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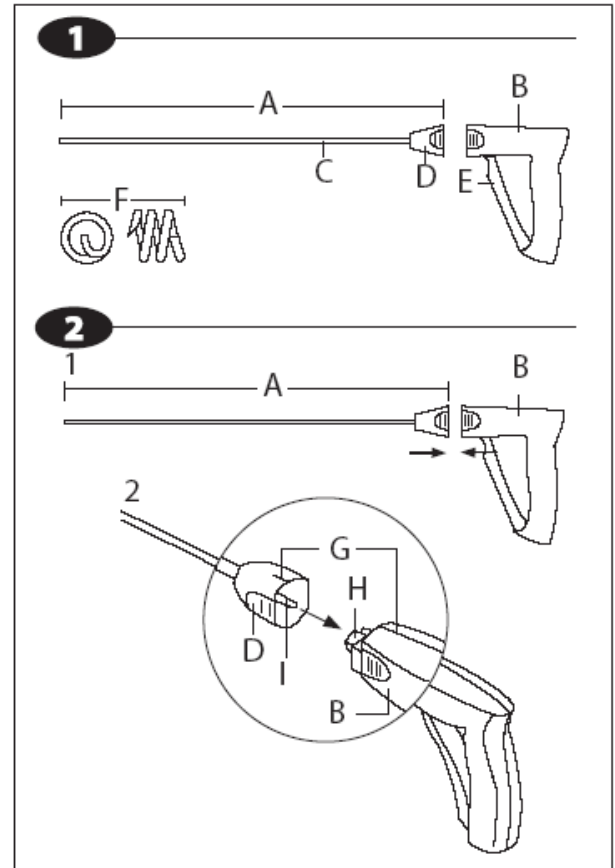
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## TACKER™ SYSTEM

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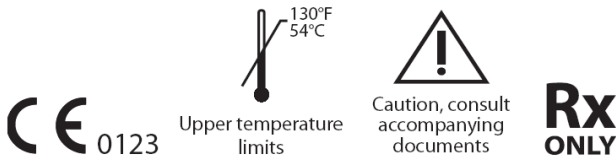
### 1 SCHEMATIC VIEW

- A) DELIVERY DEVICE
- B) HANDLE
- C) TUBE
- D) LOCKING SLEEVE
- E) LEVER
- F) HELIX FASTENER (DIAMETER 3.9 MM)

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**IMPORTANT!** This booklet is designed to assist in using this product. It is not a reference to surgical techniques. This device was designed, tested and manufactured for single patient use only. Reuse or reprocessing of this device may lead to its failure and subsequent patient injury. Reprocessing and/or resterilization of this device may create the risk of contamination and patient infection. Do not reuse, reprocess or resterilize this device.

**DESCRIPTION** The Tacker™ System is packaged in 4 different product configurations as specified on the product package.

- The Tacker™ delivery device contains 20 titanium helical fasteners and is designed to be used with the Tacker™ reusable handle.
- The Tacker™ reusable handle is available with 5 delivery devices, each containing 20 titanium helical fasteners. The reusable handle is packaged sterile and may be resterilized four (4) times for a total of five (5) uses.
- The Tacker™ single use instrument is designed to deliver up to 20 or 30 helical fasteners, depending on the product configuration as specified on the product package.
- The STAT TACK™ single use instrument is designed to deliver 15 helical fasteners. The assembled instrument, delivery device and the STAT TACK™ instruments are single use items supplied sterile and are to be discarded after use (do not resterilize). The helical fastener size is approximately 3.9 mm in diameter by 4 mm long.

**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 reusable handle may be resterilized four (4) times for a total of five (5) uses. Dispose of the handle after the intended five (5) uses.
5. Resterilization of the reusable handle after the intended number of uses may compromise the integrity of the product, which may result in product malfunction.
6. 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.

#### CLEANING

**NOTE:** The Tacker™ reusable handle is made from plastic and metal. **Warnings:** Detergents and solutions should have a pH between 7.0 and 9.5. Sterilization temperature should not exceed 275°F (135°C). The Tacker™ reusable handles are supplied sterile. Prior to re-use they must be cleaned and sterilized.

**Reprocessing Limitations:** Repeated processing no more than four (4) times for a total of five (5) uses is allowed.

#### Instructions

**Point of Use:** Remove excess soil on the Tacker™ reusable handles with disposable wipes at point of use.

**Containment and Transportation:** It is recommended that the Tacker™ reusable handles be reprocessed as soon as possible following use. They should be covered with a moist towel if reprocessing cannot be performed immediately.

**Preparation for Cleaning:** No disassembly required. Do not attempt to disassemble.

**Manual Cleaning:** The Tacker™ reusable handles should be cleaned thoroughly after every use to remove all traces of blood and debris. Pay particular attention to crevices and other hard-to-clean areas while scrubbing the handles with a soft bristle brush in warm water (20-25°C) with a mild detergent/enzymatic cleaner (such as Alconox® or

Tergazyme®). Rinse the handles thoroughly in warm, running water. Wipe and dry the handles with a soft, clean cloth.

**Automatic Cleaning:** No specific requirements

**Disinfection:** No specific requirements

**Sterilization:** Resterilization options for the Autosuture™ Tacker™ Reusable Handle: The handle may be steam autoclaved. In general, the operators should follow the manufacturer's instructions for cycle parameters for sterilization. It is recommended that the handle be sterilized in accordance with the following sterilization times and temperatures:

**Gravity Cycle:** Temperature: 270° F - 275° F (132° C - 135° C) Time: 10 minutes, wrapped

**Gravity Cycle:** Temperature: 250° F - 255° F (121° C - 124° C) Time: 15 minutes, wrapped

**Steam Sterilization (Prevacuum):** Temperature: 270° F - 275° F (132° C - 135° C) Minimum exposure time: 4 minutes, wrapped

**Maintenance:** Visually inspect the instruments for damage or wear prior to use.

**Packaging:** Place items in a Polyethylene/Tyvek® pouch or standard hospital wrap when autoclaving.

**Storage:** Store at room temperature.

**Additional Information:** When sterilizing multiple instruments in one autoclave cycle ensure that the sterilizer manufacturer's stated maximum load is not exceeded.

**Manufacturer Contact:** If needed, contact your local representative or call Customer Service at 1-800-722-8772.

#### INSTRUCTIONS FOR USE

1. Introduce the instrument through a 5 mm diameter trocar. Skip step 1 for the STAT TACK™ instrument.
  2. Under direct visualization, locate the site to be fastened.
  3. Apply gentle pressure to the site to be fastened with the distal tip of the delivery device, ensuring that the tissue and/or prosthetic mesh are in contact.
  4. To deliver a helical fastener, squeeze the handle to the full extent of its travel, then release. Allow handle to return to its original position before firing again.
  5. Inspect site of helical fastener placement to ensure fastening. Repeat steps 2-5 to deliver and place additional helical fasteners. Skip step 6 for the STAT TACK™ instrument.
  6. When complete, withdraw the Tacker™ instrument from the trocar. Skip Disassembly, Cleaning and Resterilization for the assembled instrument and the STAT TACK™ instrument (both are to be discarded after use).
- DISASSEMBLY:** To remove the delivery device from the handle, hold tube with one hand and slide locking sleeve toward tube end with other hand, remove delivery device from handle.

**2 ASSEMBLY:** The following instructions are recommended for proper function of the Tacker™ reusable handle and delivery device. Proceed to step 2 for the assembled instrument and skip both steps for the STAT TACK™ instrument.

1. Join the delivery device to the reusable handle.

**NOTE:** For ease and ensuring best fit, do not assemble at an angle.

A) DELIVERY DEVICE

B) HANDLE

Insert the drive pin into the nose of the handle aligning the indicators. Press the locking sleeve toward the handle until an audible click is heard. This will lock the delivery device to the handle.

**NOTE:** Locking sleeve will not assemble if engaged (in lock position) prior to assembly.

**NOTE:** Attach delivery device only when handle lever is fully forward.

G) ALIGNMENT INDICATOR

H) NOSE OF THE HANDLE

D) LOCKING SLEEVE

I) DRIVE PIN

B) HANDLE

**STORE AT ROOM TEMPERATURE. AVOID PROLONGED EXPOSURE TO ELEVATED TEMPERATURES.**