



Monosof™ and Dermalon™ Monofilament Nylon

Surgilon™

Braided Nylon

1300374



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 U.S.		
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, including use in cardiovascular, ophthalmic, and neurological surgery.

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.

Do not resterilize. 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.

ADVERSE REACTIONS

Adverse effects, which may be associated with the use of this product, include: wound dehiscence, gradual loss of tensile strength over time, calculi formation when prolonged contact with salt 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.



Do not use if package is opened or damaged.

Ne pas utiliser en cas d'endommagement ou d'ouverture de l'emballage.

Bei geöffnet oder beschädigter Verpackung nicht verwenden.

Non utilizzare se la confezione è aperta o danneggiata.

No usar el dispositivo si la envoltura está abierta o dañada.

Não utilizar se a embalagem estiver aberta ou danificada.

Niet gebruiken als de verpakking beschadigd of geopend is.

Får ej användas om förpackningen är öppnad eller skadad.

Må ikke anvendes, hvis emballagen er åbnet eller beskadiget.

Ei saa käyttää, jos pakkaus on avattu tai vaurioitunut.

Μη χρησιμοποιείτε αν η συσκευασία έχει ανοιχτεί ή υλοστεί ζημιά.

Nie stosować, jeżeli opakowanie zostało otwarte lub uszkodzone.

Ambalaj açılmış ya da zarar görmüşse kullanmayın.

He используйте изделие, если упаковка вскрыта или повреждена.

Pokud je balení otevřené nebo poškozené, produkt nepoužívejte.

Tilos felhasználni, ha a csomagolás kinyílt vagy megsérült.

Nepoužívajte, ak je obal otvorený alebo poškodený.

Skal ikke brukes hvis emballasjen er åpnet eller skadet.

Ne uporabljajte, če je embalaža odprta ali poškodovana.

如果包装已打开或破损，请勿使用。

如果包装已開啟或損毀，則請勿使用。

포장이 개봉되어 있거나 손상된 경우에는

사용하지 마십시오.

He използвайте, ако опаковката е отворена или повредена.

A nu se utiliza în cazul în care ambalajul este deschis sau deteriorat.

Ärge kasutage, kui pakend on avatud või kahjustatud.

Nelietot, ja iepakojuums ir atvērts vai bojāts.

Ne koristite ako je pakiranje otvoreno ili oštećeno.

Ne koristiti ako je pakovanje otvoreno ili oštećeno.

Nenaudokite, jei pakuotė atidaryta arba pažeista.

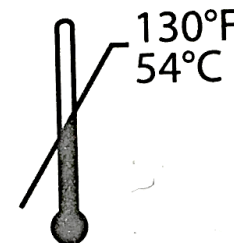
STERILE R

STERILE EO

**Rx
ONLY**



**Caution, consult
accompanying
documents**



**Upper temperature
limit**

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