**Polysorb™ Coated Braided Absorbable Suture**

**PT00129889**

**BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.**

**DESCRIPTION**
Polysorb™ braided sutures are composed of Lactomer™ glycolide/lactide copolymer which is a synthetic polyester composed of glycolide and lactide (derived from glycolic and lactic acids). Polysorb™ sutures are prepared by coiling the suture with a mixture of a caprolactone/glycolide copolymer and calcium stearate lacquer. Polysorb™ sutures are colored violet to increase visibility and are also available undyed.

Polysorb™ sutures meet all requirements established by the United States Pharmacopeia (USP) and the European Pharmacopeia (EP) except for minor variations in suture diameter. Such variations are:

<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.

**ACTIONS**
Polysorb™ sutures elicit a minimal acute inflammatory reaction in tissue, which is followed by a gradual encapsulation of the suture by fibrous connective tissue.

Progressive loss of tensile strength and eventual absorption of Polysorb™ sutures occurs by means of hydrolysis, where the Lactomer™ glycolide/lactide copolymer is broken down to glycolic and lactic acids which are 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, and 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.

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

**WARNINGS**
Reprocessing and/or resterilization of this device may create the risk of contamination, patient infection, permanent impairment or life threatening injury. Do not reprocess or resterilize this device. Sterile unless packaging 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 tracts, care should be taken to avoid prolonged contact of 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 delisision may vary with the size 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 suture 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 expansion or requiring additional support.
**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 snapped 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 license healthcare practitioner.

**ADVERSE REACTIONS**

Adverse effects: wound dehiscence, failure to provide adequate wound support in sites where expansion, stretching, or disention occur, 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**

Polysorb™ 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 ligating reels, 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.
en: Package quantity  
fr: Quantité par paquet  
de: Anzahl pro Packung  
it: Quantità per confezione  
esc: Cantidad por paquete  
pt: Quantidade na embalagem  
da: Antal anordninger i pakken  
fi: Määra pakkuusessa  
e: Locióntö te összeszerettel  
p: Liczba sztuk w pakowaniu  
r: Paket miktan  
cs: Konzervace v balení  
vn: Nội dung  
zh: 包装数量  
zh: 包装数量  
ja: 数量  
l: Määrä  
i: Jumlah  

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