Comparison of the EOTTS-HyProCure® sinus tarsi stent to other “forms of treatment.”

Foot orthosis  EOTTS HyProCure  Osteotomy

Together We Can Change Lives, One Step at a Time®
Introduction

The partial dislocation of the ankle bone (talus) on the hindfoot bones (tarsal mechanism) leads to excessive forces acting on the joints and soft tissues of the foot and ankle. These repetitive excessive forces eventually lead to joint and tissue damage. It is the secondary pathologies that eventually become symptomatic leading to pain and disability in patients. Throughout orthopedic history there have been various opinions as to the best form of treatment, if any.

There are millions of patients around the world that suffer on a daily basis as a direct or indirect result of the partial dislocation of the talus on the tarsal mechanism. The role of the physician is to provide an effective treatment to “heal” this condition, not to simply ignore it with the hope that it will get better. Even worse are the vast number of patients who are given various forms of medications to ameliorate the symptoms, meanwhile the underlying etiology remains active to exert its damage on the tissues.

This Ebook was written to compare various treatment options that are prescribed by physicians. Believe it or not, there are many medical biases when it comes to the “preferred” treatment regimen. These opinions are largely based on the training and experience of the physician. The use of sinus tarsi stents is relatively “new” in the field of orthopedics, but please understand that there has been a long evolution of methods to realign the ankle bone. The first attempts at ankle bone realignment without fusing the hindfoot bones began in the 1940’s. The HyProCure® stent has been proven to be the most successful, internal, extra-ossoues device. It has a long track record of clinical use, is backed by extensive peer-reviewed scientific research, and that is why it is the “go-to” device by leading foot and ankle surgeons, both orthopedic and podiatric, globally.
Contents

1. EOTTS-HyProCure® verse Observation
2. EOTTS-HyProCure® verse Arch Supports/Foot Orthosis
3. EOTTS-HyProCure® verse CalcaneoStop
4. EOTTS-HyProCure® verse Arthroereisis Implants
5. EOTTS-HyProCure® verse Osteotomies
6. EOTTS-HyProCure® verse Traditional Reconstruction
7. EOTTS-HyProCure® Advantage

Note:
Please click on this icon to view a video demo

HyProCure® Subtalar Implant System
FDA 510(k) cleared/CE marked
Patent protected
Consult the package insert prior to use.

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Misaligned or flat feet don’t get better, they get worse!

Misaligned or flexible flat feet have been widely dismissed as a “normal” variant by the medical community. They have ignored the hundreds of published studies that have proven the negative effects to the feet, knees, hips, and back, as well as, the quality of the life.

The most likely reason is that the symptoms of misaligned and flat feet don’t always present in childhood. The majority of symptoms appear years or decades of tissue abuse. These millions of steps will eventually lead to the destruction of joints, ligaments, and tendons.

It’s easy to ignore a problem, but the sooner a disease is addressed, the better. There is no evidence that a displaced talus will “auto” correct.
This is the result of decades of conservative care. This patient’s life has been severely affected by the “do-nothing approach.” There is pain with every step. The only option now is major reconstruction.

The talus is partially dislocated. It will remain partially dislocated and can only be realigned and stabilized with an internal physical intervention.

The talus has been internally realigned with HyProCure. There are no more excessive forces acting on this patient’s foot. The benefits far exceed any potential risks.
<table>
<thead>
<tr>
<th>Proven to realign and stabilize the talus on the tarsal mechanism</th>
<th>HyProCure®</th>
<th>Observation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proven to decrease the forces acting on the inner arch</td>
<td>√</td>
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<tr>
<td>Proven to decrease the force acting on the medial band of the plantar fascia</td>
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<td></td>
</tr>
<tr>
<td>Proven to decrease the forces acting on the posterior tibial nerve</td>
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<tr>
<td>Proven to decrease transverse plane talar dislocation</td>
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<tr>
<td>Proven to decrease sagittal plane talar dislocation deformity</td>
<td>√</td>
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</tr>
<tr>
<td>Provides a false sense of treatment</td>
<td></td>
<td>√</td>
</tr>
<tr>
<td>Allows for continued strain on the joints, bones, and soft tissues</td>
<td></td>
<td>√</td>
</tr>
<tr>
<td>Doesn’t make sense</td>
<td></td>
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</tr>
</tbody>
</table>
HyProCure® vs Observation

References


Can the talus be realigned and stabilized by something placed on the bottom of the foot?

Hundreds of millions of dollars are spent every year on over-the-counter and “custom-made” arch support or foot orthosis. Yes, these devices play a supportive role to off-weight high pressure areas of the mid- and fore-foot but, when it comes to realigning and stabilizing the TTJ, they simply cannot realign or maintain the stability of the talus.

Many claim that a foot orthosis is used to treat over-pronation but where is the proof? Over-pronation is directly linked to the partial dislocation of the talus on the calcaneus and navicular. An arch support cannot control transverse or sagittal plane alignment of the talus. There is no explanation on how exactly an orthosis reduces TTJ pronation. These devices should be considered a sub-therapeutic modality in the treatment of over-pronation.

A more alarming thought is that millions of people are “wearing” these devices in their shoes thinking they are being treated. However, their talus is still partially dislocating on the calcaneus and navicular leading to excessive forces acting on their joints, ligaments, and tendons.
HyProCure® vs. Arch Supports

Where’s the proof of talar alignment and stability with an orthosis?

Radiographic or weightbearing fluoroscopic imaging should show that an orthosis is stabilizing and realigning the talus. There are no studies showing talar realignment or stabilization.
These comparison x-rays were taken with the patient standing on their feet. We see that the ankle bone is out-of-alignment with the bare feet x-rays. We also see that there is minimal to no realignment while the patient is standing on a custom-made arch supports. Finally, it’s only after the insertion of HyProCure® that we see complete realignment of the ankle bone.
The use of over-the-counter or custom-made shoe inserts to realign and improve foot function is unproven in literature. This industry is unregulated and there is no consistency of findings. There are a wide range of devices on the market being dispensed from mail order catalogs, on-line, shoe stores, pharmacies, physical therapists, orthotists, medical supply stores, chiropractors, podiatrists, and orthopedists.

Compliance is a major issue with the use of an insole (any “corrective” device placed into the shoe) because patients don’t always wear shoes, don’t switch the insole from shoe to shoe, they walk barefoot or wear shoes that the insole cannot fit, the insoles wears-out or looses its shape.

These devices give patients a “false-sense of correction” there is no radiographic evidence of realignment of foot bones.

There are 35 peer-reviewed articles published in various medical journals by a variety of medical professionals.

There is no evidence that an insole can normalize/control transverse plane talotarsal joint instability.
There is no evidence that shows an insole can normalize/control sagittal plane osseous malalignment or instability.

Panjabi’s model explains the long-term use of an external support of a biologic structure will weaken it.

There is no high level evidence for the use of a foot orthosis for flexible flat foot.

There is a positive effect on medial-lateral sway but it is undetermined on why and what are the positive biological effects.

There is low evidence they can improve pain, reduce rearfoot eversion after loading and impact forces, reduce rearfoot inversion and eversion. But not all devices are made the same or are created equal.
HyProCure® vs. Arch Supports

Custom-made orthosis has no effect on slowing the progression of hallux valgus within 12 months of use.

Insoles have no effect to transverse plane kinematics of the tibia and knee.

Insoles have no influence on navicular drop during 1st 50% of stance phase of the gait cycle.

Foot insoles have no contact with the talus and have not shown to have positive affect to talar stability or alignment on the calcaneus.
Adhesive taping is more effective than an arch support in controlling rearfoot eversion.

There is limited evidence on which to base clinical decisions regarding the prescription of a custom-made foot orthosis for the treatment of foot pain.

There is no evidence for the justification of the use of in-shoe orthosis in the management of flexible excessive foot pronation in children.

The effect of orthoses on frontal plane rearfoot motion is considered small and probably insufficient for symptoms reduction.

Lateral wedge heel will increase the amount of foot pronation and offers a minimal effect to the knee, hip, and back.

Foot orthotic had no effect on control of talar rotation- cadaver study.

Foot orthosis did not improve hindfoot valgus malalignment.

Orthosis use in children did not slow the progression of hallux valgus/bunions, rather the deformity continued to worse.

Orthosis had no effect on EMG activity.
### HyProCure® vs Arch supports*

<table>
<thead>
<tr>
<th><strong>Proven to realign and stabilize the talus on the tarsal mechanism</strong></th>
<th>HyProCure®</th>
<th><strong>Shoe Inserts</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Proven to decreases the forces acting on the inner arch</strong></td>
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<tr>
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<td></td>
<td>√</td>
</tr>
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</table>

*This includes both over-the-counter and custom-made orthosis
References


HyProCure® vs Arch Supports

References Continued


Havenhill TG, Toolan BC, Draganich LF. Effects of a UCBL orthosis and a calcaneal osteotomy on tibiotalar contact characteristics in a cadaver flatfoot model. Foot Ankle Int. 26(8):607-13, 2005.
HyProCure® vs Arch Supports

Research Continued.


This is a procedure rarely performed in the USA but it is performed in Europe and South America. An orthopedic screw is partially drilled into the heel bone to block ankle bone motion. The screw must be removed after 2 to 3 years. There is no evidence that the correction lasts. This is mainly performed in children 12 to 16 years old.

Here we see HyProCure® doing it's job effortlessly. The ankle bone motion is restored. It is uncommon that the stent has to be removed. HyProCure® is used in both children and adults.
<table>
<thead>
<tr>
<th></th>
<th>HyProCure®</th>
<th>CalcaneoStop Screw</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bone - Joint blocking device</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Only recommended for pediatric</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>patients 12 to 16 years old</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Has to be drilled into the calcaneus</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Has to be removed within three (3) years after insertion</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Can weaken the calcaneus</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Can be used in both children and adults</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Not drilled into bone</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Can remain in situ, doesn’t have to be removed after a specific period of time</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Restores normal talotarsal joint supination/pronation</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Doesn’t make sense</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Cost effective treatment - patient doesn’t have to be brought back to the operating room for a mandatory screw removal.</td>
<td>✓</td>
<td></td>
</tr>
</tbody>
</table>

*This is a “screw” that is drilled into the floor of the sinus tarsi into the calcaneus.*
HyProCure® vs CalcaneoStop*

References


Extra-Articular Talotarsal Stabilization

There are more than 100 peer-reviewed articles published in more than 30 different medical journals on the use of extra-articular talocalcaneal stabilization procedures using a sinus tarsi implant. These range over a span of 40 years. The results were presented by both orthopedic and podiatric surgeons from around the world.

The importance of extra-articular stabilization over just destruction procedure is a common theme. Joint preservation is preferred over the elimination of joint motion. The reversibility of the procedure is a prime benefit. Patient compliance is not an issue, as seen with the use of a shoe insert/orthosis since the device is internally placed.

There is proof that patients are more active as a result of this procedure and have a better quality of life. Patient’s have less pain as a result of this procedure and their satisfaction rates where improved following the procedure. The recovery period and post-operative course is significantly shorter than other surgical corrective procedures to accomplish the same outcome.

There are multiple papers showing positive effect to reducing soft tissue damage to:

- plantar fascia
- posterior tibial tendon
- Posterior tibial nerve
- Tarsal tunnel & porta pedis pressures

There are multiple papers showing improved/normalized foot appearance – realignment. Positive affect to gait cycle – normalization of the amount of pronation. Normalization of plantar foot forces. Normalization of joint forces, reduction of forces acting on the medial column of the foot. Positive affects to both pediatric and adult patients.

There are 71 papers who used the sinus tarsi implant in patients ≤ 18 years of age and 48 who used devices in patients > 18 years of age.
Extra-osseous Talotarsal Stabilization

Unlike external measures, these devices realign the TTJ.

Positive affects to:

**Lateral x-ray:**
- Talar declination angle
- Calcaneal inclination angle
- Navicular height/position
- Talar First metatarsal angle

**Dorsoplantar x-ray:**
- Talar 1st metatarsal angle
- Talar 2nd metatarsal angle
- Talar Navicular angle/coverage
- Talar Calcaneal angle
- Calcaneocuboid
- First intermetatarsal angle
Extra-osseous Talotarsal Stabilization

Comparison of Type I Arthroereisis Devices and Type II HyProCure® Non-Arthroereisis Sinus Tarsi Stents

There are many different sinus tarsi stents cleared by the FDA for use however, they are not all the same. There is a classification system for the different types*. The type II HyProCure® stent is the most successful stent on the market due to its unique design, placement within the sinus tarsi and also the way it is anchored and how it stabilizes the ankle bone while allowing normal ankle bone motion.

Sinus tarsi implants are not all created equal.

**Type I – Arthroereisis Devices**
- Laterally placed
- Laterally anchored
- Joint – bone stopping procedure
- Reported removal rates up to 100% (depending on the specific device)
- Low long-term success rate

**Type II – Non-Arthroereisis Devices**
- Centrally placed
- Medially anchored
- Restores motion without blocking
- Success rate is up to 94%
- Strong evidence basis
- Excellent long-term success rate
Extra-osseous Talotarsal Stabilization

Sinus tarsi implants: a “kind-of-round” tire verse a round tire.

There is no evidence to support the realignment and stabilization of the talus on the tarsal mechanism with observation or external measures, such as a foot orthosis. These non-surgical interventions fail to reduce or normalize a talotarsal displacement deformity and should be considered below the standard of care in the treatment of secondary conditions related to conditions resulting from an unstable misaligned TTJ. EOTTS is a soft-tissue procedure that has proven to allow TTJ range of motion at the same time stabilizing the TTJ and maintaining joint alignment. EOTTS is a superior option to non-surgical treatment options, when indicated. There are dozens of papers providing the benefits and positive outcomes without resorting to joint destruction. The use of non-conservative surgical procedures should be used in patients who are not a candidate for the EOTTS procedure due to their more destructive nature and limitations.

Patients must have a flexible reducible talotarsal joint displacement deformity as evidenced by relaxed and neutral stance position weightbearing x-rays. The entire foot structure must be evaluated and additional misaligned or unstable structures must be also addressed.

![Average Removal Rate Graph](image-url)
### HyProCure® vs Arthroereisis*

<table>
<thead>
<tr>
<th></th>
<th>HyProCure®</th>
<th>Arthroereisis Implants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bone - Joint blocking or limiting devices</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Rarely performed as a stand-alone procedure</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Has removal rates up to 100%</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Placed into the lateral sinus tarsi</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Restores talotarsal joint range of motion – does not limit range of motion</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Anchored into the canalis tarsi</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Stabilizes the TTJ at the axis point</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Has published success rate of 94%</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Extensive evidence based published research</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Routinely used in pediatric and adult patients</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Makes sense</td>
<td></td>
<td>✓</td>
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</tbody>
</table>

*Arthroereisis devices are placed into between the ankle and heel bones to block or limit talotarsal joint motion.
Arthroereisis

References


Arthroereisis

References


Arthroereisis

References continued


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

Arthroereisis

References continued.


HyProCure® vs. Calcaneal Osteotomy

Many foot specialists will attempt to cut and shift the posterior aspect of the calcaneus – medial displacement calcaneal osteotomy. This is an aggressive procedure that is aimed at calcaneovalgus rotation of the heel. The calcaneus everts due to medial talar displacement on the calcaneus. This procedure has not been shown to realign and stabilize the talus on the calcaneus. Most patients are taken back to the surgery to removal painful screws.

If this was your x-ray or the x-ray of some you care for, would you recommend EOTTS-HyProCure or MDCO?

Here we see HyProCure® has realigned and stabilized the ankle bone on the heel bone.

Cutting and shifting the heel bone will not realign and stabilize the talus. Painful hardware must be removed.
A posterior calcaneal medial displacement osteotomy does not stabilize the talus.
<table>
<thead>
<tr>
<th>Comparison</th>
<th>HyProCure®</th>
<th>MDCO*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Requires bone cutting and shifting</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>High likelihood of painful internal hardware that will have to be removed</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Associated with a longer recovery period</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Only performed in adult patients</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Not proven to realign and stabilize the talus on the tarsal mechanism</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Does not require bone cutting, soft tissue procedure</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Low chance of device removal</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Scientifically proven to stabilize and realign the talus on the tarsal mechanism while allowing normal TTJ range of motion.</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Cost-effective solution</td>
<td>✓</td>
<td></td>
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<tr>
<td>Routinely used in pediatric and adult patients</td>
<td>✓</td>
<td></td>
</tr>
<tr>
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</tr>
</tbody>
</table>
Calcaneal Osteotomies

References


Chan JY, Williams BR, Nair BR, Nair P, Young E, Sofka C, Deland JT, Ellis SJ. The contribution of the medializing calcaneal osteotomy on hindfoot alignment in the reconstruction of the stage II adult acquired flatfoot deformity. Foot Ankle Int. 34(2):159-66, 2013.


Calcaneal Osteotomies

References

HyProCure® vs. Traditional Reconstructive Surgery

The primary method of flatfoot surgical correction has been based on multiple procedures, such as the combination of posterior, and/or anterior calcaneal osteotomy, midfoot fusion, or arthrodesis procedures. These procedures are invasive and require a long recovery process. The majority of patients will be brought back to the operating room to removal painful screws or pins. It is just a matter of time until arthritic changes are seen in distal or proximal joints. We have to ask the question: has the talus be realigned and stabilized on the calcaneus? And at what cost to the other tissues?
Other Surgical Procedures

Spring Ligament Repair:

Provides the least amount of correction to the medial column.

Lateral Column Lengthening:

Cutting and inserting bone graft into the calcaneus.
Correct a forefoot abduction, but has no effect on the arch/navicular position
Decreases hindfoot eversion and has a negative effect on 1st MPJ dorsiflexion
Limited angular correction
Leads to arthritis at the calcaneocuboid joint

Medial Cuneiform Osteotomy (Cotton):

Has no effect on Meary’s angle
Other Surgical Procedures

Subtalar Arthrodesis:

Fusion of the talus to the calcaneus
There is a positive realignment seen to the DP & lateral talar 1st metatarsal angle (Meary’s angle)

Leads to degenerative changes to the ankle, talonavicular, calcaneocuboid, and the metatarsocuboid joints

12% rate of non-union (failure of the bones to fuse)
18% fuse in a bad alignment (malalignment)
17% require painful screw removal

Fusion takes 8 to 12 weeks

Triple Arthrodesis:

15% require secondary surgery
Non-unions
Avascular necrosis
Progression of disease
Ankle joint arthritis (47%)
Over-correction
# HyProCure® vs Traditional Approach

<table>
<thead>
<tr>
<th></th>
<th>HyProCure®</th>
<th>ACO*</th>
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<tbody>
<tr>
<td>Requires bone cutting and insertion of bone graft</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Requires internal fixation</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Shown to cause chronic pain to the lateral foot</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Known to cause arthritis at the calcaneocuboid joint</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Soft tissue procedure</td>
<td>✓</td>
<td></td>
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</table>

*Anterior calcaneal osteotomy with insertion of bone graft – Evan’s Procedure.
HyProCure® vs Traditional Approach

References


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HyProCure® vs Traditional Approach

References continued


HyProCure® vs Traditional Approach


HyProCure® vs Traditional Approach

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References continued.


Cooper PS, Nowak MD, Shaer J. Calcaneocuboid joint pressures with lateral column lengthening (Evans) procedures. Foot Ankle Int. 18(4):199-205, 1997.
This simple looking stent provides the solution to a very complex condition. When arch supports aren’t enough and prior to reconstructive surgery, please consider HyProCure.
HyProCure® Advantage

HyProCure is the most successful sinus tarsi stent that has been used in both pediatric and adult patients since 2004.

There is a reason why HyProCure is the “go-to” sinus tarsi stent for leading foot and ankle surgeons in more than 60 countries.

<table>
<thead>
<tr>
<th>HyProCure</th>
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<tr>
<td>Soft tissue procedure that does not require bone drilling or cutting</td>
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<tr>
<td>Immediately realigns and stabilizes the talus on the tarsal mechanism</td>
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<td>Has the greatest published success rate over other EOTTS device</td>
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<td>Placed into the sinus tarsi of both pediatric and adults patients</td>
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<td>Provides both transverse and sagittal plane correction</td>
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<td>Proven to decrease strain on the medial arch</td>
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<td>Stabilizes a dropped navicular</td>
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<td>Decreases the strain on the medial band of the plantar fascia, posterior tibial tendon and nerve</td>
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<td>A cost-effective solution that just makes sense</td>
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<tr>
<td>&gt; 12 years of clinical use, 10,000s procedures, in &gt; 60 countries</td>
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<td>Just makes sense</td>
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References


HyProCure® Advantage

References Continued


Together We Can Change Lives, One Step at a Time®