Medical Designs, LLC Announces the National Marketing Launch of the FDA-Approved SAMBA™ Screw System, a Minimally Invasive Solution for the Treatment of SI-Joint Dysfunction

The Associated Press

SIOUX FALLS, S.D.--(BUSINESS WIRE)--Apr 17, 2013--Medical Designs, LLC, a pioneer in the development of minimally invasive spinal implants, announced today the national marketing launch of the FDA-approved SAMBA™ Screw System, a minimally invasive solution for the treatment of SI-Joint dysfunction. Invented by Dr. Wilson Asfora, the SAMBA™ Screw System received clearance in August 2012 from the Food and Drug Administration (FDA) for sacroiliac joint fixation.

Dr. Wilson Asfora and his surgical team at Sanford Health. The video screen shows bilateral SAMBA(TM) screw implants. (Photo: Business Wire) The SAMBA™ Screw System features: Technologically advanced hollow titanium bone screw with radial slots which promote fusion by allowing osteogenic and osteoconductive material to flow into the SI-Joint. Custom instrument set permits guided placement of multiple SAMBA™ Screws across the SI-Joint in a time optimized minimally invasive procedure resulting in immediate SI joint stabilization with expeditious and comfortable post-operative course. SI-Joint fusion is enhanced by a unique precision engineered applicator tool which enables delivery through the SAMBA™ Screw pressurized insertion of demineralized bone, bone substitutes, or osteogenic material into the SI-Joint. The inventor of the SAMBA™ Screw System, Dr. Asfora commented, “We have completed thirty SAMBA™ Screw procedures here in Sioux Falls and the results have been outstanding. Our design team has optimized the surgical protocol to have fewer steps compared to other techniques. The result is less time in the OR and faster patient recovery.” The cannulated design of the SAMBA™ Screw with sharp bone cutting threads, is based on the Medical Designs Asfora Bullet Cage, a lumbar fusion device which has been implanted in hundreds of patients. “We have achieved a remarkable 98% fusion rate with the Bullet Cage stand alone for one or two lumbar levels,” added Dr. Asfora. “We expect a similar rate of success with the SAMBA™ Screw.” According to a study by the Center for Spinal Stenosis and Neurologic Care, low back pain affects more than 90% of adults at some point and is the most common reason besides colds for primary care visits. Research conducted by the Department of Orthopedic Surgery at the University of Minnesota showed that up to 30% of patients presenting with low back pain had sacroiliac joint problems.

Medical Designs, LLC intends to distribute the SAMBA™ Screw System through a network of independent reps and distributors.

About Medical Designs, LLC
Based in Sioux Falls, South Dakota, Medical Designs, LLC works closely with

surgeons, biomedical engineers and medical professionals to develop and market new products for the medical marketplace. The company's primary focus is the development of spinal implants for the treatment of cervical, lumbar and SI-Joint disorders. For more information visit www.medicaldesigns.com.

About Dr. Wilson Asfora
Dr. Asfora is currently a Neurosurgeon at Sanford Health in Sioux Falls. He specializes in adult and pediatric neurosurgery, spine surgery, brain tumor surgery, cerebrovascular surgery, peripheral nerve surgery, radiosurgery and functional neurosurgery including Deep Brain Stimulation for Movement Disorders. Dr. Asfora is board certified in neurosurgery by the American Board of Neurological Surgery and by the Royal College of Physicians and Surgeons of Canada. He is licensed in the states of South Dakota, California and Florida and holds surgical privileges at the University of Miami Hospital.

Dr. Asfora has authored numerous publications on issues related to neurosurgery. Dr. Asfora holds twenty four patents and has developed numerous medical devices in current use at hospitals around the world. He is best known as the inventor of the Subdural Evacuating Port System (“SEPS”), a minimally invasive life saving device used to treat subdural hematomas and promote brain expansion without entering the subdural space. SEPS is currently marketed globally by Medtronic, Inc.

Source URL (retrieved on *07/29/2014 - 1:56pm*):
http://www.mdtmag.com/news/2013/04/medical-designs-llc-announces-national-marketing-launch-fda-approved-samba%E2%84%A2-screw-system-minimally-invasive-solution-treatment-si-joint-dysfunction