

Press Release

ST. FRANCIS MEDICAL TECHNOLOGIES, INC.® RECEIVES FDA APPROVAL FOR X STOP® TO TREAT COMMON DEGENERATIVE SPINE DISORDER

-- New Minimally Invasive Procedure Offers Patients with Lumbar Spinal Stenosis Fast Relief from Symptoms --

SAN FRANCISCO – November 22, 2005 – St. Francis Medical Technologies, Inc.® has received U.S. Food and Drug Administration (FDA) approval to market its patented X STOP® Interspinous Process Decompression (IPD®) System (“X STOP”) to alleviate the symptoms of lumbar spinal stenosis (LSS), a common spinal problem suffered mainly by the middle-aged and elderly population and often associated with debilitating pain in the back and legs. First in the category of interspinous process devices, X STOP can be surgically implanted in a minimally invasive procedure that is typically performed with local anesthesia in about an hour. Clinically proven to relieve patients’ symptoms, X STOP is well-poised to become the new standard of care for LSS patients.

“Unlike laminectomy, the X STOP procedure does not require general anesthesia, making it a more viable option for those with lumbar spinal stenosis who cannot tolerate general anesthesia as a result of their age or other health conditions,” said James F. Zucherman, M.D., co-inventor of X STOP and medical director of St. Mary’s Spine Center in San Francisco. “This new procedure fills a gap in the continuum of care that, until now, required patients to make the leap from conservative therapies, such as analgesics and injections, straight to invasive surgery”

A low-risk alternative to current treatments, the X STOP procedure is also completely reversible so it can be used as a first line surgical approach without compromising any therapeutic alternatives, including laminectomy. The X STOP is an inpatient procedure that typically takes less than one hour and allows patients to walk out of the hospital the same day due to rapid recovery and minimal risk of systemic and local complications. Additionally, as it is not fixed to any bony structures, X STOP does not result in fusion.

“Patients fear laminectomy due to its moderate to high risk, the invasiveness of the procedure and the extended recovery time, and physicians do not recommend it for the very old and sick,” said Kevin Sidow, President of St. Francis Medical Technologies. “The introduction of X STOP is demonstrative of our commitment to providing patients and healthcare professionals options other than more aggressive procedures and to helping patients quickly regain their mobility and improve their quality of life.”

Because extension (e.g., standing upright) provokes symptoms, the X STOP is designed to limit extension of the lumbar spine and keep open the canal in the lower spine that carries nerves to the legs, thereby relieving symptoms. Inserted through a small incision, the titanium alloy implant is placed posterior to neural structures to minimize the risk of neural injury. Approved in Europe and Japan in 2001, the device has been successfully implanted in more than 4,000 patients to date. St. Mary’s Medical Center, home to the two X STOP inventors Drs. James Zucherman and Kenneth Hsu, is a fully accredited acute care hospital that will serve as the primary training center for U.S. physicians who wish to use the X STOP. As a leading center for spine surgery, the St. Mary’s Spine Center was the principle investigation site where 200 patients with spinal stenosis were studied in the FDA X STOP trials.

About Lumbar Spine Stenosis

Lumbar spinal stenosis is a medical condition that is a result of the narrowing of the spinal canal. Symptoms include leg pain (“pins and needles”) that limit standing and walking, self-supporting daily activities, and work, social and recreational pursuits. Lack of activity may lead to obesity, depression and general physical deterioration.

LSS is currently treated with physical therapy, non-steroidal anti-inflammatories (NSAIDs) and/or spinal injections. Laminectomy is the most common type of surgery performed to

treat LSS. It is performed by removing parts of the bone and tissue that are acting to compress the spinal and foraminal canals.

LSS is the most common reason for back surgery in people over the age of 50 in the United States,ⁱ. In 1995 it was reported that 1.2 million physician's office visits were related to symptoms of LSSⁱⁱ, this number may be closer to 2 million today.ⁱⁱⁱ It is estimated that more than 125,000 laminectomy procedures were performed for LSS in 2003^{iv}. The financial impact in terms of health care dollars and lost work hours reaches billions of dollars each year in this country.^v Rapidly expanding numbers of people over the age of 50 represent a global health care challenge without precedent and lumbosacral pain is a significant health care issue. In 2000, the number of persons aged 60 years or older was estimated at 605 million. That number is projected to grow to almost 2 billion by 2050, when the population of older persons will be larger than the population of children (0-14 years) for the first time in human history.^{vi}

Risks and Complications of Decompressive Surgery

The standard decompressive lumbar laminectomy involves a midline incision over the involved levels of the spine, dissection down to the spinous processes and progressive removal or "unroofing" of the posterior elements of the lumbar canal (spinous processes, laminae and pedicles), as well as removal of thickened ligamenta flava.

The risks of laminectomy depend on the number of levels to be decompressed, concomitant medical problems, difficult anatomy as a result of scarring from previous operations or a markedly stenotic canal that may require extensive bone removal and dissection, as well as the overall risks imposed by general anesthesia. Potential complications of the standard decompressive laminectomy include wound infection, hematoma formation, dural tears with subsequent cerebrospinal fluid leaks and risk of meningitis, nerve root damage and the potential for creating postoperative spinal instability. Surgical blood loss is generally well tolerated, but transfusion may be required. The overall surgical mortality associated with decompressive laminectomy is approximately 1 percent.^{vii}

About St. Francis Medical Technologies

St. Francis Medical Technologies, Inc. is a privately held company based in Alameda, Calif. The company is engaged in the discovery, development, manufacturing and marketing of novel treatments for degenerative spinal disorders worldwide.

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Patent, Trademark, and Copyright Notice

The X STOP® family of spinal implants are offered by St. Francis Medical Technologies, Inc. and are protected by U.S. patents and U.S. pending patent applications, and/or their foreign equivalents, including U.S. Patent Nos.: 5,860,977; 5,876,404; 6,048,342; 6,068,630; 6,074,390; 6,090,112; 6,152,926; 6,156,038; 6,183,471; 6,190,387; 6,235,030; 6,238,397; 6,332,883; 6,419,677; 6,478,796; and 6,514,256.

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ⁱTuite GF, Stern JD, Doran SE, Papadopoulos SM, McGillicuddy JE, Oyedijo DI, et al. Outcome after laminectomy for lumbar spinal stenosis. Part I: clinical correlations. J Neurosurg 1994;81:699-706.

ⁱⁱThe Center for the Evaluative Clinical Sciences, Dartmouth Medical School. The Dartmouth Atlas of Musculoskeletal Health Care. The Trustees of Dartmouth College, 2000.

ⁱⁱⁱThe Hart LG, Deyo RA, Cherkin DC. Physician office visits for low back pain. Frequency, clinical evaluation, and treatment patterns from a U.S. national survey. Spine 1995;20:11-9.

^{iv}The Ortho FactBook™; U.S. 5th Edition; Solucient, LLC and Verispan, LLC

^vKnowledge Enterprises, Inc.

^{vi}Roberts MP. Complications of lumbar disc surgery. In: Hardy RW Jr, ed. Lumbar disc disease. 2d ed. New York: Raven, 1993:161-9.

^{vii}An Aging World 2001, U.S. Department of Commerce, UN Department of Public Information, DP/2264, March 2002.

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