

## REGENETEN<sup>®</sup> Bioinductive Implant leads to tissue induction and high rates of tendon healing in patients with large and massive rotator cuff tears

Consistent treatment success in primary repairs and revisions with no implant-related adverse events



### Study overview

- A prospective study of 23 patients (mean age, 57.9 years) with large (two tendon, n=11) and massive (three tendon, n=12) rotator cuff tears receiving primary (n=7) or revision (n=16) repairs
- Following a double-row repair, a REGENETEN Bioinductive Implant was applied over the repaired supraspinatus and infraspinatus tendons
- Primary outcome was safety. Secondary outcomes included tendon thickness as an assessment of tissue induction on each ultrasound (US) examination (3, 6, 12 and 24 months) and on a single MRI (mean follow-up, 13 months), and American Shoulder and Elbow Surgeons (ASES) score at 24 months
- Standard postoperative rehabilitation protocol for large/massive rotator cuff tears was followed



### Key results

- No implant-related adverse events were reported
- Complete tendon healing in 22/23 patients (96%) on both imaging modalities (US and MRI)
- Treatment success in 21/23 patients (91%) at 24 months; 1 healing failure and 1 clinical failure due to progression of glenohumeral osteoarthritis
- Mean tendon thickness increased from 6.29mm at 3 months to 7.72mm at 12 months, decreasing to 7.28mm at 24 months
- Mean ASES score was 82.87 at 24 months
- No significant difference in treatment success (Figure), tendon thickness or ASES score between primary and revision repair groups or between large and massive tear groups

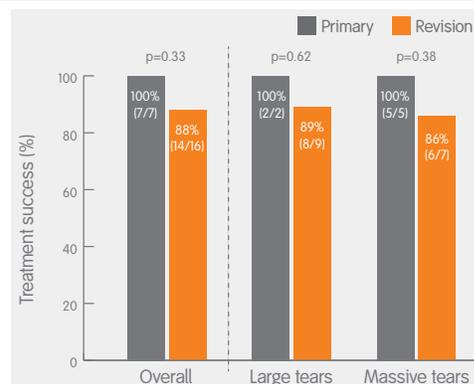


Figure. Percentage of patients achieving treatment success in primary and revision repairs



### Conclusion

Tendon healing is often unsuccessful following repair of large and massive rotator cuff tears, especially in the revision setting. In conjunction with repair of large and massive tears, REGENETEN Bioinductive Implant was safe, induced tissue formation and resulted in a relatively high tendon healing rate in both primary and revision settings. These findings are consistent with the healing response seen in partial-thickness tears.



### Considerations

- Tendon thickness was measured at the lateral edge of the articular cartilage and slightly posterior to the bicipital groove; the authors suggested a usual thickness in normal rotator cuffs of 8mm with this measurement technique



### Study citation

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.