

Instruction for Use

Trade Name: Smart Fix Head Holder (SF)

Warning

- 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.

- Prohibition of use during contact coagulation
Never allow the tip of an electro-surgical knife to make contact with this product during contact coagulation or a similar procedure.
- 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.

Please make sure to use the stopper sleeve upon fixing the skull. The device will help protect the skull and brain from the shock on the head through the head pin shaft by the ratchet mechanism of this product. (The shock may cause epidural hematoma or cerebral contusion.)

Contraindication/Prohibition

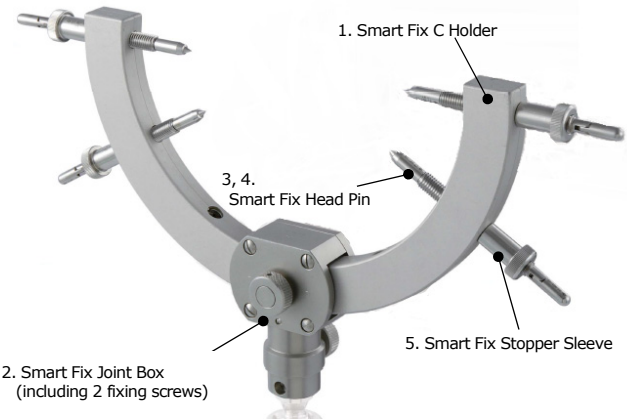
- Use for intended purpose only
Use devices for their intended purposes only. Incorrect use could cause breakage of this product.
- Use with specified products only
Use this product only with products specified by Manufacturer. Other products than those specified by Manufacturer could be incompatible with this product due to differences in design and development policies.
- Prohibition of use of chemicals
Avoid exposing this product to chemicals. Doing so could damage this product due to corrosion.
- 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.
- 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.

- 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.
- Prohibition of use of acid and household detergents
Use only medical detergents to clean this product. Do not use any acid and household detergent.
Washing this product with an improper detergent could result in discoloration or corrosion.

Symbol mark for labeling

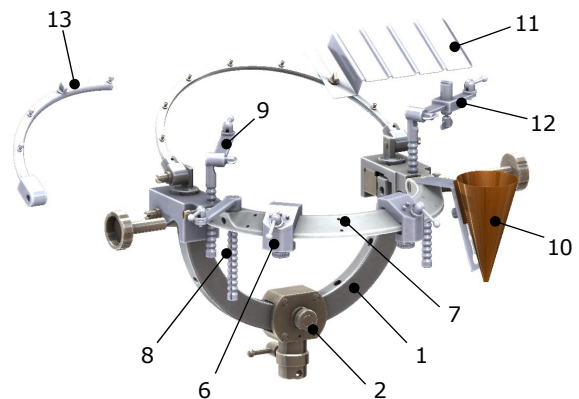


Specifications



Code No.	Product Description
1	07-951-11 Smart Fix C Holder
2	07-951-12 Smart Fix Joint Box (including 2 fixing screws)
*	07-951-33 Smart Fix Head Pin Standard **
*	07-951-34 Smart Fix Head Pin Long **
5	07-951-15 Smart Fix Stopper Sleeve
*Not CE Marked	

**Please refer to the instruction for use for Smart Fix Head Pins (MES-CK07-951-33EN-0) for details.



<Set product>

Code No.	Product Description
07-982-02	Smart Fix Basic Set

Code No.	Product Description	Qty
1	07-951-11 Smart Fix C Holder	1
2	07-951-12 Smart Fix Joint Box (including 2 fixing screws)	1
6	07-955-01 Slide Adjuster for Retractor	2
7	07-981-02 BASAL FRAME/SEMI-CIRCULAR FRAME	1
8	07-981-03 Hand Rest	1
9	07-981-04 Adjustable Hand Rest with Dome screw	1
10	07-981-06 Instrument Receptacle	1
11	07-981-07 Cotton Plate	1
12	07-981-09 Adjustable Hand Rest with Slide	1
13	07-981-10 QUARTER FRAME	1

Material: stainless steel, aluminum alloy, resin

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, refer to the instruction for use of the specified optional products (Multi-purpose Head Frame) and Smart Fix Head Pins. Before using this product, inspect, wash, and sterilize in accordance with these instructions.

Outline of use:

- Remove the head plate from the operating table, and attach and fix (optional) Table Attachment to the table with screws.
- Attach Smart Fix Joint Box (including 2 fixing screws) to the Table Attachment, and fix each joint to position the Smart Fix Joint Box (including 2 fixing screws) perpendicularly and both ends of Smart Fix C Holder horizontally to the floor. Please make sure to confirm that each joint is firmly fixed.
- Determine the optimum patient head position for the access path after craniotomy, and fix the patient's head with dedicated head pins. (Please refer to the figure below.)

Note: Turning the head pin slightly into the screw hole of Smart Fix C Holder will make it easy to attach the head pin by the ratchet mechanism.

- To fix the head, follow the procedures from 1 to 4 below. (Figures 1 to 4)

1. Fix the head provisionally with sterilized head pins while an assistant holds the patient's head. (Figure 1-1)

There are individual differences in hardness of skulls. Upon provisional fixing, fix the head with utmost care by examining the position of the head pin tip. Make sure that the patient's head moves around the head pin as a center axis under the provisional fixing condition as the arrow "A" below shows. (Figure 1-2)

1) If the patient's head does not move around the head pin as the center axis as the arrow "A" (Figure 1-2), the head pin may have been tightened too much. Loosen the head pin until the patient's head will move around the head pin as the center axis.

2) If the skull is fixed unstably and the patient's head moves up and down, tighten the head pin gradually until the patient's head does not move up and down and will move around the head pin as the center axis.

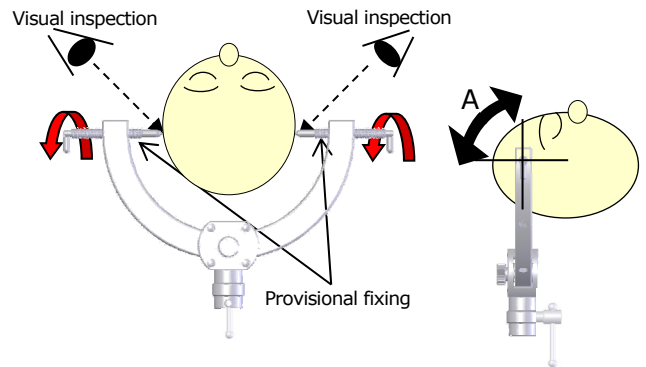


Fig.1-1

Fig.1-2

2. Insert the head pins into two places while examining the head pin tip in order to stop the patient's head from moving around the head pins as the center axis (arrow "A" Figure 1-2) and tighten them to the extent that they can hold the patient's head.

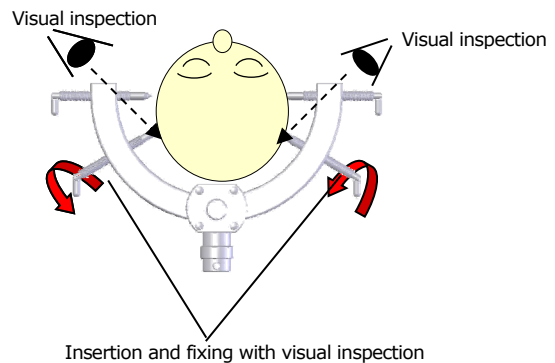


Fig.2

3. Finally turn the head pins 1/4 to 1/2 rotation which were provisionally fixed to tighten them further (Figure 3). Excessive tightening by the head pin may result in making cracks, depression, or penetration in the skull or laceration of the skin. Be sure to tighten the head pin with utmost care.

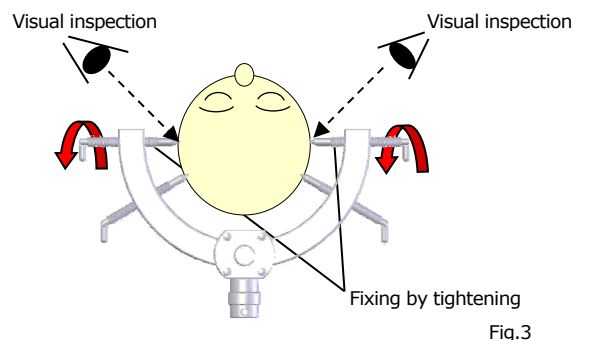


Fig.3

4. Attach Smart Fix Stopper Sleeve to each head pin used for fixing the patient's head. (Refer to the figure below.)

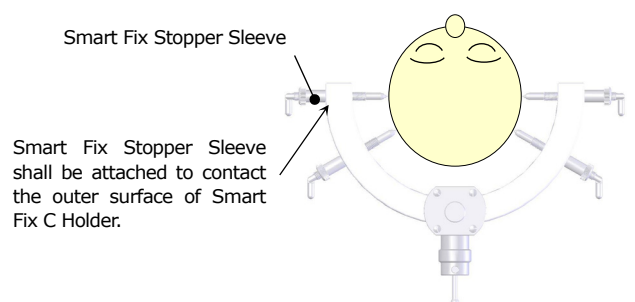


Fig. 4

- As with the progress of the operation, attach the sterilized components of the specified optional products*, if necessary.
*Specified optional products: Refer to the section "Warning/Caution".

Warning/Caution

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.
- 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.

2. Defect/Adverse event

Defect

- Deterioration, 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.

3. Fundamental precautions

- 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.

4. Cautions on use of other tools in combination with this product

- Use with specified products only
Use this product only with the products specified by Manufacturer. Other products than dedicated ones could be incompatible with this product due to differences in design and development policies.
- Specified optional products
Product name: Multi-purpose Head Frame

5. Cleaning

- If there are any concerns about the likely long-term contamination contact by the organic dirt (blood, body fluids, etc.), use the "spray detergent for pre-wash" before use which contains anti-rust and drying inhibiting materials. For more information on how to use the detergent, please refer to the manual supplied with the detergent.
- To remove dried organic dirt, we recommend hand washing with medical neutral detergent or immersion washing with neutral enzyme detergent. However, do not immerse the product for a long period of time (2 hours or more) because it may cause rust. For more information on how to use each detergent, refer to the manual supplied with the detergent.
- Using a washer-disinfector for this device simultaneously is recommended. For more information on how to use the washer, refer to the manual supplied with the washer.

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. Be careful not to impact or vibrate (including while transporting) this product.

2. Service life of the products below: 5 years

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

Code No.		Product Description
1	07-951-11	Smart Fix C Holder
2	07-951-12	Smart Fix Joint Box (including 2 fixing screws)

Service life of the products below: 1 year

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

Code No.		Product Description
3	07-951-33	Smart Fix Head Pin Standard
4	07-951-34	Smart Fix Head Pin Long
5	07-951-15	Smart Fix Stopper Sleeve

Maintenance/Inspection

1. Check prior to each use

(1) 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

(1) Immediately wash with clean water

- (1)-1 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.

(1)-2 Further remove any remaining contamination with a plastic brush.

(1)-3 Select a proper detergent for each decontamination method and maintain appropriate density and handling. Use of a neutral detergent is recommended.

(1)-4 Use a soft towel, a plastic brush or a water jet for cleaning.

(1)-5 To avoid damage, do not use a metal brush, coarse polishing agents, or apply excessive force when handling the device.

(1)-6 Reverse osmosis water is recommended to wash this product.

(1)-7 Only use reverse osmosis water for the final rinse.

(1)-8 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) 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.

(3) 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.

(4) 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.

Table 1: Applicable detergent

		Detergent	
		Neutral	Alkaline
1	Smart Fix C Holder	Yes	No
2	Smart Fix Joint Box (including 2 fixing screws)	Yes	No
3	Smart Fix Head Pin Standard	Yes	Yes
4	Smart Fix Head Pin Long	Yes	Yes
5	Smart Fix Stopper Sleeve	Yes	Yes

Yes: Applicable No: Not applicable

Table 2: Applicable disinfectant

		Disinfectant	
		Iodine	Alcohol
1	Smart Fix C Holder	No	Yes
2	Smart Fix Joint Box (including 2 fixing screws)	No	Yes
3	Smart Fix Head Pin Standard	No	Yes
4	Smart Fix Head Pin Long	No	Yes
5	Smart Fix Stopper Sleeve	No	Yes

Yes: Applicable No: Not applicable

Table 3: Applicable sterilization method

		Sterilization		
		Steam	EOG	Low temperature hydrogen peroxide gas plasma
1	Smart Fix C Holder	Yes	Yes	No
2	Smart Fix Joint Box (including 2 fixing screws)	Yes	Yes	No
3	Smart Fix Head Pin Standard	Yes	Yes	Yes
4	Smart Fix Head Pin Long	Yes	Yes	Yes
5	Smart Fix Stopper Sleeve	Yes	Yes	Yes

Yes: Applicable No: Not applicable

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 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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