# MEDICAL POLICY

| POLICY TITLE | SUBTALAR ARTHROEREISIS |
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| POLICY NUMBER | MP 1.114 |

| Effective Date: | 10/1/2023 |
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## I. POLICY

Subtalar arthroereisis is considered **investigational** as there is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

## II. PRODUCT VARIATIONS

Top

This policy is only applicable to certain programs and products administered by Capital Blue Cross and subject to benefit variations as discussed in Section VI. Please see additional information below.

FEP PPO - Refer to FEP Medical Policy Manual. The FEP Medical Policy manual can be found at:
https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies

## III. DESCRIPTION/BACKGROUND

Top

Subtalar arthroereisis has been performed for more than 50 years, with a variety of implant designs and compositions. The Maxwell-Brancheau Arthroereisis implant is the most frequently reported, although other devices such as the HyProCure, subtalar arthroereisis peg, and Kalix are also described in the medical literature. The Maxwell-Brancheau Arthroereisis implant is described as reversible and easy to insert, with the additional advantage that it does not require bone cement. In children, insertion of the Maxwell-Brancheau Arthroereisis implant may be offered as a stand-alone procedure, although children and adults often require adjunctive surgical procedures on bone and soft tissue to correct additional deformities.

**Regulatory Status**
A number of implants have been cleared for marketing by the U.S. Food and Drug Administration 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**

| 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 |

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

## IV. RATIONALE

Top

### SUMMARY OF EVIDENCE

For individuals who have flatfoot 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.

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.

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## V. DEFINITIONS

Top

**CALCANEUS** is the largest of the tarsal bones situated at the lower and back part of the foot forming the heel.

**TALUS** is the ankle bone; the bone of the tarsus which articulates with the tibia at the ankle.

## VI. BENEFIT VARIATIONS

Top

The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits and which require preauthorization. There are different benefit plan designs in each product administered by Capital Blue Cross. Members and providers should consult the member's health benefit plan for information or contact Capital Blue Cross for benefit information.

## VII. DISCLAIMER

Top

*Capital Blue Cross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice, and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital Blue Cross' Provider Services or Member Services. Capital Blue Cross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.*

## VIII. CODING INFORMATION

TOP

**Note:** This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

**Investigational; therefore, not covered:**

| Procedure Codes | | | | | | | |
|---|---|---|---|---|---|---|---|
| S2117 | 0335T | 0510T | 0511T | 28899 | | | |

## IX. REFERENCES

Top

1. *Chong DY, Macwilliams BA, Hennessey TA, et al. Prospective comparison of subtalar arthroereisis with lateral column lengthening for painful flatfeet. J Pediatr Orthop B. Jul 2015;24(4):345-353. PMID 25856275*

2. *Metcalfe SA, Bowling FL, Reeves ND. Subtalar joint arthroereisis in the management of pediatric flexible flatfoot: a critical review of the literature. Foot Ankle Int. Dec 2011;32(12):1127-1139. PMID 22381197*
3. *Graham ME, Jawrani NT, Chikka A. Extraosseous talotarsal stabilization using HyProCure(R) in adults: a 5-year retrospective follow-up. J Foot Ankle Surg. Jan-Feb 2012;51(1):23-29. PMID 22196455*
4. *Vedantam R, Capelli AM, Schoenecker PL. Subtalar arthroereisis for the correction of planovalgus foot in children with neuromuscular disorders. J Pediatr Orthop. May-Jun 1998;18(3):294-298. PMID 9600551*
5. *Nelson SC, Haycock DM, Little ER. Flexible flatfoot treatment with arthroereisis: radiographic improvement and child health survey analysis. J Foot Ankle Surg. May-Jun 2004;43(3):144-155. PMID 15181430*
6. *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*
7. *Cicchinelli LD, Pascual Huerta J, Garcia Carmona FJ, et al. Analysis of gastrocnemius recession and medial column procedures as adjuncts in arthroereisis for the correction of pediatric pes planovalgus: a radiographic retrospective study. J Foot Ankle Surg. Sep-Oct 2008;47(5):385-391. PMID 18725117*
8. *Lucaccini C, Zambianchi N, Zanotti G. Distal osteotomy of the first metatarsal bone in association with sub-talar arthroerisis, for hallux valgus correction in abnormal pronation syndrome. Chir Organi Mov. Dec 2008;92(3):145- 148. PMID 19082522*
9. *Scharer BM, Black BE, Sockrider N. Treatment of painful pediatric flatfoot with Maxwell-Brancheau subtalar arthroereisis implant a retrospective radiographic review. Foot Ankle Spec. Apr 2010;3(2):67-72. PMID 20400415*
10. *Brancheau SP, Walker KM, Northcutt DR. An analysis of outcomes after use of the Maxwell-Brancheau Arthroereisis implant. J Foot Ankle Surg. Jan-Feb 2012;51(1):3-8. PMID 22196453*
11. *Bresnahan PJ, Chariton JT, Vedpathak A. Extraosseous talotarsal stabilization using HyProCure(R): preliminary clinical outcomes of a prospective case series. J Foot Ankle Surg. Mar-Apr 2013;52(2):195-202. PMID 23313499*
12. *Scher DM, Bansal M, Handler-Matasar S, et al. Extensive implant reaction in failed subtalar joint arthroereisis: report of two cases. HSS J. Sep 2007;3(2):177-181. PMID 18751791*
13. *Saxena A, Nguyen A. Preliminary radiographic findings and sizing implications on patients undergoing bioabsorbable subtalar arthroereisis. J Foot Ankle Surg. May-Jun 2007;46(3):175-180. PMID 17466243*
14. *Cook EA, Cook JJ, Basile P. Identifying risk factors in subtalar arthroereisis explantation: a propensity-matched analysis. J Foot Ankle Surg. Jul-Aug 2011;50(4):395-401. PMID 21708340*
15. *National Institute for Health and Care Excellence (NICE). Sinus Tarsi Implant Insertion for Mobile Flatfoot [IPG305]. 2009; Accessed April 4, 2022.*
16. *Harris EJ, Vanore JV, Thomas JL, et al. Clinical Practice Guideline Pediatric Flatfoot Panel: American College of Foot and Ankle Surgeons (ACFAS). Diagnosis and*

*treatment of pediatric flatfoot. J Foot Ankle Surg. Nov-Dec 2004;43(6):341-373. PMID 15605048*

17. *Lee MS, Vanore JV, Thomas JL, et al. Clinical Practice Guideline Adult Flatfoot Panel: American College of Foot and Ankle Surgeons (ACFAS). Diagnosis and treatment of adult flatfoot. J Foot Ankle Surg. Mar-Apr 2005;44(2):78-113. PMID 15768358*
18. *Ghali, A., Mhapankar, A., Momtaz, D., Driggs, B., Thabet, A. M., & Abdelgawad, A. (2022). Arthroereisis: Treatment of Pes Planus. Cureus, 14(1), e21003.*
19. *Turner C, Gardiner MD, Midgley A, Stefanis A. A guide to the management of paediatric pes planus. Aust J Gen Pract. 2020;49(5):245-249. doi:10.31128/AJGP-09-19-5089*
20. *Piraino JA, Theodoulou MH, Ortiz J, et al. American College of Foot and Ankle Surgeons Clinical Consensus Statement: Appropriate Clinical Management of Adult-Acquired Flatfoot Deformity. J Foot Ankle Surg. 2020; 59(2): 347-355. PMID 32131002*
21. *Blue Cross Blue Shield Association Medical Policy Reference Manual. 7.01.104, Subtalar Arthroereisis, May, 2023.*

**Other Sources:**

Mondofacto On-line Medical Dictionary, Accessed April 4, 2022.

## X. POLICY HISTORY

Top

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|---|---|
| **MP-1.114** | **CAC 9/25/07** |
| | **CAC 9/30/08** |
| | **CAC 9/29/09 Consensus Review.** |
| | **CAC 5/25/10 Adopted BCBSA Criteria.** |
| | **CAC 4/26/11 Consensus.** |
| | **CAC 6/26/12 Consensus.** No change to policy statements. References updated. |
| | **7/30/13 Admin Coding Review complete.** |
| | **CAC 9/24/13 Consensus.** No change to policy statements. References updated. Rational section added. Changed FEP variation to reference the FEP policy manual. |
| | **12/19/2013- 2014** New code added to policy. |
| | **CAC 9/30/14 Consensus.** No change to policy statements. References updated. |
| | **CAC 9/29/15 Consensus review.** No change to the policy statement. Rationale and reference update**.** Coding Reviewed |
| | **CAC 9/27/16 Consensus review.** No change to the policy statement. References and rationale updated. Variation reformatting. Coding reviewed. |
| | **CAC 11/28/17 Consensus review.** No change to the policy statement. References reviewed and rationale updated. Coding reviewed. |
| | **8/16/18 Consensus review.** No change to policy statements. References updated. Rationale condensed. |
| | **1/1/19 Administrative update.** Added new codes 0510T-0511T |
| | **6/4/2019 Consensus review.** Policy statement unchanged. References updated. |
| | **6/18/2020 Consensus review.** Policy statement unchanged. Product variation, background, references, disclaimer, and benefit variation updated. Coding |

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| | reviewed. |
| | **4/9/2021 Consensus review.** No change to policy statement. References reviewed. No coding changes. |
| | **4/4/2022 Consensus review.** No change to policy statement. FEP, rationale, references updated. No coding changes. |
| | **6/16/2023 Consensus review.** No changes to policy statement. References updated. No coding changes. |

Top