Instructions for Use

Integrity™ Bone Staple Fixation System

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™ Bone Staple is a staple-shaped tack with barbed ends and is composed of polyether ether ketone (PEEK) material. The Integrity Bone Staple is used in conjunction with an associated delivery device and provides fixation of soft tissue grafts or reinforcement meshes to bone. The fixation devices are provided sterile for single-use only and are packaged in 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™ Bone Staple 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™ Bone Staple Fixation System is intended for the fixation of soft tissue grafts or reinforcement meshes to bone during rotator cuff repairs.

INDICATIONS FOR USE

The Integrity™ Bone Staple Fixation System is indicated for the fixation of soft tissue grafts or reinforcement meshes to bone during rotator cuff repairs.

CONTRAINDICATIONS

- The Integrity™ Bone Staple 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™ Bone Staples are not indicated to reinforce the strength of any tendon repair.
  - The Integrity™ Bone Staples are not indicated where there is inadequate quality of bone.

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 surgeon shall be thoroughly familiar with the implants, instruments, and surgical technique prior to performing surgery.
- Read these instructions completely prior to use.
- The Integrity™ Delivery instrument is not indicated for use with implants manufactured by any company other than Anika.
- Ensure that all fixation implants are properly secured prior to patient closure.

MRI SAFETY INFORMATION

Integrity™ Bone Staple 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 device 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.
- Overlapping fixation devices may result in damage to the devices.
- Integrity Bone Staples should be placed at least 1 mm from edge of soft tissue graft or reinforcement mesh to avoid tearing.

- Tip of Integrity™ Bone Staple Delivery Instrument is sharp, use caution when handling device.
- Inserting Bone Staple through excessive tissue or augment thickness may not provide adequate fixation.
- Application of the Integrity™ Bone Staple does not modify the postoperative treatment. The surgeon must determine motion and strength requirements according to standard practice.

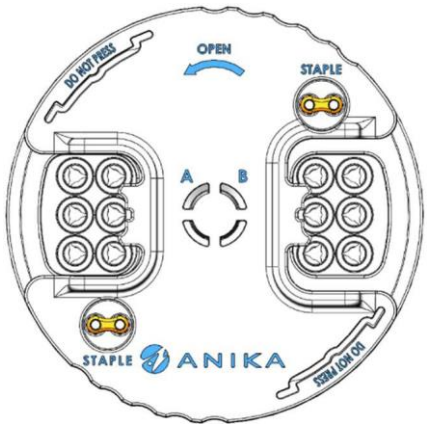
POTENTIAL ADVERSE EVENTS

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

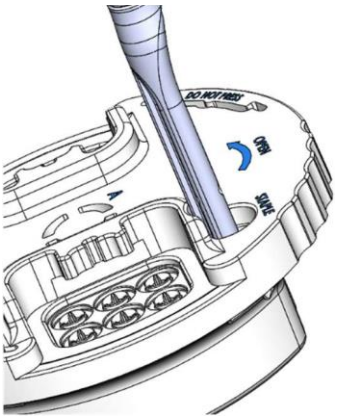
- Allergic Reaction
- Infection
- Pain
- Device may not function as intended.

DIRECTIONS FOR USE

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

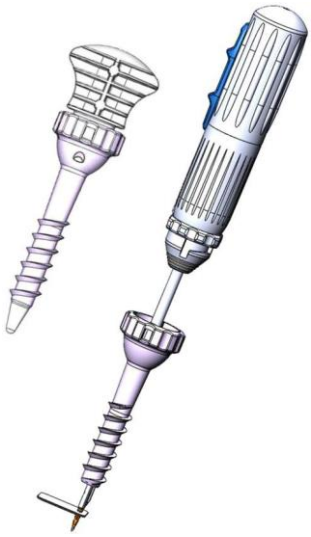


2. Insert Bone Staple Delivery Device into a cavity labeled “STAPLE” aligning trocar needle tips with Staple lumens, to retrieve a Bone Staple.

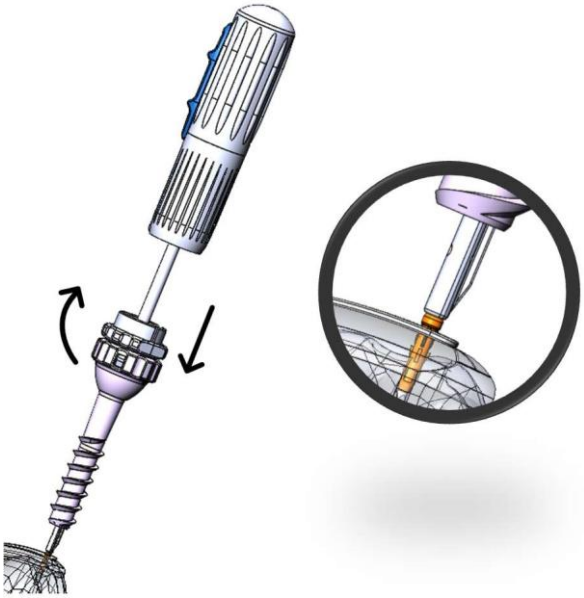


3. Pass Bone Staple through the soft tissue graft or reinforcement mesh extracorporeally.

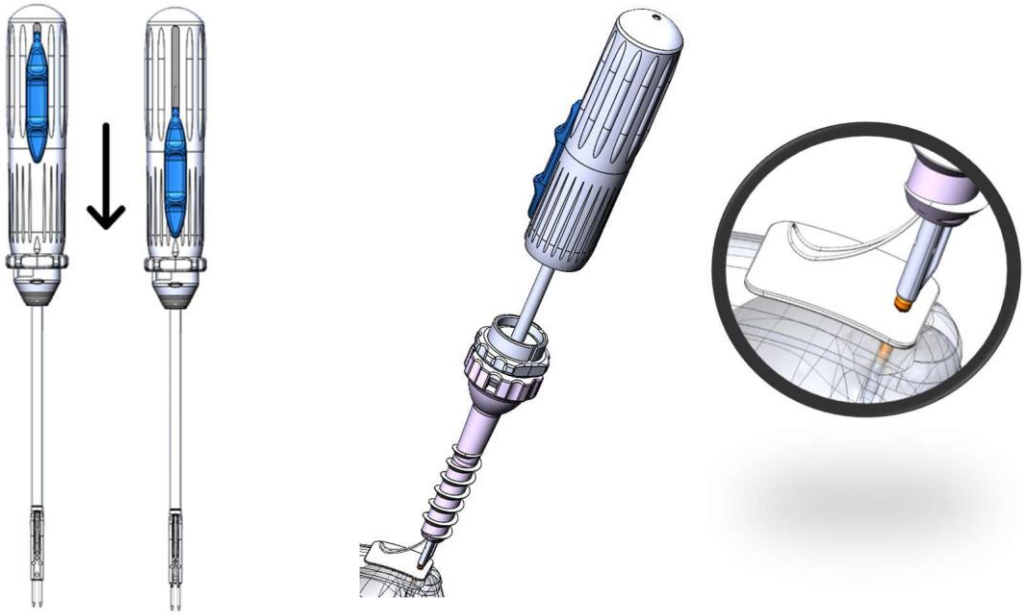
4. Pass distal end of instrument through surgical access Cannula and into position.



5. Advance Seal down to engage Cannula and rotate clockwise to secure into position. Locate the Bone Staple at the desired fixation location and impact proximal handle to seat Bone Staple into bone.



6. Advance the Actuator distally to assist in the soft tissue graft or reinforcement mesh placement. Use additional suture fixation techniques and/or devices to finalize placement and secure fixation.



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

8. 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
	Do not resterilize	REF	Catalog Number
	Do not use if package is damaged and consult instructions for use	UDI	Unique Device Identifier
	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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