Sofsilk™
Coated Braided Silk
1300379

BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

DESCRIPTION
Sofsilk™ braided silk sutures are non-absorbable, sterile, non-metastatic surgical sutures composed of natural proteinous silk fibers calibrated in mgm. The protein is derived from the domesticated silkworm species Bombyx mori of the family Bombycidae. The silk fibers are treated to remove the naturally-occurring sericin gum and braided to produce Sofsilks™ coated silk sutures. The braided sutures are available coated uniformly with either silicone or a special wax mixture to reduce bulk and to improve surface integrity which enhances handling characteristics, ease of passage through tissue, and lower non-tissue properties. Sofsilks™ sutures are available white or colored black with lycopodium contact.
Sofsilk™ sutures meet all requirements established by the United States Pharmacopeia (USP) and the European Pharmacopoeia (EP) for non-absorbable surgical sutures, except for size 8-0, which differs from USP maximum diameter requirements by 0.124 mm.

INDICATIONS
Sofsilk™ sutures are indicated for use in general soft tissue approximation and for ligation, including use in cardiovascular, ophthalmic, microsurgery, and neurological surgery.

ACTIONS
Sofsilk™ sutures elicit a minimal acute inflammatory reaction in tissue which is followed by gradual encapsulation of the suture by fibrous connective tissue. While Sofsilks™ sutures are not absorbed, progressive degradation of the proteinous silk fiber in vivo may result in gradual loss of the suture tensile strength over time.

CONTRAINDICATIONS
The use of this suture is contraindicated in patients with known sensitivities or allergies to silk.

Due to the gradual loss of tensile strength which may occur over prolonged periods in vivo, Sofsilks™ sutures should not be used where permanent retention of tensile strength is required.

WARNINGS
As with any foreign body, prolonged contact of any suture with soft solutions may result in calcific formation.

Do not renevel. Sterile unless packaging has been opened or damaged.

Do not use if any sutures are stored at room temperature. Avoid prolonged exposure to elevated temperatures.

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

Acceptable surgical practice must be followed with respect to drainage and closure of contaminated or infected wounds.

PRECAUTIONS
In handling this or any other suture material, care should be taken to avoid damage from handling. Avoid crushing or compacting 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.

ADVERSE REACTIONS
Adverse effects, which may be associated with the use of this product, include wound dehiscence, gradual loss of tensile strength over time, allergic, anaphylactic, or severe reactions in patients with known sensitivities to silk, calcium formation when prolonged contact with salt solutions occurs, enhanced bacterial infectivity, minimal acute inflammatory reaction, and transient local irritation.

HOW SUPPLIED
Sofsilk™ sutures are available white or colored black with lycopodium extract and uniformly coated with silicone or a special wax mixture, in sizes 5-0 through 8-0 (0.4 Metric).

The sutures are supplied sterile, in pre-cut lengths and cutting ends, non-nearly or affixed to needles using both permanent and removable needle attachment techniques. The sutures are available in quantities of one, two and three dozen.