EOTTS with **HyProCure®**

Patient Procedure Packet
Congratulations on your decision to have the EOTTS with HyProCure® procedure!

Your foot specialist has identified that your foot most closely matches:

**Mild TTJD ( < 10% RR*)**
- Stand Alone Procedure
- T2MA: 16°–28°
- TDA: 21°–27°
- Normal CIA
- No Equinus
- Intact PF/PTT
- Stable 1st Ray
- Normal 1st MPJ ROM

**Moderate TTJD ( < 15% RR*)**
- May Require Additional Procedures
- T2MA: 29°–40°
- TDA: 28°–33°
- Decreased CIA
- Slight/Moderate Equinus
- Questionable PF/PTT
- Moderate 1st Ray Instability
- Adequate 1st MPJ ROM

**Severe TTJD ( > 15% RR*)**
- Requires Additional Procedures
- T2MA: > 40°
- TDA: > 33°
- Decreased to Negative CIA
- Severe Equinus < 15° PF
- PF Loss/Stage 2B PTTD
- Rigid 1st Ray Deformity
- Limited 1st MPJ Rom

*RR—Removal Rate. Depending on the severity of your condition, there is an increased possibility that the HyProCure® stent may not work. There may also be other areas of the foot that may need to be addressed with an arch support/orthosis or other corrective surgery.
Normal
This is what a normal sinus tarsi looks like when standing. Notice the naturally occurring space between the heel bone and ankle bone.

Abnormal
This is what an abnormal sinus tarsi looks like when standing. The space in between the heel bone and the ankle bone collapses causing the ankles to roll inward.

HyProCured
This is what a foot stabilized with HyProCure looks like when standing. HyProCure holds the space open to keep the ankles from rolling inward and the body is in natural alignment.
Patient Success Stories

Max

_HyProCure was the best thing that ever happened to our family and the best thing that ever happened to Max._

Max is 9-years-old and he has special needs. He had been very delayed in his gross motor abilities and didn’t like to walk; he wanted to be carried all of the time. When he did walk, it was very ridged and he tired easily. We were told that this was due to his Down Syndrome, but we felt there was more going on than that. We tried special shoe inserts which seemed to help Max walk better, but there wasn’t the improvement we hoped to see.

That’s when our doctor recommended HyProCure. There’s been an immediate improvement and Max has started wanting to walk and walking faster. We are so happy to see how HyProCure has made such an impact on his quality of life. We see how proud he is of himself; he is more independent and his cognitive ability has soared. Thank you for the wonderful gift you gave to our family.

Max’s Parents

Susan

_HyProCure has been a life-changer!_  

When I was younger, I always had problems with my feet and wore corrective shoes – which did absolutely nothing in all the years I wore them. My foot started turning over and eventually I sprained it. That’s when I went to my doctor to see if anything could be done to help.

We started with orthotics, but he recommended HyProCure as the best option. I had both feet corrected separately and was fitted for custom athletic shoes in between procedures. The shoe fitter couldn’t believe the difference the procedure made in my feet. Now that I’ve had both feet done, it’s been great, and feels great – it’s been a life changer. And I can wear sandals now! Thank you, HyProCure!

Christine

_I’m so thankful I had HyProCure done!_  

My feet had always bothered me when I ran and it felt like the bones in my heel were hitting the floor every time I walked. It felt like I had no support whatsoever. Then I learned about HyProCure from my doctor. I had both feet done, my left foot first. It took me a little while, maybe two weeks, to adjust to the new way of walking after the first surgery since I was off balance now that my left foot had an arch, but the right one didn’t. Everything came together after I had my right foot done two months later. Within three weeks after the second procedure, I was walking completely normal. I’m so thankful I had the surgery done!

John

_Because of HyProCure, I don’t hurt._  

Before I was HyProCured, I would trip over myself; my feet turned in and I looked like a penguin when I walked because I kind of waddled. When I played sports it hurt to run. So it made me avoid doing those things. Now I don’t hurt or trip over myself. Today, I barely even know I had it done – it never hurts and I never have a problem with it.
It is important that you read this information completely and carefully. Please initial each section, indicating that you have read the section and understand its meaning.

Dr. ________________________ has explained to me that I have an abnormal alignment between my ankle bone (talus) and the other bones of my rear-foot (tarsal bones) that would benefit from an internal stabilization procedure.

_ _ _ _ _ _ _ _ _ _ 
(Initial here)

I am aware that there are non-surgical forms of treatment, including: no treatment, splints, padding, arch supports, orthotics, medications and special shoes. I am aware there are risks and other potential complications that can be associated with these forms of treatment including progression of the deformity and under-treatment of the condition.

_ _ _ _ _ _ _ _ _ _ 
(Initial here)

I have chosen, after much thought and consideration, including a thorough discussion with my physician, review of various forms of information including websites and brochures, to treat my condition by undergoing a surgical procedure to insert the internal bone stabilization device into my Right/Left hindfoot.

_ _ _ _ _ _ _ _ _ _ 
(Initial here)

I understand that there are potential risks and complications of the insertion of this device into my foot that include: migration or displacement of the device, synovitis (inflammatory reaction with drainage), prolonged soreness from the soft tissues adjusting to the stabilized correction, possibility of not tolerating the correction achieved by the procedure, prolonged period of “adjustment” associated with a period of pain and abnormal walking due to the new foot position, unsatisfactory results, possibility of under- or overcorrection, possibility of improper positioning of the device, healing issues, scarring, infection, need for further surgery (the need to remove the device and/or additional surgical procedures), as well as other risks associated with any surgical procedure.

_ _ _ _ _ _ _ _ _ _ 
(Initial here)

The post-procedure course has been explained to me and I will follow these instructions to the best of my abilities.

_ _ _ _ _ _ _ _ _ _ 
(Initial here)
I understand there is no such thing as a complication-free surgical procedure. Any surgical procedure has potential risks. I have reviewed the “Risk-Benefit Analysis of EOTTS with HyProCure®” and understand it fully. I have had an opportunity to ask any questions of my surgeon and those question(s) have been answered to my satisfaction. I feel that I will benefit from this procedure and it makes sense to me.

I understand there is no guarantee that this procedure will work and while the vast majority of patients who have undergone this procedure have benefited from it, there is a small minority of patients who have not benefitted and ultimately had to have the device removed through no fault of the device or their surgeon.

Patient Name:_________________________  Date:______________

Witness:______________________________  Date:______________

Patient Signature:_____________________

(Parent of Legal Guardian if patient is less than 18 years of age)
Your Extra-Osseous TaloTarsal Stabilization (EOTTS) with HyProCure procedure has been scheduled for:

Day: ____________________________
Date: ____________________________
Time: ____________________________

To minimize the risks of your operative procedure, please follow these instructions:

1. **DO NOT** eat after midnight before your surgery, unless instructed otherwise.
2. You should have your prescriptions filled and obtain your crutches or walker before surgery (if prescribed by your doctor).
3. Talk to your doctor about any medications you currently take and whether you should temporarily stop or reduce these medications. This includes both OTC (over the counter) and prescription medicines.
4. If you smoke, it is advisable for you to stop smoking prior to any surgical procedure and while you are recovering from surgery.
5. Arrange to have someone drive you home following surgery.
6. If you are under 18, a legal guardian or parent must sign an authorization for surgery.
7. Other: ____________________________________________________________________
   ____________________________________________________________________
   ____________________________________________________________________
   ____________________________________________________________________
   ____________________________________________________________________

I hereby certify by my signature that the above instructions were fully explained to me. I will endeavor to follow such instructions to the best of my ability and should any problems arise, I will contact the office immediately.

Signature: ____________________________ Date: ____________________________
(Parent of Legal Guardian if patient is less than 18 years of age)

Witness: ____________________________  Date: ____________________________
POST-EOTTS with HyProCure® Instructions

Your follow-up appointment is:____________________________________________________________

Day       Date       Time

While the amount of discomfort and swelling will vary from patient to patient, for your best personal results, please follow these instructions:

1. Sit sideways in the back seat of the car with the surgical foot elevated, while returning home from surgery.

2. Remain off your feet as much as possible for the first 3-5 days. Place a pillow under your calf so the surgical foot is elevated. It is important to walk as little as possible during this time.

3. Place an ice bag (a bag of frozen peas works best, as the bag is easy to contour over your ankle) over the surgical area 15 minutes out of every hour. This should be continued, as needed, for several weeks following surgery. Ice will significantly decrease inflammation and post-op pain.

4. Remove the dressings after 3 days and apply a strip adherent bandage. Change twice daily, unless you have been given other instructions by your doctor.

5. Wear new and supportive shoes. A “worn out” shoe will hinder your recovery and cause pain. Make sure the shoe you are wearing does not rub against the incision area.

6. DO NOT apply any ointments/gels/creams to the incision area. Do not apply hot water bags or electric heating pads to your foot; this will increase your pain.

7. Keep the operative area completely dry. While it may seem ideal to bathe right after surgery, a wet bandage can cause bacteria to grow and puts you at risk of infection. If the bandage should accidentally get wet, dry immediately with an absorbent towel and call your doctor’s office.

8. A soiled bandage is normal. Do not be alarmed if you see a moderate amount of blood on your bandage after the procedure.

9. Make sure to eat prior to taking any pain medication. Failure to do so may result in nausea, vomiting and/or light-headedness. If this happens, stop taking the pain pills.

10. Follow a light diet and abstain from the use of alcoholic beverages while taking medications. Eating salty foods and/or drinking lots of fluids will increase your swelling.

Call your doctor’s office immediately if you experience any of the following:

- Active and persistent bleeding at the incision site
- Prescribed anti-inflammatory medication is not decreasing your inflammation
- Nausea, vomiting and/or light-headedness due to medication(s)
- You experience a temperature over 101° F
- Should you incur any other problems not discussed in these instructions

I hereby certify that the above instructions were fully explained to me, and I will endeavor to follow them to the best of my ability. Should any problems arise, I will contact my doctor’s office immediately.

Signature: ___________________________ Date: ___________________________
(Parent of Legal Guardian if patient is less than 18 years of age)

Witness: ___________________________ Date: ___________________________
Post-EOTTS with HyProCure® Successful Recuperation Hints

Stay off your foot as much as possible.
Every step you take leads to increased trauma of the surgical site. The highest level of post-procedure inflammation is in the first three to five days. Rest and elevate your surgical foot as much as possible during this time.

However, you do need to use your foot.
If you “baby” your foot too much it will take longer for the soft tissues to adapt to their new functions. “Listen” to your foot; it will let you know when you are doing too much. When your foot really gets sore, take a break and let it rest. After a short time you should be able to do more. Be sensible.

Take an oral anti-inflammatory (if prescribed).
The primary reason for post-procedure pain is inflammation. A pain pill masks the pain, but does not treat the underlying reason the pain is still present – inflammation. Make sure the oral anti-inflammatory is working. There are many different brands; one could be effective for one person while not having any effect for someone else. You should feel at least some relief within a half-hour after taking the medication.

Pain pill use should be reserved for extreme pain.
You should take one pain pill prior to your anesthetic wearing off the day of surgery, possibly one prior to going to bed that evening, and finally, one the next morning. After that, pain-pill use should be a last resort if the anti-inflammatory is not working. Just like the anti-inflammatory medication, make sure the pain medication is working. If you don’t feel any improvement in the pain within a half-hour, it may not be effective for you.

Ice is your best friend.
Ice helps to decrease inflammation and swelling. Also ensure that you elevate your foot at least 10 to 15 minutes an hour. Ice should be used hourly the first 3 to 5 days, and then slowly decreased. However, ice should be used at least once or twice in the evening for several weeks following surgery. We suggest using a moist dish towel and a bag of frozen peas. Application for approximately 15 minutes is usually sufficient.

Bandages must be applied to keep the site of incision clean and dry.
However, make sure your bandages are not contributing to post-procedure pain. Your foot may develop some swelling and the bandage can act as a tourniquet. If your bandage feels extremely tight and your toes are swelling, have the bandage replaced.

New shoes will aid in a quicker recovery.
After your procedure, it is extremely important not to wear your old shoes. Discard your worn out shoes, as they will lead to increased strain on your tissues. The wear pattern on these shoes will counter-act the correction. You may notice a slight increase in soreness several months after your procedure most-likely due to the wearing of a worn out heel on your shoe.
Common Questions about EOTTS with HyProCure®

Is there drilling or screwing involved in the procedure?
There is no drilling or screwing involved with the HyProCure procedure. A small incision is made in the skin above the sinus tarsi and the stent simply slides into the natural space inside the foot. The threads on the stent are only to allow for the scar tissue to form around the grooves and lock the device in place during the normal healing process.

Are there any limitations, as far as sports go, after this procedure?
Once the tissues surrounding the stent are healed, there should be no limitation. The abnormal motion is no longer present and normal motion will occur. Usually, there is a significant improvement in running, jumping—any activity involving propulsion from the foot.

Can I still get MRIs, CT scans, etc. with HyProCure in my foot?
Yes. HyProCure is made from medical grade titanium. However, as with any procedural implant, you should inform your doctors of the implant and follow their recommendation.

If this procedure is performed on a child, does it have to be replaced later in life?
The short answer is likely no, but this is not a guarantee. Normally, once the stent is inserted into the foot it rarely has to be changed. The bones will continue to grow peripherally around HyProCure.

What are the chances of having an allergic reaction to this implant?
Titanium is the choice material used in the body since it is the least reactive. HyProCure is made entirely of medical grade titanium. Some patients develop what appears to be an allergic reaction, but this is the result of chronic inflammation of the foot.

Will I feel the implant in my foot?
As long as the implant does not displace, you should not be able to feel HyProCure after the procedure. Sometimes for the first few months a hard substance may be felt in the area of the surgery. This is scar tissue and should dissipate after several months, if present at all.

Will there be a visible scar?
The incision is less than an inch long and slender and this part of the skin heals remarkably well. With time, the scar will continue to fade.

After the HyProCure procedure, will I need to be pre-medicated prior to dental treatment or other future surgical procedures?
You will not need to pre-medicate prior to dental or other surgical procedures because the HyProCure stent is not embedded into the bone.

Will this implant get rid of all of the pains in my body?
No one can completely predict the outcome of any surgical procedure, but this solution should help improve your entire body’s alignment. As a consequence, reduction and relief of many pains caused by the foot imbalance will also be reduced or eliminated. However, it is possible that some of the joints and soft tissues in the body may have already suffered irreversible wear and tear, and in those cases other treatments or procedures might be necessary. In either case, correcting the root of the problem is still essential to stopping any further damage and to allowing for any additional therapies (if necessary) to be long lasting.

Will I still have to wear my orthotics after the procedure?
There are other reasons for orthotics to be worn. Orthotics can be used to off-weight prominent areas to the bottom of the foot. If those areas are not surgically addressed, then orthotics may still be required after the procedure.

Are there limitations to this procedure?
Yes, every surgical procedure has its limitations. In very severe cases of talotarsal displacement, other surgical procedures may be necessary to achieve optimum correction.
Physician Endorsements

Mark Jones, DPM

*If it worked for the doctor, maybe it’s right for you!*

I choose HyProCure for my patients because it worked so well for me. Three months after my HyProCure procedure, I was able to return to long distance running, tennis and basketball, as well as playing with my kids. When I recommend the procedure to patients, I think it’s valuable to them that I know what it feels like to go through. Not to mention, I’m a success story – if it worked for the doctor, maybe it’s right for you.

Joseph Picciotti, DPM

*HyProCure has been amazing in the way it lets me help my patients.*

HyProCure is an incredible addition to my practice; I’ve been using it for several years now. Because HyProCure is minimally invasive and can be done under local anesthesia, it offers me the ability to do the procedure in the office operating room where a family member can be with the child and keep them calm. It has been remarkably beneficial to the child and family.

After surgery and recovery, I’ve heard from grateful parents whose child could now walk for the first time. For instance, I spoke with a young man’s mother who was in tears of joy because her son had walked into the kitchen to give her a hug when he had never been able to walk independently before. HyProCure has just been an amazing addition to what I can offer my patients.

Darlene Kulhan, DPM

*After 35 years in practice, HyProCure makes it possible for me to offer a proven solution to fix the underlying cause to my patients symptoms.*

HyProCure opens a whole new avenue of corrective treatments for patients with abnormal pronation and talotarsal displacement. Prior to this, we could only offer orthotics to try and control hyperpronation, but now we can actually correct the displacement.

Barry Klein, DPM

*I’ve been able to use HyProCure to replace more radical surgeries.*

Prior to HyProCure, my patients required major reconstructive surgery to correct the things I’m now doing with HyProCure alone. It’s a quick, minimally invasive procedure that only takes about 15 minutes.

The thing that really impressed me about HyProCure was the first patient I had. She had tarsal tunnel syndrome, plantar fasciitis, a flexible bunion and a flexible hammertoe. I was going to do many procedures to correct this, but I decided to try HyProCure by itself first. Following the procedure, all of patient’s symptoms were resolved! She was so thrilled that she decided to do her other foot as well.

Joel Chariton, DPM

*HyProCure Is A Gift!*

I wanted to share that a recent 10-year old patient of mine has now had two HyProCure procedures. Just two weeks after the second stent, she is running and playing with a scooter, all without pain! Thank you again for the wonderful gift you have given both our patients and our doctors.