

# MEDICREA ANNOUNCES EUROPEAN LAUNCH OF UNID, THE WORLD'S FIRST PATIENT-SPECIFIC SPINAL ROD

## NEW CUSTOMIZED SPINAL ROD REPRESENTS A MAJOR INNOVATION IN SPINE SURGERY

**LYON, France (April 11, 2014)** - The <u>MEDICREA group</u> (Alternext Paris: FR0004178572-ALMED), a company that specializes in the development of innovative surgical technologies for the treatment of spinal pathologies, today announced the European launch of the **UNID**, the world's first patient-specific spinal osteosynthesis rod system.

Spinal surgeons in France have successfully implanted the customized **UNiD** rods into 43 patients with severe spinal deformities. These customized implants, which are specifically pre-contoured using x-rays and proprietary software, enable the surgeons to perfectly execute their surgical plans and accurately restore the sagittal alignment specific to each patient.

"This unique new technology provided by **MEDICREA** will make it possible to eliminate the need for surgeons to manually bend spinal rods in the operating room during the surgery," said Denys Sournac, Chairman and CEO of MEDICREA. "I fully believe this precise new way of analyzing, planning and designing patient-specific implants will significantly reduce the need for a patient with spinal deformations to undergo a subsequent operation requiring a number of vertebrae to be realigned."

The first surgical operation using **UNiD** was carried out on September 18, 2013 by Vincent **FIERE**, MD, an orthopedic surgeon at the Jean Mermoz hospital in Lyon, a leading and recognized hospital that specializes in diagnosing and surgically treating spinal deformations. Dr. **FIERE** and a number of his colleagues have since performed ten more surgeries using the **UNiD** rods.

When discussing the very first UNiD surgery, Dr. **FIERE** said, "I initially thought that the patient-specific rod was too short and overly curved. But, when I held it near the spine and then implanted it, I realized that it was simply perfect. The rod fused with the spine and allowed me to carry out the precise surgical reduction I had planned with the software that analyzes the patient's X-rays a few days beforehand. That day, I was visited by an American surgeon in the operating room, and we both felt that a major step had been made in spine surgery. **UNID** provided us with a perfect profile, strictly in line with the operation we had planned in order to restore the patient's ideal spinal balance, taking into account the anatomical specificities and pathology."

The **UNID** system includes a software application and a real-time support team that provide a seamless process by which surgeons preoperatively analyze, design, and order the patient-specific rods.

The UNID customized rod offers 4 major advantages:

#### • Surgeons can execute their operating strategy without any comprises or approximation errors.

Until now, surgeons had no alternative but to use a bending device 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. 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.

## • Surgeons can improve their success rate in terms of sagittal equilibrium.

Due to the **UNiD's** interface, with the free 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 reduce the risk of the rod breakage.

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.

#### • 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 SURGIMAP **UNID** application, MEDICREA precisely manufactures the implantable rod and delivers it within one week.

"Spine surgeons will now be able to use a simple technology enabling them to accurately perform the correction that they have planned beforehand using the latest published scientific research," Sournac said. "I am totally convinced that this new and more data-driven and industrial approach will become, in the years to come, a benchmark in spine surgery."

The **UNID** rod is a universal implant available in two alloys (Titanium TA6V ELI/Cobalt Chromium) and two diameters (5.5 mm/6 mm) which match global standards. **UNID** naturally fits into the range of implants that make up the PASSLP® thoraco-lumbar 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. FDA clearance to market **UNID** rods in the United States is expected at the end of the first half of 2014.

#### ABOUT MEDICREA (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 120 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 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 Fran.

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