Technical Data Sheet- TDS17 (Trocar Sets for Vitreoretinal Surgery)

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

1. GENERAL INFORMATION

1.1 Intended Use

A surgically invasive, single use device, which when in situ, provides three entry conduits to the posterior segment of the eye, to facilitate the introduction of various micro surgical ophthalmic instruments (e.g. Vitreoretinal forceps, scissors, fibre optic lighting, cannulae, and infusion cannulae). The devices are intended for 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, 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

Technical Data Sheet- TDS17 (Trocar Sets for Vitreoretinal Surgery)

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

Technical Data Sheet- TDS17 (Trocar Sets for Vitreoretinal Surgery)

1.10 Classification

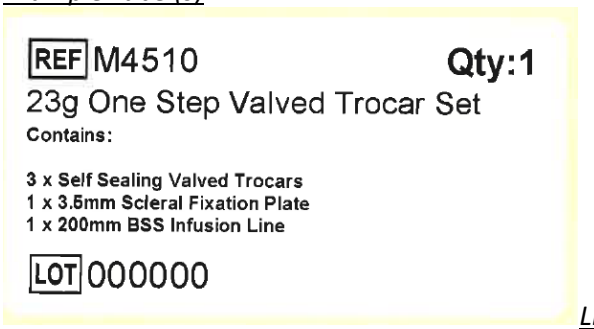
Class IIa in accordance with Annex IX Rule 6

1.11 GMDN Code

GMDN code is 46840

2. LABELLING

2.1 Example Label(s)



LBL0033 – Trocar blister

LBL0032 – Trocar box

LBL0020 – Sterile bulk

Technical Data Sheet- TDS17 (Trocar Sets for Vitreoretinal Surgery)

LBL0009 – Sterile boxes of 5

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.

Technical Data Sheet- TDS17 (Trocar Sets for Vitreoretinal Surgery)

***Appendix 1**- Product specific information*

PRODUCT SUB-GROUP	PRODUCT CODE	LABEL DESCRIPTION	HUB COLOUR	ORDERING REFERENCE	MATERIALS
Trocar Sets for Vitreoretinal Surgery	M4510	23g One Step Valved Trocar Set	N/A	M4510-02/5, 4510-02/Y	Stainless Steel Grade 420, Silicone, ABS, Single Part Epoxy Adhesive, Natural Kynar PVDF Classic Barb, Titanium, Polycarbonate
	M4512	23g Trocar Handle + 3.5mm Scleral Incision Template	N/A	M4512-02/5	Stainless Steel Grade 420, Silicone, ABS, Single Part Epoxy Adhesive, Titanium, Polycarbonate
	M4515	25g One Step Valved Trocar Set	N/A	M4515-02/5	Stainless Steel Grade 420, Silicone, ABS, Single Part Epoxy Adhesive, Natural Kynar PVDF Classic Barb, Titanium, Polycarbonate
	M4517	25g Trocar Handle + 3.5mm Scleral Incision Template	N/A	M4517-02/5	Stainless Steel Grade 420, Silicone, ABS, Single Part Epoxy Adhesive, Titanium, Polycarbonate
	03VI17	23G QUBE® TROCAR SET 3 One-Step Trocars, 3 Holding Plates, 1 BSS Infusion Cannula	N/A	03VI17-02/5	Stainless Steel Grade 420, Silicone, ABS, Single Part Epoxy Adhesive, Natural Kynar PVDF Classic Barb, Titanium, Polycarbonate
	03VI18	25G QUBE® TROCAR SET 3 One-Step Trocars, 3 Holding Plates, 1 BSS Infusion Cannula	N/A	03VI18-02/5	Stainless Steel Grade 420, Silicone, ABS, UV Adhesive, Natural Kynar PVDF Classic Barb, Titanium, Polycarbonate

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