

INSTRUCTION FOR USE

OPHTHALMIC SURGICAL KNIFE

PRODUCT

Ophthalmic Surgical Knife

(Size Gauge : 19, 20, 23, 24, 25, 27

Sterilized by EO STERILIZATION

Blade : Stainless Steel, Handle : Polycarbonate, Tray : Polycarbonate

INTENDED USE :

Ophthalmic Microsurgical Knives are used during phaco ophthalmic surgery operations in order to make precise incisions and curetting Which are among the precondition for application in delicate phaco Ophthalmic surgical interventions.

CONTRAINDICATIONS - PROHIBITIONS:

- Re-use is prohibited.
- Re-sterilizations is prohibited.
- Do not use it after expiry date.
- Do not use it if product's aseptic condition is considered spoiled by broken package.

WARNINGS :

- Read, follow and keep these Instruction for use.
- See the intended use and use the product only in accordance with it.
- Store any new products in a dry, clean and safe place.
- Avoid high temperature, high humidity, direct sunlight, soaking and preserve at room temperature.
- Do not preserve at a place with chemical products and gas occurrence.
- Preserve package material at a non-break and non-pinhole status.
- It is necessary to confirm the use period on each package and box.
- By confirming the use, period on each package and box, dispose the products whose use period is expired.
- Prior to each use, inspect the product for: loose, bent, broken, cracked, worn, or fractured components.
- If product is damaged or defective, do not use it and set it aside. Avoid contact of the delicate blades at tips with hard surfaces or other instruments.

STORAGE CONDITION :

- Keep away from direct sun light.
- Keep away from rain.
- Storage temperature should be 10 to 40 degree celcius.
- Humidity of storage area should be 35% RH to 65% RH.

DISPOSAL OF USED POUCH AND BLADES :

- After use, pieces and pouches shall be disposed off in compliance with the local regulatory requirement of handling medical waste.

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 blade which has already been sterilized will become unsterile. Proper procedure 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.
- In case of change in the performance of device fo intended use replace the defective device by new to full fill the required application.

DAMAGED PRODUCT RETURN :

- Damaged product should be return immediately to the source from where it is purchased.-



Catalogue No. /
Unique Identification No.



Lot No./Batch No.



Manufacturer



Date Of Manufacturing



Use By / Expiry Date



Sterilised By Ethylene Oxide



Do Not Reuse



Do Not Resterilize



Non-Pyrogenic



Do Not Use If Package Is Damage



Caution



Consult Instructions For Use



Authorised Representative
In The European Community



Manufactured by :

Disposafe Health and Life Care Limited

Plot No. 1 & 2, Phase-II, Sector- 59, Ballabgarh,
Faridabad-121004, Haryana (INDIA)

E-mail: info@disposafe.com, Web: www.disposafe.com
CUSTOMER CARE NO.: +91-129-4170201



CEpartner4U B.V ESDOORNLAAN 13,
3951 DB MAARN, THE NETHERLANDS.
E-mail : office@cepartner4u.com