✚ Evidence in focus

Clinical Evidence Summary

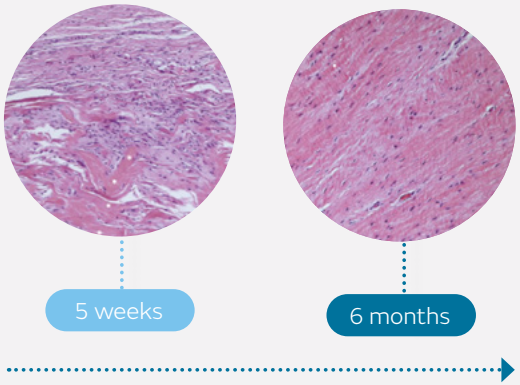
Smith+Nephew

REGENETEN◊ Bioinductive Implant

Introduction

The REGENETEN Implant has a large and growing evidence base in rotator cuff repair.[1–12] By promoting the formation of new tendon-like tissue,[1,2,6,12,13] the REGENETEN Implant changes the course of rotator cuff tear progression.[2,12,14,15]

The REGENETEN Implant is resorbed and replaced by tendon-like tissue over 6 months[1,13,†]



With a substantial body of literature evaluating its use in rotator cuff repair (>650 patients across >10 published studies),[1–12]* the REGENETEN Implant has been associated with:

- Lower re-tear rates for FT tears versus standard repair techniques[5–7,10]
- Rapid post-operative recovery[9,15,16]
- Significant and clinically meaningful post-operative improvements in clinical outcomes[3,9,17]
- Low complication rates[2,3,5–11]

Effective treatment of rotator cuff tears can be challenging. Conventional treatment of PT tears commonly involves removing healthy tissue[18] and results in lengthy rehabilitation,[19] whilst repair of large FT tears has been associated with re-tear rates >50%.[16]

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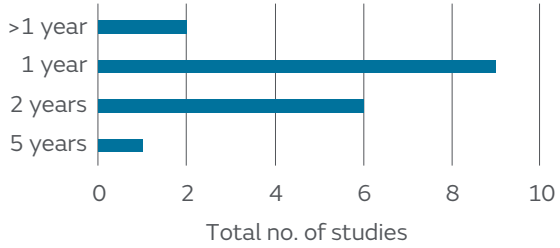
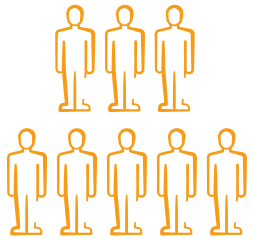
Studies

- 2 Randomised Controlled Trials (RCTs)
- 9 Human Case Series
- 2 Human Histological Case Studies
- 1 Systematic Literature Review (SLR)
- 1 Cost Analysis
- 3 Registries

Clinical studies length of follow-up





>650

total patients studied

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*As of September 2022.
† On human biopsy (n=1) and in-vivo sampling.

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

Study	Design	Tear	n=	Follow-up	Key findings
Ruiz Ibán MA, et al. **The Effect on healing rate of the addition of a bioinductive implant to a rotator cuff repair.** Preliminary report presented at: The European Society for Surgery of the Shoulder and Elbow (SECEC) Annual Congress; September 7–9, 2022; Dublin, Ireland. Please note: These are interim results, final results will be published by the end of 2023.	Randomised controlled trial	FT	Enrolled: 60 (n=30 REGENETEN group, n=30 control group) Interim follow-up: 57 (29/28)	1 year	Interim results from this study, show that rotator cuff repair with REGENETEN (REGENETEN group) compared to standard rotator cuff repair alone (control group) demonstrated: ▪ Significantly lower re-tear rates in the REGENETEN group vs control group at 1 year follow-up (3.5% vs 25.0%, p=0.022) ▪ No differences in post-operative complications between groups ▪ The failure rate at the musculotendinous junction was significantly lower in the REGENETEN group (3.5% vs 22.0%, p=0.044) ▪ Post-operative fatty infiltration was lower in the REGENETEN group compared to the control group (10.0% vs 25.0%)
Ferreira Barros A, et al. **Use of bio inductive bovine collagen patch augmentation for full thickness cuff tears - 12-month follow up results of an ongoing prospective randomised trial.** Preliminary report presented at: The European Society for Surgery of the Shoulder and Elbow (SECEC) Annual Congress; September 7–9, 2022; Dublin, Ireland.	Randomised controlled trial	FT	Enrolled: 56 (n=27 REGENETEN group, n=29 control group)	1 year	▪ Lower re-tear rates in the REGENETEN group vs control group at 1 year follow-up (7% vs 13%) ▪ Patients in the REGENETEN group experienced greater improvement in function and pain scores from pre-operative levels to 1 year post-operatively: – CMS increased on average by 40 points compared to the control group which increased by 30 (REGENETEN group average scores; 49 pre-operatively to 89 1 year post-operatively vs control group; 52 pre-operatively to 82 1 year post-operatively) – Greater reduction in VAS pain score was seen in the REGENETEN group vs control (6.8 vs 6.2) (REGENETEN group average scores; 7.5 pre-operatively to 0.7 1 year post-operatively vs control group; 7.2 at pre-operatively to 1.0 1 year post-operatively) ▪ Three cases of shoulder stiffness/adhesive capsulitis (two in the REGENETEN group, one in the control group) were reported

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Study	Design	Tear	n=	Follow-up	Key findings
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
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. [Epub ahead of print]. 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

Study	Design	Tear	n=	Follow-up	Key findings
Nherera, L. **Early economic analysis of the REGENETEN Bioinductive Implant in the treatment of full-thickness rotator cuff tears.** Poster presented at: ISPOR Conference, May 15–18, 2022; Washington, D.C., USA. Available at: Value in Health	Economic analysis	FT	NA	NA	▪ In the base case analysis, the REGENETEN Implant + SoC was dominant and resulted in reduced total costs and improved clinical outcomes, compared to SoC alone ▪ Sensitivity analyses showed that the REGENETEN Implant + SoC remained the dominant intervention from a societal perspective in FT tears of all sizes, and cost-effectiveness improved with tear size: – Medium: $31,451 per healed tear, $152,469 per QALY – Large: $18,555 per healed tear, $89,953 per QALY – Massive: $4,275 per healed tear, $20,725 per QALY ▪ A one-way sensitivity analysis demonstrated increased cost-effectiveness, in comparison to the base case analysis, in patients at a higher risk of re-tear due to the following risk factors: age >60 years, hypertension, alcohol consumption and obesity
Bushnell BD, et al. **Treatment of partial-thickness rotator cuff tear repairs with a resorbable bioinductive bovine collagen implant: 1-year results from a prospective multi-center registry.** *Orthop J Sports Med.* 2021;9(8): 23259671211027850. Available at (open access): Orthopaedic Journal of Sports Medicine	Registry	PT	272 (enrolled), 227 (at follow-up)	1 year	▪ All PROMs were significantly improved at 3, 6 and 1 year from pre-operative values, except VR-12 MCS, which was significant at 1 year ($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
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)

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

Study	Design	Tear	n=	Follow-up	Key findings
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)	1 year	▪ Significant increase in mean ASES score by 22.5 points (45.6 pre-operatively to 68.1 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 9.9 months post-operatively; p=0.007) ▪ No implant-related complications; one patient had a traumatic re-tear 4 months post-operatively
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)

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Study	Design	Tear	n=	Follow-up	Key findings
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
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

Study	Design	Tear	n=	Follow-up	Key findings
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
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

Study	Design	Tear	n=	Follow-up	Key findings
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
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 ($p\leq0.01$) ▪ 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, CMS = Constant-Murley score, FT = full-thickness, MCIDs = minimal clinically important differences, MRI = magnetic resonance imaging, NA = not applicable, PROMs = patient-reported outcome measures, PT = partial-thickness, QALY = quality-adjusted life years, 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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