

Instructions for Use

Novosyn® Quick

Caution: Federal (USA) law restricts this device to sale or use by or on the order of a physician.



The Novosyn Quick Absorbable Suture is MR Safe.

Description

Novosyn® Quick is a sterile, multifilament, braided, synthetic absorbable surgical suture material composed of a copolymer made from 90 % glycolide and 10 % L-lactide. The characteristic rapid loss of strength is achieved by use of a polymer with a lower molecular weight than regular Novosyn. Novosyn® Quick sutures are available undyed. The braided threads are coated with a mixture of equal parts of an absorbable synthetic copolymer made of glycolide and L-lactide and calcium stearate so that they slide easily without causing a sawing effect. The coating has been found to be non-antigenic and non-pyrogenic. Novosyn® Quick meets USP and EP requirements for synthetic absorbable sutures (except for an occasional slight oversize in some gauges). Knot tensile strength meets the USP and EP for collagen sutures (Chorda resorbilis sterilis).

Maximum Suture Oversize in Diameter (mm) From USP

USP suture size designation	Maximum oversize (mm)
6-0	0.021
5-0	0.036
4-0	0.041
3-0	0.036
2-0	0.041
0	0.056
1	0.046
2	0.031

Indications

Novosyn® Quick Absorbable Suture is indicated for use in general soft tissue approximation of the skin and mucosa, where only short term wound support (7-10 days) is required. Novosyn® Quick suture is not intended for use in ligation in ophthalmic, cardiovascular or neurological procedures.

Actions

Suture materials are used primarily for adaptation of the wound edges and to render possible an undisturbed wound healing. During the use of Novosyn® Quick sutures a

mild inflammatory reaction may occur, which is typical of an endogenous reaction to foreign bodies. As time passes, the suture material is encapsulated by fibrous connective tissue. Finally, Novosyn® Quick is hydrolyzed to glycolic acid and lactic acid and metabolized by the body without causing any enduring alterations of the implantation site. Absorption begins with a decline in tensile strength followed by a loss of mass. *In vitro* studies of Novosyn® Quick show that 5 days post-implantation approximately 50% of the initial tensile strength remains. All of the original tensile strength is lost by approximately at 10- 14 days post-implantation.

	Approximated remaining tensile strength
5 days	40 -50%
7 days	25 -30%
10 days	5-10%
14 days	0-2 %

The *in vivo* study showed that mass absorption of Novosyn® Quick is essentially completed at 42 days, when the tissue is normally perfused.

Contraindications

Usage of Novosyn® Quick is contraindicated for applications where extended approximation of tissues under stress or where long term wound support of closure is required.

Mode of application

To be used in accordance with surgical requirements. Normally the removal of the suture Novosyn® Quick is not required.

Warnings

- Do not resterilized. Sterile unless packaging has been opened or damaged.
- Single use only. Discard opened packages and unused sutures.
- Do not use after expiry date.
- Users should be familiar with the surgical procedures and techniques involving absorbable sutures when using Novosyn® Quick, as the risk of wound dehiscence may vary depending upon the site of application and the type of material used. Physicians should consider the in-vitro performance (under the ACTIONs section) when selecting a suture.
- Usage of Novosyn® Quick may not be advised in case of elderly or malnourished or debilitated patients, or in patients suffering from diseases or conditions which delay the wound healing process.
- Acceptable surgical practice should be followed for the management of contaminated or infected wounds.
- As this is an absorbable suture material, the use of supplemental nonabsorbable sutures should be considered by the surgeon in the closure of the sites which may undergo expansion, stretching or distention, or which may require additional support.

- As with any foreign body, prolonged contact of any suture with salt solutions, such as those found in the urinary or biliary tracts may result in calculus formation.
- As an absorbable suture, Novosyn® Quick suture may act transiently as a foreign body.
- Acceptable surgical practice should be followed for the management of contaminated or infected wounds.

Precautions

- Skin sutures which remain in place longer than 7 days may cause localized irritation and should be snipped off or removed as indicated.
- Consideration should be taken in the use of absorbable sutures in tissues with poor blood supply as suture extrusion and delayed absorption may occur.
- Subcuticular sutures should be placed as deeply as possible to minimize the erythema and induration normally associated with the absorption process.
- When working with Novosyn® Quick suture materials great care should be taken to ensure that the use of surgical instruments, such as forceps and needle holders, do not cause any crushing or crimping damage to the suture material.
- Adequate knot security requires the standard surgical technique of flat, square ties, with additional throws as indicated by surgical circumstances and the experience of the surgeon.
- Avoid prolonged exposure to elevated temperatures.
- Care should be taken to avoid damage when handling surgical needles. Grasp the needle in an area one-third (1/3) to one-half (1/2) of the distance from the attachment end to the point. Grasping in the point area could impair the penetration performance and cause fracture of the needle. Grasping at the butt or attachment end could cause bending or breakage. Reshaping needles may cause them to lose strength and be less resistant to bending and breaking. Users should exercise caution when handling surgical needles to avoid inadvertent needle stick injury.
- Discard used needles in “Sharps” containers.

Adverse Reactions

Adverse effects associated with the use of Novosyn® Quick include wound dehiscence, failure to provide adequate wound support in closure of the sites where expansion, stretching or distension occur, failure to provide adequate wound support in elderly, malnourished or debilitated patients or in patients suffering from conditions which may delay wound healing, infection, minimal acute inflammatory tissue reaction, localized irritation when skin sutures are left in place for greater than 7 days, suture extrusion and delayed absorption in tissue with poor blood supply, calculi formation in urinary and biliary tracts when prolonged contact with salt solutions such as urine and bile occurs, and transitory local irritation at the wound site. Broken needles may result in extended or additional surgeries or residual foreign bodies. Inadvertent needle sticks with contaminated surgical needles may result in the transmission of bloodborne pathogens.

Application

To be used in accordance with surgical requirements.

Sterilization

Novosyn® Quick undyed is sterilized by gamma irradiation. Do not resterilize the sutures. In case that the individual suture container has been damaged or opened before the actual use, discard the affected suture.

Storage

Store at room temperature. Avoid exposure to extreme temperatures over a long period of time. Do not use after the expiry date.

How supplied

Novosyn® Quick sutures are available undyed (beige) in sizes USP 2 to 6/0 (metric 5 to 0.7) . The sutures are supplied sterile, in pre-cut lengths and ligating reels, non-needled or attached to various types of stainless steel needles, with permanent needle attachment techniques. The boxes contain 6, 12, 24, or 36 units of sutures. Novosyn® Quick is also available as Episio-Set, containing three needle-thread combinations of Novosyn® Quick for closure of episiotomies.

CUSTOMER SERVICE

For further information regarding Novosyn® Quick Suture please contact Tissue Seal, LLC's Customer Service at 1-877-754-6458 or customerservice@tissueuseal.com

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