

'PRODUCT NAME TRADITIONAL CORNEAL TREPHINE
'PRODUCT INFORMATION AND INSTRUCTIONS FOR USE

Symbols Used

 GB- Lot Number	 GB- Use By Date	 GB- Do Not Re-use	 GB- Do not use if product is opened or damaged.	 GB- Sterilised by Ethylene Oxide	 GB - Manufacturer	 GB – Date of Manufacture	 GB – EU Authorised Representative
 GB- Catalogue Number	 GB- Caution	 COR_009 GB - Consult Electronic Instructions for Use	 GB – Caution: United States Federal law restricts medical devices to sale by or on the order of a physician	 GB- Do not resterilise	 GB – Medical Device	 GB – Unique Device Identifier	 GB - Sterile barrier system with an additional packaging layer inside

GB - INSTRUCTIONS FOR USE

Description

The **CORONET® Traditional Trephine** is a single use only device with an ultra-sharp cutting edge, supplied with a knurled finger grip for secure manual trephination.

Intended Use

The CORONET range of corneal trephines are devices used in Corneal Graft Surgery and can be used for full penetrating keratoplasty of the recipient cornea or for the preparation of the donor button during corneal transplant procedures.

CAUTIONS

- This device is supplied STERILE and ready to use.
- The device is for SINGLE USE ONLY. Do NOT re-sterilise or re-use.
- Do not use if the packaging has been opened or damaged.
- It is recommended that the trephine be left in the packaging until required, to ensure that the blade remains in perfect condition.
- This device is intended for use by trained medical persons possessing the requisite skill and experience to use the device in accordance with the prevailing standards of medical practice and in conjunction with the instructions for this device
- For safe disposal, the trephine should be considered as 'sharp' and must be immediately placed in a secure puncture-resistant bin (conforming to BS7320) which is suitable for incineration. All the components should be disposed of in accordance with hospital approved procedures.
- The product comes into contact with bodily fluids, which can be contaminated. Care should be taken in the handling and disposal of the device after use to prevent contamination.
- CAUTION: US Federal Law restricts sales and use to or on the order of a Physician
- The Coronet trephine is much sharper than a traditional trephine. Caution should be exercised at all times when handling and using this device.
- The device is supplied with the blade in perfect condition. Should the device be accidentally dropped onto a hard surface, check the blade integrity under the microscope before use and discard if the blade is damaged.
- This product contains nickel which may cause allergic reaction in patients with sensitivity to nickel. Risk assess the use of the devices in relation to the medical benefit of the procedure and take necessary precautions with patients with known sensitivity to nickel.
- To avoid damaging the blade edge, take care when removing the device from the rigid plastic container. Using finger and thumb grasp the wide end of the card inner, which passes through the lumen of the device, and lift gently. The device is presented ready for use.

Incident Reporting

Any serious incident that has occurred in relation to this device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established

Sterilisation

- The Trephine is a **SINGLE USE ONLY** device supplied sterile and ready for use. Sterilisation is by Ethylene Oxide (EO)
- **DO NOT RE-STERILISE.** Network Medical Products Ltd. assumes no liability for devices that have been re-sterilised by healthcare facilities.

HAZARDS ASSOCIATED WITH THE RE-USE OF SINGLE USE ONLY DEVICES

1. Single use devices have not been validated for re-use.
If you re-use a device you may be held **Legally Liable** for the safe performance.
2. Cross-contamination and infection risks to patients. Including transmission of:
 - CJD & Variant CJD.
 - Prion Diseases.
 - Bacterial Endotoxins.
 - Hepatitis B & Hepatitis C.
 - Risks posed by HIV and AIDS
 Note : Reprocessing may not remove all viable micro-organisms. Abnormal proteins associated with prion diseases eg. Creutzfeldt-Jakob disease (CJD) and variant Creutzfeldt-Jakob disease, have been identified in corneal tissue and are very resistant to all conventional methods of decontamination.
3. Device failure through material fatigue or degradation caused by initial use and design:
 - **Metals:** Can be damaged or subjected to rusting. Blade edges will be damaged or blunt. Needles may be bent from the original shape.
4. Patient injury from device failure and/or chemical burns from residue of decontamination agents absorbed into the materials.

This IFU is available in other languages upon request. Please contact Network Medical Products Limited for details.

PRODUCT DETAILS	
Cat Ref:	Description
52-150 4.0mm	Traditional Trephine 4.0mm Pack of 1 Sterile Single Use
52-150 5.0mm	Traditional Trephine 5.0mm Pack of 1 Sterile Single Use
52-150 5.5mm	Traditional Trephine 5.5mm Pack of 1 Sterile Single Use
52-150 6.0mm	Traditional Trephine 6.00mm Pack of 1 Sterile Single Use
52-150 6.25mm	Traditional Trephine 6.25mm Pack of 1 Sterile Single Use
52-150 6.5mm	Traditional Trephine 6.50mm Pack of 1 Sterile Single Use
52-150 6.75mm	Traditional Trephine 6.75mm Pack of 1 Sterile Single Use
52-150 7.0mm	Traditional Trephine 7.00mm Pack of 1 Sterile Single Use
52-150 7.25mm	Traditional Trephine 7.25mm Pack of 1 Sterile Single Use
52-150 7.5mm	Traditional Trephine 7.50mm Pack of 1 Sterile Single Use
52-150 7.75mm	Traditional Trephine 7.75mm Pack of 1 Sterile Single Use
52-150 8.0mm	Traditional Trephine 8.00mm Pack of 1 Sterile Single Use
52-150 8.25mm	Traditional Trephine 8.25mm Pack of 1 Sterile Single Use
52-150 8.5mm	Traditional Trephine 8.50mm Pack of 1 Sterile Single Use
52-150 8.75mm	Traditional Trephine 8.75mm Pack of 1 Sterile Single Use
52-150 9.0mm	Traditional Trephine 9.00mm Pack of 1 Sterile Single Use
52-150 9.25mm	Traditional Trephine 9.25mm Pack of 1 Sterile Single Use
52-150 9.5mm	Traditional Trephine 9.50mm Pack of 1 Sterile Single Use
52-150 9.75mm	Traditional Trephine 9.75mm Pack of 1 Sterile Single Use
52-150 10.0mm	Traditional Trephine 10.0mm Pack of 1 Sterile Single Use
52-150 10.5mm	Traditional Trephine 10.5mm Pack of 1 Sterile Single Use
52-150 11.0mm	Traditional Trephine 11.0mm Pack of 1 Sterile Single Use
52-150 11.5mm	Traditional Trephine 11.5mm Pack of 1 Sterile Single Use
52-150 12.0mm	Traditional Trephine 12.0mm Pack of 1 Sterile Single Use

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52-150 12.5mm	Traditional Trephine 12.5mm Pack of 1 Sterile Single Use
52-150 13.0mm	Traditional Trephine 13.0mm Pack of 1 Sterile Single Use
52-150 14.0mm	Traditional Trephine 14.0mm Pack of 1 Sterile Single Use
52-150 15.0mm	Traditional Trephine 15.0mm Pack of 1 Sterile Single Use
52-150 16.0mm	Traditional Trephine 16.0mm Pack of 1 Sterile Single Use