

resorba.com



# **Suture Manual**



## Content

- Introduction Page 3
- Page 6 **Principles**
- Page 12 Surgical Needles
- Page 15 **Sutures**
- Page 31 Manufacture and packaging
- Page 36 Organisational aids

This booklet on suture materials is not intended as a fully comprehensive source. For more detailed technical information, we recommend consulting specialized literature.

Detailed information on individual materials is available in our product information sheets, catalogues and package inserts, which we can provide upon request.

Additionally, our website www.resorba.com offers up-to-date and extensive information on our products and innovations.

2-0

3 metric

75 cm

3

STERLED 茶 ÷

88 II 8 / sec R ...

ıł

**RESOLON®** 

**DSM 18** 

VV

38

REF

PA

€ 0197

2029-01-03

LOT R00110826

**RESORBA** 

881512



# Introduction



In nature, injured or damaged tissue layers must be quickly closed to maintain the integrity and function of the organism. This approach has been adopted by humans from nature.

One primary goal of modern wound care is to preserve intact tissue and support damaged areas. Our suture products, based on biocompatible raw materials, enable targeted use for all types of wound care and guarantee the best possible tissue compatibility.

Surgical suture material is a typical medical product used to repair tissure. Most wound closures are still performed with sutures. The mechanical properties of the materials used are of utmost importance to temporarily replace the lost strength. Absorbable suture materials, such as PGA *RESORBA®*, support the body's natural repair processes until form and function are restored. These materials are then broken down by the body.

Non-absorbable suture materials, such as MOPYLEN®, provide longlasting support and excellent biocompatibility, particularly beneficial for long-term implants.

A wide variety of suture materials is available today for wound closure, specifically designed to suit various applications and selected to match the unique properties of the tissue.

# Requirements for an ideal suture:

- high tensile strength
- high knot security
- good tie down
- no capillary function
- good tissue tolerance
- easy passage through tissue
- sterile presentation

# The optimum use of any particular suture is determined by its:

- absorption characteristics
- thread structure, composition and diameter
- elasticity and stability
- tissue acceptance
- tensile strength

# Introduction

### A journey into the history of surgical sutures

# The development of surgical suture revisited

#### 3000 BC

First reference to a wound suture in ancient Egyptian texts.

#### 1900 - 1600 BC

Oldest surviving description of wound care in Papyri named after F. Smith (1862) and Ebers (1873), from about 1900 – 1600 BC.

#### 1100 BC

Oldest surviving suture placed about 1000 BC in the abdomen of a mummy (Rodegra 1982). Linen was already being used as suture material at that time.

#### 500 BC

Susruta, an Indian was the first to describe in detail wound sutures and the material used for it, e.g. bowstring (earliest absorbable suture material), linen thread, plant fibres, tree bark sutures and thin strips cut from tanned skin.

#### 460 BC - 199 AD

The great medical books by Hippocrates (460 - 377 BC), the most famous physician of antiquity the Roman physician Celsus (25 - 50 AD) and the physician Galen (129 - 199 AD) already contain detailed descriptions of many suture techniques. Celsus distinguished between single and continuous sutures and Galen was the first to recommend thin strings made of gut for ligating bleeding vessels.

#### 625 - 690

Paulus of Agina was the first physician to treat a bone fracture by winding wire around it.

#### 1732

Various suturing techniques still in common use today were drawn on animal skin (exhibited at the Germanic National Museum in Nuremberg).

#### 1827 - 1912

Wound infections became preventable after the introduction of the first usable disinfection and sterilisation methods (antiseptics) by Lister (1827 - 1912) and Schimmelbusch (1860 - 1895).

Production of catgut around 1930



# Introduction



#### 1868

Lister, a surgeon discovered absorbable sutures made of sheep gut string. He disinfected the sutures with carbolic acid to keep them germ-free. This is the origin of resorbable catgut sutures.

#### 1900

The beginning of the industrial manufacturing of suture material (catgut) was based on technical experience gathered in the meantime in making strings for musical instruments.

#### 1908

In 1908 F. Kuhn (1866 – 1929), a German surgeon demanded the exclusive use of surgical sutures made of catgut that had been made under especially clean, partly sterile conditions. Catgut (sterilized with potassium iodide) became the most commonly used surgical suture material next to twine and silk. After the introduction of catgut an intensive search began for other absorbable suture materials. A unsuccessful attempt was made to obtain absorbable thread from animal tissues (tendon from kangaroo tails; skin, arteries, strips of muscle, tendon and nerves from whale, rabbit, dog, deer, camel, turtle and others).

#### 1931

First production of synthetic threads from polyvinyl alcohol.

#### 1939

Perlon was specially treated to produce the synthetic thread Supramid to meet the particular requirements in surgery. After World War II it was joined by synthetic threads made from polyester and polypropylene.

#### **Until 1960**

Sutures were sterilized by bactericidal chemical solutions or by heating (steam).

#### Since 1960

Introduction of safe modern methods of sterilization with ethylene oxide gas or gamma irradiation.

#### 1968

First synthetic suture threads made from polyglycolic acid. The production of "atraumatic sutures" was also further developed and improved starting at the beginning of 1970. The basic idea of a minimal transition in diameter from needle to thread for providing the most sparing way of passing a suture through tissues was put forward over 100 years ago (Gaillard) and has been used since about 1920.

In principle, different types of suture packaging have been available since the beginning of the industrial manufacture of sutures. But it was only with the development of packaging techniques with synthetic materials around 1960, and new methods of sterilisation that it became possible to make the sterile and ready-to-use packs available nowadays.



Early packaging of sutures

### Historical classification according to raw materials

#### Natural starting materials

- Silk
- Linen (twine)
- Animal gut (catgut)
- Steel

#### Synthetic starting materials

- Polyglycolic acid
- Polylactide
- Polyamide
- Polyester
- Polypropylene
- Poly(p-dioxanone)



# Modern classification according to absorption characteristics

#### Non-absorbable

- MOPYLEN<sup>®</sup>
- MOPYLEN® CV
- RESOPREN<sup>®</sup>
- POLYESTER
- SUPOLENE
- NYLON
- RESOLON<sup>®</sup>
- SUPRAMID

#### SILK

STAINLESS STEEL

#### Long-term wound support

- CAPROLON<sup>®</sup>
- PDO RESORBA™
- RESORBA<sup>®</sup> Barbed
   Suture

# Mid-term wound support

PGA RESORBA®

# Short-term wound support

- PGA resoquick<sup>™</sup>
- GLYCOLON<sup>®</sup>

	Monofilament material	Multifilament material
Properties	no capillarity no sawing effect good knotting properties easy passage through tissue	very high tensile strength high knot security very supple simple handling
Absorbable material	GLYCOLON® CAPROLON® PDO <i>RESORBA™</i> <i>RESORBA®</i> Barbed Suture	PGA resoquick™ PGA RESORBA®
Non- absorbable material	MOPYLEN® MOPYLEN® CV RESOPREN® NYLON RESOLON® SUPRAMID* STAINLESS STEEL	POLYESTER SUPOLENE SUPRAMID** SILK

\* for USP 5-0 and 6-0

\*\* pseudo-monofilament



### Absorption

Absorbable sutures approximate the tissues during the healing process. During this time the suture's tensile strength will gradually diminish. Absorbable suture material is metabolised by endogenous proteolytic enzymes or by hydrolysis (in the case of PGA *resoquick*™, GLYCOLON®, PGA *RESORBA®*, CAPROLON®, PDO *RESORBA™* and RESORBA® Barbed Suture).

**Non-absorbable sutures** remain almost unchanged when placed within body tissues and are encapsulated within the wound scar tissue by the organism. The sutures used for skin closure are removed once the scar tissue has become sufficiently firm to hold the wound edges together (usually after 7 to 14 days). It has to be distinguished as follows:

#### Absorption time

The period in which the suture loses 50 % of its knot tensile strength. **Dissolution** 

# The period during which the suture completely dissolves within the tissue.

#### Disintegration

The period during which essentially non-absorbable suture breaks down by degradation into (smaller) pieces and thus losing its strength (e.g. polyamide).

# Characteristics of absorption

Different indications also require different tensile strengths and absorption characteristics. These particular features of different sutures can be achieved by the choice of the material and modifying the production process. In addition to the immediate, moderately quick or delayed loss of tensile strength there is also the corresponding duration of absorption.

Any given thread material can only fulfil its purpose as long as it has the desired tensile strength.



The graph shows a simplified representation of the respective tear force losses over time. Data of GLYCOLON® and PGA *RESORBA®* come from in-vitro experiments, whereas the data of CAPROLON®, PDO *RESORBA™* and PGA *resoquick™* come from in-vivo experiments. Thus, the curves are not directly comparable but serve as a simplified visual representation.

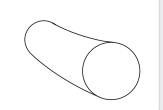
### **Thread structure**

The structure of the suture affects its capillarity and how it moves through tissue. Current suture materials can be categorized into three main types, each offering specific advantages depending on the application.

#### Monofilament

A monofilament suture consists of a single thread filament. Its smooth surface makes it easier to pass through tissue and reduces the risk of bacterial colonization. Coatings on these sutures can improve smoothness, increase flexibility and enhance handling.

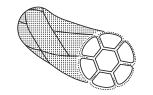
- GLYCOLON<sup>®</sup>
- CAPROLON® \*
- PDO RESORBA™
- RESORBA® Barbed Suture
- MOPYLEN<sup>®</sup>
- MOPYLEN<sup>®</sup> CV
- RESOPREN<sup>®</sup>
- NYLON
- RESOLON<sup>®</sup>
- STAINLESS STEEL



#### Multifilament - coated

A multifilament suture is composed of numerous fine individual filaments, either twisted together or braided into filament bundles. To enhance mechanical properties, multifilament sutures can be treated with specific coatings. This process fills the gaps within the filament bundles and reduces surface friction.

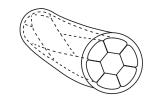
- PGA resoquick™
- PGA RESORBA®
- POLYESTER
- SUPOLENE
- SILK



#### **Pseudo-monofilament**

Pseudo-monofilament sutures combine features of both monofilament and multifilament sutures. They consist of multifilament bundles arranged in parallel and enclosed in a smooth sheath, giving them the appearance and feel of monofilaments.

SUPRAMID



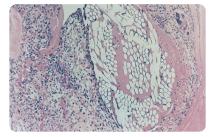


### **Tissue acceptance**

Every insertion of suture will trigger some tissue reaction within the body (see the table below).

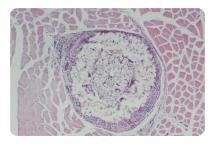
#### The causes are:

- Traumatisation of tissue on placing the suture
- Mechanical irritation of the suture's surface which cannot be avoided but reduced when using monofilament threads
- Natural immunological reaction (nonspecific foreign-body reaction and defence reaction against chemistry of the thread)

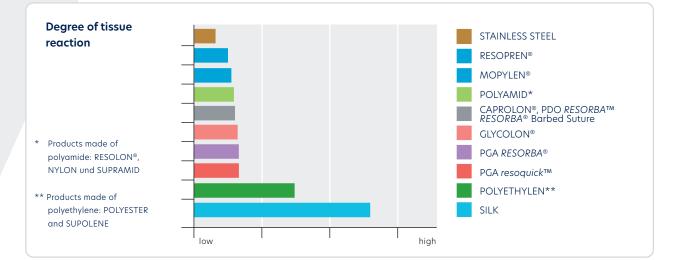


Using PGA RESORBA® as example

Microscopy of section through an intramuscular implant, **7 days postoperative.** Expectedly mild cellular infiltration is visible.



Microscopy of section through an intramuscular implant, **14 days postoperative.** The suture is embedded within the block of tissue. No evidence of either tissue reaction or encapsulation.



### Thread table

#### **Diameter of sutures**

The harmonised standards as derived from the monographs of the European Pharmacopoeia (Ph. Eur.), have established the metric classification and nomenclature for suture diameter which are mandatory for European manufacturers. The table compares the diameters with the conventional nomenclature used to date (United States Pharmacopeia). The latter has no direct connection to thread diameter so that they cannot be derived from them. In contrast, the metric EP numbers can be converted into a thread diameter: 1 metric corresponds to a thread diameter of 0.1 mm.

	8	/	® X	× ra		5				ofilomen			£	r t lloment 9e		/	0	N IN	e
Ph.Eur	Diameter range	PC4 PC	PCA rec.	MODY	MOPHIC	RESODA	POLIFES	SUDON -	NY ON	RESOLO.	SUPRA.	SILK	STAIN ESS ST	"oment El Sinti, monoficial Diometer constante	CINCU.	Capeo,	PDOPE COM	RESORBAIN BOTORBAIN	ed Suti
0.1 EP	0,010-0,019	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
0.2 EP	0,020-0,029	-	-	10-0	-	-	-	-	10-0	-	-	-	-	-	-	-	-	-	
0.3 EP	0,030-0,039	-	-	9-0	-	-	-	-	9-0	-	-	-	-	-	-	-	-	-	
0.4 EP	0,040-0,049	8-0	-	8-0	8-0	-	-	-	8-0	-	-	8-0	-	-	-	-	-	-	
0.5 EP	0,050-0,069	7-0	-	7-0	7-0	7-0	-	-	7-0	7-0	-	7-0	-	0,050-0,094	-	7-0	7-0	-	
0.7 EP	0,070-0,099	6-0	6-0	6-0	6-0	6-0	6-0	6-0	6-0	6-0	6-0	6-0	-	0,095-0,149	6-0	6-0	6-0	-	
1 EP	0,100-0,149	5-0	5-0	5-0	5-0	5-0	5-0	5-0	5-0	5-0	5-0	5-0	5-0	0,150-0,199	5-0	5-0	5-0	-	
1.5 EP	0,150-0,199	4-0	4-0	4-0	4-0	4-0	4-0	4-0	4-0	4-0	4-0	4-0	4-0	0,200-0,249	4-0	4-0	4-0	4-0	
2 EP	0,200-0,249	3-0	3-0	3-0	3-0	3-0	3-0	3-0	3-0	3-0	3-0	3-0	3-0	0,250-0,339	3-0	3-0	3-0	3-0	
2.5 EP	0,250-0,299	-	2-0	-	-	-	-	-	-	-	2-0	-	-	-	-	-	-	-	
3 EP	0,300-0,349	2-0	2-0	2-0	2-0	2-0	2-0	2-0	2-0	2-0	2-0	2-0	2-0	0,340-0,399	2-0	2-0	2-0	2-0	
3.5 EP	0,350-0,399	0	0	0	0	0	0	0	0	0	0	0	0	0,400-0,499	0	0	0	0	
4 EP	0,400-0,499	1	1	1	-	1	1	1	1	1	1	1	1	0,500-0,570	1	1	1	1	
5 EP	0,500-0,599	2	2	2	-	2	2	2	2	-	2	2	2	0,571-0,610	-	2	2	-	
6 EP	0,600-0,699	3+4	-	-	-	-	3+4	3+4	-	-	-	3+4	3+4	-	-	-	-	-	
7 EP	0,700-0,799	5	-	-	-	-	5	-	-	-	-	5	5	-	-	-	-	-	
8 EP	0,800-0,899	-	-	-	-	-	6	-	-	-	-	-	6	-	-	-	-	-	
9 EP	0,900-0,999	-	-	-	-	-	-	-	-	-	-	-	7	-	-	-	-	-	



## Tensile strength of surgical suture

Tensile strength is defined as the force required in Newton (N) to break a knot in a suture.

Since the tensile strength of a knot is decisive in surgical practice (it is necessarily less than with a linear pull), this is the only measure which is defined in official requirements. In relevant tests the thread is knotted once before the force is applied.



Requirements on the tensile strength according to Pharm.Eur.\* (harmonised standards)

Diameter metric	All other non-other structs in INJ	Syntheric Divinence Disordoment Post Disordoment Post Disordoment In Iny ECC Disordoment In Iny ECC Disordoment	Smithen monofic obsorbing Posobal Do Colloment Posobal My Scollesture in My Scollesture
0.2 metric	0.10	-	
0.3 metric	0.35	-	
0.4 metric	0.60	0.70	
0.5 metric	1.00	1.4	1.40
0.7 metric	1.50	2.5	2.50
1 metric	3.00	6.80	6.80
1.5 metric	5.00	9.50	9.50
2 metric	9.00	17.50	17.50
2.5 metric	13.00	-	-
3 metric	15.00	26.80	26.80
3.5 metric	22.00	39.00	39.00
4 metric	27.00	50.80	50.80
5 metric	35.00	63.50	63.50
6 metric	50.00	-	-
7 metric	62.00	-	-
8 metric	73.00	-	-

\*Minimum mean value from 5 tests

# Surgical needles

### **Characteristics & shapes**

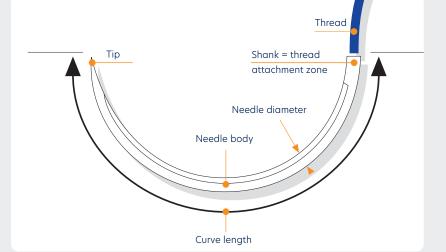
#### The characteristics of a needle

(diameter, point, length of needle curvature) should always be optimally suited to the particular indication, surgical technique and tissue conditions. The parameters to be considered are:

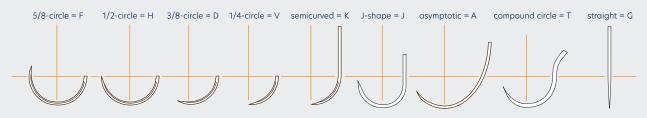
- Response to penetration (on insertion and pulling through of the needle)
- Resistance to bending
- Resistance to breaking
- · Secure positioning in needle-holder

For suturing and suture encircling of wounds, atraumatic (eyeless) needles are usually used as needle-thread combinations. Needle-thread combinations mean that the thread is inserted and firmly anchored inside a drilled shaft at the end of the needle. This provides an essentially stepfree transition from thread to needle. Any further trauma to tissue is avoided





and trauma could occur if the thread is doubled up after passing it through the eye of a needle. RESORBA® eyeless needles are made from special stainless steel with optimal flexibility and strength. Special surface treatment and precision grinding of the point or edge ensure minimal resistance on insertion and easy passage of the needle through the tissue. The firmness with which the needle is attached to the suture is tested in accordance with the regulations of harmonised standards for surgical suturing materials according to the European Pharmacopoeia.



# Surgical needles



### **Cross-sections and points**



Spatula needle □ = P 1/2 circle, 3/8 circle, 1/4 circle, or straight = HSPM, DSPM, VSPM

- For use in ophthalmic surgery and microsurgery
- Needle cross-section flattened
- PREMIUM cut
- Cuts on lateral edges



Reverse cutting needle ▼ = S 1/2 circle, 3/8 circle, semicurved or straight = HS, DS, KS, GS

- For use in firm tissue such as skin
- Triangular needle cross-section
- Also available with PREMIUM cut needles M



Inner cutting needle ▲ = SI 1/2 circle, 3/8 circle = HSI, DSI

- For use in firm tissue such as skin
- Triangular needle cross-section
- Also available with PREMIUM cut needles M



**Round-bodied cutting needle • = RT** 1/2 circle, 3/8 circle, J-shaped, asymptotic or straight = HRT, DRT, JRT, ART, GRT

- For use in firm tissue, sclerotic vessels, and implants
- Needle tip triangular in section



Blunt, round-bodied needle  $\bigcirc$  = RN 1/2 circle, 3/8 circle or semicurved = HRN, DRN, KRN

- For use in parenchymal tissue, the
- Por use in parentry manassee, the cervix, and muscle traction in the eye
   Needle tip blunt
- No puncturing of vessels or tendons



Round-bodied needle ● = R 5/8 circle, 1/2 circle, 3/8 circle, compound circle, J-shaped or straight = FR, HR, DR, TR, JR, GR

- For use in soft tissue (subcutaneous) such as muscle, fascia, mucosa
- In order to improve grip by the needle holder, the cross-section of the middle part of the needle is flattened
- Easy insertion

# Surgical needles

### Needle code

1. letter: Indicates the curvature of the needle F = 5/8 circle H = 1/2 circle D = 3/8 circle V = 1/4 circle K = semicurved J = J-shaped A = asymptotic T = compound circle G = straight				
<ul> <li>2. letter: Gives information on the type of needle and needle tip</li> <li>R = round bodied needle</li> <li>S = reverse cutting needle</li> </ul>				
3.+4. letters: Describe special features of the needle and needle tip	+			
<ul> <li>I = conventional cutting</li> <li>M = PREMIUM cut (partly hand-honed)</li> <li>N = blunt point</li> <li>T = trocar point</li> <li>P = spatulated needle</li> <li>S = stronger diameter</li> <li>X = extra strong diameter</li> <li>F = thin PREMIUM cut "THIN LINE" (partly hand-honed)</li> <li>W = flexible needle</li> </ul>				
Numbers indicate the straight (extended) length of the needle in mm	_			
S (after number) = stronger diameter F (after number) = extra thin diameter				
		н	R	Х

### **Control release needles**

To save time, e.g. when inserting single knot sutures for anastomoses of the gastrointestinal tract or layered wound closure, the needle-thread combination has been constructed with a removable needle.

After the suture has been placed, the needle can be removed from the suture with a slight pull. There is no need to adjust the scissors and cutting the needle from the thread.

30



## Table of materials

Trade name	Raw material	Structure	Thread diameter metric	Thread diameter USP	Colour	Absorption profile
PGA resoquick <sup>™</sup>	Polyglycolic acid, coated	multifilament/ braided	0.7 to 5 metric	USP 6-0 to 2	undyed	short term
GLYCOLON®	Polyglycolic acid-caprolactone	monofilament	0.7 to 4 metric	USP 6-0 to 1	violet, undyed	short term
PGA RESORBA®	Polyglycolic acid, coated	multifilament/ braided	0.4 to 7 metric	USP 8-0 to 5	violet, undyed	mid term
CAPROLON®	Poly(L-lactide-co-ɛ-caprolactone), coated	monofilament	0.5 to 5 metric	USP 7-0 to 2	violet, undyed	long term
PDO RESORBA <sup>™</sup>	Poly(p-dioxanone)	monofilament	0.5 to 5 metric	USP 7-0 to 2	violet	long term
RESORBA® Barbed Suture	Poly(p-dioxanone)	monofilament/ barbed	1.5 to 4 metric	USP 4-0 to 1	violet	long term
MOPYLEN®	Polypropylene	monofilament	0.2 to 5 metric	USP 10-0 to 2	blue	
MOPYLEN <sup>®</sup> CV	Polypropylene	monofilament	0.4 to 3.5 metric	USP 8-0 to 0	blue	
RESOPREN®	PVDF	monofilament	0.5 to 5 metric	USP 7-0 to 2	blue	
POLYESTER	Polyester, coated	multifilament/ braided	0.7 to 8 metric	USP 6-0 to 6	green, white	
SUPOLENE	Polyester, coated	multifilament/ braided	0.7 to 6 metric	USP 6-0 to 3	green, white	
NYLON	Polyamide	monofilament	0.2 to 5 metric	USP 10-0 to 2	black, white	
RESOLON®	Polyamide	monofilament	0.5 to 4 metric	USP 7-0 to 1	blue	
SUPRAMID	Polyamide	pseudo- monofilament	0.7 to 5 metric	USP 6-0 to 2	black, white	
SILK	Silk fibroin, coated	multifilament/ braided	0.4 to 6 metric	USP 8-0 to 5	black	
STAINLESS STEEL	Stainless steel	monofilament	1 to 9 metric	USP 5-0 to 7	nature	



Multifilament, short-term absorbable suture

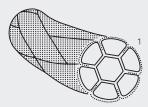
### PGA resoquick<sup>™</sup>

PGA resoquick<sup>™</sup> is a high molecular weight, linear homopolymer of glycolic acid (hydroacetic acid), which is extruded into thin filaments and braided into sutures of various diameters.

Metabolisation of the PGA suture within the tissue occurs by the uptake of water, thus reversing the synthesis. The monomeric glycolic acid is split enzymatically into CO<sub>2</sub> and H<sub>2</sub>O by the normal metabolism. The fine, precision braided filaments guarantee a very high tensile strength – as well as great suppleness.

The special coating of a mixture of calcium stearate & polycaprolactone thinly covers the fibre bundles for specific reduction of surface friction. Absorbable suture approximates the tissue during the healing phase and progressively loses its tensile strength and breaking load. The precision braided filaments of polyglycolic acid that make up PGA *resoquick*<sup>™</sup> ensure standardized and moderately rapid absorption in tissue. PGA *resoquick*<sup>™</sup> is absorbed rather quickly than PGA *RESORBA®* because this material is manufactured using a lower molecular weight PGA. The molecular weight of the PGA material is reduced during a special heat treatment process of the thread before coating.

After only seven days PGA resoquick<sup>™</sup> has already lost 56 % of its original breaking load. After 14 days all original breaking load is lost completely. Absorption of PGA resoquick<sup>™</sup> is approximately completed after 42 days.



- very supple
- very high tensile strength
- minimal tissue reaction
- smooth passage through tissue
- high knot security
- Colour: undyed
- Chemical name: polyglycolic acid
- Thread diameter: USP 6-0 2 (0.7-5 metric)
- Types of packaging:
  - needle-thread-combinations
  - precut lengths
- Sterilization method: ethylene oxide



Monofilament, short-term absorbable suture

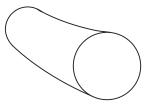
### **GLYCOLON®**

The production of GLYCOLON® involves the copolymerisation of polyglycolic acid and ɛ-caprolactone in a certain ratio.

The breakdown of the polymeric suture in the tissue occurs through water uptake, thereby reversing the synthesis.

The strength of GLYCOLON® reduces to 30 % after 7 days. The completely safe intermediary products that are formed, as well as the smooth, monofilament surface structure of the thread, result in minimal tissue reaction. The smooth, monofilament surface structures of the polymer give GLYCOLON® excellent handling and tissue passage properties. Tissue trauma as a result of suturing is not relevant to GLYCOLON®, and the monofilament structure prevents wicking of the thread without the need for additional surface treatment.

GLYCOLON<sup>®</sup> is available undyed, especially suitable for skin closure, and in violet (coloured with the physiologically harmless D+C No. 2 dye).



- high tear resistance
- excellent knot security
- atraumatic tissue
   passage
- **Colour:** undyed or violet
- Chemical name: poly(glycolic acidco-ε-caprolactone)
- Thread diameter: USP 6-0 1 (0.7-4 metric)
- Types of packaging:
  - needle-thread-combinations
- precut lengths
- Sterilization method: ethylene oxide



Multifilament, medium-term absorbable suture

### **PGA RESORBA®**

PGA *RESORBA®* is a polymer of glycolic acid. The linear, high molecular weight polyglycolic acid is synthesised in the presence of a catalyst via the intermediary product glycolide, a cyclic ester. The breakdown of the PGA suture in the tissue occurs through water uptake, thereby reversing the synthesis. Regular metabolic processes break down the glycolic acid monomers into CO<sub>2</sub> and H<sub>2</sub>O through enzymatic degradation.

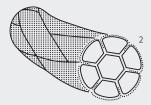
The physical and physiological properties of suture material containing 10 % lactide as copolymer differ only slightly from pure PGA sutures.

The thin, precision-braided filaments provide very high tear resistance as well as excellent suppleness. The special coating thinly encapsulates the fibre bundles resulting in a specific reduction of surface friction.

Absorbable sutures approximate the tissue during the healing phase; at the same time, they increasingly lose their tensile strength and tear resistance.

PGA RESORBA® contains precisionbraided filaments made of polyglycolic acid that result in a standardised, moderate rate of absorption in the tissue. Depending on the thread diameter 50 % of the original tensile strength of PGA RESORBA® is lost after 18 days.\*

Violet PGA *RESORBA®* is coloured with a physiologically harmless dye.



- high tear resistance
- good handling
- excellent knot security
- atraumatic tissue
   passage
- minimal tissue reaction
- Colour: violet or undyed
- Chemical name: polyglycolic acid
- Thread diameter: USP 8-0 5 (0.4-7 metric)
- Types of packaging:
  - needle-thread-combinations
  - precut lengths
- Sterilization method: ethylene oxide



Monofilament, long-term absorbable suture

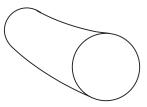
### **CAPROLON®**

In the manufacture of CAPROLON<sup>®</sup> its two components, lactide and ε-caprolactone, are co-polymerised in a fixed proportion. This creates poly(L-lactide-co-ε-caprolactone).

Because of its high lactide proportion, CAPROLON® is classified among the slowly absorbed suture materials. After implantation the breaking load of CAPROLON® decreases by about half after 7 weeks. Complete absorption by hydrolysis is completed after about 25 weeks. Tissue reaction is minimal because of the completely safe intermediary products and the monofilament structure of the thread.

CAPROLON<sup>®</sup> is coated with a blend of calcium stearate and a copolymer of L-lactide and  $\varepsilon$ -caprolactone, enhancing handling and tissue glide.

CAPROLON<sup>®</sup> is supplied undyed for skin sutures or violet.



- very high tensile strength
- minimal tissue reaction
- smooth passage through tissue
- robust and high knot security
- Colour: violet or undyed
- Chemical name: poly(L-lactide-co-ε-caprolactone)
- Thread diameter: USP 7-0 2 (0.5-5 metric)
- Types of packaging: needle-thread-combinations
- Sterilization method: ethylene oxide



Monofilament, long-term absorbable suture

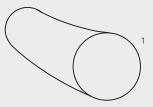
### **PDO RESORBA™**

PDO *RESORBA™* is made of the polyester poly(p-dioxanone). Because of its slow degradation profile, PDO *RESORBA™* is particularly useful where the combination of an absorbable suture and extended wound support (up to six weeks) is desirable.

After implantation the breaking load is at 50 - 60 % after 42 days. Absorption by hydrolysis is completed after about 180 to 220 days Tissue reaction is minimal because of the monofilament structure of the thread.

PDO *RESORBA™* is supplied violet.

- Colour: violet
- Chemical name: poly(p-dioxanone)
- Thread diameter: USP 7-0 2 (0.5-5 metric)
- Types of packaging: needle-thread-combinations
- Sterilization method: ethylene oxide



- very high tensile strength
- minimal tissue reaction
- smooth passage through tissue
- robust and high knot security



Monofilament, long-term absorbable suture

### **RESORBA®** Barbed Suture

*RESORBA®* Barbed Suture (PDO) is a polydioxanone knotless tissue-closure device, which is comprised of barbed dyed polydioxanone (PDO) suture material, armed with a surgical needle on one end and an end stopper at the other end.

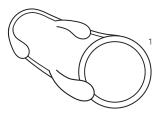
*RESORBA®* Barbed Suture (PDO) features unidirectionally oriented barbs that facilitate tissue approximation without the need for tying surgical knots.

Although the barbs in the *RESORBA*® Barbed Suture (PDO) reduce tensile strength compared to non-barbed suture material of the same size, tying knots in non-barbed sutures also deminishes their effective strength. For this reason, the strength of the *RESORBA®* Barbed Suture (PDO) can be compared to USP knot strength of non-barbed sutures.

After implantation, the tensile strength remains at 55 % after 42 days. Absorption by hydrolysis is completed after about 180 to 220 days.

*RESORBA®* Barbed Suture (PDO) is available in violet (coloured with the physiologically harmless D+C No. 2 dye).

USP strength before barbed suture	USP strength of RESORBA® Barbed Suture	Number of barbs per inch
2	1	32
1	0	33
0	2-0	42
2-0	3-0	51
3-0	4-0	54



- siliconised needles made of 300 steel
- synthetic with a long period of action
- unidirectional spiral angle cut on one side
- high tensile strength
- triangular end stopper
- Colour: violet
- Chemical name:
- poly(p-dioxanone)
- Thread diameter: USP 4-0 1 (1.5-4 metric)
- Types of packaging: needle-thread-combinations
- Sterilization method: ethylene oxide



#### Non-absorbable suture

### **MOPYLEN®**

MOPYLEN® is a synthetic suture, which is manufactured by polymerising propylene.

The suture is produced from the dyed granules using the dry spinning process. The suture is hydrophobic, meaning it absorbs practically no water and is chemically inert. MOPYLEN® is an ideal skin suture, especially in plastic surgery and anywhere, where an excellent cosmetic result is critical. The material is coloured with a physiologically harmless dye.

- **Colour:** blue
- Chemical name: isotactic polypropylene
- Thread diameter: USP 10-0 2 (0.2-5 metric)
- Types of packaging: needle-thread-combinations
- Sterilization method: ethylene oxide

### **Properties**

- excellent knot security
- consistently high tear resistance
- excellent tissue passage
- hydrophobic
- on non-ageing

#### **Dry Spinning Process:**

The dry spinning process is a manufacturing technique for producing synthetic fibers, where a polymer is dissolved in a solvent and extruded into the air through a spinneret. The solvent then evaporates, resulting in the formation of solid fibers. This method is commonly used in the production of surgical sutures and allows for the creation of threads with specific properties, such as high strength and biocompatibility.



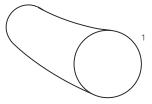
#### Non-absorbable suture

### **MOPYLEN® CV**

MOPYLEN® CV is a special suture for cardio-vascular surgery and is crimped exclusively with SURE POINT needles.

MOPYLEN® CV is a synthetic suture, which is manufactured by polymerising propylene. The suture is produced from the dyed granules using the dry spinning process. The suture is hydrophobic, i.e., it absorbs practically no water and is chemically inert. The material is dyed with a physiologically harmless dye. To reduce the memory effect, USP thicknesses 6/0 and thinner are produced in long packs.

- Colour: blue
- Chemical name: isotactic polypropylene
- Thread diameter: USP 8-0 0 (0.4-3.5 metric)
- Types of packaging: needle-thread-combinations
- Sterilization method: ethylene oxide



#### **Properties**

- excellent knot security
- consistently high tear resistance
- excellent tissue passage
- on non-ageing
- SURE POINT needles for optimised use within cardio-vascular surgery

#### **Memory Effect:**

The memory effect refers to the property of surgical sutures to retain their shape, such as bends or kinks, after being removed from the packaging. This effect can be mitigated by gently stretching the suture material.



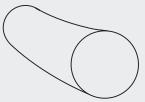
#### Non-absorbable suture

### **RESOPREN®**

RESOPREN® is a blue, monofilament, synthetic suture made of polyvinylidene difluoride (PVDF). The suture is produced from the dyed granules using the dry spinning process. RESOPREN® is chemically inert, hydrophobic and highly resistant to ageing.

The material is coloured with a physiologically harmless dye.

- **Colour:** blue
- Chemical name: polyvinylidene difluoride
- Thread diameter: USP 7-0 2 (0.5-5 metric)
- Types of packaging: needle-thread-combinations
- Sterilization method: ethylene oxide



### **Properties**

- hydrophobic, flexible and elastic
- excellent tissue passage
- extremely supple
- chemically inert
- extremely resistant to ageing

# Information that is applicable to all the synthetic sutures described:

Due to their elasticity coupled with a relatively high tensile strength, no synthetic sutures should be too tightly knotted to ensure low tension within the tissue. Excessively high tension within the tissue may lead to wound healing disturbance, or even necrotic reactions. In view of the elastic stretch and smooth surface (especially of monofilament sutures), it is recommended that an additional knot is made to ensure that the knot sits very firmly. According to Nockemann\* it is best "first to place a Surgeon's or Friction Knot and then a Square Knot over it for safety". In principle, synthetic sutures can be used universally for nearly all wounds. Absorbable PGA *RESORBA®* has proven to be especially suitable for internal sutures, as for anastomoses, fascia sutures, subcutaneous tissues and ligatures. Monofilament polyamides such as NYLON and RESOLON®, as well as hydrophobic suture material such as MOPYLEN® and RESOPREN® are widely preferred for skin sutures.



Non-absorbable suture

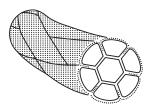
### POLYESTER

POLYESTER is produced by polycondensation of ethylene glycol and terephthalic acid. Fibres are formed using the dry spinning process. Precision-braiding and tempering transform the stretched, slightly twisted fibre bundles into a suture.

The individual fibres are hydrophobic, meaning they repel water.

The material is coloured with a physiologically harmless dye.

- Colour: green, white (no dye)
- Chemical name: polyethylene terephthalate polyester fibre
- Thread diameter: USP 6-0 6 (0.7-8 metric)
- Types of packaging:
  - needle-thread-combinations
  - precut lengths
- Sterilization method: ethylene oxide



- very high tear resistance
- excellent tissue passage
- high knot security

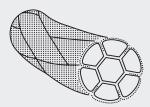


#### Non-absorbable suture

### **SUPOLENE**

Like POLYESTER, the production of SUPOLENE involves the polycondensation of ethylene glycol and terephthalic acid. Fibres are formed using the dry spinning process. The suture then undergoes precisionbraiding, dyeing and tempering and the surface is specially refined by coating. This surface treatment minimises capillarity and any sawing effect during tissue passage and knot rundown. SUPOLENE is hydrophobic, i.e., it does not absorb water. The material is coloured with a physiologically harmless dye.

- **Colour:** green, white (no dye)
- Chemical name: polyethylene terephthalate polyester fibre
- Thread diameter: USP 6-0 3 (0.7-6 metric)
- Types of packaging:
  - needle-thread-combinations
  - in precut lengths
- Sterilization method: ethylene oxide



- high tear resistance
- excellent tissue passage, no sawing effect
- very even and smooth surface properties
- very minimal tissue reaction
- o minimal capillarity

NYLON



#### Non-absorbable suture

### NYLON

NYLON is a monofilament extruded thread (pressed and drawn through dies in a malleable condition) made from polyamide 6-6.6. Due to its high tensile strength, even at the smallest thread diameters, NYLON is particularly suited for the finest sutures in microsurgery. Polyamides can bind up to 10 % water. The material is coloured with a physiologically harmless dye.

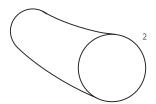
- **Colour:** white (no dye), black
- Chemical name: polyamide 6-6.6
- Thread diameter: USP 10-0 2 (0.2-5 metric)
- Types of packaging: needle-thread-combinations
- Sterilization method: ethylene oxide

### **RESOLON®**

RESOLON® is initially a monofilament polyamide 6-6.6 suture, like NYLON. However, it undergoes special treatment during the manufacturing process.

RESOLON® is exceptionally soft and supple even when dry and sterile. As a result, it has excellent handling and knotting properties for a monofilament suture, while ensuring maximum knot tear resistance.

- Colour: blue
- Chemical name: polyamide 6-6.6
- Thread diameter: USP 7-0 1 (0.5-4 metric)
- Types of packaging:
  - needle-thread-combinationsprecut lengths
- Sterilization method: ethylene oxide



- above average softness and suppleness
- superior handling and knotting properties
- ono capillarity
- excellent tissue passage



#### Non-absorbable suture

### **SUPRAMID**

SUPRAMID is available as a monofilament, non-absorbable, surgical suture made from a copolymer of polyamide 6 and polyamide 6.6. In larger diameters, it is supplied as a pseudo-monofilament, non-absorbable, surgical suture made from polyamide 6.6, a polymer of hexamethylenediamine and adipic acid with a polyamide-6 coating, a polymer of  $\varepsilon$ -caprolactam.

#### **Special feature**

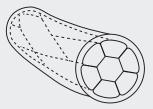
Despite its synthetic origin and peptide-like structure, SUPRAMID gradually degrades after being in tissue for an extended period. Therefore, it is primarily suitable for skin sutures or tissues that do not require permanent wound support, with few exceptions.

The material is coloured with a physiologically harmless dye.

**Colour:** white (no dye) or black

Chemical name: monofilament: polyamide 6-6.6 pseudomonofilament: polyamide 6.6 and polyamide 6

- Thread diameter: USP 6-0 2 (0.7-5 metric)
- Types of packaging:
  - needle-thread-combinations
  - in precut lengths
- Sterilization method: ethylene oxide



- above average softness and suppleness
- superior handling and knotting properties
- ono capillarity
- excellent tissue passage



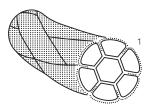
#### Non-absorbable suture

### SILK

The raw material for silk production is the cocoon of the silkworm. The delicate filaments from these cocoons are degummed to remove sericin, then spun and precision-braided.

A surface treatment is applied to impregnate the silk filament, resulting in a silk that does not exhibit unwanted capillary action. This creates a non-capillary, water-repellent suture with a smooth surface. SILK is coloured with a physiologically harmless dye.

- Colour: black
- Chemical name: silk fibroin
- Thread diameter: USP 8-0 5 (0.4-6 metric)
- Types of packaging:
  - needle-thread-combinationsprecut lengths
- Sterilization method: ethylene oxide



- ✓ very supple
- excellent knotting properties
- excellent knot security
- minimal sawing effect



#### Non-absorbable suture

### **STAINLESS STEEL**

Steel wire is utilized in surgery for its exceptional tensile strength and outstanding corrosion resistance. Made from stainless, high-strength steel alloys, it maintains its shape and functionality even under physiological conditions.

#### **Manufacturing Process:**

Liquid steel is drawn through specialized forming tools to produce wire in the desired diameters. This process ensures that the material is durable and biocompatible.

- Chemical name: stainless steel
- Thread diameter: USP 5-0 7 (1-9 metric)
- Types of packaging:
  - needle-thread-combinations
  - precut lengths
- Sterilization method: ethylene oxide



- high, unchanging tear resistance
- on stretching
- minimal tissue reaction
- no wicking effect



### Manufacture of surgical suture

Using PGA RESORBA® as an example (multifilament, braided suture made from 100 % polyglycolic acid)

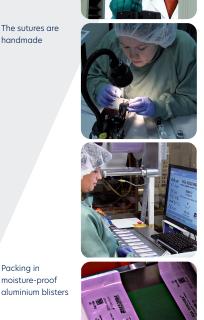
Raw material must comply with standard values aovernina diameter and knot tensile strength



Packing in

moisture-proof

The sutures are



#### Testing of material

All supplied or self-produced raw materials and excipients are tested and selected according to international criteria before use.

#### Assembly / packing

We offer a wide range of product variants for different surgical indications. In addition to special needle-thread combinations, a multiplicity of customers' requests for specific applications are also met.

#### **Sterilization**

The products are sterilized with ethylene oxide.

#### Drying

PGA RESORBA®, made of polyglycolic acid fibres, reacts with H<sub>2</sub>O. Drying of the suture after sterilization is an essential step in the manufacturing process to achieve high product safety.

#### **Final testing**

The special characteristic of PGA threads (breakdown by H<sub>2</sub>O take-up) requires great care in packaging and packaging materials. This is achieved by the almost completely automatic production of blister packs. During the production process the metal foils and their seals are tested to ensure they are intact and tight.

All surgical sutures are manufactured and tested according to the stipulated legal regulations, which are:

- a. European Pharmacopoeia (Ph. Eur.) and the harmonised norms derived from its monographs
- b DIN ISO standards
- c. MDD 93/42/ EWG
- d. MDR (EU) 2017/745

The German rules and regulations governing pharmaceutical companies are based on the basic guidelines (European or international) of the World Health Organization (WHO) for the correct production of medicinal products and quality assurance according to GMP (Good Manufacturing Practice). The contents of these GMP guidelines largely agree with the European (Ph.Eur.) and the American Pharmacopoeia (USP).

Since 14.6.1998, surgical suture material is defined solely in terms of the quality standards described in the DIN ISO or EN standard series. The CE marking allows for the sale across the entire European market (Harmonization at the European level).

### Peel-eco-pack

Sterile conditions and the use of contamination-free sutures are vital prerequisites for surgical work. This is guaranteed for our products by sterilizing them with ethylene oxide (EO) gas, and the safe combination of peelable outer and multifunctional inner wrappings.



The **peelable outer wrapping** can be opened by a non-sterile person (e.g. a Circulating Nurse in the operating room) by peeling it off so that the inner sterile contents can be safely passed on, assuring contaminationfree transfer



The **multifunctional primary packet** further protects the suture and allows for problem-free and safe removal.





- Sterile hand-over in the shortest time
   Quick and easy handling with approved suture primary packet.
- Less packing material Reduction to two multifunctional wrapping units.
- Environmentally friendly Primary packet made of recyclable paper.
- Easy handling

The layered arrangement of the atraumatic needles in the primary packet makes controlled and safe access possible.

Memory effect

The enlarged suture primary packet markedly reduces the memory effect when using monofilament suture material.

Separate withdrawal

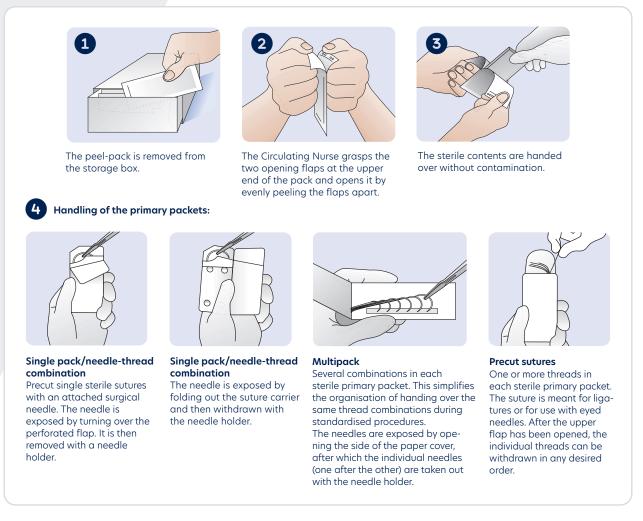
The primary packet in precut suture packs and multipacks makes it possible to withdraw single sutures.

The eco-pack fulfils the provisions of DIN 58953, part 8 / Sterile supplies.



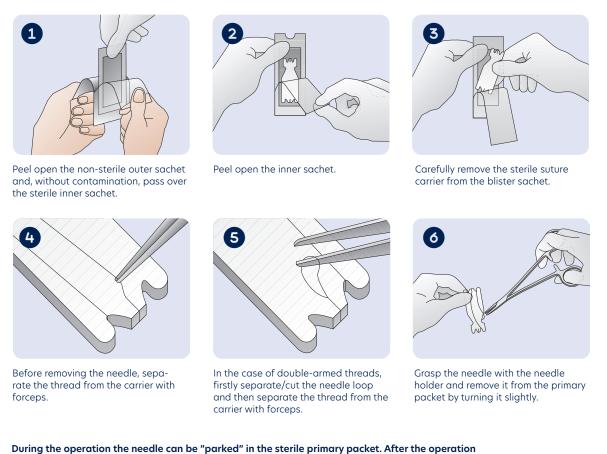
### Peel-eco-pack

A combination of peelable outer wrapping and multifunctional primary packet



### **Micro-Pack**

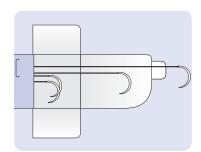
Primary packet with foam for micro- and ophthalmic surgery



the primary packet is used for depositing and checking the number of needles used.



### Other types of packaging



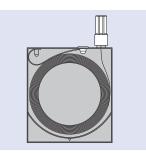
#### Multi-L-Pack

Special combinations are available in the Multi-L-Pack for preventing the memory effect. This ensures rapid, problem-free removal.



#### Ligature pack

Suture material of up to 4 m in length can be taken from a hand reel during an operation.

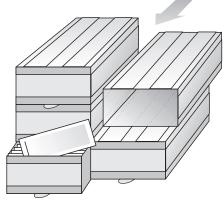


#### **Dispenser packaging**

Suture material can be removed aseptically from the dispenser. Suture material in so-called suture dispensers is predominantly used in veterinary medicine. The packaging is safe and economical.

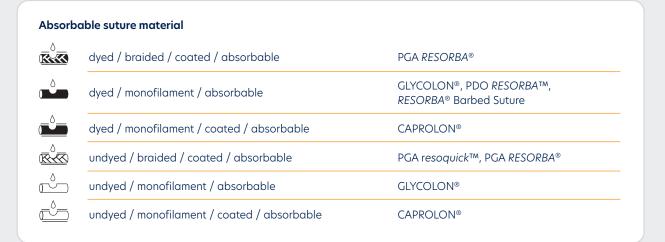
#### Suture-boxes as organisational aids

Stacked boxes for storing standard suture material packages, for clearly organised arrangement in the operating room (can be stacked vertically and/or horizontally).



# Organisational aids

### Symbols used on the packaging



#### Non-absorbable suture material

POLYESTER, SUPOLENE, SILK
MOPYLEN <sup>®</sup> , MOPYLEN <sup>®</sup> CV, RESOPREN <sup>®</sup> , NYLON, RESOLON <sup>®</sup> , SUPRAMID
SUPRAMID
POLYESTER, SUPOLENE
NYLON, SUPRAMID, STAINLESS STEEL
SUPRAMID

Organisational aids



# **Explanation of symbols**

PGA resoquick™, PGA RESORBA®	Polyglycolic acid
GLYCOLON®	Poly(glycolide-co-caprolactone)
CAPROLON®	Poly(L-lactide-co-ε-caprolactone)
PDO RESORBA™, RESORBA® Barbed Suture	Poly(p-dioxanone)
MOPYLEN <sup>®</sup> , MOPYLEN <sup>®</sup> CV	Polypropylene
RESOPREN®	Polyvinylidene difluoride
POLYESTER, SUPOLENE	Polyester
NYLON, RESOLON <sup>®</sup> , SUPRAMID	Polyamide



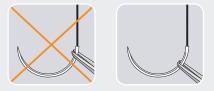
# Organisational aids

### Did you know?



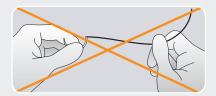
\* Some of the products listed in this brochure are already certified under Regulation (EU) 2017/745 (MDR). Other products are currently undergoing the conformity assessment process. However, they remain legally compliant with Directive 93/42/EEC (MDD).

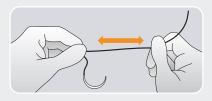
### Holding the needle



Needles should be held approx. 3/4 away from the tip. Do not clamp where the suture is swaged to the needle to avoid weakening the needle and suture.

### Stretching the thread





The thread must be stretched gently after it has been removed from the primary packet. Do not pull or rub it abruptly. Do not grasp the needle and stretch the thread!



### Knotting techniques: instrument knots



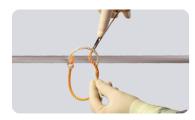
After you have penetrated the tissue with the needle, wrap the longer end of the suture around the needle holder. Then grasp the end of the suture slightly protruding from the wound.



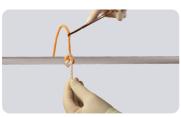
Pull the short end of the suture through the throw towards yourself.



The first loop is fastened by pulling in opposite directions.



Now wrap the needle holder again with the long end of the suture and pull the needle holder in the opposite direction.



Tighten the knot carefully. Please note that closing the needle holder too tightly can damage the suture material.



Follow the instructions on the pictures to achieve this optimum configuration of the knots. Depending on the indication and suturing technique, it may be necessary to vary the number of throws.

#### <sup>1</sup> Product portfolio manufactured by:



Healthium Medtech Limited · #472-D, 13th Cross, 4th Phase Peenya Industrial Area, Bangalore, Karnataka-560058, India Email: care@healthiummedtech.com Mfg. Lic. No: MFG/MD/2021/000367

#### <sup>2</sup> Some combinations of this product portfolio manufactured by:



Healthium Medtech Limited · #472-D, 13th Cross, 4th Phase Peenya Industrial Area, Bangalore, Karnataka-560058, India Email: care@healthiummedtech.com Mfa. Lic. No:: MFG/MD/2021/000367

39





# FREIGABE/APPROVAL

Dokument-Nr.	P1326	C	Datum	11.11.2024
Revisionsstand	2024-11	1		
Ersteller/Abt.	Marketi	ing		Stoneord为资格编码物外模制。Munkelt
Ersteller	JA 🖾	NEIN 🗆	Sig	
RA	JA 🛛	NEIN 🗆	Sig	Signier von Pragya Sakril Hovezozer (* 120 GMT
QA	JA 🖾	NEIN 🗆	Sig	Sign Range Budget Block States Block 12:04 GMT
Legal	JA 🛛	NEIN 🗆	Sig	
Druckfreigabe	JA 🛛	NEIN 🗆	Sig	Signa
FOR_VA420510_0	0323	Stand: 26	6.05.202	3 RAFAN (2205644063822140C0E030E618

The RESORBA company was founded in September 1931 as a "Fabrik medizinischer Präparate" (a manufacturer of medical devices). Since then both the company and its products have undergone continual development.

Our company's main office on the outskirts of Nuremberg has provided the basis and capacity for us to continue to fulfil future demands in medicine competently and with a high level of quality.



**RESORBA Medical GmbH** Am Flachmoor 16, 90475 Nürnberg, Germany

🕨 resorba.com | 🗳 infomail@resorba.com | 🕓 +49 9128 / 91 15 0



© 2024 · RESORBA® is a registered trademark of RESORBA Medical GmbH. All rights reserved. RESORBA Medical GmbH is an Advanced Medical Solutions Group company.