

# ORCA Xtreme™

Self-Locking Adjustable Button for Tendon Repair-Reconstruction

Bicortical Distal Biceps Tendon Repair – Surgical Technique Guide





# ORCA XTREME™

## Clinical Advantages

- **Patient specific tunnel** size preparation using a bone preserving system - Tendon to Tunnel Match™
- **Precise Tensioning** of the repair using adjustable technology
- **Screwless** tendon fixation can reduce tendon injury and implantation failure
- **Reduce gap formation** and improve healing rate

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

### Upper Extremity:

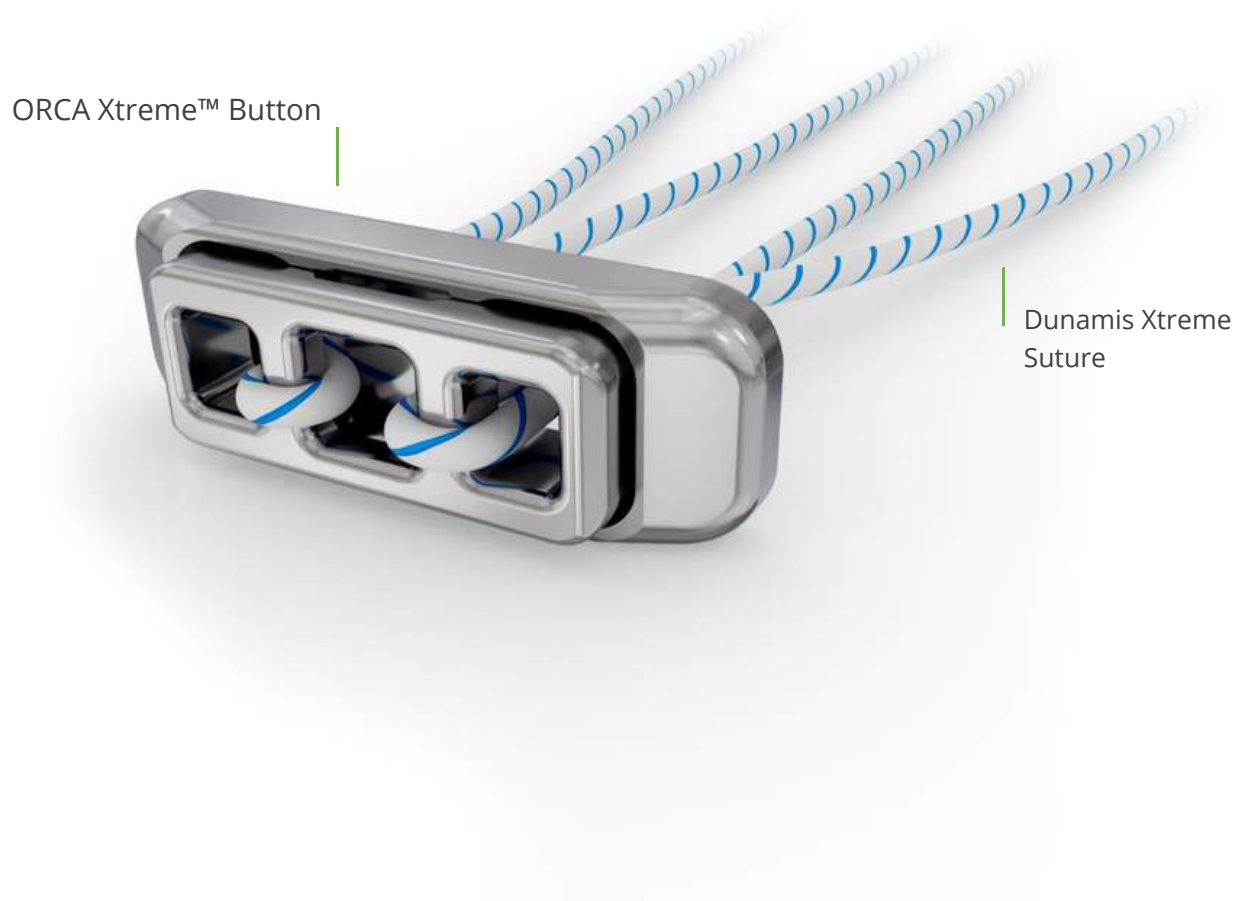
- Proximal Biceps Repair
- Distal Biceps Repair
- Pectoralis Major Repair

### Lower Extremity:

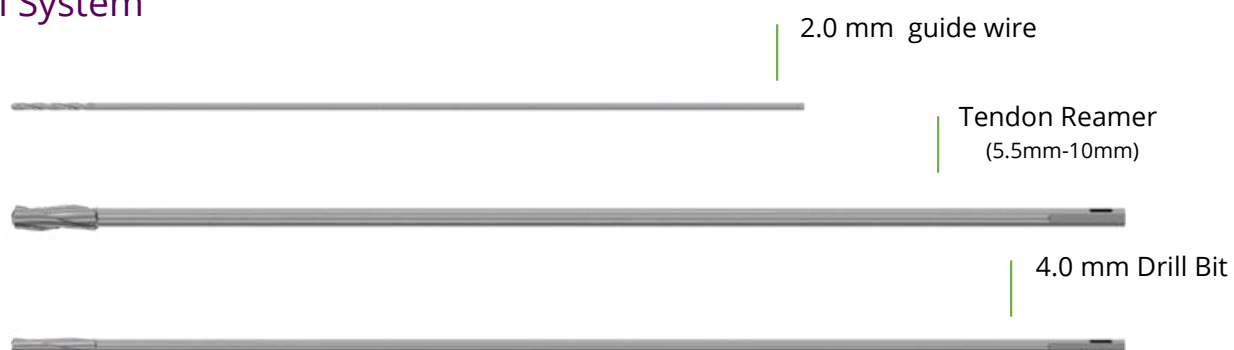
- Flat Foot Repair - FDL Tendon Transfer
- Pes Cavus – Tibialis Posterior Tendon Transfer
- Chronic Achilles Repair - FHL Tendon Transfer
- Tibialis Anterior Tendon Repair

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

## Implantable Devices

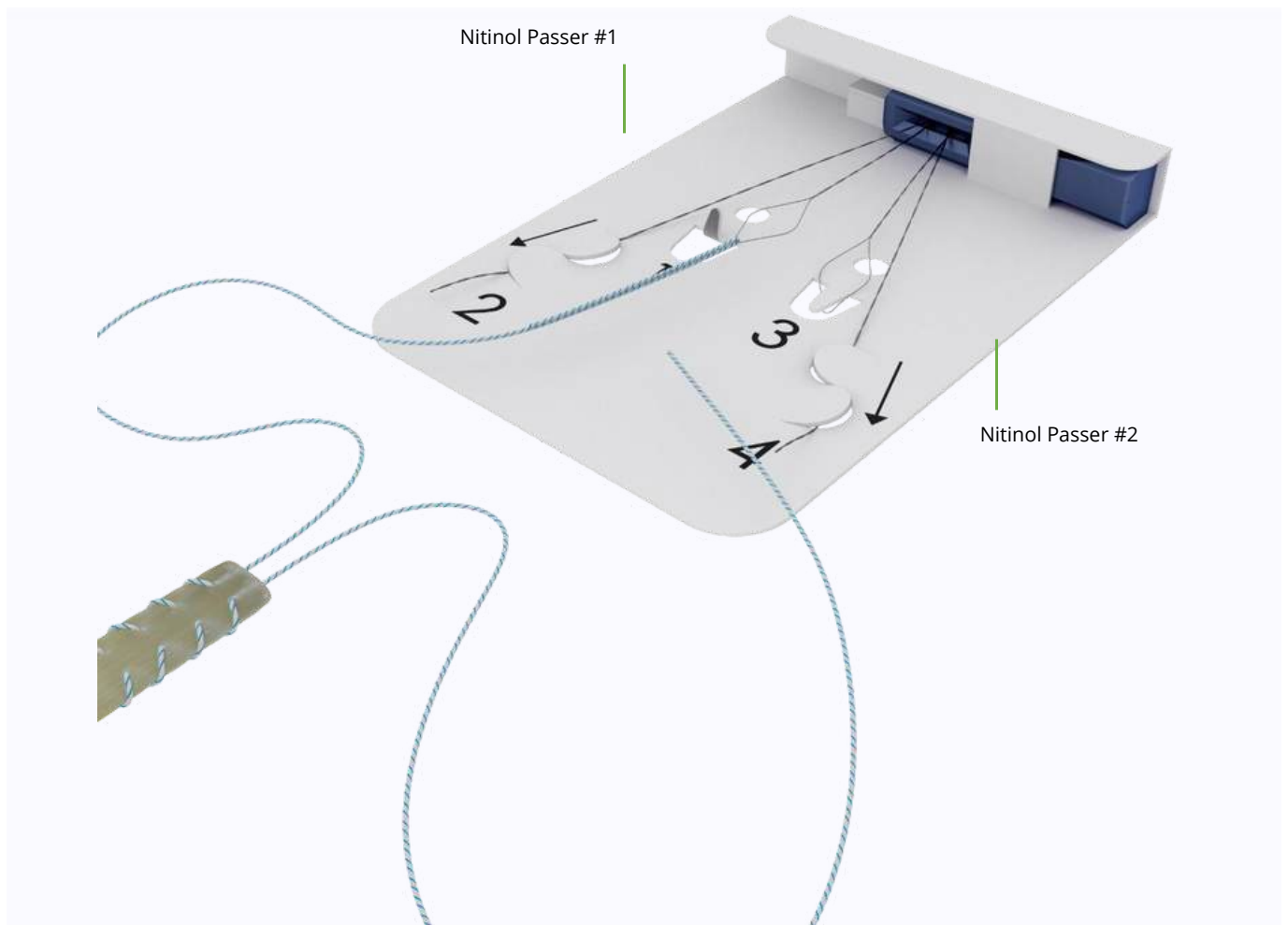


## Drill System



## Bicortical Distal Biceps Tendon Repair

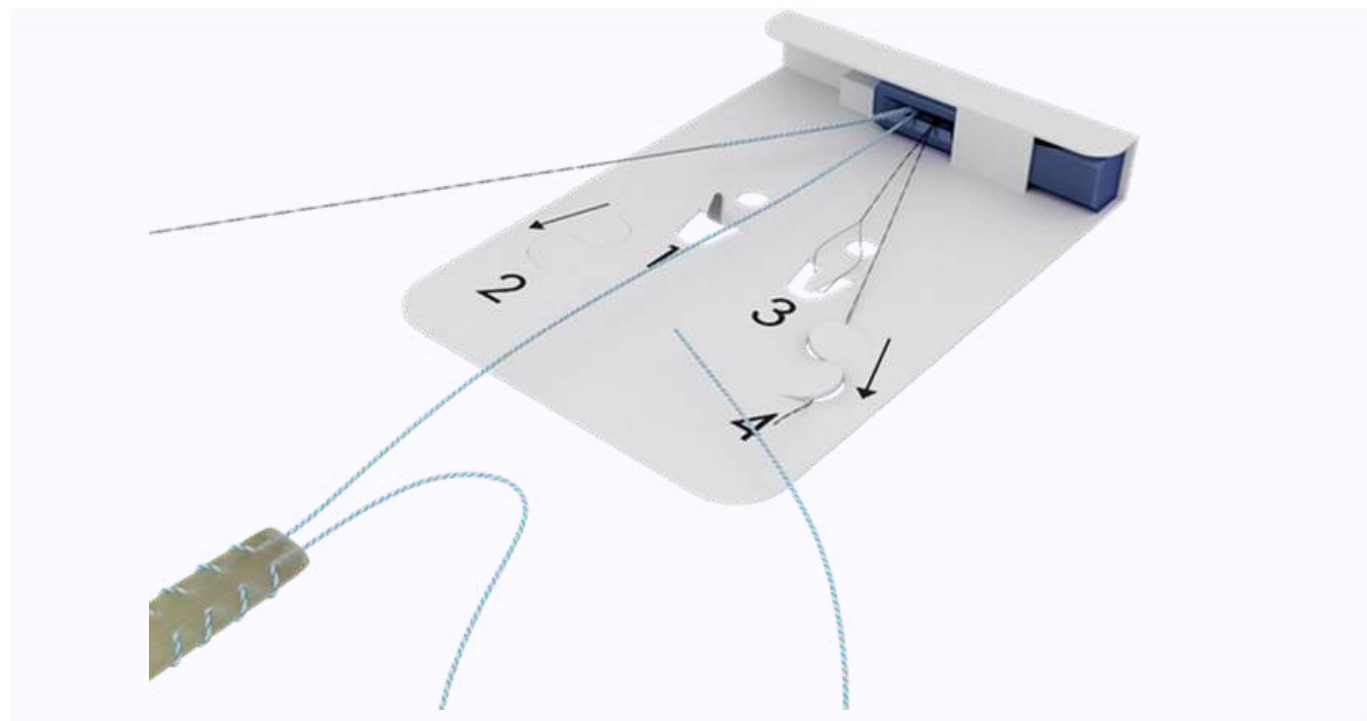
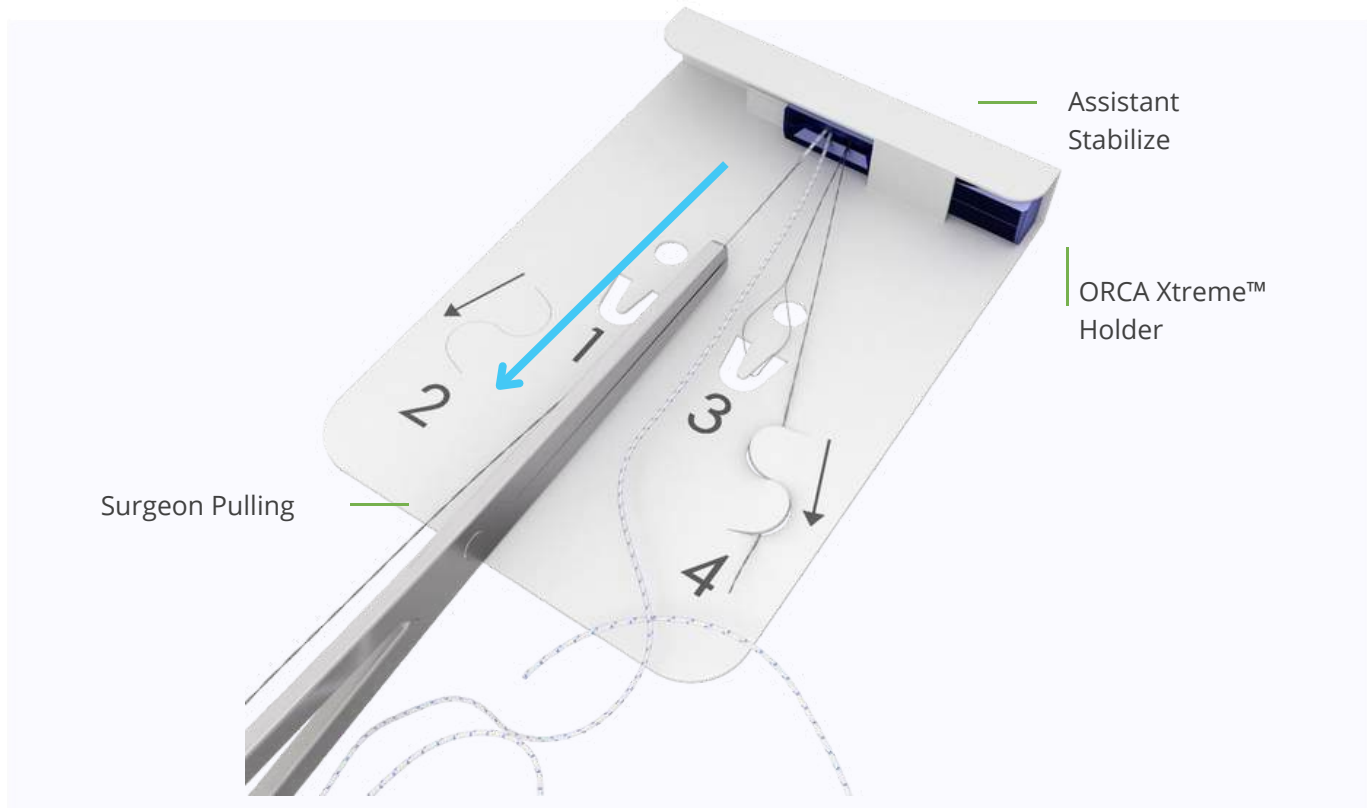
- 1 With the elbow in extension and full supination, expose the radial tuberosity. Dunamis **Xtreme suture** (DFX0034S) should be used to prepare the tendon using the surgeon's preferred technique.
- 2 Use the looped end of the nitinol suture passers to shuttle the two free Dunamis Xtreme UHMWPE suture strands. Shuttle the strands **One At A Time**.



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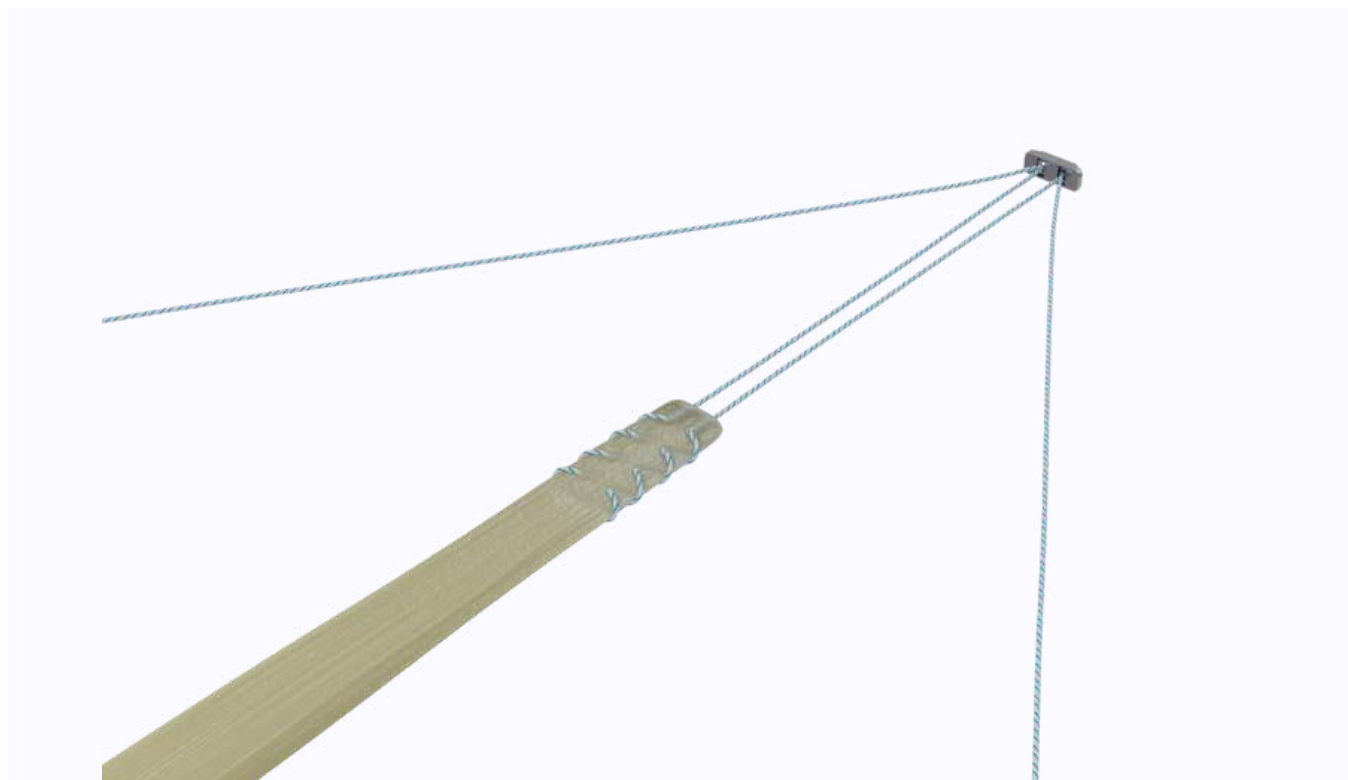
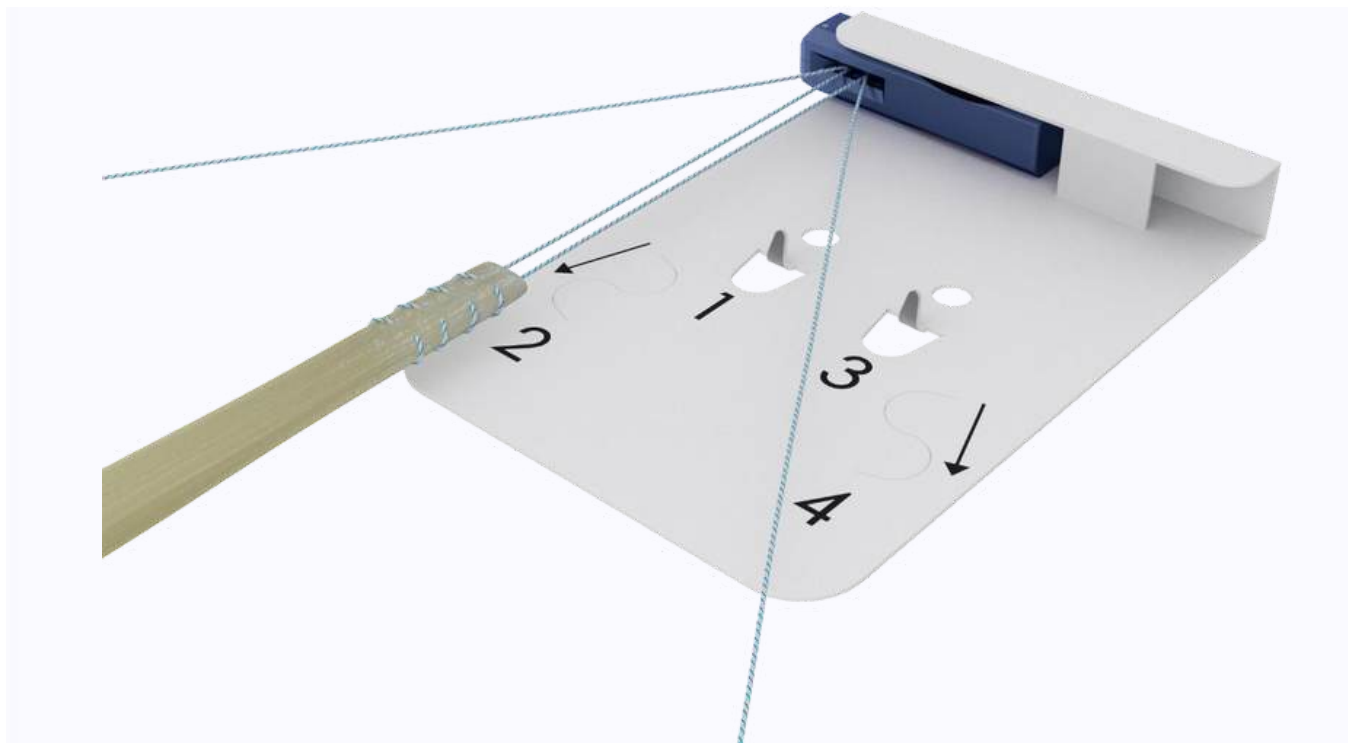
The device is nested inside a blue orca holder with pre-loaded nitinol suture passers. When shuttling the sutures through the button, pull the non-looped end in a straight line at a 90° angle from the holder. **\*\*One suture at a time\*\***

**\*\*Have surgical assistant stabilize the holder while the surgeon is pulling the nitinol passers\*\***



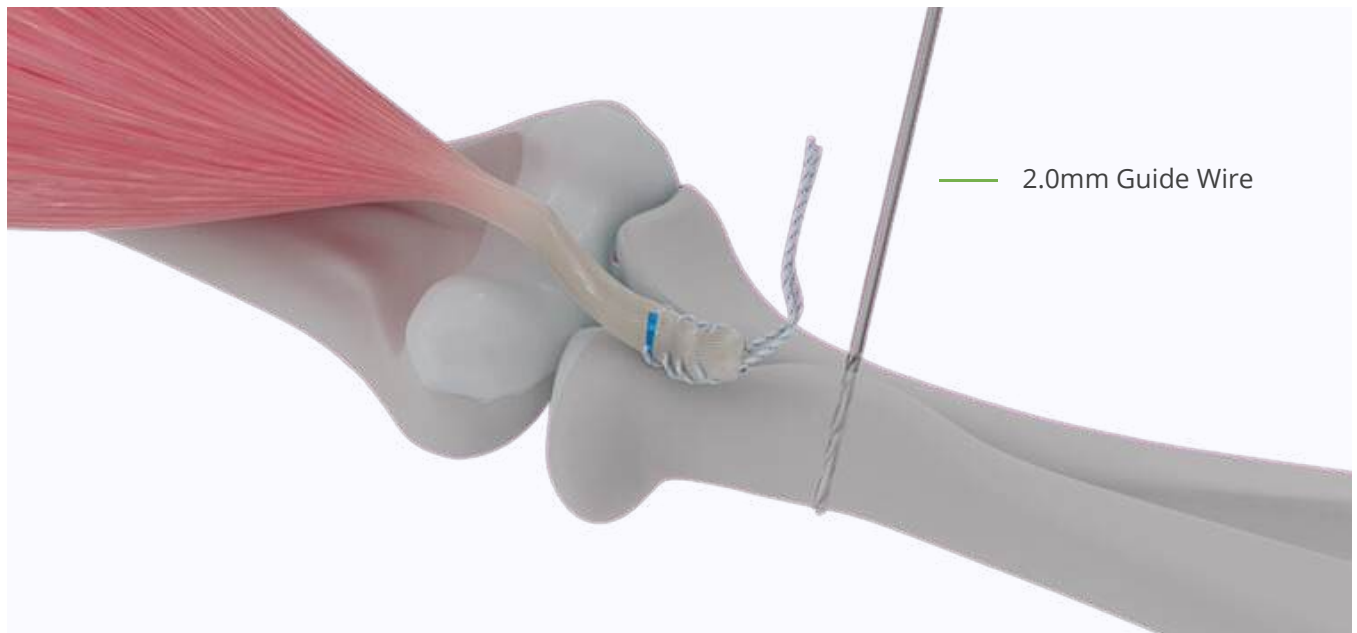
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The blue assembly holder is now disassembled, the ORCA Xtreme™ button is retrieved from the holder.



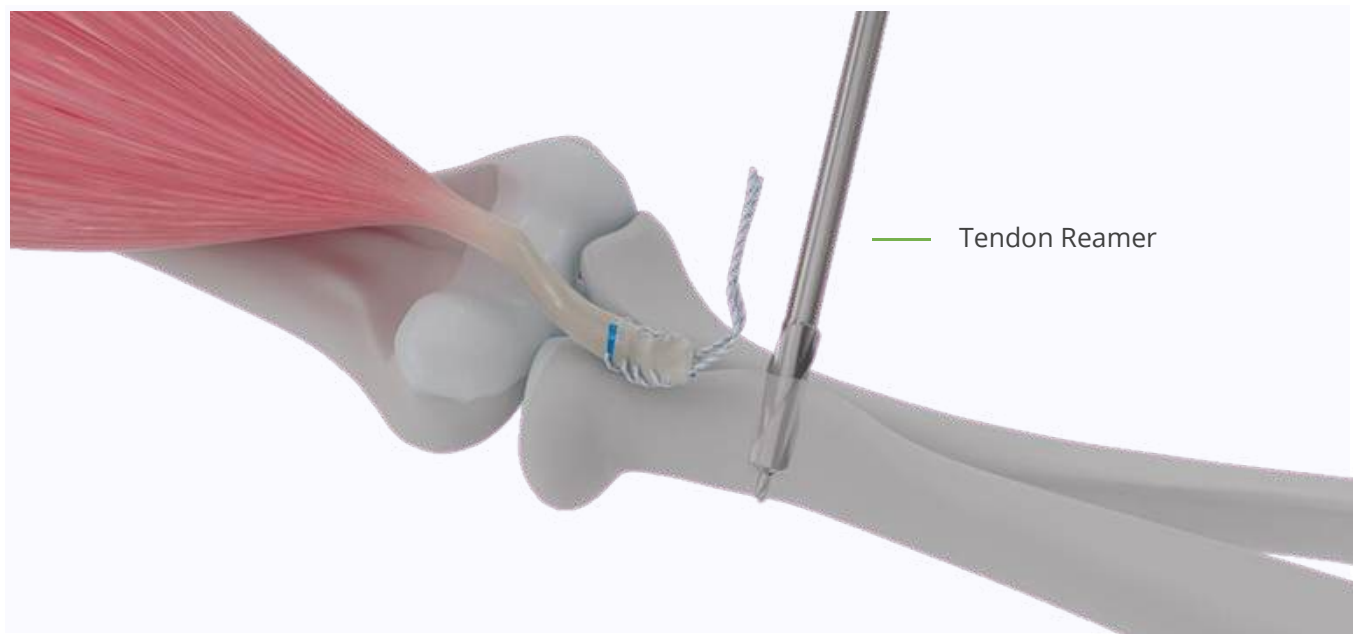
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Pass a 2.0mm guide wire bicortically through the radial tuberosity

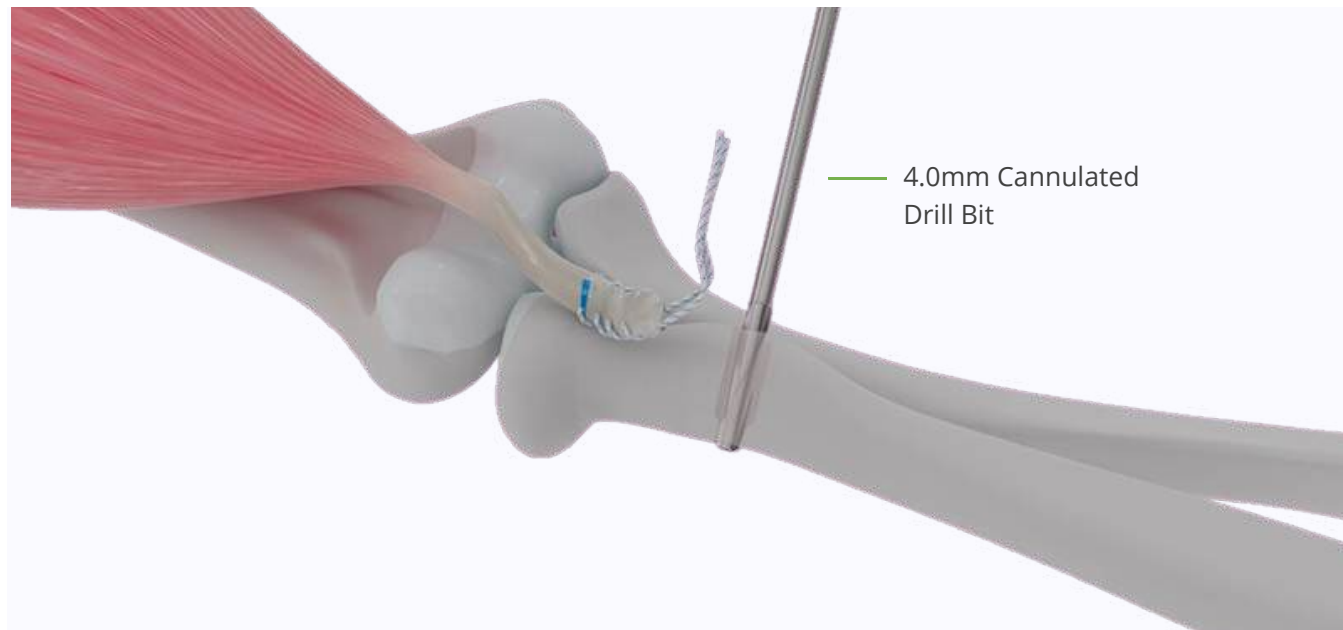


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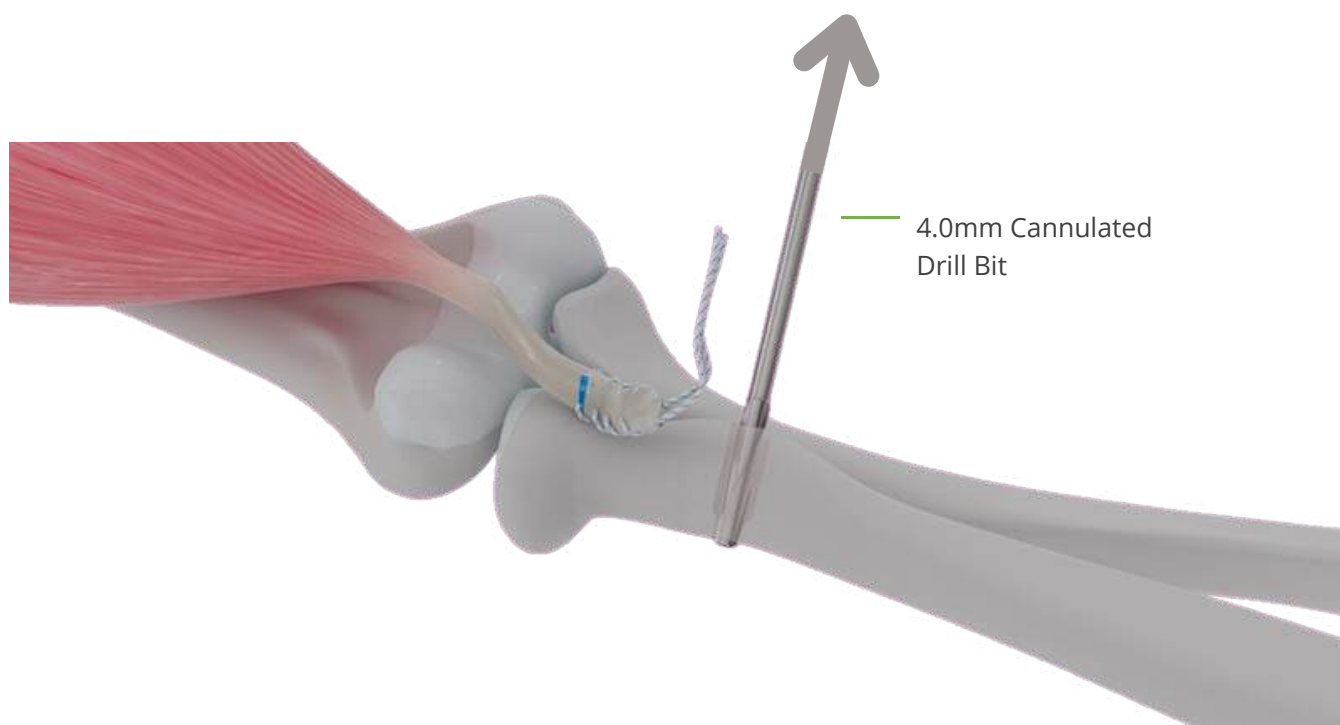
Measure the sutured tendon using a Dunamis graft sizer. Perform **unicortical** reaming using a tendon reamer that is 1 mm over the size of the measured tendon. For example, use a 7.5mm reamer if the tendon measures 7 mm.



- 7 Remove the tendon reamer and over drill an opening through the **far cortex** using a 4.0mm cannulated drill bit.

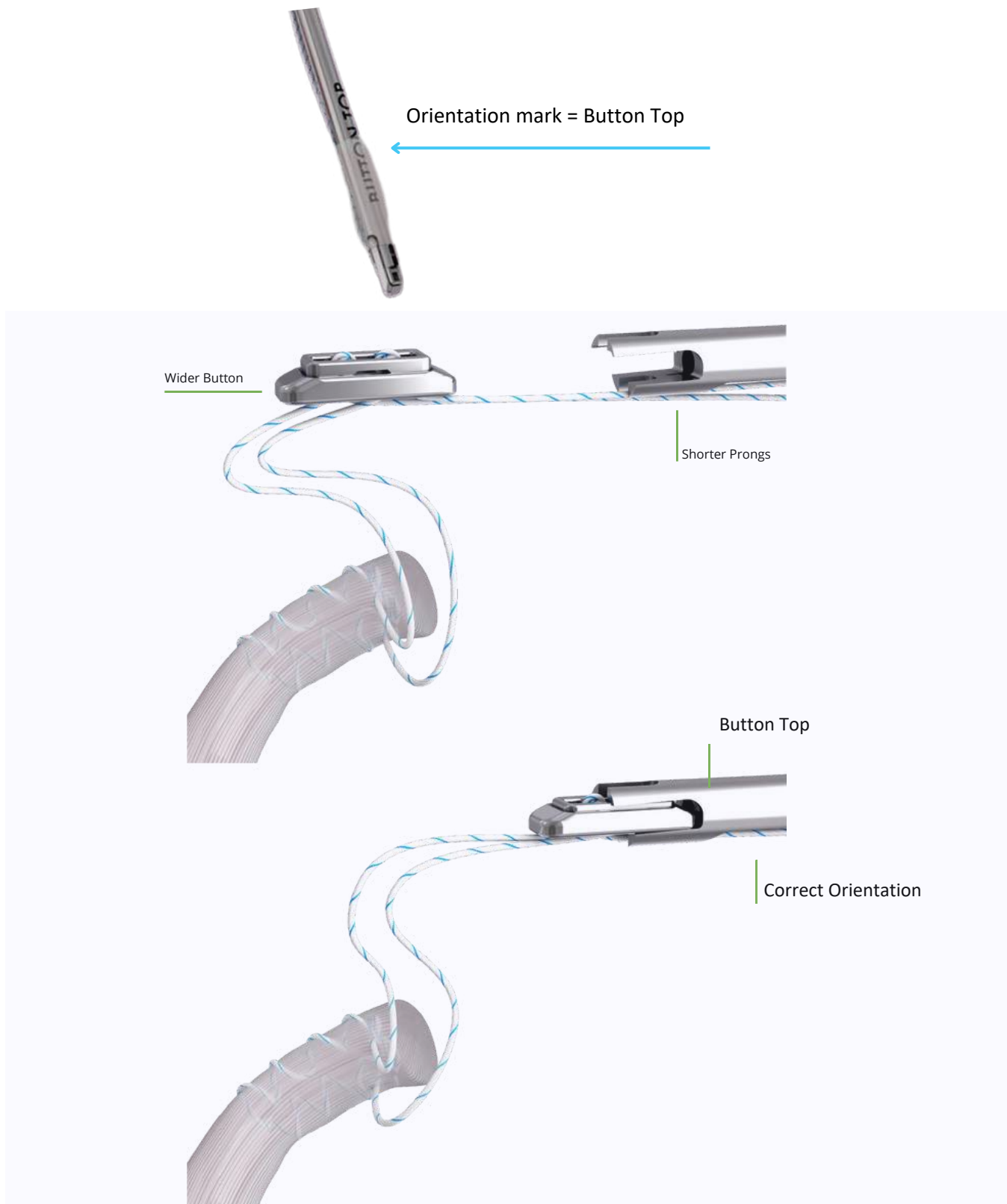


- 8 Remove the 4.0mm cannulated reamer followed by the 2.0mm guide wire.



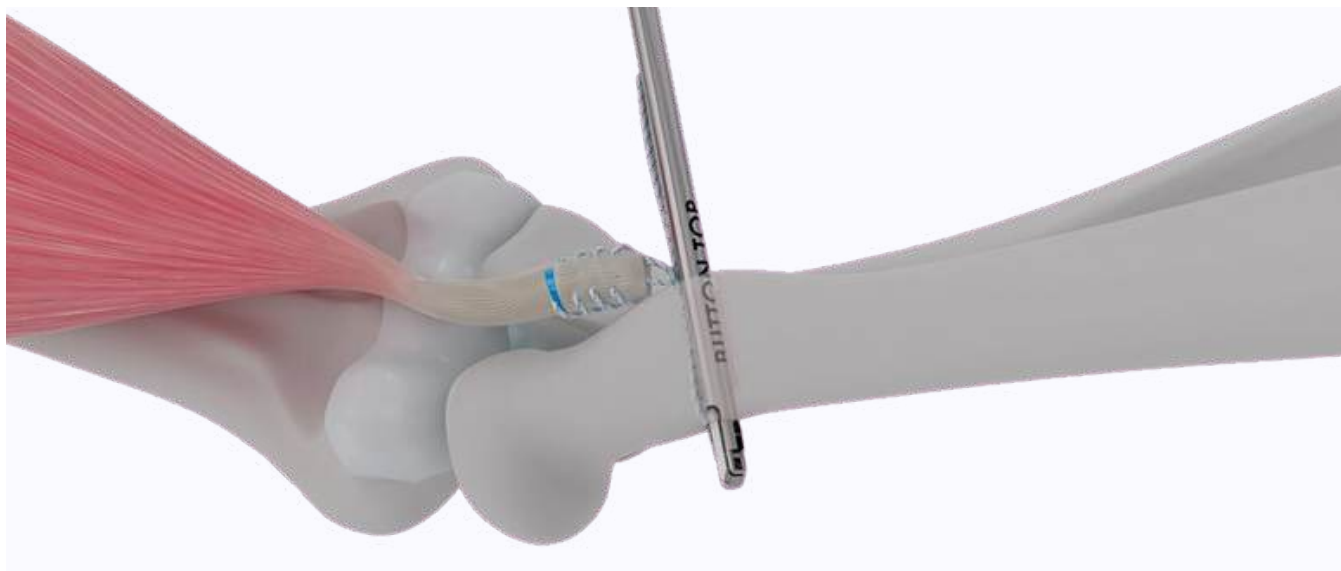
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Assemble the ORCA Xtreme™ button on the Flipper device using the orientation marks on the flipper shaft. This will allow for the proper flipping orientation of the button once deployed.



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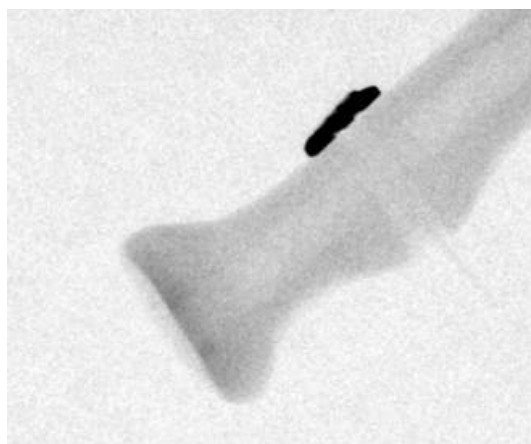
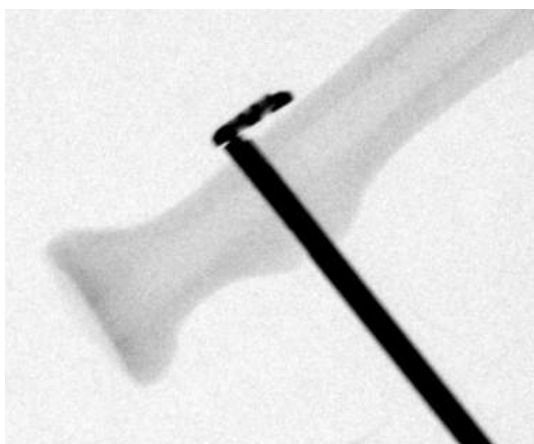
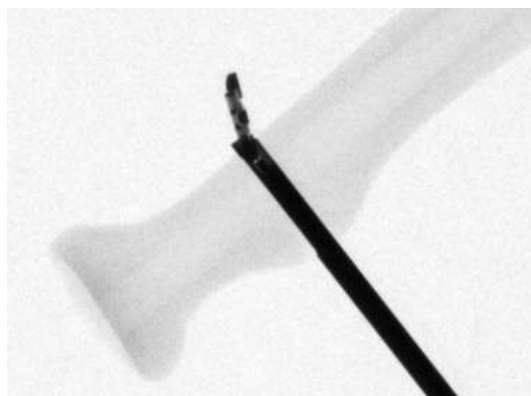
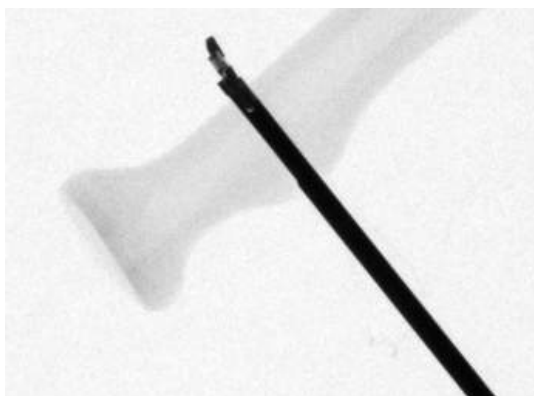
Flex the forearm to assist with button passage. Pass the loaded Flipper through the far cortex. Use fluoroscopy guidance to confirm the button has passed the far cortex before initiating the flip.



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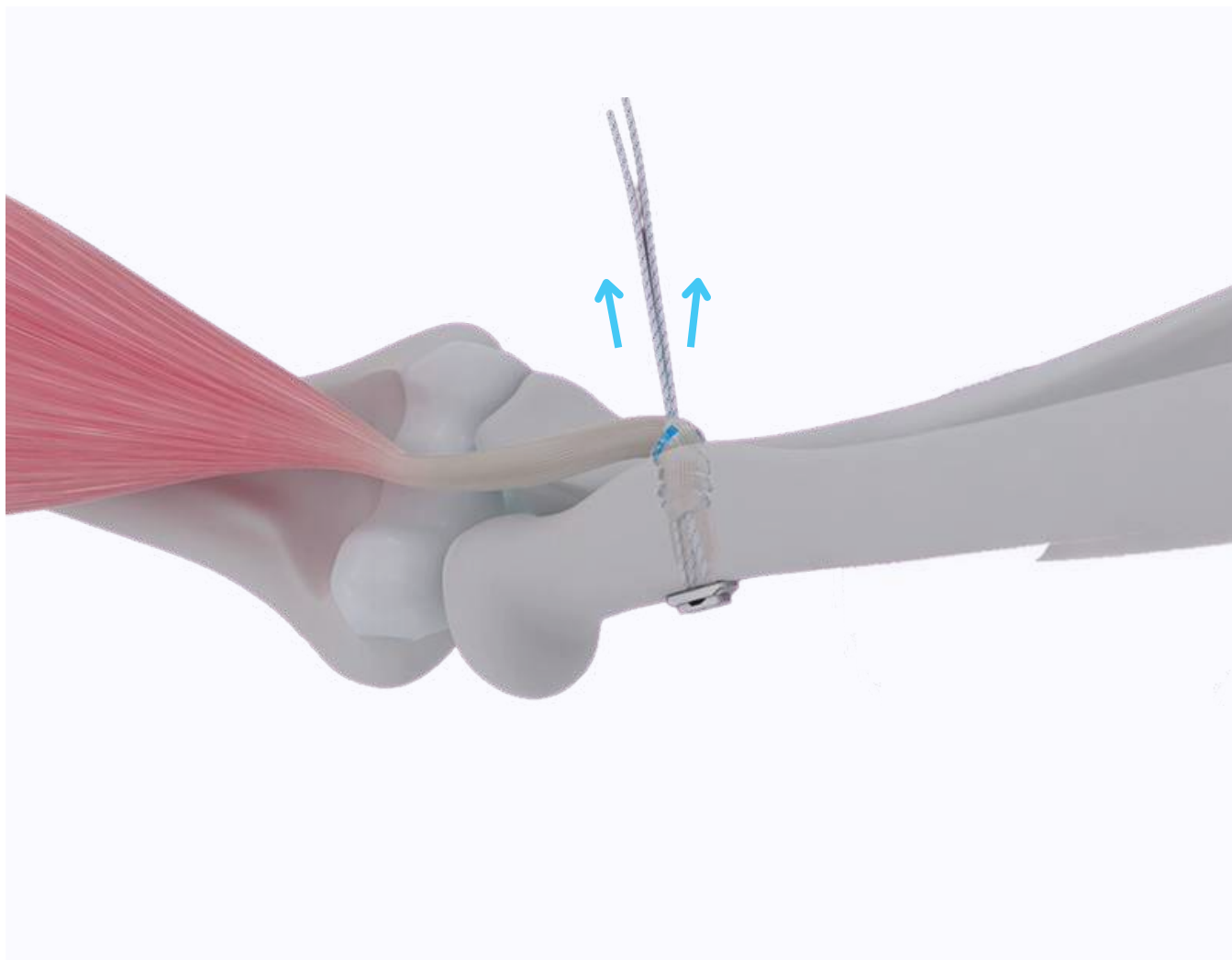
Push the lever forward from the passing position to deploy the ORCA Xtreme™ button.

Orca Xtreme™ Flipper - Unidirectional Button FLip



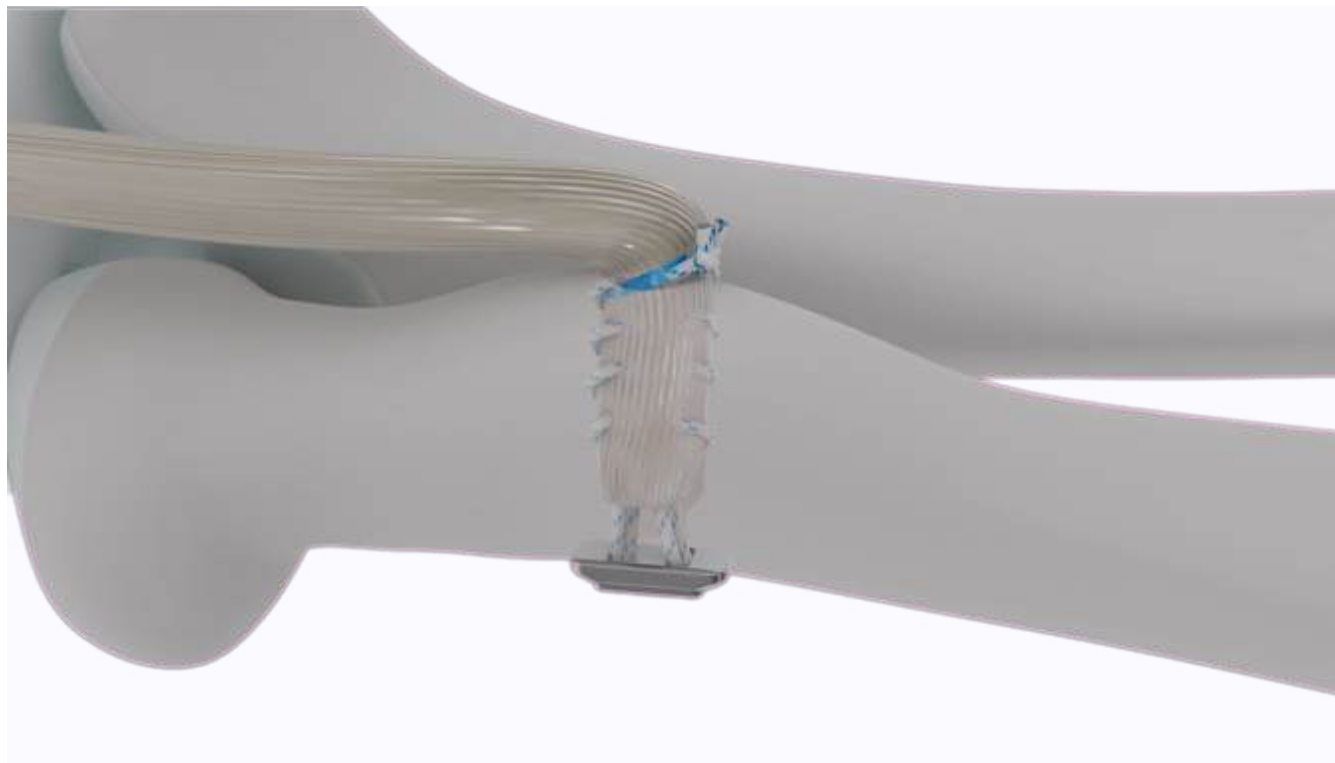
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Remove the Flipper device and confirm the ORCA Xtreme™ button has securely flipped on to the far cortex. Perform alternate tensioning of each suture strand until the tendon is fully seated in the tunnel.



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Once adequate tensioning is complete, the self-locking button will compress the sutures and lock the repair. Augment the repair by tying a knot using the surgeon's preferred technique.



Unlocked State



Locked State

Tying a knot increases the stiffness of the repair and decreases the pistoning during the healing process. Also, using the ORCA Xtreme™ increases the surface area between the tendon and bone which allows for circumferential healing.

## ORCA Xtreme™ Knotless Adjustable Button for Tendon Repair/Reconstruction

| Product Description                                              | Item Number         |
|------------------------------------------------------------------|---------------------|
| ORCA Xtreme™ Knotless Adjustable<br>Button Dunamis Xtreme Suture | AB-6900<br>DFX0034S |
| 2.0 mm Solid Drill                                               | CC0024              |
| 4.0 mm Cannulated Reamer                                         | DN-442010           |
| 5.5 mm Tenon 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 Xtreme™ Flipper                                             | FL31005             |

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.