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

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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.*

<table>
<thead>
<tr>
<th>Reference number</th>
<th>Height (mm)</th>
<th>Diameter (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>RG0001</td>
<td>3.6</td>
<td>8</td>
</tr>
<tr>
<td>RG0002</td>
<td>4.0</td>
<td>10</td>
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<td>RG0003</td>
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<td>12</td>
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<tr>
<td>RG0004</td>
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</tr>
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<td>4.5</td>
<td>16</td>
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<tr>
<td>RG0006</td>
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<td>18</td>
</tr>
<tr>
<td>RG0007</td>
<td>4.5</td>
<td>20</td>
</tr>
</tbody>
</table>

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 RegJoint™ 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.
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.
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

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

References