



OverStitch™ 2-0 Polypropylene Suture

Intended Use

The OverStitch Endoscopic Suturing System (ESS) is intended

- For endoscopic placement of suture(s) and approximation of soft tissue.
- To be used by trained gastroenterologists or surgeons that perform bariatric procedures to facilitate weight loss by reducing stomach volume through endoscopic sleeve gastropasty in adult patients with obesity with BMI between 30-50 kg/m² who have not been able to lose weight, or maintain weight loss, through more conservative measures.
to be used by trained gastroenterologists or surgeons that perform bariatric procedures to facilitate weight loss in adult patients with obesity with BMI between 30-50 kg/m².

Contraindications

For contraindications, warnings, precautions and potential adverse events, associated with the use of the OverStitch 2-0 Polypropylene Suture use with the OverStitch Endoscopic Suturing Systems, refer to the instructions for use for the applicable Endoscopic Suturing System: OverStitch Endoscopic Suturing System or OverStitch NXT Endoscopic Suturing System.

Warnings

- This device contains nickel which may cause an allergic reaction in individuals with nickel sensitivity.
- Discard unused opened 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.
- REUSE WARNING, For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

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. Federal Law (USA) restricts this device to sale by or on the order of a physician.

Adverse Events

For potential adverse events, associated with the use of the OverStitch 2-0 Polypropylene Suture use with

the OverStitch Endoscopic Suturing Systems, refer to the instructions for use for the applicable Endoscopic Suturing System: OverStitch Endoscopic Suturing System or OverStitch NXT Endoscopic Suturing System.