Regenerates tendons + revolutionizes intervention

Biologically stimulates rotator cuff tendon growth

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.\(^3\) 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\(^5\)
- Untreated rotator cuff tendinosis can progress to a partial- or full-thickness tear\(^6\)
- Larger tears requiring surgery tend to re-tear over 40% of the time\(^6\)\(^8\)

Now you can disrupt rotator cuff disease progression biologically\(^9\)

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\(^1\)\(^1\)
- Gradually absorbs within 6 months and leaves a layer of new tendon-like tissue to biologically augment the existing tendon\(^1\)\(^1\)

Demonstrated clinical efficacy

- Induction of new tendon-like tissue in all patients (N=33)\(^9\)
- Mean increase of tendon thickness of 2.2 mm (P < 0.0001) at 3 months\(^9\)
- Potentially reduce re-tears\(^1\)\(^1\)

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 < 0.0003)\(^9\)

Natural progression of rotator cuff disease

Severe Tendinosis/ Low-Grade Partial-Thickness Tears (Failed Conservative Treatment)

In conjunction with subacromial decompression (SAD)

In lieu of standard repair

High-Grade Partial-Thickness Tears

In conjunction with standard repair

Full-Thickness Tears

*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.

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References


