



# Monosof™ and Dermalon™ Monofilament Nylon

# Surgilon™ Braided Nylon

PT00119662



(92)PT00119662

**en**

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

**DESCRIPTION**

Monosof™ and Dermalon™ monofilament and Surgilon™ braided sutures are inert, nonabsorbable, sterile sutures composed of the long-chain aliphatic polymers Nylon 6 and Nylon 6.6. The braided sutures are coated uniformly with silicone to enhance handling characteristics, ease of passage through tissue and reduction of capillarity. Monosof™ monofilament sutures are nonabsorbable nylon surgical sutures which are available either dyed black, with Logwood extract, or undyed (clear). Dermalon™ monofilament sutures are nonabsorbable nylon surgical sutures and are available dyed blue. Surgilon™ braided sutures are also nonabsorbable nylon surgical sutures available dyed black or undyed (white).

Monosof™ and Dermalon™ monofilament and Surgilon™ braided nylon sutures meet all requirements established by the United States Pharmacopeia (USP) and the European Pharmacopeia (EP) except for minor variations in suture diameter for Monosof™ sizes 0, 3-0, 4-0, 5-0, 6-0 and 7-0.

Such variations are:

Maximum Suture Oversize in Diameter (mm) from USP		
USP Size	USP Size Designation (mm)	Maximum Overage (mm)
7-0	0.05-0.069	0.003
6-0	0.07-0.099	0.006
5-0	0.10-0.149	0.005
4-0	0.15-0.199	0.011
3-0	0.20-0.249	0.011
0	0.35-0.399	0.009

**INDICATIONS**

Monosof™ and Dermalon™ monofilament and Surgilon™ braided nylon sutures are indicated for use in general soft tissue approximation and/or ligation.

Monosof™ monofilament nylon sutures are also indicated for microsurgery.

**ACTIONS**

Monosof™ and Dermalon™ monofilament and Surgilon™ braided nylon sutures all elicit a minimal acute inflammatory reaction in tissue, which is followed by gradual encapsulation of the suture by fibrous connective tissue. As with any nylon suture, though not absorbed, progressive hydrolysis of the suture, in vivo, may result in gradual loss of its tensile strength over time.

**CONTRAINDICATIONS**

Due to the gradual loss of tensile strength which may occur over prolonged periods in vivo, nylon 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 salt solutions may result in calculus formation.
- Reuse, reprocessing and/or resterilization of this 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 packaging has been opened or damaged. Discard open, unused sutures. Store at room temperature. Avoid prolonged exposure to elevated temperatures.
- Users should be familiar with surgical procedures and techniques involving nonabsorbable sutures before employing Monosof™, Dermalon™, or Surgilon™ 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 infected or contaminated wounds.
- Bolster and Weight presented with Monosof™ sutures are for external use only.

**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. The use of additional throws may be particularly appropriate when knotting monofilaments.
- Dispose of used instruments in accordance with the end-user's medical and biological waste disposal requirements.

**ADVERSE REACTIONS**

Adverse effects are: wound dehiscence, gradual loss of tensile strength over time, calculi formation when prolonged contact with salts solutions occurs, enhanced bacterial infectivity, minimal acute inflammatory reaction, and transitory local irritation.

**HOW SUPPLIED**

Monosof™ monofilament nylon sutures are available either clear (undyed) or dyed black with Logwood extract, in sizes 2 (5 Metric) through 11-0 (0.1 Metric). Monosof™ sutures are available in presentations containing bolster and weight components.

Dermalon™ monofilament nylon sutures are available dyed blue with FD&C Blue No. 2 in sizes 1 (4 Metric) through 6-0 (0.7 Metric).

Surgilon™ braided nylon sutures are available dyed black or undyed (white) in sizes 3 (6 Metric) through 6-0 (0.7 Metric).

Monosof™, Dermalon™, and Surgilon™ 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.