

FDA CLEARS WORLD'S FIRST PATIENT-SPECIFIC SPINAL ROD

FIRST U.S. PATIENT IMPLANTED WITH CUSTOMIZED UNiD™ ROD ON NOV. 10

MEDICREA INTRODUCES UNiD™ PATIENT-SPECIFIC IMPLANTS AT NASS 2014

NEW YORK, NY and LYON, France (November 10, 2014) - The MEDICREA Group (Alternext Paris: FR0004178572 - ALMED), a company that specializes in the development of personalized implants produced for a patient's specific need in the treatment of spinal pathologies, today announced the company has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for UNiD™, the world's first patient-specific spinal osteosynthesis rod. The technology will be premiered at the 2014 North American Spine Society (NASS) Annual Meeting taking place on November 12-15 in San Francisco, CA at booth #2231. The first U.S. patient underwent surgery to have personalized UNiD™ rods implanted earlier today in New York.

UNiD™ features a user-friendly software tool to help surgeons preoperatively plan their surgery and order customized, industrially-produced rods to fit the specific spinal alignment needed for each individual patient. UNiD™ eliminates the need to manually contour a rod during surgery, providing surgeons with a precisely aligned rod prior to surgery and reducing the amount of time patients spend in the operating room, which directly impacts infection rate and quality of recovery.

"Understanding and restoring sagittal alignment is key towards providing better patient outcomes and preventing the need for reoperations, a major factor in rising health care costs. By providing rod customization, UNiD™ allows surgeons to precisely execute their preoperative plan and frees them from the antiquated technique of freehand bending, ensuring individual patients receive the most accurate and effective treatment. Having a more precise, personalized rod ready before even stepping foot in the operating room is a game-changer for spine surgery," said Frank J. Schwab, MD, a renowned orthopedic surgeon and spinal deformity expert, who performed the first customized UNiD™ rod surgery in the U.S. today.

The UNiD™ rod system, which has been successfully implanted in over 100 patients in Europe offers a real-time support team, the UNiD™ Lab, that provides a seamless process by which surgeons preoperatively analyze, design and order the patient-specific rod. The UNiD™ plug in, proprietary to MEDICREA, is embedded into the Surgimap software, and provides surgeons a quick and efficient option for ordering patient-specific rods. After the planning process is complete, the order is transferred to the UNiD™ Lab, which processes the request and industrially produces and labels the rod specifically for the patient.

"When we created Surgimap in 2008 our primary goal was to provide a research tool for surgeons to plan, measure and review their results," said Virginie Lafage, PhD, Co-Founder of NEMARIS. *"As we collected data we noticed a startling trend: 62 percent of patient remained sagittally malaligned after surgery¹. This was occurring not because of a lack of skills, but because surgeons have not had the best tools at their disposal. Our collaboration with MEDICREA is an important step forward for spine surgery. Combining our core competency, our software platform, with MEDICREA's hardware solution was necessary to bring a cutting-edge solution to surgeons and the patients they treat. It would not have been possible without such collaboration."*

The UNiD™ customized rod offers numerous benefits to surgeons and patients undergoing spine surgery.

- **The primary benefit of UNiD™ is it allows surgeons to plan and then execute their operating strategy without compromises or approximation errors.**
Until now, surgeons had no alternative but to use a bending device, known as a French bender, supplied in all instrument kits to bend the rods manually. This manual rod-contouring process involves estimating the curve in a very empirical manner using pre-operative X-rays displayed on a wall in the operating room. Significant error and variability exist with that approach. With UNiD™, surgeons can now be certain of implanting spinal fusion rods that are precisely adapted to the patient because UNiD™ rods are personalized and accurately curved using a design established by the surgeon during the pre-operative planning phase with the Surgimap / UNiD™ software.

Additional advantages of UNiD™ include:

- **Surgeons can improve their success rate in terms of global sagittal patient alignment.**
With the free UNiD™ application in the Surgimap software, spine surgeons have access to the most recent scientific data available on the parameters necessary to determine and restore sagittal alignment for each patient.
- **Surgeons can save time and be more efficient in the operating room.**
By eliminating the manual bending of rods during surgery, surgeons can significantly reduce operating time. This is an additional benefit, since infection rates and the quality of a patient's recovery are directly linked to the duration of the surgical procedure. As soon as the surgeon validates the rod's design in the UNiD™ application, MEDICREA precisely manufactures the implantable rod and delivers it within 5 working days.
- **Surgeons can reduce the risk of spinal implant failure.**
The UNiD™ rods, customized for each patient, are pre-contoured using a controllable and reproducible industrial process. This eliminates the intraoperative use of a bending device, which creates indentations, or notches, in the rod. Such notches are an acknowledged cause of rods breaking postoperatively, which can occur in patients – especially adults with severe spinal deformities

“MEDICREA's groundbreaking UNiD™ patient-specific rods include the most current clinical data and software development along with the latest in personalized production and industrialization to revolutionize how spine surgery is performed. UNiD™ rods provide surgeons a very precise surgical method, supporting better patient care and improved economic outcomes,” said Denys Sournac, Founder, CEO and Chairman of MEDICREA and added *“FDA approval of UNiD™ is a major milestone for MEDICREA. We started working closely with the FDA nearly 2 years ago on that strategic approval and this newly obtained clearance marks the culmination of years of research and surgery planning to bring a patient-specific spine implant to market, as well as the beginning of a new exciting era in spine surgery.”*

UNiD™ patient-specific rods are universal implants available in two alloys (Titanium TA6V ELI/Cobalt Chromium) and two diameters (5.5 mm/6 mm), that match global standards. UNiD™ naturally fits into the PASS LP® thoracolumbar fixation system, present in a worldwide market segment estimated at \$3.6 billion. The PASS LP® system is already used by numerous spine surgeons in 35 countries, and notably in the United States where this product accounts for the majority of MEDICREA USA Corporation's sales. MEDICREA's customized spine implant platform also includes the UNiD™ anterior lumbar interbody fusion (ALIF) spine cages created with a 3-D printer. With the support of specific software and advanced imaging, the UNiD™ ALIF customized cages made of Poly Ether Ketone (PEKK) exactly reproduce the anatomic details of a patient's vertebral endplates. The world's first spinal fusion surgery using the UNiD™ ALIF customized 3-D printed spine cages was performed on May 28, 2014 in France.

UNiD is the first patient-specific device cleared to treat degenerative spine conditions including scoliosis and other type of deformities, which represent a \$2 billion market opportunity in the U.S. alone. According to the National Scoliosis Foundation, an estimated six million people in the U.S. have scoliosis. Each year scoliosis patients make more than 600,000 visits to private physician offices, and an estimated 38,000 patients undergo spinal fusion surgery. Adult spinal deformity surgery is likely to increase in frequency with as much as 32 percent of the adult population suffering from scoliosis and a prevalence of 60 percent among the elderly. Hospital costs of adult spinal deformity surgery can exceed \$100,000 per patient. Revisions and reoperations place a large financial burden on the health care system – increasing the average cost of adult spinal deformity surgery by more than 70 percent. The market for revision surgeries is growing at a significant rate because of the number of corrections performed with approximation errors and misalignment over the past 20 years.

MEDICREA will be hosting a symposium on November 12 from 6:00pm to 8:00pm at the InterContinental San Francisco featuring guest speakers including Virginie Lafage PhD, Dr. Schwab and renowned San Francisco neurosurgeon Christopher Ames, MD. Topics to be discussed include integration of science into clinical practice, open procedures and osteotomy techniques in adult spinal deformity and the role of patient-specific implants into improving patient outcomes.

ABOUT SPINAL DEFORMITIES

The term spinal deformity includes several conditions in which the spine is abnormally curved or aligned. Under normal conditions, the adult spine is straight when viewed from the front and has a series of curves when viewed from the side. This alignment helps keep the body erect and the head up with a minimum of effort. Spinal deformities, or curves in the spine, often develop during growth in adolescence or as a result of aging. In some cases, they can progress during the adult years as well. Spine deformities can happen when unnatural curvature occurs, as in scoliosis (side-to-side curvature) or kyphosis and Scheuermann's disease (front-to-back curvature). It also occurs due to defect (as in spondylolisthesis) or damage to the spine. Read more - <http://www.spine-health.com/>.

ABOUT MEDICREA (www.medicrea.com)

MEDICREA is specialized 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 140 employees – including 40 people with MEDICREA USA based in New York City - with unique innovation capabilities. The company enjoys an excellent and ever-improving reputation and develops unique relationships with some of 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 specialized 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. MEDICREA has become a **pioneer and global leader** in the manufacturing of patient-specific implants, providing the world's first pre-contoured osteosynthesis rod (UNiD™ rod) utilized in spinal surgery in September 2013 followed by the first ever made-to-measure anterior lumbar interbody device (UNiD™ ALIF cage) created by 3-D printer in May 2014.

ABOUT NEMARIS (www.surgimapspine.com)

NEMARIS Inc (NYC, NY) is the editor of SURGIMAP software. The company was founded in 2008 and has since grown into a team of 20. The company reached profitability in the third quarter of 2014 and expects continued growth in 2015 with the global expansion of healthcare IT. SURGIMAP development was initiated by a group of surgeons, engineers, business leaders, software experts and programmers after they realized that most imaging tools were not user-friendly and not made for the spine specialist. Hence they started with measurement tools, added a DICOM image viewer, a database, and made this all portable so it runs on a USB key, off a mobile device or directly on the web. The SURGIMAP software is free and serves more than 2,000 spine surgeon users worldwide.

Contacts:

MEDICREA

Denys Sournac, Founder, Chairman and CEO
dsournac@medicrea.com
Fabrice Kilfiger, Chief Financial Officer
fkilfiger@medicrea.com
Tel: +33 (0)4 72 01 87 87

NewCap.

Financial Communication / Investor & Press Relations
Sophie Boulila / Pierre Laurent
Tel: +33 (0)1 44 71 94 91
medicrea@newcap.fr

MEDIA

Brian Baxter for MEDICREA
bbaxter@lazarpartners.com
Tel: +1 646-871-8491

MEDICREA is listed on ALTERNEXT Paris
ISIN: FR 0004178572 – Ticker: ALMED



¹ Radiographic Outcomes of Adult Spinal Deformity Correction: A Critical Analysis of Variability and Failures Across Deformity Patterns. (Spine Deform. 2014 - Moal B, Schwab F, Ames CP, et al.)

¹ McCarthy I, O'Brien M, Ames C, et al.: Incremental cost-effectiveness of adult spinal deformity surgery: observed quality-adjusted life years with surgery compared with predicted quality-adjusted life years without surgery. Neurosurg Focus 36:5Adult Spinal Deformity: Pathophysiology and Corrective Measures E3, 2014.

¹ McCarthy IM, Hostin RA, Ames CP, et al. Total hospital costs of surgical treatment for adult spinal deformity: an extended follow-up study. Spine J. 2014.