Smith+Nephew

REGENETEN®

Bioinductive Implant

for Rotator Cuff Repair

The REGENETEN Bioinductive Implant is designed to heal tears in the rotator cuff by helping your body grow new tendon-like tissue.[1-5] It can be used with both partial- and full-thickness tears, and may serve as an alternative to standard surgical treatment.

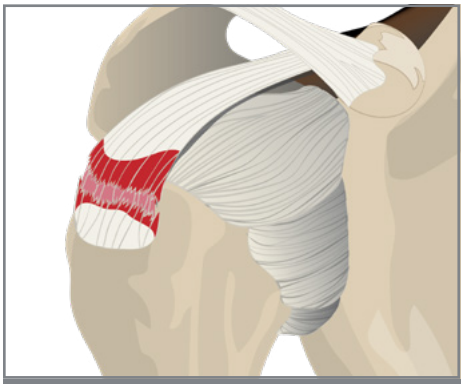
The REGENETEN Bioinductive Implant is the product to be implanted in your shoulder repair surgery.

Rotator cuff tears

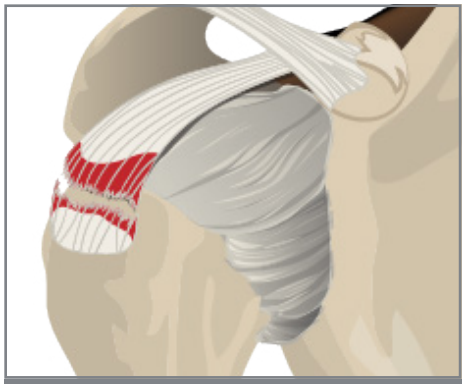
Rotator cuff tears are very common – and can also be very painful. About 1 in 5 people will have a rotator cuff tear in their lifetime.[6]

A rotator cuff tear happens when the tendon holding your shoulder joint in place becomes damaged. The tear can be caused by a sudden injury or fall, or by gradual wear over time. If left untreated, a rotator cuff tear may become larger or more severe.

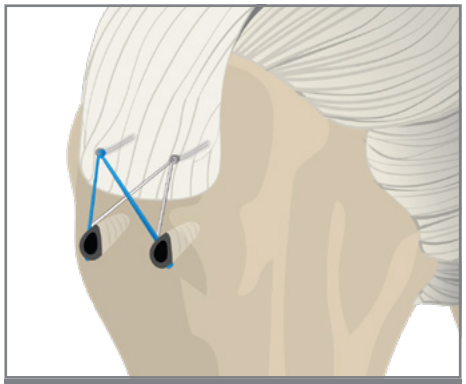
Standard surgical treatment for a rotator cuff tear involves suturing the torn tendon back together and using anchors to reattach it to the arm bone. Unfortunately, a tendon that is worn or weak may tear again.



Partial Thickness Tear



Full Thickness Tear



Standard Surgical Treatment

REGENETEN◊ Bioinductive Implant

The REGENETEN Implant offers a newer treatment option. The REGENETEN Implant is a small patch of collagen – about the size of a postage stamp – that is attached to your rotator cuff tendon during surgery. The collagen serves as a "scaffold" for the growth of new tendon-like tissue. It is then absorbed by the body.[4] Studies have shown that treatment with the REGENETEN implant:

- Helps your body grow new tendon-like tissue to repair the damaged tendon[1-5]
- Thickens the tendon by 2 mm, which helps the tendon to heal[1-4,7,8]
- May provide a faster recovery and return to activities, compared to standard surgical treatment[7*]

The REGENETEN implant helps your body to . . .

Grow new tendon-like tissue[1-5]

Thicken the tendon[1-4,7,8]

Recover more quickly[7*]

How the REGENETEN◊ Bioinductive Implant is used

The REGENETEN implant may be used in one of two ways: as an alternative to standard surgical treatment, or as an addition to it.

Alternative to standard surgical treatment

For some patients, especially those with partial-thickness tears, the REGENETEN implant may be used as an alternative to the sutures and anchors of standard treatment.

In a recent study, patients treated with the REGENETEN implant alone were compared to patients who received the standard treatment. Results showed that patients treated with the REGENETEN implant experienced:[7*]

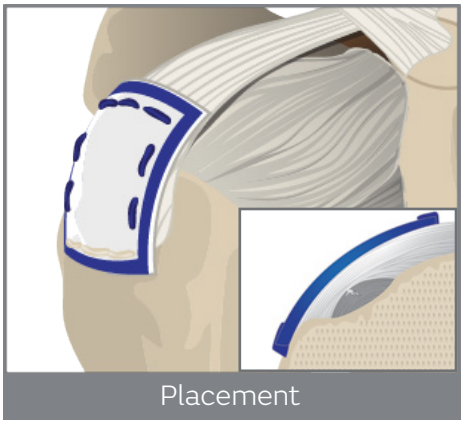
- Faster return to work
- Less time in a sling
- Less pain in the first 12 months post-surgery
- Higher satisfaction at 12 months

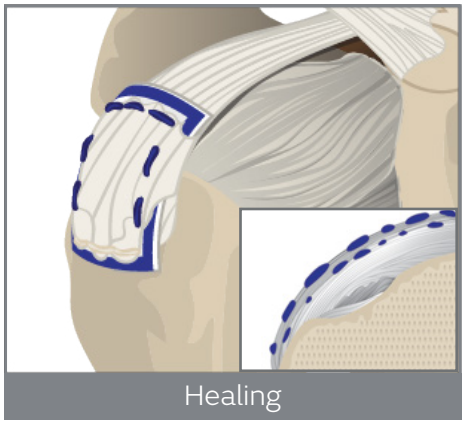
Addition to standard surgical treatment

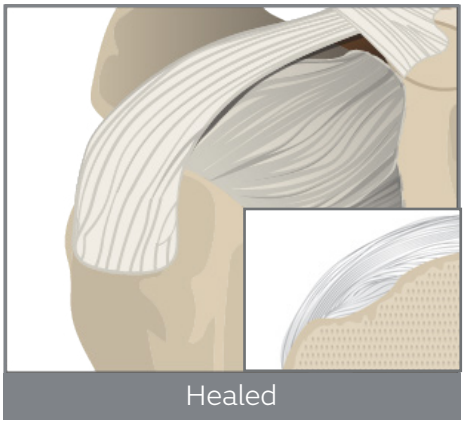
For patients with full-thickness tears, the REGENETEN implant may be used as an addition – or augmentation – to standard surgical treatment. In this situation, the surgeon completes a traditional repair with sutures and anchors, and then places the REGENETEN patch on top of it.

In a recent study, patients treated with the REGENETEN implant in addition to standard treatment were more likely to experience a successful repair than patients who received standard treatment alone.[8] In fact:

- Patients treated with the REGENETEN implant in addition to standard treatment were three times less likely to have a re-tear at 12 months.[8]


Placement


Healing


Healed

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Notes: _____

This material is intended for healthcare professional use only. Healthcare professionals may use this material to discuss treatment options with their patients. Your healthcare professional will advise you whether this product/procedure is suitable for you and your condition.

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*Study conducted in biomechanically stable full-thickness rotator cuff tears comparing isolated REGENETEN Implant (n=30) use to a transosseous equivalent repair (n=30).
References: 1. Bokor DJ, Sonnabend D, Deady L, et al. Evidence of healing of partial-thickness rotator cuff tears following arthroscopic augmentation with a collagen implant: a 2-year MRI follow-up. Muscles, Ligaments Tendons J 2016;6(1):16-25. **2.** Schlegel TF, Abrams JS, Bushnell BD, Brock JL, Ho CP. Radiologic and clinical evaluation of a bioabsorbable collagen implant to treat partial-thickness tears: a prospective multicenter study. J Shoulder Elbow Surg. 2018 27(2):242-251. **3.** Thon SG, O'Malley L, O'Brien MJ, Savoie FH. Evaluation of Healing Rates and Safety With a Bioinductive Collagen Patch for Large and Massive Rotator Cuff Tears: 2-Year Safety and Clinical Outcomes. Am J Sports Med 2019;47(8):1901-1908. **4.** Van Kampen C, Arnoczky S, Parks P, et al. Tissue-engineered augmentation of a rotator cuff tendon using a reconstituted collagen scaffold: a histological evaluation in sheep. Muscles Ligaments Tendons J. 2013;3(3):229-235. **5.** Camacho-Chacon JA, Cuenca-Espierrez J, Roda-Rojo V, et al. Bioinductive collagen implants facilitate tendon regeneration in rotator cuff tears. J Exp Orthop. Jun 8 2022;9(1):53. **6.** Rotator Cuff Disorders: The facts. OrthoBethesda website. www.orthobethesda.com. Accessed August 2024. **7.** Camacho Chacón JA, Roda Rojo V, Martin Martinez A, et al. An isolated bioinductive repair vs. sutured repair for full-thickness rotator cuff tears: 2-year results of a double blinded, randomized controlled trial. J Shoulder Elbow Surg. Published online May 9, 2024. **8.** Ruiz Ibán MÁ, García Navlet M, Moros Marco S, et al. Augmentation of a Transosseous-Equivalent Repair in Posterosuperior Nonacute Rotator Cuff Tears With a Bioinductive Collagen Implant Decreases the Retear Rate at 1 Year: A Randomized Controlled Trial. Arthroscopy. 2024;40(6):1760-1773.