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
Scleral Markers	
M7500	3.5mm/4.0mm Ophthalmic Caliper (Scleral Marker)
7500NS	3.5mm/4.0mm Ophthalmic Caliper (Scleral Marker)
Scleral Incision Templates	
M7510	3.5mm Scleral Fixation Incision Template
7510NS	3.5mm Scleral Fixation Incision Template
Notes:	
NS – Non-sterile	

The pictures below show the devices covered in the Scleral Marker family.

Fig. 8 3.5mm/4.0mm Ophthalmic Caliper Scleral Marker)

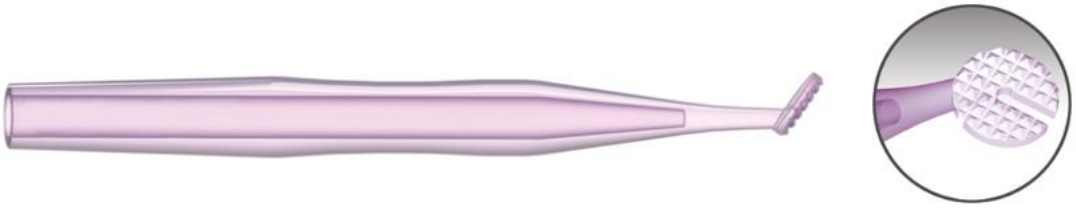

Fig. 9 3.5mm Scleral Fixation Incision Template

Notes:
All pictures not to scale

ISO 15223-1	B. Cautions (Fig. 10) and Warnings
Fig. 10 Fig. 11	- 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 markers 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-sterilize (Fig. 12) after single use.

 Fig. 12  Fig. 13	- 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).. - <u>Possible 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 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 on to the eye and unwanted cuts to the user. • Increase in the risk of structural failure e.g. blunting or snapping tips or ends. • 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 sensitization). - Ocular Trauma (including scratches and cuts to the globe). - 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 Scleral Markers.
Limitations	- These devices are single use only, do not reuse (Fig. 11). - Do not reprocess or re-sterilize (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. There are two markers in this family (see also **Table 1** and Fig. 8 and Fig. 9 above) supplied as either sterile or non-sterile: 1. <u>Ophthalmic Caliper Scleral Marker</u> Comprises of an injection moulded tube 3.5/4.0mm x 80mm made from purple Acrylonitrile butadiene styrene (ABS) polymer. It has 2 points at either end, one set are 3.5mm apart and the others 4.0mm apart. The handle is ergonomically moulded for comfort and ease of use. 2. <u>Scleral Fixation Incision Template</u> Comprises of an injection moulded handle of radius of 3.5mm, made from Makrolon Polycarbonate (USP Class VI) which is translucent with a purple tint. The template is 7.0mm diameter, with a 1mm diamond pattern on the underside and a slit into the centre. 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 sterilized using a validated Ethylene Oxide (EtO) cycle.
Intended purpose specification	A sterile or non-sterile, surgically invasive device used for stabilising the eye and marking incision or injection points during intravitreal procedure. The device is intended for transient use with limited

	contact duration of less than 24 hours. It does not require assembly and is 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	- Scleral Marker: 7500 (Non Sterile), M7500 (Sterile) Invasive device used to mark the point for any pars plana incision or injection point. They are intended for transient use. - Scleral Incision Template: 7510 (Non Sterile) Invasive device used to mark the point for any pars plana incision or injection point. They are intended for transient use. - Corneal Fixation /Incision Template: M7510 (Sterile) Surgically invasive device for marking the injection / incision points during either intravitreal injection procedure, for the treatment of Advanced Macular Degeneration (AMD), or stabilizing the eye, and indicating the incision site during Vitreoretinal procedures. They are intended for transient use.
Intended purpose (as labelling)	- Scleral Marker: 7500 (Non Sterile), M7500 (Sterile) Invasive device used to mark the point for any pars plana incision or injection point. They are intended for transient use. - Scleral Incision Template: 7510 (Non Sterile) Invasive device used to mark the point for any pars plana incision or injection point. They are intended for transient use - Corneal Fixation /Incision Template: M7510 (Sterile) Surgically invasive device for marking the injection / incision points during either intravitreal injection procedure, for the treatment of Advanced Macular Degeneration (AMD), or stabilizing the eye, and indicating the incision site during Vitreoretinal procedures. They are intended for transient use.
Indications for use	- Corneal Fixation /Incision Template Surgically invasive device for marking the injection / incision points during either intravitreal injection procedure, for the treatment of Advanced Macular Degeneration (AMD), or stabilizing the eye, and indicating the incision site during Vitreoretinal procedures. They are intended for transient use. - Scleral Incision Template and Scleral Markers Invasive device for marking the point during any pars plana incision or injection points. They are intended for transient use.
Patient population	Scleral Markers are intended for patients regardless of age, ethnicity, or gender for marking the injection / incision points.
Intended user	Qualified Ophthalmic Surgeon.
Training	- These devices are intended to be used by qualified ophthalmic surgeons. - 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.	- User: No direct contact, devices are to be used with surgical gloves. - Patient: Surgically invasive and transient (2017/745/EU) contact to the eye.
Clinical benefits	Scleral Markers are surgically invasive devices for marking the injection point during an intravitreal injection procedure for the treatment of Advanced Macular Degeneration (AMD) and to mark the point for any pars plana incision or injection point during ophthalmic surgeries like vitrectomy.
ISO 15223-1	**D. Device Use**
 Fig. 16  Fig. 17	- 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. 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.

	• 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. • Once the eye has been prepared, position the device correctly at the limbus and depress to leave the required incision or injection marks on the eye. <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 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.