



Graftys announces regulatory clearance of Graftys® Quickset in Australia and in Canada

Aix-en-Provence, April 26th, 2016 - Graftys, a French company specialized in the development, manufacturing and commercialization of synthetic orthopedic biomaterials, announced today it has received the Therapeutic Goods Administration (TGA) regulatory approval for Australia and Health Canada Medical Device License for Canada to sell its patented calcium-phosphate cement (CPC) Graftys® Quickset in these territories. Graftys® Quickset has previously received CE and FDA clearance and is already marketed in more than 25 countries.

“We are very pleased with these new approvals, which will enable us to start marketing and sell our CPC in these countries.” indicated Jean-Marc Ferrier, Executive VP and co-founder of Graftys. “The granted indications are for usage of our CPC as a bone void filler, but we intend to obtain clearance for new innovative clinical applications in the future, some of them featuring minimally invasive surgical procedures which are feasible due to the specific rheology of this device. Graftys continues to expand its presence internationally, and is at the same time preparing new products market introduction.”

“This is the result of excellent collaboration with our distributors in these territories” commented Magali Berthebaud, Regulatory Affairs and Quality Director at Graftys. “Since 2011, we have expanded the geographic territories where our CPCs are approved. We plan to continue obtaining new regulatory clearances for Graftys® Quickset, in order to reach full geographical coverage. Other product line extensions are currently under development at Graftys, to reach specific indications for use. The recent approvals in these important territories will also allow us to strengthen our existing post-market clinical data. This program may prove very useful in our efforts to obtain regulatory approval of future generations of Graftys CPCs”.

About Graftys® QuickSet

Graftys® Quickset is a resorbable calcium phosphate apatitic cement, highly injectable and well adapted to the needs of minimally invasive procedures. The proprietary formula includes a resorbable polymer which facilitates the high injectability and high resorbability; this technology also provides fast setting time, high cohesiveness, and a significant resistance to compressive force.

About Graftys

Founded in 2005, Graftys is based in Aix-en-Provence and Nantes (France), with a US office in Chicago. The company develops, manufactures and markets synthetic bioactive orthopedic biomaterials. Graftys technologies provide innovative therapeutic products in bone tissue engineering for unmet medical needs. The company partners with leading research institutions in France and is the licensee or the co-owner of 8 patent families. Graftys has received FDA clearance for three 510(k) applications with its calcium phosphate materials, which are also CE marked. Graftys products address various indications in orthopedics, traumatology, spine and dental. Graftys markets its range of products in over 25 countries, including the United States, through distribution partnerships.

For further information: <http://www.graftys.com>

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