

Sterimedix Ltd

Quality System Document QD 2125 Issue B
Technical Data Sheet Template

15/10/2019 -Issue 1

Technical Data Sheet- TDS12 (Vitreoretinal Handpieces)

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

1. GENERAL INFORMATION

1.1 Intended Use

Non-invasive devices, used in conjunction with a variety of cannulae, for specific infusion and aspiration functions during retinal procedures.

Surgically invasive device for either passive or active aspiration during retinal surgery, and 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 2

Class IIa in accordance with Annex IX Rule 6

1.11 GMDN Code

- GMDN code for below sub-groups is 47007

Vitreoretinal Heavy Liquid Infusion Handpieces

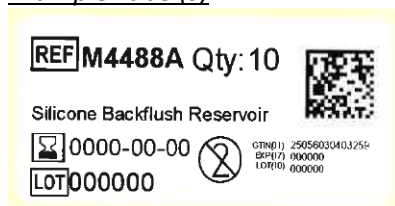
Backflush Aspiration Handpieces

Silicone Backflush Reservoir

- GMDN code for Handpieces and Cannulae is 46705

2. LABELLING

2.1 Example Label(s)



LBL0008 – Sterile boxes of 10



LBL0009 – Sterile boxes of 5



LBL0020 – Sterile bulk

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LBL0012 – Non-Sterile bulk

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 Heavy Liquid Infusion Handpieces	M4498	Heavy Liquid Infusion Handle	N/A	M4498-02/5	Stainless Steel Grade 303, Natural Kynar PVDF Classic Barb, Silicone, Silicone Adhesive, ABS, Nylon Resin
Backflush Aspiration Handpieces	M4489	Rigid Backflush Handle	N/A	M4489-02/5, 4489-02/Y, 4489NS-02/Y	
	M4489A	Active/Passive Back Flush Handle	N/A	M4489A-02/5	
	M4493	Charles Flute Handle	N/A	M4493-02/5, 4493NS-02/Y	Techtron HPV PPS PEAK
Silicone Backflush Reservoir	M4488A	Silicone Backflush Reservoir	N/A	M4488A-02/10, 4488ANS-02/Y	Silicone
Handpieces and Cannulae	M4491	Rigid Backflush Handle + 20g (0.9mm) Silicone Brush set (M4489 + M4475)	Yellow	M4491-02/5	Stainless Steel Grade 303, Natural Kynar PVDF Classic Barb, Silicone, Silicone Adhesive, ABS, Nylon Resin, Polypropylene, Stainless Steel Grade 304, Single Part Epoxy Adhesive
	M4492	23g x 1 1/4" (0.64 x 32mm) Backflush Handle with Silicone Brush	Blue	M4492-02/5, 4492-02/Y	
	M4494	Charles Flute Handle + 20g (0.9mm) Cannula (M4493 + M4471)	Yellow	M4494-02/5	Techtron HPV PPS PEAK, Polypropylene, Stainless Steel Grade 304, Single Part Epoxy Adhesive
	M4495	Charles Flute Handle + 23g (0.64mm) Aspiration Cannula	Blue	M4495-02/5	
	M4496	Rigid Backflush Handle + 20g (0.9mm) Aspiration Cannula Set	Yellow	M4496-02/5	Stainless Steel Grade 303, Natural Kynar PVDF Classic Barb, Silicone, Silicone Adhesive, ABS, Nylon Resin, Polypropylene, Stainless Steel Grade 304, Single Part Epoxy Adhesive
	M4497	23g x 1 1/4" (0.64 x 32mm) 'Rigid' Backflush Handle + 23g Aspiration Cannula	Blue	M4497-02/5	
	M4500	Backflush Handle + 25g (0.5mm) Aspiration Cannula	Orange	M4500-02/5	
	M4501	Backflush Handle + 20g (0.9mm) Aspiration Cannula	Yellow	M4501-02/5	
	M4502	Backflush Handle + 23g (0.64mm) Aspiration Cannula	Blue	M4502-02/5	
	M4503	Backflush Handle + 25g (0.5mm) Backflush/25g Soft Tip Set	Orange	M4503-02/5	

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	M4504	Active/Passive Backflush Handle + 25g x 1 1/4" (0.5 x 32mm) Soft Tip Cannula	Orange	M4504-02/5	
	M4507	25g x 1 1/4" (0.5 x 32mm) A/P Backflush Handle + Silicone Brush Set	Orange	M4507-02/5	Stainless Steel Grade 303, Natural Kynar PVDF Classic Barb, Silicone, Silicone Adhesive, ABS, Nylon Resin, Polycarbonate, UV Adhesive
	M4509	23g x 1 1/4" (0.64 x 32mm) A/P Backflush Handle + Silicone Brush set	Blue	M4509-02/5	
	M4530	Active/Passive Backflush Handle + 23g x 1 1/4" (0.64 x 32mm) Soft Tip Cannula	Blue	M4530-02/5	Stainless Steel Grade 303, Natural Kynar PVDF Classic Barb, Silicone, Silicone Adhesive, ABS, Nylon Resin, Polypropylene, Stainless Steel Grade 304, Single Part Epoxy Adhesive
	M4531	Active/Passive Backflush Handle + 20g x 1 1/4" (0.9 x 32mm) Soft Tip Cannula	Yellow	M4531-02/5	
	M4532	Backflush Handle + 27g (0.4mm) Aspiration Cannula	Grey	M4532-02/5	
	M4533	Active/Passive Backflush Handle + 27g (0.4mm) Aspiration Cannula	Grey	M4533-02/5	

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