ENGLISH

FasTouch™ Absorbable Instructions For Use

CAUTION
Federal (USA) law restricts this device to sale and use by, or on the order of a physician.

EXPIRATION DATE
The expiration date on the package is the sterility expiration date. This device should not be used after the indicated sterility expiration date.

PRODUCT DESCRIPTION:
The FasTouch™ Absorbable Fixation Device contains synthetic absorbable fasteners, preloaded into the device's 36cm long cartridge. The device is packaged as a kit containing a handle and a cartridge. The instrument is designed for use either laparoscopically through a 5mm or larger port sleeve or in open soft tissue procedures without a port sleeve. The FasTouch Absorbable Fixation Device fasteners are absorbable and made of copolymer of L-lactide and glycolide and are dyed with D&C violet No. 2.

INDICATIONS:
The FasTouch™ Absorbable device is intended to facilitate fixation of prosthetic material to soft tissues in various open and minimally invasive surgical procedures, such as hernia repairs.

MRI COMPETABILITY:
The FasTouch™ Absorbable fasteners have no metallic components and are MR safe. A patient with these implants can be scanned safely.

CONTRAINDICATIONS:
1. This device is not intended for use except as indicated.
2. Use the device only with 5mm or greater trocar.
3. Do not use the system on tissue that cannot be inspected visually for hemostasis.
4. This device should not be used for fixation to neural or vascular structures.
5. This device should not be used for fixation to bone or cartilage.
6. The area in vicinity to the tissue being fastened should be inspected to avoid inadvertent penetration of structures such as vessel, nerves, bone or cartilage.

WARNINGS:
1. This package insert is designed to assist in using the FasTouch™ Absorbable device. It is not a reference to surgical technique. For information on surgical technique, please consult the medical literature.
2. Please read all instructions before using the FasTouch™ Absorbable device.
3. Failure to properly follow the instructions may lead to surgical consequences.
4. The FasTouch™ Absorbable is provided STERILE and is intended for use in single patient use only. **DISCARD AFTER USE. DO NOT RESTERILIZE**. Reuse, reprocessing, reserialization or repackaging may lead to device failure and/or device contamination.
5. Do not use the product beyond the expiration date on the package.
6. After use, the FasTouch™ Absorbable device contains sharp parts and may be a potential biohazard. Handle and dispose in an appropriate container for disposal of medical biohazard waist in accordance with any local and federal laws regarding medical waste.
7. Check package for damage prior to use. **IF PACKAGE IS DAMAGED OR OPEN, DO NOT USE THE PRODUCT.**
8. Do not use the product if the center of the temperature indication of the foil pouch is black.
9. Endoscopic procedure should be performed only by physician having adequate training and familiarity with endoscopic technique.

10. The total distance from the surface of the tissue to the underlying structure such as nerve, bone, vessels, or viscera should be evaluated prior to application and should be a minimum of 6.9 mm.
11. Avoid tissue compression between the edge of the device and the location of counter pressure of less than 6.9mm.
12. Verify mechanical and electrical compatibility of devices from different manufacturers together in a procedure.
13. Inspect fixation site after application to ensure hemostasis.
14. Appropriate force should be applied to the device for application of fasteners. Excessive force may result in damage to the device, the material being fixated or the tissue.
15. Counter pressure should be applied on the target area. Avoid placing hand/finger directly over the area where fastener is being deployed to prevent injury.
16. The device may not fixate through prosthetic derived from biologic material such as allografts and xenograft. Prosthetic should be evaluate for compatibility prior to use

ADVERSE REACTIONS:
Adverse reactions associated with the use of this device include transitory local irritation at the implant site and a transitory inflammatory foreign body response. As with all foreign devices, potential adverse events may also include inflammation and potentiation of procedure-related infection, hemorrhage, pain, edema and erythema at wound site, hernia recurrence/wound dehiscence.

SCHEMATIC VIEW

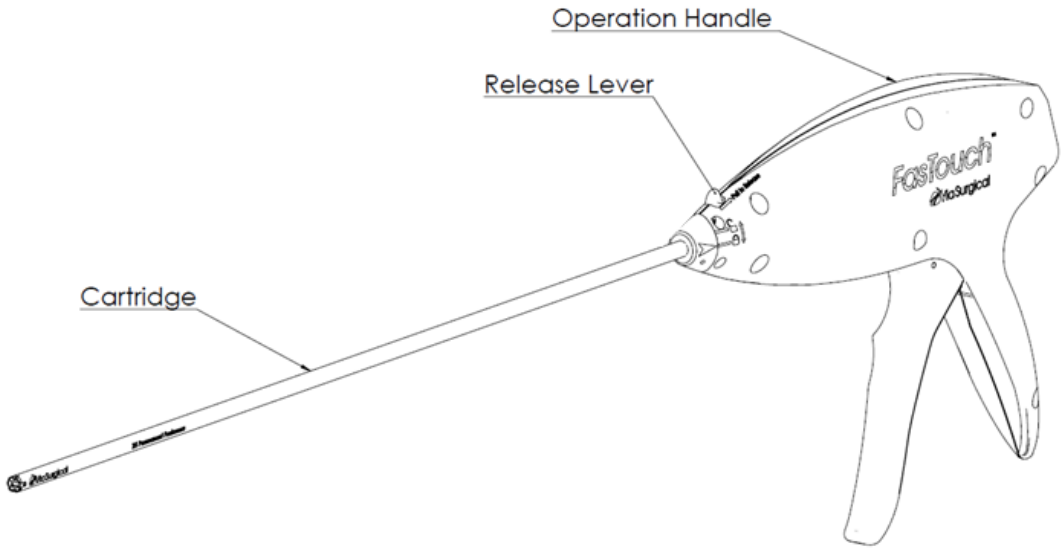

Figure 1- Schematic view of the FastTouch™ device

INSTRUCTIONS FOR USE:
1. Take the FasTouch™ Absorbable out of the sterile package using sterile technique.
2. Remove the white packaging tube out of the cartridge shaft.
3. If device cartridge is already preloaded, please go to instruction #6.

CAUTION: Unlock only for cartridge replacement.
CAUTION: Do not reload cartridge that was previously removed.

4. Slide proximal end of the cartridge into the hole in the front of the operation handle while aligning the arrow on the cartridge with alignment line near the unlock symbol. See Figure 2a-2b.

5. Rotate the cartridge clockwise ~45º until the arrow on the cartridge is pointing the lock sign on the handle, an audible click sound should be heard. See Figure 2c.

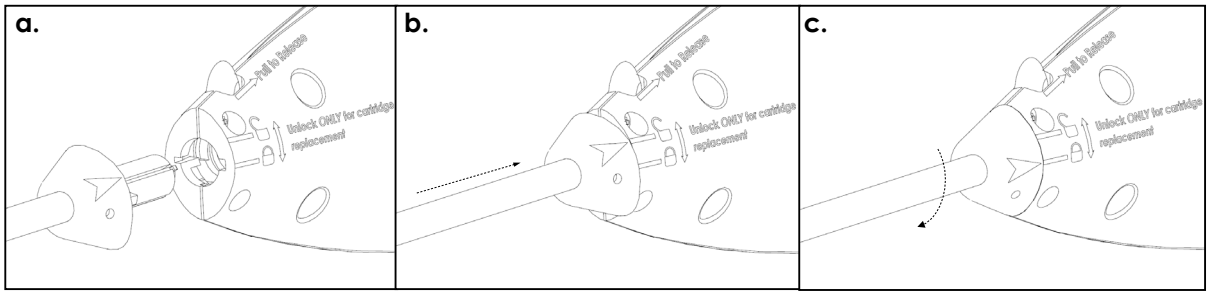

Figure 2- Cartridge loading process

6. Insert the device through appropriate sized laparoscopic port sleeve (minimal size 5mm).
7. Place the tip of the device on the prosthetic device directly over the target site and apply forward pressure until the tip of the device is in complete contact with the prosthetic device.
8. Squeeze the handle completely while applying external counter pressure.
9. Repeat steps 7-8 for application of additional fasteners.
10. If not required, pull the device from the trocar and discard with caution.

Note: The device includes two windows located at both sides of the device tip. If no fastener is visible at these windows the device is empty and cartridge should be discarded, if no additional tacks are needed the handle should also be discarded.

11. If additional fasteners are necessary, replace the cartridge according to the following steps:
12. Remove the device from the patient body.
13. Pull the release lever (located at the front of the handle) away from the shaft.
14. While holding the release lever, rotate the cartridge counter clockwise ~45º until the arrow on the cartridge is pointing the unlock sign on the handle and then pull out the cartridge out.

CAUTION: Once removed, discard the used cartridge.

15. Repeat steps 3-5 for placement of additional cartridge.
16. Repeat steps 6-8 for application of additional fasteners.

Note: No more than 75 fasteners should be applied with a single handle. The handle should be discarded after 75 fastener application and is intended only for a single patient use.

STORAGE:
Store the FasTouch Absorbable Fixation System in a dry environment at room temperature. Avoid exposure to elevated temperatures (above 40ºC). Do not use if the foil pouch or package is damaged or open, or if the center of the temperature indicator on the foil pouch is black.

	Caution, consult accompanying documents
	Manufacturing Date
	EtO Sterilization
	Single patient Use/Do not reuse
	Do not use if package is damaged or open
	Manufacturer
	Distributor
	Use By year and month
	Lot Number
	Reference Number
	Do not resterilize
	To be used by medical professional only
	Not made with natural rubber latex
	MR Safe
	Temperature Sensor Label

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