Technical Data Sheet- TDS09 (Lens Removal Cannulae)

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

1. GENERAL INFORMATION

1.1 Intended Use

Surgically invasive devices for either removing the nucleus, large fragments of the nucleus, large pieces of cortical debris, or aspirating cortical debris. These devices 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, Brunsbutteler 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
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

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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

1.10 Classification

Class IIa in accordance with Annex IX Rule 6

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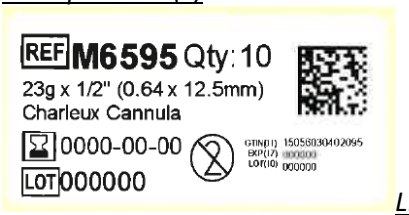
1.11 GMDN Code

GMDN code is 46705

2. LABELLING

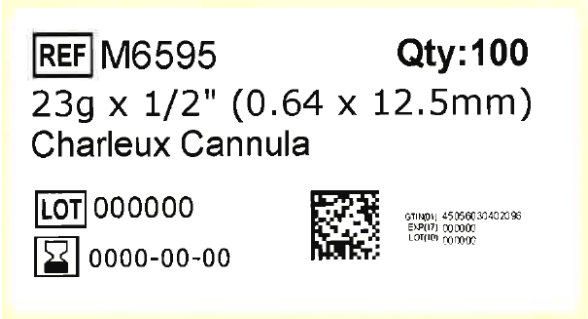
2.1 Example Label(s)



LBL0008 – Sterile boxes of 10

LBL0020 – Sterile bulk

LBL0012 – Non-Sterile bulk



LBL0024 – Sterile boxes of 100

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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
Cortex Removal Cannulae	M5620	23g x 7/8" (0.64 x 22mm) Binkhorst Hook Cannula (Right)	Blue	M5620-02/10, M5620-02/100	Polypropylene, Stainless Steel Grade 304, Single Part Epoxy Adhesive
	M5621	23g x 7/8" (0.64 x 22mm) Binkhorst Hook Cannula (Left)	Blue	M5621-02/10, M5621-02/100	
	M5622	25g x 7/8" (0.5 x 22mm) Binkhorst Hook Cannula (Right)	Orange	M5622-02/10, 5622-03NSP/Y	
	M5623	25g x 7/8" (0.5 x 22mm) Binkhorst Hook Cannula (Left)	Orange	M5623-02/10, M5623-02/10, 5623-03NSP/Y	
	M6525	21g x 5/8" (0.81 x 16mm) 0.3mm port Cortex Extraction Cann	Green	6525-03NSP/Y	
	M6575	23g x 5/8" (0.64 x 16mm) 0.3mm port Cortex Extraction Cann	Blue	M6575-02/10, M6575-02/100, 6575-03NSP/Y	
	M6575A	23g x 5/8" (0.64 x 16mm) 0.4mm port Cortex Extraction Cann	Blue	M6575A-02/10, M6575A-02/100, 6575A-03NSP/Y	
	M6575B	23g x 5/8" (0.64 x 16mm) 0.3mm port Cortex Extraction Cann	Blue	M6575B-02/10	
	M6576	23g x 7/8" (0.64 x 22mm) 0.3mm port Cortex Extraction Cann	Blue	M6576-02/10, M6576-02/100, 6576-03NSP/Y	
	M6576A	23g x 1/2" (0.64 x 12.5mm) 0.3mm port Cortex Extraction Cann	Blue	M6576A-02/10, M6576A-02/100	
	M6594	23g x 5/8" (0.64 x 16mm) Charleux Cannula	Blue	M6594, M6594-02/10, M6594-02/100, 6594-03NSP/Y	
	M6595	23g x 1/2" (0.64 x 12.5mm) Charleux Cannula	Blue	M6595-02/10, M6595-02/100, 6595-02/Y	
	M6596	24g x 1/2" (0.55 x 12.5mm) Charleux Cannula	Purple	M6596-02/10, M6596-02/100, 6596-03NSP/Y	
Nucleus Removal Cannulae	M4619	25g x 1 1/2" (0.5 x 38mm) 1 port Irrigating Vectis Cannula	Pink	M4619-02/10, 4619NS-02/Y	Polypropylene, Stainless Steel Grade 304, Single Part Epoxy Adhesive, Silver Solder
	M4620	25g x 1 1/2" (0.5 x 38mm) 2 ports Irrigating Vectis Cannula	Pink	M4620-02/10, 4620NS-02/Y	
	M4621	27g x 1 1/2" (0.4 x 38mm) 1 port Small Incision Vectis Cannula	Pink	M4621-02/10	

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