

MEDICREA Announces FDA Approval Of First Patient-Specific UNiD™ Cervical Rod For Spine Surgery (Video)

NEW YORK, NY and LYON, France (April 25, 2016) – MEDICREA,[®] (Alternext Paris: FR0004178572 - ALMED) the only medical device company offering patient-specific implant solutions for the treatment of spinal conditions, has announced **FDA approval** of the **first-ever patient-specific** UNiD[™]Cervical rod for spine surgery, secured by their complementary PASS OCT[®] posterior cervical stabilization system.

Immediately following the FDA clearance, MEDICREA successfully expanded their personalized UNiD[™] technology and services to the cervical spine with the **first implantation** of the UNiD[™] Patient-Specific Cervical Rod in New York City on February 17, 2016. With this latest addition, the Company announced that UNiD[™] Lab **personalized spinal alignment services** are now available to cover the entire cervical, thoracic and lumbar regions.

Denys SOURNAC, President and CEO, added: "The patient-specific cervical rod option is a natural extension of the UNiD[™] portfolio. By providing **patient-specific realignment implant** options for the entire spine, we are again confirming MEDICREA[®]'s leadership position in personalized, made-to-measure treatments. This continued expertise brings pioneering technologies and services to the spine that are uniquely dedicated to improving clinical results for each patient."

The service model for the UNiD[™] Cervical Rod follows the same effective collaboration between MEDICREA[®]'s UNiD[™] Lab and Spinal Surgeons worldwide, which has surpassed the creation of **custom UNiD[™] Thoracolumbar Rods for more than 650 implantations to date**. The UNiD[™] Rod is custom-designed for Cervical, Thoracic and Lumbar spine operations to scientifically match the rod's shape with the patient's unique spinal alignment and the surgeon's pre-operative plan.

Following surgical intervention in the occipito-cervical spine, the shape of the rod directly impacts the fixed position of the head and neck and **dramatically changes how the patient looks and feels**. Surgeons who do not use $UNiD^{TM}$ are forced to manually approximate the rod shape – a challenge greatly increased for rods with two diameters, which are frequently used in this type of surgery with no existing tools to accommodate the transitional point.

This challenge is doubled as two rods are systematically used in combination – a feat requiring precision that is simply not possible with the naked eye. The UNiD[™] Cervical Rod technology **removes this existing surgical barrier** by creating two strictly identical single or dual-diameter rods manufactured specifically for the patient and delivered directly to the Operating Room.

To complement the landmark announcement, MEDICREA has also <u>released a video clip</u> with **Dr**. **Themistocles Protopsaltis** (New York, NY, USA), the first surgeon worldwide to utilize MEDICREA[®]'s UNiD[™] patient-specific services on the cervical spine. This gives more context on the operation and its growing impact on the medical world.

Following the surgery, **Dr. Protopsaltis** stated "I am so happy to have the UNiD[™] Cervical Rod available. This pre-contoured patient-specific implant has **eliminated the difficulty of manually bending transition rods**, saving OR time and optimizing the execution of my operative plan. My professional collaboration with MEDICREA[®]'s UNiD[™] Lab translated easily into a seamless intra-operative experience and the best possible care I can offer my patient – a personalized treatment."

UNID[™] Patient-Specific Cervical Rods are **available in two alloys** (Titanium TA6V ELI/Cobalt Chromium) and in a single-diameter (3.5mm) or dual-diameter options (3.5mm transitioning to either 5.5mm or 6.0mm). The UNID[™] Patient-Specific Cervical Rods are secured using MEDICREA[®], s most-recent extension of their versatile 'PASS' (PolyAxial Spine System) posterior fixation platform, PASS OCT[®] Posterior Cervical Stabilization System, which allows 11mm of gentle reduction capability across all anchorages and medial or lateral rod placement.

The PASS OCT[®] System has been designed specifically to complement UNiD[™] patient-specific technology, **minimizing forces applied on the spine** when securing the rod.

Next publication : Sales for the 1st half of 2016 - July 7, after market.

ABOUT MEDICREA (www.medicrea.com)

The MEDICREA Group specializes in the design, manufacture, and distribution of innovative proprietary technologies devoted exclusively to spinal surgery. Operating in a \$10 billion market, MEDICREA's headquarters are based near Lyon, France with an implant and surgical instrument manufacturing facility located in La Rochelle, France, and four distribution subsidiaries in the USA, the UK, France and Germany.

Partnering with some of the most visionary and creative spine surgeons in France, the UK, and the USA, the products developed and patented by MEDICREA® provide neurosurgeons and orthopedic spine surgeons with **new and less-invasive surgical solutions that are faster and easier to implement than traditional techniques**.

MEDICREA® has also become **a pioneer and global leader** in the manufacturing of customized implants for personalized spinal surgery incorporating software analysis of each patient, pre-operative planning of the surgical strategy, and production of customized spinal osteosynthesis rods (UNiD[™] rod) and lumbar interbody osteosynthesis cages (UNiD[™] ALIF cage) that are made to measure by a 3D printer.

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