

CORONET

Donor Trephine Punch Specification Sheet



Product Overview

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

The free rotating trephine features exclusive CORONET® *Cathedral* Blade Technology, creating an ultra-thin and sharp blade which minimises undercut and tissue distortion

- Complete donor graft preparation system suitable for PK, DALK and DSAEK/DSEK surgery
- Sharp, clean cutting action requires minimal downward pressure to complete the cut
- Ultra-sharp and thin blade produces a vertical cut that improves approximation between the donor button and patient cornea
- Patent protected 360° graft visualisation windows, for increased accuracy
- Double sided *Cathedral* blade will not retain graft button once cut
- Anatomically shaped bowl to gently support the tissue and aid centralisation
- Marker holes to reduce risk of bubble formation
- Unique base provides a stable platform which can be easily held in place during donor preparation
- Non-glare all metal construction blade
- Supplied with protective dust cover, to shield graft from contamination during transfer from donor to patient
- Supplied sterile, single use only, one per box, declared 5-year shelf life
- Available with or without vacuum
- Manufactured in the UK

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Donor Trepine Size Options

| Trepine Size (mm) | 51-835 Donor Trepine Vacuum Punch | 51-850 Donor Trepine Punch |
|-------------------|--------------------------------------|-------------------------------|
| 6.00 | 51-835-6.00 | 51-850-6.00 |
| 6.25 | 51-835-6.25 | 51-850-6.25 |
| 6.50 | 51-835-6.50 | 51-850-6.50 |
| 6.75 | 51-835-6.75 | 51-850-6.75 |
| 7.00 | 51-835-7.00 | 51-850-7.00 |
| 7.25 | 51-835-7.25 | 51-850-7.25 |
| 7.50 | 51-835-7.50 | 51-850-7.50 |
| 7.75 | 51-835-7.75 | 51-850-7.75 |
| 8.00 | 51-835-8.00 | 51-850-8.00 |
| 8.25 | 51-835-8.25 | 51-850-8.25 |
| 8.50 | 51-835-8.50 | 51-850-8.50 |
| 8.75 | 51-835-8.75 | 51-850-8.75 |
| 9.00 | 51-835-9.00 | 51-850-9.00 |
| 9.25 | 51-835-9.25 | 51-850-9.25 |
| 9.50 | 51-835-9.50 | 51-850-9.50 |
| 9.75 | 51-835-9.75 | 51-850-9.75 |

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Material Specification

Product Component

Specification

| | |
|-------------------|---|
| Trepine Blade | Stainless Steel |
| Trepine Body | Aluminium |
| Punch Base | Polycarbonate |
| Syringe with luer | Polycarbonate, Luer-Lok (5ml capacity) |
| Blister Packaging | 0.5mm PETG Blister/ TYVEK Lid (122mm x 188mm) |
| Outer Box/Carton | 500 Micron Printed White Boxboard |

Intended Use

The CORONET® Donor Trepine punch is designed specifically for preparing donor graft tissue. Each Trepine is designated for 'SINGLE USE ONLY' and should not be re-sterilised by any method or re-used.

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

Donor Trepine Punches are all transient use, single-use, sterile, non-invasive medical devices. The classification is determined under Section III: Classification, Subsection 1 non-invasive devices, 1.2 Rule 2 second indent of the 93/42/EEC Medical Devices Directive (MDD) amended by 2007/47/EC. The classification is class IIa.