

03/03/2020 -Issue 2

Technical Data Sheet- TDS07 (Irrigation/Aspiration Cannulae and Hand Pieces)

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

**1. GENERAL INFORMATION**

*1.1 Intended Use*

Surgically invasive device for introducing balanced salt solution (BSS) into the anterior chamber to maintain the shape, and aspirate fluid and cortical debris. Some bimanual aspiration devices incorporate a micro etched tip so that they can be used for gently polishing the capsule. They 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, 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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Quality System Document QD 2125 Issue B  
Technical Data Sheet Template

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### 1.10 Classification

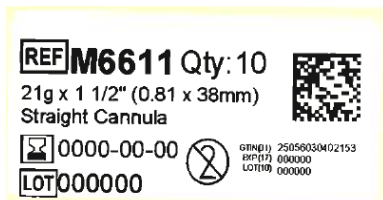
Class IIa in accordance with Annex IX Rule 6

### 1.11 GMDN Code

GMDN code is 46705

## 2. LABELLING

### 2.1 Example Label(s)



LBL0008 – Sterile boxes of 5 or 10 standard blister



LBLB0009 – Sterile boxes of 5 or 10 larger blister



LBL0020 – Sterile bulk

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**REF** 6600NS-02   
**Qty: 50** **LOT** 000000  
23g/23g (0.64/0.64mm)  
0.4mm Port  
Standard Simcoe I/A Cannula

   Sterimedix Ltd  
1 Madeley Road  
North Moons Moat  
Redditch  
Worcestershire  
B98 9NB, UK

0123  
Made in the United Kingdom  
Suitable for sterilisation by ETO using a validated cycle  
Must be sterilised before use

LBL0012 – Non-Sterile bulk



**REF** M6611 **Qty: 100**  
21g x 1 1/2" (0.81 x 38mm)  
Straight Cannula

**LOT** 000000   
 0000-00-00

GTIN(01) 55058030402154  
EXP(17) 000000  
LOT(10) 000000

LBL0024 – Sterile boxes of 100

**REF** M6600 **Qty: 50**  
23g/23g (0.64/0.64mm)  
0.4mm Port  
Standard Simcoe I/A  
Cannula

**LOT** 000000   
 0000-00-00

GTIN(01) 55058030402110  
EXP(17) 000000  
LOT(10) 000000

LBL0030 – Sterile boxes of 50

### 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
Bimanual Cannulae and Hand Pieces	M5405	21g x 5/8" (0.81 x 16mm) Bimanual Irrigation Cannula	Green	M5405-02/10, 5405-03NSP/Y	Polypropylene, Stainless Steel Grade 304, Single Part Epoxy Adhesive
	M5501	23g x 5/8" (0.64 x 16mm) 0.4mm side port Bimanual Aspiration Handle (curved micro etched)	N/A	M5501-02/5	Stainless Steel Grade 304, Single Part Epoxy Adhesive, ABS
	M5502	23g x 5/8" (0.64 x 16mm) 0.3mm side port Bimanual Aspiration Handle (curved micro etched)	N/A	M5502, M5502-02/5	
	M5505	21g x 5/8" (0.81 x 16mm) Bimanual Irrigation Handle (curved)	N/A	M5505-02/5, 5505NS-02/Y	
	M5510	20g x 3/4" (0.90 x 19mm) 0.5mm side ports Bimanual Irrigation Handle (curved)	N/A	M5510, M5510-02/5	
	M5511	20g x 3/4" (0.90 x 19mm) 0.3mm side ports Bimanual Aspiration Handle (curved micro etched)	N/A	M5511, M5511-02/5	
	M5512	21g x 5/8" (0.81 x 16mm) 0.3mm side port Bimanual Aspiration Handle (curved micro etched)	N/A	M5512, M5512-02/5	
	M5513	23g x 5/8" (0.64 x 16mm) 0.4mm side ports Bimanual Irrigation Handle (curved)	N/A	M5513, M5513-02/5	
	M5514	21g x 5/8" (0.81 x 16mm) 0.5mm side ports Bimanual Irrigation Handle (curved)	N/A	M5514, M5514-02/5	
	M5515	21g x 7/8" (0.81 x 22mm) 0.3mm side port Bimanual Aspiration Handle (curved)	N/A	M5515-02/5, 5515NS-02/Y	
	M5518	23g x 5/8" (0.64 x 16mm) 0.3mm side ports Bimanual Aspiration Handle (curved)	N/A	M5518, M5518-02/5	
	M5519	23g x 5/8" (0.64 x 16mm) Bimanual Irrigation Handle (curved)	N/A	M5519-02/5	
	M5520	21g TW x 5/8" (0.81 x 16mm) 0.4mm side port Bimanual Aspiration Handle (curved, micro etched)	N/A	M5520-02/5, 5520NS-02/Y	
	M5521	21g TW x 5/8" (0.81 x 16mm) 0.5mm side ports Bimanual Irrigation Handle (curved)	N/A	M5521-02/5, 5521-02/Y, 5521NS-02/Y	

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	M5522	21g TW x 5/8" (0.81 x 16mm) Bimanual Irrigation Handle (curved)	N/A	M5522-02/5	Polypropylene, Stainless Steel Grade 304, Single Part Epoxy Adhesive
	M5523	23g UTW x 5/8" (0.64 x 16mm) Bimanual Irrigation Handle Open End (curved)	N/A	M5523, M5523-02/5	
	M6524	21g x 5/8" (0.81 x 16mm) 0.3mm top port Bimanual Aspirating (Curved)	Green	M6524-02/10, M6524-02/100,	
Bimanual I/A Systems	M5331	21g x 5/8" (0.81 x 16mm) Bimanual Tapered Tip Irrigation/Aspiration System	N/A	M5331-02/5	Stainless Steel Grade 304, Single Part Epoxy Adhesive, ABS
	M5531	21g (0.81mm) Bimanual Irrigation/Aspiration System Bimanual Aspiration Handpiece. Thin Wall. Curved with 0.4mm side port	N/A	M5531-02/5, 5531NS-02/Y	
	M5532	21g (0.81mm) Bimanual Irrigation/Aspiration System	N/A	M5532-02/5, 5532NS-02/Y	
	M5533	21g (0.81mm) Bimanual Irrigation/Aspiration System	N/A	M5533-02/5	
	M5535	23g (0.64mm) Bimanual Irrigation/Aspiration System	N/A	M5535-02/5, 5535NS-02/Y	
	M5536	23g (0.64mm) Bimanual Irrigation/Aspiration System	N/A	M5536-02/5, 5536NS-02/Y	
	M5537	20g (0.9mm) Irrigation / 21g (0.81mm) Aspiration Bimanual System	N/A	M5537-02/5	
	M5538	25g (0.5mm) Bimanual Irrigation / Aspiration System	N/A	M5538-02/5	
	M5539	21g (0.81mm) Bimanual Irrigation/Aspiration System	N/A	M5539-02/5	
	M5540	21g (0.81mm) Bimanual Irrigation/Aspiration System	N/A	M5540-02/5	
Coaxial Cannulae and Hand Pieces	M5560	21g Soft Outer I/A Coaxial Handpiece (Straight Tip)	N/A	M5560-02/5	Stainless Steel Grade 304, Single Part Epoxy Adhesive, Loctite Adhesive, UV Adhesive, Silicone, ABS
	M5561	21g Soft Outer I/A Coaxial Handpiece (45° Angled Tip)	N/A	M5561-02/5	
	M5562	21g Soft Outer I/A Coaxial Handpiece (60° Angled Tip)	N/A	M5562-02/5	
	M5563	21g Soft Outer I/A Coaxial Handpiece (90° Angled Tip)	N/A	M5563-02/5	
	M5570	24g Soft Outer I/A Coaxial Handpiece (Straight Tip)	N/A	M5570-02/5	
	M5571	24g Soft Outer I/A Coaxial Handpiece (45° angled tip)	N/A	M5571-02/5, 5571-02/Y, 5571NS-02/Y	
	M5572	24g Soft Outer I/A Coaxial Handpiece (60° Angled Tip)	N/A	M5572-02/5	
	M5573	24g Soft Outer I/A Coaxial Handpiece (90° Angled Tip)	N/A	M5573-02/5	
	M5580	16g/21g (1.6 x 0.81mm) I/A Coaxial Handpiece (Straight Tip)	N/A	M5580, M5580-02/5	Stainless Steel Grade 303, Stainless Steel Grade 304, Single Part Epoxy Adhesive,
	M5581	16g/21g (1.6 x 0.81mm) I/A Coaxial Handpiece (Curved Tip)	N/A	M5581-02/5, 5581NS-02/Y	
M5582	16g/21g (1.6 x 0.81mm) I/A Coaxial Handpiece (45° Angled Tip)	N/A	M5582-02/5, 5582-02/Y, 5582NS-02/Y		

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	M5583	16g/21g (1.6 x 0.81mm) I/A Coaxial Handpiece (60° Angled Tip)	N/A	M5583-02/5, 5583NS-02/Y	Loctite Adhesive, UV Adhesive, Silicone, ABS
	M5584	16g/21g (1.6 x 0.81mm) I/A Coaxial Handpiece (90° Angled Tip)	N/A	M5584, M5584-02/5	
	M5590	17g/24g (1.4 x 0.55mm) I/A Handpiece (Straight Tip)	N/A	M5590-02/5	
	M5591	17g/24g (1.4 x 0.55mm) I/A Handpiece (Curved Tip)	N/A	M5591-02/5	
	M5592	17g/24g (1.4 x 0.55mm) I/A Handpiece (45° Angled Tip)	N/A	M5592-02/5, 5592NS-02/Y	
	M5593	17g/24g (1.4 x 0.55mm) I/A Handpiece (60° Angled Tip)	N/A	M5593-02/5, 5593NS-02/Y	
	M5594	17g/24g (1.4 x 0.55mm) I/A Handpiece (90° Angled Tip)	N/A	M5594-02/5	
Irrigation/ Aspiration Cannulae	M6600	23g/23g (0.64/0.64mm) 0.4mm Port Standard Simcoe I/A Cannula	Blue/Green	M6600-02/10, M6600-02/50, 6600-02/Y, 6600NS-02/Y	Polypropylene, Stainless Steel Grade 304, Single Part Epoxy Adhesive, Silver Solder, Silicone
	M6601	23g/23g (0.64/0.64mm) 0.4mm Port Reverse Simcoe I/A Cannula	Blue/Green	M6601-02/5, M6601-02/10	
	M6602	23g (0.64mm) x 30mm Standard Simcoe I/A Cannula	Blue/Green	M6602-02/10, 6602NS-02/Y	
	M6605	23g/23g (0.64/0.64mm) 0.3mm Port Standard Simcoe I/A Cannula	Blue/White	M6605-02/5, M6605-02/10, M6605-02/50, 6605NS-02/Y	Polypropylene, Stainless Steel Grade 304, Single Part Epoxy Adhesive, Silver Solder, Silicone, Kynar Resin
	M6611	21g x 1 1/2" (0.81 x 38mm) Straight Cannula	Green	M6611-02/10, M6611-02/100, 6611NS- 02/Y	Polypropylene, Stainless Steel Grade 304, Single Part Epoxy Adhesive
	M6613	23g/23g (0.64/0.64mm) 0.4mm Port Standard Simcoe I/A Cannula	Blue/Green	M6613-02/10	Polypropylene, Stainless Steel Grade 304, Single Part Epoxy Adhesive, Silver Solder, Silicone
	M6614	23g (0.64mm) x 30mm Irrigation/Left Hand Aspiration Simcoe	Blue/Green	M6614-02/10, 6614NS-02/Y	
	M6615	23g (0.64mm) x 30mm Irrigation/Right Hand Aspiration Simcoe	Blue/Green	6615NS-02/Y	
M6617	23g/23g (0.64/0.64mm) 0.3mm Port Standard Simcoe I/A Cannula	Blue/White	M6617-02/10	Polypropylene, Stainless Steel Grade 304, Single Part Epoxy Adhesive, Silver Solder, Silicone, Kynar Resin	

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	M7900A	25g TW x 7/8" Aspirating Cannula	Orange	M7900A-02/10	Polypropylene, Stainless Steel Grade 304, Single Part Epoxy Adhesive
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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