

EN (English)



Silicone Band

MODELS & VARIANTS

2.0mm, 2.5mm, 3.5mm, 4.0mm

DEVICE DESCRIPTION

A disposable Silicone band is a Silicone rubber strip of fixed width and thickness cut into small pieces of 125mm length. A Silicone Band is individually packed & sealed in a pouch before sterilization.

INTENDED USE / INDICATION FOR USE

A disposable sterile Silicone Band is used as an encircling device for the eyeball during a retinal detachment surgery.

MATERIALS USED

Silicone Rubber

TARGET AGE GROUP

Can be used for all age groups.

INTENDED USER

Any of the registered medical doctor/medical professionals.

DURATION OF USE

Long term use (more than 30 days).

STORAGE CONDITIONS

Store at specified temperature and relative humidity (Temperature in between 10°C to 30°C and relative Humidity in between 45% to 65%).

CONTRAINDICATIONS

The device should not be used in patients who show hypersensitivity to any of the materials used in construction of the device.

HOW SUPPLIED

Silicone Band is supplied sterile, packed in two peel open pouch. Both are sterile packs.

Such packed pouches are enclosed within an outer printed box. The overall packing contains Silicone Band and medical literature insert, in an outer enclosing box, with external identification stickers.

CAUTION/ WARNING

- Do not use if package is damaged and consult Instructions for use.
- Do not use the device if the sterilized package is open or damaged.

- The product is designed for single use only.
- The use of this product is restricted to a qualified doctor or medical practitioners.
- Store at specified temperature and humidity.
- Keep out of reach of children.
- Do not re-sterilize the device by any method. Madhu Instruments assumes no liability for the devices that have been re-sterilized.
- Do not use the device after sterility expiry date.
- Keep out of reach of children.

PRECAUTIONS

- Ensure before use that product/package is not tampered or damaged.
- When handling the product care should be taken to avoid damage from handling.

DIRECTION FOR USE

- Check the package sealing integrity to ensure sterility.
- Select the suitable size of Silicone Band and inspect visually.
- Open the Silicone Band from sterile packaging.
- Wash it with saline water.
- Use as an encircling device for the eyeball during a retinal detachment surgery as per standard surgical procedures.

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, the shelf life for sterile products is recommended to 5 years from the date of sterilization.

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 report to Madhu Instruments Pvt. Ltd.

DISPOSAL OF THE USED DEVICE

The used device should be disposed off in compliance applicable local, state and country's laws and regulations.

EXPLICATION OF SYMBOLS:

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
	Batch Code

Symbol	Meaning
	Handle with care
	Maximum stacking
	Use by date
	Do not use if package is damaged and consult Instructions for use
	Do not re-use
	Single Sterile Barrier System, sterilized using Ethylene Oxide
	Double Sterile Barrier System, sterilized using Ethylene Oxide
	Double Sterile Barrier System with protective packaging outside, sterilized using Ethylene Oxide
	Do not re-sterilize
	Catalogue Number
	Unique device identifier

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