Instructions for Use

Integrity™ Tissue Tack and Delivery Instrument

This Instructions for Use is intended exclusively for distribution within the United States.

In an effort to best meet the needs of our customers and minimize waste, these Instructions for Use are being provided in electronic format. This document is subject to change; the most current version of this IFU is available online. If unsure if using the latest revision, please reprint the IFU at www.anikaifu.com. If a paper copy is preferred it may be requested, free of charge, by contacting Anika Therapeutics, Inc. at www.anikaifu.com. The onus resides with the user to ensure that the most up to date IFU is used.

Products may not be available in all markets. Product availability is subject to the regulatory clearance in individual markets. Please contact your local representative if you have questions about product availability in your area.

℞ ONLY

Caution: Federal Law restricts this device to sale by or on the order of a physician.

Read these instructions completely prior to use.

DEVICE DESCRIPTION

The Integrity™ Tissue Tack is an absorbable dart-shaped tack that is composed of absorbable synthetic polyester derived from lactic acid and dyed with D&C Violet #2. The Integrity™ Tissue Tack is used in conjunction with an associated delivery device and provides fixation of a prosthetic or biologic material to soft tissue.
The Tissue Tacks are available in 7mm and 8mm lengths. They are contained within a Caddy for placement and presentation.

HOW SUPPLIED

The fixation implant devices are provided sterile for single-use only and are packaged in a caddy within a dual sterile seal configuration. The delivery devices are also provided sterile for single use only.
Contents of the package are sterile unless the package is opened or damaged. The Integrity™ Tissue Tack and Delivery Instrument and packaging do not contain natural rubber latex. DO NOT use if package is damaged or if labeling is incomplete or illegible.

INTENDED USE

The Integrity™ Tissue Tack Fixation System is intended for the approximation of soft tissue and fixation of surgical mesh to tissues during open or arthroscopic surgical procedures, such as rotator cuff repair.

INDICATIONS FOR USE

The Integrity™ Tissue Tack Fixation System is indicated for the fixation of prosthetic or biologic material to soft tissues in various minimally invasive and open surgical procedures, such as rotator cuff repair.

CONTRAINDICATIONS

- The Integrity™ Tissue Tack and Delivery instrument is not designed, sold, or intended for use except as described in the indications for use and is contraindicated in the following situation:
  - The Integrity™ Tissue Tacks are not indicated to affix soft tissue to adjoining soft tissue or to reinforce the strength of any tendon repair.
  - The Integrity™ Tissue Tacks are not indicated where there is inadequate soft tissue support or an irreparable tendon system.

WARNINGS

- Do not use if the package is damaged. Do not use if the product sterilization barrier or its packaging is compromised.
- Contents are sterile unless package is opened or damaged. DO NOT RESTERILIZE.
- For single use only.
- Discard any open, unused product. Do not use after the expiration date.
- The Integrity™ Tissue Tack Delivery Device is not intended to deliver implants manufactured by any company other than Anika.
- The surgeon shall be thoroughly familiar with the implants, instruments, and surgical technique prior to performing surgery.
- Read these instructions completely prior to use.
- Ensure that all fixation implants are properly secured prior to patient closure.

MRI SAFETY INFORMATION

Integrity™ Tissue Tack is MRI safe.

STORAGE

- Store at room temperature: 59°F (15°C) to 86°F (30°C). Keep dry.
- Avoid temperatures more than 104°F (40°C).
- Outer package includes a temperature indicator. Do not use if central circle of the indicator on the product appears black. In the event of a temperature breach, the indicator window will turn from white to black.

PRECAUTIONS

- Prior to use, inspect the device to ensure it is not damaged. Do not use a damaged device.
- Hazards associated with reuse of this devise include, but are not limited to, patient infection and/or device malfunction. Surgeon or Physician should discuss general risks and potential complications associated with this

and any surgical procedure with the patient prior to patient consent.

- Do not advance instrument against resistance or damage to device may occur.
- Overlapping fixation devices may result in damage to the devices.
- Application of the Integrity™ Tissue Tack does not modify the postoperative treatment. The surgeon must determine motion and strength requirements according to standard practice.

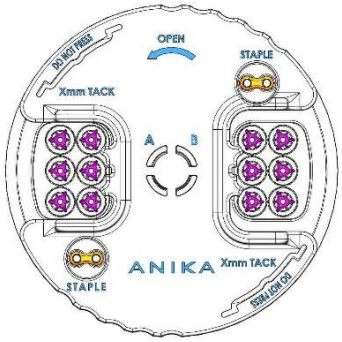
POTENTIAL ADVERSE EVENTS

The following are potential adverse events that may occur from the surgical procedure or complications with the device:

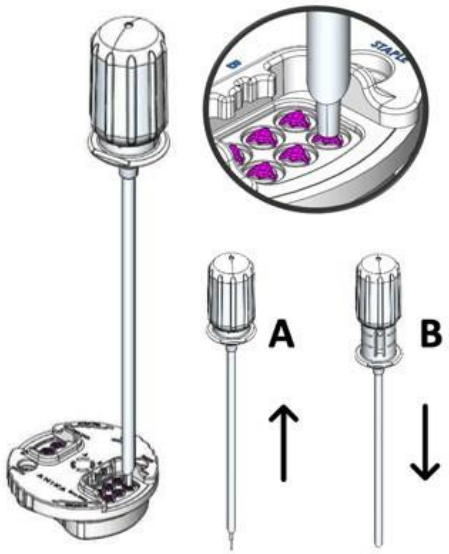
- Allergic Reaction
- Infection
- Pain
- Device may not function as intended.

DIRECTIONS FOR USE

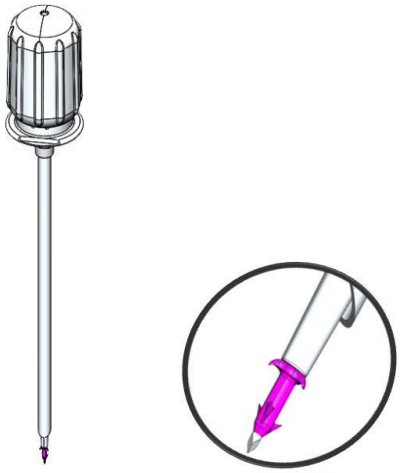
1. Rotate Caddy Cover counterclockwise to reveal Fixation Implants. Note: Tissue Tacks may be packaged with other implants, including Bone Staples.



2. Retract protective sheath to proximal position (**A**). Insert visible trocar needle tip into the central lumen of a Tissue Tack. Retract Instrument from caddy with Tissue Tack loaded distally. Extend protective sheath to distal position (**B**) to protect the loaded Tissue Tack for insertion into joint space.



3. At target site, retract protective sheath to proximal position (**A**), fully seat Tissue Tack into soft tissue by lightly impacting the proximal handle with a mallet.



Delivery Instrument, Tissue Tack shown with a loaded TissueTack.

4. Remove Delivery Device. Confirm adequate fixation has been achieved.

5. Dispose of the devices according to the appropriate environmental health safety guidelines.

Rx ONLY	CAUTION: U.S. Federal law restricts this device to sale by or on the order of a physician	www.anikaifu.com	Consult electronic instructions for use
STERILE R	Sterilized using irradiation	LOT	Lot number
	Double sterile barrier system		Use by date
MR	MR Safe		Manufacturer
	Do not reuse		Date of Manufacture
STERILIZE	Do not resterilize	REF	Catalog Number
	Do not use if package is damaged and consult instructions for use	UDI	Unique Device Identifier
40 °C	Upper limit of temperature		Keep Dry

FOR FURTHER INFORMATION

If further information on this product is needed, please contact Anika Customer Service at 1-888-721-1600 in the U.S., or an authorized representative.

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Made in USA

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