# INSTRUCTION FOR USE

**PRODUCT**
**Myringotomy Blade/ Knife (Sterile)**

(Sizes: Spear and Lance)
(Stainless Steel, ABS and LDPE)
Sterilized by Gamma radiation of minimum 25 kGy and not more than 32 kGy (2.5 M Rads to 3.2 M.Rads)

**INSTRUCTION FOR USE (IFU)**

**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-up of fluid, or to drain pus from the middle ear.
The device is invasive device and for transient use.

**MODE OF ACTION**

Myringotomy knife is made of Stainless-steel strip with specific shaft long and 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 tube to protect the sharp edge.

**INDICATIONS**

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

**CONTRAINDICATIONS**

– 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 in cardiac/ ophthalmic surgery.

**INSTRUCTIONS**

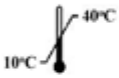
– Inspect package of device for its intactness expiring and then remove from package
– Peel off the device from the individual packing.
– Blade of device must not contact with any other surface unless it might be damage.
– The lancet blade of myringotomy is designed and sharpened to pierce and then incise the tympanic membrane resulting in a clean-cut incision.
– The shaft may be angled to prevent obstruction of the optic axis. measured and marked.

**WARNING**

– Read instruction for use
– The product should be used only by a qualified surgeon,


Keep away from sunlight

Moisture limitation



Temperature limitation


Do not use if package is damaged


Consult for IFU


Non-Pyrogenic


Caution/ Warning (Read IFU before use)

Product reference/Art. No.

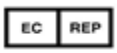

Do Not Reuse

Lot Number/Batch Number


Date of Manufacturing


Use By / Expiry Date

Single sterile barrier sterilized by gamma radiation



European Authorized Representative


Manufactured by


Do not resterilize


Keep dry

Medical Device symbol

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# INSTRUCTION FOR USE

Doctor or paramedic.
– 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 off 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.

**STORAGE CONDITION:**
– Keep away from direct sun light.
– Keep away from rain
– Storage temperature should be 10 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 off the product in accordance with accepted medical practice and applicable local, state and country laws and regulations

Keep away from sunlight

65% RH / 35% RH — Moisture limitation

40°C / 10°C — Temperature limitation

Do not use if package is damaged

Consult for IFU

Non-Pyrogenic

Caution/ Warning (Read IFU before use)

REF — Product reference/Art. No.

Do Not Reuse

LOT — Lot Number/Batch Number

Date of Manufacturing

Use By / Expiry Date

STERILE R — Single sterile barrier sterilized by gamma radiation

EC REP — European Authorized Representative

Manufactured by

Do not resterilize

Keep dry

MD — Medical Device symbol

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# INSTRUCTION FOR USE

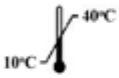
for handling of bio-medical waste

**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.


Keep away from sunlight

Moisture limitation



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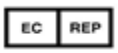

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