# Novosyn®
## Instructions for use

### Description
Novosyn® is a sterile, absorbable surgical suture material produced from a copolymer composed of 90% glycolate and 10% L-lactate. Novosyn® is coloured violet with the colouring D&C Violet No. 2 (C. I. 60725) to make it recognizable, but is also available undyed in the natural beige colour. The braided threads are treated with a absorbable synthetic coating consisting of a mixture of equal parts of a copolymer consisting of glycolate and L-lactate and calcium stearate so that they slide easily without causing a sawing effect.
Novosyn® fulfils all the requirements of the European. Pharm. and United States Pharm. - current edition - for sterile, synthetic, absorbable sutures (except for an occasional slight oversize in some gauges).

Maximum Suture Oversize in Diameter (mm) From USP

| USP suture size designation | Maximum oversize (mm) |
|---|---|
| 8-0 | 0,007 |
| 7-0 | 0,01 |
| 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® suture is indicated for use in general soft tissue approximation and/or ligation, including use in ophthalmic procedures, but not for use in cardiovascular and neurological tissues.

### Actions
Suture materials are used primarily for adaptation of the wound edges to render possible an undisturbed wound healing. During the use of Novosyn® sutures a mild inflammatory reaction may occur, which is typical for an endogenous reaction to a foreign body. As time passes the suture material is encapsulated by fibrous connective tissue. Novosyn® is metabolized to glycolic acid and lactic acid by hydrolysis without causing any enduring change in the region of the wound. Studies *in vitro* demonstrate that approximately the 75% of the original tensile strength remains after 14 days of implantation for sizes 6/0 and larger and approximately 56% for sizes 7/0 or smaller. At 21 days, approximately the 52% of the original tensile strength remains for sizes 6/0 and larger and approximately 35% for sizes 7/0 or smaller. And at 28 days, approximately the 23% of the original tensile strength remains for sizes 5/0 and larger.

| | **Approximated remaining tensile strength** |
|---|---|
| **14 days (USP 6/0 and larger)** | 75 % |
| **14 days (USP 7/0 and smaller)** | 56 % |
| **21 days (USP 6/0 and larger)** | 52 % |
| **21 days (USP 7/0 and smaller)** | 35 % |
| **28 days (USP 5/0 and larger)** | 23 % |

The *in vivo* study showed that mass absorption of Novosyn® is essentially completed between 56-70 days, when the tissue is normally perfused.

**Contraindications**
Novosyn® suture materials are contra-indicated for applications where prolonged support of the wound closure by the suture material is required (e.g. cardio-vascular surgery).

**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®, 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® 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® 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® 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® 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 is sterilized by ethylene oxide gas. 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® sutures are available in dyed violet and undyed (beige) in the sizes USP 2 (5 metric) through USP 8/0 (0.4 metric) in TD packages of 6 units, in DAL packages of 12 units and in DDP packages of 12, 24 or 36 units with or without needles.

Novosyn is supplied sterile.

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

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

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