FDA Clears First Patient-Specific Implant System for Total Knee Replacement

Burlington, Mass.- February 3, 2011 - ConforMIS [1] has received 510(k) clearance from the U.S. Food and Drug Administration to commercially market its iTotal® CR Knee Replacement System. The iTotal CR is the only true patient-specific system available for patients who would traditionally receive a standard total knee replacement (TKR).
The iTotal CR builds on ConforMIS patented iFit® [2] technology for generating patient-specific implants and individualized jigs. As with all ConforMIS implants, the system uses computer modeling to build a 3D image of a patients knee from CT scans. That image then guides the proprietary design and manufacture of not just the jigs, but the personalized implants that resurface the patients articular surfaces.

The patient-specific process produces customized implants with unparalleled advantages. Each iTotal CR is made to fit an individual patient precisely without the under-sizing and overhang common with standard systems. The ability to maximize coverage for each patient is combined with one of the broadest implant contact areas in the industry, resulting in extremely low polyethylene contact stress.

In addition, the iTotal CR is engineered to do more than just greatly improve fit. Patient specific technology on the femur preserves significantly more bone than a traditional TKR. The design software generates medial and lateral articulating surface geometries for each patient that more closely mimic a patients natural geometry while correcting for deformity.

"The ability to give patients a long lasting, natural feeling knee has been the holy grail of orthopedics for decades," said Wolfgang Fitz, MD, a member of the surgeon design team. "A patient-specific total knee that reconstructs the surface geometry of the condyles has the potential to create a knee replacement that is as close to normal as it gets."

"The iTotal 510(k) clearance marks a new phase in ConforMIS leadership of the patient-specific category by expanding our product line to address the full range of opportunities in the multi-billion dollar knee market, the largest segment in orthopedics," said Philipp Lang, MD, CEO of ConforMIS. "In introducing the only true patient-specific total knee system, we are creating opportunities for innovation that will dramatically change the way patients and surgeons approach orthopedics."

The commercial release version of the iTotal CR Knee Resurfacing System was 510(k) cleared in early January 2011. The iTotal system will be available in limited release to a select group of surgeons in 2011.

For more information on ConforMIS visit www.conformis.com [1].

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, spanning knee, hip, shoulder, spine, and small joints. ConforMIS knee implants and instrumentation are designed to address all stages of osteoarthritis, the most common reason for knee replacement surgery [3]. 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 [4] and become a fan on Facebook at www.facebook.com/ConforMIS [5].

Source URL (retrieved on *10/20/2014 - 12:56am*):
http://www.mdtmag.com/news/2011/02/fda-clears-first-patient-specific-implant-system-total-knee-replacement

Links:
[1] http://www.conformis.com/
[2] http://www.conformis.com/Physicians/Image-to-Implant-Technology/iFit-Technology
[3] http://www.conformis.com/Patients/About-Knee-Replacement-Surgery/Total-Partial-Knee-Replacement
[4] http://twitter.com/ConforMIS
[5] http://www.facebook.com/ConforMIS