

CORONET

Standard Trephine Specification Sheet



Product Overview

The CORONET® Standard 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
- All metal constructed blade with non-glare finish
- Double sided *Cathedral* blade to ensure a clean cut ensures graft button is not retained
- Available with or without graticule cross hair
- 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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Standard Trephine Size Options

Size (mm)	51-900	51-901 (with Cross Hair)
6.00	51-900-6.00	51-901-6.00
6.25	51-900-6.25	51-901-6.25
6.50	51-900-6.50	51-901-6.50
6.75	51-900-6.75	51-901-6.75
7.00	51-900-7.00	51-901-7.00
7.25	51-900-7.25	51-901-7.25
7.50	51-900-7.50	51-901-7.50
7.75	51-900-7.75	51-901-7.75
8.00	51-900-8.00	51-901-8.00
8.25	51-900-8.25	51-901-8.25
8.50	51-900-8.50	51-901-8.50
8.75	51-900-8.75	51-901-8.75
9.00	51-900-9.00	51-901-9.00
9.25	51-900-9.25	51-901-9.25
9.50	51-900-9.50	51-901-9.50
9.75	51-900-9.75	

Material Specification

Product Component	Specification
Trephine Blade	Stainless Steel
Trephine Body	Aluminium
Blister Packaging	0.5mm PETG Blister/ TYVEK Lid (51.6mm x 51.6mm)
Outer Box/Carton	500 Micron Printed White Boxboard

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Intended Use

The CORONET® Standard Trephine 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

The CORONET® Standard Trephines range of products 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.