

# CORONET

## Clear-Vue™ Recipient Vacuum Trephine Specification Sheet



### Product Overview

The CORONET™ Clear-Vue™ Recipient Vacuum Trephine has been specifically designed to deliver a reliable and consistent vertical incision, giving improved wound architecture and reduced endothelial cell loss.

The trephine features exclusive CORONET™ *Cathedral* Blade Technology, creating an ultra-thin and sharp blade, to minimise undercut and tissue distortion. \*Blade progression 0.063mm downward per quarter turn and 0.252mm per full rotation.

- Developed specifically for full Penetrating Keratoplasty surgery (PK)
- Lightweight and transparent body with open windows for 360° visualisation
- Patent pending skirt sits on limbus as opposed to cornea and conforms to all topography's
- Vacuum function forms away from incision and holds trephine securely in place with minimal impact on IOP
- Improved cross hair for easier centralisation
- Ultra-thin blade provides improved approximation between the donor button and patient cornea
- Ergonomic finger grips work in harmony with natural hand position
- Marker pin feature enables tracking of blade progression
- Supplied sterile, single use only, one per box, declared 3 year shelf life
- Manufactured in the UK

# CORONET

## Clear-Vue™ Recipient Vacuum Trepine Specification Sheet

### Recipient Vacuum Trepine Size Options

#### Trepine Size (mm)

#### Product Code

6.50	51-842-6.50
6.75	51-842-6.75
7.00	51-842-7.00
7.25	51-842-7.25
7.50	51-841-7.50
7.75	51-842-7.75
8.00	51-842-8.00
8.25	51-842-8.25
8.50	51-842-8.50
8.75	51-842-8.75
9.00	51-842-9.00
9.50	51-842-9.50

### Material Specification

#### Product Component

#### Specification

Trepine Blade and cross hair	Stainless Steel (Blade Depth 1.15mm)
Trepine Body and finger grips	Polycarbonate
Skirt	Thermoplastic Elastomer
Black Capstan	ABS
Tubing	Medical Grade Silicone
Syringe	Luer-Lok (5ml capacity)
Blister Packaging	0.76mm PETG Blister/ TYVEK Lid (271mm x 82mm)
Outer Box/Carton	500 Micron Printed White Boxboard

# CORONET

## Clear-Vue™ Recipient Vacuum Trephine Specification Sheet

### Intended Use

The CORONET™ Recipient Vacuum Trephine is designed specifically for performing a full Penetrating Keratoplasty (PK) 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

### Sterilisation

Products are sterilised by Ethylene Oxide (EO) according to a validated cycle and the requirements of BS EN ISO 11135-1:2007, by an 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.