ISO 15223-1	A. Identification
Fig 1.	**Manufacturer** (Fig. 1): Sterimedix Limited, Thornhill Road, North Moons Moat, Redditch, Worcestershire, B98 9ND, UK. Tel: +44 (0)1527 501480. Fax: +44 (0)1527 501491. Email: info@sterimedix.com
EC REP Fig 2.	**European Authorized representative** (Fig. 2): Bausch & Lomb GmbH, Brunsbutteler Damm, 165-173, 13581, Berlin, Germany.
Fig. 3	These Instructions For Use (IFU) (Fig. 3) are for the following Sterimedix Limited single-use Medical Devices listed in **Table 1** below (Fig. 4). These devices are provided and labelled as being either sterilised by Ethylene Oxide (Fig. 5) or Non-Sterile (Fig. 6) (see **Table 1**). They are all packed in a single barrier system. Sterile devices are ready to use from the pack, the non-sterile devices are to be sterilised prior to use. These devices are identified either on the device itself or its immediate labelling, with the Catalogue number (Fig. 4), Lot number (Fig. 7) and the unique device identifier in both human and machine readable forms.
REF Fig. 4	
STERILE EO Fig.5	
NON STERILE Fig. 6	
LOT Fig. 7	

Table 1: Device List

REF	Device Name
Refractive Cannulae	
M2801	25g x 7/8" (0.5 x 22mm) Lin Lasik Cannula
M2802	25g x 1 1/8" (0.5 x 29mm) Buratto Lasik Irrigating Cannula
M2804	25g x 7/8" (0.5 x 22mm) 6 ports Lasik Irrigation Cannula
M2817	27g x 7/8" (0.4 x 22mm) 4 ports Lasik Irrigating Cannula
M2819	27g x 7/8" (0.4 x 22mm) Lasik Irrigating Cannula
M2822	25g x 7/8" (0.5 x 22mm) 6 ports Lasik Irrigating Cannula
M2824	26g x 7/8" (0.45 x 22mm) Spatulated Tip Lasik Irrigating Cannula (Slade)
M3913	25g x 7/8" (0.5 x 22mm) Lasik Irrigating Cannula (Formed)
M3914	23g x 7/8" (0.64 x 22mm) Lasik Irrigating Cannula (Formed)
SD5250	25g (0.5mm) x 22mm Lasik Irrigating Cannula (6 ports)
Notes:	
Outside diameter gauge sizes - 23g = 0.64mm, 25g = 0.5mm, 26g = 0.45mm, 27g = 0.4mm. Tip Styles (See Fig. 8) A = 6 ports at 2, 4, and 6mm. B = 4 ports 2 and 4mm. C = 6 ports at 2, 4 and 6mm (closed tip). D = Spatulated tip. E = 2 ports. F = Flattened tip	

The pictures below show examples of devices covered in the Refractive Cannulae family.

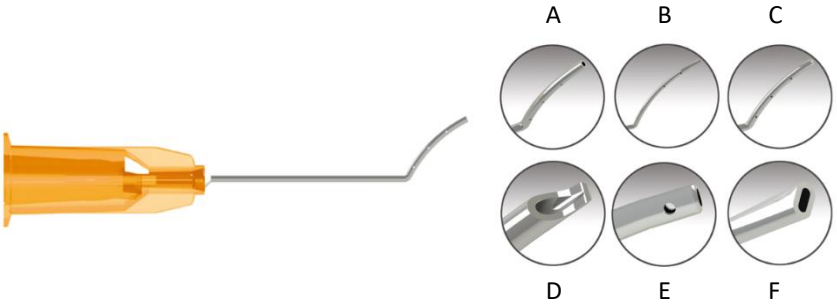

Fig. 8 Example of Formed Cannulae and Tips (See Table 1)

Fig. 9 Example of Angled Cannula (M2801)

Notes:
All pictures not to scale
Pictures show examples and not the full range

ISO 15223-1	B. Cautions (Fig. 10) and Warnings
 Fig. 10  Fig. 11  Fig. 12  Fig. 13	- Non-sterile devices must be sterilised before use. - These medical devices are very delicate and can also cause a biocontamination / infection risk after use, as such they must be handled with care and only by trained healthcare professionals. - These devices are single-use and should be disposed of in a single-use sharps container meeting the requirements of BS EN ISO 23907-1:2019 or similar. If not available follow your risk assessed procedures for disposal of sharps provided by your hospital or facility. - The cannula are surgically invasive devices and are only intended for transient use. - Devices are single use only, do not reuse (Fig. 11) and do not re-sterilise (Fig. 12) after single use. - If the package has been damaged or unintentionally opened prior to use, do not use (Fig. 13) and dispose of and replace with a new device (see "After use" below). - The cannula have a female luer connector, they are designated for refractive procedures with a syringe which has a male luer connector. - <u>Sharps injury:</u> • Use caution when handling sharp devices to prevent the risk of cuts or needle stick injuries. • Keep sharp tips and edges away from the body, especially the fingers. • Follow your facility procedures in the event of a sharps injury. - <u>Reuse of single use device may:</u> • Increase the risk of acute toxicity (including irritation, pyrogenicity and inflammation). • Increase the risk of chronic toxicity (including cytotoxicity and sensitisation). • Increase the risk of post operative infection. • Damage the integrity of the device and increase the risk of cuts or ocular trauma to the patient, depositing fragments inside the eye and unwanted cuts to the user. • Increase in the risk of structural failure e.g. restriction of the flow rates. • Increase the risk of patient injury associated with the residues from decontamination agents left in/on the device.
Other risks and possible side-effects	- Acute toxicity (including irritation, pyrogenicity and inflammation). - Chronic toxicity (including cytotoxicity and sensitisation). - Post operative complications including infection, microfolds, epithelial ingrowth, interface haze, interface debris, superficial punctate keratitis, and diffuse lamellar keratitis). These risks are inherent to the procedures in which the device is used that is corneal refractive surgery procedures but are not specifically related to the devices in question. - Deterioration in patient condition (including as a result of cancelled surgery). - Extended or cancelled surgery if correct and new device is not available. - Risks of injury, cuts and infection.
Contraindications	- There are no reported contraindications for the Refractive Cannulae.
Limitations	- These devices are single use only, do not reuse (Fig. 11). - Do not reprocess or re-sterilise (Fig. 12) after single use. - See "Intended user" below for requirements of user.
Personal Protective Equipment (PPE)	- During handling of devices PPE should be worn including protective surgical gloves. - Follow your facility health and safety procedures and wear the required PPE as trained.
Handling	- These devices are fragile and must be handled with care. - Special care must be taken with devices with delicate tips to ensure tips are not bent, blunt or snapped. - Do not knock or drop devices and avoid putting them under undue stresses or strains. - Dispose of and replace any damaged devices
Environment  Fig. 14  Fig. 15	- Sterile devices should be stored in a clean, dry and well-ventilated area. - Store devices away from direct sunlight (Fig. 14), keep dry (Fig. 15). - Store in an environment with controlled access to prevent any unwanted damage or contamination to the devices or packaging.
	C. Device Features

Description	All medical devices manufactured by Sterimedix are latex and phthalate free. Examples of pictures of the cannulae and tips can be seen in Fig 8 and Fig 9 above. A full list of products is shown in **Table 1** above). The Refractive Cannulae comprises of a length of stainless steel (grade 304) micro tube, with an open or closed end and with or without side ports at the proximal end. They have a moulded polymer tapered connector bonded to the distal end. They are surgically invasive devices for administering anaesthesia during ophthalmic surgery, into either the muscle cone, or around the globe, or into the Sub Tenon space. They are intended for transient use. These devices are either supplied as non-sterile or sterilised using a validated Ethylene Oxide (EtO) cycle.
Intended purpose specification	A sterile or non-sterile, surgically invasive device, single-use lumen device used after ablation, to wash particulate away from either the anterior or posterior sides of the flap and from the stromal bed. The device is intended for transient use with limited contact duration of less than 24 hours. It can be assembled by a qualified Scrub Nurse for use by an Ophthalmic Surgeon on patients of any age, gender or ethnicity that have been risk assessed and deemed suitable for the operation.
Intended use	For use after ablation, to wash particulate away from either the anterior or posterior sides of the flap, and from the stromal bed.
Intended purpose (as labelling)	Refractive Cannulae are surgically invasive ophthalmic devices for use during refractive procedures. They are used after ablation, to wash particulate away from either the Anterior or Posterior sides of the flap, and from the stromal bed. They are intended for transient use.
Indications for use	For use after ablation, to wash particulate away from either the Anterior or Posterior sides of the flap, and from the stromal bed (IFU).
Patient population	Refractive Cannulae are intended for patients involved during refractive procedures to wash away the particulate from either anterior or posterior sides of the flap, and from the stromal bed; regardless of age, ethnicity, or gender.
Intended user	- Assembly: Qualified Scrub Nurse or Ophthalmic Surgeon trained and proficient in their use. - Application: Qualified Ophthalmic Surgeon.
Training	- These devices are intended to be: • Assembled onto the syringe by a qualified Scrub Nurse or Ophthalmic Surgeon trained and proficient in their use. • Used by a qualified Ophthalmic Surgeon. • These medical devices are very delicate and can also cause a biohazard risk after use, as such they must be handled with care and only by suitably trained staff.
Organs / parts of the body / tissues or body liquids contacted by the device.	<u>Refractive Cannulae</u> - User: No direct contact, devices are to be used with surgical gloves. - Patient: Surgically invasive, transient (2017/745/EU) contact to the anterior or posterior sides of the flap and the stromal bed
Clinical benefits	Refractive Cannulae are surgically invasive devices and are used after ablation, to wash particulate away from either the anterior or posterior sides of the flap, and from the stromal bed and are intended for transient use (IFU). Corneal refractive surgery procedures are widely performed to permanently correct refractive errors. Refractive surgeries are safe, predictable and present high rates of satisfaction which reshapes the cornea and thereby corrects myopia and hyperopia. LASIK provides a safe and simple re-treatment option after SMILE, which avoids the disadvantages of surface ablation, such as haze and inflammation, particularly when used as a re-treatment. Thin-flap LASIK is an appropriate choice when a thicker cap has been used to avoid tissue slivers or cryptic buttonhole. - Design features to facilitate the surgical procedure: • Available in a wide range of sizes with color-coding for clear identification of cannula gauge size. • Available in 23, 25, 26 and 27 gauge with several tip designs (formed, angled, spatulated, flattened) with or without side ports to fit various surgical indications and surgeon's preference. No specific claims are made for the devices other than that they will fulfil their intended purpose and deliver the clinical benefits described above over the device lifetime.
ISO 15223-1	**D. Device Use**

 Fig. 16  Fig. 17	- <u>Non-Sterile Devices:</u> Must be sterilised before use, see Section E below. Sterile devices follow as below. - <u>Sterile Devices:</u> Supplied sterile and ready to use, there is no maintenance or servicing required. • Before using the sterile device, check to ensure the sterile symbol (Fig. 5) is present on the labelling, the use by date (Fig. 16) has not passed, and the packaging has not been damaged or unintentionally opened and thus the sterility is compromised (Fig. 13). • Inspect the device and labelling to ensure it is the correct product and correct size. • Open the blister in the designated area by peeling the pull tab away (Fig. 17) from the blister, then transfer directly to the sterile field. Keep the device in the sterile field after opening and prior to use. • Visually inspect the cannula and any device it is to be secured to ensure no damage has occurred during storage or handling or after assembly. • The size and style of cannula to be used will be specified by the Ophthalmic Surgeon. • Connect the cannula to the syringe male luer connector. Rotate the cannula fully until it locks in place, ensure it is secure. • Ensure there is a suitable flow rate through the cannula. • Once assembled, the cannula can then be used to wash particulate away from either the anterior or posterior sides of the flap and from the stromal bed. • Flow rates are to be checked and controlled manually by the Ophthalmic Surgeon. <u>Note:</u> - In the event of any failures above, dispose of the rejected device (see “End of life /after use” below) and replace with a new one. - It is recommended to count the devices before and after use to ensure no devices are missing at the end of the procedure.
End of life /after use	These devices are single-use and should be disposed of in a single-use sharps container meeting the requirements of BS EN ISO 23907-1:2019 or similar, or by your risk assessed procedures provided by your hospital or facility.
	E. Processing
Sterilisation	- Sterile devices are supplied ready to use, further processing is not required. These processing instructions relate to non-sterile devices only. - All devices sold by Sterimedix Ltd are intended for single use and are not intended for reprocessing. However, non-sterile devices may be sold CE marked for inclusion into single-use procedure packs that have been packed under article 12 of 93/42/EEC and subsequent amendments, or article 22 of regulation (EU) 2017/745 and subsequent amendments. These reprocessing instructions have therefore been prepared according to EN ISO 17664:2017 to ensure appropriate information is passed onto such procedure pack manufacturers about the appropriate sterilisation methods that may be employed on Sterimedix devices.
Limitations on Reprocessing	Although the device is intended for single use, the device has been validated to go through two EtO sterilisation cycles to allow for any potential rework in the event of an interrupted sterilisation cycle. The device should not be reprocessed after use.
Preparation	- No further cleaning is required, devices are supplied clean within a protective barrier ready for sterilisation. - Inspect the devices and packaging before processing to ensure there has been no damage during transit, storage and handling.
Packaging	Assembly with other devices in a procedure pack must be performed under controlled conditions to prevent contamination and/or deterioration of the Sterimedix product. This includes: - Use of a cleanroom where non-viable particles are controlled to ISO14644-1:2015 class 8 (or better) and where microbiological contamination is controlled as per EN ISO 14968 series or EN 17141 standards. - Verification that the devices with which the Sterimedix product is packed are compatible with the Sterimedix devices, considering their intended use. This includes ensuring that the accompanying devices will not shed particles or leach substances that could compromise the biocompatibility of the Sterimedix devices at any point in their life cycle.

Sterilant	- Additional sterilisation methods may be possible for these devices, but these have not been validated by Sterimedix Ltd. - These instructions have been validated by Sterimedix Ltd as being capable of preparing a medical device for sterilisation. It remains the responsibility of the processor to ensure that the sterilisation, as actually performed using equipment, materials and personnel in the processing facility, achieves the desired result. This requires verification and/or validation and routine monitoring of the process.
Sterilisation	Ethylene Oxide sterilisation cycle validated to EN ISO 11135:2014 using *Bacillus atrophaeus* biological indicators in a process challenge device that is equivalent or greater than the challenge presented by most difficult to sterilise location within the product. Many different parameters are used in commercial ETO sterilisation and quoting specific parameters would be unnecessarily restrictive. The validation method used by Sterimedix is the overkill approach, i.e. annex B of EN ISO 11135:2014. So long as the fractional and half cycles pass the EN ISO 11135 requirements on the cycle used by the procedure pack manufacturer, differences between their cycle specifications and those used by Sterimedix Ltd are not critical.
Storage	The devices sold by Sterimedix Ltd should be stored as described in the Handling and Environment sections above. Re-sterilisers should also pay attention and follow any additional storage or handling requirements of any packaging materials they use.
	F. Regulatory
Regulations / Directives	These instructions for use have been compiled to meet the requirements of the Medical Device Regulation 2017/745 and the Medical Device Directive 93/42/EEC.
Incident reporting	Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the Competent Authority of the member state in which the user and / or patient is established.