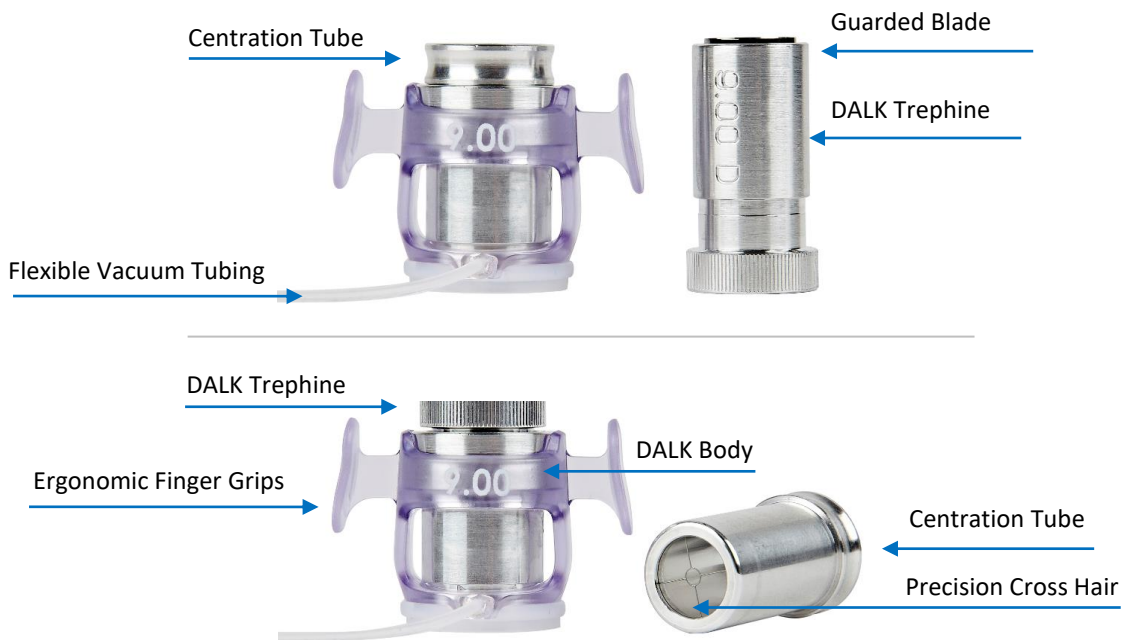


# CORONET

## DALK Clear-Vue™ Recipient Vacuum Trepphine 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

# CORONET

## DALK Clear-Vue™ Recipient Vacuum Trephine Specification Sheet

### 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 blade/cross hair	Stainless steel
Centration tube	Aluminium
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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## DALK Clear-Vue™ Recipient Vacuum Trehine Specification Sheet

### Sterilisation

Products are sterilised by Ethylene Oxide (EO) according to a validated cycle and the requirements of BS EN ISO 11135-1 (Current).

### Conformity to the European Directives

The CORONET® Recipient Vacuum Trehine 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.