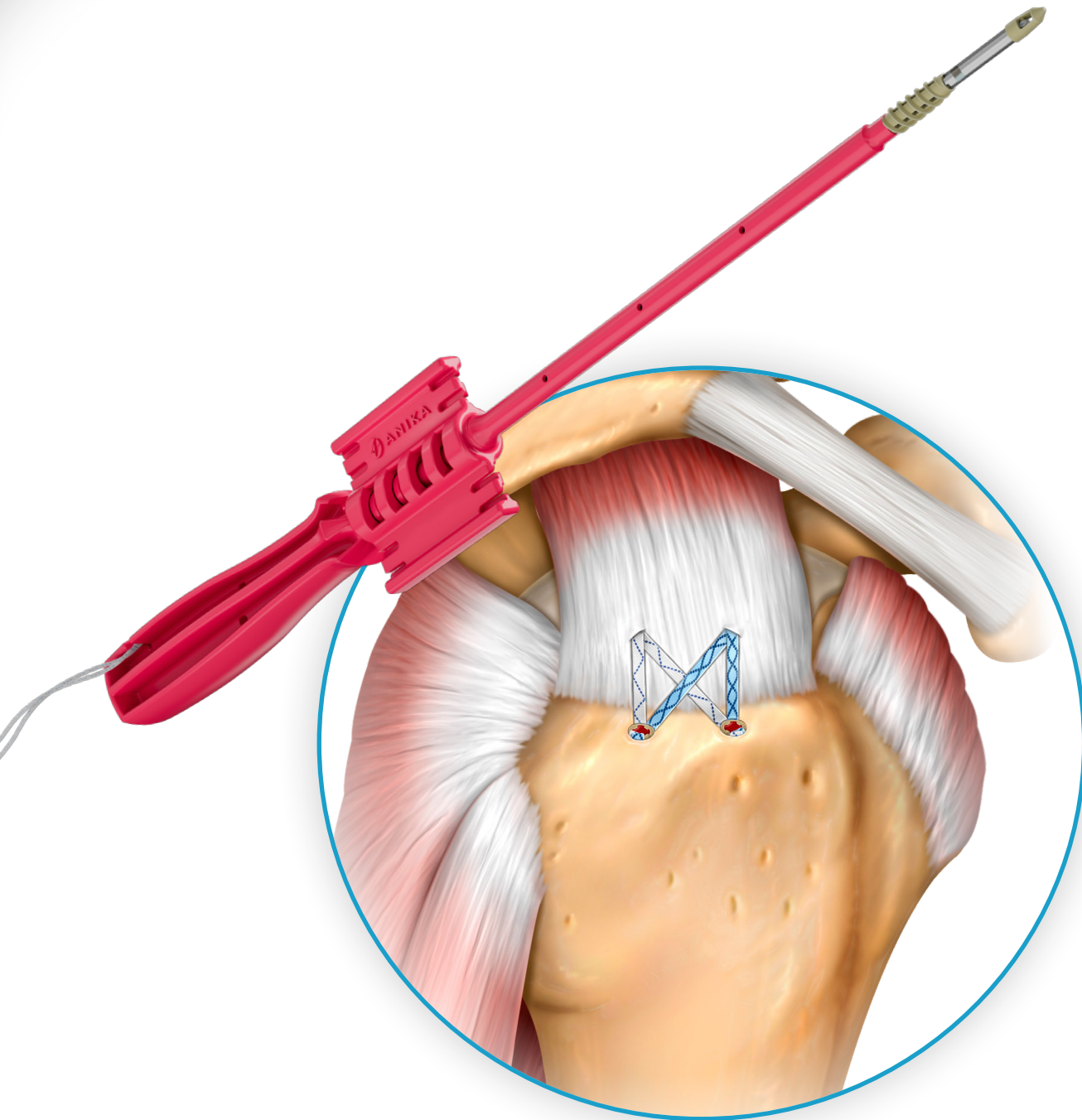


X-Twist™ Fixation System

Rotator Cuff Repair
Surgical Technique Guide



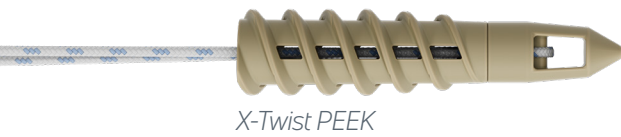
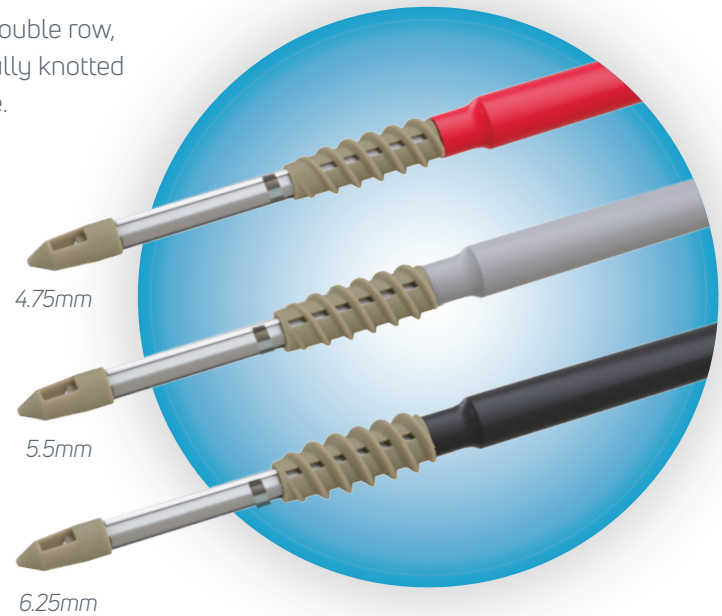
X-Twist Fixation System

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.

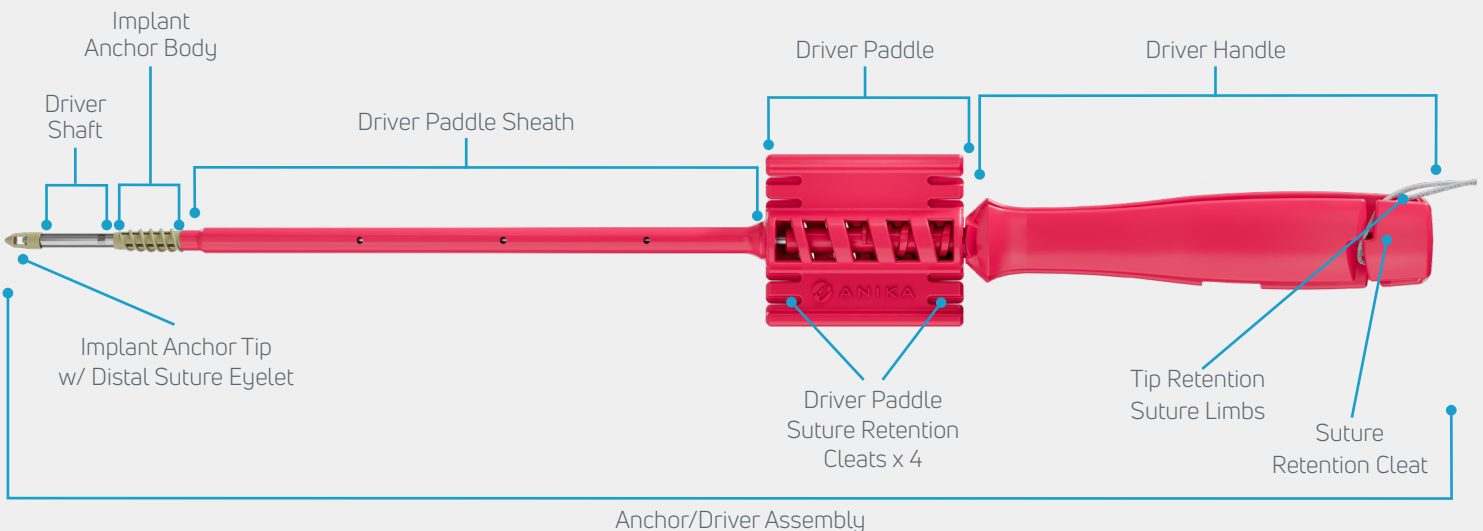


X-Twist PEEK

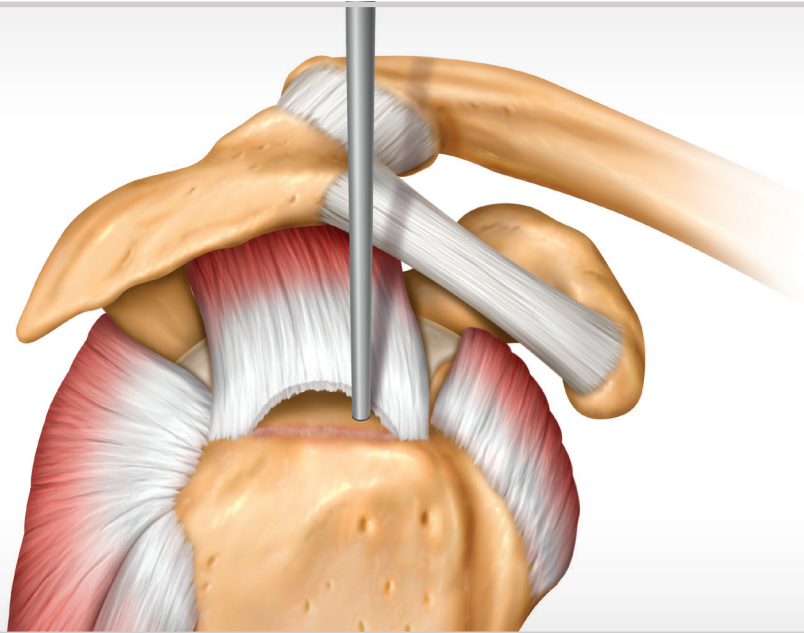


X-Twist Biocomposite
70% PLGA/30% BTCP and PEEK eyelet

X-Twist Suture Anchor



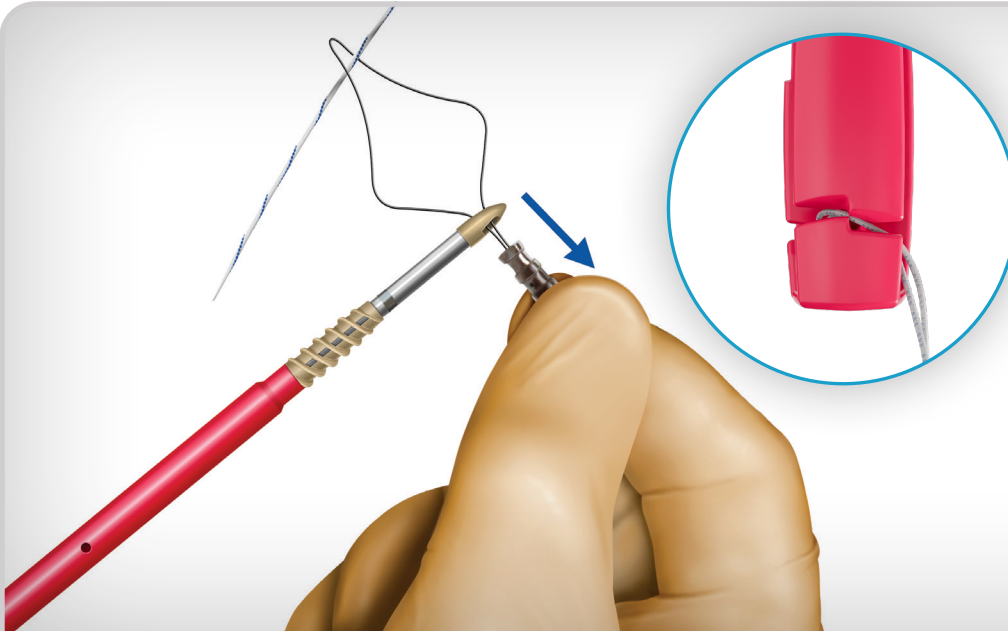
Rotator Cuff Repair *X-Twist™ Fixation System*



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.

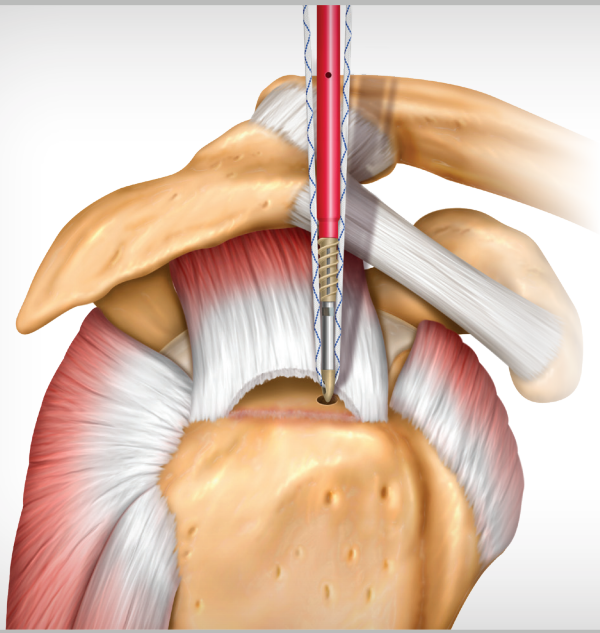


Note: If the anchor tip is pulled away from the shaft during suture passage (or at any other point), release the tip retention suture from the suture retention cleat of the driver handle. Then, re-apply tension by pulling the tip retention suture limbs simultaneously from the back of the driver handle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

step
2

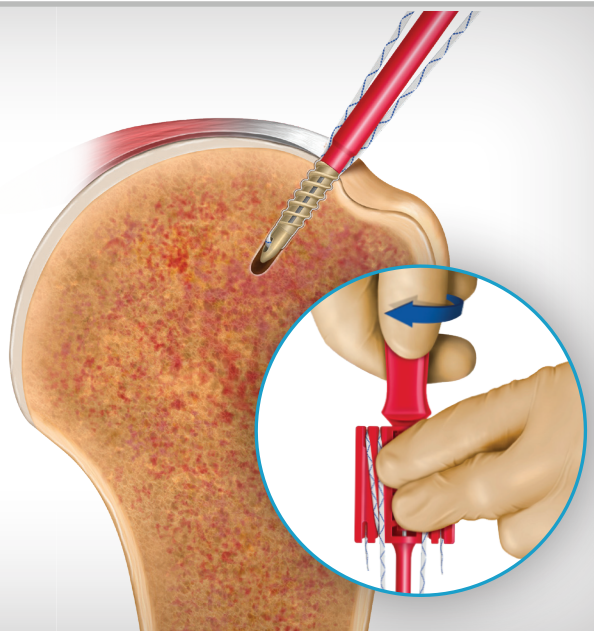
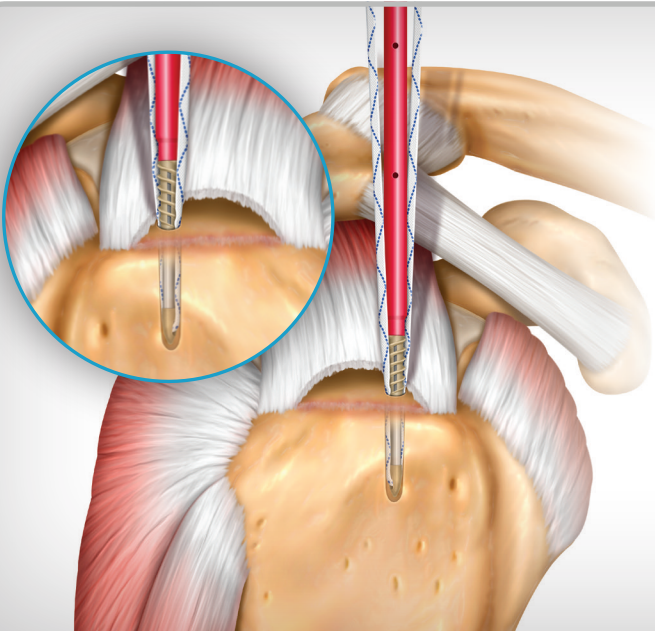
Use the suture threader to preload a 1.6mm or 2mm suture tape into the distal suture eyelet of the medial row X-Twist anchor.

Rotator Cuff Repair *X-Twist™ Fixation System*



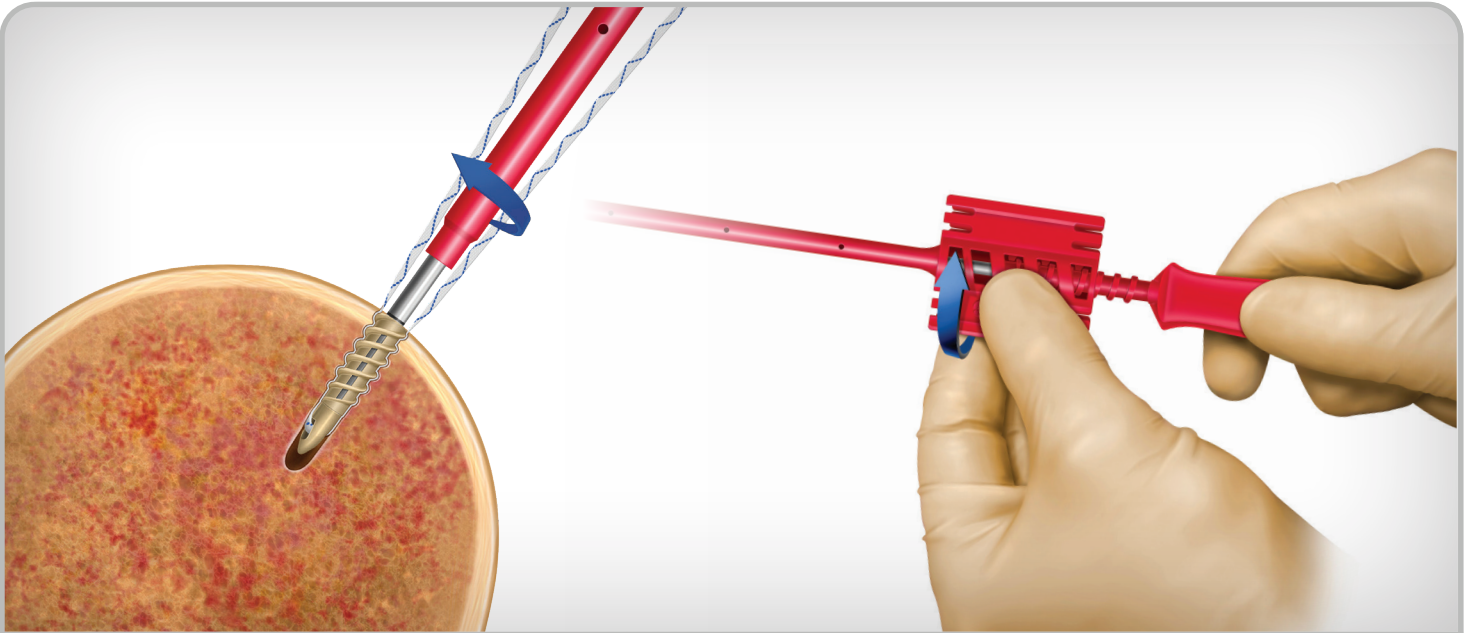
step
3

Align insertion angle with the pilot hole trajectory and advance the X-Twist anchor tip until the threaded anchor body contacts bone.



step
4

Holding the driver paddle stationary with one hand, rotate 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 remains flush with the bone.



step
4a

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.

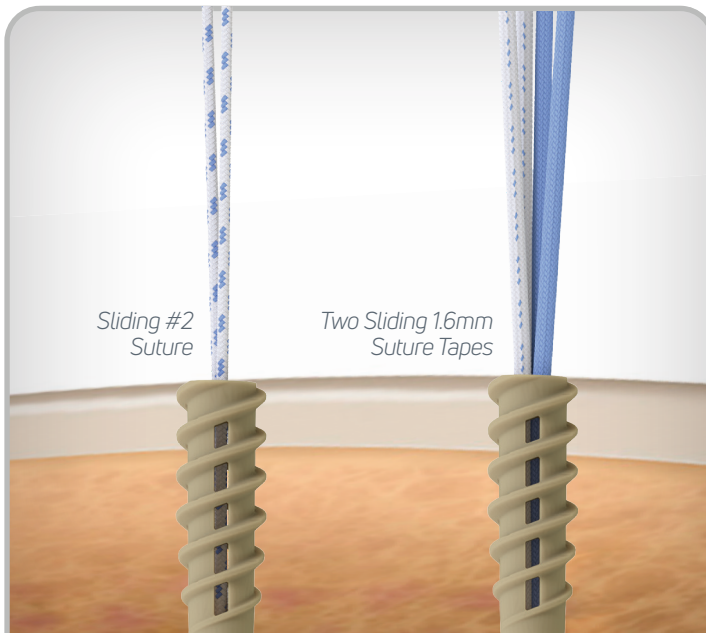


step
5

Once proper insertion depth is confirmed, unclasp and release all sutures. Pull the driver away from the implant to remove the driver.

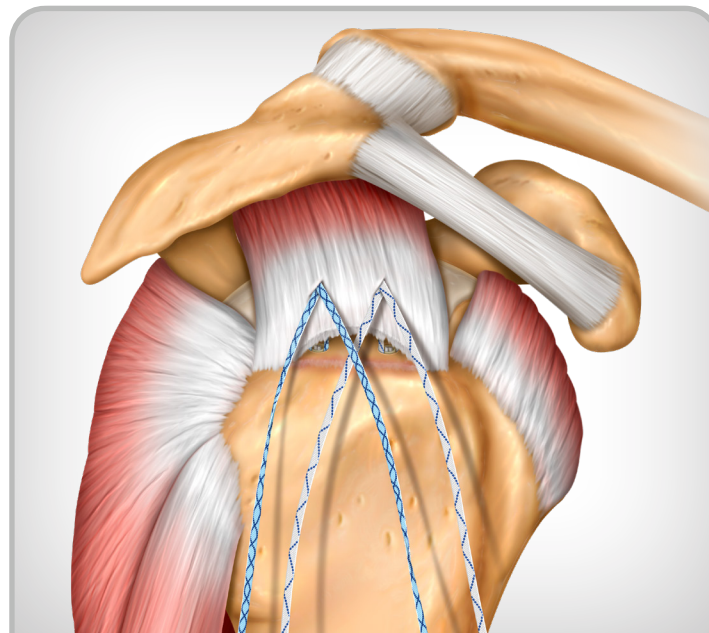
Note: Do not twist handle upon driver removal.

Rotator Cuff Repair *X-Twist™ Fixation System*



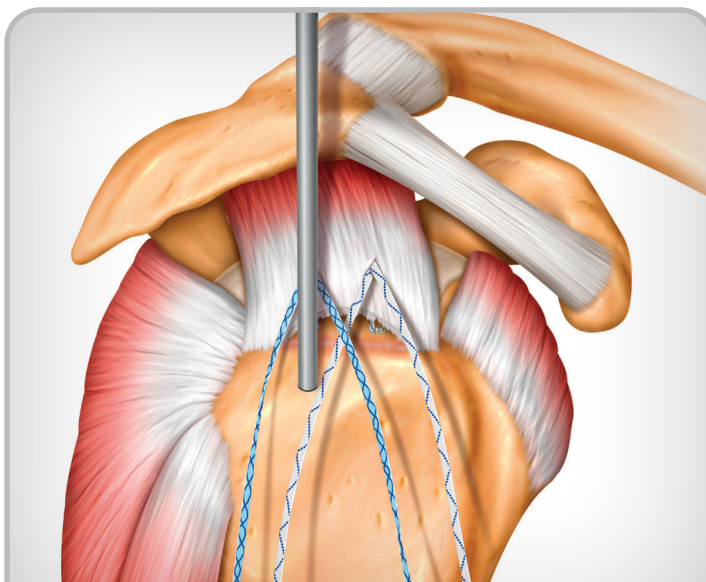
step
5a

The remaining sliding retention suture(s) may be incorporated into the repair or discarded. Repeat steps 1-5 for additional medial row anchor(s).



step
6

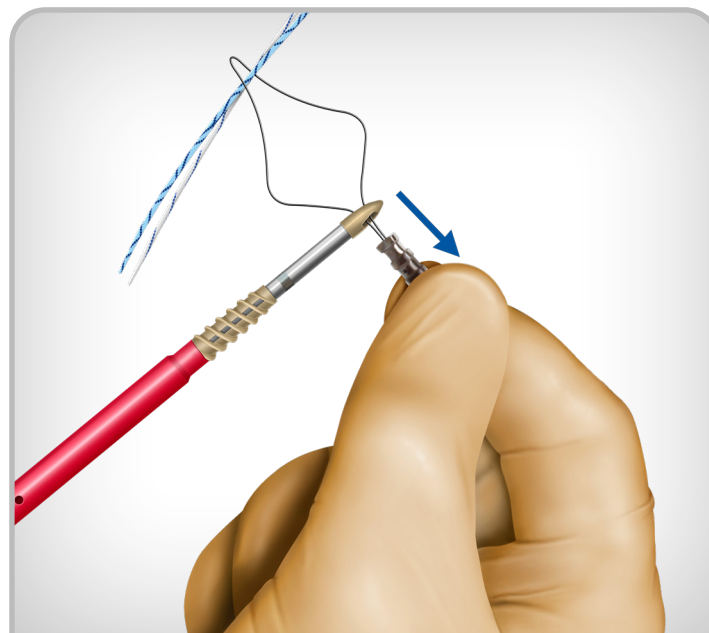
Pass the suture tapes through the rotator cuff tendon medially (lateral to the musculotendinous junction) using preferred suture passing technique.



step
7

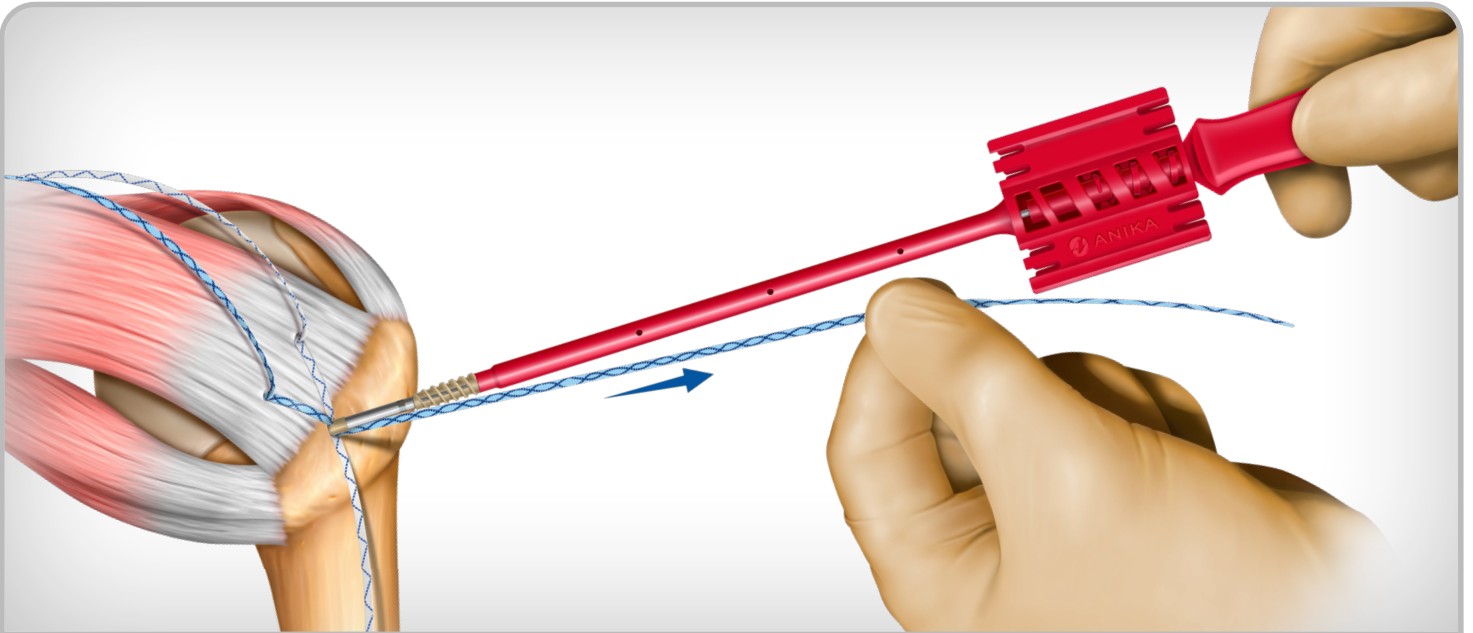
Identify the lateral anchor site and create a pilot hole using the X-Twist awl (XT04701). Insert the awl until the laser line is flush with the bone.

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.



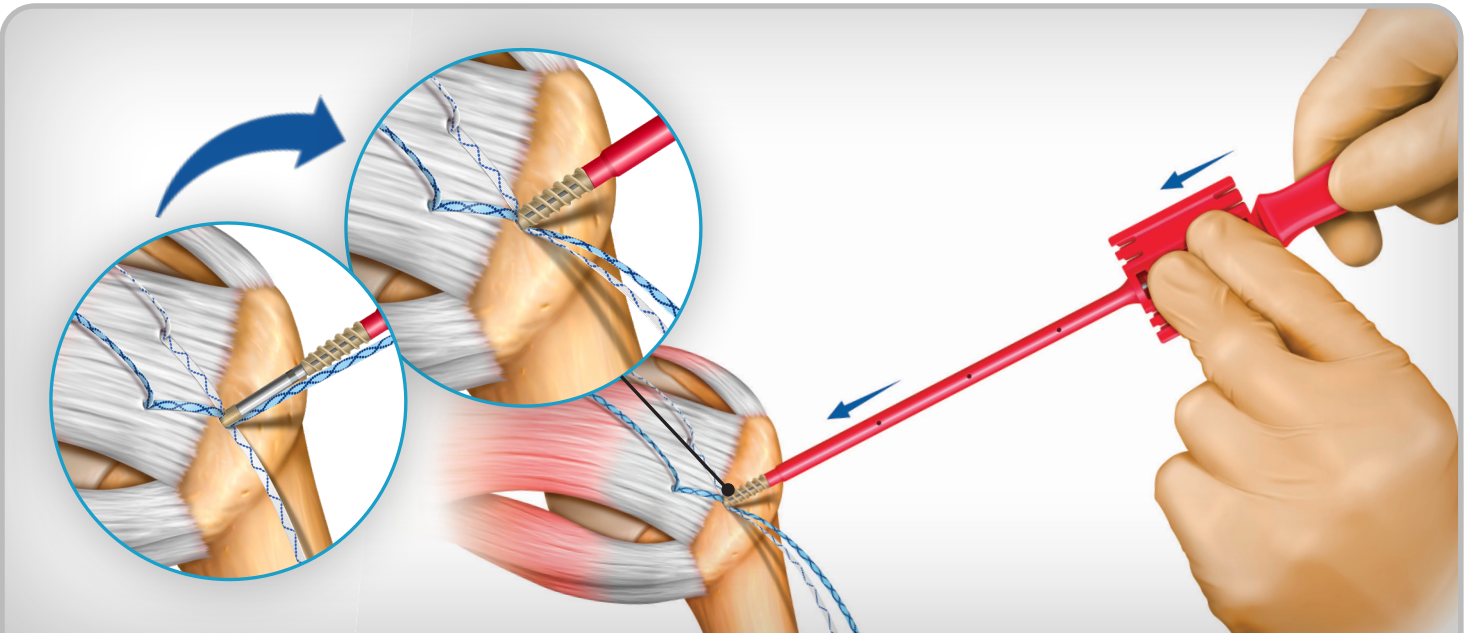
step
8

Use the suture threader to load medial row suture tape tails into the distal tip of the lateral row X-Twist suture anchor. Pull the threader tab to shuttle the loaded sutures through the anchor's distal suture eyelet.



step
9

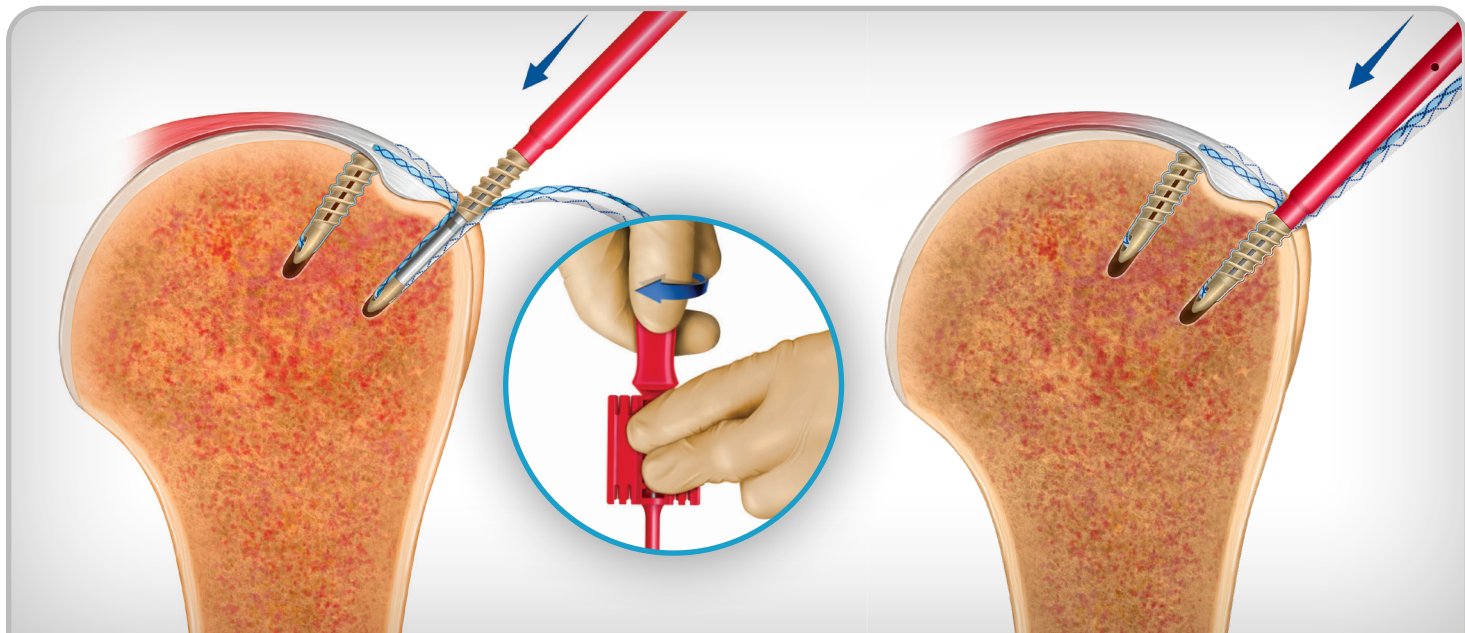
Remove slack prior to lateral anchor insertion by pulling each suture or suture tape limb individually. The X-Twist anchor tip is designed to be placed superficially in the pilot hole during this step to facilitate lateral row tensioning.



step
10

Once desired lateral row tensioning is achieved, mind the proper anchor insertion angle and push the X-Twist anchor tip into the pilot hole, advancing until the laser line breaches the tunnel aperture. Confirm proper construct tensioning. Additional tension may be applied by pulling individually on suture tape tails while maintaining counter pressure on the driver handle.

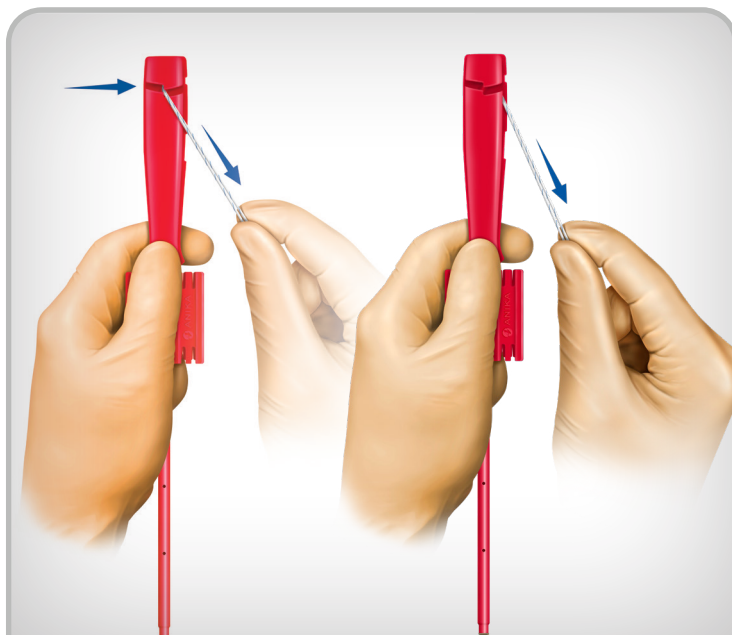
Rotator Cuff Repair *X-Twist™ Fixation System*



step
11

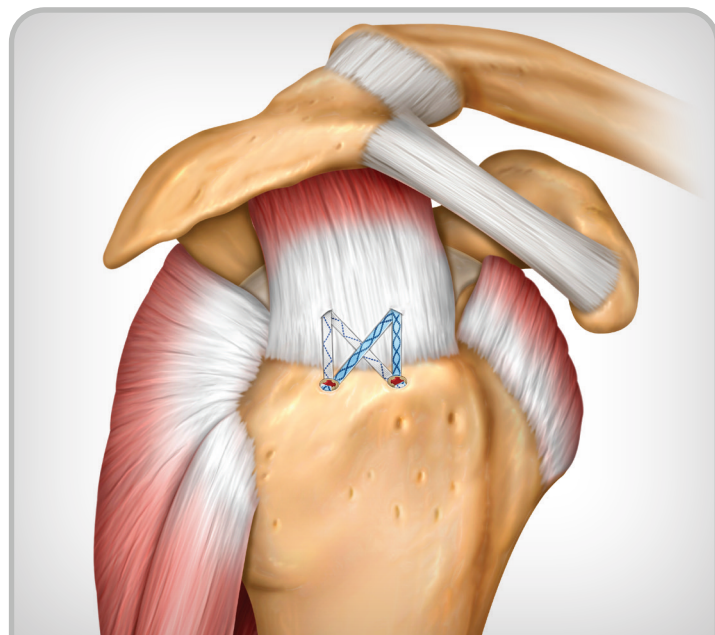
Hold the driver paddle stationary with one hand while rotating the driver handle clockwise with the other hand to advance the X-Twist anchor body down the driver shaft and into the prepared hole. Continue advancing until the proximal aspect of the anchor body is flush with the bone.

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.



step
12

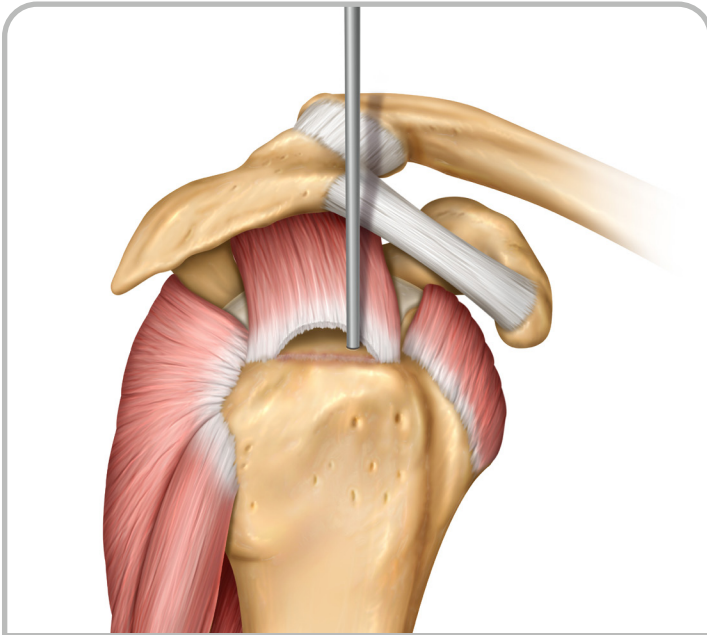
Uncleat and release all sutures. Pull the driver away from the implant. **Note:** Do not twist handle upon driver removal. The remaining sliding retention suture(s) may be incorporated into the repair or discarded. Cut excess suture tape limbs.



step
13

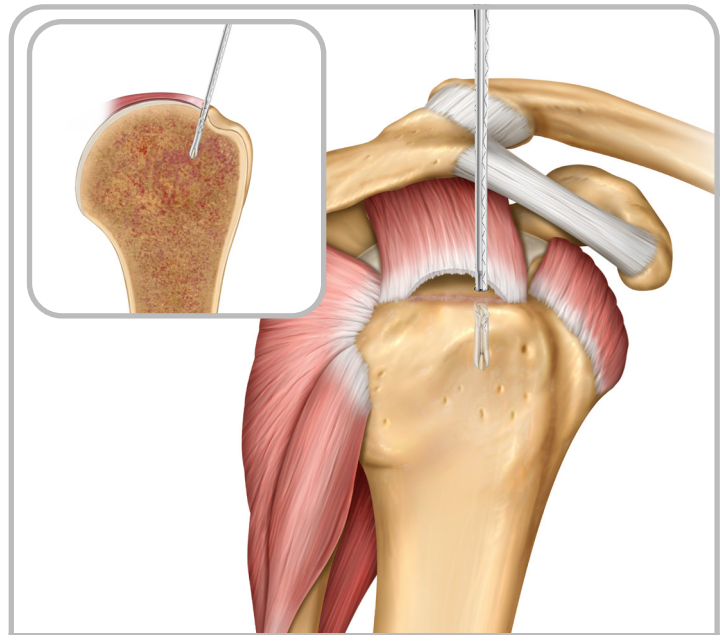
Repeat steps 7-12 to complete the double row repair with additional X-Twist lateral row anchor(s).

Alternative Medial Row Repair Technique



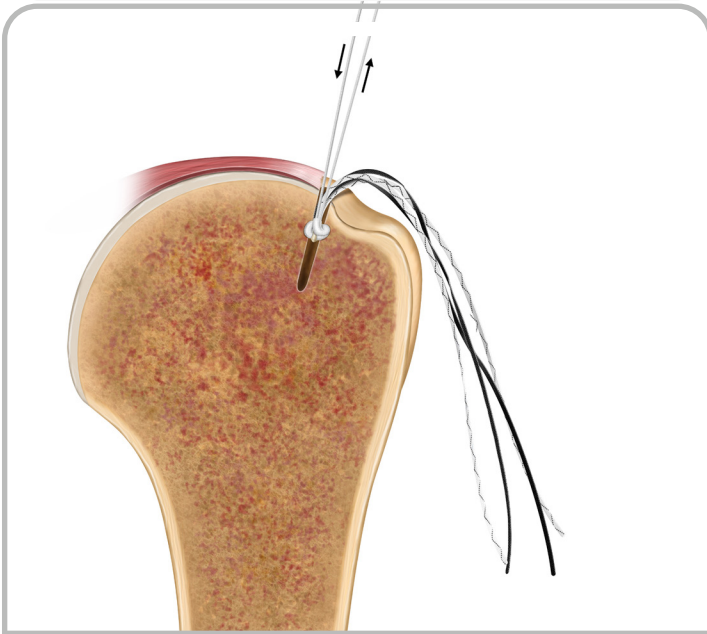
step
1

The rotator cuff footprint is prepared, and pilot holes are created near the articular margin using the 3.2mm Awl (10365) to the 2nd laser line.



step
2

Tap the 3.2mm Draw Tight Suture-Based Anchor into the pilot hole until laser line is reached. Uncleave all sutures and remove driver.



step
3

Pull the white deployment sutures in a pistoning motion to deploy the implant.

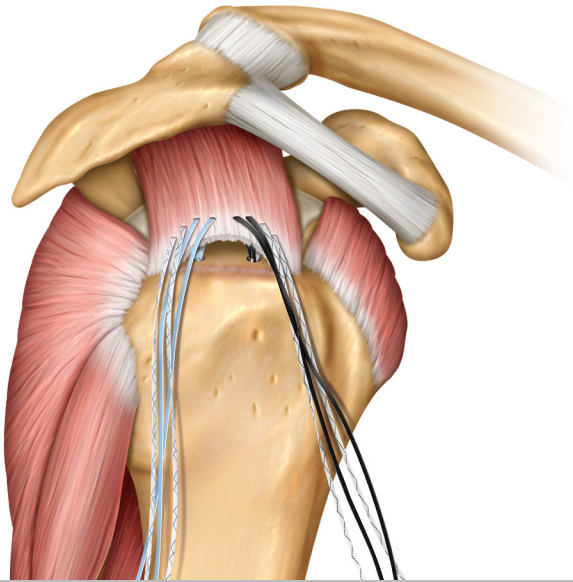


step
4

Release the white deployment sutures and pull the sliding suture tapes for final deployment confirmation.

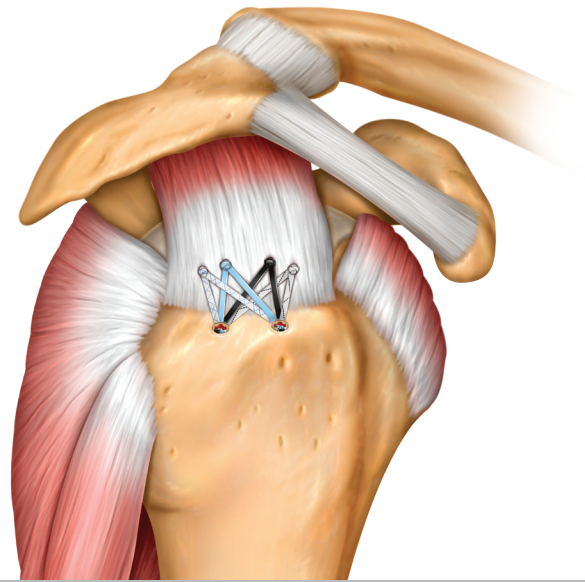
Note: Suture anchors are also available with two #2 sutures.

Alternative Medial Row Repair Technique



step 5

The white deployment sutures are cut, and 1.6mm suture tapes are passed through the rotator cuff in a mattress configuration using preferred suture passing technique. The suture tapes can be tied for primary fixation or individual suture tails can be incorporated into lateral row fixation.



step 6

Complete Steps 7-13 as previously described to complete the lateral row repair, using the X-Twist™ suture anchor(s).

X-Twist Instrument Guide

X-Twist Size	Bone Quality	Pilot Hole/Bone Socket Prep	Instrument Part Numbers
4.75mm	Soft	3.6mm Awl for X-Twist 4.75mm	XT04702
	Normal	X-Twist Awl for 4.75-5.5mm (4.1mm)	XT04701
	Hard	X-Twist Awl for 4.75-5.5mm (4.1mm) followed by the 4.75mm Tap	XT04701 XT04700
		OR	
		4mm Drill with 4mm Drill Guide, Tap (Optional)	11000U 11241 XT04700
5.5mm	Soft	X-Twist Awl for 4.75-5.5mm (4.1mm)	XT04701
	Normal	X-Twist Awl for 4.75-5.5mm (4.1mm)	XT04701
	Hard	X-Twist Awl for 4.75-5.5mm (4.1mm) followed by the 5.5mm Tap	XT04701 XT05500
		OR	
		4mm Drill with 4mm Drill Guide followed by the 5.5mm Tap	11000U 11241 XT05500
6.25mm	Soft	X-Twist Awl for 4.75-5.5mm (4.1mm)	XT04701
	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/1, #2 suture (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
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 Biocomposite Screw-In Suture Anchors				
Part #	Diameter (mm)	Length (mm)	Description	Material
XT44700	4.75	23	X-Twist Biocomposite 4.75mm, w/1, #2 Suture (blu/wht)	Biocomposite
XT44702	4.75	23	X-Twist Biocomposite 4.75mm, w/2, 1.6mm Suture Tapes (blu, blu/wht)	Biocomposite
XT44703	4.75	23	X-Twist Biocomposite 4.75mm, w/2, 1.6mm Suture Tapes (blk, blk/wht)	Biocomposite
XT45500	5.5	23	X-Twist Biocomposite 5.5mm, w/1, #2 Suture (blu/wht)	Biocomposite
XT45502	5.5	23	X-Twist Biocomposite 5.5mm, w/2, 1.6mm Suture Tapes (blu, blu/wht)	Biocomposite
XT45503	5.5	23	X-Twist Biocomposite 5.5mm, w/2, 1.6mm Suture Tapes (blk, blk/wht)	Biocomposite
XT46200	6.25	23	X-Twist Biocomposite 6.25mm, w/1, #2 Suture (blu/wht)	Biocomposite



Suture Tape				X-Twist Instrumentation			
Part #	Size (mm)	Description	QTY/ Box	Part #	Description	Sterile/Non-sterile	Single-use/Reusable
20032S	1.6	Parcus Braid® suture tape (wht/blu)	1	XT04701	X-Twist 4.75-5.5mm awl	Non-sterile	Reusable
20034S	1.6	Parcus Braid suture tape (wht/blk)	1	XT04702	3.6mm Awl for X-Twist 4.75mm	Non-sterile	Reusable
20174S	1.6	Parcus Braid infinity loop (wht/blu) w/ straight needle	1	XT04700	X-Twist 4.75mm tap	Non-sterile	Reusable
20042	2	Parcus Braid suture tape (wht/blu)	6	XT05500	X-Twist 5.5mm tap	Non-sterile	Reusable
20042S	2	Parcus Braid suture tape (wht/blu)	1	XT00001	X-Twist sterilization tray	Non-sterile	Reusable
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				

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/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 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 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 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

Anika Therapeutics, Inc.

Parcus Medical, LLC

6423 Parkland Dr, Sarasota, FL 34243

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

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