

ORCA[™]

Self-Locking Adjustable Button for Tendon Repair-Reconstruction

Bicortical Proximal Biceps Tendon Repair – Surgical Technique Guide



The ORCA™ button is designed to simplify and streamline the process of tendon repair reconstruction by using a self-locking adjustable button. It utilizes a proprietary inter-locking technology which captures the suture strands and maintains the repair under tension.

Indications

The ORCA™ is intended for tendon repair-reconstruction in the following indications:

Upper Extremity:

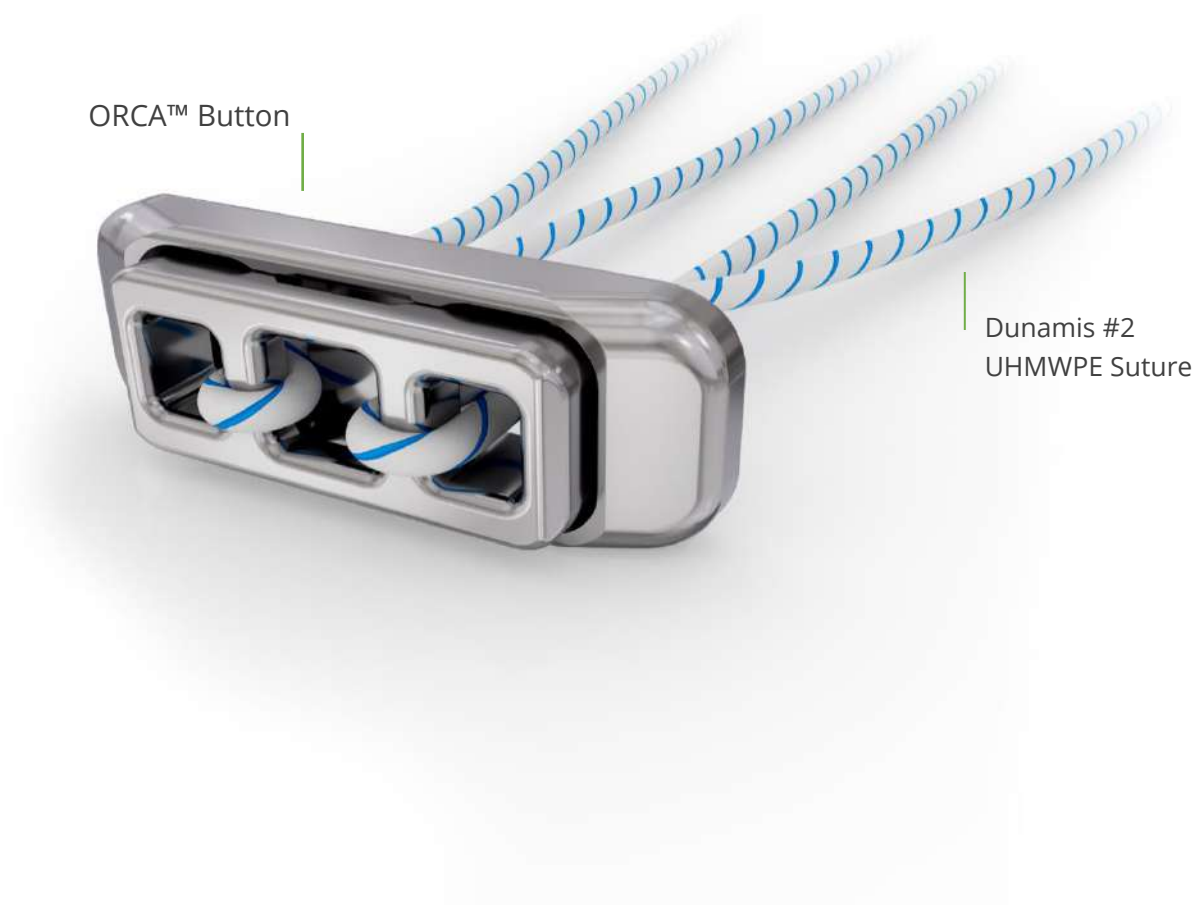
- Proximal Biceps Repair
- Distal Biceps Repair
- Pectoralis Major Repair

Lower Extremity:

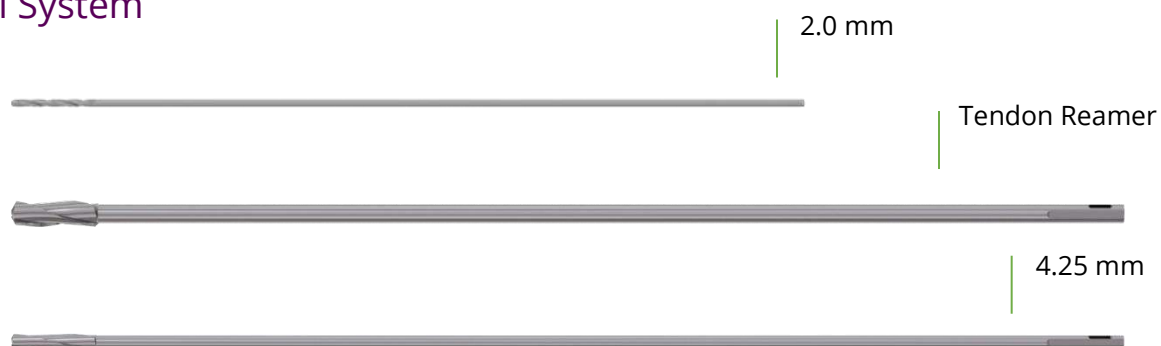
- Flat Foot Repair - FDL Tendon Transfer
- Pes Cavus – Tibialis Posterior Tendon Transfer
- Chronic Achilles Repair - FHL Tendon Transfer
- Tibialis Anterior Tendon Repair

Prior to performing this technique, please consult the Instruction for Use provided with this device.

Implantable Devices

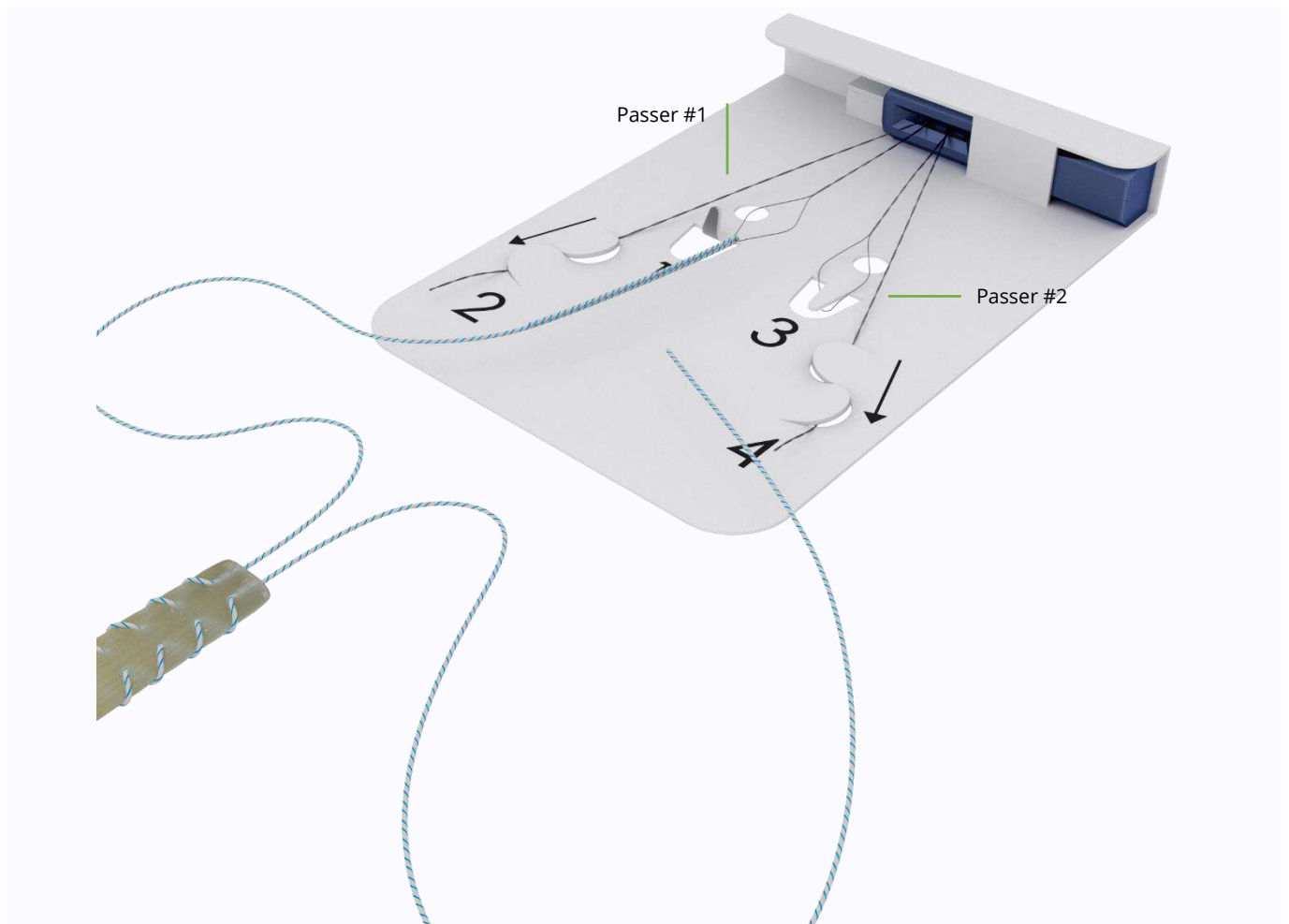


Drill System



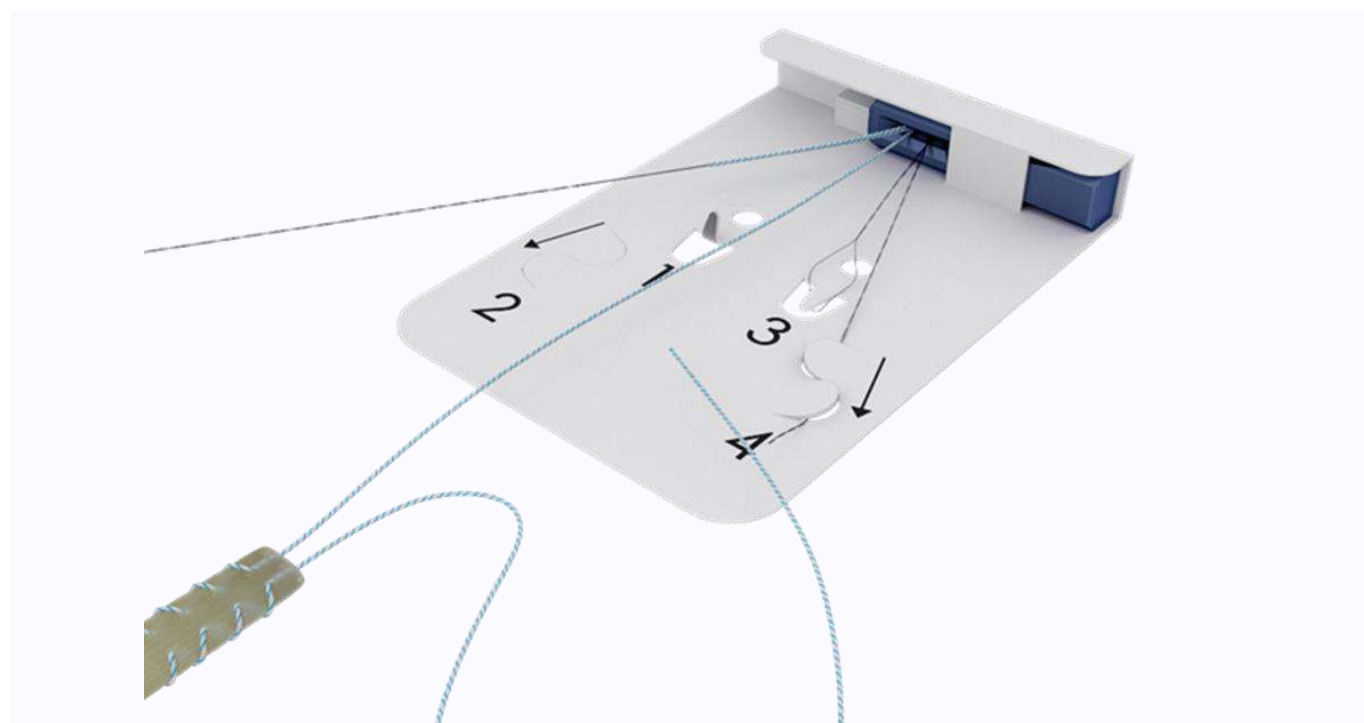
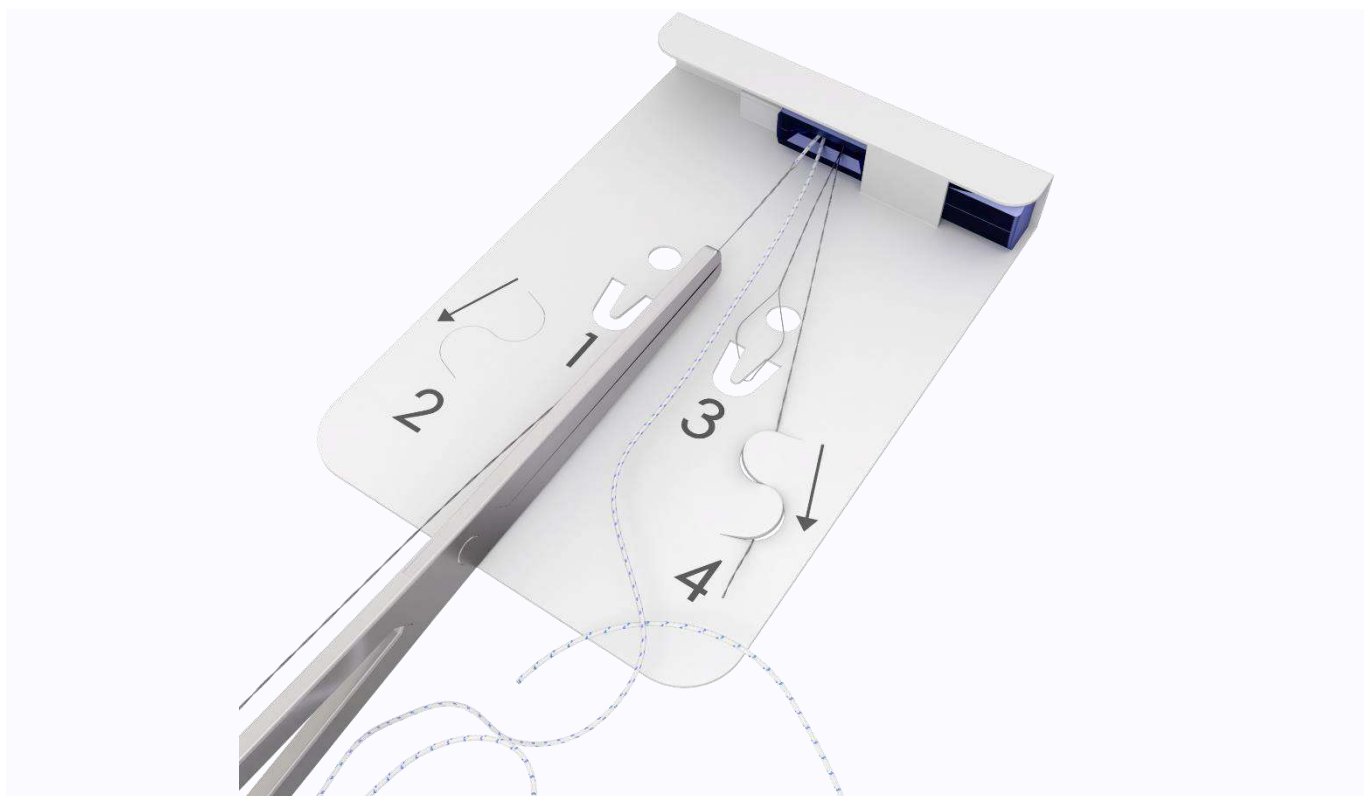
Bicortical Proximal Biceps Tendon Repair

- 1 Make an incision over the bicipital groove to retrieve the biceps tendon. Dunamis #2 suture should be used to prepare the tendon using the surgeon's preferred technique.
- 2 Use the looped end of the nitinol suture passers to shuttle the two free Dunamis #2 UHMWPE suture strands. Shuttle the strands **One At A Time**.



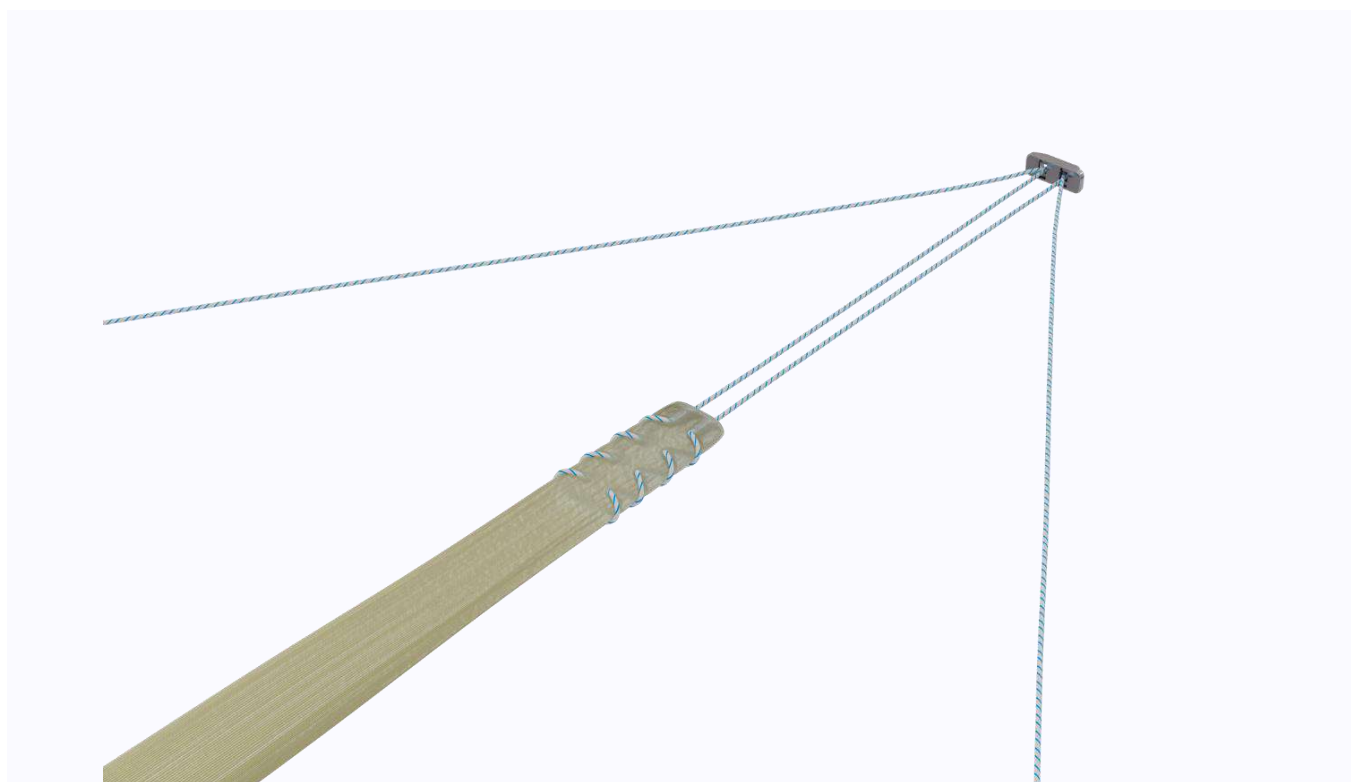
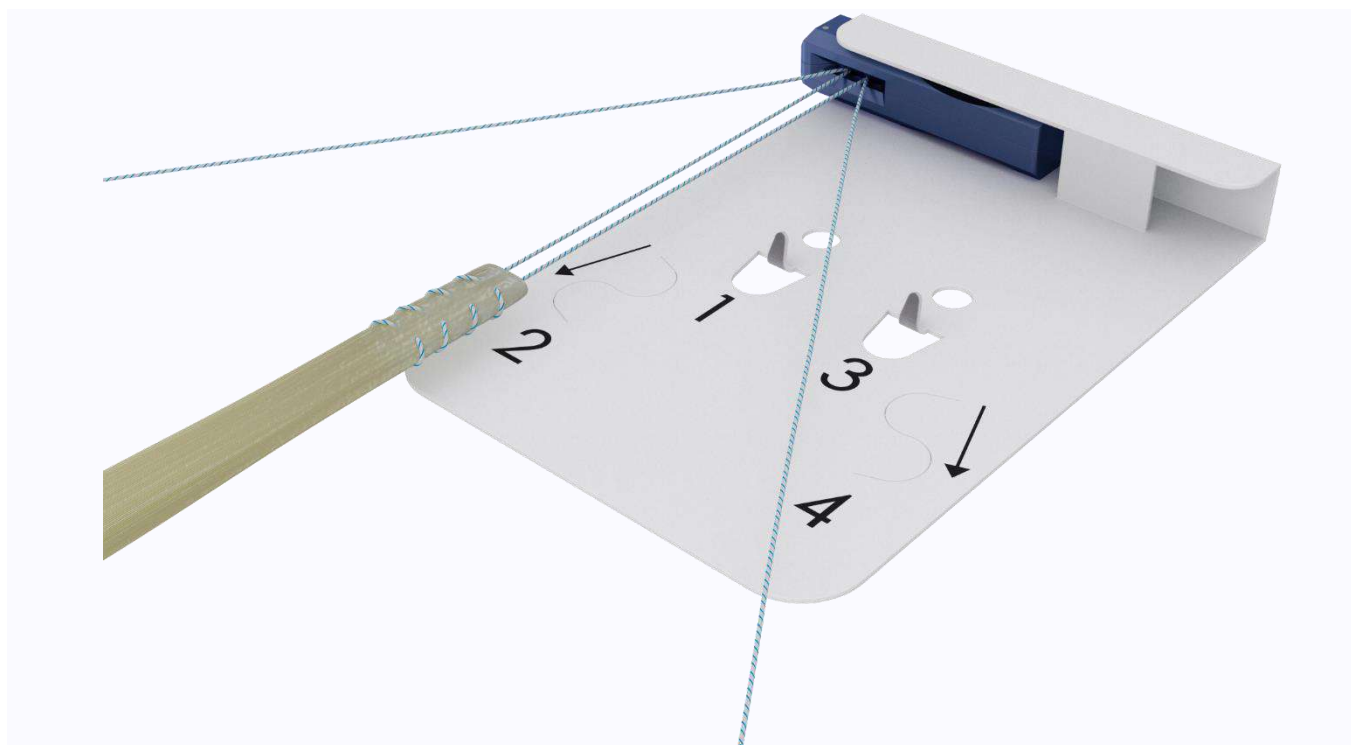
3

When shuttling the sutures through the button, align the needle driver with the slot of the blue assembly holder. The slot is located on the face of the assembly holder.



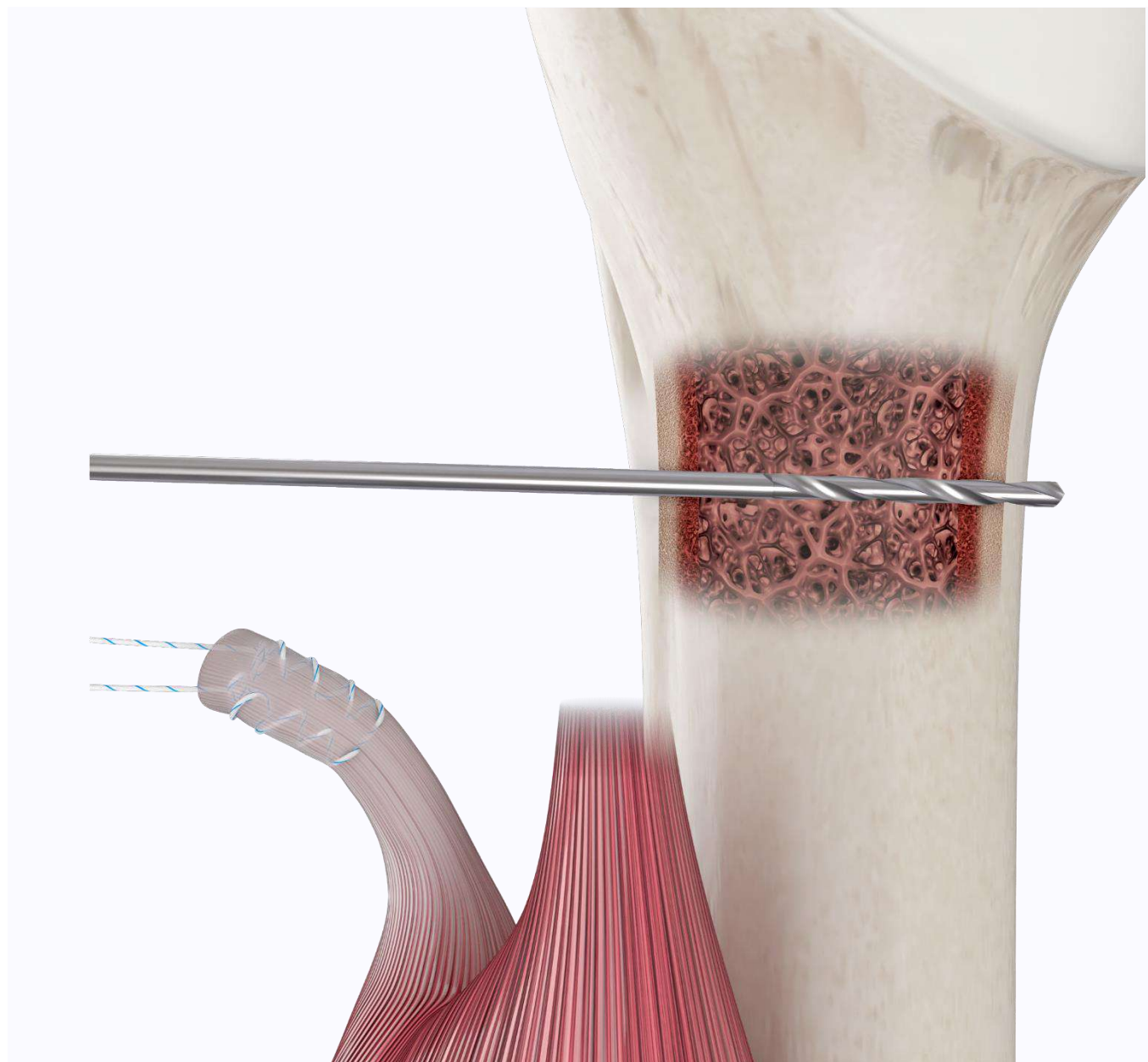
4

The blue assembly holder is now disassembled, the ORCA™ button is retrieved from the holder.



5

Use a 2.0 mm guide wire to drill through both cortices of the proximal humerus.



6

Perform unicortical reaming using a tendon reamer that is 1 mm over the size of the measured tendon. For example, use an 8mm reamer if the tendon measures 7 mm.



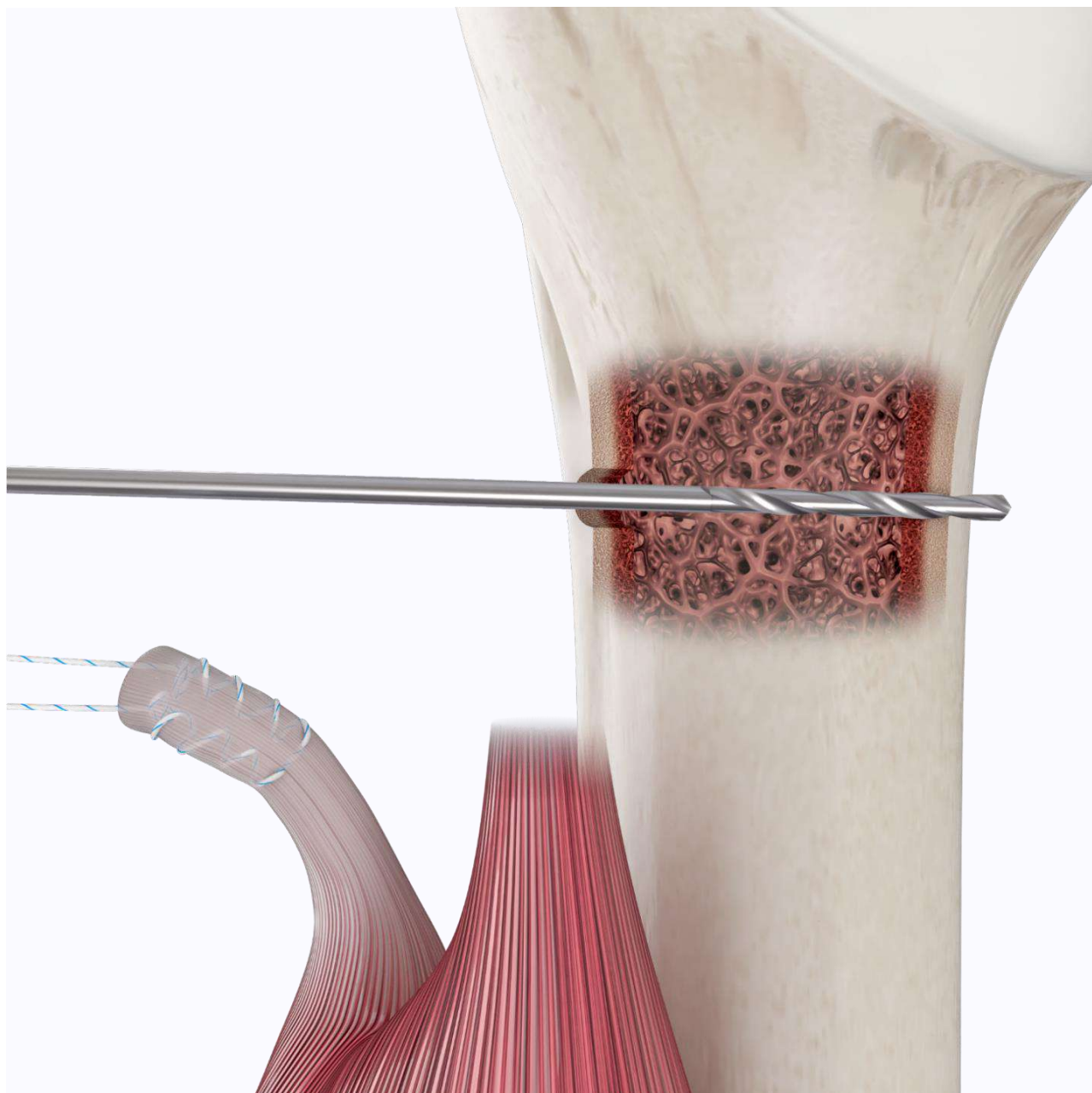
7

Remove the tendon reamer and over drill an opening through the **far cortex** using a 4.25mm cannulated drill bit.



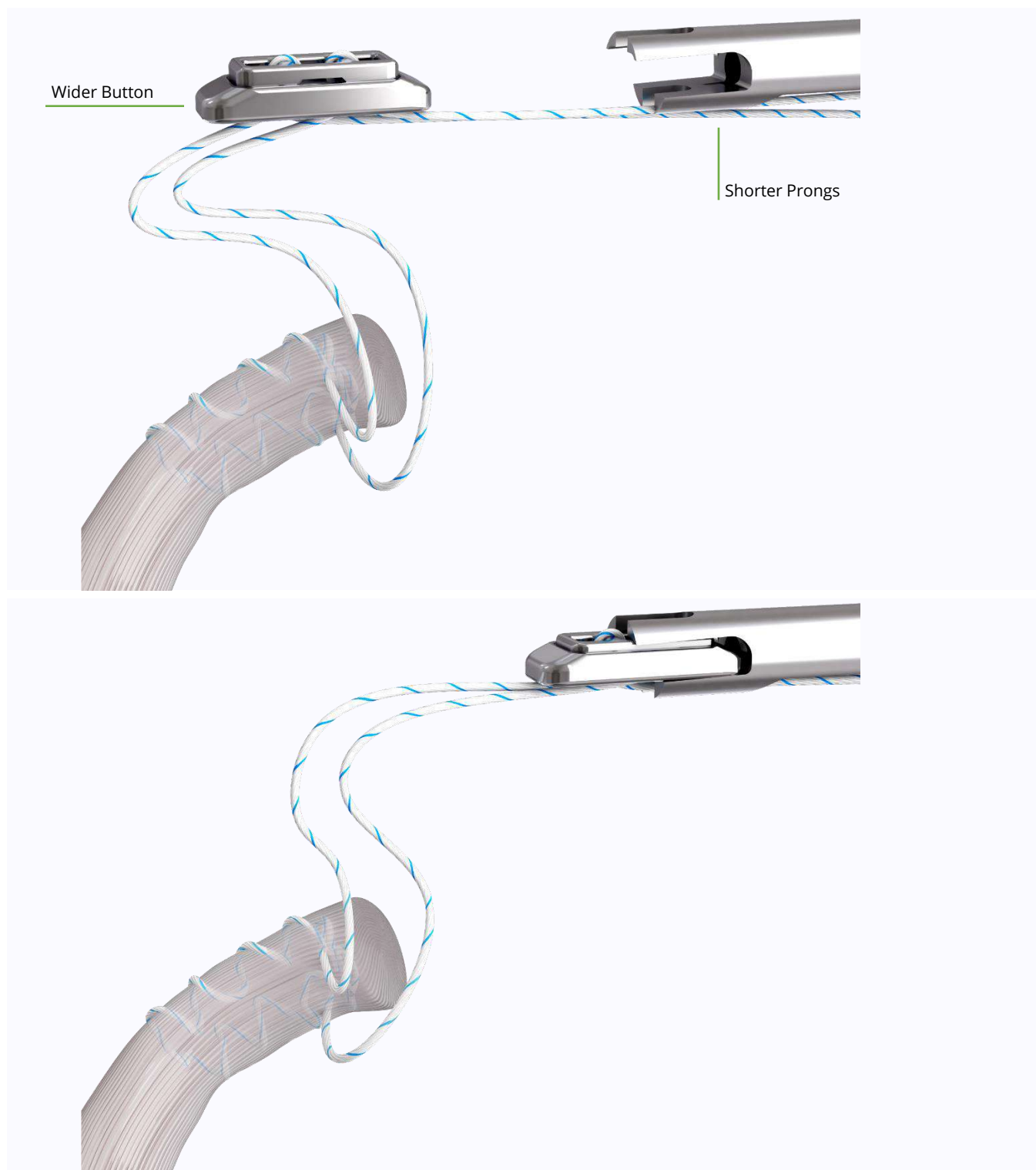
8

Remove the 4.25mm cannulated reamer followed by the guide wire.



9

Assemble the ORCA™ button on the Flipper device. The wider button of the two-button construct should be aligned with the shorter prongs on the capture end of the Flipper. This will allow for the proper flipping orientation of the button once deployed.



10

Pass the loaded Flipper through the near cortex and deploy the ORCA™ button by inserting the pusher device through the Flipper.



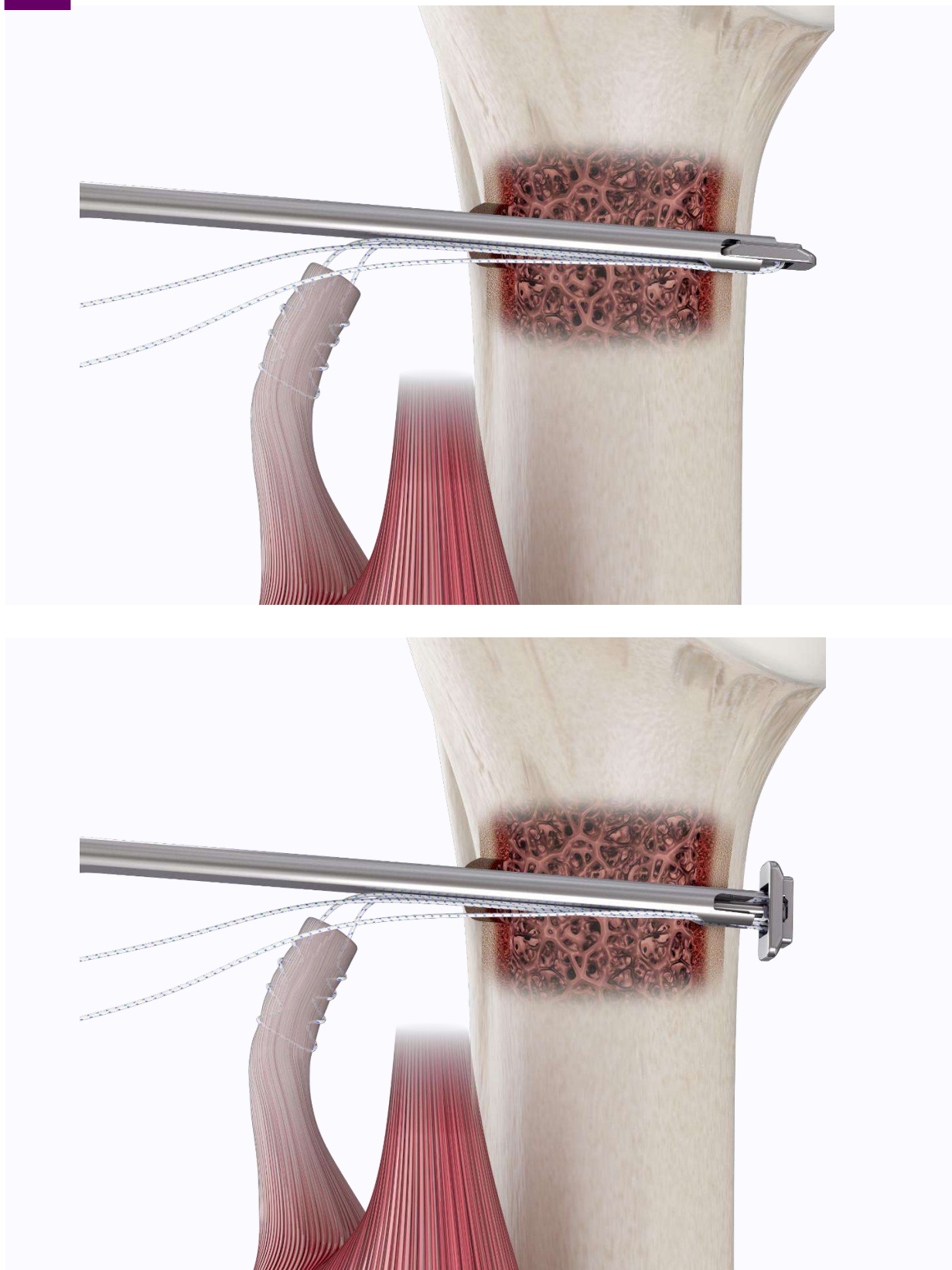
11

Align the arrows marked on the Flipper device and apply pressure on the plunger to deploy the button.



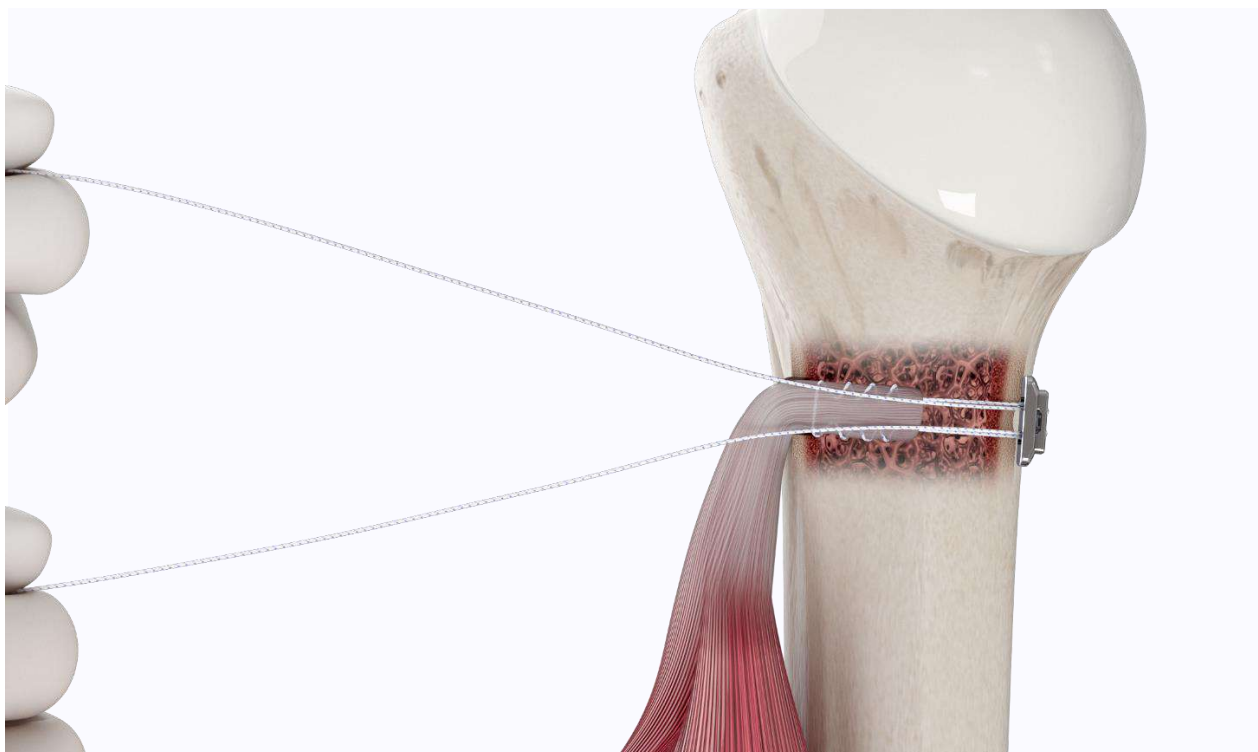
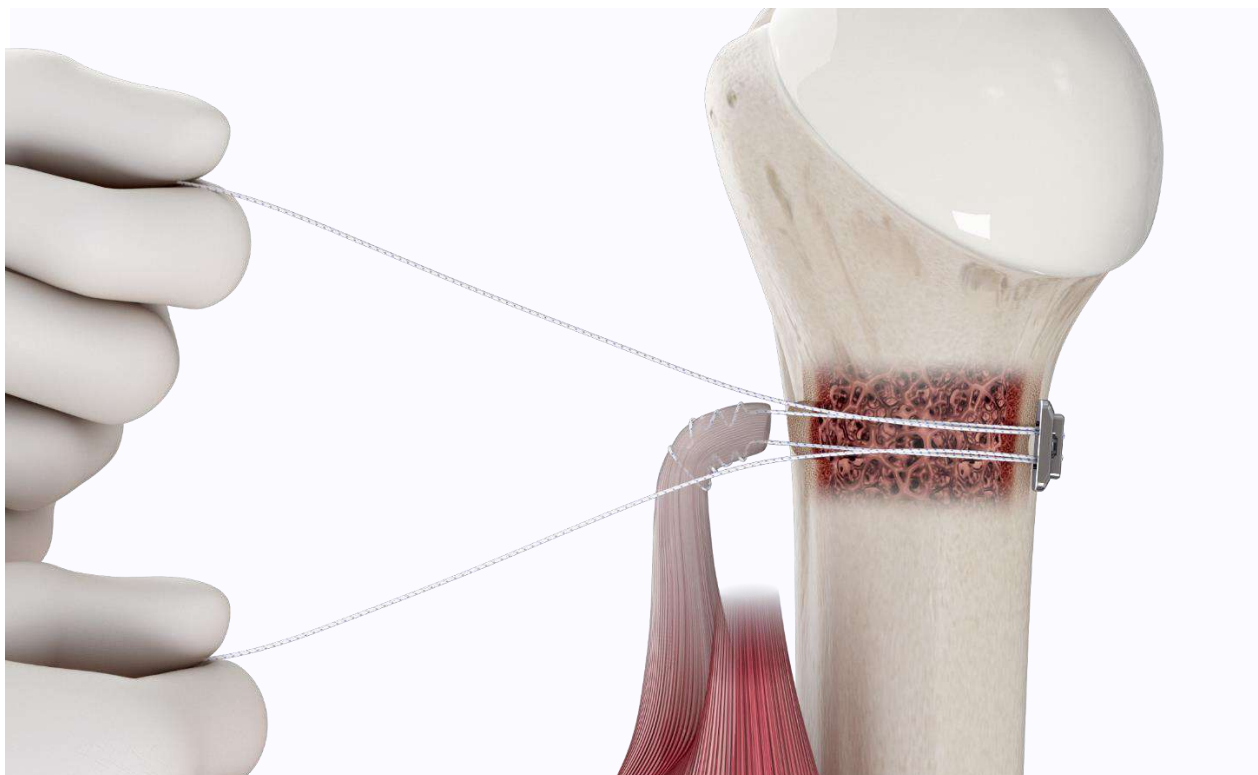
12

Remove the Flipper device and confirm the ORCA™ button has securely flipped behind the far cortex.



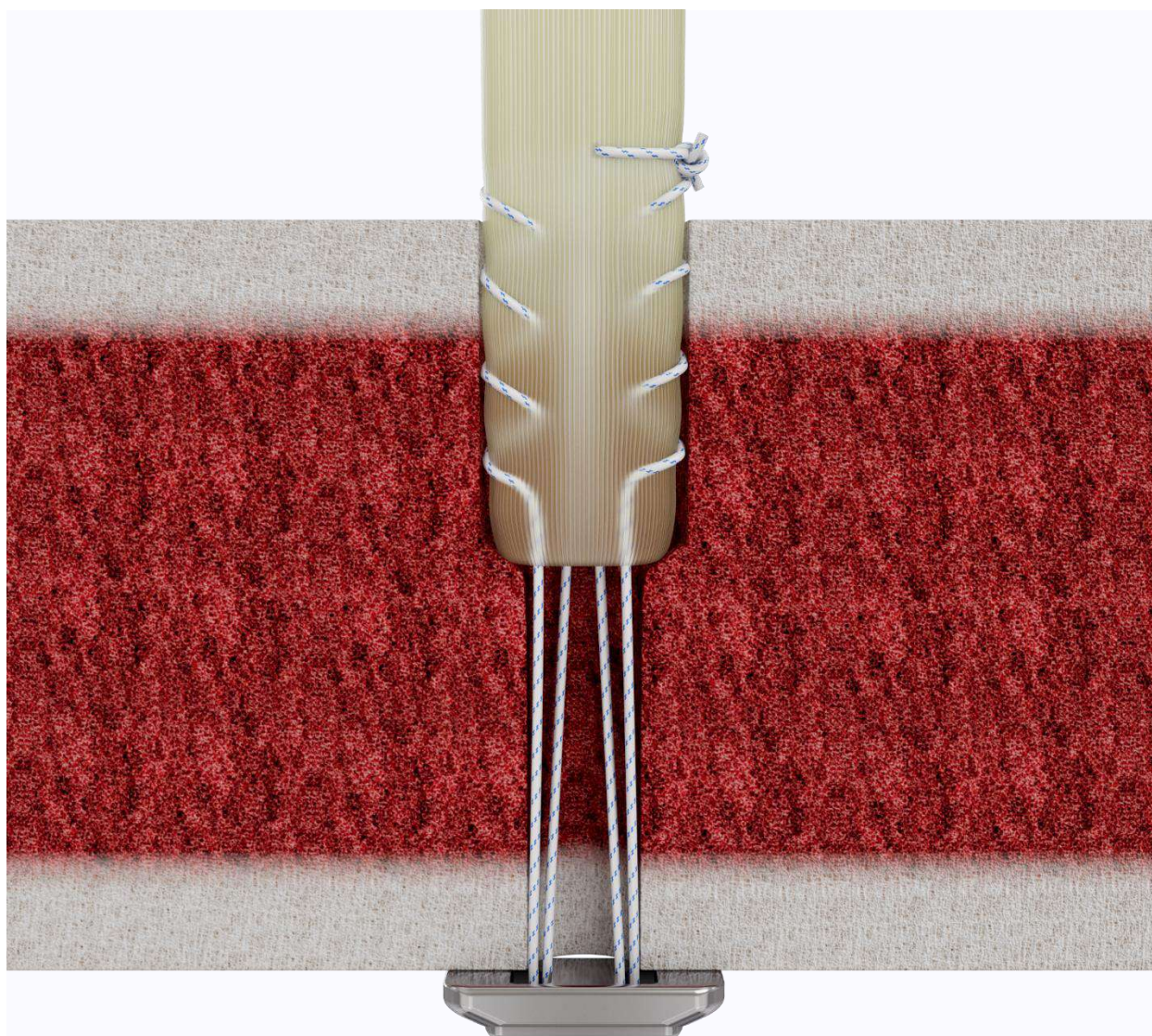
13

Pull alternate suture strands to precisely tension the repair. Once the tendon is adequately tensioned, the ORCA™ button will collapse, locking the sutures under tension. ****hand tension only****



14

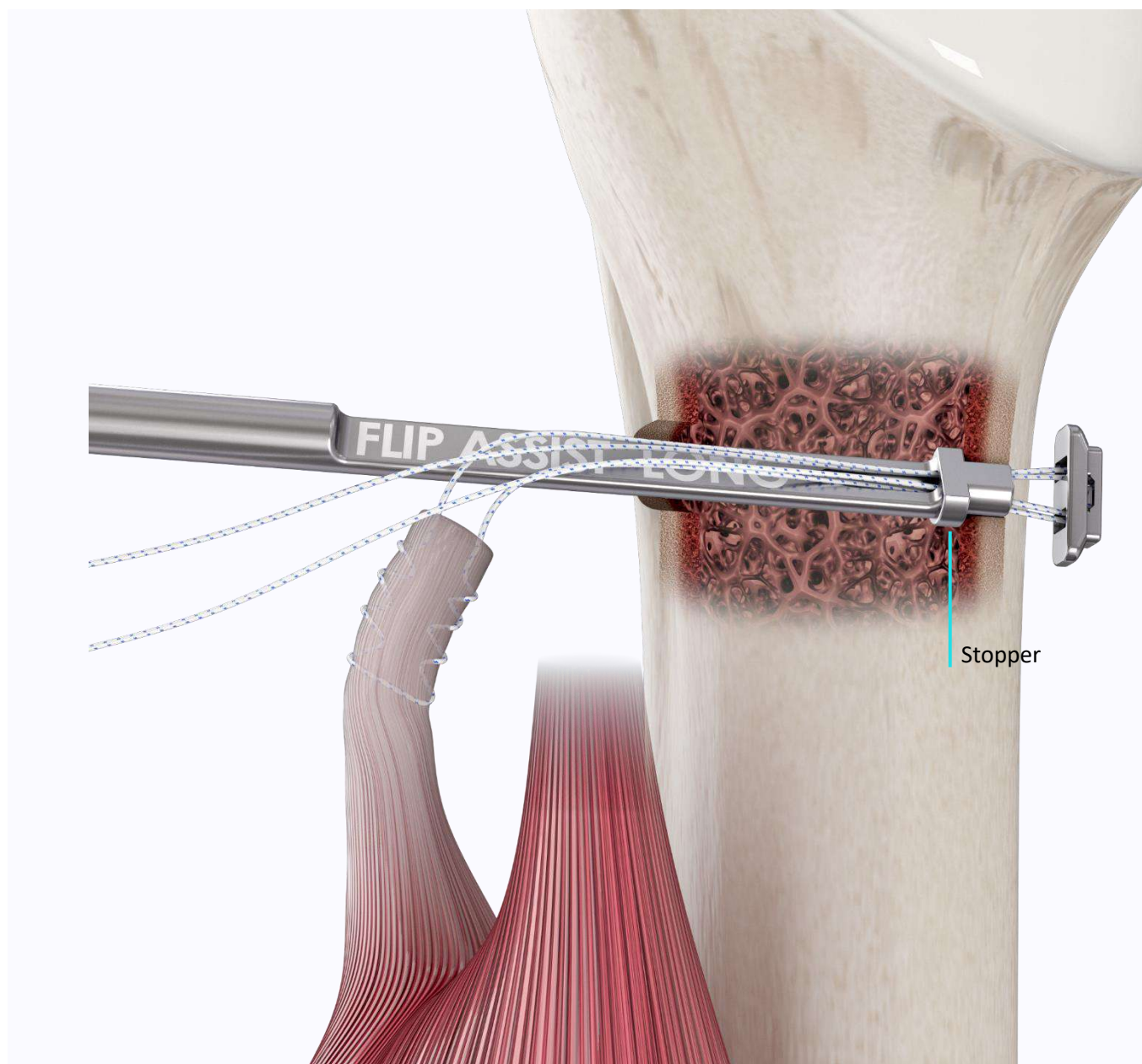
Augment the repair by tying a knot using the surgeon's preferred technique.



Optional Technique

13.B

Pass the free strands through the Flip assist, pass the Flip assist through the tunnel until the bone meets the stopper.



14.B Keep tension on the free strands and pull slack out of the sutured tendon while guiding the button towards the Flip assist. This will allow you to tension the ORCA™ button on the cortex without suture entrapment.

14.C Pull alternate suture strands to precisely tension the repair. ****hand tension only****



Ordering Information

Product Description	Item Number
ORCA™ Knotless Adjustable Button	AB-6200
Dunamis #2 UHMWPE Suture	DFX-2-36-S-WBL-26
2.0 mm Solid Drill	CC0024
4.25 mm Cannulated Reamer	32100513-ZA05
5.5 mm Tendon Reamer	DM-4775
6 mm Tendon Reamer	DM-4731
6.5 mm Tendon Reamer	DM-4776
7 mm Tendon Reamer	DM-4732
7.5 mm Tendon Reamer	DM-4733
8 mm Tendon Reamer	DM-4734
8.5 mm Tendon Reamer	DM- 4735
9 mm Tendon Reamer	DM-4736
9.5 mm Tendon Reamer	DM-4737
10 mm Tendon Reamer	DM-4738
ORCA™ Flipper	100310
Flip assist Short	HP002
Flip Assist Long	HP003
Flip Assist XL	HP004

This surgical technique has been developed in cooperation with PrithviRaj R. Chavan, MD. This description of technique is provided as an educational tool and clinical aid to assist properly licensed medical professionals in the usage of specific Dunamis Medical products. As part of this 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 medical literature and the products instructions for use.