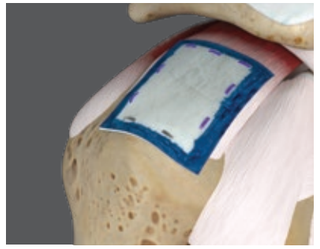
REGENETEN◇ Bioinductive Implant System



The right solution for your patients

- Stimulates the body's natural healing response to support new tendon growth and disrupt disease progression[2]
- Clinically proven to increase tendon thickness[1,13]
- Delivers excellent outcomes in patient satisfaction, recovery, and pain scores[1]

Ordering information

Implants	
Order #	**Description**
2169-3	Large Arthroscopic Bioinductive Implant (1)
2169-2	Medium Arthroscopic Bioinductive Implant (1)
Anchors	
Order #	**Description**
2503-A	Bone Anchors (3) with Arthroscopic Delivery System
2504-1	Tendon Anchors (8)
Accessory Devices	
Order #	**Description**
4173-1	Tendon Marker (2)
4402	Tendon Stabilizing Guide (1)
2503-S	Bone Anchor (1)

Another innovation from Smith & Nephew Shoulder Solutions.

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Supporting healthcare professionals for over 150 years

References

1. 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.* 2017. doi: http://dx.doi.org/10.1016/j.jse.2017.08.023. **2.** 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. *MLTJ.* 2016;6(1):16-25. **3.** Washburn R, Anderson TM, Tokish JM. Arthroscopic rotator cuff augmentation: Surgical technique using bovine collagen bioinductive implant. *Arthroscopy Techniques.* 2017:6(2);e297-e301. **4.** Mather RC, Koenig L, Acevedo D et al. The societal and economic value of rotator cuff repair. *J Bone Joint Surg Am.* 2013;95:1993-2000. **5.** Lin JC, Weintraub N, Aragaki DR. Nonsurgical treatment for rotator cuff injury in the elderly. *Am Med Dir Assoc.* 2008;9(9):626-32. doi: 10.1016/j.jamda.2008.05.003. **6.** Yamanaka K and Matsumoto T. The joint side tear of the rotator cuff: A followup study by arthrography. *Clinical Orthopaedics and Related Research.* 1994: 304,68-73. **7.** Keener JD, Galatz LM, Teefey SA et al. A prospective evaluation of survivorship of asymptomatic degenerative rotator cuff tears. *J Bone Joint Surg Am.* 2015;97:89-98. **8.** Bishop J, Klepps S, Lo IK, Bird J, Gladstone JN, Flatow EL. Cuff integrity after arthroscopic versus open rotator cuff repair: A prospective study. *J Shoulder Elbow Surg.* 2006;15(3):290-299. **9.** Heuberer PR, Smolen D, Pauzenberger L et al. Longitudinal long-term magnetic resonance imaging and clinical follow-up after single-row arthroscopic rotator cuff repair. *Am J Sports Med.* 2017;45(6):1283-1288. **10.** Henry P, Wasserstein D, Park S, et al. Arthroscopic repair for chronic massive rotator cuff tears: A systematic review. *Arthroscopy.* 2015;31(12):2472-80. **11.** Chen Q. Proof-of-concept finite element modelling of effect of tissue induction on rotator cuff tears. Material and Structural Testing Core, Mayo Clinic, Rochester, MN. **12.** Van Kampen C, et al. Tissue-engineered augmentation of a rotator cuff tendon using a reconstituted collagen scaffold: A histological evaluation in sheep. *MLTJ.* 2013;3:229-235. **13.** Bokor DJ, Sonnabend D, Deady L et al. Preliminary investigation of a biological augmentation of rotator cuff repairs using a collagen implant: a 2-year MRI follow-up. *MLTJ.* 2015;5(3):144-150.

REGENERATES TENDONS.[1,2] REVOLUTIONIZES INTERVENTION.

Biologically stimulates rotator cuff tendon growth[1]

- Demonstrated clinical efficacy[1]
- Excellent safety profile[1]
- Impressive patient outcomes[1]

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REGENETEN◇
Bioinductive Implant

Supporting healthcare professionals

Changing the course of rotator cuff disease.

Rotator cuff disease is a significant and costly problem[2-4] that causes ongoing pain and limits patients' mobility.[5] Progressive in nature, small tears tend to grow in size and severity over time, eventually requiring surgery.[1-3]

- Up to 80% of partial-thickness tears increase in size within 2 years[6]
- Untreated rotator cuff tendinosis can progress to a partial- or full-thickness tear[7]
- Larger tears requiring surgery tend to re-tear over 40% of the time[8-10]

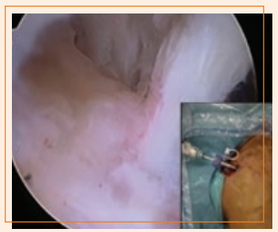
REGENETEN◇ Bioinductive Implant

Now you can disrupt rotator cuff disease progression biologically[1]

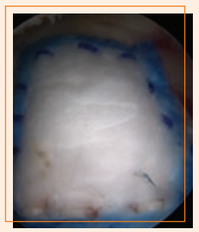
The REGENETEN Bioinductive Implant stimulates the body's natural healing response to support new tendon growth and disrupt disease progression.[1,2] Derived from highly purified bovine Achilles tendon, it creates an environment that is conducive to healing.[1,2]

Biologically improve healing

- Proprietary, highly porous implant design facilitates the formation of new tendon-like tissue[1,2]
- New tissue reduces the peak strain at the site of the tear[11]
- Gradually absorbs within 6 months and leaves a layer of new tendon-like tissue to biologically augment the existing tendon[12]



Arthroscopic view of rotator cuff tear



Implant in situ

12 months Post-Op

Addressing disease progression at every stage

Natural Progression of Rotator Cuff Disease

Severe Tendinosis/ Low-Grade Partial-Thickness Tears (Failed Conservative Treatment)	High-Grade Partial-Thickness Tears	Full-Thickness Tears
In conjunction with subacromial decompression (SAD)	In lieu of standard repair	In conjunction with standard repair

REGENETEN Bioinductive Implant

Proven results. Positive outcomes.[1*]

Demonstrated clinical efficacy

- Induction of new tendon-like tissue in all patients (N=33)
- Mean increase of tendon thickness of 2.2 mm ($P < 0.0001$) at 3 months
- Reduction in defect size of at least 1 grade†

Excellent safety profile

- No foreign body/inflammatory reaction
- No implant-related complications

Impressive patient outcomes

- High patient satisfaction (94%) after 1 year
- Rapid recovery: average 23 days of sling time
- Significantly improved ASES pain score at 1 year ($P < 0.0001$)‡

*Results from a prospective multi-center study of patients with partial-thickness tears. Patients had chronic, degenerative, intermediate grade (n=12) or high grade (n=21) partial-thickness tears of the supraspinatus tendon. The REGENETEN Bioinductive Implant was attached following arthroscopic subacromial decompression without repair. Clinical outcomes were assessed pre-op and at 3 and 12 months post-op using American Shoulder and Elbow Surgeons (ASES) and Constant-Murley (CM) scores. Post-op tendon healing and thickness was assessed with MRI.

†In 31 (94%) patients over 12 months.

‡ASES pain score improved from 4.2 ± 0.4 standard error of mean (SEM) at baseline to 0.6 ± 0.2 (SEM) at 1 year.