FEP 7.01.104 Subtalar Arthroereisis

Effective Date: July 15, 2018
Related Policies: None

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, and are summarized in Table 1. In general, these devices are indicated for insertion into the sinus tarsi of the foot, allowing normal subtalar joint motion while blocking excessive pronation.

Table 1. Representative Subtalar Implant Devices Cleared by FDA

<table>
<thead>
<tr>
<th>Device</th>
<th>Manufacturer</th>
<th>Date Cleared</th>
<th>510(k) No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subtalar MBA®</td>
<td>Integra LifeSciences</td>
<td>07/96</td>
<td>K960692</td>
</tr>
<tr>
<td>OsteoMed Subtalar Implant System</td>
<td>OsteoMed</td>
<td>08/03</td>
<td>K031155</td>
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<tr>
<td>BioPro Subtalar Implant</td>
<td>BioPro</td>
<td>09/04</td>
<td>K041936</td>
</tr>
<tr>
<td>HyProCure Subtalar Implant System</td>
<td>Graham Medical Technologies</td>
<td>09/04</td>
<td>K042030</td>
</tr>
<tr>
<td>MBA® Implant</td>
<td>Kinetikos Medical</td>
<td>09/05</td>
<td>K051611</td>
</tr>
<tr>
<td>Metasurg Subtalar Implant</td>
<td>Metasurg</td>
<td>05/07</td>
<td>K070441</td>
</tr>
<tr>
<td>Subtalar Implant</td>
<td>Biomet Sports Medicine</td>
<td>07/07</td>
<td>K071498</td>
</tr>
<tr>
<td>Arthrex ProStop Plus Arthroereisis Subtalar Implant</td>
<td>Arthrex</td>
<td>01/08</td>
<td>K071456</td>
</tr>
<tr>
<td>Trilliant Surgical Subtalar Implant</td>
<td>Trilliant Surgical</td>
<td>02/11</td>
<td>K103183</td>
</tr>
<tr>
<td>Metasurg Subtalar Implant</td>
<td>Metasurg</td>
<td>08/11</td>
<td>K111265</td>
</tr>
<tr>
<td>NuGait™ Subtalar Implant System</td>
<td>Ascension Orthopedic</td>
<td>08/11</td>
<td>K111799</td>
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<tr>
<td>Disco Subtalar Implant</td>
<td>Trilliant Surgical</td>
<td>12/11</td>
<td>K111834</td>
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<tr>
<td>OsteoSpring FootJack Subtalar Implant System</td>
<td>OsteoSpring Medical</td>
<td>12/11</td>
<td>K112658</td>
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<tr>
<td>IFS Subtalar Implant</td>
<td>Internal Fixation Systems</td>
<td>12/11</td>
<td>K113399</td>
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<tr>
<td>The Life Spine Subtalar Implant System</td>
<td>Life Spine</td>
<td>0616</td>
<td>K160169</td>
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</tbody>
</table>

FDA: Food and Drug Administration.

Table 1. Representative Subtalar Implant Devices Cleared by FDA

* FDA 510(k) database search product code HWC (03/08/18).

POLICY STATEMENT

Subtalar arthroereisis is considered investigational.
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BENEFIT APPLICATION

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

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. Also, 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

Guidance from the National Institute for Health and Care Excellence (2009) 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 ACFAS published practice guidelines for the diagnosis and treatment of pediatric and adult 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.

The policies contained in the FEP Medical Policy Manual are developed to assist in administering contractual benefits and do not constitute medical advice. They are not intended to replace or substitute for the independent medical judgment of a practitioner or other health care professional in the treatment of an individual member. The Blue Cross and Blue Shield Association does not intend by the FEP Medical Policy Manual, or by any particular medical policy, to recommend, advocate, encourage or discourage any particular medical technologies. Medical decisions relative to medical technologies are to be made strictly by members/patients in consultation with their health care providers. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that the Blue Cross and Blue Shield Service Benefit Plan covers (or pays for) this service or supply for a particular member.
REFERENCES


POLICY HISTORY

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<tr>
<th>Date</th>
<th>Action</th>
<th>Description</th>
</tr>
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<tbody>
<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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<tr>
<td>December 2017</td>
<td>Update Policy</td>
<td>Policy updated with literature review through February 5, 2018; no references added. Policy statement unchanged.</td>
</tr>
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</table>

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