

CORONET

Guarded Trephine Specification Sheet



Product Overview

The CORONET® Guarded Trephine has been specifically designed to deliver a reliable and consistent vertical incision, giving improved wound architecture and reduced endothelial cell loss.

Each trephine features exclusive CORONET® *Cathedral* Blade Technology, creating an ultra-thin and sharp blade, to minimise undercut and tissue distortion.

- Ultra-sharp and thin blade provides improved approximation between the donor button and patient cornea
- Lightweight ergonomically balanced aluminium body
- Graticule pinpoint cross hair provides superior positioning Available in two fixed depth blade options 300µm and 400µm
- All metal constructed blade with non-glare finish
- Double sided *Cathedral* blade to ensure a clean vertical cut and that the graft button is not retained
- Compatible with CORONET® Artificial Anterior Chamber (51-935)
- Supplied sterile, single use only, one per box, declared 5-year shelf life
- Manufactured in the UK

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Guarded Trepine Size Options

| Size (mm) | 51-860 300µm | 51-865 400µm |
|-----------|--------------|--------------|
| 7.00 | 51-860-7.00 | 51-865-7.00 |
| 7.50 | 51-860-7.50 | 51-865-7.50 |
| 8.00 | 51-860-8.00 | 51-865-8.00 |
| 8.50 | 51-860-8.50 | 51-865-8.50 |

Material Specification

| Product Component | Specification |
|------------------------------|-------------------------------------------------|
| Trepine blade and cross hair | Stainless Steel |
| Trepine Body | Aluminium |
| Blister Packaging | 0.5mm PETG Blister/ TYVEK Lid (51.6mm x 51.6mm) |
| Outer Box/Carton | 500 Micron Printed White Boxboard |

Intended Use

The CORONET® Guarded Trepine is to be used for either trephination of the donor button or trephination of the recipient eye during corneal transplant surgery. The ultra-thin blade profile cuts cleanly through the corneal tissue allowing for a better approximation between the donor button and the patient cornea.

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

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The CORONET® Guarded 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.