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
Anaesthetic Cannulae	
M0278	19g x 1" (1.1 x 25mm) Sub-Tenon Cannula
M0279	20g x 1" (0.9 x 25mm) Sub-Tenon Cannula
SD5176	19g (1.1mm) x 25mm Sub-Tenon's Anaesthetic Cannula
Anaesthetic Needles	
M0275	25g x 1 1/2" (0.5 x 38mm) Standard Retrobulbar Needle
M0285	30g x 5/8" (0.3 x 16mm) Facial Infiltration Needle
M0637	25g x 1 1/2" (0.5 x 38mm) Atkinson Point Retrobulbar Needle
M0638	23g x 1 1/2" (0.64 x 38mm) Atkinson Point Retrobulbar Needle
M0641	27g x 7/8" (0.4 x 22mm) Peribulbar Needle
M0641A	27g x 1 1/4" (0.4 x 32mm) Peribulbar Needle
M0642	25g x 1 1/4" (0.5 x 32mm) Peribulbar Needle
M0642A	25g x 7/8" (0.5 x 22mm) Peribulbar Needle
M0643	23g x 1 1/4" (0.64 x 32mm) Peribulbar Needle
SD1275	25g (0.5mm) x 38mm Retrobulbar Needle
SD1637	25g (0.5mm) x 38mm Retrobulbar Needle (Atkinson)
SD5108	25g (0.5mm) x 32mm Peribulbar Needle (Atkinson)
SD5109	27g (0.4mm) x 32mm Peribulbar Needle (Atkinson)
Notes:	
Outside diameter gauge sizes – 19g = 1.1mm, 20g = 0.9mm, 23g = 0.64mm, 25g = 0.5mm, 27g = 0.4mm, 30g = 0.3mm	

The pictures below show examples of devices covered in the Anaesthetic Cannulae and Needle family.

Fig. 8 Example of Anaesthetic Cannulae

Fig. 9 Example of Anaesthetic Needles

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	- (Fig. 10) 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). - Only use cannula designated for anaesthetic procedures with a male luer connector to international standards. - <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). - Pain. - Ocular Trauma (including anterior or posterior capsule rupture, possibly leading to vitreous loss and/or retinal damage, iris trauma or prolapse, IOL loop malposition, capsulorhexis phimosis, minimal corneal edema, anterior chamber flare, high IOP, narrowing of anterior chamber, Tongue-like lesions of the capsulotomies, change in central corneal thickness). - Chemosis, sub-conjunctival and/or retro-bulbar haemorrhage, ecchymoses, globe injury, muscular palsy. - Post operative infection. - Deterioration in patient condition (inc. as a result of cancelled surgery) - Extended surgery and/or surgical complications. - Also risks of injury, cuts and infection.
Contraindications	- There are no reported contraindications for Anaesthetic Cannulae and Needles
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 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. The cannulae are split into 2 main subfamilies (see also **Table 1** and Fig. 8 to Fig. 9 above): 1. Anaesthetic Cannulae 2. Anaesthetic Needles Anaesthetic Needles and Cannulae comprises of: - A length of stainless steel (grade 304) micro tube, pointed at the proximal end, with a moulded polymer tapered connector bonded to the distal end (Needle). - A length of stainless steel (grade 304) micro tube, smooth and rounded at the proximal end, flattened throughout most of its length, with a moulded polymer tapered connector bonded to the distal end (Cannulae). 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 then either supplied as non-sterile or sterilised using a validated Ethylene Oxide (EtO) cycle.
Intended purpose specification	A sterile or non-sterile anaesthetic single-use device used for administering anaesthesia during ophthalmic surgery, into either the muscle cone, or around the globe, or into the Sub Tenon space. It is a single use device. The device is intended for transient use with limited contact duration of less than 24 hours. The device is designed to be stored dry, away from direct sunlight, used in a controlled environment and handled with surgical gloves.
Intended use	Surgically invasive device for administering anaesthesia into either the muscle cone, or around the globe, or into the sub tenon space, and intended for transient use.
Intended purpose (as labelling)	The Anaesthetic Needles and Cannulae are indicated for use in 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.
Indications for use	Anaesthetic Needles and Cannulae 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.
Patient population	Anaesthetic Needles and Cannulae are intended for patients requiring anaesthesia during ophthalmic surgery, administering anaesthesia into either the muscle cone, or around the globe, or into the Sub Tenon space; regardless of age, ethnicity, or 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 syringe by a qualified Scrub Nurse. • Used by qualified ophthalmic surgeons trained in anterior chamber 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>Anaesthetic Cannulae and Needles</u> - User: No direct contact, devices are to be used with surgical gloves. - Patient: Surgically invasive, transient (2017/745/EU) contact to either the muscle cone, around the globe or in the Sub Tenon space.
Clinical benefits	Anaesthetic Needles and Cannulae are surgically invasive devices and are used 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. High success rates and relative safety have been attained for various described ophthalmic regional anaesthetic techniques including topical, needle-based intraconal and extraconal blocks as well as needle or cannula based sub-Tenon's blocks. The European Commission "Scientific Committee on Emerging and Newly Identified Health Risks" has recommended the use of single use devices to avoid cross contamination from vCJD (Variant Creutzfeldt-Jakob disease) because there is no validated cleaning process for medical devices that might be contaminated with TSE (Transmissible Spongiform Encephalopathy) agents such as vCJD.

	Clinical Evaluation for Anaesthetic Needles and Cannulae- 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 be inserted into the muscle cone, around the globe or into the sub tenon space and the anaesthetic injected. • Flow rates are 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.