Instruction for Use

Ultra-High-Molecular-Weight Polyethylene (UHMWPE) suture material

Sterile, nonabsorbable

DESCRIPTION

HyperSuture™ products are multifilament, non-absorbable, sterile, surgical suture composed of UHMWPE. These braided sutures are available white (undyed), blue, white/black, white/blue, and white/blue/black. The Threadstone HyperSuture products satisfy the requirements of the United States Pharmacopoeia for sterile non-absorbable surgical suture except where indicated on the individual package.

INDICATIONS

HyperSuture™ sutures (both cables and tapes) are indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular surgery, and the use of allograft tissues for orthopedic procedures.

CONTRAINDICATIONS

None Known.

WARNINGS

Do not use if sealed package is tampered with or damaged. Discard sutures that have been open even if unused. Suture should NOT be re-sterilized.

HyperSuture™ products may elicit only a slight acute inflammatory reaction in tissues, followed by gradual encapsulation of suture by fibrous connective tissue.

User should be familiar with surgical procedures and techniques involving non-absorbable sutures before employing HyperSuture™ products 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.

As with any foreign body, prolonged contact of any suture with salt solutions may results in calculus formation.

Re-processing of products intended for single use only may result in degraded performance or a loss of functionality. Re-use of single use only products may result in exposure to viral, bacterial, fungal, or prionic pathogens. Validated cleaning and sterilization methods and instructions for reprocessing to original specifications are not available for the Threadstone HyperSuture products. These products are not designed to be re-cleaned, re-disinfected, or re-sterilized.

PRECAUTIONS

Avoid excessive handling (i.e., crushing or crimping resulting from use of surgical instruments such as forceps and 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. Strong familiarity with surgical procedure and techniques for non-absorbable sutures is required before use. In order to not damage the needle, always grasp it 1/5 ~ 1/2 of the distance from the crimped end to the point. Do not bend the needle, as this leads to a loss of stability. Discard used needles in appropriate containers (“sharps”). This device should be handled and disposed of in accordance with all applicable regulations including, without limitation, those pertaining to human health and safety and the environment.

ADVERSE REACTIONS

Adverse effects associated with the use of this device include wound dehiscence, calculi formation when prolonged contact with salt solution occur, enhanced bacterial infectivity, minimal acute inflammatory tissue reaction, and transitory local irritation.

As with any foreign body, prolonged contact of any suture with salt solutions may results in calculus formation.

HOW SUPPLIED

HyperSuture™ cables are available in USP 2-0, 2, and 5. HyperSuture™ tapes are available in Threadstone 0.8mm tape (0.7~0.85mm), 1.5mm tape (1.4~1.6mm), and 2.0mm tape (1.9~2.3 mm).

HyperSuture™ tape sizes have tapering diameter compliant to the following USP sizes and are equivalent to the corresponding USP sizes:

- HyperSuture™ 0.8mm Tape: USP 2-0 equivalent
- HyperSuture™ 1.5mm Tape: USP 2 equivalent
- HyperSuture™ 2.0mm Tape: USP 5 equivalent

HyperSuture™ products are available in all white UHMWPE (undyed), all blue UHMWPE dyed with Chromium-Cobalt-Aluminum Oxide, or white UHMWPE (undyed) with blue UHMWPE tracers dyed with [Phthalocyaninate (2-)] copper, and/or with black nylon tracers dyed with Hematine. The sutures are supplied sterile, in pre-cut lengths of 36 inches or 40 inches, straight or looped and with trocar point drilled-end needle, if requested. The shelf boxes contain up to twelve (12) single poly/Tyvek pouched sutures.

STORAGE

Store at not more than 25 °C protected from moisture and direct heat. *Do not* use after the indicated expiration date on the packaging.

CAUTION

Federal (USA) law restricts this device to sale and use by, or on the order of, a physician or veterinarian.

MRI SAFETY INFORMATION

The devices described in this IFU are composed entirely of materials that are electrically nonconductive, nonmetallic, and nonmagnetic with the exception of needles. The HyperSuture™, without needle, is MR safe.



MR SAFE


NON-PYROGENIC


DO NOT USE IF PACKAGE IS DAMAGED



DO NOT RESTERILIZE


SINGLE USE ONLY


CAUTION: READ INSTRUCTIONS



ETHYLENE OXIDE STERILIZATION



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