Zimmer Holdings Announces Milestones in Minimally Invasive Joint Replacement

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WARSAW, Ind., Dec 09, 2005 /PRNewswire-FirstCall via COMTEX News Network/ -- Zimmer Holdings, Inc. (NYSE: ZMH; SWX: ZMH), a leader in the orthopaedics industry, announced today that it is now following more than 2,500 Minimally Invasive Solutions(TM) (MIS(TM)) 2-Incision(TM) Hip Replacement Procedure cases in active clinical studies. The Company estimates that in total more than 3,000 of the innovative procedures have been performed worldwide since inception in 2001.

Working with surgeon developers, Zimmer pioneered the MIS 2-Incision technique, launching an industry-wide drive in orthopaedics to make total joint replacement surgery less invasive, less painful and easier for patients to recover from. Clinically demonstrated benefits of Zimmer MIS 2-Incision hip replacement compared to traditional surgery include: a shorter hospital stay -- 1 to 2 days (rather than 3 to 5 days), with many patients able to go home in less than 24 hours; faster, less painful rehabilitation; and the possibility of a quicker return to work and daily activities.

"The MIS 2-Incision technique has delivered incredible benefits for thousands of patients and launched a movement that has literally changed the way hip replacement surgery is performed," said Ray Elliott, Zimmer Chairman, President and CEO. "When performed as we envisioned it -- on the right patients, with Zimmer Institute training and using our patented technique -- the procedure has produced these benefits with no higher complication rate than traditional, more invasive surgery, and has been shown to produce savings in total costs while typically improving three month clinical outcomes."

In 2,655 clinical study cases reported to Zimmer by surgeons since 2001, the following rates of complications were reported. These levels are well within the rates reported in scientific literature for traditional, open hip replacement using non-cemented implants.

- Total Intraoperative Femoral Fracture: 125/2655=4.7%
    - Severe Intraoperative Femoral Fracture: 12/2655=0.5%
    - Postoperative Femoral Fracture: 13/2655=0.5%
    - Dislocation: 15/2655=0.6%
    - Nerve Deficit: 48/2655=1.8%
    - Early Post-operative Revision: 26/2655=1.0%

"There has been a great deal of misinformation about complication rates with the MIS 2-Incision procedure, often provided by surgeons who we did not train at the Zimmer Institute and who did not use our patented surgical technique," said Elliott. "These complication rates show that in the hands of a wide variety of orthopaedic surgeons, the procedure can produce early post- operative benefits with no greater complication rates than traditional surgery."

Although early MIS 2-Incision procedures were done in urban teaching institutions, surgeons in community practice have since offered it to their patients. "I have performed more than 360 2-Incision cases over the past two years and use the procedure on nearly all of my patients, heavy or thin, and from people in their early 30s to one patient who was an active 99-year-old," said Dr. Jack W. Bowling, Jr., an orthopaedic surgeon with the Wilmington Orthopaedic Group, Wilmington, North Carolina. "Patients are really driving the interest in this procedure via word-of-mouth -- they are just so happy with their results and they are passing that message on to their friends and family." Dr. Bowling said he did experience a bit of a learning curve, but says complications are now virtually non-existent. He said he typically discharges patients from the hospital 36 to 48 hours after their joint replacement surgery.*

According to patient Eric Morgan, the pain he was experiencing finally reached a point that he had to move forward with something he had been dreading -- total hip replacement. "I had researched hip replacement for a couple years because I was in such pain I knew I was going to need it, but I was never willing to accept that I was going to be off my feet for six months -- I'm a general contractor and I have three kids and I just couldn't afford that," said Mr. Morgan. "Then one afternoon I was doing a walkthrough with a customer and she introduced me to a 65-year-old gentleman who said he had just had his hip replaced two weeks ago -- and he had just walked up a set of stairs and was walking fine without any kind of aid. That led to an hour conversation which led me to Dr. Bowling. Dr. Bowling and this procedure saved my life ... it gave me back my quality of life." According to Mr. Morgan, he was back to work, half days, one week after surgery and then back to "full strength" the second week. "I went to physical therapy a few days after the surgery and the therapist could not believe I had had a hip replacement -- I had to get my X-rays and show him," said Mr. Morgan. "He said I was off the charts and there wasn't anything else he could do for me."*

Dr. William F. Hefley, Jr., an orthopaedic surgeon with Martin, Bowen, Hefley Knee and Sports in Little Rock, Arkansas, says his patients have had similar experiences. "With my more than 200 2-Incision cases, I have been very impressed at how quickly patients recover -- they are up and going faster, they have less pain, they return to work more quickly and typically are walking without any kind of support within two weeks," said Dr. Hefley. "Most of my patients are out of the hospital within 24 hours of their procedure and the complication rates I've seen have been very low. But the most impressive thing is how quickly patients get back to their regular life. Several patients have returned to work in three days.

I had one patient, a pilot, who was flying again after 10 days. We're literally giving people their lives back much more quickly than with traditional hip replacement surgery."*

According to Bettye Platt, a patient of Dr. Hefley's, she had heard a "buzz" about minimally invasive joint replacement and was motivated to learn about it and drive 250 miles to Little Rock to have the procedure done. "I walked out of the hospital (the day after the procedure) with a cane and I never used a walker. I never used crutches and I took nothing stronger than extra-strength Tylenol. I didn't have to go through any painful physical therapy or anything. My friends were just astounded."*

A fan of University of Arkansas basketball, she enjoyed her return to the arena following surgery. "Our seats are almost down on the floor level and it's straight down," she said. "Three-and-a-half weeks after the surgery, I was walking down to our seats with no assistance."*

Zimmer says that the clear patient benefits of the MIS 2-Incision procedure have resulted in the development of other minimally invasive techniques that are being adopted by orthopaedic surgeons who preferred other approaches. "We have seen a tremendous response to our MIS Anterolateral Hip Replacement Technique, which involves a single incision, but maintains the muscle sparing advantages of the 2-Incision procedure," said Elliott. "Developments are just as exciting in knee replacement, with more than 1,500 surgeons now trained to perform the Zimmer MIS Quad-Sparing(TM) Total Knee Replacement Procedure and with electromagnetic computer navigation available in a low cost, portable system."

*Individual results may vary

The following outlines milestones and issues associated with the groundbreaking MIS 2-Incision surgical procedure:

Background

Zimmer has been and continues to be the pioneer in the development, rigorous clinical evaluation and teaching of minimally invasive orthopaedic surgery. Zimmer's growing portfolio of 13 minimally invasive technologies and approaches to surgery enable surgeons and hospitals to provide patients with superior orthopaedic medical care. Zimmer believes that these patient benefits will translate into benefits to the overall health care system by minimizing the immediate impact of surgery and returning patients more quickly to active, productive lives.

The first, and most advanced minimally invasive technique for total hip replacement, was pioneered by a team of surgeons in partnership with Zimmer. Years of development, extensive clinical trials and field experience have demonstrated that patients who received this new minimally invasive technique to hip

replacement have significantly faster recovery and use fewer healthcare system resources than conventional technique patients.

Zimmer began working with Dr. Dana Mears of the University of Pittsburgh on the MIS 2-Incision approach to total hip arthroplasty in 1997, initially through cadaveric studies. Preliminary development of a clinical trial designed to assess safety and performance of the MIS 2-Incision approach likewise began in collaboration with Dr. Mears in 1998. In the years that followed, Zimmer continued to devote time and resources to refining the procedure in cadaver studies and to developing MIS compatible instruments and clinical trial protocols.

Pilot Study

Based on this promising development work, Zimmer, Dr. Mears and other medical advisors concluded that the procedure's potential to deliver patient benefits was sufficient to support clinical development and the Company initiated a pilot study. Zimmer required its clinical partners to obtain from each hospital a formal Institutional Review Board (IRB) approval for the clinical protocol. Zimmer also required the patient's approval of informed consent agreements that would allow intraoperative and perioperative issues to be meticulously tracked. The pilot study included 244 cases performed by 13 U.S. surgeons and 6 international surgeons at 17 clinical centers. This prospective, multicenter study was designed to evaluate operative and postoperative variables associated with primary hip arthroplasty using the MIS 2-Incision Hip Procedure.

The IRB-approved pilot study was launched in February of 2001. Richard Berger, MD (Rush-Presbyterian-St. Luke's Medical Center) was the first of the 19 surgeons to perform the MIS 2-Incision Hip Procedure in clinical practice. The surgeons participating in the pilot study provided additional guidance on refining the technique and instrumentation, implant and patient selection.

Initial findings revealed promising, indeed surprising, patient outcomes, including rapid return to activities of daily living. Unfortunately, early patient functional outcomes were not rigorously evaluated as part of the pilot study. Although the pilot study revealed that surgeons experienced a learning curve with this new technique, no new complications or failure modes were associated with the MIS 2-Incision Hip Procedure. An elevated risk of intraoperative femoral fractures (6%) and dislocations (3%) was associated with implant selection, patient selection, surgeon training and experience and the number of MIS 2-Incision cases performed. Although somewhat elevated, these complication rates are within the normal range of clinical experience. Changes in the surgical technique, refinement of the instruments and surgeon experience resulted in a reduction of complications as the study progressed. In August of 2002, the pilot study was closed to enrollment and patients were followed at regular intervals for two years.

Zimmer Creates an Index Study for Further Improvement

Zimmer responded to these pilot study findings by standardizing the technique and instrumentation and, in October 2002, by developing and initiating a comprehensive training program for surgeons interested in performing the procedure. As an unprecedented condition of training, Zimmer initiated an "index case study," requiring surgeons to report patient demographics, operative details and complications for each of their first 10 cases performed after training. The clinical findings from this comprehensive database of early clinical experiences on 1,491 cases are an integral part of the training process, enabling new students to learn from their predecessors.

Formal Surgeon Training - The Zimmer Institute

The results of the index study showed that results improved as surgeons gained more experience with the procedure. The goal then became to maximize patient outcomes by improving the surgeon's overall proficiency, and minimizing the learning curve as much as possible.

Zimmer established The Zimmer Institute in April 2003. Training for the MIS 2-Incision procedure inaugurated the state-of-the-art surgical laboratory at Zimmer's headquarters in Warsaw, Indiana. Incorporating sound instructional design and adult learning principles, Zimmer partnered with orthopaedic surgeons to develop an exceptional training platform combining didactic, small group, interactive, and hands-on cadaver sessions. Two surgeon facilitators, provided with a complete set of teaching resources, act as lecturers, moderators and coaches during the 11-hour, two-day course. In order to diminish potential complications, these facilitators provide an essential, real-time feedback mechanism for learners throughout the training experience. The future of training at The Zimmer Institute will include advancements in training technology such as interactive online learning and virtual reality, as well as innovative educational techniques to address a myriad of learning styles and preferences. Today, the Zimmer Institute operates at Zimmer headquarters and at 22 satellite and contract facilities worldwide. In each location, the experience is based on the learning techniques and curriculum established by a surgeon advisory panel and Zimmer's own curriculum and education experts.

Beyond the Learning Curve - Results from Experienced Surgeons

Surgeons highly experienced with the MIS 2-Incision report very positive postoperative patient outcomes and low complication rates with this technique. In the November 2003 issue of JBJS, Dr. Paul Duwelius, Dr. Berger and Dr. Mark Hartzband reported an exceedingly low incidence of early perioperative complication rates in 300 cases. Berger et al (CORR December 2004) reported rapid rehabilitation and recovery in 100 consecutive MIS 2-Incision cases without increasing complications. No readmissions, reoperations, dislocations, or significant complications were reported at three

months postoperatively. A list of journal citations regarding the MIS 2-Incision procedure can be found at the end of this news release.

Ongoing Outcomes Studies

At the conclusion of the IRB-approved pilot study, it was evident that the MIS 2-Incision hip procedure was safe and reproducible, but the study was not designed to demonstrate direct patient benefits from this procedure compared to more invasive hip replacement procedures. Zimmer developed an innovative and comprehensive outcome study program to research several types of primary hip replacement surgery. A primary THA outcome study was launched in November 2002. This outcomes study was one of the first comprehensive studies to assess early postoperative patient outcomes.

The study is not randomized and has a broad inclusion criterion that allows surgeons to enroll a variety of patients. The early postoperative time period is recorded utilizing daily pain logs, weekly patient questionnaires and early post-operative assessments in the surgeon's clinic. The patients take home a diary to record their health status, pain and function and return the forms to the surgeon's office. To date, 16 surgeons have enrolled a total of 659 patients in this study. An early look at the results of this outcomes study validates the index case study findings that surgeons who routinely perform the technique experience extremely low key complication rates.

Alternatives to the MIS 2-Incision Procedure

Those surgeons who have incorporated the MIS 2-Incision technique into their practices have been extremely gratified with the surgical experience and the excellent early patient outcomes. Today many of these surgeons feel that the Zimmer MIS 2-Incision hip procedure in their hands offers their patients the highest level of care that they can provide. The Zimmer MIS 2-Incision hip procedure offers the opportunity for unparalleled early patient outcomes and a return to function and quality of life that today's patient desires. Nevertheless, the procedure is technically challenging and is not for every surgeon or patient. The MIS 2-Incision is one procedure among a host of Minimally Invasive Solutions to total hip arthroplasty that Zimmer supports. Zimmer's MIS hip procedure portfolio consists of procedures aimed to address a range of surgeon philosophies and experience levels. Zimmer has long supported Mini Posterolateral and Mini Anterolateral hip procedures and earlier this year Zimmer introduced the MIS Anterolateral hip procedure as another muscle sparing solution to total hip replacement. Zimmer will soon introduce its MIS Anterior and MIS Posterolateral hip procedures to strengthen its MIS leadership position by offering the most comprehensive MIS portfolio in total hip arthroplasty; the MIS 2-Incision hip procedure will continue to play a critical role. As the MIS landscape evolves, surgeons are expected to adopt procedure philosophies consistent with the goals of their patients and practice.

Economic Value-Added of the MIS 2-Incision Procedure

As it became apparent that the MIS 2-Incision Hip Procedure improved short-term post-operative clinical outcomes and reduced morbidity, Zimmer sought to quantify the price at which those improvements could be attained by analyzing resource utilization at all points of patient care -- from hospitals to rehabilitation providers and physicians. Early economic value studies by Zimmer suggested a 30 percent improvement in three-month patient outcomes with a 30% reduction in overall costs. As that study reaches completion, the results will be submitted for publication in a scientific journal.

Computer Navigation in MIS Hip Surgery

Zimmer has also been a leader in applying navigational technology to minimally invasive joint replacement. The use of such technology is designed to improve the accuracy of implant placement and subsequent patient outcomes. The Company earlier this year launched an electromagnetic navigation system for minimally invasive knee procedures and plans to release a similar system for hip procedures. It has also released a low cost, portable navigation unit to bring the benefits of navigation to all hospitals, including suburban, community and academic medical hospitals. The term "electromagnetic" refers to the method used to locate and track the implants and instruments relative to patient anatomy. The technology consists of an electromagnetic field transmitter that generates a local magnetic field around a specific area of anatomy. The localization system, armed with magnetic sensors, is able to identify the position of instrumentation. The system's ability to track the implant and instrument positions is not related to line of sight relative to the emitter. Electromagnetic mini reference trackers are attached to the patient's bones and the surgical instruments, producing a real-time, three- dimensional video display of the surgical procedure. The use of electromagnetic technology eliminates the insertion of pins through the patient's skin, which is required with traditional systems.

MIS 2-Incision Procedure Journal References

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About the Company

Founded in 1927 and headquartered in Warsaw, Indiana, Zimmer is the worldwide #1 pure-play orthopaedic leader in designing, developing, manufacturing and marketing reconstructive and spinal implants, trauma and related orthopaedic surgical products. Zimmer has operations in more than 24 countries around the world and sells products in more than 100 countries. Zimmer's 2004 sales were approximately $3 billion. The Company is supported by the efforts of more than 6,500 employees worldwide.

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