







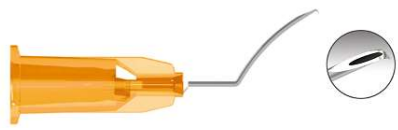


ISO 15223-1	A. Identification																																																												
 Fig 1.	<p>Manufacturer (Fig. 1): Sterimedix Limited, Thornhill Road, North Moons Moat, Redditch, Worcestershire, B98 9ND, UK. Tel: +44 (0)1527 501480. Fax: +44 (0)1527 501491. Email: info@sterimedix.com</p>																																																												
 Fig 2.	<p>European Authorized representative (Fig. 2): Bausch & Lomb GmbH, Brunsbutteler Damm, 165-173, 13581, Berlin, Germany.</p>																																																												
 Fig. 3	<p>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.</p>																																																												
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 Fig. 7	<p style="text-align: center;">Table 1: Device List</p> <table border="1"> <thead> <tr> <th>REF</th> <th>Device Name</th> </tr> </thead> <tbody> <tr> <td colspan="2">Formed Irrigating Cystotomes</td> </tr> <tr> <td>M3001</td> <td>27g x 5/8" (0.4 x 16mm) Endocapsular Cystotome (curved)</td> </tr> <tr> <td>M3602</td> <td>25g x 5/8" (0.5 x 16mm) Side Cutting Cystotome (Formed)</td> </tr> <tr> <td>M3610</td> <td>25g x 5/8" (0.5 x 16mm) Irrigating Cystotome (Formed)</td> </tr> <tr> <td>M3610B</td> <td>25g x 5/8" (0.5 x 16mm) Irrigating Cystotome (Formed) 45° Tip</td> </tr> <tr> <td>M3610C</td> <td>25g x 5/8" (0.5 x 16mm) Irrigating Cystotome (Fmd. short tip)</td> </tr> <tr> <td>M3610S</td> <td>27g x 7/8" (0.4 x 22mm) Irrigating Cystotome (Formed)</td> </tr> <tr> <td>M3615</td> <td>25g x 7/8" (0.5 x 22mm) Irrigating Cystotome (Formed)</td> </tr> <tr> <td>M3615A</td> <td>25g x 7/8" (0.5 x 22mm) Irrigating Cystotome (Angled)</td> </tr> <tr> <td>M3617</td> <td>27g x 5/8" (0.4 x 16mm) Irrigating Cystotome (Angled)</td> </tr> <tr> <td>M3626</td> <td>25g x 5/8" (0.5 x 16mm) Irrigating Cystotome (Angled)</td> </tr> <tr> <td>M3626A</td> <td>25g x 5/8" (0.5 x 16mm) Irr. Cystotome (Formed short curve)</td> </tr> <tr> <td>M3627</td> <td>27g x 5/8" (0.4 x 16mm) Irr. Cystotome (Formed short curve)</td> </tr> <tr> <td>M3627A</td> <td>25g x 5/8" (0.5 x 16mm) Irrigating Cystotome (Reverse Fmd.)</td> </tr> <tr> <td>M3629</td> <td>27g x 5/8" (0.4 x 16mm) Irrigating Cystotome (Reverse Fmd.)</td> </tr> <tr> <td>M3629A</td> <td>30g x 5/8" (0.3 x 16mm) Irrigating Cystotome (Formed)</td> </tr> <tr> <td>M3630</td> <td>27g x 5/8" (0.4 x 16mm) Endocapsular Cystotome (curved)</td> </tr> <tr> <td>SD1610</td> <td>25g (0.5mm) x 16mm (90°) Formed Cystotome</td> </tr> <tr> <td>SD1618</td> <td>27g (0.4mm) x 16mm (90°) Formed Cystotome</td> </tr> <tr> <td>SD5004</td> <td>25g (0.5mm) x 16mm (90°) Angled Cystotome</td> </tr> <tr> <td colspan="2">Formed Capsularhexis Cystotomes</td> </tr> <tr> <td>M3000D</td> <td>25g x 5/8" (0.5 x 16mm) Capsularhexis Cystotome (Fmd. short curve)</td> </tr> <tr> <td>M3000E</td> <td>27g x 5/8" (0.4 x 16mm) Capsularhexis Cystotome (Fmd. short curve)</td> </tr> <tr> <td>M3000F</td> <td>27g x 5/8" (0.4 x 16mm) Capsularhexis Cystotome (Formed)</td> </tr> <tr> <td>M3000G</td> <td>25g x 5/8" (0.5 x 16mm) Capsularhexis Cystotome (Formed)</td> </tr> <tr> <td>SD4804</td> <td>25g (0.5mm) x 16mm Capsularhexis Cystotome (Formed)</td> </tr> <tr> <td>SD5042</td> <td>27g (0.4mm) x 16mm (90°) Formed Capsularhexis Cystotome</td> </tr> <tr> <td colspan="2">Notes:</td> </tr> <tr> <td colspan="2">Outside diameter gauge sizes – 19g = 1.1mm, 20g = 0.9mm, 23g = 0.64mm, 25g = 0.5mm, 27g = 0.4mm, 30g = 0.3mm</td> </tr> </tbody> </table>	REF	Device Name	Formed Irrigating Cystotomes		M3001	27g x 5/8" (0.4 x 16mm) Endocapsular Cystotome (curved)	M3602	25g x 5/8" (0.5 x 16mm) Side Cutting Cystotome (Formed)	M3610	25g x 5/8" (0.5 x 16mm) Irrigating Cystotome (Formed)	M3610B	25g x 5/8" (0.5 x 16mm) Irrigating Cystotome (Formed) 45° Tip	M3610C	25g x 5/8" (0.5 x 16mm) Irrigating Cystotome (Fmd. short tip)	M3610S	27g x 7/8" (0.4 x 22mm) Irrigating Cystotome (Formed)	M3615	25g x 7/8" (0.5 x 22mm) Irrigating Cystotome (Formed)	M3615A	25g x 7/8" (0.5 x 22mm) Irrigating Cystotome (Angled)	M3617	27g x 5/8" (0.4 x 16mm) Irrigating Cystotome (Angled)	M3626	25g x 5/8" (0.5 x 16mm) Irrigating Cystotome (Angled)	M3626A	25g x 5/8" (0.5 x 16mm) Irr. Cystotome (Formed short curve)	M3627	27g x 5/8" (0.4 x 16mm) Irr. Cystotome (Formed short curve)	M3627A	25g x 5/8" (0.5 x 16mm) Irrigating Cystotome (Reverse Fmd.)	M3629	27g x 5/8" (0.4 x 16mm) Irrigating Cystotome (Reverse Fmd.)	M3629A	30g x 5/8" (0.3 x 16mm) Irrigating Cystotome (Formed)	M3630	27g x 5/8" (0.4 x 16mm) Endocapsular Cystotome (curved)	SD1610	25g (0.5mm) x 16mm (90°) Formed Cystotome	SD1618	27g (0.4mm) x 16mm (90°) Formed Cystotome	SD5004	25g (0.5mm) x 16mm (90°) Angled Cystotome	Formed Capsularhexis Cystotomes		M3000D	25g x 5/8" (0.5 x 16mm) Capsularhexis Cystotome (Fmd. short curve)	M3000E	27g x 5/8" (0.4 x 16mm) Capsularhexis Cystotome (Fmd. short curve)	M3000F	27g x 5/8" (0.4 x 16mm) Capsularhexis Cystotome (Formed)	M3000G	25g x 5/8" (0.5 x 16mm) Capsularhexis Cystotome (Formed)	SD4804	25g (0.5mm) x 16mm Capsularhexis Cystotome (Formed)	SD5042	27g (0.4mm) x 16mm (90°) Formed Capsularhexis Cystotome	Notes:		Outside diameter gauge sizes – 19g = 1.1mm, 20g = 0.9mm, 23g = 0.64mm, 25g = 0.5mm, 27g = 0.4mm, 30g = 0.3mm	
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<p>Fig. 8 Example of 27g x 5/8" Endocapsular Cystotome, Formed, Curved (M3630)</p>	<p>Fig. 9 Example of 27g x 7/8" Irrigating Cystotome, Formed, Short Tip (M3610S)</p>																																																												

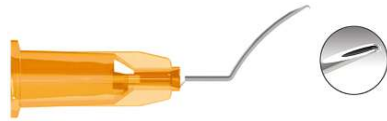


Fig. 10 Example of 25g x 5/8" Side Cutting Cystotome, Formed (M3602)



Fig. 11 Example of 25g x 5/8" Irrigating Cystotome Reverse Formed, Short Curve (M3627A)



Fig. 12 Example of 25g x 5/8" - Irrigating Cystotome Angled (M3626)

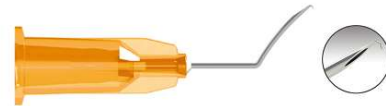


Fig. 13 Example of 27g x 5/8" Irrigating Cystotome Formed, Reverse Tip (M3629)

Notes:

All pictures not to scale

Pictures show examples and not the full range

ISO 15223-1

B. Cautions (Fig. 14) and Warnings



Fig. 14



Fig. 15



Fig. 16







Fig. 17

- (Fig. 14) 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 (Fig. 15) 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. 15) and do not re-sterilize (Fig. 16) after single use.
- If the package has been damaged or unintentionally opened prior to use, do not use (Fig. 17) and dispose of and replace with a new device (see "After use" below).
- Only use cannula designated for cystotome 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.
- Reuse of single use device may:
 - 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 the risk of structural failure e.g. restriction of the flow rates, removal or splitting of the silicone tip etc.
 - Increase the risk of patient injury associated with the residues from decontamination agents left in/on the device.

Other risks and possible side-effects

- The potential risks of the procedures identified in the published literature include: Endophthalmitis, inflammation of the eye, postoperative hyphema, posterior capsular opacification, raised IOP, corneal decompensation, cystoids macular oedema and retinal detachment. All above mentioned risks are inherent to the procedures in which the device of interest is used, that is in cataract surgery and phacoemulsification, but are not specifically related to the devices in question.
- Risk of blockage and being unable to perform the intended function. Replacement product required resulting in potential delays to surgery.
- Risk of the cannula dislodging from the syringe during surgery, which may or may not result in damage to the eye or delay in the procedure.
- Risk of material defects (broken tip, scratch, dent, impurities, etc.).
- Post operative infection.

	<ul style="list-style-type: none"> - 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 known contraindications for Cystotomes
Limitations	<ul style="list-style-type: none"> - These devices are single use only, do not reuse (Fig. 15). - Do not reprocess or re-sterilize (Fig. 16) 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. 18 Fig. 19	<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. 18), keep dry (Fig. 19). - 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. The cannulae are split into 3 main subfamilies (see also Table 1 and Fig. 8 to Fig. 13 above):</p> <ol style="list-style-type: none"> 1. Straight Irrigating Cystotome 2. Formed Irrigating Cystotomes 3. Formed Capsularhexis Cystotomes <ul style="list-style-type: none"> - A length of stainless steel (grade 304) micro tube, pointed at the proximal end. The point may be angled at 45° or 90° and the length either straight, curved, or formed. A moulded polymer tapered connector is bonded to the distal end. - Capsularhexis cystotomes vary from the above in that the angled pointed tip is twisted through 90° so that the cutting edges are positioned to the front and rear, rather than side to side. - The formed variants are shaped to conform to the crystalline lens, with the shorter curved models being suited to patients with deeper set eyes or smaller pupils. - They are surgically invasive devices intended for patients requiring capsularhexis, intercapsular, endocapsular or opening capsulotomies, during cataract surgery, regardless of age, ethnicity, or gender. They are intended for transient use. These devices are either supplied as non-sterile or sterilized using a validated Ethylene Oxide (EtO) cycle.
Intended purpose specification	A sterile or non-sterile, single-use lumen device used for used for performing either capsularhexis, intercapsular endocapsular or can opening capsulotomies during cataracts surgery. 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	<ul style="list-style-type: none"> - Straight Irrigating Cystotome Irrigating Cystotomes are surgically invasive devices intended for either intercapsular, endocapsular, or can opener capsulotomy techniques, and are intended for transient use. - Formed Irrigating Cystotomes Surgically invasive devices intended for capsulorhexis, intercapsular, endocapsular, or can opening capsulotomies. The formed variants are shaped to conform to the crystalline lens, with the shorter curved models being suited to patients with deeper set eyes or smaller pupils and are intended for transient use. - Formed Capsularhexis Cystotomes Surgically invasive device for capsulorhexis, intercapsular, endocapsular, or can opening capsulotomies. The formed variants are shaped to conform to the crystalline lens, with the shorter curved models being suited to patients with deeper set eyes or smaller pupils and are intended for transient use.
Intended purpose (as labelling)	For either capsularhexis, intercapsular, endocapsular or can opening capsulotomies. The form variants are shaped to conform to the crystalline lens, with the shorter curved models being suited to patients with deeper set eyes or smaller pupils.
Indications for use	- Capsularhexis Cystotomes

	<p>Surgically invasive device for capsularhexis, intercapsular, endocapsular or can opening capsulotomies. The formed variants are shaped to conform to the crystalline lens, with the shorter curved models being suited to patients with deeper set eyes or smaller pupils and are intended for transient use.</p> <ul style="list-style-type: none"> - Angled Irrigating Cystotome: Surgically invasive device for capsularhexis, intercapsular, endocapsular, or can opening capsulotomies. The formed variants are shaped to conform to the crystalline lens, with the shorter curved models being suited to patients with deeper set eyes or smaller pupils and are intended for transient use. - Cystotome – Straight Irrigating Cystotomes are surgically invasive devices intended for either intercapsular, endocapsular, or can opener capsulotomy techniques, and are intended for transient use.
Patient population	Cystotomes are intended for patients requiring capsularhexis, intercapsular, endocapsular, or opening capsulotomies, during cataract surgery, regardless of age, ethnicity, or gender.
Intended user	<ul style="list-style-type: none"> - Assembly: Qualified Scrub Nurse or qualified Ophthalmic Surgeon. - Application: Qualified Ophthalmic Surgeon.
Training	<ul style="list-style-type: none"> - These devices are intended to be: <ul style="list-style-type: none"> • Assembled onto the syringe by a qualified Scrub Nurse. • Used by qualified ophthalmic surgeons trained in cataract 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.	<p><u>Cystotome Cannulae</u></p> <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 anterior chamber of the eye in particular the capsule bag and lens.
Clinical benefits	<p>Cystotomes are used for capsularhexis, intercapsular, endocapsular or can opening capsulotomies. Cystotome is a surgically invasive instrument designed to be used in capsulotomy (rarely known as cystotomy) which is one of the important steps of cataract surgery to make an opening in the anterior capsule to remove cataractous lens.</p> <p>The formed Cystotomes’ variants are shaped to conform to the crystalline lens, while the shorter curved variants may facilitate the surgery in deeper eyes or smaller pupils.</p> <p>Clinical benefits of Cystotomes are indirect and contribute to a successful ophthalmic surgery:</p> <ul style="list-style-type: none"> • Medical devices in question facilitate ophthalmic surgical procedures • They contribute to maintain the low rate of complications. <p>Moreover, they are available in a wide range of sizes with color-coding for clear identification of cannula gauge size to fit the different indications.</p>
ISO 15223-1	D. Device Use
 Fig. 20  Fig. 21	<ul style="list-style-type: none"> - <u>Non-Sterile Devices:</u> Must be sterilised before use, see Section E below. Sterile devices follow as below. - <u>Sterile Devices:</u> 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. 20) has not passed, and the packaging has not been damaged or unintentionally opened and thus the sterility is compromised (Fig. 17). • 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. 21) 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 until it locks in place, ensure it is secure.

	<ul style="list-style-type: none"> • Ensure there is a suitable flow rate through the cannula where applicable. • Once assembled, the cannula can be inserted into the eye for performing the capsulorhexis, intercapsular, endocapsular or can opening capsulotomies during cataract surgery. • Flow rates are controlled manually by the Ophthalmic Surgeon using the applicable flow control functions of the devices the cannula is attached to. <p><u>Note:</u></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.
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	<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 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	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.