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]

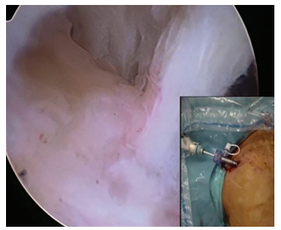
- **Up to 80% of partial-thickness tears increase in size within two years[6]**
- **Untreated rotator cuff tendinosis can progress to a partial- or full-thickness tear[7]**
- **Larger tears requiring surgery tend to re-tear over 40% of the time[8-10]**

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

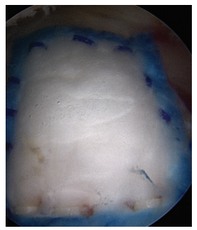
The REGENETEN Bioinductive Implant stimulates the body's natural healing response to support new tendon growth and disrupt disease progression.[1,2] Derived from highly purified bovine Achilles tendon, it creates an environment that is conducive to healing.[1,2]

Biologically improve healing

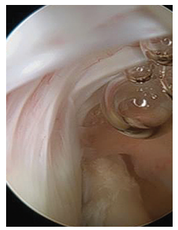
- Proprietary, highly porous implant design facilitates the formation of new tendon-like tissue[1,2]
- New tissue reduces the peak strain at the site of the tear[11]
- Gradually absorbs within 6 months and leaves a layer of new tendon-like tissue to biologically augment the existing tendon[12]



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
4565	Medium Bioinductive Implant with Arthroscopic Delivery (1)
4566	Large Bioinductive Implant with Arthroscopic Delivery (1)
Anchors	
Reference #	Description
4403	Bone Anchors (3) with Advanced Delivery System
2504-1	Tendon Anchors (8)
Accessory Devices	
Reference #	Description
4173-1	Tendon Marker (2)
4402	Tendon Stabilizing Guide (1)
2503-S	Bone Anchor (1)

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Printed in USA. 13508 V4 03/20

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