

Tornier Announces U.S. FDA Clearance of Simpliciti(TM) Shoulder System

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New Class of Ultra Short-Stem Total Shoulder Arthroplasty Will Increase Access to Treatment for Patients With Compromised Shoulder Function and Severe Pain

AMSTERDAM, The Netherlands, March 10, 2015 (GLOBE NEWSWIRE) -- Tornier N.V. (Nasdaq:TRNX), a global medical device company focused on providing surgical solutions to orthopaedic extremity specialists, today announced that it has received clearance from the U.S. Food and Drug Administration (FDA) to market the Simpliciti™ Shoulder System, which is a unique, bone sparing total shoulder arthroplasty system designed to treat patients experiencing severe shoulder joint pain, compromised range of motion, loss of strength and functionality. This novel, first to market system in the United States provides surgeons with an efficient, repeatable surgical technique that is intended to preserve both the patient's native bone and avoid further trauma to the surrounding soft tissue.

Dr. R. Sean Churchill, lead investigator in the Investigational Device Exemption (IDE) study, said, "In my practice, a new category of younger, more active patients has emerged. These patients are more demanding and aren't satisfied with modifying their lifestyle as a result of shoulder pain. The humeral canal sparing design and revision optionality of the Simpliciti Shoulder System allows me to address this patient population that I have been hesitant to treat with traditional implant systems." Dr. Churchill continued, "Another benefit of the ultra short-stem design is the absence of a metal implant extending into the distal humeral canal, thereby reducing the risk of a mid-shaft humerus fracture, which can serve to compromise typical total shoulder implants."

Designed in partnership with shoulder surgeons to address the challenges associated with implantation of conventional, long stemmed prostheses, Simpliciti provides upper extremity surgeons with an innovative humeral component, which is intended to deliver the freedoms of precise anatomic placement without the constraints of fixed inclinations, medial offset or posterior offset. Simpliciti is intended to uniquely deliver anatomic results without the procedural complexity of traditional stemmed components. Designed to minimize bone removal and soft tissue disruption, the Simpliciti Shoulder System provides surgeons with an earlier intervention option for treatment of younger patients with shoulder osteoarthritis.

Dr. T. Bradley Edwards, two-time recipient of the prestigious Neer Award recognizing outstanding clinical science in the field of shoulder and elbow surgery, stated, "Simpliciti delivers anatomic results without the procedural complexity of traditional stemmed components. The specific features of the system enable physicians to minimize bone disruption thereby reducing procedure times, minimizing blood loss and exposure to anesthesia. These benefits appeal not only to the surgeon, but to the hospital administrators looking to improve patient satisfaction while managing procedure costs."

Dave Mowry, President and CEO, Tornier said, "We are very pleased with the results of the Simpliciti clinical study which supported the FDA's swift clearance of this innovative product. Studies, such as the Simpliciti IDE, serve as a testament to Tornier's ongoing commitment to responsible science and technological evolution that provides extremity surgeons and their patients with unique solutions to address the debilitating results of osteoarthritis." Mr. Mowry continued, "Similar to our market leading Aequalis Ascend Flex shoulder system, we plan to introduce the Simpliciti product through a measured process to ensure education and training paces our product deployment. We believe building long-term success in this new category will take an investment in training and education while allowing the market time to develop."

The Simpliciti clearance comes as the result of a comprehensive IDE study conducted with U.S. surgeons from 2011 through 2014, including an exhaustive two-year follow-up to ensure the efficacy of this system. Simpliciti is a natural extension of Tornier's anatomic, bone preserving philosophy that places 'true' anatomic restoration within the reach of all surgeons.

The Simpliciti Shoulder System is indicated for patients with severely painful and/or disabled shoulder joints resulting from osteoarthritis or traumatic arthritis.

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About Tornier

Tornier is a global medical device company focused on serving extremities specialists who treat orthopaedic conditions of the shoulder, elbow, wrist, hand, ankle and foot. The Company's broad offering of over 95 product lines includes joint replacement, trauma, sports medicine, and biologic products to treat the extremities, as well as joint replacement products for the hip and knee in certain international markets. Since its founding nearly 70 years ago, Tornier's "Specialists Serving Specialists" philosophy has fostered a tradition of innovation, intense focus on surgeon education, and commitment to advancement of orthopaedic technology stemming from its close collaboration with orthopaedic surgeons and thought leaders throughout the world. For more information regarding Tornier, visit www.tornier.com.

Forward-Looking Statements

Statements contained in this release that relate to future, not past, events are forward-looking statements under the Private Securities Litigation Reform Act of 1995. Forward-looking statements are based on current expectations of future events and often can be identified by words such as "believe," "expect," "plan," "intend," "should," "project," "anticipate," "will," "can," "may," "could," "continue," other words of similar meaning or the use of future dates. Examples of forward-looking statements in this release include anticipated benefits of the Simpliciti Shoulder System and Tornier's expectations regarding the anticipated effectiveness, market acceptance and commercial success of the Simpliciti Shoulder System. Forward-looking statements by their nature address matters that are, to different degrees, uncertain. Uncertainties and risks may cause Tornier's actual results to be materially different than those expressed in or implied by Tornier's forward-looking statements. For Tornier, such uncertainties and risks include, among others, the market acceptance and success of the Simpliciti Shoulder System; regulatory actions and approvals; Tornier's future operating results and financial performance; Tornier's reliance on its independent sales agencies and distributors to sell its products and the effect on its business and operating results of agency and distributor changes, transitions to direct selling models in certain geographies and the recent transition of its U.S. sales channel towards focusing separately on upper and lower extremity products; fluctuations in foreign currency exchange rates; the effect of global economic conditions; the European sovereign debt crisis and austerity measures; risks associated with Tornier's international operations and expansion; the timing of regulatory approvals and introduction of new products; physician acceptance, endorsement, and use of new products; the effect of regulatory actions, changes in and adoption of reimbursement rates and product recalls; competitor activities; Tornier's manufacturing capacity; Tornier's leverage and access to credit under its credit agreement; and changes in tax and other legislation. More detailed information on these and other factors that could affect Tornier's actual results are described in Tornier's filings with the U.S. Securities and Exchange Commission, including its most recently filed annual report on Form 10-K for the fiscal year ended December 28, 2014. Tornier undertakes no obligation to update its forward-looking statements.

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