

Instructions for Use

Trade Name: Radiolucent Multi-Purpose Head Frame
(Spring Hook, (Titanium))

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. Not doing so may give rise to serious problems or adverse events.

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).

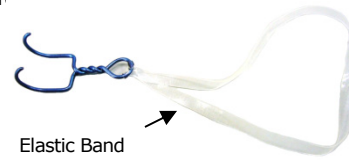
For the market outside the US

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 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 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.
7. Do not use 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.
8. Do not use an autoclave
Elastic Band is not suitable for sterilization with an autoclave. This product must be sterilized with ethylene oxide gas.

Shape / Structure



Elastic Band

Code No.	Product Description
07-985-15	Spring Hook, (Titanium) with Elastic Band

Material: titanium alloy, polyester-based polyurethane

Intended Purpose

This product is a surgical instrument intended to withdraw an incised scalp to expose the skull during a surgical procedure.

Instructions for Use

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

Caution

1. Warning
Device must be sterilized by users in accordance with validated sterilization conditions or the validated sterilization conditions which validity is proven by medical organizations in each country or region.
2. 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.

Storage and Shelf 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 (except Elastic Band)
(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 jet 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 simultaneously for this device is recommended.

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3. Dry this product immediately after washing it.
 - 3.1 After cleaning, please rinse the frame fully, for more than 5 minutes, with warm or cold water without additives.
 - 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 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.
- Elastic Band must be sterilized with ethylene oxide gas.

(1) Spring Hook

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	15 min
126 °C	10 min
134 °C	3 min

(2) Elastic Band

The recommended sterilization parameters are as follows,

ethylene oxide gas	
temperature	: 35 °C - 70 °C
relative humidity	: ≥ 40 % RH
gas concentration	: 400 mg/l - 1100 mg/l
exposure time	: ≥ 1 h

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.

* **Name and address of manufacturer**



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