

# CERTIFICATE

Number: 2194636

The management system of the organization(s) and locations mentioned on the addendum belonging to:

## Assut Medical Sàrl

Avenue de Rochettaz 57  
1009 Pully  
Switzerland

including the implementation meets the requirements of the standard:

# EN ISO 13485:2016

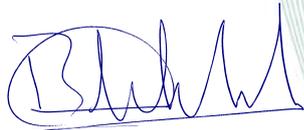
### Scope:

Design, manufacturing and distribution of sterile surgical sutures, pacing wires, micro-surgical knives and non-sterile atraumatic needles for the area of surgery

Certificate expiry date: 22 February 2023  
Certificate effective date: 22 February 2020  
Certified since: 20 September 2016

This certificate is valid for the organization(s) and/or locations mentioned on the addendum.

DEKRA Certification B.V.



B.T.M. Holtus  
Managing Director



J.A. van Vugt  
Certification Manager

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# ADDENDUM

To certificate: 2194636

The management system of the organization(s) and/or location(s) of:

## Assut Medical Sàrl

Avenue de Rochettaz 57  
1009 Pully  
Switzerland

Certified additional organization(s) and/or locations:

Organization/Location

## Assut Medical Sàrl

Sur le Crêt 13  
2606 Corgemont  
Switzerland

Scope:

Design and manufacturing of sterile surgical sutures, pacing wires, micro-surgical knives and non-sterile atraumatic needles for the area of surgery

## Assut Medical Sàrl

Av. De Lavaux 35 P.O. Box 5  
CH-1009 Pully / Lausanne  
Switzerland

Scope:

Design and distribution of sterile surgical sutures, pacing wires, micro-surgical knives and non-sterile atraumatic needles for the area of surgery

Addendum expiry date: 22 February 2023

Addendum effective date: 22 February 2020

# EC CERTIFICATE

Number: 2194636CE03

## Full Quality Assurance System

**Directive 93/42/EEC on Medical devices, Annex II excluding (4)**

(Devices in Class IIa, IIb or III)

Manufacturer:

**Assut Medical Sàrl**

**Avenue de Rochettaz 57**

**1009 Pully**

**Switzerland**

For the product category(ies)

**Absorbable surgical sutures**

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EC-Directive which apply to them:

# 0344

Documents, that form the basis of this certificate:

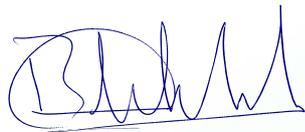
**Certification Notice 2194636CN, initially dated 20 September 2016**

**Addendum, initially dated 23 September 2016**

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Council Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments. The manufacturer has implemented a quality assurance system for design, manufacture and final inspection for the above mentioned product category in accordance to the provisions of Annex II of Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance. For placing on the market of Class III devices an additional EC design examination certificate according to Annex II (4) is mandatory. The necessary information related to the quality management system of the manufacturer, including facilities and the reference to the relevant documentation, of the products concerned and the assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 12 December 2022  
Issued for the first time: 23 September 2016  
Reissued: 12 December 2017

DEKRA Certification B.V.



B.T.M. Holtus  
Managing Director



J.A. van Vugt  
Certification Manager

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DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands  
T +31 88 96 83000 F +31 88 96 83100 www.dekra-certification.com Company registration 09085396

# ADDENDUM

Belonging to certificate: 2194636CE03

1/1

## CE MARKING OF CONFORMITY MEDICAL DEVICES

Absorbable surgical sutures

Issued to:

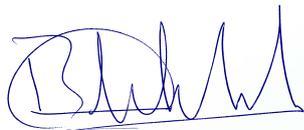
**Assut Medical Sàrl**  
**Avenue de Rochettaz 57**  
**1009 Pully**  
**Switzerland**

This certificate covers the following product(s):

- AssuCryl® MonoSlow (PDO)
- AssuCryl® Lactin (PGLA)
- AssuCryl® (PGA)
- AssuCryl® Rapid (PGA)
- AssuCryl® MonoRapid (PGCL)

Initial date: 23 September 2016  
Revision date: 4 April 2019

DEKRA Certification B.V.

A blue ink signature of B.T.M. Holtus, consisting of stylized, overlapping loops and lines.

B.T.M. Holtus  
Managing Director

A blue ink signature of J.A. van Vugt, featuring a large, flowing initial 'J' followed by the name 'A. van Vugt'.

J.A. van Vugt  
Certification Manager

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# EC CERTIFICATE

Number: 2194636CE01

## Full Quality Assurance System

**Directive 93/42/EEC on Medical devices, Annex II excluding (4)**

(Devices in Class IIa, IIb or III)

Manufacturer:

**Assut Medical Sàrl**

**Avenue de Rochettaz 57**

**1009 Pully**

**Switzerland**

For the product category(ies)

**Non-absorbable surgical sutures**

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EC-Directive which apply to them:

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# ADDENDUM

Belonging to certificate: 2194636CE01

1/1

## CE MARKING OF CONFORMITY MEDICAL DEVICES

Non-absorbable surgical sutures

Issued to:

**Assut Medical Sàrl**  
**Avenue de Rochettaz 57**  
**1009 Pully**  
**Switzerland**

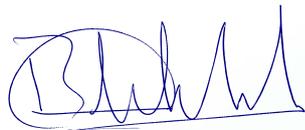
This certificate covers the following product(s):

- Astralen (Polyester) with or without pledgets – Class III
- Nylon (Polyamide) – Class III
- Polypropylene – Class III
- Silk – Class III
- PTFE Pledgets – Class III
- Supramid (Polyamide) – Class IIa
- Surgical Steel – Class IIb
- Astralen/Polyester Tape – Class IIb
- AssuTopFiber® (UHMWPE) – Class IIb, Rule 8

Initial date: 23 September 2016

Revision date: 4 April 2019

DEKRA Certification B.V.

A blue ink signature of B.T.M. Holtus, consisting of stylized, overlapping loops and lines.

B.T.M. Holtus  
Managing Director

A blue ink signature of J.A. van Vugt, featuring a large, flowing 'J' and 'V'.

J.A. van Vugt  
Certification Manager

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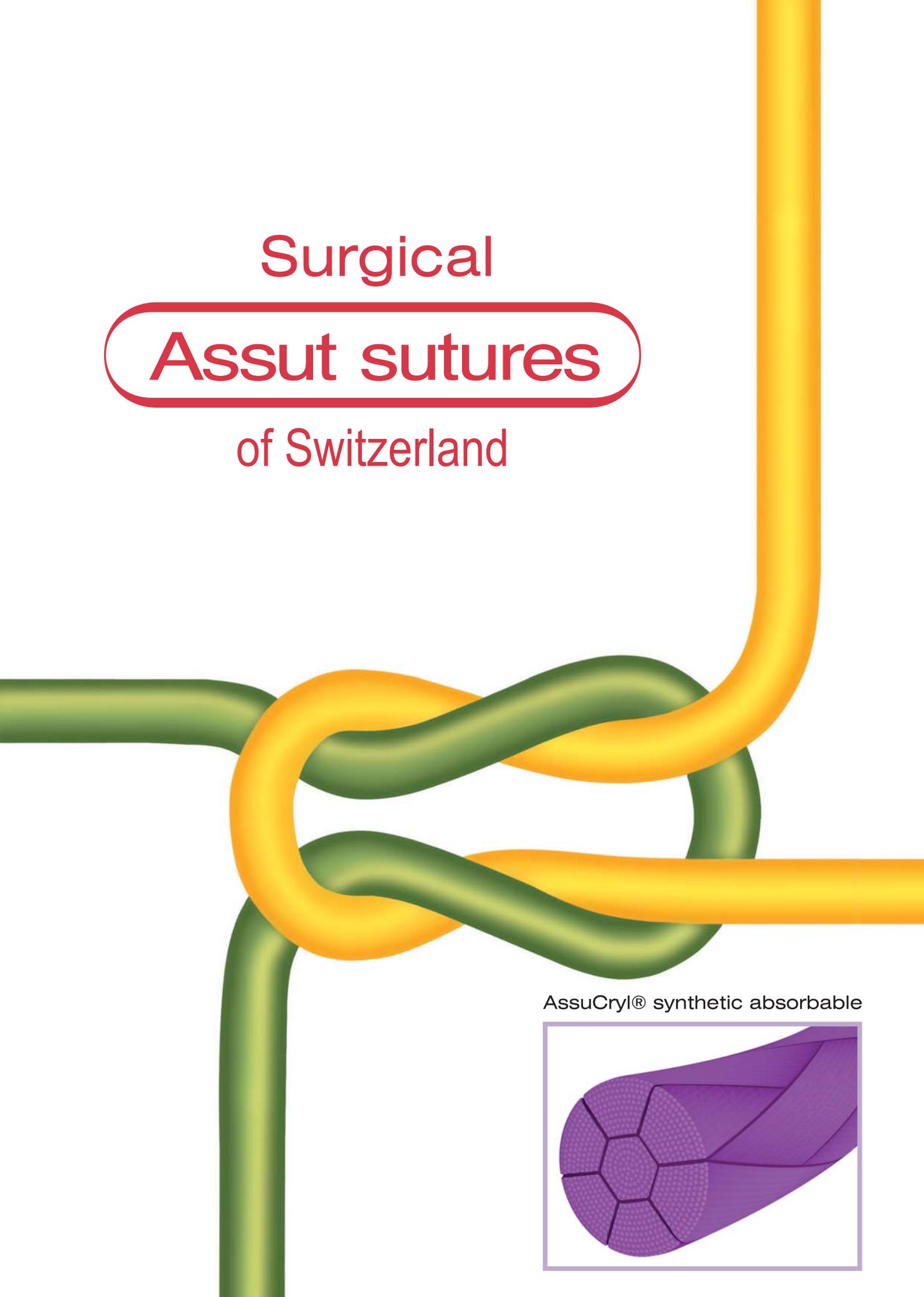
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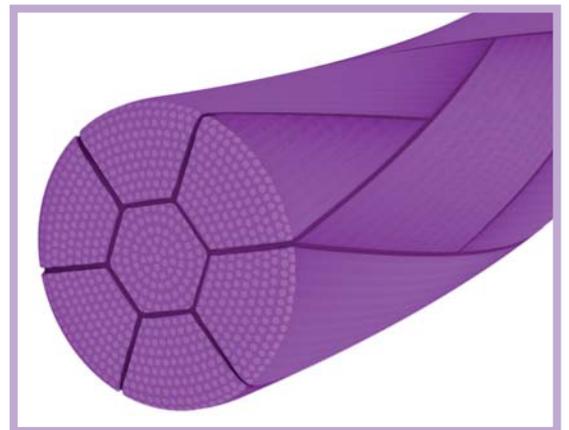
Surgical

Assut sutures

of Switzerland



AssuCryl® synthetic absorbable



# Assut sutures

of Switzerland



[www.assutsutures.com](http://www.assutsutures.com)



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# Introduction

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Assut Medical Sàrl, with factory located since 1962 in the famous Swiss region of the watch-industry and fine metal technology, is specialized in the manufacturing of atraumatic surgical needles and sterile surgical sutures.

Constantly adapting and enlarging its range of products to meet modern surgery requirements, Assut sutures are designed and made for all surgical specialties and renown world-wide. Assut sutures meet the surgeon's requirements in all surgical procedures.

With a long history providing surgical sutures of the highest quality, you can count on a team of dedicated Personnel, Technicians and Specialists.

The way our products are shown and described hereafter will make it easy for you to choose and order your sutures. Our company is EN ISO 9001/EN ISO 13485 certified. Our production and products are in compliance with the requirements according to the European medical device directive 93/42/EEC and all our sutures are CE-marked.

Assut Medical Sàrl

AT THE SERVICE OF SURGERY

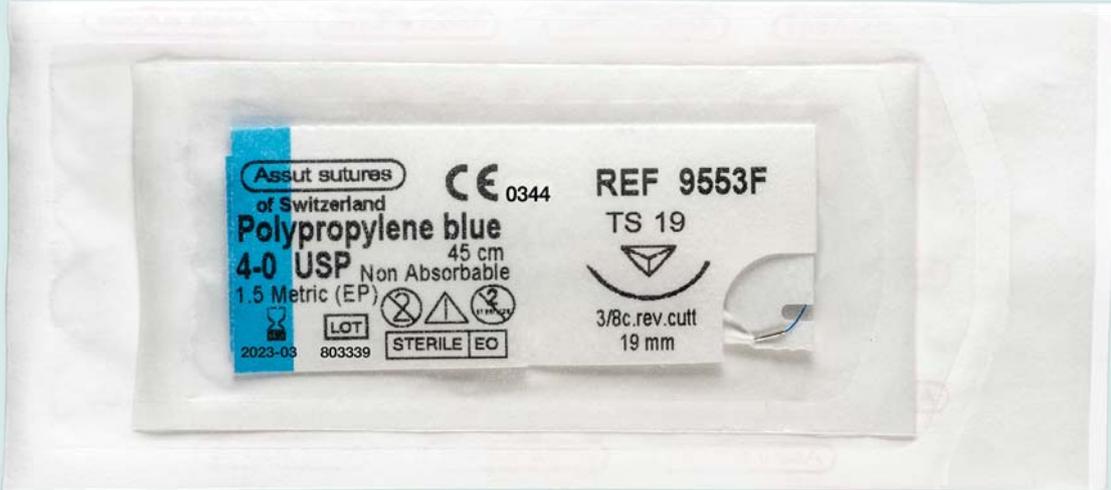
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## Contents

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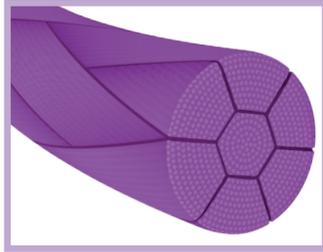
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# Assut sutures of Switzerland



# Suture Materials and Colour Codes

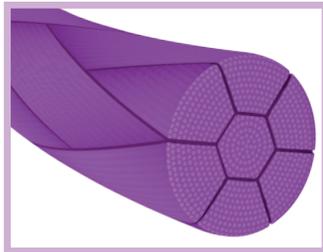
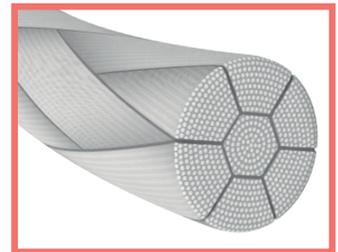
## Absorbable



**AssuCryl®  
synthetic absorbable**  
Braided, coated synthetic absorbable PGA. Predictable absorption time. High initial tensile strength. Easy and secure knotting. Excellent knot sliding and smooth to handle. Violet and undyed (white). Absorption essentially complete between 60 and 90 days.



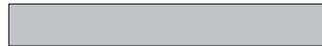
**AssuCryl® Rapid  
synthetic absorbable**  
Braided, coated synthetic absorbable PGA. Predictable shorter absorption time. High initial tensile strength. Easy and secure knotting with excellent knot sliding, smooth to handle. Undyed (white) only. Absorption essentially complete between 40 to 45 days.



**AssuCryl® Lactin  
synthetic absorbable**  
Braided, coated synthetic absorbable PGLA. Predictable absorption time. High initial tensile strength. Easy and secure knotting. Excellent knot sliding and smooth to handle. Violet and undyed (white). Absorption essentially complete between 56 and 70 days.



**AssuCryl® MonoSlow  
synthetic absorbable**  
Monofilament synthetic absorbable PDO (Polydioxanone), violet. High initial tensile strength, easy to handle and smooth passage through tissue. Absorption essentially complete between 180 to 210 days.



**AssuCryl® MonoRapid  
synthetic absorbable**  
Monofilament synthetic absorbable PGCL (Poliglecaprone). Available in violet or undyed. Easy to handle and smooth passage through tissue. Absorption essentially complete between 90 to 120 days.



## Non - Absorbable



**Polyester coated/Astralen**  
Green braided polyester with improved tensile strength and knot security, siliconized. A modern braiding technique gives the strand a smooth and uniform surface that minimizes the trauma.



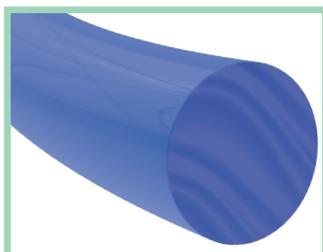
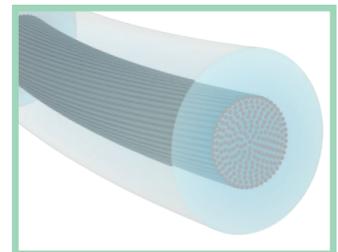
**Polypropylene**  
Blue monofilament polypropylene is flexible and ties securely. Extremely well tolerated, its smooth and uniform surface allows easy passage through tissue with minimum trauma.



**Silk**  
Black braided surgical silk on twisted core for greater tensile strength. Wax treatment and new braiding technique render the silk uniform and smooth and facilitate its handling.



**Supramid**  
Black monofilament polyamide with supersoft core, resulting in superior pliability and knot security. The uniform and smooth surface permits effortless passage through tissue with minimum trauma. Supramid is extremely well tolerated.



**Monofil Nylon/Polyamide**  
Blue monofilament polyamide with high tensile strength. The uniform and smooth surface permits effortless passage through tissue with minimum trauma. Extremely well tolerated.



**Surgical Steel**  
Monofilament stainless steel with very high tensile strength and excellent knot security. This strand causes minimum tissue reaction.



# Information on Labelling

Symbol	Meaning
	Do not re-use. Disposable product
	Expiry-date. Use until year/month
	Lot Number
	Sterilized with Ethylene Oxide
	Sterilized with Gamma-Irradiation
	See instructions for use
	CE Mark of the Notified Body
	Product Number
	Maximum Temperature °C
	Do not use if packaging is damaged
	Do not re-sterilize

## Information on REF

Each Assut product has a REF (Prod.No.) with either 3, 4 or more digits. The prefix or suffix letter(s), if any, refer to the suture material, such as:

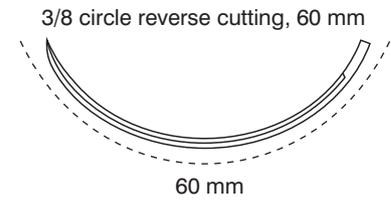
Prefix	Suffix
<b>M</b> Monofilament	<b>TH</b> 30 cm long strand
<b>R</b> Rapid	<b>THF</b> 35 cm long strand
<b>S</b> Slow	<b>TE</b> 38 cm long strand
<b>B</b> Reel	<b>F</b> 45 cm long strand
<b>L</b> Lactin	<b>S</b> 60 cm long strand
	75 cm long strand
	<b>E</b> 80 cm long strand
	<b>N</b> 90 cm long strand
	<b>H</b> 100 cm long strand
	<b>HT</b> 120 cm long strand
	<b>HF</b> 150 cm long strand
	<b>HE</b> 180 cm long strand
	<b>T</b> 200 cm long strand
	<b>TF</b> 240 cm long strand
	<b>W</b> White (or undyed)

# Needle shape and cross-section

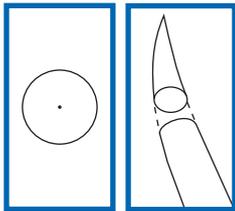
## Logical needle codes

The shape, cross-section and length of needles are given by the needle codes, for example TS 60. The first letter refers to the shape of the needle, the second to the cross-section. The number stands for the needle length along the body (mm).

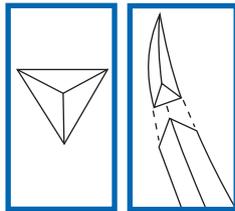
## TS 60



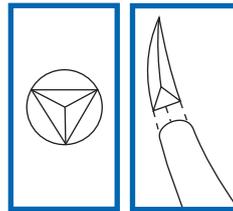
Round-bodied (taper)



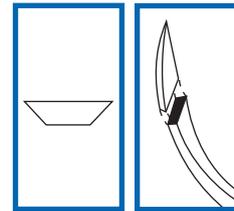
Reverse cutting



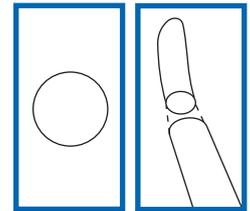
Cutting taper



Spatula



Blunt point



Needle Code	Needle Shape	Cross-section	Symbol
<b>HR</b>	<b>H</b> ½ circle	<b>R</b> Round-Bodied (taper)	
<b>HRG</b>	<b>H</b> ½ circle	<b>R</b> Round-Bodied (taper) <b>G</b> heavy	
<b>HRM</b>	<b>H</b> ½ circle	<b>R</b> Round-Bodied (taper) <b>M</b> Micropoint	
<b>HS</b>	<b>H</b> ½ circle	<b>S</b> Cutting	
<b>HSG</b>	<b>H</b> ½ circle	<b>S</b> Cutting <b>G</b> heavy	
<b>HSP</b>	<b>H</b> ½ circle	<b>SP</b> Spatula	
<b>HSR</b>	<b>H</b> ½ circle	<b>SR</b> Cutting taper	
<b>HSRG</b>	<b>H</b> ½ circle	<b>SR</b> Cutting taper <b>G</b> heavy	
<b>KSP</b>	<b>K</b> 1/4 circle	<b>SP</b> Spatula	
<b>TR</b>	<b>T</b> 3/8 circle	<b>R</b> Round-Bodied (taper)	
<b>TRM</b>	<b>T</b> 3/8 circle	<b>R</b> Round-Bodied (taper) <b>M</b> Micropoint	
<b>TS</b>	<b>T</b> 3/8 circle	<b>S</b> Cutting	
<b>TSP</b>	<b>T</b> 3/8 circle	<b>SP</b> Spatula	
<b>TS-P</b>	<b>T</b> 3/8 circle	<b>S</b> Cutting <b>P</b> Precision Point	
<b>TSR</b>	<b>T</b> 3/8 circle	<b>SR</b> Cutting taper	
<b>RR</b>	<b>R</b> straight	<b>R</b> Round-Bodied (taper)	
<b>RS</b>	<b>R</b> straight	<b>S</b> Cutting	
<b>FR</b>	<b>F</b> 5/8 circle	<b>R</b> Round-Bodied (taper)	
<b>HTT</b>	<b>H</b> ½ circle	<b>TT</b> Blunt-Point	
<b>HMR</b>	<b>HM</b> straight-curved	<b>R</b> Round-Bodied (taper)	
<b>HMS</b>	<b>HM</b> straight-curved	<b>S</b> Cutting	
<b>SKT</b>	<b>SK</b> straight-curved	<b>T</b> Cutting	

# Needle-chart

**RR-needles**   
straight, Round-Bodied (taper)

**RR-22**



**RR-30**



**RR-45**



**RR-50**



**RR-60**



**TR-needles**   
3/8 circle, Round-Bodied (taper)

**TR-13**



**TR-17**



**TR-22**



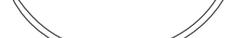
**TR-27**



**TR-32**



**TR-38**



**TR-45**



**TR-55**



**TR-65**



**TTT-needle**   
3/8 circle, Round-Bodied, Blunt point

**TTT-60**



**TTT-85**



**HTT-needle**   
1/2 circle, Round-Bodied, Blunt point

**HTT-50**



**HRG-needles**   
1/2 circle, Round-Bodied (taper) heavy

**HRG-22**



**HRG-27**



**HRG-32**



**HRG-38**



**HRG-40**



**HRG-50**



**HRG-65**



**FR-needles**   
5/8 circle, Round-Bodied (taper)

**FR-27**



**FR-38**



**FR-40**



**HR-needles**   
1/2 circle, Round-Bodied (taper)

**HR-13**



**HR-17**



**HR-20**



**HR-22**



**HR-25**



**HR-27**



**HR-30**



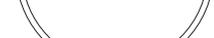
**HR-32**



**HR-35**



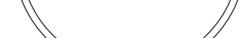
**HR-38**



**HR-40**



**HR-45**



**HR-50**



**HR-55**



**HR-65**



**HR-70**



**TS-needles**   
3/8 circle, reverse cutting

**TS-12**



**TS-15**



**TS-17**



**TS-19**



**TS-24**



**TS-27**



**TS-30**



**TS-38**



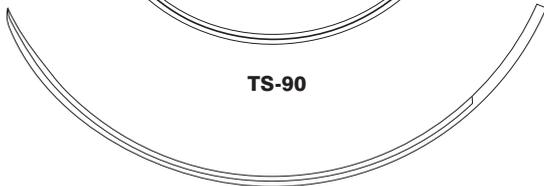
**TS-45**



**TS-60**



**TS-90**



**TSR-needle**   
3/8 circle, cutting taper

**TSR-14**



**TSR-27**



**HSRG-needles**   
1/2 circle, cutting taper, heavy

**HSRG-27**



**HSRG-38**



**HSRG-45**



**TS-P needles**   
3/8 circle, reverse cutting  
Precision Point

**TS-12P**



**TS-15P**



**TS-19P**



**TS-24P**



**RS-needles**   
straight, cutting

**RS-45**



**RS-50**



**RS-58**



**RS-75**



**RS-90**



**RSK-90**

with breakable feature



**HMR-40** taper



**SKT-30** cutting



**HS-needles**   
1/2 circle, reverse cutting

**HS-12**



**HS-17**



**HS-19**



**HS-21**



**HS-24**



**HS-27**



**HS-30**



**HS-38**



**HS-40**



**HS-45**



**HS-52**



**HSP-needles**  
1/2 circle, Spatula

**HSP 6**



**HSP 8**



**TSP-needles**  
3/8 circle, Spatula

**TSP 6**



**TSP 8**

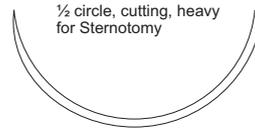


**KSP-needles**  
1/4 circle, Spatula

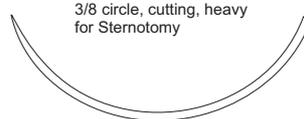
**KSP 8**



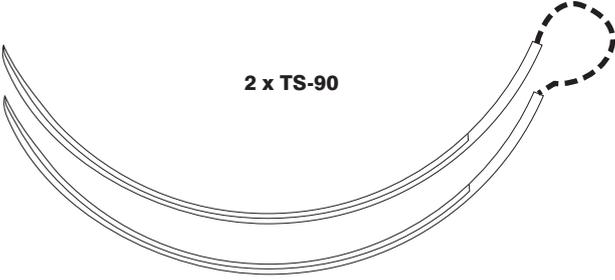
**HCS-50**   
1/2 circle, cutting, heavy  
for Sternotomy



**TCS-50**   
3/8 circle, cutting, heavy  
for Sternotomy



# Monofil Nylon / Polyamide blue

Length	Thread Colour	Needle Code and Length in mm	USP	EP	REF
		3/8 circle cutting, double-armed 			
100 cm 100 cm	blue blue	<p><b>2 x TS-90</b></p> 	0 1	3.5 4	51796H 51797H
		straight cutting 			
75 cm 75 cm 75 cm	blue blue blue	<p><b>RS-50</b></p> 	3 - 0 2 - 0 0	2 3 3.5	5834 5835 5836
75 cm 75 cm 100 cm 75 cm	blue blue blue blue	<p><b>RS-58</b></p> 	3 - 0 2 - 0 2 - 0 0	2 3 3 3.5	5844 5845 5845H 5846

## Ophthalmic sutures Black Monofilament Nylon

Length	Thread Colour	Needle Code and Length in mm	USP	EP	REF
30 cm	black	<p><b>2 x TSP 6</b></p>  <p>Curved, 6,2 mm long, spatula 150 microns, double armed</p>	10 - 0	0.2	584560
30 cm 30 cm	black black	<p><b>2 x TSP 7</b></p>  <p>Curved, 6,4 mm long, spatula 200 microns, double armed</p>	10 - 0 9 - 0	0.2 0.3	586660 586669

## Microsurgical sutures

Length	Thread Colour	Needle Code and Length in mm	USP	EP	REF
13 cm	black	<p><b>TRM 4</b></p>  <p>Curved, chord 3 mm, 4 mm long, taper 100 microns, Micropoint</p>	10 - 0	0.2	541320
13 cm	black	<p><b>TRM 5</b></p>  <p>Curved, chord 3 mm, 5 mm long, taper 100 microns, Micropoint</p>	10 - 0	0.2	543320
13 cm	black	<p><b>RRM 4</b></p>  <p>Straight, 4 mm long, taper 75 microns, Micropoint</p>	10 - 0	0.2	535220

# Assut sutures

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