CORONET

DMEK EndoGlide™ Specification Sheet

Product Overview

The CORONET® DMEK EndoGlide™ has been specifically designed to provide controlled graft unfolding with minimal cell loss.

DMEK EndoGlide™ Key Features:

- Minimal 2.65mm incision required
- Suitable for endothelium up to 9.00mm
- Tri-fold delivery technique
- Transparent closed cartridge
- Uses controlled pull through paracentesis approach
- Forceps guide bridge
- Anterior chamber maintainer recommended
- Supplied sterile, single use, 5-year shelf life
- Supplied one per box
- Patent Protected
- Manufactured in the UK

For best results use in conjunction with the DMEK EndoGlide™ Forceps and EndoGlide™ Support Platform.

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EndoGlide™ Range	Product Code
DMEK EndoGlide™	**51-826**
EndoGlide™ Support Platform	53-920
Tan EndoGlide™ Placement Forceps	53-951
Tan EndoGlide™ Loading Forceps	53-952

Material Specification

Product Component	Specification
Preparation Base	Polycarbonate
Cartridge	Polycarbonate
Introducer	ABS
Blister Packaging	0.7mm PETG Blister/ TYVEK Lid (122x188mm)
Outer Box/Carton	500 Micron Printed White Boxboard

Intended Use

The device is intended solely for the delivery and insertion of previously prepared donor cornea tissue for transplantation during DMEK procedure.

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).

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Conformity to the European Directives

The EndoGlide™ DMEK 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.

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