

Sterimedix Ltd

Quality System Document QD 2125 Issue B
Technical Data Sheet Template

15/10/2019 -Issue 2

Technical Data Sheet- TDS02 (Anterior Chamber Maintenance Cannulae)

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

1. GENERAL INFORMATION

1.1 Intended Use

Surgically invasive device for maintaining and forming the anterior or posterior chamber by infusing or aspirating balanced salt solution (BSS), air, or viscoelastic substances, and is 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

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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

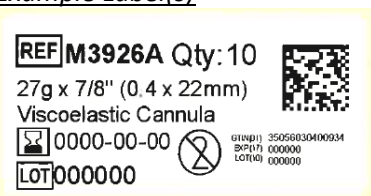
Class IIa in accordance with Annex IX Rule 6

1.11 GMDN Code

GMDN code is 46705

2. LABELLING

2.1 Example Label(s)



LBL0008 – Sterile boxes of 5, 10 and some 100



LBL0020 – Sterile bulk



LBL0012 – Non-Sterile bulk

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REF M3926A	Qty:100
27g x 7/8" (0.4 x 22mm)	
Viscoelastic Cannula	
LOT 000000	
 0000-00-00	<small>GTIND(1) 45256030400921 EXP(1) 00:00:00 LOT(1) 00:00:00</small>

LBL0024 – Sterile boxes of 100 standard blister

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
Anterior Chamber Maintenance Cannulae	M2270	30g x 7/8" (0.3 x 22mm) Rycroft Anterior Chamber Cannula	Yellow	M2270, M2270-02/10, M2270-02/100, 2270-02/Y, 2270-03NSP/Y	Polypropylene, Stainless Steel Grade 304, Single Part Epoxy Adhesive
	M2270A	30g x 7/8" (0.3 x 22mm) Rycroft Anterior Chamber Cannula	Yellow	M2270A-02/10, M2270A-02/100, 2270A-03NSP/Y	
	M2273	30g x 7/8" (0.3 x 22mm) Rycroft Anterior Chamber Cannula	Yellow	M2273-02/10, M2273-02/100, 2273-02/Y, 2273-03NSP/Y	
	M2273A	27g x 7/8" (0.4 x 22mm) Rycroft Anterior Chamber Cannula	Grey	M2273A-02/10, M2273A-02/100, 2273A-02/Y, 2273A-03NSP/Y	
	M2273B	20g x 7/8" (0.9 x 22mm) Rycroft Anterior Chamber Cannula	Yellow	M2273B-02/10, 2273B-02/Y, 2273B-03NSP/Y	
	M2273G	23g x 7/8" (0.64 x 22mm) Rycroft Anterior Chamber Cannula	Blue	M2273G-02/10, 2273G-02/Y, 2273G-03NSP/Y	
	M2275	25g x 7/8" (0.5 x 22mm) Rycroft Anterior Chamber Cannula	Orange	M2275-02/10 M2275-02/100, 2275-02/Y, 2275-03NSP/Y	
	M2278	27g x 7/8" (0.4 x 22mm) Rycroft Anterior Chamber Cannula	Grey	M2278-02/10, M2278-02/100	
	M2279	27g x 7/8" (0.4 x 22mm) 11mm Bend Rycroft Anterior Chamber Cannula	Grey	M2279-02/10, M2279-02/100, 2279-03NSP/Y	
	M2280	27g x 7/8" (0.4 x 22mm) Transzonular Injection Cannula	Grey	M2280-02/10, M2280-02/100, 2280-03NSP/Y	
	M2639	25g x 1" (0.5 x 25mm) Rycroft Anterior Chamber Cannula	Orange	M2639-02/10, M2639-02/100, 2639-02/Y, 2639-03NSP/Y	
M2642	21g x 7/8" (0.81 x 22mm) Rycroft Anterior Chamber Cannula	Green	M2642-02/10, M2642-02/100		
Viscoelastic Cannulae	M2272	26g x 7/8" (0.45 x 22mm) Viscoelastic Cannula	Brown	M2272-02/10, M2272-02/100, 2272-02/Y, 2272-02S/Y, 2272-03NSP/Y	Polypropylene, Stainless Steel Grade 304, Single Part Epoxy Adhesive, Thermo Plastic Elastomer
	M2639A	25g x 7/8" (0.5 x 22mm) Viscoelastic Cannula	Orange	M2639A-02/10, M2639A-02/100, 2639A-02/Y, 2639A-02S/Y, 2639A-02SP/Y, 2639A-03NSP/Y	
	M2639C	25g x 7/8" (0.5 x 22mm) Viscoelastic Cannula	Orange	2639C-02S/Y, 2639C-02SP/Y	Polypropylene, Stainless Steel Grade 304, Single Part Epoxy Adhesive
	M3909	23g x 7/8" (0.64 x 22mm) Viscoelastic Cannula	Blue	M3909-02/10, M3909-02/100, 3909-01S/Y, 3909-02/Y, 3909-02S/Y, 3909-02SP/Y, 3909-03NSP/Y	
	M3910	21g x 7/8" (0.81 x 22mm) Viscoelastic Cannula (Straight)	Green	M3910-02/10, 3910-03NSP/Y	
	M3910A	21g x 7/8" (0.81 x 22mm) Viscoelastic Cannula	Green	M3910A-02/10, M3910A-02/100, 3910A-02/Y, 3910A-03NSP/Y	

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	M3917	27g x 7/8" (0.4 x 22mm) Formed Viscoelastic Cannula	Grey	M3917-02/10, 3917-02/Y, 3917-03NSP/Y		
	M3924N	27g RW x 1" (0.4 x 26mm) Viscoelastic Cannula (Straight)	Grey	M3924N-02/100, 3924N-02/5		
	M3925	27g x 7/8" (0.4 x 22mm) Viscoelastic Cannula (Angled)	Grey	M3925-02/100, 3925-02/5		
	M3925N	27g RW x 7/8" (0.4 x 22mm) Viscoelastic Cannula (Angled)	Grey	M3925N-02/100, 3925N-02/5		
	M3926A	27g x 7/8" (0.4 x 22mm) Viscoelastic Cannula	Grey	M3926A-02/10, M3926A-02/100, 3926A-02/Y, 3926A-02S/5000, 3926A-02S/Y, 3926A-02SP/Y, 3926A-03NSP/Y		
	M3927	27g x 7/8" (0.4 x 22mm) Viscoelastic	Grey	M3927-02/10, M3927-02/100, 3927-02/Y, 3927-03NSP/Y		
	M7909A	25g TW x 7/8" Aspirating Cannula	Orange	7909A-02S/Y		
Wash out Cannulae	M9280	19g x 1" (1.1 x 25mm) Washout Cannula	Cream	M9280-02/10, M9280-02/100, 9280-02/Y, 9280-03NSP/Y		
	M9281	16g x 1" (1.6 x 25mm) Washout Cannula	White	M9281-02/10, M9281-02/100, 9281-03NSP/Y		
A.C. Maintainers	M2656	20g x 9/64" (0.9 x 3.5mm) A.C. Maintainer (Micro etched)	Yellow	M2656-02/5, M2656-02/10	Polypropylene, Stainless Steel Grade 304, Single Part Epoxy Adhesive, Silicone	
	M2657	20g x 9/64" (0.9 x 3.5mm) Self Retaining A.C. Maintainer	Yellow	M2657-02/5, M2657-02/10, 2657NS-02/Y		Stainless Steel Grade 303, Silicone Tube, Natural Kynar PVDF Classic Barb
	M2658	23g x 9/64" (0.64 x 3.5mm) Self Retaining A.C. Maintainer	Blue	M2658-02/5, M2658-02/10		

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
-01S/Y	Sterile, packed in Double Smaller Blister, in bulk
-02S/Y	Sterile, packed in Smaller Blister, in bulk
-02SP/Y	Sterile, packed in Smaller Blister, in a protector, in bulk
-02S/5000	Sterile, packed in Smaller Blister, Box of 5000