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Integra LifeSciences Announces Commercial Expansion of the Cadence® Total Ankle System

PLAINSBORO, N.J., March 28, 2017 (GLOBE NEWSWIRE) -- Integra LifeSciences Holdings Corporation (NASDAQ:IART), a leading global medical technology company, today announced full commercial availability of its Cadence® Total Ankle System, a new ankle prosthesis developed in partnership with four world leading foot and ankle surgeons — Dr. Tim Daniels (University of Toronto), Dr. David Pedowitz (Rothman Institute, Philadelphia, Pa.), Dr. Selene Parekh (Duke University, Durham, N.C.) and Dr. Christopher Hyer (Orthopedic Foot & Ankle Center, Westerville, Ohio).

More than 200 Cadence total ankle procedures have been successfully performed in seven countries, since initial clinical use more than a year ago. During this period, instrumentation updates and enhanced surgeon training were introduced, designed to further improve quality, patient safety, and procedural efficiency of the system.

Integra completed corrective actions required to close an FDA recall related to the clarification of the system surgical technique, which addressed a small percentage of intra-operative posterior tibial fractures occurring due to technique error. The recall required no return of product, and since the implementation of the clarified surgical technique, no subsequent posterior tibial fractures have occurred in more than 100 procedures.

The Cadence system has garnered positive feedback among its users for advancements in implant and instrument design, along with a streamlined surgical technique. Cadence incorporates several features to accommodate various patient anatomies, reduce potential clinical complications, and address common challenges associated with ankle arthroplasty procedure. Key implant features include:

- Side-specific, anatomical tibial components, designed to avoid fibular impingement.
- Side-specific, anatomical talar components, designed to minimize resected talar bone and to preserve vascularity in the ankle.
- Bearing insert components manufactured from a highly crosslinked ultra-high molecular weight polyethylene (HXL UHMWPE) for improved wear characteristics, and patent pending-biased sagittal profile options to address patients with subluxed talar anatomy.

"I've implanted over 50 Cadence Total Ankle prostheses. I am very impressed with the versatility, reliability, reproducibility, and short-term outcomes of this implant," said Dr. Tim Daniels. "The streamlined and reliable operative instruments and techniques of this procedure, combined with an anatomical design, offer significant advantages over other ankle systems on the market today."

The Cadence Total Ankle System was previously available in a limited market release. The Cadence system is now fully available in the United States, Canada, and select European countries. Integra plans to initiate several global post-market clinical studies with the Cadence system to further support product efficacy.

About Integra
Integra LifeSciences is dedicated to limiting uncertainty for clinicians, so they can concentrate on providing the best patient care. Integra offers innovative solutions, including leading plastic and regenerative technologies, in specialty surgical solutions, orthopedics and tissue technologies. For more information, please visit www.integralife.com.

This news release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include, but are not limited to, statements concerning the products and services provided by Integra. Such forward looking statements involve risks and uncertainties that could cause actual results to differ materially from predicted or expected results. Among other things, the willingness of surgical professionals to use Integra products may affect the prospects for their use in surgical procedures. In addition, the economic, competitive, governmental, technological and other factors, identified under the heading "Risk Factors" included in Item IA of Integra's Annual Report on Form 10-K for the year ended December 31, 2015 and information contained in subsequent filings with the Securities and Exchange Commission could affect actual results.

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