



Defining the Future  
of Endoscopic Surgery™



English 2  
[Endoscopic HeliX Tacking System]  
Patient Leaflet

X-Tack™ Endoscopic HeliX Tacking System (160cm)  
X-Tack™ Endoscopic HeliX Tacking System (235cm)  
OverStitch™ Suture Cinch  
Suture Cinch - Long

**Product Code:**  
XTACK-160-H  
XTACK-235-H  
CNH-G01-000  
CNH-C01-213-L

Caution: Please read all instructions prior to use

**STERILE EO**



## 1 Device Information

X-Tack™ Endoscopic HeliX Tacking System

## 2 Intended Purpose

The X-Tack Endoscopic Helix Tacking System is intended for approximation of soft tissue in minimally invasive gastroenterology procedures, e.g. closure of ESD/EMR sites, fistula, and perforation/leaks. The X-Tack System is not to be used for acutely bleeding ulcers.

Device is intended for patients undergoing an endoscopic procedure performed by a trained physician to approximate soft tissue in minimally invasive gastroenterology procedures, e.g. closure of ESD/EMR sites, fistula, and perforation/leaks.

This device is to be used only by a trained physician.

## 3 Risk Information

### 3.1 Residual Risk Information

The materials used in this device elicit minimal acute inflammatory reaction in tissue, followed by gradual encapsulation of the device by fibrous connective tissue.

### 3.2 Interaction with Equipment

#### 3.2.1 Procedure

The X-Tack Endoscopic Helix Tacking System is only compatible with the Apollo Endosurgery's Suture Cinch. This device should not be used with any other equipment aside from compatible flexible endoscopes.

The X-Tack Endoscopic Helix Tacking System is compatible with an endoscope (gastroscope or colonoscope) with a 2.8 mm or larger working channel. Gastric and Colonic X-Tack devices have a working length of 155 and 235 cm, respectively. The system has been verified as compatible with Olympus, Pentax and Fuji gastroscopes. Note that the gastric X-Tack scope liner is approximately 2 inches shorter than the Fuji gastroscope channel. Take care when introducing X-Tack into Fuji gastroscopes.

#### 3.2.2 MRI Safety

Non-clinical testing has demonstrated that the sutures and cinch assembly deployed by the X-Tack Endoscopic Helix Tacking System are MR Conditional.

A patient with this suturing assembly 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 suturing assembly 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 assembly extends approximately 10 mm from this device when imaged with a gradient echo pulse sequence and a 3.0 T MRI system.

## 4 Device Use

There are no preventative examination or maintenance requirements of the device. Monitoring of the device will be done by your physician and will be dependent on the standard of care for follow-up associated with the clinical condition treated with the device.

Adverse effects associated with the use of this device include Pharyngitis / Sore throat, Nausea and / or Vomiting, Abdominal pain and / or Bloating, Hemorrhage, Hematoma, Conversion to laparoscopic or open procedure, Stricture, Infection / Sepsis, Pharyngeal, gastric, colonic and/or esophageal perforation, Esophageal, gastric, colonic and/or pharyngeal laceration, Intra-abdominal (hollow or solid) visceral injury, Aspiration, Wound dehiscence, Acute inflammatory tissue reaction, and Death. Broken tacks may result in extended or additional surgeries or residual foreign bodies.

Should a patient start experiencing any adverse events as stated above, they should contact their physician.

The device is considered a permanent implant. The suture construct is does not resorb and is not typically removed. Removal would require another medical procedure.

The closing construct is a permanent implant but it can be released/dislodged as part of the normal healing process. Depending on specific medical circumstances, the physician may elect to replace or remove a dislodged construct with another medical procedure. To date, this would be a rare event

There are no precautions the patient should take as this is a permanent implant.

A patient should discuss any concerns with their physician following the procedure.

## 5 Material Information

The X-Tack Endoscopic Helix Tacking System is comprised of a suture product, manufactured from non-absorbable polypropylene material attached to an implantable helical tack manufactured from stainless steel. The implant is complete with a polyetheretherketone (PEEK) plastic cinch.

There are no leachable compounds of potential exposure in the OverStitch 2-0 Polypropylene Suture that would pose a significant toxicological risk to the patient. However, trace amounts of cobalt were detected in during bench testing. As such, the following statement has been to the IFU:

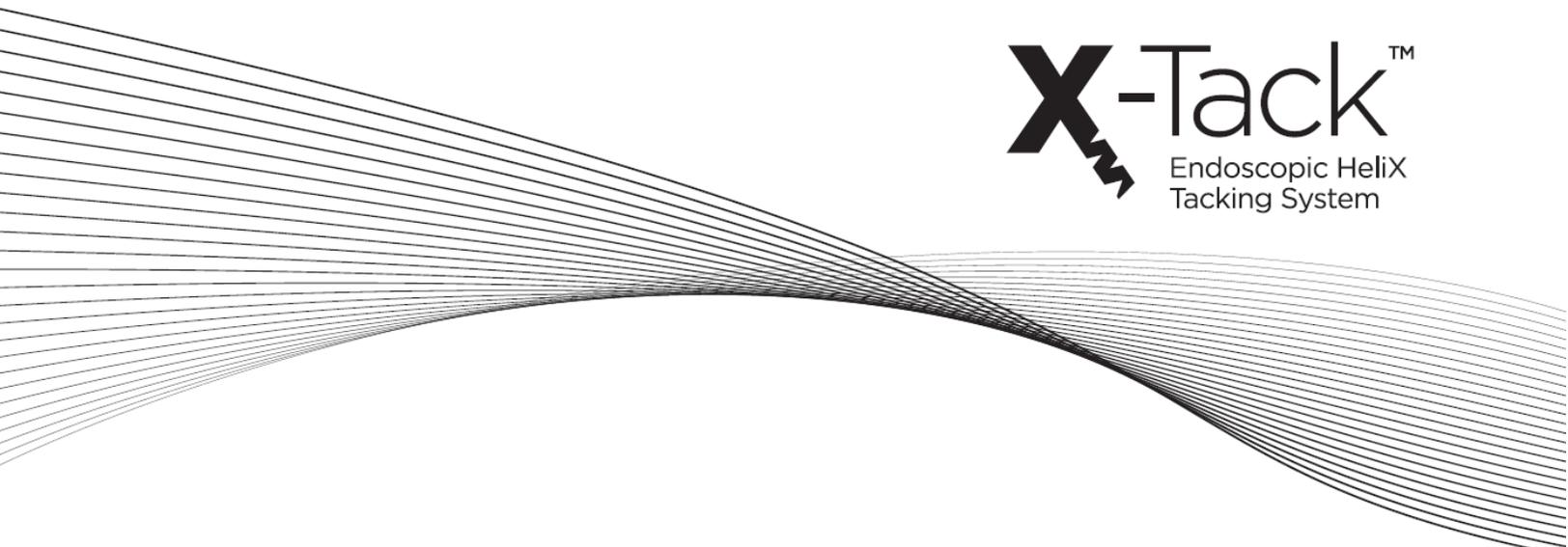
CMR Statement - The stainless steel components within this device contain the following substance(s) defined as a CMR (carcinogenic, mutagenic or toxic to reproduction) 1A/1B and/or endocrine disrupting in a concentration above 0.1% weight by weight:

Cobalt (CAS No. 7740-48-8; EC No. 231-158-0)

Current scientific evidence supports medical devices manufactured from these cobalt alloys or stainless steels containing cobalt do not cause increased risk of cancer or adverse reproductive effects.

## 6 Reporting Serious Incidents

Any serious incident that occurs in relation to the device should be reported to Apollo Endosurgery, Inc. ([www.apolloendo.com](http://www.apolloendo.com)) and the Therapeutic Goods Administration (<https://www.tga.gov.au/>).



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Endoscopic HeliX  
Tacking System



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