

Description

CliniSolv is a synthetic absorbable monofilament sterile surgical suture composed of Poly (p-dioxanone) (PDO). CliniSolv is dyed violet with D & C violet No.2. CliniSolv meets all the requirements established by the B.P., U.S.P. and E.P.

Indications

CliniSolv is indicated for soft tissue approximation and / or ligation, including use in ophthalmic procedures, but not for use in cardiovascular and neurological procedures.

Actions

CliniSolv elicits a minimal acute inflammatory reaction in tissues, which if followed by gradual encapsulation of the suture by fibrous connective tissue. Progressive loss of tensile strength and eventual absorption of CliniSolv Synthetic Absorbable Suture occurs by means of hydrolysis, where the polymer degrades to glycolic acid which is subsequently absorbed and metabolised by body. Absorption begins as a loss of tensile strength without appreciable loss of mass. Implantation studies in animals indicate that CliniSolv(2USP) retains approximately 60-70% of its tensile strength at 4 weeks post-implantation, with approximately 50-60% remaining at six weeks. Absorption of Monofilament Synthetic Absorbable Sutures is essentially complete between 180 and 220days.

Contra-indications

This suture, being absorbable, should not be used where extended approximation of tissue is required.

Warning

As with any foreign body, prolonged contact of this or any other suture with salt solutions such as those found in the urinary tract, may result in calculus formation. Users should be familiar with surgical procedures and techniques involving absorbable sutures before employing CliniSolv synthetic absorbable suture for wound closure, as a risk of wound dehiscence may vary with the site of application and the suture material used. Acceptable surgical practice should be followed with respect to drainage and closure of contaminated or infected wounds. The use of this suture may be inappropriate in patients suffering from conditions that may delay wound healing. As this is an absorbable suture material, the use of supplemental non-absorbable sutures should be considered by the surgeon in the closure of sites undergoing expansion, stretching or distension, or which may require additional support.

Precautions

Under some circumstances, notably orthopaedic procedures, immobilisation by external support may be employed at the discretion of the surgeon. Skin sutures which must remain in place longer than seven days may cause localised irritation and should be snipped off or removed as indicated. In handling this or any other suture material care should be taken to avoid damage. Avoid crushing or crimping damage due to the application of surgical instruments, such as forceps or needle holders. Adequate knot security requires the accepted practice of flat, square ties, with additional throws as warranted by the surgical circumstances and the experience of the surgeon. To avoid damage to 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" container.

Sterility

CliniSolv sutures are sterilized by Ethylene oxide gas. Do not use if package is opened or damaged. Discard opened unused sutures.

Storage



Recommended storage condition: between 15°C to 30°C, away from direct heat. Do not use after expiry date.

Adverse Reaction

Adverse reactions associated with the use of this device include wound dehiscence, failure to provide wound support in closure of the abdomen, chest joints, and other sites where expansion, stretching or distension occur, failure to provide adequate wound support in elderly, malnourished or debilitated patients, or in patients suffering from cancer, anaemia, obesity, diabetes, infected or other conditions which may delay wound healing, enhance bacteria infectivity, minimal acute inflammatory tissue reaction, localised irritation when skin closures are left in place for greater than seven days, calculi formation in urinary and biliary tracts when prolonged contact with salt solutions, such as urine and bile occurs, and pain and oedema at the wounds site. Broken needles may result in extended or additional surgeries or residual foreign bodies. Inadvertent needle sticks with contaminated surgical needles may result in transmission of blood-borne pathogens.

How supplied

CliniSolv Synthetic Absorbable Monofilament Suture is available in sizes 6/0 through 2 dyed violet with D & C Violet No.2. The suture is supplied in non-needled standard lengths (ligatures) or attached to various needle types in boxes of one dozen.



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