Subtalar Arthroereisis

Description
Arthroereisis is a surgical procedure that purposely limits movement across a joint. Subtalar arthroereisis (STA) or extraosseous talotarsal stabilization is designed to correct excessive talar displacement and calcaneal eversion by reducing pronation across the subtalar joint. Extraosseous talotarsal stabilization is also being evaluated as a treatment of talotarsal joint dislocation. It is performed by placing an implant in the sinus tarsi, which is a canal located between the talus and the calcaneus.

FDA REGULATORY STATUS
A number of implants have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. For example, in 2004, the HyProCure® Subtalar Implant System/Extra Osseous Fixation Device (GraMedica, Macomb, MI) was cleared for marketing by FDA through the 510(k) process (K042030); in 2010, the SubFix™ arthroereisis implant (Memometal Technologies, Bruz, France) was cleared (K093820); and, in 2008, the Arthrex ProStop Plus™ (Arthrex, Naples, FL) was cleared (K071456). In 1996, the Subtalar MBA® Implant (now owned by Integra LifeSciences, Plainsboro, NJ) was cleared for marketing by FDA through the 510(k) process (K960692). FDA determined that the Subtalar MBA® Implant was substantially equivalent to existing devices on the market before device regulation. According to the FDA summary, the primary indication for the Subtalar MBA® Implant is “as a spacer for stabilization of the subtalar joint. It is designed to block the anterior and inferior displacement of the talus, thus allowing normal subtalar joint motion but blocking excessive pronation and the resulting sequela.”¹ In 2005, the Subtalar MBA® Implant was cleared for marketing by FDA through the 510(k) process (K051611). This implant employs the same basic mechanical features as the predicate MBA implant but is composed of a material (poly L-lactic acid) that is resorbed by the body. Predicate devices include the OsteoMed Talar-Fit™ (K031155), Nexa Orthopedics Subtalar Peg (K032902, K033046), arthroereisis implant Talus of Vilex (TOV; K041289), Instrateck (K080280), and Wright Medical Smith Sta-Peg (K792670). FDA product code: HWC.

POLICY STATEMENT
Subtalar arthroereisis is considered investigational.

BENEFIT APPLICATION
Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).
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RATIONALE

Summary of Evidence
For individuals who have flatfoot or talotarsal joint dislocation who receive STA, the evidence includes mainly single-arm case series and a small nonrandomized controlled trial comparing STA with lateral column calcaneal lengthening. Relevant outcomes are symptoms, functional outcomes, and quality of life. The small nonrandomized comparative trial (N=24 feet) is considered preliminary, and interpretation of the case series evidence is limited by the use of adjunctive procedures in addition to STA, creating difficulties in determining the extent to which each modality contributed to the outcomes. Another limitation of the published data is the lack of long-term outcomes, which is of particular importance because the procedure is often performed in growing children. In addition, some studies have reported high rates of complications and implant removal. The evidence is insufficient to determine the effects of the technology on health outcomes.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

National Institute for Health and Care Excellence
A 2009 guidance from the U.K.’s National Institute for Health and Care Excellence concluded that current evidence on the safety and efficacy of sinus tarsi implant insertion for mobile flatfoot was inadequate in quality and quantity.16

American College of Foot and Ankle Surgeons
The American College of Foot and Ankle Surgeons (ACFAS) published practice guidelines for the diagnosis and treatment of adult and pediatric flatfoot in 2004 and 2005 (neither is included in the ACFAS library of current clinical practice guidelines).17,18

ACFAS guidelines on adult flatfoot have stated:

“In the adult, arthroereisis is seldom implemented as an isolated procedure. Because of the long-term compensation and adaptation of the foot and adjunctive structures for flatfoot function, other ancillary procedures are usually used for appropriate stabilization. Long-term results of arthroereisis in the adult flexible flatfoot patient have not been established. Some surgeons advise against the subtalar arthroereisis procedure because of the risks associated with implantation of a foreign material, the potential need for further surgery to remove the implant, and the limited capacity of the implant to stabilize the medial column sag directly.”

ACFAS guidelines on pediatric flatfoot have stated: “proponents of this procedure (arthroereisis) argue that it is a minimally invasive technique that does not distort the normal anatomy of the foot. Others have expressed concern about placing a permanent foreign body into a mobile segment of a child’s foot. The indication for this procedure remains controversial in the surgical community.”

U.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage
There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

REFERENCES
FEP 7.01.104 Subtalar Arthroereisis

7. Needleman RL. A surgical approach for flexible flatfeet in adults including a subtalar arthroereisis with the MBA sinus tarsi implant. Foot Ankle Int. Jan 2006;27(1):9-18. PMID 16442023

POLICY HISTORY

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<th>Date</th>
<th>Action</th>
<th>Description</th>
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<tr>
<td>December 2013</td>
<td>Update Policy</td>
<td>Policy updated with literature review through June 22, 2017; no references added. Policy statement unchanged, but “not medically necessary” corrected to “investigational”.</td>
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