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## Medacta Announces Completion of First Surgeries with MySpine Patient-Matched Technology in the United States

- -- 3D-printed, patient-specific surgical guides for the most complex spinal deformity cases
- -- Recently named a Best New Technology in Thoracolumbar Care by Orthopedics This Week

CHICAGO, Illinois, [month] XX, 2014 – Medacta USA, the American subsidiary of Medacta International, the privately held, family-owned global leader in the design of innovative joint replacement and spine surgery products, today announced the completion of the first successful surgeries in the United States utilizing MySpine Patient-Matched Technology. MySpine utilizes Medacta's proven 3D-reconstruction and rapid 3D-printing technologies to produce customized patient-specific surgical guides intended to support spinal surgeons during the most complex deformity cases. Designed to better help surgeons identify pedicle entry points, screw trajectories, and implant specifications, MySpine is intended to potentially increase the accuracy, efficiency, and outcomes of spinal procedures.

MySpine received 510(k) clearance by the U.S. Food & Drug Administration (FDA) in May 2014, and is the first product available in the US to produce tailor-made patient-specific guides for the spine vertebrae utilizing proprietary CT scan algorithms and sophisticated 3-D medical printing technology. Paired with Medacta's M.U.S.T. Pedicle Screw System, MySpine supports spine surgeons during the critical steps of pedicle screw placement by offering the potential for improved accuracy, as well as reduced surgical time and radiation exposure. Medacta's patient-matched technology is also the foundation of Medacta's MyKnee and MyHip\* product lines, which have pioneered advancements in two other orthopedic markets.

The first two surgeries with MySpine were completed by Samuel S Jorgenson, M.D. and Richard Manos, M.D. of the Spine Institute of Idaho. Dr. Jorgenson observed: "The MySpine customized placement guides offer a welcome new approach to dealing with the nuances and complexities of a patient's spinal anatomy". Dr. Manos added: "The customized pre-operative process provides a high level of precision and accuracy. This cuts down on the overall time of the procedure, and will help us deliver more efficient care to the multiple patients we see each day with challenging spinal cases."

The MySpine clinical experience was most recently detailed in a study published in the *Journal of Spinal Disorders and Techniques*, which tracked results from four patients with severe scoliosis whose navigational templates and placement guides were manufactured using MySpine's CT-based 3-D models. Of 76 implanted pedicle screws, 84 percent of the pedicle screws were completely intrapedicular, 96.1 percent within less than 2mm cortical breech. No screw-related clinical complaints were reported postoperatively. The study abstract is available online at: http://bit.ly/1qNVvcF

"The pedicle screw is one of the spine surgeon's most commonly used tools, but its widespread prevalence doesn't make its proper placement any less challenging. The practice remains technically demanding, with a very small margin of error," said Francesco Siccardi, Executive Vice President, Medacta International. "MySpine utilizes Medacta's innovative Patient-Matched Technology to create pedicle screw placement guides unique to the patient, giving surgeons added confidence and support that can increase procedural efficiencies, improve outcomes, and contribute to healthcare sustainability."

Earlier this month, trade publication *Orthopedics This Week* recognized MySpine as a best New Technology for Spine Care in 2014, an award that honors exemplary and innovative spine surgery products. Selected as a winner in the Thoracolumbar Care category, MySpine was chosen on the basis of its originality, clinical relevance and likelihood of improving patient outcomes by a distinguished panel of leading surgeons and venture capitalists with extensive experience brining spine technologies to market.

For more information on MySpine, please visit the Medacta website: <a href="https://www.medacta.com/en/usa/medical-professionals/products/spine/myspine-0#">https://www.medacta.com/en/usa/medical-professionals/products/spine/myspine-0#</a> or the abstract of the clinical publication which is available online at: <a href="http://bit.ly/1qNVvcF">http://bit.ly/1qNVvcF</a>

## **About MySpine Patient-Matched Technology**

MySpine is indicated as a thoracic and lumbar posterior pedicle targeting guide for patients requiring spinal fusion between the levels of T1 to L5.

MySpine Screw Placement Guides are intended to be used as anatomical perforating guides specific for a single patient anatomy to assist intraoperatively in the positioning of pedicle screws in the vertebral body. MySpine is intended for use with M.U.S.T. Pedicle Screw System and its cleared indications for use. Use of the guides involves surgical planning software used pre-operatively to plan the surgical placement of the components on the basis of patient radiological images with identifiable placement anatomical landmarks and surgical equipment components. These components include patient-specific guides fabricated on the basis of the surgical plan to precisely reference the placement of the implant components intraoperatively per the surgical plan.

MySpine Screw Placement Guides are intended for single use only.

## About Medacta USA, Inc.

A subsidiary of Medacta International, Medacta USA, Inc. is a leading manufacturer of orthopedic implants, spine surgical systems, and instrumentation. Medacta's revolutionary approach and responsible innovation have resulted in standard of care breakthroughs in hip replacement with the AMIS® system and total knee replacement with MyKnee® patient matched technology. Over the last 10 years, Medacta has grown dramatically by taking a holistic approach and placing value on all aspects of the care experience from design to training to sustainability. Medacta USA is headquartered in Chicago, Illinois. For more information about the company, please visit <a href="https://www.medacta.com">www.medacta.com</a>.