

**Lyon: August 1<sup>st</sup>, 2014** - The **MEDICREA Group (FR0004178572-ALMED)**, which specializes in the development of innovative surgical technologies for the treatment of spinal pathologies and is listed on Alternext - Paris, announces that the FDA has approved the **K-JAWS<sup>®</sup> Cervical Compression Staple** for all cervical fixation indications carried out with interbody cages.

## **MEDICREA'S K-JAWS<sup>®</sup> OBTAINS FDA APPROVAL FOR ITS MARKETING IN THE UNITED STATES**

MEDICREA has just obtained FDA approval to market its **K-JAWS<sup>®</sup> Cervical Compression Staple** in the United States *"Given this technology's highly innovative aspect and its unique design on the market, this approval process was the longest and most complex we have ever had to administer with the FDA, but we have now reached a decisive milestone,"* says Denys SOURNAC, Chairman and CEO of MEDICREA. *"Following an examination of the product's clinical data – almost 5,000 units have already been implanted outside the United States since the product's launch in 2006 –the FDA has approved our cervical staple in the US market for the same indications as cervical plates. This approval has given rise to the creation of a new product code in the FDA's internal classification, giving the product a unique position on the spinal column fixation device market."*

This breakthrough innovation targets an American cervical fixation market estimated at \$1.2 billion that is today occupied by relatively homogenous cervical plate and standalone cage ranges that differ little from each other.

The **K-JAWS<sup>®</sup>** implant is considerably less invasive and much quicker to insert than any cervical plate currently on the market. Its principle, which consists in fixing two adjacent vertebra by compression around a previously-inserted interbody cage, results in exceptional stability thanks to the axial localization of the compression forces, at the level of the spine's vertebral bodies.

In 2009, MEDICREA signed a licensing pre-agreement for the exclusive use of this proprietary technology with a major American partner, regarding the marketing of the **K-JAWS<sup>®</sup>** in the United States and, as an option, the rest of the world. Given the significantly longer than expected time taken to obtain FDA approval for the **KJAWS<sup>®</sup>**, MEDICREA is no longer bound by this agreement.

*"We are therefore free to openly negotiate again, which is particularly fitting given that since then other companies had indicated their interest in distributing the product subject to the Company obtaining FDA approval in the United States. Furthermore, our American distribution subsidiary has significantly expanded, and at this stage we don't rule out structuring this subsidiary to directly address the 5,000 American surgeons who could potentially use the **K-JAWS<sup>®</sup>** with our own teams, backed by a network of regional agents. Over the coming quarters, we will therefore assess the various options open to us, external or internal, to market and promote our technology."* concludes Denys SOURNAC.

**Next publication:** 2014 first-half results and third-quarter sales: October 14<sup>th</sup> 2014, after market.

### **ABOUT MEDICREA ([www.medicrea.com](http://www.medicrea.com))**

MEDICREA specializes in the design, development, manufacture, and distribution of orthopedic implants dedicated to spinal surgery. In a \$10 billion market, MEDICREA is a very dynamic small to medium-sized business of 130 employees with unique innovation capabilities. The Company enjoys an excellent and ever-improving reputation and develops unique relationships with the most visionary and creative spine surgeons in France, the UK, and the USA. Products developed and patented by MEDICREA provide neurosurgeons and orthopedic surgeons specializing in the spine with new and less-invasive surgical solutions that are faster and easier to implement than traditional techniques. The Group's headquarters are based near Lyon, France, and it also has a manufacturing facility for surgical instruments and implants located in La Rochelle as well as three distribution subsidiaries in the USA, the UK, and France.

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