

Core Essence Receives FDA Approval for SECURUS™, an Innovative Knotless Suture Anchor System

Yardley, PA, April 8, 2009 – Core Essence Orthopaedics, Inc., a medical device company focused on soft tissue and skeletal repair of the extremities, today announced that it has received 510(k) regulatory approval from the Food and Drug Administration (FDA) for SECURUS™, a novel knotless suture anchor system used in minimally invasive, arthroscopic surgery. SECURUS provides increased flexibility, simplicity, and ease for surgeons seeking to employ minimally invasive techniques in the surgical treatment of rotator cuff repair.

“SECURUS is a game-changing product in the area of rotator cuff repair,” said Shawn Huxel, co-founder and Chief Executive Officer of Core Essence. “In the U.S., rotator cuff repair represents a \$600 million device market opportunity, a market that continues to increase as the population ages. And yet today, only a small fraction of shoulder tendon repairs are performed using the less invasive arthroscopic surgical approach — the approach preferred by most patients — because surgeons have been dissatisfied with the tools available for these less invasive procedures.”

SECURUS is specifically designed to give surgeons the motivation to make the transition to minimally invasive surgery at the precise time when the demand for arthroscopic surgery is more significant than ever. The 510(k) regulatory approval means Core Essence will be on track to ramp up distribution over the course of 2009.



SECURUS is an innovative implantable platform system that locks down sutures in arthroscopic tendon repair surgeries, particularly high volume shoulder procedures focusing on rotator cuff repair. The product is available in 5.5mm and 7.0mm diameters to address varying degrees of bone quality, as well as rescue potential. In addition, the SECURUS system presents a number of distinct advantages to alternatives currently available on the market, including: consistent, reproducible bone and suture retention strength, tactile tensioning of sutures (allowing the

surgeon to 'feel' the tension in the soft tissue prior to locking the anchor), and a readily revisable implant system. Unlike most current knotless anchors, SECURUS can be adjusted intraoperatively and even removed and replaced.

Dr. Andrew Rokito, Chief of the Division of Shoulder and Elbow Surgery at the New York University Hospital for Joint Diseases and a member of Core Essence's Scientific Advisory Board, explained, "I was extremely intrigued when I first learned about SECURUS. Because of its unique, intuitive, tactile feel, SECURUS is ideal for surgeons who currently prefer to perform open surgeries due to a lack of effective surgical tools designed for arthroscopic use. I am convinced SECURUS will encourage surgeons to perform more rotator cuff procedures arthroscopically due to its simple and elegant features."

In addition to SECURUS, Core Essence has recently launched novel orthopedic product platforms including Seg-Way™, a synchronized endoscopic guide system for carpal tunnel syndrome; reNOVO™, a suture anchor system, and reVERTO™, a shape memory staple system indicated for arthrodesis and skeletal fixation procedures.

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About Core Essence Orthopaedics, Inc.

Core Essence Orthopaedics, Inc. (CE Ortho) is a privately held orthopaedic device company focused on the development, manufacture and commercialization of solutions for minimally invasive soft tissue and arthroscopic musculoskeletal repair for the extremity market. CE Ortho's intuitive and innovative technologies are driven by increasing demands for alternatives to complicated surgical procedures. CE Ortho devices enable surgeons to build on classic and familiar surgical techniques with novel instruments and implants that simplify procedures and can be quickly mastered. The company's proprietary technologies provide solutions to the growing volume of tendon and ligament repairs required by the active lifestyles of patients of all ages. For more company information, please visit www.ceortho.com.