PRODUCT NAME ENDOGLIDE™ FORCEPS, 27G
PRODUCT INFORMATION, CLEANING AND MAINTENANCE INSTRUCTIONS AND INSTRUCTIONS FOR USE

Symbols Used

LOT GB- Lot Number	EC REP GB – EU Authorised Representative	NON STERILE GB- Non Sterile	GB- Do not use if product is opened or damaged and consult instructions for use	GB – Manufacturer	GB – Date of Manufacture
REF GB- Catalogue Number	GB- Caution	COR_025 GB - Consult Electronic Instructions for Use	Rx only GB – Caution: United States Federal law restricts medical devices to sale by or on the order of a physician	MD GB – Medical Device	UDI GB – Unique Device Identifier

GB - INSTRUCTIONS FOR USE

Description

Over time, many different kinds of instruments and tools have been developed for surgical procedures. Some surgical instruments are designed for general use in surgery, while others are designed for a specific procedure or surgery. Accordingly, the nomenclature of surgical instruments follows certain patterns, such as a description of the action it performs (for example, scalpel, hemostat), the name of its inventor(s) (for example, the EndoGlide forceps), or a compound scientific name related to the kind of surgery. EndoGlide forceps have been developed from established designs for intraocular forceps and have squeeze action handles and 27g needle tube. The microforcep tips are 1.5mm long and grooved over the first 0.66mm to enable the surgeon to grasp the very edge of the stromal tissue.

Intended Use

A surgical instrument is a specially designed tool or device for performing specific actions during a surgical procedure, such as modifying biological tissue or providing access for viewing the tissue. The EndoGlide Forceps have been designed specifically to assist the surgeon when using the DMEK EndoGlide during DMEK procedures. The EndoGlide Loading Forceps have a straight shaft and are the correct length for the surgeon to pull-through the donor cornea tissue into the cartridge chamber. The EndoGlide Placement Forceps have a radiussed curve shaft which can be inserted into the anterior chamber through a nasal parasentesis to grasp the donor tissue and draw it out of the cartridge into the anterior chamber.

Our instruments are designed for use by ophthalmic surgeons, who have a good knowledge of their features and how they should be used. It is the responsibility of the surgeon to choose the most suitable instrument for the surgical technique being performed, based on his experience and expertise.

Cleaning and Maintenance

This instrument is not delivered sterile; and consequently it is necessary to clean and sterilise it in accordance with these instructions prior to use.
These instructions are intended for use by persons with the required specialist knowledge and training. All persons handling the platform should be knowledgeable in the use and handling of surgical instruments, accessories and related equipment.

CAUTION

- 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.
- CAUTION: US Federal Law restricts sales and use to or on the order of a Physician
- If the product is opened or damaged, inspect under magnification for any possible damage to the instrument prior to use
- Instruments must be used for their specified purpose and incorrect use could damage the instrument.
- Care should be taken in the handling and disposal of the device after use to prevent contamination
- Before using, examine the instrument. Do not use instruments that show problems or defects.
- Follow instructions and warnings as issued by manufacturers of any decontaminants, disinfectants and cleaning agents used. Wherever possible avoid use of mineral acids and harsh, abrasive agents.
- No part of the process shall exceed 140°C.
- Devices with long, narrow cannula, hinges and blind holes require particular attention during cleaning.
- Do not use peroxide or hydrogen on titanium instruments or on anodised surfaces in order to avoid decolourisation.
- TAKE CARE **NOT TO DROP THE INSTRUMENT ONTO A HARD SURFACE** as this will likely cause damage requiring the instrument to be repaired.
- 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.
- Network Medical recommends the use of an alkaline detergent CE marked for use with titanium medical devices.
- Network Medical have validated the cleaning of this device (manual and Automated wash) using a Prolystica 2 x Alkaline Detergent 2ml/l.

Note: When reprocessing medical devices, always handle with care, wearing protective clothing, gloves and eyewear in accordance with local Health & Safety procedures.

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.

Limitations on Reprocessing

- Repeated processing has minimal effect on these instruments.
- End of life is normally determined by wear and damage in use.

Instructions

- Wherever possible, do not allow blood, debris or bodily fluids to dry on the instruments. For best results and to prolong the life of the medical device clean and reprocess immediately after use. If they cannot be reprocessed immediately, use an enzymatic foam spray cleaner to help prevent soil from drying.
- Instruments should be flushed clean of all residues, dried and inspected after each use.
- It is imperative that as much moisture as possible is eliminated from all of the instrument crevices, since moisture promotes corrosion of the instrument.
- Flushing, drying and inspecting the instrument under magnification helps to ensure that the instrument is kept in optimum condition for the next surgical procedure.

We recommend that you strictly follow the instructions given below in order to guarantee the longevity of your instruments. The life of an instrument depends on the care given to it whilst it is being used, cleaned and maintained.

Preparation at point of use

- Ensure staff who will be processing the devices are trained in handling the devices due to their delicate nature.
- Wherever possible do not allow debris (e.g. blood or other bodily fluids) to dry on the devices. For best results and to maximise instrument life, process as soon as is reasonably practical after use.
- Ensure all instruments exposed during the surgery are reprocessed, even if they were not used as they may have been inadvertently contaminated.
- Remove excess soil by rinsing in pure water (below 40°C) as soon as possible after use.

Rinsing – post-op

It is recommended that the following rinsing procedure be carried out immediately after use. We recommend that instruments are flushed and dried using a flush tube (not supplied).

1) Fill the syringe with the appropriate substance (i.e. distilled water, alcohol or air), for maximum results it is recommended that Maximum Recovery Diluents be used. Close the jaws of the forceps and gently introduce the tip into the opening of the flush tube, take great care that the tips of the jaws do not snag with the walls of the tube. Insert the distal tip of the instrument into the silicone tubing at the distal tip of the syringe and flush the appropriate substance through the instrument by gently pressing the piston of the syringe (some pressure will be required to enter the mechanism). Repeat this process five times. Do not flush the instrument with any fluid that might leave residue, such as tap water or saline. Extra care must be taken with the curved EndoGlide forceps.

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Pack the devices in a suitable container, to prevent unwanted movement and damage to the instruments during transportation and processing.
Care must be taken to prevent unwanted contamination. Follow hospital/facility approved procedures using trained staff for transporting contaminated devices.

Cleaning : Manual

2) The instrument should be flushed thoroughly with a gentle detergent
3) Remove the detergent by flushing the instrument through with 70% alcohol
4) Blow one or two syringes of air through the instrument to remove most of the alcohol.
5) Clean the exterior of the instrument handle and shaft carefully with a moist surgical sponge (moisten with Isopropyl alcohol). Avoid direct contact with the delicate tip of the instrument.
6) Carefully hand dry the exterior of the instrument using instrument wipe or hospital approved tissue paper, an industrial hot air dryer, drying cabinet or filtered air gun can also be used.
7) After cleaning, the instrument should be carefully inspected under magnification for any possible wear or damage prior to sterilisation.

Cleaning : Automated

- **Load the instrument into it's own individual sterilising tray ensuring the handle is in the open position**
- **Use only either CE marked or validated washer-disinfector machines (to BS EN ISO 15883 series standards where applicable) and low-foaming, alkali or enzymatic cleaning agents and detergents following the manufacturers' instructions for use, warnings, concentrations and recommended cycles.**
- **Sonication** is permitted.

The validated Cycle is as below

Validated Cycle	Washer / Disinfector, Microwash Tray, Prolystica 2 x Alkaline Detergent 2ml/l. detergent and RO/deionised water.		
	Stage	Temperature	Time
	Wash 1	< 40°C (UK)	4 minutes
	Wash 2	65.5°C (UK)	15 seconds
	Wash 3	65.0°C (UK)	6 minutes
	Cool rinse	< 40°C (UK)	15 seconds
	Thermal Rinse	90-95°C	1 minute
	Drying cycle	-	20 minutes. Ensure devices are fully dry before removal

Cleaning : Inspection

After cleaning, visually inspect all surfaces, cannulations, ratchets, joints, holes and lumens for complete removal of soil and fluids. If ANY soil or fluid is still visible, return the instrument for repeat decontamination.

Inspection and Function Testing

- Visually inspect and check all instruments for damage and wear; cutting edges are free of nicks and present a continuous edge; jaws and teeth align correctly; all articulated instruments have smooth movement without excess play; locking mechanisms fasten securely and close easily; long, slender instruments are not distorted; any component parts fit and assemble correctly with mating components.
- Remove for **repair or replacement any blunt, worn out, flaking, fractured or damaged instruments.**

Note: If an instrument is returned to the manufacturer / supplier, the instrument **must** be decontaminated and sterilised and be accompanied by the relevant documented evidence.

Sterilisation

- Ensure all instruments are thoroughly cleaned before sterilising
- Place the instrument in an individual perforated sterilising tray, ensuring the handle remains in the open position.
- The packaging of the instruments must be suitable for steam sterilisation e.g. single or double paper / foil sterilisation packaging.
- Follow local protocols to applicable regulatory guidance for autoclave sterilization. Network Medical have validated the following autoclave protocol as shown below:.

Autoclave Prevacuum (dynamic air removal) sterilization cycle or gravity sterilization cycle.	Autoclave	CE marked and maintained to applicable regulatory guidance
	Water	Pure water
	Holding Time (E.g. Sterilization time)	3 to 3½ minutes
	Sterilization temperature	134°C to 137°C 273.2° F to 278.6°F
Load the autoclave as described in the autoclave manufacturer's instructions for use, do not overload.		
Ensure the autoclave has fully finished the cycle before opening the door. Failure to do so may result in wet product. All product and packaging must be dry when the autoclave cycle has finished. If not, they should be reprocessed and the autoclave reviewed for suitability.		

Storage

Ensure instruments are dry before storage, and stored in dry, clean conditions at an ambient room temperature.

NOTE:

- **These instructions have been validated to ISO 17664 Sterilisation of Medical Devices – Information to be provided by Manufacturer for the processing of Resterilisation medical devices.**
- **It is the responsibility of the reprocessor to ensure that the reprocessing as actually performed using equipment; materials and personnel in the reprocessing facility achieve the desired result. This requires validation and routine monitoring of the process.**
- **Any deviation by the reprocessor from the instructions provided must be properly evaluated for effectiveness and potential adverse consequences.**

Warnings including association of use of reusable surgical instruments with occurrence of CjD & vCjD.:

- There is a risk of cross-contamination and infection risks to patients including transmission of CJD & Variant CJD.
- Follow hospital/facility approved procedures or recommendations in "Transmissible Spongiform Encephalopathy Agents: Safe Working And The Prevention Of Infection" compiled by the Advisory Committee on Dangerous Pathogens Spongiform Encephalopathy Advisory Committee for processing devices that have been exposed to unconventional slow viruses or prion diseases such as Creutzfeldt Jakob Disease (C.J.D), Kuru, Gerstmann-Straussler-Scheinker Syndrome (G.S.S.), Fatal Familial Insomnia (F.F.I.), Scrapie, Bovine Spongiform Encephalopathy (B.S.E.) etc.
- Segregate instruments used on high risk tissues for patients born after 1st January 1997. See NICE IPG 196 (2006)

Warnings including association of use of instruments with occurrence of Toxic Anterior Segment Syndrome (TASS)

- Residuals from cleaning agents not removed during the cleaning process can be one of the causes of TASS. Follow these instructions explicitly when using, decontaminating and cleaning and sterilising the forceps.

Any damaged instruments should be returned for repair to Network Medical Products Ltd. Please contact us for details.
This IFU is available in other languages upon request. Please contact Network Medical Products Limited for details.

PRODUCT DETAILS	
Cat Ref:	**Description**
53-955	Tan EndoGlide Placement Forceps 27G
53-956	Tan EndoGlide Loading Forceps 27G

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