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Technical Data Sheet- TDS11 (Vitreoretinal Cannulae)

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

1. GENERAL INFORMATION

1.1 Intended Use

Surgically invasive devices for specific infusion and aspiration functions during retinal procedures, and are intended for either transient or short term 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
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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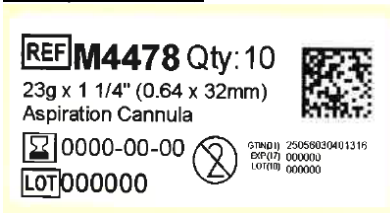
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1.11 GMDN Code

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
Vitreoretinal Cannulae	M4410	20g (0.9mm) Subretinal Fluid Cannula (6mm)	Yellow	M4410-02/10, 4410NS-02/Y	Polypropylene, Stainless Steel Grade 304, Single Part Epoxy Adhesive, Silver Solder, Silicone
	M4447	23g x 4mm VFI Cannula	Blue	M4447-02/10, M4447-02/100, 4447-02/Y, 4447NS-02/Y	Polycarbonate, Stainless Steel Grade 304, UV Adhesive
	M4448	25g x 4mm VFI Cannula	Orange	M4448-02/10, 4448-02/Y, 4448NS-02/Y	
	M4470	20g/23g x 1 1/4" (0.9/0.64 x 32mm) Reducing Aspiration Cannula	Yellow	M4470-02/10	Polypropylene, Stainless Steel Grade 304, Single Part Epoxy Adhesive, Silver Solder
	M4470C	20g/23g (0.9/0.64mm) Reducing Aspiration Cannula (Curved Tip)	Yellow	M4470C-02/10	Polypropylene, Stainless Steel Grade 304, Single Part Epoxy Adhesive
	M4471	20g x 1 1/4" (0.9 x 32mm) Aspiration Cannula	Yellow	M4471-02/10, 4471-02/Y	
	M4477	25g x 1 1/4" (0.5 x 32mm) Aspiration Cannula	Orange	M4477-02/10, M4477-02/100, 4477-02/Y, 4477NS-02/Y	
	M4478	23g x 1 1/4" (0.64 x 32mm) Aspiration Cannula	Blue	M4478-02/10, M4478-02/100, 4478-02/Y, 4478NS-02/Y	
	M4478B	23g UTW x 1 1/4" (0.64 x 32mm) Aspiration Cannula	Blue	M4478B-02/10, 4478BNS-02/Y	
	M4486	27g x 1 1/4" (0.4 x 32mm) Aspiration Cannula	Grey	M4486-02/10, 4486-02/Y, 4486NS-02/Y	
Heavy Liquid Infusion Cannulae	M4450	19g x 1/2" (1.1 x 12.5mm) Silicone Oil Removal Cannula	Cream	M4450-02/10	Polycarbonate, Stainless Steel Grade 304, UV Adhesive
	M4451	16g x 3/8" (1.6 x 10mm) High Viscosity Injection Cannula	White	M4451-02/10	
	M4452	23g (0.64mm) x 8mm Viscous Fluid Injection Cannula	Blue	M4452-02/10, M4452-02/100, 4452-02/Y	
	M4453	25g (0.4mm) x 7mm Viscous Fluid Injection Cannula	Orange	M4453-02/10, M4453-02/100	Polypropylene, Stainless Steel Grade 304, Single Part Epoxy Adhesive
	M4454	20g (0.90mm) x 7mm Viscous Fluid Injection Cannula	Yellow	M4454-02/10, 4454-02/Y	
	M4473	18g x 1 1/4" (1.24 x 32mm) Heavy Oil Removal Cannula	Pink	M4473-02/10	Polypropylene, Stainless Steel Grade 304, Single Part Epoxy Adhesive
M4474	20g/25g (0.9/0.5mm) Perfluorocarbon Coaxial Cannula	Yellow	M4474-02/10, M4474-02/100	Polypropylene, Stainless Steel Grade 304, Single Part Epoxy Adhesive, Silver Solder	

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	M4499	23g/30g (0.64/0.3mm) Perfluorocarbon Coaxial Cannula	Blue	M4499-02/10, M4499-02/100, 4499-02/Y	
	M4499A	25g (0.5mm) Perfluorocarbon Coaxial Cannula	Orange	M4499A-02/10	Polycarbonate, Stainless Steel Grade 304, UV Adhesive, Silver Solder
Silicone Brush Cannulae	M4449	25g x 1 1/4" (0.5 x 32mm) Silicone Brush Cannula	Orange	M4449-02/10	Polycarbonate, Stainless Steel Grade 304, UV Adhesive, Silicone
	M4459	23g x 1 1/4" (0.64 x 32mm) Silicone Brush	Blue	M4459-02/10, M4459-02/100	Polypropylene, Stainless Steel Grade 304, Single Part Epoxy Adhesive, Silicone, Silicone Adhesive
	M4475	20g x 1 1/4" (0.9 x 32mm) Silicone Brush Cannula	Yellow	M4475-02/10	
Silicone Tip Cannulae	M4456	25g x 1 1/4"(0.5 x 32mm) Soft Tip Cannula	Orange	M4456-02/10, M4456-02/100, 4456-02/Y, 4456NS-02/Y	
	M4457	20g x 1 1/4"(0.9 x 32mm) Soft Tip Cannula	Yellow	M4457-02/10, 4457-02/Y	
	M4458	23g x 1 1/4" (0.64 x 32mm) Soft Tip Cannula	Blue	M4458-02/10, 4458-02/Y, 4458NS-02/Y	

KEY	
REFERENCE	DEFINITION
-02/X	Sterile, Blister Packed, Box of X
NS-02/Y	Non-Sterile, Blister Packed, in Bulk
-02/Y	Sterile, in Bulk