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Adoption of Total Ankle Prostheses Pushes Forward By *Maria Fontanazza 2010-09-28 06:56*

In recent years, patients have been seeking surgical options that provide better range of motion. Total ankle replacements offer patients both a wider range of motion and a procedure that minimizes bone loss versus fusion. Tornier's (Edina, MN) Salto Talaris total ankle prosthesis, which has been on the U.S. market since December 2006, recently surpassed the 3000 implant mark in the United States. The device is modeled after the human anatomy and helps surgeons recreate the natural flexion and extension axis of the ankle. Historically, insurance companies such as Aetna have considered total ankle arthroplasty (specifically two-piece implants) to be experimental, because its "clinical value has not been established." A quick search of total ankle replacements on the BlueCross BlueShield's Mississippi site stated that such replacements are considered medically necessary only when used with an FDA-approved device.

Current two-part ankle prostheses (fixed-bearing design) on the U.S. market include DePuy's Agility, Wright Medical's Inbone, and the Salto Talaris. FDA's approval of the **S.T.A.R. ankle**, a three-part ankle replacement manufactured by Small Bone Innovations, is expected to change the landscape of the total ankle replacement market both in the areas of reimbursement and adoption, partially because its approval was backed by a full clinical trial. Since the product's three-part, mobile bearing design pushed it into the category of a Class III device, it was subject to more rigorous requirements than the Agility, Salto Talaris, and Inbone devices, which received 510(k) clearance. Integra Life Sciences's Hintegra prosthesis also has a three-part design but is not available in the United States.