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
Lachrymal Cannulae	
M9272	23g x 1/2" (0.64 x 12.5mm) 0.3mm Port Lachrymal Cannula (Bullet tip)
M9274	21g x 1 1/2" (0.81 x 38mm) Lachrymal Cannula (Curved)
M9275	26g x 3/4" (0.45 x 19mm) Short Lachrymal Cannula (Straight)
M9276	26g x 1 1/4" (0.45 x 32mm) Lachrymal Cannula (Curved)
M9277	25g x 1 1/8" (0.5 x 29mm) Lachrymal Cannula (Curved)
M9278	25g x 7/8" (0.5 x 22mm) 0.2mm Port Lachrymal Cannula (Straight)
M9279	19g/23g Reducing x 1 1/2" (1.1/0.64 x 38mm) Lachrymal Cannula
M9282	26g (0.45 x 30mm) Lachrymal Cannula (Curved)
SD1276	26g (0.45mm) x 32mm Lachrymal Cannula (Curved)
SD1615	21g (0.81mm) x 38mm Lachrymal Cannula (Curved)
Notes:	
Outside diameter gauge sizes – 19g = 1.1mm, 21g = 0.8mm, 23g = 0.64mm, 25g = 0.5mm, 26g = 0.45mm	

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

Fig. 8 Example of Straight Lachrymal Cannulae e.g. M9275.

Fig. 9 Example of Curved Lachrymal Cannulae E.g. M9276.

Fig. 10 Example of Straight Lachrymal Cannulae with 0.2mm side port (e.g. M9278).

Fig. 11 Example of Curved Lachrymal Cannulae with 0.2mm side port and tapered tip.

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

ISO 15223-1	B. Cautions (Fig. 12) and Warnings
Fig. 12	- (Fig. 12) 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.

 Fig. 13  Fig. 14  Fig. 15	- 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 (Fig. 13) do not reuse 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) but 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 lachrymal trauma to the patient, depositing fragments inside the lachrymal system 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. • Increase in the risk of Lachrymal Duct Trauma (including creation of a false passage and injury to the nasolacrimal duct, canaliculi and puncta, bleeding, laryngospasm, or aspiration).
Other risks and possible side-effects	- Acute toxicity (including irritation, pyrogenicity and inflammation). - Chronic toxicity (including cytotoxicity and sensitisation). - Lachrymal Duct Trauma (inc. creation of a false passage and injury to the nasolacrimal duct, canaliculi and puncta, bleeding, laryngospasm, or aspiration) - Post operative infection (e.g., dacryocystitis). - Deterioration in patient condition (inc. as a result of cancelled surgery) - Extended surgery and/or surgical complications. - Also risks of injury, cuts and infection. - Probing may not be successful if the obstruction is due to a bony protrusion of the inferior turbinate into the nasolacrimal duct or when the duct is oedematous (swollen) due to infection such as dacryocystitis.
Contraindications	- There are no reported contraindications for the Lachrymal 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 A length of stainless steel (grade 304) micro tube, where the proximal end is smooth and rounded at its tip, and the tube may be straight or curved. A moulded polymer tapered connector is bonded to the distal end.

	They are surgically invasive devices used to probe or irrigate the lachrymal system during ophthalmic surgery. 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, single-use lumen device used for probing and irrigating the lachrymal ducts to remove any blockages and re-establish patency during ophthalmic surgery. 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 probing and irrigating the lachrymal ducts. They are intended for transient use.
Intended purpose (as labelling)	Lachrymal Cannulae are surgically invasive devices for probing and irrigating the lachrymal ducts. They are intended for transient use. Sterimedix lachrymal cannulae are prescription only devices, intended for use by qualified medical professionals.
Indications for use	Lachrymal Cannulae are surgically invasive devices for probing and irrigating the lachrymal ducts. They are intended for transient use. Sterimedix lachrymal cannulae are prescription only devices, intended for use by qualified medical professionals.
Patient population	Patients scheduled for surgical probing and irrigating the lachrymal ducts. Paediatric and adult (including pregnant and/or breast-feeding women) populations that do not meet contraindications. Gender should not have any impact on safe and efficient use of target devices.
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 lachrymal system 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.	Lachrymal Cannulae and Needles - User: No direct contact, devices are to be used with surgical gloves. - Patient: Surgically invasive, transient (2017/745/EU) contact with the lachrymal system.
Clinical benefits	Lachrymal Cannulae are a surgically invasive devices for probing and irrigating the lachrymal ducts. They are intended for transient use. Sterimedix Lachrymal Cannulae are prescription only devices, intended for use by qualified Medical professionals. Lachrymal Cannulae are single-use, sterilised instruments used for probing and irrigating the lachrymal ducts to remove any blockages and re-establish patency during ophthalmic surgery. SCENIHR (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 [EFF08 Clinical Evaluation for Lachrymal Cannulae Issue 2].
ISO 15223-1	**D. Device Use**
 Fig. 18  Fig. 19	- 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. 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 lachrymal canal to irrigate or probe as required • 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 (Fig. 14).
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 to be 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.