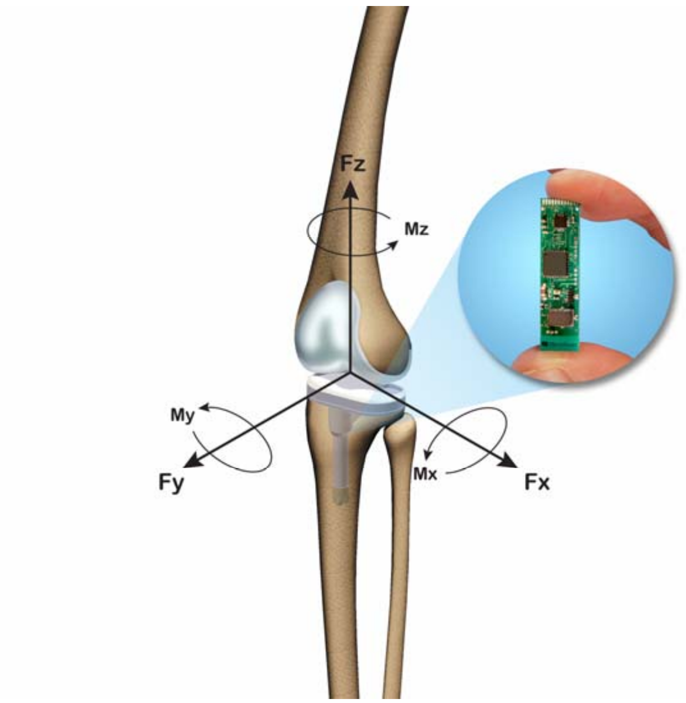
FOR IMMEDIATE RELEASE:

MicroStrain wireless sensors measure 3-D force and torque data in live human knee replacement

Williston, Vermont – November 3, 2006 - Orthopaedic implants keep getting smarter. For the first time, a patient has received an investigational, full artificial knee replacement that can wirelessly report digital, 3 dimensional torque and force data back to computers.



These advances greatly enhance capabilities compared to the first smart knee implant (implanted on March 9th, 2004). That system reports only knee compressive forces.

The second generation implant provides a wealth of new information: twisting, bending, compressive, and shearing loads across the human knee – all reported dynamically *in vivo*. These data will provide key inputs for new designs, techniques for implantation, and actual use of knee replacements. Historically, knee implants have been designed using predictions based on theoretical data. With this new technology, the smart total knee replacement that can transmit multi-axis loading information directly from patients.

In-depth analysis can now be undertaken of forces and torques transmitted across the knee joint during normal human activities such as stair climbing, rising from a chair and walking. The results of this analysis can be used to develop design improvements, refine surgical instrumentation, guide postoperative physical therapy and potentially detect the individual activities that would overload the implant.

Telemetry has been used to measure forces in hip, spine and femur but the available space in the knee replacement had previously posed severe barriers. MicroStrain develops wireless microsensors for a wide variety of applications and has focused on making very small wireless strain sensing systems. In fact, the second generation implant handles twelve (12) channels of strain data - vs. only four (4) strain channels for the first generation system.

The micro-miniature, micro-power nature of their wireless transmitter electronics and innovative multi-channel strain measurement technology has enabled this break though. Batteries are completely eliminated by using an integral miniature coil within the implant, to harvest energy from an externally applied alternating field, which powers the implant. The remote powering coil is secured to the outside of the patient's shin, away from the knee.

Using a wireless antenna, the implant transmits digital sensor data to a computer in a readable format. The twelve strain gauges are input to a computer, which uses a stored calibration matrix to convert the raw strain data into 3-D torques and forces about the knee.

"MicroStrain is excited to contribute its wireless measurement technology to the team that made this breakthrough possible", said Steven Arms, President of MicroStrain Inc. "Our expertise in multi-channel strain sensing, power management, hermetic packaging, and digital telemetry have allowed the realization of this revolutionary new smart total knee replacement".

This project is an initiative undertaken by clinicians, scientists and industry beginning in 1993. Each participant contributed established expertise (1, 2, 3). Scripps Clinic biomechanical laboratory, under the direction of Darryl D'Lima, M.D and Clifford Colwell, M.D., has been utilizing the prototype of the replacement knee to perform evaluation implants for the past ten years. The clinical staff of the Scripps Clinic worked in tandem with MicroStrain Inc. and two other implant manufacturing companies to design and pretest these implants, making them ready for implantation in patients. After exhaustive safety testing, the implant was approved by Scripps Hospital's Internal Review Board for research purposes and is not yet available commercially. This work has led to award-winning publications on *in vivo* knee compression forces - measured by the first generation smart total knee replacement (4,5). The second generation implant builds on this experience to advance the technology to the next step.

A custom titanium alloy total knee replacement was provided as the basis for the device. The tibial component accepts standard, commercially available high molecular weight polyethylene inserts. The stem portion is hollow – and this hollow space is used to house MicroStrain's wireless strain gauge electronics. A polyethylene cap is threaded onto the distal end of the stem, and protects the hermetically sealed radio antenna. The electronics, including the sensing elements, are fully contained within the implant, which is hermetically sealed using laser welding techniques. The finished, sealed implant is tested for hermeticity using fine helium leak detection methods, the same methods that are used to test advanced pacemakers.

The array of twelve sensitive piezoresistive strain gauges were embedded within the implant's custom designed tibial component (6). The strain gauged knee was pre-calibrated prior to implantation. For the first time, orthopaedic researchers now have the tools to measure 3-D forces and torques in live human knees. As the recipient of this smart implant progresses during rehabilitation, 3-D load and torque data will be collected, for the first time, by Dr. D'Lima and his staff at Scripps Clinic during activities of daily living, including walking, climbing stairs, running, etc.

This system is currently a research device only and is not commercially available.

About MicroStrain Inc. MicroStrain is a privately held corporation based in Williston Vermont. MicroStrain produces smart, wireless, microminiature displacement, orientation and strain sensors. Applications include advanced automotive controls, health monitoring, inspection of machines and civil structures, smart medical devices and navigation/control systems for unmanned vehicles. For further information please visit MicroStrain's website at www.microstrain.com or call 802-862-6629.

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