

04/12/2019 -Issue 2

Technical Data Sheet- TDS05 (Hydrodissection Cannulae)

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

**1. GENERAL INFORMATION**

*1.1 Intended Use*

Surgically invasive device for delivering fluids and viscoelastic to facilitate the separation of the cortex from the nucleus, and for insertion under the nucleus and expressing it using viscoelastic. 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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### 1.10 Classification

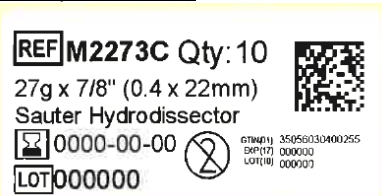
Class IIa in accordance with Annex IX Rule 6

### 1.11 GMDN Code

GMDN code is 46705

## 2. LABELLING

### 2.1 Example Label(s)



LBL0008 – Sterile boxes of 10



LBL0020 – Sterile bulk



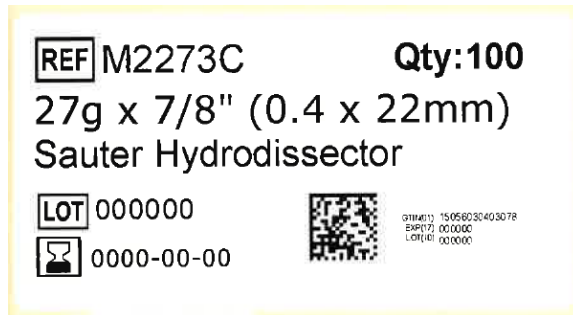
LBL0012 – Non-Sterile bulk

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LBL0024 – Sterile boxes of 100

### **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
Hydrodissection Cannulae	M2273C	27g x 7/8" (0.4 x 22mm) Sauter Hydrodissector	Grey	M2273C-02/10, M2273C-02/100, M2273C-02SP/100, 2273C-02/Y, 2273C-02SP/Y, 2273C-03NSP/Y	Polypropylene, Stainless Steel Grade 304, Single Part Epoxy Adhesive
	M2273D	25g x 7/8" (0.5 x 22mm) Sauter Hydrodissector	Orange	M2273D-02/10, M2273D-02/100, 2273D-02/Y, 2273D-03NSP/Y	
	M2273E	27g x 7/8" (0.4 x 22mm) Helsinki Hydrodissector	Grey	M2273E, M2273E-02/10, M2273E-02/100, 2273E-02/Y, 2273E-03NSP/Y	
	M2273F	25g x 7/8" (0.5 x 22mm) Helsinki Hydrodissector	Orange	M2273F-02/10, 2273F-03NSP/Y	
	M2273H	27g x 7/8" (0.4 x 22mm) Hydrodissection Cannula (Curved)	Grey	M2273H-02/10, 2273H-02/Y, 2273H-03NSP/Y	
	M2274	25g x 7/8" (0.5 x 22mm) Kellan Hydrodissection Cannula Curved	Orange	M2274-02/10, M2274-02/100, 2274-03NSP/Y	
	M3900	25g x 7/8" (0.5 x 22mm) Hydrodissection Cannula	Orange	M3900, M3900-02/10, M3900-02/100, 3900-02/Y, 3900-03NSP/Y	
	M3901	25g x 7/8" (0.5 x 22mm) Hydrodissection Cannula 'J' Shaped (Flat Tip)	Orange	M3901-02/10, M3901-02/100	
	M3902	27g x 7/8" (0.4 x 22mm) Hydrodissection Cannula	Grey	M3902-02/10, M3902-02/100, 3902-02/Y, 3902-03NSP/Y	
	M3904	27g x 3/4" (0.4 x 19mm) Hydrodissection Cannula (Chang)	Grey	M3904, M3904-02/10, M3904-02/100, 3904-02/Y	
	M3906A	25g x 7/8" (0.5 x 22mm) Hydrodissection Cannula 'J' Shaped	Orange	M3906A-02/10, M3906A-02/100, 3906A-02/Y, 3906A-03NSP/Y	
	M3908	25g x 7/8" (0.5 x 22mm) Cortical Cleaving Hydrodissection Cannula	Orange	M3908-02/10, 3908-02/Y, 3908-03NSP/Y	
	M3911	27g x 7/8" (0.4 x 22mm) Cortical Cleaving Hydrodissection Cannula	Grey	M3911-02/10, M3911-02/100, 3911-02/Y, 3911-03NSP/Y	
	M3911A	27g x 7/8" (0.4 x 22mm) Cortical Cleaving Hydrodissection Cannula	Grey	M3911A-02/10, M3911A-02/100, 3911A-03NSP/Y	
	M3912	23g x 7/8" (0.64 x 22mm) MacKool Hydrodissection Cannula	Blue	M3912-02/10, M3912-02/100, 3912-03NSP/Y	
	M3916	25g x 7/8" (0.5 x 22mm) Femtosecond Hydrodissector	Orange	M3916-02/10, M3916-02/100, 3916-02/Y, 3916-03NSP/Y	
M3919	27g x 7/8" (0.4 x 22mm) Hydrodissector (Akahoshi)	Grey	M3919-02/10, M3919-02/100, 3919-02/Y, 3919-03NSP/Y		
M3920	27g x 7/8" (0.4 x 22mm) Frankfurt Hydrodissection Cannula	Grey	3920NS-02/Y		
M3992	30g x 7/8" (0.3 x 22mm) Hydrodissection Cannula	Yellow	M3992-02/10, M3992-02/100, 3992-02/Y, 3992-03NSP/Y		
Hydrolineation Cannulae	M3907	25g x 7/8" (0.5 x 22mm) Hydrodelineation Cannula (Tapered)	Orange	M3907-02/10, 3907-03NSP/Y	

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	M3921	25g x 7/8" (0.5 x 22mm) Hydrodelineation Cannula (Tapered)	Orange	M3921-02/10, 3921-03NSP/Y
Viscoexpression Cannulae	M3899	25g x 7/8" (0.5 x 22mm) Viscoexpression Cannula (Flat Tip)	Orange	M3899-02/10, M3899-02/100
	M3899A	25g x 7/8" (0.5 x 22mm) Viscoexpression Cannula (Round Tip)	Orange	M3899A-02/10, M3899A-02/100, 3899A-02/Y, 3899A-03NSP/Y
	M3899B	27g x 7/8" (0.4 x 22mm) Viscoexpression Cannula (Round Tip)	Grey	M3899B-02/10, M3899B-02/100

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
-02SP/Y	Sterile, packed in Smaller Blister, in a protector, in bulk
-02SP/100	Sterile, packed in Smaller Blister, in a protector, Box of 100