ENGLISH

FasTouch 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 Fixation Device contains 25 synthetic permanent 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 (larger diameter sleeves will require use of a converter) or in open soft tissue procedures without a port sleeve. The FasTouch Fixation Device fasteners are permanent and made of aromatic polycarbonate-based thermoplastic urethane.

INDICATIONS:
The FasTouch 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 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 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 device.
3. Failure to properly follow the instructions may lead to surgical consequences.
4. The FasTouch is provided STERILE and is intended for use in single patient use only. DISCARD AFTER USE. DO NOT RESTERILIZE.
5. If package is damaged or open, do not use the product. Check package for damage prior to use.
6. Endoscopic procedure should be performed only by physician having adequate training and familiarity with endoscopic technique.
7. The total distance from the surface of the tissue to the underlying bone, vessels, or viscera should be evaluated prior to application and should be a minimum of 6.9 mm.
8. Avoid tissue compression between the edge of the device and the location of counter pressure of less than 6.9mm.

9. Verify mechanical and electrical compatibility of devices from different manufacturers together in a procedure.
10. Inspect fixation site after application to ensure hemostasis.
11. 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.
12. The device may not fixate through prosthetics derived from biologic material, prosthetic should be evaluated 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

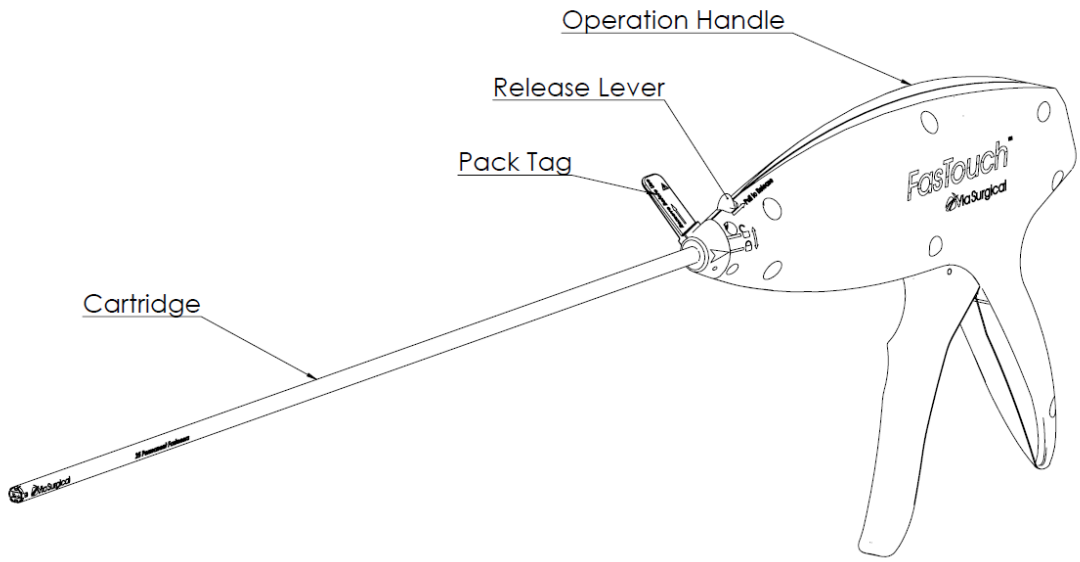


Figure 1- Schematic view of the FastTouch™ device

INSTRUCTIONS FOR USE:

1. Take the FasTouch out of the sterile package using sterile technique.
2. If device cartridge is already preloaded, please go to instruction #6.
3. 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.
4. Rotate the cartridge clockwise ~45º until the arrow on the cartridge is pointing the lock sign on the handle. See Figure 2c.
5. Remove the pack tag by pulling it away from the shaft. See figure 2d.

CAUTION: do not remove the pack tag before the cartridge is placed and locked.

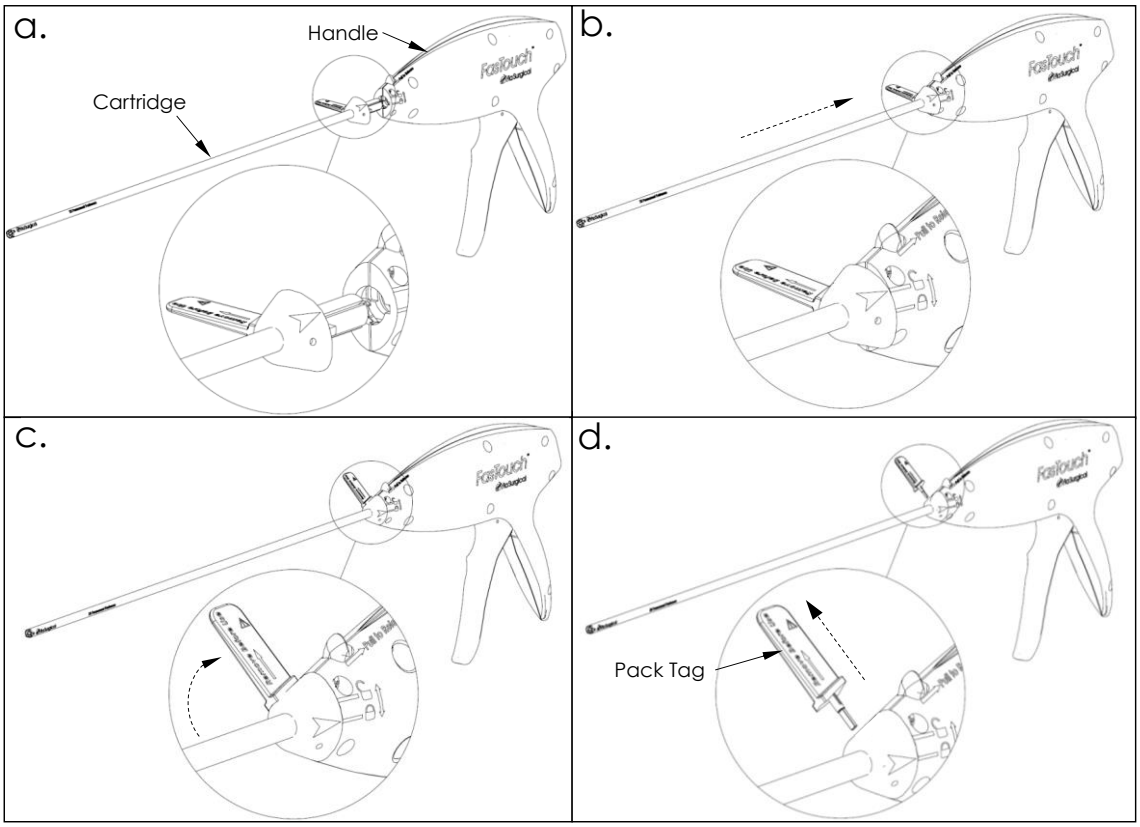


Figure 2- Cartridge loading process

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 come is in complete contact with the prosthetic device.
8. Squeeze the handle completely while applying external counter pressure.
   Note: the handle will return to its initial position only after a complete squeeze. If the handle did not return to its initial stage squeeze it completely before removing the tip of the device from the tissue.
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 then the handle should also be discarded.

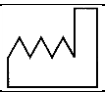
11. If additional fasteners are necessary, replace the cartridge according to the following steps:
12. Remove the device from the patient body.
13. Pull the release lever (located at the front of the handle) away from the shaft.
14. While holding the release lever, rotate the cartridge counter clockwise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

STORAGE:

Store the FasTouch at room temperature.

Do not use if the package is damaged or open.

	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
	Authorized Representative in the European Community
	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

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