Interference Fixation Device

MedShape Solutions, Inc. has announced the introduction, and first human clinical use, of ExoShape™ CL, a 2-part PEEK Altera™ interference fixation device that simplifies and improves soft tissue graft fixation during anterior cruciate ligament (ACL) reconstructive surgery. MedShape intends to initiate a full market release of the product in June 2011.

ExoShape's design supports the evolution of reconstruction techniques to more accurately replicate complex native ACL functionality. This unique fixation device features a nonrotational deployment technique that preserves the surgeon's desired soft tissue graft bundle orientation and tension during single-tunnel double-bundle procedures, eliminating undesirable variables common to previous techniques.

When used with soft tissue grafts, traditional interference screws exhibit low fixation strength and can damage the graft during insertion. Many surgeons have turned to "sheath-and-screw" devices that offer improved graft fixation and graft protection. However, sheath-and-screw solutions can compromise graft bundle orientation due to sheath rotation within the tibial tunnel, the result of the significant manual torque required to drive the screw into the sheath and achieve adequate graft fixation. The need to drive screws in a direction counter to the desired direction of graft tension also can introduce undesirable laxity into the graft construct.

ExoShape addresses these issues with a series of design improvements. The ExoShape device's unique deployment gun facilitates full expansion of the PEEK Altera shape memory sheath without rotational motion, thereby accurately preserving the surgeon's desired graft bundle orientation. The deployment gun and deployment cartridge combination utilizes a closed force loop for sheath expansion, eliminating the need for forward force on the sheath. This allows the surgeon to confirm desired graft tension prior to final device deployment. Graft tension remains unchanged during ExoShape deployment.

The use of MedShape's proprietary PEEK Altera polymer enables the sheath to be precompressed to a low profile for easy insertion, and then fully expanded for effective graft-to-tunnel compression and secure graft fixation. The ExoShape deployment gun provides a convenient mechanical advantage for easy deployment of the ExoShape PEEK Altera shape memory sheath.

For more information on ExoShape, contact MedShape, 1575 Northside Drive, Suite 440,Atlanta, GA 0318l; phone (877) 343-7016; fax (877) 343-7017; http://www.medshape.com

Great Toe Arthroplasty System

Ascension Orthopedics, Inc., a leader in orthopedic extremity implants, announces the expansion of the MOVEMENT™ Great Toe Implant System to include a total arthroplasty component. This complete great toe arthroplasty system now allows surgeons the intraoperative choice to perform hemi-resurfacing for either side of the joint or total joint replacement.

Available in 4 sizes, the MOVEMENT Great Toe Implant System provides cannulated instrumentation for ease of use and utilizes a conical reaming approach for minimal bone resection and retention of plantar soft tissue attachments. This truly modular system provides surgeons a complete solution for great toe arthroplasty in one instrument set.

The MOVEMENT Great Toe Implant System reflects Ascension's dedication to expanding its foot and ankle product offering, which includes: the Total Foot System, a procedure-specific, locking plate system for forefoot, midfoot and hindfoot surgery; the CAPTURE™ Screw System, a comprehensive cannulated fixation solution for extremity surgeons; and the PyroSphere™ TMT, the first PyroCarbon implant available for the foot.

For more information, contact Ascension Orthopedics, 8700 Cameron Road, Austin TX 78754; phone (512) 836-5001; fax (512)836-6933; http://www.ascensionortho.com

Patient-Specific TKR Implant System

ConforMIS 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 traditionally would receive a standard total knee replacement (TKR).

The iTotal CR builds on ConforMIS' patented iFit® 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 patient's knee from computed tomography (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

The journal's New Products/Product News section does not evaluate or recommend products. The information published in this section is most often obtained from public news sources, including manufacturers' announcements.

with unparalleled advantages. Each iTotal CR is made to fit an individual patient precisely, without the undersizing 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 that more closely mimic a patient's natural geometry while correcting for deformity.

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

For more information on ConforMIS, contact ConforMIS, Inc., 11 North Avenue, Burlington, MA 01803; phone (781) 345-9001; fax (781) 345-0147; http://www.conformis.com

App for Image Review

The FDA has issued 510(k) clearance of MIM Software's Mobile MIM application, the first mobile image viewing application to receive clearance for diagnostic use on Apple Inc.'s iPhone and iPad devices.

The application is the first cleared by the FDA for viewing images and making medical diagnoses based on CT, magnetic resonance imaging (MRI), and nuclear medicine technology, such as positron emission tomography (PET). It is not intended to replace full workstations and is indicated for use only when there is no access to a workstation.

To learn more, contact MIM Software Inc., 25200 Chagrin Blvd., Suite 200

Cleveland, OH 44122; phone (866) 421-2536; fax (216) 455-0601; http://www.mimsoftware.com

Sacroiliac Joint Fusion System

Zyga Technology, Inc. announced the FDA has granted the company 510(K) clearance to market the SImmetry™ Sacroiliac Joint Fusion System. The SImmetry Sacroiliac Joint Fusion System is intended for treating such conditions as degenerative sacroiliitis and sacroiliac joint disruptions. The SImmetry Sacroiliac Joint Fusion System consists of a range of threaded, cannulated implants and associated instrumentation. The implants are designed to transfix the sacrum and ilium, providing stability for bony fusion.

Sacroiliac joint dysfunction has been shown to be the source of pain for up to 30% of patients suffering from low back pain. Sacroiliac joint dysfunction can cause SI joint pain, and it is typically characterized by sacroiliac ligament pain, lower back pain, buttock pain, or pain in one or both legs. Patients with this condition typically receive SI joint injections, which temporarily address the problem, but require long-term repeat treatments. Traditional, open fusion of the SI joint has been performed for decades but is limited in practice due to its complexity, high complication rate, and generally poor outcomes.

To learn more, contact Zyga Technology, Inc., 700 10th Avenue South, Suite 400, Minneapolis, MN 55415; phone (612) 455-1061; http://www.zygatech.com

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