# OverStitch 2-0 Polypropylene Suture Assembly

PLY-G02-020-APL

Instructions for Use

**DESCRIPTION**

The OverStitch 2-0 Polypropylene Suture is comprised of sterile packaged non-absorbable polypropylene suture attached to an implantable anchor manufactured from cobalt chromium and stainless steel. The anchor component is intended to function with the OverStitch Endoscopic Suturing System to perform stitching operations and serves as an anchor to secure suture placement. The suture is manufactured from an isotactic crystalline stereoisomer of polypropylene, a synthetic linear polyolefin. The suture pigment uses CU-Phthalocyanine Blue Dye (below 0.5 WT %) to enhance visibility. The suture material meets the requirements established by the USP.

**OPERATION**

For detailed instructions for use of the OverStitch 2-0 Polypropylene Suture with the OverStitch Endoscopic Suturing System, refer to the OverStitch Endoscopic Suturing System instructions for use. See GRF-00002-00 or GRF-00400-00.

**INTENDED USE**

The OverStitch Endoscopic Suturing System is intended for endoscopic placement of suture(s) and approximation of soft tissue.

**ACTIONS**

The polypropylene suture material comprising the OverStitch 2-0 Polypropylene Suture elicits minimal acute inflammatory reaction in tissue, which is followed by gradual encapsulation of the suture by fibrous connective tissue. The suture material is not absorbed, nor is any significant change in strength retention known to occur in vivo.

**WARNINGS**

- Do not re-sterilize. Discard unused sutures.
- Users should be familiar with surgical procedures and techniques involving nonabsorbable sutures before using the OverStitch 2-0 Polypropylene Suture for wound closure, as risk of wound dehiscence may vary with the site of application and the suture material used.
- As any foreign material in the presence of bacterial contamination may enhance bacterial infectivity, acceptable surgical practice must be followed with respect to drainage and closure of infected or contaminated wounds.
- Do not reuse. The reuse of single-use devices can cause cross-contamination and affect the device safety, performance and effectiveness, exposing patients and staff to unnecessary risk. The design and material used are not compatible with conventional cleaning and sterilization procedures.
- Do not use if package is damaged
- Use by expiry date
- Keep in cool dry place away from any direct heat

**PRECAUTIONS**

In handling the suture material, care should be taken to avoid damage from handling. Avoid crushing or crimping damage of the anchor due to application of surgical instruments such as forceps or needle holders. Use of an OverStitch Suture Cinch is required to secure placement of sutures.

**ADVERSE REACTIONS**

Adverse effects associated with the use of this device include wound dehiscence, infection, minimal acute inflammatory tissue reaction, and, pain, edema and erythema at the wound site. Broken anchors may result in

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extended or additional surgeries or residual foreign bodies. Inadvertent anchor sticks with contaminated surgical needles may result in the transmission of bloodborne pathogens.

**MR Status:**

Non-clinical testing has demonstrated that the sutures deployed by the OverStitch Endoscopic Suturing System are MR Conditional.
A patient with this Anchoring System can be safely scanned immediately after placement in an MR system meeting the following conditions:
-- Static magnetic field of 1.5 T or 3.0 T
-- Maximum spatial field gradient of 2,000 gauss/cm (20 T/m)
-- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg

Under the scan conditions defined above, the Anchoring System is expected to produce a maximum temperature rise of less than 2° C after 15 minutes of continuous scanning. In non-clinical testing, the image artifact caused by the Anchoring System extends approximately 10 mm from this device when imaged with a gradient echo pulse sequence and a 3.0 T MRI system.

**STERILITY**

The OverStitch 2-0 Polypropylene Suture is sterilized by Ethylene Oxide (EO), and is sterile unless package is opened or damaged. Do not re-sterilize or reuse.

**SYMBOLS USED ON LABELING**

| | | | | | |
|---|---|---|---|---|---|
|  | Do not reuse |  | Do not use if package is damaged | REF | Catalog number |
|  | Use-by date |  | Sterilized using ethylene oxide (EO) | LOT | Batch code |
|  | Caution |  | Consult instructions for use | Rx Only | CAUTION: Federal (USA) law restricts this device to sale and use by, or on the order of, a physician |
| QTY | Quantity |  | Manufacturer | | |
|  | MR Conditional | | | | |


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