

Teflon Block

DEVICE DESCRIPTION

A sterile disposable Teflon block is made of plastic polymer. Teflon Block is individually packed & sealed in a pouch before sterilization.

INTENDED USE/ INDICATION FOR USE

The corneo sclera tissue is placed over the Teflon Block and the donor button then punched out. A disposable piece of sterile Teflon Block is used to put the corneo sclera tissue in its corneal curvature.

CONTRAINDICATIONS

Not known

HOW SUPPLIED

Teflon Block is supplied sterile packed in a peel open pouch. Such pouch is enclosed within an outer printed box. The overall packing contains Teflon Block and medical literature insert, in an outer enclosing box, with external identification stickers.

CAUTIONS

Do not use the device if the sterilized package is open or damaged.

WARNING

- Madhu Instruments Pvt. Ltd. does not hold any responsibility if the device is reused. Reusing the device may cause serious problems to patients are as under-
 - The corneal curvature deformed after using. The used Teflon Block might not be in a position to be used again due to this deformed shape.
 - Re-use of device may lead to microbial contamination due to presence of Pseudomonas.
 - Contagious and communicable disease such as HIV, Hepatitis, contagious disease/communicable disease/ undue diseases etc.
- Only qualified medical practitioner should use the device.
- Sterility is guaranteed only when the packing is neither opened nor damaged.
- Do not re-sterilize the device by any method. Madhu Instruments Pvt. Ltd. assumes no liability for devices that have been re-sterilized.
- Do not reuse the device.
- Read instruction before use.
- Store at specified temperature and humidity.
- The used Teflon Block and pouch should be disposed off in compliance with the local regulatory requirements.



- Do not use the device after sterility expiry date.
- For External use only.
- Keep out of reach of children.

PRECAUTIONS

- When handling the product care should be taken to avoid damage from handling. Avoid cuts and crimping damage to the product due to application of surgical instruments such as forceps, blades etc.

DIRECTION FOR USE

- Open the pouch of sterile piece of Teflon Block (BY AN UNSTERILE PERSON) and drop on a sterile surface without touching it.

EXPIRATION DATE

The expiration date of the product is the sterility expiration date. The product should not be used after the indicated sterility expiration date.

RETURN OF DAMAGED PRODUCT

Return the product in its original packing identified by the batch number, purchase information, your reference and reason for return. Please contact your local distributor office regarding product return/exchange.

REPORTING

Adverse events and/or potentially sight-threatening complications that may reasonably be regarded as product related and that were not previously expected in nature, severity or incidence must be reported to Madhu Instruments Pvt. Ltd.

DISPOSAL OF THE USED DEVICE

The used device should be disposed off in compliance with the local regulatory requirements.

EXPLICATION OF SYMBOL:

Symbol	Meaning
	Caution
	Manufacturer
	Date and Country of Manufacture
	Consult instructions for use
	Keep away from sunlight
	Medical Device
	Do not use hook
	This side up
	Temperature Limit
	Humidity Limitation
	Keep Out of reach of children
	Handle with care

Symbol	Meaning
	Maximum stacking
	Batch Code
	Use by date
	Do not use if package is damaged
	Do not re-use
	Single Sterile Barrier System, Sterilised using Ethylene Oxide
	Single Sterile Barrier System with protective packaging outside, Sterilised using Ethylene Oxide
	Do not re-sterilize
	Catalogue Number
	Unique device identifier
	Model Number

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