

MES-CK07-951-01MMEN-0
PREPARED: (2023-07-28) (Version 3)

Instructions for Use

Trade Name: Head Pin SUS

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.
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.

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.

Contraindication / Prohibition

1. Use for intended purpose only
Use devices for their intended purposes only. Incorrect use could cause this product to break.
2. Prohibition of use of chemicals
Avoid exposing this product to chemicals. Doing so could damage this product due to corrosion.
3. 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.
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
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 household detergents
Use only medical detergents to clean this product. Do not use any household detergent. Washing this product with an improper detergent could result in discoloration or corrosion.

Code No.	Product Description
07-951-01MM	Head Pin, Standard, SUS
07-951-02MM	Head Pin, Short Tip, for Adult, SUS
07-951-03MM	Head Pin, Short Tip, for Pediatric, SUS

Material: stainless steel

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. See the instruction manual and pay attention to the procedure to fix patient's head.

Caution

1. Warning
 - 1.1 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.
 - 1.2 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 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.
2. Defect/Adverse event
 - 2.1 Defect
 - Corrosion and pitting caused by use of chemicals
 - Damage or breakage caused by the corrosion or pitting
 - 2.2 Adverse event
 - Broken pieces of metal from the damaged instrument falling into the patient.
 - Penetration or depression in the skull bone when inserting the screw pin
 - Scalp screwed in and compression necrosis by inserting the screw pin
3. Other caution
 - 3.1 Before using this product, inspect appearance and construction. Do not use if there are any deformations, cracks or anything wrong in sliding motion.
 - 3.2 During an operation, always monitor that there are no problems for the patient.
 - 3.3 Use for fixing head in neurosurgical procedures only.
 - 3.4 Do not use this product with other products.
 - 3.5 Only health professional (doctor, nurse and so on) allowed to use this product.

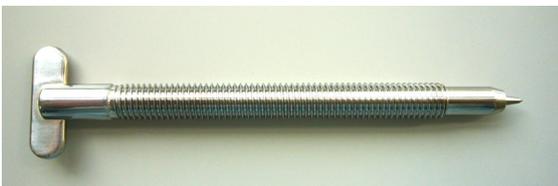
Storage/Life

1. Do not store the device in high temperature areas. Do not store in areas of high humidity where the temperature may vary wildly causing condensation. Do not store on or near chemicals.
2. Service life of this product: 1 year
(Subject to the specified maintenance, inspection and proper storage)

Maintenance / Inspection

1. Checking matters before use
 - 1.1 Operational and functional checks
Conduct daily and pre-operation checks of this product to make sure that it works properly.
2. Checking matters after use

Shape / Structure



2.1 Immediate washing with clean water

- 2.1.1 Wash and rinse with clean water immediately and immerse in neutral enzyme detergent in case the device is exposed to bleach or antiseptic solution, which may contain chlorine or iodine. Then remove all the contaminated matter by hand or an ultrasonic-cleaner.
- 2.1.2 Remove any remaining contamination with a brush.
- 2.1.3 Select a proper detergent for each decontamination method and maintain appropriate density and handling. Use of a neutral detergent is recommended.
- 2.1.4 Use a soft towel, a plastic brush or a water jet for cleaning.
- 2.1.5 Do not use a metal brush, coarse polishing agents, or apply excessive force when handling the device.
- 2.1.6 Use distilled or deionized water to wash this product.
- 2.1.7 Use fully demineralized water (Reverse Osmosis) for final rinse.
- 2.1.8 Using an ultrasonic washing machine simultaneously for this device is recommended.

2.2 Dry this product immediately after washing it.

- 2.2.1 After cleaning, please rinse the device fully, for more than 5 minutes, with warm or cold water without additives.
- 2.2.2 Dry this product immediately after washing it. Do not leave it wet for a longer time than necessary.

2.3 Use distilled or deionized water.

Use distilled water or deionized water to wash this product. Residual chlorine and organic matters in tap water could cause stains and rust.

2.4 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

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.

Application table of washing, disinfection and sterilization.

Washing	Neutral	Alkali	Enzyme
	○	○	○
Disinfection	Alcohol		Iodine
	○		×
Sterilization	Steam	EOG	Plasma
	○	○	○

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 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.

Packing

1 piece per pack

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.

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 damage on purpose. All other warranty terms and conditions are subject to regulations of MIZUHO Corporation.



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