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NAVIO™ ASSISTED PARTIAL KNEE REPLACEMENT

Search the medical literature and you will not yet find studies published about Blue Belt Technologies' Navio™ Orthopedic Surgical System. However, talk with orthopedic surgeon Raul Marquez, MD, an instructor on the use of computer aided technology and navigation techniques, and you'll quickly learn that this innovative system offers clinical advantages. "The Navio™ is excellent," said Dr. Marquez, who is on staff at Cornerstone Regional Hospital in Edinburg, TX.

Navio™ Orthopedic Surgical System

What Makes the Navio™ System Unique?

Computed Tomography (CT) Free
- No pre-operative imaging required.
- Saves patient from radiation exposure.

Handheld with Precision and Reproducibility
- Reliability and consistency outcomes.
- Puts robotics into the surgeon's hand.
- Reduces the presence of outliers.

Open Platform
- Open implant architecture offers greater choice to robotic-assisted procedures.

Portability
- No complex calibration required.
- Easy operating room integration.
- Quick room turnover.
- Small footprint.

Surgeon Controlled
- Reduces the reliance on the manufacturing representative to drive a case forward.
- Puts the control in the surgeon's hands.

Cost Efficiency
- Economically sound.
- Low cost-of-entry.
- Rapid and achievable results.

Other orthopedic surgeons echo Dr. Marquez's sentiment. Pennsylvania-based orthopedic surgeon Brian R. Hamlin, MD, who performs about 150 primary knees and 30 to 40 partial knee surgeries per year, said, "I have been working with Blue Belt since 2011 regarding development of workflows and improving usability. Surgeons that have an interest in partial knee replacement and desire to give their patients the greatest likelihood of long term success should seriously consider a robotic-assisted system like the Navio™ System."

The Navio™ System Gives Surgeons Precise Robotic Control

FDA granted 510(k) clearance to sell and market the Navio™ System in December 2012 and the first unit was sold in the U.S. in January 2013. Six months prior to this, however, Navio™ received CE marking (formerly the EC mark) for distribution in Europe. Therefore, the first Navio™ assisted partial knee replacement was performed in Belgium in July 2012.

Across the last year, surgeons around the globe trialed the Navio™ System in various practice settings, including teaching hospitals, community hospitals, and outpatient ambulatory surgical centers. They used five different manufacturer's implant systems to perform precision partial knee replacement surgery using the Navio™ robotic-assisted system. The results revealed the accuracy and consistency of the Navio™.

The Navio™ system incorporates patented technology to provide precise robotic control to surgeons via an intelligent, handheld, computer-assisted bone cutting tool. Thereby, it provides the pluses of robotics, while also allowing surgeons to be in better control of the surgical procedure.

Surgeries Go "As Planned"

"My experience [with the Navio™] to date has been very good. In all cases the final result matched perfectly to our plan." Dr. Hamlin said. Through a CT-free approach, Navio enables kinematic and anatomic registration, sophisticated implant planning with soft-tissue balancing techniques and robotic-assisted bone preparation for precise and repeatable results.

"Ultimately we all desire as orthopedic surgeons to provide for our patients the best outcomes. We know from data using traditional techniques that long term outcomes are directly related to the accuracy of implant placement/position. Therefore, it only makes sense that a system that allows one to place the implants in a position that optimizes alignment, gap balance, and tracking should be embraced." Dr. Hamlin explained.

"The Navio™ offers exceptional accuracy—what you plan is what you get" said Dr. Marquez, who has performed close to 7,000 surgeries in his career—of those, 500 were performed using robotics. The Navio™ software permits surgeons to strategically place the implant while simultaneously balancing the soft tissue of the knee. By controlling the exposure of the bur from the guard, the Navio™ prevents clinicians from cutting outside the defined boundaries while placing the implant.

Ease of Use, Accuracy, and Affordability Set the Navio™ Apart

Robotic-assisted systems allow surgeons to better tailor treatment plans to each patient and more accurately prepare the bone to ensure positive outcomes. Orthopedic surgeons who have used the Navio™ System highlighted three tangible benefits of this new robotic-assisted system.

Ease of Use

"The Navio is less cumbersome than other robotic-assisted systems. Compared to other systems it is much smaller, which makes it easier to transfer from one place to another for surgery and for cleaning, said Dr. Marquez.

"I prefer Navio™ over the competing robotic technology due to ease of use. It is an imageless system. The patients' important anatomic landmarks are registered at the beginning of the procedure building a virtual representation of their femoral and tibial anatomy from which the surgical procedure is planned." Dr. Hamlin said.

Accuracy

"Accuracy is superb," said Dr. Hamlin. "The Navio™ System cuts the bone exactly where you plan. The ability to have a balanced gap throughout the range of motion is far superior to what one can do with a freehand technique."

"Compared to conventional techniques, robotic assistance with the Navio™ System has substantially improved the precision of bone preparation, prosthesis alignment, and soft tissue balance in partial knee replacement, all of which may improve outcomes and durability." Jess Lonner, MD, orthopedic surgeon at the Rothman Institute in Philadelphia said.

Affordability

"Compared to other systems, the Navio™ is both safer and more affordable." Patients usually recover faster." said Dr. Marquez. "There is less soft tissue dissection. Patients often have an excellent range of motion and many do not require physical therapy. In general, patients experience about half the usual recuperation time."

"The cost for the Navio™ System is significantly less than the competing robotic-assisted systems on the market. On a case-by-case basis it is less expensive for the patient and the healthcare system—as no pre-op imaging is required. This is going to become even more significant as we move towards bundled payments." Dr. Hamlin noted.

About Blue Belt Technologies

Blue Belt Technologies, Inc. is developing the next generation of "smart" surgical instruments for initial use in orthopedic procedures.

For more information about the Navio™ Orthopedic Surgical System, please call Blue Belt Technologies at 763-452-4950, or visit www.BlueBeltTech.com.