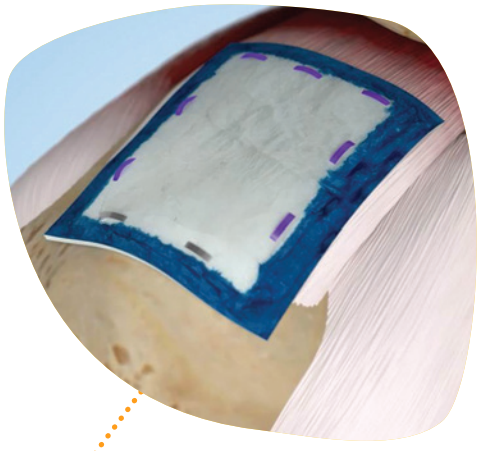


Redefining healing potential

An integral part of Advanced Healing Solutions

Smith+Nephew

REGENETEN◊
Bioinductive Implant

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]

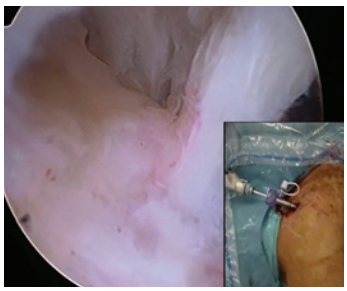
- **Up to 80% of partial-thickness tears increase in size within two years[6]**
- **Untreated rotator cuff tendinosis can progress to a partial- or full-thickness tear[7]**
- **Larger tears requiring surgery tend to re-tear over 40% of the time[8-10]**

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

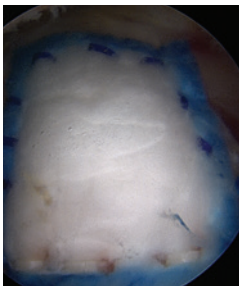
The REGENETEN Bioinductive Implant stimulates the body's natural healing response to support new tendon growth and disrupt disease progression.[1,2] Derived from highly purified bovine Achilles tendon, it creates an environment that is conducive to healing.[1,2]

Biologically improve healing

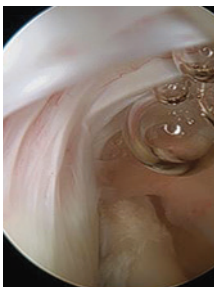
- Proprietary, highly porous implant design facilitates the formation of new tendon-like tissue[1,2]
- New tissue reduces the peak strain at the site of the tear[11]
- Gradually absorbs within 6 months and leaves a layer of new tendon-like tissue to biologically augment the existing tendon[12]



Arthroscopic view of rotator cuff tear



Implant in situ



12 months post-op

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
- Potentially reduce re-tears[13]

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 ($P < 0.0001$)‡

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

*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.

‡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.

Ordering information

Implants	
Reference #	Description
72205306	Medium Bioinductive Implant with Arthroscopic Delivery (1)
72205307	LargeBioinductive Implant with Arthroscopic Delivery (1)
Anchors	
Reference #	Description
72205205	Bone Anchors (3) with Arthroscopic Delivery System
72205201	Tendon Anchors (8)
Accessory Devices	
Reference #	Description
72205202	Tendon Marker (2)
72205206	Tendon Stabilizing Guide (1)
72205199	Bone Anchor (1)

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For detailed product information, including indications for use, contraindications, precautions and warnings, please consult the product's applicable Instructions for Use (IFU) prior to use.

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, 2011. **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.