NANOedge
Ophthalmic Blades

Micro Incision Blade

MODELS & VARIANTS
Lance Tip (15 to 45°), Slit (1.2 to 4.0mm), MVR (19G, 20G, 23G, 25G), Crescent (1 to 2.5 mm), Enlarger (5.0 to 5.5mm)

DEVICE DESCRIPTION
Stainless steel blade affixed to a plastic handle with a good grip. Each blade is placed in a protective plastic storage tray before sealing in a peel open pouch. Individually packed blades are supplied sterile.

INTENDED USE/ INDICATION FOR USE
Sterile single use micro incision blades for making corneal or sclera incision during ophthalmic surgical procedures.

MATERIALS USED
Stainless Steel, Polycarbonate

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 10ºC to 30ºC 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
Micro Incision Blades are supplied sterile, in individual pouches. 10 or 50 such pouches are enclosed within an outer printed box. The overall packing contains micro incision blades 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.
- Do not re-use it may lead to cross contamination.
- 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
- 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.
- Select the suitable size of Micro Incision Blades and inspect visually.
- Remove the Micro Incision Blades from sterile packaging and remove the Protective cover.
- Insert the Micro Incision Blades at incision site.
- Use the Micro Incision Blades for making corneal or sclera incision during ophthalmic 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's 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 with applicable local, state and country's laws and regulations.

EXPLICATION OF SYMBOL:

Symbol	Meaning
	Caution
	Manufacturer
	Date and Country of Manufacture
	Consult instructions for use
	Keep away from sunlight
MD	Medical Device
	Do not use hook
	This side up
10°C 30°C	Temperature Limit
45% 65%	Humidity Limitation
	Keep Out of reach of children
	Handle with care

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

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