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STRATAFIX™ Spiral PGA-PCL
Knotless Tissue Control Device
Synthetic Absorbable Surgical Suture Material

Rx only **CAUTION:** Federal (USA) law restricts this device to sale and use by, or on the order of, a physician.

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Knotless Tissue Control Device
Synthetic Absorbable Surgical Suture Material

DESCRIPTION

STRATAFIX™ Spiral PGA-PCL Knotless Tissue Control Device consists of barbed suture material, armed with a surgical needle on each end. Barbs allow for tissue approximation without the need to tie surgical knots.

STRATAFIX™ Spiral PGA-PCL Device is a sterile synthetic absorbable monofilament suture prepared from a copolymer of glycolide and e-caprolactone. The suture is provided dyed violet or undyed. The pigment for the violet dyed suture is D&C Violet No. 2. This polymer has been found to be nonantigenic, nonpyrogenic and elicits only a slight tissue reaction during absorption.

While the formation of barbs in the STRATAFIX™ Spiral PGA-PCL Device reduces the tensile strength relative to non-barbed suture material of the same size, tying of knots in non-barbed suture materials also reduces their effective strength. For this reason, the strength of the STRATAFIX™ Spiral PGA-PCL Device can be compared to USP knot strength of non-barbed sutures. Additionally, USP designations for diameter are used to describe the STRATAFIX™ Spiral PGA-PCL Device prior to barbing, except for minor variation in suture diameter with a maximum overage of 0.1 mm.

TENSILE STRENGTH

USP SUTURE SIZE	SUTURE TENSILE STRENGTH (kgf)	STRATAFIX™ SPIRAL PGA-PCL EQUIVALENT SIZE
2-0	2.68	0
3-0	1.77	2-0
4-0	0.95	3-0

ACTIONS

Two important characteristics describe the *in vivo* performance of absorbable sutures: first, tensile strength retention and second, the absorption rate (loss of mass). STRATAFIX™ Spiral PGA-PCL Device has been formulated to minimize the variability of these characteristics and to provide wound support through the critical wound healing period.

In vivo studies demonstrate that STRATAFIX™ Spiral PGA-PCL Device retains approximately 62% of its original strength 7 days post implantation and approximately 27% of its original tensile strength at 14 days post implantation. Absorption of STRATAFIX™ Spiral PGA-PCL Device is essentially complete between 90 and 120 days.

INDICATIONS

STRATAFIX™ Spiral PGA-PCL Device is indicated for use in soft tissue approximation where the use of absorbable sutures is appropriate.

CONTRAINDICATIONS

STRATAFIX™ Spiral PGA-PCL Device is not to be used where extended approximation of tissue under stress is required and is not to be used in conjunction with or for fixation of prosthetic devices (e.g. heart valves or synthetic grafts) that are non-absorbable in nature.

WARNINGS

Do not resterilize. Discard opened, unused STRATAFIX™ Spiral PGA-PCL Device and associated surgical needles.

Users should be familiar with surgical procedure and techniques involving absorbable sutures before employing STRATAFIX™ Spiral PGA-PCL Device for wound closure, as risk of wound dehiscence may vary with the site of application and the suture material used. Physicians should consider the *in vivo* performance (under ACTIONS section) when selecting a suture for use in patients. The use of this suture may be inappropriate in elderly, malnourished or debilitated patients, or in patients suffering from conditions which may delay wound healing.

The safety and effectiveness of STRATAFIX™ Spiral PGA-PCL Device has not been established for use in fascial closures (including abdominal wall, thoracic and extremity fascial closures), gastrointestinal anastomoses, cardiovascular tissue, neural tissue, osseous tissue, tendinous tissue, ophthalmic surgery or for use in microsurgery.

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. As an absorbable suture, STRATAFIX™ Spiral PGA-PCL Device may act transiently as a foreign body. Acceptable surgical practice should be followed for the management of contaminated or infected wounds.

As this is an absorbable suture material, the use of supplemental nonabsorbable sutures should be considered by the surgeon in the closure of the sites which may undergo expansion, stretching or distention or which may require additional support.

PRECAUTIONS

STRATAFIX™ Spiral PGA-PCL Device contains bidirectionally oriented barbs to anchor tissues and does not require knots to approximate opposing edges of a wound. Tying of knots with STRATAFIX™ Spiral PGA-PCL Device will damage the barbs and potentially reduce their effectiveness. For the bidirectional forces to be created and for the device to function properly, both sides of the STRATAFIX™ Spiral PGA-PCL Device must be engaged in the tissue. Additionally, when completing placement, an additional backstitch or bite of tissue lateral to the end of the incision is required to lock the device in place.

Avoid contacting STRATAFIX™ Spiral PGA-PCL Device and associated needles with other materials (e.g. surgical gauze, drapes, etc.) in the surgical field to prevent ensnaring on the barbs. If the barbs catch, carefully pull the material in the opposite direction of the needle to disengage it from the barbs.

Care should be taken to avoid damage when handling. Avoid crushing or crimping the suture material with surgical instruments, such as needle holders and forceps. Do not pull the STRATAFIX™ Spiral PGA-PCL Device out of the package by the needles as this can cause the barbs to catch on one another. Do not attempt to remove memory in the polymer by running fingers down the suture material as this can damage the barbs.

Infections, erythema, foreign body reactions, transient inflammatory reactions and in rare instances dehiscence are typical or foreseeable risks associated with any suture and hence are also potential complications associated with STRATAFIX™ Spiral PGA-PCL Device.

When using STRATAFIX™ Spiral PGA-PCL Device subcutaneously, the device should be placed as deeply as possible in order to minimize erythema and induration usually associated with absorption.

Acceptable surgical practice should be followed with respect to drainage and closure of infected wounds.

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 may include, wound dehiscence, failure to provide adequate wound support in closure of the site where expansion, stretching or distension occur, failure to provide adequate wound support in elderly, malnourished or debilitated patients or in patients suffering from conditions which may delay wound healing, infection, minimal acute inflammatory tissue reaction, localized irritation when skin sutures are left in place for greater than 7 days, suture extrusion and delayed absorption in tissue with poor blood supply, calculi formation in urinary and biliary tracts when prolonged contact with salt solutions such as urine and bile occurs and transitory local infection 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.

APPLICATION

Use as required per surgical procedure. Deeper layers of the wound are to be closed in such a fashion as to take tension off of the dermal edges.

To deploy STRATAFIX™ Spiral PGA-PCL Device, the first end should be should be pulled through the tissue until the center transition zone has reached the tissue. Estimation of the center can be aided by taking a single bite of tissue, then aligning the two needles until the tip of the first deployed needle is brought together with the swage of the second needle. Taking one arm of the STRATAFIX™ Spiral PGA-PCL Device, at least two arcs should then be loosely completed through the tissue. This is then repeated with the other arm of the STRATAFIX™ Spiral PGA-PCL Device. Once at least four arcs have been deployed, each of the strands can then be grasped and the tissue approximated to the desired tension.

To remove the entire STRATAFIX™ Spiral PGA-PCL Device: Cut the STRATAFIX™ Spiral PGA-PCL Device at the midline, between the opposing barbed segments, and then pull the lateral ends to remove the device.

STERILITY

STRATAFIX™ Spiral PGA-PCL Device is sterilized by ethylene oxide gas. Do not resterilize. Do not use if package is opened or damaged. Discard opened unused sutures. Do not use after expiration date.

HOW SUPPLIED

STRATAFIX™ Spiral PGA-PCL Device is available sterile, in various barb configurations (e.g. 7 cm x 7 cm), dyed violet or undyed in various lengths and USP diameter sizes, 3-0 through 0 (metric sizes 2 through 3.5). STRATAFIX™ Spiral PGA-PCL Device is double armed with various size needles.

SYMBOLS USED FOR LABELING

REF	Product Code		Date of Manufacture
	Consult, see instructions for use		Manufacturer
	Do not reuse	STERILE EO	Sterilized using ethylene oxide
	Do Not Resterilize		Use by
	Do not use if package is damaged	LOT	Lot Code
CE 0120	CE mark and identification number of notified body. Product conforms to the essential requirements of The Medical Device Directive 93/42/EEC.	EC REP	Authorized Representative in the European Community
Rx only	**CAUTION:** Federal (USA) law restricts this device to sale and use by, or on the order of, a physician.		