SCAFFDEX OY FIELD SAFETY NOTICE

RegJoint bioabsorbable small joint implant

Maarit Forstén 14th March 2018

FIELD SAFETY NOTICE 14TH MARCH 2018

RegJoint bioabsorbable small joint implant
Change in instructions for use
Highlighting the importance of maintaining the porous structure of the implant

Contents

1 DETAILS OF THE DEVICE

RegJoint™ (reference number RG000N) is a porous, tissue engineered, bioabsorbable implant meant for surgical treatment of arthrosis in small joints in hands and feet. Specific target joints are metatarsophalangeal I-V (MTP I-V), carpometacarpal I (CMCI), metacarpophalangeal II-V (MCP II-V), and proximal interphalangeal (PIP) joints. It is available in seven different sizes; see table 1.

Table 1. Available RegJoint™ product sizes and reference numbers.

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

2 TIGHT IMPLANTATION MAY INCREASE RISK OF STRONG FOREIGN BODY REACTIONS

Since launching 2011 considerably over seven thousand (7000) RegJoint™ implants have been sold. We can safely assume that there are over 6000 implanted RegJoints™ today. Up to date altogether 15 implant removals have been reported to Scaffdex Ltd. which gives us an official removal rate of 0,25%. All reported cases have been carefully investigated by the company and in the beginning of year 2018 Scaffdex quality management team went through all the removals and found one common factor between some of the cases. In 4 cases (27%) of the 15 removals the tight implantation technique may have had influence on the occurrence of the foreign body reaction.

2.1 Study based information

Mattila and Waris have published their results about 23 osteoarthritis patients treated with RegJoint™ implant using press-fit technique and selection of the implant sizes from the bigger end of the product sizes after partial trapeziectomy. The first publication of this study after one year *Unfavourable short-term outcomes of a poly-L/D-lactide scaffold for thumb trapeziometacarpal arthroplasty* (Mattila & Waris, 2015) and the second article

two years later *Bioabsorbable poly-L/D-lactide (96/4) scaffold arthroplasty (RegJoint™) for trapeziometacarpal osteoarthritis: a 3-year follow-up study* (Mattila, et al., 2017) state that 7 patients of 23 developed a clinically manifested foreign-body reaction in 6-12 months post-op. and 3 of these 7 cases resulted in implant removal. Calculatory removal rate 13% significantly exceeds general statistics. These 3 patients are included in Scaffdex statistics above. Those 4 patients who had a symptomatic foreign body reaction but did not have their implant removed, got eventually a functional, pain free joint. Their symptoms disappeared after the implant had totally absorbed.

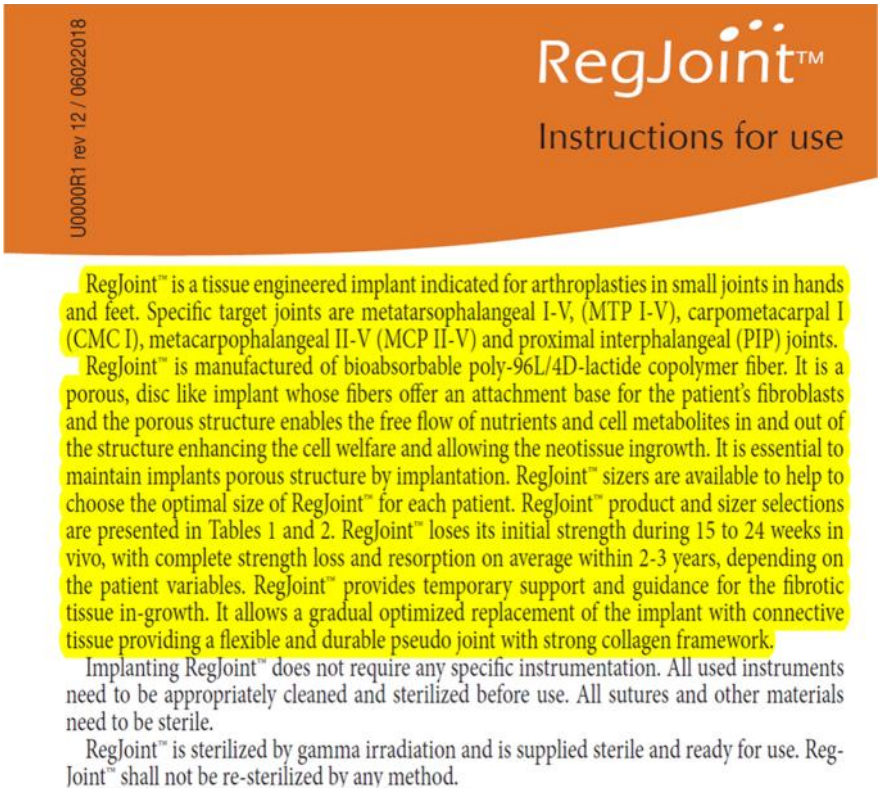
After the first publication Scaffdex carefully investigated the possible reasons for this exceptional result and interviewed both authors. January 2018 Scaffdex received the LOT information of the implants related with the seven strong foreign body reactions. After careful checking of all the steps of production Scaffdex was able to eliminate the possibility of manufacturing failure. The theory of too tight implantation relating to strong foreign body reactions was strengthened by a case in U.K. (March 2017) where a practicing surgeon was "filling" the resected CMC I joint gap with two middle size implants. Foreign body reaction started after the implant degradation began leading to pain, swelling and eventually implant removal. Therefore, based on our current knowledge of the clinical performance of this implant and earlier and ongoing clinical trials, we have a reason to believe that a tight implantation technique may have a role in the appearance of the strong foreign body reactions.

Also, the opinion of the most experienced RegJoint™ experts supports the tissue engineered fundamental principle that the scaffold must maintain the porous structure also after the implantation. This facilitates the cell welfare and leads to good quality neotissue which can handle the acidic degradation products of the implant better than the surrounding tissue only.

2.2 Changes in the instructions for use

RegJoint instructions for use has always had the mention about a porous implant. Recently underlining the importance of maintaining this porous structure during and after the implantation has become evident. RegJoint™ instructions for use (IFU) were up-dated February 2018 to highlight this fact. Accordingly, Scaffdex ended up making some clarifications to RegJoint IFU introduction and CMC I surgical instructions.

In pictures 1 and 2 the changes are highlighted with yellow colour. Picture 1 is from the introduction where the tissue engineered nature of RegJoint™ implant is mentioned for the first time in this IFU. Also, the reasons why the implant should keep its porous structure is explained. Then there is a clear note that it is essential for the correct use of this implant to maintain its porous structure.



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RegJoint™

Instructions for use

RegJoint™ is a tissue engineered implant indicated for arthroplasties in small joints in hands and feet. Specific target joints are metatarsophalangeal I-V, (MTP I-V), carpometacarpal I (CMC I), metacarpophalangeal II-V (MCP II-V) and proximal interphalangeal (PIP) joints.

RegJoint™ is manufactured of bioabsorbable poly-96L/4D-lactide copolymer fiber. It is a porous, disc like implant whose fibers offer an attachment base for the patient's fibroblasts and the porous structure enables the free flow of nutrients and cell metabolites in and out of the structure enhancing the cell welfare and allowing the neotissue ingrowth. It is essential to maintain implants porous structure by implantation. RegJoint™ sizers are available to help to choose the optimal size of RegJoint™ for each patient. RegJoint™ product and sizer selections are presented in Tables 1 and 2. RegJoint™ loses its initial strength during 15 to 24 weeks in vivo, with complete strength loss and resorption on average within 2-3 years, depending on the patient variables. RegJoint™ provides temporary support and guidance for the fibrotic tissue in-growth. It allows a gradual optimized replacement of the implant with connective tissue providing a flexible and durable pseudo joint with strong collagen framework.

Implanting RegJoint™ does not require any specific instrumentation. All used instruments need to be appropriately cleaned and sterilized before use. All sutures and other materials need to be sterile.

RegJoint™ is sterilized by gamma irradiation and is supplied sterile and ready for use. RegJoint™ shall not be re-sterilized by any method.

Picture 1. Changes in the introduction of the new RegJoint™ IFU revision 12.

Picture 2 is a part of the surgical technique instructions for CMC I operation. There is an addition to the instruction concerning the correct implant size and the use of RegJoint™ sizer instruments. The optimal implant diameter size is covering the cortical edges of the bone but does not exceed them significantly. Thickness of the resected gap should be big enough not to compromise the porous structure of the implant after the implantation. Good advice is not to pull the thumb while using the sizer instrument.

Picture 6. Radial nerve and the deep branch of the radial artery.

Picture 7. Resection lines.

nerve and the deep branch of the radial artery. Picture 6.

- The first carpometacarpal (CMC) joint is identified, the capsule released and opened dorsoradially
- The first metacarpal is released carefully proximally to correct the prevailing adduction contracture
- The resection of the proximal part of the first metacarpal is done by using an oscillating saw. The resection line of the proximal part of the first metacarpal is perpendicular with respect to the metacarpal. The resection of the cartilage surface of the trapezium is performed using a courrette or an oscillating saw. Picture 7.
- Other options are partial or complete trapezium resections without metacarpal resection. The extension of the resection is proportional to the joint laxity.
- Perform synovectomy and revise osteophytes.
- RegJoint™ sizers can be used to evaluate the correct size of the implant. While measuring the size do not pull the thumb. The ideal size completely covers the cortical edges but does not significantly exceed them (Picture 2). Make sure that the porous structure of the implant is retained after implantation.
- RegJoint™ is fixed with transosseous resorbable sutures (e.g. PDS 2-0, with UCL needle⊙). Alternatively, the scaffold can be fixed into the joint capsule or with

Picture 2. Changes in surgical technique of first carpometacarpal (CMC I) joint in IFU revision 12.

3 ACTIONS TO BE TAKEN BY THE USERS' OF REGJOINT™

Scaffdex is making this change in the RegJoint™ instructions for use to prevent unnecessary harm, foreign body reactions and possible implant removals caused by too tight implantation of RegJoint™ implant. Please pay attention to this change. We appreciate your collaboration.

4 TRANSMISSION OF THIS FIELD SAFETY NOTICE

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

Please transfer this notice to other organisations on which this action has an impact.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

5 CONTACT PERSON

Maarit Forstén

RN, MSc Eng.

Product Manager

Tel. +358 50 5432912

E-Mail: maarit.forsten@scaffdex.com

Address: Scaffdex Oy

Näsilinnankatu 48 E, 4th floor

FI-33200 Tampere

FINLAND, Europe

Scaffdex customer service: orders@scaffdex.com

The undersign confirms that this notice has been notified the appropriate Regulatory Agency

Tuija Annala, CEO

References

Mattila, S., Ainola, M. & Waris, E., 2017. Bioabsorbable poly-L/D-lactide (96/4) scaffold arthroplasty (RegJoint™) for trapeziometacarpal osteoarthritis: a 3-year follow-up study. *Journal of Hand Surgery (European Volume)*, 22 August.p. 7.
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