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	**Table 1: Device List**
 Fig. 6	
 Fig. 7	

REF	Device Name
Intradermal Needles	
M0286	27g TW (0.4mm) x 12.7mm Needle with 10° bevel
M0287	30g TW (0.3mm) x 12.7mm Needle with 10° bevel
M0288	29g TW (0.34mm) x 12.7mm Needle with 10° bevel
M0289A	30g TW (0.3mm) x 4mm Needle with 13° bevel
M0293	27g TW (0.4mm) x 19mm Needle with 10° bevel
Intradermal Cannulae	
AE1702	18g UTW (1.25mm) x 70mm ST Cannula
AE1711	20g UTW (0.9mm) x 60mm ST Cannula
AJ1701	18g UTW (1.25mm) x 70mm FT Cannula
Intradermal Cannulae and Needles	
AJ1500	18g TW (1.25mm) x 80mm FT Cannula + 19g RW (1.1mm) x 25mm Needle
AJ1561A	27g UTW (0.4mm) x 4mm FT Cannula + 25g TW (0.5mm) x 12.7mm Needle
AJ1831A	22g TW (0.7mm) x 70mm FT Cannula + 21g TW (0.81mm) x 16mm Needle
AJ1832A	22g TW (0.7mm) x 60mm FT Cannula + 21g TW (0.81mm) x 16mm Needle
AJ1833A	22g TW (0.7mm) x 50mm FT Cannula + 21g TW (0.81mm) x 16mm Needle
AJ1840A	23g UTW (0.64mm) x 70mm FT Cannula + 21g TW (0.81mm) x 16mm Needle
AJ1842A	23g UTW (0.64mm) x 50mm FT Cannula + 21g TW (0.81mm) x 16mm Needle
AJ1850A	25g UTW (0.5mm) x 50mm FT Cannula + 23g TW (0.64mm) x 12.7mm Needle
AJ1851A	25g UTW (0.5mm) x 40mm FT Cannula + 23g TW (0.64mm) x 12.7mm Needle
AJ1852A	25g UTW (0.5mm) x 40mm GTI Cannula + 23g TW (0.64mm) x 12.7mm Needle
AJ1861A	27g UTW (0.4mm) x 40mm FT Cannula + 25g TW (0.5mm) x 12.7mm Needle
AJ1863A	27g UTW (0.4mm) x 37mm FT Cannula + 25g TW (0.5mm) x 12.7mm Needle
AJ1870A	30g UTW (0.3mm) x 30mm FT Cannula + 27g RW (0.4mm) x 12.7mm Needle
Notes:	
Outside diameter gauge sizes – 16g = 1.6mm, 19g = 1.1mm, 20g = 0.9mm, 21g = 0.8mm, 23g = 0.64mm, 25g = 0.5mm, 26g = 0.45mm, 27g = 0.4mm, 30g = 0.3mm	
Tubing acronyms: RW = Regular Wall TW = Thin Wall UTW = Ultra-Thin Wall	Cannula hub acronyms: FT = Fine Thread ST = Screw Thread

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

Examples of Intradermal Needles

Fig. 8 Examples of Intradermal Needles

Example of Intradermal Cannulae

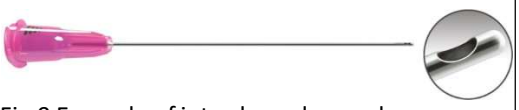

Fig.9 Example of intradermal cannula

Examples of Intradermal Cannulae and Needles

Fig. 10 Example of rounded tip intradermal cannula and needle

Fig. 11 Example of the grooved tip injection cannula AJ1852A

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. 13  Fig. 14  Fig. 15  Fig. 16	- (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. - 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). - Only use cannula designated for intradermal procedures with a male luer slip connector to international standards. - (Fig. 16) Contains substances categorized as hazardous (i.e., Cobalt, present in stainless steel up to 1% w/w). There are no residual risks identified as a result of this included substance. - <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). - Intradermal damage (including bruising and tearing of skin). - Post operative infection (including erythematous nodules, abscesses, bacterial biofilm). - Damage to deeper structures (e.g. Facial paresis/paralysis)

	- Vascular occlusion/embolism, which can result in local tissues skin necrosis and in worst-case irreversible vision loss due to retinal artery occlusion. - Patient dissatisfaction (e.g. due to extended, delayed or cancelled surgery or poor cosmetic results). - Extended or cancelled surgery if correct and new device is not available. - Also risks of injury, cuts and infection. - Delayed complications • Nodular masses (inflammatory or non-inflammatory nodules) • Foreign body granulomas
Contraindications	- There are no reported contraindications for Intradermal Cannulae and Needles however there are contraindications to the subcutaneous injection of the dermal filler. They can be absolute or down to a physician's discretion: including but not limited to active skin infection (Impetigo, herpes simplex, massive demodex folliculorum, pityrosporum, Propionibacterium acnes, cystic acne, viral warts, fungal infections), active localised infection (Ear, nose, or throat infections, dental abscess, periodontitis), active generalised infection (Gastroenteritis, urinary bladder infection, tuberculosis), allergy/hypersensitivity (hypersensitivity to filler components including lidocaine, chronic urticaria, and Quincke's edema), active collagenoses (mixed connective tissue disease, active morphea, active systemic lupus), active anticoagulant medication, hemostatic or coagulation disorders (bleeding disorders, hemophilia, hemoglobin pathology, thalassemia)
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. 17 Fig. 18	- Sterile devices should be stored in a clean, dry and well-ventilated area. - Store devices away from direct sunlight (Fig. 17), keep dry (Fig. 18). - 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 3 main subfamilies (see also **Table 1** and Fig. 8 to Fig. 11 above): 1. Intradermal Needles 2. Intradermal Cannulae 3. Intradermal Cannulae and Needles The needles comprise 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. The cannulae comprise of a length of stainless steel (grade 304) micro tube, where the proximal end is smooth and rounded or pointed at its tip. The AJ1852A has a grooved tip to optimise subcision without damaging critical bodies or vessels. A moulded polymer tapered connector is bonded to the distal end. The cannulae and needles are packed into a blister which is sealed using a TYVEK lid. These devices are then either supplied as non-sterile or sterilised using a validated Ethylene Oxide (EtO) cycle.
Product Description	A sterile or non-sterile dermatological single-use lumen device used for either: - Intradermal Cannulae: The cannula has a length of stainless steel (grade 304) tube, closed at the proximal end and with an adjacent side port. The tube is generally straight and a moulded polymer tapered connector is bonded to the distal end. - Intradermal Needles: The needle has 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. - Intradermal cannulae and needles: They are to be used with Syringes with either a 6% luer slip or luer lock connector.

	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	Subcutaneous administration of dermal filler and autologous fat.
Intended purpose (as labelling)	Intradermal Cannulae and Needles are surgically invasive devices intended for subcutaneous administration of dermal filler or autologous fat. Silkann® Grooved Tip Injection (GTI) Cannula® is specifically designed to release of tethering bands to facilitate infiltration of the dermal filler
Indications for use	Subcutaneous injection of dermal filler or autologous fat is indicated in a variety of applications including treatment of correction of attritional loss in facial volume including HIV-related lipoatrophy correction of tear trough deformity treatment of acne scar and cosmetic procedures to reduce facial lines and wrinkles and/or for lip augmentation (thickening).
Patient population	Intradermal Cannulae and Needles is intended for patients requiring subcutaneous administration of dermal filler or autologous fat for soft tissue augmentation regardless of age, ethnicity, or gender.
Intended user	- Assembly: Qualified Scrub Nurse or qualified Dermatologic Surgeon. - Application: Qualified Dermatologic Surgeon.
Training	- These devices are intended to be: • Assembled onto the syringe by a qualified Scrub Nurse. • Used by qualified Dermatologic Surgeons trained in subcutaneous administration of dermal fillers. • 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>Intradermal Cannulae and Needles</u> - User: No direct contact, devices are to be used with surgical gloves. - Patient: Surgically invasive, transient (2017/745/EU) contact with the patient's skin.
Clinical benefits	Intradermal Cannulae and Needles provide clinical benefit by facilitating the procedure: • Facilitates the subcutaneous administration of dermal filler or autologous fat • Facilitates the infiltration of the dermal filler by release of the tethering bands Performance clinical endpoints: • Treatment Efficacy Response rate# [%] based on Qualitative Goodman and Baron Scar Grades • Mean % reduction/improvement based on Quantitative Goodman and Baron Scar Scores • Scar reduction (%) No specific claims are made for the device other than that they will fulfil their intended purpose and deliver the clinical benefits described above over the device lifetime
Clinical performance characteristics	The devices are designed to be compatible with male Luer slip or Luer lock connector for intravascular or hypodermic applications. Other than this, there are no specific claims are made for the device other than that they will fulfil their intended purpose and deliver the clinical benefits described above over the device lifetime.

Symbols	D. Device Use
 Fig. 19  Fig. 20	- 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. 19) 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. 20) 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 Dermatologic 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 subcutaneous layer and the dermal filler injected. • Flow rates are controlled manually by the Dermatologic 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 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 MD Fig. 21	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. The product is classified as a Medical Device (Fig. 21)
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.