

Product Name: OPHTHALMIC INTRAOCULAR SURGICAL BLADES
APPA BLADE - (MICRO SURGICAL BLADES)

Intended Use & Indications for use

Ophthalmic Intraocular Surgical Blades (Micro Surgical Blades) are intended to make incision on the cornea, to perform the cataract surgery.

Warnings

1. Only qualified professionals are recommended to use and handle the product.
2. Select the appropriate type of blade for each surgical purpose.
3. Avoid using the blade if the package is damaged or tainted.
4. Do not try to manipulate the product.

Precautions for Use

1. Precaution should be taken while handling the blades so as not to damage the cutting edges.
2. Use the blade as soon as it is unpacked and dispose it with care as per your institutions procedures to prevent infection.
3. Take extreme care in handling. External injury caused by contaminated blade can lead to pathogenic infection linked to blood disorders.
4. Do not use if the blade tip is deformed or damaged.

Contraindications

1. Do not use on patient who is too sensitive or allergic to metals.

Prohibitions

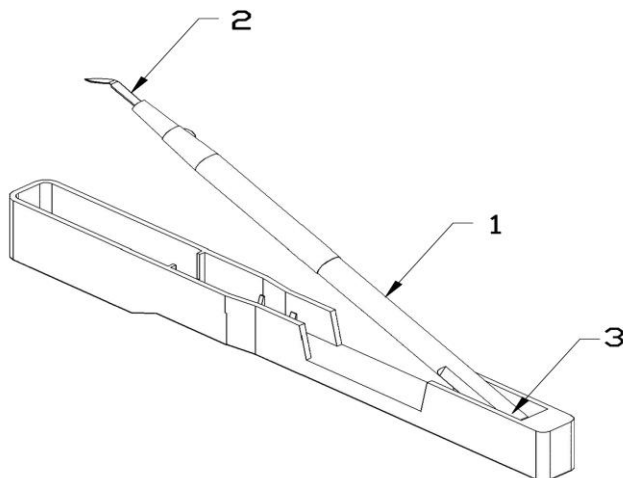
1. Do not wipe the edge of the blade or use if the blade has been hit against or in contact with parts other than the eyeball.
2. Do not use the product beyond shelf life period.
3. Do not use for other than ophthalmic surgery.
4. Do not reuse or re-sterilize. Reuse or re-sterilize may compromise the structural integrity and/or might lead to damage or infection to the patient.

Description of the device

This blade is sterilized and has a handle with a grip. The blade is secured in a knife holder. The handle and knife holder are made of polycarbonate and the blade is made of stainless steel.

Operating the device

1. Taking out the blade – pull the part identified as 1 from the knife holder and raise the blade. Care should be taken as the blade tip 2 may lose its sharpness once it touches an object.
2. Put the blade back to the knife holder – hold the blade with the blade edge facing downward, push part 3 into the corner of the knife holder and then lightly press part 1 until it slides into the knife holder



Storage & Expiration

1. Avoid using the product if any scars and pinholes are seen on the packaging material.
2. Avoid exposure to direct sunlight, high humidity and high temperature.
3. Do not use the product if the expiration date is overdue.
4. Discard blades that are kept unused for long time after unpacked.
5. Use the blades on a first-in-first-out basis.
6. This product may be used up to 3 years after the date of production as indicated on the package label, as long as it is maintained in accordance with the storage procedure.



Sterilized using ethylene oxide



Do not re-use



Do not re-sterilize



Consult Instructions for Use



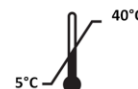
Do not use if package is damaged



Keep dry



Keep away from sunlight



Store between 5°C to 40°C



Storage humidity
30% - 75% RH



Medical Device

Packaging

1 piece per pouch or blister

Reporting to Appasamy Associates Private Limited

Any complications or unidentified adverse effect should be reported to Appasamy Associates Private Limited by mail (see below for address) or by Email (feedbacks@appasamy.com).

Manufactured by:

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Manufacturing License Number: MFG/MD/2024/000302
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