Baxano's iO-Tome™ Device Receives FDA Clearance

The Associated Press

SAN JOSE, Calif.--(BUSINESS WIRE)--Oct 9, 2012--Baxano, Inc., a Silicon Valley based medical device company and manufacturer of the iO-Flex® System utilized in spinal decompression surgery, announced today that it has received FDA clearance to market its new iO-Tome™ instrument.

The iO-Tome instrument utilizes Baxano's flagship iO-Flex platform to deliver a new MicroBlade Shaver® design configured to rapidly and precisely remove the facet joint which is commonly performed in spinal fusion applications.

"One of the more technically challenging steps of a less invasive fusion procedure such as a transforaminal lumbar interbody fusion (TLIF) is performing a good facetectomy," commented Robert Isaacs, MD, a neurosurgeon from Durham, North Carolina. "This new instrument can change this step to be simple, fast, safe and repeatable in all hands and could reduce the learning curve significantly." Baxano has experienced rapid adoption of its iO-Flex Technology for use in direct lumbar decompressions with and without fusion. With the introduction of the iO-Tome device for performing facet joint removal, Baxano now offers these surgeons another advanced technology for patients that require spinal fusion. An estimated 300,000 lumbar spinal fusions are performed each year in the United States.

"This instrument creates a precise window at the treatment level that provides direct visualization of the neural structures and clear access to the disc for placement of the selected interbody implant," stated Gurvinder Deol, MD, an orthopedic spine surgeon performing initial evaluations of the technology in Raleigh, North Carolina. "It will be especially helpful in procedures where the surgeon is trying to minimize the exposure size, such as many of the emerging midline fusion techniques that require a facetectomy." "The iO-Tome represents a tremendous step forward into the fusion market for Baxano," said Tony Recupero, President and Chief Executive Officer. "The development of an efficient instrument that has the potential to save substantial OR time, provide reproducible results, and is compatible with emerging spinal fusion technologies further highlights the capabilities of our core '-inside-out-' technology platform." Baxano will be exhibiting and featuring the complete iO-Flex System including the iO-Tome instrument this month at the annual meetings of both the Congress of Neurological Surgeons (CNS) in Chicago, Illinois and the North American Spine Society (NASS) meeting in Dallas, Texas.

About Baxano, Inc. Baxano, Inc., based in San Jose, California, is a privately held company, which was founded in 2005 with the vision to create flexible tools to provide precision lumbar decompression from the "inside out." These platform technologies will form the basis for future product offerings. Baxano's mission is to

develop innovative tools that restore spine function, preserve healthy tissue, and enable a better quality of life for patients. Along with its dedication to advanced technology development, Baxano is focused on providing exceptional value to patients, customers, investors, and employees.

Caution: Federal law restricts this device to sale by or on the order of a physician. For complete information regarding Intended/Indications for Use, Precautions, Warnings, and potential adverse events, please refer to respective Instructions for Use.

For more information about Baxano, the iO-Flex System, or the company's post-market clinical studies, please visit: www.baxano.com [1] or contact media relations representative Paul Williams at 310/569-0023 or paul@medialinecommunications.com [2].

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