

NUROLON*

NYLON SUTURE

NONABSORBABLE SURGICAL SUTURE, U.S.P.

DESCRIPTION

NUROLON* nylon suture is a nonabsorbable sterile surgical braided suture composed of the long-chain aliphatic polymers Nylon 6 or Nylon 6,6. NUROLON sutures are dyed black to enhance visibility in tissue. The suture is also available undyed (clear).

NUROLON suture meets all requirements established by the United States Pharmacopoeia (U.S.P.) for nonabsorbable surgical suture.

INDICATIONS

NUROLON suture is indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurological procedures.

ACTIONS

NUROLON suture elicits a minimal acute inflammatory reaction in tissue, which is followed by a gradual encapsulation of the suture by fibrous connective tissue. While nylon is not absorbed, progressive hydrolysis of the nylon in vivo may result in gradual loss of tensile strength over time.

CONTRAINDICATIONS

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

WARNINGS

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

As with any foreign body, prolonged contact of any suture with salt solutions, such as those found in the urinary or biliary tracts, may result in calculus formation. Acceptable surgical practices should be followed for the management of infected or contaminated wounds.

Do not resterilize. Discard opened packages and unused sutures.

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.

As with any suture material, adequate knot security requires the accepted surgical technique of flat and square ties with additional throws as warranted by surgical circumstance and the experience of the surgeon.

To avoid damaging needle points and swage areas, grasp the needle in an area one-third (1/3) to one-half (1/2) of the distance from the swaged end to the point. Reshaping needles may cause them to lose strength and be less resistant to bending and breaking. Users should exercise caution when handling surgical needles to avoid inadvertent needle sticks. Discard used needles in "sharps" containers.

ADVERSE REACTIONS

Adverse effects associated with the use of this device include wound dehiscence, gradual loss of tensile strength over time, calculi formation in urinary and biliary tracts when prolonged contact with salt solutions such as urine and bile occurs, infection, minimal acute inflammatory tissue reaction, and transitory local irritation at the wound site. Broken needles may result in extended or additional surgeries or residual foreign bodies. Inadvertent needle sticks with contaminated surgical needles may result in the transmission of bloodborne pathogens.

HOW SUPPLIED

NUROLON sutures are available in U.S.P. sizes 6-0 through 1 (metric sizes 0.7-4.0) in a variety of lengths with and without permanently attached needles.

NUROLON sutures are available in U.S.P. sizes 4-0 through 1 (metric sizes 1.5-4.0) attached to CONTROL RELEASE* removable needles.

NUROLON sutures are available in one, two and three dozen boxes.

ETHICON, LLC.

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San Lorenzo, Puerto Rico 00754-0982

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