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
Cortex Removal Cannulae	
M5620	23g x 7/8" (0.64 x 22mm) Binkhorst Hook Cannula (Right)
M5621	23g x 7/8" (0.64 x 22mm) Binkhorst Hook Cannula (Left)
M5622	25g x 7/8" (0.5 x 22mm) Binkhorst Hook Cannula (Right)
M5623	25g x 7/8" (0.5 x 22mm) Binkhorst Hook Cannula (Left)
M6525	21g x 5/8" (0.81 x 16mm) 0.3mm port Cortex Extraction Cann
M6575	23g x 5/8" (0.64 x 16mm) 0.3mm port Cortex Extraction Cann
M6575A	23g x 5/8" (0.64 x 16mm) 0.4mm port Cortex Extraction Cann
M6575B	23g x 5/8" (0.64 x 16mm) 0.3mm port Cortex Extraction Cann
M6576	23g x 7/8" (0.64 x 22mm) 0.3mm port Cortex Extraction Cann
M6576A	23g x 1/2" (0.64 x 12.5mm) 0.3mm port Cortex Extraction Cann
M6594	23g x 5/8" (0.64 x 16mm) Charleux Cannula
M6595	23g x 1/2" (0.64 x 12.5mm) Charleux Cannula
M6596	24g x 1/2" (0.55 x 12.5mm) Charleux Cannula
SD5075	23g (0.64mm) x 16mm 0.3mm port Cortex Extraction Cannula
SD5106	24g (0.55mm) x 12.5mm Charleux Cannula
SD5107	23g (0.64mm) x 12.5mm Charleux Cannula
Nucleus Removal Cannulae	
M4619	25g x 1 1/2" (0.5 x 38mm) 1 port Irrigating Vectis Cannula
M4620	25g x 1 1/2" (0.5 x 38mm) 2 ports Irrigating Vectis Cannula
M4621	27g x 1 1/2" (0.4 x 38mm) 1 port Small Incision Vectis Cannula
Notes:	
Outside diameter gauge sizes – 21g = 0.8mm, 23g = 0.64mm, 24g = 0.6mm, 25g = 0.5mm, 27g = 0.4mm	

The pictures below show examples of devices covered in the Lens Removal family.

Fig. 8 Example of Cortex Extractor Curved With 0.3mm or 0.4mm top port

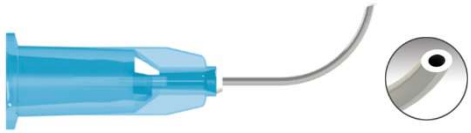

Fig. 9 Example of Cortex Extractor Curved Charleux with 0.3mm bevelled end port

Fig. 10 Example of 1 Port Irrigating Vectis

Fig. 11 Example of 2 Port Irrigating Vectis

	Notes: All pictures not to scale Pictures show examples and not the full range
ISO 15223-1	**B. Cautions (Fig. 10) and Warnings**
 Fig. 12  Fig. 13  Fig. 14  Fig. 15	- Non-sterile devices (Fig.6) 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. 13) and do not re-sterilise (Fig. 14) after single use. - If the package has been damaged or unintentionally opened prior to use, do not use (Fig. 15) and dispose of and replace with a new device (see “After use” below). - The cannula have a female luer connector, they are designated for anaesthetic procedures with a syringe which has a male luer connector. - <u>Sharps injury:</u> • Use caution when handling any sharp devices to prevent the risk of cuts or needle stick injuries. • Keep any 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 infection. - Ocular Trauma (inc. Capsule damage, Iris damage, Retina damage, Sclera damage, Descement's membrane damage, Vitreous haemorrhage, glaucoma, postoperative hyphema, posterior capsular opacification, raised IOP, corneal decompensation, cystoids macular oedema and retinal detachment.). - 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. - Incorrect use or disposal could result in cross infection.
Contraindications	- There are no reported contraindications for Lens Removal Cannulae.
Limitations	- These devices are single use only, do not reuse (Fig. 13). - Do not reprocess or re-sterilise (Fig. 14) 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 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. 16 Fig. 17	- Sterile devices should be stored in a clean, dry and well-ventilated area. - Store devices away from direct sunlight (Fig. 16), keep dry (Fig. 17). - 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. The cannulae are split into 2 main subfamilies (see also **Table 1** and Fig. 8 to Fig. 11 above): 1. Cortex Removal Cannulae 2. Nucleus Removal Cannulae Cortex Removal Cannulae comprises of a length of stainless steel (grade 304) micro tube with a blunt proximal end and a moulded polymer tapered connector bonded to the distal end. Nucleus Removal Cannulae comprises of a length of stainless steel (grade 304) micro tube which has been bent and shaped into a general "loop-shape" with one or two ports at the proximal end and a moulded polymer tapered connector bonded to the distal end. They are surgically invasive devices for either removing the nucleus, large fragments of the nucleus, large pieces of cortical debris, or aspirating cortical debris during ophthalmic surgery. 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 removing the nucleus, large fragments of the nucleus, large pieces of cortical debris, or aspirating cortical debris. 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	Surgically invasive devices for either removing the nucleus, large fragments of the nucleus, large pieces of cortical debris, or aspirating cortical debris. These devices are intended for transient use.
Intended purpose (as labelling)	The Lens Removal Cannulae are surgically invasive devices for either removing the nucleus, large fragments of the nucleus, large pieces of cortical debris, or aspirating cortical debris. They are intended for transient use.
Indications for use	Surgically invasive devices for either removing the nucleus, large fragments of the nucleus, large pieces of cortical debris or aspirating cortical debris. These devices are intended for transient use.
Patient population	Patients scheduled for surgical removal the nucleus, large fragments of the nucleus, large pieces of cortical debris or aspirating cortical debris. Paediatric and adult (including pregnant and/or breast-feeding women) populations that do not meet contraindications and regardless of gender.
Intended user	- Assembly: Qualified Scrub Nurse or qualified Ophthalmic Surgeon. - Application: Qualified Ophthalmic Surgeon.
Training	- These devices are intended to be: • Assembled onto the IA source (e.g., phacoemulsification machine, drip stand, syringe), or in the case of the Simcoe a syringe by a qualified Scrub Nurse. • Used by qualified ophthalmic surgeons trained in IA procedures. • 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>Lens Removal Cannulae</u> - User: No direct contact, devices are to be used with surgical gloves. - Patient: Surgically invasive, transient (2017/745/EU) contact to the inside of the eye, the capsule and lens.
Clinical benefits	Clinical benefits of Bausch & Lomb Lens Removal Cannulae family listed below are indirect and contribute to a successful ophthalmic surgery: • Medical devices in question facilitate ophthalmic surgical procedures. These devices are used for removing the nucleus, large fragments of the nucleus, large pieces of cortical debris, or aspirating cortical debris. Using these cannulae can facilitate removing nuclear fragments in the anterior chamber which could otherwise lead to persistent iritis, corneal edema, corneal pannus, and corneal decompensation which have necessitated penetrating keratoplasty and increased glaucoma. Use of a cannula to remove sub incisional cortex has been described as a method that provides good visualisation, less irrigation and less swirling of the contents of the anterior chamber, which is associated with the irrigation/ aspiration method. In addition, using the cannula prevents the need for re-entering the eye with the irrigation/aspiration hand piece. • They contribute to maintaining the low rate of complications.

	By carefully controlling small degrees of direct aspiration using a cannula, the fragment can be efficiently removed to avoid future complications of retained lenticular material. Moreover, they are available in a wide range of sizes with color-coding for clear identification of cannula gauge size to fit the different indications.
ISO 15223-1	**D. Device Use**
 Fig. 18  Fig. 19	- <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. 18) has not passed, and the packaging has not been damaged or unintentionally opened and thus the sterility is compromised (Fig. 15). • 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. 19) 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 be inserted into the eye and the lens extracted. • Flow rates are to be checked and controlled manually by the Ophthalmic Surgeon using the applicable flow control functions of the devices the cannula is attached to. <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.