

ISO 15223-1	A. Identification																																																																																																										
<p>Fig 1.</p>	<p><b>Manufacturer (Fig. 1):</b> 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</p>																																																																																																										
<p>Fig 2.</p>	<p><b>European Authorized representative (Fig. 2):</b> Bausch &amp; Lomb GmbH, Brunsbutteler Damm, 165-173, 13581, Berlin, Germany.</p>																																																																																																										
<p>Fig. 3</p>	<p>These Instructions For Use (IFU) (Fig. 3) are for the following Sterimedix Limited single-use Medical Devices listed in <b>Table 1</b> below (Fig. 4). These devices are provided and labelled as being either sterilised by Ethylene Oxide (Fig. 5) or Non-Sterile (Fig. 6) (see <b>Table 1</b>). 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.</p>																																																																																																										
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Fig. 12 Example subretinal fluid cannula.



Fig. 15 Example of silicone brush cannula (see Fig. 18).



Fig. 16 Examples of soft tip cannula cannula (see Fig. 17).

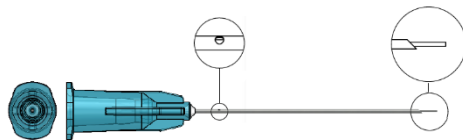


Fig. 19 Example of perfluorocarbon coaxial Cannula (dual bore) showing single port and inner tube.

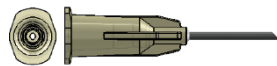


Fig. 21 Example of silicone oil removal cannula.



Fig. 23 Example aspiration cannula.

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



Fig. 13



Fig. 14

Fig. 13 and Fig. 14 Examples reducing aspiration cannula straight and curved.

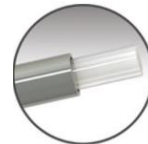


Fig. 17 Example of soft tip cannula (tubular).

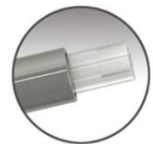


Fig. 18 Example of silicone brush formed by tube with 4 slots.



Fig. 20 Heavy oil removal cannula.

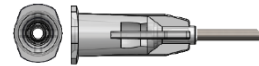


Fig. 22 Example of high viscosity injection cannula.

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

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**B. Cautions (Fig. 23 and Warnings**



Fig. 24





Fig. 25





Fig. 26



- (Fig. 24) 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. 25) and do not re-sterilize (Fig. 26) after single use.
- If the package has been damaged or unintentionally opened prior to use, do not use (Fig. 27) and dispose of and replace with a new device (see "After use" below).
- Only use the cannula on medical devices designated for vitreoretinal procedures with a male 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.

<p>Fig. 27</p>	<p>- <u>Reuse of single use device may:</u></p> <ul style="list-style-type: none"> <li>• Increase the risk of acute toxicity (including irritation, pyrogenicity and inflammation).</li> <li>• Increase the risk of chronic toxicity (including cytotoxicity and sensitization).</li> <li>• Increase the risk of post operative infection.</li> <li>• 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.</li> <li>• Increase in the risk of structural failure e.g. restriction of the flow rates.</li> <li>• Increase the risk of patient injury associated with the residues from decontamination agents left in/on the device.</li> </ul>
<p>Other risks and possible side-effects</p>	<ul style="list-style-type: none"> <li>- Acute toxicity (including irritation, pyrogenicity and inflammation).</li> <li>- Chronic toxicity (including cytotoxicity and sensitization).</li> <li>- Post operative infection.</li> <li>- Ocular trauma, (including retinal detachment / perforation, traumatic lens damage, cataract, intraocular haemorrhage, sustained ocular hypertension / hypotony, decompression retinopathy, iris traumas, capsule ruptures with vitreous loss, IOL loop malposition, narrowing of the anterior chamber, wound leak cystoid macular oedema, delayed recovery, cuts).</li> <li>- Deterioration in patient condition (including as a result of cancelled surgery).</li> <li>- Extended or cancelled surgery if correct and new device is not available.</li> <li>- Surgical complications, (inflammation, infection, wound leak, hypotony, corneal oedema, phototoxicity, iatrogenic retinal break, metamorphopsia, traumatic lens damage, cataract, intraocular haemorrhage, glaucoma, capsule rupture with or without vitreous loss, cystoid macular oedema, cataract in phakic patients, ocular venous air embolism).</li> </ul>
<p>Contraindications</p>	<p>There are no reported contraindications for Vitreoretinal Cannulae</p>
<p>Limitations</p>	<ul style="list-style-type: none"> <li>- These devices are single use only, do not reuse (Fig. 25).</li> <li>- Do not reprocess or re-sterilize (Fig. 26) after single use.</li> <li>- See “Intended user” below for requirements of user</li> </ul>
<p>Personal Protective Equipment (PPE)</p>	<ul style="list-style-type: none"> <li>- During handling of devices PPE should be worn including protective surgical gloves.</li> <li>- Follow your facility health and safety procedures and wear the required PPE as trained.</li> </ul>
<p>Handling</p>	<ul style="list-style-type: none"> <li>- These devices are fragile and must be handled with care.</li> <li>- Special care must be taken with devices with delicate tips to ensure tips are not bent or snapped.</li> <li>- Do not knock or drop devices and avoid putting them under undue stresses or strains.</li> <li>- Dispose of and replace any damaged devices</li> </ul>
<p>Environment</p>  <p>Fig. 28</p>  <p>Fig. 29</p>	<ul style="list-style-type: none"> <li>- Sterile devices should be stored in a clean, dry and well-ventilated area.</li> <li>- Store devices away from direct sunlight (Fig. 28), keep dry (Fig. 29)</li> <li>- Store in an environment with controlled access to prevent any unwanted damage or contamination to the devices or packaging.</li> </ul>
<p><b>C. Device Features</b></p>	
<p>Description</p>	<p>All medical devices manufactured by Sterimedix are latex and phthalate free. The cannulae are split into 4 main subfamilies (see also <b>Table 1</b> and Fig. 8 to Fig. 23 above):</p> <ol style="list-style-type: none"> <li>1. Vitreoretinal Cannulae</li> <li>2. Heavy Liquid Infusion Cannulae</li> <li>3. Silicone Brush Cannulae</li> <li>4. Silicone Tip Cannulae</li> </ol> <p>These devices comprise of multiple parts to form a Vitreoretinal Cannula:</p> <ul style="list-style-type: none"> <li>• A length of stainless steel (grade 304) micro tube, where the proximal end is smooth and rounded at its tip, which may be either square cut, bevelled or with a reduced diameter. A moulded polymer tapered connector is bonded to the distal end; or</li> <li>• A length of stainless steel (grade 304) micro tube, where the proximal end is smooth and rounded at its tip, which may be either square cut, or with a reduced diameter. Silicone rubber tubing maybe inserted into the inner diameter, or over the outer reduced diameter of stainless-steel tubes and cut so that a short length of the silicone protrudes beyond the proximal end of the</li> </ul>

	<p>stainless tube – giving the cannula a soft tip. A moulded polymer tapered connector is bonded to the distal end; or</p> <ul style="list-style-type: none"> <li>• Two lengths of stainless steel (grade 304) micro tube placed co-axially and their respective inner diameters isolated from each other. At the proximal end, irrigation is achieved through the inner tube; and passive aspiration is achieved between the outer and inner tubes. The flow of the passively aspirated fluid may be controlled using a fingertip, to cover the aspiration port, situated adjacent to a moulded polymer tapered connector, which is bonded to the distal end.</li> </ul> <p>The cannulae are packed individually into a blister which is sealed using a TYVEK lid. These devices are then either supplied as non-sterile or sterilized using a validated Ethylene Oxide (EtO) cycle. The selection of the different gauges and tip designs is at the discretion of the surgeon according to their preferred surgical technique depending on clinical conditions.</p> <ul style="list-style-type: none"> <li>• Standard blunt metal cannula are intended for general injection or aspiration. They have been designed with smooth bevel tip to facilitate their insertion, a thin wall to allow a high flow rate for a maximum fluid/air exchange.</li> <li>• The soft tip allow a gentle access to the retina. They could be ideal for aspiration of fluid from on or beneath the surface of the retina.</li> <li>• Cannulas with Soft flexible silicone brush tips have been designed to allow a gentle brushing and manipulation of the retina for removal of blood or debris of aspiration from the retina surface.</li> <li>• The Luer lock hub enables easy, secure connection to a backflush handle or syringe.</li> </ul>
Use specification	A sterile or non-sterile ophthalmic, single-use lumen device used to irrigate or aspirate substances to or from the posterior segment of the eye. It is used in various vitreoretinal and vitrectomy procedures. It is a surgically invasive device with limited exposure to the mucous membrane of the eye and the contents of the posterior segment of the eye. If the cannula is supplied with a soft tip or silicone brush, it can be used to manipulate the internal structures of the eye to permit aspiration from behind the retina. It is intended to be assembled by a qualified scrub nurse for use by a Vitreoretinal Surgeon on patients of any age, gender or ethnicity that have been risk assessed and deemed suitable for the operation. 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 devices for specific infusion and aspiration functions during aspiration during retinal procedures, and are intended for either transient or short term use.
Intended purpose	The Vitreoretinal Cannulae are surgically invasive devices for specific infusion and aspiration functions during retinal procedures, and are intended for either transient or short term use.
Indications for use	The devices are indicated for vitreoretinal surgery in various clinical conditions.
Patient population	Vitreoretinal Cannulae are intended for patients requiring vitreoretinal surgery, regardless of age, ethnicity, or gender.
Intended user	<ul style="list-style-type: none"> <li>- Assembly: Qualified scrub nurse or vitreoretinal surgeon.</li> <li>- Application: Qualified ophthalmic / vitreoretinal surgeon.</li> </ul>
Training	<ul style="list-style-type: none"> <li>- These devices are intended to be: <ul style="list-style-type: none"> <li>• Assembled into the irrigation aspiration system by a qualified scrub nurse</li> <li>• Used by qualified Vitreoretinal Surgeons.</li> <li>• 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.</li> </ul> </li> </ul>
Organs / parts of the body / tissues or body liquids contacted by the device.	<ul style="list-style-type: none"> <li>- <u>Vitreoretinal Cannulae</u> <ul style="list-style-type: none"> <li>• User: No direct contact, devices are to be used with surgical gloves.</li> <li>• Patient: Surgically invasive, transient (2017/745/EU) contact to the eye. The soft tips or silicone brushes can come into contact with the retina, choroid and/or retinal pigment epithelium.</li> </ul> </li> </ul>
Clinical benefits	<p>Vitreoretinal cannulae are intended for use during vitreoretinal surgery providing the benefits listed below:</p> <ul style="list-style-type: none"> <li>- Design features to facilitate the surgical procedure: <ul style="list-style-type: none"> <li>• Available in a wide range of sizes with color-coding for clear identification of cannula gauge size to fit the different indications.</li> <li>• Available in 16, 18, 19, 20, 23, 25, 27 and 30 gauge with several tip designs (blunt tip, brush tip, soft tip and dual bore tip) to fit various surgical indications and surgeon's preference.</li> </ul> </li> <li>- Patient benefits:</li> </ul>

	<ul style="list-style-type: none"> <li>• Anatomical success and an improvement/maintenance of the visual acuity as a result of the Vitreoretinal surgical procedure.</li> <li>• Small gauge cannula designed for minimally invasive procedures:             <ul style="list-style-type: none"> <li>○ Self-sealing sutureless sclerotomy using small gauges</li> <li>○ Reduced ocular trauma: reduced tissue damage, reduced conjunctival scarring</li> <li>○ Reduced inflammation</li> <li>○ Decreased corneal astigmatism</li> <li>○ Reduced operating times</li> <li>○ Faster post-operative recovery</li> </ul> </li> </ul> <p>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.</p>
<p>ISO 15223-1</p>	<p><b>D. Device Use</b></p>
 <p>Fig. 30</p>  <p>Fig. 31</p>	<p>- <u>Non-Sterile Devices:</u> Must be sterilised before use, see Section E below. Sterile devices follow as below.</p> <p>- <u>Sterile Devices:</u> Supplied sterile and ready to use, there is no maintenance or servicing required.</p> <ul style="list-style-type: none"> <li>• Before using the sterile device, check to ensure the sterile symbol (Fig. 5) is present on the labelling, the use by date (Fig. 30) has not passed, and the packaging has not been damaged or unintentionally opened and thus the sterility compromised (Fig. 27).</li> <li>• Inspect the device and labelling to ensure it is the correct product and correct size.</li> <li>• Open the blister in the designated area by peeling the pull tab away (Fig. 31) from the blister, then transfer directly to the sterile field. Keep the device in the sterile field after opening and prior to use.</li> <li>• Visually inspect the cannula and any device it is to be secured to, ensure no damage has occurred during storage or handling.</li> <li>• The size and style of cannula to be used will be specified by the Vitreoretinal Surgeon</li> <li>• Connect the cannula to the irrigation or aspiration devices male luer connector. Rotate the cannula until it locks in place, ensure it is secure.</li> <li>• If the device is to be connected to an active aspiration pump, follow the IFUs supplied by the pump manufacturer for attachment to the machine.</li> <li>• Ensure any automated aspiration flow rates are checked prior to use by following their manufacturer’s IFU.</li> <li>• Once assembled, the cannula can be inserted into the posterior segment through the incision in the globe.</li> <li>• The brushes or soft tips on the cannula can be used manipulate structures inside the posterior segment of the eye.</li> <li>• Active flow rates are controlled by the aspiration pump, non-active flow rates are controlled manually by the Vitreoretinal Surgeon using the applicable flow control functions of the devices the cannula is attached to.</li> </ul> <p><u>Note:</u></p> <ul style="list-style-type: none"> <li>- 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.</li> <li>- It is recommended to count the devices before and after use to ensure no devices are missing at the end of the procedure.</li> </ul>
<p>End of life /after use</p>	<p>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.</p>
	<p><b>E. Processing</b></p>
<p>Sterilisation</p>	<ul style="list-style-type: none"> <li>- Sterile devices are supplied ready to use, further processing is not required. These processing instructions relate to non-sterile devices only.</li> <li>- 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</li> </ul>

	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	<ul style="list-style-type: none"> <li>- No further cleaning is required, devices are supplied clean within a protective barrier ready for sterilisation.</li> <li>- Inspect the devices and packaging before processing to ensure there has been no damage during transit, storage and handling.</li> </ul>
Packaging	<p>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:</p> <ul style="list-style-type: none"> <li>- 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.</li> <li>- 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.</li> </ul>
Sterilant	<ul style="list-style-type: none"> <li>- Additional sterilisation methods may be possible for these devices, but these have not been validated by Sterimedix Ltd.</li> <li>- 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.</li> </ul>
Sterilisation	<p>Ethylene Oxide sterilisation cycle validated to EN ISO 11135:2014 using <i>Bacillus atrophaeus</i> 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.</p> <p>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.</p>
Storage	<p>The devices sold by Sterimedix Ltd should be stored as described in the Handling and Environment sections above.</p> <p>Re-sterilisers should also pay attention and follow any additional storage or handling requirements of any packaging materials they use.</p>
<b>F. Regulatory</b>	
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.