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Technical Data Sheet- TDS03 (Capsule Polishing Cannulae)*Please see Appendix 1 for product specific information including ordering references & materials***1. GENERAL INFORMATION****1.1 Intended Use**

Surgically invasive device 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 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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REF M8605	Qty:100
27g x 7/8" (0.4 x 22mm) Silicone Tip Capsule Polisher	
LOT 000000	
 0000-00-00	<small>GTIN(1) 45056133402256 EXP(1) 0000/00 LOT(1) 0000/00</small>

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
Capsule Polishing Cannulae	M8603	21g x 7/8" (0.81 x 22mm) Capsule Polisher (Micro etched tip)	Green	M8603-02/10	Polypropylene, Stainless Steel Grade 304, Single Part Epoxy Adhesive
	M8604	21g x 1" (0.81 x 25mm) 0.3mm Port Posterior Capsule Polisher (Micro etched tip)	Green	M8604-02/10, M8604-02/100, 8604-02/Y, 8604-03NSP/Y	
	M8604A	23g x 7/8" (0.64 x 22mm) 0.3mm Port Posterior Capsule Polisher (Micro etched tip)	Blue	M8604A, M8604A-02/10, M8604A-02/100, 8604A-02/Y, 8604A-03NSP/Y	
	M8604B	21g x 7/8" (0.81 x 22mm) 0.3mm Port Posterior Capsule Polisher (Micro etched tip)	Green	M8604B-02/10, M8604B-02/100, 8604B-03NSP/Y	
Silicone Tipped Polishers	M8605	27g x 7/8" (0.4 x 22mm) Silicone Tip Capsule Polisher	Grey	M8605-02/10, M8605-02/100, 8605-02/Y, 8605-02SP/Y, 8605-03NSP/Y	Polypropylene, Stainless Steel Grade 304, Single Part Epoxy Adhesive, Silicone
	M8605A	23g x 7/8" (0.64 x 22mm) Silicone Tip Capsule Polisher	Blue	M8605A-02/10, M8605A-02/100, 8605A-03NSP/Y	
	M8608	27g x 7/8" (0.4 x 22mm) Silicone Tip Capsule Polisher (Curved)	Grey	M8608-02/10, M8608-02/100, 8608-02/Y, 8608-03NSP/Y	
Cannulae Olive Tipped Cannulae	M8620	23g x 1" (0.64 x 25mm) Olive Tip Cannula (Straight)	Blue	M8620-02/10, M8620-02/100, 8620-03NSP/Y	Polypropylene, Stainless Steel Grade 303, Stainless Steel Grade 304, Single Part Epoxy Adhesive Silver Solder
	M8620C	23g x 1" (0.64 x 25mm) Olive Tipped Cannula (Curved)	Blue	M8620C-02/10, M8620C-02/100, 8620C-02/Y, 8620C-03NSP/Y	
	M8621	23g x 1" (0.64 x 25mm) Olive Tip Cannula (Micro etched) (Curved)	Blue	M8621-02/10, M8621-02/100, 8621-02/Y, 8621-03NSP/Y	
	M8622	25g x 1" (0.5 x 25mm) Olive Tipped Cannula (Angled) micro etched olive	Orange	M8622-02/10, 8622-03NSP/Y	
Posterior Scrapers	M8645	23g x 7/8" (0.64 x 22mm) Posterior Capsule Scraper	Blue	M8645-02/10	Polypropylene, Stainless Steel Grade 304, Single Part Epoxy Adhesive

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