

Date: 4th June 2024**AUTHORIZATION LETTER****TO WHOM SO EVER IT MAY CONCERN**

We, TI Medical Private Limited (Formerly known as Lotus Surgicals Pvt Ltd) manufacturers of various medical surgical products having corporate office at 505-507, Suncity Business Tower, Sector-54, Golf Course Road, Gurugram, Haryana-122002 & manufacturing factory at 1051/1&2, Twin Industrial Estate, Selaqui, Dehradun, Uttarakhand 248197, India.

Do hereby assign SRL SANMEDICO having a registered office at A. Corobceanu Street 7A, apt. 9, Chişinău MD-2012, Moldova as authorized representative in correspondence with the conditions of directive 93/42/EEC.

We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

For TI Medical Private Limited


Dr. Mukesh Agrawal
Head-International Business & Strategy



Place: Gurugram
Date: 04-06-2024

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.

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



A handwritten signature in blue ink, appearing to read 'Rukiye BALKAN', is positioned above the name of the Deputy General Manager.

Rukiye BALKAN
Deputy General Manager

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

SZUTEST UYGUNLUK DEĞERLENDİRME A.Ş.

Tatlısu Mahallesi, Akif İnan Sk. No 1 Ümraniye 34774 İSTANBUL / TÜRKİYE

FR.MED.34 R.04

Szutest.com.tr

NOTIFIED BODY CONFIRMATION LETTER
No: MD0012-CL-01

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation (EU) 2023/607 amending Regulation (EU) 2017/745 as regards the transitional provisions for certain medical devices.

This letter confirms that **SZUTEST Konformitätsbewertungsstelle GmbH**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **2975** on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Company Name	TI Medical Private Limited
Address	Khasra No. 1051 / 1&2, Twin Industrial Estate, Selaqui, Dehradun 248197, Uttarakhand, INDIA
SRN Number (if available)	IN-MF-00026561

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded, and for which the SZUTEST Konformitätsbewertungsstelle GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but SZUTEST Konformitätsbewertungsstelle GmbH has not yet taken responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance with the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 31 December 2027 for Class III devices and Class IIb implantable devices excluding well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips, and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of SZUTEST Konformitätsbewertungsstelle GmbH,

MEHMET ISIKLAR
General Manager

SZUTEST
Konformitätsbewertungsstelle GmbH
Friedrich-Ebert-Anlage 36
60325 Frankfurt am Main
USt-IdNr.: DE15019575
info@szutest-germany.de

SZUTEST Konformitätsbewertungsstelle GmbH-NB 2975
Friedrich-Ebert-Anlage 36 D-60325 Frankfurt am Main /GERMANY



To check the validity of this confirmation letter please scan the barcode. To manually check, go to <https://public.szutest-germany.de/> use the first 3 digits of the manufacturer name and confirmation letter No. For further information please contact md_confirmation@szutest-germany.de

Table 1: Devices covered by this letter and for which SZUTEST Konformitätsbewertungsstelle GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (Under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A



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Table 2: Devices covered by this letter and for which SZUTEST Konformitätsbewertungsstelle GmbH is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (Under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Braided Coated Polyglycolic Acid Suture	Class III	Same	Certificate #1: 2195-MED-381435801 Rev No: 03 Revision Date:20.06.2019 Issue Date:24.12.2014 Expiry Date:26.05.2024 NB 2195 : Szutest Uygunluk Değerlendirme A.Ş. Certificate #2: 2195-MED-381435801-D01 Rev No: 03 Revision Date:20.06.2019 Issue Date:13.02.2015 Expiry Date:26.05.2024 NB 2195 : Szutest Uygunluk Değerlendirme A.Ş.
Braided Coated Polyglactin 910 Suture Braided Coated Short Term Polyglactin 910 Suture	Class III	Same	Certificate #1: 2195-MED-381435801 Rev No: 03 Revision Date:20.06.2019 Issue Date:24.12.2014 Expiry Date:26.05.2024 NB 2195 : Szutest Uygunluk Değerlendirme A.Ş. Certificate #2: 2195-MED-381435801-D01 Rev No: 03 Revision Date:20.06.2019 Issue Date:13.02.2015 Expiry Date:26.05.2024 NB 2195 : Szutest Uygunluk Değerlendirme A.Ş.
Monofilament Poly(p-dioxanone) Suture	Class III	Same	Certificate #1: 2195-MED-381435801 Rev No: 03 Revision Date:20.06.2019 Issue Date:24.12.2014 Expiry Date:26.05.2024 NB 2195 : Szutest Uygunluk Değerlendirme A.Ş. Certificate #2: 2195-MED-381435801-D01 Rev No: 03 Revision Date:20.06.2019 Issue Date:24.12.2014 Expiry Date:26.05.2024 NB 2195 : Szutest Uygunluk Değerlendirme A.Ş.



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Monofilament Polydioxanone Barbed Suture	Class III	Same	<p>Certificate #1: 2195-MED-381435801 Rev No: 03 Revision Date:20.06.2019 Issue Date:24.12.2014 Expiry Date:26.05.2024 NB 2195 : Szutest Uygunluk Değerlendirme A.Ş.</p> <p>Certificate #2: 2195-MED-381435801-D01 Rev No: 03 Revision Date:20.06.2019 Issue Date:13.02.2015 Expiry Date:26.05.2024 NB 2195 : Szutest Uygunluk Değerlendirme A.Ş.</p>
Monofilament Poly (glycolide Co- Caprolactone) Suture	Class III	Same	<p>Certificate #1: 2195-MED-381435801 Rev No: 03 Revision Date:20.06.2019 Issue Date:24.12.2014 Expiry Date:26.05.2024 NB 2195 : Szutest Uygunluk Değerlendirme A.Ş.</p> <p>Certificate #2: 2195-MED-381435801-D01 Rev No: 03 Revision Date:20.06.2019 Issue Date:13.02.2015 Expiry Date:26.05.2024 NB 2195 : Szutest Uygunluk Değerlendirme A.Ş.</p>
Braided Coated Silk Suture	Class IIb	Same	<p>Certificate #1: 2195-MED-381435801 Rev No: 03 Revision Date:20.06.2019 Issue Date:24.12.2014 Expiry Date:26.05.2024 NB 2195 : Szutest Uygunluk Değerlendirme A.Ş.</p>
Monofilament Polyamide Suture	Class IIb	Same	<p>Certificate #1: 2195-MED-381435801 Rev No: 03 Revision Date:20.06.2019 Issue Date:24.12.2014 Expiry Date:26.05.2024 NB 2195 : Szutest Uygunluk Değerlendirme A.Ş.</p>
Monofilament Polypropylene suture	Class IIb	Same	<p>Certificate #1: 2195-MED-381435801 Rev No: 03 Revision Date:20.06.2019 Issue Date:24.12.2014 Expiry Date:26.05.2024 NB 2195 : Szutest Uygunluk Değerlendirme A.Ş.</p>



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Braided Coated Polyester Suture	Class IIb	Same	Certificate #1: 2195-MED-381435801 Rev No: 03 Revision Date:20.06.2019 Issue Date:24.12.2014 Expiry Date:26.05.2024 NB 2195 : Szutest Uygunluk Değerlendirme A.Ş.
Monofilament Stainless Steel 316 L	Class IIb	Same	Certificate #1: 2195-MED-381435801 Rev No: 03 Revision Date:20.06.2019 Issue Date:24.12.2014 Expiry Date:26.05.2024 NB 2195 : Szutest Uygunluk Değerlendirme A.Ş.
Poly (Glycolide co-caprolactone) and Polypropylene Mesh	Class III	Same	Certificate #1: 2195-MED-381435801 Rev No: 03 Revision Date:20.06.2019 Issue Date:24.12.2014 Expiry Date:26.05.2024 NB 2195 : Szutest Uygunluk Değerlendirme A.Ş. Certificate #2: 2195-MED-381435801-D02 Rev No: 01 Revision Date:20.06.2019 Issue Date:13.02.2015 Expiry Date:26.05.2024 NB 2195 : Szutest Uygunluk Değerlendirme A.Ş.
Monofilament Polypropylene Mesh	Class III	Same	Certificate #1: 2195-MED-381435801 Rev No: 03 Revision Date:20.06.2019 Issue Date:24.12.2014 Expiry Date:26.05.2024 NB 2195 : Szutest Uygunluk Değerlendirme A.Ş. Certificate #2: 2195-MED-381435801-D02 Rev No: 01 Revision Date:20.06.2019 Issue Date:13.02.2015 Expiry Date:26.05.2024 NB 2195 : Szutest Uygunluk Değerlendirme A.Ş.

Confirmation Letter Revision History

Date	Version of the letter	Action
2024/01/03	MD0012-CL-01	Initial Issue



To check the validity of this confirmation letter please scan the barcode. To manually check, go to <https://public.szutest-germany.de/> use the first 3 digits of the manufacturer name and confirmation letter No. For further information please contact md_confirmation@szutest-germany.de

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



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>.

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: 27.05.2024
 Dehradun, Uttarakhand

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

Annexure-1: Product Details

Product Name		Generic Name	Brand Name	MD Class	Rule	GMDN Code
Surgical Sutures	Absorbable Surgical Sutures	Braided coated poly glycolic acid	Solus	III	8	16584
		Braided coated Poly (Glycolide-Co-L -Lactide) / Polyglactin 910	Solus 910	III	8	17471
		Braided Coated Short-Term Poly (Glycolide-Co-L- Lactide) /Polyglactin-910	Solus Swift-910	III	8	17471
		Monofilament Poly (Glycolide Co-Caprolactone)	Monolus	III	8	16584
		Monofilament Poly (p-Dioxanone)	Mass	III	8	16584
		Monofilament Poly (p-Dioxanone)	Barb-E	III	8	16584
	Non-Absorbable surgical sutures	Braided coated polyester	Esterlus	III	8	13906
		Braided coated silk	Silkus	III	8	13910
		Monofilament polypropylene	Prolus	III	8	13909
Monofilament polyamide		Nylus	III	8	38000	
Surgical Mesh	Partially Absorbable surgical Mesh	Poly (Glycolide Co-Caprolactone) And Polypropylene	Pro- Ab	III	8	44756

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

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 described here, meet the provision of Medical Devices Rules 2017 (India).
 All supporting documentation is retained under premises of the manufacturer.

Classification : Class C
Conformity Assessment Route : As per [Sub-rule (1) Rule 4] Medical Devices Rules 2017 (India)
Licensing Authority : Central Drugs Standard Control Organisation,
 Ministry of Health, Govt. of India
Licence Number: : MFG/MD/2024/000202

Product Details	Generic Name	Brand Name	GMDN Code
	Chromic Catgut Suture	Logut	13898
	Plain Catgut Suture		

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: 26.03.2024
 Dehradun, Uttarakhand

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



PRODUCT CATALOGUE

PRODUCT CATALOGUE

Absorbable Sutures

Non-Absorbable Sutures

Medical Devices



Lotus Surgicals Pvt. Ltd.

404, Prathamesh Tower B, Raghuvanshi Mills Compound
Senapati Bapat Marg, Lower Parel, Mumbai 400 013 INDIA

Tel: 91-22-66572555 Telefax: 91-22-24913543

Email: info@lotus-surgicals.com Web: www.lotus-surgicals.com

Trademarks and trade names of LOTUS SURGICALS PVT. LTD. (as at December 2020)

Solus[®] - Braided Coated Polyglycolic Acid Suture
Solus 910[®] - Braided Coated Poly(Glycolide-co-L-lactide) [Polyglactin-910] Suture
Solus 910[®] **AM+** - Braided Coated Poly(Glycolide-co-L-lactide) [Polyglactin-910] Suture with Antibacterial (Triclosan)
Solus Swift[®] **910** - Braided Coated Short-term Poly(Glycolide-co-L-lactide) [Polyglactin-910] Suture
Mass[®] - Poly(P-dioxanone) Monofilament Suture
Monolus[®] - Poly(Glycolide-co-caprolactone) [Poliglecaprone 25] Suture
Logut[®] - Chromic and Plain Catgut Suture
Esterlus[®] - Braided Coated Polyester Suture
Silkus[®] - Black Braided Silk Suture
Prolus[®] - Blue Monofilament Polypropylene Suture - Cardiovascular and Other Specialities
Nylus[®] - Black Monofilament Polyamide Suture
Stelus[®] - Monofilament 316 L Stainless Steel Suture
übersonic[™] - Ultrasonic Surgical System
ProSec[®] - Surgical Cutters and Skin Staplers
ProLap[®] - Laparoscopic Instruments
Hemosec[®] - Titanium Clips and Appliers
Hemolus[™] - Absorbable Hemostat (Oxidized Regenerated Cellulose)
Pro-Visc[®] **3D** - Composite Dual-side Mesh for Intra-peritoneal Placement
EndoTack[™] - Titanium Tacker for Surgical Mesh Fixation
Prolus[®] **Mesh** ♦ **Prolus**[®] **Lite** - Polypropylene Meshes for Hernia Repair
Pro-AB[®] - Partially Absorbable Surgical Mesh for Hernia Repair
Freedom[®] - Trans-Obturator Needles and Sling System
ProLysate[®] - Handrub and Surgical Handwash

Acknowledgements

All other trademarks are acknowledged as the property of their respective owners.

Lotus Surgicals reserves the right to modify specifications without notice.

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Ultra-modern Clean Room (Class 10,000) Infrastructure

OVERVIEW



Lotus' ultra modern 60,000 square feet facility in Dehradun, India, is at par with the best Medical Device manufacturing facilities in the world. Since inception, Lotus has been committed to creating a world-class manufacturing facility capable of delivering superior quality Sterile Medical Devices to domestic and international markets. In pursuit of this objective, Lotus has spared no effort in selecting from the world market the highest quality manufacturing and testing equipment available.

Lotus Surgicals has an ultra-modern Clean Room facility for manufacturing various medical devices. The infrastructure complies with the specifications, testing and validation norms of International Regulatory Agencies such as COPP(WHO/GMP), ISO, CE, USFDA and EU.

The entire manufacturing area of 20,000 square feet is designed to meet Class 10,000 cleanliness standard of US FED 209E (i.e. not more than 10,000 particles of size 0.5 microns per cubic feet of air) equivalent to ISO Class 7. This provides an environment which not only protects from external contamination but also reduces the bio-burden on the product prior to sterilization, thus ensuring low amounts of endotoxins post-sterilization.

This catalogue enlists the various needle suture combinations along with other medical devices manufactured by Lotus which can be used with utmost confidence. Lotus can also provide needle-suture combinations that are not listed in this catalogue, on request.

As per International Manufacturing and Quality Standards — CE, ISO 9001:2015, and EN ISO 13485:2016.

A Certificate of Pharmaceutical Product (WHO/GMP) Certified Company.

In technical consultation with H&A Consultants, Williamsburg, VA 23188, USA.

Meets Class 10,000 cleanliness standard of US FED 209E (i.e. not more than 10,000 particles of size 0.5 microns per cubic feet of air) equivalent to ISO Class 7. This includes individual Class 10,000 Clean Rooms for storage (critical components), preparation (sutures), assembly, packaging and sterilization.

Air handling systems designed to ISO requirements (ISO 14644), provide air of high quality with respect to particulates. Processing areas receive clean and filtered air with a minimum of 60 air changes per hour in the core process areas.

All process areas have terminal High Efficiency Particulate (HEPA) Filters with an efficiency of 99.97% down to 0.3 micron.

Differential pressure of 12-15 Pascals maintained effectively between adjacent rooms to prevent ingress of particulates (viable and non-viable).

Unidirectional air flow in a laminar fashion across all workstations, along with temperature and relative humidity control.

Pre-sterilized clothing and door inter-locking systems for personnel, as well as well-designed air locks and dynamic pass boxes for movement of materials.

Fully automatic in-line packaging system that eliminates human error and handling.

Product sterilization with 100% Ethylene Oxide Gas, Residual EtO compliance as per ISO 10993-7 and EtO Sterilization process have been validated as per ISO 11135:2014.

Quality Management System (QMS) developed to meet and exceed international standards.



Notified body 0123



Notified body 2195



EN ISO 13485



GOOD MANUFACTURING PRACTICE

CONSISTENT QUALITY

LABEL INFORMATION

Lotus uses the following symbols (from European Standard EN ISO 15223-1:2016) on its product labels.

Symbol	Meaning
	CE-mark and identification number of notified body. Product conforms to the essential requirements of the Medical Device Directive 93/42/EEC
	See instructions for use
	Do not reuse
	Keep away from sunlight
	Keep dry
	Do not use if the package is damaged
	Use by Month & Year
	Month & Year of Manufacture
	Manufactured by
	Authorized representative in the European Community
	Lot Number
	Method of Sterilization – Ethylene Oxide
	Method of Sterilization – Irradiation

NEEDLE POINT PROFILES

Needle Profile	Symbol
TAPER POINT	
BLUNT POINT	
TAPER CUT	
CONVENTIONAL CUTTING	
REVERSE CUTTING	
SPATULATED	

NEEDLE SHAPE PROFILES

Needle Profile	Shape
5/8 CIRCLE	
1/2 CIRCLE	
3/8 CIRCLE	
1/4 CIRCLE	
STRAIGHT	
J TYPE	

SUTURE SIZE CHART

United States Pharmacopoeia (USP) Size	Metric Size (Gauge No.)
12--0	0.01
11--0	0.1
10--0	0.2
9--0	0.3
8--0	0.4
7--0	0.5
6--0	0.7
5--0	1
4--0	1.5
3--0	2
2--0	3
0	3.5
1	4
2	5
3 and 4	6
5	7

ABSORBABLE SUTURES

The Lotus range of Synthetic Absorbable Sutures:

Synthetic Absorbable Sutures (Braided)

- Solus® - Braided Coated Polyglycolic Acid
- Solus 910® - Braided Coated Poly(Glycolide-co-L-lactide) [Polyglactin-910]
- Solus 910® AM+ - Braided Coated Poly(Glycolide-co-L-lactide) [Polyglactin-910] with Antibacterial (Triclosan)
- Solus Swift® 910 - Braided Coated Short-term Poly(Glycolide-co-L-lactide) [Polyglactin-910]

Synthetic Absorbable Sutures (Monofilament)

- Mass® - Poly(P-dioxanone) Monofilament
- Monolus® - Poly(Glycolide-co-caprolactone) [Poliglecaprone 25]



Hermetically sealed aluminium peel-off pouches





Sterilization and Degassing Room

Since Synthetic Absorbable Sutures are hygroscopic in nature, each batch manufactured is subjected to moisture analysis using a Coulometric Karl Fischer Titrator. The batches are released only if the moisture content on the suture is less than 300 ppm. This ensures that the sutures have a shelf life of 5 years and there is no loss of strength during this shelf life.

The entire range of Synthetic Absorbable Sutures from Lotus is available in hermetically sealed aluminium peel-off pouches developed in consultation with Dupont, USA - world renowned experts in packaging and industrial polymers. These peel-off pouches are far more user-friendly than conventional tear-open packs. The Synthetic Absorbable Sutures are packed on a fully automatic in-line packaging machine where forming, sealing, trimming, printing and cutting are all done in a continuous motion, thus eliminating human error and handling. This enables not only increased productivity, but also ensures minimum human contact.



Custom-built In-line Automatic Packaging Machine



Solus®

Braided Coated Polyglycolic Acid

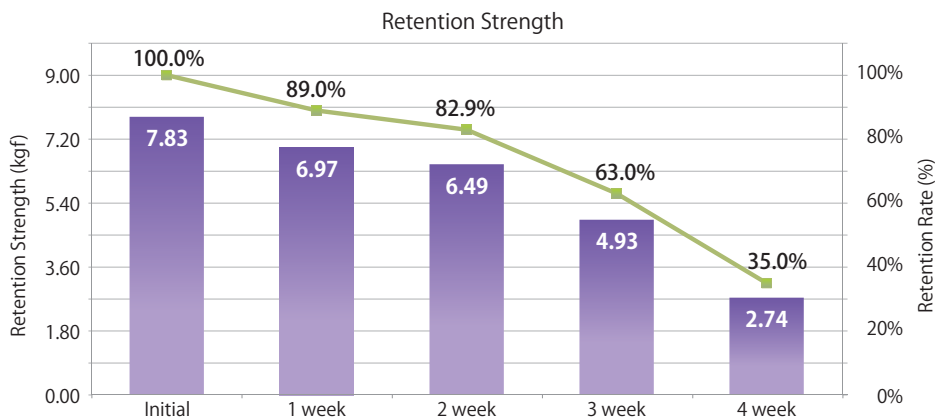
Product Details:

Composition	Polyglycolic Acid
Construction	Braided
Coating	Polycaprolactone and Calcium Stearate
In vitro retention of strength	83% at 2 weeks
Tissue Reaction	Non-antigenic, non-pyrogenic and elicits only a mild tissue reaction during the absorption process
Absorption Time	Completely absorbed in 60-90 days
Sterilization	100% Ethylene Oxide
Available in Sizes	8-0, 7-0, 6-0, 5-0, 4-0, 3-0, 2-0, 0, 1, 2
Colour	Violet and Undyed
Shelf Life	5 years
Packaging	Box of 12 and 36 sutures

Distinctive Features:










- ◆ Soft and smooth feel that helps in easy passage through the tissue with minimal trauma.
- ◆ Good knotting properties because of better and modern braiding technology.
- ◆ Very high initial tensile strength and excellent handling.
- ◆ No extra lubrication required.
- ◆ Smooth tie down.
- ◆ Less than 200 ppm of moisture ensuring full 5 years shelf life.
- ◆ Knot pull strength and needle swage strength greater than USP limits.

Tensile Strength Retention:



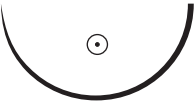




SOLUS® - Synthetic Absorbable Sutures
Braided Coated Polyglycolic Acid

TAPER POINT

Needle Length	Needle Profile	Suture Length	Suture Size								
			8-0	7-0	6-0	5-0	4-0	3-0	2-0	0	1
9 mm 	3/8 Circle	30 cm			LNW 9575 LNW 2672						
9.3 mm Double Armed 	3/8 Circle	30 cm	LNW 9577								
16 mm 	1/2 Circle	45 cm				LNW 2303					
		70 cm					LNW 2305				
20 mm 	1/2 Circle	45 cm					LNW 2304 S				
		45 cm (10 lengths per foil)						LNW 2504			
		70 cm					LNW 2304	LNW 2437			
25 mm 	1/2 Circle	70 cm Undyed						LNW 2123			
		90 cm						LNW 2528			
25 mm Double Armed 	1/2 Circle	90 cm						LNW 2528 DA			
27 mm 	5/8 Circle Premium	75 cm							LNW 2318 HAL		
30 mm 	1/2 Circle	30 cm							LNW 2030		
		45 cm							LNW 2317 M		
		45 cm (5 lengths per foil)							LNW 2508		
		45 cm (10 lengths per foil)							LNW 2503		
		70 cm							LNW 2341	LNW 2342	
		90 cm							LNW 2317	LNW 2338	
		90 cm Undyed							LNW 2317-3		
		110 cm							LNW 2317 VS		LNW 2827 VS
36 mm 	1/2 Circle	90 cm Undyed						LNW 945	LNW 946		








SOLUS® - Synthetic Absorbable Sutures Braided Coated Polyglycolic Acid

TAPER POINT

Needle Length	Needle Profile	Suture Length	Suture Size							
			6-0	5-0	4-0	3-0	2-0	0	1	2
40 mm 	½ Circle	45 cm					LNW 2345 M	LNW 2346 M		
		45 cm (5 lengths per foil)						LNW 2507		
		45 cm (10 lengths per foil)						LNW 2502	LNW 2501	
		70 cm						LNW 2546		
		90 cm					LNW 2345	LNW 2346 LNW 2346-3	LNW 2360	
		90 cm Undyed						LNW 2346 U		
		110 cm						LNW 2346 VS LNW 2346 VS-3		
		120 cm							LNW 2360 L	
40 mm HEAVY 	½ Circle	20 cm							LNW 2347 SP	
		45 cm							LNW 2347 M	
		70 cm							LNW 2359	
		90 cm							LNW 2347 LNW 2347-3	LNW 2352
		90 cm Undyed							LNW 2344 LNW 2344-3	
		110 cm							LNW 2347 VS LNW 2347 VS-3	LNW 2352 VS
		120 cm							LNW 2350	
		45 mm HEAVY 	½ Circle	90 cm						
120 cm									LNW 2347 PB L	
50 mm 	½ Circle	75 cm							LNW 9251	
		90 cm						LNW 2346 SP		
50 mm HEAVY 	½ Circle	75 cm								LNW 2355
		100 cm							LNW 2448	
		110 cm							LNW 2448 L	












SOLUS® - Synthetic Absorbable Sutures
Braided Coated Polyglycolic Acid

TAPER CUT

Needle Length	Needle Profile	Suture Length	Suture Size						
			6-0	5-0	4-0	3-0	2-0	0	1
17 mm 	½ Circle	45 cm				LNW 2515			
30 mm 	½ Circle	45 cm					LNW 2511 HK		
		70 cm						LNW 2518 SP	
30 mm HEAVY 	½ Circle	45 cm							LNW 2511 G
36 mm 	½ Circle	90 cm (OB-GY)				LNW 2516		LNW 2517	
38 mm 	½ Circle	45 cm					LNW 2511 A		
40 mm 	½ Circle	45 cm						LNW 1045	
		90 cm (OB-GY)						LNW 2518	LNW 2519
		90 cm Undyed						LNW 2518 U	
		110 cm						LNW 2518 L	
40 mm HEAVY 	½ Circle	70 cm							LNW 2363
		90 cm (OB-GY)							LNW 2364












SOLUS® - Synthetic Absorbable Sutures
Braided Coated Polyglycolic Acid

CUTTING

Needle Length	Needle Profile	Suture Length	Suture Size							
			6-0	5-0	4-0	3-0	2-0	0	1	2
16 mm 	3/8 Circle Premium	45 cm		LNW 2442		LNW 2471				
		70 cm Undyed			LNW 2443					
16 mm 	3/8 Circle	45 cm			LNW 2465					
19 mm 	3/8 Circle Premium	70 cm Undyed				LNW 2402 S				
		90 cm Undyed				LNW 2402				
22 mm 	3/8 Circle	45 cm				LNW 2401				
22 mm 	1/2 Circle	90 cm				LNW 2472				
25 mm 	3/8 Circle Premium	90 cm Undyed				LNW 2328				
26 mm 	3/8 Circle	90 cm Undyed					LNW 2404			
45 mm  	Straight	90 cm			LNW 2388					
60 mm  	Straight	76 cm					LNW 2390			
		90 cm								LNW 2354
		90 cm Undyed				LNW 2389				



SOLUS® - Synthetic Absorbable Sutures
Braided Coated Polyglycolic Acid

REVERSE CUTTING



Needle Length	Needle Profile	Suture Length	Suture Size							
			6-0	5-0	4-0	3-0	2-0	0	1	2
12 mm 	3/8 Circle	45 cm	LNW 2671		LNW 2494	LNW 2495				
12 mm 	3/8 Circle Premium	45 cm		LNW 2493						
23 mm 	1/2 Circle	30 cm Undyed					LNW 2693 SA(S)			
		45 cm					LNW 2510 SB			
		70 cm					LNW 2510 SB/L			
		90 cm Undyed					LNW 2693 SA			
23 mm HEAVY 	1/2 Circle	35 cm							LNW 2826	
		70 cm							LNW 2826 L	
24 mm 	3/8 Circle	70 cm Undyed				LNW 936				
24.3 mm 	3/8 Circle	70 cm				LNW 2522				
26 mm 	3/8 Circle	70 cm Undyed				LNW 2407				
27 mm 	5/8 Circle	45 cm					LNW 2694	LNW 2511 SB	LNW 2827	
		70 cm						LNW 2511 SB/L		
30 mm 	J Type	90 cm						LNW 2512	LNW 2828	
36 mm 	1/2 Circle	45 cm						LNW 2534 M		
								LNW 2534 DS		
		90 cm						LNW 2534		
									LNW 2534 T	
40 mm 	1/2 Circle	45 cm					LNW 2382 M			
		90 cm					LNW 2382	LNW 2422	LNW 2478	
		90 cm Undyed					LNW 2382 U			

SOLUS® - Synthetic Absorbable Sutures Braided Coated Polyglycolic Acid

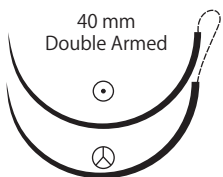
REVERSE CUTTING

Needle Length	Needle Profile	Suture Length	Suture Size							
			6-0	5-0	4-0	3-0	2-0	0	1	2
40 mm HEAVY 	½ Circle	45 cm							LNW 2421 M	
		90 cm							LNW 2421 LNW 2421 T	LNW 2351
		(1 x 90 cm) (9 x 45 cm)								LNW 2509-9
50 mm HEAVY 	½ Circle	90 cm							LNW 2438	LNW 2353

SPATULATED

Needle Length	Needle Profile	Suture Length	Suture Size							
			8-0	7-0	6-0	5-0	4-0	3-0	2-0	
6 mm 	⅜ Circle Micro Point	30 cm	LNW 2348	LNW 2561						
8 mm Double Armed 	¼ Circle Premium Point	45 cm			LNW 2670					

DOUBLE ARMED

Needle Length	Needle Profile	Suture Length	Suture Size					
			4-0	3-0	2-0	0	1	2
40 mm Double Armed 	½ Circle Round Bodied, ½ Circle Taper Cut	140 cm				LNW 2340	LNW 2140 GF	
		160 cm					LNW 2160 GF	
		180 cm			LNW 2220 GF	LNW 2380 GF	LNW 2180 GF	LNW 2280 GF

PRE-CUT SUTURES

Suture Length	Suture Size					
	4-0	3-0	2-0	0	1	2
3 x 45 cm	WN 2604	WN 2603	WN 2602	WN 2601		

Packaging : Box of 12



Solus 910[®]

Braided Coated Poly(Glycolide-co-L-lactide) [Polyglactin-910]

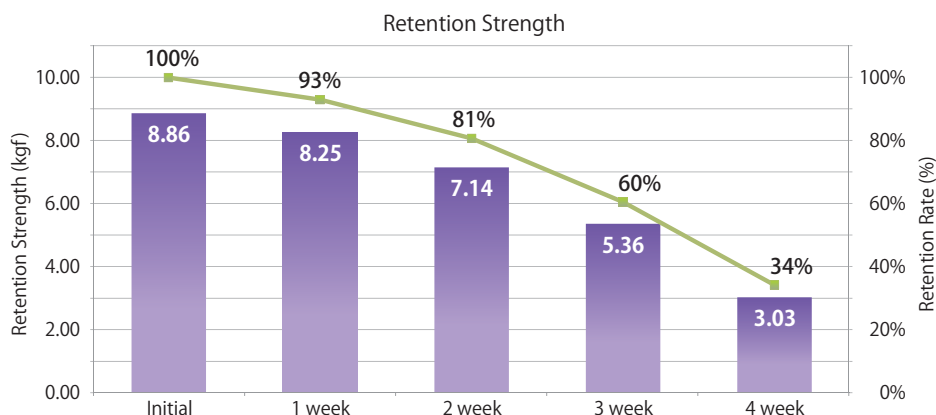
Product Details:

Composition	Poly(Glycolide-co-L-lactide) [Polyglactin-910]
Construction	Braided
Coating	Poly(Glycolide-co-L-lactide) [Glaomer 37] and Calcium Stearate
In vitro retention of strength	81% at 2 weeks
Tissue Reaction	Non-antigenic, non-pyrogenic and elicits only a mild tissue reaction during the absorption process
Absorption Time	Completely absorbed in 54-70 days
Sterilization	100% Ethylene Oxide
Available in Sizes	8-0, 7-0, 6-0, 5-0, 4-0, 3-0, 2-0, 0, 1,2
Colour	Violet and Undyed
Shelf Life	5 years
Packaging	Box of 12 and 36 sutures

Distinctive Features:











- ◆ Soft and smooth feel that helps in easy passage through the tissue with minimal trauma.
- ◆ Good knotting properties because of better and modern braiding technology.
- ◆ Very high initial tensile strength and excellent handling.
- ◆ Smooth tie down.
- ◆ Less than 200 ppm of moisture ensuring full 5 years shelf life.
- ◆ Very low capillarity.
- ◆ No extra lubrication required.

Tensile Strength Retention:



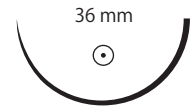
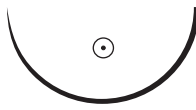




SOLUS 910® - Synthetic Absorbable Sutures
Braided Coated Poly(Glycolide-co-L-lactide) [Polyglactin-910]

TAPER POINT

Needle Length	Needle Profile	Suture Length	Suture Size												
			8-0	7-0	6-0	5-0	4-0	3-0	2-0	0	1				
9 mm 	3/8 Circle	30 cm			LNW 9575-910 LNW 2672-910										
9.3 mm Double Armed 	3/8 Circle	30 cm	LNW 9577-910												
16 mm 	1/2 Circle	45 cm				LNW 2303-910									
		70 cm						LNW 2305-910							
19 mm 	1/2 Circle	70 cm						LNW 2420-910							
20 mm 	1/2 Circle	45 cm				LNW 2520-910	LNW 2304 S-910								
		45 cm (10 lengths per foil)							LNW 2504-910						
		70 cm						LNW 2304-910	LNW 2437-910						
22 mm 	1/2 Circle	70 cm							LNW 2322-910						
25 mm 	1/2 Circle	70 cm Undyed							LNW 2123-910						
		90 cm							LNW 2528-910						
25 mm Double Armed 	1/2 Circle	90 cm							LNW 2528 DA-910						
27 mm 	5/8 Circle Premium	75 cm								LNW 2318-910 HAL					
30 mm 	1/2 Circle	30 cm								LNW 2030-910					
		45 cm								LNW 2317 M-910					
		45 cm (5 lengths per foil)								LNW 2508-910					
		45 cm (10 lengths per foil)								LNW 2503-910					
		70 cm								LNW 2341-910	LNW 2342-910				
		90 cm								LNW 2317-910	LNW 2338-910				
										LNW 2317-3-910					
		90 cm Undyed										LNW 2337-910			
110 cm									LNW 2317 VS-910			LNW 2827 VS-910			


SOLUS 910® - Synthetic Absorbable Sutures
Braided Coated Poly(Glycolide-co-L-lactide) [Polyglactin-910]

TAPER POINT








Needle Length	Needle Profile	Suture Length	Suture Size										
			6-0	5-0	4-0	3-0	2-0	0	1	2			
 <p>36 mm</p>	½ Circle	90 cm						LNW 2436-910					
		90 cm Undyed						LNW 945-910	LNW 946-910				
 <p>40 mm</p>	½ Circle	45 cm						LNW 2345 M-910	LNW 2346 M-910				
		45 cm (5 lengths per foil)							LNW 2507-910				
		45 cm (10 lengths per foil)							LNW 2502-910	LNW 2501-910			
		70 cm							LNW 2546-910				
		90 cm						LNW 2345-910	LNW 2346-910	LNW 2360-910			
		90 cm Undyed							LNW 2346-3-910				
		110 cm							LNW 2346 U-910				
		120 cm							LNW 2346 VS-910				
 <p>40 mm HEAVY</p>	½ Circle	20 cm								LNW 2360 L-910			
		45 cm									LNW 2347 SP-910		
		70 cm									LNW 2347 M-910		
		90 cm									LNW 2359-910		
		90 cm Undyed									LNW 2347-910	LNW 2352-910	
											LNW 2347-3-910		
											LNW 2344-910		
											LNW 2344-3-910		
 <p>45 mm HEAVY</p>	½ Circle	90 cm								LNW 2347 PB-910			
		120 cm									LNW 2347 PB L-910		
 <p>48 mm</p>	½ Circle	90 cm								LNW 2548-910			
 <p>50 mm</p>	½ Circle	75 cm								LNW 9251-910			
		90 cm								LNW 2346-910 SP			

SOLUS 910® - Synthetic Absorbable Sutures
Braided Coated Poly(Glycolide-co-L-lactide) [Polyglactin-910]

TAPER POINT










Needle Length	Needle Profile	Suture Length	Suture Size						
			5-0	4-0	3-0	2-0	0	1	2
50 mm HEAVY 	½ Circle	75 cm							LNW 2355-910
		100 cm						LNW 2448-910	
		110 cm						LNW 2448 L-910	

TAPER CUT

Needle Length	Needle Profile	Suture Length	Suture Size							
			6-0	5-0	4-0	3-0	2-0	0	1	
17 mm 	½ Circle	45 cm				LNW 2515-910				
30 mm 	½ Circle	45 cm					LNW 2511 HK-910			
		70 cm						LNW 2518-910 SP		
30 mm HEAVY 	½ Circle	45 cm							LNW 2511 G-910	
36 mm 	½ Circle	90 cm							LNW 2425-910	
		90 cm (OB-GY)				LNW 2516-910		LNW 2517-910		
38 mm 	½ Circle	45 cm					LNW 2511 A-910			
40 mm 	½ Circle	45 cm						LNW 1045-910		
		90 cm (OB-GY)						LNW 2518-910	LNW 2519-910	
		90 cm Undyed						LNW 2518 U-910		
		110 cm						LNW 2518 L-910		
40 mm HEAVY 	½ Circle	70 cm							LNW 2363-910	
		90 cm (OB-GY)							LNW 2364-910	













SOLUS 910® - Synthetic Absorbable Sutures
 Braided Coated Poly(Glycolide-co-L-lactide) [Polyglactin-910]

CUTTING

Needle Length	Needle Profile	Suture Length	Suture Size							
			6-0	5-0	4-0	3-0	2-0	0	1	2
16 mm 	3/8 Circle Premium	45 cm		LNW 2442-910		LNW 2471-910				
		70 cm Undyed			LNW 2443-910					
16 mm 	3/8 Circle	45 cm			LNW 2465-910					
19 mm 	3/8 Circle Premium	70 cm Undyed				LNW 2402 S-910				
		90 cm Undyed				LNW 2402-910				
22 mm 	3/8 Circle	45 cm				LNW 2401-910				
22 mm 	1/2 Circle	90 cm				LNW 2472-910				
25 mm 	3/8 Circle Premium	90 cm Undyed				LNW 2328-910				
26 mm 	3/8 Circle	90 cm Undyed					LNW 2404-910			
45 mm 	Straight	90 cm			LNW 2388-910					
60 mm 	Straight	76 cm					LNW 2390-910			
		90 cm								LNW 2354-910
		90 cm Undyed				LNW 2389-910				




SOLUS 910® - Synthetic Absorbable Sutures
Braided Coated Poly(Glycolide-co-L-lactide) [Polyglactin-910]

REVERSE CUTTING



Needle Length	Needle Profile	Suture Length	Suture Size								
			6-0	5-0	4-0	3-0	2-0	0	1	2	
12 mm 	3/8 Circle	45 cm	LNW 2671-910		LNW 2494-910	LNW 2495-910					
12 mm 	3/8 Circle Premium	45 cm		LNW 2493-910							
16 mm 	3/8 Circle	45 cm		LNW 2516-910							
		70 cm Undyed			LNW 2416-910						
		75 cm			LNW 2561-910						
19 mm 	3/8 Circle	70 cm Undyed			LNW 2419-910						
23 mm 	1/2 Circle	30 cm Undyed					LNW 2693 SA(S)-910				
		45 cm					LNW 2510 SB-910				
		70 cm					LNW 2510 SB/L-910				
		90 cm Undyed					LNW 2693 SA-910				
23 mm HEAVY 	1/2 Circle	35 cm							LNW 2826-910		
		70 cm							LNW 2826 L-910		
24 mm 	3/8 Circle	67 cm				LNW 2319-910					
		70 cm Undyed				LNW 936-910					
24.3 mm 	3/8 Circle	70 cm				LNW 2522-910					
26 mm 	3/8 Circle	70 cm Undyed				LNW 2407-910					
27 mm 	3/8 Circle	45 cm					LNW 2694-910	LNW 2511 SB-910	LNW 2827-910		
		70 cm						LNW 2511 SB/L-910			
30 mm 	J Type	90 cm						LNW 2512-910	LNW 2828-910		
36 mm 	1/2 Circle	45 cm						LNW 2534 M-910			
								LNW 2534 DS-910			
		90 cm							LNW 2534-910		
									LNW 2534 T-910		

SOLUS 910® - Synthetic Absorbable Sutures
Braided Coated Poly(Glycolide-co-L-lactide) [Polyglactin-910]

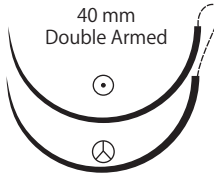
REVERSE CUTTING

Needle Length	Needle Profile	Suture Length	Suture Size							
			6-0	5-0	4-0	3-0	2-0	0	1	2
 40 mm	½ Circle	45 cm					LNW 2382 M-910			
		90 cm					LNW 2382-910	LNW 2422-910	LNW 2478-910	
		90 cm Undyed					LNW 2382 U-910			
 40 mm HEAVY	½ Circle	45 cm							LNW 2421 M-910	
		90 cm							LNW 2421-910	LNW 2351-910
		(1 x 90 cm) (9 x 45 cm)							LNW 2421 T-910	
 50 mm HEAVY	½ Circle	90 cm							LNW 2509-9-910	
									LNW 2438-910	LNW 2353-910

SPATULATED

Needle Length	Needle Profile	Suture Length	Suture Size						
			8-0	7-0	6-0	5-0	4-0	3-0	2-0
 6 mm	¾ Circle Micro Point	30 cm	LNW 2348-910						
 8 mm Double Armed	¼ Circle Premium Point	45 cm			LNW 2670-910				

DOUBLE ARMED








Needle Length	Needle Profile	Suture Length	Suture Size					
			4-0	3-0	2-0	0	1	2
 40 mm Double Armed	½ Circle Round Bodied, ½ Circle Taper Cut	140 cm				LNW 2340-910	LNW 2140 GF-910	
		160 cm					LNW 2160 GF-910	
		180 cm			LNW 2220 GF-910	LNW 2380 GF-910	LNW 2180 GF-910	LNW 2280 GF-910

PRE-CUT SUTURES



Suture Length	Suture Size					
	4-0	3-0	2-0	0	1	2
3 x 45 cm	WN 2604-910	WN 2603-910	WN 2602-910	WN 2601-910		

Packaging : Box of 12






SOLUS 910® AM+ - Synthetic Absorbable Sutures
 Braided Coated Poly(Glycolide-co-L-lactide) [Polyglactin-910]
 with Antibacterial (Triclosan)
 TAPER POINT

Needle Length	Needle Profile	Suture Length	Suture Size					
			5-0	4-0	3-0	2-0	0	1
16 mm 	½ Circle	45 cm	LAM 2303-910					
20 mm 	½ Circle	70 cm		LAM 2304-910				
		90 cm			LAM 2437-910			
30 mm 	½ Circle	70 cm				LAM 2341-910		
		90 cm				LAM 2317-910	LAM 2338-910	
36 mm 	½ Circle	90 cm Undyed				LAM 945-910	LAM 946-910	LAM 947-910
40 mm 	½ Circle	90 cm				LAM 2345-910	LAM 2346-910	
40 mm 	½ Circle GS Needle	90 cm				LAM 2357-910	LAM 2358-910	LAM 2360-910
40 mm HEAVY 	½ Circle	70 cm						LAM 2359-910
		90 cm						LAM 2347-910
		120 cm						LAM 2350-910






TAPER CUT

Needle Length	Needle Profile	Suture Length	Suture Size					
			5-0	4-0	3-0	2-0	0	1
36 mm 	½ Circle	90 cm			LAM 2516-910			LAM 2319-910
		90 cm (OB-GY)					LAM 2517-910	
40 mm 	½ Circle	90 cm					LAM 2518-910	
		90 cm (OB-GY)						LAM 2519-910

SOLUS 910® AM+ - Synthetic Absorbable Sutures
Braided Coated Poly(Glycolide-co-L-lactide) [Polyglactin-910]
with Antibacterial (Triclosan)
CUTTING

Needle Length	Needle Profile	Suture Length	Suture Size						
			4-0	3-0	2-0	0	1	2	
16 mm 	3/8 Circle	45 cm	LAM 2465-910						
22 mm 	3/8 Circle	45 cm		LAM 2401-910					
22 mm 	1/2 Circle	90 cm		LAM 2472-910					
25 mm 	3/8 Circle	90 cm Undyed		LAM 2328-910					
26 mm 	3/8 Circle	90 cm Undyed			LAM 2404-910				

REVERSE CUTTING

Needle Length	Needle Profile	Suture Length	Suture Size					
			4-0	3-0	2-0	0	1	2
23 mm HEAVY 	1/2 Circle	35 cm					LAM 2826-910	
		70 cm					LAM 2826E-910	
24 mm 	3/8 Circle	70 cm		LAM 2936-910				
		70 cm Undyed		LAM 936-910				
36 mm 	1/2 Circle	90 cm				LAM 2534-910		
40 mm 	1/2 Circle	90 cm			LAM 2382-910			LAM 2478-910
40 mm HEAVY 	1/2 Circle	90 cm					LAM 2421-910	



Solus Swift® 910

Braided Coated Short-term Poly(Glycolide-co-L-lactide) [Polyglactin-910]

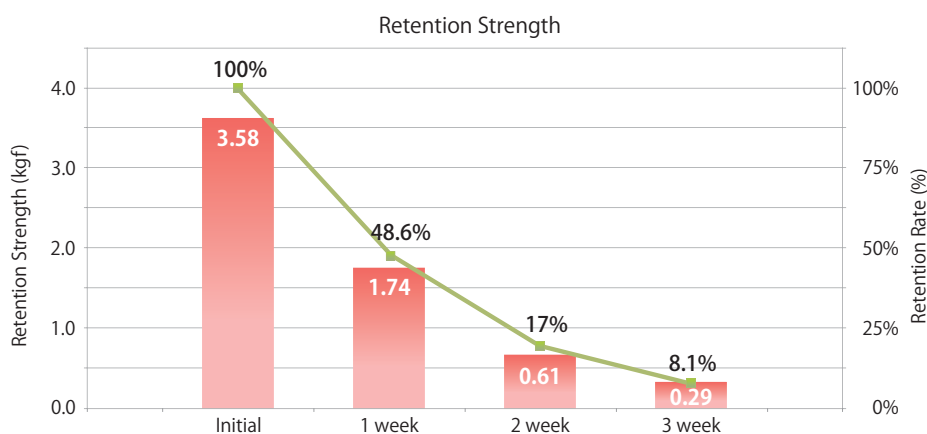
Product Details:

Composition	Poly(Glycolide-co-L-lactide) [Polyglactin-910]
Construction	Braided
Coating	Polycaprolactone and Calcium Stearate
In vitro retention of strength	Approximately 45% at 1 week
Tissue Reaction	Non-antigenic, non-pyrogenic and elicits only a mild tissue reaction during the absorption process
Absorption Time	Absorption essentially completed in 42 days
Sterilization	100% Ethylene Oxide
Available in Sizes	6-0, 5-0, 4-0, 3-0, 2-0, 0, 1, 2
Colour	Undyed
Shelf Life	5 years
Packaging	Box of 12 sutures

Distinctive Features:



- ◆ High initial tensile strength.
- ◆ Soft and smooth feel that helps in easy passage through the tissue with minimal trauma.
- ◆ Good knotting properties because of better and modern braiding technology.
- ◆ Excellent handling and smooth tie down.

Tensile Strength Retention:





SOLUS SWIFT® 910 - Synthetic Absorbable Sutures
Braided Coated Short-term Poly(Glycolide-co-L-lactide) [Polyglactin-910]






TAPER POINT

Needle Length	Needle Profile	Suture Length	Suture Size						
			6-0	5-0	4-0	3-0	2-0	0	1
26 mm 	½ Circle	70 cm				LNW 2764			
36 mm 	½ Circle	90 cm						LNW 2036	
		100 cm					LNW 2761 RB		

TAPER CUT







Needle Length	Needle Profile	Suture Length	Suture Size						
			6-0	5-0	4-0	3-0	2-0	0	1
36 mm 	½ Circle	70 cm					LNW 2762 ML		
		90 cm					LNW 2762		
		100 cm					LNW 2761		
		110 cm					LNW 2762-ER	LNW 2763	
40 mm 	½ Circle	70 cm						LNW 2763 ML	
		110 cm						LNW 2763 SP	

CUTTING

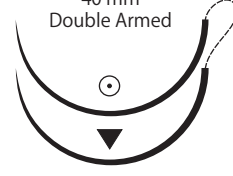
Needle Length	Needle Profile	Suture Length	Suture Size						
			6-0	5-0	4-0	3-0	2-0	0	1
12 mm 	¾ Circle Premium	45 cm	LNW 9913	LNW 9915					
16 mm 	¾ Circle	45 cm			LNW 2718	LNW 2719			
16 mm 	¾ Circle Premium	75 cm			LNW 9918	LNW 9919			
21.8 mm 	½ Circle	45 cm				LNW 9935			
22 mm 	½ Circle	70 cm				LNW 2735			

SOLUS SWIFT® 910 - Synthetic Absorbable Sutures
 Braided Coated Short-term Poly(Glycolide-co-L-lactide) [Polyglactin-910]

REVERSE CUTTING

Needle Length	Needle Profile	Suture Length	Suture Size						
			6-0	5-0	4-0	3-0	2-0	0	1
10 mm 	3/8 Circle	45 cm	LNW 2716	LNW 2717					
26 mm 	3/8 Circle	45 cm				LNW 2732 S			
		70 cm				LNW 2732			
26 mm 	3/8 Circle Premium	75 cm					LNW 9933		
35 mm 	3/8 Circle	60 cm						LNW 2721	
36 mm 	3/8 Circle	60 cm					LNW 2720		
40 mm 	1/2 Circle	60 cm					LNW 2720 SP		

DOUBLE ARMED

Needle Length	Needle Profile	Suture Length	Suture Size							
			6-0	5-0	4-0	3-0	2-0	0	1	
40 mm Double Armed 	1/2 Circle Round Bodied, 1/2 Circle Reverse Cutting	90 cm							LNW 2666	
		140 cm						LNW 2777		
		180 cm						LNW 2777 L		



Mass[®]

Poly(P-dioxanone) Monofilament

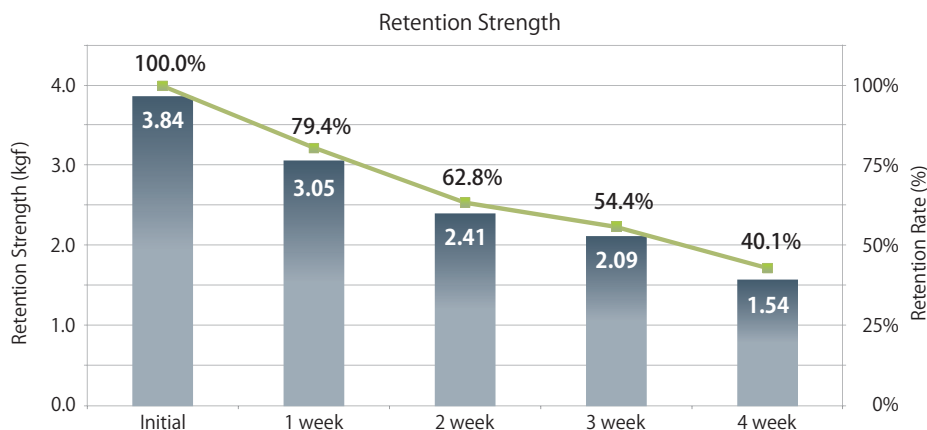
Product Details:

Composition	Poly(P-dioxanone)
Construction	Monofilament
Coating	None
In vitro retention of strength	Approximately 60% at 2 weeks
Tissue Reaction	Non-antigenic, non-pyrogenic and elicits only a mild tissue reaction during the absorption process
Absorption Time	Absorption essentially completed between 180 to 210 days
Sterilization	100% Ethylene Oxide
Available in Sizes	6-0, 5-0, 4-0, 3-0, 2-0, 0, 1
Colour	Violet and Undyed
Shelf Life	5 years
Packaging	Box of 12 sutures

Distinctive Features:











- ◆ Ideal for internal tissues where a long lasting, absorbable suture is preferable.
- ◆ Very high initial tensile strength and excellent pliability.
- ◆ Smooth passage through tissue and lesser reactivity.

Tensile Strength Retention:



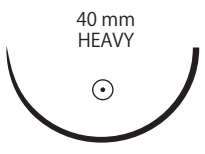
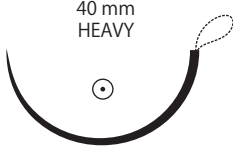
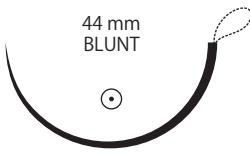

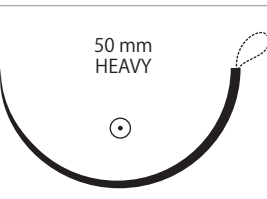
MASS® - Synthetic Absorbable Sutures
Poly(P-dioxanone) Monofilament

TAPER POINT

Needle Length	Needle Profile	Suture Length	Suture Size						
			6-0	5-0	4-0	3-0	2-0	0	1
13 mm 	3/8 Circle	70 cm		LNW 1013					
13 mm Double Armed 	3/8 Circle	70 cm		LNW 1013 DA					
13 mm 	1/2 Circle	45 cm			LNW 9102				
		70 cm		LNW 9513 SA					
13 mm Double Armed 	1/2 Circle	45 cm			LNW 9102 DA				
		70 cm	LNW 9613	LNW 9513					
17 mm 	1/2 Circle	90 cm			LNW 9109		LNW 9108		
20 mm 	1/2 Circle	70 cm			LNW 9304	LNW 9237			
20 mm Double Armed 	1/2 Circle	70 cm			LNW 9304 DA	LNW 9237 DA			
30 mm 	1/2 Circle	70 cm				LNW 9332			
30 mm HEAVY 	1/2 Circle	70 cm						LNW 9254	
31 mm 	1/2 Circle	70 cm					LNW 9133		




MASS® - Synthetic Absorbable Sutures
Poly(P-dioxanone) Monofilament

TAPER POINT



Needle Length	Needle Profile	Suture Length	Suture Size							
			6-0	5-0	4-0	3-0	2-0	0	1	
 <p>40 mm HEAVY</p>	½ Circle	90 cm							LNW 9371	LNW 9352
 <p>40 mm HEAVY</p>	½ Circle	150 cm (LOOP)								LNW 9261
 <p>44 mm BLUNT</p>	½ Circle	150 cm (LOOP)								LNW 9367
 <p>45 mm HEAVY</p>	½ Circle	90 cm								LNW 9248
 <p>50 mm HEAVY</p>	½ Circle	150 cm (LOOP)								LNW 9262

MASS® - Synthetic Absorbable Sutures
Poly(P-dioxanone) Monofilament

TAPER CUT






Needle Length	Needle Profile	Suture Length	Suture Size						
			6-0	5-0	4-0	3-0	2-0	0	1
30 mm 	½ Circle	70 cm					LNW 9334		
40 mm 	½ Circle	90 cm							LNW 9218
45 mm 	½ Circle	90 cm							LNW 9354

CUTTING

Needle Length	Needle Profile	Suture Length	Suture Size						
			6-0	5-0	4-0	3-0	2-0	0	1
12 mm 	¾ Circle Premium	45 cm	LNW 9861						
16 mm 	¾ Circle Premium	45 cm		LNW 9872	LNW 9873				

MASS® - Synthetic Absorbable Sutures
 Poly(P-dioxanone) Monofilament

REVERSE CUTTING

Needle Length	Needle Profile	Suture Length	Suture Size							
			6-0	5-0	4-0	3-0	2-0	0	1	
11 mm 	3/8 Circle	45 cm	LNW 9611							
19 mm 	3/8 Circle	70 cm		LNW 9519						
27 mm 	5/8 Circle	70 cm								LNW 9227
40 mm HEAVY 	1/2 Circle	90 cm								LNW 9221
48 mm 	1/2 Circle	90 cm								LNW 9374



Monolus[®]

Poly(Glycolide-co-caprolactone) [Poliglecaprone 25]

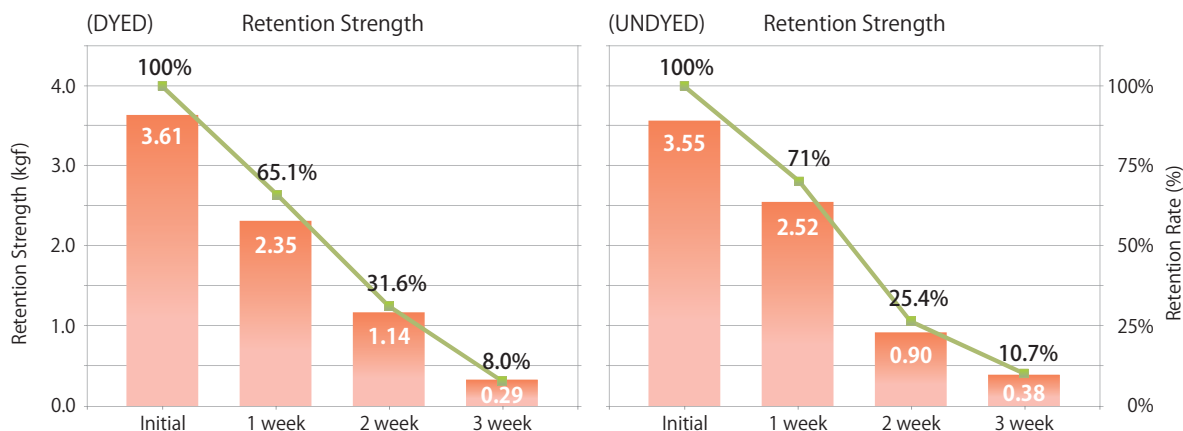
Product Details:

Composition	Poly(Glycolide-co-caprolactone) [Poliglecaprone 25]
Construction	Monofilament
Coating	None
In vitro retention of strength	Remains approximately 30% at 2 weeks in dyed and approximately 20% at 2 weeks in undyed
Tissue Reaction	Non-antigenic, non-pyrogenic and elicits only a mild tissue reaction during the absorption process
Absorption Time	Completely absorbed in 90 to 120 days
Sterilization	100% Ethylene Oxide
Available in Sizes	6-0, 5-0, 4-0, 3-0, 2-0, 0, 1
Colour	Dyed and Undyed
Shelf Life	5 years
Packaging	Box of 12 sutures

Distinctive Features:





- ◆ High initial tensile strength.
- ◆ Soft and smooth feel that helps in easy passage through the tissue with minimal trauma.
- ◆ Excellent handling properties and high pliability.
- ◆ Ideal suture for use in sub cuticular closure.

Tensile Strength Retention:








MONOLUS® - Synthetic Absorbable Sutures
Poly(Glycolide-co-caprolactone) [Poliglecaprone 25]



TAPER POINT

Needle Length	Needle Profile	Suture Length	Suture Size						
			6-0	5-0	4-0	3-0	2-0	0	1
16 mm 	3/8 Circle	70 cm			LNW 1648				
25 mm 	1/2 Circle	70 cm				LNW 1664	LNW 1665		
30 mm 	1/2 Circle	70 cm					LNW 1641	LNW 1642	
36 mm 	1/2 Circle	70 cm					LNW 1666		

CUTTING

Needle Length	Needle Profile	Suture Length	Suture Size						
			6-0	5-0	4-0	3-0	2-0	0	1
12 mm 	3/8 Circle Premium	45 cm	LNW 833						
16 mm 	3/8 Circle Premium	45 cm		LNW 3204	LNW 3205				
25 mm 	3/8 Circle Premium	70 cm				LNW 1326			
25 mm 	3/8 Circle	70 cm					LNW 1602		
60 mm 	Straight	70 cm				LNW 1650			

REVERSE CUTTING

Needle Length	Needle Profile	Suture Length	Suture Size						
			6-0	5-0	4-0	3-0	2-0	0	1
16 mm 	3/8 Circle	70 cm			LNW 1205				
25 mm 	3/8 Circle	45 cm				LNW 3326 (M)-S			
		70 cm				LNW 3326 (M)			

CATGUT SUTURES

The Lotus range of Catgut Sutures:

Absorbable Sutures (Monofilament)

- Logut® - Chromic and Plain





Logut®

Chromic and Plain Catgut

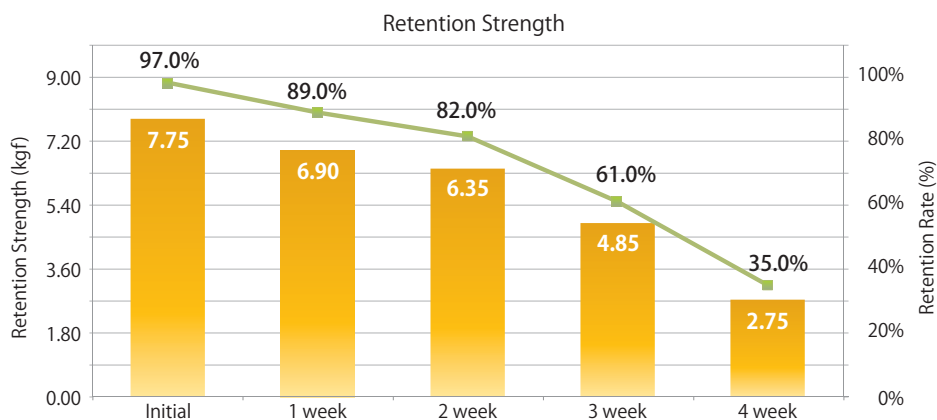
Product Details:

Composition	Purified connective tissue (collagen) derived from the sub-mucous layer of sheep (bovine) intestine
Construction	Monofilament/Twisted
Coating	Plain sutures are without coating, Chromic sutures have been tanned by treatment with chromium salt in the trivalent form and coloured with oxidized pyrogallol, colour index 76515
In vivo retention of strength	Effective strength is usually lost between 10-12 days in case of plain catgut and by 21-30 days in case of chromic catgut
Tissue Reaction	Moderate tissue inflammation occurs which is characteristic of a foreign body response. Loss of tensile strength and loss of mass follows as the proteolytic enzymatic digestive process dissolves the surgical catgut
Absorption Time	Absorption is essentially complete in 60-90 days
Sterilization	Packed in sterilizing fluid, the constituents of which are Isopropanol, Water, Sodium Benzoate and Ethylene Oxide
Available in Sizes	5-0, 4-0, 3-0, 2-0, 0, 1, 2, 3
Colour	Beige and Tanned Brown
Shelf Life	5 years
Packaging	Box of 12 and 36 sutures









Distinctive Features:

- ◆ Soft and smooth feel that helps in easy passage through the tissue with minimal trauma.
- ◆ Very high initial tensile strength and excellent handling.
- ◆ Catgut suture with the highest quality collagen maintaining a composition of 97-98%. Higher percentage of collagen allows for superior tensile strength.








Tensile Strength Retention:



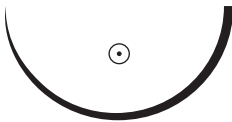


LOGUT® - Catgut Sutures
 Sterilised Surgical Gut
CHROMIC
 TAPER POINT

Needle Length	Needle Profile	Suture Length	Suture Size									
			7-0	6-0	5-0	4-0	3-0	2-0	0	1	2	
16 mm 	1/8 Circle	76 cm				LNW 5048C						
17 mm 	1/2 Circle	75 cm			LNW 4317							
20 mm 	1/2 Circle	76 cm					LNW 4237					
25 mm 	1/2 Circle	76 cm					LNW 4238					
26 mm 	1/2 Circle	70 cm						LNW 4123STP				
		75 cm					LNW 4222					
30 mm 	3/8 Circle	76 cm						LNW 4216	LNW 4217			
							LNW 5033	LNW 4235				
30 mm 	1/2 Circle	75 cm					LNW 4237L	LNW 4241S				
		76 cm					LNW 4239	LNW 4241	LNW 4242	LNW 4257		
35 mm 	1/2 Circle	76 cm										LNW 4230

LOGUT® - Catgut Sutures
 Sterilised Surgical Gut
CHROMIC
 TAPER POINT

Needle Length	Needle Profile	Suture Length	Suture Size									
			7-0	6-0	5-0	4-0	3-0	2-0	0	1	2	
40 mm 	3/8 Circle	76 cm							LNW 4220	LNW 4221		
40 mm 	1/2 Circle	75 cm							LNW 4245S	LNW 4258S		
		76 cm							LNW 4245	LNW 4246		LNW 4260
40 mm HEAVY 	1/2 Circle	76 cm								LNW 4258	LNW 4259	
		90 cm										LNW 4259L
		152 cm								LNW 4258XL	LNW 4259XL	
45 mm 	Straight	76 cm							LNW 4204	LNW 4205		
45 mm 	3/8 Circle	76 cm						LNW 4223	LNW 4225	LNW 4226		
		100 cm										LNW 4226L
45 mm 	1/2 Circle	75 cm										LNW 4228SL
		76 cm							LNW 4249			
		152 cm										LNW 4228L
45 mm HEAVY 	1/2 Circle	100 cm								LNW 4229	LNW 4227	LNW 4228



LOGUT® - Catgut Sutures
 Sterilised Surgical Gut
CHROMIC
TAPER POINT

Needle Length	Needle Profile	Suture Length	Suture Size							
			6-0	5-0	4-0	3-0	2-0	0	1	2
48 mm HEAVY 	½ Circle	90 cm					LNW 4448C			
		100 cm							LNW 4348	LNW 4384
50 mm HEAVY 	½ Circle	76 cm							LNW 42485	
		100 cm							LNW 4248	
63 mm BLUNT 	¾ Circle	76 cm							LNW 4267	






BLUNT POINT

Needle Length	Needle Profile	Suture Length	Suture Size							
			6-0	5-0	4-0	3-0	2-0	0	1	2
65 mm HEAVY 	½ Circle	90 cm							LNW 4365	






LOGUT® - Catgut Sutures
 Sterilised Surgical Gut
CHROMIC
 TAPER CUT

Needle Length	Needle Profile	Suture Length	Suture Size									
			6-0	5-0	4-0	3-0	2-0	0	1	2		
35 mm HEAVY 	½ Circle	75 cm										LNW 4231
40 mm 	½ Circle	100 cm							LNW 4279			

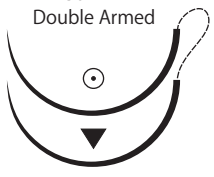
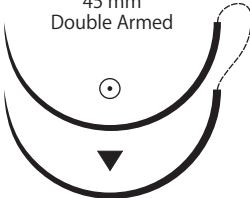
CUTTING

Needle Length	Needle Profile	Suture Length	Suture Size									
			6-0	5-0	4-0	3-0	2-0	0	1	2		
16 mm 	⅜ Circle	76 cm			LNW 4280							
22 mm 	⅜ Circle	76 cm				LNW 4201						
24 mm 	⅜ Circle	76 cm					LNW 4826					
35 mm 	⅜ Circle	76 cm						LNW 4824				
60 mm 	⅜ Circle	76 cm								LNW 4262		

LOGUT® - Catgut Sutures
 Sterilised Surgical Gut
CHROMIC
 REVERSE CUTTING

Needle Length	Needle Profile	Suture Length	Suture Size								
			6-0	5-0	4-0	3-0	2-0	0	1	2	
12 mm 	3/8 Circle	76 cm		LNW 4268							
16 mm 	1/2 Circle	76 cm				LNW 4284					
19 mm 	3/8 Circle	70 cm				LNW 4210					
		76 cm			LNW 4286						
20 mm 	3/8 Circle	75 cm			LNW 4828						
26 mm 	3/8 Circle	76 cm				LNW 4203					


LOGUT® - Catgut Sutures
 Sterilised Surgical Gut
CHROMIC
DOUBLE ARMED

Needle Length	Needle Profile	Suture Length	Suture Size							
			6-0	5-0	4-0	3-0	2-0	0	1	2
36 mm Double Armed 	½ Circle Round Bodied, ½ Circle Reverse Cutting	152 cm					LNW 4277			
45 mm Double Armed 	½ Circle Round Bodied, ½ Circle Reverse Cutting	152 cm						LNW 4276	LNW 4275	


PRE-CUT SUTURES

Suture Length	Suture Size							
	6-0	5-0	4-0	3-0	2-0	0	1	2
152 cm						WN 2214	WN 2215	WN 2216

LOGUT® - Catgut Sutures
 Sterilised Surgical Gut
PLAIN
TAPER POINT

Needle Length	Needle Profile	Suture Length	Suture Size								
			6-0	5-0	4-0	3-0	2-0	0	1	2	
30 mm 	3/8 Circle	76 cm						LNW 5033P			

CUTTING

Needle Length	Needle Profile	Suture Length	Suture Size								
			6-0	5-0	4-0	3-0	2-0	0	1	2	
20 mm 	1/2 Circle	76 cm			LNW 4272						

PRE-CUT SUTURES

Suture Length	Suture Size							
	6-0	5-0	4-0	3-0	2-0	0	1	2
152 cm					WN 2003	WN 2004	WN 2005	

NON-ABSORBABLE SUTURES

The Lotus range of Non-Absorbable Sutures:

Non-Absorbable Sutures (Braided)

- Esterlus® - Braided Coated Polyester
- Silkus® - Black Braided Silk

Non-Absorbable Sutures (Monofilament)

- Prolus® - Blue Monofilament Polypropylene
- Nylus® - Black Monofilament Polyamide
- Stelus® - Monofilament 316 L Stainless Steel





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 	3/8 Circle	75 cm Green		LS 6890	LS 6891				
13 mm Double Armed 	1/2 Circle	75 cm Green			LS 6892				
		75 cm White			LS 6893				
13 mm Double Armed  Pledget 3mm x 3mm x 1.5mm	1/2 Circle	75 cm Green			LS 6892-PL-3				
		75 cm White			LS 6893-PL-3				
25 mm 	1/2 Circle	100 cm Green				LS 655			
25 mm Double Armed  Pledget 3mm x 3mm x 1.5mm	1/2 Circle	90 cm					LS 6226-PL-3		
26 mm Double Armed 	1/2 Circle	75 cm Green				LS 6832			
		100 cm Green				LS 6552			


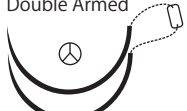



TAPER CUT

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 	1/2 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	1/2 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	1/2 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			



Silkus®

Black Braided Silk

Product Details:












Composition	Silk
Construction	Braided
Coating	Coated with Silicon to give 'hand' to the suture
In vitro retention of strength	Although Silkus® is classified as a non-absorbable suture, however, progressive degradation of the silk fibre in vivo may result in gradual loss of tensile strength over time
Tissue Reaction	Silk being a natural fibre elicits an inflammatory reaction, which is followed by gradual encapsulation of the suture by fibrous connective tissue
Absorption Time	Non-absorbable
Sterilization	100% Ethylene Oxide
Available in Sizes	8-0, 7-0, 6-0, 5-0, 4-0, 3-0, 2-0, 0, 1
Colour	Black
Shelf Life	5 years
Packaging	Box of 12 sutures

Distinctive Features:

- ◆ Coated with silicon to allow easy passage through tissue, limit absorption and increase ductility.
- ◆ Knot pull strength and needle swage strength greater than USP limits.
- ◆ Packed using Tyvek paper for extra security.
- ◆ Dyed black for better visibility.

SILKUS® - Non-Absorbable Sutures
Black Braided Silk

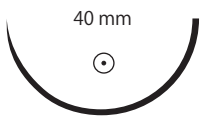

TAPER POINT

Needle Length	Needle Profile	Suture Length	Suture Size						
			6-0	5-0	4-0	3-0	2-0	0	1
10 mm 	3/8 Circle	76 cm		LNW 5095					
12 mm 	3/8 Circle	76 cm		LNW 5027					
13 mm 	3/8 Circle	76 cm	LNW 5029						
16 mm 	3/8 Circle	76 cm		LNW 5081	LNW 5082				
16 mm 	1/2 Circle	76 cm			LNW 5049				
		90 cm			LNW 5050				
20 mm 	1/2 Circle	76 cm			LNW 5086	LNW 5087			
25 mm 	1/2 Circle	76 cm				LNW 5070			
		90 cm				LNW 5085			
30 mm 	3/8 Circle	76 cm						LNW 5017	
30 mm 	1/2 Circle	75 cm					LNW 5230		
		76 cm					LNW 5333	LNW 5334	
		90 cm					LNW 5331	LNW 5332	
35 mm 	3/8 Circle	90 cm				LNW 5100			
37 mm 	1/2 Circle	75 cm							LNW 5137


SILKUS® - Non-Absorbable Sutures

Black Braided Silk




TAPER POINT

Needle Length	Needle Profile	Suture Length	Suture Size							
			5-0	4-0	3-0	2-0	0	1	2	
40 mm 	½ Circle	70 cm								LNW 5073
50 mm 	Straight	76 cm				LNW 5208				

TAPER CUT










Needle Length	Needle Profile	Suture Length	Suture Size							
			6-0	5-0	4-0	3-0	2-0	0	1	
25 mm 	½ Circle	76 cm					LNW 5670			

CUTTING

Needle Length	Needle Profile	Suture Length	Suture Size							
			6-0	5-0	4-0	3-0	2-0	1-0	0	1
16 mm 	¾ Circle	76 cm			LNW 5001	LNW 5002				
		90 cm			LNW 5000	LNW 5003				
60 mm 	Straight	76 cm					LNW 5290			
60 mm 	¾ Circle	76 cm								LNW 5062
		90 cm								LNW 5062 L


SILKUS® - Non-Absorbable Sutures
Black Braided Silk

REVERSE CUTTING

Needle Length	Needle Profile	Suture Length	Suture Size							
			6-0	5-0	4-0	3-0	2-0	0	1	
8 mm 	3/8 Circle Micro Point	38 cm	LNW 5043							
10 mm 	3/8 Circle Micro Point	38 cm	LNW 5012							
12 mm 	3/8 Circle	76 cm		LNW 5080						
		90 cm		LNW 5079						
24 mm 	3/8 Circle	75 cm				LNW 5342				
26 mm 	3/8 Circle	76 cm				LNW 5028				
45 mm 	3/8 Circle	76 cm					LNW 5036	LNW 5037		
		90 cm					LNW 5036 L	LNW 5037 L		
45 mm 	1/2 Circle	76 cm						LNW 5038		
50 mm 	3/8 Circle	76 cm								LNW 5063
50 mm 	1/2 Circle	76 cm					LNW 5052			

SILKUS® - Non-Absorbable Sutures
Black Braided Silk

SPATULATED

Needle Length	Needle Profile	Suture Length	Suture Size							
			6-0	5-0	4-0	3-0	2-0	0	1	
8 mm 	¼ Circle Micro Point	38 cm	LNW 5088							

PRE-CUT SUTURES

Suture Length	Suture Size							
	4-0	3-0	2-0	0	1	2	3	4
2 x 75 cm	WN 211	WN 212	WN 213	WN 214	WN 215	WN 216	WN 217	WN 218
2 x 35 cm		WN 222	WN 223	WN 224				

Packaging : Box of 12

SILKUS® REELS - Non-Absorbable Sutures
Black Braided Silk Reels
Non-Sterile

Suture Length per Reel	Suture Size							
	5-0	4-0	3-0	2-0	0	1	2	3
25 meters	LR 820	LR 821	LR 822	LR 823	LR 824	LR 825	LR 826	LR 828

Packaging : Box of 6 reels



Prolus®

Blue Monofilament Polypropylene

Cardiovascular and Other Speciality Sutures



Product Details:

Composition	Polypropylene
Construction	Monofilament
Coating	None
In vitro retention of strength	Prolus® is not subject to any degradation or loss of tensile strength
Tissue Reaction	Prolus® elicits a minimal inflammatory reaction in the tissue, followed by gradual encapsulation of the suture by fibrous tissue
Absorption Time	Non-absorbable
Sterilization	100% Ethylene Oxide
Available in Sizes	8-0, 7-0, 6-0, 5-0, 4-0, 3-0, 2-0, 0, 1
Colour	Blue
Shelf Life	5 years
Packaging	Box of 12 sutures









Distinctive Features:

- ◆ Extremely high tensile strength.
- ◆ Knot pull strength exceeds USP limits.
- ◆ Extremely smooth material resulting in minimal tissue trauma.
- ◆ Prolus® sutures used in cardiovascular surgery are straight packed to minimize memory.
- ◆ Allows for secured knot tying.
- ◆ Packed using Tyvek paper for extra security.









PROLUS® - Non-Absorbable Sutures
 Blue Monofilament Polypropylene
CARDIOVASCULAR SUTURES
 TAPER POINT

Needle Length	Needle Profile	Suture Length	Suture Size										
			8-0	7-0	6-0	5-0	4-0	3-0	2-0	0	1		
6 mm CA-160 Double Armed 	3/8 Circle	60 cm	PL 2086-F										
6 mm CA-180 Double Armed 	3/8 Circle	60 cm		PL 2076									
8mm CA-180 Double Armed 	3/8 Circle	60 cm		PL 2078-F									
8 mm CA-200 Double Armed 	3/8 Circle	45 cm	PL 2088-S										
		60 cm	PL 2088	PL 2078									
		75 cm	PL 2088-L	PL 2078-L									
8 mm PCA-200 Double Armed 	3/8 Circle	60 cm	PL 2088-PV	PL 2078-PV									
9 mm CA-180 Double Armed 	3/8 Circle	60 cm	PL 2089										
9 mm CA-200 Double Armed 	3/8 Circle	60 cm		PL 2079									
		75 cm		PL 2079-L									
9mm CA-240 Double Armed 	3/8 Circle	60 cm		PL 2079-T	PL 8709								
		75 cm			PL 8709-L								







PROLUS® - Non-Absorbable Sutures
 Blue Monofilament Polypropylene
CARDIOVASCULAR SUTURES
 TAPER POINT

Needle Length	Needle Profile	Suture Length	Suture Size									
			8-0	7-0	6-0	5-0	4-0	3-0	2-0	0	1	
10 mm CA-200 Double Armed 	3/8 Circle	60 cm	PL 2080									
10 mm CA-220 Double Armed 	3/8 Circle	60 cm		PL 2070								
				PL 2710								
10 mm AA-280 Double Armed 	3/8 Circle	60 cm			PL 8691							
					PL 8804							
		75 cm			PL 8804-L							
10 mm LTF 330 Double Armed 	1/2 Circle	60 cm			PL 8207							
10 mm LTF 330 Double Armed  Pledget 3mm x 3mm x 1.5mm	1/2 Circle	60 cm			PL 8207-PL-3							
10 mm Double Armed 	1/2 Circle	60 cm				PL 8803						
		75 cm				PL 8803-L						
10 mm Double Armed  Pledget 3mm x 3mm x 1.5mm	1/2 Circle	60 cm				PL 8803-PL-3						
13 mm AA-240 Double Armed 	3/8 Circle	60 cm			PL 8726							
		75 cm			PL 8725							
		90 cm			PL 8723							







PROLUS® - Non-Absorbable Sutures
 Blue Monofilament Polypropylene
CARDIOVASCULAR SUTURES
 TAPER POINT

Needle Length	Needle Profile	Suture Length	Suture Size								
			8-0	7-0	6-0	5-0	4-0	3-0	2-0	0	1
13 mm AA-240 Double Armed  Pledget 3mm x 3mm x 1.5mm	3/8 Circle	60 cm			PL 8726-PL-3						
13 mm AA-280 Double Armed 	3/8 Circle	45 cm			PL 8726-T-S						
		60 cm			PL 8726-T						
		75 cm			PL 8725-T						
13 mm Double Armed 	3/8 Circle	75 cm				PL 8721					
13 mm LTF 330 Double Armed 	1/2 Circle	60 cm			PL 8206	PL 8205					
13 mm LTF 330 Double Armed  Pledget 3mm x 3mm x 1.5mm	1/2 Circle	60 cm			PL 8206-PL-3	PL 8205-PL-3					
13 mm LTF 430 Double Armed 	1/2 Circle	60 cm					PL 8204				
		75 cm					PL 8204 L				
13 mm LTF 430 Double Armed  Pledget 3mm x 3mm x 1.5mm	1/2 Circle	60 cm					PL 8204-PL-3				
13 mm Double Armed 	1/2 Circle	45 cm				PL 8710-S					
		75 cm				PL 8710					


PROLUS® - Non-Absorbable Sutures
 Blue Monofilament Polypropylene
CARDIOVASCULAR SUTURES
 TAPER POINT

Needle Length	Needle Profile	Suture Length	Suture Size									
			8-0	7-0	6-0	5-0	4-0	3-0	2-0	0	1	
13 mm Double Armed  Pledget 3mm x 3mm x 1.5mm	½ Circle	75 cm				PL 8710-PL-3						
16 mm Double Armed 	½ Circle	90 cm				PL 8556	PL 8557					
16 mm Double Armed  Pledget 3mm x 3mm x 1.5mm	½ Circle	90 cm				PL 8556-PL-3						
20 mm Double Armed 	½ Circle	90 cm					PL 8761					
26 mm 	½ Circle	75 cm						PL 8832				
26 mm Double Armed 	½ Circle	90 cm					PL 8521 PL 8521 T	PL 8522				









PROLUS® - Non-Absorbable Sutures
 Blue Monofilament Polypropylene
CARDIOVASCULAR SUTURES
 TAPER CUT

Needle Length	Needle Profile	Suture Length	Suture Size									
			8-0	7-0	6-0	5-0	4-0	3-0	2-0	0	1	
8 mm CCA-220 Double Armed 	3/8 Circle	60 cm		PL 2078-CC								
17.4 mm Double Armed 	1/2 Circle	90 cm				PL 8517						
17.5 mm Double Armed 	1/2 Circle	90 cm					PL 8935	PL 8936	PL 8937			
		150 cm							PL 8937-L			
17.5 mm Double Armed  Pledget 3mm x 3mm x 1.5mm	1/2 Circle	90 cm					PL 8935-PL-3					
25 mm Double Armed 	1/2 Circle	90 cm						PL 8976				
26 mm Double Armed 	1/2 Circle	90 cm							PL 8977			
		150 cm							PL 8977-L			



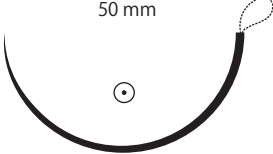
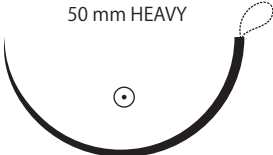
CARDIOVASCULAR SUTURES
 REVERSE CUTTING

Needle Length	Needle Profile	Suture Length	Suture Size									
			8-0	7-0	6-0	5-0	4-0	3-0	2-0	0	1	
12 mm RE 280 	3/8 Circle	70 cm			PL 878							







PROLUS® - Non-Absorbable Sutures
Blue Monofilament Polypropylene
OTHER SPECIALITY SUTURES
TAPER POINT

Needle Length	Needle Profile	Suture Length	Suture Size									
			8-0	7-0	6-0	5-0	4-0	3-0	2-0	0	1	
16 mm 	3/8 Circle	70 cm				LNW 881						
16 mm Double Armed 	3/8 Circle	70 cm				LNW 882						
16 mm 	1/2 Circle	70 cm					LNW 849					
		90 cm					LNW 848					
20 mm 	1/2 Circle	70 cm						LNW 887				
25 mm 	1/2 Circle	70 cm						LNW 838				
		90 cm						LNW 825				
26 mm 	1/2 Circle	90 cm								LNW 824		
30 mm 	1/2 Circle	70 cm							LNW 841	LNW 842		
		90 cm							LNW 844	LNW 846		
30 mm HEAVY 	1/2 Circle	70 cm								LNW 830	LNW 840	







PROLUS® - Non-Absorbable Sutures
Blue Monofilament Polypropylene
OTHER SPECIALITY SUTURES
TAPER POINT

Needle Length	Needle Profile	Suture Length	Suture Size									
			8-0	7-0	6-0	5-0	4-0	3-0	2-0	0	1	
40 mm 	½ Circle	150 cm (LOOP)									LNW 833	
40 mm HEAVY 	½ Circle	70 cm										LNW 843
		90 cm										LNW 843 L
50 mm 	½ Circle	150 cm (LOOP)									LNW 834	
50 mm HEAVY 	½ Circle	150 cm (LOOP)										LNW 835






PROLUS® - Non-Absorbable Sutures
 Blue Monofilament Polypropylene
OTHER SPECIALITY SUTURES
 TAPER CUT

Needle Length	Needle Profile	Suture Length	Suture Size								
			8-0	7-0	6-0	5-0	4-0	3-0	2-0	0	1
17 mm 	½ Circle	70 cm					LNW 899				
25 mm 	½ Circle	70 cm							LNW 807	LNW 805	
		90 cm							LNW 806		
25 mm Double Armed 	½ Circle	90 cm							LNW 877		
30 mm HEAVY 	½ Circle	90 cm								LNW 894	
		100 cm									LNW 896
36 mm 	½ Circle	90 cm							LNW 850		
45 mm HEAVY 	½ Circle	100 cm									LNW 845

PROLUS® - Non-Absorbable Sutures
Blue Monofilament Polypropylene
OTHER SPECIALITY SUTURES
CUTTING

Needle Length	Needle Profile	Suture Length	Suture Size								
			8-0	7-0	6-0	5-0	4-0	3-0	2-0	0	1
13 mm 	3/8 Circle	70 cm			LNW 817						
16 mm 	3/8 Circle	45 cm					LNW 815				
		60 cm					LNW 816				
		70 cm					LNW 870				
16 mm Double Armed 	3/8 Circle	70 cm					LNW 870-DA				
22 mm 	3/8 Circle	70 cm						LNW 018			
25 mm 	3/8 Circle	45 cm						LNW 820			
		60 cm						LNW 821			
		70 cm						LNW 802			
60 mm 	Straight	70 cm						LNW 888			

PROLUS® - Non-Absorbable Sutures
 Blue Monofilament Polypropylene
OTHER SPECIALITY SUTURES
 REVERSE CUTTING

Needle Length	Needle Profile	Suture Length	Suture Size									
			8-0	7-0	6-0	5-0	4-0	3-0	2-0	0	1	
12 mm 	3/8 Circle	45 cm					LNW 879					
		70 cm				LNW 880						
		90 cm				LNW 889						
13 mm 	3/8 Circle Premium	70 cm				LNW 862						
45 mm 	3/8 Circle	70 cm							LNW 863			
45 mm HEAVY 	1/2 Circle	100 cm									LNW 883	
45 mm HEAVY Double Armed 	1/2 Circle	100 cm									LNW 883 DA	



Nylus®

Black Monofilament Polyamide

Product Details:





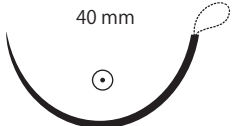

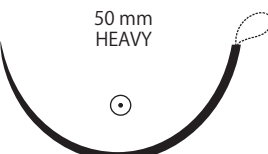
Composition	Nylon
Construction	Monofilament
Coating	None
In vitro retention of strength	Although Polyamide is non-absorbable, however, progressive hydrolysis may cause a gradual loss over time of tensile strength because of its lack of adherence to tissue
Tissue Reaction	Nylus® suture elicits a minimal inflammatory reaction in the tissue, followed by gradual encapsulation of the suture by fibrous connective tissue
Absorption Time	Non-absorbable
Sterilization	100% Ethylene Oxide
Available in Sizes	11-0, 10-0, 9-0, 8-0, 7-0, 6-0, 5-0, 4-0, 3-0, 2-0, 0, 1
Colour	Black
Shelf Life	5 years
Packaging	Box of 12 sutures

Distinctive Features:

- ◆ Easy passage through tissue because of low frictional co-efficient.
- ◆ Excellent elasticity.
- ◆ Knot pull strength and needle swage strength greater than USP limits.
- ◆ Packed using Tyvek paper for extra security.
- ◆ Superior cutting needles which are excellent for use in plastic surgery.
- ◆ Ideal for use in skin closures.







NYLUS® - Non-Absorbable Sutures
 Black Monofilament Polyamide

TAPER POINT




Needle Length	Needle Profile	Suture Length	Suture Size								
			11-0	10-0	9-0	8-0	3-0	2-0	0	1	
3.8 mm 	3/8 Circle	13 cm	LNW 2881 G	LNW 2870 G							
5.1 mm 	3/8 Circle	13 cm		LNW 2850 G	LNW 2829 G						
6 mm 	3/8 Circle Micro Point	38 cm			LNW 3709	LNW 3708					
6.5 mm 	3/8 Circle	13 cm				LNW 2808 G					
		25 cm			LNW 2800 G						
40 mm 	1/2 Circle	150 cm (LOOP)								LNW 3340	
40 mm HEAVY 	1/2 Circle	100 cm								LNW 3346	LNW 3347
50 mm HEAVY 	1/2 Circle	150 cm (LOOP)									LNW 3348
		200 cm (LOOP)									LNW 3348 K

NYLUS® - Non-Absorbable Sutures Black Monofilament Polyamide

CUTTING









Needle Length	Needle Profile	Suture Length	Suture Size							
			6-0	5-0	4-0	3-0	2-0	0	1	
13 mm 	3/8 Circle Premium	45 cm	LNW 3351S							
		70 cm	LNW 3351							
16 mm 	3/8 Circle	35 cm		LNW 3315						
		70 cm			LNW 3318	LNW 3321				
		90 cm			LNW 3319					
19 mm 	3/8 Circle	45 cm			LNW 3356					
		60 cm			LNW 3357					
		70 cm			LNW 3567					
26 mm 	3/8 Circle	70 cm	LNW 3331							
55 mm 	Straight	100 cm					LNW 3255			
60 mm 	Straight	70 cm				LNW 3388	LNW 3390	LNW 3389		

REVERSE CUTTING

Needle Length	Needle Profile	Suture Length	Suture Size							
			6-0	5-0	4-0	3-0	2-0	0	1	
10 mm 	3/8 Circle	38 cm			LNW 3326					
		70 cm	LNW 3320	LNW 3322						
12 mm 	3/8 Circle	70 cm		LNW 3317						
		90 cm		LNW 3316						
12 mm 	3/8 Circle Premium	70 cm			LNW 3752					




NYLUS® - Non-Absorbable Sutures
Black Monofilament Polyamide

REVERSE CUTTING

Needle Length	Needle Profile	Suture Length	Suture Size							
			6-0	5-0	4-0	3-0	2-0	0	1	
13 mm 	3/8 Circle	60 cm		LNW 3353						
16 mm 	3/8 Circle	70 cm				LNW 3332				
26 mm 	3/8 Circle	35 cm				LNW 3328 S				
		45 cm					LNW 3302			
		70 cm				LNW 3328				
		90 cm				LNW 3328 L				
40 mm 	3/8 Circle	70 cm					LNW 3333			
40 mm HEAVY 	1/2 Circle	100 cm						LNW 3334	LNW 3335	
45 mm 	3/8 Circle	35 cm					LNW 3336 S			
		70 cm					LNW 3336	LNW 3337		
		90 cm					LNW 3336 L			
		110 cm					LNW 3336 EL			
45 mm HEAVY 	1/2 Circle	100 cm							LNW 3338	
50 mm HEAVY 	1/2 Circle	100 cm							LNW 3362	

NYLUS® - Non-Absorbable Sutures
Black Monofilament Polyamide

SPATULATED

Needle Length	Needle Profile	Suture Length	Suture Size											
			11-0	10-0	9-0	8-0	7-0	6-0	5-0	4-0	3-0	2-0	0	
6 mm 	3/8 Circle Premium Micro Point	38 cm		LNW 3720										
6 mm Double Armed 	3/8 Circle Micro Point	38 cm			LNW 3714	LNW 3324								
6 mm Double Armed 	3/8 Circle Premium Micro Point	38 cm		LNW 3717										

PRE-CUT SUTURES

Suture Length	Suture Size					
	4-0	3-0	2-0	0	1	2
2 x 35 cm			WN 703	WN 704	WN 705	
2 x 76 cm			WN 903	WN 904	WN 905	WN 906

Packaging : Box of 12



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	
45 mm 	½ Circle	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					

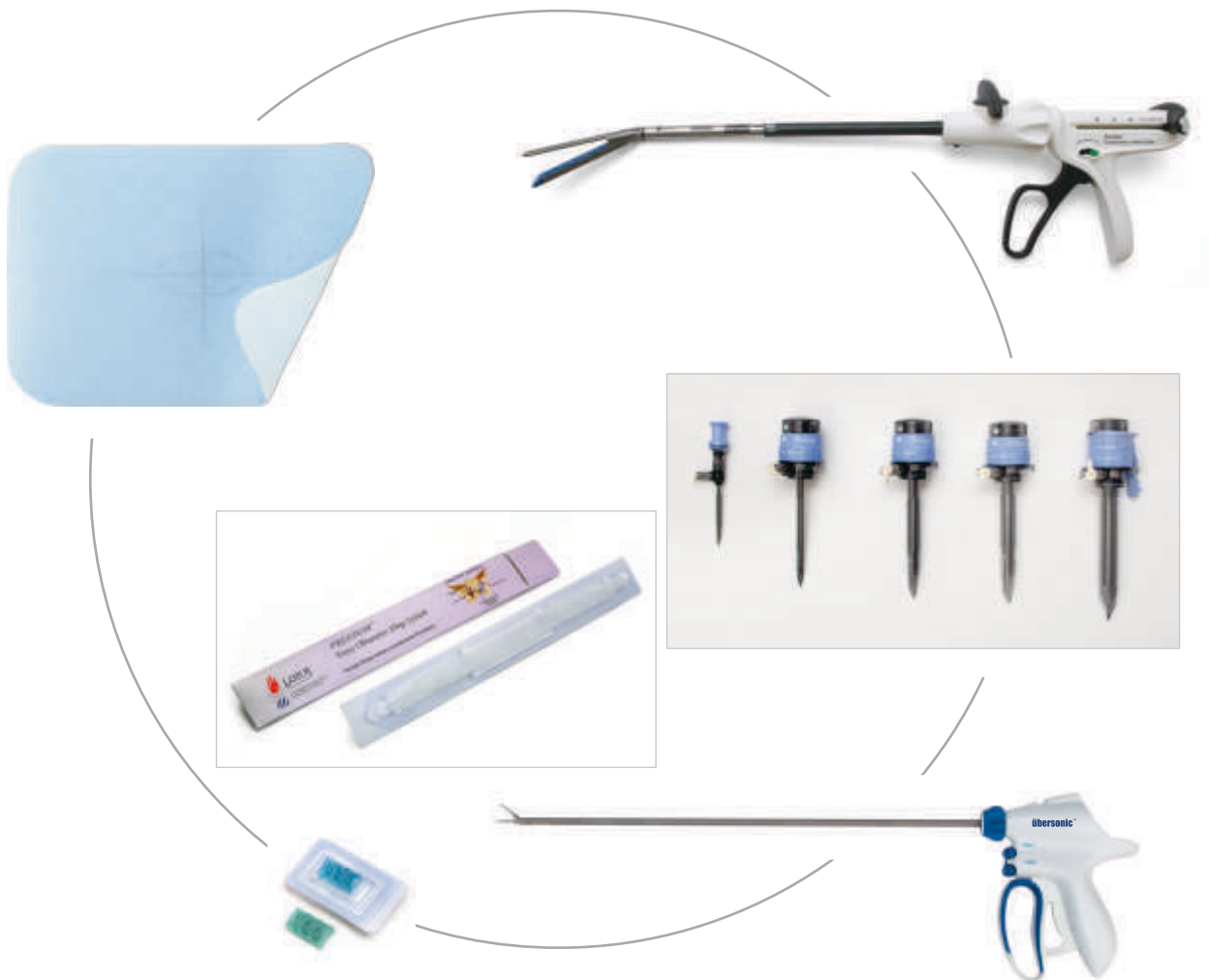
CONVENTIONAL CUTTING

Needle Length	Needle Profile	Suture Length	Suture Size							
			0	1	2	3	4	5	6	7
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 	¾ Circle	75 cm (2 x 75 cm)						LS 647		

MEDICAL DEVICES

Medical Devices from Lotus:

- **übersonic™** - Ultrasonic Surgical System
- **ProSec®** - Surgical Cutters and Skin Staplers
- **ProLap®** - Laparoscopic Instruments
- **Hemosec®** - Titanium Clips and Appliers
- **Hemolus™** - Absorbable Hemostat (Oxidized Regenerated Cellulose)
- **Pro-Visc® 3D** - Composite Dual-side Mesh for Intra-peritoneal Placement
- **EndoTack™** - Titanium Tacker for Surgical Mesh Fixation
- **Prolus® Mesh ♦ Prolus® Lite** - Polypropylene Meshes for Hernia Repair
- **Pro-AB®** - Partially Absorbable Surgical Mesh for Hernia Repair
- **Freedom®** - Trans-Obturator Needles and Sling System
- **ProLysate®** - Handrub and Surgical Handwash



übersonic™ Generator



for Open Surgery



for Laparoscopy



übersonic™ Transducer



übersonic™

Ultrasonic Surgical System

Generator and Transducer

Product Description:

The übersonic™ Generator is a high-performance ultrasonic-energy surgical system that provides advanced technology and touchscreen simplicity in one sleek and user-friendly unit. The übersonic™ Transducer is the device that connects the Generator to the ultrasonic shears.

GENERATOR

Distinctive Features:

- ◆ Universal connector and automatic instrument recognition.
- ◆ Touchscreen for easy setup, operation, and on-screen diagnostics.
- ◆ High-resolution display with wider viewing angles.
- ◆ Compact design, takes up less space in the OR.
- ◆ Converts electrical energy to mechanical energy delivered via high-frequency vibrations.
- ◆ No electricity transfer to, or through, the patient.
- ◆ Blade vibrates 55,000 times per second to simultaneously seal and transect tissue.

TRANSDUCER

Distinctive Features:

- ◆ Multi-use component.
- ◆ Lighter hand piece capable of higher amplitude.
- ◆ Can be used over 150 surgeries.
- ◆ Universal industry-compatible design.
- ◆ Can fit existing ultrasonic generators in the market.
- ◆ Can also be used with other instruments in the market.

Ref. Code	Product Description	Ref. Code	Product Description
LUGEN	übersonic™ Generator	LUTD 55	Transducer – Laparoscopic
LUFWS	Generator Footswitch	LUTD 55M	Transducer – Open Surgery
LUBPC	Universal Bipolar Cable		

Packaging:

Generator along with Footswitch provided in 1 unit per pack.
Transducer provided in 1 unit per pack. To be sterilized before use.

übersonic™ PRO+
Ultrasonic Laparoscopic Shears



übersonic™ MAESTRO
Ultrasonic Shears for Open Surgery

übersonic™

Ultrasonic Surgical System

übersonic™ PRO+ Ultrasonic Laparoscopic Shears

Product Description:

übersonic™ Pro+ is a surgical instrument used in laparoscopic procedures that uses ultrasonic vibrations to perform simultaneous cutting and coagulation of tissue. It provides secure grasping, precise cutting and reliable sealing to delicate structures without traumatizing underlying tissue.

Distinctive Features:

- ◆ Refined blade design.
- ◆ Delivers energy intelligently.
- ◆ Responds to changing tissue conditions.
- ◆ Provides enhanced audible feedback.
- ◆ Enables greater surgical precision and performance.
- ◆ Compatible with existing Ultrasonic Generators and Transducers in the market.

Ref. Code	Product Description	Diameter	Shaft Length
LULS 23	Ultrasonic Laparoscopic Shears	5mm	23cm
LULS 36	Ultrasonic Laparoscopic Shears	5mm	36cm
LULS 45	Ultrasonic Laparoscopic Shears	5mm	45cm

Packaging:

Instrument provided sterile in 1 unit per pack.

übersonic™ MAESTRO Ultrasonic Shears for Open Surgery

Product Description:

übersonic™ Maestro Shears for Open Surgery offer unmatched precision with strong sealing ability. They are designed for a wider range of surgical procedures in order to reduce the number of surgical devices needed to achieve hemostasis.

Ref. Code	Product Description	Length
LUOS 09	Ultrasonic Open Surgery Shears	9cm
LUOS 17	Ultrasonic Open Surgery Shears	17cm

Packaging:

Instrument provided sterile in 1 unit per pack.

übersonic™ MARVEL

Integrated Bipolar & Ultrasonic Laparoscopic Shears



übersonic™

Ultrasonic Surgical System

übersonic™ MARVEL Integrated Bipolar & Ultrasonic Laparoscopic Shears

Product Description:

übersonic™ Marvel is a surgical instrument that provides dual system functionality of both bipolar as well as ultrasonic interface for its laparoscopic shears, enabling greater convenience through compatibility with existing RF Generators already in use.

Distinctive Features:

- ◆ Multi-function design.
- ◆ Can be used simultaneously as a Bipolar instrument.
- ◆ Convenient and time-saving operation.
- ◆ Compatible with existing RF Generators used in hospitals.
- ◆ Compatible with existing Ultrasonic Generators and Transducers in the market.

Ref. Code	Product Description	Diameter	Shaft Length
LULS 23RF	Ultrasonic + Bipolar Laparoscopic Shears	6mm	23cm
LULS 36RF	Ultrasonic + Bipolar Laparoscopic Shears	6mm	36cm
LUBPC	Universal Bipolar Cable	–	–

Packaging:

Instrument provided sterile in 1 unit per pack.

Universal ELC Instrument



Endoscopic Linear Cutter

Product Description:

ProSec® Endoscopic Linear Cutter is a single-use instrument that places two triple-staggered height-progressive rows of titanium staples and simultaneously divides the tissue between the two triple rows. The rotating and articulating reload has a stepped cartridge face having varied-height staples (in Variable Tissue Compression Reloads). The reload comprises a complete assembly of a cartridge, anvil and knife bar. The instrument is used with a 12mm trocar (15mm for extra-thick tissue) in endoscopic surgical procedures.

UNIVERSAL ELC INSTRUMENT

Distinctive Features:

- ◆ Two stapler shaft lengths.
- ◆ One-handed grasping mechanism.
- ◆ 2-way 45° articulation of reload angle.

CODE	DESCRIPTION	SHAFT LENGTH
LPECB	Endoscopic Linear Cutter Standard Shaft	160mm
LPECBL	Endoscopic Linear Cutter Extra-long Shaft	260mm

Packaging:

ELC Instrument provided sterile in 1 unit per pack.

ELC Reload Cartridge



Endoscopic Linear Cutter

ELC RELOAD CARTRIDGE

Distinctive Features:

- ◆ Stronger streamlined fixed anvil.
- ◆ Reinforced and integrated i-beam design.
- ◆ Brand-new knife blade in each firing.
- ◆ Stepped cartridge face (in Variable Tissue Compression Reloads).
- ◆ Variable staple heights from inner to outer (in Variable Tissue Compression Reloads).

CODE	DESCRIPTION	TROCAR Ø (mm)	OPEN LEG LENGTH (mm)	CLOSED STAPLE HEIGHT (mm)
LPECR60WC	ELC 60mm Articulating Reload for Thin/Vascular Tissue	12	2.5	1.0
LPECR45BC	ELC 45mm Articulating Reload for Medium Tissue	12	3.5	1.5
LPECR60BC	ELC 60mm Articulating Reload for Medium Tissue			
LPECR60GC	ELC 60mm Articulating Reload for Thick Tissue	15	4.8	2.0
LPECR60YC	ELC 60mm Articulating Reload for Thick+ Tissue	12	4.2	2.4

Variable Tissue Compression Reloads

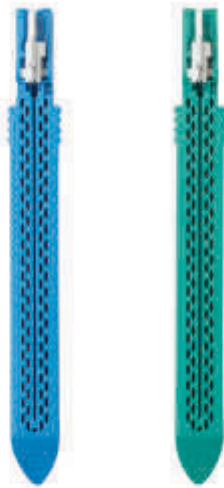
CODE	DESCRIPTION	TROCAR Ø (mm)	OPEN LEG LENGTH (mm)	CLOSED STAPLE HEIGHT (mm)
LPECR60W	ELC 60mm Articulating Reload for Vascular/Medium Tissue	12	2.0/2.5/3.0	0.88 ~ 1.5
LPECR45B	ELC 45mm Articulating Reload for Medium/Thick Tissue	12	3.0/3.5/4.0	1.5 ~ 2.25
LPECR60B	ELC 60mm Articulating Reload for Medium/Thick Tissue			
LPECR60G	ELC 60mm Articulating Reload for Extra-Thick Tissue	15	4.0/4.5/5.0	2.25 ~ 3.0

Packaging:

ELC Instrument provided sterile in 1 unit per pack.

ELC Reload cartridges are available separately in 6 units per pack.

Linear Cutter Instrument



Reload Cartridges

Linear Cutter

Product Description:

ProSec® Linear Cutter is a single-use instrument that places two double-staggered rows of titanium staples and simultaneously divides the tissue between the two rows. The reload comprises a complete assembly of a cartridge and knife bar. The instrument is used for resection and side-to-side anastomosis in open GI and Thoracic procedures.

Distinctive Features:

- ◆ Reinforced instrument forks.
- ◆ Brand new knife blade in each cartridge.
- ◆ Unique cartridge surface provides minimum tissue slippage for precise transection.
- ◆ Better mucosal capture improves staple line integrity and leak resistance.
- ◆ Rear or centre hinge clamping for one-handed positioning.
- ◆ Adjustable firing knob.
- ◆ Quick release button.
- ◆ Safety lock-out.
- ◆ Ergonomic rubber inlay grips.

CODE	DESCRIPTION	OPEN LEG LENGTH	CLOSED STAPLE HEIGHT
LPLC60U	Linear Cutter 60mm Instrument	–	–
LPLCR60UB	Linear Cutter 60mm Reload for Medium Tissue	3.8mm	1.5mm
LPLCR60UG	Linear Cutter 60mm Reload for Thick Tissue	4.8mm	2.0mm
LPLC80U	Linear Cutter 80mm Instrument	–	–
LPLCR80UB	Linear Cutter 80mm Reload for Medium Tissue	3.8mm	1.5mm
LPLCR80UG	Linear Cutter 80mm Reload for Thick Tissue	4.8mm	2.0mm

Packaging:

Instrument provided sterile in 1 unit per pack.
Reload cartridges are available in separate packs.



Curved Cutter

Product Description:

ProSec® Curved Cutter is a single-use instrument used in colo-rectal procedures that require deeper access within the pelvis. Its unique curved head places 2 double staggered rows of staples and a curved blade cuts in between. Prosec® Curved Cutter allows for placement of a 40mm cutline in the width of a 30mm space with low pelvic access.

Distinctive Features:

- ◆ Curved head enables deep pelvic access.
- ◆ Easier placement for better tissue manipulation.
- ◆ Ability to transect perpendicular to the rectum helps avoid a longer staple line.
- ◆ Less tissue movement for more controlled transection.
- ◆ Simultaneous stapling and cutting.
- ◆ Optimized staple formation.

CODE	DESCRIPTION	LENGTH	STAPLE LEG LENGTH	CLOSED STAPLE HEIGHT
LPCC40G	Curved Cutter	40mm	4.8mm	2.0mm

Packaging:

Disposable instrument with built-in cartridge provided sterile in 1 unit per pack.



Circular Stapler

Product Description:

ProSec® Circular Stapler is a single-use instrument that places two staggered circular rows of titanium staples and a circular knife divides the inner tissue. It is used in open and laparoscopic surgical procedures. Circular staplers are used for end-to-end anastomosis after bowel resection and in esophagogastric surgery.

Distinctive Features:

- ◆ Low profile anvil with atraumatic anvil edge.
- ◆ Detachable anvil for ease of tying purse-string suture over shaft.
- ◆ Extra staples per row.
- ◆ Extra-long shaft for versatile Open and Laparoscopic use.
- ◆ Airtight design.
- ◆ Barlocked cartridge attachment.
- ◆ Available in 4 different diameters.

CODE	OUTER DIAMETER	INNER DIAMETER	STAPLE	HEIGHT	FORMED HEIGHT
LPCS25	25mm	17mm	22	4.8mm	2.0mm
LPCS29	29mm	21mm	26	4.8mm	2.0mm
LPCS31	31mm	23mm	28	5.0mm	2.2mm
LPCS33	33mm	25mm	32	5.2mm	2.2mm

Packaging:

Instrument with cartridge provided sterile in 1 unit per pack.



Hemorrhoid Stapler

Product Description:

ProSec® Hemorrhoid Stapler is a single-use instrument used for a stapled hemorrhoidectomy, also known as stapled hemorrhoidopexy. The procedure involves the removal of abnormally enlarged hemorrhoidal tissue, followed by the repositioning of the remaining rectal tissue back to its normal anatomical position.

Distinctive Features:

- ◆ Quick-close adjusting knob.
- ◆ 4 suture-threader ports.
- ◆ Clear anoscope reference markings.
- ◆ One-piece fixed anvil.
- ◆ More staples for better hemostasis.
- ◆ Available in 2 diameter sizes.

CODE	OUTER DIAMETER	INNER DIAMETER	STAPLE	HEIGHT	FORMED HEIGHT
LPHS32	32mm	24mm	32	4.0mm	0.8 - 2.0mm
LPHS34	34mm	26mm	34	4.0mm	0.8 - 2.0mm

Each sterile Instrument Set contains:

- | | | |
|--|---|-------------|
| <ul style="list-style-type: none"> ProSec® Hemorrhoid Stapler Suture Threader Transparent Circular Dilator Obturator Anoscope | } | Accessories |
|--|---|-------------|

Packaging:

Instrument set provided sterile in 1 unit per pack.



Skin Stapler

Product Description:

The ProSec® Plus Skin Stapler is a sterile, single patient use instrument designed to deliver rectangular, stainless steel staples for routine wound closure. The staples are made of lubricant-coated stainless steel. The ProSec® Plus Skin Stapler places single staples to close surgical incisions. It is supplied sterile and is preloaded for single patient use.

Product Details:

Staple Dimensions	<u>Wide</u>
Wire Diameter	0.60 mm
Span	7.2 mm
Leg Length	4.9 mm

Packaging

ProSec® Plus Skin Stapler	Box of 5
Staple Remover	Box of 20

Distinctive Features:

- ◆ Easy staple extraction.
- ◆ Superior cosmetic results - promotes blood supply and faster scar-free healing.
- ◆ Minimizes staple rotation.
- ◆ Uncompromised visibility, comfort and control.
- ◆ Staples are coated with lubricant.

Indications:

The ProSec® Plus Skin Stapler has application for routine skin closure in a wide variety of surgical procedures.

Code	Description
LPSSP	ProSec® Plus Skin Stapler
LSR	Staple Remover



ProLap®

Laparoscopic Instruments






Single-use Laparoscopic Bladeless Trocars

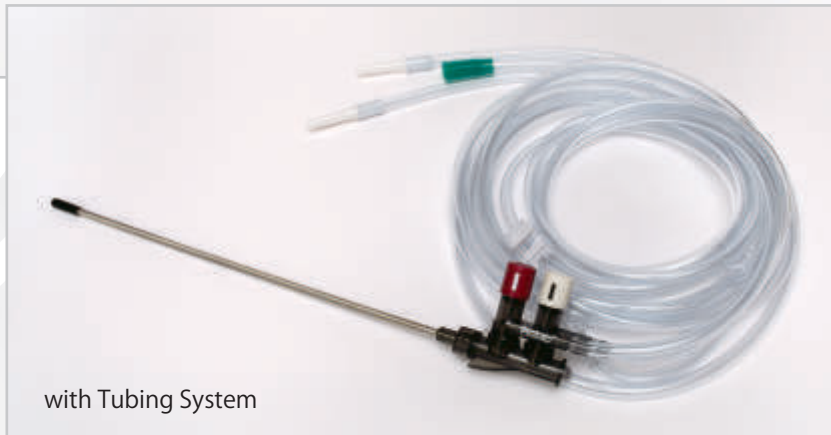
Product Description:

ProLap® Bladeless Trocar is a single-use instrument for Minimally Invasive Surgery (MIS) to puncture the abdominal wall for creating a working tunnel and maintaining the pneumoperitoneum during laparoscopic surgical procedures. The device finds use in laparoscopic surgery in gastro-enterology, colo-rectal, urology and gynaecology.

Distinctive Features:

- ◆ Bladeless obturator penetrates by dilating.
- ◆ 3-way stopcock design capable of rapid deflation, protecting against contamination.
- ◆ Blunt traumatic tip decreases the risk of damage to internal tissue.
- ◆ Tooth-like screw thread design to improve fixation.
- ◆ Universal seal provided for accommodation of 5mm to 10mm or 5mm to 12mm sized instruments.
- ◆ 5mm-12mm device can be used for visible trocar by inserting 10mm laparoscopic scope through obturator.

CODE	DEVICE	DESCRIPTION	PACKAGING
LBT3		Bladeless Trocar 3mm	1 unit per pack, 1 sealed pack per box
LBT5		Bladeless Trocar 5mm	
LBT10		Bladeless Trocar 5-10mm	
LBT12		Bladeless Trocar 5-12mm	
LBT15		Bladeless Trocar 15mm	
LBT10-2		Trocar Kit: Bladeless Trocar 5mm x 1 Bladeless Trocar 5mm Sleeve x 1 Bladeless Trocar 5-10mm x 1 Bladeless Trocar 5-10mm Sleeve x 1 Veress Needle x 1	1 unit each of kit contents in a single sealed pack, 1 sealed pack per box



ProLap®

Laparoscopic Instruments




Single-use Laparoscopic Suction & Irrigation Cannula

Product Description:

ProLap® Laparoscopic Suction & Irrigation Cannula with Tubing System is a single-use instrument for Minimally Invasive Surgery (MIS) procedures as a multi-purpose tool with suction and irrigation capabilities during laparoscopy.

Distinctive Features:

- ◆ Intuitive operation button for aspiration and irrigation.
- ◆ Ergonomic handle design for better control of instrument.
- ◆ Compatible with standard aspiration and irrigation machines in hospitals.

CODE	DEVICE	DESCRIPTION	PACKAGING
LLC 105-T		S&I Cannula w/Tubing System 5mm	3 sealed packs per box
LLC 110-T		S&I Cannula w/Tubing System 10mm	3 sealed packs per box
LLC 112-T		S&I Cannula w/Tubing System 12mm	3 sealed packs per box

Also available in single units in individual sealed packs.



Laparoscopic Retriever



Veress Needle

ProLap®

Laparoscopic Instruments

Single-use Laparoscopic Retriever

Product Description:

ProLap® Laparoscopic Retriever is a single-use instrument consisting of a tube and retrieval bag, designed for retrieving specimen in Minimally Invasive Surgery (MIS) procedures. The instrument is available in two sizes as per the dimensions of the retrieval bag.

Distinctive Features:

- ◆ Two sized bags to provide for adaptation to different specimens.
- ◆ Purse-string suture for easy closure of bag before withdrawal.
- ◆ Cost effective and convenient to use.

CODE	DEVICE	DESCRIPTION	PACKAGING
LLR90		Retriever 90mm x 155mm	6 sealed packs per box
LLR120		Retriever 120mm x 200mm	6 sealed packs per box

Also available in single units in individual sealed packs.

Single-use Veress Needle

Product Description:

ProLap® Veress Needle is a single-use instrument used to establish pneumoperitoneum prior to abdominal laparoscopy.

Distinctive Features:

- ◆ Spring-loaded blunt stylet mechanism.
- ◆ 14 gauge stainless steel needle.
- ◆ Comfortable gripping action on needle.

CODE	DEVICE	DESCRIPTION	PACKAGING
LVN120		Veress Needle	6 sealed packs per box

Also available in single units in individual sealed packs.

Hemosec®
Titanium Clips



Hemosec®
Clip Appliers

Hemosec®

Titanium Clips and Appliers

Product Description:

The Hemosec® Clip Applier is a reusable instrument designed to deliver and close metallic ligating clips. This instrument is used with Hemosec® Clips which are produced from titanium. The clips are designed for the ligation of tubular structures where a non absorbable ligating device is indicated.

The ligating clips are positioned around a tubular structure and closed by applying pressure to the handles of the applier.

Distinctive Features:

- ◆ Chevron shape of clips facilitates safe “tips-first” closing action.
- ◆ Serrated inner surface and heart-shaped cross-section of the clips allows secure closing.
- ◆ Diamond shaped grooving for atraumatic secure ligation.
- ◆ Triangular shaped wire for easy squeeze application.
- ◆ Adhesive cartridge backing ensures precise and effortless clip loading.
- ◆ **Control:** Jaws respond directly to the surgeon's hand, allowing complete control over clip closure.
- ◆ **Security:** Titanium clip manufacturing process ensures superior retention and reliability.
- ◆ **Comfort:** Ergonomically designed handle provides comfort and control.
- ◆ Colour-coded clips and corresponding colour-coded appliers for different sizes of clips.

TITANIUM CLIPS

Clip Size	Code	Packaging
Small	HTC S-6	Cartridge of 6 Small Clips; Box of 24 Cartridges
Medium	HTC M-6	Cartridge of 6 Medium Clips; Box of 24 Cartridges
Medium-Large	HTC ML-6	Cartridge of 6 Medium-Large Clips; Box of 18 Cartridges
Large	HTC L-6	Cartridge of 6 Large Clips; Box of 18 Cartridges

CLIP APPLIERS

Codes		Sizes
Open Appliers	Laparoscopic Appliers	for Clip Size
LOA-S	—	Small
LOA-M	LLA-M	Medium
LOA-ML	LLA-ML	Medium-Large
LOA-L	LLA-L	Large

Packaging: 1 Applier per Box



Hemolus™

Absorbable Hemostat (Oxidized Regenerated Cellulose)

Product Details:

Composition	Oxidized regenerated cellulose derivatives
Construction	Knitted fabric
Coating	None
Mechanism of Action	Absorbable hemostat upon contact with blood, transforms into a sticky, translucent gel that slows further diffusion of liquid molecules. It is fully bio-compatible and is broken down and completely absorbed by the body at rates that depend on the amount placed and the availability of fluid in the area where it has been applied
Tissue Reaction	When used properly in minimal amounts, Hemolus™ is absorbed from the sites of implantation with practically no tissue reaction
Degradation Time	2–4 weeks after in vivo implantation
Sterilization	Gamma Irradiation
Colour	White with pale yellow
Shelf Life	3 years
Packaging	Box of 12 pcs.

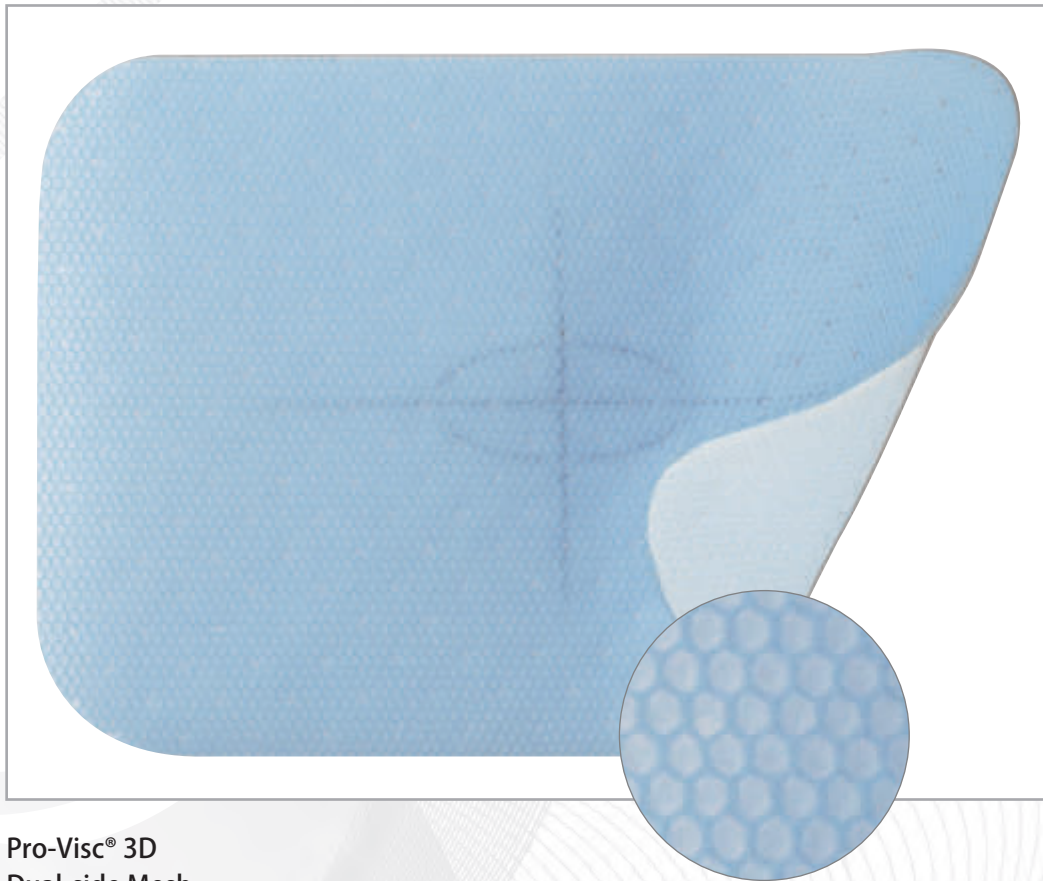
Distinctive Features:

- ◆ Material that drapes and wraps well.
- ◆ In addition to its local hemostatic properties, Hemolus™ is bactericidal In Vitro against a wide range of gram positive and gram negative organisms.

Available in Sizes

Oxidised Regenerated Cellulose [Original - Knit]

Code	Size
LH 1951	2 inch x 14 inch
LH 1952	4 inch x 8 inch
LH 1953	2 inch x 3 inch
LH 1954	½ inch x 2 inch



**Pro-Visc® 3D
Dual-side Mesh**

Pro-Visc® 3D

Composite Dual-side Mesh for Intra-peritoneal Placement

Product Description:

The first dual-side mesh in the market for intra-peritoneal placement, Pro-Visc® is a macro-perforated structure featuring two distinct sides – a permeable peritoneal side in polyester for good fibroblast colonization and rapid tissue fixation; and a non-absorbable and non-adherent smooth side in polyurethane allowing fluid transfer and contact with viscera. The dual-side mesh has a visual mark printed on it for easy mesh centering.

Product Details:

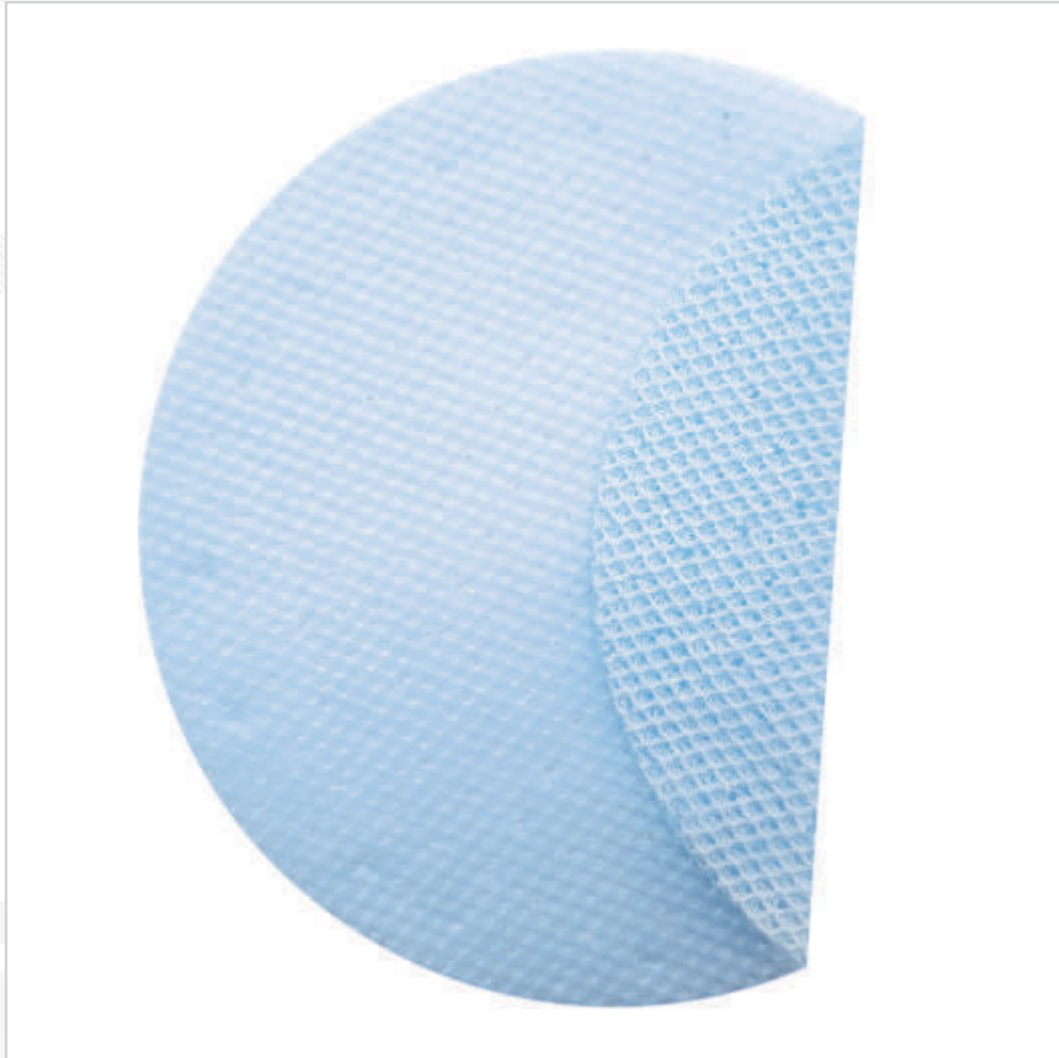
Composition	Polyester and Polyurethane
Absorption Time	Non-Absorbable
Sterilization	100% Ethylene Oxide
Mesh Weight	210 g/m ²
Mesh Thickness	1.5 mm
Elongation	32%
Maximum Force	23 kgf
Available in Sizes	Ø12 cm, 6 x 11 cm, 7.6 x 15 cm, 10 x 15 cm, 15 x 15 cm, 15 x 20 cm, 20 x 30 cm, 30 x 30 cm

Distinctive Features:

- ◆ Over 10 years human clinical experience.
- ◆ Pre-cut and entirely macro-perforated prosthesis.
- ◆ No viral contamination risk (100% synthetic materials).
- ◆ Excellent multidirectional mechanical properties and resistance to tearing.
- ◆ Ready for use prosthesis, with no preparation before implantation (minimum septic risks).
- ◆ Visual mark printed for easy mesh centering.
- ◆ 3D Honeycomb knitted structure for superior tissue integration and patient comfort.

Indications:









- ◆ Designed for intra-peritoneal placement.
- ◆ Treatment for ventral and umbilical hernias.
- ◆ Adapted to coelioscopy and laparotomy.



**Pro-Visc® 3D
Dual-side Mesh (circular)**

PRO-VISC® 3D
 Composite Dual-side Mesh for Intra-peritoneal Placement

3D Honeycomb Knitted Mesh

Mesh Shape	Mesh Size	Code	Packaging
	Ø 12 cm (Ø 4.7")	LH3D 1200	1 Unit per Box
	6 x 11 cm (2.3" x 4.3")	LH3D 66	1 Unit per Box
	7.6 x 15 cm (3" x 6")	LH3D 114	1 Unit per Box
	10 x 15 cm (4" x 6")	LH3D 150	1 Unit per Box
	15 x 15 cm (6" x 6")	LH3D 225	1 Unit per Box
	15 x 20 cm (6" x 8")	LH3D 300	1 Unit per Box
	20 x 30 cm (8" x 12")	LH3D 600	1 Unit per Box
	30 x 30 cm (12" x 12")	LH3D 900	1 Unit per Box



EndoTack™

Titanium Tacker

Product Description:

The EndoTack™ Titanium Tacker is a single-use instrument designed for the fixation of prosthetic material (surgical mesh) to soft tissue in laparoscopic and open hernioplasty. The instrument contains titanium alloy helical-shaped tacks which are fastened on firing of the device trigger. The instrument has a shaft diameter of 5 mm and can be used in laparoscopy through a 5 mm or larger trocar. The helical tacks deployed in the device are made of Ti-6Al-4V ELI Titanium alloy, compliant with the requirements of ASTM F136 standard for surgical implants.

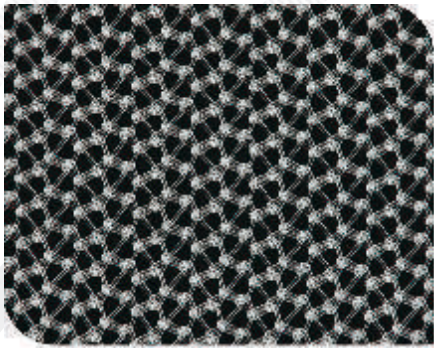
Product Details:

Material	Ti-6Al-4V ELI titanium alloy
Absorption	Non-absorbable
Tack Diameter	4 mm
Tack Height	3.8 mm
Tacker Shaft Diameter	5 mm
Trocar Usage	5 mm trocar or larger
Target Tissue Thickness	Minimum 5 mm
Mesh Usage	4 mm or larger pores
Shelf Life	4 years
Packaging	1 unit per pack

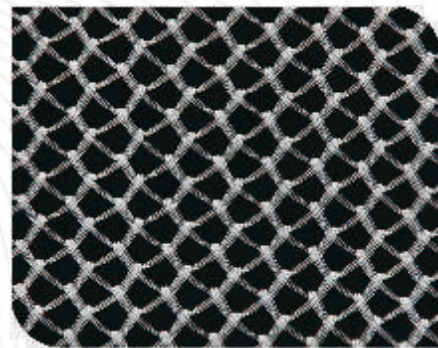
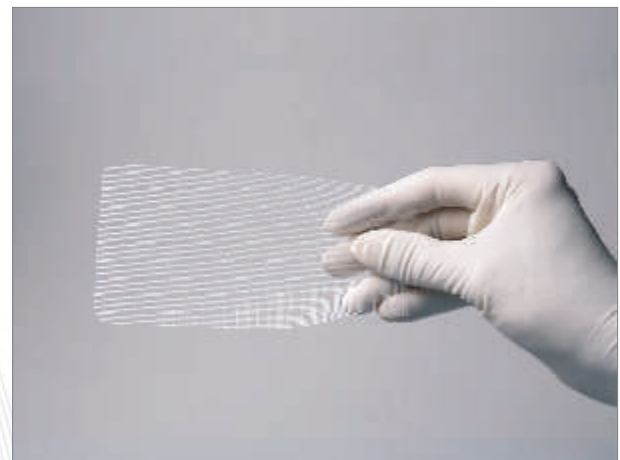
Distinctive Features:

- ◆ Titanium alloy tacks fully compliant with surgical implant standards.
- ◆ Easy and permanent mesh fixation with reliable effects.
- ◆ Precise and convenient tack firing through trigger mechanism.

Code	Shaft Length	Number of Tacks
LETT30L	360 mm	30 Helical Tacks



Prolus® Mesh - Standard
(magnified view)



Prolus® Mesh - Lite
(magnified view)

Prolus® ♦ Prolus® Lite

Polypropylene Meshes for Hernia Repair

Product Details:

Composition	Polypropylene
Construction	Monofilament
Absorption Time	Non-Absorbable
Sterilization	100% Ethylene Oxide

	Prolus® Standard	Prolus® Lite
Mesh Weight	80 g/m ²	45 g/m ²
Mesh Thickness	0.50 mm	0.43 mm
Pore Size	0.5 x 0.7 mm	1.3 x 1.0 mm
Elongation	89%	77%
Maximum Force	25 kgf	19 kgf
Available in Sizes	6 x 11 cm, 7.6 x 15 cm, 10 x 15 cm, 12 x 15 cm, 15 x 15 cm, 15 x 30 cm, 30 x 30 cm	
Shelf Life	5 years	
Packaging	1, 3 and 6 sheets per box	

Distinctive Features:





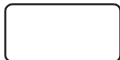
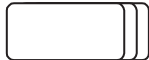






- ◆ Laser cut providing precise shape and preventing edges from fraying.
- ◆ Permeable giving it high capacity for colonization, good tissue ingrowth and integration.
- ◆ Transparent and flexible for easy use in coelioscopy and laparotomy. Fits perfectly against the cavity wall and avoids fragmentation.
- ◆ Excellent multi-directional mechanical properties and exceptional resistance to tearing.
- ◆ No shrinkage providing long term material stability.
- ◆ High strength and burst resistance for permanent support.
- ◆ Good shape memory.

Indications:

- ◆ Abdominal wall reinforcement.
- ◆ Treatment of incisional, inguinal, femoral, umbilical and ventral hernias.
- ◆ Use in both coelioscopy and laparotomy.

PROLUS® Mesh
Polypropylene Meshes for Hernia Repair

PROLUS® STANDARD : PROLUS® LITE

Mesh Shape	Mesh Size	Code	Packaging
	6 x 11 cm (2.3" x 4.3")	LM 66-1	1 Rectangular Sheet per Box
	6 x 11 cm (2.3" x 4.3")	LM 66-3	3 Rectangular Sheets per Box
	6 x 11 cm (2.3" x 4.3")	LM 66-6	6 Rectangular Sheets in a Plastic Box
	6 x 11 cm (2.3" x 4.3")	LM-PS	1 Pre-shaped Mesh per Box
	7.6 x 15 cm (3" x 6")	LM 114-1	1 Rectangular Sheet per Box
	7.6 x 15 cm (3" x 6")	LM 114-3	3 Rectangular Sheets per Box
	7.6 x 15 cm (3" x 6")	LM 114-6	6 Rectangular Sheets in a Plastic Box
	10 x 15 cm (4" x 6")	LM 150-1	1 Rectangular Sheet per Box
	12 x 15 cm (4.6" x 6")	LM 180-1	1 Rectangular Sheet per Box
	15 x 15 cm (6" x 6")	LM 225-1	1 Square Sheet per Box
	15 x 30 cm (6" x 12")	LM 450-1	1 Rectangular Sheet per Box
	30 x 30 cm (12" x 12")	LM 900-1	1 Square Sheet per Box

PROLUS® Mesh
 Polypropylene Meshes for Hernia Repair

HERNIA KIT

Kit Contents	Code	Packaging
1 Kit = Mesh : LM 66-1; Sutures : 1 Foil each of LNW 841, LNW 842, and either LNW 2407-910 or LNW 3326 (M)	HK 66-1	1 Hernia Kit per Box
1 Kit = Mesh : LM 114-1; Sutures : 1 Foil each of LNW 841, LNW 842, and either LNW 2407-910 or LNW 3326 (M)	HK 114-1	1 Hernia Kit per Box



Pro-AB®
Partially Absorbable Mesh

Pro-AB[®]

Partially Absorbable Surgical Mesh for Hernia Repair

Product Details:

Composition	Poly (glycolide-co-caprolactone), Polypropylene
Construction	Monofilament
Absorption Time	Partially Absorbable
Sterilization	100% Ethylene Oxide
Shelf Life	5 years
Packaging	1 unit per box

Mesh Size	Code
Ø12 cm (Ø4.7")	LAM 1200
6 x 11 cm (2.3" x 4.3")	LAM 66
7.6 x 15 cm (3" x 6")	LAM 114
10 x 15 cm (4" x 6")	LAM 150
15 x 15 cm (6" x 6")	LAM 225
15 x 20 cm (6" x 8")	LAM 300
20 x 30 cm (8" x 12")	LAM 600
30 x 30 cm (12" x 12")	LAM 900

Distinctive Features:

- ◆ Light weight mesh (Polypropylene amount < 30 gms/m²).
- ◆ Excellent handling and better patient comfort.
- ◆ Good initial stiffness during implantation.
- ◆ Excellent burst strength.
- ◆ Good flexibility after absorption.
- ◆ Better tissue integration due to large pores.
- ◆ Blue visible strips aid orientation and placement.
- ◆ Composed from tried and tested materials over a long period of time.

Indications:

- ◆ Treatment of inguinal and ventral hernias.



Freedom®
Trans-Obturator Sling



Freedom®
Trans-Obturator Needles

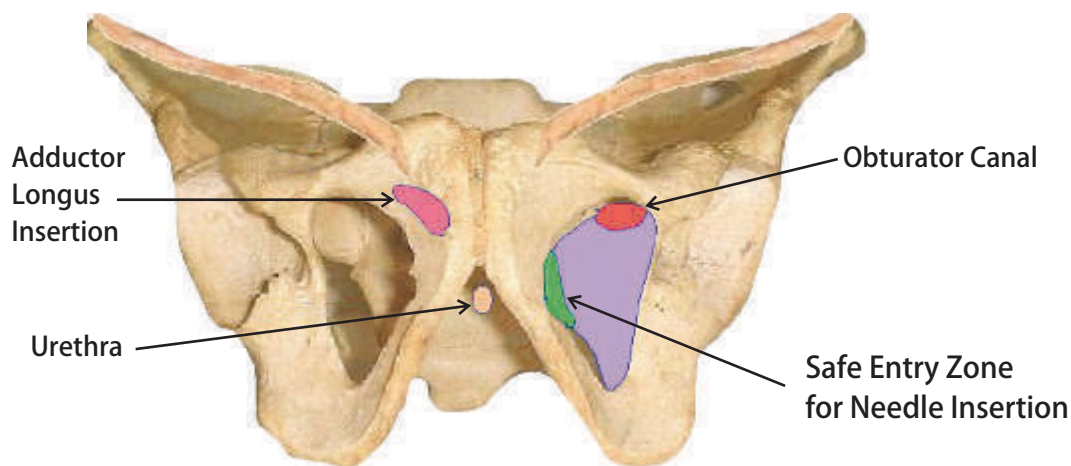
Freedom[®] Trans-Obturator Needles and Sling System

for Female Stress Urinary Incontinence


Product Description:

The Freedom[®] Trans Obturator Sling System is intended for the placement of a sub-urethral mesh for the treatment of female stress urinary incontinence (SUI) resulting from urethral hyper mobility and/or intrinsic sphincter deficiency.

Obturator Anatomy:



Product Details:

Sling:	Monofilament Dia. mm (in)	Typical Pore Size mm (in)	Burst Strength kpa (psi)	Break Strength N/2.5 cm (lbs/in)		Break Elongation (%)		Thick mm (in)	Wt. g/m ² (oz/yd ²)
				MD	CMD	MD	CMD		
	0.15 (.006)	1.3 x 1.0 (.051 x .039)	1172 (162)	526 (118)	492 (111)	107	175	0.59 (.023)	100 (2.9)

Code	Description
F VM-S	Freedom [®] Trans-Obturator Sling System
F RM-NDL	1 Set of Freedom [®] Trans-Obturator Needles with CD
F RM-KIT	Kit of 1 Set Freedom [®] Needles + 3 Freedom [®] Trans-Obturator Sling System + CD



ProLysate®

Handrub and Surgical Handwash

Product Description:

ProLysate® is a combination of Chlorhexidine and Ethanol, engineered to provide instant and cumulative protection against micro-organisms residing on intact skin surfaces. ProLysate® works by disrupting the microbe's cell membrane, thereby causing cell lysis and killing the organism.

Product Details:

ProLysate® Handrub

Chlorhexidine/Alcohol Skin Antiseptic
Chlorhexidine Gluconate Solution IP 2.5% v/v
(equivalent to 0.5% w/v Chlorhexidine Gluconate)
Ethanol IP (Absolute Alcohol) 70% v/v
Emollient and Moisturiser
Colour: Carmosine

ProLysate® Surgical Handwash

Chlorhexidine Skin Antiseptic
Chlorhexidine Gluconate Solution IP 20% v/v
(equivalent to 4% w/v Chlorhexidine Gluconate)
Non-ionic detergent base q.s.
Emollient and Moisturiser
Colour: Carmosine

Distinctive Features:

- ◆ Instant and cumulative protection against microbes.
- ◆ Well balanced formulation containing emollients and moisturisers.
- ◆ Extremely skin friendly and non-irritating.

Indications:

ProLysate® Handrub has application for instant hand antisepsis and skin antisepsis.

ProLysate® Surgical Handwash has application for antimicrobial hand washing, surgical hand washing and body wash.

Code	Description	Packaging
PHR 100	ProLysate® Handrub	100 ml.
PHR 500	ProLysate® Handrub	500 ml.
PHW 100	ProLysate® Surgical Handwash	100 ml.
PHW 500	ProLysate® Surgical Handwash	500 ml.



MISCELLANEOUS PRODUCTS

Miscellaneous Medical Products for Various Surgical Procedures:

LOTUS® UMBILICAL COTTON TAPE

Lotus® Sterile Umbilical Cotton Tape is available in pre-cut lengths to tie off the umbilical stump during the catheterization process. It is also used to tie off the umbilical cords of newborn infants. The Umbilical Cotton Tape also finds application in a wide range of procedures, as well as for a variety of veterinary purposes.

Product Details:

Composition	White Woven Cotton
Sterilization	100% Ethylene Oxide
Shelf Life	5 years
Packaging	12 pouches packed in a mono carton

Code	Size	Quantity per Pack	Quantity per Box
LW 276	3 mm x 75 cm Cotton Tape	1 length	12 Foils
LW 276 A	3 mm x 25 cm Cotton Tape	3 lengths	12 Foils

LOTUS® TEMPORARY CARDIAC PACING WIRE

Lotus® Temporary Cardiac Pacing Wire is a sterile single use product that provides a conductive connection between an external pacemaker and the myocardium. It is used for treating post-operative cardiac arrhythmia of heart surgery.

Product Details:

Composition	Sheathed Multi-filament Steel Wire with Needles
Sterilization	100% Ethylene Oxide
Shelf Life	5 years
Packaging	12 pouches packed in a mono carton

Code	Needle Description	Wire Type	Quantity per Pack	Quantity per Box
LFEP 13	18 mm ½ Circle Taper Cut and 63 mm Straight Cutting Edge, Breakaway Needle	Electrode Blue 60 cm Pacing Wire	1	12 Foils
LFEP 15	26 mm ½ Circle Taper Cut and 63 mm Straight Cutting Edge, Breakaway Needle	Electrode Blue 60 cm Pacing Wire	1	12 Foils

LOTUS® BONE WAX

Lotus® Bone Wax is a sterile mixture of beeswax and isopropyl palmitate, a wax-softening agent, used to help control bleeding from bone surfaces.

Product Details:

Composition	Bees Wax I.P., Iso Propyl Palmitate U.S.P.
Colour	Opaque
Odour	Waxy Odour
Sterilization	Sterilized by Gamma Radiation
Shelf Life	5 years
Packaging	12 pouches packed in a mono carton

Distinctive Features:

- ◆ Helps local haemostasis by functioning like a mechanical barrier.
- ◆ Bio-chemically inert and minimally resorbable.
- ◆ Compatible with body tissues, does not induce skin irritation or any allergic reactions.

Code	Contents per Pack	Quantity per Pack	Quantity per Box
LW 810	2.5 grams	1	12 Foils

LOTUS® PLEDGETS

Lotus® Pledgets are sterile single use products, pre-cut rectangular and square-shaped, for use where the surgeon may consider it advantageous to buffer the suture line.

Product Details:

Composition	PTFE (Polytetrafluoroethylene)
Sterilization	100% Ethylene Oxide
Shelf Life	5 years
Packaging	6 pledgets per pouch; 10 pouches per mono carton

Code	Pledget Size	Quantity per Pouch	Quantity per Box
LCP 10	3 mm x 3 mm x 1.5 mm	6 sterile pledgets per foil	10 foils per box
LCP 10-T	3 mm x 3 mm x 0.5 mm	6 sterile pledgets per foil	10 foils per box
LCP 20	6 mm x 3 mm x 1.5 mm	6 sterile pledgets per foil	10 foils per box

LOTUS® SURGICAL KITS

Ready Kits for Specific Surgical Procedures:

Lotus® Surgical Kits are ready combinations of sutures (and meshes, where required), to be utilized for specific surgical procedures. Each kit is configured for single patient use.

HERNIA KIT

Kit Contents	Code	Packaging
1 Kit = Mesh : LM 66-1; Sutures : 1 Foil each of LNW 841, LNW 842, and either LNW 2407-910 or LNW 3326 (M)	HK 66-1	1 Hernia Kit per Box
1 Kit = Mesh : LM 114-1; Sutures : 1 Foil each of LNW 841, LNW 842, and either LNW 2407-910 or LNW 3326 (M)	HK 114-1	1 Hernia Kit per Box

C-SECTION KIT

Kit Contents	Code	Packaging
1 Kit = Sutures : 1 Foil each of LNW 2364-910, LNW 2518-910, LNW 3326 (M)	LCS KIT	4 Kits per Box

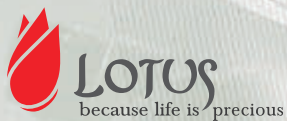
ABDOMINAL HYSTERECTOMY KIT

Kit Contents	Code	Packaging
1 Kit = Sutures : 3 Foils of LNW 2364-910, and 1 Foil of LNW 3326 (M)	LAH KIT	4 Kits per Box

Lotus® Surgical Kits can also be customised to suit individual doctor requirements.



LOTUS



Lotus Surgicals Pvt. Ltd.

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Senapati Bapat Marg, Lower Parel, Mumbai 400 013 INDIA
Tel: 91-22-66572555 Telefax: 91-22-24913543
Email: info@lotus-surgicals.com
Web: www.lotus-surgicals.com



Notified body 0123

INSTRUCTIONS FOR USE

(Doc. No.: TI/IFU/02, Issue No.: 02, Rev No.: 01, Dt: 24/05/2024)



A Brand of TI MEDICAL

STERILE ABSORBABLE SURGICAL SUTURES BRAIDED COATED POLYGLYCOLIC ACID SUTURE

Braided coated Polyglycolic acid suture with needle (Violet)

Braided coated Polyglycolic acid suture without needle (Violet)

Braided coated Polyglycolic acid suture with needle (Undyed)

Braided coated Polyglycolic acid suture without needle (Undyed)

BRAND NAME: - Solus/ PGA 30/ VICOSORB PGA

USP Sizes	Metric size (Gauge No.)	Needle profile
8-0	0.4	Taper Point (Round Body), Taper Cutting, Reverse Cutting, Blunt, Spatulated, Trocar Point, Diamond Point
7-0	0.5	
6-0	0.7	
5-0	1	
4-0	1.5	
3-0	2	
2-0	3	
1-0	3.5	
1	4	
2	5	
3&4	6	
Needle curvature: 1/2 Circle, 1/4 Circle, 3/8 Circle, 5/8 Circle, Straight & J type		

DEVICE DESCRIPTION:

This device is a synthetic, absorbable, sterile, surgical suture, made from Polyglycolide and these sutures are coated with a mixture, composed of Glacomer 37 and Calcium Stearate. This suture is available in undyed and violet colour. The violet colour sutures are dyed by adding D & C Violet # 2, during polymerization. These sutures are available in a range of gauge sizes and lengths, non-needled or attached to stainless steel needles of varying types and sizes. The finished sutures are packed in aluminum foil pouch and this primary package is sterilized by using ETO. These pouches are supplied in 12, 24, or 36 units per mono carton along with Instruction for Use (IFU). It complies with the requirements of the United States Pharmacopoeia for "Absorbable Surgical

Suture". This suture is intended to use only in a sterile clinical environment.

INTENDED PURPOSE:

Braided coated Polyglycolic acid suture is intended for use in general soft tissue approximation and/or ligation.

INDICATIONS FOR USE:

The device is used for the closure of general soft tissue and/or ligation especially in general surgery, skin closure, gastrointestinal surgery, gynaecology, obstetrics, plastic surgery, urology, ophthalmic surgery, and orthopaedics.

INTENDED PATIENT POPULATION:

This device is intended for the closure of wounds or surgical incisions on the skin or any other body tissues and ligation of tubules in patients of varying age groups in line with the intended use, indication, and contraindication.

INTENDED USERS:

This device is used by general surgeons, gynaecologists, ophthalmologic surgeons, gastrointestinal surgeons, and other qualified medical professionals.

CLINICAL BENEFITS:

- Elimination of suture removal
- Reduced tissue reaction
- Customized absorption rates
- Facilitates wound healing
- Reduced patient discomfort

PERFORMANCE CHARACTERISTICS:

- High tensile strength
- Low tissue reactivity
- Good knot security
- Better handling characteristics
- Breaks down by hydrolysis

TYPE OF USE:

This device is for single use only. Reuse of the device can lead to dangerous biological contamination causing severe consequences to the patient.

CONTRAINDICATIONS:

This suture, being absorbable, should not be used where an extended approximation of tissues is required.

LIMITATIONS:

It is not for use in cardiovascular and neurologic tissues.

OVERALL QUALITATIVE AND QUANTITATIVE INFORMATION:

Raw Material	Quantity / Concentration	Formulation
Braided coated Polyglycolic acid suture (Violet).		
Suture Material	Polyglycolide	≥ 94.9 % (C ₂ H ₂ O ₂) _n
	D&C VIOLET NO. 2	≤ 0.1 % C ₂₁ H ₁₅ NO ₃
Coating Material	Glacomer 37 (60%)	≤ 5 % [(C ₂ H ₂ O ₂) _x -(C ₃ H ₄ O ₂) _y] _n (where x: y = 3:7)
	Calcium stearate (40%)	
Braided coated Polyglycolic acid suture (Undyed).		
Suture Material	Polyglycolide	≥ 95.0 % (C ₂ H ₂ O ₂) _n
Coating Material	Glacomer 37 (60%)	≤ 5 % [(C ₂ H ₂ O ₂) _x -(C ₃ H ₄ O ₂) _y] _n (where x: y = 3:7)
	Calcium stearate (40%)	

WARNINGS:

- Do not use this device if package is found open/damaged.
- Discard open packages and unused sutures.
- Do not reprocess or re-sterilize as it may compromise the structural integrity of the device and/ or lead to device failure, which, in turn, may result in patient injury or illness and may also create a risk of contamination of the device and/or cause patient infection or cross-infection.
- The device should be disposed of in accordance with the user's country's disposal regulations and Hospital/Clinic protocol. If not disposed of properly it may lead to environmental pollution, needle pricks, and infectious diseases.
- Do not make the sutures wet or moist during handling, prior to being implanted in tissue.
- Do not open the device in an unsterile environment.
- Users should be familiar with surgical procedures and techniques involving absorbable sutures

before employing these sutures for wound closure as the risk of wound dehiscence may vary with the site of application and the suture material used.

- Surgeons should consider the in-vivo performance when selecting a suture for use in patients. The use of this suture may be inappropriate in elderly, malnourished, or debilitated patients, or in patients suffering from conditions which may delay wound healing.
- Prolonged contact of Braided coated Polyglycolic Acid Suture with a salt solution such as those found in urinary and biliary tracts may result in calculus formation.
- Acceptable surgical practice should be followed for the management of contaminated or infected wounds.
- Use of this suture on patients who are allergic to polyglycolic acid, calcium stearate may lead to Edema/Infection/ Inflammation/ Delay in wound healing/ post-surgery infection.
- Users should be familiar with surgical procedures and techniques involving absorbable sutures before employing sutures for wound closure, as risk of wound dehiscence may vary with the site of application and the suture material used.

PRECAUTIONS:

- Skin sutures, which remain in place for more than 7 days may cause localized irritation and should be snipped off or removed as indicated.
- As this is an absorbable suture material, the use of supplemental non absorbable sutures should be considered by the surgeon in the closure of sites undergoing expansion, stretching or distention or which may require additional support.
- When handling this or any other suture, 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. 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.
- Consideration should be taken in the use of absorbable sutures in tissues with poor blood

INSTRUCTIONS FOR USE

(Doc. No.: TI/IFU/02, Issue No.: 02, Rev No.: 01, Dt: 24/05/2024)

supply as suture extrusion and delayed absorption may occur.

- Under some circumstances, notably Orthopaedic procedures, immobilization of joints by external support may be employed at the discretion of the surgeon.
- Avoid excessive tension when tying the sutures, as it may lead to tissue ischemia or damage. Use the appropriate tension for the specific surgical procedure and the patient's condition.
- Consider the patient's medical history, allergies, and individual factors that may affect the choice and use of sutures.

RESIDUAL RISKS/ UNDESIRABLE SIDE EFFECTS:

- The suture may act transiently as a foreign body and may cause transient local irritation or inflammation and discomfort at the wound site.
- Bacterial pathogens colonizing the suture surface may lead to surgical site infection.

STERILITY:

Do not re-sterilize as the Braided coated Polyglycolic acid sutures are sterilized by using Ethylene Oxide.

APPLICATION:

Sutures should be selected and implanted depending on the patient's condition, surgical history, surgical technique, and wound size.

HANDLING OF THE DEVICE:

1. 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.



2. Project the sterile card on the sterile table only after peeling apart the peelable foil completely.
3. Hold the card in your gloved left hand securely without bending it as shown in the figure.



4. Arm the needle with an appropriate needle holder using the no-touch technique. Remove the needed suture with a smooth and moderate pull in a direction parallel to the card. (Suture with needle).



5. Remove the suture with the help of the forceps or sterilized glove in a direction parallel to the card with smooth and moderate pull (Suture without needle).
6. If resistance is observed while removing. Then relax the suture and pull again. Please do not pull against the swaged end of the suture.

STORAGE:

Recommended storage condition is to store at a temperature below 26°C, away from moisture & direct sunlight. Do not use it after the expiry date.

LINK TO THE SUMMARY OF SAFETY CLINICAL PERFORMANCE:

- The SSCP is available in the European database on medical devices (EUDAMED) where it is linked to the Basic UDI-DI.
- The URL to the EUDAMED: <https://ec.europa.eu/tools/eudamed>
- The Basic UDI-DI for searching the intended SSCP in EUDAMED is 89042482SOL001PE.

COMPETENT AUTHORITY:

Name: Federaal Agentschap voor Geneesmiddelen en Gezondheidsproducten
Address: Avenue Galilée/Galileelaan 5/03, 1210 Bruxelles-Brussel, Brussel – Bruxelles, Belgium
Mail: notifications.meddev@fagg-afmps.be
Tel: +32 2 528 40 00

NOTE: Any serious incident that occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

EXPLANATION OF SYMBOLS	
Symbol	Title
	CE Logo with Notified Body Number
	Manufacturer
	Authorized Representative in the European Community/ European Union
	Date of Manufacture
	Sterilized using Ethylene Oxide
	Do not re- use
	Do not re-sterilize
	Batch code
	Use-by Date
	Catalogue Number
	Caution
	Do not use if package is damaged and consult instructions for use
	Keep away from Sunlight
	Unique Device Identifier
	Upper limit of temperature

	Single Sterile Barrier System used in combination with Sterilized using ethylene oxide
	Single Sterile Barrier System with protective packaging outside
	Medical device
	Consult instructions for use or consult electronic instructions for use
	Importer
	Distributor
	Keep dry

OBELIS S.A
 Bd. Général Wahis, 53
 1030 Brussels,
 Belgium

TI Medical Private Limited
 (Formerly known as Lotus Surgicals Pvt. Ltd.)
 Khasra No. 1051/1&2, Twin Industrial Estate,
 Selaqui, Dehradun 248197, Uttarakhand, INDIA.
 Customer Care Number (24x7): +91 135 2698661
 Email: info@timedical.murugappa.com
 Website: www.timedical.com

Mfg. Lic. No.: MFG/MD/2024/000202

INSTRUCTIONS FOR USE

(Doc. No.: TI/IFU/09, Issue No.: 02, Rev No.: 01, Dt: 24/05/2024)



A Brand of TI MEDICAL

STERILE NON-ABSORBABLE SURGICAL SUTURES MONOFILAMENT POLYAMIDE SUTURE

Monofilament Polyamide Suture with Needle (Black)

Monofilament Polyamide Suture without Needle (Black)

Monofilament Polyamide Suture with Needle (Blue)

Monofilament Polyamide Suture without Needle (Blue)

Brand Name: Nylus/Nylon/NYLEX

USP Sizes (Black)	Metric size (Gauge No.)	Needle profile
11-0	0.1	Straight cutting, Reverse cutting, Taper point, Taper cutting, Reverse cutting precision point, round-bodied, spatulated cutting, Micro point cutting
10-0	0.2	
9-0	0.3	
8-0	0.4	
7-0	0.5	
6-0	0.7	
5-0	1	
4-0	1.5	
3-0	2	
2-0	3	
0	3.5	
1	4	
2	5	

Needle Curvature: Straight 1/2 circle, and 3/8 circle

USP Sizes (Blue)	Metric Size (Gauge No.)	Needle Profile
4-0	1.5	Not Applicable
3-0	2	
2-0	3	
0	3.5	
1	4	
2	5	

DEVICE DESCRIPTION:

This is a synthetic non-absorbable, sterile, single-use, monofilament surgical suture, composed of long chain-aliphatic polymers, Polyamide 6, and Polyamide 6.6. It is available as dyed black to enhance the visibility in tissue. It is available in a range of gauge sizes and lengths, attached to stainless steel needles of varying types and sizes, and non-needed. The finished sutures are packed in a medical-grade paper and poly-film pouch and then sealed. These primary packs are sterilized by using ETO and are supplied in 12, 24, or 36 units per mono carton along with Instruction for Use (IFU), and such multiple mono cartons are packed in the master cartons. These sutures comply with the requirements of the United States Pharmacopoeia for "Non-Absorbable Surgical Suture" and are intended to be used only in a sterile clinical environment like an operating room.

INTENDED PURPOSE:

Monofilament Polyamide Suture is intended for use in general soft tissue approximation and/or ligation.

INDICATION FOR USE:

This Suture is indicated for repairing or joining the soft tissues of wounds or incisions through approximation and for ligation of tubal structures, during ophthalmic, orthopedic, plastic, microsurgeries, and ligament/tenon repairs.

INTENDED PATIENT POPULATION:

This is intended for the closure of wounds or surgical incisions on the skin or any other body tissue and ligation of tubules in patients of varying age groups in line with the intended use, indication, and contraindication.

INTENDED USERS:

Used by trained & experienced surgeons, registered nurses & other medical personnel only.

CLINICAL BENEFITS:

- Better healing of the wounds
- Patient Satisfaction
- Better tissue healing
- Low risk of wound complications
- Low rate of tissue reactivity
- Minimum inflammatory reaction

PERFORMANCE CHARACTERISTICS:

- Good knot security
- Excellent handling

- Better tensile strength stability

TYPE OF USE:

This device is for single use only. Reuse of the device can lead to Cross-contamination causing severe consequences to the patient.

CONTRAINDICATIONS:

- Use of this suture to prolonged contact with the salt solution such as those found in the urinary and biliary tract can result in calculus formation.
- This suture may be inappropriate in patients suffering from conditions that may delay wound healing.

LIMITATIONS:

Monofilament Polyamide sutures should not be used in Cardiovascular surgery, Urinary tract surgery, Biliary tract surgery, and Gastrointestinal surgery.

OVERALL QUALITATIVE AND QUANTITATIVE INFORMATION:

Sl. No.	Raw Material	Composition	Formulation
Monofilament Polyamide Suture (Black)			
1	Polyamide 6-6.6	≥ 99.5%	PA-6: NH-(CH ₂) ₅ CO PA-6.6: C ₁₂ H ₂₂ N ₂ O ₂
2	Pigment Black 7	≥ 0.5%	Cn
Monofilament Polyamide Suture (Blue)			
1	Polyamide 6-6.6	≥ 99.5%	PA-6: NH-(CH ₂) ₅ CO PA-6.6: C ₁₂ H ₂₂ N ₂ O ₂
2	Copper Phthalocyanine	≥ 0.5%	C ₃₂ H ₁₆ CuN ₈

WARNINGS:

- Do not use tampered or damaged products that happened during the process of transportation and storage.
- Do not use improperly labelled pack.
- Do not open the pack in a non-sterile environment.
- Discard open, unused packs.
- Do not use the expired product.

- Do not expose the pack to chemical disinfectants containing oxidizing agents like Hydrogen Peroxide or other similar chemicals, this may affect the product quality.
- To be disposed of as per the user's country disposal regulations and hospital/clinic protocol. If not disposed of properly it may lead to environmental pollution, needle pricks, and infectious diseases.

PRECAUTIONS:

- Read and follow the instruction before performing the surgery.
- Sutures should be handled by trained professionals familiar with surgical procedures & techniques.
- Care should be taken to avoid damage from handling surgical needles.
- Avoid crushing or crimping damage due to the application of surgical instruments such as forceps or needle holder.
- As this is a non-absorbable suture, the surgeon in the closure of sites undergoing expansion, stretching or distention, which may require additional support, should consider the use of supplemental non absorbable suture. Under some circumstances, notably orthopedic procedures, immobilization by external support may be employed at the discretion of the surgeon.
- Closely monitoring the wound and suture site for signs of infection or microbial adhesion.
- Improper handling of sutures may lead to unnecessary infections and bleeding.
- Mismanagement of sutures at the surgical site by patients may lead to bleeding, infection, inflammation, wound dehiscence, and/or stitch abscess.

RESIDUAL RISK / UNDESIRABLE SIDE EFFECTS:

- Use of Monofilament Polyamide on patients who have an unknown clinical history of allergy may lead to allergic reactions, rashes, or inflammation.
- As a non-absorbable suture, it may act transiently as a foreign body. As with any foreign material in the presence of the foreign body, bacterial infectivity, acceptable surgical practice must be followed with respect to drainage and closure of infected or contaminated wounds.

STERILITY:

These sutures are sterilized by using Ethylene Oxide. Do not re-sterilize.

INSTRUCTIONS FOR USE

(Doc. No.: TI/IFU/09, Issue No.: 02, Rev No.: 01, Dt: 24/05/2024)

APPLICATION:

Monofilament polyamide sutures should be selected and implanted depending on the patient's condition, surgical history, surgical technique, and wound size.

HANDLING OF THE DEVICE:

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



2. Grasp transparent poly film with the thumb and index finger of the left hand, gripping the pack between knuckles thus exposing to sterile card.
3. Project the sterile card onto the sterile table only after peeling apart the peelable foil completely.



4. Arm the needle with an appropriate needle holder using the no-touch technique. Remove the needled suture with a smooth and moderate pull in a direction parallel to the card. (Suture with needle).



5. Remove the suture with the help of the forceps or sterilized glove in a direction parallel to the card with smooth and moderate pull (Suture without needle).
6. If resistance is observed while removing. Then relax the suture and pull again. Please do not pull against the swaged end of the suture.

STORAGE:

Recommended storage condition is to store at a temperature below 26°C, away from moisture & direct sunlight. Do not use it after the expiry date.

LINK TO THE SUMMARY OF SAFETY CLINICAL PERFORMANCE:

- The SSCP is available in the European database on medical devices (EUDAMED) where it is linked to the Basic UDI-DI.
- The URL to the EUDAMED: <https://ec.europa.eu/tools/eudamed>
- The Basic UDI-DI for searching the intended SSCP in EUDAMED is: 89042482NYL008R9.

COMPETENT AUTHORITY:

Name: Federaal Agentschap voor Geneesmiddelen en Gezondheidsproducten
Address: Avenue Galilée/Galileelaan 5/03, 1210 Bruxelles-Brussel, Brussel – Bruxelles, Belgium
Mail: notifications.meddev@fagg-afmps.be
Tel: +32 2 528 40 00

NOTE: Any serious incident that occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.



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 Belgium



TI Medical Private Limited
 (Formerly known as Lotus Surgicals Pvt. Ltd.)
 Khasra No. 1051/1&2, Twin Industrial Estate,
 Selaqui, Dehradun 248197, Uttarakhand, INDIA.
 Customer Care Number (24x7): +91 135 2698661
 Email: info@timedical.murugappa.com
 Website: www.timedical.com

Mfg. Lic. No.: MFG/MD/2024/000202

EXPLANATION OF SYMBOLS	
Symbol	Title
	CE Logo with Notified Body Number
	Manufacturer
	Authorized Representative in the European Community/ European Union
	Date of Manufacture
	Sterilized using Ethylene Oxide
	Do not re- use
	Do not re-sterilize
	Batch code
	Use-by Date
	Catalogue Number
	Caution
	Do not use if package is damaged and consult instructions for use
	Keep away from Sunlight
	Unique Device Identifier
	Upper limit of temperature

	Single Sterile Barrier System used in combination with Sterilized using ethylene oxide
	Single Sterile Barrier System with protective packaging outside
	Medical device
	Consult instructions for use or consult electronic instructions for use
	Importer
	Distributor
	Keep dry

INSTRUCTIONS FOR USE

(Doc. No.: TI/IFU/12, Issue No.: 02, Rev No.: 01, Dt: 24/05/2024)



STERILE NON-ABSORBABLE SURGICAL SUTURES BRAIDED COATED POLYESTER SUTURE

Braided coated Polyester Suture with Needle (Green)

Braided coated Polyester Suture without Needle (Green)

Braided coated Polyester Suture with Needle (White)

Braided coated Polyester Suture without Needle (White)

Braided coated Polyester Suture with Needle (Green & White)

Brand Names: Esterlus/Polyester/POLYCRON

USP Sizes (with Needle)	Metric size (Gauge No.)	Needle profile
5-0	1	Taper point, Micro point spatulated, Taper cut, Diamond point, Reverse cutting, Reverse round bodied heavy, circle cutting.
4-0	1.5	
3-0	2	
2-0	3	
0	3.5	
1	4	
2	5	
5	7	
Needle Curvature: ¼ circle, ½ circle, and 5/8 circle		
USP Sizes without Needle	Metric size (Gauge No.)	Needle profile
4-0	1.5	Not Applicable
3-0	2	
2-0	3	
0	3.5	
1	4	
2	5	

DEVICE DESCRIPTION:

This is a non-absorbable, sterile, single-use surgical suture, composed of fine filaments of polyethylene terephthalate. The fine polyester fibers are braided to produce a suture that remains soft & pliable. The

device is coated with silicon which helps in easy passage through the tissue without irritation. It is available in dyed green color(D & C green No.6) that can be attached to various needle types, shapes, and lengths or non-needled. These are packed in a suture card which is further packed & sealed. Based on the number of sutures(10,4,1) wound in the suture card and packed in the Medical Grade paper & poly-film pouch (1 suture) and Tyvek pouch (10 and 4 sutures). However, the primary packing (Medical grade pouch) is terminally sterilized by ethylene oxide. These pouches are supplied in 6, 12, 24, or 36 units per box packing configuration along with Instruction for Use (IFU) and such multiple mono cartons are packed in the master carton. These sutures comply with the requirements of the United States Pharmacopoeia for "Non-Absorbable Surgical Suture". These sutures are intended to be used only in a sterile clinical environment like the operating room.

INTENDED PURPOSE:

Braided coated polyester suture is intended for use in general soft tissue approximation and/or ligation.

INDICATION FOR USE:

These sutures are indicated for repairing or joining the soft tissues of wounds or incisions through approximation and for ligation of tubal structures, during gynecological surgery orthopedic surgery, ophthalmic surgery, hernia repair, and prosthetic implantations.

INTENDED PATIENT POPULATION:

This is intended for the closure of wounds or surgical incisions on the skin or any other body tissue and ligation of tubules in patients of varying age groups in line with the intended use, indication, and contraindication.

INTENDED USERS:

Used by trained & experienced orthopedic surgeons, gynecologists, registered nurses & other medical personnel only.

CLINICAL BENEFITS:

- Excellent Fracture healing
- Minimal tissue reactivity
- Patient Comfort & Satisfaction
- Reduction in the rate of wound complications
- Favorable Handling Characteristics

PERFORMANCE CHARACTERISTICS:

- Outstanding knot security
- Excellent tissue support

TYPE OF USE:

This device is for single use only. Reuse of the device can lead to cross-contamination causing severe consequences to the patient.

CONTRAINDICATIONS:

Do not expose the suture to prolonged contact with the salt solution such as those found in the urinary and biliary tract which may result in calculus formation.

LIMITATIONS

There is no evidence of limitations.

OVERALL QUALITATIVE AND QUANTITATIVE INFORMATION:

Raw Material	Composition	Formulation
Braided coated Polyester Suture - Green		
Polyethylene terephthalate	> 98%	(C10H8O4)n
D&C No. 6 Green	< 0.75%	Cn
Nu-Sil MED-2174 Elastomer	1-2%	(R2SiO)x
Braided coated Polyester Suture - White		
Polyethylene terephthalate	> 98%	(C10H8O4)n
Nu-Sil MED-2174 Elastomer	1-2%	(R2SiO)x

WARNINGS:

- Do not use tampered or improperly labelled pack.
- Do not use the damaged product happened during the process of transportation and storage.
- Do not open the pack in a non-sterile environment.
- This suture may be inappropriate in patients suffering from conditions that may delay wound healing.
- Do not use the expired product.

- Do not dispose of the waste in a normal bin. To be disposed of as per the user's country disposal regulations and hospital/clinic protocol. If not disposed of properly it may lead to environmental pollution, needle pricks, and infectious diseases.

PRECAUTIONS:

- Ensure the package is intact before opening.
- Read the labelling instructions thoroughly on the package before opening it.
- Read and follow the instruction before performing the surgery.
- Sutures should be handled by trained professionals.
- Only trained surgeons must perform the approximation procedure.
- Care should be taken to avoid damage from handling surgical needles.
- Avoid crushing or crimping damage due to application of surgical instruments such as forceps or needle holder.
- Avoid off-label use and misuse of the suture.
- Allergy tests must be recommended for patients of unknown sensitivities.
- Additional support may be required in the closure of sites undergoing expansion, stretching, or distention.
- Closely monitoring the wound and suture site for signs of infection or microbial adhesion.
- Suture should be removed after the wound is healed, to prevent any complications.
- Improper handling of suture may lead to unnecessary infections and bleeding.
- Mismanagement of suture at the surgical site by patients may lead to bleeding, infection, inflammation, wound dehiscence and/or stitch abscess.
- Early removal of suture post-surgery may lead to bleeding, infection, and/or wound dehiscence.

RESIDUAL RISK / UNDESIRABLE SIDE EFFECTS:

- Use of Polyester sutures on patients who have an unknown clinical history of allergy may lead to allergic reactions, rashes or inflammation.
- As a non-absorbable suture, it may act transiently as a foreign body. As with any foreign material in the presence of the foreign body, bacterial infectivity, acceptable surgical practice must be followed with respect to drainage and closure of infected or contaminated wounds.

INSTRUCTIONS FOR USE

(Doc. No.: TI/IFU/12, Issue No.: 02, Rev No.: 01, Dt: 24/05/2024)

STERILITY:

Braided-coated Polyester sutures are sterilized by Ethylene Oxide. Do not re-sterilize the product.

APPLICATION:

These sutures should be selected and implanted depending on the patient's condition, surgical history, surgical technique, and wound size.

HANDLING OF THE DEVICE:

1. Hold the foil in your left hand and grasp the foil flap between the thumb and index finger of the right hand.



2. Grasp transparent poly film with the thumb and index finger of the left hand, gripping the pack between knuckles thus exposing to sterile card.
3. Project the sterile card onto the sterile table only after peeling apart the peelable foil completely.



4. Arm the needle with an appropriate needle holder using the no-touch technique. Remove the needled suture with a smooth and moderate pull in a direction parallel to the card. (Suture with needle).



5. 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.

STORAGE:

Recommended storage condition is to store at a temperature below 26°C, away from moisture & direct sunlight. Do not use it after the expiry date.

LINK TO THE SUMMARY OF SAFETY CLINICAL PERFORMANCE:

- The SSCP is available in the European database on medical devices (EUDAMED) where it is linked to the Basic UDI-DI.
- The URL to the EUDAMED: <https://ec.europa.eu/tools/eudamed>.
- The Basic UDI-DI for searching the intended SSCP in EUDAMED is 89042482EST009MC.

COMPETENT AUTHORITY:

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Mail: notifications.meddev@fagg-afmps.be
Tel: +32 2 528 40 00

NOTE: Any serious incident that occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

EXPLANATION OF SYMBOLS	
Symbol	Title
	CE Logo with Notified Body Number
	Manufacturer
	Authorized Representative in the European Community/ European Union
	Date of Manufacture
	Use-By Date

	Sterilized using Ethylene Oxide
	Do not re-use
	Do not re-sterilize
	Batch code
	Catalog number
	Keep dry
	Caution
	Do not use if the package is damaged and consult instructions for use
	Keep away from Sunlight
	Unique Device Identifier
	Upper limit of Temperature
	Single Sterile Barrier System used in combination with Sterilized using ethylene oxide
	Importer

	Distributor
	Single sterile barrier system with protective packing outside
	Medical Device
	Consult instructions for use

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