

15/10/2019 -Issue 2

Technical Data Sheet- TDS04 (Cystotomes)

Please see Appendix 1 for product specific information including ordering references & materials

1. GENERAL INFORMATION

1.1 Intended Use

Surgically invasive device for capsularhexis, intercapsular, endocapsular, or can opening capsulotomies during cataract surgery. . 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.

1.2 Certification

All Sterimedix Ltd products are manufactured at the site below

| STERIMEDIX FACILITY | NOTIFIED BODY |
|---|--|
| Thornhill Road North Moons Moat Redditch Worcestershire B98 9ND United Kingdom | NB Number 0123 TUV SUD Product Service GmbH, Ridlerstr. 65, D-80339 Munich |

Sterimedix has appointed a European Representative (EC Rep) as per the below

Bausch & Lomb GmbH, Brunsbütteler Damm, 165-173, 13581, Berlin, Germany

1.3 Packaging Materials

Primary packaging

Either -

Blister - Pentamed® Film (PET'G'/'A'PET/PET'G')

Blister lid - Tyvek® with all over lacquer

or -

In Protector without blister – Protector – Polyethylene

Secondary packaging –

Sterile: Box - White Board

Sterile or Non-Sterile: Bulk - Double PE sealed bags labelled on the inner bag

1.4 Materials of Concern

| MATERIAL | DECLARATION |
|-----------------|--|
| DEHP/Phthalates | Devices do not contain referenced material |
| Latex | Devices do not contain referenced material |
| PVC | Devices do not contain referenced material |

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| | |
|-----------------------------|---|
| Bisphenol A (BPA) | Some devices may contain very low levels of BPA CAS 80-05-7 as a residue from the epoxy synthesis process which is used as a bonding agent. However, levels are below the 0.1% SVHC threshold |
| Substances of animal origin | Devices do not contain referenced material |
| Conflict Minerals | Devices are free from any Conflict Minerals referring to gold, tin, tantalum and tungsten, the derivatives of cassiterite, columbite-tantalite and wolframite, extracted in the Democratic Republic of the Congo (DRC) and surrounding countries. |

1.5 REACH

Based on current available information Sterimedix has not been able to identify any substances above 0.1% in any of its final devices which have been included on the Candidate List as a SVHC.

1.6 Instructions for Use (IFU)

As per Annex I, 13.1, Paragraph 4 by way of exception, no such instructions for use are needed for devices in Class I or IIa if they can be used safely without any such instructions. Therefore, unless otherwise stated, Sterimedix does not provide IFU's.

1.7 Shelf Life

Shelf life for all Sterile devices is 5 years

Non-Sterile N/A

There are no specific storage or transport conditions. Generic instructions such as Store in a cool dry place, keep out of direct sunlight, do not use if box is damaged are displayed on the box packaging with the appropriate symbology.

1.8 Sterilisation, Resterilisation/Reprocessing

All Sterimedix devices are validated to be sterilised via EtO Cycle 25 only at the Sterigenics Plant in Derbyshire*. After initial sterilisation, Sterimedix devices may be resterilised using the same EtO cycle once more. Sterimedix devices can be sterilised a maximum of two times**.

*Those using another EtO sterilisation cycle for Sterimedix devices are responsible for validating their own cycle to ensure sterility has been achieved and can be maintained.

**Some devices may have already undergone two sterilisation cycles before leaving Sterimedix. This will be represented by a "Z" at the end of the Lot number of the batch.

Further information be found in declaration "ST41 Sterimedix Sterilisation reprocessing instructions".

1.9 Sterile & Non-Sterile products

Non-Sterile devices are identical to Sterile devices in materials, manufacturing and control, with the exception of the packaging- and sterilisation-process

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1.10 Classification

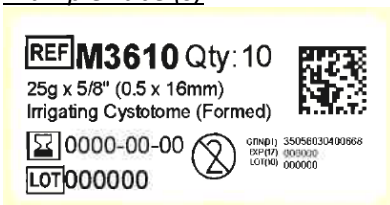
Class IIa in accordance with Annex IX Rule 6

1.11 GMDN Code

GMDN code for Anaesthetic Cannulae is 46705

2. LABELLING

2.1 Example Label(s)



LBL0008 – Sterile boxes of 10



LBL0020 – Sterile bulk



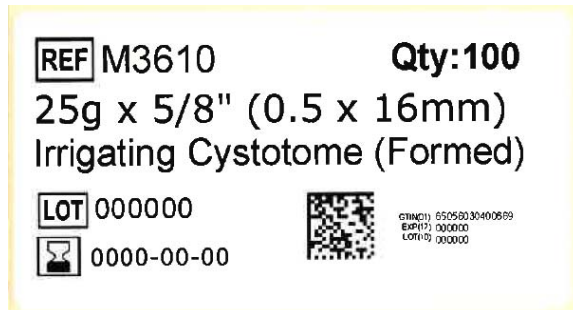
LBL0012 – Non-Sterile bulk

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LBL0024 – Sterile boxes of 100

3. DISCLAIMER

All information has been collated to the best of our knowledge and based on information currently available to us. This document can be updated without further notification.

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Appendix 1- Product specific information

| PRODUCT SUB-GROUP | PRODUCT CODE | LABEL DESCRIPTION | HUB COLOUR | ORDERING REFERENCE | MATERIALS |
|---------------------------------|---|--|---|--|--|
| Formed Irrigating Cystotomes | M3001 | 27g x 5/8" (0.4 x 16mm) Endocapsular Cystotome (curved) | Grey | 3001-03NSP/Y | Polypropylene, Stainless Steel Grade 304, Single Part Epoxy Adhesive |
| | M3602 | 25g x 5/8" (0.5 x 16mm) Side Cutting Cystotome (Formed) | Orange | M3602-02/10, M3602-02/100, 3602-02/Y, 3602-03NSP/Y | |
| | M3610 | 25g x 5/8" (0.5 x 16mm) Irrigating Cystotome (Formed) | Orange | M3610, M3610-02/10, M3610-02/100, 3610-02/Y, 3610-03NSP/Y | |
| | M3610B | 27g x 5/8" (0.4 x 16mm) Irrigating Cystotome (Formed) | Grey | M3610B, M3610B-02/10, M3610B-02/100, 3610B-02/Y, 3610B-03NSP/Y | |
| | M3610C | 25g x 5/8" (0.5 x 16mm) Irrigating Cystotome (Formed) 45° Tip | Orange | M3610C-02/10, M3610C-02/100, 3610C-02/Y, 3610C-03NSP/Y | |
| | M3610S | 25g x 5/8" (0.5 x 16mm) Irrigating Cystotome (Fmd. short tip) | Orange | M3610S-02/10, M3610S-02/100, 3610S-03NSP/Y | |
| | M3615 | 27g x 7/8" (0.4 x 22mm) Irrigating Cystotome (Formed) | Grey | M3615-02/10, 3615-03NSP/Y | |
| | M3615A | 25g x 7/8" (0.5 x 22mm) Irrigating Cystotome (Formed) | Orange | M3615A-02/10, M3615A-02/100, 3615A-03NSP/Y | |
| | M3617 | 25g x 7/8" (0.5 x 22mm) Irrigating Cystotome (Angled) | Orange | 3617-03NSP/Y | |
| | M3626 | 27g x 5/8" (0.4 x 16mm) Irrigating Cystotome (Angled) | Grey | M3626, M3626-02/10, 3626-02/Y, 3626-03NSP/Y | |
| | M3626A | 25g x 5/8" (0.5 x 16mm) Irrigating Cystotome (Angled) | Orange | M3626A, M3626A-02/10, 3626A-03NSP/Y | |
| | M3627 | 25g x 5/8" (0.5 x 16mm) Irr. Cystotome (Formed short curve) | Orange | M3627-02/10, M3627-02/100, 3627-02/Y, 3627-03NSP/Y | |
| | M3627A | 27g x 5/8" (0.4 x 16mm) Irr. Cystotome (Formed short curve) | Grey | M3627A-02/10, 3627A-03NSP/Y | |
| | M3629 | 25g x 5/8" (0.5 x 16mm) Irrigating Cystotome (Reverse Fmd.) | Orange | M3629-02/10, M3629-02/100, 3629-02/Y, 3629-03NSP/Y | |
| | M3629A | 27g x 5/8" (0.4 x 16mm) Irrigating Cystotome (Reverse Fmd.) | Grey | M3629A-02/10 | |
| M3630 | 30g x 5/8" (0.3 x 16mm) Irrigating Cystotome (Formed) | Yellow | M3630-02/10, M3630-02/100, 3630-03NSP/Y | | |
| Formed Capsularhexis Cystotomes | M3000D | 25g x 5/8" (0.5 x 16mm) Capsularhexis Cystotome (Fmd. short curve) | Orange | M3000D-02/10, M3000D-02/100, 3000D-02/Y, 3000D-03NSP/Y | |
| | M3000E | 27g x 5/8" (0.4 x 16mm) Capsularhexis Cystotome (Fmd. short curve) | Grey | M3000E-02/10, M3000E-02/100, 3000E-03NSP/Y | |
| | M3000F | 27g x 5/8" (0.4 x 16mm) Capsularhexis Cystotome (Formed) | Grey | M3000F-02/10, M3000F-02/100, 3000F-03NSP/Y | |
| | M3000G | 25g x 5/8" (0.5 x 16mm) Capsularhexis Cystotome (Formed) | Orange | M3000G-02/10, M3000G-02/100, 3000G-03NSP/Y | |

| KEY | |
|-----------|--|
| REFERENCE | DEFINITION |
| -02/X | Sterile, Blister Packed, Box of X |
| -03NSP/Y | Non-Sterile, in a Printed Protector, in Bulk |
| -02/Y | Sterile, in Bulk |