ADVANCED MEDICAL SOLUTIONS

admedsol.com

Suture Manual

RESORBA® Sutures

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.

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

Until 1960

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

Since 1960

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

1968

First synthetic suture threads made from polyglycolic acid.

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

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

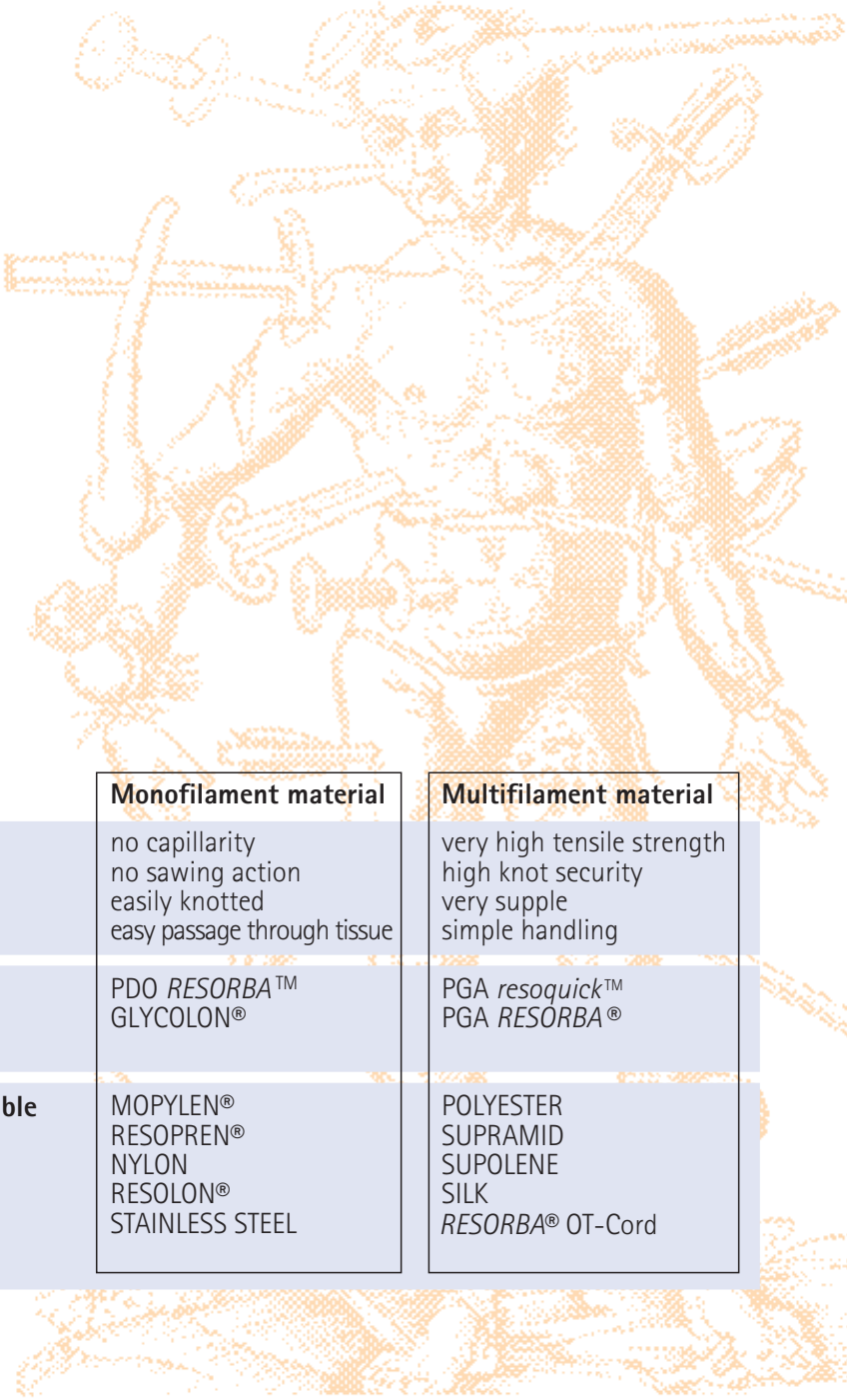
Early packaging of sutures

Historical classification according to raw materials

- **Natural starting materials:**
  Silk, linen (twine), animal gut (catgut), steel
- **Synthetic starting materials:**
  Polyglycolicacid, polylactide, poly(p-dioxanone), polyamide, polyester, polypropylene, PVDF, UHMWPE

Modern classification according to absorption characteristics

- **Non-absorbable**
  SILK, RESOPREN®, MOPYLEN®, POLYESTER, SUPOLENE, STAINLESS STEEL, RESOLON®, NYLON, SUPRAMID, *RESORBA*® OT-Cord
- **Long-term wound support**
  PDO *RESORBA*™
- **Mid-term wound support**
  PGA *RESORBA*®
- **Short-term wound support**
  PGA *resoquick*™, GLYCOLON®



	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:	PDO *RESORBA*™ GLYCOLON®	PGA *resoquick*™ PGA *RESORBA*®
Non-absorbable material:	MOPYLEN® RESOPREN® NYLON RESOLON® STAINLESS STEEL	POLYESTER SUPRAMID SUPOLENE SILK *RESORBA*® OT-Cord

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™*, PDO *RESORBA™* 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

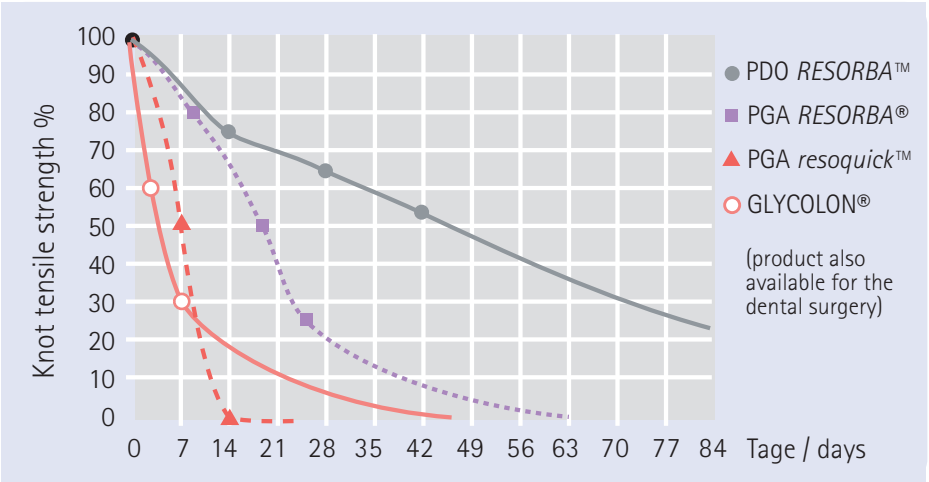
The period during which essentially non-absorbable suture break down by degradation into (smaller) pieces and thus losing its strength (e.g. polyamide).

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.

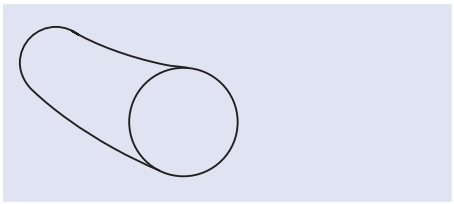


In-vitro trial of suture degradation by measuring the knot tensile strengths of GLYCOLON®, PGA resoquick™, PGA RESORBA® and PDO RESORBA™. Suture size: 3-0 USP (2 metric).

Thread structure

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

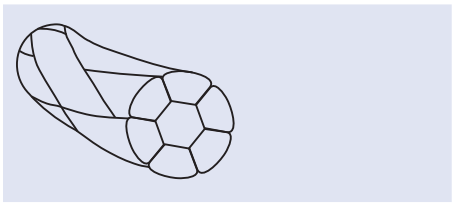
Monofilament



A monofilament consists of only one thread filament.

- PDO *RESORBA*™
- GLYCOLON®
- MOPYLEN®
- NYLON
- RESOLON®
- RESOPREN®
- STAINLESS STEEL

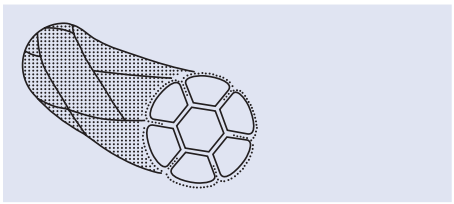
Multifilament



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

- *RESORBA*® OT-Cord

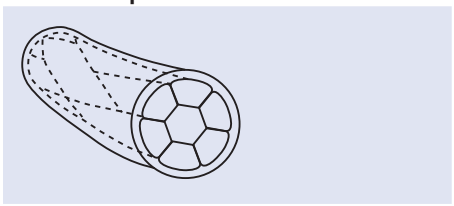
Multifilament coated



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
- 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.

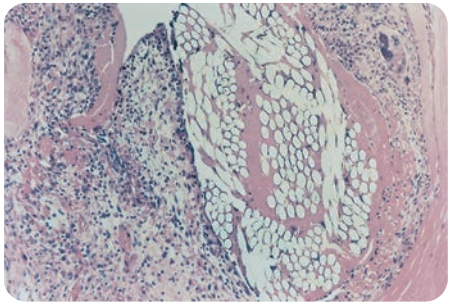
- SUPRAMID

Tissue acceptance

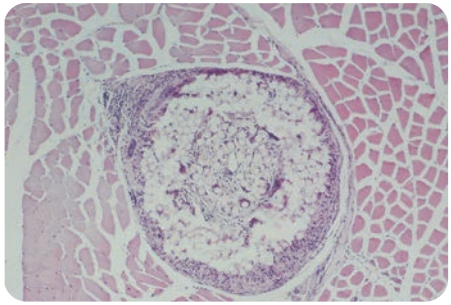
Every insertion of suture will trigger some tissue reaction within the body (see table). The causes are:

- 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

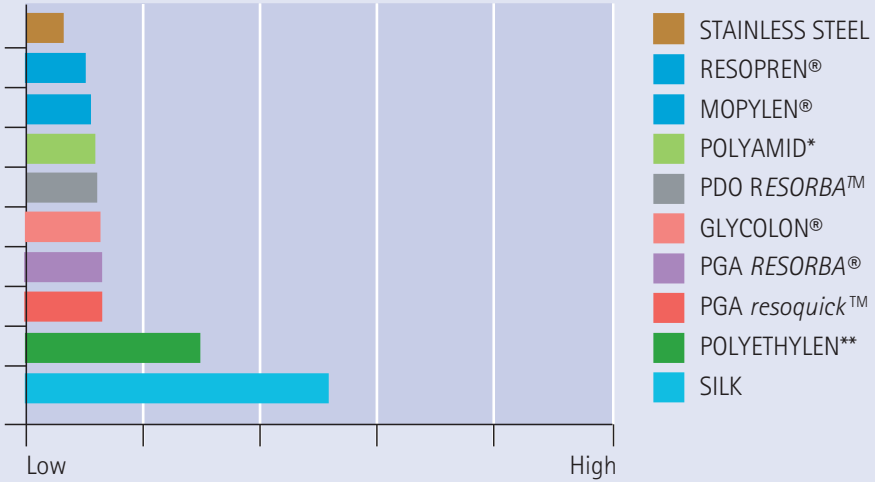


Microscopy of section through an intramuscular implant,
7 days postoperative
Expectedly mild cellular infiltration is visible.



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.

Degree of tissue reaction



*Products made of polyamide: RESOLON®, NYLON, SUPRAMID

**Products made of polyethylene: POLYESTER, SUPOLENE, *RESORBA*® OT-Cord

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®	SUPRAMID	SILK	STEEL monofilament	RESORBA® OT-Cord	Synth. monofilament Diameter range in mm	GLYCOLON®	PDO *RESORBA™*
0.1 EP	0,010-0,019	–	–	_	–	–	–	–	–	–	–	–	–	–	–	–
0.2 EP	0,020-0,029	–	–	10-0	–	–	–	10-0	–	–	-	–	–	–	–	–
0.3 EP	0,030-0,039	–	–	9-0	–	–	–	9-0	–	–	-	–	–	–	–	–
0.4 EP	0,040-0,049	8-0	8-0	8-0	–	–	–	8-0	–	–	8-0	–	–	–	–	–
0.5 EP	0,050-0,069	7-0	7-0	7-0	7-0	–	–	7-0	7-0	–	7-0	–	–	0,050-0,094	–	7-0
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	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	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	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	0,400-0,499	0	0
4 EP	0,400-0,499	1	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	2	0,571-0,610	–	2
6 EP	0,600-0,699	3+4	-	–	–	3+4	3+4	–	–	–	3+4	3+4	–	–	–	–
7 EP	0,700-0,799	5	-	–	–	5	–	–	–	–	–	5	–	–	–	–
8 EP	0,800-0,899	–	–	–	–	6	–	–	–	–	–	6	–	–	–	–
9 EP	0,900-0,999	–	–	–	–	-	–	–	–	–	–	7	–	–	–	–

Tensile strength of surgical suture

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

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

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

Diameter metric	All other non-absorbable sutures in N	Synthetic, multi-filament, absorbable sutures (PGA *RESORBA*®)	Synthetic, monofilament, absorbable sutures (PDO *RESORBA*™)
0.2 metric	0.10	-	
0.3 metric	0.35	-	
0.4 metric	0.60	0.70	
0.5 metric	1.00	1.4	1.40
0.7 metric	1.50	2.5	2.50
1 metric	3.00	6.80	6.80
1.5 metric	5.00	9.50	9.50
2 metric	9.00	17.50	17.50
2.5 metric	13.00	-	-
3 metric	15.00	26.80	26.80
3.5 metric	22.00	39.00	39.00
4 metric	27.00	50.80	50.80
5 metric	35.00	63.50	63.50
6 metric	50.00	-	-
7 metric	62.00	-	-
8 metric	73.00	-	-

*Minimum mean value from 5 tests

Surgical needles

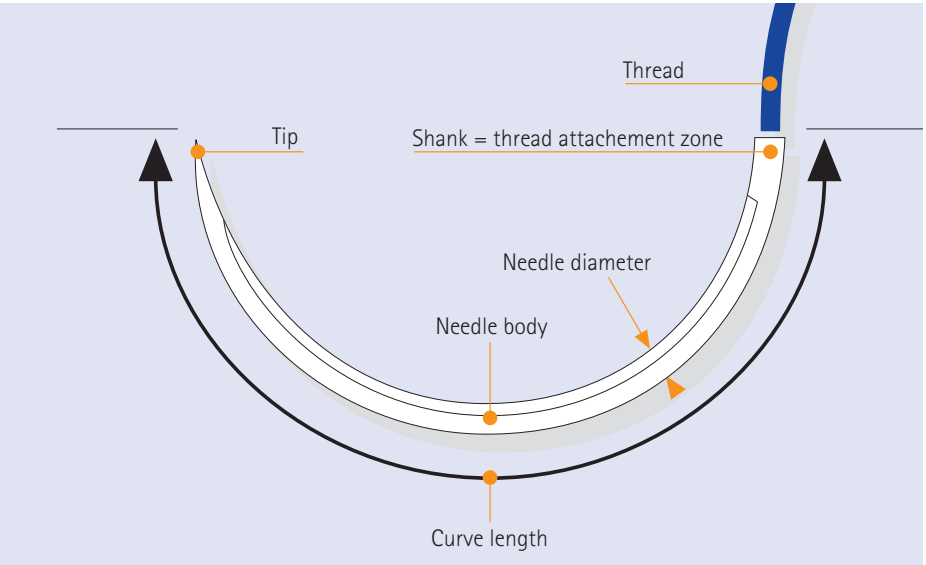
Needle characteristics

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:

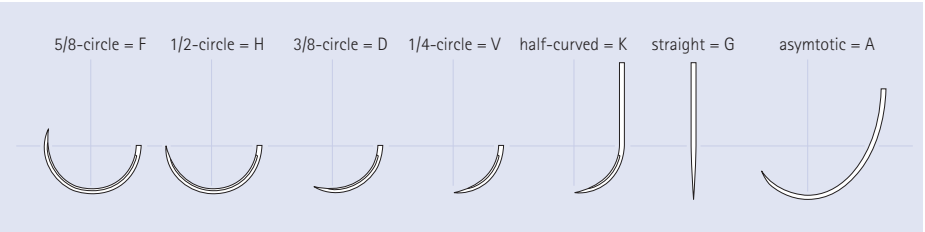
- Response to penetration (on insertion and pulling through of the needle)
- Resistance to bending
- Resistance to breaking
- Secure seating in needle-holder

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 according to the European Pharmacopoeia.



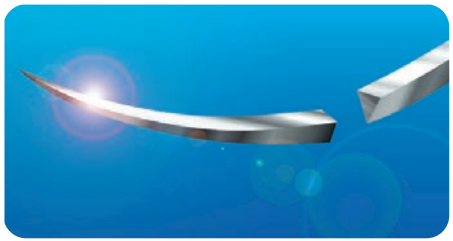
Needle shapes



Cross-section and point of the needle

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

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



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

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

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

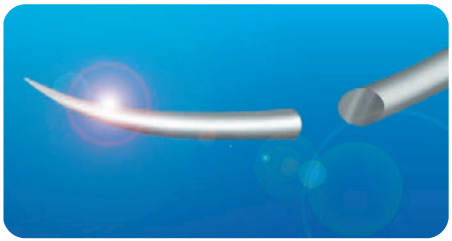
- For use in firm tissue such as skin
- Triangular needle cross-section
- Also available with PREMIUM cut needles M

4. Round-bodied cutting needle ▼ = RT
1/2 circle, 3/8 circle or straight = HRT, DRT, GRT, ART

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

5. Blunt, round-bodied needle ○ = RN
1/2 circle, 3/8 circle or semicurved = HRN, DRN, KRN

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



6. Round-bodied needle ● = R
5/8 circle, 1/2 circle, 3/8 circle or straight = FR, HR, DR, GR

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

Needle code

1. letter: Indicates the curvature of the needle
F = 5/8 circle
H = 1/2 circle
D = 3/8 circle
V = 1/4 circle
K = semicurved
A = asymptotic
G = straight

2. letter: Gives information on the type of needle and needle tip
R = round bodied needle
S = reverse cutting needle

3.+4. letters: Describe special features of the needle and needle tip
I = conventional cutting
M = PREMIUM cut (partly hand-honed)
N = blunt point
T = trocar point
P = spatulated needle
S = stronger diameter
X = extra strong diameter
F = thin PREMIUM cut "THIN LINE" (partly hand-honed)
W = flexible needle

Numbers indicate the straight (extended) length of the needle in mm
S (after number) = stronger diameter
F (after number) = extra thin 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.

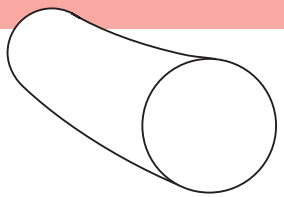
After the suture has been placed, the needle can be removed from the suture with a slight pull.

There is no need to adjust the scissors and cutting the needle from the thread.

Table of materials

Trade name	Raw material	Structure	Thread diameter, metric	Thread diameter, USP	Colour	Absorption profile
PGA *resoquick*™	Polyglycolic acid, coated	multifilament/braided	0.4 to 5 metric	USP 8-0 to 2	undyed	short term
GLYCOLON®	Polyglycolic acid-caprolactone	monofilament	0.7 to 4 metric	USP 6-0 to 1	violet, undyed	short term
PGA *RESORBA*®	Polyglycolic acid, coated	multifilament/braided	0.4 to 7 metric	USP 8-0 to 5	violet, undyed	mid term
PDO *RESORBA*™	Poly(p-dioxanone)	monofilament	0.5 to 5 metric	USP 7-0 to 2	violet, undyed	long term
MOPYLEN®	Polypropylene	monofilament	0.2 to 5 metric	USP 10-0 to 2	blue	
RESOPREN®	PVDF	monofilament	0.5 to 5 metric	USP 7-0 to 2	blue	
POLYESTER	Polyester	multifilament/braided	0.7 to 8 metric	USP 6-0 to 6	green, white	
SUPOLENE	Polyester, coated	multifilament/braided	0.7 to 6 metric	USP 6-0 to 3	green, white	
NYLON	Polyamide	monofilament	0.2 to 5 metric	USP 10-0 to 2	black, white	
RESOLON®	Polyamide	monofilament	0.5 to 4 metric	USP 7-0 to 1	blue	
SUPRAMID	Polyamide	pseudomonofilament	0.7 to 5 metric	USP 6-0 to 2	black, white	
SILK	Silk fibroin	multifilament/braided	0.4 to 6 metric	USP 8-0 to 3	black	
STAINLESS STEEL	Stainless steel	monofilament	0.7 to 9 metric	USP 6-0 to 7	nature	
RESORBA® OT-Cord	Ultra High Molecular Weight Poly-Ethylene	multifilament/braided	1.5 to 5 metric	USP 4-0 to 2	white	

GLYCOLON®



The production of GLYCOLON® involves the copolymerisation of polyglycolic acid and ε-caprolactone in a certain ratio. The breakdown of the polymeric suture in the tissue occurs through water uptake, thereby reversing the synthesis.
The strength of GLYCOLON reduces to 30% after 7 days. The completely safe intermediary pro-ducts that are formed, as well as the smooth, monofilament surface structure of the thread, result in minimal tissue reaction.
The smooth, monofilament surface structures of the polymer give GLYCOLON® excellent handling and tissue passage properties.

Tissue trauma as a result of suturing is not relevant to GLYCOLON®, and the monofilament structure prevents wicking of the thread without the need for additional surface treatment.

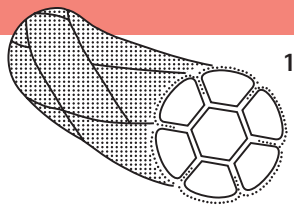
GLYCOLON® is available undyed, especially suitable for skin closure, and in violet (coloured with the physiologically harmless D+C No. 2 dye).

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

Properties:

- **high tear resistance**
- **excellent knot security**
- **atraumatic tissue passage**

PGA *resoquick*™



PGA *resoquick*™ is a high molecular weight, linear homopolymer of glycolic acid (hydroacetic acid), which is extruded into thin filaments and braided into sutures of various diameters.
Metabolisation of the PGA suture within the tissue occurs by the uptake of water, thus reversing the synthesis. The monomeric glycolic acid is split enzymatically into CO_2 and H_2O by the normal metabolism. The fine, precision braided filaments guarantee a very high tensile strength - as well as great suppleness. The special coating of a mixture of calcium stearate & polycaprolactone thinly covers the fibre bundles for specific reduction of surface friction. Absorbable suture approximates the tissue during the healing phase and progressively loses its tensile strength and breaking load.

The precision braided filaments of polyglycolic acid that make up PGA *resoquick*™ ensure standardized and moderately rapid absorption in tissue. PGA *resoquick*™ is absorbed rather quickly than PGA *RESORBA*® because this material is manufactured using a lower molecular weight PGA. The molecular weight of the PGA material is reduced during a special heat treatment process of the thread before coating.

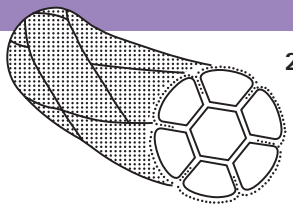
After only seven days PGA *resoquick*™ has already lost 50% of its original breaking load. After 14 days all original breaking load is lost completely. Absorption of PGA *resoquick*™ is approximately completed after 42 days.

- Colour: undyed
- Chemical name: polyglycolic acid
- Thread diameter: USP 8-0 -2 (0.4-5 metric)
- Types of packaging:
  - needle-thread-combinations
  - precut lengths
- Sterilization method: ethylene oxide

Properties

- **very supple**
- **very 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 weight polyglycolic acid is synthesised in the presence of a catalyst via the intermediary product glycolide, a cyclic ester. The breakdown of the PGA suture in the tissue occurs through water uptake, thereby reversing the synthesis. Regular metabolic processes break down the glycolic acid monomers into CO_2 and H_2O through enzymatic degradation. The physical and physiological properties of suture material containing 10% lactide as copolymer differ only slightly from pure PGA sutures.

The thin, precision-braided filaments provide very high tear resistance as well as excellent suppleness. The special coating thinly encapsulates the fibre bundles resulting in a specific reduction of surface friction. Absorbable sutures approximate the tissue during the healing phase; at the same time, they increasingly lose their tensile strength and tear resistance.

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

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

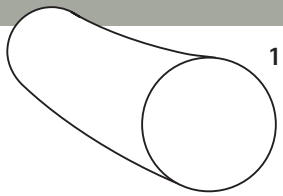
- Colour: violet or undyed
- Chemical name: polyglycolic acid
- Thread diameter: USP 8-0 -5 (0.4-7 metric)
- Types of packaging:
  - needle-thread-combinations
  - precut lengths
- Sterilization method: ethylene oxide

Properties:

- **high tear resistance**
- **good handling**
- **excellent knot security**
- **atraumatic tissue passage**
- **minimal tissue reaction**

* Articles manufactured by Healthium are experience loss of strength down to 55% after 21 days

PDO *RESORBA*™



PDO *RESORBA*™ is made of the polyester poly (p-dioxanone).
Because of its slow degradation profile, PDO *RESORBA*™ is particularly useful where the combination of an absorbable suture and extended wound support (up to six weeks) is desirable. After implantation the breaking load is at 55% after 42 days. Absorption by hydrolysis is completed after about 25 - 31 weeks.
Tissue reaction is minimal because of the monofilament structure of the thread.

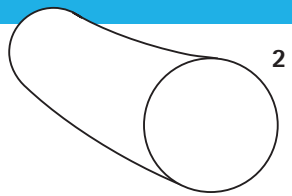
PDO *RESORBA*™ is supplied undyed or violet.

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

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 polymerising propylene. The suture is produced from the dyed granules using the dry spinning process.

The suture is hydrophobic, i.e., it absorbs practically no water and is chemically inert.

MOPYLEN® is an ideal skin suture, especially in plastic surgery and anywhere, where an excellent cosmetic result is critical.

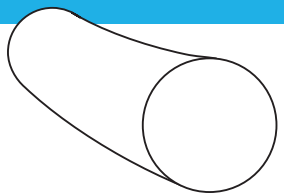
The material is coloured with a physiologically harmless dye.

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

Properties:

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

RESOPREN®



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

The material is coloured with a physiologically harmless dye.

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

Properties:

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

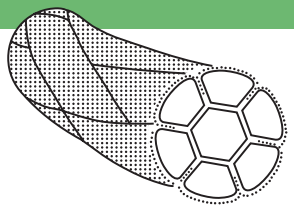
Information that is applicable to all the synthetic sutures described:
Due to their elasticity coupled with a relatively high tensile strength, no synthetic sutures should be too tightly knotted to ensure low tension within the tissue. Excessively high tension within the tissue may lead to wound healing 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.

[1] Die chirurgische Naht, by Paul Ferdinand Nockemann; Thieme Verlag

POLYESTER



POLYESTER is produced by polycondensation of ethylene glycol and terephthalic acid. Fibres are formed using the dry spin-ning process. Precision-braiding and tempering transform the stretched, slightly twisted fibre bundles into a suture. The individual fibres are hydrophobic, i.e., they repel water.

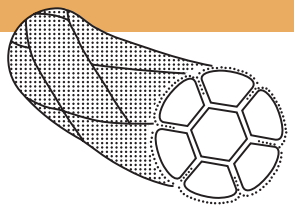
The material is coloured with a physiologically harmless dye.

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

Properties:

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

SUPOLENE



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

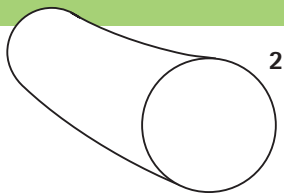
The material is coloured with a physiologically harmless dye.

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

Properties:

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

NYLON



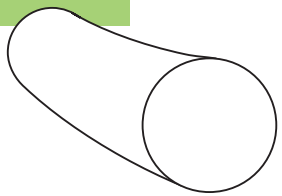
NYLON is a monofilament extruded thread (pressed and drawn through dies in a malleable condition) made from polyami-de 6-6.6.
Because of its high tensile strength, even when the fibre diameter is very fine, NYLON is particularly suitable for very fine suturing in microsurgery.
Polyamides can bind up to 10% water. The material is coloured with a physio-logically safe dye.

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

Properties:

- **above-average softness and suppleness**
- **superior handling and knotting properties**
- **no capillarity**
- **excellent tissue passage**

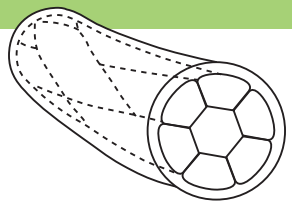
RESOLON®



RESOLON® is initially a monofilament polyamide 6-6.6 suture, like NYLON. However, it undergoes special treatment during the manufacturing process.
RESOLON® is exceptionally soft and supple even when dry and sterile.
As a result, it has excellent handling and knotting properties for a monofilament suture, while ensuring maximum knot tear resistance.

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

SUPRAMID



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

Special feature

The peptide structure of SUPRAMID allows it to degrade gradually after it has remained in the tissue for a while, despite its synthetic origin.

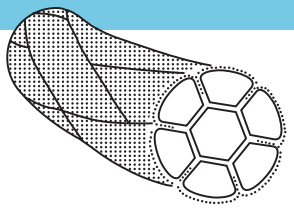
This suture is therefore, with few exceptions, only suitable for skin sutures or for tissue that does not require permanent support.
The material is coloured with a physiologically harmless dye.

- Colour: white (no dye) or black
- Chemical name:
  monofilament: polyamide 6-6.6
  pseudomonofilament:
  polyamide 6.6 and polyamide 6
- Thread diameter: USP 6-0 -2
  (0.7-5 metric)
- Types of packaging:
  - needle-thread-combinations
  - in precut lengths
- Sterilization method:
  ethylene oxide

Properties:

- **above-average softness and suppleness**
- **superior handling and knotting properties**
- **no capillarity**
- **excellent tissue passage**

SILK



1

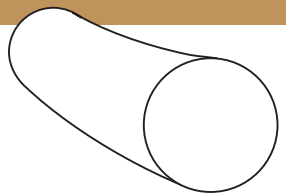
The raw material for producing silk is the cocoon of the silkworm. These very fine silk filaments undergo degumming (removing sericin, a viscous binding protein), spinning and precision-braiding.
A surface treatment waterproofs the silk filament. This process results in silk without any undesirable wicking, i.e. a non-capillary, hydrophobic suture with a smooth surface.
SILK is coloured with a physiologically harmless dye.

- Colour: black
- Chemical name: silk fibroin
- Thread diameter: USP 8-0 -3 (0.4-6 metric)
- Types of packaging:
  - needle-thread-combinations
  - precut lengths
- Sterilization method: ethylene oxide

Properties:

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

STAINLESS STEEL



A mineral product manufactured from a stainless, non-corroding steel alloy.

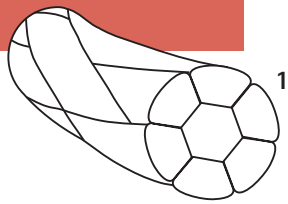
Steel fibres are drawn from liquid steel through a suitable die to the required diameters.

- 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:

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

RESORBA® OT-Cord



RESORBA® OT-Cord is made of UHMWPE (Ultra High Molecular Weight Poly-Ethylene). Because of its non-absorbable profile, and outstanding strength, *RESORBA*® OT-Cord is well suited for permanent wound support.

RESORBA® OT-Cord is availlable in white.

- Colour: White
- Chemical name: UHMWPE
- Thread diameter: USP 4-0 - 2 (1.5 - 5 metric)
- Types of packaging:
  - needle thread combinations
  - precut lengths
- Sterilisation method: ethylene oxide

Properties:

- **braided suture with all fibre configuration with sturdy central core as backbone for better knotting**
- **excellent strength: stronger than steel on a weighted basis**
- **high flexural strength**
- **e-braid construction for better handling and excellent knot strength**
- **vibrant tracer colours for enhanced visibillity**

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

The sutures are handmade

Packing in moisture-proof alublisters

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_2O. 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_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.

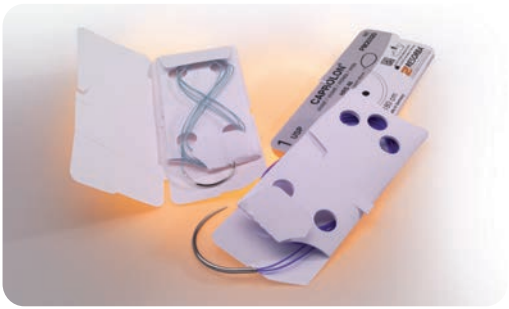
All surgical sutures are manufactured and tested according to the stipulated legal regulations, which are:

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

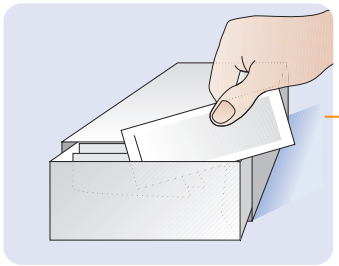
- **Separate withdrawal**

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

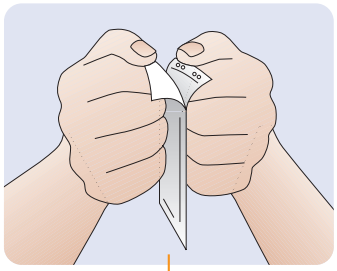
The **eco-pack** fulfils the provisions of DIN 58953, part 8 / Sterile supplies.

Peel-eco-pack

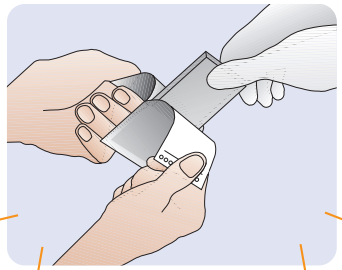
A combination of peelable outer wrapping and multifunctional primary packet



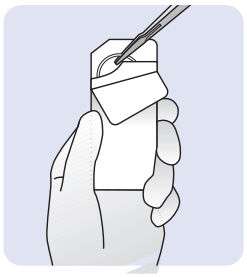
1. The peel-pack is removed from the storage box.



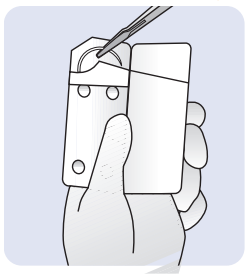
2. The Circulating Nurse grasps the two opening flaps at the upper end of the pack and opens it by evenly peeling the flaps apart.



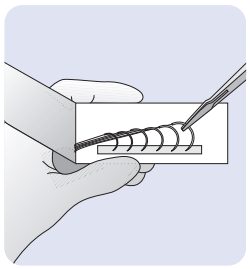
3. The sterile contents are handed over without contamination.



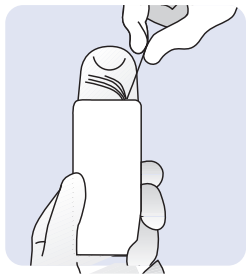
Single pack/needle-thread combination
Precut single sterile sutures with an attached surgical needle. The needle is exposed by turning over the perforated flap. It is then removed with a needle holder.



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



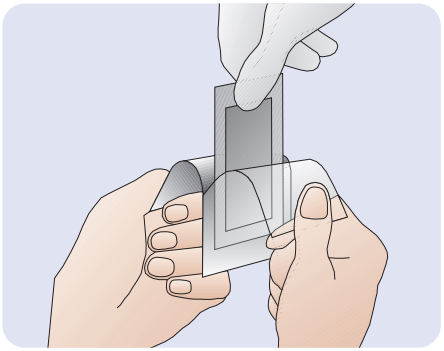
Multipack
Several combinations in each sterile primary packet. This type of packaging simplifies the organisation of handing over the same thread combinations during standardised procedures. The needles are exposed by opening the side of the paper cover, after which the individual needles (one after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



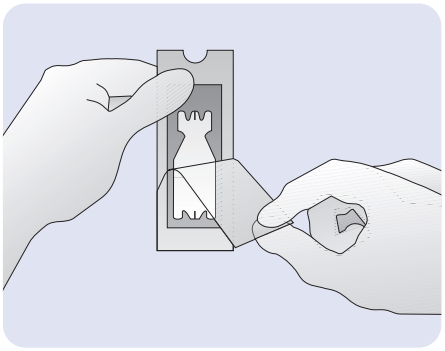
Pre-cut sutures
One or more threads in each sterile primary packet. The suture is meant for ligatures or for use with eyed needles. After the upper flap has been opened, the individual threads can be withdrawn in any desired order.

Micro-Pack

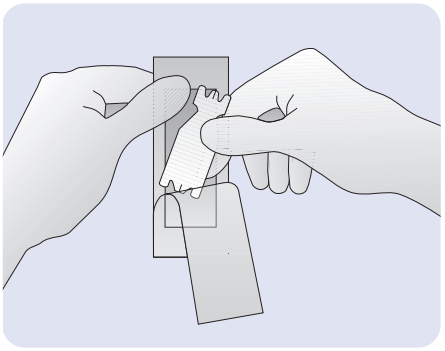
Primary packet with foam for micro- and ophthalmic surgery



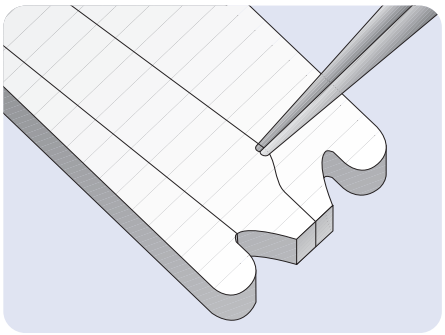
1. Peel open the non-sterile outer sachet and, without contamination, pass over the sterile inner sachet.



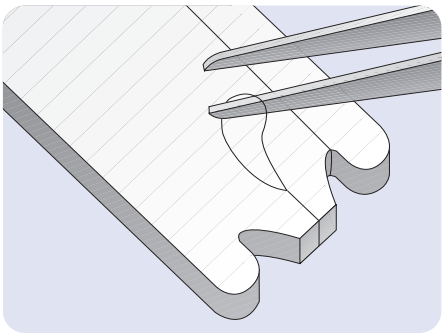
2. Peel open the inner sachet.



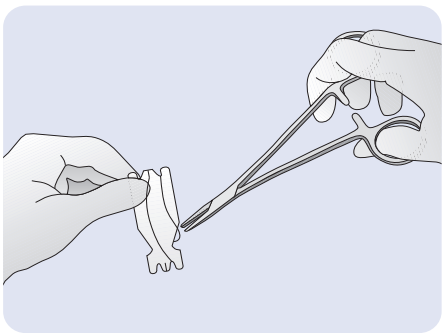
3. Carefully remove the sterile suture carrier from the blister sachet.



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



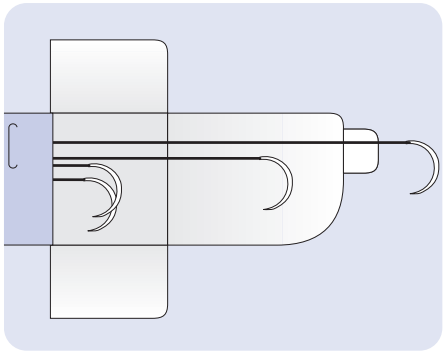
5. In the case of double-armed threads, firstly separate/ cut the needle loop and then separate the thread from the carrier with forceps.



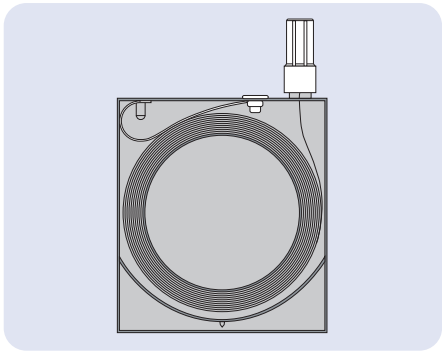
6. Grasp the needle with the needle holder and remove it from the primary packet by turning it slightly.

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.

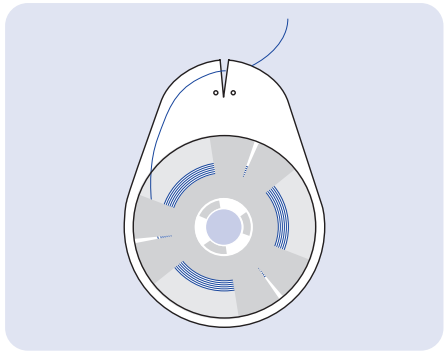
Types of packaging



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

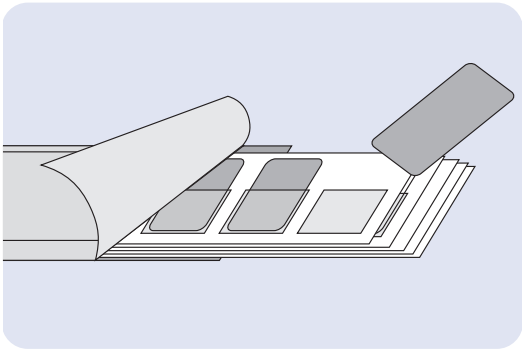


Dispenser packaging
Suture material can be removed aseptically from the dispenser. Suture material in so-called suture dispensers is predominantly used in veterinary medicine. The packaging is safe and economical.



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

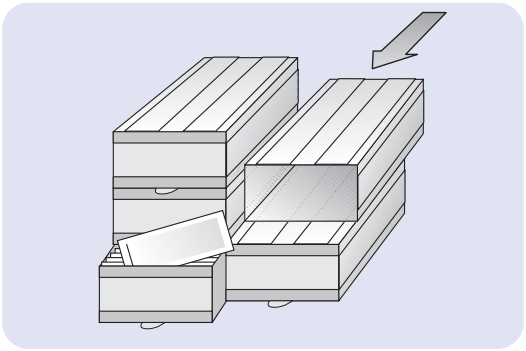
Organisational aids



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 purchase: due to production
- Lettering with all necessary data (indication, contents, ...)
- 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).

Symbols used on the packaging

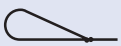
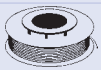
Absorbable suture material	
 dyed / braided / coated / absorbable	PGA *RESORBA*®
 dyed / monofilament / absorbable	PDO *RESORBA*™ , GLYCOLON®
 undyed / braided / coated / absorbable	PGA *RESORBA*®, PGA *resoquick*™
 undyed / monofilament / absorbable	PDO *RESORBA*™, GLYCOLON®

Nonabsorbable suture material	
 dyed / braided / coated / non-absorbable	SUPRAMID, SUPOLENE, POLYESTER, SILK
 dyed / monofilament / non-absorbable	MOPYLEN®, RESOPREN®, SUPRAMID, NYLON, RESOLON®
 undyed / braided / coated / non-absorbable	SUPRAMID, SUPOLENE, POLYESTER
 white / braided / non-absorbable	*RESORBA*® OT-Cord
 undyed / monofilament / non-absorbable	SUPRAMID, 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
PDO	PDO *RESORBA*™	Poly(p-dioxanone)
PP	MOPYLEN®	Polypropylene
PVDF	RESOPREN®	Polyvinylidene difluoride
PET	POLYESTER	Polyester
PET	SUPOLENE	Polyester
PA	NYLON	Polyamide
PA	RESOLON®	Polyamide
PA	SUPRAMID	Polyamide
UHMWPE	*RESORBA*® OT-Cord	Ultra High Molecular Weight Poly-Ethylene

Explanation of symbols

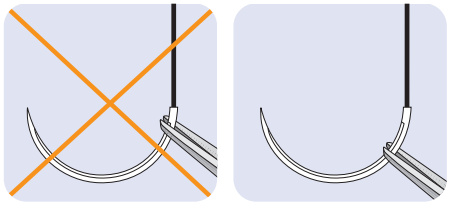
A	control release needle		loop suture
	loop		ligature pack

Did you know?

A short lesson in symbols used for medical products

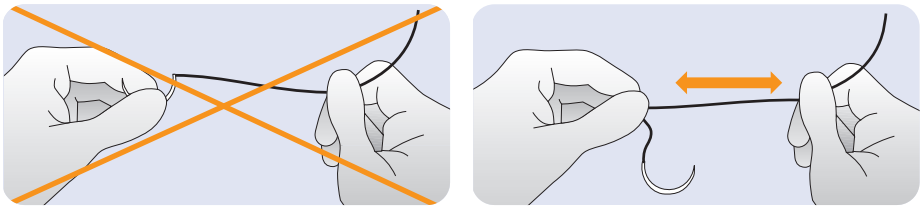
REF	= Reference number
LOT	= Batch number
	= Use by year - month - day
	= Consult instructions for use
	= Do not reuse
	= Do not resterilize
	= Do not use if package is damaged
STERILE EO	= Sterilized using ethylene oxide
STERILE R	= Sterilized using irradiation
25°C	= Upper Limit of Temperature
CE 0197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

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.

[1] Product portfolio manufactured by:

Healthium Medtech Private Limited · No. 472/D, 13th Cross, 4th Phase
Peenya Industrial Area, Bangalore 560 058, India
Mfg. Lic. No.: MFG/MD/2019/000139 · Email: care@healthiummedtech.com

[2] Some combinations of this product portfolio manufactured by:

Healthium Medtech Private Limited · No. 472/D, 13th Cross, 4th Phase
Peenya Industrial Area, Bangalore 560 058, India
Mfg. Lic. No.: MFG/MD/2019/000139 · Email: care@healthiummedtech.com

RESORBA®
Sutures

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.

P1326 2021-02

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**