



*Innovative back microsurgery*

**Press release**

**Major improvement in patients' pain, function and quality of life  
after the Implantation of SpineJack® at 1 year**

*An international clinical study on 103 patients confirms the excellent  
performance of SpineJack® in treating acute fresh traumatic vertebral  
compression fractures*

**Toulouse, May 19 2014 - VEXIM (FR0011072602 – ALVXM / PEA-PME eligible)**, a medical device company specializing in the minimally-invasive treatment of vertebral fractures, announces today that the 12-month results of an international study on 103 patients confirm the excellent performance of SpineJack®<sup>1</sup> in treating acute fresh traumatic vertebral compression fractures.

This prospective observational study was conducted consecutively in 14 clinical sites across France, Germany, Switzerland, Spain, Italy and Austria, and recruited patients with a high rate of complex fractures (59%).

The results revealed statistically significant advantages of SpineJack® in terms of patients' pain, function and quality of life over 12 months.

Vertebral pain was assessed using a Visual Analog Scale (VAS), and showed a significant average decrease of 82% at 12 months (79% at post op). By contrast, a recent study<sup>2</sup> in The Spine Journal found balloon kyphoplasty and the KIVA device decreased vertebral pain by 68% and 67%, respectively.

The decrease in pain effected by SpineJack® also allowed a major reduction in analgesic consumption. 12 months after the operation, 98.7% of patients were using mild analgesics or no medication at all.

Functional capacity was measured using the Oswestry Disability Index (ODI). Results showed a significant improvement of 86% in ODI scores at 12 months, following an improvement of 81% at 3 months. This compares to an improvement of 58% for balloon kyphoplasty and 50% for the KIVA device at 1 year, as reported by a recent publication<sup>2</sup> in The Spine Journal.

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<sup>1</sup> SpineJack® 2<sup>nd</sup> generation

<sup>2</sup> Korovessis P et al. Balloon Kyphoplasty Versus KIVA Vertebral Augmentation—Comparison of 2 Techniques for Osteoporotic Vertebral Body Fractures - A Prospective Randomized Study. SPINE Volume 38, Number 4, pp 292–299

The reported rate of adjacent fractures at 12 months was 2.9%; compared with 11% to 21% for vertebroplasty and kyphoplasty techniques<sup>3</sup>, this is very low and suggests a direct link between optimal endplate restoration by SpineJack® and a significant reduction in risk of further fractures.

In terms of overall satisfaction, 99% of surgeons involved in the study assessed SpineJack®'s technical performance and safety as very good or good. No implant-related complication was reported.

The final results at 24 months should be published during the first half of 2015.

Dr. Frank Hassel, Chief Spine Surgeon at Loretto Hospital Freiburg (Germany) and one of the study's clinical investigators, comments: *"These 12-month results consolidate the growing breadth of recognized clinical evidence demonstrating SpineJack®'s performance in the treatment of acute fresh trauma vertebral compression fractures, even severe. SpineJack® offers thus to both physicians and patients, a new, minimally invasive treatment option associated with an excellent functional recovery and improvement in patient's pain and quality of life."*

Vincent Gardès, CEO of VEXIM, concludes: *« We are naturally very pleased with the progress made by our largest international study carried out in renowned European medical centers. This highlights our ability to provide surgeons faced with highly-complex vertebral fractures with an efficient solution, with all the benefits of a minimally-invasive gesture. »*

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#### **About VEXIM, the innovative back microsurgery specialist**

Based in Balma, near Toulouse (France), VEXIM is a medical device company created in February 2006. The Company has specialized in the creation and marketing of mini-invasive solutions for treating traumatic spinal pathologies. Benefitting from the financial support of its longstanding shareholders, Truffle Capital<sup>4</sup> and Banexi Venture, and from OSEO public subsidies, VEXIM has designed and developed the SpineJack®, a unique implant capable of repairing a fractured vertebra and restoring the balance of the spinal column. The Company currently has 57 staff. It has its own sales teams in France, Germany, Italy, Spain, Switzerland and the United Kingdom, as well as distributors notably in Argentina, India, Taiwan, Belgium, South Africa, Colombia, Chile, Panama and in the following countries where the product is currently being registered: Mexico, Brazil, Venezuela, Ecuador and Peru. VEXIM has been listed on NYSE Alternext Paris since May 3, 2012. For further information, please go to [www.vexim.com](http://www.vexim.com)

#### **SpineJack®<sup>5</sup>, a revolutionary implant for treating Vertebral Compression Fractures**

The revolutionary aspect of the SpineJack® lies in its ability to restore a fractured vertebra to its original shape, restore the spinal column's optimal anatomy and thus remove pain and enable the patient to recover their functional capabilities. Thanks to a specialized range of instruments, inserting the implants into the vertebra is carried out by mini-invasive surgery, guided by X-ray, in approximately 30 minutes, enabling the patient to be discharged shortly after surgery. The SpineJack® range consists of 3 titanium implants with 3 different diameters, thus covering 95% of vertebral compression fractures and all patient morphologies. SpineJack® technology benefits from the support of international scientific experts in the field of spine surgery and worldwide patent protection until 2029.

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<sup>3</sup> - Lindsay R, Silverman SL, Cooper C et al. (2001) Risk of new vertebral fracture in the year following a fracture. JAMA 285(3):320-323.

- Fribourg D, Tang C, Sra P, Delamarter R, Bae H. Incidence of subsequent vertebral fracture after kyphoplasty. Spine. 2004;29:2270-6

<sup>4</sup> Founded in 2001 in Paris, Truffle Capital is a leading independent European private equity firm. It is dedicated to investing in and building technology leaders in the IT, life sciences and energy sectors. Truffle Capital manages €550m via FCPRs and FCPIs, the latter offering tax rebates (funds are blocked during 7 to 10 years). For further information, please visit [www.truffle.fr](http://www.truffle.fr) and [www.fcpi.fr](http://www.fcpi.fr).

<sup>5</sup> This medical device is a regulated health product that, with regard to these regulations, bears the CE mark. Please refer to the Instructions for Use.

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