Polysorb™
Coated Braided Absorbable Suture

PT00129889

BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

DESCRIPTION
Polysorb™ braided sutures are composed of Lactomer™ glycolide/lactide copolymers which is a synthetic polymer composed of glycolide and lactide (derived from glycolic acid and lactic acid). Polysorb™ sutures are prepared by coiling the suture with a mixture of a copolymer of glycolide and lactide, which is subsequently absorbed and metabolized by the body. Absorption begins as a loss of tensile strength without appreciable loss of mass. Studies indicate tensile strength averages for Polysorb™ sutures are approximately 140% of USP and E.P. minimum knot strength initially, approximately 80% at two weeks and in excess of 30% at three weeks post implant. Absorption of Polysorb™ sutures is essentially complete between the 50th and 70th day.

CONTRAINDICATION
Polysorb™ sutures, being absorbable, should not be used where extended approximation of tissue is required.

WARNINGS
Replicer or use of the device may create the risk of contamination, patient infection, permanent impairment or life threatening injury. Do not reuse, reprocess or resterilize this device. Sterile unless packaged has been opened or damaged. Discard open, unused sutures. Store at room temperature. Avoid prolonged exposure to elevated temperatures.

In surgery of the urinary or biliary tract, care should be taken to avoid prolonged contact with this, or any other suture with salt solutions, as calculus formation may result.

Users should be familiar with surgical procedures and techniques involving absorbable sutures before employing Polysorb™ sutures for wound closure, as the risk of wound dehiscence may vary with the site of application and the suture material used.

As any foreign material in the presence of bacterial contamination may enhance bacterial infectivity, acceptable surgical practice must be followed with respect to drainage and closure of contaminated or infected wounds. The use of this care may be inappropriate in patients with any conditions which, in the opinion of the surgeon, may cause or contribute to delayed wound healing.

As this is an absorbable suture material, the use of supplemental nonabsorbable sutures should be considered by the surgeon in closure of the abdomen, chest, joints or other sites subject to tension or requiring additional support.

<table>
<thead>
<tr>
<th>Maximum Suture Oversize in Diameter (mm) from USP</th>
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<tbody>
<tr>
<td>USP Size</td>
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INDICATIONS
Polysorb™ sutures are indicated for use in soft tissue approximation or ligation and ophthalmic surgery, but not in cardiovascular or neural tissue.
**PRECAUTIONS**

In handling this or any other suture material, care should be taken to avoid damage from handling. Avoid crushing or crimping damage due to application of surgical instruments, such as forceps or needle holders.

Adequate knot security requires the accepted surgical technique of flat, square ties, with additional throws as warranted by surgical circumstance and the experience of the surgeon.

Skin sutures which must remain in place longer than 7 days may cause irritation and should be snipped off or removed as indicated.

Under some circumstances, notably orthopedic procedures, immobilization by external support may be employed at the discretion of the surgeon.

Dispose of used instruments in accordance with the end-user's medical and biological waste disposal requirements. For RX Only. Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

**ADVERSE REACTIONS**

Adverse effects: wound dehiscence, failure to provide adequate wound support in sites where expansion, stretching, or disention occurs, failure to provide adequate wound support in patients with conditions which may delay wound healing, localized irritation when skin sutures are left in place greater than 7 days, calculus formation when prolonged contact with salt solutions occurs, enhanced bacterial infectivity, minimal acute inflammatory reaction, and transitory local irritation.

**HOW SUPPLIED**

Polypropylene sutures are available in USP sizes 2 (5 Metric) through 8-0 (0.4 Metric). They are available undyed (natural) or violet colored. The sutures are supplied sterile, in pre-cut lengths and firing reams, non-needled or affixed to various needle types using both permanent and removable needle attachment techniques. The sutures are available in box quantities of one, two and three dozen.

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<th>Syneture™</th>
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<td><strong>STERILE</strong> E0</td>
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**en**: Sterilized using ethylene oxide  
**fr**: Sterilisé à l'oxyde d'éthylène  
**de**: Mit Ethylenoxid sterilisiert  
**it**: Sterilizzato con ossido di etilene  
**es**: Estérilizado con oxido de etileno  
**nl**: Steriliserd met ethylengas  
**sv**: Steriliserad med ethylenoxid  
**da**: Steriliseret med ethylenoxid  
**el**: Σεριλίζεται με αιθένη  
**fi**: Sterilisoitu ethylenoxidilla  

**ru**: Стерилизовано по технологии CS  
**zh**: 灭菌乙氧乙烷灭菌  

**hu**: Etilén-oxid sterilizált  
**sk**: Sterilizované etylenovým oxidom  
**no**: Steriliseret med etylenoxid  

**bg**: Стерилизирани с етиленов оксид  
**hr**: Sterilizirani s etilenovim oxidom  

**zh**: 使用环氧乙烷灭菌  

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**en**: Single Use  
**fr**: Usage unique  
**de**: Einmalgebrauch  
**es**: Ún solo uso  
**pt**: Uso único  

**en**: Use only  
**de**: Nur verwenden  
**es**: ¡Únicamente para uso  
**pt**: Somente para uso  

**en**: Do not re-use  
**de**: Nicht erneut verwenden  
**es**: No se puede reutilizar  
**pt**: Não se permite reutilizar  

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**zh**: 一次性使用  

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**ko**: 1회용  
**zh**: 单一用途