

Rose Touch

Rose Bengal Strips

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.

INTENDED USE / INDICATION FOR USE

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

MATERIALS USED

Whatman filter paper, Sticker Paper

TARGET AGE GROUP

Can be used for all age groups.

INTENDED USER

Any of the registered medical doctor/medical professionals.

DURATION OF USE

Transient Use (Less than 60 Minutes).

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 manufacturing of the device.

HOW SUPPLIED

Rose Bengal strips are supplied sterile, in individual pouches. Such packed pouches are enclosed within an outer printed box. The overall packing contains Rose Bengal strips and medical literature inserted 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.

return. Please contact your local distributor's office regarding product return/exchange.

REPORTING

Adverse events and/or potentially sight-threatening complications that may reasonably be regarded as product

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



- The product is designed for single use only.
- Reusing the device may cause the transfer of contagious and communicable disease to the patient and other serious problems to patients due to re-use of device such as HIV, Hepatitis, contagious diseases/communicable disease/undue diseases etc.
- The use of this product is restricted to a qualified doctor or medical practitioners.
- 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.
- For External use only.

PRECAUTIONS

- Ensure before use that product/packaging 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.
- Remove the Rose Bengal from sterile packaging.
- 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 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

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 applicable local, state and country's laws and regulations.

Symbol	Meaning
	Handle with care
	Maximum stacking
	Batch Code
	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
	Single Sterile Barrier System with protective packaging outside, sterilized using Ethylene Oxide
	Do not re-sterilize
	Catalogue Number
	Unique device identifier

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