Advanced Medical Solutions Ltd

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Suture Manual

RESORBA®

REPAIR AND REGENERATE

List of Contents

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 are happy to send these on request.
Visit our website: www.resorba.com for constantly updated and comprehensive information on our products and developments.

Introduction

In nature, damaged or destroyed tissue layers must be covered over quickly to preserve the integrity and functions of the organism. We have taken this technique from nature and recreated it for humans.

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

The surgical suture is a typical medical device used for tissue repair and 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 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).

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 Resolon Twist ™ 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)
- **Synthetic starting materials:**
  Polyglycolic acid, polylactide, polyamide, polyester, polypropylene, PVDF

Modern classification according to absorption characteristics

- **Non-absorbable**
  SILK, RESOPREN™, MOPYLEN™, POLYESTER, SUPOLENE, STAINLESS STEEL
- **Pseudo-absorbable**
  RESOLON™*, NYLON*, RESOLON TWIST™*
- **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:	GLYCOLON™	PGA *resoquick*™ PGA *RESORBA*™
Non-absorbable material:	MOPYLEN™ RESOPREN™ NYLON RESOLON™ STAINLESS STEEL	POLYESTER RESOLON TWIST™ SUPOLENE SILK STAINLESS STEEL

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 *RESORBA*™, PGA *resoquick*™ and GLYCOLON™).

Non-absorbable sutures remains almost unchanged when placed within body tissues and is 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 –14 days).

It has to be distinguished as follows:

Absorption time

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

Disintegration

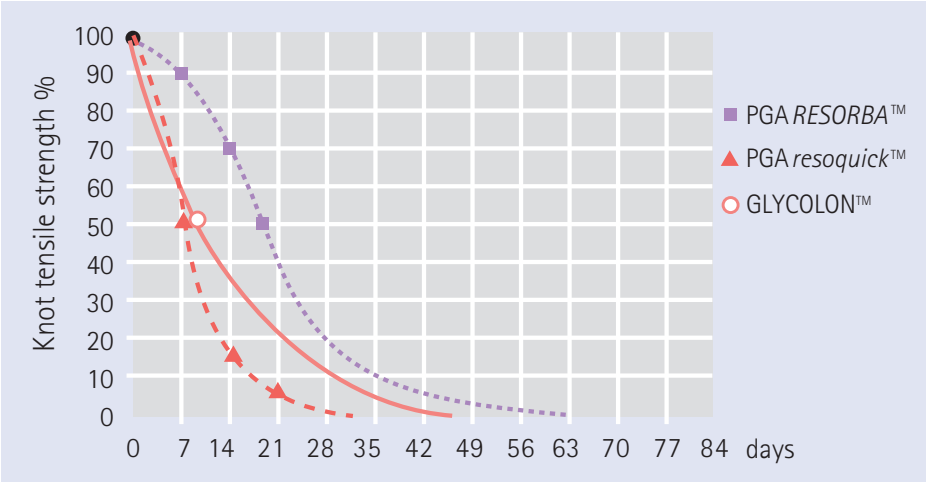
The period during which essentially non-absorbable suture break down by degradation into (smaller) pieces and thus losing its strength (e.g. polyamide).

Dissolution

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

Characteristics of absorption

Different indications also require different tensile 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.

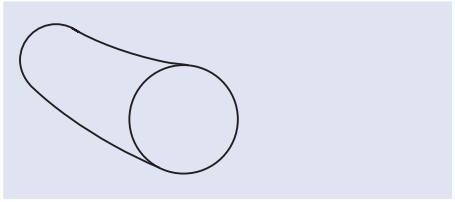


In-vitro trial of suture degradation by measuring the knot tensile strengths of GLYCOLON™, PGA *resoquick*™, PGA *RESORBA*™.
Suture size: 3-0 USP (2 metric).

Thread structure

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

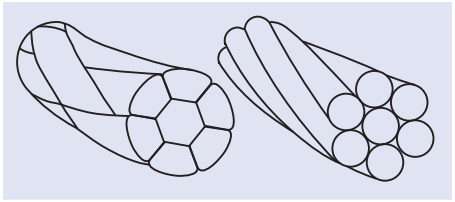
Monofilament



A monofilament consists of only one thread filament.

- GLYCOLON™
- MOPYLEN™
- NYLON
- RESOLON™
- RESOPREN™
- STAINLESS STEEL, monofilament

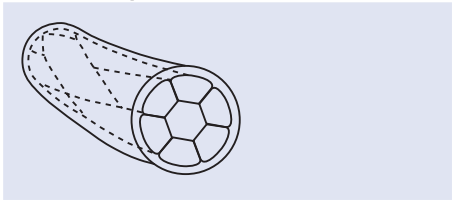
Multifilament



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

- STAINLESS STEEL, multifilament
- POLYESTER
- SILK

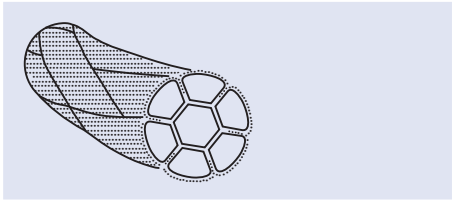
Coated or pseudo-monofilament



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.

- RESOLON TWIST™

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.

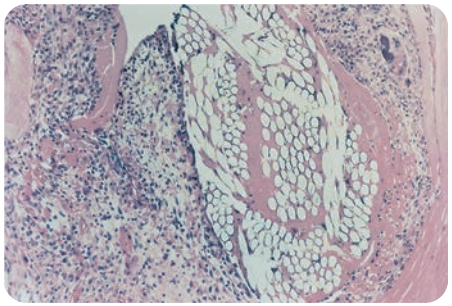
- PGA *RESORBA*™
- PGA *resoquick*™
- SUPOLENE

Tissue acceptance

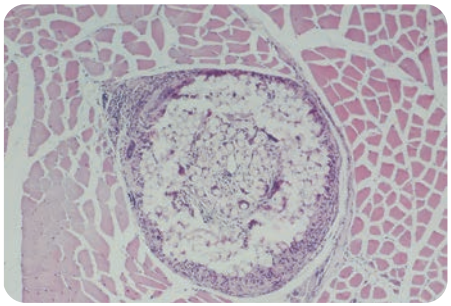
Every insertion of suture will trigger some tissue reaction within the body (see table). The causes are:

- 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)

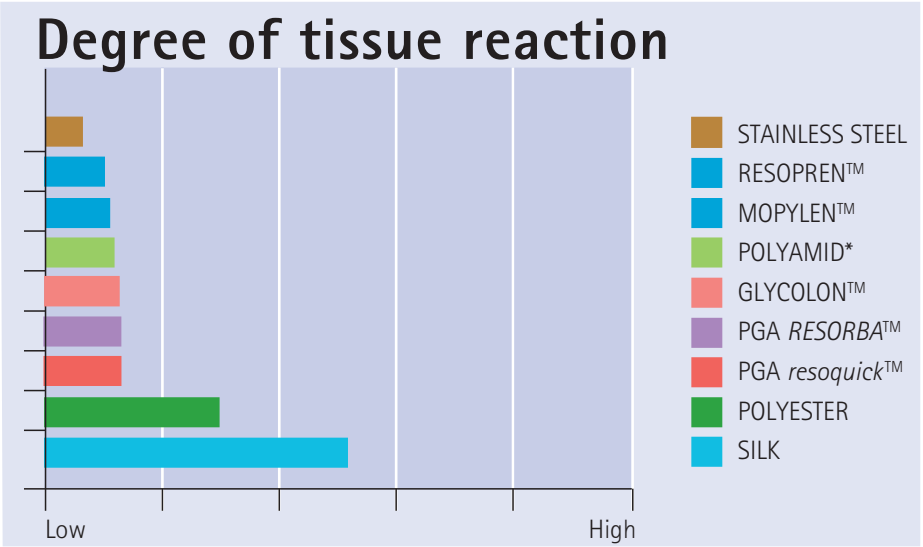
Tissue acceptance, using PGA *RESORBA*™ as example



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.



*Products made of polyamide: RESOLON™, NYLON, RESOLON TWIST™

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 = 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™	RESOLON TWIST™	SILK	STAINLESS STEEL monofilament, multifilament	**Synth. monofilament** Diameter in mm	GLYCOLON™
0.1 EP	0.010-0,019	-	-	-	-	-	-	11-0	11-0	-	-	-	-	
0.2 EP	0.020-0.029	10-0	-	10-0	-	-	-	10-0	10-0	-	10-0	-	-	-
0.3 EP	0.030-0.039	9-0	-	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	-	8-0	-	-	-
0.5 EP	0.050-0.069	7-0	-	7-0	7-0	7-0	-	7-0	7-0	7-0	7-0	-	0.050-0.094	-
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
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
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
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
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
3.5 EP	0.350-0.399	0	0	0	0	0	0	0	0	0	0	0	0.400-0.499	0
4 EP	0.400-0.499	1	1	1	1	1	1	1	1	1	1	1	0.500-0.570	1
5 EP	0.500-0.599	2	2	2	-	2	2	2	2	2	2	2	0.571-0.610	-
6 EP	0.600-0.699	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	-	
9 EP	0.900-0.999	-	-	-	-	7	-	-	-	7	-	7	-	-

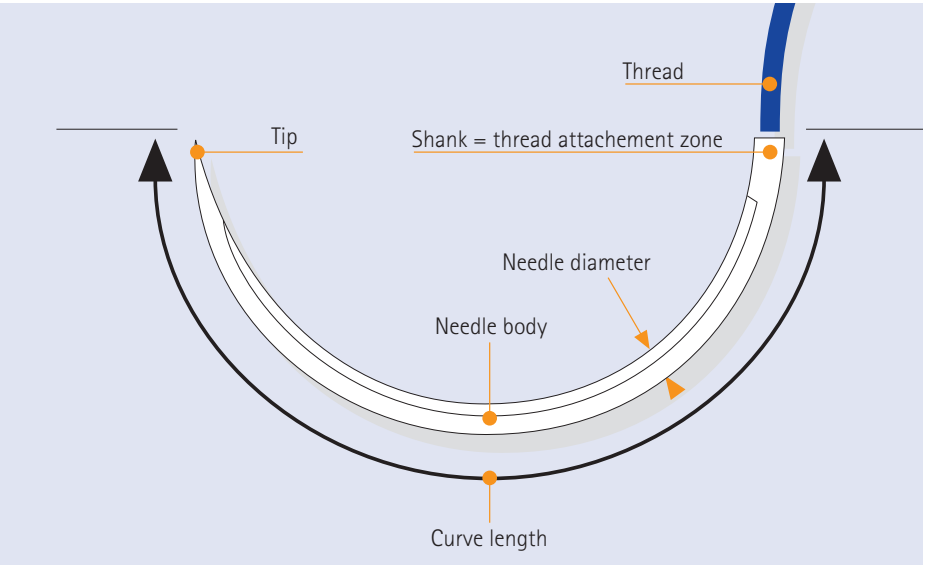
Needle characteristics

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:

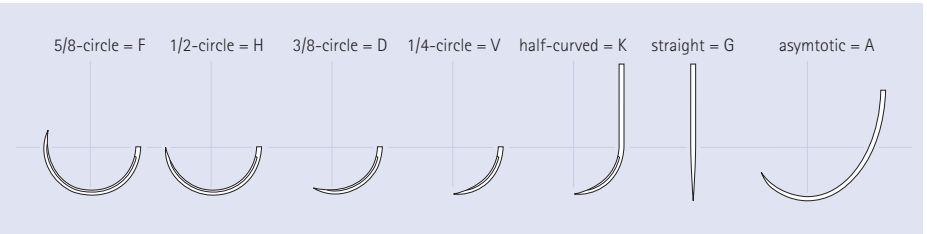
- Response to penetration (on insertion and pulling through of the needle)
- Resistance to bending
- Resistance to breaking
- Secure seating in needle-holder

For suturing and suture encircling of wounds, atraumatic (eyeless) needles are usually used as needle-thread combinations. Needle-thread 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.



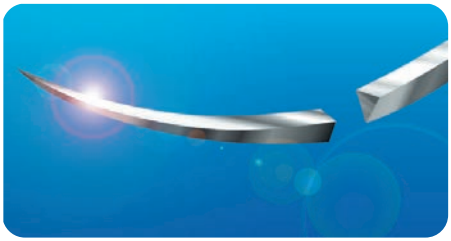
Needle shapes



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

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

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

4. 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 tip triangular in section

5. 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

6. 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
- 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 = semi 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 (partly hand-honed)
N = blunt point
T = trocar point
P = spatula-needle (PREMIUM)
S = stronger diameter
X = extra strong diameter
F = thin PREMIUM-cut "THIN LINE" (partly hand-honed)

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

S (after number) = stronger diameter
F (after number) = extra thin diameter
A (after number) = control release needle

Control release needles

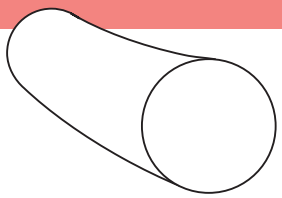
To save time, e.g. when inserting single-knot sutures for anastomoses of the gastrointestinal tract or layered wound closure, the needle-thread combination has been constructed with a removable needle.

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	0.7 to 4 metric	USP 6-0 to 1	violet, undyed	7-9 days
PGA *resoquick*™	Polyglycolic acid, coated	multifilament/ braided	0.7 to 5 metric	USP 6-0 to 2	undyed	7 days
PGA *RESORBA*™	Polyglycolic acid, coated	multifilament/ braided	0.2 to 7 metric	USP 10-0 to 5	violet, undyed	21 days
MOPYLEN™	Polypropylen	monofilament	0.2 to 5 metric	USP 10-0 to 2	blue	
RESOPREN™	PVDF	monofilament	0.4 to 4 metric	USP 8-0 to 1	blue	
POLYESTER	Polyester	multifilament/ braided	0.5 to 9 metric	USP 7-0 to 7	green, white	
SUPOLENE	Polyester, coated	multifilament/ braided	0.7 to 7 metric	USP 6-0 to 5	green, white	
NYLON	Polyamide	monofilament	0.1 to 5 metric	USP 11-0 to 2	black, white	
RESOLON™	Polyamide	monofilament	0.1 to 5 metric	USP 11-0 to 2	blue	
RESOLON TWIST™	Polyamide	pseudomonofilament	0.5 to 9 metric	USP 7-0 to 7	white	
SILK	Silk fibroin	multifilament/ braided	0.2 to 8 metric	USP 10-0 to 6	black, white	
STAINLESS STEEL	Stainless steel	monofilament, multifilament/twisted	0.7 to 9 metric	USP 6-0 to 7	nature	

GLYCOLON™



The two material components polyglycolic acid and - 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. Tissue reaction is minimal because of the completely safe intermediary products and the monofilament structure of thread. GLYCOLON™ has a smooth surface providing good 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™.

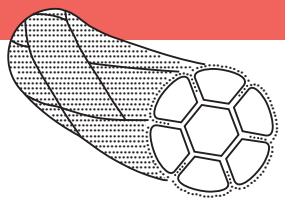
It is indicated for use in general soft tissue approximation and/or ligation, but not for use in cardiovascular or neurological tissues, microsurgery or ophthalmic surgery.
GLYCOLON™ is supplied undyed or violet.

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

Properties:

- **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_2 and H_2O 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.

PGA *resoquick*™ is indicated for use in general soft tissue approximation, including ophthalmic (e.g. conjunctiva) procedures, but not in cardiovascular or neurological procedures.

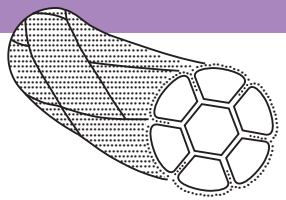
Absorbable suture approximates the tissue during the healing phase and progressively loses its tensile strength and breaking load. After only seven days PGA *resoquick*™ has already lost 50% of its original breaking load. After 14 days the breaking load is lost completely.

- 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*™



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PGA *RESORBA*™ is indicated for use in general soft tissue approximation and/or ligation, including use in ophthalmic surgery, but not in cardiovascular surgery or neural tissue.

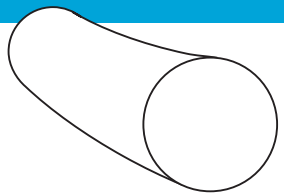
Absorbable suture material approximates the tissue during the healing phase and progressively loses its tensile strength and breaking load. The precision-braided filaments of polyglycolic acid that make up PGA *RESORBA*™ ensure standardised and moderately rapid absorption in tissue. About 21 days after 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-thread-combinations
  - precut lengths
- Sterilization method: ethylene oxide

Properties:

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

MOPYLEN™



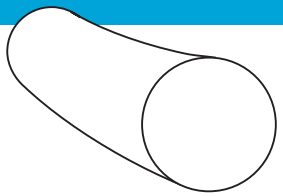
MOPYLEN™ is a synthetic suture which is manufactured by polymerisation of propylene. The suture is made from the dyed granules by dry spinning.
The suture is hydrophobic, i.e. it absorbs practically no water and is chemically inert. Due to its non-thrombogenic properties MOPYLEN™ is suitable for cardiac, ophthalmic, neurological 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: polypropylene
- Thread diameter: USP 10-0 -2 (0.2-5 metric)
- Types of packaging: needle-thread-combinations
- Sterilization method: ethylene oxide

Properties:

- **permanent high tensile strength**
- **non-ageing**
- **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-ageing. Because of its high non-ageing quality and high knot security, RESOPREN™ is particularly suitable for long-term implantation in vascular surgery. Furthermore it is intended for use in general soft tissue approximation and/or ligation, including ophthalmic and neurological procedures.
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)
- Types of packaging: needle-thread-combinations
- Sterilization method: ethylene oxide

Properties:

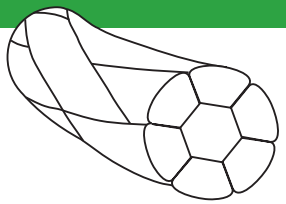
- **particularly supple**
- **chemically inert**
- **extremely non-ageing**
- **very good passage through tissue**
- **hydrophobic**

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 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 be made to ensure that the knot sits very firmly. According to Nockemann[1] 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 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.

[1] 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.

POLYESTER sutures are indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic, orthopaedic and neurological procedures.

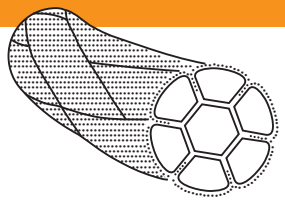
The material is coloured with a physiologically safe dye.

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

Properties:

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

SUPOLENE



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

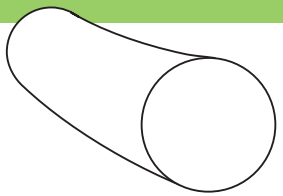
The fibres are produced by the dry spinning method. The suture is then precisionbraided, dyed, tempered and the surface specially refined by coating the suture. This surface treatment reduces to a minimum capillarity and the sawing action during passage through the tissue and the knot rundown. Since the single filament of 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
- Thread diameter: USP 6-0 -5 (0.7-7 metric)
- Types of packaging:
  - needle-thread-combinations
  - in precut lengths
- Sterilization method: ethylene oxide

Properties:

- **excellent passage through tissue, no sawing action**
- **very slight tissue reaction**
- **high tensile strength**
- **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. Furthermore it is indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurological procedures.

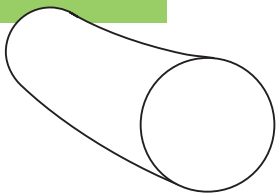
Polyamides can bind up to 10% water. The material is coloured with a physiologically safe dye.

- 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-thread-combinations
  - in precut lengths
- Sterilization method: ethylene oxide

Properties:

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

RESOLON™

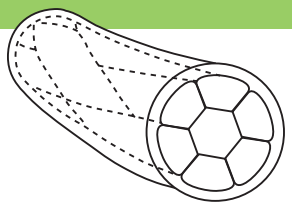


RESOLON™ is initially like NYLON, a monofilament polyamide 6-6.6 thread. However, it undergoes special treatment during production. RESOLON™ is exceptionally soft and supple, even when sterile and dry. This gives the monofilament thread excellent handling and knotting properties with optimum knot security.

The indications for use are the same as for NYLON.

- Colour: blue
- Chemical name: polyamide 6-6.6
- Thread diameter: USP 11-0 -2 (0.1-5 metric)
- Types of packaging:
  - needle-thread combinations
  - in precut lengths
- Sterilization method: ethylene oxide

RESOLON TWIST™



RESOLON TWIST™ 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 a 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 ε-caprolactam polymer.

Special feature

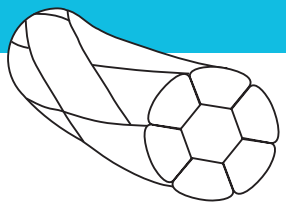
Despite its synthetic origin, due to its peptide structure RESOLON TWIST™ is gradually degraded after lying in tissue for a while. Therefore, with a few exceptions, it is only suitable for general soft tissue approximation and/or ligation. The material is coloured with a physiologically safe dye.

- Colour: white (no dye)
- 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

Properties:

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

SILK



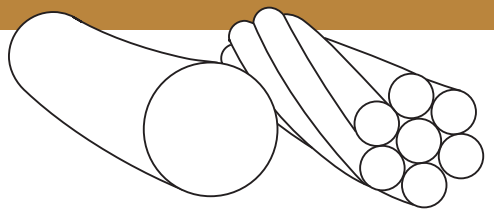
The raw material in the production of this suture is the cocoon of a silkworm.
These very fine silk threads are degummed (sericin, a viscous protein, is boiled off), spun and precision-braided. The silk thread is impregnated by treating its surface. This process results in silk made without any undesirable wick effect, i.e. a noncapillary, hydrophobic thread with a smooth surface.
SILK sutures are intended for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurological procedures.
Black silk is coloured with physiologically safe dyes.

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

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.
Stainless steel is indicated for use in abdominal wound closure, hernia repair, sternal closure and orthopaedic procedures including cerclage and tendon repair.

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

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

Testing of material

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

The sutures are handmade, in part as custom-made products

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_2O. Drying of the suture after sterilization is an essential step in the manufacturing process to achieve high product safety.

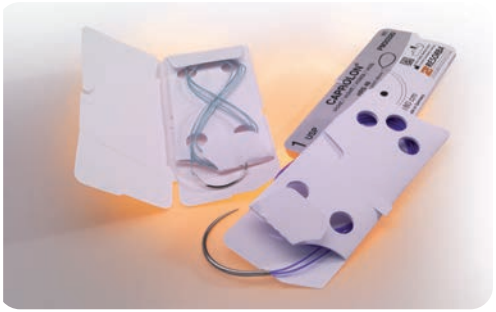
Packing in moisture-proof alublisters

Final testing

The special characteristic of PGA threads (breakdown by H_2O 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.

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 Circulating Nurse 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.

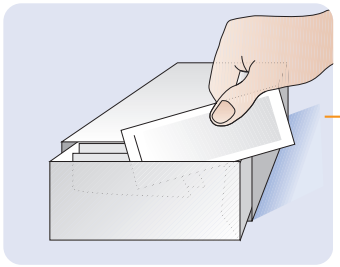
- **Separate withdrawal**

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

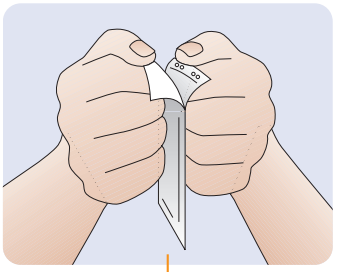
The **eco-pack** fulfils the provisions of DIN 58953, part 8 / Sterile supplies.

Peel-eco-pack

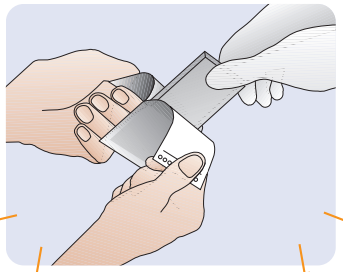
A combination of peelable outer wrapping and multifunctional primary packet



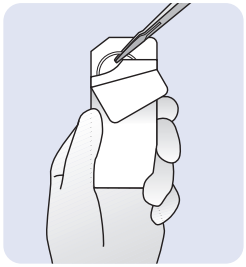
1. The peel-pack is removed from the storage box.



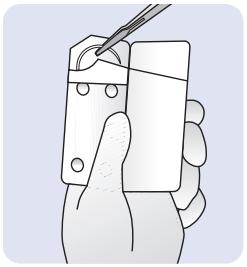
2. The Circulating Nurse grasps the two opening flaps at the upper end of the pack and opens it by evenly peeling the flaps apart.



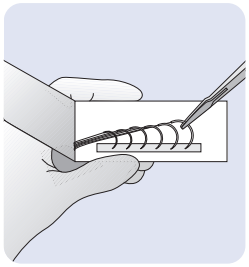
3. The sterile contents are handed over without contamination.



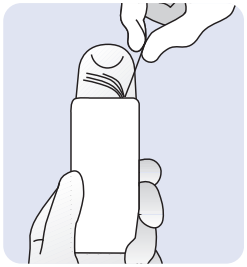
Single pack/needle-thread combination
Precut single sterile sutures with an attached surgical needle. The needle is exposed by turning over the perforated flap. It is then removed with a needle holder.



Single pack/needle-thread combination
The needle is exposed by folding out the suture carrier and then withdrawn with the needle holder.



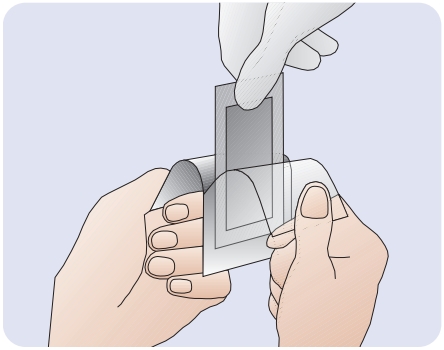
Multipack
Several combinations in each sterile primary packet. This type of packaging simplifies the organisation of handing over the same thread combinations during standardised procedures. The needles are exposed by opening the side of the paper cover, after which the individual needles (one after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



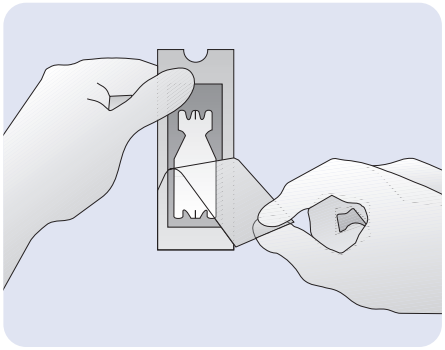
Pre-cut sutures
One or more threads in each sterile primary packet. The suture is meant for ligatures or for use with eyed needles. After the upper flap has been opened, the individual threads can be withdrawn in any desired order.

Micro-Pack

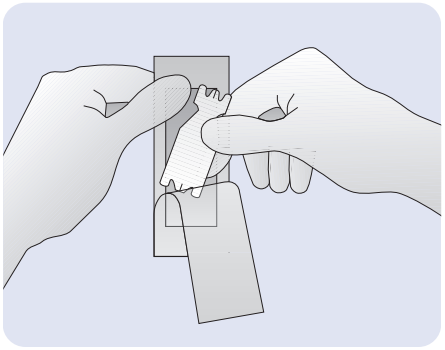
Primary packet with foam for micro- and ophthalmic surgery



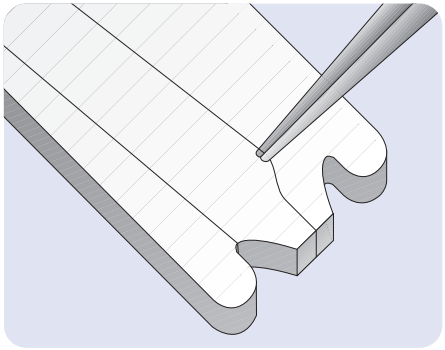
1. Peel open the non-sterile outer sachet and, without contamination, pass over the sterile inner sachet.



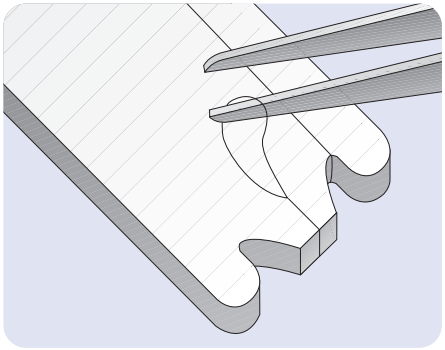
2. Peel open the inner sachet.



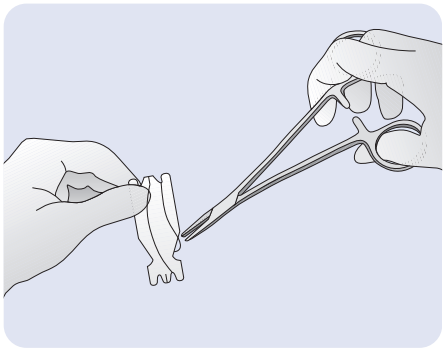
3. Carefully remove the sterile suture carrier from the blister sachet.



4. Before removing the needle, separate the thread from the carrier with forceps.

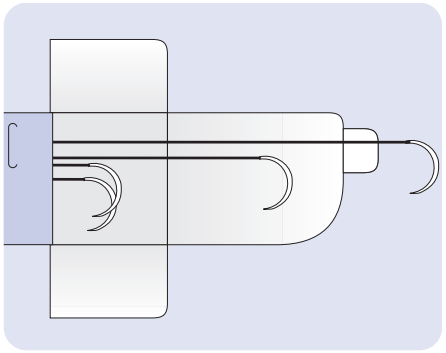


5. In the case of double-armed threads, firstly separate/ cut the needle loop and then separate the thread from the carrier with forceps.



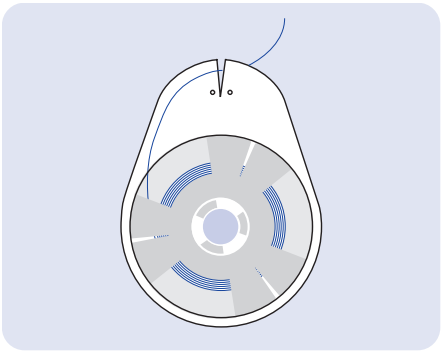
6. Grasp the needle with the needle holder and remove it from the primary packet by turning it slightly.
7. During the operation the needle can be "parked" in the sterile primary packet. After the operation the primary packet is used for depositing and checking the number of needles used.

Types of packaging



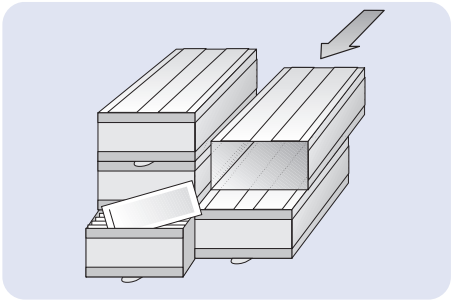
Multi-L-Pack

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.



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 orders

Should you require a combination that does not feature in our catalogue, we will prepare it for you according to individually needs at no additional price provided that it is technically possible to do so. Please note that delivery times are longer than with standard orders and that there is no exchange possible.

New symbols used on the packaging

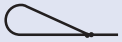
Absorbable suture material	
 dyed / braided / coated / absorbable	PGA *RESORBA*™
 dyed / monofilament / absorbable	GLYCOLON™
 undyed / braided / coated / absorbable	PGA *RESORBA*™, PGA *resoquick*™
 undyed / monofilament / absorbable	GLYCOLON™

Nonabsorbable suture material	
 dyed / braided / coated / nonabsorbable	SUPOLENE
 dyed / braided / nonabsorbable	POLYESTER, SILK
 dyed / twisted / coated / nonabsorbable	RESOLON TWIST™
 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	RESOLON TWIST™, STAINLESS STEEL
 undyed / twisted / nonabsorbable	STAINLESS STEEL
 undyed / monofilament / nonabsorbable	NYLON, STAINLESS STEEL

Explanation of symbols used for the chemical composition of synthetic sutures

PGA-PCL	GLYCOLON™	Poly(glycolide-co-caprolactone)
PGA	PGA *resoquick*™	Polyglycolic acid
PGA	PGA *RESORBA*™	Polyglycolic acid
PP	MOPYLEN™	Polypropylene
PVDF	RESOPREN™	Polyvinylidene difluoride
PET	POLYESTER	Polyester
PET	SUPOLENE	Polyester
PA	NYLON	Polyamide
PA	RESOLON™	Polyamide
PA	RESOLON TWIST™	Polyamide

Explanation of symbols

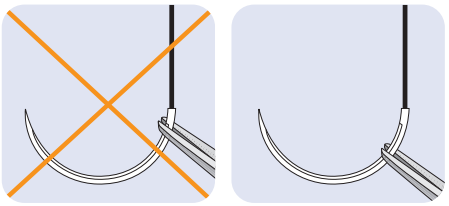
A	control release needle		loop suture
	loop		ligature pack

Did you know?

A short lesson in symbols used for medical products

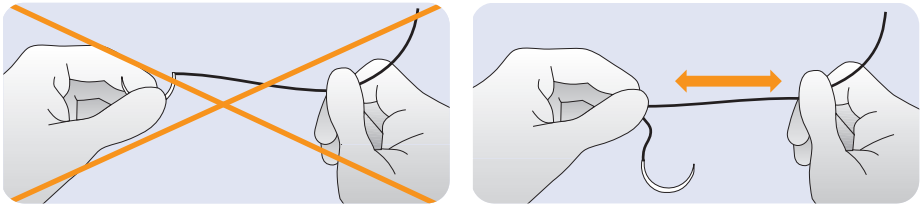
REF	= Reference number
LOT	= Batch number
	= Use by year / month
	= Consult instructions for use
	= Do not reuse
	= Do not resterilize
	= Do not use if package is damaged
STERILE EO	= Sterilized using ethylene oxide
STERILE R	= Sterilized using irradiation
25°C	= Upper Limit of Temperature
CE 0197	= 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



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

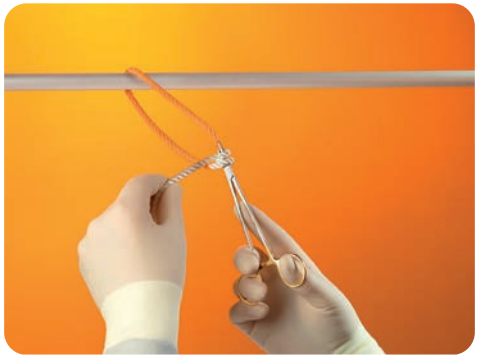


The thread must be stretched gently after it has been removed from the primary packet. Do not pull or rub it abruptly. Do not grasp the needle and stretch the thread!

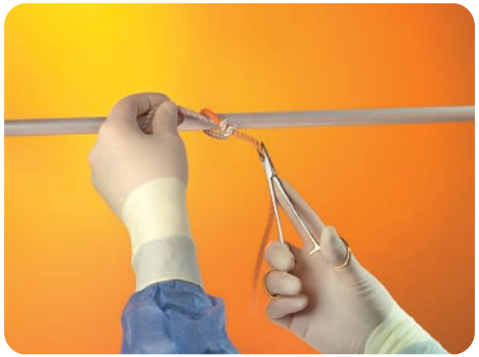

1 USP
CAPROLON®
PM20320
HRS 48
180 cm
2-0 USP
PGA resoquick™
PR30303
HRS 27
70 cm
5-0 USP
GLYCOLON®
PB41509
DSM 16
45 cm
3-0 USP
PGA RESORBA®
PA10371
HRS 35
90 cm
0 USP
POLYESTER
B114
HS 27
75 cm
2-0 USP
SUPOLENE
YSM305
DS 40
45 cm
3-0 USP
SEIDE
41417
DS 24
45 cm
3-0 USP
RESOPREN®
77157
DSM 16
90 cm
4-0 USP
MOPYLEN®
70220
2x HR 27
90 cm
4-0 USP
SUPRAMID
6061
HRT 18
90 cm
9-0 USP
NYLON
5204
2x DSPM 7
50 cm
RESORBA

2-0 USP
STAHLDRAHT
LE99093
GR 51
HS 22
35 cm
2021-03-31
RESORBA
5 USP
TITAN
L75445
HRTX 60
4 x 45 cm
RESORBA

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.

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

For films on further suturing and knotting techniques, see: www.resorba.com

Notes

Notes

RESORBA®

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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RESORBA Medical GmbH, Am Flachmoor 16, 90475 Nürnberg, Germany
Tel: +49 9128 / 91 15 0 **Fax:** +49 9128 / 91 15 91 **Email:** infomail@resorba.com **www.resorba.com**