

EN (English)

Rose Bengal Strips

INTENDED USE

A disposable sterile Rose Bengal Strip is used as a vital stain when superficial conjunctival or corneal tissue change is suspected.

DEVICE DESCRIPTION

A disposable Whatman filter paper No. 1 round blunt tip (impregnated with Rose Bengal dye) sandwiched between a sticker paper stick (overall length 60mm). Each strip is packed individually in pouches before sterilization.

HOW SUPPLIED

Rose Bengal strips are supplied sterile, in individual pouches. 100 such pouches are enclosed within an outer printed box. The overall packing contains Rose Bengal strips and medical literature insert, in an outer enclosing box, with external identification stickers.

⚠ WARNING

- Madhu Instruments Pvt. Ltd. does not hold any responsibility if the device is reused. Reusing the device may cause serious problems to patients such as HIV, Hepatitis, contagious disease/communicable disease/undue diseases etc.
- 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 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.
- Not to be used with soft contact lenses.
- The used strip 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.

DIRECTION FOR USE

- Moisten Rose Bengal impregnated strip with sterile water or sterile ophthalmic solution.
- Tear fluid from the lower fornix may be used.
- While the patient looks up, touch conjunctiva or fornix with moistened tip.
- For optimal results, the patient should blink several times after application.

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.

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.

EXPLICATION OF SYMBOL:

Symbol	Meaning
	Caution/Warning (Read instruction before use)
	Manufacturer Logo
	Date of Manufacturing
	Do not re-sterilize
	Consult IFU
	Keep away from sunlight
	Don't re-use
	This side up
	Do not use hook

Symbol	Meaning
	Batch/Lot Number
	Date of Expiry
	Temperature Limitation
	Do not use if package damaged
	Moisture Limitation
	EO Sterile Product/Device
	Handle with care
	Maximum stacking

Mfg. Facility: **MADHU INSTRUMENTS PVT. LTD.**

A 260, Okhla Industrial Area Phase-I, New Delhi-110020 India

MADHU INSTRUMENTS PVT. LTD.

F-90/3D, Okhla Industrial Area Phase-I, New Delhi-110020 India

Customer Care No. : 91-11-42701030, 42701031

Email: customercare@madhuinstruments.com

Website: www.madhuinstruments.com

Ref. No. MIPL/IFU/A2/02, Issue No .02, Issue Date: 01.06.2015, Rev. No.: 01, Rev. Date: 01.02.2020