

ISO 15223-1	A. Identification																																																														
<p>Fig 1.</p>	<p>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</p>																																																														
<p>Fig 2.</p>	<p>European Authorized representative (Fig. 2): Bausch & 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 Table 1 below. 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.</p>																																																														
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<p>Fig. 8 M4498 Heavy liquid infusion handle with finger control and male luer lock.</p>																																																															
<p>Fig. 9 M4489 Example Passive Backflush Handle</p>	<p>Fig. 10 M4489A Example Active/Passive Backflush Handle</p>																																																														
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Fig. 13 Example Silicone Tip

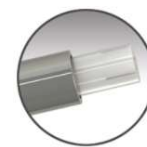












Fig. 14 Example silicone Brush


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

ISO 15223-1	B. Cautions and Warnings
 Fig. 15  Fig. 16  Fig. 17  Fig. 18  Fig. 19	<ul style="list-style-type: none"> - (Fig. 15) Non-sterile devices must be sterilised before use - These medical devices are very delicate and can also cause a biocontamination 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. - The handpieces are non-contact devices and are only intended for transient use. - Devices are single use only, do not reuse (Fig. 16) and do not re-sterilise (Fig. 17) after single use. - If the package has been damaged or unintentionally opened prior to use, do not use (Fig. 18) and dispose of and replace with a new device (see “After use” below). - Only use cannula designated for vitreoretinal procedures with a female luer connector to international standards. - (Fig. 19) 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> <ul style="list-style-type: none"> • 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> <ul style="list-style-type: none"> • 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 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	<ul style="list-style-type: none"> - Acute toxicity (including irritation, pyrogenicity and inflammation) - Chronic toxicity (including cytotoxicity and sensitisation) - Post operative infection. - 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). - Deterioration in patient condition (including as a result of cancelled surgery). - Extended or cancelled surgery if correct and new device is not available. - 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).
Contraindications	There are no reported contraindications for Vitreoretinal Handpieces
Limitations	- These devices are single use only, do not reuse (Fig. 16).

	<ul style="list-style-type: none"> - Do not reprocess or re-sterilize (Fig. 17) after single use. - See “Intended user” below for requirements of user
Personal Protective Equipment (PPE)	<ul style="list-style-type: none"> - 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	<ul style="list-style-type: none"> - 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. 20  Fig. 21	<ul style="list-style-type: none"> - Sterile devices should be stored in a clean, dry and well-ventilated area. - Store devices away from direct sunlight (Fig.20), keep dry (Fig. 21) - Store in an environment with controlled access to prevent any unwanted damage or contamination to the devices or packaging.
C. Device Features	
Description	<p>All medical devices manufactured by Sterimedix are latex and phthalate free. See also Table 1 and Fig. 8 to Fig. 14 above.</p> <p>The handpieces are non-invasive devices, used in conjunction with a variety of surgically invasive cannulae, for specific infusion and aspiration functions during retinal procedures. The device comprises a number of parts to form a Backflush Handpiece. These may be either Passive – Aspiration by means of the pressure within the eye (intraocular pressure); or Active – Aspiration by means of connecting to a vacuum pump.</p> <ul style="list-style-type: none"> - The Charles Flute handle consists of a polymer handpiece containing a lumen that passes from the male luer slip connector to the hole in the bowl shaped appendage. The surgeon controls the flow by using their fingertip to block or unblock the hole thus controlling the pressure. - (a) Backflush handpieces are an ABS polymer tubular hand piece with a side port adjacent to its proximal end. A moulded silicone component (open at its proximal end and closed at its distal end) is inserted into the bore of the hand piece, so that the side port in the silicone component is aligned and corresponds with the side port of the handpiece. A male Luer Lock component is inserted into the distal end of the silicone component, compressing the silicone against the Acrylonitrile butadiene styrene (ABS) polymer handle to affect a seal, and allow fluid to aspirate through the side ports. The surgeon may control the flow using his fingertip. - (b) As (a) but with the distal end of the moulded silicone component opened, to attach a silicone rubber tube which extends beyond the distal end of the ABS hand piece. A female Luer component is inserted into the distal end of the silicone tube to create an Active device or capped to create a Passive device. <p>Backflush versions offer the option of reflux, enabling the user to release tissue or substances aspirated in error.</p> <p>The hand piece may be packed either singly, or with a cannula to form a set, and has a primary pack in the form of a blister, which is sealed using a TYVEK lid. These devices are sterilized using a validated Ethylene Oxide (EtO) cycle.</p>
Use specification	<ul style="list-style-type: none"> - <u>Vitreoretinal Heavy Liquid Infusion Handpieces:</u> A sterile ophthalmic, single-use lumen device used with a vitreoretinal cannula to introduce, and remove, heavy liquids into the posterior segment of the eye to help repair retinal detachments such as giant retinal tears. It is intended to be assembled by a qualified scrub nurse for use by Vitreoretinal Surgeons 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. It does not directly contact the user and has only limited indirect patient contact via the cannula and heavy liquid. - <u>Backflush Aspiration Handpieces:</u> A sterile ophthalmic, single-use lumen device used with a variety of vitreoretinal cannulae to aspirate substances, such as subretinal fluid, blood, gases or other fluids from the posterior segment of the eye. It is used in various vitreoretinal and vitrectomy procedures. If designated as active, aspiration is controlled by connecting to an ophthalmic aspiration pump at the distal end. If passive, aspiration is brought about by the pressure differential between the higher intraocular pressure and the lower atmospheric pressure. The user can control aspiration by manually covering/ uncovering the hole in the silicone insert. It is intended to be assembled by a qualified scrub nurse for use by Vitreoretinal Surgeons on patients of any age, gender or ethnicity that have been risk assessed and deemed

	<p>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. It does not directly contact the user and has only limited indirect patient contact via the cannula.</p> <ul style="list-style-type: none"> - <u>Backflush Aspiration Handpieces with Cannula:</u> A sterile ophthalmic, single-use lumen device used to aspirate substances, such as subretinal fluid, blood, gases, or other fluids from the posterior segment of the eye. It is used in various vitreoretinal and vitrectomy procedures. If designated as active, aspiration is controlled by connecting to an ophthalmic aspiration pump at the distal end. If passive, aspiration is brought about by the pressure differential between the higher intraocular pressure and the lower atmospheric pressure. The user can control aspiration by manually covering/ uncovering the hole in the silicone insert. 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, this 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 Vitreoretinal Surgeons 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	<ul style="list-style-type: none"> - <u>Vitreoretinal Heavy Liquid Infusion Handpieces and Backflush Aspiration Handpieces:</u> Non-invasive devices, used in conjunction with a variety of cannulae, for specific infusion and aspiration functions during retinal procedures. - <u>Handpieces and Cannulae:</u> Surgically invasive device for either passive or active aspiration during retinal surgery, and intended for transient use.
Intended purpose	<ul style="list-style-type: none"> - The Vitreoretinal Handpieces: Vitreoretinal Heavy Liquid Infusion Handpieces, and Backflush Aspiration Handpieces are non-invasive devices, used in conjunction with a variety of cannulae, for specific infusion and aspiration functions during retinal procedures. - The Vitreoretinal Handpieces and Cannulae are surgically invasive devices for either passive or active aspiration during retinal surgery and intended for transient use.
Indications for use	<ul style="list-style-type: none"> - The Vitreoretinal Handpieces are indicated for vitreoretinal surgery in various clinical conditions. - Vitreoretinal Heavy Liquid Infusion Handpieces are indicated specifically for the infusion of heavy liquids during vitreoretinal surgery. - Backflush Aspiration Handpieces are indicated for use in either passive or active aspiration during intraocular posterior segment surgical procedures.
Patient population	Vitreoretinal Handpieces are intended for patients requiring vitreoretinal surgery, regardless of age, ethnicity, or gender.
Intended user	<ul style="list-style-type: none"> - Assembly - Qualified scrub nurse or Vitreoretinal surgeon. - Application - Vitreoretinal surgeon
Training	<ul style="list-style-type: none"> - These devices are to be intended to be used by qualified Vitreoretinal 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.	<ul style="list-style-type: none"> - <u>Handpieces</u> <ul style="list-style-type: none"> • User: No direct contact, devices are to be used with surgical gloves. • Patient: No direct contact. - <u>Cannula</u> <ul style="list-style-type: none"> • User: No direct contact, devices are to be used with surgical gloves. • 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.
Clinical benefits	<p>Vitreoretinal Handpieces are intended for use during vitreoretinal surgery providing the benefits listed below:</p> <ul style="list-style-type: none"> - Design features to facilitate the surgical procedure: <ul style="list-style-type: none"> • Ergonomic design for control and precision during surgical manoeuvres. • Fingertip control for aspiration. • Removable and replaceable plug for conversion from passive to active aspiration using one single instrument. • Available in a wide range of sizes, including 20-, 23-, 25- and 27-gauge (G), with color-coding for clear identification of instrument gauge size to fit the different indications. • Available in 20-, 23-, 25 and 27- G with several tip designs, according to the surgical indication

	<p>dual bore tip.</p> <ul style="list-style-type: none"> - Patient benefits: <ul style="list-style-type: none"> • Small gauge, 23- and 25- G, designed for minimally invasive procedures. • Self-sealing sutureless sclerotomy using small gauges. • Reduced ocular trauma: reduced tissue damage, reduced conjunctival scarring. • Reduced inflammation. • Decreased corneal astigmatism. • Reduced operating times. • Faster post-operative recovery. <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>Clinical performance characteristics</p>	<p>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.</p>
<p>ISO 15223-1</p>	<p>D. Device Use</p>
 <p>Fig. 22</p>  <p>Fig. 23</p> <p>Silicone insert</p>  <p>Fig. 24</p>	<ul style="list-style-type: none"> - 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. <ul style="list-style-type: none"> • Before using the sterile device, check to ensure the sterile symbol (Fig. 5) is present on the labelling, the use by date (Fig. 22) has not passed, the packaging has not been damaged or unintentionally opened and thus the sterility compromised (Fig. 18). • 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. 23) 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 device, and any cannula to be secured to it, to ensure no damage has occurred during storage or handling. • If not already attached, secure a cannula of the size specified by the Vitreoretinal Surgeon, to the male luer slip connector. Rotate the cannula fully until it locks in place. • 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. • Ensure any cannula or tubing are correctly and securely attached to the handpiece. • Check any automated aspiration flows prior to use by following their manufacturer’s IFU. • Once assembled, the cannula can be inserted into the posterior segment through the incision in the globe. • The brushes or soft tips on the cannula can be used manipulate structures inside the posterior segment of the eye. • Manual (passive) aspiration is brought about by the pressure differential between the higher intraocular pressure and the lower atmospheric pressure. The user can control the aspiration by manually covering/ uncovering the drainage hole in the silicone insert (Fig.24). • Active aspiration rates are controlled by the aspiration pump. • Backflush versions offer the option of reflux, enabling the user to release tissue or substances aspirated in error by compressing the silicone insert (Fig. 24). <p>Note:</p> <ul style="list-style-type: none"> - 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.
<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>

E. Processing	
Sterilisation	<ul style="list-style-type: none"> - 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	<ul style="list-style-type: none"> - 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	<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"> - 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	<ul style="list-style-type: none"> - 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	<p>Ethylene Oxide sterilisation cycle validated to EN ISO 11135:2014 using <i>Bacillus atropheus</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>
F. Regulatory	
Regulations / Directives  Fig.25	<p>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.</p> <p>The product is classified as a Medical Device (Fig. 25)</p>
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.