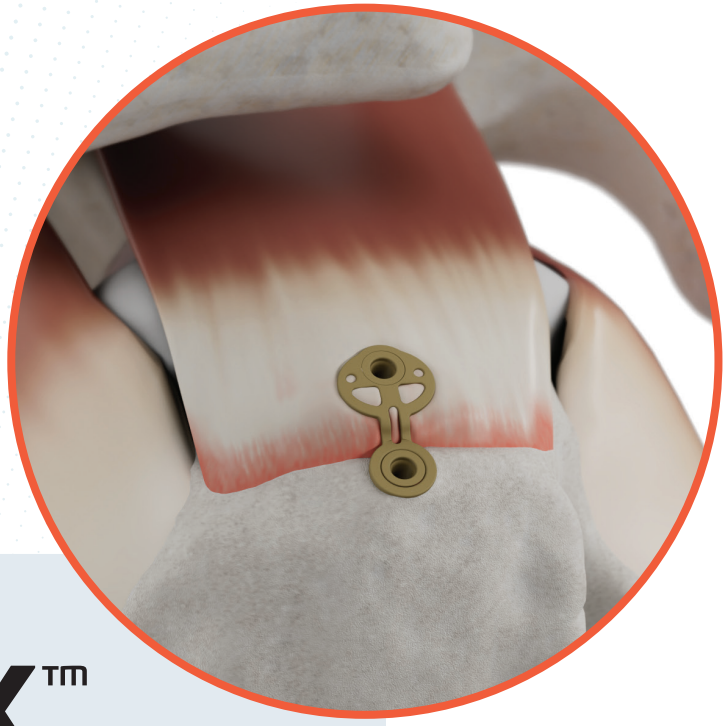


SINEFIX™

REVOLUTIONIZING ROTATOR CUFF REPAIR

No Knots.

No Sutures.

No Compromise.

See Last Page

Inovedis

THE SINEFIX SYSTEM

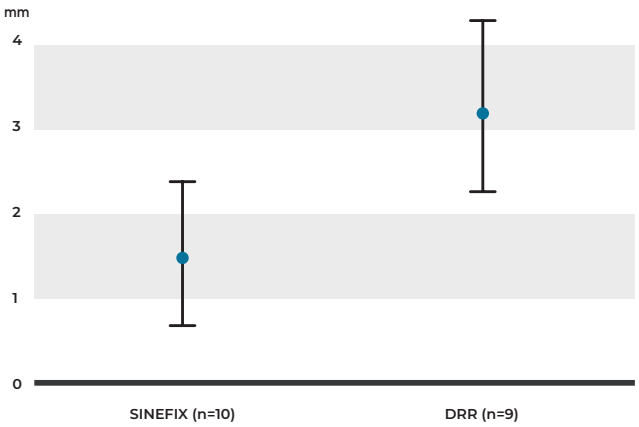
Rotator Cuff Lesions (RCL) are primarily treated arthroscopically using suture anchor technology. However, this method is difficult to learn and highly dependent on the manual dexterity and practical experience of the individual surgeon. SINEFIX™ is intended for soft tissue to bone reattachment in rotator cuff repairs for tendon ruptures up to 2cm and aims to improve and simplify tendon fixation. It consists of a PEEK Base Plate with fine pins to prevent the tendon from slipping out, plus a Lateral and Medial PEEK Anchor.

The Base Plate is placed over the tendon and attached to the humerus with the Anchors. The Medial Anchor goes through the tendon, while the Lateral Anchor goes directly into the bone, lateral of the tendon. This design keeps the tendon vital by ensuring blood circulation and eliminates the need for knot tying and complex suture management, making it a more accessible technique for surgeons.

ROTATOR CUFF REFIXATION: A Biomechanical Evaluation of a New Implant

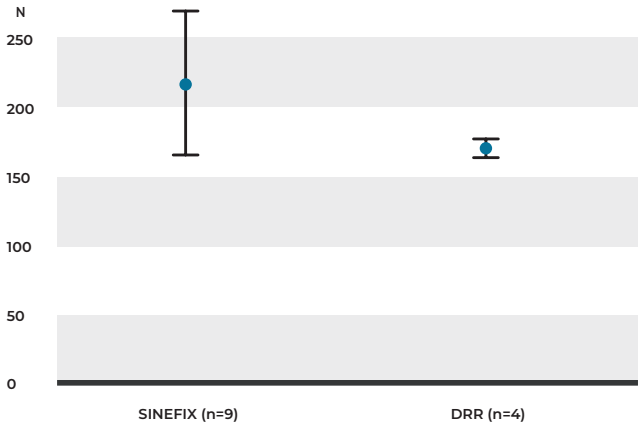
Philip Kasten, Jordi Borst, Daphne Gengler, Huub ter Braak, Friedrich Dehlinger[3], Lukas Floess[4], Stefan Welte[3]

Gap Formation Under Cyclic Loading up to 62 N



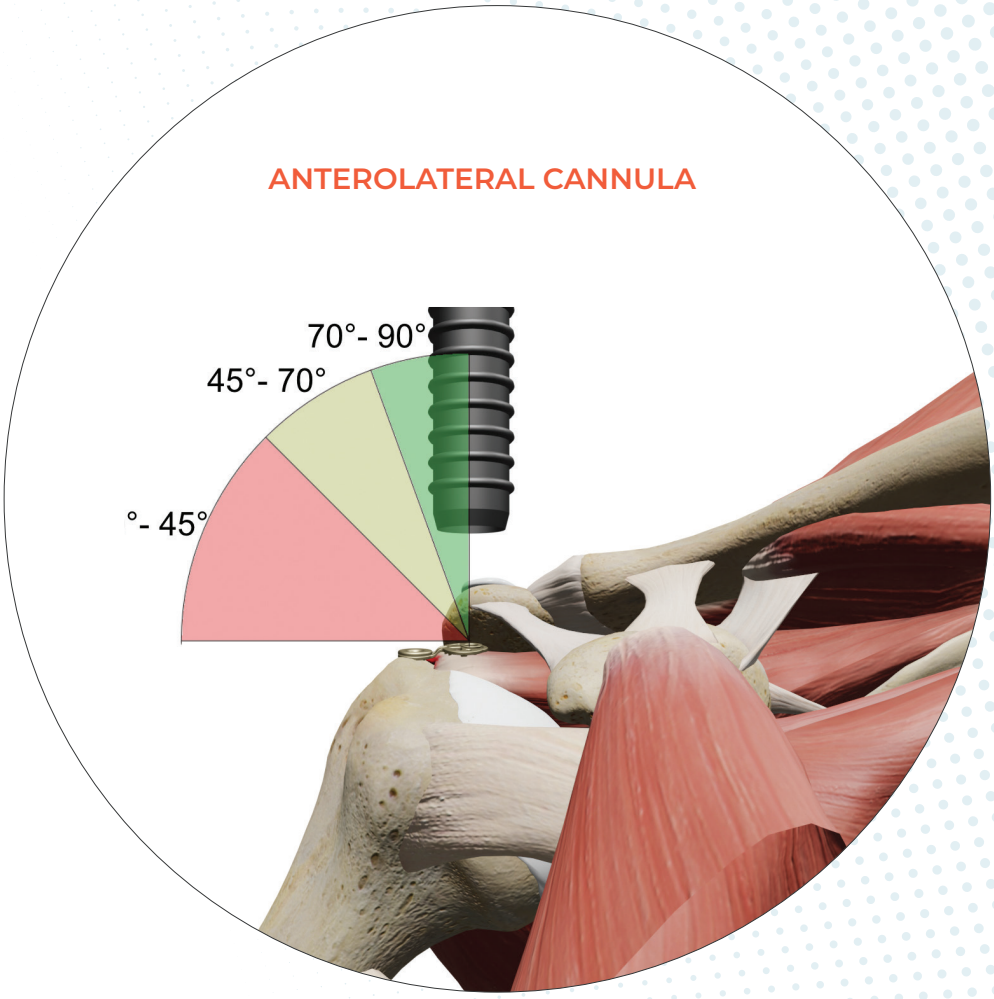
All (n=10) tendons refixed with SINEFIX™ survived cyclic loading up to 62N with a gap formation up to 1.49 millimeter (SD 0.84). In contrast, with the DR method, one tendon remained less stable (n=9) with a gap formation of 3.19 millimeters (SD 0.91) (p=0.001).

Pullout Forces



The maximum pullout forces with SINEFIX™ (n=6) were 215N (SD 55) versus DRR (n=4) with 166N (SD 15) (p=0.084).

The Sinefix implant has at least as high maximum pullout forces and gap formation as a double-row refixation (DRR) with “all-suture” anchors during cyclic loading



GENERAL ARTHROSCOPY AND PORTAL PLACEMENT

Create a lateral portal and determine the type, configuration and size of the tear as well as the degree of tendon retraction. Debride the insertion area on greater tuberosity with a shaver to create a bleeding bed to promote bone tendon healing.

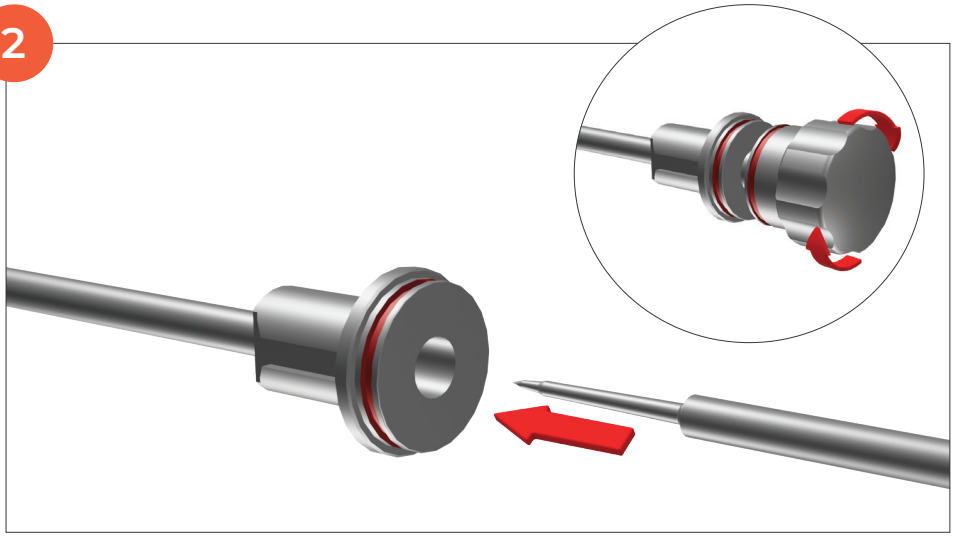
NOTE: If the exposed footprint cannot be punctured at an angle of 45-90° with the cannula under arthroscopic view, another arthroscopic technique must be used, or a mini open access must be created.

IMPLANTATION OF BASE PLATE AND MEDIAL ANCHOR

1

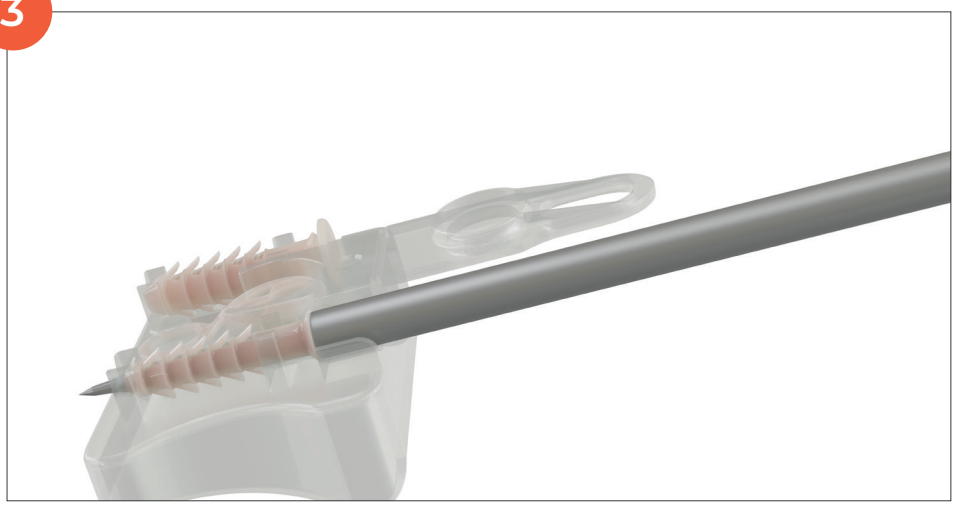
STEP 1
If the footprint can be reached with the cannula via the required impact angle, the anterolateral port can be created.

2



STEP 2
Assemble the Medial Anchor Inserter by placing the Medial Anchor Pushrod into the Medial Anchor Release Tube by rotating the Medial Anchor Pushrod clockwise.

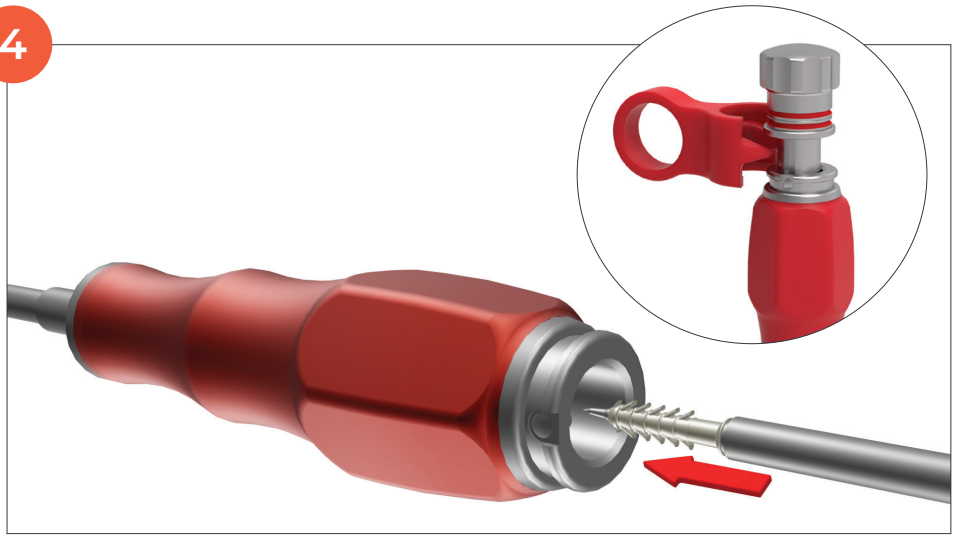
3



STEP 3
Steadily hold the inlay on the table with your finger while attaching the Medial Anchor on the Medial Anchor Inserter. The inlay is marked with M for the Medial Anchor.

Make sure that the head of the Medial Anchor is fully pushed against the Medial Anchor Inserter.

4



STEP 4

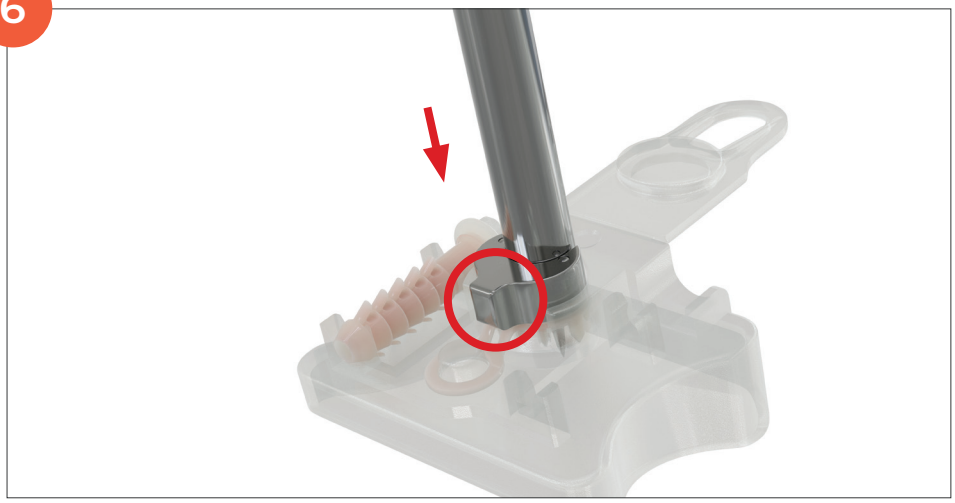
Pass the Medial Anchor Inserter through the Baseplate Inserter leaving space between the Medial Anchor Inserter and the Base Plate Inserter for the Stop Clip.

5

STEP 5

Make sure the Medial Anchor Inserter is properly aligned with respect to the Base Plate Inserter using the guidelines. Once it is lined up, push the Stop Clip onto the Medial Anchor Inserter.

6

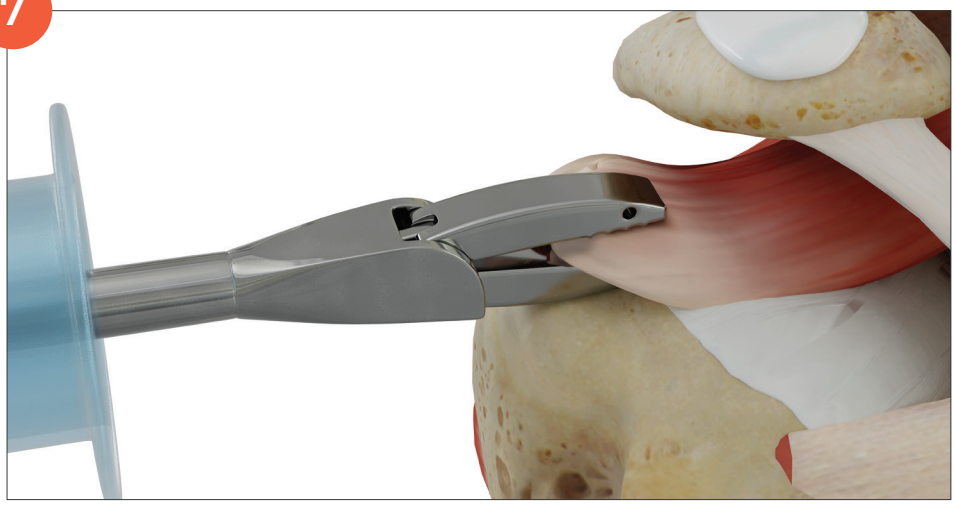


STEP 6

Steadily hold the inlay on the table and attach the Base Plate onto the Base Plate Inserter. Be sure to align the notch on the Baseplate Inserter to the tab of the SINEFIX implant.

There will be an audible click when the Base Plate is secured.

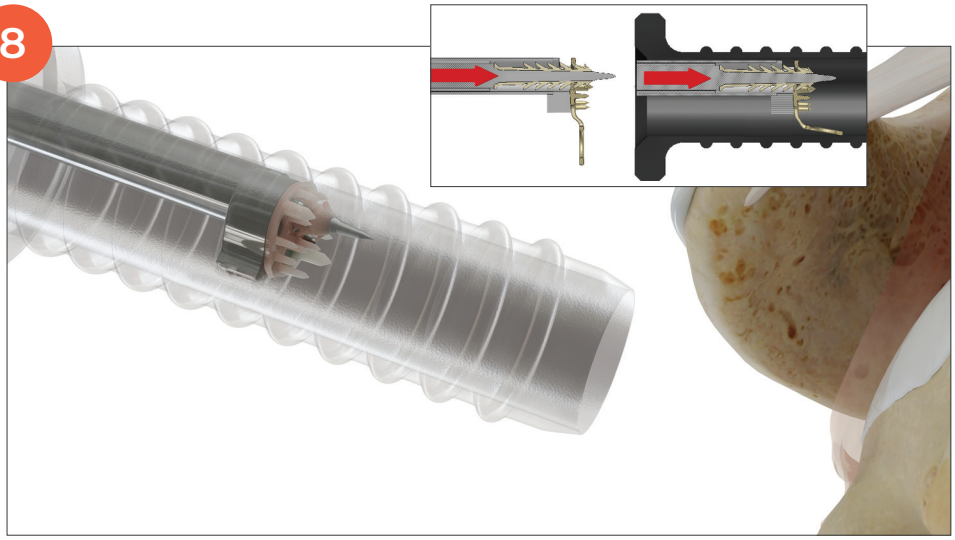
7



STEP 7

Pull the detached tendon over the insertion site using a tissue grasper via the lateral portal using lowest possible tension. It may be necessary to mobilize the tendon.

8

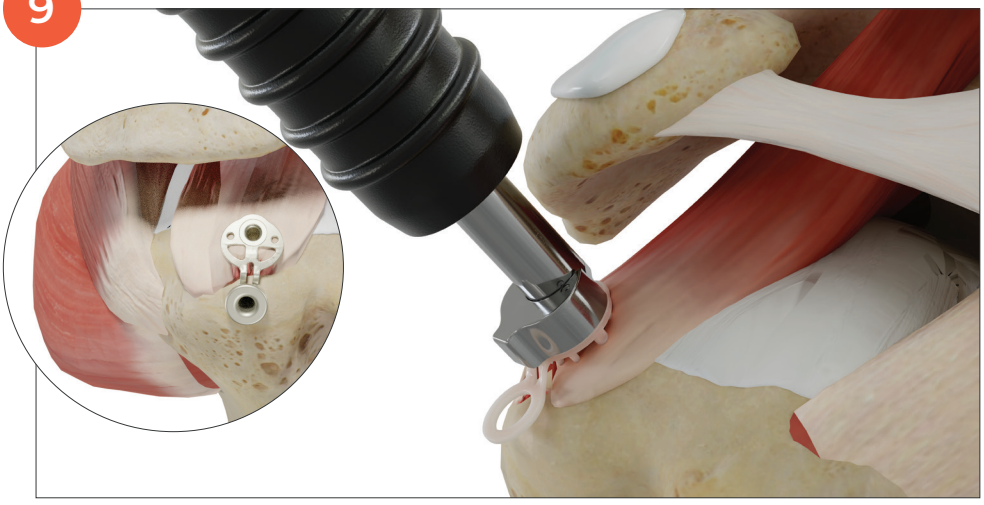


STEP 8

Pass the SINEFIX Medial Anchor and Base Plate through the 12 mm trocar. The Base Plate is slightly larger than the trocar, and must be pushed through the trocar as shown with the tab bent forward.

NOTE: The Base Plate tab should be pointing down when attached.

9

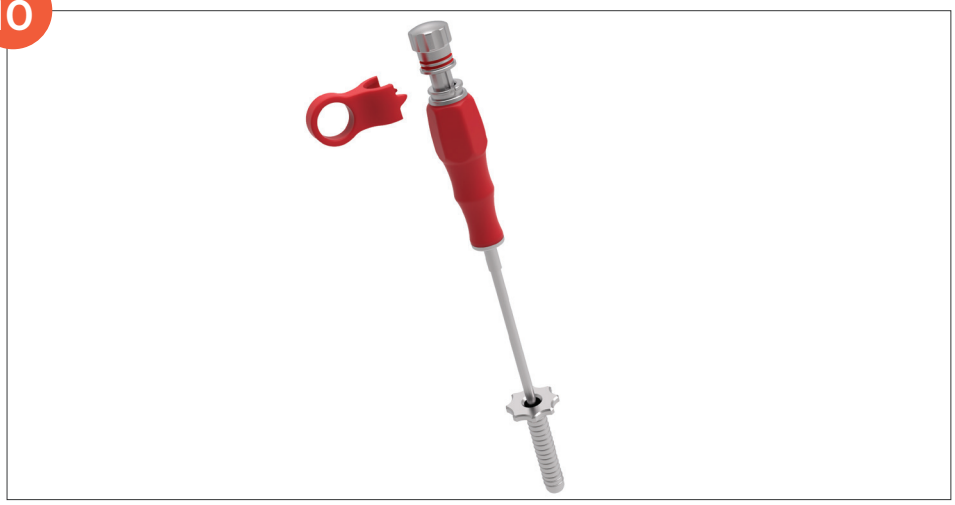


STEP 9

Place the implant over the tendon and the footprint while using axial pressure to fix the SINEFIX Base Plate into final position.

SINEFIX should be positioned so that the lateral edge of the implant is still above the tendon stump (it should not be over the edge of the tendon). The flap of the implant for the Lateral Anchor should be positioned just lateral to the footprint.

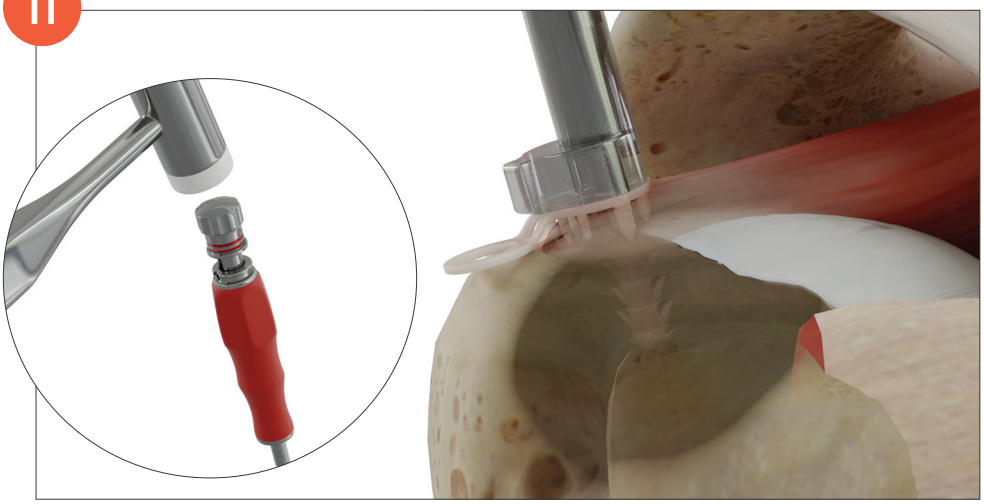
10



STEP 10

When correctly positioned, remove the Stop Clip from the Medial Anchor Inserter by placing your index finger into the Stop Clip and thumb on top of the Medial Anchor Inserter and pulling.

11

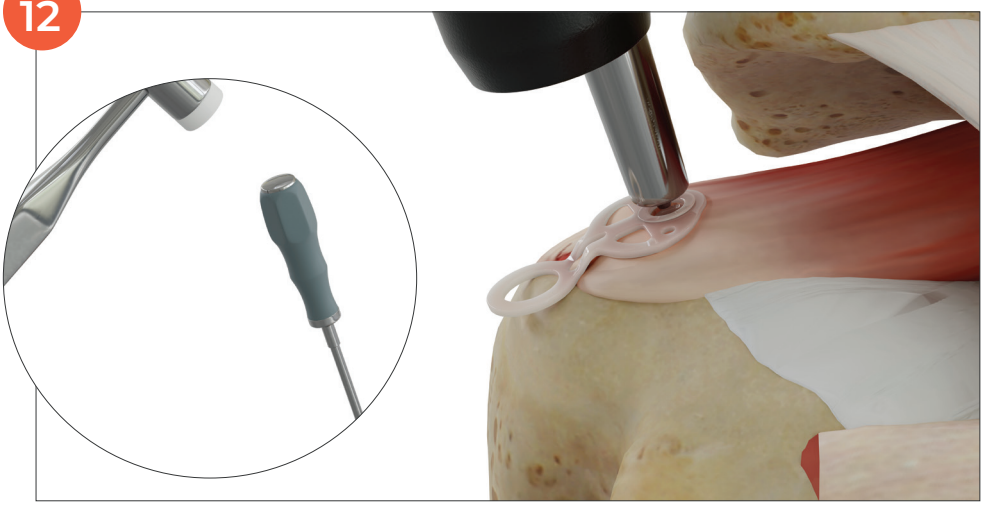


STEP 11

Drive the Medial Anchor in using the mallet with light strokes until you feel the mechanical stop. The impact angle to the footprint is a minimum of 45°, ideally 70°-90° (refer to page 3).

Remove the Medial Anchor Inserter and Medial Anchor Release Tube. The fine pins of the SINEFIX Base Plate should be fully immersed into the tendon but not into the bone.

12



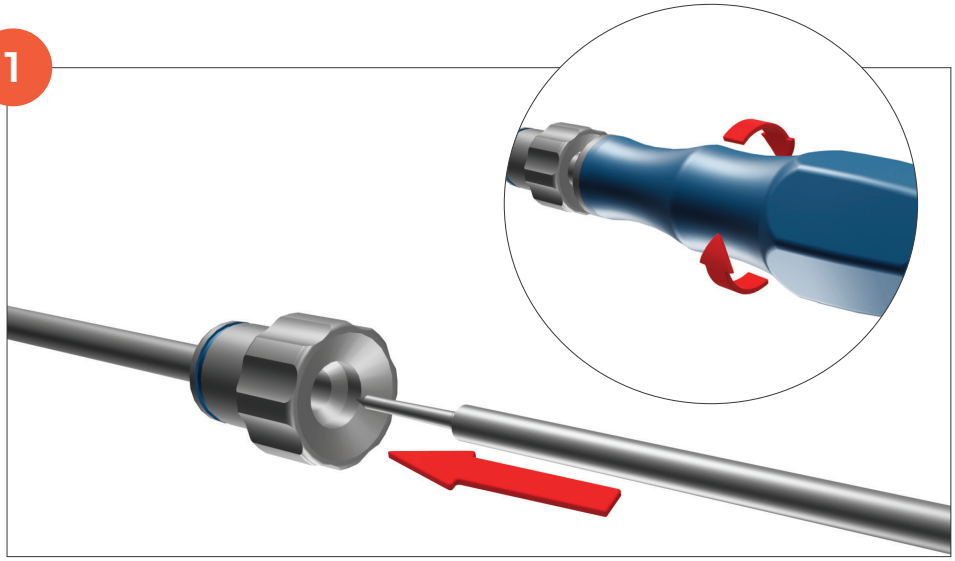
STEP 12

Lightly hammer the implant in further with the Repusher until the short pins on the underside of the implant are completely immersed in the tendon. The surface of the SINEFIX Base Plate should not push in the tendon to ensure blood circulation to the tendon.

NOTE: Do not over pressurize the tendon.

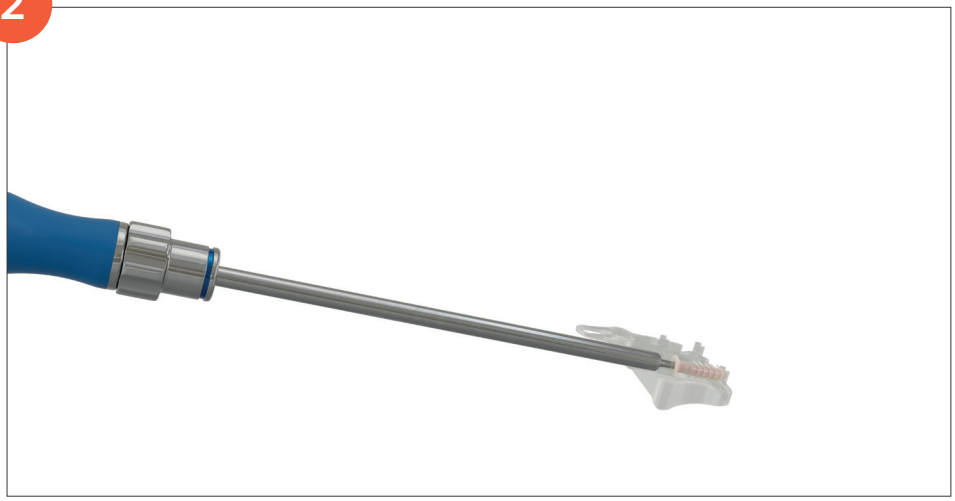
IMPLANTATION OF LATERAL ANCHOR

1



STEP 1
Assemble the Lateral Anchor Inserter by placing the Lateral Anchor Pushrod into the Lateral Anchor Release Tube.

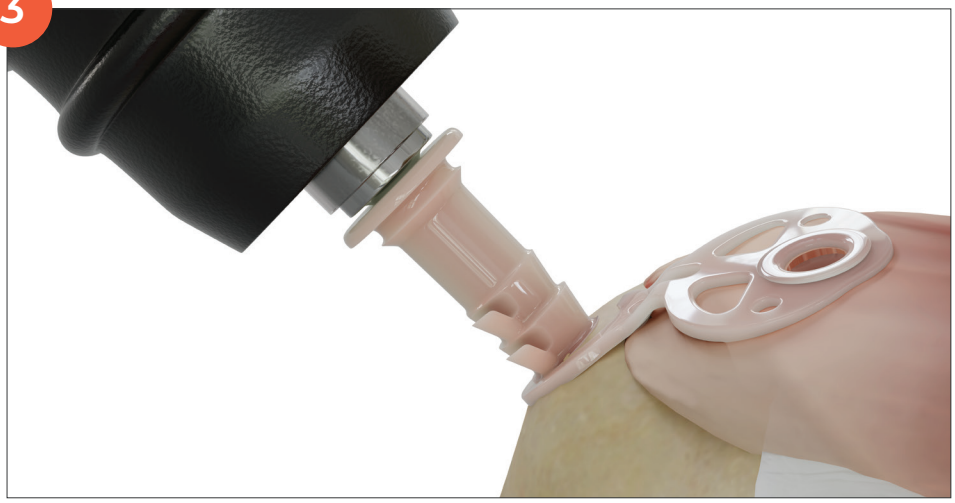
2



STEP 2
Hold the inlay on the table and attach the Lateral Anchor to the Lateral Anchor Inserter. Hold the Lateral Anchor in place with your finger while attaching on the Lateral Anchor Inserter. The inlay is marked with L for the Lateral Anchor.

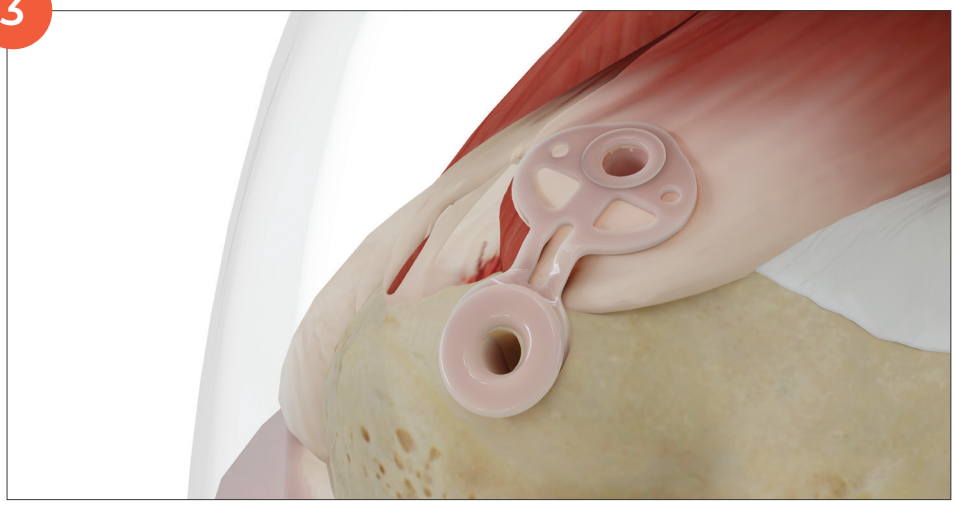
Ensure that the head of the anchor is fully pushed against the Lateral Anchor Pushrod.

3

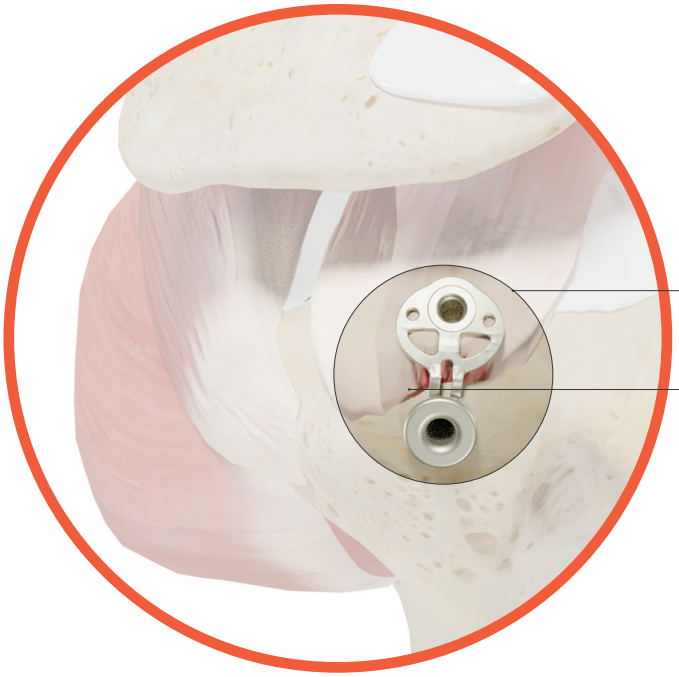


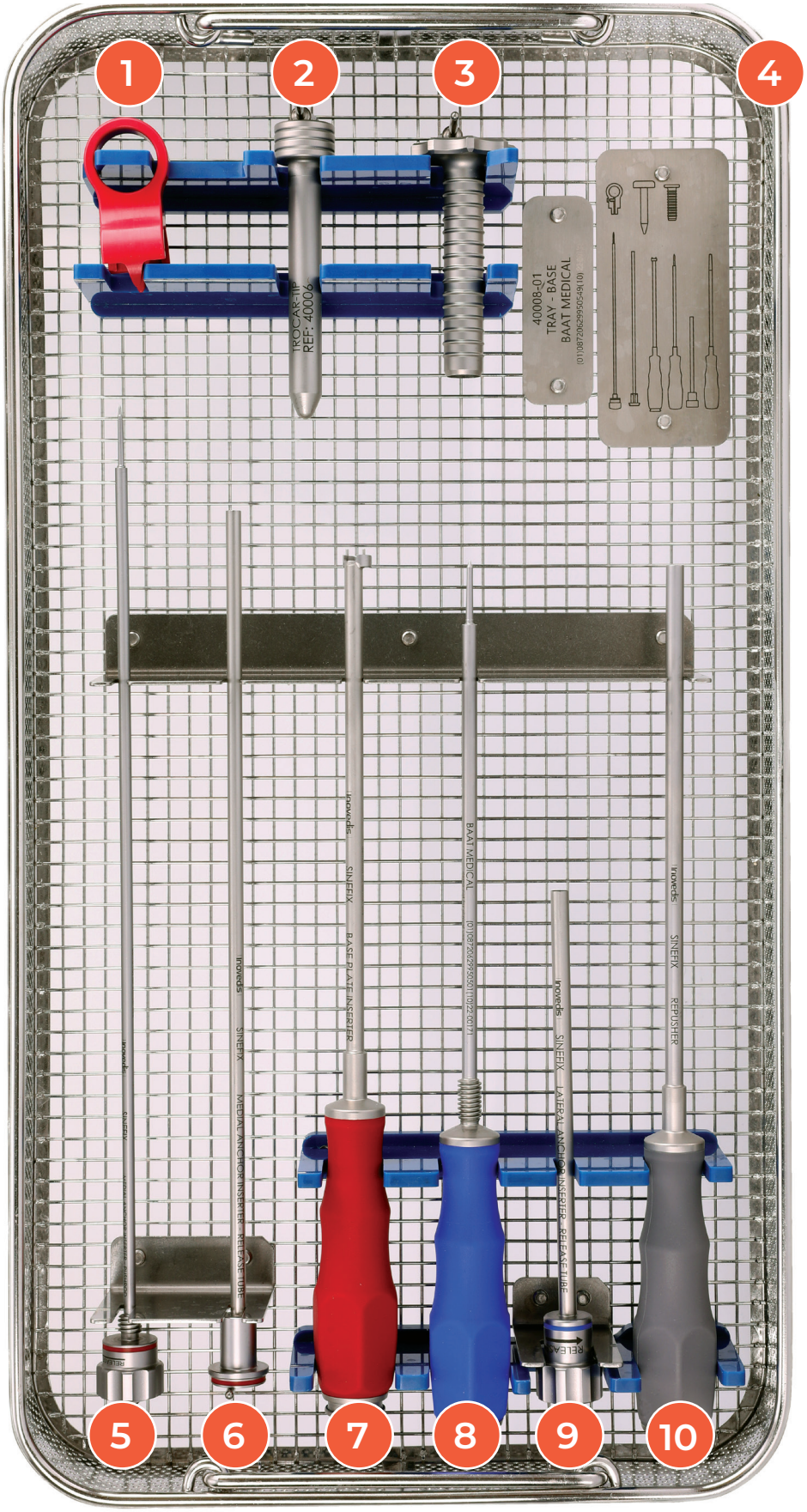
STEP 3
Insert the Lateral Anchor via the accessory anterolateral portal. Drive the Lateral Anchor into the bone using the mallet with light strokes at a 90° angle perpendicular to the Medial Anchor.

3



STEP 4
The implant's flexible tab for the Lateral Anchor fits to the bone as it enters.





SINEFIX INSTRUMENT SET

1. Stop Clip
2. Trocar
3. Trocar Tip
4. Tray
5. Medial Anchor Pushrod
6. Medial Anchor Release Tube
7. Base Plate Inserter
8. Lateral Anchor Pushrod
9. Lateral Anchor Release Tube
10. Repusher

ORDERING INFORMATION

Part Number		Quantity
30001	**SINEFIX™** Rotator Cuff Repair Device for rotator cuff tears <2cm (package of 5 PEEK implants)	5
	SINEFIX™ Instrument Set Reusable surgical instruments to facilitate implantation of the SINEFIX implant.	
40002	**Base Plate Inserter** to insert and release the SINEFIX Base Plate and enable insertion of the Medial Anchor.	1
40003	**Medial Anchor Inserter** to insert and release the Medial Anchor through the Base Plate Inserter. Comes with Medial Anchor Pushrod and Medial Anchor Release Tube.	1
40004	**Lateral Anchor Inserter** to insert and release Lateral Anchor. Comes with Lateral Anchor Pushrod and Lateral Anchor Release Tube.	1
40005	**Stop Clip** used to hold the position of the Medial Anchor Inserter in the Base Plate Inserter until the Medial Anchor is released	1
40006	**Trocar** to provide access channel for instruments	1
40007	**Repusher** to push anchors to final position	1
40008	**Tray—** Dedicated instrument tray to facilitate transport, handling, cleaning and sterilization of the instruments	1

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This brochure is provided as an educational tool and clinical aid to INFORM properly licensed medical professionals in the usage of specific Inovedis products. Please refer to instructions for use and the surgical technique for a complete list of indications, contraindications, warnings / precautions and a complete description of the operating procedure.

As part of the professional usage, the medical professional must use their professional judgment in making any final determinations in product usage and technique. In doing so, the medical professional should rely on their own training and experience and should conduct a thorough review of pertinent medical literature and the products directions for use.

Postoperative management is patient specific and dependent on the treating professional's assessment. Individual results will vary and not all patients will experience the same post operative activity level or outcomes.

USA Federal Law restricts this device to sale by or on the order of a physician.

SINEFIX is not approved for sale outside the U.S.

Inovedis

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