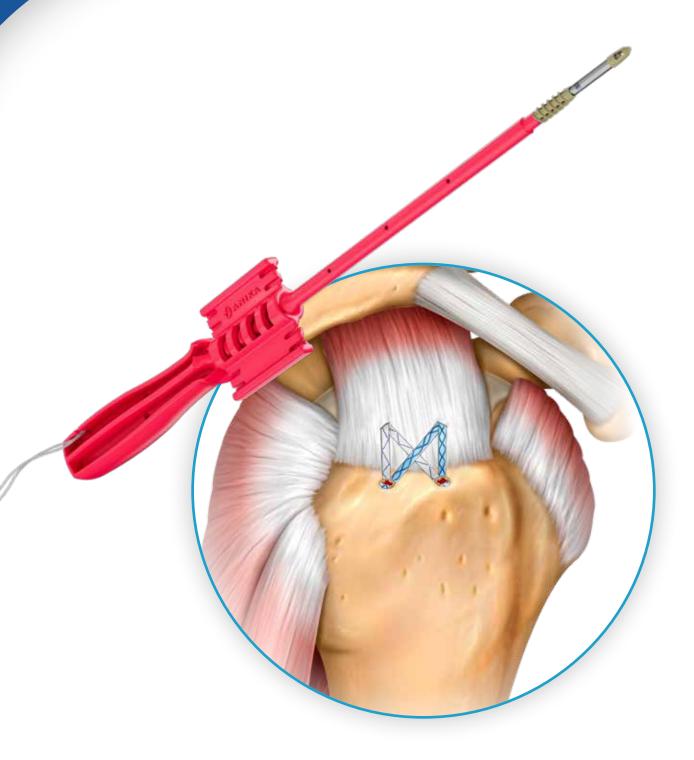


X-Twist[™] Fixation System

Rotator Cuff Repair Surgical Technique Guide



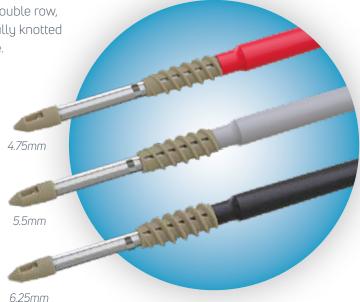
X-Twist Fixation System

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.

Available in either PEEK or biocomposite material, X-Twist anchors come in three diameters: 4.75mm, 5.5mm, and 6.25mm. It includes two sliding suture and suture tape options: one #2 suture and two 1.6mm suture tapes.

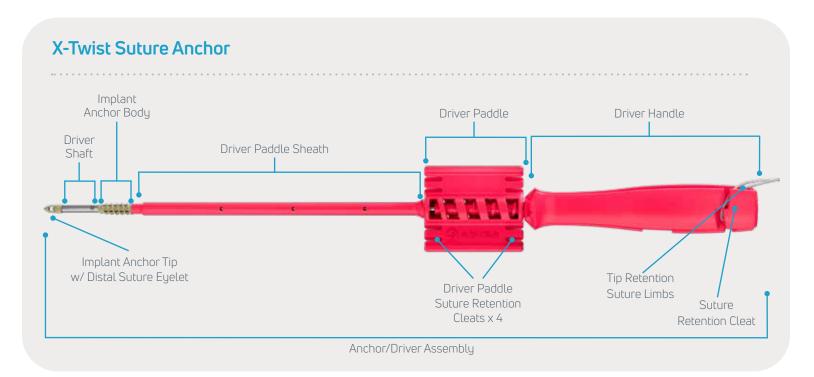
The X-Twist system has multiple indications for attaching soft tissue to bone throughout the body. Please refer to the Instructions for Use (IFU) for a complete list of indications.

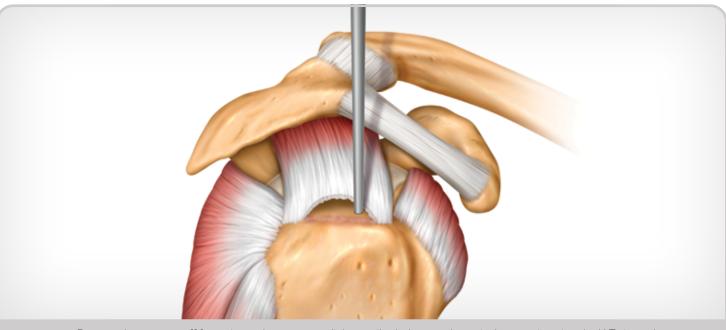






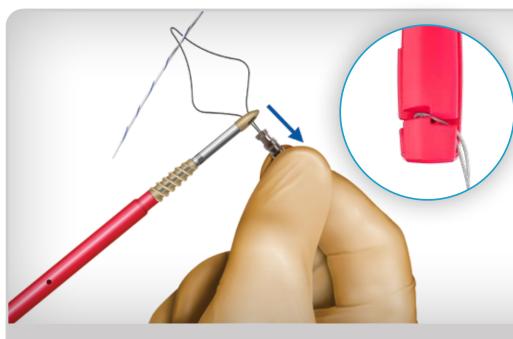
X-Twist Biocomposite
70% PLGA/30% BTCP and PEEK eyelet





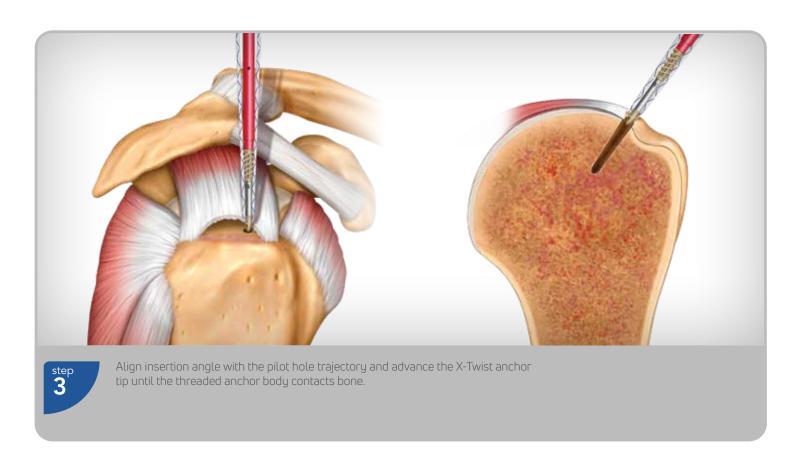
step 1 Prepare the rotator cuff footprint and create a medial row pilot hole near the articular margin using the X-Twist awl (XT04701). Insert the awl until the laser line is flush with the bone.

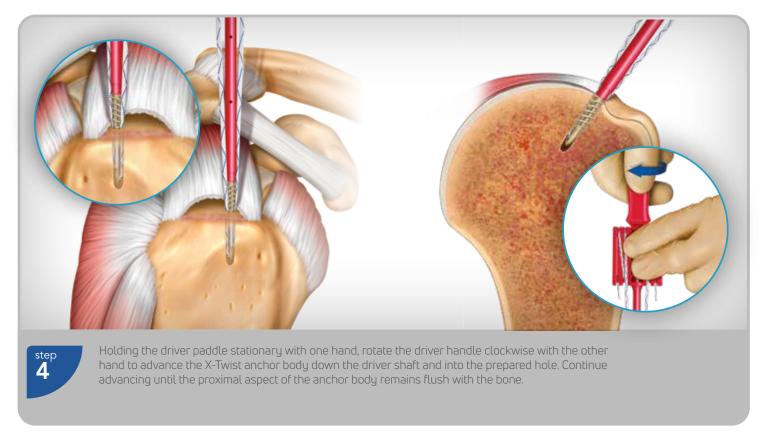
Optional: In soft bone, use the 3.6mm awl (XT04702) for X-Twist 4.75mm anchors. Insert the awl until the laser line is flush with the bone. In hard bone, use the X-Twist tap (XT04700 or XT05500) after using the awl. Advance the tap until the laser line is flush with the bone.

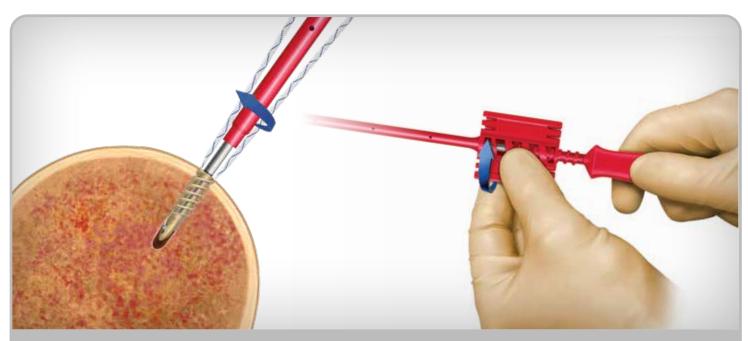


Note: If the anchor tip is pulled away from the shaft during suture passage (or at any other point), release the tip retention suture from the suture retention cleat of the driver handle. Then, re-apply tension by pulling the tip retention suture limbs simultaneously from the back of the driver handle to reapproximate the anchor tip back to the driver shaft. Once the anchor tip is reseated on the driver shaft, secure the retention suture limbs under tension back to the suture retention cleat of the driver handle.

step 2 Use the suture threader to preload a 1.6mm or 2mm suture tape into the distal suture eyelet of the medial row X-Twist anchor.

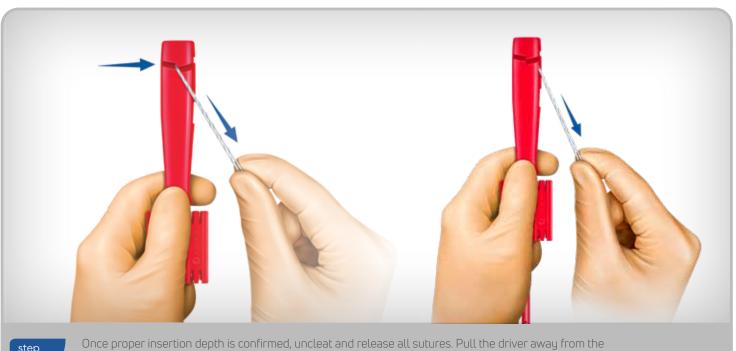






step **4**a

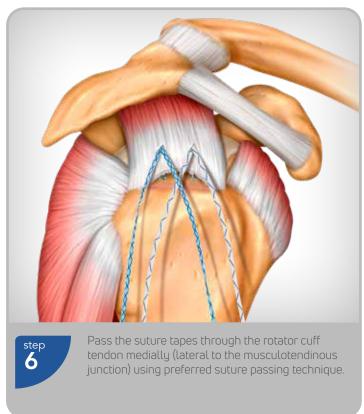
Optional: Following anchor body insertion, the driver paddle sheath may be partially retracted by rotating the driver paddle clockwise in order to facilitate visual confirmation of proper insertion depth. Further advancement of the anchor may proceed under direct visualization, if needed.

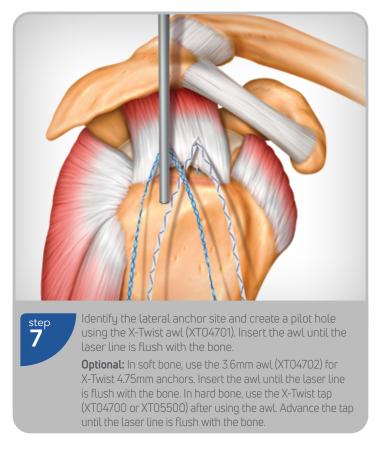


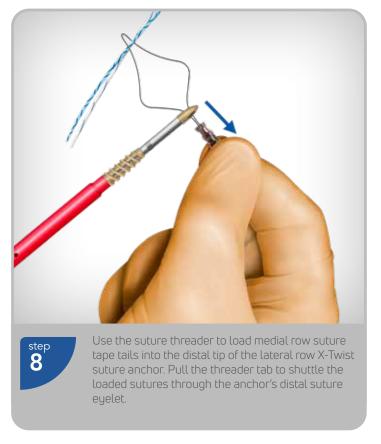
implant to remove the driver.

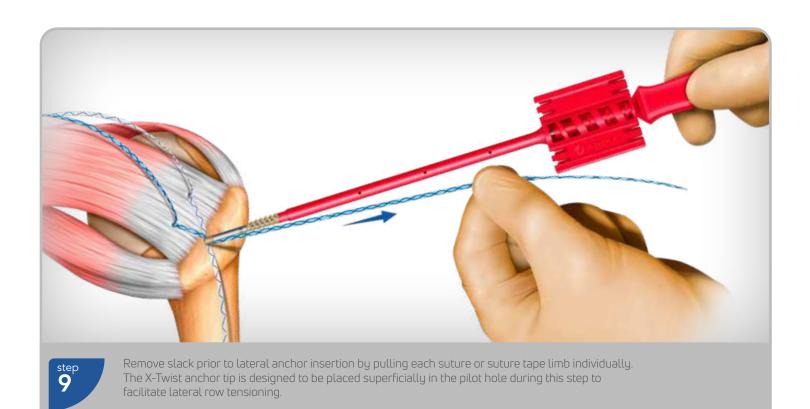
Note: Do not twist handle upon driver removal.

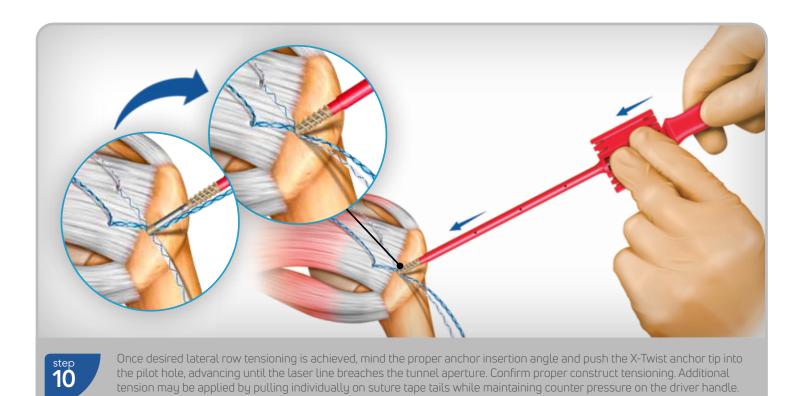


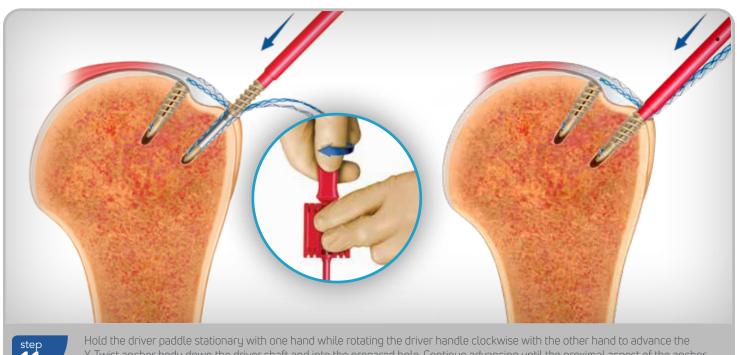






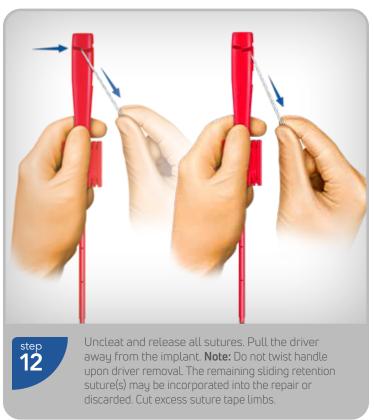






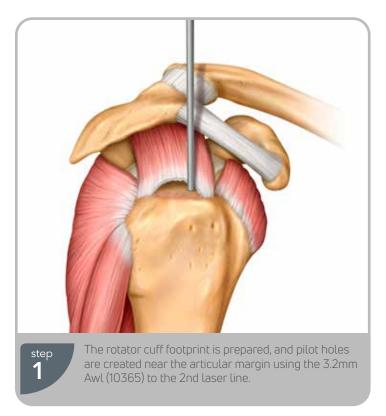
Hold the driver paddle stationary with one hand while rotating the driver handle clockwise with the other hand to advance the X-Twist anchor body down the driver shaft and into the prepared hole. Continue advancing until the proximal aspect of the anchor body is flush with the bone.

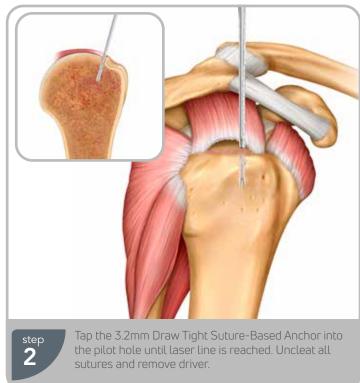
Optional: As shown in step 4a, the driver paddle sheath may be partially retracted to facilitate visual confirmation of proper insertion depth. Further advancement of the anchor may proceed under direct visualization, if needed.

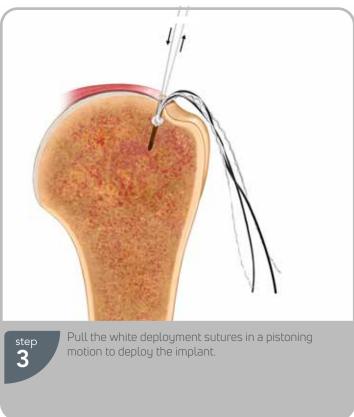


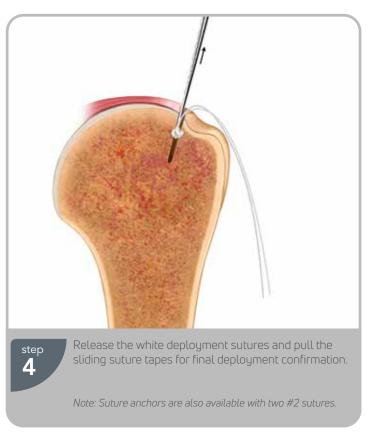


Alternative Medial Row Repair Technique

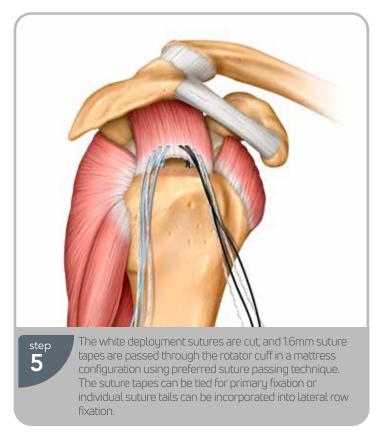








Alternative Medial Row Repair Technique





X-Twist Ins	X-Twist Instrument Guide					
X-Twist Size	Bone Quality	Pilot Hole/Bone Socket Prep	Instrument Part Numbers			
	Soft	3.6mm Awl for X-Twist 4.75mm	XT04702			
	Normal	X-Twist Awl for 4.75-5.5mm (4.1mm)	XT04701			
4.75mm		X-Twist Awl for 4.75-5.5mm (4.1mm) followed by the 4.75mm Tap	XT04701 XT04700			
4.7 5111111	Hard	OR				
	Tialu	4mm Drill with 4mm Drill Guide, Tap (Optional)	11000U 11241 XT04700			
	Soft	X-Twist Awl for 4.75-5.5mm (4.1mm)	XT04701			
	Normal	X-Twist Awl for 4.75-5.5mm (4.1mm)	XT04701			
5.5mm		X-Twist Awl for 4.75-5.5mm (4.1mm) followed by the 5.5mm Tap	XT04701 XT05500			
5.511111	Hard	OR				
	паги	4mm Drill with 4mm Drill Guide followed by the 5.5mm Tap	11000U 11241 XT05500			
	Soft	X-Twist Awl for 4.75-5.5mm (4.1mm)	XT04701			
6.25mm	Normal	N/A	N/A			
	Hard	N/A	N/A			

Alternative Repair Constructs



Knotless Double Row Bridge Repair

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



Knotless Single Row Repair

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

Product Listing

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



Product Listing

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

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 PEE	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/one 2mm suture tape (blu)	PEEK			
11350	4.5	12.6	Twist SST, screw-in, suture anchor, w/one 2mm suture tape (blk)	PEEK			
11351	5.5	12.6	Twist SST, screw-in, suture anchor, w/one 2mm suture tape (blu)	PEEK			
11352	5.5	12.6	Twist SST, screw-in, suture anchor, w/one 2mm suture tape (blk)	PEEK			

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/two 1.6mm suture tapes (wht/blu & wht/blk)	PEEK	
11283	4.5	12.6	Twist, screw-in, suture anchor, w/two 1.6mm suture tapes (blu, wht/blu)	PEEK	
11285	4.5	12.6	Twist, screw-in, suture anchor, w/two 1.6mm suture tapes (blk, wht/blk)	PEEK	
11004	5.5	12.6	Twist, screw-in, suture anchor, w/two 1.6mm suture tapes (wht/blu & wht/blk)	PEEK	
11284	5.5	12.6	Twist, screw-in, suture anchor, w/two 1.6mm suture tapes (blu, wht/blu)	PEEK	
11286	5.5	12.6	Twist, screw-in, suture anchor, w/two 1.6mm suture tapes (blk, wht/blk)	PEEK	
11005	6.5	12.6	Twist screw-in suture anchor w/two 16mm suture tanes (wht/hlu & wht/hlk)	PFFK	

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/two #2 sutures (blu & wht/grn)	PEEK		
10517T	5.5	12.6	Twist, screw-in, suture anchor, w/two #2 sutures (blu & wht/grn)	PEEK		
10518T	6.5	12.6	Twist, screw-in, suture anchor, w/two #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		

Anika Therapeutics, Inc.

Parcus Medical, LLC

6423 Parkland Dr, Sarasota, FL 34243

1-888-721-1600 | customerservice@anika.com

www.anika.com | Anika. Restore Active Living." | Stay Active"



