

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

PREPARED:(2023-11-21) (Version 3)

Instruction 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. 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 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 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 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 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.

Specifications



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

Material: 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.

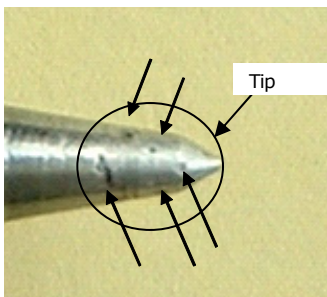
Instructions for use

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

Warning / Caution

1. Important fundamental cautions
 - (1) Sterilization
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) Fixing head and neck
Confirm that there is sufficient airway and no twisting of the patient's carotid when setting a head position for fixing cranium. Fit cranium adequately not to screw a head pin too much and avoid skull penetration, scalp screwed in and compression necrosis. There is a possibility of depression in the skull bone. Be especially careful when using for a child or osteoporotic patient.
 - (3) About the head pin
 - Corrosion
Corrosion (vermiculate 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.)

• Damage

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

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
- Lowering of holding force
- Breakage
- Crack
- Deformation
- Discoloration

Adverse event

- Broken pieces of metal from the damaged instrument falling into the patient
- The broken of the head pin tip
- Serious health damage
- Injury
- Penetration
- Laceration
- Contamination
- Allergic reaction
- Foreign body reaction

3. Interacting

- 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.

- Specified combination product

Code No. 07-988-51

Product Description: MRI Head Arm HM

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

When it is used for the elderly, 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

- Before using this product, inspect appearance and construction. Do not use in case there are any deformation, cracks or anything wrong in its constructions or functionality / sliding motion.
- 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: 1 year

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

Maintenance/Inspection

1. Check prior to each use

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

Conditions of cleaning validated by the manufacturer are as follows,

(1) Cleaning

- Clean the device immediately after use.
- Take care not to allow the head pins to make contact with other devices.
- Use the deionized water as much as possible when rinsing the product.

<In case of using washer disinfector (automatic washing)>

Stage	Procedure	Temperature (°C [°F])	Time (min)	Quality of water	Remarks
I	Preclean	10 [50]	3	Tap water (Drinking water)	10 °C (normal temperature)
II	Washing	50 [122]	10		Neutral enzyme type detergent 0.5%
III	Rinsing	10 [50]	1	Deionized water (or Tap water)	10 °C (normal temperature)
IV	Rinsing	10 [50]	1		10 °C (normal temperature)
V	Hot water Disinfection	-	-	Deionized water (or Tap water)	Follow the program of the device
VI	Drying	-	-	-	

<In case of using Ultrasonic cleaner>

- ① Fully immerse this device in the water (tap water) of the washing tank.
- ② Clean the product using ultrasonic cleaner.
Cleaning time: 40 °C (104 °F), 10 minutes
Detergent: Neutral enzyme type detergent 0.5%
- ③ Rinse the product with running water (deionized water or tap water) for a minute.
- ④ Dry thoroughly.

(2) Inspection

Refer to the Warning/Caution section as well.

Inspect the tip of the Head Pins using a loupe or a microscope. Visually inspect the other parts. Do not use the product if the following conditions are found.

- Corrosion
- Pitting
- Breakage
- Deformation
- Discoloration
- Screw is crushed or damaged

- Remaining contamination

(3) Packaging

Pack the device using standard medical packaging material (non-woven fabric or sterilized bag) with protective sterile barrier complying with ISO 11607 for steam sterilization.

(4) Sterilization

Perform sterilization treatment under sterilization condition "134 °C (273 °F), 3 minutes or more" with a prevacuum type autoclave sterilizer which was confirmed to function properly.

Do not use low temperature hydrogen peroxide gas plasma sterilization. The surface fades and affects its properties.

(5) Storage

Do not store the device in high temperatures, or in areas with high humidity and/or where the temperature varies. Please store the device in clean dust-free and nonsplashed area.

3. General Requirements

- (1) Sterilization equipment should be validated to assure that it sterilizes specific load configurations properly. The end user is responsible to validate the sterilization process in the individual sterilizer and assure the sterility.
- (2) Sterilization equipment should be cleaned and maintained in accordance with standardized operating procedures specified by its manufacturer.

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.



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