

# Sterimedix Ltd

Quality System Document QD 2125 Issue B  
Technical Data Sheet Template

15/10/2019 -Issue 1

## Technical Data Sheet- TDS16 (Intradermal Cannulae & Needles)

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

### 1. GENERAL INFORMATION

#### 1.1 Intended Use

Subcutaneous administration of dermal filler.

#### 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
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

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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.
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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

1.10 Classification

Class IIa in accordance with Annex IX Rule 6

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### 1.11 GMDN Code

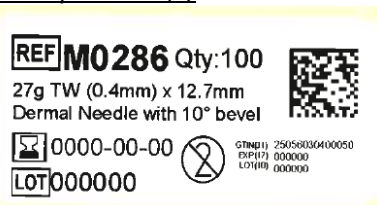
- GMDN code for Intradermal Needles is 59230
- GMDN code for below sub-groups is 46676

*Intradermal Cannulae*

*Intradermal Cannulae and*

## 2. LABELLING

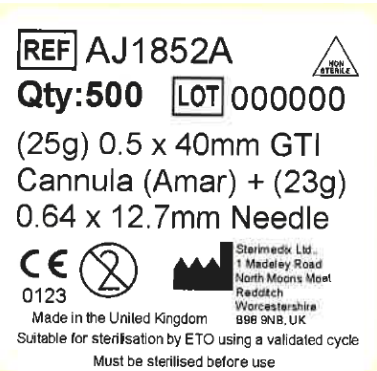
### 2.1 Example Label(s)



LBL0008 – Sterile boxes of 100



LBL0020 – Sterile bulk 02/Y



LBL0012 – Non-Sterile bulk

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**REF** AE1702 **Qty:100**  
18g (1.25mm) x 70mm  
Silkann Aesthetic Cannula (Fat Transfer)


**LOT** 000000  GTIN(EI) 15056030402538  
EXP(YY) 000000  
LOT(YY) 000000


 0000-00-00

 Not compatible with Juvederm syringes

LBL0022 – AE product bulk


**REF** AJ1832A **Qty:100**  
22g (0.7mm) x 60mm and 21g  
(0.81mm) x 16mm Needle  
Silkann Aesthetic Cannula (FT)  
& Sharp Needle

**LOT** 000000  GTIN(EI) 25056030402672  
EXP(YY) 000000  
LOT(YY) 000000

 0000-00-00

LBL0031 – AJ product bulk

**REF** AE1702 **Qty:40**  
18g (1.25mm) x 70mm  
Silkann Aesthetic Cannula (Fat Transfer)

 Not compatible with Juvederm syringes

**LOT** 000000  GTIN(EI) 25056030402635  
EXP(YY) 000000  
LOT(YY) 000000

 0000-00-00

LBL0053 – AE product boxed

**REF** AJ1832A **Qty:25**  
22g (0.7mm) x 60mm and 21g (0.81mm) x 16mm  
Needle  
Silkann Aesthetic Cannula (FT) & Sharp Needle

**LOT** 000000  GTIN(EI) 15056030402675  
EXP(YY) 000000  
LOT(YY) 000000

 0000-00-00

LBL0060 – AJ Product boxed

### 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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## Technical Data Sheet- TDS16 (Intradermal Cannulae & Needles)

### Appendix 1- Product specific information

PRODUCT SUB-GROUP	PRODUCT CODE	LABEL DESCRIPTION	HUB COLOUR	ORDERING REFERENCE	MATERIALS
Intradermal Needles	M0286	27g TW (0.4mm) x 12.7mm Dermal Needle with 10° bevel	Grey	M0286-02/100, 0286-02/Y, 0286-02F/Y	Polypropylene, Stainless Steel Grade 304, Single Part Epoxy Adhesive, Silicone Oil Needle Coating
	M0287	30g TW (0.3mm) x 12.7mm Dermal Needle with 10° bevel	Yellow	M0287-02/100, 0287-02/Y, 0287-02F/Y	
	M0288	29g TW (0.34mm) x 12.7mm Dermal Needle with 10° bevel	Red	M0288-02/100, 0288-02F/Y	
	M0289A	30g TW (0.3mm) x 4mm Dermal Needle with 13° bevel	Yellow	M0289A-02/100, 0289A-02F/Y	
	M0290	25g TW x 1/2" (0.5 x 12.7mm) Dermal Needle with 10° bevel	Orange	0290-02F/Y	
	M0293	27g TW (0.4mm) x 19mm Dermal Needle with 10° bevel	Grey	M0293-02/100, 0293-02/Y	
Intradermal Cannulae	AE1702	18g (1.25mm) x 70mm Silkann Aesthetic Cannula (Fat Transfer)	Pink	AE1702-02/40	Polycarbonate, Stainless Steel Grade 304, Single Part Epoxy Adhesive
	AE1711	20g (0.9mm) x 60mm Silkann Aesthetic Cannula (Fat Transfer)	Yellow	AE1711-02/40	
	AJ1701	18g (1.25mm) x 70mm Silkann Aesthetic Cannula Fine Thread	Pink	AJ1701-02/40, AJ1701-02/Y	Polycarbonate, Stainless Steel Grade 304, UV Adhesive
Intradermal Cannulae and Needles	AJ1500	18g (1.25mm) x 80mm and 19g (1.1mm) x 25mm Needle Silkann Cannula & Sharp Needle	Pink	AJ1500-02/Y	Polycarbonate, Polypropylene, Stainless Steel Grade 304, UV Adhesive, Single Part Epoxy Adhesive, Silicone Oil Needle Coating
	AJ1561A	27g x 40mm Cannula + 25g x 12.7mm Needle Silkann Aesthetic Cannula and Sharp Needle	Grey	AJ1561A-02/Y	
	AJ1831A	22g (0.7mm) x 70mm and 21g (0.81mm) x 16mm Needle Silkann Aesthetic Cannula (FT) & Sharp Needle	Black	AJ1831A-02/25, AJ1831A-02/Y	
	AJ1832A	22g (0.7mm) x 60mm and 21g (0.81mm) x 16mm Needle Silkann Aesthetic Cannula (FT) & Sharp Needle	Black	AJ1832A-02/25	
	AJ1833A	22g (0.7mm) x 50mm and 21g (0.81mm) x 16mm Needle Silkann Aesthetic Cannula (FT) & Sharp Needle	Black	AJ1833A-02/25, AJ1833A-02/Y	
	AJ1840A	23g (0.64mm) x 70mm and 21g (0.81mm) x 16mm Needle Silkann Aesthetic Cannula (FT) & Sharp Needle	Blue	AJ1840A-02/25	
	AJ1842A	23g (0.64mm) x 50mm and 21g (0.81mm) x 16mm Needle Silkann Aesthetic Cannula (FT) & Sharp Needle	Blue	AJ1842A-02/25	

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AJ1850A	25g (0.5mm) x 50mm and 23g (0.64mm) x 12.7mm Needle Silkann Aesthetic Cannula (FT) & Sharp Needle	Orange	AJ1850A-02/25
AJ1851A	25g (0.5mm) x 40mm and 23g (0.64mm) x 12.7mm Needle Silkann Aesthetic Cannula (FT) & Sharp Needle	Orange	AJ1851A-02/40, AJ1851A-02/Y
AJ1852A	(25g) 0.5 x 40mm GTI Cannula (Amar) + (23g) 0.64 x 12.7mm Needle	Orange	AJ1852A-02/10, AJ1852A-02/40, AJ1852ANS-02/Y
AJ1861A	27g (0.4mm) x 40mm and 25g (0.5mm) x 12.7mm Needle Silkann Aesthetic Cannula (FT) & Sharp Needle	Grey	AJ1861A-02/40, AJ1861A-02/Y
AJ1863A	27g (0.4mm) x 37mm and 25g (0.5mm) x 12.7mm Needle Silkann Aesthetic Cannula (FT) & Sharp Needle	Grey	AJ1863A-02/40, AJ1863A-02/Y
AJ1870A	30g (0.3mm) x 30mm and 27g (0.4mm) x 12.7mm Needle Silkann Aesthetic Cannula (FT) & Sharp Needle	Yellow	AJ1870A-02/40, AJ1870A-02/Y

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
-02F/Y	Sterile, in Bulk