FEP Medical Policy Manual

FEP 7.01.104 Subtalar Arthroereisis

Annual Effective Policy Date: April 1, 2026

Original Policy Date: December 2012

Related Policies:

None

Subtalar Arthroereisis

Description

Description

Arthroereisis is a surgical procedure that purposely limits movement across a joint. Subtalar arthroereisis 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.

OBJECTIVE

The objective of this evidence review is to determine whether subtalar arthroereisis improves the net health outcome in individuals who have flatfoot or talotarsal joint dislocation.

POLICY STATEMENT

Subtalar arthroereisis is considered **investigational**.

POLICY GUIDELINES

None

BENEFIT APPLICATION

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

FDA REGULATORY STATUS

A number of implants have been cleared for marketing by the U.S. Food and Drug Administration through the 510(k) process, a sampling of which 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. FDA Product Code: HWC.

Table 1. Representative Subtalar Implant Devices Cleared by U.S. Food and Drug Administration[a]

Device	Manufacturer	Date Cleared	510(k) No.
Subtalar MBA	Integra LifeSciences	07/96	K960692
OsteoMed Subtalar Implant System	OsteoMed	08/03	K031155
BioPro Subtalar Implant	BioPro	09/04	K041936
HyProCure Subtalar Implant System	Graham Medical Technologies	09/04	K042030
MBA Resorb Implant	Kinetikos Medical	09/05	K051611
Metasurg Subtalar Implant	Metasurg	05/07	K070441
Subtalar Implant	Biomet Sports Medicine	07/07	K071498
Arthrex ProStop Plus Arthroereisis Subtalar Implant	Arthrex	01/08	K071456
Trilliant Surgical Subtalar Implant	Trilliant Surgical	02/11	K103183
Metasurg Subtalar Implant	Metasurg	08/11	K111265
NuGait™ Subtalar Implant System	Ascension Orthopedic	08/11	K111799
Disco Subtalar Implant	Trilliant Surgical	12/11	K111834
OsteoSpring FootJack Subtalar Implant System	OsteoSpring Medical	12/11	K112658
IFS Subtalar Implant	Internal Fixation Systems	12/11	K113399
The Life Spine Subtalar Implant System	Life Spine	06/16	K160169
Incore Subtalar System	Nextremity Solutions, Inc.	12/21	K213301
Bioplan subtalar implant	BRM Extremities	12/22	K222820

[a] FDA 510(k) database search product code HWC

RATIONALE

Summary of Evidence

For individuals who have flatfoot who receive subtalar arthroereisis, the evidence includes single-arm observational studies, systematic reviews of observational data, and a small nonrandomized controlled trial comparing subtalar arthroereisis 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 observational evidence is limited by the use of adjunctive procedures in addition to subtalar arthroereisis, 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 that the technology results in an improvement in the net health outcome.

For individuals who have talotarsal joint dislocation who receive subtalar arthroereisis, the evidence consists of 1 prospective single-arm study of talotarsal stabilization using HyProCure. Relevant outcomes are symptoms, functional outcomes, and quality of life. Although improvements in pain and function were observed, the current evidence on the use of subtalar arthroereisis for treatment of talotarsal joint dislocation is insufficient to draw conclusions about treatment efficacy with certitude. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information" if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

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.[18,]

American College of Foot and Ankle Surgeons

Piraino et al (2020) published the following Clinical Consensus Statement on the appropriate clinical management of adult-acquired flatfoot deformity: "Subtalar arthroereisis should not be considered as a single corrective procedure for stage IIB AAFD [adult flatfoot]."[19,]

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

REFERENCES

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POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
December 2012	New policy	
December 2013	Replace policy	Policy update with literature review through August 2013. Policy statement and summary unchanged.
December 2017	Replace policy	Policy updated with literature review through June 22, 2017; no references added. Policy statement unchanged, but "not medically necessary, corrected to "investigational,.
June 2018	Replace policy	Policy updated with literature review through February 5, 2018; no references added. Policy statement unchanged.

Date	Action	Description
June 2019	Replace policy	Policy updated with literature review through February 5, 2019; no references added. Policy statement unchanged.
June 2020	Replace policy	Policy updated with literature review through January 31, 2020; no references added. Policy statement unchanged.
June 2021	Replace policy	Policy updated with literature review through January 11, 2021; reference added. Policy statement unchanged.
June 2022	Replace policy	Policy updated with literature review through January 17, 2022; no references added. Policy statement unchanged.
June 2023	Replace policy	Policy updated with literature review through January 16, 2023; no references added. Policy statement unchanged.
December 2024	Replace policy	Policy updates with literature review through March 2, 2024; no references added. Policy statement unchanged.
March 2026	Replace policy	Policy updates with literature review through February 25, 2025; references added. Policy statements unchanged.