✚ Evidence in focus

Clinical Evidence Summary

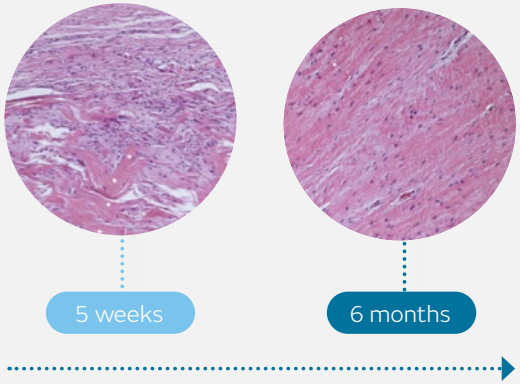
Smith+Nephew

REGENETEN◊ Bioinductive Implant

Introduction

The REGENETEN Implant has a large and growing evidence base in rotator cuff repair.[1–13] The REGENETEN Implant supports the body's natural healing response to facilitate new tendon-like tissue growth and change the course of rotator cuff tear progression.[1,2,12–16]

The REGENETEN Implant is resorbed and shows tendon-like tissue at 6 months[*1,13,14]



With a substantial body of literature evaluating its use in rotator cuff repair (>650 patients across >10 published studies),[†1–13] the REGENETEN Implant has been associated with:

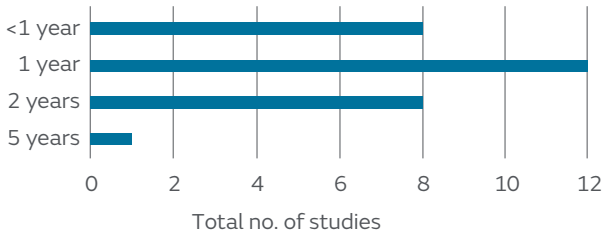
- Lower re-tear rates than reported for standard repair techniques[4–6,10,17]
- Rapid post-operative recovery[9,13,18]
- Significant and clinically meaningful post-operative improvements in clinical outcomes, compared to pre-operative levels[3,9,19]
- Low complication rates[2,3,5–10,13]

Effective treatment of rotator cuff tears can be challenging. Conventional treatment of PT tears commonly involves removing healthy tissue[20] and results in lengthy rehabilitation,[21] whilst repair of large FT tears has been associated with re-tear rates >50%.[22]

29 REGENETEN Implant publications

- 2 Randomised Controlled Trials (RCTs)[5,13]
- 15 Human Case Series[‡2,6-8,10-12,15,19,23,24-28]
- 2 Human Histological Case Studies[1,4]
- 5 Systematic Literature Reviews (SLRs)[29-33]
- 2 Cost Analyses[34,35]
- 3 Registries[3,9,18]

Clinical studies length of follow-up



>800 total patients studied

*On human biopsy (n=1) and in vivo sampling. †As of July 2024. ‡Representing 11 independent cohorts.

Overview of REGENETEN◊ Bioinductive Implant clinical study publications in rotator cuff repair

Study	Design	Tear	n= (of patients)	Follow-up	Key findings
Ruiz Ibán MA, et al. **Augmentation of a transosseous equivalent repair in posterosuperior nonacute rotator cuff tears with a bioinductive collagen implant decreases the retear rate at one year. A randomised controlled trial.** *Arthroscopy.* 2024;40(6):1760–1773. Available at (open access): Arthroscopy: The Journal of Arthroscopic & Related Surgery	Randomised controlled trial	FT	124 (enrolled), 122 (at follow-up) (REGENETEN Implant group n=60; control group n=62)	1 year	At 12 months follow-up, compared with repair alone, repair of medium and large full-thickness tears augmented with the REGENETEN Implant demonstrated: ▪ Significantly lower re-tear rate (8.3 vs 25.8%; p=0.01) ▪ Significantly better tendon integrity (defined as Sugaya grades 1–3; 91.7 vs 74.2%; p=0.03) ▪ A three times lower risk of re-tear (RR=0.32; 95% CI: 0.13–0.83) ▪ No differences in clinical outcome measures between groups ▪ No difference in the number of serious or minor complications
Camacho Chacón JA, et al. **An isolated bioinductive repair vs sutured repair for full-thickness rotator cuff tears: 2-year results of a double blinded, randomized controlled trial.** *J Shoulder Elbow Surg.* 2024 May 09. 2024;33(9):1894–1904. Available at: Journal of Shoulder and Elbow Surgery	Randomised controlled trial	FT	60 (REGENETEN Implant group n=30; control group n=30)	2 years	Patients with full-thickness rotator cuff tears, with an intact stable rotator cable, who received an IBR using the REGENETEN Implant at 2 years post-operatively demonstrated: ▪ Superior collagen organisation, without inflammation, seen on biopsy (p<0.0001) – Control group showed poorly organised collagen in 80% of patients ▪ Significantly thicker tendon at 6 months, compared to the control group, maintained throughout the follow-up period (p<0.0001) ▪ Healed tendon at 12 months (all patients had 100% tendon gap fill-in) ▪ Significantly better ASES and CMS scores at all timepoints, compared to the control group (p<0.0001) – Significantly lower VAS pain score at 6 months, compared to the control group (p<0.0001) – No difference in VAS pain score between groups at 24 months ▪ Significantly faster return to work and fewer days in a sling, compared to the control group (p<0.0001) ▪ Significantly fewer physical therapy sessions, compared to the control group (p<0.0001)

Study	Design	Tear	n= (of patients)	Follow-up	Key findings
Bushnell BD, et al. **Rotator cuff repair with a bioinductive bovine collagen implant has a low incidence of post-operative stiffness: review of 406 shoulders.** Poster presented at the Annual Academy of Orthopaedic Surgeons (AAOS) Annual Congress; March 7–11 2023; Las Vegas, Nevada, USA.	Case series	PT + FT	406 cases (368 patients, some patients had a bilateral rotator cuff repair)	32-month average follow-up (range: 2–102 months)	▪ A low incidence of post-operative stiffness (3.2%; 13/406) with a minimum of 2 months follow-up: – 1.5% (4/269) in full-thickness tears – 6.6% (9/137) in partial-thickness tears ▪ A low incidence of cases requiring secondary intervention for post-operative stiffness (2.7%; 11/406) with a minimum of 2 months follow-up: – Arthroscopic lysis of adhesions (n=10) – Isolated manipulation (n=1) ▪ Most of the patients who experienced stiffness (11/13) had one or more risk factors for stiffness including: – Diabetes – Smoking/tobacco use – Thyroid disease – Workers' compensation status
McIntyre LF, et al. **Resorbable bioinductive collagen implant is cost effective in the treatment of rotator cuff tears**. *Arthrosc Sports Med Rehabil.* 2023;5(2):e367–374. Available at: Arthroscopy, Sports Medicine and Rehabilitation	Economic analysis	FT	100	N/A	▪ In the base case anaylsis, the REGENETEN Implant + SoC resulted in improved healing/re-tear rates, at an increased cost, compared with SoC alone ▪ When analysed by tear size, the cost-effectiveness of the REGENETEN Implant + SoC relative to SoC alone improved with increasing tear size ▪ In the scenario analysis including the impact on return to work, the REGENETEN Implant + SoC was cost-saving compared with SoC alone, saving $469,017 per 100 treated patients with full-thickness rotator cuff tears ▪ One-way sensitivity analysis demonstrated increased cost-effectiveness, compared with the base case analysis, in patients at a higher risk of re-tear due to the following risk factors: age >60 years, hypertension, alcohol consumption and obesity
Camacho-Chacon JA, et al. **Bioinductive collagen implants facilitate tendon regeneration in rotator cuff tears.** *J Exp Orthop.* 2022;9(1):53. Available at: Journal of Experimental Orthopaedics	Case series	PT + FT	30 (enrolled), 29 (at follow-up)	1 year	▪ No evidence of inflammatory, scarring or ischaemic changes in histological examination of all samples at 6 months post-operatively – No evidence of any remaining REGENETEN Implant ▪ MRI demonstrated complete healing in 27 patients after 6 months; mean tendon thickness increased significantly by 1.84mm (from 4.18mm pre-operatively to 6.02mm; p=0.001) – All patients showed filling of the defect at 6 months with 90% completely filled and 10% with greater than 50% of the defect filled – No evidence of tear propagation at 1 year – Neotendon was indistinguishable from native tendon on MRI in all samples at 6 months and 1 year ▪ Patients experienced statistically significant improvements vs pre-operative values in VAS pain score (p=0.003), ASES (p=0.001) and CMS (p=0.001) at 6 months post-operatively, which were sustained at 1 year

Study	Design	Tear	n= (of patients)	Follow-up	Key findings
Bushnell BD, et al. **Two-year outcomes with a bioinductive collagen implant used in augmentation of arthroscopic repair of full-thickness rotator cuff tears: Final results of a prospective multi-center study.** *JSES Int.* 2022. 2022;31(12):2532–2541. Available at: Journal of Shoulder and Elbow	Case series	FT	115	2 years	▪ Between baseline and 2 year follow-up, the average mean tendon thickness increased by 12.5% for medium tears and 17.1% for large tears ▪ Overall re-tear rate of medium tears; 4.6% at 3 months (3/66) and 10.6% at 1 year and 2 years (7/66) ▪ Overall re-tear rate of large tears; 20.4% at 3 months (10/49), 24.5% at 1 year (12/49) and 28.6% at 2 years (14/49) ▪ Significantly lower re-tear rate in patients who had repair with double-row (12/91, 13.2%) technique at 2 years, compared to single-row technique (p=0.0061) – Re-tear rates with single-row (9/24, 37.5%) technique at 2 years ▪ More than 90% of patients had significant post-operative improvements in both medium and large tears in ASES Shoulder and CMS scores that exceeded respective MCIDs (p<0.001) ▪ Most patients (97.1%) surveyed were satisfied with the procedure; 100% of patients surveyed would recommend the procedure to a friend ▪ Nine re-operations were required: seven for persistent symptoms, one for superficial infection and one for inflammation and osteopenia
Bushnell BD, et al. **Treatment of partial-thickness rotator cuff tear repairs with a resorbable bioinductive bovine collagen implant: 1-year results from a prospective multi-center registry.** *Orthop J Sports Med.* 2021;9(8): 23259671211027850. Available at (open access): Orthopaedic Journal of Sports Medicine	Registry	PT	272 (enrolled), 227 (at follow-up)	1 year	▪ All PROMs were significantly improved at 3, 6 and 1 year from pre-operative values, except VR-12 MCS, which was significant at 1 year (p<0.05) – MCIDs for ASES, SANE and WORC scores were met or exceeded by >90% of patients at 1 year ▪ In higher grade tears (≥grade 2) and compared with the augmented takedown and repair group (n=26), isolated bioinductive repair (REGENETEN Implant without surgical repair; n=201) resulted in: – Significantly better ASES, SANE and WORC scores at 2 and 6 weeks (p<0.05) – No significant differences in 1 year outcomes, except VR-12 PCS, which was significantly improved with isolated bioinductive repair (p=0.0213) – Significantly less sling time (19.1 vs 34.3 days; p<0.0001) and faster return to non-overhead sports (72.2 vs 128.9 days; p=0.0192); no other significant differences in recovery

Study	Design	Tear	n= (of patients)	Follow-up	Key findings
McIntyre LF, et al. **Full-thickness rotator cuff tears can be safely treated with a resorbable bioinductive bovine collagen implant: one-year results of a prospective, multicenter registry.** *Arthrosc Sports Med Rehabil.* 2021;3(5):e1473-e1479. Available at (open access): Arthroscopy, Sports Medicine and Rehabilitation	Registry	FT	210 (enrolled), 192 (at follow-up)	1 year	▪ At 6 months and 1 year, ASES, SANE, VR-12 PCS and WORC were significantly improved from pre-operative values (p<0.001) – MCIDs were met or exceeded by 90.5% of patients for ASES, 84.3% of patients for SANE and 87.2% of patients for WORC were observed – VR-12 MCS was significantly improved at 6 months (p=0.002); no significant difference to pre-operative values at 1 year ▪ An ad-hoc analysis demonstrated similar results at 1 year regardless of tear size ▪ Mean duration of post-operative recovery (days): sling time, 36.3 (n=188); return to driving, 24.0 (n=135); return to work, 48.4 (n=128); return to non-overhead sports, 105.4 (n=71), return to overhead sports, 131.7 (n=42) ▪ 18 patients required re-operation;* re-tear (n=11), infection† (n=3), shoulder stiffness/adhesive capsulitis (n=3), bursitis (n=1) or implant displacement after a fall (n=1)
Schlegel TF, et al. **Isolated bioinductive repair of partial thickness rotator cuff tears using a resorbable bovine collagen implant: Two-year radiologic and clinical outcomes from a prospective multicentre study.** *J Shoulder Elbow Surg.* 2021;30(8):1938–1948. Available at: Journal of Shoulder and Elbow Surgery	Case series	PT	33 (enrolled), 31 (at follow-up)	2 years	▪ At 2 years, 87% of tears had reduced in size by >50% from pre-operative measurements ▪ No compliant patient progressed to a full-thickness tear; one non-compliant patient progressed ~1 month after surgery ▪ Significant increase in mean tendon thickness from pre-operative values to 2 years: 1.2mm in intermediate-grade tears; 1.8mm in high-grade tears (p≤0.012) ▪ Improvements in CMS met or exceeded MCIDs for all patients with intermediate-grade tears and 94% of patients with high-grade tears ▪ No significant difference in clinical outcomes, tear healing or tendon thickness based on tear location
Dai A, et al. **Collagen-based bioinductive implant for treatment of partial thickness rotator cuff tears.** *Bull Hosp Jt Dis.* 2020;78(3):195–201. Available at (open access): Bulletin of the Hospital for Joint Diseases	Case series	PT	30 (eligible), 24 (at follow-up)	Mean: 19.1 months	▪ Significant increase in mean ASES score by 22.5 points (45.6 pre-operatively to 68.1 at 19.1 months post-operatively; p=0.001) ▪ Significant decrease in mean VAS pain from 8.3 pre-operatively to 3.8 at 19.1 months (p<0.001) ▪ Improvements in ASES score and VAS pain from pre-operative values were greatest in articular-sided and intrasubstance tears ▪ Mean patient satisfaction score was 7.5/10 ▪ Mean tendon thickness significantly increased by 0.8mm (5.7mm preoperatively to 6.5mm at 9.9 months post-operatively; p=0.007) ▪ No implant-related complications; one patient had a traumatic re-tear 4 months post-operatively

*Re-operations can be attributed to multiple reasons.
†Includes two recurrent infections, which were resolved with treatment.

Study	Design	Tear	n= (of patients)	Follow-up	Key findings
Thon SG, et al. **REGENETEN bio-inductive collagen scaffold for rotator cuff tears: indications, technique, clinical outcomes, and review of current literature.** *Ann Jt.* 2020;5:41. Available at (open access): Annals of Joint	Review	PT + FT	251	Mean: 14.9 months (10.8–32.0 months)	Review article including Bokor 2015, Bokor 2016, Schlegel 2018, Thon 2019, and McIntyre 2019, reporting: ▪ 92–94% patient satisfaction in partial thickness tears (2 studies) ▪ 94–100% healing rate in partial thickness tears (2 studies) ▪ 89–91% patient satisfaction in full thickness tears (2 studies) ▪ 96–100% healing rate in full thickness tears (2 studies) ▪ 3.9% reoperation rate (10/251; 5 studies) ▪ 5.9% (15/251) failure rate (lack of patient satisfaction, lack of tendon healing, or need for reoperation) based on 5 studies ▪ 9.9% (25/251) complication rate (5 studies)
Micheloni GM, et al. **Bio-inductive implant for rotator cuff repair: our experience and technical notes.** *Acta Biomed.* 2020;91:14-S. Available at (open access): Acta Biomedica	Case series	PT + FT	4	6 weeks	▪ In 4 patients (1 PT tear receiving isolated bioinductive repair, 3 FT tears receiving a REGENETEN Implant to augment surgical repair), no complications were found at 6 weeks follow-up ▪ Increase in procedure duration by 10 minutes

Study	Design	Tear	n= (of patients)	Follow-up	Key findings
McIntyre LF, et al. **Patient-reported outcomes after use of a bioabsorbable collagen implant to treat partial and full-thickness rotator cuff tears.** *Arthroscopy.* 2019;35(8):2262–2271. Available at: Arthroscopy	Registry	PT + FT	203 (eligible), 173 (at follow-up)	1 year	For patients with partial-thickness tears (n=90): ▪ MCIDs were achieved in VAS pain from 2 weeks (5.3 at baseline to 3.3 at 2 weeks and 1.1 at 1 year; p<0.001) and ASES score from 6 weeks (47.0 at baseline to 60.6 at 6 weeks and 85.6 at 1 year; p<0.001) ▪ Mean VAS pain and ASES score at 3 months were significantly improved compared to published results from patients undergoing transtendon or takedown repair without a REGENETEN Bioinductive Implant (p<0.05) ▪ Significant improvements were observed from 6 weeks in SANE score (42.5 at baseline to 59.4 at 6 weeks and 86.6 at 1 year; p<0.001), VR-12 PCS (35.8 at baseline to 39.1 at 6 weeks and 49.7 at 1 year; p<0.002) and WORC Index (38.2 at baseline to 53.5 at 6 weeks and 84.4 at 1 year; p<0.001) ▪ Time in sling and time to return to driving and sport were found to be shorter than published results for standard surgical techniques For patients with full-thickness tears (n=83): ▪ MCIDs were achieved in VAS pain from 2 weeks (5.2 at baseline to 3.7 at 2 weeks and 1.2 at 1 year; p<0.001) and ASES score from 3 months (45.5 at baseline to 68.4 at 3 months and 83.8 at 1 year; p<0.001) ▪ Significant improvements from 6 weeks in WORC index (35.0 at baseline to 41.1 at 6 weeks and 80.1 at 1 year; p<0.001), and from 3 months in SANE score (39.2 at baseline to 63.3 at 3 months and 80.7 at 1 year; p<0.001) and VR-12 PCS (34.5 at baseline to 40.8 at 3 months and 45.7 at 1 year; p<0.001) ▪ Shorter time to return to driving and sport compared to published results for standard surgical techniques
Thon SG, et al. **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. Available at: American Journal of Sports Medicine	Case series	FT	23	2 years	▪ No implant-related adverse events ▪ Tendon healing in 22/23 patients (96%) on ultrasound at 2 years ▪ Treatment success in 21/23 patients (91%) at 2 years; one healing failure and one failure due to progression of glenohumeral osteoarthritis ▪ Mean tendon thickness on ultrasound increased from 6.29mm at 3 months to 7.72mm at 1 year, decreasing to 7.28mm at 2 years

Study	Design	Tear	n= (of patients)	Follow-up	Key findings
Bokor DJ, et al. **Healing of partial-thickness rotator cuff tears following arthroscopic augmentation with a highly-porous collagen implant: a 5-year clinical and MRI follow-up.** *Muscles Ligaments Tendons J.* 2019;9(3):338–347. Available at (open access): Muscles, Ligaments and Tendons Journal	Case series	PT	11	5 years	▪ 8/11 patients (73%) had no decline in tendon integrity between 2 and 5 years ▪ Mean tendon thickness significantly decreased between 2 and 5 years (5.9 vs 5.2mm; p=0.0012), but remained significantly greater than pre-operative values (4.3mm; p<0.0001) ▪ Significant improvements from baseline in ASES total score and ASES pain score were sustained to 5 years (p≤0.01) and were not significantly different to 2 year values
Schlegel TF, et al. **Radiologic and clinical evaluation of a bioabsorbable collagen implant to treat partial-thickness tears: a prospective multicenter study.** *J Shoulder Elbow Surg.* 2018;27(2):242–251. Available at: Journal of Shoulder and Elbow Surgery	Case series	PT	33	1 year	▪ Reduction in tear size of ≥1 grade from baseline in 31/33 patients (94%) at 1 year – 8/33 patients (24%) had no visible defect ▪ Significant increase in mean tendon thickness on 1 year MRI versus pre-operative values (p<0.0001) ▪ Improvements in ASES pain, ASES shoulder index and CMS were significant at 1 year compared with pre-operative values (p<0.0001) – Improvements in each score were greater than twice the respective MCIDs ▪ 30/33 patients (94%) were satisfied with the results of their procedure at 1 year
Arnoczky SP, et al. **Histologic evaluation of biopsy specimens obtained after rotator cuff repair augmented with a highly porous collagen implant.** *Arthroscopy.* 2017;33(2):278–283. Available at: Arthroscopy	Case series	FT	7	Up to 9 months	▪ At the earliest time period (5 weeks), the biopsy showed host cell ingrowth and early collagen formation ▪ At 3 months, there was increased collagen formation, maturation and organization on the surface of the implant ▪ By 6 months, the implant was no longer visible, with new tendon-like tissue and oriented collagen indicative of functional loading ▪ No evidence of foreign body or inflammatory reactions at any time point

Study	Design	Tear	n= (of patients)	Follow-up	Key findings
Bokor DJ, et al. **Evidence of healing of partial-thickness rotator cuff tears following arthroscopic augmentation with a collagen implant: a 2-year MRI follow-up.** *Muscles Ligaments Tendons J.* 2016;6(1):16–25. Available at (open access): Muscles, Ligaments and Tendons Journal	Case series	PT	13	2 years	▪ At 3 months after surgery there was a significant increase in mean tendon thickness of 2.2mm at 3 months versus pre-operative values (p<0.0001) ▪ At 2 years, new tissue was indistinguishable from underlying tissue in 12/13 patients (92%) ▪ Tendon thickness at 2 years was significantly greater (p<0.0001) than pre-operative values ▪ At 1 year, all assessable patients had a reduction in tear size of ≥1 grade, with complete tear disappearance in 7 of 10 patients with a measurable pre-operative tear size ▪ Significant improvement in clinical scores over the 2 year follow-up period from pre-operative values: CMS, Constant-Murley pain score, ASES total score and ASES pain score (p≤0.01) ▪ Outcomes were satisfactory for 12/13 patients (92%) at 2 years
Bokor DJ, et al. **Preliminary investigation of a biological augmentation of rotator cuff repairs using a collagen implant: a 2-year MRI follow-up.** *Muscles Ligaments Tendons J.* 2015;5(3):144–150. Available at (open access): Muscles, Ligaments and Tendons Journal	Case series	FT	9	2 years	▪ No MRI evidence of re-tear or gap formation, with the integrity of all repaired tendons intact at 2 years ▪ Significant increase in mean tendon thickness versus published values at 3, 6, 12 and 24 months (p<0.01), with an average of 2mm new tissue over the bursal surface ▪ New tissue rapidly matured, improved in quality and was indistinguishable from the native tendon by 1 year ▪ From 1 to 2 years, tendon thickness slightly decreased, likely reflecting continued functional remodeling ▪ Significant improvement in clinical scores at 2 years versus pre-operative measures: CMS and Constant-Murley pain score (both p<0.001); ASES score and ASES pain score (both p<0.001) ▪ Outcomes were satisfactory for 8/9 patients (89%) at 2 years

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Abbreviations
ASES = American Shoulder and Elbow Surgeons; CI = confidence interval; CMS = Constant-Murley score; FT = full-thickness; IBR = isolated bioinductive repair; MCIDs = minimal clinically important differences; NA = not applicable; PROMs = patient-reported outcome measures; PT = partial-thickness; QALY = quality-adjusted life years; RR = relative risk; SANE = single assessment numeric evaluation; SoC = standard of care; VAS = visual analogue scale; VR-12 MCS = Veterans RAND 12 Item Health Survey Mental Component Score; VR-12 PCS = Veterans RAND 12 Item Health Survey Physical Component Score; WORC = Western Ontario Rotator Cuff.

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31499 V7 10/24. Published October 2024.

Developed by Evidence Communications, Global Clinical & Medical Affairs
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