



FDA News

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FDA Approves New Total Ankle Replacement System

The U.S. Food and Drug Administration today approved a total ankle replacement system for arthritic or deformed ankles that may preserve some range of motion in the joint.

The new prosthesis is a mobile-bearing device, which relies on bearings that move across a surface of polyethylene, a flexible plastic. The device is the first of its type.

Once arthritis or injury destroys the cartilage that cushions the ankle bone, the joints can become painful enough to warrant total ankle replacement.

The Scandinavian Total Ankle Replacement (STAR) System is an alternative to fusion surgery and may allow for greater rotation and movement in the joint. Fusion surgery involves cementing the shin bone (tibia) – the thicker of the two bones in the lower leg – to the talus bone in the ankle. The procedure stabilizes the ankle, but significantly decreases the ability to move the foot up and down.

“This device offers another treatment alternative to fusion surgery, and more closely imitates the function of a natural ankle,” said Daniel G. Schultz, M.D., director of the FDA’s Center for Devices and Radiological Health. “For the first time in the United States, a patient may retain some ankle mobility with this non-constrained, mobile-bearing device.”

The FDA has already cleared several fixed-bearing ankle devices, which are also options to fusion surgery. In fixed-bearing ankle system, the articulating surface is molded, locked or attached to one of its metallic components.

For two years, researchers followed a subgroup of a 224-patient clinical study and found that the STAR system demonstrated similar rates of adverse events, surgical interventions and major complications as fusion surgery.

As a condition of FDA approval, the company will evaluate the safety and effectiveness of the device during the next eight years.

The STAR Ankle is owned by Small Bone Innovations Inc. of Morrisville, Pa.

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