# Medical Coverage Policy

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# Subtalar Joint Implantation (Subtalar Arthroereisis)

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## Related Coverage Resources

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## Overview

This Coverage Policy addresses subtalar joint implantation—also referred to as subtalar arthroereisis or extraosseous subtalar joint implantation—a surgical procedure in which an implant is inserted into the sinus tarsi. The procedure has been proposed for the treatment of pes planus, posterior tibial tendon dysfunction, and talotarsal joint dislocation.

## Coverage Policy

**Subtalar joint implantation (subtalar arthroereisis/extraosseous talotarsal stabilization) is considered experimental, investigational or unproven for ANY indication, including but not limited to treatment of any of the following:**

- rigid or flexible pes planus (i.e., flatfoot)
- posterior tibial tendon dysfunction
- talotarsal joint subluxation/dislocation

## Coding Information

**Notes:**

1. This list of codes may not be all-inclusive since the American Medical Association (AMA) and Centers for Medicare and Medicaid Services (CMS) code updates may occur more frequently than policy updates.
2. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

**Considered Experimental/Investigational/Unproven when used to report subtalar joint implantation (subtalar arthroereisis/extraosseous talotarsal stabilization)**

| CPT®* Codes | Description |
|---|---|
| 28899 | Unlisted procedure, foot or toes |
| 0335T | Insertion of sinus tarsi implant |
| 0511T | Removal and reinsertion of sinus tarsi implant |

| HCPCS Codes | Description |
|---|---|
| S2117 | Arthroereisis, subtalar |

## General Background

Pes planus (i.e., flatfoot), also referred to as pes planovalgus, is defined as the loss of the normal medial longitudinal arch, and may be characterized as flexible or rigid. Most cases of pes planus are flexible, with presence of a normal arch during non-weight bearing that flattens when weight bearing. If an acceptable medial longitudinal arch does not appear with non-weight bearing, pes planus is considered to be rigid. Anatomical abnormalities that may be associated with pes planus include a valgus posture of the heel; mild subluxation of the subtalar joint; eversion of the calcaneus at the subtalar joint; lateral angulation at the midtarsal joint; supination of the forefoot relative to the hindfoot; and shortening of the Achilles tendon.

Pes planus may be congenital or acquired. The condition often begins in childhood or adolescence and may persist into adulthood, although many children with pes planus outgrow the condition with no treatment. The occurrence of flatfeet can be caused by many factors. It could be present at birth (congenital pes planus) or develop later in life (acquired pes planus). Congenital flatfeet is found to be highest in African-American women. Acquired flatfeet can be caused by age, obesity and not wearing footwear in early childhood. In addition, improper function of extrinsic and intrinsic foot muscles at birth or later in life has been reported to cause flat foot (Kodithuwakku Arachchige, et al., 2019). Pes planus may be associated with pain in the heel, arch, ankle, or along the outside of the foot, pain from shin splints, and weakness or fatigue in the foot or leg.

Treatment options for symptomatic pes planus include foot orthoses, stretching, shoe modification, nonsteroidal anti-inflammatory drugs (NSAIDS), physical therapy, and corticosteroid injections. Surgery may be considered when conservative treatment does not adequately alleviate symptoms. Surgical options include arthrodesis, osteotomy, excision of bone or bone spurs, synovectomy, or tendon transfer. Operative management usually involves a combination of bony and soft-tissue procedures performed during the same operation, and rarely involves an isolated procedure.

Arthroereisis (i.e., stabilization of the joint using an implant), also referred to as extraosseous subtalar joint implantation, has been investigated as a surgical treatment of pes planus, posterior tibial tendon dysfunction and talotarsal joint dislocation. Arthroereisis may be performed alone or in combination with other procedures. Arthroereisis is intended to decrease subtalar range of motion, improve the weight-bearing position during the gait cycle, and limit calcaneal eversion, by the insertion of an implant into the sinus tarsi. Implant devices can be classified into the following three categories based on their biomechanical properties: self-locking wedges, axis-altering devices, and impact-blocking devices. Studies comparing the efficacies or safety of the various available implants are lacking. Complications of subtalar arthroereisis include persistent sinus tarsi pain, foreign body reaction, implant failure, talar fracture, undercorrection, and osteonecrosis of the talus (Grear, 2021; Soomekh and Baravarian, 2006; Pinney and Linn, 2006; Lee, et al., 2005; Harris et al., 2004).

**U.S. Food and Drug Administration (FDA):** Numerous implants used in subtalar arthroereisis/extraosseous talotarsal stabilization have received FDA clearance through the 510(k) premarket notification process. Examples include:

- bioBLOCK® Implant (Integra LifeSciences [Kinetikos Medical, Inc.])
- Horizon® Subtalar (BioPro, Inc.)
- HyProCure Subtalar Implant System and HyProCure II (GraMedica)
- OsteoMed Talar-Fit™ Subtalar Arthroereisis Implant (Acumed, LLC)
- ProStop® Arthroereisis Subtalar Implant (Arthrex, Inc.)
- STA-Peg Implant (Wright Medical)

- SubFix Arthroereisis Implant (Stryker)
- Subtalar MBA® (Integra LifeSciences [Kinetikos Medical, Inc.])
- Talex™ Subtalar Stabilization System (Vilex, LLC.)
- Life Spine Subtalar Implant System (Centric Medical [Life Spine Inc.])

**Literature Review:** Available evidence regarding the safety and efficacy of subtalar arthroereisis for the treatment of podiatric disorders consists primarily of case series, prospective noncomparative studies, and retrospective analyses with small patient populations and limited follow-up (Moraca, et al., 2025; Lin, et al., 2024; Shi, et al., 2023; Szesz, et al., 2023; Garcia Bistolfi, et al., 2022; Silva, et al., 2021; Indino, et al., 2020; Junxian, et al., 2020; Walley, et al., 2019; Caravaggi, et al., 2018; Viladot Voegeli, et al., 2018). While some clinical and radiographic improvements have been seen with the use of subtalar arthroereisis in managing pes planus, the procedure has been associated with high rates of complications (e.g., sinus tarsi pain, device extrusion, talar fracture) and revisions. Similarly, some positive results have been reported in adults with flexible posterior tibial tendon deficiency, however the need for implant removal in that population has been reported as high as 46% (Grear, 2021). At present, there is insufficient evidence in the published peer-reviewed medical literature to demonstrate improved safety, efficacy, and long-term outcomes with the use of subtalar arthroereisis versus conservative treatment or alternative surgical procedures.

Ahmed et al. (2020) conducted a prospective randomized controlled trial that evaluated and compared the effectiveness of subtalar arthroereisis and lateral column lengthening in the correction of symptomatic flexible pes planovalgus (PPV) in ambulatory cerebral palsy (CP) patients. The study enrolled 35 patients aged 5–12 years that included 57 feet. Patients were divided into 2 groups: group 1, subtalar arthroereisis group (n=28); group 2, lateral column lengthening group (n=29). The primary outcomes assessed the improvement in clinical outcomes, forefoot abduction and hindfoot valgus. The secondary outcome assessed patient/parent satisfaction and tolerance to brace or shoes which were assessed 12 months after surgery. Patients were assessed clinically and radiologically, both preoperatively and 12 months postoperatively. The follow-up period ranged from 12 to 22 months (average 15.6 months). There was a statistically significant improvement in all outcomes parameters after both procedures when compared to the preoperative parameters. No statistically significant differences were observed between the two groups regarding the outcomes of both procedures except arthroereisis was statistically significant both clinically and radiographically (p=0.026) in the correction of hindfoot valgus. Author noted limitations included the small patient population and short-term follow-up. The authors concluded that both procedures are valid options for the surgical management of PPV in ambulatory children with spastic CP. However, further investigation and long-term outcome studies are needed to demonstrate the efficacy and safety of arthroereisis.

A prospective case series conducted by Saxena et al. (2016) evaluated the rate and risk factors for implant removal due to sinus tarsi pain following subtalar joint arthroereisis (STA) in adults treated for acquired flatfoot deformity including posterior tibial tendon dysfunction (PTTD). The inclusion criteria were an arthroereisis procedure for adult acquired flatfoot deformity (AAFD)/PTTD, age > 18 years, and a follow-up period of two years. Patients (n=100) underwent 104 STA procedures. The mean follow-up period was 6.5 (range 2–17) years with two patients lost to follow-up. The primary outcome measured was the incidence of STA implant removal in patients treated for AAFD/PTTD. The study also assessed whether age, size of implant or endoscopic gastrocnemius recession (EGR) affected the incidence of implant removal. The overall incidence of implant removal was 22.1%. Patient age was not clinically significant (p=0.09) however, implant size was clinically significant (p=0.02) with 11-mm implants removed more frequently. Endoscopic gastrocnemius recession did not exert any influence on the rate of implant removal (p=0.19). The author noted limitation of the study was the lack of some follow-up data, such as removal of the STA implant elsewhere after the study period, and lack of radiographic analysis pre- and postoperatively. Other factors that were not considered in the study might have contributed to implant removal, including body mass index and the severity of the deformity. The authors concluded that removal of the implant is common due to sinus tarsi pain.

Bresnahan et al. (2013) reported preliminary outcomes of a prospective case series to evaluate subjective outcomes after extraosseous talotarsal stabilization using the HyProCure stent as a standalone procedure for treatment of recurrent and/or partial talotarsal joint dislocation (35 patients/46 feet). Pediatric (> three years old) and adult patients were included. Inclusion criteria were kept intentionally broad to an effort to promote external validity. The Maryland Foot Score (MFS) questionnaire was used to evaluate outcomes and patient satisfaction. At one year, the mean MFS score improved from 69.53 ± 19.56 to 89.17 ± 14.41. Foot pain decreased by 63.97%, foot functional activities improved by 14.39%, and foot appearance improved by 25.49%. Implants were removed in two patients; one due to discomfort when walking and during activities, and one due to failure to relieve symptoms. At six months, four patients (six feet) showed no improvement in MFS scores, and at one year, three patients (six feet) showed no improvement. At one year, 14 of 35 patients (16 of 30 feet) were lost to follow-up.

A retrospective review by Graham et al. (2012) was conducted to determine long-term functional outcomes and device-tolerance following treatment of flexible talotarsal joint deformity using the HyProCure device (n=83, 117 feet). The mean postoperative Maryland Foot Score (MFS) was 88 out of 100; 52% of patients reported complete alleviation of foot pain, 69% had no limitations on their feet functional abilities, and 80% were completely satisfied with the appearance of their feet. The implant was removed in seven of 117 feet (6%) due to prolonged pain (4), psychogenic reaction (3), and postoperative infection (1). The authors stated that, based on positive long-term subjective outcomes, this procedure may be a treatment option for stabilizing the talotarsal joint and eliminating pain and improving quality of life. The authors acknowledged limitations of this study, including the inability to quantify improvement in terms of preoperative subjective patient satisfaction scores due to the study’s retrospective nature.

Brancheau et al. (2012) published a retrospective review of 35 consecutive patients with flexible flatfoot treated with the Maxwell-Brancheau Arthroereisis (MBA) implant from 1996 to 2000. The mean age at the time of treatment was 14.3 years (range 5–46 years). Sixty adjunct procedures were performed in the 35 included patients in conjunction with the implant procedure. Preoperative and postoperative anteroposterior and lateral radiographs of angles (talocalcaneal, calcaneocuboid, first to second intermetatarsal angle, calcaneal inclination, and talar declination) were compared at a mean of 36 months (range 18–48 months) and improvements were all considered to be statistically significant ($p<0.001$) The authors noted that correction of radiographic parameters is not always a reliable predictor of patient satisfaction with a surgical outcome, and that the presence of pain or disability is a more reliable indicator of surgical success. A subgroup of 24 patients also answered a subjective questionnaire at a mean of 33 months (range 12–55 months) postoperatively. The presenting chief complaints were resolved in 23 of the 24 patients. Patients reported no pain in 24 of 40 feet, moderate pain in two feet, and mild pain in 13 feet. There was an 11.9% complication rate. Pain and restricted motion of the subtalar joint was the most common complaint requiring implant removal; implants were removed in nine patients. The authors noted limitations of the study, including the inclusion of patients of all ages without use of a survey validated for all age groups, significant numbers of patients lost to follow-up, and lack of statistical analysis that may have allowed associations between variables and specific outcomes.

Metcalfe et al. (2011) conducted a meta-analysis to evaluate arthroereisis in the treatment of pediatric flatfoot. Seventy-six studies met the inclusion criteria. Data could not be pooled for statistical analysis due to several factors; the literature consists primarily of ad hoc case reports and retrospective case series; methodological variations (e.g. device type, inclusion criteria, surgical technique, adjunctive procedures, and outcome measures). Few studies applied validated clinical or patient reported outcome measures. Eight of the nine radiographic parameters reported showed significant improvement following arthroereisis reflecting increased static arch height and joint congruency. Only small increases were seen in calcaneal inclination angle. Arthroereisis was associated with a number of complications, including sinus tarsi pain, device extrusion, and under-correction. Complication rates ranged between 4.8% and 18.6%, with unplanned removal rates between 7.1% and 19.3%. The authors stated that although literature suggests high patient satisfaction rates, qualitative outcome data based on disease specific, validated outcome tools may improve current evidence and permit comparison of future study data.

Scharer et al. (2010) conducted a retrospective review to evaluate outcomes of pediatric patients who received Maxwell-Brancheau arthroereisis (MBA) subtalar implants for treatment of painful flatfoot deformities. The authors reviewed charts and radiographs of 39 patients (68 feet) treated between 2000 and 2006. The mean age was 12 years (range 6–16 years), and the mean period of follow-up was 24 months (range 6–61 months). The surgical procedures consisted of 68 MBA implants, 12 gastrocnemius recessions, six Achilles tendon lengthenings, and four Kidner procedures. There were ten (15%) complications, consisting of ten re-operations in ten feet. Implants were exchanged in nine feet due to implant migration, under-correction, and overcorrection. One reoperation was performed for implant removal due to persistent sinus tarsi pain. Radiographic evaluation demonstrated an improvement in talonavicular joint coverage and lateral and anterior-posterior talocalcaneal angles. The authors noted that significantly more study is needed on subtalar arthroereisis, and indicated additional studies should evaluate long-term follow-up in pediatric patients to assess the longevity of correction and need for future treatment.

Needleman (2006) conducted a case series to determine the functional outcomes and radiographic results of reconstructive foot and ankle surgery that included arthroereisis with the Maxwell-Brancheau Arthroereisis (MBA) sinus tarsi implant. A total of 23 patients (28 feet) were treated between 1998 and 2003. Indications for surgery and study inclusion were failure of nonoperative management to relieve foot pain and restriction of activity because of flexible flatfoot in adult patients. The average follow-up was 44 months. The average preoperative American Orthopaedic Foot and Ankle Society (AOFAS) score was 52, improving to 87 at final follow-up ($p<0.00001$). The average overall satisfaction was 8.3 on a 10-point scale, and 18 patients (78%) said they would have the surgery again. The MBA implant was surgically removed in 11 of 28 feet (39%) because of sinus tarsi pain. In nine of these 11 feet, the implant was removed eight months or more after the procedure.

A retrospective review conducted by Nelson et al. (2004) evaluated the results of arthroereisis with the MBA implant in 37 patients (67 feet) treated for flexible flatfoot by a single surgeon between 1998 and 2002. Included patients had failed an average of eight months of conservative therapy consisting of any combination of shoe-gear modifications, activity modifications, physical therapy, stretching exercises, oral anti-inflammatory medication, over the counter shoe inserts, and prescription orthotics. The average age at the time of surgery was 13.7 years (range 6–45), and the average age of pediatric patients was 11.9 years (range 6–17). Radiographic measurements showed significant improvement in the talo-first metatarsal angle, lateral talar declination angle and talocalcaneal angle. Of the 37 patients, 34 were pediatric, and 27 returned a postoperative Child Health Questionnaire (CHQ). The questionnaire was completed by a parent. Preoperative CHQs were not completed. The postoperative results were therefore compared to population norms. The results of the CHC, demonstrated scores better than population norms in the role emotional behavior domain, global behavior domain, and parent time domain, with no difference in the remaining domains. Two patients with pain due to sinus tarsi syndrome required implant removal, and two patients required implant readjustment because of poor positioning.

**Professional Societies/Organizations**

**American College of Foot and Ankle Surgeons (ACFAS):** The ACFAS published a consensus statement on the appropriate clinical management of adult-acquired flatfoot deformity (AAFD). The consensus statement indicated that the following statement is "neither appropriate nor inappropriate": "subtalar arthroereisis should not be considered as a single corrective procedure for stage IIB AAFD". Per ACFAS, there is limited literature demonstrating the use of a subtalar implant alone to address pronation of the foot in type IIa deformity. ACFAS also stated that the most identified complication is sinus tarsi pain due to presence of the implant; explantation resolves the pain (Piraino, et al., 2020).

## Health Equity Considerations

Health equity is the highest level of health for all people; health inequity is the avoidable difference in health status or distribution of health resources due to the social conditions in which people are born, grow, live, work, and age.

Social determinants of health are the conditions in the environment that affect a wide range of health, functioning, and quality of life outcomes and risks. Examples include safe housing, transportation, and neighborhoods; racism, discrimination and violence; education, job opportunities and income; access to nutritious foods and physical activity opportunities; access to clean air and water; and language and literacy skills.

## Medicare Coverage Determinations

| | Contractor | Determination Name/Number | Revision Effective Date |
|---|---|---|---|
| NCD | | No Determination found | |
| LCD | | No Determination found | |

Note: Please review the current Medicare Policy for the most up-to-date information.
(NCD = National Coverage Determination; LCD = Local Coverage Determination)

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## Revision Details

| Type of Revision | Summary of Changes | Date |
|---|---|---|
| Annual Review | • No clinical policy statement changes. | 10/15/2025 |
| Annual Review | • No clinical policy statement changes. | 10/15/2024 |
| Annual Review | • No clinical policy statement changes. | 10/15/2023 |