

## REVOLUTIONIZING ROTATOR CUFF REPAIR

Optimize outcomes.

Respect biology.

Increase efficiency.



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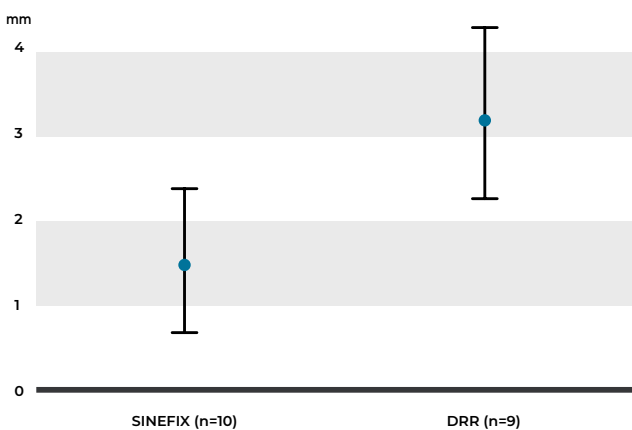
# THE SINEFIX SYSTEM

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. The PEEK 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 plate with two PEEK anchors and additional teeth that prevents the tendon from slipping out (Gap formation). The implant can be attached in two steps in such a way that the humerus and tendon are firmly connected to one another over a large area. SINEFIX also aims to maintain the vitality of the tendon, ensuring blood circulation and thus the biological healing process.

## ROTATOR CUFF REFIXATION: A Biomechanical Evaluation of a New Implant

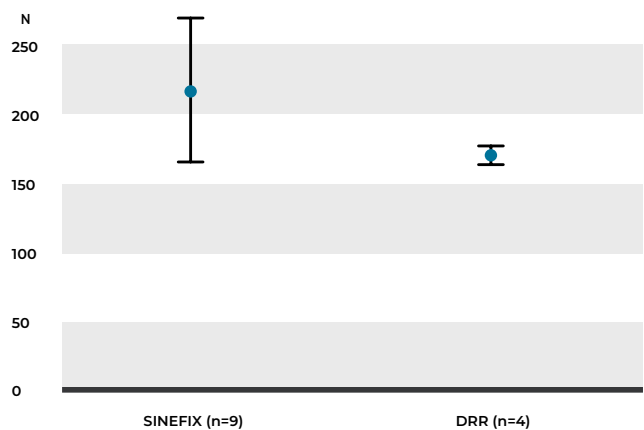
Philip Kasten, Jordi Borst, Daphne Gengler, Huub ter Braak, Friedrich Dehlinger<sup>3</sup>, Lukas Floess<sup>4</sup>, Stefan Welte<sup>3</sup>

### Gap Formation Under Cyclic Loading up to 62 N



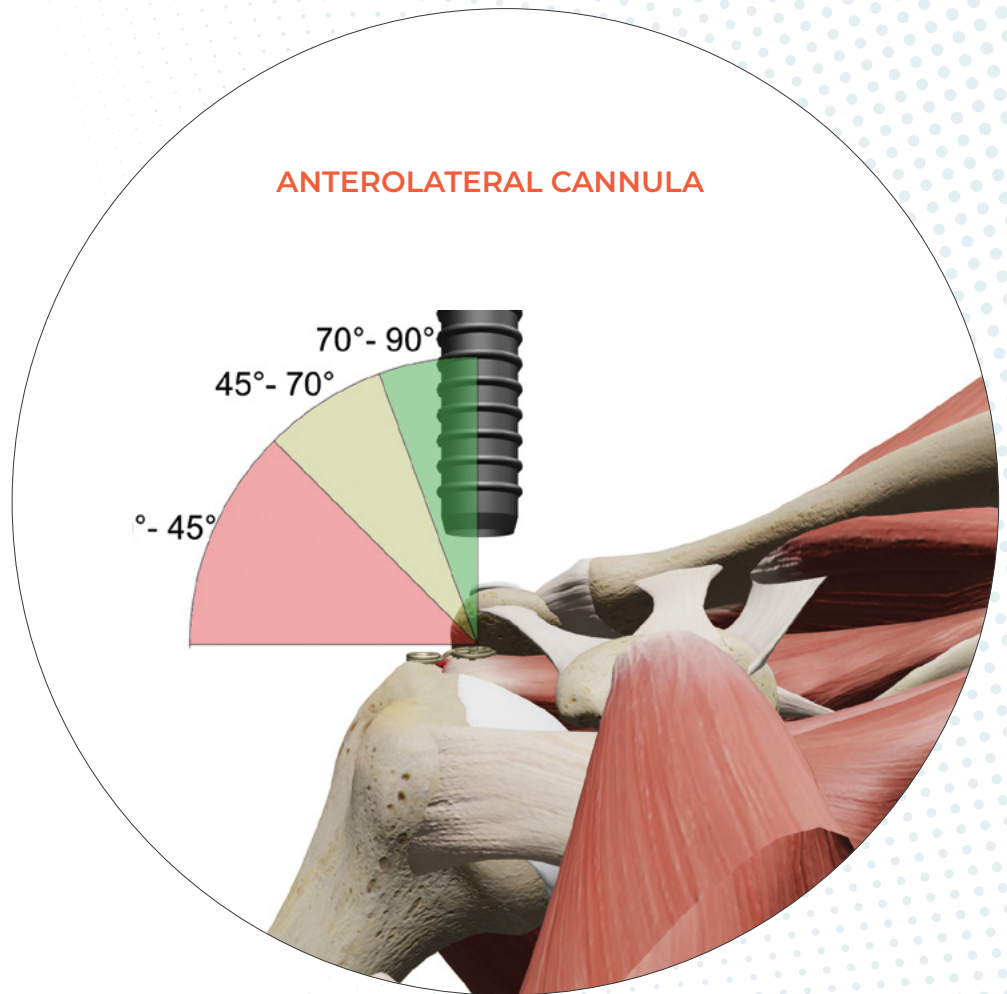
All (n=10) tendons refixed with SINEFIX™ survived cyclic loading up to 62N with a gap formation up to 1.49 millimeter (SD 0.84). In contrast, with the DR method, one tendon remained less stable (n=9) with a gap formation of 3.19 millimeters (SD 0.91) (p=0.001).

### 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



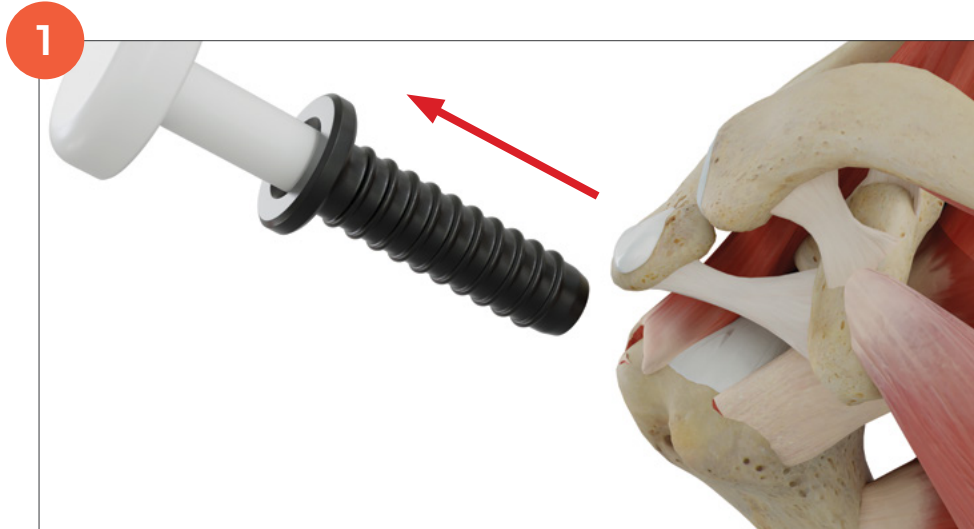
## GENERAL ARTHROSCOPY AND PORTAL PLACEMENT

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.

Place an anterolateral portal, which is needed for implanting SINEFIX™. If the footprint can be reached with the cannula via the required impact angle, the anterolateral port can be created.

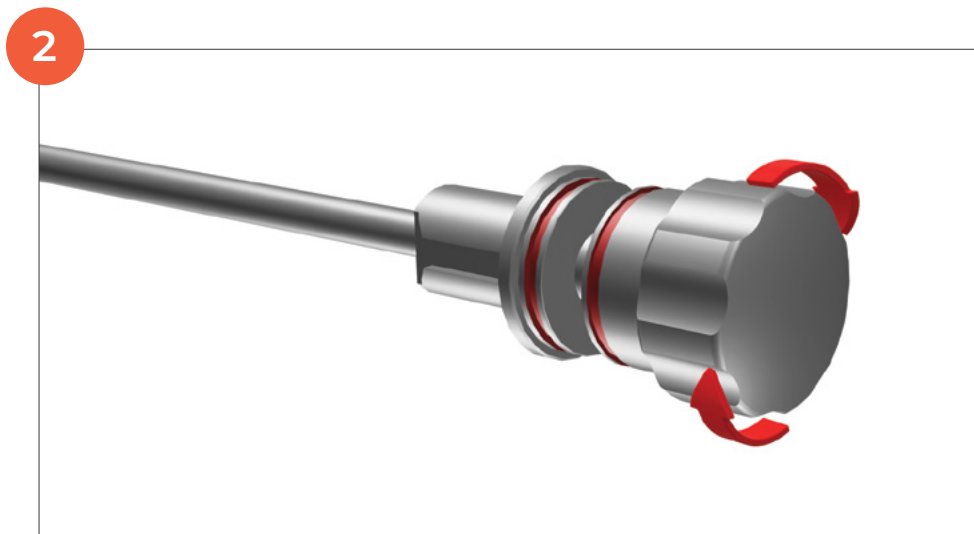
**NOTE:** If the exposed footprint cannot be punctured at an angle of 45-90° with the cannula under arthroscopic view, another arthroscopic technique must be used, or a mini open access must be created.

# IMPLANTATION OF BASE PLATE AND MEDIAL ANCHOR



## STEP 1

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



## STEP 2

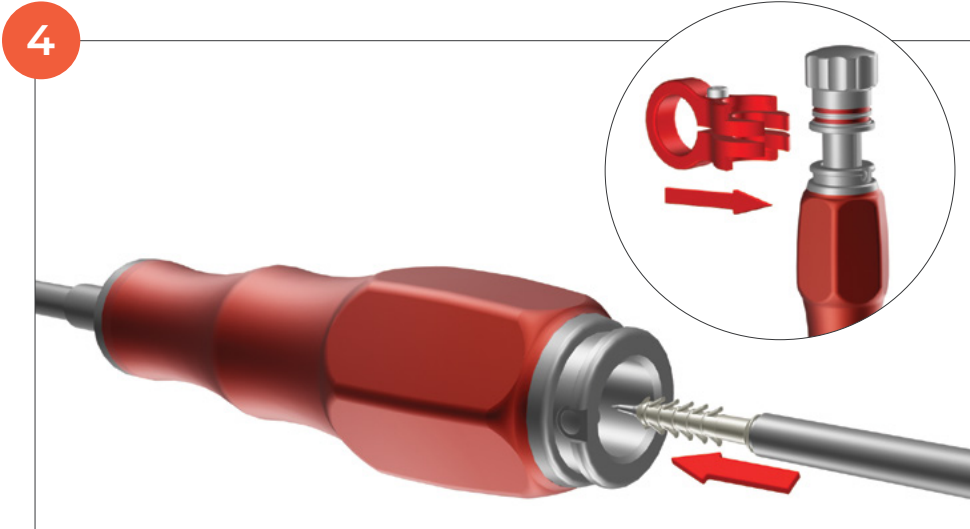
Assemble the Medial Anchor Inserter by placing the Medial Anchor Pushrod into the Medial Anchor Release Tube.



## STEP 3

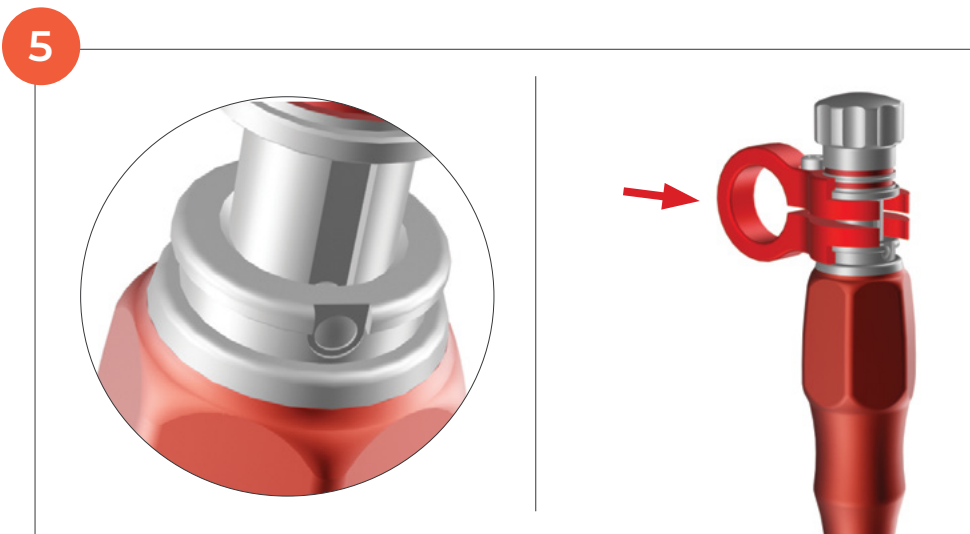
Steadily hold the inlay on the table with your finger while attaching the Medial Anchor on the Medial Anchor Inserter. The inlay is marked with M for the Medial Anchor.

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



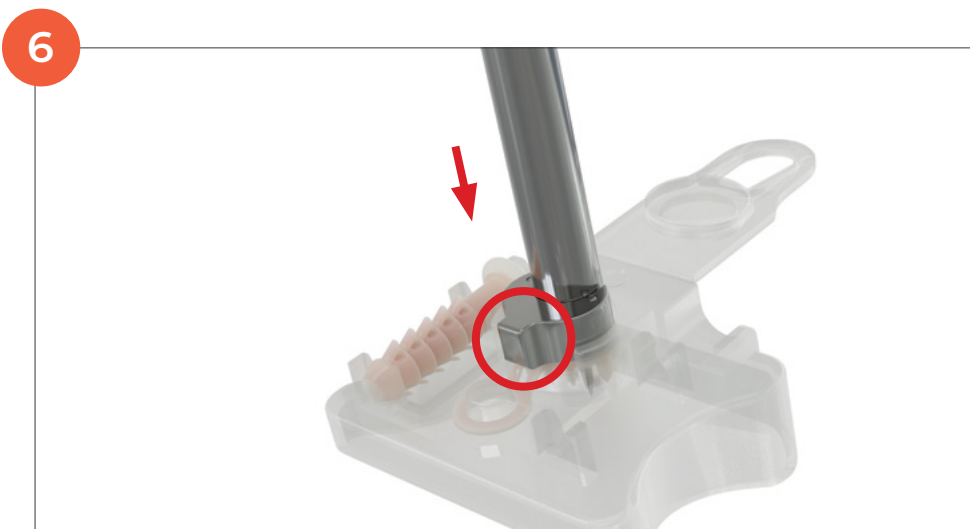
**STEP 4**

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.



**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.



**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.

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### 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.

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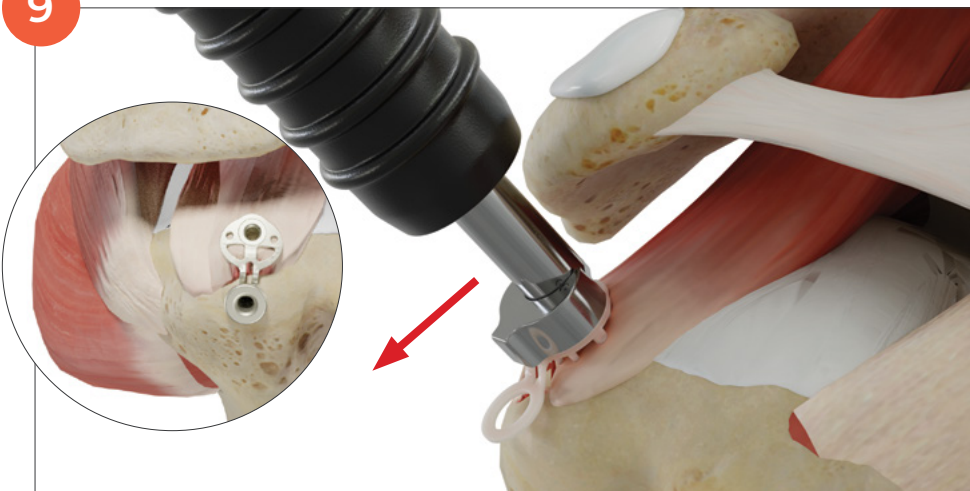


### STEP 8

Pass the SINEFIX Medial Anchor and Base Plate through the 12 mm trochar. The tab for the Lateral Anchor bends backward to allow the implant to pass through the trocar.

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

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### STEP 9

Place the implant over the tendon and pull over the footprint. Using axial pressure, the SINEFIX Base Plate is fixed 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.**

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**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.

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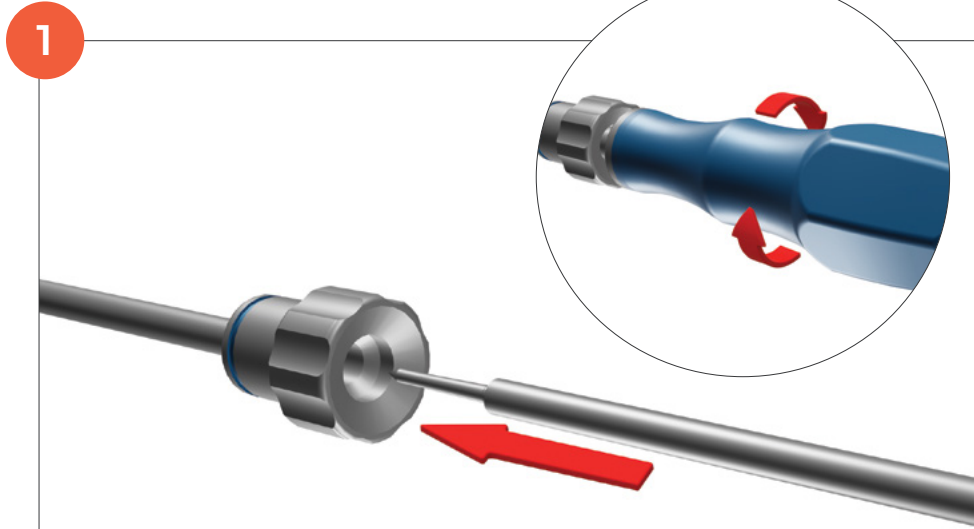


**STEP 12**

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



## STEP 1

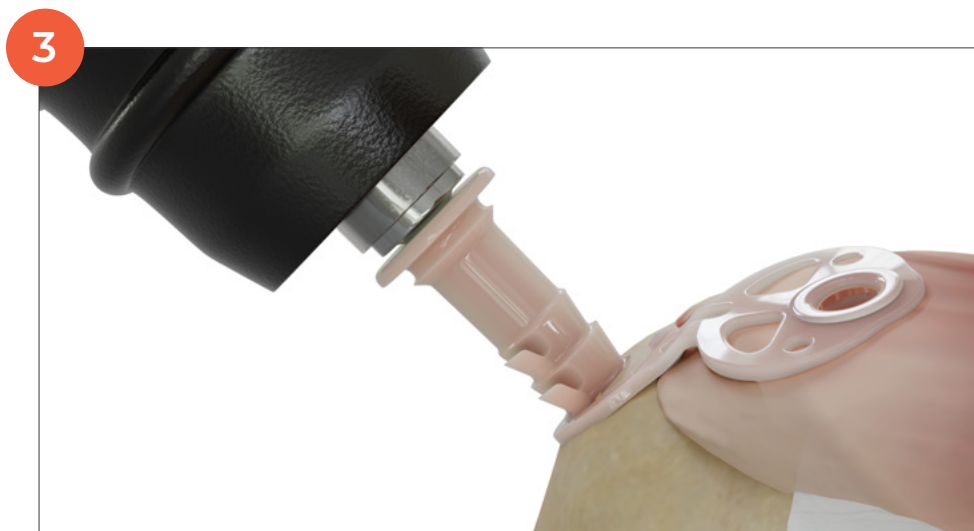
Assemble the Lateral Anchor Inserters by placing the Lateral Anchor Pushrod into the Lateral Anchor Release Tube.



## STEP 2

Hold the inlay on the table and attach the Lateral Anchor to the Lateral Anchor Inserters. Hold the Lateral Anchor in place with your finger while attaching on the Lateral Anchor Inserters. 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.

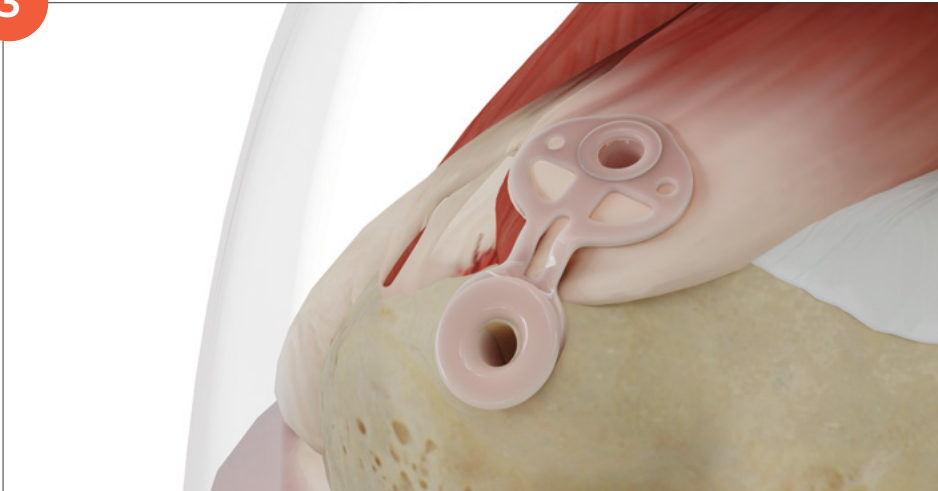


## STEP 3

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.

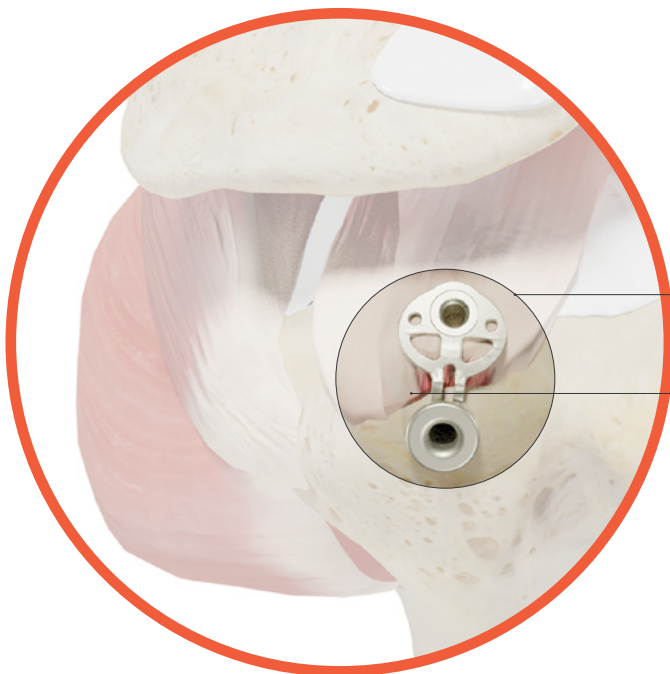


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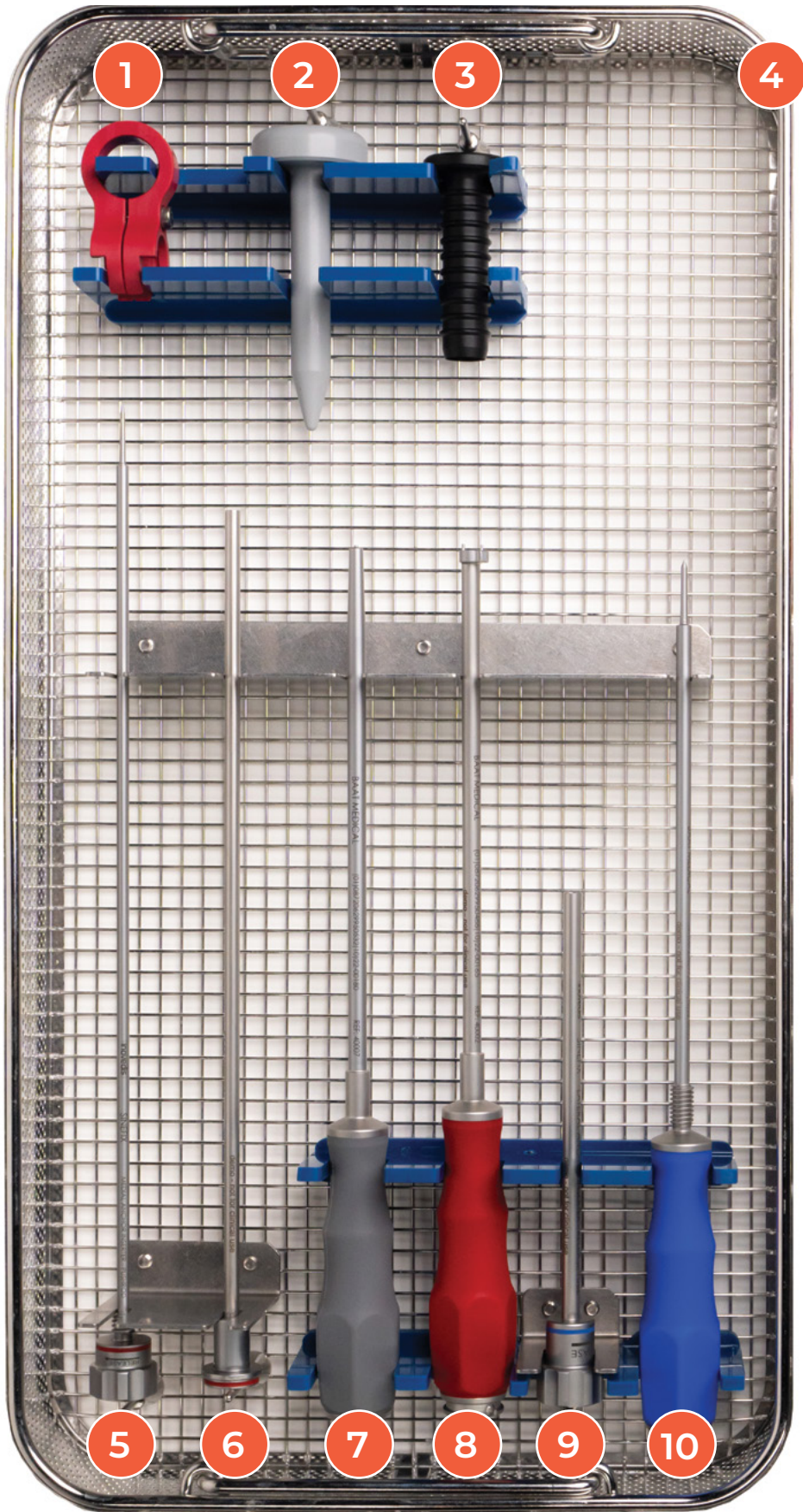
**STEP 4**

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



**FOOTPRINT**

**LATERAL EDGE**



### SINEFIX INSTRUMENT SET

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

# ORDERING INFORMATION

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

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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.

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