

Instructions for Use



Trade Name: Raney Scalp Clip

Warning

1. Prohibition of secondary processing of this device.
Do not apply any secondary processing to this device. For example, do not apply impacts or vibration markings to the surface of this device. Doing so could break this device.
2. Handle with care.
Handle this device with care, as it can be deformed or damaged. Rough handling could significantly reduce the service life of tools and appliances.
3. Prohibition of use of polishing powder and wire wool.
When cleaning this device, do not attempt to polish its surfaces with rough polishing powder or wire wool. This could cause scratches on the surfaces of this device and result in the breakage.
4. Do not use household detergents.
Ensure the use of "medical" detergent only. Do not use household detergent.

Contraindication / Prohibition

1. Use for intended purpose only
Use tools for their intended purposes only. Incorrect use could cause breakage of this device.
2. Prohibition of use of chemicals
Avoid exposing this device to chemicals such as acids or bases stronger than pH 4 or pH 9 because they could deteriorate this device and cause damage.
3. Prohibition of secondary processing of this device.
Do not apply any secondary processing to this device. For example, do not apply impacts or vibration markings to the surface of this device. Doing so could break this device.
4. Use with a dedicated pair of Raney Scalp Clip Forceps. Do not use the forceps of another manufacturer.

Shape / Structure



Code No.	Product Description
07-062-00	Raney Scalp-Clip, Plastic 50pcs/pack (disposable)

Material: Polyacetal resin

Intended Purpose / Potency or Effect

This device is used to stop bleeding from the scalp during surgery.
This is a single-use device.

Instructions for Use

Before using this product, inspect, wash, and sterilize in accordance with these instructions.
Directions for use: Use with a dedicated pair of Raney scalp clip forceps and apply this device over a piece of gauze to the wound margin. Do not apply directly to the scalp.

Caution

1. Warning
This 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.

2. Important notes

- Do not use the device for anything other than its intended purpose. Improper use may cause damage. Do not use this device for other than stopping bleeding from the scalp.
 - This is a single-use device.
3. Cautions on use of other tools in combination with this device
 - Use with a dedicated pair of Raney Scalp Clip Forceps. Using other forceps may degrade the closing force and/or functional characteristics of this device.
 4. Defect/Adverse event
 - Using this device may cause necrosis of the scalp. Pay close attention to the affected area to avoid necrosis.

Storage and Shelf Life

Do not store this device in high temperatures or in areas with high humidity where the temperature has drastic variations.

Maintenance / Inspection

1. Operational and functional checks
Conduct daily and pre-operation checks of this device to make sure that it works properly.
2. Dry this device immediately after washing it.
Dry this device immediately after washing it. Do not leave it wet for a longer time than necessary.
3. Sterilization
This device must be sterilized by users in accordance with validated sterilization procedures that are regulated by medical organizations in each country or region.
EOG sterilization and autoclaving are applicable and EOG sterilization is recommended.
Moist-heat sterilization conditions are provided by ISO/TS 17665-2 and CDC guideline 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

CDC (Refer to the Guideline)	
Temp.	Minimum exposure time
132°C / 270°F	3 Min

Do not use hydrogen peroxide gas plasma sterilization as it may degrade the characteristics of the material.

Packing

50 pieces per pack

Reference

Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008 (CDC)

Matters related to warranty period

MIZUHO Corporation will repair defective parts of this device 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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