

Silicone Band

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.

CONTRAINDICATIONS

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

HOW SUPPLIED

Silicone Band is supplied sterile, packed in a peel open pouch. The overall packing contains Silicone Band 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 as under: -**
 - a. The used Silicone Band might be has usual impurities or flashes. Do not use the Silicone Tire if Silicone Band has usual impurities or flashes around the edges.
- Only qualified medical practitioner should use the device.
- Do not use the device if the sterilized package is open or damaged.
- Sterility is guaranteed only when the packing is neither opened nor damaged.
- Do not re-sterilize the device by any method. Madhu Instruments assumes no liability for the devices that have been re-sterilized.
- Do not reuse the device.

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

EXPLANATION OF SYMBOLS:

| Symbol | Meaning |
|--------|------------------------------|
| | Caution |
| | Manufacturer |
| | Date of Manufacture |
| | Do not re-sterilize |
| | Consult instructions for use |
| | Keep away from sunlight |
| | Do not re-use |
| | This side up |
| | Do not use hook |



- Read instruction before use.
- Store at specified temperature and humidity.
- The remaining pieces of Silicone Band (if any) 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

- Most of the hospitals have washing machines to clean the surgical instruments. If cleaning of instruments is done manually, precautions have to be taken to reduce the risk of contamination through dirty instruments. When sharp instruments are cleaned and there is a risk of puncturing the skin, the instruments should be disinfected first (e.g. with a liquid disinfectant). Always wear gloves when cleaning instruments that are contaminated.

DIRECTION FOR USE

- Open the sterile Silicone Band pouch (BY AN UNSTERILE PERSON) and drop the inner pouch on a sterile surface without touching it.
- Open the inner pouch and take out the Silicone Band. Wash it with saline water. Cut the length of the Band as per requirement.
- A Silicone Band is for single use only.

EXPIRATION DATE

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

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 with the local regulatory requirements.

| Symbol | Meaning |
|--------|----------------------------------|
| | Batch Code |
| | Use by date |
| | Temperature Limit |
| | Do not use if package is damaged |
| | Humidity Limitation |
| | Sterilised using Ethylene Oxide |
| | Handle with care |
| | Maximum stacking |

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