

Instruction for Use

Trade Name: Smart Fix Head Holder (SF)

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 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 skull crack, skull depression, skull penetration and skin laceration, avoid inserting a head pin to the skull temporal bone.

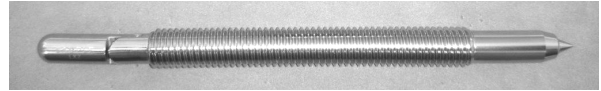
Contraindication/Prohibition

1. Use for intended purpose only
Use devices for their intended purposes only. Incorrect use could cause breakage of this product.
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 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 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.

Symbol mark for labeling

 : Medical Device

Specifications



Code No.	Product Description
07-951-33	Smart Fix Head Pin Standard
07-951-34	Smart Fix Head Pin Long

Material: Stainless Steel

Assigned combination product

Trade Name: Smart Fix Head Holder (SF)

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 neurosurgical procedures.

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
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. 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. 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.
4. Other caution
 - Before using this product, inspect appearance and construction. Do not use in case there are any deformation, crack or anything wrong in sliding motion.
 - During an operation, always monitor that there are no problems for the patient.
 - Use for fixing head in neurosurgical procedure only.

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, immediately wash: 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 plastic brush.
 - 2.3 Select a proper detergent for each decontamination method and maintain appropriate density and handling.
 - 2.4 Use a soft towel, a plastic brush, or a water gun 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 the 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 water or reverse osmosis water at least
Use distilled water or reverse osmosis water to wash and sterilize this product at least. 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.
Do not use this product without applying anticorrosive lubricant on its sliding part. [Galling could occur.]

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
	YES	YES	YES
Disinfection	Alcohol		Iodine
	YES		NO
Sterilization	Steam	EOG	Plasma
	YES	YES	YES

- Sterilization of the device may be accomplished by steam. The recommended sterilization parameters are as follows;

ISO/TS17665-2	
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 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 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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