

## EN (English)

JACOB CAIRS Trephine

### JACOB CAIRS Trephine

**APPLICABLE FOR THE MODELS**  
(6.50mm-8.00mm, 7.75mm-8.75mm, 8.00mm-9.50mm)

#### DEVICE DESCRIPTION

EO gas sterilized single use ultrasharp thin profile double cutting-edge circular blades of different diameters mounted on a stainless-steel shell designed for a precise and symmetrical cut of the corneal tissue.

#### INTENDED USE/ INDICATION FOR USE

JACOB CAIRS Trephine are used to create allogenic donor tissue ring of desired thickness for making the Corneal allogenic intrastromal ring segments (CAIRS).

#### MATERIALS USED

Stainless Steel

#### 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.

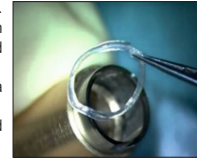
#### HOW SUPPLIED

JACOB CAIRS is individually packed and sealed in an inner blister and an outer pouch. Such packed pouch is enclosed within an outer printed box. The overall packing contains Fixed Depth Trephine 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. Reusing the device may cause transfer Contagious and communicable disease such as HIV, Hepatitis etc.
- The used JACOB CAIRS Trephine 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.
- 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 JACOB CAIRS Trephine and inspect visually.
- Open the blister and take out the trephine from the holder taking care not to touch the blade to any surface.
- For manually cutting the corneal tissue, hold the jacob cairs trephine with the blades facing downwards.
- Gently put the trephine on the tissue and push to cut out the allogenic donor tissue ring.
- Jacob CAIRS trephine can also be used by attaching it to an Endothelial Punch.
- Put back the used trephine in the blister and dispose in compliance with local regulation.

#### 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

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 SYMBOLS:

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
	Maximum stacking

Symbol	Meaning
	Batch Code
	Handle with care
	Use by date
	Do not use if package is damaged and consult instructions for use
	Do not re-use
	Single Sterile Barrier System, with inside protective packaging sterilized using Ethylene Oxide
	Single Sterile Barrier System with inside and outside protective packaging, sterilized using Ethylene Oxide
	Do not re-sterilize
	Catalogue Number
	Unique device identifier

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