stop the patient's head from moving around the Ti 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.

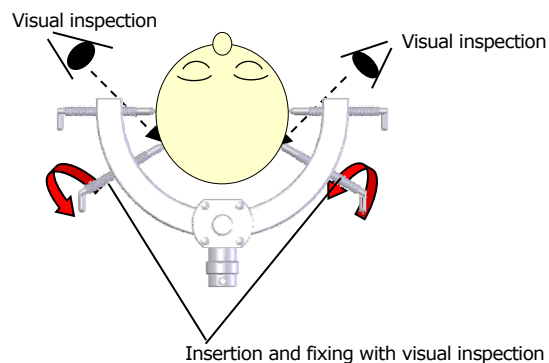


Fig.2

- (3) Finally turn the Ti head pins 1/4 to 1/2 rotation which were provisionally fixed to tighten them further (Figure 3). **Excessive over-tightening by the Ti head pin may result in harm to the patient (e.g. cracks, depressions, or penetrations in the skull or lacerations of the skin). Be sure to tighten the Ti head pin with utmost care.**

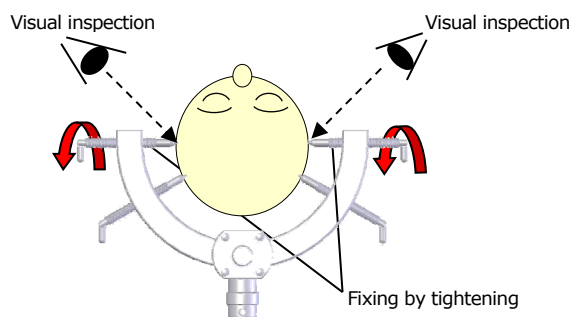


Fig.3

6. Make sure that the head frame and MRI do not interfere with a checking device which is the accessory of the dedicated operating table system.

CAUTIONS & WARNINGS

1. WARNING

(1) Sterilization

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) Fixation of head and neck

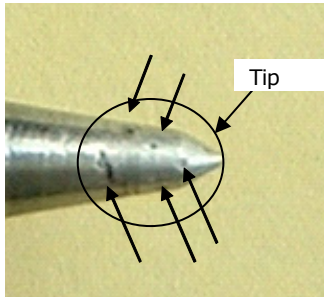
When setting the head position to fix the cranium, ensure the patient's airway is adequately secured and that the carotid artery is not kinked. When fixing the cranium with the head pin, fix it appropriately so as not to over tighten, paying sufficient attention to penetration of the skull, scalp involvement, compression necrosis, and so on. There is a possibility of skull collapse. Mount it paying sufficient attention to children and osteoporosis patients, particularly.

(3) About the head pin

• Corrosion

Corrosion (verruculate holes: see the picture below) which has considerably progressed can be found with the naked eye, but it is difficult to detect small corrosions with the naked eye. Please check the tip with a loupe or microscope, etc. **If corrosion is found on the tip surface, do not use and contact your Mizuho representative for replacement. Be sure to aware the complications associated to corrosion as well (e.g.,**

breakage of a headpin, failure to adequately retain the skull in a fixed position, the tip of broken headpin buried to a skull, material break down, failure to perform, etc.)



When cleaning, rinse with distilled water or deionized water so that body fluids, chemicals, detergents, or residual chlorine etc. in tap water do not remain on the surface, and dry quickly after washing. (Please refer to items related to maintenance and inspection.)

Complications associated to corrosion

• Damage

Be sure to observe the tip using a magnifier or a microscope when dropping onto a hard place such as the floor. Check that there is no damage before use. Do not bring the tip of the head pin into contact with other devices during cleaning.

2. Defect/Adverse event

Defect

- Corrosion or pitting caused by use of chemicals
- Damage or breakage caused by the corrosion or pitting

Adverse event

- Broken pieces of metal from the damaged instrument falling into the patient.
- The presence or absence of breakage of the head pin tip after surgery

If damage is found, check the presence of damaged fragments in the patient's body in CT or MRI film.

3. Cautions on use of other tools in combination with this product

- 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.
- Designated operating tables are as follows:

18-352-20	MST-7300BX-MRI-Mg-T(ASIA)
18-352-21	MST-7300BX-MRI-NMg-P(ASIA)
18-352-22	MST-7300BX-MRI-NMg(ASIA)
18-352-30	MST-7300BX-MRI-Mg-T(EU)
18-352-31	MST-7300BX-MRI-NMg-P(EU)
18-352-32	MST-7300BX-MRI-NMg(EU)
18-352-70	MST-7300BX-MRI-Mg-T(US)
18-352-71	MST-7300BX-MRI-NMg-P(US)
18-352-72	MST-7300BX-MRI-NMg(US)

4. Indication to the elderly, infant, and person with osteoporosis or skull fracture

When it is used for the elderly, risk of fractures, **cracks, depressions, or penetrations in the skull or lacerations of the skin**, etc. may occur due to loads or moments caused by operations during surgery owing to osteoporosis, etc. Please use it carefully.

5. Other caution

- This product should be mounted on a dedicated operating table. It cannot be mounted on operating tables other than dedicated one.
- Before using this product, inspect appearance and construction. Do not use in case there are any deformations, cracks or anything wrong in its construction or functionality/sliding motions.
- Before fixing the skull, make sure that all the joints are securely fixed.
- Upon fixing the head pins, do not fix the bottom and top side, but the intermediate portion of the skull.

Storage/Life

1. Storage

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. Life

Service life of this product

(Subject to following manufacturer's specified maintenance, inspection and proper storage requirements.)

- MRI Head Arm HM : 5 years
- MRI Head Pin Ti : 1 year
- MRI Head Pin Ti 90mm : 1 year
- MRI Head Frame Arm with Joint : 5 years
- MRI Base Table 7300 : 5 years

Note: Even within the service life, if sudden failure, significant consumption, deterioration, or breakage, etc. of parts (mattresses and small parts, etc.) occurs depending on use situation or use frequency, replacement of corresponding parts is necessary.

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

Note: In regards to clean, disinfection, and sterilization procedures for the following products, please refer to the instructions for use for MRI Head Pin Ti (CK07-988-02EN-0) for details.

B	MRI Head Pin Ti
	MRI Head Pin Ti 90mm

(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 07-988-05 MRI Base Table 7300.

- (2) Fully dry this product immediately after washing it
Do not leave product wet as residual water may cause damage or staining.
- (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 staining 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.

● Applicability of the detergent

		Washing		
		Neutral	Alkali	Enzyme
A	MRI Head Arm HM	Yes	No	No
C	MRI Head Frame Arm with Joint	Yes	No	No
D	MRI Base Table 7300	Yes	No	No
E	MRI Pad for 7300 Head Frame	No	No	No

● Applicability of the disinfection

		Disinfection		
		alcohol	iodine	chlorine
A	MRI Head Arm HM	Yes	No	No
C	MRI Head Frame Arm with Joint	Yes	No	No
D	MRI Base Table 7300	Yes	No	No
E	MRI Pad for 7300 Head Frame	Yes	No	No

● Applicability of the sterilization

		Sterilization		
		steam	EOG	plasma
A	MRI Head Arm HM	Yes	Yes	No
C	MRI Head Frame Arm with Joint	No	No	No
D	MRI Base Table 7300	No	No	No
E	MRI Pad for 7300 Head Frame	No	No	No

- 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

CDC (Refer to the Guideline)	
Temp.	Minimum exposure time
132°C / 270°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 market 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

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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The Netherlands