

Instructions for use

Product Name: OPHTHALMIC SURGICAL INSTRUMENTS –
CORNEOSCLERAL PUNCHES
(MICRO SURGICAL INSTRUMENTS)

Intended use & Indications for use

A hand-held, manual ophthalmic surgical instrument designed to excise a segment of tissue (frequently in the form of a disc) from the sclera or cornea of a patient or from grafts taken from cadaver donors.

Warnings

1. Only qualified professionals are recommended to use and handle the product.
2. These devices must be used alone and not intended for combination (connection) with other devices.
3. Avoid using the product 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 product so as not to damage the edges.
2. Use the device as soon as it is unpacked and dispose it with care as per your institutions procedure to prevent infection.
3. Take extreme care in handling. External injury caused by contaminated product can lead to pathogenic infection linked to blood disorders.
4. Do not use if the product is deformed or damaged.

Contraindications

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

Prohibitions

1. Do not use the product if it is 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

Product is sterilized and is for single use only. Corneoscleral Punches are made of stainless steel.

Storage and 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 product that are kept unused for a long time after unpacked.
5. Use the product 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



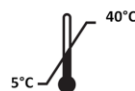
Do not use if package is damaged



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:

Appasamy Associates Private Limited, SF No. 144/1, Navammal Kapper Village, M.N.Kuppam, Thennal (Post), Kandamangalam (Taluk), Tamilnadu – 605102, India
Tel: +91-7695814612, 7695814613.
E-mail: mnk@appasamy.com Website: www.appasamy.com

Marketed by

Appasamy Associates Private Limited, No. 20, First Street, SBI Officer's Colony, Arumbakkam, Chennai – 600106, Tamilnadu, India.
Phone: 044-32980153, 32980154; Fax: 044-23630721, 23631208.
E-mail: info@appasamy.com Website: www.appasamy.com

Authorized Representative in Europe:

Amstermed B.V, Saturnusstraat 46-62, Unit 032, 2132 HB Hoofddorp, The Netherlands.
Phone: +31 23 5656337, E-mail: info@amstermed.nl
Website: www.amstermed.nl



RD-SI/COP/IFU/REV08