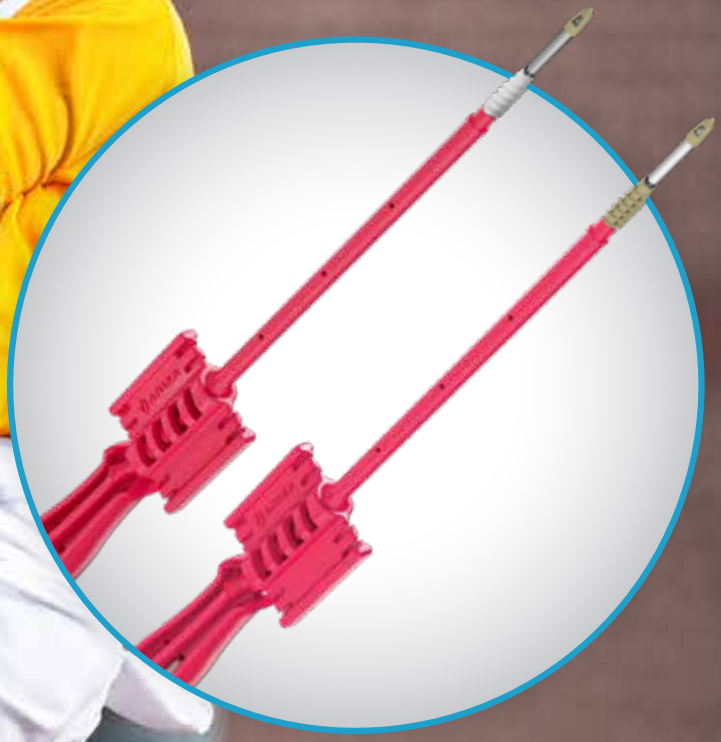
ANIKA

X-Twist™

Fixation System

Value Analysis Committee
Brochure



Simply Versatile

A system designed for reproducibility and confidence in soft tissue repair

ANIKA
Sports Medicine

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.®

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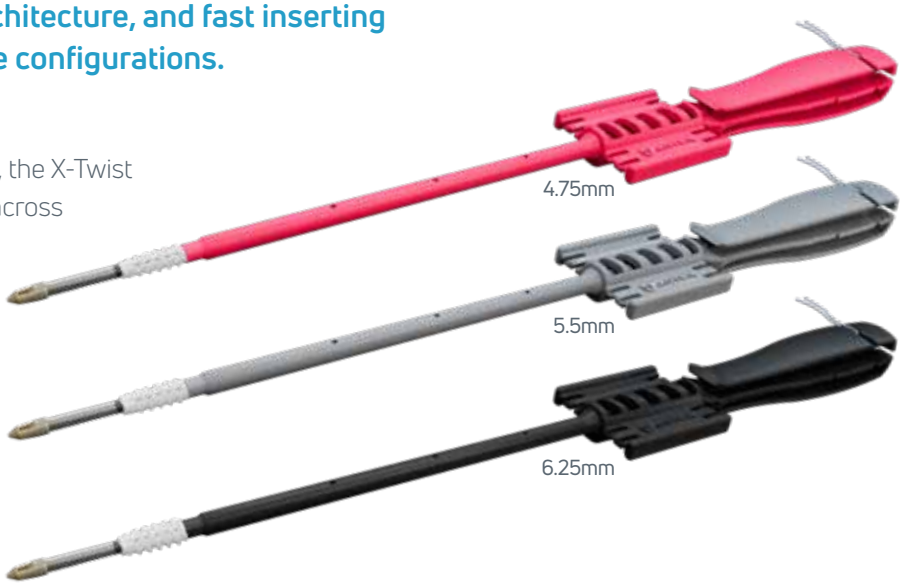
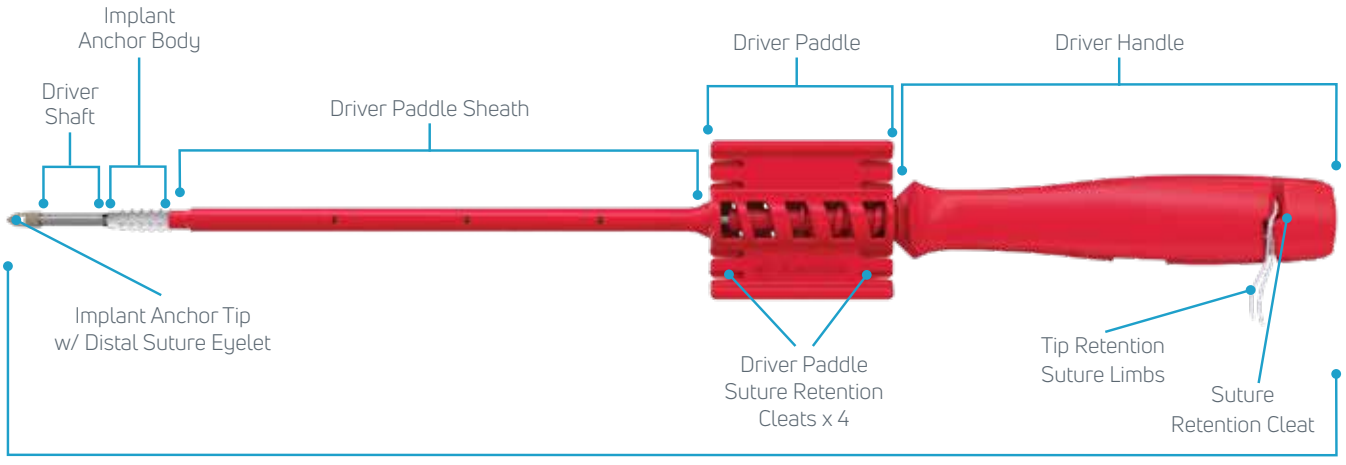
X-Twist Fixation System

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

Available in PEEK or biocomposite material, the X-Twist Fixation System is designed for versatility across procedures:

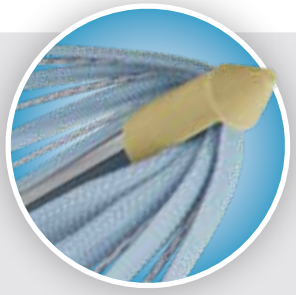
- Single or double row
- Medial and/or lateral row applications
- Knotless and fully knotted constructs





Anchor/Driver Assembly

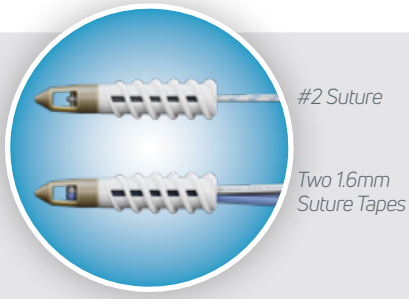
Product Features



High Suture Tape Capacity

Simultaneously accommodates four 2mm tapes plus three #2 sutures in the distal PEEK eyelet

Maximize surface area compression, points of fixation, and load sharing to support a secure repair



Sliding Retention Sutures

Can be incorporated into repair or discarded

Anchor can be used like a traditional double-loaded anchor with multiple sliding 1.6mm suture tapes

Open Architecture Design

1.4mm vents run along four sides of the fully threaded anchor body

Enhance marrow element flow to support repair site healing and fixation site bony ingrowth

Unique X-Spline™ Drive

X-Spline drive provides two times the torsional efficiency of a traditional hex drive

Reliable insertion even in hard bone

Double Helix Design

Two independent threads in double helix relationship with high-threaded pitch

Fast insertion with 3 ¼ turns

Multiple Material Choices

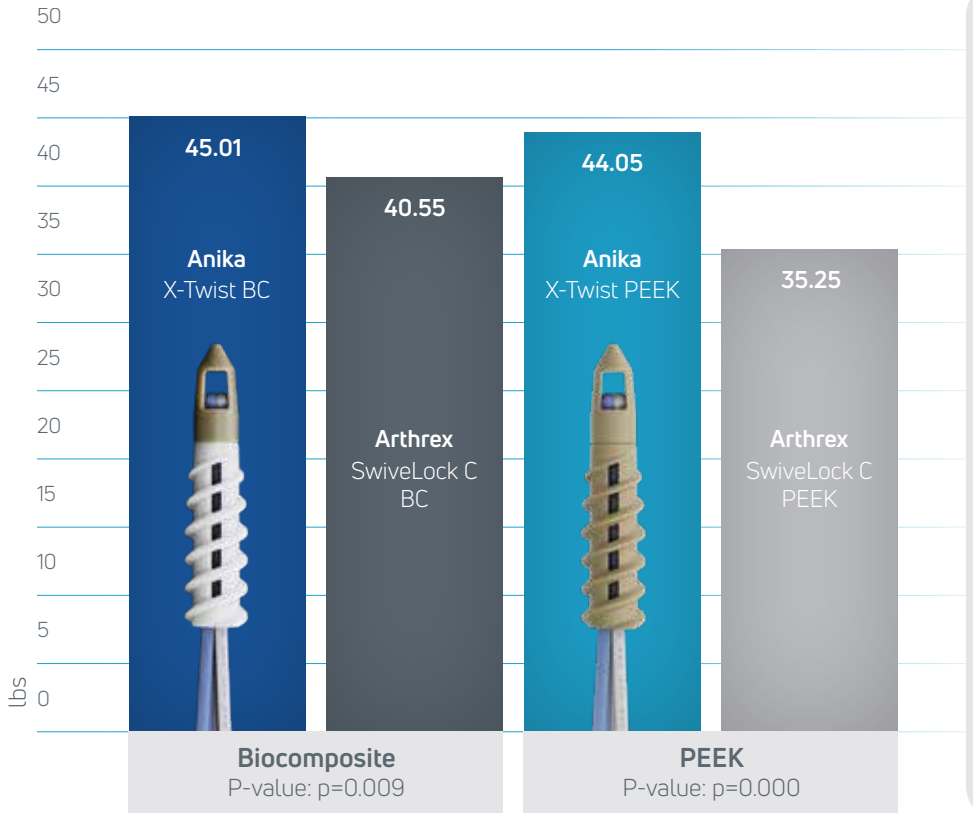
Choose from clinically proven materials; **PEEK** for strong, stable bio-inert fixation with a nonresorbable material or **biocomposite** (70% PLGA and 30% β-TCP) that promotes gradual bony ingrowth over time

Bench Top Testing

Secure Fixation with Fully Threaded Design

X-Twist's fully threaded anchors provide purchase into cortical and cancellous bone, resulting in a strong, stable repair that resists micromotion and pullout.

PULL-OUT STRENGTH COMPARISON*
Anika X-Twist™ vs. Arthrex® SwiveLock® C



Anika X-Twist Biocomposite demonstrated*:

12% stronger

pull-out strength than the Arthrex SwiveLock C biocomposite anchors

Anika X-Twist PEEK demonstrated:

25% stronger

pull-out strength than the Arthrex SwiveLock C PEEK anchors

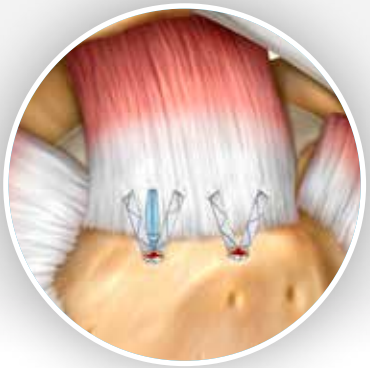
*N = 8/product; Tensile strength testing completed in 10 lb/ft³ polyurethane foam bone block laminated with a 3mm thick 20 lb/ft³ polyurethane foam layer. Full data on file.

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. Please refer to the IFU or the Technique Guide for specific technique steps.

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.

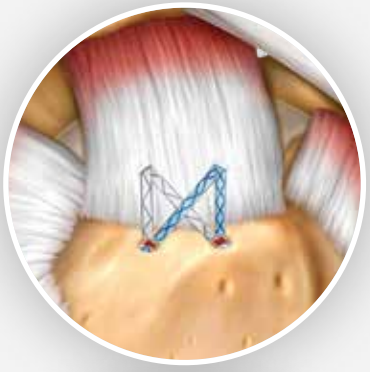
Single Row Repair



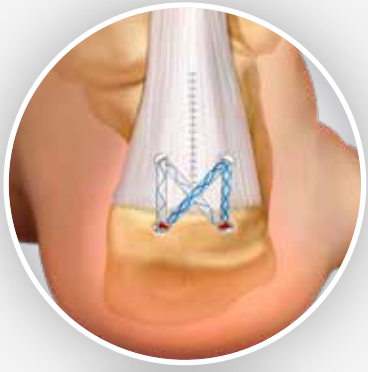
Knotless with inverted mattress stitch using 2mm suture tapes, with and without a knotless rip-stop suture

Knotted with 2mm suture tapes

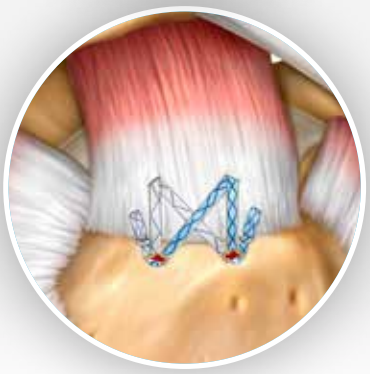
Double Row Bridge Repair



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



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



Knotless with dog-ear reduction

Medially knotted with four sets of suture tapes 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
27650	Repair, primary, open or percutaneous, ruptured Achilles tendon	5114	A2
27652	Repair, primary, open or percutaneous, ruptured Achilles tendon; with graft (includes obtaining graft)	5114	J8
27654	Repair, secondary, Achilles tendon, with or without graft	5114	J8
29827	Arthroscopy, shoulder, surgical; with rotator cuff repair	5114	A2

Hospital Inpatient: Medicare Severity-Diagnosis Related Group (MS-DRG)	
MS-DRG	**Description**
503	Foot Procedures with MCC
504	Foot Procedures with CC
505	Foot Procedures without CC/MCC
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)

Competitive Comparison

Feature	Anika X-Twist	Arthrex SwiveLock C
Anchor Material(s)	PEEK Biocomposite *(70% PLGA and 30% β-TCP)*	PEEK Biocomposite *(85% PLLA and 15% β-TCP)*
Fenestrations	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
Distal Eyelet Material	PEEK	PEEK
Distal Eyelet/Knotless Capactiy	Accommodates up to four 2mm tapes plus three #2 sutures	Accommodates two 2mm tapes plus two #2 sutures
Sliding Suture Tape Options	Available with double sliding 1.6mm suture tapes	No sliding suture tape options
Secondary Knotless Mechanism Option	No	Yes
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
Drive Mechanism	X-Spline Drive	Traditional Hex Driver
Mechanical Performace (Mean Pullout Strength)	PEEK: 44.05 lbs BC: 45.01 lbs	PEEK: 35.25 lbs BC: 44.05 lbs
Insertion	3 ¼ turns	8 turns
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

X-Twist PEEK Suture Anchor

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.

Instructions For Use

X-Twist Biocomposite Suture Anchor

DEVICE DESCRIPTION

The X-Twist Biocomposite Suture Anchor consists of the implants (anchor and anchor tip) and the anchor driver assembly. The anchor and anchor tip are provided affixed to the driver and sterile. The X-Twist Biocomposite anchor is molded using a composite of βTCP (beta-tricalcium-phosphate) and PLGA (poly-lactic-co-glycolic acid). The anchor tip is molded using PEEK (polyetheretherketone). The anchor is fully threaded, double-helical, cannulated, and has inline fenestrations on each quarter-turn face. The anchor tip is retained on the driver via retention suture(s) or suture tape(s) that are passed through the driver cannulation, looped over the retention bridge within the tip, and returned out the proximal end of the driver handle and cleated. These devices are to be used with a drill, awl, and/or bone tap. The X-Twist Biocomposite Suture Anchors are provided sterile and in 4.75mm, 5.5mm, or 6.25mm diameters.

INTENDED USE

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

Shoulder: Rotator Cuff Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair

Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair

Knee: Anterior Cruciate Ligament Repair, Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis, Quadriceps Tendon Repair, Meniscal Root Repair, Secondary or adjunct fixation for ACL/PCL reconstruction or repair, MPFL Repair/Reconstruction

Elbow: Ulnar/Radial Collateral Ligament Reconstruction, Lateral Epicondylitis Repair

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. Suture anchor performance is directly related to the quality of bone into which the anchor is placed.
5. Patient's inability or unwillingness to follow the surgeon's prescribed post-operative regimen.
6. Any situation that would compromise the ability of the user to follow the directions for use or using the device for an indication other than those listed.

INTENDED PATIENT POPULATION

Potential patients for this device include patients with symptomatic primary or recurrent tear of soft tissue amenable to repair. Patient selection factors to be considered include patient's need to obtain pain relief and improve function, patient's overall well-being, including ability and willingness to follow instructions and comply with activity restrictions.

INTENDED USERS

The intended users for the device are orthopedic surgeons that are trained to perform the indicated procedures.

INTENDED USER ENVIRONMENT

The intended use environments for the device include hospitals, outpatient surgical settings, and ambulatory surgery sites.

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. Attempting to implant an anchor into hard, dense bone or into implant sites that are smaller than the recommended diameter may cause anchor failure (breakage) during insertion.
4. Always try to approach the targeted site as close to perpendicular as possible. Off-axis anchor insertion may damage the device.
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. The patient should be advised of the use and limitations of this device.
7. Pre-operative planning and evaluation, surgical approaches and technique, and familiarity of the implant, including its instrumentation and limitations are necessary components in achieving a good surgical result.
8. 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.
9. This device must never be re-sterilized.
10. Only the recommended instrumentation should be used to implant this device (see Instrumentation).
11. This device must not be used if any of the temperature sensitive warning labels are red.

CAUTIONS

1. Applying excessive torque to the driver handle and/or paddle may cause driver failure.
2. Improper fixation of the anchor and/or suture may leave the implant loose leading to soft tissue irritation, bone/tissue damage, and/or post operative failure

ADVERSE EFFECTS / POTENTIAL COMPLICATIONS

1. Infection, both deep and superficial
2. Allergies and other reactions to the device materials
3. Loss of fixation via suture or anchor pull out can occur
4. Suture or suture anchor breakage can occur

MR SAFETY INFORMATION

The implantable portion of these devices are MR-Safe.

MATERIAL SPECIFICATIONS

- Anchor Body: The anchor body is molded with a composite of βTCP (beta-tricalcium-phosphate) and PLGA (poly-lactic-co-glycolic acid).
- Anchor Tip: The anchor tip is molded with PEEK (polyetheretherketone).
- Shaft: Stainless Steel
- Handle/paddle: Acrylonitrile Butadiene Styrene (ABS)
- Suture: The suture anchors are preloaded with non-absorbable surgical sutures or suture tape made of UHMWPE (ultra-high molecular weight polyethylene). The suture or suture tape may contain undyed or dyed trace filaments of nylon or PET (polyethylene terephthalate).
- No Hazardous substances.

INSTRUMENTATION

Anchor Size	Bone Quality	Instrumentation
4.75mm	Soft	3.6mm Awl (XT04702)
	Normal/Hard	4mm drill (XT04705) followed by 4.75mm Tap (XT04700, XT04703)
5.5mm	Soft	4.1mm Awl (XT04701)
	Normal/Hard	4mm drill (XT04705) followed by 5.5mm Tap (XT05500, XT05501)
6.25mm	Soft	4.1mm Awl (XT04701)
	Normal/Hard	N/A – intended for soft bone only

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 (temperature indicator label is red), or has been altered in any way.
- The X-Twist Biocomposite Suture Anchors are provided double pouched. The device must be stored in both pouches. While the outer pouch provides a sterile and moisture barrier, the inner pouch only preserves the sterility of the device and does not prevent moisture from getting to the suture anchor. Devices stored within only one layer of packaging should be discarded.
- Please contact Anika Therapeutics Customer Service to report any package/label damage or alterations.

STERILIZATION

- The contents were sterilized by ethylene oxide (EO)

STORAGE

- These devices 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. The X-Twist Biocomposite Suture Anchors must be stored below 25°C (77°F). Do not use the device if the temperature sensitive warning labels are red.

GENERAL INSTRUCTIONS FOR USE (Follow the surgical technique guide for procedure specific instructions.)

- Evaluate the target implant site for bone quantity and quality.
- Select the appropriate anchor size. The 6.25mm anchor is used primarily in bone of suboptimal quality.
- Inspect the device before using.
- Create a pilot hole using the appropriately sized awl, drill and/or tap corresponding to the implant diameter.
- Advance the awl into the desired anchor insertion site until laser line is flush with the bone. When preparing hard bone, advance the appropriately sized tap until the laser line is flush with the bone. Note: An improper bone preparation depth may result in poor anchor positioning.
- Sutures may be loaded onto the X-Twist Biocomposite Suture Anchor by passing through the distal eyelet of the anchor tip using the provided suture threader.

  NOTE: The distal eyelet can accommodate up to six (6) strands of 1.6mm suture tape, #2 suture, or a combination thereof. Alternatively, the distal eyelet will accommodate up to four (4) strands of 2mm suture tape concurrently with up to three (3) #2 sutures.
- Align the insertion angle of the anchor tip with the prepared pilot hole and advance the anchor tip until the anchor body contacts the bone while maintaining suitable suture tension.
- Advance the anchor body down the driver shaft and into the prepared hole by holding the driver paddle stationary with one hand and simultaneously rotating the driver handle clockwise with the other hand until the anchor body is flush with the bone. Ensure the laser etch line on the driver is flush with the surface of the bone prior to advancing anchor body into the pilot hole.
- Uncleat all sutures from the handle before withdrawing the driver.
- Pull the driver away from the implant for removal. **Do not twist the handle upon removal.** Any remaining retention sutures may be incorporated into the repair or removed from the anchor body cannulation by pulling on one limb.
- Cut and remove any excess suture or suture tape limbs not used in the repair.

  Reuse/Cleaning of instrumentation

  Refer to the instrumentation IFU for proper cleaning, sterilization, and inspection instructions as required.

DEVICE DISPOSAL

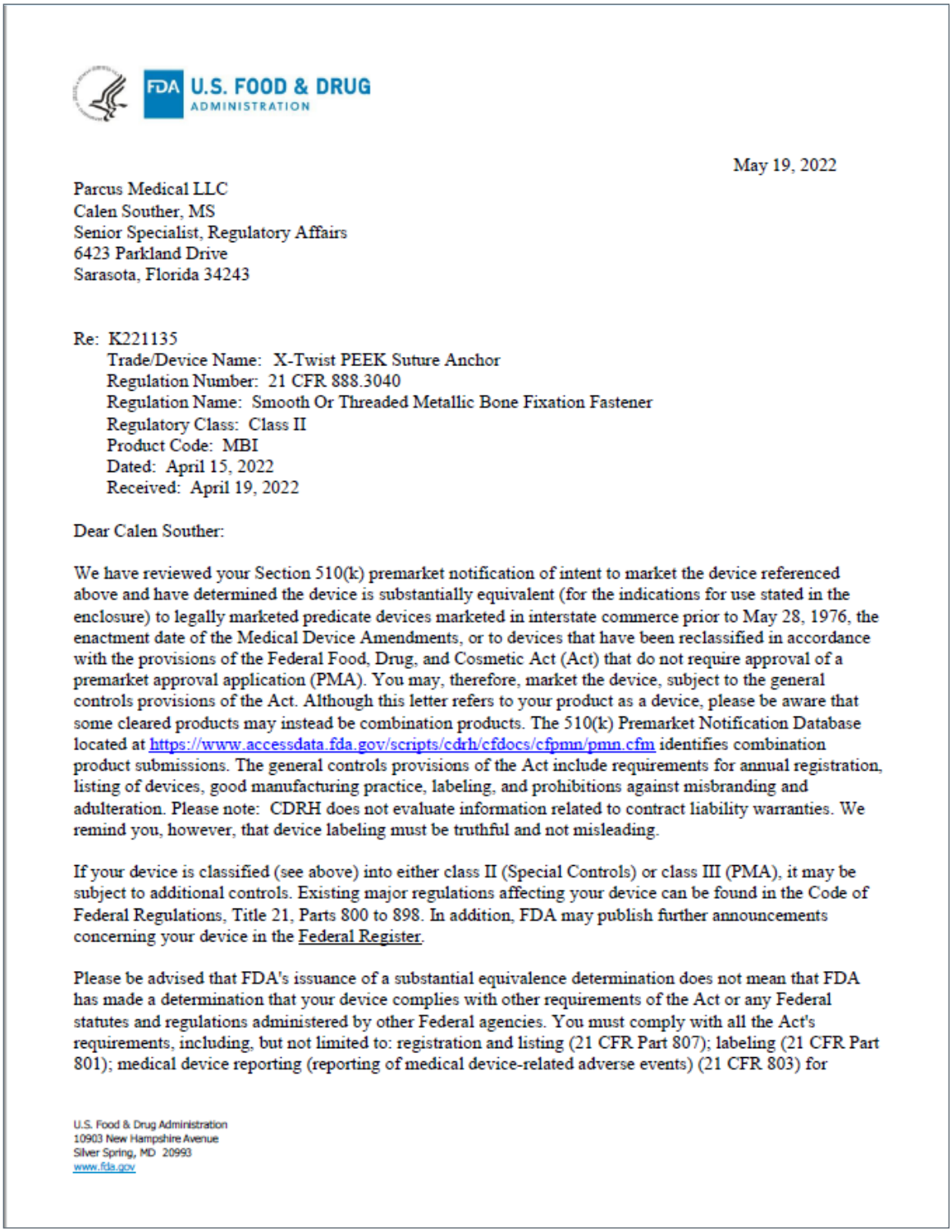
- Devices that have been removed from the packaging and not used or were explanted from a patient must be properly disposed of in accordance with the institution's policy.

ADVERSE / REPORTABLE EVENT

- Any serious incident that occurs in relation to the device should be reported to Anika Therapeutics at globalcomplaints@anika.com.

FDA Clearance

X-Twist PEEK Suture Anchor



U.S. FOOD & DRUG ADMINISTRATION

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

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
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

FDA Clearance

X-Twist Biocomposite Suture Anchor

U.S. FOOD & DRUG ADMINISTRATION

September 18, 2023

Parcus Medical
Calen Souther
Manager, Regulatory Affairs
6455 Parkland Drive
Sarasota, Florida 34243

Re: K232513
Trade/Device Name: X-Twist Biocomposite Suture Anchor
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: MAI
Dated: August 18, 2023
Received: August 18, 2023

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 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.

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Sincerely,

Sara S. Thompson -S

For

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

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 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.

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 24 hours. All coding inquiries are answered by a credentialed, coding specialist.

Contact Information:

MCRA Phone: 800-436-1377

MCRA Email: USReimbursement@anika.com

Packaging and Sterilization

Implants

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

The X-Twist Biocomposite Suture Anchors must be stored below 25°C (77°F).
Do not use the device if the temperature sensitive warning labels are red.

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

X-Twist Biocomposite Screw-In Suture Anchors				
Part #	Diameter (mm)	Length (mm)	Description	Material
XT44700	4.75	23	X-Twist Biocomposite 4.75mm, w/one #2 Suture (blu/wht)	Biocomposite
XT44702	4.75	23	X-Twist Biocomposite 4.75mm, w/two 1.6mm Suture Tapes (blu, blu/wht)	Biocomposite
XT44703	4.75	23	X-Twist Biocomposite 4.75mm, w/two 1.6mm Suture Tapes (blk, blk/wht)	Biocomposite
XT45500	5.5	23	X-Twist Biocomposite 5.5mm, w/one #2 Suture (blu/wht)	Biocomposite
XT45502	5.5	23	X-Twist Biocomposite 5.5mm, w/two 1.6mm Suture Tapes (blu, blu/wht)	Biocomposite
XT45503	5.5	23	X-Twist Biocomposite 5.5mm, w/two 1.6mm Suture Tapes (blk, blk/wht)	Biocomposite
XT46200	6.25	23	X-Twist Biocomposite 6.25mm, w/one #2 Suture (blu/wht)	Biocomposite

Suture Tape			
Part #	Size (mm)	Description	QTY/ Box
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
20042	2	Parcus Braid suture tape (wht/blu)	6
20042S	2	Parcus Braid suture tape (wht/blu)	1
20238	2	Anika Braid suture tape (wht/blu)	12
20238S	2	Anika Braid suture tape (wht/blu)	1
20239	2	Anika Braid suture tape (blu)	12
20239S	2	Anika Braid suture tape (blu)	1
20240	2	Anika Braid suture tape (blk/blu)	12
20240S	2	Anika Braid suture tape (blk/blu)	1

X-Twist Instrumentation^			
Part #	Description	Sterile/ Non-sterile	Single-use/ Reusable
XT04700	X-Twist 4.75mm tap	Non-sterile	Reusable
XT04701	X-Twist 4.75-5.5mm awl	Non-sterile	Reusable
XT04702	X-Twist 3.6mm awl	Non-sterile	Reusable
XT04703	X-Twist 4.75mm tap, DEX*	Non-sterile	Reusable
XT04705	X-Twist 4.0mm drill, DEX*	Non-sterile	Reusable
XT04706	X-Twist 3.6mm drill, DEX*	Non-sterile	Reusable
XT05500	X-Twist 5.5mm tap	Non-sterile	Reusable
XT05501	X-Twist 5.5mm tap, DEX*	Non-sterile	Reusable
XT00001	X-Twist sterilization tray	Non-sterile	Reusable
11241	4mm x 100mm drill guide	Non-sterile	Reusable

^See IFU or Technique Guide for instrumentation guide by anchor size and bone quality
*DEX = Distal Extremity

Notes

Notes

Anika Therapeutics, Inc.
Parcus Medical, LLC
6423 Parkland Dr., Sarasota, FL 34243
1-888-721-1600 | customerservice@anika.com
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