

MES-CK07-951-33EN-0

PREPARED: (2017-10-26) (Version 3)\*\*  
(2015-11-30) (Version 2)\*

## Instructions for Use

Trade Name: Smart Fix Head Holder (SF)

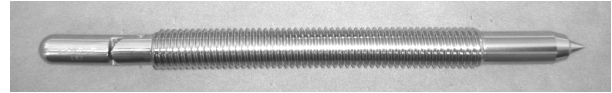
### Warning

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. Not doing so may give rise to serious problems or adverse events.
2. When the device is used on a patient where there is a suspicion of Creutzfeldt-Jakob Disease (CJD), 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](http://www.a-k-i.org) or AAMI Standard ST79 for more information related to cleaning and sterilization.
3. Possibility of penetration and depression in the skull bone. Hardness of skull bone is different with each person. Be careful and check with eyes when you insert a screw pin (head pin), not to insert beyond necessity to prevent skull crack, skull depression and skull penetration and skin laceration. Because the skull temporal bone (the temple area) is thin, insertion could cause skull crack, skull depression and skull penetration and skin laceration. Avoid inserting a screw pin to the skull temporal bone.

### Contraindication / Prohibition

1. Use for intended purpose only  
Use tools for their intended purposes only. Incorrect use could cause breakage of this product.
2. Use with specified products only  
Use this product with only 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. Handle with care  
Handle this product with care, as it can be deformed or damaged. Rough handling could significantly reduce the service life of tools and appliances.
6. 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.
7. 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.

### Shape / Structure



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

Material: Stainless Steel

### Intended Purpose

This product is a surgical instrument used to hold the cranium for fixing head and neck at a fixing position. It is generally used in neurosurgical procedure.

### Specification

Assigned combination product  
Trade Name: Smart Fix Head Holder (SF)

### 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 under the standard sterilization conditions or the validated sterilization conditions which validity is proven by medical organizations in each country or region.
  - 1.2 Fixing head and neck  
Confirm that there are sufficient airway maintenance and no twist of carotid for patient, when setting a head position for fixing cranium. Fit cranium adequately not to screw pin too much and be careful about skull penetration and 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.
2. Defect/Adverse event
  - Prohibition of use of chemicals  
Avoid exposing this product to chemicals. Doing so could damage this product and cause corrosion.
3. Other caution
  - 3.1 Before using this product, inspect appearance and construction.  
Do not use in case there are any deformation, crack 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 procedure 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 temperatures or in areas with high humidity where the temperature has drastic variations.
2. Service life of this product: 1 year  
(Subject to the specified maintenance, inspection and proper storage)

## Maintenance / Inspection

1. Operational and functional checks  
Conduct daily and pre-operation checks of this product to make sure that it works properly.
2. Immediate washing with clean water
  - 2.1 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.
  - 2.2 Remove any remaining contamination with a brush.
  - 2.3 Select a proper detergent for each decontamination method and maintain appropriate density and handling. Use of a neutral detergent is recommended.
  - 2.4 Use a soft towel, a plastic brush, or a water gun for cleaning.
  - 2.5 Do not use a metal brush, coarse polishing agents, or apply excessive force when handling the device.
  - 2.6 Use distilled water or deionized water to wash this product.
  - 2.7 Use fully demineralized water (Reverse Osmosis) for final rinse.
  - 2.8 Using an ultrasonic washing machine for this device simultaneously is recommended.
3. Dry this product immediately after washing it.
  - 3.1 Please rinse the frame fully, for more than 5 minutes, by warm or cold water without additives after cleaning.
  - 3.2 Dry this product immediately after washing it. Do not leave it wet for a longer time than necessary.
4. 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.
5. 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.
6. 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,

ISO17665-2	
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

- When the device is used on a patient where there is a suspicion of Creutzfeldt-Jakob Disease (CJD), make sure to adhere to the most recent and updated restrictions available in each country and/or region for its reuse.

Temp.	Minimum exposure time
134°C / 273.2°F	18 Min

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

### \* Name and address of manufacturer



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