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**August 26, 2009**

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## **FOR IMMEDIATE RELEASE**

### **Spinal Implant Developed by Sanford Clinic Neurosurgeon Receives FDA 510(k) Market Clearance as a Lumbar Intervertebral Body Fusion Device**

SIOUX FALLS, SD - [Sanford Health](http://Sanford Health), a comprehensive health care provider in the Upper Midwest, announced today a spinal implant developed by Sanford Clinic Neurosurgeon, [Wilson Asfora, MD, Sanford Clinic Neurosurgery & Spine](#), has received United States Food and Drug Administration (FDA) 510(k) market clearance as a lumbar intervertebral body fusion device. On August 14, 2009, the FDA gave 510(k) clearance to the Asfora Bullet Cage, a product which is designed for use in posterior lumbar interbody fusion surgeries to treat degenerative disc disease. The Asfora Bullet Cage will be manufactured and sold by Medical Designs, LLC, a Sioux Falls company owned by Dr. Asfora.

“We congratulate Dr. Asfora on the FDA approval of his spinal implant,” said Dave Link, Sanford Health Executive Vice President. “At Sanford Health, our goal is to foster an environment which supports the efforts of our physicians to develop innovative solutions for the global health care market.”

Commenting on the FDA approval, Dr. Asfora said, “the 510 (k) clearance of the Asfora Bullet Cage represents the culmination of a decade of clinical research. Clinical experience to date demonstrates up to a 98 percent rate of interbody fusion of one or two levels in hundreds of cases using simply locally harvested bone without unexpected complications and without the use of pedicle screws and Bone Morphogenic Protein.”

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Dr. Asfora currently serves as a Neurosurgeon at Sanford Clinic 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 with the American Board of Neurological Surgery and the Royal College of Physicians and Surgeons of Canada. Dr. Asfora has been with Sanford Health since 2007 and has worked as a Neurosurgeon since 1989.

Dr. Asfora has authored dozens of publications on issues related to neurosurgery. In addition, he has developed numerous medical devices in use at hospitals around the world including:

- ∞ 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 now marketed globally by Medtronic, Inc.
- ∞ The Dakota Knife, a surgical instrument for the transection of the Carpal Ligament in open, limited-open, or minimally invasive Carpal Tunnel surgery.
- ∞ The Odontoid Curved Drill Guide, a surgical tool for anterior screw fixation of odontoid fractures. The device is particularly useful in Barrel Chested patients.

Through a research affiliation with Sanford Health, [Dr. Asfora](#) is currently leading a nation wide team of engineers, clinicians and regulatory experts in the development of new medical technologies for use in the fields of pain therapy, vascular surgery and pediatric diagnostics.

### **About Sanford Health**

Based in Sioux Falls, SD, Sanford Health’s comprehensive, integrated system includes nearly 440 providers in 128 clinic and satellite clinics. It also includes 23 hospitals, 12 nursing homes, 18 assisted living facilities and congregate living locations, 27 home health services and 19 pharmacies. With more than 10,000 employees, Sanford Health is the largest employer in the region. Its primary, 500-bed nonprofit tertiary care hospital in Sioux Falls, SD, serves an average of more than 50,000 inpatients annually. With more than 1.25 million outpatient visits each year, Sanford Health has served the 80,000 square mile, five-state region of South Dakota, Iowa, Minnesota, Nebraska and North Dakota for more than 110 years. Sanford Health is the largest healthcare system between Denver, CO and Mayo Clinic in Rochester, MN. Its divisions include Sanford USD Medical Center, Sanford Clinic, Sanford Health Network, Sanford Health Plan and Sanford Health Foundation. For more information, visit [www.sanfordhealth.org](http://www.sanfordhealth.org).

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