

### X-Twist™ Fixation System

### Simply Versatile

Supports use in a wide variety of repair constructs providing reproducibility and confidence in repairing soft tissue to bone

Reference Guide

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This reference guide is designed to provide you with the necessary information to promote Anika's newest Sports Medicine product, the X-Twist™ Fixation System.

This guide will support your sales efforts by providing features and benefits, key messaging, competitive information, and questions to ask your surgeon to understand how you can convert business to Anika's Sports Medicine portfolio.

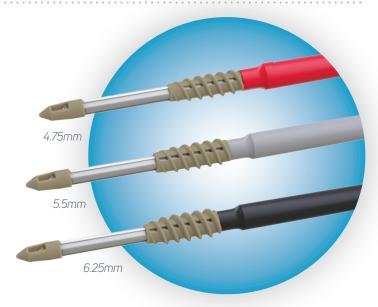
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### Product Messaging

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

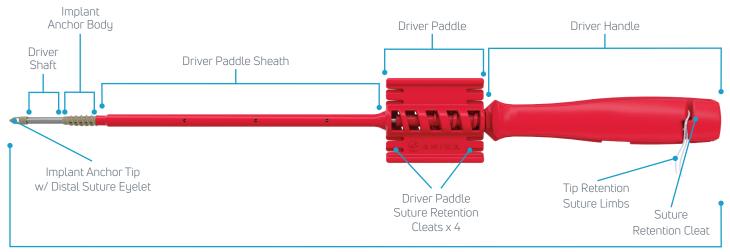
The anchor is made of PEEK and is available in three diameters: 4.75mm, 5.5mm, and 6.25mm with three sliding suture and suture tape options: #2 suture, 1.6mm suture tape, and two 1.6mm suture tapes.

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.



#### Supports current preferred technique, no technique adjustment required

- Can be used as either medial row or lateral row anchor
- Compatible in constructs with different medial or lateral row anchors (such as suture-based Draw Tight™ or Twist PEEK)
- Permits knotless or fully knotted constructs
- Suture tensioning is established prior to fixation into bone, supporting reproducible soft tissue reduction and compression over the repair site
- Supports case flexibility: drop-in replacement for current product, minimal learning curve
- Indicated in multiple procedures across multiple joints: shoulder, knee, elbow, foot and ankle



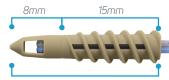
Anchor/Driver Assembly

### Features & Benefits

#### **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

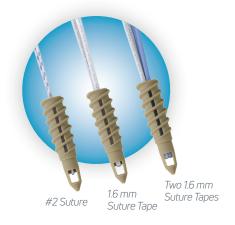
Ample distal eyelet and 20 vents surrounding the anchor body



23mm Implant Length

#### **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 & 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<sup>™</sup> 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

#### Instruments

#### Color coded by anchor size

· Taps match anchor diameter and color scheme

#### Single instrument tray

- · Compact design to facilitate back table management
- · Re-usable, sterilizable instrument tray supports lower cost per case

X-Twist Awl	For X-Twist sizes 4.75mm, 5.5mm, and 6.25mm
X-Twist 4.75mm Tap	For hard bone applications
X-Twist 5.5mm Tap	For hard bone applications



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

# Competitive Comparison

### **Bench Top Testing**

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

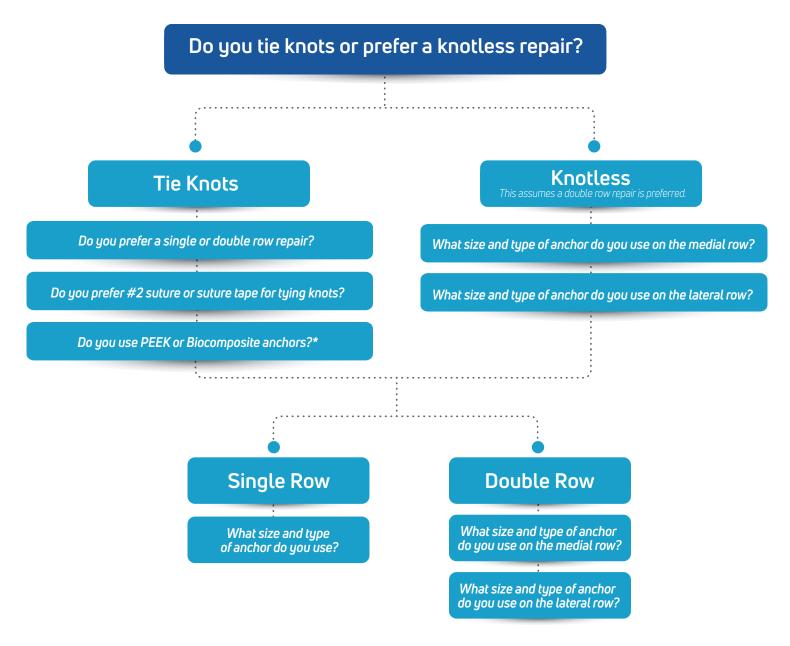
- · Preloaded with 2mm Suture Tape
- · Straight Pull-Out Test
- · 20/10 laminated foam block

#### · Same medium Arthrex uses in marketing data & publications Mean Pullout Strength (lbs)\* 70.0 60.0 50.0 40.0 30.0 ANIKA 20.0 Arthrex 67.2 62.3 SwiveLock C 10.0 Arthrex SwiveLock C Anika X-Twist 4.75mm | PEEK 4.75mm | BioComposite \*Data on file.

### **Product Comparison**

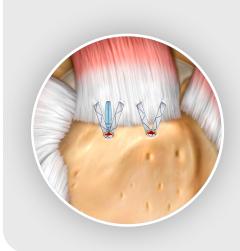
Features	Anika X-Twist	Arthrex SwiveLock C
Distal Eyelet/Knotless Capactiy	Accommodates four 2mm tapes plus three #2 sutures	Accommodates two 2mm tapes plus two #2 sutures
Fenestrations	Twenty, 1.4mm vents surrounding the anchor body	BioComposite anchor has "pin hole" vents; PEEK anchor has larger fenestrations 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 1/4 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 for convenience and faster/easier suture passing
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

# Qualifying the Customer



<sup>\*</sup> If they ONLY use Biocomposite anchors, recommend our Twist Biocomposite anchors and Push-in Knotless Biocomposite anchors, and let them know we will have Biocomposite X-Twist anchors available in 2023.

# Repair Combinations



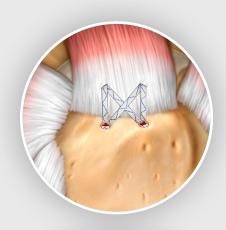
### Single Row Repair

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

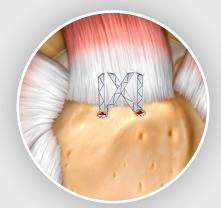


Knotted with 1.6mm knotted suture tape

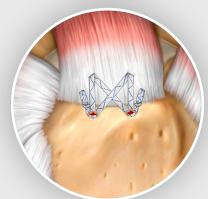
### Double Row Bridge Repair



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



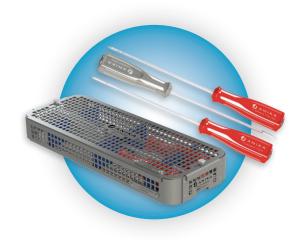
Medially knotted with four sets of suture tape and a knotless lateral row

# Ordering Information

X-Twist Screw	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 Instru	mentation		
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



# Alternative Ordering Information

#### Compatible Medial Row Anchor Options

Based upon patient presentation, surgeons may choose to use an alternative medial row anchor from the Anika Sports Medicine portfolio.

#### **Suture Based Anchors**

Draw Tight <sup>™</sup> Su	Draw Tight" Suture-Based Anchors				
Part #	Diameter (mm)	Description	Material		
10820	3.2	Draw Tight, push-in, suture-based anchor, w/2, #2 sutures (blu & blu/blu)	UHMWPE & PEEK		
10588	3.2	Draw Tight, push-in, suture-based anchor, w/2, #2 sutures (wht/blu & wht/blk)	UHMWPE & PEEK		
11288	3.2	Draw Tight, push-in, suture-based anchor, w/2, 1.6mm suture tapes (blu, wht/blu)	UHMWPE & PEEK		
11289	3.2	Draw Tight, push-in, suture-based anchor, w/2, 1.6mm suture tapes (blk, wht/blk)	UHMWPE & PEEK		

Instrumentation	Instrumentation for Draw Tight Suture-Based Anchors				
Part #	Diameter (mm)	Description	Sterile/Non-sterile	Single-use/Reusable	
10365	3.2	Awl	Non-sterile	Reusable	

#### **PEEK Anchors**

Twist SST PE	Twist SST PEEK Screw-In Suture Anchors w/ Tape				
Part #	Diameter (mm)	Length (mm)	Description	Material	
11349	4.5	12.6	Twist SST, screw-in, suture anchor, w/1, 2mm suture tape (blu)	PEEK	
11350	4.5	12.6	Twist SST, screw-in, suture anchor, w/1, 2mm suture tape (blk)	PEEK	
11351	5.5	12.6	Twist SST, screw-in, suture anchor, w/1, 2mm suture tape (blu)	PEEK	
11352	5.5	12.6	Twist SST, screw-in, suture anchor, w/1, 2mm suture tape (blk)	PEEK	

Twist PEEK S	Twist PEEK Screw-In Suture Anchors w/Two Suture Tapes				
Part #	Diameter (mm)	Length (mm)	Description	Material	
11003	4.5	12.6	Twist, screw-in, suture anchor, w/2, 1.6mm suture tapes (wht/blu & wht/blk)	PEEK	
11283	4.5	12.6	Twist, screw-in, suture anchor, w/2, 1.6mm suture tapes (blu, wht/blu)	PEEK	
11285	4.5	12.6	Twist, screw-in, suture anchor, w/2, 1.6mm suture tapes (blk, wht/blk)	PEEK	
11004	5.5	12.6	Twist, screw-in, suture anchor, w/2, 1.6mm suture tapes (wht/blu & wht/blk)	PEEK	
11284	5.5	12.6	Twist, screw-in, suture anchor, w/2, 1.6mm suture tapes (blu, wht/blu)	PEEK	
11286	5.5	12.6	Twist, screw-in, suture anchor, w/2, 1.6mm suture tapes (blk, wht/blk)	PEEK	
11005	6.5	12.6	Twist, screw-in, suture anchor, w/2, 1.6mm suture tapes (wht/blu & wht/blk)	PEEK	

Twist PEEK Screw-In Suture Anchors w/ Two #2 Sutures								
Part #	Diameter (mm)	Length (mm)	Description	Material				
10511T	4.5	12.6	Twist, screw-in, suture anchor, w/2, #2 sutures (blu & wht/grn)	PEEK				
10517T	5.5	12.6	Twist, screw-in, suture anchor, w/2, #2 sutures (blu & wht/grn)	PEEK				
10518T	6.5	12.6	Twist, screw-in, suture anchor, w/2, #2 sutures (blu & wht/grn)	PEEK				

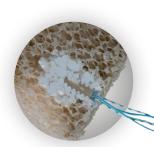
Instrumentation for Twist PEEK Screw-In Suture Anchors						
Part #	Diameter (mm)	Description	Sterile/Non-sterile	Single-use/Reusable		
10365	3.2	Awl	Non-sterile	Reusable		
10338	4.1	Awl	Non-sterile	Reusable		
10609	4.5	Punch/tap	Non-sterile	Reusable		
10277	5.5	5.5mm or 6.5mm punch/tap	Non-sterile	Reusable		
10540U	3.2	Drill bit, w/positive stop	Non-sterile	Reusable		
10541U	4	Drill bit	Non-sterile	Reusable		

# Additional Pull-Through Products

While selling X-Twist, keep in mind the opportunity to cross-sell other products in the Anika portfolio that may help enhance patient outcomes in rotator cuff repair.

#### Tactoset for hardware augmentation

Tactoset® is indicated for the augmentation of hardware, such as soft tissue anchors, and can provide greater than twice the pullout strength of non-augmented anchors.\* Augmenting with Tactoset increases the density of poor-quality bone caused by cysts or osteoarthritis, allowing for placement of anchors in the ideal repair location, and resulting in additional suture anchor pull-out strength.

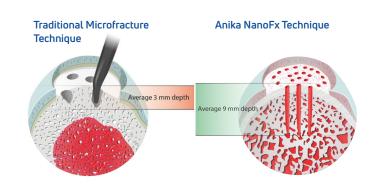


Representation of anchor augmented with Tactoset within trabecular bone

Tactoset						
Part #	Description	Sterile/Non-sterile	Single-use/Reusable			
1000040	11G delivery cannula set including: 1 drillable outer cannula with removable drillable stylet; 1 inner cannula for end delivery; 1 inner cannula for side delivery; 1 push rod	Sterile	Single-use			
6000041	Tactoset material set including: 1 prefilled mixing syringe containing Tacoset powder; 1 glass syringe containing Tactoset setting solution; 4 Luer lock syringes (1 mL); 1 female-female Luer lock connector	Sterile	Single-use			

#### NanoFx for bone preparation

The NanoFx® (Nanofracture®) system consists of a reusable hand instrument and a single-use disposable PleuriStik™ k-wire. This system is ideally suited to aid in bone preparation for rotator cuff repair. The 1mm PleuriStik disrupts less surface area than a standard microfracture technique and was purposefully designed to reduce damage to the subchondral plate. It penetrates down to a standardized 9mm depth to reach the targeted marrow cells, three times deeper than comparable microfracture techniques.



NanoFx Instrumentation					
Part #	Description	Sterile/Non-sterile	Single-use/Reusable		
5500-1020	NanoFx Hand Instrument	Non-sterile	Reusable		
FURS-2101	PleuriStik Guide Wire	Sterile	Single-use		
FURS-0100	Thumble Thumb Tab Accessory	Sterile	Single-use		

<sup>\*</sup> Data on file, Anika Therapeutics, Inc.



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