



INSTRUCTION FOR USE



Revision No. 2

Dated: 15-05-2017

SINGLE USE INSTRUMENTS:

Single -use instruments are available in a variety of tip configurations, diameters and lengths, and are packaged and sterilised in clear or blue tinted blisters.



The following information is printed on the blister or on the blister lid:

- (1) **REF** - REF. Number;
- (2) Product Description including the diameter of the instrument;
- (3) **LOT** - the LOT Number; and
- (4)  - the Expiry date of the product;
- (5)  - the product is for SINGLE USE ONLY – DO NOT RE-USE;
- (6) **STERILE|EO** - Sterilised using ETHYLENE OXIDE GAS



NOTES:

- (1) Before opening the sterile product, visually inspect the blister and its seal to ensure its integrity.
- (2) Check that the instrument is correct.
- (3) Open the blister in a designated sterile field


DO NOT USE:

- (1)  - if the blister is damaged; or
- (2)  - if the blister has previously been opened.

! - WARNINGS

- (1)  - SINGLE USE ONLY – DO NOT REUSE.
- (2)  - DO NOT RE-STERILIZE AFTER SINGLE USE.
- (3) AFTER USE, DISPOSE OF THE INSTRUMENT IMMEDIATELY, IN ACCORDANCE WITH REGULATIONS.
- (4) THESE INSTRUMENTS ARE SURGICALLY INVASIVE DEVICE, AND ARE FOR TRANSIENT OR SHORT TERM USE.

MANUFACTURER:

 Sterimedix Limited, 1 Madeley Rd, North Moons Moat, Redditch, Worcestershire, B98 9NB, United Kingdom

PRODUCT FAMILIES:

- (1) Anaesthetic Needles & Cannulae
- (2) Anterior Chamber Maintenance Cannulae
- (3) Capsule Polishing Cannulae
- (4) Cystotomes
- (5) Hydrodissection Cannulae
- (6) Infusion Cannulae
- (7) Irrigating / Aspirating Cannulae & Handpieces
- (8) Lachrymal Cannulae
- (9) Lens Removal Cannulae
- (10) Refractive Cannulae
- (11) Vitreoretinal Cannulae
- (12) Vitreoretinal Handpieces
- (14) Scleral Markers / Incision Template
- (17) Trocar Sets
- (18) Irrigating Luer Handle
- (19) Surgical Corneal Cannulae

INDICATIONS FOR USE (for the Product family 14):

- (14) Invasive device used to mark the point for either Pars Plana incision or injection point.



- INSTRUCTIONS FOR USE – Product family 14.

- (1) Before opening the blister, - visually check the labelling and the product, to ensure that the instrument required, is correct.
- (2) Ensure that the blister and the blister seal is not damaged
- (3) Open the blister in a designated sterile field, by peeling the pull tab away from the blister.
- (4) Place the instrument in the sterile field.
- (5) SCLERAL MARKER – Select the required distance – Either 3.5mm or 4.0mm
- (6) Using either a surgical marking pen or a surgical marker pad, - apply colour to the selected Points.
- (7) Mark the Sclera either 3.5mm or 4.0mm from the Limbus.
- (8) INCISION TEMPLATE – Place the outside edge of the template on the Limbus. The centre (at the end of the cut-out channel) indicates the Scleral incision point.



- INSTRUCTION FOR USE

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INDICATIONS FOR USE (for the Product families 1 to 12 inclusive, 18, and 19.):


These single use instruments are intended for use by suitably trained and qualified people, in Ophthalmic surgical procedures.

- (1) For administering anaesthesia into either the muscle cone, or around the globe, or into the Sub Tenon space.
- (2) For maintaining and forming the Anterior Chamber by infusing or aspirating Balanced Salt Solution (BSS), Air, or Viscoelastic Substances.
- (3) For polishing and cleaning the residual cortex from the capsular bag. Silicone tipped polishers provide for gentle polishing and atraumatic insertion and removal. Micro etched tips are slightly roughened to facilitate gentle polishing.
- (4) For either 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.
- (5) For delivering fluids and viscoelastic to facilitate the separation of the cortex from the nucleus, and for insertion under the nucleus and expressing it using viscoelastic.
- (6) For Infusing Air, Balanced Salt Solution (BSS) or Heavy Liquids / Gases to maintain the form and intraocular pressure within the Posterior segment, during Vitreoretinal procedures.
- (7) For introducing Balanced Salt Solution (BSS) into the anterior chamber to maintain the shape, and aspirate fluid and cortical debris. Some bimanual aspiration devices incorporate a micro etched tip so that they can be used for gently polishing the capsule.
- (8) For probing and irrigating the lachrymal ducts.
- (9) For either removing the nucleus, large fragments of the nucleus, large pieces of cortical debris, or aspirating cortical debris.
- (10) For use after ablation, to wash particulate away from either the Anterior or Posterior sides of the flap, and from the stromal bed.
- (11) For specific infusion or aspiration functions during Vitreoretinal procedures.
- (12) Non-invasive devices, used in conjunction with a variety of cannulae, for specific infusion and either passive or active aspiration functions during retinal procedures.
- (18) A non-invasive irrigating medical device, intended to improve the handling characteristics of irrigating cannulae and other devices with a female luer inlet.
- (19) For intrastromal air injection, to facilitate the removal of the corneal stroma down to Descemet's membrane, during corneal graft procedures in both the donor and the recipient.

THESE INSTRUMENTS ARE SURGICALLY INVASIVE DEVICE, AND ARE FOR TRANSIENT OR SHORT TERM USE.



- INSTRUCTIONS FOR USE – Product families 1 to 12 inclusive, 18, and 19.

- (1) Before opening the blister, - visually check the labelling and the product, to ensure that the instrument required, is correct.
- (2) Ensure that the blister and the blister seal is not damaged
- (3)  Open the blister in a designated sterile field, by peeling the pull tab away from the blister.
- (4) Place the instrument in the sterile field.
- (5) Connect the instrument to either
 - (a) a syringe with male luer lok connector; or
 - (b) The appropriate male or female luer connector.
- (6) Dispose of the instrument safely, in accordance with regulatory requirements, immediately after use.

INDICATIONS FOR USE (for the Product family 17):

- (17) A device, which when in situ, provides three entry conduits to the posterior segment of the eye, to facilitate the introduction of various micro surgical ophthalmic instruments (e.g. Vitreoretinal forceps, scissors, fibre optic lighting, cannulae, and infusion cannula).



- INSTRUCTIONS FOR USE – Product family 17.

- (1) Before opening the blister, - visually check the labelling and the product, to ensure that the instrument required, is correct.
- (2) Ensure that the blister and the blister seal is not damaged
- (3) Open the blister in a designated sterile field, by peeling the pull tab away from the blister.
- (4) Place the instrument in the sterile field.
- (5) Place the outside edge of the template on the Limbus. The centre (at the end of the cut-out channel) indicates the Scleral incision point.
- (6) Use the Trocars to form a leak tight Pars Plana Incisions.
- (7) Connect the infusion line to the appropriate Trocar cannula.

MANUFACTURER:



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