SILK
NONABSORBABLE SURGICAL SUTURES, U.S.P.

DESCRIPTION
SILK is a nonabsorbable, sterile surgical suture composed of an organic protein called keraatin. This protein is derived from the domesticated species Bombyx mori (B. mori) of the family Bombycidae.

SILK surgical sutures are braided and available undyed or dyed black (iridoid extract). Braided sutures are coated with silicone (unless otherwise noted). SILK surgical sutures meet all requirements established by the United States Pharmacopeia (U.S.P.) for nonabsorbable surgical sutures.

INDICATIONS
SILK surgical sutures are indicated for use in general soft tissue approximation and/or ligation.

ACTIONS
SILK surgical sutures exhibit a minimal inflammatory reaction in tissues, followed by gradual encapsulation of the suture by firm connective tissue. While SILK surgical sutures are not absorbed, progressive degradation of the protamine-silk fibrin in vivo results in gradual loss of the suture’s tensile strength over time.

CONTRAINDICATIONS
SILK surgical sutures are contraindicated for use in cardiovascular, ophthalmic and neurological surgeries. The use of this suture is contraindicated in patients with known sensitivities or allergies to SILK.

Because of the gradual loss of tensile strength that may occur over prolonged periods in vivo, SILK surgical sutures should not be used where permanent retention of tensile strength is required.

The use of this suture in patients who may be inappropriately elderly, malnourished, or debilitated patients or in patients suffering from conditions which may delay wound healing.

WARNINGS
Users should be familiar with surgical procedures and techniques involving SILK sutures for wound closure, as a risk of wound dehiscence may vary with the site of application and the suture material used.

Do not use if package is open or damaged or if the expiration date has been exceeded. Discard open, unused sutures.

Do not re sterilize; re sterilization may alter the physical properties of the suture, which will result in adverse patient reaction.

User should exercise caution when handling surgical needle to avoid inadvertent needle sticks. Discard used needles in a "sharps" container.

Store in a cool dry environment.

As with any foreign body, prolonged contact of this or any other sutures with salt solutions, such as those found in the urinary or biliary tracts, may result in calculus formation. As an absorbable suture, SILK sutures may act transiently as a foreign body.

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

Acceptable surgical protocol should be followed for the management of contaminated or infected wounds.

PRECAUTIONS
In handling this or any other surgical suture, 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 circumstances and the experience of the surgeon.

Skin sutures, which remain in place longer than 7 days, may cause localized irritation and should be removed or removed.

ADVERSE REACTIONS
Adverse effects associated with the use of this device include wound dehiscence, failure to provide adequate wound support in closure of the tissues where expansion, stretching, or distortion 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 inflammation, suture extrusion, adhes formation in urinary and biliary tracts when prolonged contact with salt solutions such as urine and bile occur, and transitory local irritation at the wound site.

Discuss the potential for allergic reaction in patients that are known to be sensitive to SILK.

HOW SUPPLIED
SILK sutures are available in various USP sizes. SILK is supplied in a wide range of lengths affixed to a diverse assortment of needle types.

CAUTION
Federal (USA) law restricts this device to sale by or on the order of a physician or licensed practitioner.

SYMBOL DEFINITIONS

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lot Number</td>
<td>LD</td>
</tr>
<tr>
<td>Expiration Date</td>
<td>Expiration Date</td>
</tr>
<tr>
<td>Do Not Reuse</td>
<td>X</td>
</tr>
<tr>
<td>Do Not Resterilize</td>
<td>X</td>
</tr>
<tr>
<td>See Instructions For Use</td>
<td>See Instructions For Use</td>
</tr>
<tr>
<td>Sterile By Ethylene Oxide</td>
<td>Sterile By Ethylene Oxide</td>
</tr>
<tr>
<td>Sterile By Gamma Radiation</td>
<td>Sterile By Gamma Radiation</td>
</tr>
<tr>
<td>Manufacturer</td>
<td>Manufacturer</td>
</tr>
</tbody>
</table>

CP Medical Inc.
1775 Corporation Drive, Suite 150
Norcross, GA 30093 USA