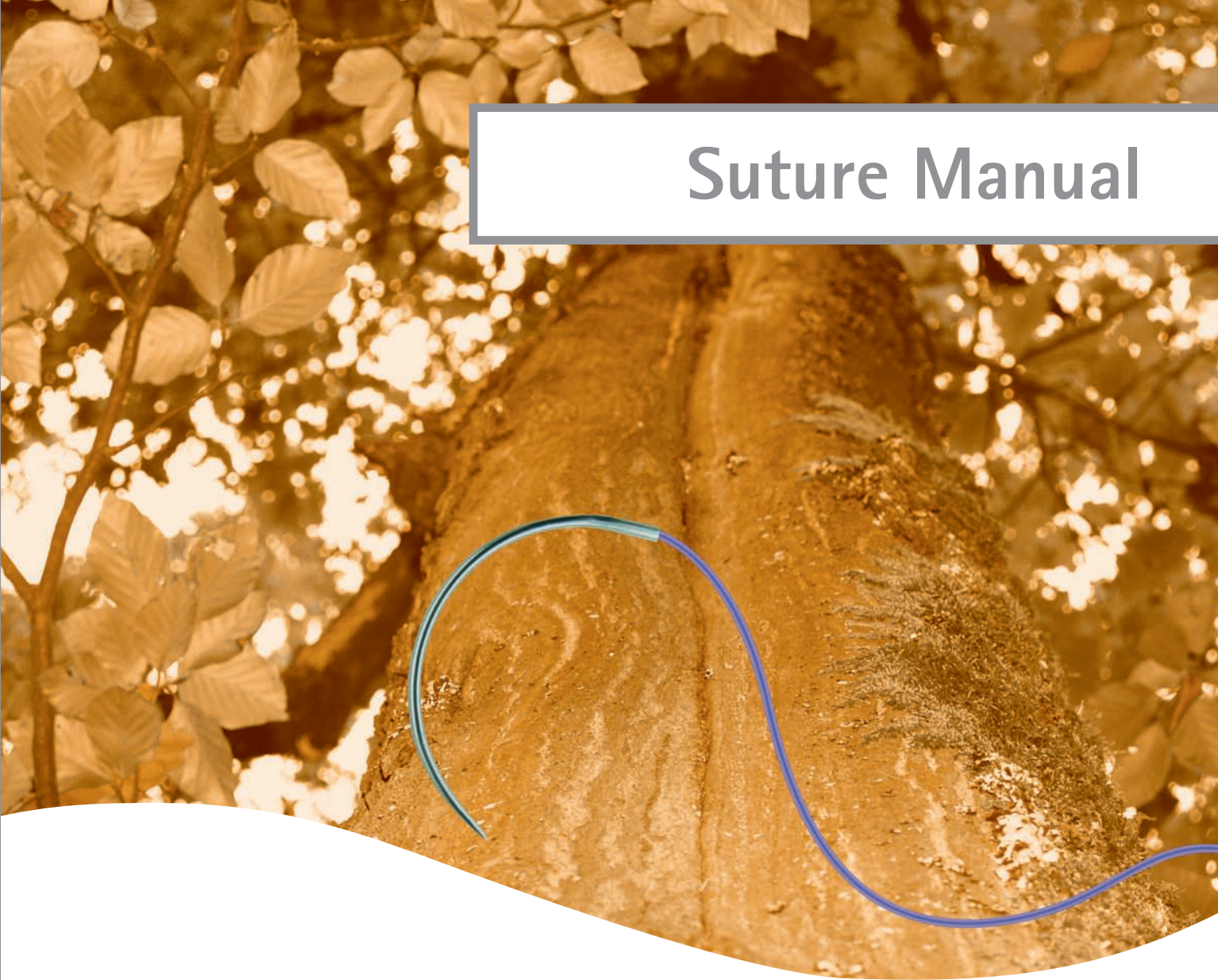


# Suture Manual



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No claim is made for the completeness of the information given about the suture material: this must be gathered from the relevant literature for healthcare specialists.

More detailed information concerning the materials can be obtained from the information leaflets in each package. We shall be pleased to send these on request.

Visit our website: [www.resorba.com](http://www.resorba.com) for constantly updated and comprehensive information on our products and developments.

In nature, damaged or destroyed tissue layers must be covered over quickly to preserve the integrity and functions of the organism. We humans have copied this response from nature.

It is the aim of modern wound care, first and foremost, to preserve intact tissues and support the damaged parts. Our suture materials, based on biocompatible raw materials, make possible the targeted application of every kind of wound care, and guarantees the best possible tissue acceptability.

Surgical suture is a typical medical device for tissue repair. Most wound closures are still done with sutures. The mechanical properties of the inserted material are of the greatest importance in temporarily replacing the lost strength.

Absorbable materials, e.g. PGA *RESORBA*®, support the natural healing process until form and function are restored. Such materials are subsequently metabolised by the organism.

Non-absorbable suture materials (e.g. MOPYLEN®) guarantee lasting support and best biotolerance, which is especially essential for long-term implants.

A large number of suture materials are nowadays used in wound closure. In many respects they are adapted to their specific use (indication) and are chosen for the particular 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

## A journey into the history of surgical sutures

### The development of surgical suture revisited



*Production of catgut around 1930*

### 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. 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).

### 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

Beginning of the industrial manufacture of suture material (catgut), 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. This 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. An 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, this 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



*Early packaging of sutures*

development of packaging techniques with synthetic materials around 1960, and of new methods of sterilisation that it became possible to make the sterile and ready-for-use packs available nowadays.

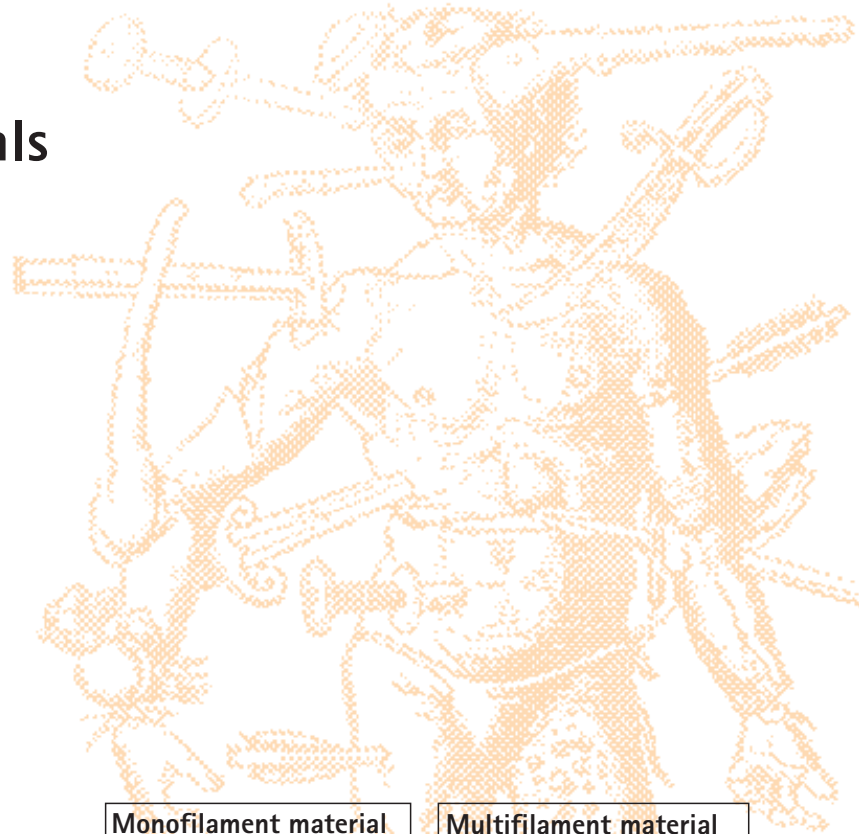
## Historical classification according to raw materials

- **Natural starting materials:**  
Silk, linen (twine), animal gut (catgut)
- **Synthetic starting materials:**  
Polyglycolic acid, polylactide, polyamide, polyester, polypropylene, PVDF

## Modern classification according to absorption characteristics

- **Non-absorbable**  
SILK, RESOPREN®, MOPYLEN®, POLYESTER, SUPOLENE, WIRE
- **Pseudo-absorbable**  
RESOLON®\*, NYLON\*, SUPRAMID\*
- **Slow absorption**  
CAPROLON®
- **Medium-term absorption**  
PGA *RESORBA*®
- **Fast absorption**  
PGA *resoquick*™, GLYCOLON®

\*Polyamide is not fully inert, but a pseudo-absorbable material, early hydrolytic degradation having been observed after more than 6 months.



	Monofilament material	Multifilament material
Properties	no capillarity no sawing action easily knotted easy passage through tissue	very high tensile strength high knot security very supple simple handling
Absorbable material:	CAPROLON® GLYCOLON®	PGA <i>resoquick</i> ™ PGA <i>RESORBA</i> ®
Non-absorbable material:	MOPYLEN® RESOPREN® NYLON RESOLON® STAINLESS STEEL	POLYESTER SUPRAMID SUPOLENE SILK STAINLESS STEEL

## Absorption

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

**Non-absorbable suture** remains almost unchanged when placed within body tissues, and is encapsulated within the wound scar 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 –14 days). It has to be distinguished:

### Absorption time

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

### Disintegration

The period during which essentially non-absorbable suture breaks down by degra-

dation into (smaller) pieces and thus loses its strength (e.g. polyamide)

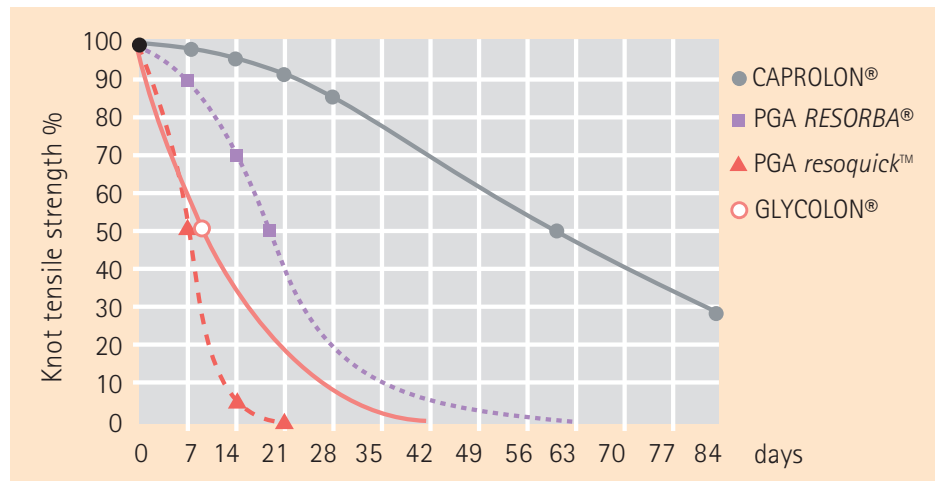
### Dissolution

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

## Characteristics of absorption

Different indications also require different tensile strength and absorption characteristics. These particular features of diffe-

rent 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.

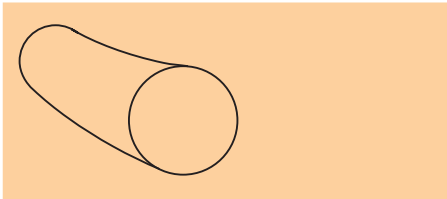


*In-vitro* trial of suture degradation by measuring the knot tensile strengths of GLYCOLON®, PGA *resoquick*™, PGA RESORBA® and CAPROLON®. Suture size: 3-0 USP (2 metric).

## Thread structure

The structure of a thread affects its passage through tissue and its capillarity. We distinguish between four basic thread structures:

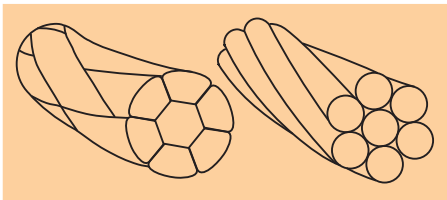
### Monofilament



*A monofilament consists of only one thread filament.*

- GLYCOLON®
- CAPROLON®
- MOPYLEN®
- RESOPREN®
- RESOLON®
- NYLON
- STAINLESS STEEL, monofilament

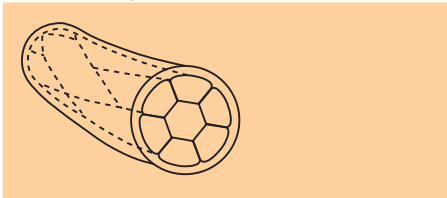
### Multifilament



*A multifilament consists of many thin elementary fibres which are either twisted, entwined or braided into bundles.*

- STAINLESS STEEL, multifilament
- POLYESTER
- SILK

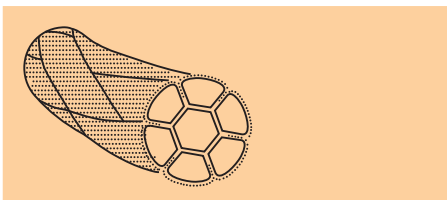
### Coated or pseudo-monofilament



*The thread interior (the so-called thread core), a bundle of parallel filaments, is imbedded in a mantle-like or tube-like coating that provides a smooth cover.*

- SUPRAMID

### Multifilament coated



*Multifilaments can be treated with various special coating materials to improve their mechanical properties. In this way gaps between the filament bundles are evened out and surface friction is reduced.*

- PGA RESORBA®
- PGA resoquick™
- SUPOLENE

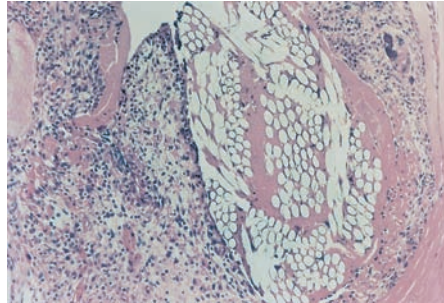
## Tissue acceptance

Every insertion of suture triggers some tissue reaction within the body (see table).

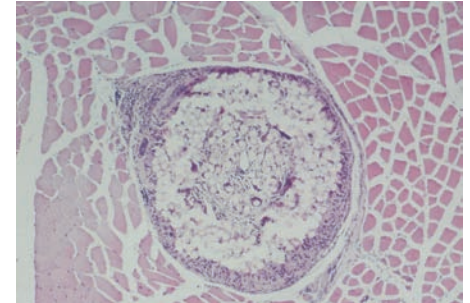
The causes are:

- Traumatization of tissue on placing the suture
- Mechanical irritation by 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)

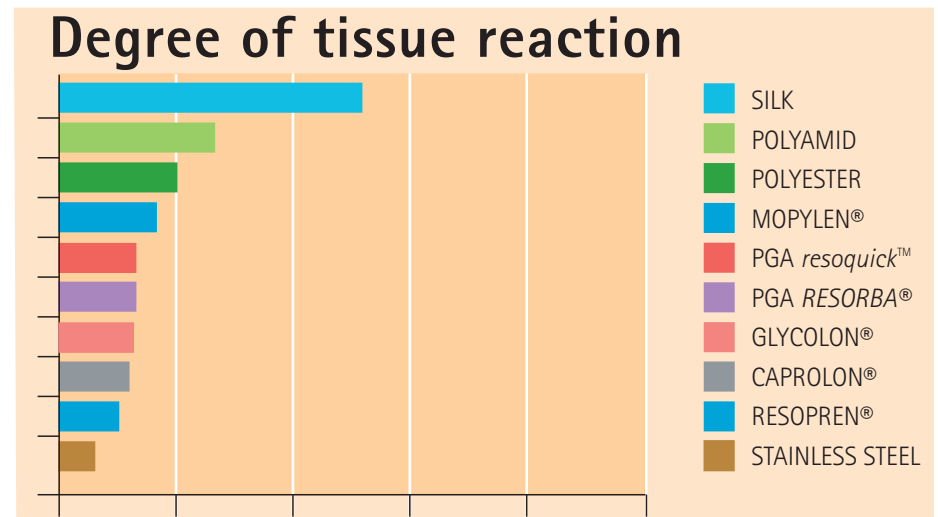
## Tissue acceptance, using PGA RESORBA® as example



*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.



# Principles

## 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 man-

datory for European manufacturers. The table compares the diameters with the conventional nomenclature used to date (United States Pharmacopoeia). The latter have 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 = thread diameter of 0.1 mm.

## Thread table

Ph.Eur	Diameter range in mm	PGA RESORBA®	PGA resoquick™	MOPYLEN®	RESOPREN®	POLYESTER	SUPOLENE	NYLON monofilament RESOLON®	SUPRAMID	SILK	STAINLESS STEEL multifilament	STAINLESS STEEL monofilament	Synth. monofilament Diameter in mm	GLYCOLON®	CAPROLON®
0.1 EP	0.010-0.019							11-0							
0.2 EP	0.020-0.029	10-0		10-0				10-0		10-0					
0.3 EP	0.030-0.039	9-0		9-0				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
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
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	0.150-0.199	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	0.200-0.249	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	0.250-0.339	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	0.340-0.399	2-0	2-0
3.5 EP	0.350-0.399	0	0	0	0	0	0	0	0	0	0	0	0.400-0.499	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
5 EP	0.500-0.599	2	2	2		2	2	2	2	2	2	2	0.571-0.610		2
6 EP	0.600-0.699	3+4				3+4	3+4		3+4	3+4	3+4	3+4			
7 EP	0.700-0.799	5				5	5		5	5		5			
8 EP	0.800-0.899					6	6		6	6		6			
9 EP	0.900-0.999					7	7		7			7			

## Tensile strength of surgical suture

Tensile strength is defined as the force required in Newtons 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 Ph.Eur.\***  
(harmonised standards)

Diameter metric	All other non-absorbable sutures in N	Synthetic, multi-filament, absorbable sutures (PGA RESORBIA®)	Synthetic, mono-filament, absorbable sutures (CAPROLON®)
0.2 metric	0.10	-	
0.3 metric	0.35	0.45	
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

## Needle characteristics

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 seating in needle-holder

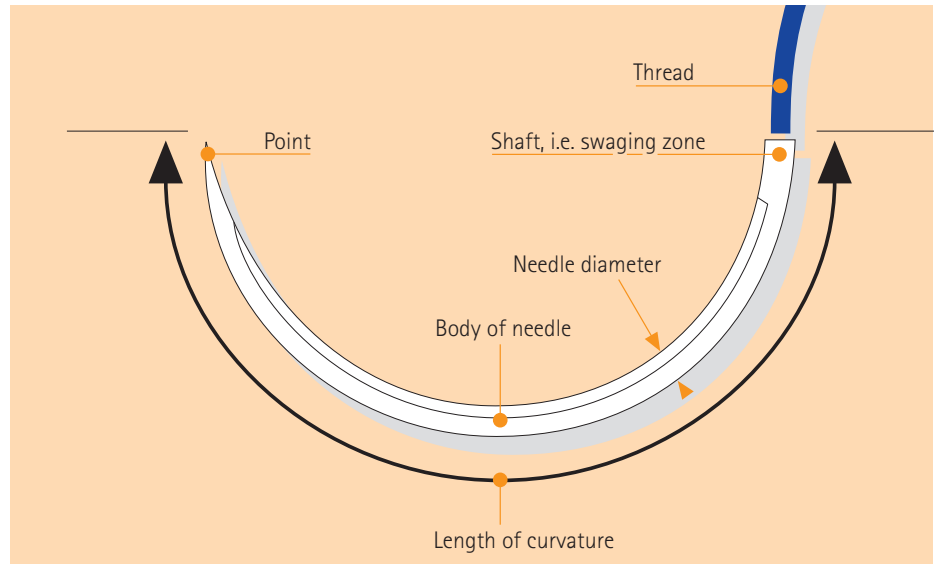
For suturing and suture encircling of wounds, atraumatic (eyeless) needles are usually used as needle-thread combinations. Needle-thread combination means, the thread is inserted and firmly anchored inside a drilled shaft at the end of the needle. This provides an essentially step-free transition from thread to needle.

Thus any further trauma to tissue is avoided, as could occur if the thread is doubled up after passing it through the eye of a needle.

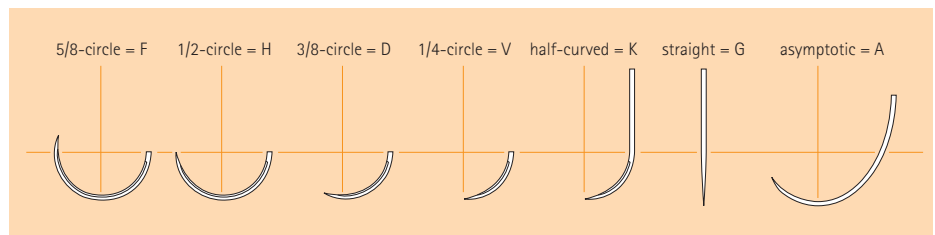
RESORBA's eyeless needles are made from

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.



## Needle shapes



## Cross-section and point of the needle



### 1. Spatula needle ◻ = P

1/2-, 3/8- or 1/4-circle or straight = HSPM, DSPM, VSPM, GSPM

- For ophthalmic and microsurgery
- Flattened needle body
- PREMIUM-cut
- Lateral cutting edge



### 2. Reverse cutting needle ▼ = S

1/2-, 3/8-half-curved or straight, 1/2 = HS, DS, KS, GS

- For firm tissue, e.g. skin
- Triangular needle cross-section
- Some needles available as PREMIUM-cut: M, MF, and MFX



### 3. Round-bodied cutting needle

◉◉ = RT

1/2-, 3/8-circle, asymptotic or straight = HRT, DRT, GRT, ART

- For firm tissue, sclerotic vessels, and prostheses
- Needle point with three or four cutting edges, thus producing a narrow puncture canal which penetrates tissue like a cutting ▼ needle (some available as PREMIUM-cut)



### 4. Blunt, round-bodied needle ○ = RN

1/2-, 3/8-circle or half-curved = HRN, DRN, KRN

- For parenchymatous tissue, cervix and muscles of the eye
- Blunt needle point
- Cannot pierce vessels or tendons



### 5. Round-bodied needle ● = R

5/8-, 1/2-, 3/8-circle or straight = FR, HR, DR, GR

- For soft (subcutaneous) tissue, e.g. muscle, fascia, mucosa
- The middle of the needle is flat for better seating in the needle-holder
- Conical tapering fine needle tips
- Easy tissue penetration

## Needle code

### 1. letter: defines the needle curvature

F = 5/8 circle  
H = 1/2 circle  
D = 3/8 circle  
V = 1/4 circle  
K = half-curved  
A = asymptotic  
G = straight

### 2. letter: defines the shape of the needle body and point

R = round-bodied needle  
S = cutting needle

### 3.+4. letters: define special forms of the needle body and point

M = PREMIUM-cut (e.g. hand-cut)  
N = blunt point  
T = cutting point  
P = spatula-needle (PREMIUM)  
S = larger diameter  
X = extra large diameter  
F = finely PREMIUM-cut "THIN LINE"  
(in some cases hand cut)

### Numbers define the length of the needle when straight (length of needle curvature) in mm

S (after number) = larger diameter  
F (after number) = extra small diameter  
A (after number) = control release needle

H R X 30

## Control release needles

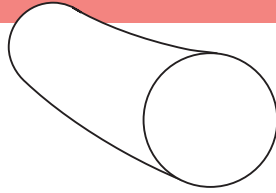
To save time, e.g. when inserting single-knot sutures for anastomoses of the gastrointestinal tract or layered wound closure, the needle-thread combination has been constructed with a removable needle.

After the suture has been placed, the needle can be removed from the suture with a slight pull.

## Table of materials

Trade name	Raw material	Structure	Thread diameter, metric	Thread diameter, USP	Colour	Tensile strength, 50%
GLYCOLON®	Polyglycolic acid-caprolactone	monofilament metric	0.7 to 4 metric	6-0 to 1 USP	violet, undyed	9 days 50%
PGA <i>resoquick</i> ™	Polyglycolic acid, coated	multifilament/braided	0.7 to 5 metric	6-0 to 2 USP	undyed	7 days 50%
PGA <i>RESORBA</i> ®	Polyglycolic acid, coated	multifilament/braided	0.2 to 7 metric	10-0 to 5 USP	violet, undyed	14-21 days 50%
CAPROLON®	[Poly(L-lactide-co-ε-caprolactone)]	monofilament	0.5 to 5 metric	7-0 to 2 USP	violet, undyed	45 days 50%
MOPYLEN®	Polypropylene	monofilament	0.2 to 5 metric	10-0 to 2 USP	blue	
RESOPREN®	PVDF	monofilament	0.4 to 4 metric	8-0 to 1 USP	blue	
POLYESTER	Polyester	multifilament/braided	0.5 to 9 metric	7-0 to 7 USP	green, white	
SUPOLENE	Polyester, coated	multifilament/braided	0.7 to 9 metric	6-0 to 7 USP	green, white	
NYLON	Polyamid	monofilament	0.1 to 5 metric	11-0 to 2 USP	white, black	
RESOLON®	Polyamid	monofilament	0.5 to 4 metric	7-0 to 1 USP	blue	
SUPRAMID	Polyamid	pseudo-monofilament	0.5 to 9 metric	7-0 to 7 USP	white, black	
SILK	Silk fibroin	multifilament/braided	0.2 to 8 metric	10-0 to 6 USP	white, blue, black	
STAINLESS STEEL	Stainless steel	monofilament, multifilament/twisted	0.7 to 9 metric	6-0 to 7 USP		

## GLYCOLON®



The two material components polyglycolic acid and  $\epsilon$ -caprolactone are copolymerised in a certain ratio to make GLYCOLON®.

Metabolization of the polymer suture within the tissue occurs by the uptake of water, thus reversing the synthesis.

GLYCOLON® loses half of its tensile strength after about 9 days after implantation. Complete absorption by hydrolysis is completed after about 6 weeks.

Tissue reaction is minimal because of the completely safe intermediary products and the monofilament structure of thread.

GLYCOLON® with its smooth surface provides excellent handling properties and very good passage through tissue. Tissue traumatization is minimal and there is no undesirable wick effect due to the monofilament structure of GLYCOLON®.

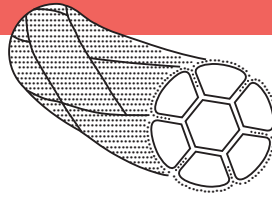
GLYCOLON® is supplied undyed for skin sutures or violet (dyed with the physiologically safe dye D+C No. 2).

- Colour: undyed or violet
- Chemical name:  
[poly(glycolic acid-co- $\epsilon$ -caprolactone)]
- Thread diameter: USP 6-0 -1  
(0.7-4 metric)
- Types of packaging:
  - needle-suture-combination
  - precut length
- Sterilization method: ethylene oxide

### Properties:

- **good flexibility**
- **very good passage through tissue**
- **optimum tissue compatibility**
- **high tensile strength**
- **reliable knot security**

## PGA *resoquick*™



PGA *resoquick*™ is a polymer of glycolic acid. The linear, high-molecular glycolic acid is synthesised in the presence of a catalyser to a cyclic ester via an intermediary product, glycolide.

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. Suture material containing 10% lactide as copolymerisate differs only slightly in its physical and physiological properties from pure PGA sutures. The fine, precision-braided filaments guarantee a very high tensile strength as well as great suppleness. The special resolactone coating thinly covers the fibre bundles

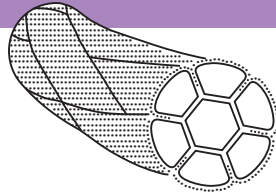
for specific reduction of surface friction. Absorbable suture approximates the tissue during the healing phase and progressively loses its tensile strength and breaking load. After only seven days PGA *resoquick*™ has already lost 50% of its original breaking load. After 14 – 21 days the breaking load is lost completely.

- 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: gamma irradiation

### Properties

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

## **PGA RESORBA®**



PGA RESORBA® is a polymer of glycolic acid. The linear, high-molecular glycolic acid is synthesised in the presence of a catalyser to a cyclic ester via an intermediary product, glycolide.

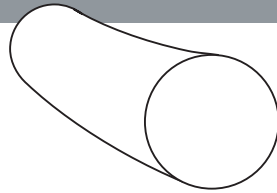
Metabolisation of the PGA suture material within the tissue occurs by the uptake of water, thus reversing the synthesis. The monomeric glycolic acid is split enzymatically into CO<sub>2</sub> and H<sub>2</sub>O by the normal metabolism. Suture material containing 10% lactide as copolymerisate differs only slightly in its physical and physiological properties from pure PGA sutures. The fine, precision-braided filaments guarantee a very high tensile strength as well

as great suppleness. The special resolac-tone coating thinly covers the fibre bundles for specific reduction of surface friction. Absorbable suture material 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 RESORBA® ensure standardised and moderately rapid absorption in tissue. About 14 days after implantation, but depending on the suture thickness, PGA RESORBA® still has at least 50% of its original breaking load (= half-life). Violet PGA RESORBA® is coloured with a physiologically harmless dye by spin dying.

- Colour: violet or undyed
- Chemical name: polyglycolic acid
- Thread diameter: USP 10-0 -5 (0.2-7 metric)
- Types of packaging:
  - needle-suture combinations
  - precut lengths
- Sterilization method: ethylene oxide

### **Properties:**

- **high tensile strength**
- **very supple**
- **minimal tissue reaction**
- **smooth passage through tissue**
- **high knot security**

**CAPROLON®**

In the manufacture of CAPROLON® its two components, lactide and  $\epsilon$ -caprolactone, are co-polymerised in a fixed proportion. This creates poly(L-lactide-co- $\epsilon$ -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 8 weeks (half-life). 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.

The monofilament is coated with resolactone to improve its handling and its passage through tissue.

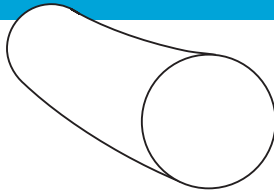
CAPROLON® is supplied undyed for skin sutures or violet (dyed with the physiologically safe dye D+C No.2).

- Colour: undyed or violet
- Chemical name: [poly(L-lactide-co- $\epsilon$ -caprolactone)]
- Thread diameter: USP 7-0 -2 (0.5-5 metric)
- Types of packaging: - needle-suture combinations
- Sterilization method: ethylene oxide

**Properties:**

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

## **MOPYLEN®**



MOPYLEN® is a synthetic suture which is manufactured by polymerisation of propylene. The suture is made from the dyed granules by dry spinning.

The suture is hydrophobic, i.e. it absorbs practically no water and is chemically inert. Due to its non-thrombogenic properties MOPYLEN® is suitable for cardiac and vascular surgery, and for sutures which, as permanent implants, must remain unchanged in the tissues, even in inflammatory or infected wounds. Furthermore, MOPYLEN® is an ideal skin suture, especially in plastic surgery and wherever an especially good cosmetic result of the suture is required.

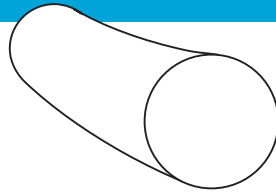
The material is coloured with a physiologically safe dye.

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

### **Properties:**

- **permanent high tensile strength**
- **non-aging**
- **hydrophobic**
- **excellent passage through tissue**
- **high knot security**

## RESOPREN®



RESOPREN® is a blue monofilament synthetic suture made of polyvinylidene difluoride (PVDF). The suture is made from the dyed granules by dry spinning.

RESOPREN® is chemically inert, hydrophobic, and extremely non-aging.

Because of its high non-aging quality and high knot security, RESOPREN® is particularly suitable for long-term implantation in vascular surgery. The material is coloured with a physiologically safe dye.

- Colour: blue
- Chemical name: polyvinylidene difluoride
- Thread diameter: USP 8-0 -1 (0.4-4 metric)
- Type of packaging: - needle-suture combinations
- Sterilization method: ethylene oxide

**Properties:**

- particularly supple
- chemically inert
- extremely non-aging
- very good passage through tissue
- hydrophobic

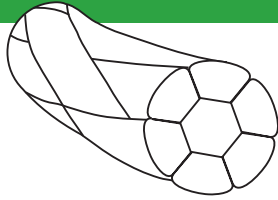
**Information that is applicable to all the synthetic sutures described:**

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 disturbances, or even necrotic reactions. In view of the elastic stretch and smooth surface (especially of monofilament sutures), it is recommended that an additional knot be made to ensure that the knot sits very firmly. According to Nockemann<sup>1</sup> 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 proved to be especially good 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. MOPYLEN® and RESOPREN® are especially favoured in vascular surgery because of their antithrombogenicity.

<sup>1</sup> Die chirurgische Naht, by Paul Ferdinand Nockemann; Thieme Verlag

## **POLYESTER**



POLYESTER is manufactured by polycondensation of ethylene glycol and terephthalic acid.

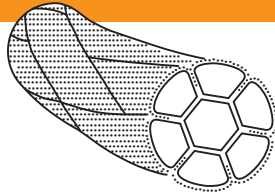
The fibres are produced by the dry spinning method. The stretched, slightly twisted fibre bundles are then formed into a suture by precision-braiding and tempering. The fibre is hydrophobic, i.e. it does not absorb water. The material is coloured with a physiologically safe dye.

- Colour: green, white (no dye)
- Chemical name:  
polyethylene  
terephthalate polyester fibre
- Thread diameter: USP 7-0 -7  
(0.5-9 metric)
- Types of packaging:
  - needle-suture combinations
  - in precut lengths
- Sterilization method:  
ethylene oxide or gamma irradiation

### **Properties:**

- **high tissue acceptability**
- **high tensile strength**
- **excellent passage through tissue**
- **high knot security**

# SUPOLENE



SUPOLENE, like polyester, is manufactured by polycondensation of ethylene glycol and terephthalic acid.

The fibres are produced by the dry spinning method. The suture is then precision-braided, dyed, tempered and the surface specially refined by coating the suture.

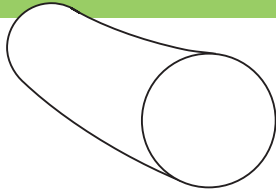
This surface treatment reduces to a minimum capillarity and the sawing action during passage through the tissue and the knot rundown. Since SUPOLENE is hydrophobic, i.e. it does not absorb water, is non-ageing and therefore suitable for cardiovascular surgery for securing implants and grafts. The material is coloured with a physiologically safe dye.

- Colour: green, white (no dye)
- Chemical name: polyethylene terephthalate polyester fibre
- Thread diameter: USP 6-0 -7 (0.7-9 metric)
- Types of packaging:
  - needle-suture combinations
  - in precut lengths
- Sterilization method: ethylene oxide or gamma irradiation

## Properties:

- excellent passage through tissue, no sawing action
- very slight tissue reaction
- resistant to endogenous enzymes
- very even and smooth surface characteristics
- low capillarity

## NYLON



NYLON is a monofilament extruded thread (pressed and drawn through dies in a malleable condition) made from polyamide 6-6.6.

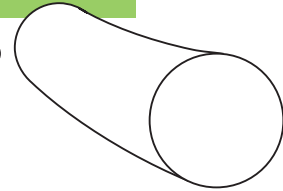
Because of its high tensile strength, even when the fibre diameter is very fine, NYLON is particularly suitable for very fine suturing in microsurgery. Polyamides can bind up to 10% water. The material is coloured with a physiologically safe dye.

- Colour: white (no dye), black
- Chemical name: polyamide 6-6.6
- Thread diameter: USP 11-0 -2 (0.1-5 metric)
- Types of packaging:
  - needle-suture combinations
  - in precut lengths
- Sterilization method: ethylene oxide or gamma irradiation

### Properties:

- above-average softness and suppleness
- very easy handling and knotting properties
- no capillarity
- excellent passage through tissues
- only slight tissue reaction

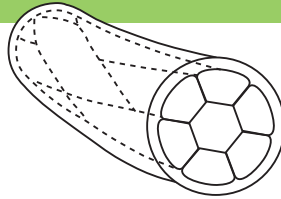
## RESOLON®



RESOLON® is initially like NYLON, a monofilament polyamide thread. However, it undergoes special treatment during production. RESOLON® is exceptionally soft and supple, even when sterile and dry. This gives the monofilament thread excellent handling and knotting properties with optimum knot security.

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

## SUPRAMID



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

### Special feature

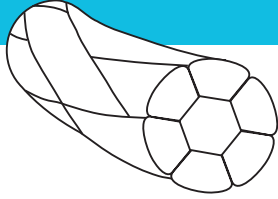
Despite its synthetic origin, due to its peptide structure SUPRAMID is gradually degraded after lying in tissue for a while. Therefore, with a few exceptions, it is only suitable for skin sutures. The material is coloured with a physiologically safe dye.

- Colour: white (no dye) or black
- Chemical name:
  - monofilament: polyamide 6-6.6
  - pseudomonofilament: polyamide 6.6 and polyamide 6
- Thread diameter: USP 7-0 -7 (0.5-9 metric)
- Types of packaging:
  - needle-thread combinations
  - in precut lengths
- Sterilization method: ethylene oxide or gamma irradiation

### Properties:

- very supple
- good knotting properties
- minimal tissue reaction
- no capillarity

## SILK



The raw material in the production of this suture is the cocoon of the silkworm.

These very fine silk threads are degummed (sericin, a viscous protein, is boiled off), spun and precision-braided. The silk thread is impregnated by treating its surface.

This process results in silk made without any undesirable wick effect, i.e. a non-capillary, hydrophobic thread with a smooth surface.

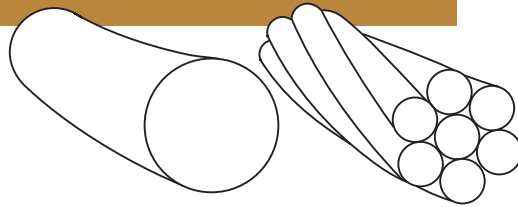
Black or blue (virgin) silk is coloured with physiologically safe dyes.

- Colour: white (without dye), black or blue
- Chemical name: silk fibroin
- Thread diameter: USP 10-0 -6 (0.2-8 metric)
- Types of packaging:
  - thread-needle combinations
  - in precut lengths
- Sterilization method: ethylene oxide or gamma irradiation

### Properties:

- very supple
- excellent knotting properties
- low sawing action
- high knot security

## STAINLESS STEEL



A mineral product, manufactured from stainless, non-corroding steel alloy. Very thin steel fibres are drawn from liquid steel through a suitable die and twisted into a multifilament thread to the required thicknesses. Stainless steel is also available as a pure monofilament.

- Chemical name: stainless steel
- Thread diameter: USP 6-0 -7 (0.7-9 metric)
- Types of packaging:
  - needle-thread combinations
  - in precut lengths
- Sterilization method: ethylene oxide or gamma irradiation

### Properties:

- very low tissue reaction
- high, unchanging tensile strength
- no wick effect
- no stretch

## 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 governing diameter and knot tensile strength*



*Multiple suture packs are made up, in part semi-automatically, according to the client's demands*



*Packing in moisture-proof alublisters*



*Each blister pack is tested for its closeness*



### 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:**

- European Pharmacopoeia (Ph. Eur.) and the harmonised norms derived from its monographs.
- DIN-ISO standards
- MDD 93/42 EEC

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, **CE marking**, for sale in the entire European market (European harmonisation), and analogously regulated in Germany by the Medical Devices Act (Medizinproduktegesetz: MPG).

## 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 or gamma irradiation (R), and the safe combination of peelable outer and multifunctional inner wrappings.



### Peelable outer wrapping

Can be opened by a non-sterile person (e.g. a floater in the operating room) by peeling it off so that the inner sterile contents can be safely passed on, assuring contamination-free transfer.



### Multifunctional primary packet

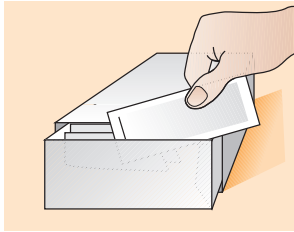
This further protects the suture and allows for problem-free and safe removal.

- **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 pre-cut suture packs and multipacks makes it possible to withdraw single sutures.

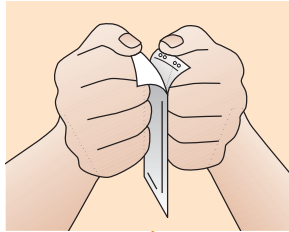
The **eco-pack** fulfils the provisions of DIN 58953, part 8 / Sterile supplies.

## Peel-eco-pack

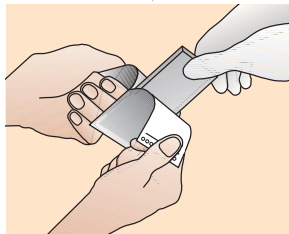
A combination of peelable outer wrapping and multifunctional primary packet



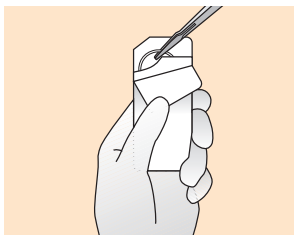
1. The peel-pack is removed from the storage box.



2. The floater grasps the two opening flaps at the upper end of the pack and opens it by evenly peeling the flaps apart.

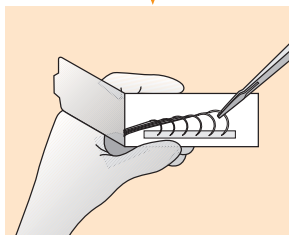


3. The sterile contents are handed over without contamination.



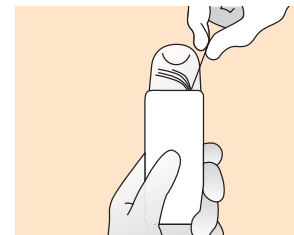
### Single pack/needle-thread combination

Precut single sterile sutures with an attached surgical needle. The needle is exposed by turning over the perforated flap. It is then removed with a needle-holder.



### Multipack

Several combinations in each sterile primary packet. This type of packaging simplifies the organisation of handing over the same thread combinations during standardised procedures. The needles are exposed by opening the side of the paper cover, after which the individual needles (one after the other) are taken out with the needle-holder.

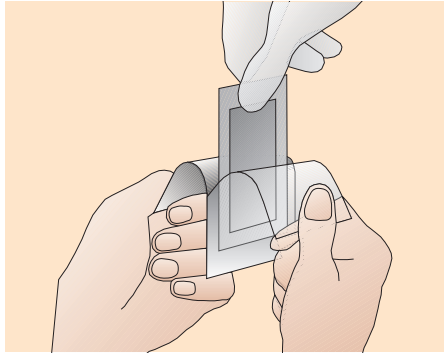


### Pre-cut sutures

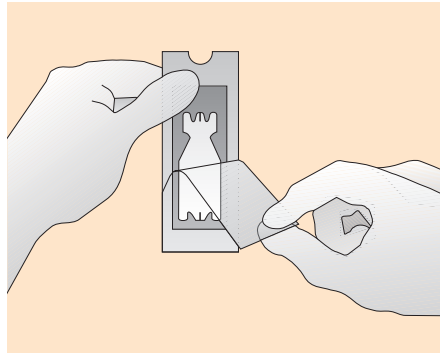
One or more threads in each sterile primary packet. The suture is meant for ligatures or for use with eyed needles. After the upper flap has been opened, the individual threads can be withdrawn in any desired order.

## Micro-pack

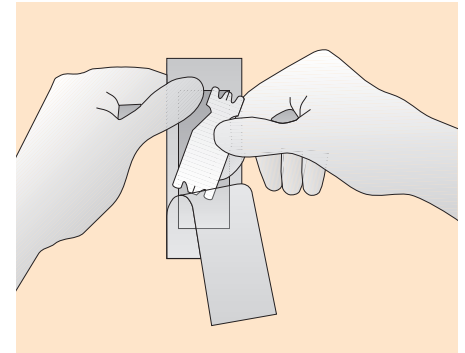
### Primary packet with foam for micro- and ophthalmic surgery



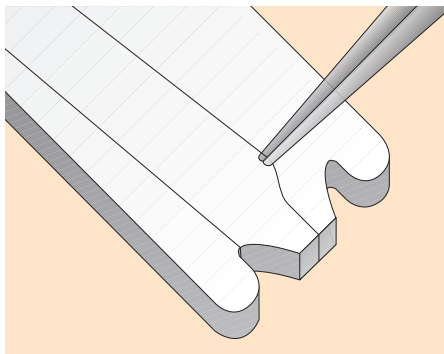
1. Peel open the non-sterile outer sachet and, without contamination, pass over the sterile inner sachet.



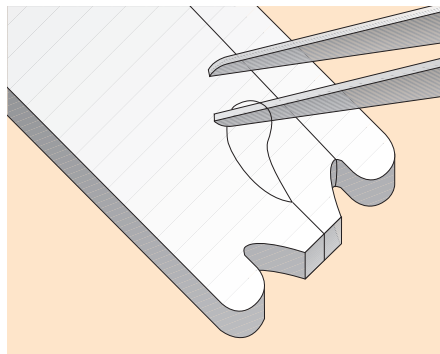
2. Peel open the inner sachet.



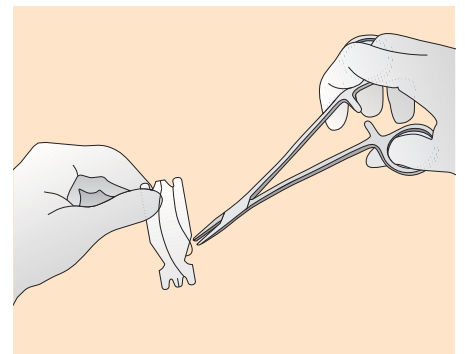
3. Carefully remove the sterile primary packet from the blister sachet.



4. Before taking the needle out first remove the fixed thread from the primary packet with forceps.



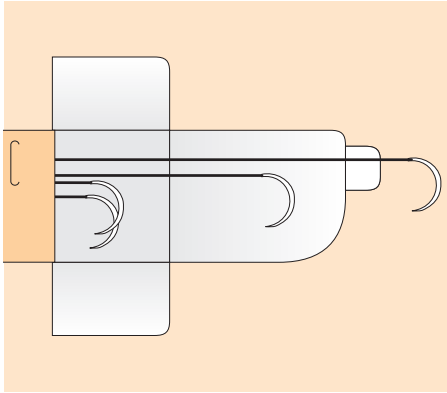
5. With double swaged sutures first ease out or cut off the loop, then separate the thread from the primary packet with forceps.



6. Grasp the needle with the needle-holder and remove from the primary packet by turning it slightly.

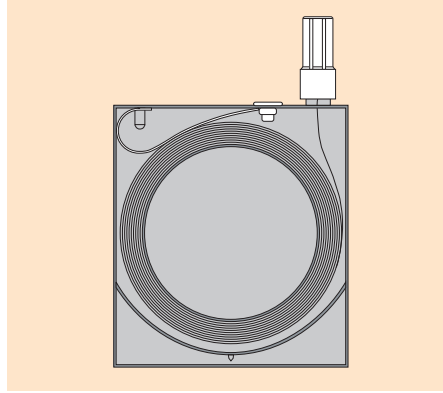
7. During the operation the needle can be "parked" in the sterile primary packet. After the operation the primary packet is used for depositing and checking the used needles.

## Types of packaging



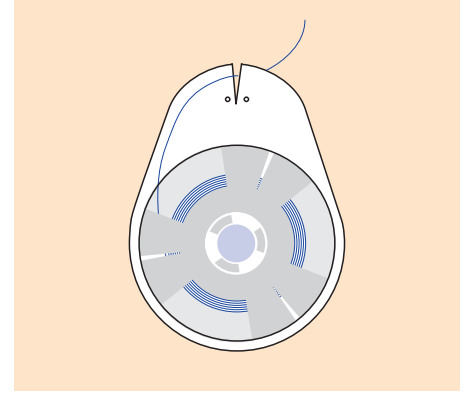
### Multi-L-Pack

Special combinations in the Multi-L-Pack are available to avoid the memory effect. This ensures problem-free and quick removal.



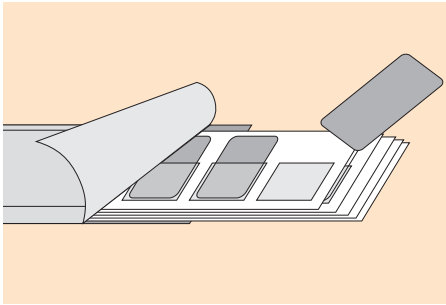
### Dispenser packaging

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.



### Ligature pack

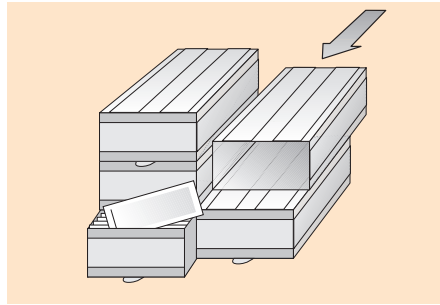
Suture material of up to 4 m in length can be taken from a hand reel during an operation.



## Set pack

Individualised sets can be made up with different suture materials for specific indications according to the client's specifications for materials, quantity and order of use:

- Minimum number: 72 sets
- Printed with all relevant information (indication, contents etc.)
- Only one LOT number for the whole set









## Suture-Box











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

## Special combinations

Should you require a combination which you cannot find in our product range we will provide it without extra charge according to your individual needs, if technically possible. Please note the longer delivery period and a minimum order of 15 dozen suture material blisters (non-returnable).

## New symbols used on the packaging





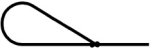

absorbable suture material		
	dyed / braided / coated / absorbable	PGA RESORBA®
	dyed / monofilament/ coated / absorbable	CAPROLON®
	dyed / monofilament / absorbable	GLYCOLON®
	undyed / braided / coated / absorbable	PGA RESORBA®, PGA resoquick™
	undyed / monofilament/ coated / absorbable	CAPROLON®
	undyed / monofilament / absorbable	GLYCOLON®

nonabsorbable suture material		
	dyed / braided / coated / nonabsorbable	SUPOLENE
	dyed / braided / nonabsorbable	POLYESTER, SILK
	dyed / twisted / coated / nonabsorbable	SUPRAMID
	dyed / twisted / nonabsorbable	SILK
	dyed / monofilament / nonabsorbable	MOPYLEN®, RESOPREN®, NYLON, RESOLON®
	undyed / braided / coated / nonabsorbable	SUPOLENE
	undyed / braided / nonabsorbable	POLYESTER, SILK
	undyed / twisted / coated / nonabsorbable	SUPRAMID, STAINLESS STEEL
	undyed / twisted / nonabsorbable	STAINLESS STEEL
	undyed / monofilament / nonabsorbable	NYLON, STAINLESS STEEL

## Explanation of symbols used for the chemical composition of synthetic sutures

<b>PGA-PCL</b>	GLYCOLON®	Poly(glycolide-co-caprolactone)
<b>PGA</b>	PGA <i>resoquick</i> ™	Polyglycolic acid
<b>PGA</b>	PGA <i>RESORBA</i> ®	Polyglycolic acid
<b>P(LA/CL)</b>	CAPROLON®	Poly(lactide-caprolactone)
<b>PP</b>	MOPYLEN®	Polypropylene
<b>PVDF</b>	RESOPREN®	Polyvinylidene difluoride
<b>PET</b>	POLYESTER	Polyester
<b>PET</b>	SUPOLENE	Polyester
<b>PA</b>	NYLON	Polyamid
<b>PA</b>	RESOLON®	Polyamid
<b>PA</b>	SUPRAMID	Polyamid

## Explanation of symbols


	control release needle		loop suture
	Resoclip		ligature pack
	loop		pledgets


## Did you know?


A short lesson in symbols used for medical products


**REF** = Reference number


**LOT** = Batch number

 = Use by year / month

 = Consult instructions for use


 = Do not reuse

 = Do not re-sterilize


 = Do not use if package is damaged

**STERILE EO** = Sterilized using ethylene oxide

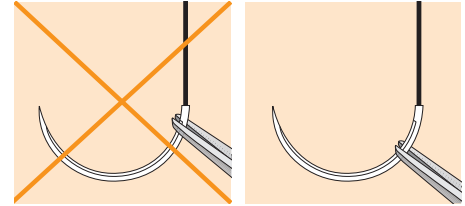
**STERILE R** = Sterilized using irradiation

 <sup>25°C</sup> = Upper Limit of Temperature

**CE** <sub>1275</sub> = CE mark and identification Number of the Notified Body. Product conforms to the essential requirements of the Medical Device Directive 93/42 ECC.

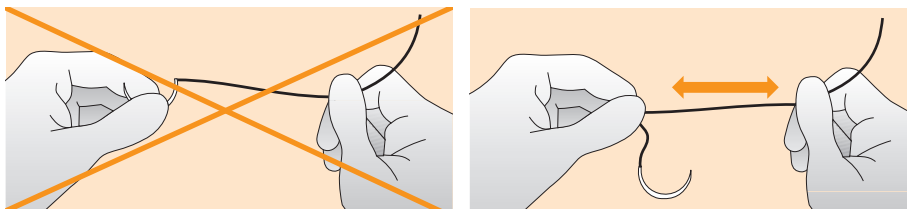
 = HIBC-Code

## How to hold the needle



The needle must be held in the needle-holder at approx. 3/4 of the length of the needle from its point. Do not hold it in the swaging zone to avoid damage to the suture or the needle.

## 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!



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.

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REPAIR AND REGENERATE