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## **Wright Medical Announces First Patient Implanted in U.S. INFINITY™ Total Ankle System Post-Market Study; Provides Update on UK Post-Market Study**

*Company expands leadership position in total ankle replacement by initiating one of the largest data collection studies globally for total ankle replacement surgery*

### **U.S. Study Recruitment Commences**

Wright Medical Group N.V., a global leader in the orthopaedic extremities market, today announced the first patient implanted in the U.S.-based INFINITY™ Total Ankle System Follow-Up Study at the Campbell Clinic in Memphis, Tennessee.

The primary objective of the multi-center, non-randomized, prospective study of 200 patients is to evaluate 10-year implant survivorship in patients with ankle joints damaged by severe rheumatoid arthritis, post-traumatic arthritis, or degenerative arthritis who received the INFINITY™ Total Ankle System for primary ankle arthroplasty.

The secondary objective is to characterize the improvements after implantation with the INFINITY™ Total Ankle System over a 10 year period using patient reported outcome measures related to quality of life, pain and functional scores, as well as x-ray assessments.

"With the growing popularity and increasing demand for alternatives to ankle fusion, there is a real need for quality, forward-looking studies that document the results of total ankle replacement surgery to further validate our clinical decision making," said Dr. G. Andrew Murphy of the Campbell Clinic and a Primary Investigator for the study. "Wright Medical is leading the way in this progress, and we expect to glean valuable data from this study of the INFINITY™ Total Ankle System."

### **UK Study Progresses**

In 2016, Wright Medical launched the post-market INFINITY™ Total Ankle study in the UK. The multi-center, non-randomized, prospective study of 500 total ankle replacement patients will evaluate 10 year implant survivorship and outcomes throughout the lifecycle of the INFINITY™ Total Ankle System. Wright has enrolled more than 100 patients across multiple sites in the UK, including England and Scotland, as of Q3 2017. As in the U.S.-based study, the secondary objective of the UK study is to characterize improvements after implantation with the INFINITY™ Total Ankle System over a 10-year period.

"It is increasingly important for industry and clinicians to work together to provide patients, colleagues and healthcare providers with robust clinical evidence to support new systems," said Mr. David Townshend, MBBS FRCS (Orth), Consultant Orthopaedic Surgeon, Northumbria NHS Healthcare Trust, UK and Chief Investigator for the study. "We are delighted that Wright has taken the opportunity to sponsor a high quality multi-centre follow-up study in the United Kingdom to evaluate the INFINITY total ankle replacement, and we look forward to sharing these results."

“The undertaking of both the US and UK post-market clinical studies are a testament to Wright's ongoing commitment to foot and ankle surgeons and their patients,” said Ann Burgess, VP Global Clinical Affairs, Wright Medical. “By collecting longitudinal patient outcomes through real-world experience of non-design surgeons at centers of excellence around the globe, Wright will generate important information that will drive the continued evolution of the treatment and technologies addressing end-stage ankle arthritis for years to come.”

Of the roughly 50,000 end-stage ankle arthritis patients in the US each year, an estimated 8,000 will receive a total ankle replacement in 2017 and the rest will receive an ankle fusion or conservative care. With an ankle fusion, patients undergo a surgical operation where screws or plates are used to join or “fuse” the bones of the tibia and the talus in order to create a solid and immobile ankle joint with the goal to alleviate pain. Patients who receive a total ankle replacement undergo a surgical operation where ankle replacement implants are used to resurface the ends of the tibia and talus that have been damaged from ankle arthritis, with the intent to help alleviate pain and maintain mobility in the ankle joint.

### **About the INFINITY Total Ankle System**

The INFINITY™ Total Ankle System combines a low-profile implant design and seamless integration with PROPHECY™ Pre-Operative Navigation Alignment Guides. It also features a distinctive talar resurfacing option for preservation of talar bone and a tibia design that is compatible with the Company's existing INBONE™ II System.

The INFINITY™ Total Ankle System is intended to give a patient limited mobility by reducing pain, restoring alignment and replacing the flexion and extension movement in the ankle joint. Individual results and activity levels after surgery vary and depend on many factors including age, weight and prior activity level. There are risks and recovery times associated with surgery and there are certain individuals who should not undergo surgery. More information on Wright Medical's products can be found at [www.wright.com](http://www.wright.com).