

CORONET

EndoGlide™ Ultrathin Specification Sheet



Product Overview

The EndoGlide™ Ultrathin, has been specifically designed to provide the best clinical results during DSAEK surgery, by enabling maximum control and protection of the donor graft throughout the procedure. The patent protected design allows the donor graft to be loaded into the delivery cartridge utilising a unique 'double coil' principal, minimising endothelial touch and protecting the donor graft during insertion to the recipient.

EndoGlide™ Ultrathin Key Features:

- Utilises a paracentesis approach to provide maximum control
- Accommodates donor endothelium up to 9.5 mm diameter and 70µm to 250µm in thickness
- Suitable for use with small eyes, and eyes with shallow anterior chambers or high vitreous pressure
- Stable anterior chamber throughout insertion procedure due to the 'closed' system
- Allows use of Anterior Chamber Maintainer if required
- Transparent cartridge for all-round visualisation
- Supplied sterile, single use only, one per box, declared 5-year shelf life
- Manufactured in the UK

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

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EndoGlide™ Range

Product Code

EndoGlide™ Ultrathin

51-823

Tan EndoGlide™ Placement Forceps

53-951

Tan EndoGlide™ Loading Forceps

53-952

Material Specification

Product Component

Specification

Preparation Base and Saddle

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 a DSEK or DSAEK 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™ Ultrathin 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.