



OverStitch™ 2-0 Polypropylene Suture Assembly

Intended Use

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

Contraindications

None known

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 Events

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