

# Tips and Tricks for Augmenting Rotator Cuff Repair With a Bio-inductive Collagen Implant



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**Abstract:** The contemporary literature suggests that a primary feature of recurrence of rotator cuff tear after arthroscopic repair is failure of tendon healing, which can occur for multiple reasons, including compromised tissue quality. Recently, the use of augmentation implants, grafts, or scaffolds has emerged as a strategy to address the issue of deficient rotator cuff tissue. A resorbable bio-inductive collagen implant (REGENETEN; Smith & Nephew, Andover, MA) has been shown to increase tendon thickness when applied in rotator cuff repair. This article presents an experienced surgeon's tips for implanting this device. In addition, we review the current literature about this bio-inductive implant.

The recent arthroscopic rotator cuff repair (ARCR) literature reflects an increasing interest among expert shoulder surgeons in augmenting suture and anchor-based repairs.<sup>1-3</sup> This attention on augmentation reflects the concept that although current biomechanically validated techniques can restore the native footprint of the tendon, failure to heal and recurrence of tears remain ongoing challenges.<sup>4</sup>

Rates of retear after ARCR vary from 5% to 57% in the recent literature.<sup>5,6</sup> A meta-analysis of Kunze et al.<sup>4</sup> on retear rates comparing knotted and knotless transosseous-equivalent repair techniques found no significant difference in rates but reported that retear is a persistent issue. Evidence suggests that retears and failure to heal can be attributed to intrinsic biological factors of the healing environment, such as hypovascularity and compromised tissue quality.<sup>7,8</sup>

One emerging approach for rotator cuff repair (RCR) augmentation is to use a highly porous, collagen bio-inductive implant (REGENETEN; Smith & Nephew, Andover, MA). Although the implant's mechanism of action is not fully understood, it has been shown that it induces tissue ingrowth and new host tissue formation on the bursal surface.<sup>3</sup> Prior studies on partial- and full-thickness repairs using this implant have shown earlier discontinuation of sling use, a faster return to work, and superior functional scores at 6 months compared with previously published data on similar tear patterns.<sup>2,9,10</sup> Although a lack of comparative studies with and without use of the augmentation remains, published results to date have generated increasing enthusiasm for its application. Thus, we present tips and techniques for the use of a bio-inductive implant to augment ARCR.

## Surgical Considerations

As use of the bio-inductive implant increases, indications for its use are evolving. At present, indications may be guided by the surgeon's perception of retear risk or benefit from potentially quicker functional recovery and experience with the implant. Relative indications for consideration of implant application include patient factors that may affect healing such as diabetes, autoimmune disease, smoking history, and tear characteristics, as well as operative findings such as large or massive tear size, revision repair, poor-quality tendon tissue, delamination, diffuse fraying (especially on the bursal side), and complex or unusual tear patterns such as medial intratendinous tears or type 2 failures. In our practice, optimizing hemoglobin A<sub>1c</sub> levels and smoking cessation are essential preoperatively. The use of

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implant application may warrant consideration in patients with high-activity level goals and/or demands, and diffuse tendinopathy on preoperative magnetic resonance imaging should be considered as well in indicating implant application. The most common indications for use in the senior author's (T.S.) practice include large or massive tear size, complex tear pattern, revision repair, poor tissue quality, and diffuse tendinopathy or substantial fraying of the bursal cuff layers in high-demand patients.

Surgeons should not fall into the trap of thinking that augmenting with a resorbable collagen implant means that they can use a less robust construct for the underlying repair. An interlinked double-row RCR maximizing the tape and/or suture limbs across the tear is recommended. In addition, when bio-inductive implant augmentation is used, care should be taken to prepare the bone lateral to the cuff repair margin so that the implant can heal to bone just lateral to the cuff insertion.

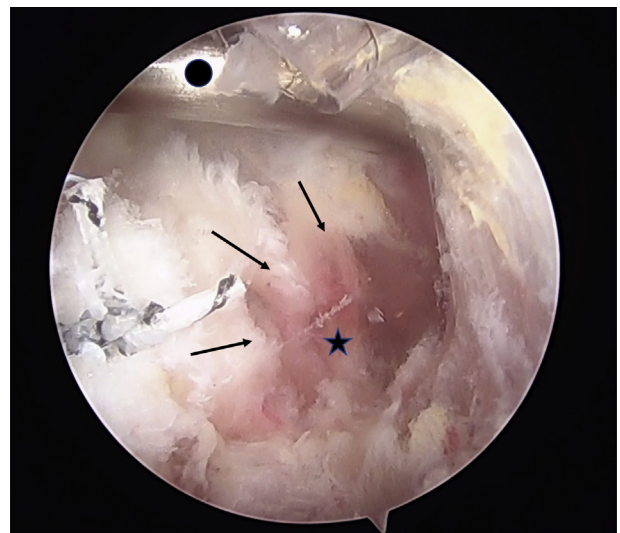
At surgery, prior to placement of the implant, all other arthroscopic procedures, such as subacromial decompression or acromioplasty, distal clavicle excision, and biceps tenotomy or tenodesis, should be completed in addition to the underlying RCR. Open subpectoral biceps tenodesis is performed after bio-inductive scaffold implantation. The portals from RCR can generally be used for deployment and fixation of the collagen implant.

### Our Preferred Technique: Graft Placement and Fixation

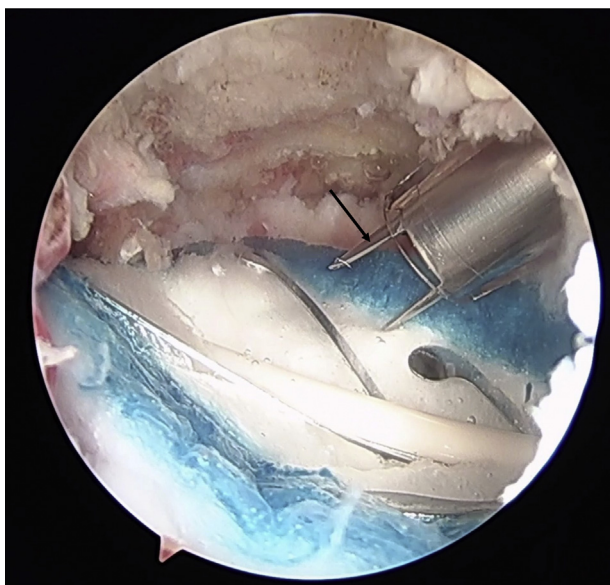
The senior author prefers to perform ARCR with the patient in the beach-chair position with a hydraulic arm positioner. The lateral portal is routinely made 3 fingerbreadths distal to the inferior edge of the acromion. This position enables all steps of double-row RCR plus subsequent bio-inductive implant deployment and fixation. Anecdotally, other surgeons have communicated a need to create a new, more distal lateral portal after ARCR to achieve the appropriate trajectory for bio-inductive implant deployment. That has not been our experience, but we suspect it is because of the routine use of a more proximal lateral working portal in ARCR. Our preferred lateral portal location additionally facilitates routine distal placement of lateral-row RCR anchors. Far distal lateral-row anchor placement optimizes the RCR construct by gaining purchase into bone with greater density and allows ample room for subsequent bone anchor fixation of the lateral margin of the bio-inductive implant. Prior to implant insertion, soft-tissue swelling due to tenacious bursitis or the length of time needed to complete RCR should be addressed with shaver debridement and/or radio-frequency controlled ablation to ensure adequate visualization.

The senior surgeon (T.S.) finds it easiest to deploy the implant unconstrained through a well-dilated lateral portal focusing on a parallel-to-tendon approach, although it can also be delivered through a cannula and over a guide pin. A straight instrument (e.g., switching stick) is used to plot the implant trajectory, and the arm position is adjusted as needed to ensure that the graft deploys centrally over the repair (Fig 1). (A new portal can be created—and should be if needed to facilitate proper implant delivery—however, we have not found this necessary with our preferred routine portal location). The graft should be positioned in the subacromial space such that the lateral margin will overlay at least 5 mm of the greater tuberosity lateral to the cuff margin (Fig 1) and medially at the muscle-tendon junction, medial to the medial row of repair sutures. Implantation of the tendon anchors will often cause 3 to 5 mm of medialization, which should be accounted for during positioning, so aiming for 1 cm is a good rule of thumb. We prefer the large implant size for most cases, increasing repair coverage to maximize the implant's bio-inductive properties, but the medium size may be more appropriate in smaller patients and its use may be technically easier early in a surgeon's learning curve.

The implant and its anchors are packaged separately. The implant comes preloaded on its deployment apparatus. The anchor set consists of PEEK (polyether ether ketone) bone anchors loaded on inserters, a gun-like



**Fig 1.** Prepared greater tuberosity lateral to repair and use of switching stick to determine bio-inductive implant trajectory. The subacromial space in a right shoulder viewed from the posterior portal shows the lateral margin of arthroscopic rotator cuff repair (arrows), the prepared greater tuberosity footprint at least 5 mm lateral to the rotator cuff repair margin (star), and the use of a straight instrument (circle) (in this case, a switching stick) through a well-dilated lateral portal to determine the trajectory for bio-inductive implant deployment.



**Fig 2.** Medial soft-tissue anchor deployment. The sub-acromial space in a right shoulder viewed from the posterior viewing portal shows soft-tissue anchor (arrow) deployment through a previously made superolateral portal along the anterior edge of the medial half of the bio-inductive implant. Anchors are placed inside the blue border as shown.

bone anchor insertion device with a punch, a puck containing the poly-L/D-lactic acid tendon anchors, and cannulas and inserters for the tendon anchors. After positioning the graft, the safety is released and the trigger is pulled to retract the delivery tube and unfurl the graft on its deployment frame. Patience is warranted during graft deployment because it often takes several seconds to fully hydrate and unfurl (Video 1).

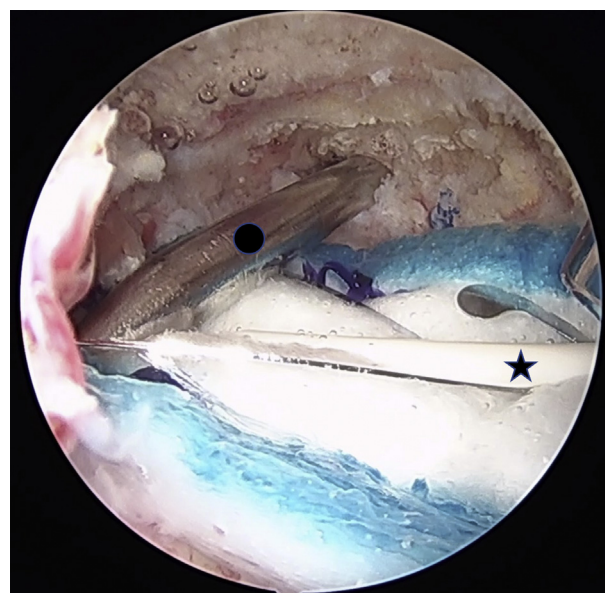
Once the implant is unfurled, attention can be directed to soft-tissue fixation. A soft-tissue anchor cannula is introduced via the superolateral portal used for suture anchor placement during RCR (Fig 2). The obturator tip of this cannula is pointed, so care must be taken to avoid fouling the implant surface during insertion. Moreover, the tendon anchor inserter fits snugly in the cannula, so care must be taken to not advance the cannula and scuff the implant. Manually stabilizing the cannula from outside the shoulder can help. The tendon anchors are barbed to catch and hold the collagen implant to underlying tendon. Optimal insertion is at a perpendicular angle and engages both legs of the anchor into the underlying tendon with the base of the anchor contacting the implant. It is important to maintain downward pressure while firing the anchors to avoid the device's "kickback" from losing contact with the tissue. Anchors are placed peripherally along the anterior, medial, and posterior aspect of the medial half of the implant, just inside the blue border.

If the anchors do not engage properly, it is possible to carefully remove them by grasping as much of the

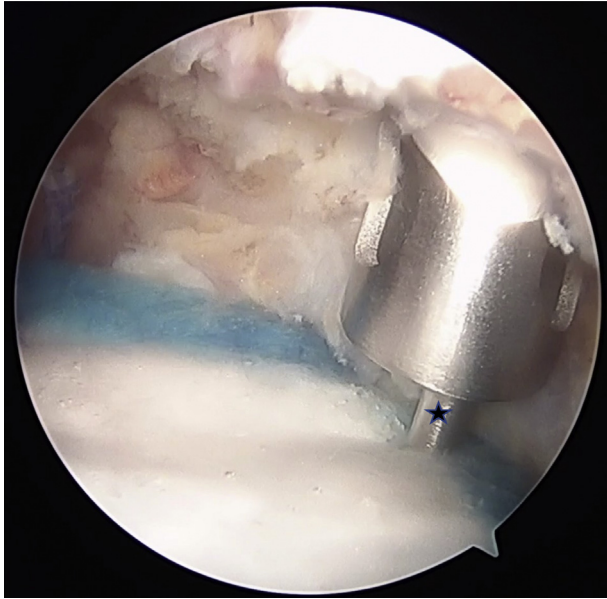
exposed anchors as possible. However, it is easy to tear the implant while attempting this. Instead, the senior author recommends 2 alternate strategies: First, an "anchor-on-anchor" technique can be performed, placing a second anchor around the first, generally rotated 90° axially. Second, the proud portion can be clipped with a meniscal punch. This is unlikely to cause issues, as long as what is left behind is well fixed and the barbed leg is buried, because the anchor is resorbable. Similarly, if an anchor is deployed too forcefully, creating a tear in the implant, a stacked anchor placed perpendicular to the first can span and affix the implant across the focal tear.

The delivery device is then removed by slightly lowering the handle and gently pulling it out. A switching stick through an anterior portal on the medial aspect of the implant can help stabilize the collagen implant and offload the anchors during inserter removal (Fig 3). The switching stick can also be used as a soft-tissue retractor against the deltoid fascia, akin to the use of retractors in elbow arthroscopy. Additional soft-tissue anchors can be placed as needed to secure the medial aspect of the collagen implant. In most cases, we use 7 to 10 soft-tissue anchors.

Bone anchor placement follows. The bone anchor inserter is introduced via the lateral portal, and its sheath is then retracted to expose the bone punch pins (Fig 4). The pins are engaged in the collagen implant



**Fig 3.** Stabilization of implant medially during removal of insertion device. The subacromial space in a right shoulder viewed from the posterior portal shows a straight instrument (circle) placed through a previously made anterior portal to stabilize the collagen implant during removal of the insertion device (star) after implant-to-tendon fixation medially with soft-tissue anchors.



**Fig 4.** Bone anchor insertion. The subacromial space in a right shoulder viewed from the posterior portal shows bone anchor (star) placement through the anterior lateral edge of the bio-inductive implant into the prepared greater tuberosity.

and used to gently tension it laterally; then, they are advanced through and positioned against the underlying bone ending as perpendicular as possible. The

**Table 1.** Key Steps of Implantation

1. Prepare the greater tuberosity lateral to where the repaired rotator cuff tendon will only to account for subsequent bio-inductive collagen implant contact with bone.
2. Repair the rotator cuff tear with meticulous technique. Note that an interlinked double-row repair is recommended, which maximizes the suture and/or tape limbs crossing the tear, with lateral-row anchors in a distal position to avoid interference with the bone anchors for the collagen implant.
3. Use a switching stick to ensure lateral portal placement and arm positioning to enable an implant trajectory that will place it centrally over the repair.
4. Deploy the implant through the well-dilated lateral portal while viewing from the posterior portal.
5. Implant the graft medially at the musculotendinous junction (medial to the medial row) and laterally at least 5 mm lateral to the cuff repair margin. Account for slight medialization that may occur during placement of soft-tissue anchors.
6. Place soft-tissue anchors through a superolateral portal peripherally along the medial, anterior, and posterior aspect of the medial half of the implant, inside the blue border.
7. Stabilize the implant medially while withdrawing the implant insertion device.
8. Place bone anchors through the lateral portal. Note that, generally, 2 anchors for medium-size grafts and 3 anchors for large-size grafts are sufficient.
9. Assess the stability of the implant. If needed, augment with additional soft-tissue anchors.
10. Perform additional biological augmentation on top of the implant and/or at the rotator cuff tendon-to-bone interface per surgeon discretion.

**Table 2.** Pearls and Pitfalls

**Pearls**

- All other arthroscopic procedures should be performed prior to inserting the collagen implant.
- The large size is recommended in most cases.
- A switching stick or other instrument should be used to confirm the appropriate trajectory and positioning for implant insertion.
- A switching stick in the anterior portal can be used to retract the deltoid fascia to help with visualization.
- The cannulas should be stabilized during soft-tissue anchor insertion, and the anchors should be inserted as perpendicularly as possible.
- Suboptimal tendon anchor deployment can be managed by placement of another anchor over it in perpendicular orientation and/or by clipping the prominent portion with a meniscal punch.
- Stabilizing the medial aspect of the collagen implant with a switching stick from the anterior working portal offloads the soft-tissue anchors and implant during removal of the deployment mechanism.
- When placing lateral bone anchors, the surgeon should engage the tips of the punch pins and use them to gently tension the implant in a lateral direction.
- Additional orthobiological augmentation can be performed.

**Pitfalls**

- Implant placement prior to completing all other arthroscopic procedures should be avoided.
- Failure to confirm that the portal location and arm position will allow proper collagen implant positioning may result in difficulty achieving desired implant placement.
- Anecdotally, medial malposition is the most common error in implant placement; failure to position the lateral aspect of the implant over bone and account for several millimeters of medialization prior to delivering the first tendon anchors may cause excessive medialization of the implant and result in an inability to anchor to the greater tuberosity.
- Inadvertent advancement of the soft-tissue anchors or their cannulas or the cannula obturator can damage the integrity of the collagen implant.
- Insufficient pressure during soft-tissue anchor placement results in proud anchors.
- Excessive pressure during soft-tissue anchor placement can tear the collagen implant.
- Bone anchor placement too close to its lateral margin risks loss of fixation due to tearing through the implant.
- Separation of the collagen implant–tendon interface should be avoided.

punch is advanced with mallet taps on its back end and is then ejected and replaced in the center of the inserter with a bone anchor, which is impacted into place. Placing the bone anchor too closely to the collagen implant edge can cause the collagen implant to tear. Likewise, it is important to avoid over-tensioning the implant because the bone anchors introduce additional tension on insertion. Care must be taken to ensure that the inserter is not toggled during the bone anchor implantation steps. Generally, 2 bone anchors are sufficient for medium implants and 3 are optimal for large implants to maximize graft-to-tuberosity contact. The stability of the implant augmentation to the cuff repair can then be assessed ([Video 1](#)) and augmented with additional soft-tissue anchors if needed.

**Table 3.** Currently Available Literature on Bio-inductive Implant Augmentation of RCR

Authors	Findings
Schlegel et al. <sup>9</sup>	<ul style="list-style-type: none"> <li>• 33 chronic, degenerative, high- or intermediate-grade partial-thickness, articular-sided tears treated with bio-inductive implant applied on bursal surface</li> <li>• Mean 2.0-mm increase in tendon thickness at 1-yr MRI follow-up</li> </ul>
McIntyre et al. <sup>2</sup>	<ul style="list-style-type: none"> <li>• Only 1 retear, in noncompliant patient</li> <li>• Multicenter, retrospective case series of patients with partial- (n = 90) and full-thickness (n = 83) tears at 1-yr follow-up</li> <li>• Both primary and revision cases included</li> <li>• In partial-thickness group, 84% and 83% met or exceeded MCID in ASES shoulder score and VAS pain score; mean time for return to driving, work, and non-overhead athletic activity was 15 d, 37 d, and 66 d, respectively</li> <li>• In full-thickness group, 72% and 77% met or exceeded MCID in ASES score and VAS pain score; mean time for return to driving, work, and non-overhead athletic activity was 25 d, 51 d, and 119 days</li> <li>• No implant-related complications</li> </ul>
Thon et al. <sup>21</sup>	<ul style="list-style-type: none"> <li>• Prospective study of complete repairs of full-thickness, large (2-tendon) and massive (3-tendon) tears</li> <li>• All were complete repairs augmented with bio-inductive implant</li> <li>• At minimum of 6 mo of follow-up, 22 of 23 showed tendon healing on ultrasound or MRI; mean MRI cuff thickness was 5.13 mm</li> <li>• 2 of 23 failed clinically (additional surgery) despite healed tendon</li> <li>• Mean ASES score of 83</li> <li>• No adverse events related to implant</li> </ul>
Bokor et al. <sup>22</sup>	<ul style="list-style-type: none"> <li>• Prospective study of 9 full-thickness tears augmented with bursally applied bio-inductive implant</li> <li>• MRI at 3, 6, 12, and 24 mo</li> <li>• Induced significant tissue that matured over time and became indistinguishable from underlying tendon at 24 mo</li> <li>• Significant improvements in all clinical scores</li> </ul>

ASES, American Shoulder and Elbow Surgeons; MCID, minimal clinically important difference; MRI, magnetic resonance imaging; VAS, visual analog scale.

Additional biological augmentation of the repair can be performed, for example with platelet-rich plasma and bone marrow concentrate. In these cases, we recommend injecting them over the top of the implant or into the bone-tendon interface of the repair. The implant is meant to directly overlay the rotator cuff to encourage tissue ingrowth, and thus, the placement of injectable biological agents under the implant should be avoided because this could theoretically separate the implant from the underlying rotator cuff tendon and, as a result, impair bio-induction and incorporation. [Tables 1](#) summarizes the key steps, and [Table 2](#) presents technical pearls and pitfalls; the technique is shown in full in [Video 1](#).

## Discussion

Recurrent tear or nonhealing after ARCR remains a challenge for all shoulder surgeons. Nonhealing has been correlated with worse functional outcomes and pain scores.<sup>11-13</sup> Recent studies support the concept that large or massive and recurrent tears are at the highest risk of repair failure.<sup>14,15</sup> For larger tears, tension overload from conventional repair techniques in conjunction with poor tissue quality at the site of repair likely contributes to observed failure rates.<sup>16-18</sup>

Similarly, patients undergoing revision surgery have failure rates as high as 56% with significantly worse tendon quality reported.<sup>19,20</sup> These findings give impetus to using biological augmentation for ARCR in patients with large or massive tears, revision and compromised tissue quality cases, and patients with risk factors for failure.

The bio-inductive implant described in this article has shown the ability to form dense, regularly oriented connective tissue that histologically resembles native tendon.<sup>3</sup> Human studies have reported a mean 2-mm increase in tendon thickness on early magnetic resonance imaging follow-up,<sup>9</sup> highlighting the scaffold-like property of the implant to stimulate blood flow and tissue healing.

Patient-reported outcomes have been favorable compared with historical outcomes without the collagen implant. Return to various activities has been shown to be quicker than in previous reports without the augmentation,<sup>2</sup> although there is potential for selection bias in terms of patient candidacy for accelerated rehabilitation. [Table 3](#) summarizes published literature on the particular bio-inductive implant described in this article.<sup>2,9,21,22</sup> In a study of ARCR for large and massive tears, Thon et al.<sup>21</sup> reported high healing rates and

favorable outcomes for this challenging subset of rotator cuff surgical procedures. Our experience has been similar. In addition, the use of an acellular (non-bio-inductive) dermal patch (ArthroFlex Acellular Dermal Matrix; Arthrex, Naples, FL) with biological augmentation (bone marrow aspirate concentrate) for these challenging large or revision tears has recently been shown to provide clinical benefit in patients who achieved greater cellular ingrowth into the patch.<sup>23</sup>

There are limitations to our current understanding of the bio-inductive collagen implant. Longer-term and comparative studies of tears treated with and without the implant are still needed to more rigorously characterize its effect on postoperative recovery as well as clinical outcomes and particularly structural integrity rates after ARCR. Future work is also needed to optimize and better define indications for its use. Continued monitoring for adverse reactions is needed given its theoretical potential for causing an immune response, although it is important to note that such a response has not been reported to date. Finally, cost-effectiveness studies could help meld indications with current efforts toward value-based care.

In summary, the current literature and our experience with a bio-inductive scaffold suggest that this implant is a useful adjunct for complex and revision RCR. The technical recommendations in this article may help surgeons achieve outcomes comparable to those presented in the current literature.

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