

## **Advanced Orthopaedics & Spine Medicine to Host Clinical Trial of FDA Approved Personalized Knee Implant**

**North Cypress, Texas – April 26, 2011** – Dr. David Mack of [Advanced Orthopaedics & Spine Medicine](#) and [North Cypress Medical Center](#) is participating in a ten year follow-up trial of the ConforMIS [iUni® G2](#) knee resurfacing device, an FDA cleared implant for patients with osteoarthritic damage in a single compartment of the knee. Unlike traditional total knee replacement which replaces the entire joint, the ConforMIS partial knee resurfacing device allows for the targeted and minimally invasive treatment of just the diseased area of the knee in properly indicated patients.

In addition to a more targeted treatment approach, the iUni G2 uses advanced computer modeling and the latest manufacturing technology to provide an individually designed and manufactured implant for each patient. Using CT scans of the patient's knee, each implant has a shape and size that is based on the patient's own anatomy. The personalized shape and fit allows for greater bone and tissue preservation and the potential for more natural knee motion, in addition to a faster recovery than traditional total knee replacement.

The post-market trial involves patient screening and assessment to determine eligibility, a surgical procedure to implant the device, follow-up visits at the clinic, and long-term monitoring to gather information on the function and durability of pain relief from the iUni G2 implant.

“We are excited to participate in the iUni trial, which is designed to evaluate the long-term performance of this customized approach to unicompartmental knee replacement in treating osteoarthritis,” said Dr. David Mack, Principal Investigator of the clinical trial at Advanced Orthopaedics & Spine Medicine. “This clinical trial will help demonstrate and deliver long-term impacts for our patients.”

The iUni G2 trial will enroll adult patients whose doctors have recommended a unicompartmental knee implant due to osteoarthritis. Potential participants will receive a baseline assessment to determine their eligibility for the study as well as questionnaires about symptoms and quality of life. Those determined ineligible will have the opportunity to discuss alternatives with their doctors. Those who are selected for participation will undergo surgery to implant a custom iUni G2, and then be required to return to the clinic for follow-up assessments, including questionnaires and X-rays, for a period of five years. After that, investigators will conduct follow-up interviews once a year via telephone or e-mail for 10 years after the procedure.

For more information about the trial, visit [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

For more information about ConforMIS, visit [www.conformis.com](http://www.conformis.com).

### **About ConforMIS, Inc.**

ConforMIS, Inc. is a privately-held company that develops and commercializes medical devices for osteoarthritis treatment and joint damage. Its proprietary intellectual property includes more than 250 patents and patent applications in the areas of imaging software, image processing, implant design, surgical techniques, instrumentation, and manufacturing. ConforMIS implants

and instrumentation are designed to treat osteoarthritis, the most common reason for [knee replacement surgery](#). All devices have been cleared by the US Food and Drug Administration for marketing in the US. In 2009, ConforMIS was named a winner of the Medical Design Excellence Awards, the premier recognition for contributions and advances in the design of medical products, for its iUni and iDuo resurfacing implants. Follow ConforMIS on Twitter at [@ConforMIS](#) and become a fan on Facebook at [www.facebook.com/ConforMIS](http://www.facebook.com/ConforMIS).

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