ANIKA

Anika. *Restore Active Living.*™

X-Twist™ Fixation System

Rotator Cuff Repair

Value analysis committee | Product information kit

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, soft tissue repair and bone preserving joint technologies.

Anika. *Restore Active Living.™*

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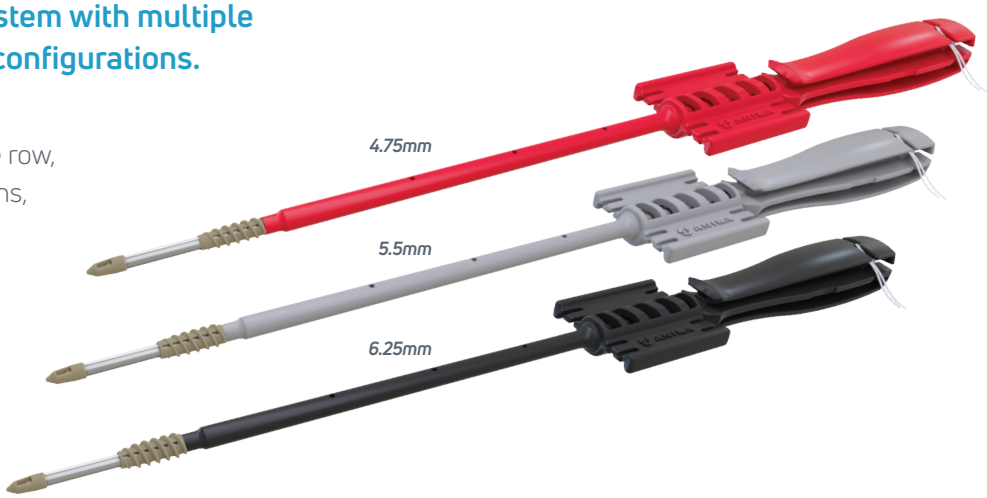
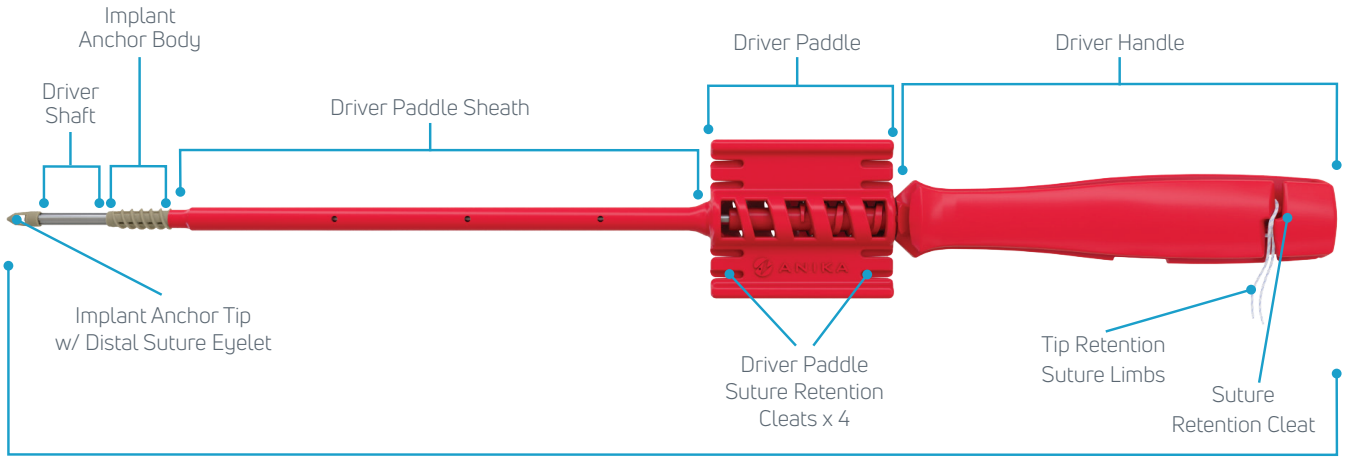
X-Twist Fixation System

The X-Twist™ is a knotless, open architecture, and fast inserting suture anchor system with multiple sliding suture and suture tape configurations.

The X-Twist system is designed for procedural versatility: single or double row, in medial and/or lateral row applications, and in both knotless and fully knotted constructs, to reproducibly and confidently repair soft tissue to bone.



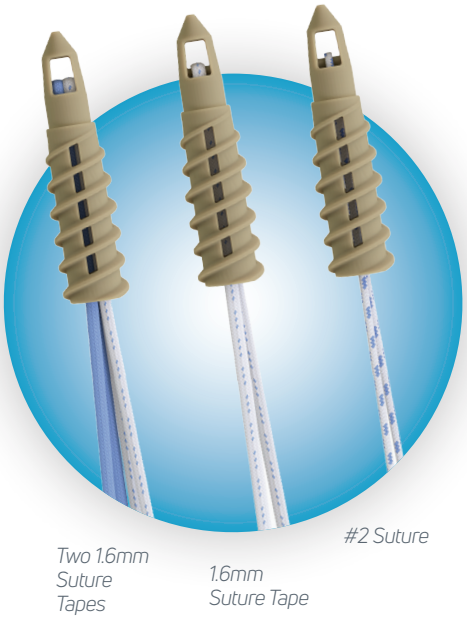


Anchor/Driver Assembly

Anchor Design

Feature	Details	Advantage
Distal eyelet	Accommodates four 2mm tapes plus three #2 sutures simultaneously	Multiple tapes/sutures maximize the surface area of tendon to bone compression, points of fixation, and load sharing to support a secure repair and potentially reduce the need for additional suture anchors
Anchor body	Double helix threaded design with high thread pitch	Requires fewer handle rotations for insertion than other suture anchors
Open architecture	Twenty, 1.4mm vents surrounding the anchor body	Intended to enhance marrow element flow to the repair site to support healing and support bony ingrowth for long-term stability
Fully threaded	Consistent bone to anchor purchase points across the anchor body	Provides purchase into cortical and cancellous bone resulting in a stable repair that resists micromotion and pullout

Ample distal eyelet and 20 vents surrounding the anchor body



Suture Options

Feature	Details	Advantage
Solid color and striped sutures	Solid: Blue, Black, White Striped: Blue/White, Black/White	Support intra-operative suture management
Sliding retention sutures	#2 suture or 1.6mm suture tape Can be incorporated into repair or discarded – as desired	Options for addressing patient specific needs. Multiple suture configurations may support O.R. standardization and control cost
Static suture tape	1.6mm or 2mm For medial row X-Twist anchor	Provides a broad footprint, maximizing the surface area of tendon to bone compression to support tendon integrity and healing to bone

Driver

X-Spline™ drive

- Unique "X" shaped spline drive geometry
- Holds anchor body securely to driver supporting accurate placement
- Provides over 2 times the torsional efficiency of a traditional hex drive design for reliable insertion, even in hard bone

Suture cleats on driver paddle

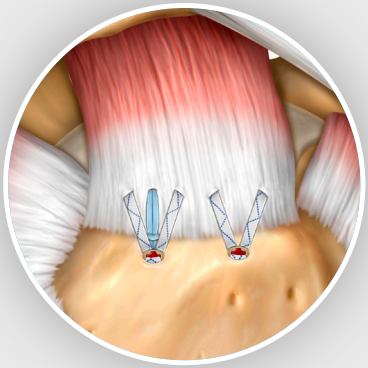
- 4 suture retention cleats
- Help organize suture limbs to prevent tangling

X-Spline drive provides over 2 times the torsional efficiency of traditional hex drive

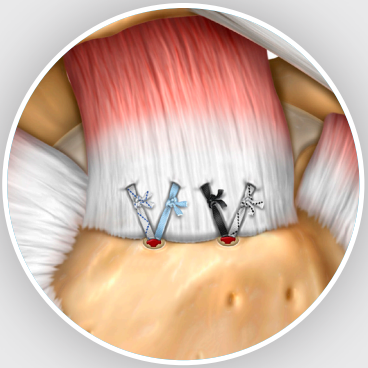
Repair Constructs

The versatile X-Twist system allows surgeons to continue to use their preferred method of fixation without making any changes to their current technique. The X-Twist can be used in a single or double row, in medial and/or lateral row applications, and in both knotless and fully knotted constructs minimizing the learning curve for this implant.

Single Row Repair

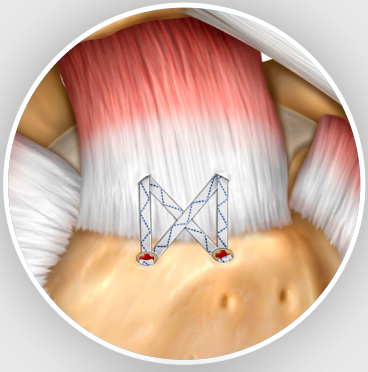


Knotless with inverted mattress stitch using 2mm suture tape, with and without a knotless rip-stop suture

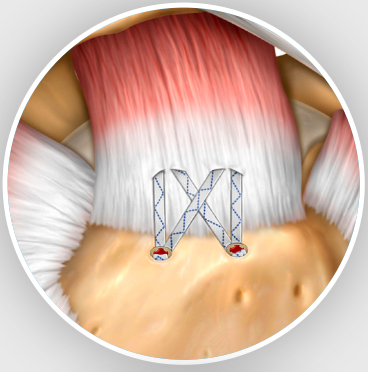


Knotted with 1.6mm suture tape

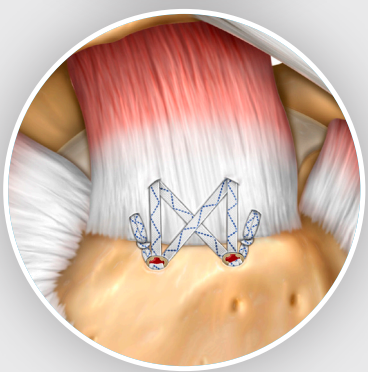
Double Row Bridge Repair



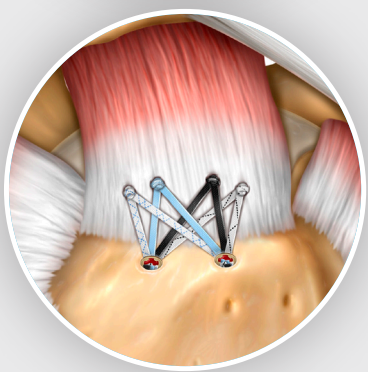
Knotless with two sets of 2mm suture tape and only two suture passes



Knotless with two sets of 2mm suture tape and four suture passes



Knotless with dog-ear reduction



Medially knotted with four sets of suture tape and a knotless lateral row

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:

Ambulatory Surgical Center/Outpatient Setting			
CPT Code	**Description**	**Ambulatory Payment Classification**	**ASC Payment Indicator**
23410	Repair of ruptured musculotendinous cuff (eg, rotator cuff) open; acute	5114	A2
23412	Repair of ruptured musculotendinous cuff (eg, rotator cuff) open; chronic	5114	A2
23420	Reconstruction of complete shoulder (rotator) cuff avulsion, chronic (includes acromioplasty)	5114	A2
29827	Arthroscopy, shoulder, surgical; with rotator cuff repair	5114	A2

Hospital Inpatient: Medicare Severity-Diagnosis Related Group (MS-DRG)	
MS-DRG	**Description**
510	Shoulder, Elbow or Forearm Procedure, Except Major Joint Procedure with MCC
511	Shoulder, Elbow or Forearm Procedure, Except Major Joint Procedure with CC
512	Shoulder, Elbow or Forearm Procedure, Except Major Joint Procedure without CC/MCC

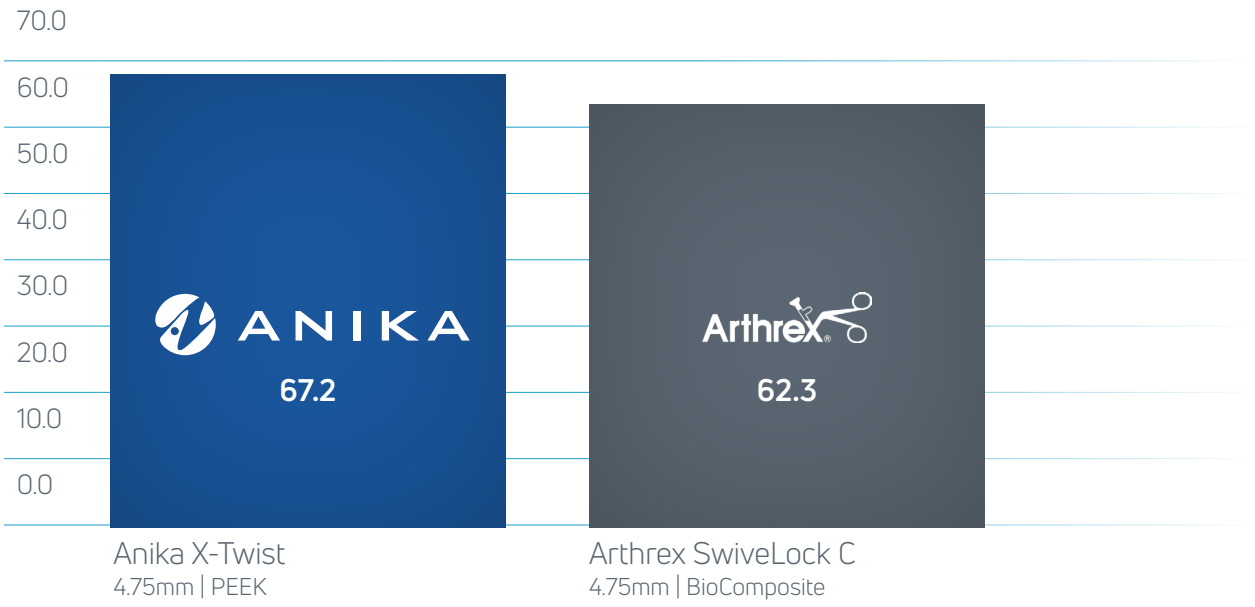
HCPCS (Healthcare Common Procedure Coding System)	
Code	**Description**
C1763	Connective tissue, non-human (includes synthetic)
C1713	Anchor/screw for opposing bone-to-bone or soft tissue-to-bone (implantable)

Bench Top Testing

The X-Twist PEEK anchor outperformed the Arthrex SwiveLock C BioComposite anchor in head-to-head testing for mean pullout strength.

- Preloaded with 2mm Suture Tape
- Straight Pull-Out Test
- 20/10 laminated foam block
  - Same medium Arthrex uses in marketing data & publications

Mean Pullout Strength (lbs)*



*Data on file.

Competitive Comparison

Feature	Anika X-Twist	Arthrex SwiveLock C
Distal Eyelet/Knotless Capactiy	Accommodates up to four 2mm tapes plus three #2 sutures	Accommodates two 2mm tapes plus two #2 sutures
Fenestrations	Twenty, 1.4mm vents surrounding the anchor body	BioComposite anchor has "pin hole" vents; PEEK anchor has larger fenestrations on two sides of the anchor body
Sliding Suture Tape Options	Available with sliding 1.6mm suture tape or double sliding 1.6mm suture tapes	No sliding suture tape options
Secondary Knotless Mechanism Option	No	Yes
Insertion	Fast - 3 ¼ turns	8 turns
Medial Row Anchors	Designed for one or multiple medial row suture tapes to be loaded through distal eyelet during surgery on the back table	Specific options preloaded with FiberTape Loop
Mechanical Performace (Mean Pullout Strength)	67.2 lbs	62.3 lbs
6mm Back-Up Implant	Yes - Fully functional X-Twist 6.25mm anchor	No - Adapted round headed 6.25mm Tenodesis screw without cortical engagement

Instructions For Use

DESCRIPTION OF DEVICE

The X-Twist PEEK Suture Anchor consists of an implantable anchor and anchor tip that are provided assembled to a driver. Retention suture(s) or suture tapes(s) are preloaded through the driver cannulation to secure the anchor tip onto the driver shaft. The anchor tip can be loaded with additional suture(s) or suture tapes(s) if needed for the intended surgical procedure. Clockwise rotation of the driver allows for advancement of the fully threaded anchor and anchor tip into the prepared bone socket to serve as the point of fixation for soft tissue repair.

INDICATIONS

The X-Twist PEEK Suture Anchors are indicated for attachment of soft tissue to bone. These products are intended for the following indications:

Shoulder: Rotator Cuff Repair, Acromioclavicular Separation Repair, Bankart Lesion Repair, Biceps Tenodesis, Capsular Shift or Capsulolabral Reconstruction, Deltoid Repair, SLAP Lesion Repair.

Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Posterior Oblique Ligament Repair, Extra Capsular Reconstruction, Iliotibial Band Tenodesis, Patellar Ligament and Tendon Avulsion Repair.

Foot/Ankle: Lateral Stabilization, Medial Stabilization, Midfoot Reconstruction, Achilles Tendon Repair, Hallux Valgus Reconstruction, Metatarsal Ligament Repair.

Elbow: Tennis Elbow Repair, Biceps Tendon Reattachment.

Hand/Wrist: Scapholunate Ligament Reconstruction, Ulnar or Radial Collateral Ligament Reconstruction, TFCC.

CONTRAINDICATIONS

1. Any active infection.
2. Blood supply limitations or other systemic conditions that may retard healing.
3. Foreign body sensitivity, if suspected, should be identified and precautions observed.
4. Insufficient quality or quantity of bone.
5. Patient's inability or unwillingness to follow surgeon's prescribed post-operative regimen.
6. Any situation that would compromise the ability of the user to follow the instructions for use or using the device for an indication other than those listed.

ADVERSE EFFECTS

1. Infection, both deep and superficial.
2. Allergies and other reactions to device materials.

WARNINGS

1. Caution: Federal Law restricts this device to sale by or on the order of a physician.
2. The fixation provided by this device should be protected until healing is complete. Failure to follow the postoperative regimen prescribed by the surgeon could result in the failure of the device and compromised results.
3. Size selection of the implant should be made with care taking into consideration the quality and quantity of bone into which the implant is to be placed.
4. In cases where bone quality is suspect, the 6.25 mm X-Twist PEEK Anchors should be used to maximize fixation strength. The 6.25 mm X-Twist PEEK Anchors may also be used in cases in which attempted insertion of a 4.75 mm or 5.5 mm PEEK Anchor does not offer satisfactory fixation strength.
5. Any decision to remove the device should take into consideration the potential risk of a second surgical procedure. Adequate postoperative management should be followed after implant removal.

6. Pre-operative planning and evaluation, surgical approaches and technique, and familiarity of the implant, including its instrumentation and limitations are necessary for achieving a good surgical result and minimizing the risks to patients associated with prolonged surgery time.
7. This device must never be reused. Reuse or re-sterilization may lead to changes in material characteristics such as deformation and material degradation which may compromise device performance. Reprocessing of single use devices can also cause cross-contamination leading to patient infection.
8. Insertion of the anchor off axis from the hole may result in implant failure.
9. Failure to insert the driver to the depth indicated by the laser mark may result in the anchor being left proud which could cause soft tissue irritation and pain.
10. Appropriate instrumentation should be used to implant this device.

MRI SAFETY INFORMATION

- The implantable portion of this device is MR Safe.

PACKAGING AND LABELING

- Do not use this product if the packaging or labeling has been damaged, shows signs of exposure to moisture or extreme temperature, or has been altered in any way.
- Please contact Parcus Medical Customer Service to report any package damage or alterations.

STERILIZATION

- This device is supplied in sterile packaging. The contents are sterilized by EO gas. This device must never be re-sterilized.
- The reusable instrumentation used in conjunction with the X-Twist PEEK products shall be cleaned and/or sterilized only in accordance with the Instructions for Use included with those devices.

STORAGE

- Products must be stored in the original unopened package in a dry place and must not be used beyond the expiration date indicated on the package.

MATERIAL SPECIFICATIONS

- X-Twist PEEK Suture Anchor Body and Tip: The implantable portion of this device is polyetheretherketone (PEEK) and UHMWPE.
- Suture/suture tape (as applicable): This device may be provided with non-absorbable, sterile, surgical suture products composed of ultra-high molecular weight polyethylene (UHMWPE). The suture or suture tape may be provided undyed (white), dyed blue, dyed black or with trace filaments of black nylon, blue PET, or green PET. Suture products may be provided with stainless steel needles, heat-tipped ends, or tipped ends using cyanoacrylate.
- Inserter Shaft: Stainless Steel. This component is for single use and is not intended to be implanted. It is radio-opaque and can, therefore, be detected with conventional X-Ray or fluoroscopy.
- Inserter Handle: Acrylonitrile butadiene styrene (ABS). This component is for single use and intended for transient use.
- Suture Threader: Nitinol and stainless-steel. This component is for single use and not intended for invasive use.

SPECIFIC INSTRUCTIONS FOR USE

When applicable, see the corresponding surgical technique for additional information.

- X-Twist PEEK Suture Anchors:
  - This device is designed such that sutures will be placed through the distal eyelet in the PEEK tip and will be secured when the anchor is advanced into the prepared socket. The distal eyelet of the X-Twist PEEK Anchors will accommodate up to six (6) strands of 1.6 mm suture tape, #2 suture, or a combination thereof.

FDA Clearance

May 19, 2022

Parcus Medical LLC
Calen Souther, MS
Senior Specialist, Regulatory Affairs
6423 Parkland Drive
Sarasota, Florida 34243

Re: K221135
Trade/Device Name: X-Twist PEEK Suture Anchor
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI
Dated: April 15, 2022
Received: April 19, 2022

Dear Calen Souther:

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

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www.fda.gov

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:

Laura C. Rose, 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

Medical Education

Anika Therapeutics is committed to providing you with quality medical education programs.

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 health leaders.

Examples of program content includes:

- Surgical instruction from expert surgeons
- Peer to peer discussion of current practices, products and techniques
- Dialog with thought leaders on critical topics
- Didactic and hands on experiences
- Localized sawbones or cadaveric instruction designed to fit your schedule and patient needs

Contact your local Anika Representative to learn about upcoming events or schedule a one-on-one demonstration.

Services and Support

Our commitment

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 Sports Medicine Customer Service: 1-877-746-2972

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 to provide our customers with answers to critical reimbursement questions. To access this service, simply call our main customer service line to schedule a discussion with one of our reimbursement experts.

Anika Customer Service: 1-888-721-1600

Packaging and Sterilization

Implants

X-Twist Fixation System implants are individually packaged and are sterile.
The shelf-life is five years.

Instrument Tray

There is an X-Twist Fixation System instrument tray. The instrument tray is provided non-sterile.

The reusable instrumentation used in conjunction with the X-Twist PEEK products shall be cleaned and sterilized only in accordance with the Instructions for Use included with those devices.

Packaging

Instrument Tray

Ordering Information

X-Twist Screw-In Suture Anchors				
Part #	Diameter (mm)	Length (mm)	Description	Material
XT24700	4.75	23	X-Twist PEEK 4.75mm, w/1, #2 suture (blu/wht)	PEEK
XT24701	4.75	23	X-Twist PEEK 4.75mm, w/1, 1.6mm suture tape (blu/wht)	PEEK
XT24702	4.75	23	X-Twist PEEK 4.75mm, w/2, 1.6mm suture tapes (blu, blu/wht)	PEEK
XT24703	4.75	23	X-Twist PEEK 4.75mm, w/2, 1.6mm suture tapes (blk, blk/wht)	PEEK
XT25500	5.5	23	X-Twist PEEK 5.5mm, w/1, #2 suture (blu/wht)	PEEK
XT25501	5.5	23	X-Twist PEEK 5.5mm, w/1, 1.6mm suture tape (blu/wht)	PEEK
XT25502	5.5	23	X-Twist PEEK 5.5mm, w/2, 1.6mm suture tapes (blu, blu/wht)	PEEK
XT25503	5.5	23	X-Twist PEEK 5.5mm, w/2, 1.6mm suture tapes (blk, blk/wht)	PEEK
XT26200	6.25	23	X-Twist PEEK 6.25mm, w/1, #2 suture (blu/wht)	PEEK

X-Twist Instrumentation			
Part #	Description	Sterile/ Non-sterile	Single-use/ Reusable
XT04701	X-Twist 4.75-5.5mm awl	Non-sterile	Reusable
XT04700	X-Twist 4.75mm tap	Non-sterile	Reusable
XT05500	X-Twist 5.5mm tap	Non-sterile	Reusable
XT00001	X-Twist sterilization tray	Non-sterile	Reusable

Suture Tape			
Part #	Size (mm)	Description	QTY/ Box
20042	2	Parcus Braid® suture tape (wht/blu)	6
20042S	2	Parcus Braid suture tape (wht/blu)	1
20032S	1.6	Parcus Braid suture tape (wht/blu)	1
20034S	1.6	Parcus Braid suture tape (wht/blk)	1
20174S	1.6	Parcus Braid infinity loop (wht/blu) w/ straight needle	1

Notes

Notes

Anika Therapeutics, Inc.
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www.anika.com | Anika. Restore Active Living.™ | Stay Active®

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Sports Medicine