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
 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.
 Fig. 4	
 Fig.5	
 Fig. 6	
 Fig. 7	

Table 1: Device List

REF	Device Name
Bimanual Cannulae and Hand Pieces	
M5405	21g x 5/8" (0.81 x 16mm) Bimanual Irrigation Cannula
M5501	23g x 5/8" (0.64 x 16mm) 0.4mm side port Bimanual Aspiration Handle (curved micro etched)
M5502	23g x 5/8" (0.64 x 16mm) 0.3mm side port Bimanual Aspiration Handle (curved micro etched)
M5505	21g x 5/8" (0.81 x 16mm) Bimanual Irrigation Handle (curved)
M5510	20g x 3/4" (0.90 x 19mm) 0.5mm side ports Bimanual Irrigation Handle (curved)
M5511	20g x 3/4" (0.90 x 19mm) 0.3mm side ports Bimanual Aspiration Handle (curved micro etched)
M5512	21g x 5/8" (0.81 x 16mm) 0.3mm side port Bimanual Aspiration Handle (curved micro etched)
M5513	23g x 5/8" (0.64 x 16mm) 0.4mm side ports Bimanual Irrigation Handle (curved)
M5514	21g x 5/8" (0.81 x 16mm) 0.5mm side ports Bimanual Irrigation Handle (curved)
M5515	21g x 7/8" (0.81 x 22mm) 0.3mm side port Bimanual Aspiration Handle (curved)
M5518	23g x 5/8" (0.64 x 16mm) 0.3mm side ports Bimanual Aspiration Handle (curved)
M5519	23g x 5/8" (0.64 x 16mm) Bimanual Irrigation Handle (curved)
M5520	21g TW x 5/8" (0.81 x 16mm) 0.4mm side port Bimanual Aspiration Handle (curved, micro etched)
M5521	21g TW x 5/8" (0.81 x 16mm) 0.5mm side ports Bimanual Irrigation Handle (curved)
M5522	21g TW x 5/8" (0.81 x 16mm) Bimanual Irrigation Handle (curved)
M5523	23g UTW x 5/8" (0.64 x 16mm) Bimanual Irrigation Handle Open End (curved)
M6524	21g x 5/8" (0.81 x 16mm) 0.3mm top port Bimanual Aspirating (Curved)
Bimanual IA Systems	
M5331	21g x 5/8" (0.81 x 16mm) Bimanual Tapered Tip Irrigation/Aspiration System
M5531	21g (0.81mm) Bimanual Irrigation/Aspiration System Bimanual Aspiration Handpiece. Thin Wall. Curved with 0.4mm side port
M5532	21g (0.81mm) Bimanual Irrigation/Aspiration System
M5533	21g (0.81mm) Bimanual Irrigation/Aspiration System
M5535	23g (0.64mm) Bimanual Irrigation/Aspiration System
M5536	23g (0.64mm) Bimanual Irrigation/Aspiration System
M5537	20g (0.9mm) Irrigation / 21g (0.81mm) Aspiration Bimanual System
M5538	25g (0.5mm) Bimanual Irrigation / Aspiration System
M5539	21g (0.81mm) Bimanual Irrigation/Aspiration System
M5540	21g (0.81mm) Bimanual Irrigation/Aspiration System
M5543	21g (0.81mm) Bimanual Irrigation/Aspiration System
Coaxial Cannulae and Hand Pieces	
M5560	21g Soft Outer IA Coaxial Handpiece (Straight Tip)
M5561	21g Soft Outer IA Coaxial Handpiece (45° Angled Tip)
M5562	21g Soft Outer IA Coaxial Handpiece (60° Angled Tip)
M5563	21g Soft Outer IA Coaxial Handpiece (90° Angled Tip)
M5570	24g Soft Outer IA Coaxial Handpiece (Straight Tip)
M5571	24g Soft Outer IA Coaxial Handpiece (45° angled tip)

M5572	24g Soft Outer IA Coaxial Handpiece (60° Angled Tip)
M5573	24g Soft Outer IA Coaxial Handpiece (90° Angled Tip)
M5580	16g/21g (1.6 x 0.81mm) IA Coaxial Handpiece (Straight Tip)
M5581	16g/21g (1.6 x 0.81mm) IA Coaxial Handpiece (Curved Tip)
M5582	16g/21g (1.6 x 0.81mm) IA Coaxial Handpiece (45° Angled Tip)
M5583	16g/21g (1.6 x 0.81mm) IA Coaxial Handpiece (60° Angled Tip)
M5584	16g/21g (1.6 x 0.81mm) IA Coaxial Handpiece (90° Angled Tip)
M5590	17g/24g (1.4 x 0.55mm) IA Handpiece (Straight Tip)
M5591	17g/24g (1.4 x 0.55mm) IA Handpiece (Curved Tip)
M5592	17g/24g (1.4 x 0.55mm) IA Handpiece (45° Angled Tip)
M5593	17g/24g (1.4 x 0.55mm) IA Handpiece (60° Angled Tip)
M5594	17g/24g (1.4 x 0.55mm) IA Handpiece (90° Angled Tip)
Irrigation/Aspiration Cannulae	
M6601	23g/23g (0.64/0.64mm) 0.4mm Port Reverse Simcoe IA Cannula
M6605	23g/23g (0.64/0.64mm) 0.3mm Port Standard Simcoe IA Cannula
M6611	21g x 1 1/2" (0.81 x 38mm) Straight Cannula
M6613	23g/23g (0.64/0.64mm) 0.4mm Port Standard Simcoe IA Cannula
M6614	23g (0.64mm) x 30mm Irrigation/Left Hand Aspiration Simcoe
M6615	23g (0.64mm) x 30mm Irrigation/Right Hand Aspiration Simcoe
M6617	23g/23g (0.64/0.64mm) 0.3mm Port Standard Simcoe IA Cannula
M7900A	25g TW x 7/8" Aspirating Cannula
Notes:	
Outside diameter gauge sizes – 16g = 1.6mm, 17g = 1.4mm, 20g = 0.9mm, 21g = 0.8mm, 23g = 0.64mm, 24g = 0.6mm, 25g = 0.5mm.	

Bimanual

The pictures below show examples of devices covered in the Bimanual Irrigation / Aspiration (IA) Handpiece / System family.

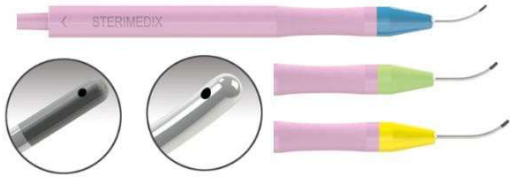

Fig. 8 Bimanual Aspiration Handpiece Curved With/Without Micro-Etched Port e.g., M5501, M5502, M5511, M5512, M5515, M5518 & M5520

Coloured Tips: Yellow 20g, Green 21g, Blue 23g.

Fig. 9 Bimanual Irrigation Handpiece Curved Bevelled Tip, Side Port and Open End e.g., M5505, M5510, M5513, M5514, M5519, M5521 & M5523.
Coloured Tips: Yellow 20g, Green 21g, Blue 23g.

Fig. 10 Examples Of 25g Handpieces Blue Irrigation, Pink Aspiration. Coloured Tip: Orange 25g.

Fig. 11 Examples Of Other Tips Available, Tapered With Or Without Micro-Etching.

Coaxial

The pictures below show examples of devices covered in the Coaxial Handpiece family.

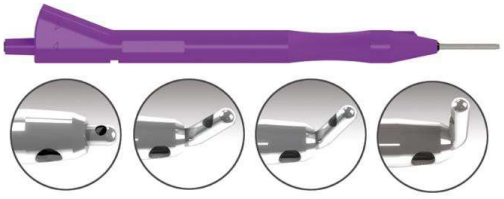

Fig. 12 Straight IA Handpiece: Straight, 45°, 60° & 90° tips e.g., M5580, M5582, M5583 & M5584

Fig. 13 Straight Soft Outer IA Handpiece: 21g, 45°, 60° & 90° tips e.g.,M5561, M5562 & M5563

Fig. 14 Straight Soft Outer IA Handpiece 24g 45°, 60° & 90° tips (e.g.,M5571, M5572 & M5573)

Fig. 15 Curved IA Handpiece e.g., M5581, M5591

Cannulae

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

Fig. 16 Aspiration Cannula Curved Top Port e.g., M6524

Fig. 17 Bimanual Aspiration Cannula Curved 45° Bevelled Tip e.g., M5405

Fig. 18 Straight Cannula (e.g., M6611)

Fig. 19 IA Cannula Standard With Silicone Tubing e.g., M6613, M6614

Notes:
All pictures not to scale
Pictures show examples and not the full range, see www.sterimiedix.com for further details.

ISO 15223-1	B. Cautions (Fig. 20) and Warnings
 Fig. 20  Fig. 21  Fig. 22  Fig. 23	- 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 (Fig. 21) 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. 21) and do not re-sterilize (Fig. 22) after single use. - If the package has been damaged or unintentionally opened prior to use, do not use (Fig. 23) and dispose of and replace with a new device (see "After use" below). - Only use cannula designated for IA procedures with a male or female luer connector to international standards. - Sharps injury: • 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. - Reuse of single use device may: • Increase the risk of acute toxicity (including irritation, pyrogenicity and inflammation). • Increase the risk of chronic toxicity (including cytotoxicity and sensitization). • 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 the risk of structural failure e.g. restriction of the flow rates, removal or splitting of the silicone etc. • 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 (inc. irritation, pyrogenicity & inflammation). - Ocular Trauma (including anterior or posterior capsule rupture, possibly leading to vitreous loss and/or retinal damage (e.g. detachment, cystoid macular edema), 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 (CCT), posterior capsule opacification, endophthalmitis. - 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. - Risk of blockage and being unable to perform the intended function. Replacement product required resulting in potential delays to surgery. - Risk of the cannula dislodging from the syringe during surgery, which may or may not result in damage to the eye or delay in the procedure. - Risk of material defects (broken tip, scratch, dent, impurities, etc.).
Contraindications	- There are no reported contraindications for Irrigation / Aspiration Cannulae and Handpieces.
Limitations	- These devices are single use only (Fig. 21), do not reuse. - Do not reprocess or re-sterilize (Fig. 22) 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. 24 Fig. 25	- Sterile devices should be stored in a clean, dry and well-ventilated area. - Store devices away from direct sunlight (Fig. 24), keep dry (Fig. 25). - 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. A length of stainless steel (grade 304) micro tube, where the proximal end of an Irrigator may be open ended or closed with an adjacent side port(s), and the proximal end of an Aspirator is closed with an adjacent top port. The tubes may be straight, curved (formed) or angled. A moulded polymer tapered connector, or a moulded handle is bonded to the distal end. Due to their diversity they have been divided into sub-families and in each of them there are several models. These devices are split into 2 main subfamilies (see also Fig. 8 to Fig. 19 above): 1. Single lumen device - Bimanual Cannulae, Handpieces and Systems 2. Dual lumen device - Coaxial IA Handpieces and Cannulae with an inner lumen for irrigation and outer lumen for aspiration - Coaxial IA Handpieces and Cannulae.
Intended purpose specification	A sterile or non-sterile, single-use lumen device used for used for performing either irrigation or aspiration, or manipulation of the capsule during cataracts surgery. 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 introducing BSS into the anterior chamber to maintain the shape, and aspirate fluid and cortical debris. Some bimanual aspiration devices incorporate a micro etched tip so that they can be used for gently polishing the capsule. They are intended for transient use
Intended purpose (as labelling)	IA Cannulae and Handpieces are intended for introducing BSS into the anterior chamber to maintain the shape, and aspirate fluid and cortical debris. Some bimanual aspiration devices incorporate a micro etched tip so that they can be used for gently polishing the capsule. They are intended for transient use.
Indications for use	- <u>Bimanual Aspiration Cannula:</u> Surgically invasive device for introducing BSS into the anterior chamber to maintain the shape, and aspirate fluid and cortical debris. Some bimanual aspiration devices incorporate a micro etched tip so that they can be used for gently polishing the capsule. They are intended for transient use.

	- Bimanual Irrigation/Aspiration System Surgically invasive device for introducing BSS into the anterior chamber to maintain the shape, and aspirate fluid and cortical debris. Some bimanual aspiration devices incorporate a micro etched tip so that they can be used for gently polishing the capsule. They are intended for transient use. - Irrigating/Aspirating Co-Axial Handpiece Surgically invasive device for introducing BSS into the anterior chamber to maintain the shape, and aspirate fluid and cortical debris. Some bimanual aspiration devices incorporate a micro etched tip so that they can be used for gently polishing the capsule. They are intended for transient use. - IA Cannula Surgically invasive device for introducing BSS into the anterior chamber to maintain the shape, and aspirate fluid and cortical debris. Some bimanual aspiration devices incorporate a micro etched tip so that they can be used for gently polishing the capsule. They are intended for transient use.
Patient population	Irrigation/Aspiration Cannulae and Handpieces are intended for patients requiring cataract surgery, 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 IA source (e.g., phacoemulsification machine) 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.	IA Handpieces and Cannulae - User: No direct contact, devices are to be used with surgical gloves. - Patient: Surgically invasive, transient (2017/745/EU) contact to the anterior segment of the eye in particular the capsule bag and lens.
Clinical benefits	Clinical benefits of Bausch+Lomb Irrigation/ Aspiration Cannulae and Hand Pieces family listed below are indirect and contribute to a successful ophthalmic surgery: • Facilitate ophthalmic surgical procedure (by maintaining the shape of anterior chamber and by aspirating fluid and cortical debris) One of the most crucial steps in posterior polar cataract emulsification is the removal of the epinucleus and cortex. Bimanual IA Handpieces and Cannulae allow easy access circumferentially to the capsular bag, causes minimal incision distortion, and allow the maintenance of a closed chamber. • Contribute to maintain the low rate of complications. **Design features to facilitate the surgical procedure:** • Available in a wide range of sizes with color-coding for clear identification of cannula gauge size to fit the different indications. • Available in 16, 17, 20, 21, 23, 24 and 25 gauge with several tip designs (straight, curved or angled) to fit various surgical indications and surgeon's preference.
ISO 15223-1	**D. Device Use**

 Fig. 26  Fig. 27	- Non-Sterile Devices: Must be sterilised before use, see Section E below. Sterile devices follow as below. - Sterile Devices: 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. 26) has not passed, and the packaging has not been damaged or unintentionally opened (Fig. 23) and thus the sterility is compromised. • 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. 21) 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 / handpiece 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 or handpiece to be used will be specified by the Ophthalmic Surgeon. • Connect the cannula / handpiece to the luer connector on the IA source (e.g. Phaco-emulsification machine). Rotate the cannula until it locks in place, ensure it is secure. • Ensure there is a suitable flow rate through the handpiece or cannula where applicable. • Once assembled, the handpiece or cannula can be inserted into the eye for performing the applicable irrigation and aspiration procedure during cataract surgery.
	• Flow rates are controlled manually by the Ophthalmic Surgeon using the applicable flow control functions of the devices the cannula is attached to. Note: - 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 sterilize 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.