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Instructions for Use

SURGICAL STEEL

Monofilament Stainless Steel Wire – non absorbable sterile surgical suture

Description

Surgical Steel is a sterile, monofilament, non absorbable surgical suture composed of stainless steel. The suture is available attached to stainless steel needle.

Surgical Steel sutures are manufactured according to the requirements of the European Pharmacopoeia for sterile non-absorbable sutures and with the essential requirements of the directive 93/42/EEC.

Indications

Surgical Steel sutures are for use in abdominal wound closure, hernia repair, sternal closure and orthopaedic procedures including cerclage and tendon repair.

Application

Surgical Steel suture selection depends on the condition of the patient, the size of the tissue and wound and the experience of the surgeon.

Performance

The implantation of the Surgical Steel suture in tissues results to an initial inflammatory reaction, followed by gradual encapsulation of the suture by connective tissues and is not absorbed.

Contra indications

The use of Surgical Steel is contraindicated in patients with known sensitivity or allergy to stainless steel or constituent metals, such as chromium and nickel.

Warnings / Precautions / Interactions

Surgical Steel sutures should be used only from members of experienced surgical teams. Users must be familiar with suture handling and knotting techniques. Knot security requires standard surgical technique of flat and square ties according to the experience of the surgeon and the nature of the operation. Unnecessary knot tension and suture handling with surgical instruments such as needle holders or forceps can damage the surface and weaken the suture and therefore must be avoided.

The image produced by NMR Imaging Equipment could be distorted in patients with stainless steel sutures. There is a minimal risk of suture movement during procedures using NMR Imaging Equipment.

With Surgical Steel sutures, kinking or excessive twisting should be avoided and special care should be taken in relation to sternal dehiscence. Surgical Steel sutures can be difficult to knot. Unless large loops are thrown when forming knots the material is liable to fracture at the final throw. The sutures may also be secured by twisting the two ends of the wire together, either manually or mechanically, taking care to avoid fracture of the material.

Special care should be taken in handling of surgical needles. The needle should be grasped with the needle holder in an area 1/3 to 1/2 of the distance from the

attachment end to the point. Grasping the needle from the opposite end area can damage the point or even cause a needle fracture. Deformed needles should not be forced to their original shape as this can cause loss of strength or even needle fracture. Used needles should be safely discarded in special containers.

Adverse reactions

The use of the suture in some patients can cause allergic response or temporary local irritation which is followed from temporary inflammatory reaction. As every foreign body it can enhance an existing infection.

Sterilization

Surgical Steel sutures are sterilized with Ethylenoxide gas. The sterilization is mentioned on each single package. It is intended to be used only once and it should be discarded if its package is damaged or opened. Unused open sutures must be discarded. Sutures should not be re-sterilized.

Storage

Store below 25°C, away from direct heat and moisture. Never use after expiration date.

Symbols used on labeling



: *Date of production*



: *Do not reuse*



: *Sterile unless the package is damaged or opened.
Method of sterilization : Ethylene Oxide*



: *See instructions for use*



: *Use until Year & Month*

REF

: *Product Number*



: *Batch Number*

CE0653

: *CE-mark and identification number of notified body.
Product conforms to the essential requirements of the
Medical Device Directive 93/42/EEC.*

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