

CORONET

Recipient Vacuum Trephine Specification Sheet



Product Overview

The CORONET® 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)
- Precise, ultra sharp, thin profile blade provides a vertical incision, reducing undercut and tissue distortion
- Vacuum function holds trephine securely in place
- Graticule pinpoint cross hair allows accurate positioning
- Ergonomic finger grips work in harmony with natural hand position
- All metal constructed blade with non-glare finish
- Marker pin feature to enable tracking of blade progression
- Double sided *Cathedral* blade to ensure a reliable and consistent vertical incision
- Supplied sterile, single use only, one per box, declared 5-year shelf life
- Manufactured in the UK

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Recipient Vacuum Trephine Size Options

Trephine Size (mm)	Product Code
6.50	51-840-6.50
6.75	51-840-6.75
7.00	51-840-7.00
7.25	51-840-7.25
7.50	51-840-7.50
7.75	51-840-7.75
8.00	51-840-8.00
8.25	51-840-8.25
8.50	51-840-8.50
8.75	51-840-8.75
9.00	51-840-9.00
9.50	51-840-9.50

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Material Specification

Product Component	Specification
Trephine Blade and cross hair	Stainless Steel (Blade Depth 1.15mm)
Trephine Body and finger plates	Aluminium
Black Capstan	ABS
Tubing	Medical Grade Silicone
Syringe	Luer-Lok (5ml capacity)
Blister Packaging	PETG Blister/ TYVEK Lid
Outer Box/Carton	500 Micron Printed White Boxboard

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 (current).

Conformity to the European Directives

The CORONET® Recipient Vacuum Trephine is 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.