

Integrity™ Implant System

Rotator Cuff Repair

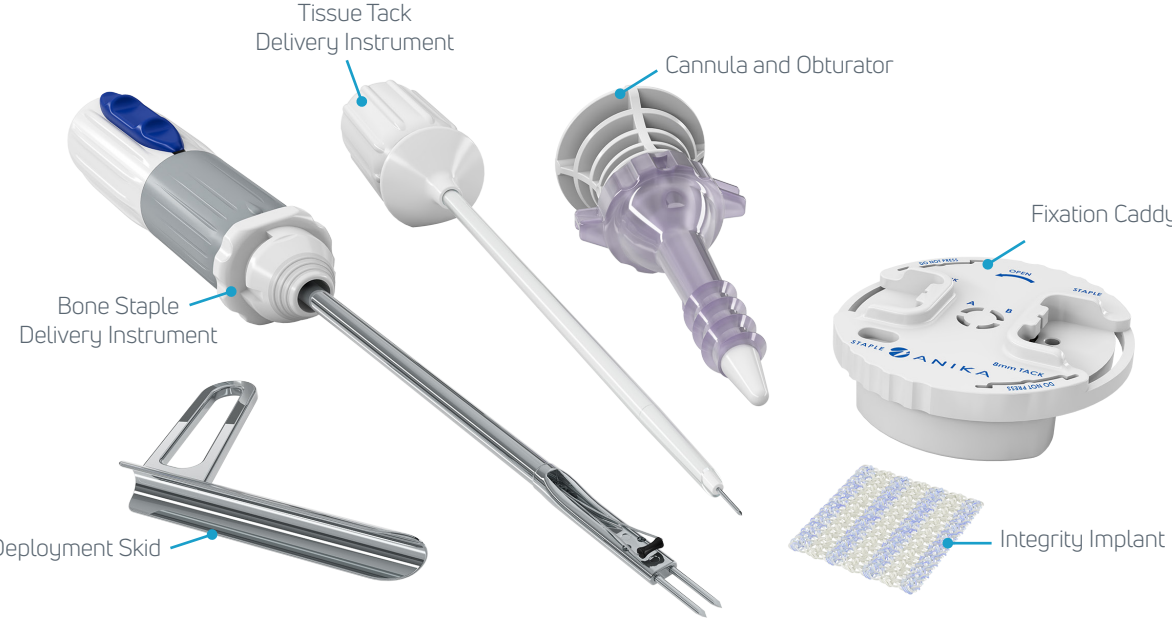
Surgical Technique Guide



Integrity Implant System

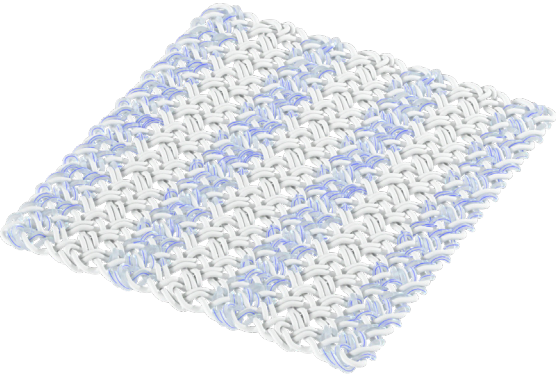
Product Overview

The **Integrity™ Implant** is a synthetic scaffold for rotator cuff repair that provides reliable strength, regenerative biology and a streamlined, precise technique.



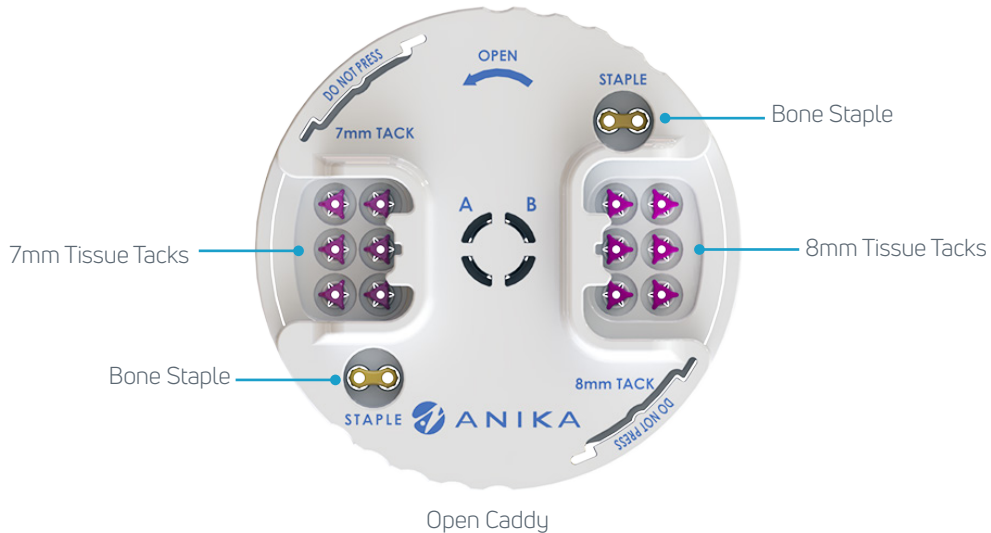
Integrity Implant

The Integrity Implant is a porous, knitted scaffold constructed of Anika's Hyaff® material, a proven hyaluronic acid technology that supports tissue regeneration and resorbs over time, reinforced with non-absorbable PET (polyethylene terephthalate).



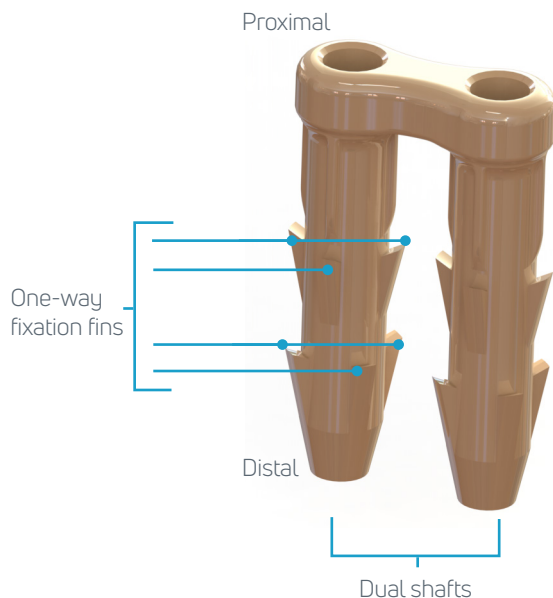
Implant Fixation Kit

The Implant Fixation Kit is a sterile, single-use only implant caddy that includes two Bone Staples, six 7mm Tissue Tacks, and six 8mm Tissue Tacks. The caddy is also used to insert the Bone Staple into the Integrity Implant during the surgical procedure.



Integrity Bone Staple

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 the Integrity Implant to bone. The fixation devices are provided sterile for single-use only and are packaged in a caddy for placement and presentation.



Material

- PEEK (polyether ether ketone)

Structure

- Reinforced shaft for rigidity
- Dual shaft: exit point for sharp tines from bone delivery tool

Fixation Fins

- Provide multiple tissue fixation points
- Sixteen fins per bone staple

Quantity

- Two bone staples per caddy

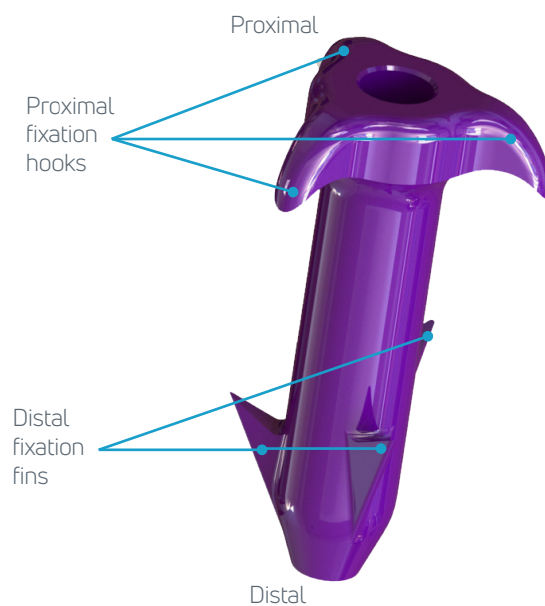
Integrity Implant System

Product Overview

Integrity Tissue Tack

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 the Integrity Implant to soft tissue.

The Tissue Tacks are available in 7mm and 8mm lengths. They are provided sterile for single-use only and are packaged in a caddy for placement and presentation.



Material

- PLGA: Poly(lactic-co-glycolic acid)
- Effective resorption in 6-12 months

Structure

- Reinforced shaft for rigidity
- Single shaft: exit point for sharp tine from tissue tack delivery tool

Fixation Points

- Multiple tissue fixation points
- Proximal end: triangular fixation via three hooks
- Three perimeter distal fins

Quantity

- Six 7mm tissue tacks per caddy
- Six 8mm tissue tacks per caddy

Rotator Cuff Surgical Technique

Integrity Implant System

STEP 1

Carry out your standard technique for repairing the injured rotator cuff tendon. Determine the tendon width in millimeters (mm) using a suitable measuring instrument. Select the appropriately sized Integrity Implant slightly smaller than the width of the tendon.

STEP 2

Rotate Implant Fixation Kit (caddy) counterclockwise to reveal Bone Staples and Tissue Tacks.

Note: *Firmly hold the implant caddy over a sterile hard surface when opening to ensure implants remain securely in the caddy.*

STEP 3

To load Bone Staple, insert the distal tines of the Bone Staple Delivery Instrument into the back of the Bone Staple until positive stop. Gently pull Delivery Instrument handle back to remove Bone Staple from the caddy. Bone Staple is now ready to be inserted into the Integrity Implant.

Note: *Keep implant caddy on a firm sterile surface when loading.*



Integrity Rotator Cuff Surgical Technique *Continued*

STEP 4

Rotate Implant Fixation Kit clockwise to close caddy and prepare for assembly of the Bone Staple to the Integrity Implant. Load Integrity Implant with white and blue orientation lines perpendicular to the Bone Staple within the implant loading zone.

Note: *The Integrity Implant does not have a top or bottom orientation.*

Proceed to insert the Bone Staple/Delivery Instrument assembly through the middle section of the implant at a 90° angle with the roller facing the outer caddy edge. If needed, pickups may be used to stabilize Integrity Implant while loading.

Note: *Side A is for the 20x25mm Implant while Side B is for the 25x30mm Implant.*

Insert the Bone Staple through the Integrity Implant and then into the two holes on the caddy implant loading zone. Continue to insert Bone Staple until positive stop. Push by hand; do not use a mallet. Ensure Bone Staple is approximately 4mm from edge of Integrity Implant. When removing the Integrity Implant and Bone Staple from the caddy, grasp the Implant to the Inserter so the construct does not disassociate.



STEP 5

Insert Integrity Cannula and Obturator into lateral portal to establish your working portal for the Bone Staple and Integrity Implant. Turn Cannula clockwise to advance into the joint. Please note, the Integrity Cannula does not include an internal seal. The Staple Delivery Instrument seal may be used to control outflow and joint pressure.

STEP 6

Partially pass the distal tip with assembled Integrity Implant and Bone Staple through the Cannula without protruding into the subacromial space. Advance seal down to engage Cannula and rotate quarter turn clockwise to secure and lock into position. The distal end of the Delivery Instrument has a seal that will securely connect to the proximal hub of the Cannula. This will minimize the amount of outflow coming through the proximal portion of the Cannula.



ALTERNATIVE CANNULA

If a non-rigid arthroscopic cannula is chosen to be used in deploying the Integrity Implant, a reusable stainless steel Deployment Skid is available to facilitate in the passage of the delivery instruments and implants.

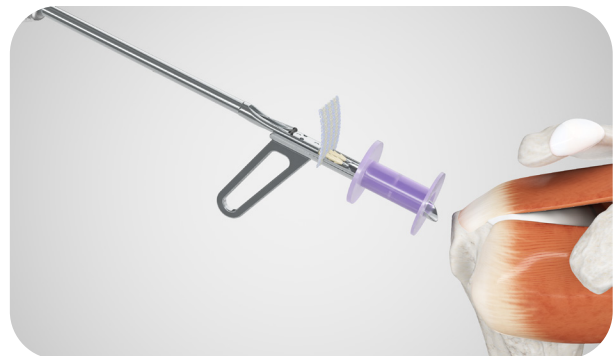
Prior to surgery, confirm that the Deployment Skid easily passes through the non-rigid cannula to be used, as individual manufacturers' valve configurations vary. The Skid is to be used with non-rigid cannulas with an inner diameter of 10mm or larger.

Introduce the Deployment Skid into the distal opening of the non-rigid cannula.

Advance slowly allowing the distal tip of the Skid to center on the valve construct. Continue advancing to dilate and open the valve. Fluid flow out of the cannula will temporarily increase as the valve is opened. Pass instruments and implants through the passage created by the Skid.

Remove the Skid to allow the valve elements to return to their normal functional position.

Skid may be utilized in a handle-superior or handle-inferior orientation, per surgeon preference. Arthroscopic visibility may be enhanced in the handle-inferior orientation.



Integrity Rotator Cuff Surgical Technique *Continued*

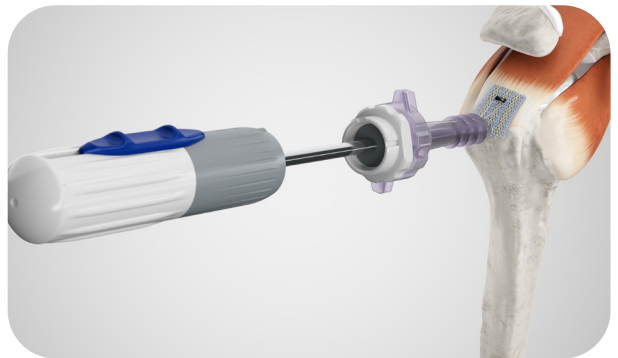
STEP 7

Proceed to implant the Bone Staple at the appropriate lateral position on the greater tuberosity. Place Bone Staple at an angle that allows good fixation while still allowing easy deployment of the Integrity Implant and mallet down to a positive stop. Ensure Bone Staple is properly seated prior to removal of the Bone Staple Delivery Instrument. If necessary, the Bone Staple Delivery Instrument may be reinserted back into the Bone Staple to increase deployment depth.



STEP 8

Push the blue slider on the Bone Staple Delivery handle forward to extend the roller and to flatten out the Integrity Implant medially on the supraspinatus. Deployment can also be facilitated by using arthroscopic instruments to fine tune implant placement.



Note: Leave roller fully extended prior to soft tissue fixation.

STEP 9

Rotate Implant Fixation Kit counterclockwise to reveal Tissue Tacks. To load Tissue Tacks, retract protective sheath to the proximal position. Insert the distal tine of the Tissue Tack Delivery Instrument into the back of the Tack until positive stop. Pull Delivery Instrument handle straight back to remove Tack from the caddy. Extend protective sheath to the distal position to protect the loaded Tack for insertion into the joint space.

Note: Keep implant caddy on a firm sterile surface when loading.

Choose between the 7mm or 8mm Tissue Tacks based upon tendon thickness and surgeon preference.



STEP 10

A dual or single portal approach may be utilized.

Dual portal approach: Utilize small stab incisions, similar to those used for percutaneously placing medial row anchors, to insert the Tissue Tacks.

Single portal approach: Lateral portal can be utilized to insert a variety of instruments to assist in holding the patch.

STEP 11

Once at the desired target site for the Tissue Tack, retract protective sheath to expose the Tack, depress tab on Tack Delivery handle, and push Tissue Tack Delivery handle forward with gentle mallet taps to fully insert Tack.

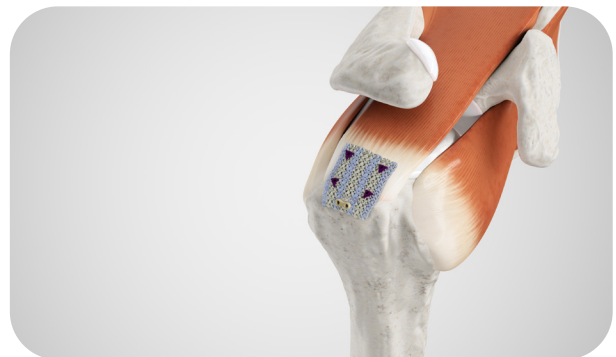
Note: *The beveled edge of the Tack sheath may be utilized to smooth out the Integrity Implant.*



To remove handle, use counterpressure on the sheath. Give a small twist and pull Tissue Tack Delivery Instrument straight back to disconnect from the Tack. Leave sheath in joint space and determine next Tack location. Remove Tack Delivery handle from sheath and repeat steps to implant additional Tissue Tacks. If necessary, the Tack Delivery Instrument may be reinserted into the Tack to adjust deployment depth.

STEP 12

Final construct should consist of one lateral Bone Staple and a minimum of four Tissue Tacks.



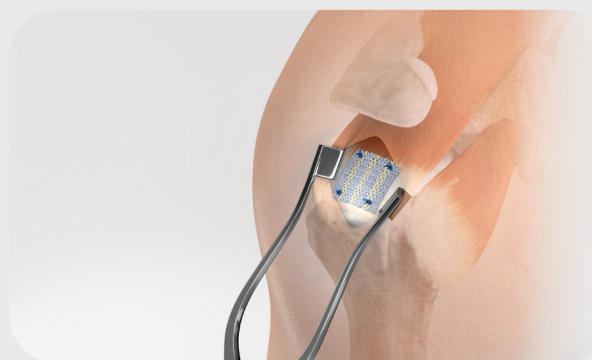
Integrity Rotator Cuff Surgical Technique *Continued*

ALTERNATIVE TECHNIQUE

Mini-Open Technique – Suture Only

Use desired suture and a low-tension suture technique to secure the Integrity Implant to the tendon.

Apply Integrity Implant on the tendon with the stripes aligned with the direction of the tendon fibers.



INTEGRITY ORDERING INFORMATION

Part Number	Description
6000100	20x25mm Integrity Implant
6000101	25x30mm Integrity Implant
6000102	Integrity Implant Fixation Kit, including PEEK Bone Staples and PLGA Tissue Tacks
6000118	Integrity Delivery Instrument, Bone Staple
6000120	Integrity Delivery Instrument, Tissue Tack
6000122	Integrity Cannula/Obturator Kit
6000128	Deployment Skid (Reusable Instrument)

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