

Instructions for Use

Trade Name: Raney Clip

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.

Contraindication / Prohibition

1. Prohibition of use of clip applicators made by other companies
Only designated applicators should be used for Raney Scalp-Clip. [Using applicators from other manufacturers may alter the clip's closing pressure or mechanical properties.]
2. Use for intended purpose only
Use devices for their intended purposes only. Incorrect use could cause this product to break.
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 surface 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	Closing force
07-061-01	Raney Scalp-Clip Stainless steel, 10pcs/pack	≥ 800 gf (7.8 N)



Code No.	Product Description	Closing force
07-061-02	Raney Scalp-Clip Stainless steel, Low pressure, 10pcs/pack	≤ 600 gf (5.9 N)

Material: Stainless Steel

Intended Purpose

The Raney Clip is a non-sterile surgical instrument consisting of either two blades joined at a central point or an "alpha" type single component. This device is used to stop bleeding from the scalp during surgery. This product is reusable.

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. (Refer to matters related to maintenance and inspection.)

Directions for use: Use this device with a dedicated pair of Raney scalp clip applicators. Apply the clip over a piece of gauze at the wound margin. Do not apply the clip directly to the scalp.

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.

2. Precautions

• Prohibited uses:

Do not use this product for purposes other than hemostasis of the scalp.

• Reusable up to two times:

Although made of stainless steel, this product may rust when exposed to physiological saline or disinfectants used during surgery. Rusting may also occur due to immersion cleaning or machine washing.

• Definition of use:

Any of the following actions constitutes use of the product:

- Opening the sterile package
- Grasping with applicator
- Applying the clip to a 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.

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. **However, this device can only be used a maximum of two times.**)

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 jet for cleaning.
 - 2.5 Avoid using metallic brushes or rough polishing agents, applying excessive force, dropping or bumping the device, etc.
 - 2.6 Reverse osmosis water is recommended to wash this product.
 - 2.7 Only use reverse osmosis water for the final rinse.
 - 2.8 It is recommended to use a washer-disinfector for this device.
3. After cleaning, fully rinse for more than 5 minutes, with warm or cold water without any additives.
 - 3.1 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.
4. Use distilled water or reverse osmosis water
Use distilled water or reverse osmosis water to wash and sterilize this product. Residual chlorine and organic matters in tap water may cause stainings and/or rust and may damage the instrument.
5. 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.
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.

Sterilization of the device may be accomplished by steam.

The recommended sterilization parameters are as follows,

ISO/TS 17665-2	
Temperature	Minimum exposure time
121°C / 250°F*	15 min
126°C / 259°F*	10 min
134°C / 273°F*	3 min

* According to the Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008 (Update: May 2019)

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 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 device, 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

10 pieces per package

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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