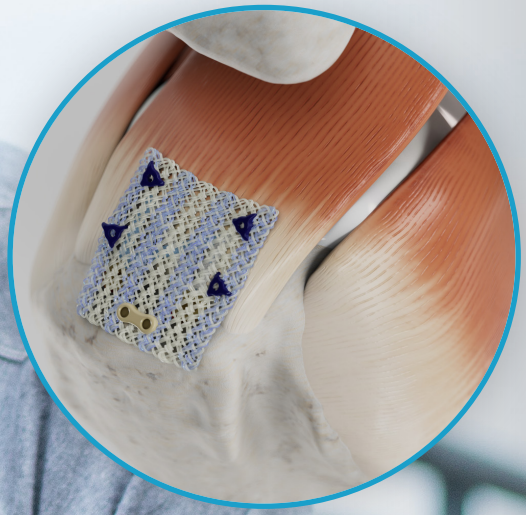
ANIKA

Integrity™

Implant System

Value Analysis Committee Brochure



ANIKA
Regenerative Solutions

ANIKA

Anika is a global joint preservation company that creates and delivers meaningful advancements in early intervention orthopedic care. We partner with clinicians to understand what they need most to treat their patients and we develop minimally invasive products that restore active living for people around the world.

We are committed to leading in high opportunity spaces within orthopedics, including osteoarthritis pain management, regenerative solutions, sports medicine, and Arthrosurface.

Anika. Restore Active Living.®

Table of Contents

Product Introduction 4

Material Science 5

Biological Role of Endogenous Hyaluronic Acid 6

Strength and Porosity 7

Components 8-10

Surgical Technique Approaches 11

Preclinical Data 12

Competitive Information 13

Reimbursement 14-15

Instructions for Use 16-21

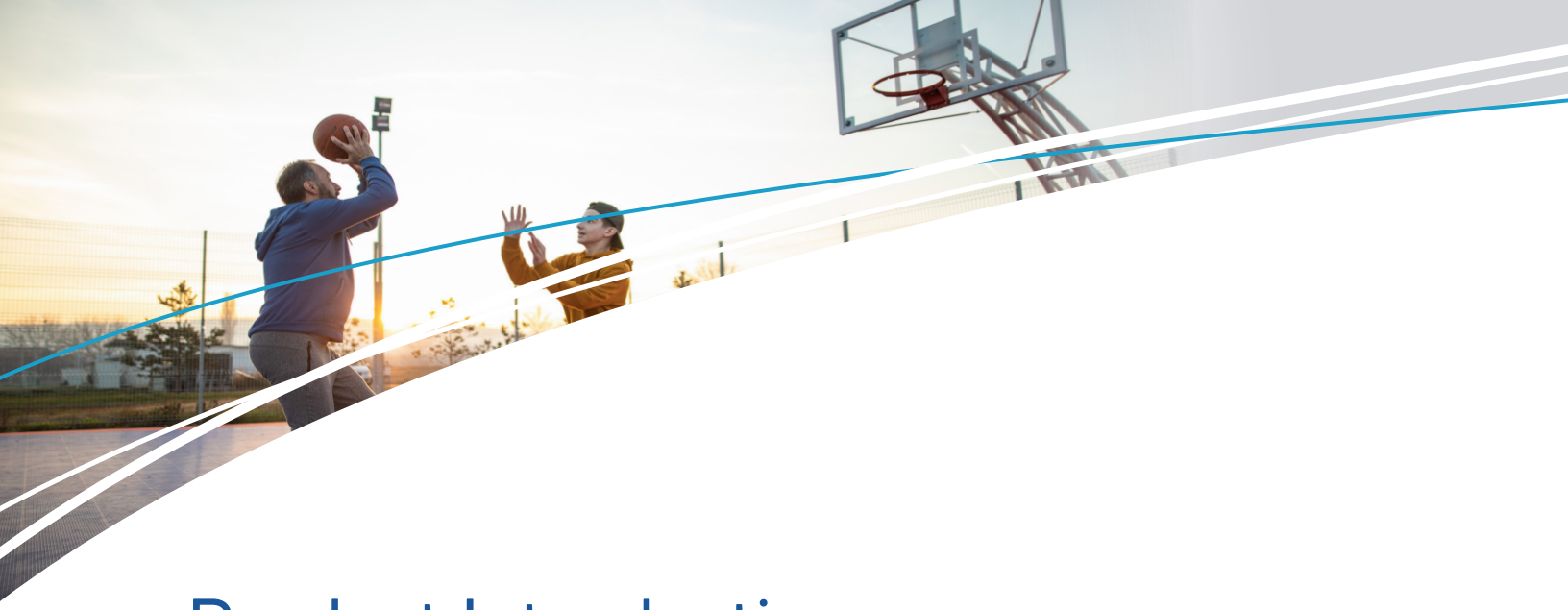
FDA Clearance 22-27

Medical Education 28

Services and Support 29

Packaging, Sterilization, and Ordering Information 30

References 31



Product Introduction

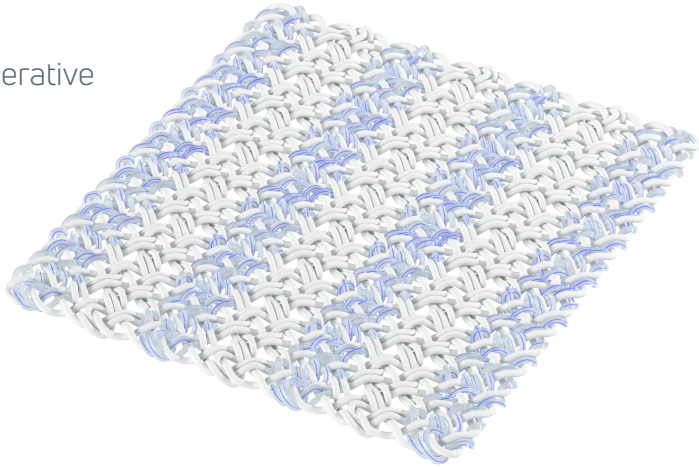
The Anika Integrity Implant is a synthetic scaffold for rotator cuff repair that provides reliable strength, regenerative biology and a streamlined, precise technique

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]

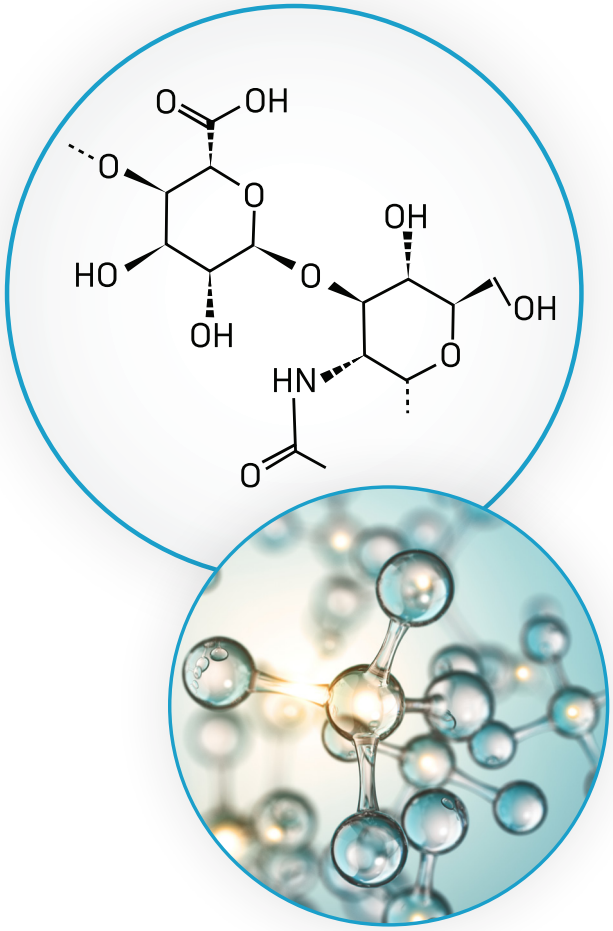
PET (Polyethylene terephthalate)[7]

- 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]

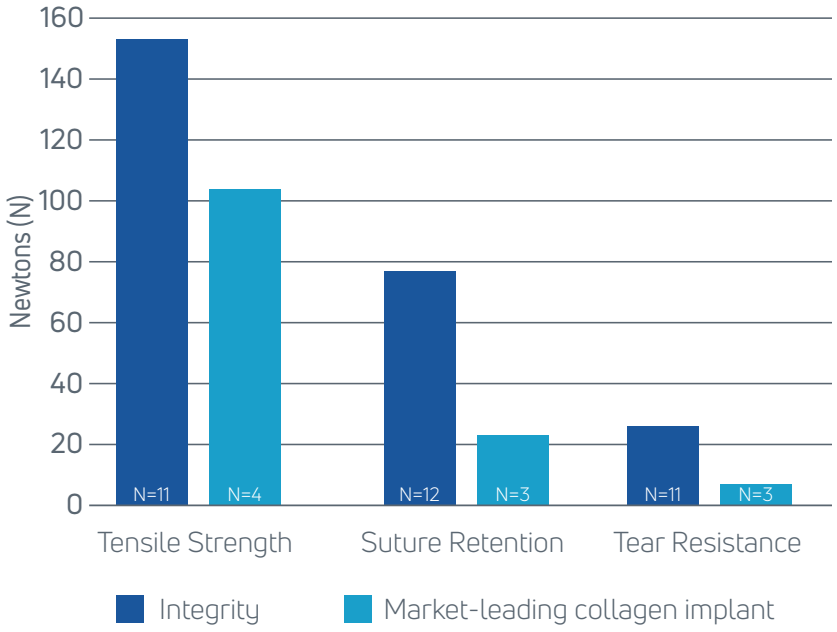


At a Macroscopic Level

- 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

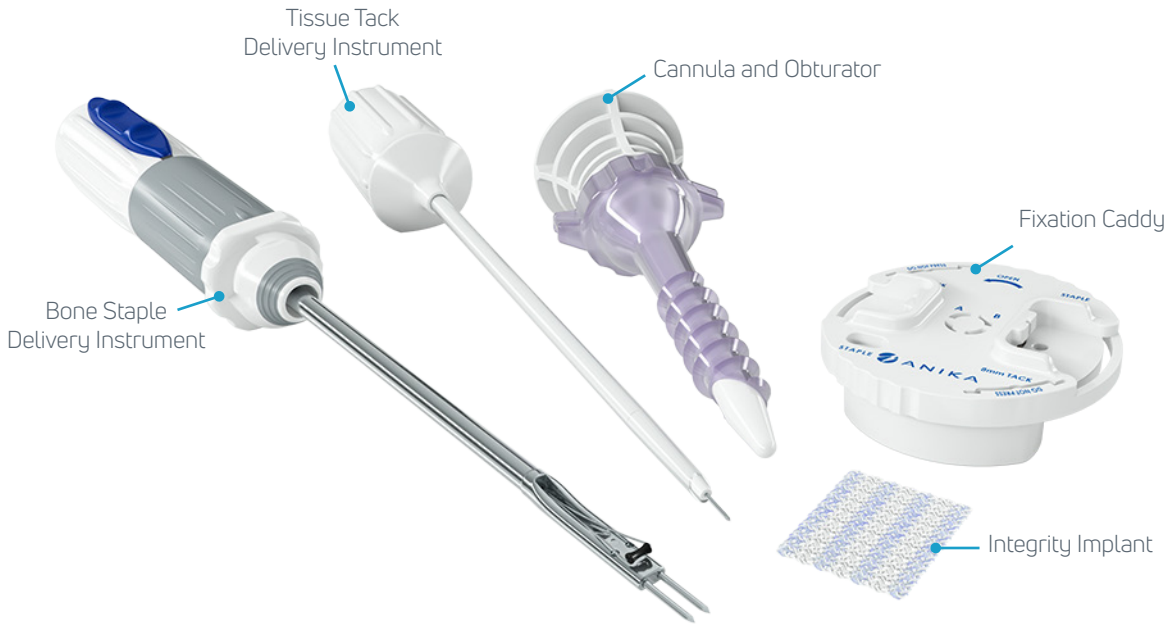
A porous structure optimizes the interaction between the implant and the native cells to aid in the tissue regeneration process.

Scanning electron microscope (SEM) image. 100x magnification

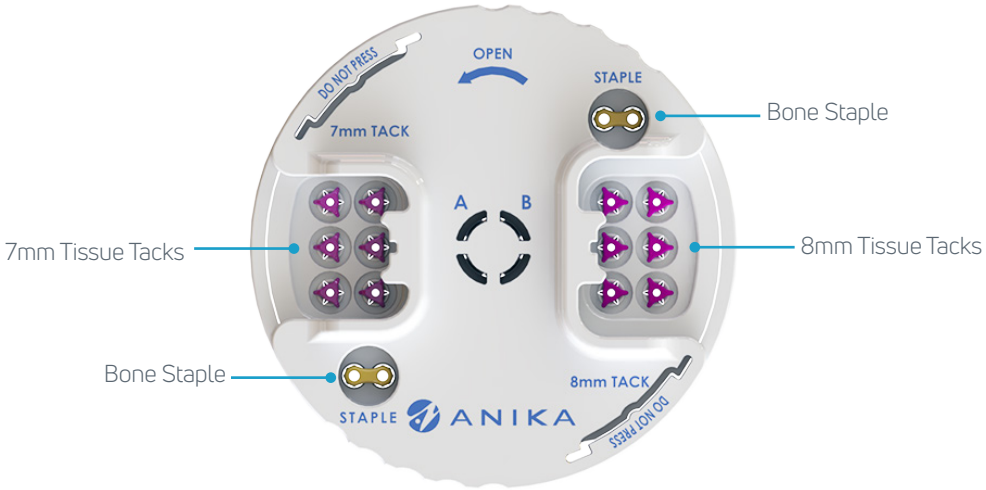
At 100x magnification, the Integrity Implant exhibits excellent porosity.[11]

Components

Integrity Implant System Overview



Implant Fixation Kit



Open Caddy

Integrity Implant

Material

80% HYAFF 20% PET

Structure

Flexible knitted structure provides additional:

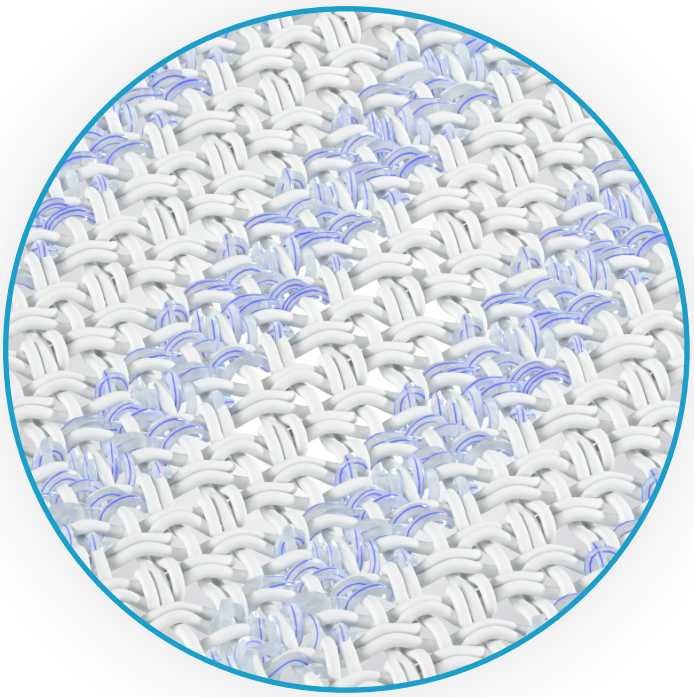
- Tensile/shear strength
- Tear resistance
- Suture retention strength

Edges

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

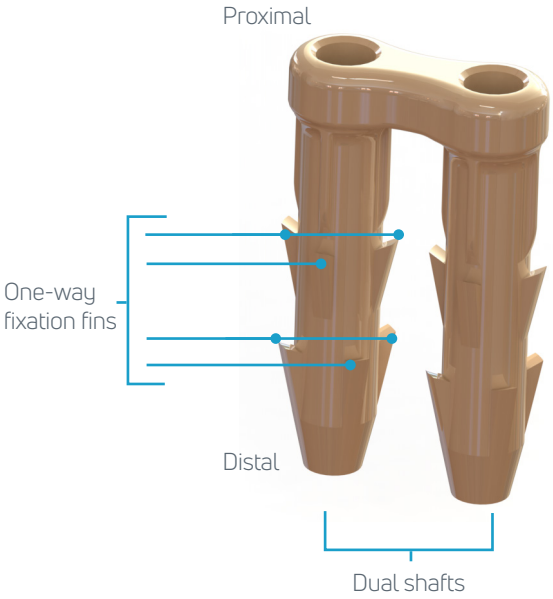
Dimensions

- Available in two sizes: 20x25mm, 25x30mm
- 0.75mm nominal thickness



Components

Bone Staple



Material

- PEEK (polyether ether ketone)

Structure

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

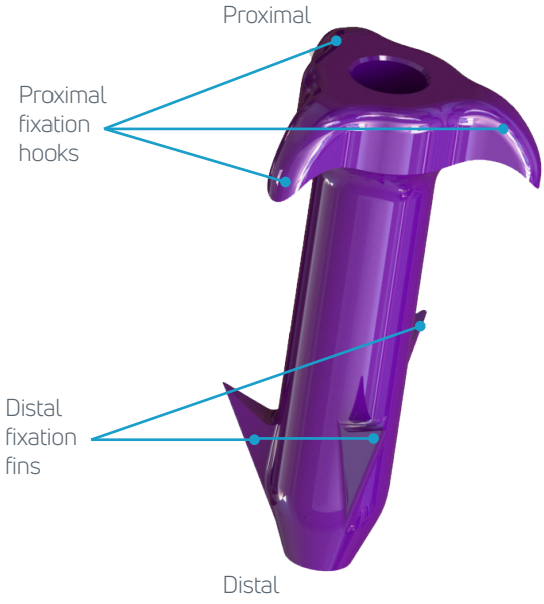
Fixation Fins

- 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

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.

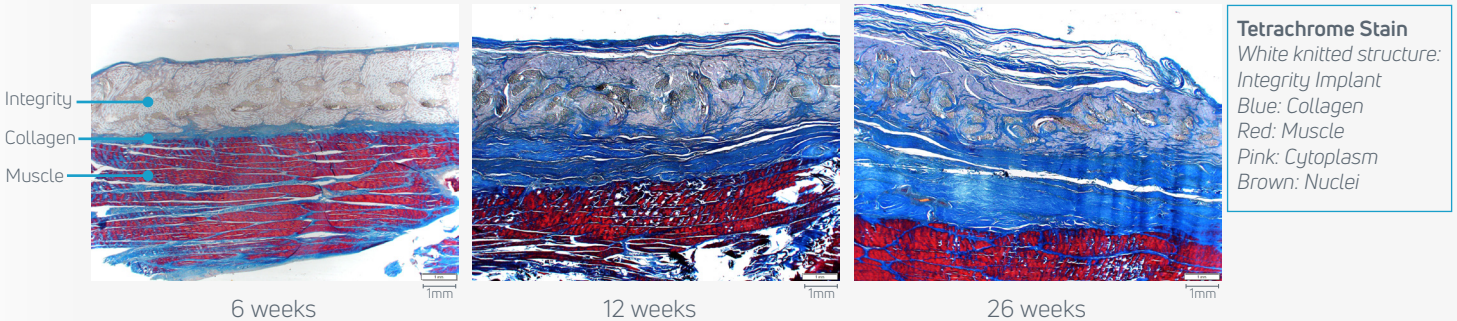
An ovine model was chosen for this study as it has been demonstrated as an appropriate model for the purpose of assessing device interactions with host tissue in different sites and is applicable to use in humans. The products tested were Anika's Integrity Implant, the market-leading collagen implant 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	✓	✓	✗	✗	✗
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 Reimbursement

CPT Code[i]	Description	2024 Medicare Physician Payment[ii]	2024 OPPS (APC Payment & Status Indicator)[iii]	ASC (Payment Indicator & Payment Rate)[iv]	2024 Inpatient (MS-DRG & Payment)[v]
Subscapularis/Rotator Cuff					
23410	Repair of ruptured musculo-tendinous cuff (eg, rotator cuff) open; acute	$836.67	J1 $6,614.63	A2 $3,137.69	DRG 512 $10,318.28*
23412	Repair of ruptured musculo-tendinous cuff (eg, rotator cuff) open; chronic	$868.87	J1 $6,614.63	A2 $3,137.69	DRG 512 $10,318.28*
23420	Reconstruction of complete shoulder (rotator) cuff avulsion, chronic (includes acromioplasty)	$992.56	J1 $6,614.63	A2 $3,137.69	DRG 512 $10,318.28*
29827	Arthroscopy, shoulder, surgical; with rotator cuff repair	$1,086.08	J1 $6,614.63	A2 $3,137.69	DRG 512 $10,318.28*
23939	Unlisted procedure, shoulder	Carrier Priced	T $207.01	IO	DRG 512 $10,318.28*

Foot & Ankle Reimbursement

CPT Code[i]	Description	2024 Medicare Physician Payment[ii]	2024OPPS (APC Payment & Status Indicator)[iii]	ASC (Payment Indicator & Payment Rate)[iv]	2024 Inpatient (MS-DRG & Payment)[v]
Achilles					
27650	Repair, primary, open or percutaneous, ruptured Achilles tendon;	$669.95	J1 $6,614.63	A2 $3,137.69	DRG 501 $8,840.68*
27652	Repair, primary, open or percutaneous, ruptured Achilles tendon; with graft (includes obtaining graft)	$672.32	J1 $6,614.63	J8 $4,159.83	DRG 501 $8,840.68*
27654	Repair, secondary, Achilles tendon, with or without graft	$726.54	J1 $6,614.63	J8 $4,152.61	DRG 501 $8,840.68*
27899	Unlisted procedure, leg or ankle	Carrier Priced	T $207.01	IO	DRG 501 $8,840.68*

Reimbursement Hotline Contact Information:

1-800-436-1377
USReimbursement@anika.com

i. CPT® is a registered trademark of the American Medical Association (AMA). Copyright 2023 AMA. All CPT codes are owned and licensed by the American Medical Association
ii. https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices Addendum B: CY 2023 Relative Value Units (RVUs) and related information used in determining final Medicare payments
iii. https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/addendum-a-b-updates
iv. https://www.cms.gov/medicare/payment/prospective-payment-systems/ambulatory-surgical-center-asc/asc-payment-rates-addenda
v. https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps

Instructions For Use

Integrity Implant

DESCRIPTION
The Integrity Implant is designed to provide an augmentation layer over an injured tendon. The patch is comprised of a knitted porous mesh of resorbable Hyaff-11 P100 TBA multifilament fibers and non-absorbable poly (ethylene terephthalate) [PET] multifilament fibers of a single composite layer of resorbable Hyaff-11 multifilament fibers and non-absorbable poly (ethylene terephthalate) [PET] fibers. The implant is an easy-to-handle, pliable, nonfriable, porous patch 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

- U.S. Federal Law restricts this device to sale by or on the order of a physician.
- 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
- Device may not function as intended.

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 a Integrity Implant size that is slightly smaller than the width of the tendon.
4. Place the implant over the tendon in the desired location to augment the tendon repair.
5. Secure the Integrity Implant to the tendon and bone by applying fixation at least 2 mm from the outer edge. Ensure that the implant is in good contact with the tendon.
6. Close the incision in standard fashion.

STORAGE

- Keep dry.
- Store at room temperature: <40C.
- Avoid temperatures more than 113°F (45°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-C

Instructions For Use

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 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.

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

IFU: AML-3000171 REV-B

Instructions For Use

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 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.

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.

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-3000170 REV-B

FDA Clearance *Integrity Implant*

U.S. FOOD & DRUG ADMINISTRATION

August 17, 2023

Anika Therapeutics, Inc.
Wei Zhao
Executive Director, Regulatory Affairs
32 Wiggins Ave.
Bedford, Massachusetts 01730

Re: K223538
Trade/Device Name: Integrity™ Implant
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: OWX
Dated: July 18, 2023
Received: July 18, 2023

Dear Wei Zhao:

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

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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,

Jesse Muir -S

Jesse Muir, Ph.D.
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.

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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.

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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*

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.

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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

Anika Medical Education's mission 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

Anika 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.

Examples program includes:

- National courses and labs, lead by renowned faculty, on various orthopedic concepts.
- Visiting Surgeon Programs (VSPs) that provide surgical observation within an experts operating room.
- 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 medicaleducation@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.

Services and Support

Customer Service

Anika values our customers and is 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

Medical Services and Support

Our Medical Services and Support center was created to assist our customers in today's evolving healthcare environment. This unique support team provides technical and clinical information on procedures involving Anika products and/or other inquiries. Our support staff consists of knowledgeable health professionals, including surgeons, prepared to answer your questions and address your resource needs.

Anika Medical Services and Support: 1-888-721-1600

Reimbursement Hotline

Anika has partnered with reimbursement experts at MCRA to provide a dedicated hotline for reimbursement and coding questions. MCRA's coding, reimbursement, and compliance experts have over 50 years of combined healthcare policy and finance services experience, and have a proven track record servicing over 250 clients nationwide. The Anika dedicated hotline is available via phone or email and inquiries should expect a response within 24hrs. All coding inquiries are answered by a credentialed, coding specialist.

Contact Information:

MCRA Phone: 800-436-1377

MCRA Email: USReimbursement@anika.com

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.

Instruments

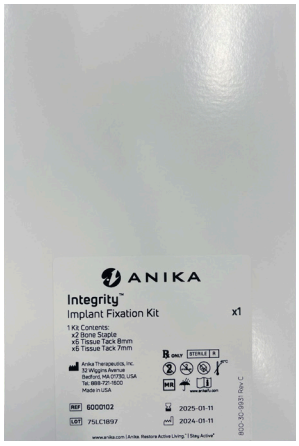
The delivery devices are provided sterile for single use only. The current shelf-life is 1 year.

Store at room temperature: 59°F (15°C) to 86°F (30°C).

Packaging

Integrity Implant

Implant Fixation Kit



Delivery Instrument, Bone Staple

Ordering Information

Implants	
6000100	20x25mm Integrity Implant
6000101	25x30mm Integrity Implant

Implant Fixation Kit	
6000102	Integrity Implant Fixation Kit, including PEEK Bone Staples and PLGA Tissue Tacks

Instruments	
6000118	Integrity Delivery Instrument, Bone Staple
6000120	Integrity Delivery Instrument, Tissue Tack
6000122	Integrity Cannula/Obturator Kit

Anika offers a comprehensive portfolio of soft tissue anchors in a broad range of size, material, and suture options. For additional information about Anika's product offerings, visit **www.anika.com** or contact your local sales representative.

References

1. Data on file, Anika Therapeutics, Inc.
2. Campoccia, Davide, et al. "Semisynthetic resorbable materials from hyaluronan esterification." Biomaterials 19.23 (1998): 2101-2127
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4. https://hyalofast.anikatherapeutics.com/product-information/key-features/
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6. https://anika.com/medical/products/hyalofast/
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8. Necas, J. B. L. B. P., et al. "Hyaluronic acid (hyaluronan): a review." Veterinarni medicina 53.8 (2008): 397-411.
9. Spicer, Andrew P., and Janet YL Tien. "Hyaluronan and morphogenesis." Birth Defects Research Part C: Embryo Today: Reviews 72.1 (2004): 89-108.
10. Zhang, Ling-Tao, et al. "Hyaluronic acid promotes osteogenic differentiation of human amniotic mesenchymal stem cells via the TGF-β/Smad signalling pathway." Life sciences 232 (2019): 116669.
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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
13. Cooper, Carol A., et al. "Inflammation and hyaluronic acid." Alternative & complementary therapies 14.2 (2008): 78-84.

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