

Statement: RegJoint™ removals

Clinical studies with RegJoint™ bioabsorbable spacer were performed during 1997-2006. Approximately 300 patients and 500 joints were operated with RegJoint™ in the studies.

During the study period one (1) RegJoint™ implant removal was reported to the study Sponsor. In later follow-up in the study clinics altogether eleven (11) implant removals have been reported.

After the RegJoint™ launch in November 2011 approximately 2000 implants have been used. Until today three (3) implant removals have been reported to the manufacturer Scaffdex Oy.

Reasons for implant removals have been instability of the operated joint (8), infection or suture /K-wire tract fistulae (4) and pain and osteolysis (2).

Thus the current total removal rate of RegJoint™ is 0.6%.

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