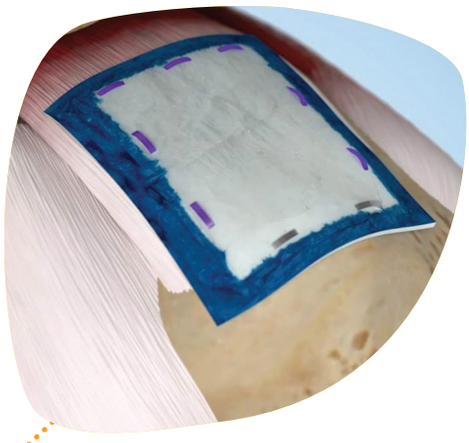


Regenerates tendons ✚ revolutionizes intervention

Arthroscopic procedural guide

Smith+Nephew

REGENETEN◊
Bioinductive Implant

1. Surgical Setup

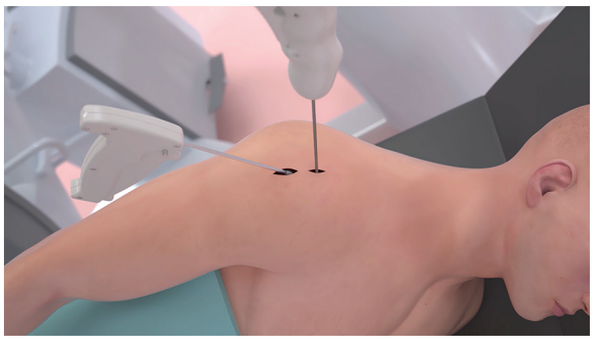
a. Place patient in lateral decubitus or beach chair position.

b. Inspect joint space.

c. While in the articular space, use the biceps tendon as reference for the anterior edge of the Supraspinatus Tendon. Place one Tendon Marker at the anterior, lateral insertion and the second Tendon Marker 1 cm more medial of that point.

d. Enter the subacromial space and perform a complete bursectomy for optical visualization of the rotator cuff. Perform an acromioplasty as indicated.

e. Ablate the soft tissue lateral to the insertion of the tendon to allow the lateral end of the implant to be in direct contact with bone.



2. Implant Prep and Insertion

a. Place the Tendon Stabilization Wire at the lateral edge of the rotator cuff footprint, 5-7 mm lateral to the insertion of the tendon, and lightly impact with mallet into the bone.

b. Prepare delivery system.

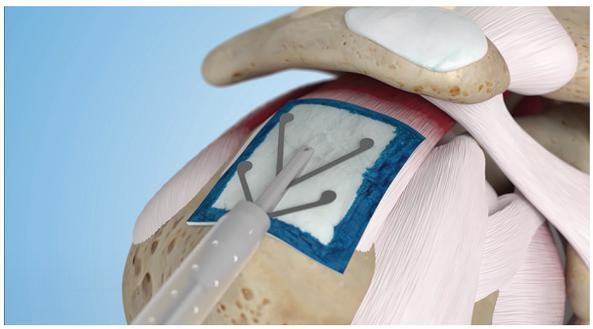
c. Following the groove on the bottom side of the implant sheath, introduce the implant along the wire, until the red-button indicator becomes prominent, indicating that the implant is in the appropriate medial-to-lateral position.

   i. The Tendon Stabilization Wire is designed to and will bend as pressure on the delivery device is applied. Visual confirmation of implant placement is required.

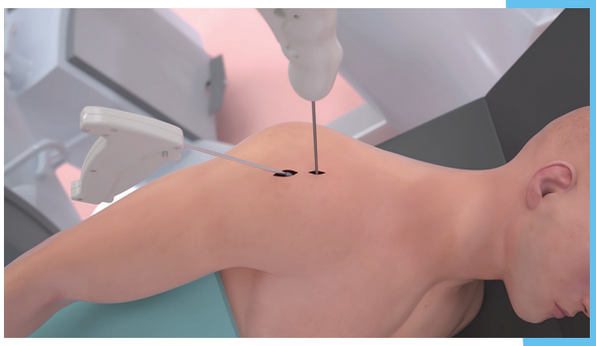
d. Release the safety (black button on right side of delivery device).

e. Slowly squeeze the trigger, retracting the clear plastic tube back and allowing the implant to unfurl and deploy.

   i. If the implant does not immediately unfurl, continued hydration in the shoulder space will soften the implant and allow it to unfurl.



3. Fixation of Implant



a. Tendon Anchor Placement:

- **i.** Use the provided cannulas to optimize the Tendon Anchor Inserter approach angle and anchor placement.
- **ii.** Load the Tendon Anchor Inserter and place it through the cannula.
- **iii.** Select the fixation position inside the blue border, then insert the metal pins through the implant with a quick motion and into the underlying tendon; squeeze the trigger to deploy the anchor while maintaining downward pressure on the Tendon Anchor Inserter. Repeat until the medial, anterior, and posterior edges of the implant are attached.
- **iv.** The implant delivery instrument should be removed after affixing the medial half of the implant. A total of 5 or 6 tendon anchors are typically used.
- **v.** Remove tendon markers.
- **vi.** To remove the Bioinductive Implant Delivery Device, instruct the person holding the handle to drop their hand towards the floor before pulling the delivery handle out of the shoulder space.

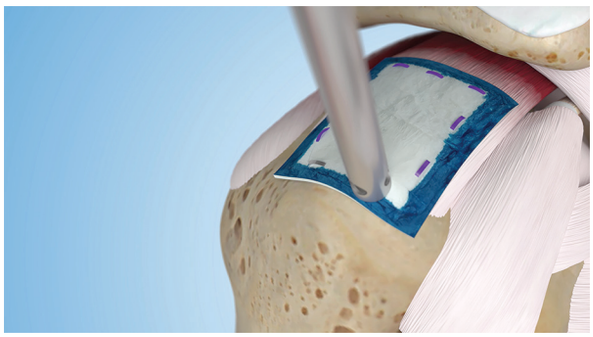
b. Bone Anchor Placement:

- **i.** Using the Bone Anchor Inserter (as presented to physician) insert into the subacromial space through the lateral portal.
- **ii.** Using the slide release lever, retract the sheath to reveal the bone punch pins. Using the Bone Anchor pins, slightly tension the implant laterally to achieve intimate contact between the implant, tendon, and bone.
- **iii.** Maintaining a perpendicular angle to the bone surface, use a mallet to drive the pins into the bone until the system is fully seated, creating pilot holes.

b. Bone Anchor Placement (continued):

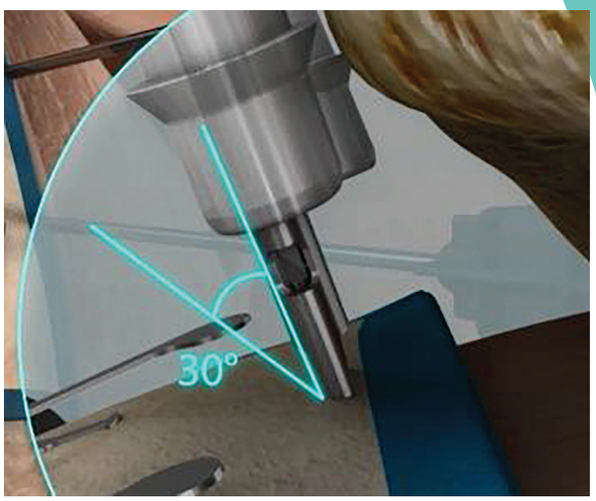
- **iv.** Squeeze the trigger to remove the Bone Punchwhile maintaining pressure without removing the Anchor Inserter.
- **v.** Load the PEEK Bone Anchor Inserter into the inserter and advance by hand initially to ensure alignment and insertion into the pilot holes. Then lightly tap the Bone Anchor Inserter until flush with the surface of the implant. (Recommend using at least two Bone Anchors.)

c. Confirm stability and placement of implant with a probe, adding Tendon or Bone Anchor if necessary. Remove instruments and close wounds as usual.hydration in the shoulder space will soften the implant and allow it to unfurl.



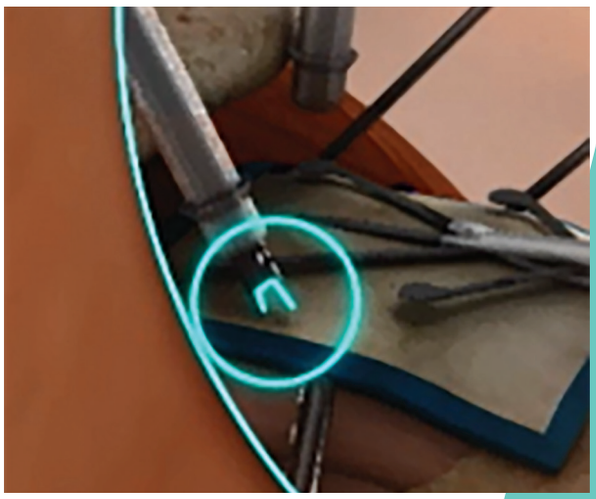
Quick Tips

- Ensure the tendon markers are parallel to the biceps tendon.
- Ensure the guidewire is in the correct position on the greater tuberosity.
- Proper portal placement is important for optimal tendon and bone anchor deployment.
- Make an accessory portal just off the acromion edge for perpendicular delivery of medial anchors.
- Abduct the arm for optimal visualization of the lateral anchors.
- Maintain a steady grip and downward pressure on the Bone Anchor Inserter during punch removal.
- Nonparallel placement of the tendon markers can affect implant orientation.

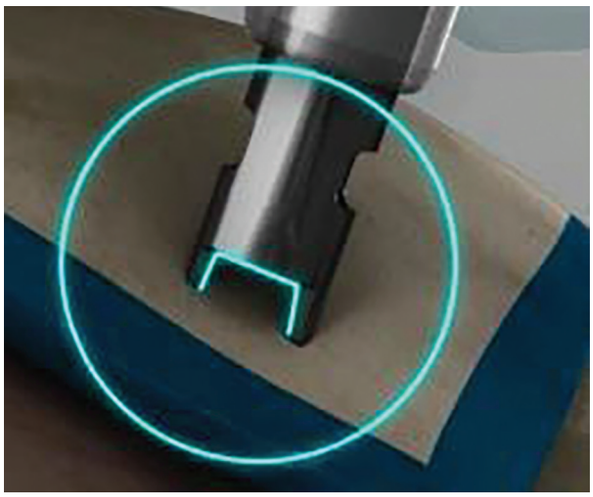


Surgical Pearls

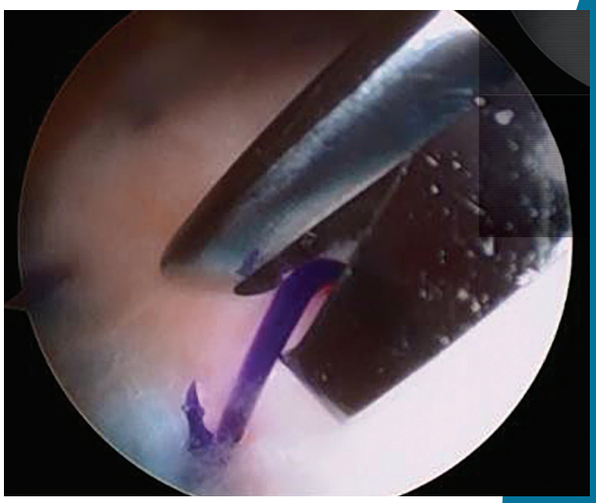
- **Bursectomy:** It is important for the implant to be in direct contact with the tendon, therefore, removing all of the bursal tissue on the superficial surface of the supraspinatus tendon is important. The goal is to have the newly induced tissue become well-integrated with the underlying tendon to ensure that the new tissue will carry load and reduce the strain in the tendon. A thorough bursectomy is also helpful in achieving good visualization for proper location of the Implant.
- **Lateral Footprint:** It is important to clean the soft tissue from the bone lateral to the insertion of the tendon, which may be conveniently done arthroscopically using an ablation instrument. The goal is to have the lateral end of the implant overlap 5 mm onto bone to allow for adequate bone fixation. *Direct contact with bone enables the new tissue to form a natural insertion into bone, as with the fibrocartilagenous transition zone observed in the sheep studies.2
- **Angle for Tendon Anchoring:** Both legs of the Tendon Anchor Inserter must be in contact with the implant for proper tendon anchoring. If anchor delivery is attempted with one leg not in contact, as shown below, on the right, then one leg of the anchor will not be fully seated into the tendon. Do not deliver a tendon anchor unless both legs of the inserter are in contact with the implant. With both legs in contact with the implant, the tilt of the inserter is also important. Ideally, the inserter will be perpendicular to the implant, but tendon anchoring at an angle up to 30° is acceptable, as shown below on the left.



- **Proper Tendon Fixation Technique:** Punch the legs of the Tendon Anchor Inserter through the implant and into the tendon until the base of the “U” contacts the implant. While applying moderate pressure, with the implant slightly compressed, squeeze the trigger to deliver a tendon anchor. Let up on the pressure before releasing the trigger. After releasing the trigger, pull the Tendon Anchor Inserter out of the tendon. Do not squeeze the trigger more than once.
- **Location of Tendon Anchors:** Begin anchoring on the medial half of the implant, deploying a minimum of three anchors along the medial edge. When deploying anchors, it is best to place both legs of the anchor inside the blue border for a mattress-style placement of the anchors. Optionally, the anchor may be oriented perpendicular to the edge of the implant with one leg of the inserter positioned just inside the blue border and the other leg off the edge of the implant. With three to five successfully deployed anchors on the medial half, remove the delivery instrument and continue deploying remaining anchors as needed. If additional support is necessary when removing the delivery instrument, push the Tendon Anchor Inserter through the implant into the tendon, pinning the implant in place while removing the delivery instrument. Placement of the Tendon Anchor Inserter should be biased to the middle of the implant without impeding the ability to remove the delivery instrument.
- **Nearing the Footprint:** If moderate pressure will not allow the base of the “U” to contact the implant, as shown below, then the legs of the anchor are hitting bone. If this occurs, do not apply more pressure to try to force the inserter in further. Excessive force may bend the legs of the inserter and make it impossible to load additional anchors. Try changing the angle for anchoring up to a 30° angle to try to fully insert the inserter. If moderate force at an angle will not allow the base of the “U” to contact the implant, then an anchor should not be delivered. If too much force is inadvertently applied and the legs of the inserter become bent, do not try to straighten the legs; instead, use a new Tendon Anchor Inserter.



- **Loose Tendon Anchor:** If a tendon anchor is not fully inserted into the tendon, especially if one leg of the anchor is not in the tendon, as shown, the exposed part of the anchor should be clipped off and retrieved, or the anchor may be removed completely. If the entire anchor is removed, care must be taken that the barb of the anchor does not tear the implant. Grasp the bridge of the anchor as close as possible to where the leg of the anchor penetrates the implant and pull the anchor straight out.
- **Non-Perpendicular Bone Punch:** If the inferior-lateral portal is too inferior, it may be difficult to get the bone punch perpendicular to the humeral head. If this occurs, do not try to tension the lateral end of the implant with the bone punch at a sharp angle to the humeral head. Instead, make another portal slightly above the existing portal to enable the bone punch to contact the humeral head at a 90° angle.
- **Removal of Bone Anchor Inserter:** After removing the Bone Anchor Inserter, the nubs of the inserter must be pulled out of the bone. To avoid bending the nubs, the inserter must be pulled straight out. Do not rock the inserter back-and-forth to loosen the nubs, which might bend the nubs and prevent the inserter from being used for a subsequent bone anchor.
- **Proud Bone Anchor:** If a bone anchor bridge is not fully seated on the implant, push the anchor further into the bone. The design of the barbs on the anchor will allow the anchor to advance into the holes, but provide resistance to the anchor backing out of the holes.
- **Torn Implant Edge:** If an anchor is placed too close to the edge of the implant, it may cause the edge to tear. If that occurs, place an anchor on each side of the tear to hold down the edge.
- **Excessive Implant Fraying:** If the implant becomes excessively frayed during the implantation procedure, such that the implant begins to delaminate, it is recommended that the implant be removed and a new implant used.
- **Anchoring Angle:** If the angle for tendon or bone anchoring is too far from perpendicular and rotation or ab/adduction of the arm is insufficient to improve the angle for anchoring, create a new portal in a position that will improve the angle for anchoring.
- **Cannula Size for Implant Delivery:** It is not recommended to use a cannula to deliver the Bioinductive Implant. However, if the physician insists, the cannula should be no less than 10 mm in diameter, as this will decrease mobility of the implant delivery.



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