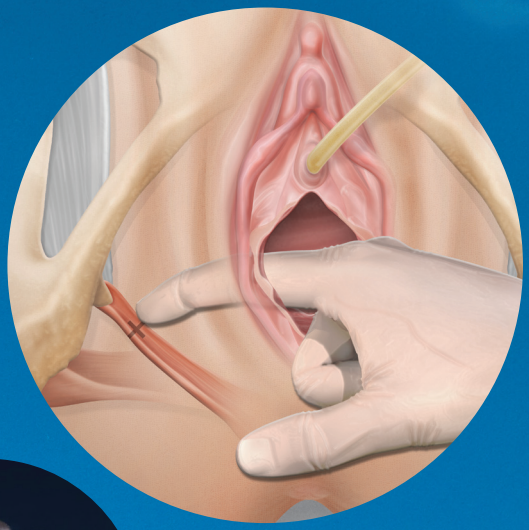
Stat Tack™

Coloplast

Fixation system

Permanent Fixation for use with Restorelle® DirectFix pre-shaped synthetic mesh or with Tutoplast® processed Axis™ Dermis and Suspend® Fascia Lata

Allows access through a minimal dissection plane to pelvic support structures



Comes pre-loaded with 15 helical titanium tacks

The helical application of the tack allows for fixation with only 4mm penetration into support tissue. This low profile has the potential to decrease risk to neurovascular structures.

Ordering Information 800.258.3476

Stat Tack Fixation Device

DESCRIPTION	ORDER NUMBER
Fixation device preloaded with 15 permanent titanium tacks	501260

Restorelle DirectFix

DESCRIPTION	ORDER NUMBER
DirectFix A 16 cm x 11 cm	501450
DirectFix P 14 cm x 15 cm	501460

Axis Tutoplast Processed Dermis

DESCRIPTION	ORDER NUMBER
4 cm x 7 cm	939247
4 cm x 12 cm	939412
3 cm x 4 cm	939234
5 cm x 8 cm	939258
6 cm x 8 cm	939268
6 cm x 12 cm	939612
8 cm x 12 cm	939812

Suspend Tutoplast Processed Fascia Lata

DESCRIPTION	ORDER NUMBER
4 cm x 7 cm	937201
4 cm x 12 cm	937412
6 cm x 8 cm	937268
7 cm x 12 cm	937712

INDICATIONS The Autosuture™ Tacker™ System is indicated to affix prosthetic material or approximate tissue in a variety of endoscopic or other surgical procedures.

CONTRAINDICATIONS
1. Do not use the Tacker™ System instrument on tissue(s) which cannot be inspected visually for hemostasis.
2. A minimum of 4 mm tissue thickness is required when applying the helical fastener over underlying bone, vessels, or viscera. If the total distance from the surface of the tissue to the underlying structure(s) is less than 4 mm, or may be compromised to a total distance of less than 4 mm, use of the device is contraindicated.
3. This device should not be used in tissues that have a direct anatomic relationship to major vascular structures. This would include the deployment of helical fasteners in the diaphragm in the vicinity of the pericardium, aorta or inferior vena cava during diaphragmatic hernia repair.
4. Do not use in ischemic or necrotic tissue.

WARNINGS AND PRECAUTIONS
1. Endoscopic procedures should be performed only by physicians having adequate training and familiarity with endoscopic techniques. A thorough understanding of the operating principles, risks versus benefits, and the hazards involved in utilizing an endoscopic approach is necessary to avoid possible injury to the user and/or patient.
2. Verify mechanical and electrical compatibility of devices from different manufacturers prior to using them together in a procedure.
3. After the application of the Tacker™ System instrument, always inspect the surgical site carefully to ensure hemostasis. Minor bleeding may be controlled with electrocautery or manual sutures.
4. The single use instrument, delivery device and STAT TACK™ instrument are supplied sterile and are intended for use in a single procedure only. Discard after use. Do Not Resterilize.

Coloplast Corp. 800.258.3476
www.us.coloplast.com

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