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Simplify Medical Announces CE Mark for New MRI Compatible Cervical Artificial Disc

Simplify Disc™ provides spine surgeons and their patients with an MRI friendly cervical artificial disc meeting a significant unmet clinical need

Mountain View, California, January 30, 2015 / PRNewswire / -- Simplify Medical, Inc. is pioneering disc arthroplasty with a non-metal, MRI friendly cervical artificial disc. The Company announced today that it received a CE mark for its Simplify Disc™. CE Mark allows for marketing and commercialization in the European Union and additional countries that accept the CE Mark. ISO13485 certification was obtained in 2008. Simplify Disc is a cervical disc replacement composed of MRI friendly materials designed to eliminate invasive CT scans, reduce radiation exposure, and provide a metal-free option to patients. Simplify Disc has endplates designed to be more compliant with the vertebral bodies under loading common to the cervical spine and includes disc heights as small as 4mm for smaller patient anatomy.

“The CE Mark represents a significant achievement for Simplify Medical, enabling us to commercialize our Simplify Disc internationally and expand upon our successful clinical experience that served as the basis for approval,” said Simplify Medical CEO, David Hovda. “Because we have MRI friendly, durable materials using advanced medical polymers and ceramic, we can provide a metal-free solution to surgeons and patients. MRI imaging is the most accurate option for evaluating soft tissue in the spine, non-invasive for patients, and avoids ionizing radiation and contrast injections associated with CT/Myelograms.”

Simplify Disc enables range of motion similar to intact natural discs, while providing lower disc heights to treat patients with smaller anatomy, and a streamlined implantation procedure. Simplify Medical expects to begin a U.S. IDE clinical study in 2015, leveraging its considerable motion preservation experience and clinical data.

Simplify Cervical Disc

The Simplify Disc is an MRI compatible artificial disc composed of MRI friendly materials utilizing advanced polymers and ceramic, eliminating the need for radiation-intensive CT/Myelograms. The PEEK-on-ceramic articulation is designed for low levels of wear to optimize long-term durability, and Simplify Disc offers low height implant options for patients with smaller cervical disc spaces for whom larger implants are not optimal.

About the Artificial Disc Market

The *Journal of Orthopaedic Sports Physical Therapy* (2008;38(9):A1-A34) reports that 22-70% of the population will have neck pain at some point in their lives with chronic neck pain of greater than 6 months duration affecting 14% of individuals with neck pain.

Neck pain is second only to low back pain in annual workers' compensation costs in the U.S.

About Simplify Medical

Simplify Medical is focused on cervical spinal disc arthroplasty, using innovative MRI friendly materials designed to decrease the need for ionizing radiation and enhance patient options. Simplify Medical is located in Mountain View, California. To learn more, visit our website at www.simplifymedical.com.

Caution: the Simplify Disc is an Investigational device in the United States and is limited by law to investigational use.