

Instructions for Use

**Trade Name: Radiolucent Multi-Purpose Head Frame
Head Pin, (Radiolucent, Carbon 2)**

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 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.

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 surfaces of this product and result in rust or corrosion.
5. 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.
6. 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
07-986-07	Head Pin, (Radiolucent, Carbon 2)

Material: titanium alloy, carbon fiber reinforced resin

Specification

Assigned combination product
Trade Name: Radiolucent Multi-Purpose Head Frame

Intended Purpose

This product is a surgical instrument used to hold the cranium for head and neck fixation. It is generally used in neurosurgical procedures.

Instructions for Use

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

CAUTIONS & WARNINGS

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. Important fundamental cautions

- Upon use of this device, be sure to fully understand this manual and the one for the radiolucent multi-purpose head frame in advance. Also, pay full attention to the patient safety and use the device in accordance with the manual. Failure to do so may cause serious defects or adverse events.
- 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 pin too much and avoid skull penetration, scalp rolled-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. Defect/Adverse event

- Defect
- lowering of holding force
 - rattling
 - breakage
 - crack
 - deformation
 - deterioration
- Adverse event
- serious health damage
 - injury
 - penetration
 - laceration
 - contamination

4. Other cautions

- Before using this product, inspect appearance and construction. Do not use if there are any deformations or cracks or anything wrong in 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.
- During an operation, always monitor that there are no problems for the patient.
- Be sure to clean the device after use. When using a detergent upon cleaning, be sure to use a neutral detergent.
- Use for fixing head in neurosurgical procedures only.
- Do not use iodine disinfectant for the device.

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 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
 - 2.1 Immediately wash with clean water
If exposed to bleach or antiseptic solutions, 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.
 - 2.2 Further remove any remaining contamination with a soft nylon brush.
 - 2.3 Select a proper detergent for each decontamination method and maintain appropriate density and handling.
 - 2.4 Use a soft towel, a soft nylon brush, or a water jet for cleaning.
 - 2.5 To avoid damage, do not use a metal brush, coarse polishing agents, or apply excessive force when handling the device.
 - 2.6 Reverse osmosis water is recommended to wash this product.
 - 2.7 Only use reverse osmosis water for final rinse.
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)
 - 2.8 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.
 - 2.9 Use distilled or deionized water at least
Use distilled or deionized 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.
 - 2.10 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, such as an autoclave, that are regulated by medical organizations in each country or region.

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.

Packing

1 piece per package

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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