

References:

Data on file, Scaffdex Ltd

Ellä V, Gomes M, Reis R, Törmälä P, Kellomäki M. Studies of P(L/D)LA 96/4 non-woven scaffolds and fibres; properties, wettability and cell spreading before and after intrusive treatment methods. *J Mater Sci: Mater Med* (2007) 18:1253–1261

Ellä V, Annala T, Länsman S, Nurminen M, Kellomäki M. Knitted polylactide 96/4 L/D structures and scaffolds for tissue engineering: Shelf life, in vitro and in vivo studies. *Biomater 1:1, 1-12; July/August/September 2011; © 2011 Landes Bioscience*

Honkanen PB, Kellomäki M, Lehtimäki MY et al. Bioreconstructive joint scaffold implant arthroplasty in metacarpophalangeal joints: short-term results of a new treatment concept in rheumatoid arthritis patients. *Tissue Eng.* 2003, 9: 957–65

Honkanen PB, Kellomäki M, Konttinen Y, Mäkelä S, Lehto M. A Midterm Follow-Up Study of Bioreconstructive Polylactide Scaffold Implants in Metacarpophalangeal Joint Arthroplasty in Rheumatoid Arthritis Patients. *The Journal of Hand Surgery (European Volume, 2009) 34E: 2: 179–185*

Honkanen PB, Tihonen R, Skyttä ET, Ikävalko M, Lehto M, Konttinen Y: Bioreconstructive Poly-L/D-Lactide Implant Compared with Swanson Prosthesis in Metacarpophalangeal Joint Arthroplasty in Rheumatoid Patients: A Randomised Clinical Trial. *J Hand Surg Eur Vol OnlineFirst*, published on July 13, 2010 as doi:10.1177/1753193410375777.

Honkanen P. Metacarpophalangeal arthroplasty and partial wrist fusion as a surgical treatment in rheumatoid hand disease. Doctoral thesis. Acta Universitatis Tamperensis; 1698; 2012

Ikävalko M, Skyttä E, Belt E: One-Year Results of Use of Poly-L/D-Lactic Acid Joint Scaffolds And Bone Packing in Revision Metacarpophalangeal Arthroplasty. *Journal of Hand Surgery (European Volume, 2007) 32E: 4: 427–433*

Kellomäki M, Puumanen K, Waris T, Törmälä P. In vivo degradation of composite membrane of P(e-CL/LLA) 50/50 film and P(L/D)LA 96/4 mesh. In: Stallforth H, Revell P (Eds.) *Materials for medical engineering*. Euromat, Weinheim, 2000, Vol. 2: 73–9.

Lämsä T, Tamminen S, Hemmilä P, Kainulainen H, Kivijärvi P. Implantation Study: Biocompatibility of poly-(96L/4D) – lactide copolymer mesh in the rat subcutis. Sponsor Scaffdex Ltd, Tampere 2008

Länsman S, Pääkkö P, Ryhänen J, Kellomäki M, Waris E, Törmälä P, Waris T, Ashammakhi N. Poly-L/D-lactide (PLDLA) 96/4 fibrous implants: histological evaluation in the subcutis of experimental design. *J Craniofac Surg.* 2006 Nov;17(6):1121-8.

Mai S, Mai B: Ein- bis Zwei-Jahreserfahrungen mit einem neuen biodegradierbaren Implantat für kleine Gelenke. *Orthopädische Praxis* 43, 4, 2007: 159-167

Saikku-Bäckström A, Tulamo R-M, Pohjonen T, Törmälä P, Räihä JE, Rokkanen P. Material properties of absorbable self-reinforced fibrillated poly-96L/4D-lactide (SR-PLA96) rods; a study in vitro and in vivo. *Journal of Materials Science: Materials in Medicine* 1999;10:1-8.

Saikku-Bäckström A, Tulamo R-M., Räihä JE, Kellomäki M, Toivonen T, Törmälä P, Rokkanen P. Intramedullary fixation of cortical bone osteotomies with absorbable self-reinforced fibrillated poly-96L/4D-lactide (SR-PLA96) rods in rabbits. *Biomaterials* 2000;22:33-43

Tiihonen R, Skyttä E, Ikävalko M, Kaarela K, Belt E: Comparison of Bioreplaceable Interposition Arthroplasty with Metatarsal Head Resection in the Rheumatoid Foot. One-Year Results of a Prospective, Randomised Clinical Study. *Foot Ankle Int.* 2010 Jun;31(6):505-10

Tiihonen R, Skyttä E, Kaarela K, Ikävalko M, Belt E. Reconstruction of the trapeziometacarpal joint in inflammatory joint disease using interposition of autologous tendon or poly-L-D-lactic acid implants: a prospective clinical trial. *J Plast Surg Hand Surg.* 2012 Apr;46(2):113-9

Waris E, Ashammakhi N, Lehtimäki M et al. The use of biodegradable scaffold as an alternative to silicone implant arthroplasty for small joint reconstruction: an experimental study in minipigs. *Biomaterials.* 2008a, 29: 683–91.

RegJoint™
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Contact information

Tuija Annala
Managing Director
Mobile: +358 40 505 3351

Minna Leppänen
Clinical Specialist
Mobile: +358 40 504 4423

 **scaffdex**

Scaffdex Oy
Kalkunkatu 21 B
FI-33330 Tampere
FINLAND

Fax: +358 3 318 0722
Email: orders@scaffdex.com
www.scaffdex.com

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Principles of RegJoint™

- Indicated in small joint arthroplasties
- A porous bioabsorbable 96L/4D poly-L/D-lactide copolymer small joint spacer
- Implanted in situ to form a living, functional, flexible tissue



Advantages of RegJoint™

- Significantly improved functionality in operated limbs
- Significantly decreased pain in operated limbs
- No weight or function restrictions after rehabilitation period
- Excellent appearance of operated limbs
- No risk of implant breakage due to bioabsorbable material
- No need for implant removal due to bioabsorbable material
- No significant osteolysis during implant resorption
- Restoration of the structure and function maintained after implant resorption
- Possibility to use intramedullary bone grafting to fill osteolytic cavities in revision arthroplasties
- Over 10 years clinical experience

Operational technique of RegJoint™

- The size of RegJoint™ is chosen to completely cover the bone of the affected joint
- Implant is sutured with bioabsorbable stitches inside the joint space
 - causes no stress and shields the diaphysis
 - valuable especially in cases with major bone resorption
- No specific instrumentation needed
- No medullary preparation needed

Clinical experience prior to regulatory approval

- Approximately 210 hand and 50 feet patients included in clinical trial with long-time follow-up
- Over 200 patients in controlled studies
- 160 rheumatoid arthritis and 100 OA/ other joint diseases
- Excellent pain relief and functionality
- No significant adverse events

Availability of RegJoint™

- RegJoint™ is available in European Union and Turkey
- Currently used in an increasing number of hospitals and clinics, updated user information available from Scaffdex

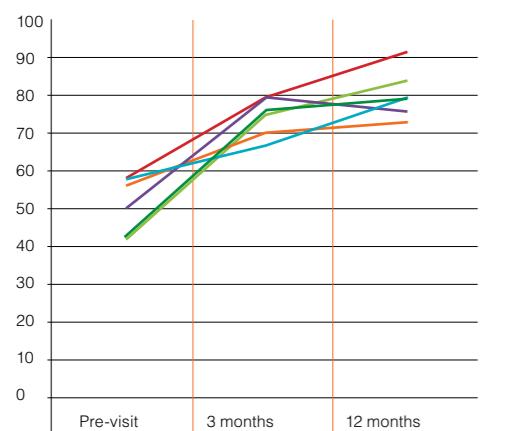
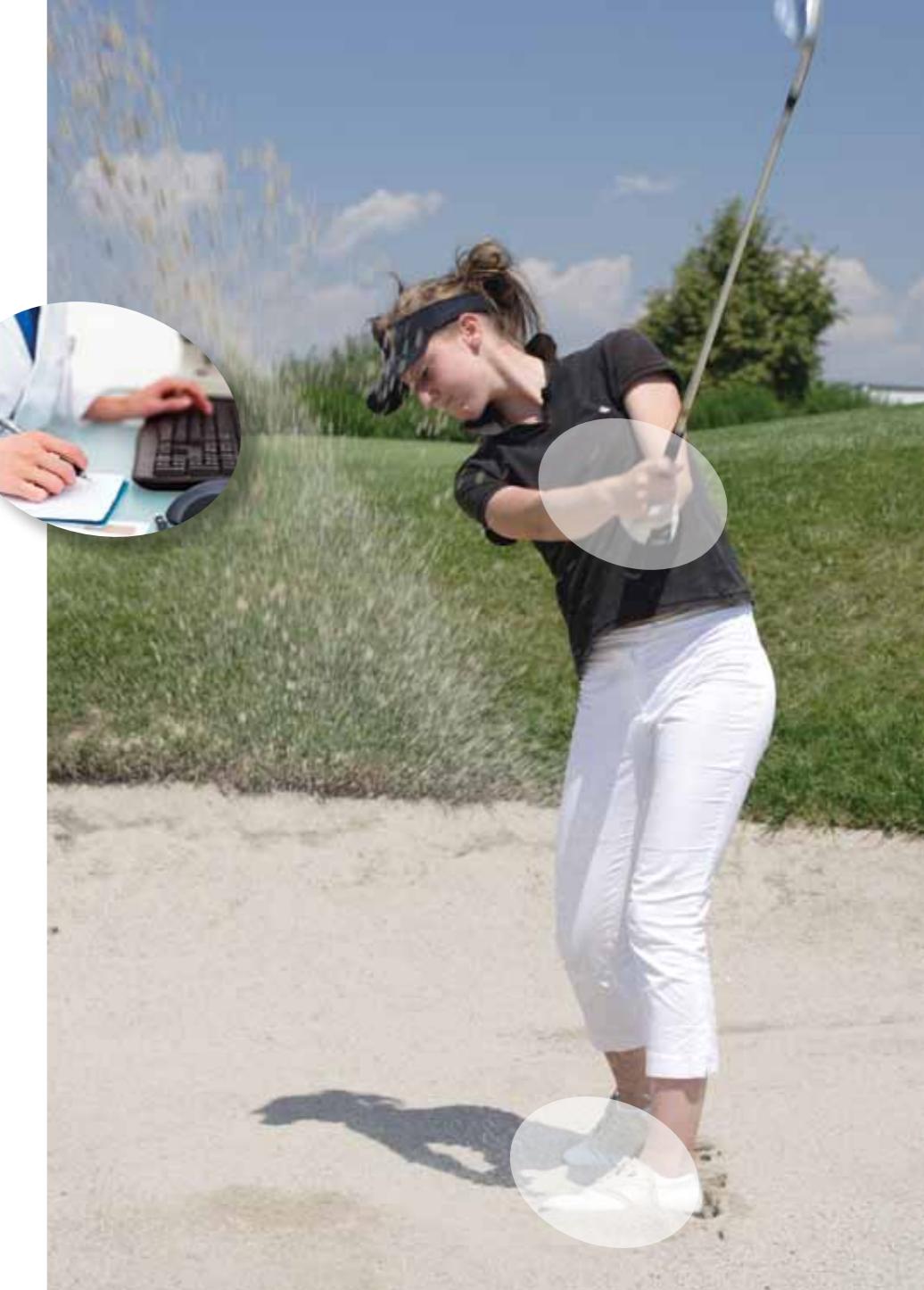


Figure 1: Change in mean AOFAS score in operated feet (N=85).

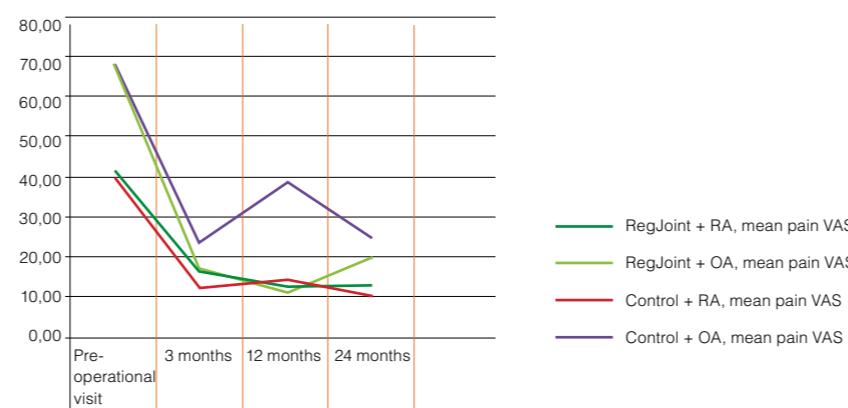


Figure 2: Change in mean pain scores by Visual Analogue Scale in operated hands (N =254).

Product selection

Product	Reference number	Height (mm)	Diameter (mm)
RegJoint™	RG0001	3.6	8
RegJoint™	RG0002	4.0	10
RegJoint™	RG0003	4.0	12
RegJoint™	RG0004	4.5	14
RegJoint™	RG0005	4.5	16
RegJoint™	RG0006	4.5	18
RegJoint™	RG0007	4.5	20