CORONET

DALK Clear-Vue™ Recipient Vacuum Trephine Specification Sheet

Product Features:

Controlled DALK incision in three simple steps

1. Position trephine 2. Remove centration tube 3. Insert guarded trephine

No need to calibrate or measure depth of trephine!

- Separate centration tube with precision cross hair reduces parallax
- Ultra-thin, sharp guarded trephine blade with exclusive CORONET® Cathedral blade technology provides a straight walled cut and reduces endothelial cell loss
- Patent protected soft adaptive skirt conforms to individual eye topography
- Light weight body sits on limbus and forms a secure vacuum away from incision
- Transparent body with ergonomic finger grips and open windows for 360° visualisation
- Developed specifically for Deep Anterior Lamellar Keratoplasty (DALK)
- Supplied sterile, single use only, one per box, 5-year shelf life
- Manufactured in the UK

*Fixed depth blade will cut once inserted

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DALK Clear-Vue™ Recipient Vacuum Trephine Size Options

Trephine Size (mm)	Product Code
7.50	51-844-7.50
8.00	51-844-8.00
8.50	51-844-8.50
9.00	51-844-9.00

Material Specification

Product Component	Specification
Guarded trephine	Stainless steel
Centration tube and cross hair	Stainless steel
DALK body and finger grips	Polycarbonate
Skirt	Thermoplastic elastomer
Tubing	Medical grade silicone
Syringe	Luer-lok (5ml capacity)
Blister packaging	0.76mm PETG Blister/ TYVEK Lid (122x188mm)
Outer box/carton	500 Micron printed White boxboard

Intended Use

Designed specifically for performing Deep Anterior Lamellar Keratoplasty (DALK) on the recipient eye, during corneal graft surgery.

Instructions for Use

The instructions for use and suggested surgical technique are supplied in the form of a multi-lingual leaflet with instructions given in diagram form where appropriate. The international symbols used on the packaging are explained in each language. A leaflet is supplied with each product

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Sterilisation

Products are sterilised by Ethylene Oxide (EO) according to a validated cycle and the requirements of BS EN ISO 11135-1 (Current). The approved sterilisation sub-contractor, Synergy Health Plc. Doncaster, England. The products have a declared sterile shelf life of three years. Devices are designated for Single Use Only.

Conformity to the European Directives

The CORONET® Recipient Vacuum Trephine is are classified as a surgically invasive device intended for transient use, (Rule 6, Annex IX 93/42/EEC Medical Devices Directive, as amended by 2007/47/EEC) and is therefore classified as a Class IIa device.

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