EN (English)



Hydrodissection / Hydrodelineation Cannula

APPLICABLE FOR THE MODELS

23G, 25G, 27G, 30G

DEVICE DESCRIPTION

This is a disposable ophthalmic cannula of different gauge and needle lengths. This device is supplied sterile in peel open pouches.

INTENDED USE / INDICATION FOR USE

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A disposable sterile ophthalmic cannula used to effectively separate layers & nucleus and cortex in cataract surgery procedures. Flatted tip design allows cannula's insertion under anterior capsule and distribute fluid in a fan-like manner for dissection of nucleus from cortex and capsule.

MATERIAL USED

Stainless Steel, Polypropylene

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 manufacture of the device.

Hydrodissection / Hydrodelineation Cannula are supplied sterile, in individual pouches, such packed pouches are enclosed within an outer printed box. The overall packing contains Hydrodissection / Hydrodelineation Cannula 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.

 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/
- 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.

PRECAUTIONS

- Before use, please make sure that the product or packaging has not been 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 Hydrodissection / Hydrodelineation Cannula and inspect visually.
- Remove the cannula from sterile packaging.
- Insert the cannula at incision site.
- Use the Hydrodissection / Hydrodelineation Cannula for separate layers &nucleus and cortex in cataract surgery 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

Symbol

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

Meaning

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

EXPLICATION OF SYMBOLS:

| Symbol | Meaning |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|
| \triangle | Caution |
| | Manufacturer |
| W. | Date and Country of Manufacture |
| []i | Consult instructions for use |
| 类 | Keep away from sunlight |
| MD | Medical Device |
| 8 | Do not use hook |
| 100.0 | This side up |
| 10°C 30°C | Temperature Limit |
| 45% | Humidity Limitation |
| (fi) | Keep Out of reach of children |
| NAME OF THE PARTY | Handle with care |

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Maximum stacking LOT Batch Code Use by date Do not use if package is damaged and consult instructions for use (2) Do not re-use C €2460 Conformity of European Norm with Notified Body Number EC REP Authorized Representative in European Community STERILEEO Single Sterile Barrier System, sterilized using Ethylene Oxide Single Sterile Barrier System with protective packaging outside, (STERILE EO) sterilized using Ethylene Oxide Do not re-sterilize REF Catalogue Number Unique device identifier UDI

EC REP

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