

## 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.

### TARGET AGE GROUP

Use All Age Groups

### DURATION OF USE

Transient Use (Less than 60 Minutes). It is recommended to withdraw the product after 60 minutes from the patient. The user is accountable for any type of problem taking place in case of use after 60 minutes of the same device.

### STORAGE CONDITIONS

- Store at specified temperature and humidity (Temperature in between 10°C to 30°C and Humidity in between 45% to 65%).

### CONTRAINDICATIONS

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

### INDICATION/INTENDED APPLICATION

Eyeball (Supporting devices for Ophthalmic Surgery)

### MODE OF ACTION

Each micro incision blade consists of a SS blade affixed to a plastic handle with a good grip. They come in various shapes and sizes for specific application during an ophthalmic surgical procedure. A surgeon holds the blade with the handle and uses the blade tip to make the desired incision at the desired location.

### 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.

### MATERIALS USED

Stainless Steel, Polycarbonate

### CAUTIONS

Do not use the device if the sterilized package is open or damaged.

### DIRECTION FOR USE

- Open the sterile pouch (BY AN UNSTERILE PERSON) and then drop the blade with tray on a sterile surface without touching it.
- Remove the blade slowly taking care not to touch the blade edge with the tray.
- The blade handle is for single use only
- The product should be stored at Temperature 10°C-30°C and Humidity 45%-65%.
- Mishandling or improper transport can cause damage to the device or packaging.

### DEVICE LIFE

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

### EXPLANATION OF SYMBOL:

Symbol	Meaning
	Caution
	Manufacturer
	Date and Country of Manufacture
	Do not re-sterilize
	Consult instructions for use
	Keep away from sunlight
	Do not re-use
	Authorized Representative in European Community
	This side up
	Do not use hook
	Medical Device
	Unique device identifier
	Model Number



### WARNING

- Madhu Instruments Pvt. Ltd does not hold any responsibility if the device is reused. Reusing the device may cause serious problems to patients are as under: -
  - The used micro incision blade might not have enough sharpness and may not comply with the claim.
  - The blade gets deformed after cutting. The used blade might not be in a position to be used again due to this deformed shape.
  - Re-use of device may lead to microbial contamination due to presence of Pseudomonas.
  - Contagious and communicable disease such as HIV, Hepatitis, contagious disease/communicable disease/undue diseases etc.
- Only qualified medical practitioner should use the device as per the intended use.
- 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.
- The used micro incision blade and pouch should be disposed off in compliance with the local regulatory requirements.
- Do not use the device after sterility expiry date.
- The device is not for implant
- Keep out of reach of children.

### PRECAUTIONS

- When handling the product care should be taken to avoid damage from handling. Avoid crushing and crimping damage to the product due to application of surgical instruments.

### 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 reported 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
	Conformity of European Norm with Notified Body Number
	Batch Code
	Use by date
	Temperature Limit
	Do not use if package is damaged
	Humidity Limitation
	Single Sterile Barrier System, sterilized using Ethylene Oxide
	Handle with care
	Maximum stacking
	Single Sterile Barrier System with protective packaging outside, sterilized using Ethylene Oxide
	Catalogue Number
	Keep Out of reach of children

### MADHU INSTRUMENTS PVT. LTD.

Mfg. Facility: A 260, Okhla Industrial Area Phase-I, New Delhi-110020 India.  
 Regd. Adl.: F-90/3D, Okhla Industrial Area Phase-I, New Delhi-110020 India  
 Customer Care No.: 011-42701030, 42701031  
 Email: customercare@madhuinstruments.com  
 Website: www.madhuinstruments.com

### EC REP

#### Obelis s.a.

Bd. Général Wahis 53  
 B-1030 Brussels, Belgium  
 Phone: 32.2.732.59.54, Fax: 32.2.732.60.03  
 E-mail: mail@obelis.net