NETWork
Medical Products England

CORONET
ENDOGLIDE
ULTRATHIN

PRODUCT INFORMATION AND INSTRUCTIONS

NETWORK MEDICAL PRODUCTS LTD
Coronet House, Kearsley Road,
Ripon, North Yorkshire, HG4 2SG, UK
Tel: +44 (0)1765 609555 Fax: +44 (0)1765 608476
e-mail: info@networkmedical.co.uk

CE 0120

GB SYMBOLS

LOT Lot Number

STERILE EO

Sterilised by Ethylene Oxide

Do not use if product is opened or damaged

Do not reuse

REF Catalog Number

Use Until Date

Caution

ES SÍMBOLOS

LOT Número de lote

STERILE EO

Esterilizado con óxido de etileno

No utilizar si el paquete está abierto o dañado

No reutilizar

REF Número de Catálogo

Usar antes de la fecha

Cuidado

FR SYMBOLES

LOT Numéro de lot

STERILE EO

Stérilisé à l'oxyde d'éthylène

Ne pas utiliser si l'emballage est ouvert ou endommagé

ne pas réutiliser

REF Numéro du catalogue

Utiliser avant le (date)

Mise en garde

PT SÍMBOLOS

LOT Número do Lote

STERILE EO

Esterilizado por Óxido de Etileno

Não use se a embalagem estiver aberta ou danificada

Não reutilize

REF Número do Catálogo

Use Até o Dia

Cuidado

DE SYMBOLE

LOT Losnummer

STERILE EO

Sterilisiert durch Ethylenoxid-Gas

Nicht verwenden, wenn die Packung bereits offen oder besch digt ist.

Nur zum einmaligen Gebrauch bestimmt

REF Katalognr

Verwendbar bis

Warnhinweis

TR SEMBOLLER

LOT Lot Numarası

STERILE EO

Etilen Oksitle Steril Edilmiştir

Paket açılmış ya da zarar g rm şse kullanmayın

Yeniden kullanmayın

REF Katalog Numarası

Son Kullanım Tarihi

Uyarı

IT SIMBOLI

LOT Numero di lotto

STERILE EO

Sterilizzato ad ossido di etilene

Non usare se la confezione aperta o danneggiata

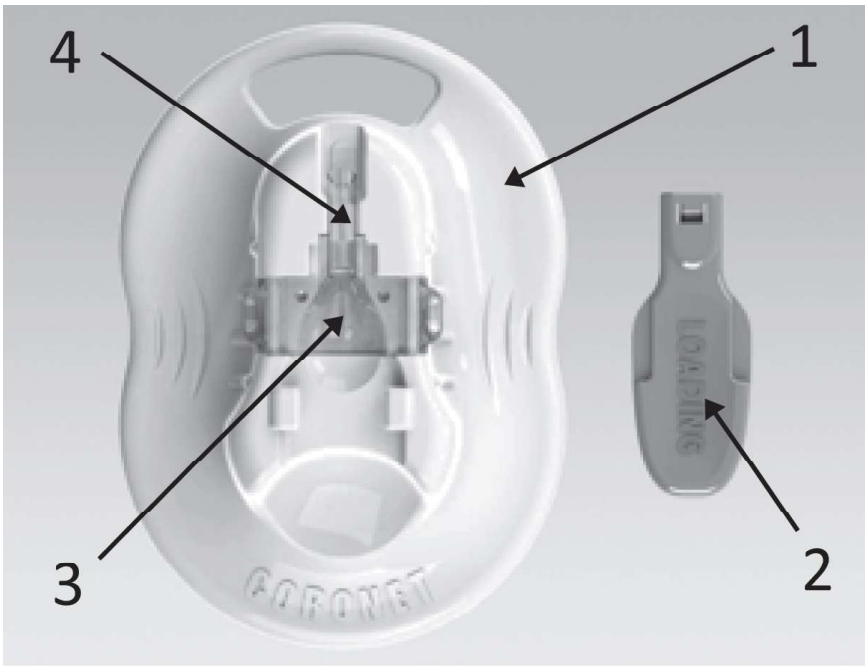
Non riutilizzare

REF Numero di catalogo

Scadenza

Avvertenza

EndoGlide Ultrathin



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GB	**EndoGlide Preparation Base**	**EndoGlide Introducer**	**EndoGlide Saddle**	**EndoGlide Cartridge**
FR	Base de Préparation EndoGlide	Introducteur EndoGlide	Sellette EndoGlide	Cartouche EndoGlide
DE	EndoGlide Präparierbasis	EndoGlide-Inserter	EndoGlide-Sattel	EndoGlide-Patrone
IT	Base di preparazione EndoGlide	Introduttore EndoGlide	Sella EndoGlide	Cartuccia EndoGlide
ES	Base de Preparación de EndoGlide	Introductor EndoGlide	Montura EndoGlide	Cartucho EndoGlide
PT	Base de Preparação EndoGlide	Introdutor EndoGlide	Sela EndoGlide	Cartucho EndoGlide
TR	EndoGlide Preparat Kaidesi	EndoGlide ntrodüseri	EndoGlide Yatak Kovanı	EndoGlide Kartu

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EndoGlide Ultrathin Surgical Technique

Instructions for Use

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.

Description

The EndoGlide Ultrathin (UT) is a device designed particularly to meet the needs of the corneal graft surgeon performing DSEK (Descemet's Stripping Endothelial Keratoplasty) or DSAEK (Descemet's Stripping Automated Endothelial Keratoplasty) procedures using ultrathin donor tissue. The device is a sterile four-part single use only delivery system for the previously prepared donor tissue, which allows the surgeon to hold and deliver the tissue in a manner which minimises any endothelial cell damage and consequent loss of function.

CAUTIONS

- This device is for SINGLE USE ONLY. Do NOT re-sterilise or re-use.
- Do not use if the blister pack has been opened or damaged.
- Place the preparation base on a flat, sterile surface before use.
- If using the EndoGlide Support Platform, place the preparation base in the mount prior to commencing the procedure.
- Carefully place the donor cornea, comprising the posterior lenticule only, endothelial surface up within the well of the Preparation Base before proceeding further.
- Before removing the cartridge from the preparation base ensure that the locking mechanism has engaged correctly and that the two parts are securely locked together.
- CAUTION should be exercised when inserting the cartridge if the patient has an intraocular lens implant.

Protocol For Surgical Technique

Recipient cornea preparation

1. **Wound construction**

   A temporal scleral or clear corneal incision may be used to insert the EndoGlide UT containing the donor tissue. For scleral incisions, a 4.5 mm blade should be used. For clear corneal incisions, a 4.9mm blade should be used. In both cases, the wound depth should be at least 1.5mm deep to

create a self-sealing wound.

2. **AC maintainer**

   Use an AC maintainer to ensure formation of the AC during insertion. Placement of the AC maintainer could be adjacent to either the superior or inferior aspect of the temporal incision so as not to obstruct the donor incision. BSS flow through the maintainer should be away from the incision and low to moderate during the entire insertion procedure.

3. **Nasal paracentesis**

   Perform a 1mm paracentesis at the nasal limbus or clear cornea opposite to the temporal incision through which to introduce the Tan EndoGlide Placement Forceps (TEP Forceps) to pull the donor tissue into the AC.

Donor Cornea Preparation and Sizing

1. The EndoGlide UT is specifically designed for loading and insertion of an ultrathin posterior lenticule prepared by a microkeratome. (Note : the EndoGlide UT can be used with lenticules of thickness 70 to 250µm).
2. Donor trephination with a suitable Coronet Donor Punch: the Coronet EndoGlide UT is designed to enable insertion of a corneal donor up to 9.5mm in diameter.

Cartridge preparation

The procedure should be performed under the operating microscope with the preparation base positioned on a flat, stable, sterile surface. If using the EndoGlide Support Platform, the preparation base should be placed in the mount before commencing the procedure. Loading the donor can however be performed without the support platform. Prepare the recipient cornea as above, so that the donor tissue insertion may be performed immediately after the donor is coiled in the cartridge. Note that the cartridge is supplied pre-loaded onto the preparation base.

1. Positioning of EndoGlide Cartridge

The cartridge and saddle are supplied pre-loaded on the preparation base.

2. Donor tissue placement

Maximal forward placement of the donor to abut the cartridge opening makes it easier to grasp the donor for the coiling process. This brings the donor edge closer to the loading forceps, and positions the donor at the ideal height for easy grasping with the forceps for the pull-through.

There are two methods for tissue placement – **a**. for use with a single lenticule, or **b**. for use when supplied with both the anterior and posterior lenticules.

a. Single Lenticular Method

- Place a small amount of BSS in the well of the preparation base for

lubrication. Inject BSS into the inner chamber of the cartridge, which can be completely filled. Using a Paton spatula, carefully place the donor cornea endothelial surface up in the well of the preparation base. Apply the BSS cannula to the edge of the lenticule, and gently push the lenticule close to the entrance of the saddle.

- After correct positioning of the donor, place a very thin stream of dispersive viscoelastic onto the donor surface, along the long axis of the cartridge, prior to donor coiling. This provides for additional endothelial protection during the pull-through process.

b. Double (anterior and posterior) Lenticular Method

- Place a small amount of BSS in the well of the preparation base and carefully inject BSS into the inner chamber of the cartridge, which should be completely filled. Using a Paton spatula, carefully place the donor cornea, comprising both the anterior and posterior lenticules, endothelial surface up. Physical separation may be gently performed via gentle hydro-dissection of the two lenticules. Apply the BSS cannula to the edge of the lenticule, and gently push the lenticule close to the entrance of the saddle.
- After correct positioning of the donor, place a very thin stream of dispersive viscoelastic onto the donor surface, along the long axis of the cartridge, prior to donor coiling. This provides for additional endothelial protection during the pull-through process.

3. Curling procedure

Introduce the Tan EndoGlide Loading Forceps (TEL forceps) through the anterior opening of the cartridge into the chamber up to the level of saddle, where the leading edge of the donor will be positioned. Using the TEL forceps grasp the edge of the donor, and gradually pull it into the cartridge chamber. As the donor tissue enters the cartridge, the sides of the donor tissue will naturally curl upwards, without wrinkling, along the upward curving walls of the saddle tunnel, and the tissue will form a double coil configuration in the cartridge. It is usually unnecessary to use a cannula to stroke the edges of the donor upwards along the side walls of the chamber. Pull the donor tissue all the way in, until the leading anterior edge just reaches the anterior opening of the cartridge. Gently release the donor tissue from the forceps and remove the forceps out of the cartridge. If the tissue remains attached to the teeth of the forceps, slight rotational movements of the forceps along its long axis will facilitate tissue release. The donor should now be fully formed in a double coil configuration within the cartridge. **NOTE:** This is inferior at this stage as the cartridge is positioned upside down on the preparation base.

The EndoGlide Introducer

1. Removal of Donor Anterior Lenticule (Double Lenticular Method only)

Remove the donor anterior lenticule from the well of the Preparation Base and discard.

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2. **Removal of the Saddle**

   Holding the 'saddle' between finger and thumb, release the component one side at a time and then lift off vertically to remove the saddle before positioning the introducer.

3. **Attachment of the EndoGlide Introducer**

   The introducer slides into position behind the cartridge using the guiding grooves. Advance the introducer, with word "**LOADING**" facing uppermost, into the posterior end of the cartridge until it fully engages with a hard stop.

4. **Removal of the EndoGlide Cartridge, Introducer and donor complex**

   The loaded cartridge, with the introducer attached, may now be removed in its' entirety from the preparation base by sliding the assembly backwards and out of the grooves of the base. The cartridge is now ready for insertion into the recipient eye.

EndoGlide Cartridge Insertion

NOTE: After removing the introducer and cartridge from the base, turn the assembly right-side up (the word "**INSERTION**" printed on the Introducer should now be uppermost) to ensure correct orientation for insertion into the recipient eye.

1. Grasp the introducer right way up with the thumb and forefinger for easy insertion into the wound (thumb uppermost) (similar to insertion of a thumbdrive into the USB port of a computer).
2. With the AC maintainer on low flow, gently slide the anterior tongue (glide) of the cartridge through the temporal wound, to advance the cartridge into the AC. The flat surface of the tongue ensures moderate closure of the wound to reduce egress of AC fluid and prevents iris prolapse through the wound.
3. Grip the anterior lip of the wound (to prevent lip inversion), and introduce the sloping anterior opening of the cartridge fully into the wound until the uppermost edge of the opening is completely engaged through the wound. Advancement should be fairly rapid to reduce chamber collapse. Continue to advance the cartridge further until the anterior opening is seen through the cornea to be fully within the AC. At this point the forward edge of the cartridge tongue (glide) is positioned across the pupil and over the nasal iris, and the EndoGlide should snugly seal the wound.

Donor Pull-Through and Removal of the EndoGlide

With one hand still holding the introducer and cartridge in position (the EndoGlide can be used to steady the eye at this point), insert the TEP Forceps into the AC through the nasal paracentesis with the other hand. Advance the forceps into the AC, over the cartridge glide, into the anterior opening of the

cartridge to reach the leading stromal edge of the donor tissue. Grasp the donor and gently pull the donor tissue out of the cartridge chamber into the AC. Keep the cartridge and introducer in position during this stage. Whilst still holding onto the donor tissue with the TEP Forceps, retract the cartridge and introducer out of the eye. The wound will close, and the AC will remain deep due to the AC maintainer. Once the donor tissue is fully placed in the AC, it will automatically start to uncurl in the anatomically correct endothelial down position. Gentle sideways "to-and-fro" shaking of the donor with the forceps will easily assist in uncurling if one wing remains slightly curled. During this process, the AC should remain deep and fully formed with the AC maintainer still on. If the edges of the donor are caught on the iris, and do not fully uncoil, deepening the chamber by increasing AC maintainer flow may help achieve full uncurling. Gently tapping the cornea from the corneal surface may also assist in full donor uncurling. **Note: do not release the donor with the forceps at this stage.**

Donor centration and air injection

1. Ensure that the donor is centrally placed over the recipient cornea with the forceps. Inject a small amount of air (2mm size) with an air cannula beneath the donor – the air bubble ensures that the donor continues to float up against the recipient stromal surface. Do not attempt to insert a large air bubble at this stage. If the donor is not completely central, a large bubble will quickly press the donor up against the recipient stromal surface, initiating sticking and make subsequent donor positioning difficult.
2. Finally, release the donor from the TEP forceps and retract the forceps out of the eye. If there is concern that the wound is not fully self-sealing, and there is high vitreous pressure (in which case the AC may shallow and the donor may shoot out through the wound if it is released) then before releasing the donor, the AC maintainer may be shut off or reduced, and the lip of the wound may be held down with forceps before releasing the donor fully. Full wound closure, air tamponade and completion of the DSAEK procedure should then be performed in the usual manner.

Sterilisation

- The EndoGlide Ultrathin is supplied sterile and ready for use. Sterilisation is by Ethylene Oxide (EO)

Hazards associated with RE-USE of this Single Use Only device:

1. This single use device has 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 the transmission of:

- CJD & Variant CJD.

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- 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. Plastics can be weakened, warped or become brittle. The accuracy, function and performance of the device **will be seriously affected if the device is re-sterilised.**
4. Patient injury from device failure and/or chemical burns from residue of decontamination agents absorbed into the materials.
5. **Separating components -** Forcibly separating the introducer from the cartridge after primary use will lead to leakage of aqueous from the back of the cartridge and loss of intraocular pressure in any re-use.

PRODUCT DETAILS

Cat Ref:	***51-823***
Description	**ENDOGLIDE ULTRATHIN** Preparation base, Introducer, Saddle and Cartridge
Packaging	1 device per box Preparation base, Introducer, Saddle and Cartridge STERILE SINGLE USE ONLY

Also Recommended for use with the EndoGlide Ultrathin

53-920	EndoGlide Support Platform
53-951	Tan EndoGlide Placement Forceps
53-952	Tan EndoGlide Loading Forceps

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