(English)

PRODUCT

Myringotomy Blade/ Knife (Sterile) GMDN code: 63660

(Sizes: Spear and Lance)

(Stainless Steel, ABS and LDPE) Sterilized by Gamma radiation of minimum 25 kGy

DEVICE DESCRIPTION

Myringotomy knife is made of Stainless-steel long consistently sharp, angled blade facilitates a clean cut as Lance tip and Spear tip assembled with ABS hollow cylindrical handle at knife knob and then cover with LDPE made hollow cylindrical cap to protect the sharp edge. The device is sterilized by Gamma Radiation & Expiry is 5 years from the date of manufacturing.

INTENDED USE

The device is under category of surgically used for tiny incision in the eardrum (tympanic membrane) to relieve pressure caused by excessive build of fluid, or to drain pus from the middle ear. The device is invasive device and for transient use.

MODE OF ACTION

The grip of handle and angled cut myringotomy blade facilitates a clean cut during the incision in tympanic membrane of ear. It can directly use for incision after opening the primary pack.

INDICATIONS

- Tiny Incision.
- Different size for different operating part of ear.
- Removal of pressure of excessive build-up of fluid.

CONTRAINDICATIONS/ RESIDUAL RISK

- Re-used of device can work as carrier for communicable disease to patient and/or user.
- Adverse event may be happen if device are used after expiry date as expiry date of product is expiry date of sterility.
- Do not use if patient is allergic with stainless steel metal.
- Do not use in cardiovascular, ophthalmic surgery & neurovascular surgeries.

PATEINT TARGET GROUP

The device can be used on all group of patients.

INTENDED USERS

The device shall be used by qualified ear surgeon/doctor/ ENT surgeon.

PREPARATION FOR DECONTAMINATION:

No requirement

APPLICATION ON THE BODY:

Tympanic membrane of ear

CLEANING AUTOMATED:

No cleaning is required before use of the device.

CLEANING MANUAL:

No cleaning is required before use of device.

DISINFECTION

No disinfection required.

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EC REP
MDSS GmbH, Schiffgraben 41,
D-30175 Hannover, Germany

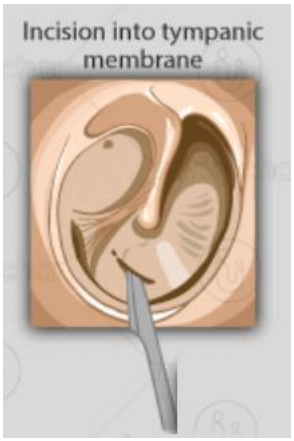
MAINTENANCE
No requirement

INSPECTION & FUNCTION TESTING:
Check for smooth functioning of medical device. Visually inspect for damage.

ADDITIONAL INFORMATION:
NA

DESCRIPTION OF COMPONENT PARTS:
None

SYSTEM PREPARATION:
Check the label for manufacturing and expiry dates (do not use the medical device after expiry). Make sure the package is not damaged. Visually examine the pouch to see if there are any damages.



INSTRUCTIONS FOR USE

- Inspect package of device for its intactness expiring and then remove from package.
- Peel off the device from the individual packing.
- Care must be taken while handling the blade. Do not touch the sharp edge of blade with any hard surface. The sharp edge may get blunt.
- With grip on handle choose the sight for incision.
- After use, dispose of the blade in sharp container.

WARNING

- Read instruction for use.
- The product should be used only by a qualified surgeon, Doctor.
- Before use always check integrity of product and packing along with expiry date.
- For single use only, if re-used this can work as carrier for Communicable disease, HIV, Hepatitis, contagious dieses, undue diseases to patient and/or user.
- Use product immediately after opening the pack.
- PARAMOUNT is not responsible for any possible consequences resulting from improper use.
- PARAMOUNT do not hold any responsibility if device re-used or re-sterile.
- Sterility of product is not guaranteed if packet is broken/torn.
- Re-sterilization and re-use of blade cause to change in mechanical properties and material used.
- Re-sterilization and re-use of blade may not meet the intended use as blade may be blunt.
- Keep out of reach of children.
- After use of products must be disposed of as per country law of bio-waste handling rule

PRECAUTIONS:

- Always open the pouch from peel apart direction to avoid injury.
- Devices are extremely sharp, use care while handling.
- Care must be taken so that the pouch is not opened in an unsterile area otherwise the device which has already been sterilized by Gamma radiation will become unsterile. Proper procedures must be used as applicable for handling any sterile product.
- Care must be taken during disposal of device to avoid any contact or injury due to the sharp nature of the device.
- Proper care must be taken while use of the device to avoid any injury or accident.
- In case of changes in the performance of device for intended use replace the defective device by new to full fill the required application.

KNOWN CHARACTERISTICS OF DEVICE IN CASE OF RE-USE

- Difficult to cut at incision site during reuse.
- Any infectious disease can transfer.

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STORAGE CONDITION

- Keep away from direct sun light.
- Keep away from rain.
- Storage temperature should be 10°C to 40°C.
- Humidity of storage area should be 35% RH to 65 % RH.
- Keep away from children.
- Store in cool and dry place.

DISPOSAL SYSTEM

Discard the Device in proper waste container & dispose of the Product in accordance with accepted medical practice and applicable local, state and country laws and regulations or handling of bio-medical waste.

PACKAGING

The device is supplied in box of 6. The box contains soft blister pouches with external identification on the box.

RETURN OF DEVICE

The return of defective device it should be carried out within a week of receipt of the product along with the evidence or damaged product and the product should not have been used under any circumstances, at any condition.

ADVERSE EVENT

The improper use / misuse of device may occur adverse event to patient or user. e.g., deep cut, injury to user during use. Any serious incident that has occurred in relation to the device, should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

ELECTRONIC VERSION OF IFU:

Available on the website **www.paramountblades.com.**

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