ANIKA

Integrity™

Implant System

Value Analysis Committee Brochure

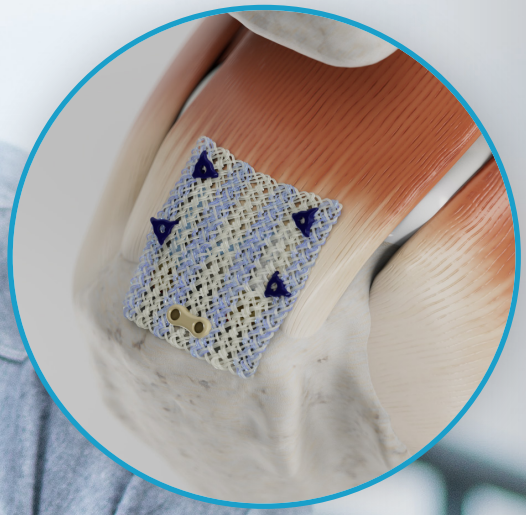


Table of Contents

Anika is the global leader in the design, development, manufacturing, and commercialization of hyaluronic acid (HA) innovations. In partnership with clinicians, our sole focus is dedicated to delivering and advancing osteoarthritis (OA) pain management and orthopedic regenerative solutions. At our core is a passion to deliver a differentiated portfolio that improves patient outcomes around the world.

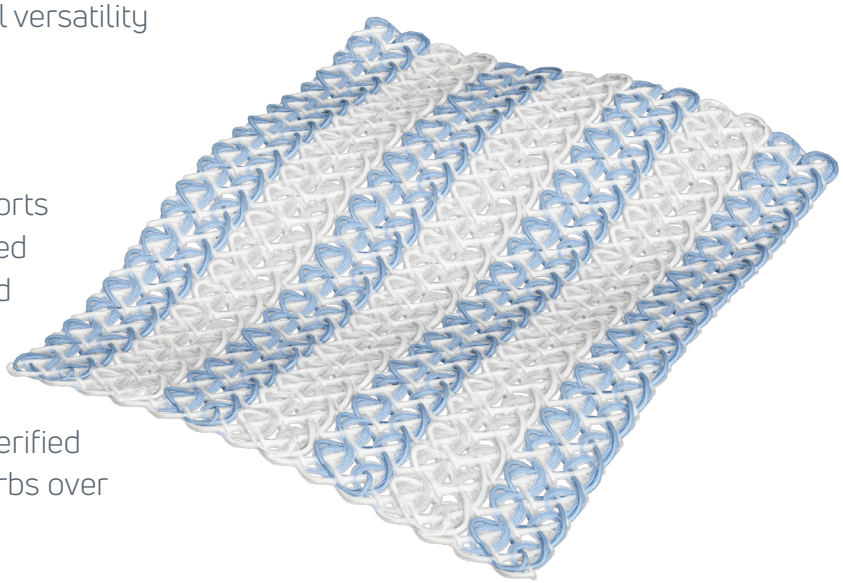
Anika. Restore Active Living.®

Integrity™ Product Introduction

The Integrity Implant is a hyaluronic acid-based scaffold intended for rotator cuff repair, Achilles repair, and other tendon repair applications that provides reliable strength, regenerative biology and a streamlined, precise technique.

Reliable strength

- Integrity provides higher tensile strength, suture retention, and tear resistance in a thin knitted format[1]
- Inherently strong scaffold can be confidently manipulated arthroscopically and enables surgical versatility



Regenerative biology

- Hyaluronic acid-based scaffold supports regenerative healing through improved cell infiltration, tissue remodeling, and tendon thickening
- Porous, flexible construct knitted using **Hyaff**®, Anika's proven solid esterified hyaluronic acid technology that resorbs over time as tissue remodels

Streamlined technique

- "Lateral first" fixation, unique instrumentation, and simplified surgical technique allow for precise implant placement

Material Science

Anika's 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).

HYAFF-11

- Benzyl ester modified derivative of hyaluronic acid (HA), a naturally occurring substance in the body
- Hydrophobic properties allow for good cell adhesion and viability
- Increased residence time *in vivo* compared to native HA
- Once Hyaff degrades releasing HA, it is naturally resorbed into the body[5]
  - HA is a natural and major component of the human body and is highly biocompatible[5]
- Fibers can be knitted to form robust structures[3]

Hyaff derivatives have been used globally for more than 20 years with excellent results in terms of safety and efficacy.[4]

Anika has been developing, manufacturing, and selling HA-based products for over 30 years[6]

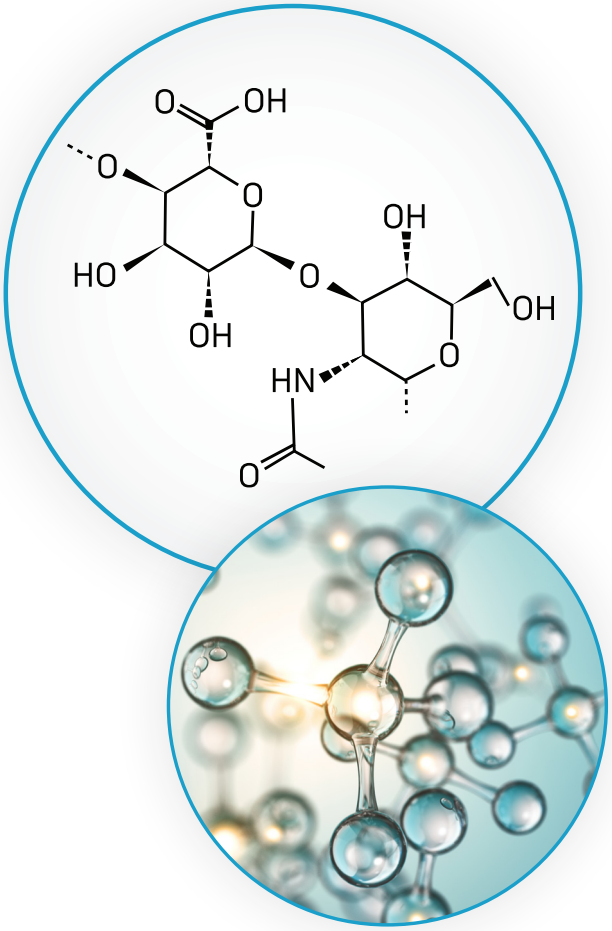
PET (Polyethylene terephthalate)[7]

- A common thermoplastic polyester used in sutures since the 1950's, in vascular prostheses since the 1960's, and in surgical meshes and other permanent implants since the 1970's
- Well known for its biostability, promotion of tissue ingrowth, well characterized fibrotic response, and long history of human implantation
- Known for its ease of manufacturability and high strength as a medical fiber/textile

Biological Role of Endogenous Hyaluronic Acid

At a Cellular Level

- Endogenous hyaluronic acid (HA) is the main ligand for CD44 receptors to regulate specific cell types to modulate inflammation and healing[8]
- Involves morphogenesis (the shaping of organisms by the embryological process of differentiation of cells and tissues)[9]
- Promotes cell proliferation through activation of TGF-β/BMP signaling[10]

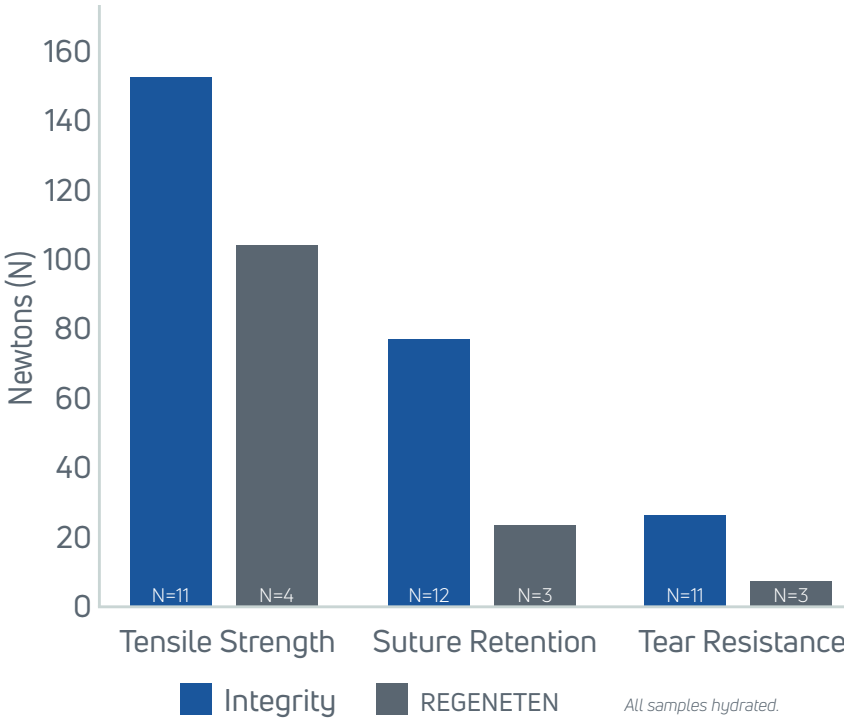


At a Macroscopic Level

- Helps in the growth and development of new cells and tissues, and repairing injured cells and tissues[8]
- Binds to water, creating a viscous fluid that provides lubrication and serves as a shock absorber in the joint[8]
- Plays an important role in reducing joint inflammation and pain caused by injury or tissue degeneration[13]

Strength and Porosity

Strength[1]



All samples hydrated.

Integrity demonstrated:

Nearly 50% greater
tensile strength

Over 3X
suture retention strength

Over 3X
tear resistance

Porosity

A porous structure optimizes the interaction between the implant and the native cells to aid in the tissue regeneration process.

Scanning electron microscope (SEM) image. 100x magnification

At 100x magnification, the Integrity Implant exhibits excellent porosity.[11]

Composition & Design

Integrity Implant

Material

80% Hyaff, 20% PET

Edges

- Lock stitch construction with laser-cut edge
- Thick, blue borders for orientation

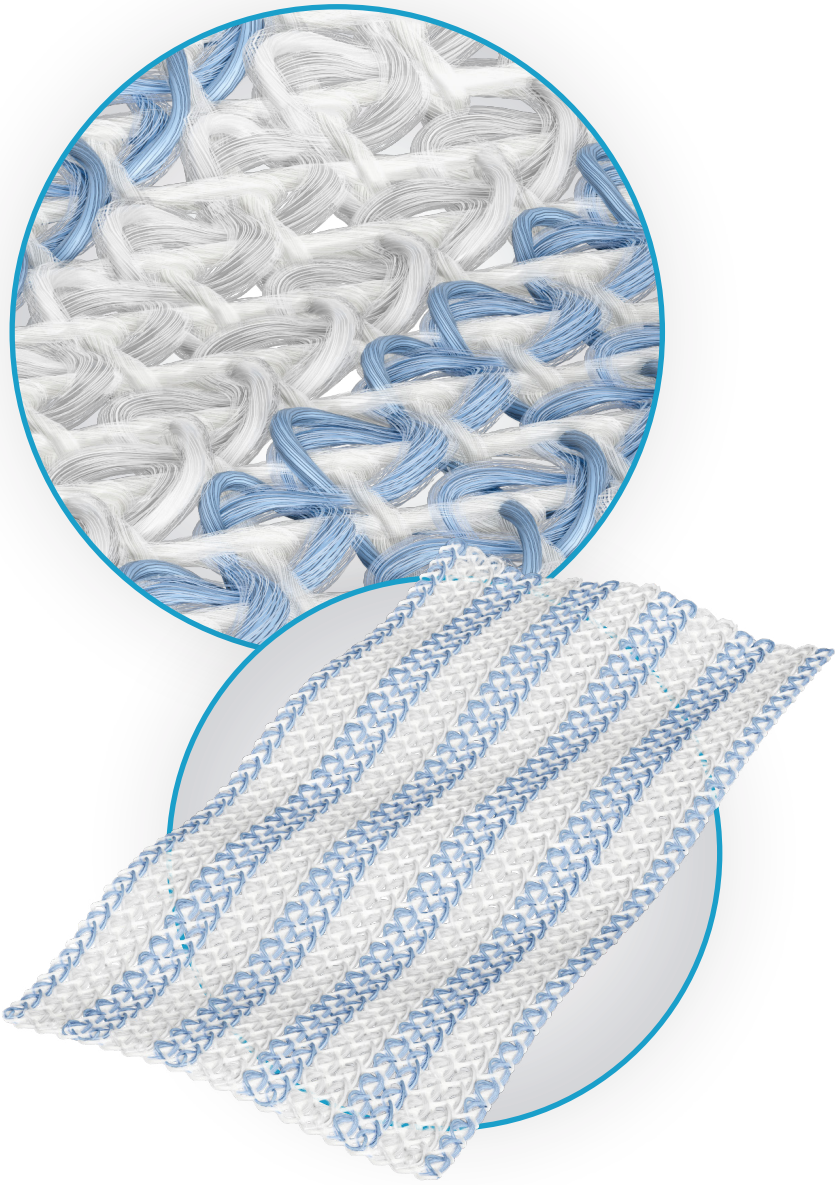
Structure

Flexible knitted structure provides additional:

- Tensile/shear strength
- Tear resistance
- Suture retention strength

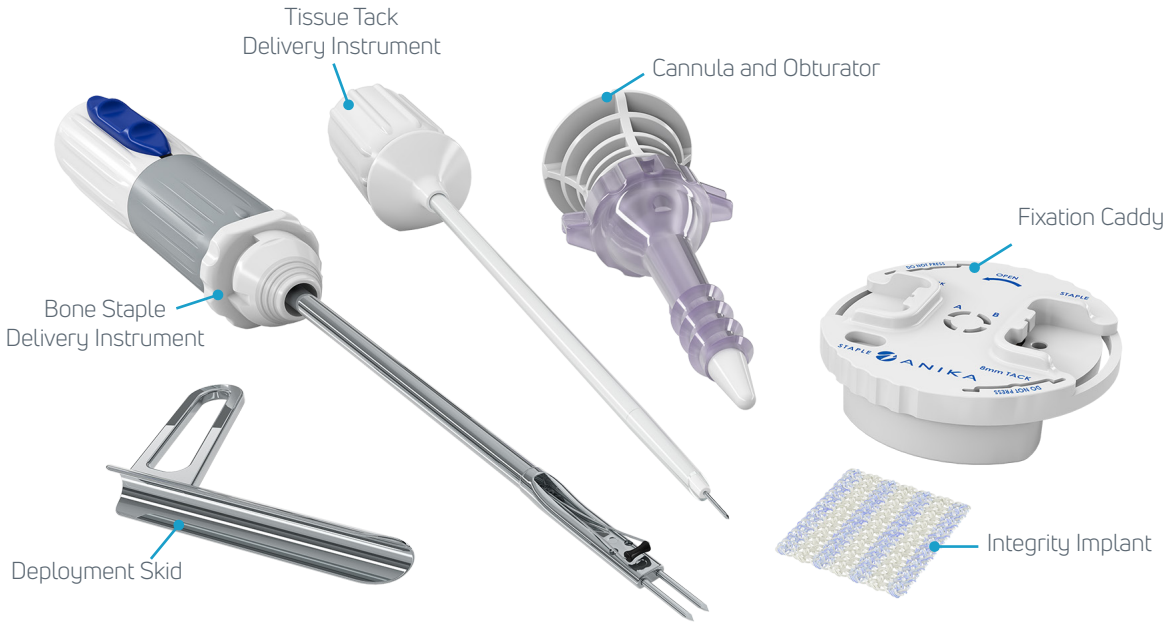
Dimensions

- Available in four sizes:
  - 20x25mm
  - 25x30mm
  - 25x60mm
  - 40x60mm
- 0.75mm nominal thickness

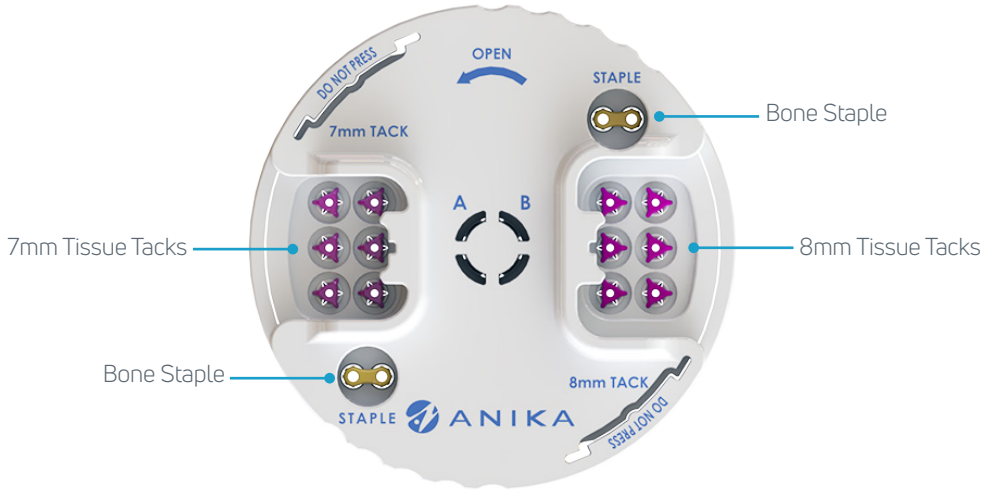


Rotator Cuff System Components

Integrity Implant System for Rotator Cuff Repair



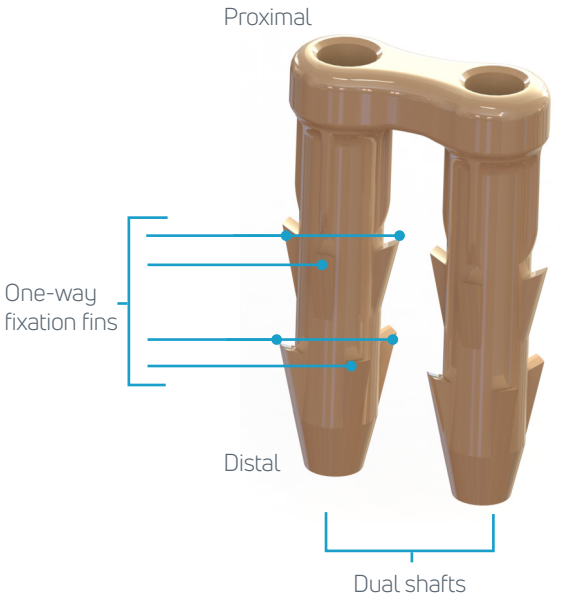
Fixation Caddy (Implant Fixation Kit)



Open Caddy

Rotator Cuff System Components *Continued*

Bone Staple



Material

- PEEK (polyether ether ketone)

Structure

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

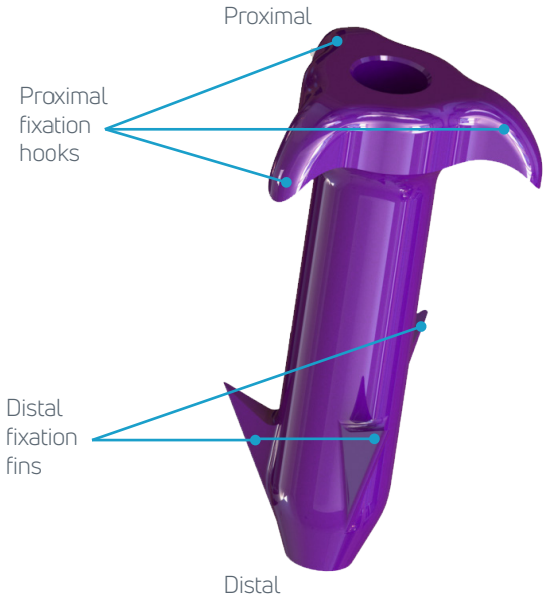
Fixation Fins

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

Quantity

- Two bone staples per caddy

Tissue Tack



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

Surgical Technique Approaches

The Integrity Implant is a medical device intended for the management and protection of tendon injuries such as the rotator cuff and Achilles tendon. The implant can be confidently manipulated *in situ*, is easy to handle, porous, and pliable in both the dry and hydrated state.

An arthroscopic or open approach may be used. If arthroscopic, a single portal or dual portal may be utilized. If open, the surgeon may use an all-suture technique to secure the Integrity Implant to the injured tendon.

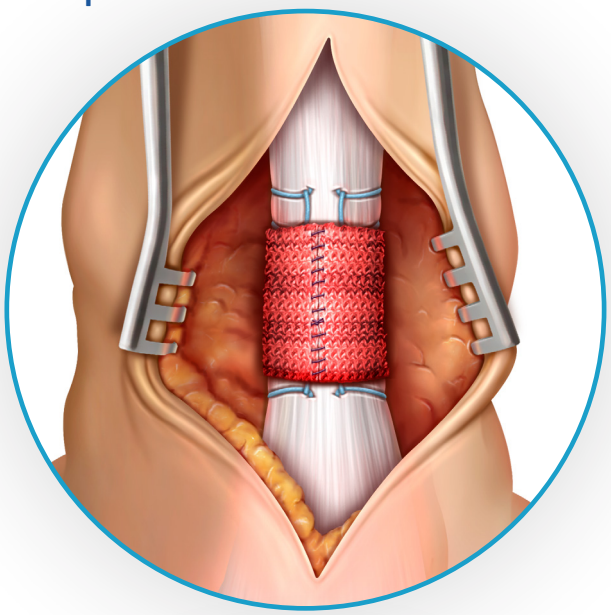
Dual Portal Simplified Rotator Cuff Surgical Technique:

1. Place lateral cannula and accessory cannula
2. Insert Bone Staple Delivery Instrument into caddy to retrieve Bone Staple
3. Position Integrity Implant in caddy and insert Bone Staple through Integrity Implant extracorporeally
4. Pass distal end of instrument loaded with Integrity Implant and Bone Staple through lateral cannula
5. Advance seal down to engage cannula and rotate clockwise to secure into position
6. Locate the desired fixation location for the Bone Staple and impact proximal handle with a mallet to seat Bone Staple into bone
7. Advance the actuator distally to roll out the Integrity Implant and keep roller in place
8. Insert Tissue Tack Delivery Instrument into caddy to retrieve a Tissue Tack
9. Pass Tissue Tack through accessory cannula and fixate Integrity Implant to soft tissue by lightly impacting the proximal handle with a mallet
10. Repeat with desired number of tissue tacks to achieve adequate fixation
11. Close surgical site in standard fashion

Surgical Technique Approaches *Continued*

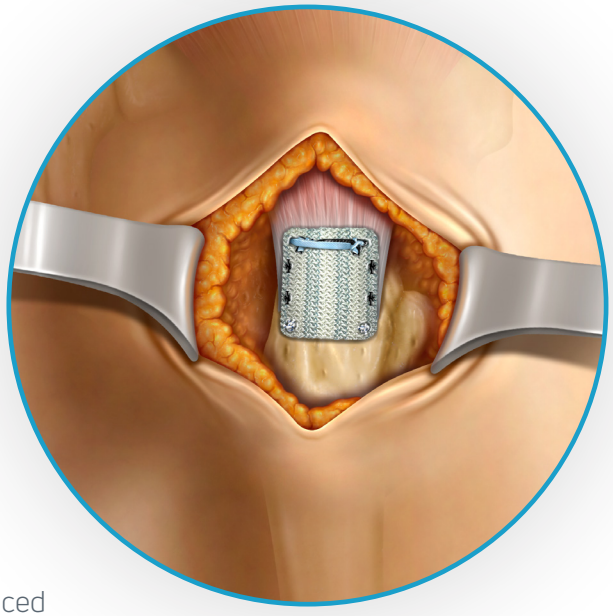
Simplified Achilles Mid-Substance Surgical Technique:

1. Make an incision according to tendon tear location and place retractors to isolate the tendon
2. Perform initial repair of the tendon utilizing preferred sutures
3. Carefully wrap the Integrity Implant around the tendon covering the affected zone of repair
4. Utilizing a 4.0 absorbable suture, incorporate the Integrity Implant and tendon together proximal and distal to the zone of injury with a running suture pattern to minimize knot irritation
5. Once the Integrity Implant is secured to the tendon, perform closure in layers



Simplified Gluteus Medius Surgical Technique:

1. Identify the tear and prepare the footprint
2. Place two double loaded suture anchors at the medial aspect of the gluteus medius footprint
3. Use a loop suture to pass both sets of sutures through the tear
4. Place the Integrity Implant over the repair and pass the remaining sutures from the medial row through the Integrity Implant using a loop suture
5. Tie one limb from each remaining suture pair. Tension the remaining limbs and use a "pulley technique" to compress the tied sutures over the Integrity Implant
6. Tie and cut the remaining two suture limbs to complete the fixation of the Integrity Implant proximally
7. Pass one limb of the stay suture from the previously placed knotless anchors through the Integrity Implant distally at each corner and tie to the remaining stay suture
8. Place an absorbable #1 suture on either side of the Integrity Implant to complete the fixation



Preclinical Data

Study Objective

To characterize bone ingrowth, local tissues response, and biomechanical effectiveness of repair of the rotator cuff with Anika's Integrity Implant test group using an overlay technique compared to the leading competitive commercially available collagen device.

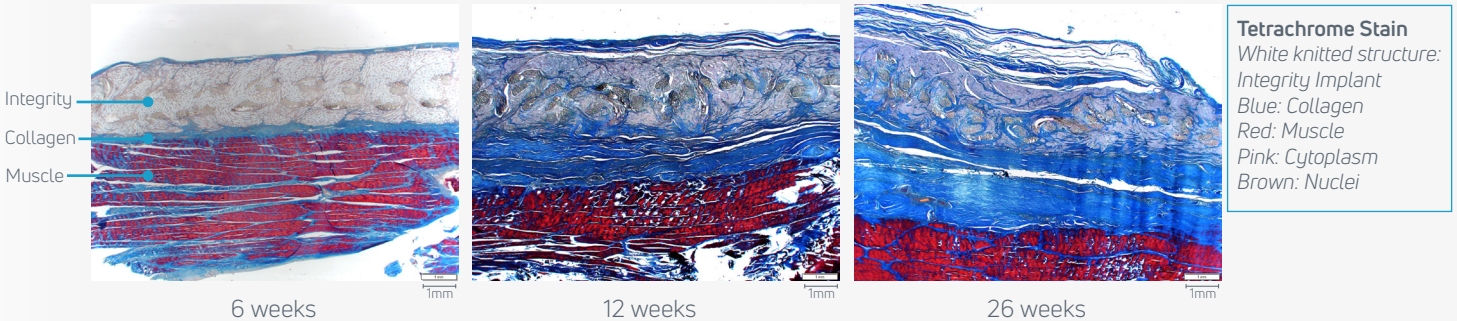
An ovine model was chosen for this study as it has been demonstrated as an appropriate model for the purpose of assessing device interactions with host tissue in different sites and is applicable to use in humans. The products tested were Anika's Integrity Implant, the market-leading collagen implant and a control group (which had an injury but no implant).

Time points were taken at 6, 12, and 26 weeks. Endpoints taken were histological response via an MRI assessment (T3) and biomechanical testing.

Findings

- As early as 12 weeks post-implantation, fibroblast infiltration and regularly oriented new collagenous tissue formation had occurred within the Integrity repair, demonstrating greater regenerative capacity compared to the market leader[1]
- At 26 weeks, within the resorbing Integrity structure, new collagenous tissue infiltration forming a new network of tendon tissue had occurred, resulting in nearly 3 times greater thickness in the repaired tendon than the competitive collagen device[1]
- Tendon thickness is thought to improve the local biomechanical environment of the tear by reducing tendon strain, thus optimizing its healing potential[12]

Histology shows Integrity's increased tendon thickness,nearly 3 times greater than the market-leading collagen implant.[1]



6 weeks | 12 weeks | 26 weeks

Tetrachrome Stain
White knitted structure: Integrity Implant
Blue: Collagen
Red: Muscle
Pink: Cytoplasm
Brown: Nuclei

Competitive Information

Competitive Cross-Reference Chart

Overlay Only

Product	Integrity™	REGENETEN™	Tapestry®	BioBrace®	CuffMend™
Company	**Anika**	Smith & Nephew	Zimmer Biomet	ConMed	Arthrex
Material	**HYAFF® +PET**	Type 1 Collagen	Type 1 Collagen + PDLLA	Type 1 Collagen + PLLA	Acellular Dermis
High Implant Strength	✓	✗	✗	✓	✓
Streamlined Delivery System *(including tendon & bone fixation implants)*	✓	✓	✓	✗	✗
Regenerative Biology	✓*	✓	✓	✓	✗**

** Indicates improved cellular response in internal studies as compared to REGENETEN*
*** Surgeon perception of mixed clinical results, higher failure rates and tissue limitations like strength and propensity to stretch (SmartTrak 2023)*

Reimbursement

Coding guide

Note: It is the provider's responsibility to determine and submit appropriate codes for services that are rendered. This information is meant as a reference and should not be interpreted as providing clinical advice, dictating reimbursement policy, or substituting for the judgment of a practitioner.

Reimbursement laws, regulations, and payor policies change frequently, therefore, it is recommended that providers consult with their payors, coding specialists, and/or legal counsel regarding coverage, coding and payment issues.

Potential procedure codes include:

SHOULDER

Subscapularis/Rotator Cuff

Code	Description	ASC Indicator
23410	Repair of ruptured musculotendinous cuff (eg, rotator cuff) open; acute	A2
23412	Repair of ruptured musculotendinous cuff (eg, rotator cuff) open; chronic	A2
23420	Reconstruction of complete shoulder (rotator) cuff avulsion, chronic (includes acromioplasty)	A2
29827	Arthroscopy, shoulder, surgical; with rotator cuff repair	A2
23939	Unlisted procedure, shoulder	Not paid

Biceps/Triceps

Code	Description	ASC Indicator
23430	Tenodesis of long tendon of biceps	J8
24340	Tenodesis of biceps tendon at elbow (separate procedure)	J8
24341	Repair, tendon or muscle, upper arm or elbow, each tendon or muscle, primary or secondary (excludes rotator cuff)	A2
24342	Reinsertion of ruptured biceps or triceps tendon, distal, with or without tendon graft	A2

HIP

Gluteus Medius

Code	Description	ASC Indicator
27006	Tenotomy, abductors and/or extensor(s) of hip, open (separate procedure)	G2
27299	Unlisted procedure, pelvis or hip joint	Not paid

Reimbursement *Continued*

KNEE

Quad Tendon

Code	Description	ASC Indicator
27385	Suture of quadriceps or hamstring muscle rupture; primary	A2
27386	Suture of quadriceps or hamstring muscle rupture; secondary reconstruction, including fascial or tendon graft	A2
27899	Unlisted procedure, leg or ankle	Not paid

Patellar Tendon

Code	Description	ASC Indicator
27380	Suture of infrapatellar tendon; primary	A2
27381	Suture of infrapatellar tendon; secondary reconstruction, including fascial or tendon graft	J8
27418	Anterior tibial tubercleplasty (eg, Maquet type procedure)	G2
27899	Unlisted procedure, leg or ankle	Not paid

FOOT & ANKLE

Achilles

Code	Description	ASC Indicator
27650	Repair, primary, open or percutaneous, ruptured Achilles tendon	A2
27652	Repair, primary, open or percutaneous, ruptured Achilles tendon; with graft (includes obtaining graft)	J8
27654	Repair, secondary, Achilles tendon, with or without graft	J8
27899	Unlisted procedure, leg or ankle	Not paid

Peroneal Tendon

Code	Description	ASC Indicator
28200	Repair, tendon, flexor, foot; primary or secondary, without free graft, each tendon	A2
28202	Repair, tendon, flexor, foot; secondary with free graft, each tendon (includes obtaining graft)	J8
27899	Unlisted procedure, leg or ankle	Not paid

Instructions For Use

Integrity Implant

DESCRIPTION
The Integrity Implant is designed to provide an augmentation layer over an injured tendon. The implant is a knitted porous mesh comprised of a single composite layer of resorbable Hyaff-11 multifilament fibers and non-absorbable polyethylene terephthalate (PET) fibers. The implant is easy-to-handle, pliable, nonfriable, and porous in both the dry and hydrated state.

HOW SUPPLIED
The Integrity Implant is provided sterile, for single use only, in multiple sizes in a thermoformed tray with peelable lid and outer polymer packaging. DO NOT use if package is damaged or if labeling is incomplete or illegible.

INTENDED USE
The Integrity Implant is a medical device intended for the management and protection of tendon injuries.

INDICATIONS FOR USE
The Integrity Implant is intended for the management and protection of tendon injuries in which there has been no substantial loss of tendon tissue.

CONTRAINDICATIONS
The Integrity Implant is not designed, sold, or intended for use except as described in the indications for use and is contraindicated in the following situations:

- To replace damaged tendon or to reinforce the strength of any tendon repair.
- Use in the presence of infection.
- Conditions which would limit the patient's ability or willingness to restrict activities or follow direction during the healing period.
- For patients with hypersensitivity to the product components.

Contraindications may be relative or absolute and must be carefully weighed against the patient's entire evaluation

WARNINGS
- Discard any open, unused product.
- Do not use after the expiration date.
- It is the surgeon's responsibility to be familiar with the appropriate surgical techniques prior to the use of this device.
- Do not attempt to trim or otherwise modify the Integrity Implant prior to implantation.

PRECAUTIONS
- Should be used immediately after opening of the pouch. Do not store the product in the tray once the pouch is opened.
- 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.
- The Integrity Implant should not be applied until bleeding and infection are controlled.
- Application of the Integrity Implant does not modify the postoperative treatment. The surgeon must determine motion and strength requirements according to standard practice.

POSSIBLE ADVERSE EFFECTS
The following are potential adverse events that may occur from the surgical procedure or complications with the device:
- Allergic Reaction
- Infection
- Pain

MRI SAFETY INFORMATION
The Integrity Implant is MRI Safe.

INSTRUCTIONS FOR USE
1. Follow standard procedures for treatment of the injured tendon.
2. Determine the tendon width in millimeters (mm) using a suitable measuring instrument.
3. Select an Integrity Implant size that is appropriate for the intended anatomy.
4. Place the implant over the tendon in the desired location to augment the tendon repair.
5. Secure the Integrity Implant to the tendon or tendon/bone by applying fixation at least 2 mm from the outer edge. If using Integrity Bone Staple, apply approximately 4mm from the edge of the Implant. Ensure that the implant is in good contact with the tendon.
6. Close the incision in standard fashion.

STORAGE
- Keep dry.
- Store in a cool and dry place at room temperature.
- 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 red. In the event of a temperature breach, the indicator window will turn from white to red.

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 any questions about product availability in your area.

Please refer to the electronic IFU for the most recent and full version. https://www.anikaifu.com/

IFU: AML-3000153 REV-G

Instructions For Use *Continued*

Integrity Bone Staple

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 Instrument and provides fixation of soft tissue grafts or reinforcement meshes to bone. The Integrity™ Bone Staples are provided sterile for single-use only and are packaged in a caddy for placement and presentation.

HOW SUPPLIED
The Integrity™ Bone Staples are provided sterile for single-use only and are packaged in a caddy within a dual sterile seal packaging configuration. The caddy may also contain other implants, including Tissue Tacks. The Delivery Instrument is packaged separately and provided sterile for single use only. Contents of each 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 approximately 4 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.
- Insertion of Integrity™ Bone Staples 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.

POSSIBLE ADVERSE EFFECTS
The following are potential adverse events that may occur from the surgical procedure or complications with the Integrity™ Bone Staple or associated Delivery Instrument:
- Allergic Reaction
- Infection
- Pain
- Device may not function as intended.

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Please refer to the electronic IFU for the most recent and full version. https://www.anikaifu.com/

IFU: AML-3000171 REV-C

Instructions For Use *Continued*

Integrity Tissue Tack

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 Instrument and provides fixation of a prosthetic or biologic material 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.

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 caddy may also contain other implants, including Integrity™ Bone Staples. The Delivery Instrument is packaged separately and is 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 Instrument 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.

POSSIBLE ADVERSE EFFECTS
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.

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IFU: AML-3000170 REV-D

Instructions For Use *Continued*

Deployment Skid Cannula Access Tool

DESCRIPTION
The Deployment Skid Cannula Access Tool (Skid) is a reuseable surgical stainless steel cannula access tool, designed to facilitate passage of delivery instruments and implants through commercially available non-rigid arthroscopic cannulas. The device is a semi-circular partial tube that can be inserted into the proximal opening of a cannula to open or bypass fluid control valves so that Anika instruments and implants can pass more easily into the arthroscopic surgical site. The Skid is rounded and blunted distally to avoid damage to the cannula and valves. These instruments are designed for repeated use, with proper care and handling.

INSTRUCTIONS FOR USE
Prior to surgery, confirm that the 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 Skid into distal opening of non-rigid cannula. Advance slowly allowing the distal tip of the Skid to center on valve construct. Continue advancing to dilate and open valve. Fluid flow out of the cannula will temporarily increase as valve is opened. Pass instruments and implants through the passage created by the Skid. Remove Skid to allow 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.

WARNINGS AND PRECAUTIONS
This product is provided NON-STERILE. The product must be properly cleaned and sterilized before each use. Remove and discard any plastic shipping materials before cleaning and sterilizing the instruments. The surgeon shall be thoroughly familiar with the implants, instruments, and surgical technique prior to performing the procedure. The Skid should be regularly inspected for any signs of wear or damage.

CLEANING
Cleaning the Skid by hand rather than by mechanical cleaning will prolong the life of the instrument. Clean all surfaces and crevices, of all debris, using a soft bristle brush or cleaning stylet. Remove all traces of blood or other residues immediately. Do not allow these to dry. The Skid should be cleaned while submerged in warm water with an appropriate neutral pH detergent. Always follow the manufacturer's instructions when preparing and using detergents. Do not use steel brushes as they can accelerate wear and corrosion of the instrument. Rinse instrument thoroughly with distilled water. Dry instrument immediately after cleaning.

STERILIZATION
Recommended parameters for steam sterilization are as follows:

Cycle	Temperature	Minimum Exposure Time
Vacuum	270° F/ 132° C	4 minutes

Recommended dry time is 30 minutes.

Parameters may vary based on manufacturer, installation, or maintenance of sterilization equipment. On-going testing must be performed by the user to confirm inactivation of all forms of microorganisms.

The Skid should be processed in double wrapped configuration using an FDA (or applicable regulatory agency) cleared sterilization wrap. Sterilizing in liquid solutions is not recommended.
Do not sterilize at temperatures greater than 275° F/ 135° C.

Note: Anika does not define the maximum number of uses appropriate for reusable instruments. The useful life of these devices depends on many factors, including the method and duration of each use and handling between uses. Careful inspection and functional test of the instrument before use is the best method of determining the end of useful life.

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 any questions about product availability in your area.

Please refer to the electronic IFU for the most recent and full version. https://www.anikaifu.com/

IFU: AML-3000184 REV-A

FDA Clearance *Integrity Implant*

U.S. FOOD & DRUG ADMINISTRATION

June 17, 2025

Anika Therapeutics, Inc.
Shajunath Nirupama
Sr. Regulatory Affairs Specialist
32 Wiggins Ave
Bedford, Massachusetts 01730

Re: K250997
Trade/Device Name: Integrity™ Implant
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: OWX
Dated: April 21, 2025
Received: April 22, 2025

Dear Shajunath Nirupama:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

CHRISTOPHER FERREIRA -S

Christopher Ferreira, MS
Assistant Director
DHT6C: Division of Restorative, Repair and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

FDA Clearance *Integrity Bone Staple Fixation System*

U.S. FOOD & DRUG ADMINISTRATION

May 22, 2023

Anika Therapeutics Inc.
Shajunath Nirupama
Sr. Regulatory Affairs Specialist
32 Wiggins Avenue
Beford, Massachusetts 01730

Re: K223860
Trade/Device Name: Integrity™ Bone Staple Fixation System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI
Dated: May 4, 2023
Received: May 5, 2023

Dear Shajunath Nirupama:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal

statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Sara S. Thompson -S

For

Yu-Chieh Chiu, Ph.D.
Acting Assistant Director
DHT6C: Division of Restorative, Repair, and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

FDA Clearance *Integrity Tissue Tack Fixation System*

FDA U.S. FOOD & DRUG ADMINISTRATION

May 8, 2023

Anika Therapeutics, Inc.
Shajunath Nirupama
Sr. Regulatory Affairs Specialist
32 Wiggins Avenue
Bedford, Massachusetts 01730

Re: K222487
Trade/Device Name: Anika Tissue Tack Fixation System
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable Staple
Regulatory Class: Class II
Product Code: GDW
Dated: August 15, 2022
Received: August 17, 2022

Dear Shajunath Nirupama:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

U.S. Food & Drug Administration
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Silver Spring, MD 20993
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requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mark Trumbore -S

Digitally signed by Mark Trumbore -S
Date: 2023.05.08 11:03:49 -04'00'

Mark Trumbore
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Medical Education & Support

The mission of our Medical Education program is to connect health care providers through meaningful education by providing them with the knowledge, skills and tools to restore active living in their patients.

Tailored programs to support practice advancement

Our medical education programs are designed to provide clinicians with focused and flexible modalities, in-depth education on products and techniques, and interactive exchanges with other thought leaders.

Example programs include:

- National courses and labs, lead by renowned faculty, on various orthopedic concepts.
- Surgeon to Surgeon (S2S) discussions on techniques, clinical evidence and products.
- Didactic and hands on experiences with thought leaders on current topics.
- Localized sawbones or cadaveric instruction labs designed to fit your schedule and patient needs.

Contact us at **MedEd@anika.com** or reach out to your Regional Director, Sales Manager or Local Anika Representative to learn about upcoming events or to schedule a one-on-one demonstration.

Customer Service & Support

We value our customers and are committed to providing quality support services. Whether it's placing orders, answering billing questions, providing cross references or sharing other documentation, our dedicated Customer Service Specialists are available and ready to assist you.

Anika Customer Service: 1-888-721-1600

Packaging, Sterilization, and Ordering Information

Implants

The Integrity Implant is provided sterile, for single use only, in a thermoformed tray with peelable lid and outer polymer packaging. The current shelf-life is 1 year.

The fixation implant devices (bone staples and tissue tacks) are provided sterile for single-use only and are packaged in a caddy within a dual sterile seal configuration. The current shelf-life of the fixation implants is 1 year. Store at room temperature: <40°C.

Single-Use Instruments

The bone staple delivery instrument, tissue tack delivery instrument, and cannula/obturator are provided sterile and are for single use only. The current shelf-life is 1 year. Store at room temperature: 59°F (15°C) to 86°F (30°C).

Reusable Instrument

The deployment skid is a reuseable surgical stainless steel cannula access tool, and is provided NON-STERILE. The product is designed for repeated use and must be properly cleaned and sterilized before each use. Steam sterilization vacuum cycle at a temperature of 270° F/ 132° C for 4 minutes is recommended, with a dry time of 30 minutes.

Ordering Information

Integrity Implants	
6000100	20x25mm Integrity Implant
6000101	25x30mm Integrity Implant
6000113	25x60mm Integrity Implant
6000114	40x60mm Integrity Implant
Implant Fixation Kit	
6000102	Integrity Implant Fixation Kit, including PEEK Bone Staples and PLGA Tissue Tacks
Single-Use Instruments	
6000118	Integrity Delivery Instrument, Bone Staple
6000120	Integrity Delivery Instrument, Tissue Tack
6000122	Integrity Cannula/Obturator Kit
Reusable Instrument	
6000128	Deployment Skid Cannula Access Tool

Packaging Examples

Integrity Implant

Implant Fixation Kit

References

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11. Data on file. Walsh, W.R. Rotator cuff healing with Anika technology: 6 and 12 weeks. SORL Protocol: ANI2021-5. 2022.
12. Schlegal, T. F., M.D. (2017). Radiologic and clinical evaluation of a bioabsorbable collagen implant to treat partial-thickness tears: A prospective multicenter study. Journal of Shoulder and Elbow Surgery. https://doi.org/10.1016/j.jse.2017.08.023
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