Digitally signed by Dolgopol Iulian
Date: 2024.06.03 14:24:58 EEST
Reason: MoldSign Signature
Location: Moldova

Manufacturer's Declaration

In relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	TI Medical Private Limited
Manufacturer address and contact details	Khasra No. 1051/1&2, Twin Industrial Estate, Selaqui, Dehradun 248197, Uttarakhand, INDIA
Single Registration Number (SRN)	IN- MF-00026561
Authorised Representative name (if applicable)	OBELIS S.A.
Authorised Representative address and contact details	Bd. Général Wahis, 53 1030 Brussels, Belgium Tel: +32.2.732.59.54 Fax: +32.2.732.60.03 E-mail: mail@obelis.net Web:www.obelis.net
Notified body name (if applicable)	SZUTEST Konformitätsbewertungsstelle GmbH
Notified body number (if applicable)	2975
Directive Certificate number(s) to which this confirmation is made (if applicable)	MD0012-CL-01
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	26.05.2024
End date of extended validity/transition period	31 December 2027 for class III Devices 31 December 2028 for class IIb Devices

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[2]
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service, namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above or in the attached schedule
- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

Factory Address:
TI Medical Private Limited
(Formerly known as Lotus Surgicals Pvt. Ltd.)
Khasra No. 1051/1&2, Twin Industrial Estate, Selaqui, Dehradun 248197, Uttarakhand, INDIA
Tel. No.: +91 135 2698661/709 | Email: info@lotus-surgicals.com | Website: www.lotus-surgicals.com | CIN: U33110MH2005PTC156940

Choose applicable statements:

☐ Expired *before* 20 March 2023:
☑ Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or
☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or
☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:

☑ Formal application(s) to the notified body in accordance with Section 4.3, first sub para- graph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, there- fore the transition period will end on 26 May 2024.

[2] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

☐ Expired/expires after 20 March 2023:

Choose one applicable statement:

☑ Formal application(s) to the notified body in accordance with Section 4.3, first subpara- graph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, there- fore the transition period will end on 26 May 2024.

➢ **Unclassified devices**
In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Factory Address:
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Khasra No. 1051/1&2, Twin Industrial Estate, Selaqui, Dehradun 248197, Uttarakhand, INDIA
Tel. No.: +91 135 2698661/709 | Email: info@lotus-surgicals.com | Website: www.lotus-surgicals.com | CIN: U33110MH2005PTC156940

Choose one applicable statement:

- ☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitutes and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Quality Management System (QMS)**

Choose one applicable statement:

- ☐ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.
- ☑ A QMS in accordance with Article 10(9) MDR is in place.
- ☐ A notified body has issued the attached certificate for the MDR-compliant QMS.

➢ **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the MDD 93/42/EEC.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

For TI Medical Pvt Ltd

TI MEDICAL PRIVATE LIMITED ★ DEHRADUN ★

LOTUS® because life is precious A Brand of TI Medical

Dr. Anup Kumar Mamgain
Sr. General Manager
Quality, Regulatory and Design & Development
Email: anoop.mamgain@timedical.murugappa.com

Factory Address:
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Tel. No.: +91 135 2698661/709 | Email: info@lotus-surgicals.com | Website: www.lotus-surgicals.com | CIN: U33110MH2005PTC156940

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
Braided Coated Polyglycolic Acid Suture	MD0012-CL-01	26.05.2024	SZUTEST Konformitätsbewertungsstelle GmbH 2975	SZUTEST Konformitätsbewertungsstelle GmbH 2975	31 December 2027	
Braided Coated Polyglactin 910 Suture Braided Coated Short Term Polyglactin 910 Suture	MD0012-CL-01	26.05.2024	SZUTEST Konformitätsbewertungsstelle GmbH 2975	SZUTEST Konformitätsbewertungsstelle GmbH 2975	31 December 2027	
Monofilament Poly(p-dioxanone) Suture	MD0012-CL-01	26.05.2024	SZUTEST Konformitätsbewertungsstelle GmbH 2975	SZUTEST Konformitätsbewertungsstelle GmbH 2975	31 December 2027	
Monofilament Polydioxanone Barbed Suture	MD0012-CL-01	26.05.2024	SZUTEST Konformitätsbewertungsstelle GmbH 2975	SZUTEST Konformitätsbewertungsstelle GmbH 2975	31 December 2027	
Monofilament Poly (glycolide Co-Caprolactone) Suture	MD0012-CL-01	26.05.2024	SZUTEST Konformitätsbewertungsstelle GmbH 2975	SZUTEST Konformitätsbewertungsstelle GmbH 2975	31 December 2027	
Braided Coated Silk Suture	MD0012-CL-01	26.05.2024	SZUTEST Konformitätsbewertungsstelle GmbH 2975	SZUTEST Konformitätsbewertungsstelle GmbH 2975	31 December 2027	
Monofilament Polyamide Suture	MD0012-CL-01	26.05.2024	SZUTEST Konformitätsbewertungsstelle GmbH 2975	SZUTEST Konformitätsbewertungsstelle GmbH 2975	31 December 2027	
Monofilament Polypropylene suture	MD0012-CL-01	26.05.2024	SZUTEST Konformitätsbewertungsstelle GmbH 2975	SZUTEST Konformitätsbewertungsstelle GmbH 2975	31 December 2027	
Braided Coated Polyester Suture	MD0012-CL-01	26.05.2024	SZUTEST Konformitätsbewertungsstelle GmbH 2975	SZUTEST Konformitätsbewertungsstelle GmbH 2975	31 December 2027	
Monofilament Stainless Steel 316 L	MD0012-CL-01	26.05.2024	SZUTEST Konformitätsbewertungsstelle GmbH 2975	SZUTEST Konformitätsbewertungsstelle GmbH 2975	31 December 2027	
Poly (Giycolide co-caprolactone) and Polypropylene Mesh	MD0012-CL-01	26.05.2024	SZUTEST Konformitätsbewertungsstelle GmbH 2975	SZUTEST Konformitätsbewertungsstelle GmbH 2975	31 December 2027	
Monofilament polypropylene Mesh	MD0012-CL-01	26.05.2024	SZUTEST Konformitätsbewertungsstelle GmbH 2975	SZUTEST Konformitätsbewertungsstelle GmbH 2975	31 December 2027	

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Tel. No.: +91 135 2698661/709 | Email: info@lotus-surgicals.com | Website: www.lotus-surgicals.com | CIN: U33110MH2005PTC156940

SZUTEST

EC CERTIFICATE

According to Annex II of the Directive 93/42/EEC on Medical Devices

Full Quality Assurance System

Certificate Number: 2195-MED-381435801

Manufacturer: **LOTUS SURGICALS Pvt. Ltd.**
Khasra No. 1051 / 1&2, Twin Industrial Estate, Selaqui, Dehradun – 248197, Uttarakhand, INDIA

Product(s):
(1) Sterile Non Absorbable Monofilament Stainless Steel Surgical Sutures
(2) Sterile Non Absorbable Mesh
(3) Sterile Absorbable and Non Absorbable Surgical Sutures
(4) Sterile Partially Absorbable Surgical Mesh

Model(s): Product specifications are stated on the second page.

Reference Report No: MM0327-P004-R01, MM0327-P004-R02

Szutest, Notified Body 2195, declares that the aforementioned manufacturer has implemented a quality assurance system according to Annex II (excluding section 4), Section 3 of the directive 93/42/EEC on medical devices. This quality assurance system covers those aspects of manufacturing concerned with securing and maintaining safe conditions of the respective product(s) and conforms to the provisions of this Directive. The approved quality system is subject to surveillance pursuant to Annex II, Section 5 of Directive 93/42/EEC and unannounced audits.

Szutest must be informed of any significant changes in the design and/or construction of the product(s).

This EC certificate is valid till 2024-05-26.

SZUTEST UYGUNLUK DEĞERLENDİRME A.Ş.

Issue Date: 2014-12-24
Revision No.: 03 Recertification
Revision Date: 2019-06-20

Rukiye BALKAN
Deputy General Manager

This electronic certificate has been issued on 23.03.2017 24_2195-MED-381435801 Rev.03

SZUTEST UYGUNLUK DEĞERLENDİRME A.Ş.
Tatlısu Mahallesi, Akif İnan Sk. No:1 Ümraniye 34774 İSTANBUL / TÜRKİYE
Szutest.com.tr

SZUTEST

Certificate Number: 2195-MED-381435801

Product Specifications

Product Categories	Type (Models)	Generic Name
Sterile Non- Absorbable Monofilament Stainless Steel Surgical Sutures	Stelus ®	Monofilament stainless steel 316 L
Sterile Non Absorbable Surgical Mesh	Prolus ® Mesh	Polypropylene Mesh
	Prolus ® Lite Mesh	Polypropylene Mesh
	Prolus ® Ultra Lite Mesh	Polypropylene Mesh
	Pro-Visc ®	Polyester and Polyurethane Composite Mesh
	Pro-Visc ® 3D	Polyester and Polyurethane Composite Mesh
Sterile Absorbable Surgical Sutures	Solus ®	Braided Coated Polyglycolic Acid
	Solus Swift ®	Braided Coated Short Term Polyglycolic Acid
	Solus 910 ®	Braided Coated Poly (Glycolide-Co-L-Lactide) / Polyglactin - 910
	Solus Swift 910 ®	Braided Coated Short Term Poly (Glycolide-Co-L-Lactide) / Polyglactin - 910
	Monolus ®	Monofilament Poly (Glycolide Co-Caprolactone)
	Mass ®	Monofilament Poly (p-dioxanone)
	Barb-E ®	Monofilament Poly (p-dioxanone)
Sterile Non Absorbable Surgical Sutures	Esterlus ®	Braided Coated Polyester
	Silkus ®	Braided Coated Silk
	Prolus ®	Monofilament Polypropylene
	Nylus ®	Monofilament Polyamide
Sterile Partially Absorbable Surgical Mesh	Pro- AB ®	Poly (Glycolide Co-Caprolactone) and Polypropylene Mesh

This version of certificate has come into force on 23.03.2017. 2/2. 2195-MED-381435801 Rev.02

SZUTEST UYGUNLUK DEĞERLENDİRME A.Ş.
Tatlısu Mahallesi, Akif İnan Sk. No:1 Ümraniye 34774 İSTANBUL / TÜRKİYE
Szutest.com.tr

TI MEDICAL | murugappa

LOTUS® because life is precious
A Brand of TI MEDICAL

DECLARATION OF CONFORMITY

We,
TI Medical Private Limited
Khasra No. 1051/1&2,
Twin Industrial Estate, Selaqui,
Dehradun — 248197 Uttarakhand, India

Declare under our sole responsibility that the product names described in the list attached meet the provision of the Council Directive 93/42/EEC for medical devices.
All supporting documentation is retained under premises of the manufacturer.

Classification	:	MDD 93/42/EEC *III (Annex II & IV Rule 8)*
Conformity Assessment Route	:	Annex II of directive 93/42/EEC amended by MDD/2007/47/EEC
Notified Body/ NB Identification Number	:	SZUTEST, Turkey (2195)
CE Certificate Number	:	2195-MED-381435801
CE Certificate valid until	:	31.12.2027
EC Representative	:	Obelis S.A Bd. Général Wahis 53, B-1030 Brussels, Belgium Tel: +(32) 2. 732.59.54 Fax: +(32) 2.732.60.03 E-Mail : mail@obelis.net
ISO Certification Body	:	SZUTEST, Turkey
ISO Certificate Number	:	31917101
ISO Certificate valid until		16.06.2025
Product Details	:	As per Annexure-1

Applicable and Harmonized standards :

MDD 93/42/EEC, ISO 9001: 2015, EN ISO 13485: 2016, EN ISO 14971:2019, ISO 11135:2014/Amd1 :2018, EN ISO 10993-1:2018, EN ISO 10993-2:2022, EN ISO 10993-3:2014, EN ISO 10993-5:2009, EN ISO 10993-6:2016, EN ISO 10993-7:2008/ AC:2019, EN ISO 10993-9:2019, EN ISO 10993-10:2021, EN ISO 10993-11-2017, EN ISO 10993-12:2021, EN ISO 14644-1:2015, ISO 14644-2:2015, ISO 14644-3-2019, ISO 14644-4:2022, EN ISO-14644-5:2004, EN ISO 11607-1:2019 , EN ISO 11607-2:2019, EN ISO 11138-1:2017, EN ISO 11138-2:2017, EN ISO 14155 :2020, EN ISO 11737:1:2018, EN ISO 11737-2:2019, MEDDEV 2.7/1, Rev. 04, June 2016, MEDDEV 2.12-1, Rev.08, Jan 2013, IEC 62366-1:2015/ Amd 1:2020, EN ISO 10993-13:2010, EN ISO 10993-14:2001, EN ISO 10993-16:2017, EN ISO 10993-17:2002, EN ISO 10993-18:2020, EN ISO 11135-1:2014, EN ISO 15223-1:2021, EN ISO 20417:2021.

Name and position | **Date/place**

General Manager
(Quality, Regulatory and Design & Development)

Date: 29.05.2024
Dehradun, Uttarakhand

Annexure-1: Product Details

Product Name		Generic Name	Brand Name	MD Class	Rule	GMDN Code
Surgical Sutures	**Non-Absorbable surgical sutures**	Braided coated polyester	Esterlus	III	8	13906

Factory Address:
TI Medical Private Limited
(Formerly known as Lotus Surgicals Pvt. Ltd.)
Khasra No. 1051/1&2, Twin Industrial Estate, Selaqui, Distt. Dehradun, 248197 (Uttarakhand), INDIA.
Tel. No.: +91 135 2698661 | Email: info@lotus-surgicals.com | Website: www.lotus-surgicals.com | CIN: U33110MH2005PTC15694

SZUTEST

CERTIFICATE

Medical Devices Quality Management System

CERTIFICATE NO: 31917101

TI Medical Private Limited

Khasra No. 1051 / 1&2, Twin Industrial Estate, Selaqui, Dehradun 248197, Uttarakhand, INDIA

EN ISO 13485:2016

Design & Development, Manufacture and Supply of Absorbable & Non-Absorbable Surgical Suture, Non-Absorbable & Partially Absorbable Surgical Mesh and Absorbable Hemostate. Production & Distribution of Staplers (Skin & Endoscopic), Clips and Laparoscopic Instruments

Approves that the Medical Devices Quality Management System implemented for above scope.

First Issue Date	20.06.2019
Issue Date	17.06.2022
Expiry Date	16.06.2025
Revision Date/No	28.12.2023 / 2

TÜRKAK BDS NO
YS-2865-5FD8

TÜRKAK
Tıbbi Cihazlar K. Y. S.
TS EN ISO/IEC 17021-1
AB-0044-YS

Deputy General Manager

The certificate inquiry is made by reading the QR codes by mobile devices, providing necessary information on http://public.szutest.com.tr or by using BDS No on https://tdbs.turkak.org.tr.


LS 4845
ESTERLUS™
75 CM POLYESTER
5
12
LOTUS
ESTERLUS™
FOLD BACK
LS 4845
ESTERLUS™
75 CM POLYESTER
LOTUS

Esterlus®

Braided Coated Polyester

Product Details:

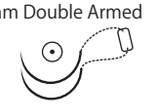
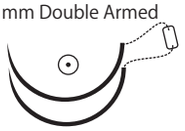
Composition	Polyester
Construction	Braided
Coating	Coated with Silicon to provide for smoother and better handling
In vitro retention of strength	Esterlus® sutures are not subject to degradation or loss of tensile strength
Tissue Reaction	Esterlus® sutures elicit only a mild tissue reaction
Absorption Time	Non-absorbable
Sterilization	100% Ethylene Oxide
Available in Sizes	5-0, 4-0, 3-0, 2-0, 0, 1, 2, 3, 4, 5
Colour	Green and White
Shelf Life	5 years
Packaging	Box of 6 and 12 sutures

Distinctive Features:

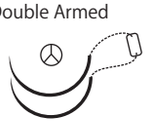
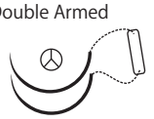
- Coated with silicon which helps in easy passage through the tissue with minimal trauma.
- Excellent strength & handling properties.
- Dyed for good visibility in the surgical arena.
- Flexible, elongates to support for optimum knotting.
- Smooth tie-down properties.

ESTERLUS® - Non-Absorbable Sutures
Braided Coated Polyester

TAPER POINT

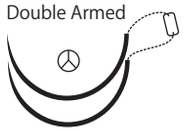
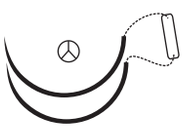
Needle Length	Needle Profile	Suture Length	Suture Size						
			6-0	5-0	4-0	3-0	2-0	0	1
13 mm Double Armed 	⅜ Circle	75 cm Green		LS 6890	LS 6891				
13 mm Double Armed 	½ Circle	45 cm Green			LS 6892 XS				
		75 cm White			LS 6893				
13 mm Double Armed  Pledget 3mm x 3mm x 1.5mm	½ Circle	75 cm Green			LS 6892-PL-3				
		75 cm White			LS 6893-PL-3				
20 mm Double Armed 	½ Circle	75 cm Green				LS 6949	LS 6874		
25 mm Double Armed  Pledget 3mm x 3mm x 1.5mm	½ Circle	90 cm					LS 6226-PL-3		
26 mm Double Armed 	½ Circle	75 cm Green				LS 6832			
		100 cm Green				LS 6552			

TAPER CUT

Needle Length	Needle Profile	Suture Length	Suture Size						
			6-0	5-0	4-0	3-0	2-0	0	1
17.5 mm Double Armed 	½ Circle	75 cm 5 Green & 5 White					LS 10B52		
		90 cm Green			LS 6935	LS 6936	LS 6937		
		90 cm White					LS 6917		
17.5 mm Double Armed  Pledget 3mm x 3mm x 1.5mm	½ Circle	75 cm 5 Green & 5 White					LS 10B55-PL-3		
		90 cm Green				LS 6936-PL-3	LS 6937-PL-3		
		90 cm White					LS 6917-PL-3		
17.5 mm Double Armed  Pledget 6mm x 3mm x 1.5mm	½ Circle	75 cm 5 Green & 5 White					LS 10B55		
		90 cm Green					LS 6937-PL-6		
		90 cm White					LS 6917-PL-6		
		90 cm 4 Green					LS 4B37		

ESTERLUS® - Non-Absorbable Sutures
Braided Coated Polyester

TAPER CUT

Needle Length	Needle Profile	Suture Length	Suture Size							
			3-0	2-0	0	1	2	3	4	5
26 mm Double Armed 	½ Circle	75 cm 5 Green & 5 White		LS 10B72						
		90 cm Green		LS 6977						
		90 cm White		LS 6987						
26 mm Double Armed  Pledget 3mm x 3mm x 1.5mm	½ Circle	75 cm 5 Green & 5 White		LS 10B77-PL-3						
		90 cm Green		LS 6977 PL-3						
		90 cm White		LS 6987-PL-3						
26 mm Double Armed  Pledget 6mm x 3mm x 1.5mm	½ Circle	75 cm 5 Green & 5 White		LS 10B77						
		90 cm Green		LS 6977-PL-6						
		90 cm White		LS 6987-PL-6						
		90 cm 4 Green		LS 4B77						
45 mm HEAVY 	½ Circle	75 cm 1 Green per foil					LS 4842			
		75 cm 4 Green per foil (multi-strand)					LS 4843			
55 mm HEAVY 	½ Circle	75 cm 1 Green per foil								LS 4845
		75 cm 4 Green per foil (multi-strand)								LS 4846

REVERSE CUTTING

Needle Length	Needle Profile	Suture Length	Suture Size						
			4-0	3-0	2-0	0	1	2	3
23 mm 	½ Circle	75 cm Green				LS 6517	LS 6942		
40 mm 	½ Circle	75 cm Green					LS 6941		

LOTUS
because life is precious

Stelus®

Monofilament 316 L Stainless Steel

Product Details:

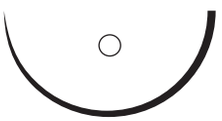
Composition	316 L Stainless Steel
Construction	Monofilament
Coating	None
In vitro retention of strength	Stelus® is not subject to any degradation or loss of tensile strength
Tissue Reaction	Stelus® sutures show very low tissue reactivity
Absorption Time	Non-absorbable
Sterilization	100% Ethylene Oxide
Available in Sizes	1, 2, 4, 5, 6, 7
Colour	Metallic Silver
Shelf Life	5 years
Packaging	Box of 12 x 6 = 72 sutures Box of 12 x 4 = 48 sutures Box of 12 x 2 = 24 sutures Box of 12 x 1 = 12 sutures

Distinctive Features:

- Stelus® sutures are laser welded.

STELUS® - Non-Absorbable Sutures
Monofilament 316 L Stainless Steel

BLUNT POINT

Needle Length	Needle Profile	Suture Length	Suture Size						
			0	1	2	3	4	5	6
40 mm 	½ Circle	45 cm (4 x 45 cm)		LS 661	LS 662				
45 mm 	½ Circle	45 cm (4 x 45 cm)					LS 664	LS 651	LS 649
		75 cm (2 x 75 cm)						LS 643	LS 645
		75 cm (6 x 75 cm)							LS 756 VS

TAPER CUT

Needle Length	Needle Profile	Suture Length	Suture Size						
			0	1	2	3	4	5	6
40 mm 	½ Circle	45 cm (4 x 45 cm)		LS 660	LS 650				

CONVENTIONAL CUTTING

Needle Length	Needle Profile	Suture Length	Suture Size							
			0	1	2	3	4	5	6	7
40 mm 	½ Circle	45 cm			LS 659					
48 mm 	½ Circle	45 cm (4 x 45 cm)					LS 652	LS 653	LS 654	LS 654-T
		45 cm (6 x 45 cm)							LS 654-6	
		75 cm (2 x 75 cm)						LS 646	LS 644	
57 mm HEAVY 	⅜ Circle	75 cm (2 x 75 cm)						LS 647		

TI Medical Private Limited

(Formerly known as Lotus Surgicals Pvt. Ltd.)

Khasra No. 1051/1&2, Twin Industrial Estate, Selaqui,
Dehradun 248197, Uttarakhand, INDIA.

LOTUS® because life is precious
A Brand of **TI MEDICAL**

FRONT

INSTRUCTIONS FOR USE

BRAIDED COATED POLYESTER

Brand Name-ESTERLUS®

DESCRIPTION:
ESTERLUS® suture meets requirements established by the United States Pharmacopoeia (U.S.P.) non-absorbable surgical suture.

ESTERLUS® Polyester is a non absorbable, sterile, surgical suture, composed of fine filaments of Polyester and Poly Ethylene. The fine polyester fibers are braided to produce firm suture that remains soft and pliable. Polyester meets all the requirements, established by the United States Pharmacopeia for Non absorbable Surgical suture.

PERFORMANCE:
ESTERLUS® sutures elicit a minimal initial inflammatory tissue reaction followed by gradual encapsulation of the suture by fibrous connective tissue. There is no meaningful decline in polyester suture strength over time.

INTENDED USERS:
Trained and registered healthcare professional only.

INDICATIONS:
ESTERLUS® suture is indicated for use in general soft tissue approximation and/or ligation including use in cardiovascular surgery.

INTENDED PATIENT POPULATION:
ESTERLUS® suture can be used in patients irrespective of age and gender, inline with intended use, indication and contraindication.

APPLICATION:
Sutures should be selected and implanted depending on patient condition, surgical experience, surgical technique and wound size.

CONTRAINDICATIONS:
None known.

WARNINGS/ PRECAUTIONS/INTERACTIONS:
Before employing ESTERLUS ® sutures for wound closure, users should be familiar with surgical procedures and techniques involving non absorbable sutures, as risk of wound dehiscence may vary with the site of application and the suture material used. As with any foreign body, prolonged contact of any suture with salt solutions, such as those found in the urinary or biliary tracts may result in calculus formation.

Acceptable surgical practice should be followed for the management of contaminated or infected wounds.

In handling this or any other suture material, care should be taken to avoid damage from handling. Avoid crushing or crimping damage due to application of surgical instruments such as forceps or needle holders.

Care should be taken to avoid damage when handling surgical needles. Grasp the needle in an area one third (1/3) to one half (1/2) of the distance from the attachment end to the point. Grasping in the point area could impair the penetration performance and cause fracture of the needle. Grasping at the butt or attachment end could cause bending or breakage. Reshaping needles may cause them to lose strength and be less resistant to bending and breaking Users should exercise caution when handling surgical needles to avoid inadvertent needle stick injury. Discard used needles in 'Sharps' containers.

ADVERSE REACTIONS:
Adverse reaction associated with the use of ESTERLUS® may include minimal initial inflammatory tissue reaction and transient local irritation at the wound site. As with all foreign bodies, Polyester sutures may aggravate an existing infection.

SUPPLY:
Polyester suture is available in U.S.P. sizes and EP Metric sizes. The suture is supplied sterile in pre-cut length and attached to various needle type, shape and length. 12 unit, 24 unit & 36 unit packs are packed in a printed box. As per requirement such boxes are packed in a master carton.

STERILITY:
ESTERLUS® suture are sterilized by Ethylene Oxide Gas. Do not re-sterilize. Do not use, if package is opened or damaged. Discard opened unused sutures as well as damaged primary packs.

USP Sizes(mm)	Metric Size (Gauge No.)	Needle Profile	Needle Curvatur
10-0	0.2	Taper Point (Round Body), Taper Cut, Cutting, Reverse Cutting, Blunt, Spatulated, Trocar Point, Diamond Point	1/2 Circle
9-0	0.3		
8-0	0.4		1/4 Circle
7-0	0.5		
6-0	0.7		3/8 Circle
5-0	1		
4-0	1.5		
3-0	2		5/8 Circle
2-0	3		
1-0	3.5		
1	4		Straight
2	5		
3&4	6		
5	7		

STORAGE :
Recommended storage conditions: Store below 26°C, away from moisture and direct heat. Do not use after expiry date.

DISPOSAL:
Discard used sutures and needles contaminated with blood in the container meant for "infectiouswaste". Unused expired pouches should be incinerated.

EC REP Obelis s.a Bd. Général Wahis 53 B-1030 Brussels, BELGIUM Tel: +(32) 2. 732.59.54 Fax: +(32) 2.732.60.03 E-Mail : mail@obelis.net

CE 2195

Doc. No.: TIMPL/IFU/12 **Issue No.: 02** **Revision No.: 00** **Revision Date: 11.01.2024**

SYMBOLS USED ON LABELING:-

- MD — Medical Device
- CE 2195 — CE Logo with Notified Body Number
- Do not re-use
- Keep away from sunlight
- Manufactured by
- LOT — Lot Number
- Date of Manufacture(MM/YYYY)
- Use by(MM/YYYY)
- STERILE EO — Sterilized using Ethylene Oxide
- Caution, consult accompanying documents
- EC REP — Authorized Representative in the European Community
- Temperature Limitation (store below 26°C)
- Do not resterilize
- Do not use if package is damaged
- Consult Instructions for use
- Keep Dry

BACK

General Instructions for opening and handling of Lotus packages are mentioned below:

(I) Recommended technique for opening and handling Peelable Aluminum foil Pack

a) Hold pack in your hand. Grasp the upper foil flap in your right hand and lower foil flap in your left hand. Roll thumbs outward separating the flaps and exposing sterile card.

b) Project the sterile card on the sterile table only after peeling apart the peelable foil completely. For paper / tyvek packing follow step (II)

c) Hold the card in the gloved left hand securely without bending it as shown in the figure.

d) Arm the needle with an appropriate needle holder using the no-touch technique.

e) Remove the needled suture with a smooth and moderate pull in a direction parallel to the card. If resistance is observed while removing. then relax the suture and pull again. Please do not pull against the swaged end of the suture.

(II) Recommended technique for opening and handling Primary foil Paper / Tyvek Pack

a) Hold the foil in left hand, grasp foil flap between thumb and index-finger of right hand, thus exposing poly film.

b) Grasp transparent poly film with thumb and index-finger of left hand, gripping pack between knuckles.

c) Roll thumbs outward separating the flaps and exposing sterile primary foil paper/tyvek. Keep constant pressure between knuckles for best control.

d) Remove the needled suture with a smooth and moderate pull in a direction parallel to the card. If resistance is observed while removing. then relax the suture and pull again. Please do not pull against the swaged end of the suture.

INSTRUCTIONS FOR USE

BRAIDED COATED POLYESTER

ESTERLUS®

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TI Medical Private Limited
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Selaqui, Dehradun 248197, Uttarakhand, INDIA
Customer Care Number (24x7): +91 135 2698661
www.lotus-surgicals.com info@lotus-surgicals.com

Mfg. Lic. No.: XXX/XX/XXXX/XXXXXX

SUPPLIER NAME:	"XYZ"	USE COLOR:
PRODUCT:	Instruction Leaflet for ESTERLUS	PANTONE RED PANTONE BLACK
DIMENSION:	220mm L x110mm W +/- 2mm	
WEIGHT(GSM):	60 +/- 5% GSM	
PREPARED BY:	VERIFIED BY:	APPROVED BY:
"DESIGNER"	"D&D EXECUTIVE"	"D&D HEAD"
OTHER REMARK:		ARTWORK DOC. NO. : TIMPL/IFU/12 REVISION NO.: 00