

Fuse Right Hammer Toe Solution by FootScientific, Inc.

Cost Advantage *O.R. Ease and Speed Advantage* *Quality Advantage*

Training Packet

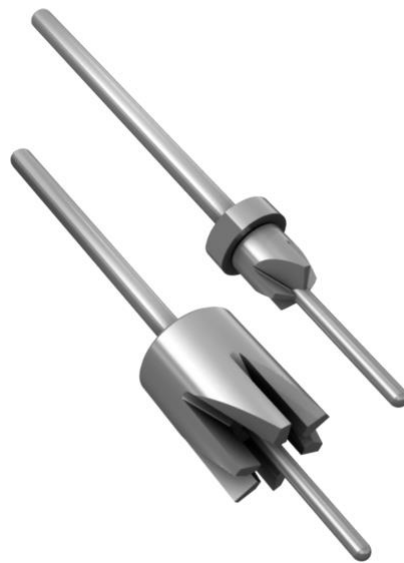


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Fuse Right Hammer Toe Solution Features:

The **Fuse Right™** surgical experience encompasses thousands of procedures in over fifteen years. Revision rates have been remarkably low due to the high fusion rates enabled with this system. We are now offering this as a reusable solution at low cost.

Patients report less pain and swelling than with traditional PIP arthroplasty or fusion procedures, and are generally satisfied with the knowledge they do not have a permanent implant in place.

Surgeons report reduced healing times, reduced infection rates, reduced non-compliance complications, and markedly reduced revision rates.

Fuse Right™ is designed for greater precision, improved ease of use, and precise peg and socket creation while reducing the risk of excessive bone removal. **Fuse Right™** also controls for incremental toe shortening and provides post-operative toe stability and repeatability of outcomes.

Fuse Right is Ideally Suited for the Following Conditions:

1. Classic hammer toe deformity.
2. Minimal to moderate transverse plane deviation (varus/valgus), associated with a rigid flexion contracture of the PIP joint.
3. A revision hammer toe procedure where “molding” has occurred and the toe has deformed after a prior procedure. Using **Fuse Right™**, the toe can be salvaged and stabilized, reliably resisting deformation at the PIP joint over time.
4. Any Proximal Interphalangeal (PIP) joint deformity, rigid or flexible with early dislocation or subluxation of the Metatarso-phalangeal (MTP) joint.

Revision procedures using Fuse Right are less common than with conventional PIP arthroplasty techniques. **Fuse Right™** represents a new generation of this class of device, designed for greater precision, ease of use and precise peg and socket creation with less worry of removing excessive bone. **Fuse Right™** also allows control of incremental toe shortening as desired. Post-operative toe stability and repeatability of outcomes are the critical features of **Fuse Right™**.

Patient Comfort / Convenience / Healing Time:

While most hammer toe procedures require about 4 weeks for initial recovery, the immediate stability created by Fuse Right generally results in:

- Less pain in all stages of healing
- Reduction in the healing time of soft tissues, resulting in reduced infection risk
- In the rare case of hammer toe revision surgery, a prior Fuse Right procedure leaves no implant in place and preserves the bone stock. This provides a less complex remedy relative to the difficulty and dangers associated with implant revisions

Ease and speed of Use:

- **Fuse Right™** comes complete with reamers, pilot drill, implants (threaded and smooth wires of ideal length) and pin caps.
- Strong and reliable construct *even without* an implant or wire for all toes with adequate bone stock.

Practitioners will generally achieve adequate comfort and proficiency after 6-10 hammer toe procedures. A competent surgical assistant will be valuable in ensuring soft tissue protection. Review of the surgical video is recommended prior to first use.

Comparison to Other Procedures:

1. **Tendon transfer** (Girdlestone-Taylor): Viable alternative to **Fuse Right™** when intervening on a “flexible hammer toe”.
2. **Arthroplasty** (Flat-Cut): Often leads to molding, and the toe remains vulnerable to gradual deformity and eventual dysfunction. Greater vulnerability to Infection.
3. **Flat-cut Fusion**: Also much more vulnerable to non-union and molding than with the use of **Fuse Right™**. Greater vulnerability to infection
4. **Implant Arthroplasty** (or fusion):

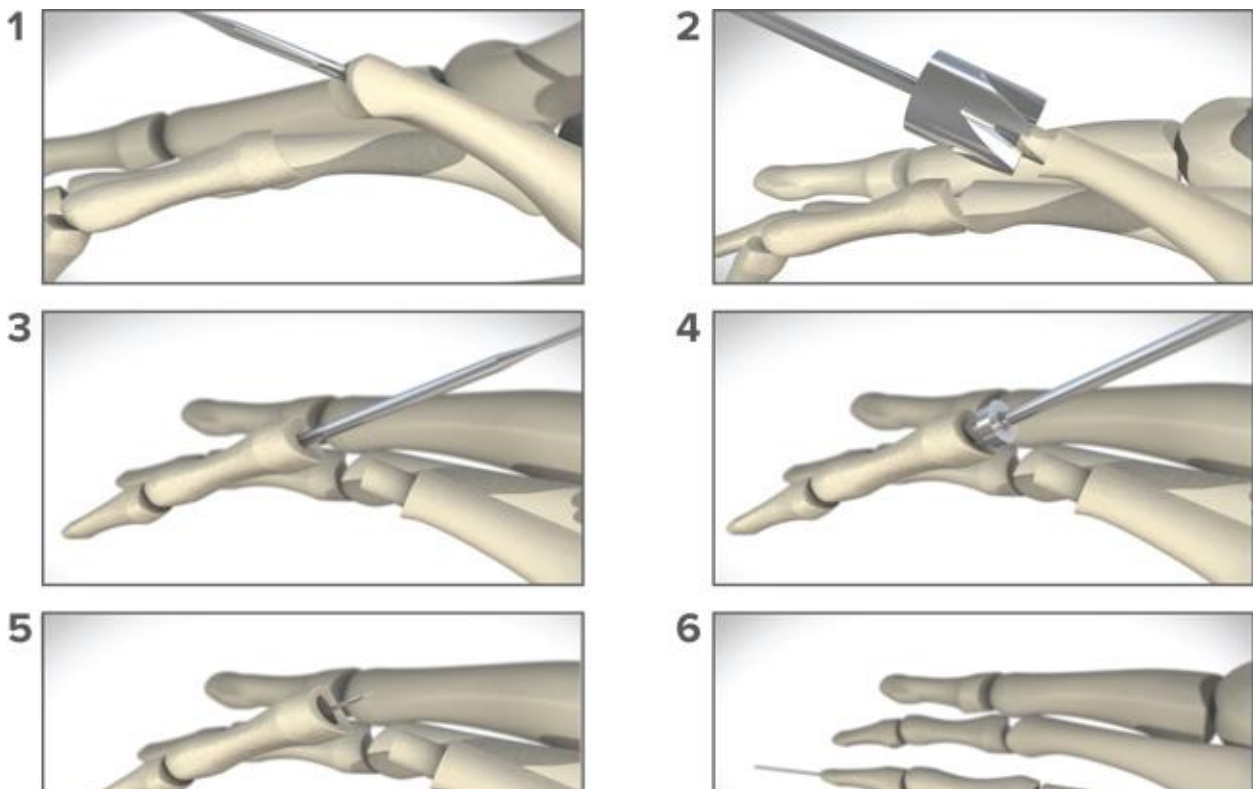
COST: Significantly more costly than **Fuse Right™** and especially given the option **Fuse Right™** offers for several toe corrections in one procedure without added cost and the benefit inherent in its durability as a reusable device.

TIME: Fuse Right.™ takes less time in the O.R. than typical implant work – can be consistently less than 10 to 12 minutes per toe. Implants can interfere with revision surgery resulting in increased complication rates and precious operating room time

QUALITY: Similar stability to fusion implants, but the natural, bone to bone connection is preferable to a very large segment of providers, many of whom insist on performing flat cut fusions for lack of a better alternative that considers time, cost, and ease of use. A retained metal implant in a lesser toe has also shown to be a comfort issue for many patients, sometimes well after surgery.

Because Fuse Right avoids the use of an intramedullary permanent implant, the system provides a useful solution for the treatment of “crossover toe” or MTP varus or valgus deformity. During a **Fuse Right™** procedure, the surgeon can advance an adequately sized k-wire across the MPJ to help correct for this issue.

Finally, a ten degree angle is achievable with **Fuse Right™** which is not the case with many procedures/products.



Fuse Right Hammer Toe Solution FAQ's:





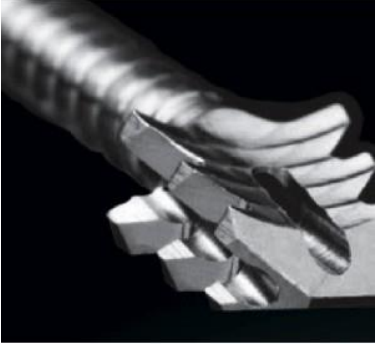

QUESTIONS	ANSWERS
What fusion percentages do you have over the last 15 years?	We estimate a 91-97% fusion rate. In the remaining (symptomatic) fibrous non-unions, the Fuse Right system can usually be used to effectively revise the fusion following initial debridement.
What comes in the kit?	1 Female Reamer 1 Male Reamer
What mm is the toe shortened?	2-4 millimeters
How do I achieve the 10-degree angle?	The final peg angle is achieved by drilling the pilot hole drill at the desired angle relative to the long axis of the phalanx. Recommended angle is between 1 and 10 degrees, and may result in the drill exiting the dorsal cortex if aiming for a 10 degree or higher angle.
Is it re-usable or disposable?	It is re-usable for up to 8 toes after which the surgical center should carefully monitor flute edge dullness, and replace at an absolute maximum of 15 toes.
Can I cross the MPJ?	Yes, Fuse Right allows the K-Wire or Bio-pin to cross the MPJ when needed. Note that the pin will follow the path of the initial pilot hole.
How does it compare to a flat cut arthroplasty?	A flat cut has reduced stability relative to a stable peg and hole construct. Increased potential for Molding with adjacent toes, chronic swelling, and eventual dysfunction results from non-unions following flat cut procedures.
Can you use it on a diabetic foot?	Yes.
Can you use it on the 5 th digit?	Yes. This is best performed on a 3-bone 5 th toe. Symptomatic stiffness can result in the presence of a delta phalanx.
Can you use it on a patient with osteoporosis or low quality bone stock?	Yes. We recommend using a new set of reamers in patients with osteoporotic bone due to the increased risk of fracture with dull devices.
How long does the k-wire stay in?	We recommend 4 weeks as a routine, with up to 6 weeks in revisions - or per surgeon preference.
How much time in the OR?	After the initial 3-5 case surgeon experience, average procedure time ranges 5-15 minutes.



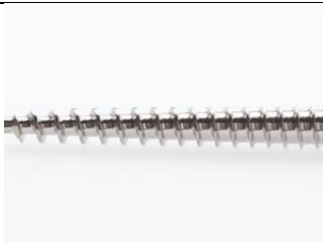


What do you do if you have to revise it?	Fuse Right system is especially tailored to effectively revise a PIP fusion non-union using standard technique after non-union debridement.
What happens if the peg breaks off?	Peg fracture is rare but can occur in osteoporotic bone. Repeat reaming typically restores stability with minimal shortening.
Is there adequate bone in the peg?	Greater than 50% of metaphyseal bone remains in the peg, leaving a cancellous outer surface for increased surface area for fusion. Peg fracture seldomly presents as an issue.
Have you had swelling occur?	The peg and hole construct creates immediate stability, reducing the incidence of prolonged post-operative swelling often seen in flat-cut fusion or arthroplasty.

Fuse Right Hammer Toe Solution Cost Comparison:

All prices shown represent a typical market representation taken from 2015. Please help us keep this updated.

Product Name:	Graphic Representation:	MSRP:	Notes:
FootMind, Inc.: Fuse Right Hammer Toe Solution		\$69.00 per toe*	*With an initial price of \$690.00, if the surgical center reams only ten toes the price is \$69.00 per toe. 15 toes = \$46 per toe.
Wright Medical: Pro-Toe VO		\$655.00	
Stryker: Smart-Toe		\$800.00	
Ortho Helix: IFS		\$1620 (2012)	
Orthopro: iFuse HT	 <p><i>iFuse HT Angled Implant</i></p>	\$1350	

<p>BME: Hammer Lock</p>		<p>\$1150</p>	
<p>Acumed: Biotrak Pin</p>		<p>\$492 (2011)</p>	
<p>Metasurg: Digifuse</p>		<p>\$400 (2012)</p>	
<p>Stryker: X-Fuse</p>		<p>\$1025 (2011)</p>	
<p>OsteoMed: ExtremiFuse Hammertoe Fixation System</p>		<p>Info unavail.</p>	
<p>Trilliant Surgical: Two-Step Hammer Toe Implant System</p>		<p>Info unavail.</p>	

<p>Nextremity Solutions: Nextra Hammertoe Implant</p>		<p>Info unavail.</p>	
<p>Biomet: Weil-Carver Hammertoe Implant</p>		<p>Info unavail.</p>	
<p>Acumed: Hammertoe Fusion Set</p>		<p>Info unavail.</p>	
<p>Wright Medical: Weil Hammertoe Implant</p>		<p>Info unavail.</p>	
<p>Integra: IPP-ON</p>		<p>Info unavail.</p>	

<p>Arrowhead: Arrow Lok Hybrid</p>		<p>Info unavail.</p>	
<p>Tornier: Stay Fuse</p>		<p>Info unavail.</p>	
<p>Solana Surgical: Ten Fuse PIP</p>		<p>Info unavail.</p>	
<p>Tornier RFS</p>		<p>\$184 + \$83 (Disposable Applicator)</p>	
<p>Arthrex: Trim-it Pin</p>		<p>\$190.00</p>	

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use Right Hammer Toe Solution Marketing Material:

www.FootScientific.com

Dr. Robert Faux's Fuse Right Hammer Toe Solution Training Transcript:

ASC's and many hospitals continue to see the implantation of toe fusion devices, many of which are comprised of metals of various thicknesses and lengths. The size of these implants relative to the volume of a lesser toe creates a potential for cold intolerance and thermal conduction-related discomfort. Permanent toe fusion implants also add significant complexity to revision hammer toe surgery that can result in bone loss and vascular compromise. All of these elements argue against the implantation of toe fusion devices where feasible.

Secondarily, the cost of the majority of implants is unsustainably high, especially as each toe receiving correction needs its own implant. It is not uncommon for up to 4 hammertoe procedures to be performed in one surgery, making the ASC expense prohibitive. This problematic expense positions Fuse Right as a disruptive device that allows for the stability of a fusion implant without the patient intolerance issues, the revision surgery problems and with significant cost savings for ASC's and hospital systems.

My understanding is that reimbursement for hammertoe fusions (28285) for most ASCs ranges from \$250-500 and hospitals is marginally higher. If the implant costs \$400-1100 per toe (in some cases higher), ASCs stand to lose substantial revenue on each hammer toe procedure scheduled. These losses won't be sustainable. We're going to see that the market will drive us to perform hammertoe fusions without an implant – returning to the less stable K-Wire-only construct (flat cut fusion, or arthroplasty). The type of permanent that works consistently with Fuse Right is an absorbable implant, which is less expensive and does not require subsequent removal.

The pilot drill or k-wire initiates a pilot hole in both ends of the joint and then the male and female reamers are used. The length of surgery, once a surgeon feels comfortable with it, averages about 10 minutes. The procedure time approaches and can even exceed traditional arthroplasty or flat-cut procedures for PIP fusion. The male reamer decorticates the joint and creates a peg that protrudes from the proximal phalanx, and the receptacle on the opposite side is created by the female reamer. This construct interdigitates to effectively create a very stable fusion sight that dramatically improves the likelihood of fusion. The pin / k-wire or bio-absorbable implant adds additional stability. Symptomatic non-unions are exceedingly rare in my experience.

Some of the key concepts:

Stability, potentially implant free, reduced molding, it doesn't shorten the toe excessively, and soft tissues fare better during and after surgery than with most hammertoe surgical alternatives.

Surgeon preference for MPJ/MTP crossing options during hammer toe reconstruction makes Fuse Right an essential tool for many. The vast majority of PIP fusion implants limit Proximal joint stabilizing options. Those offered typically allow only a smaller diameter k-wire to pass through the implant,

creating a higher risk for wire deformation or breakage. Fuse Right is designed to be used with a smooth 0.0625 in. K-wire that can be easily driven across the proximal joint after adequate joint collateral ligament release/reefing and/or tendon transfer procedures. Only Fuse right can help correct toes from crossing over later.

A higher degree flexion angle for PIP fusion can be achieved by planning the pilot drill angle for the proximal phalanx at the desired acuity. The drill then exits the dorsal cortex to achieve this. For this reason, crossing the proximal (MTP/MPJ) joint The 10-degree angle is not recommended when crossing the MTP joint to stabilize proximal instability.

K-wire fixation for hammer toe repairs is often criticized for infection risk and for difficulty in achieving consistent central placement of the wire. Implants are often justified as a means to avoid post-op infection risk.

Infection risk is increased in k-wire fixation from the obvious explanation of the exposed wire and open pathway past the body's defenses. Less discussed is the greater factor of reduced stability from flat-cut fusion constructs and the micromotion created thereby. This motion increases the incidence of early pin loosening and soft tissue microtrauma, both of which markedly increase infection risk.

Fuse right dramatically reduces this infection risk from wires by creating immediate stability of the construct that reduces micromotion and soft-tissue trauma.

In my experience, Fuse right has dramatically reduced my infection rate with pins in toes. Cellulitis is rare and post-op swelling seems significantly reduced. I would estimate my infection rate with the system at less than 2-3% or better. I also feel greater confidence in the stability of the surgery and its outcome if I have to pull a pin earlier than planned because of the intrinsic stability of the peg and hole construct. Early pin removal after a flat-cut fusion invariably leads to immediate deformity due to lack of stability.

Secondly, k-wire insertion accuracy is consistently straightforward due to the pilot hole placement with the starting drill or wire. I can't recall ever failing to position the wire centrally in any of these surgeries because the pilot hole that was originally drilled down the phalanx, or soft center of the bone, creates a guide for the pin; it always goes in and out the same way. Perhaps the only challenging part of the surgery is pilot hole placement, but its not that difficult because it tends to find its own path down the center of the canal.

Q: Do you ever drill and then check with an X-Ray?

A: You could, but, no. The drill automatically guides itself into the phalanx. You can actually tell the surgeon that once he's started drilling, it will "fall in". You want to try to get it drilled so that it drops into the phalanx and falls in and down the center. With the middle phalanx, it's not going to find it's way because you're holding the toe in extension. Basically, you're holding the DIP joint in extension when you drill. you begin at the center of the middle phalanx base, then you direct the drill out the end of the distal phalanx closer to the nail to avoid hyperextension of the DIP joint. This drill path will determine the later trajectory of the k-wire. The pilot hole should be drilled completely to the base off the proximal phalanx and out the end of the distal phalanx.

For efficiency when using an assistant for retraction, I usually complete the pilot drill and reamer steps together first on the proximal phalanx and then on the distal side. This avoids unnecessary changes of position for the assistant and streamlines the sequence. It's usually easier to drill one, ream it, drill the other, ream it and then put in your pins.

The equipment that we recommend is Microaire's pencil grip airpower, Hall Micro, or TPS. (Anything that has a pencil grip for precision.) A pistol grip can also be used effectively with the pilot drill/k-wire and individual reamers (peg and hole cutters) utilizing the large and small pin collets.

Most of the guys you will be selling this to have extensive experience with hammer toe surgeries. PIP fusion is the most frequent CPT code in foot and ankle. I think it takes between 4 and 10 of these procedures to become reasonably competent.

Q. Can it be used on the fifth toe?

A. The hole cutter/reamer can sometimes exceed the diameter of a small 5th middle phalanx and ream out a cortex on one side. If this occurs, the stability remains very acceptable and the surgeon can proceed with fixation. If anticipated, I recommend cheating slightly more in a plantar direction with the starting hole to keep the dorsal cortex intact. We prefer to have at least 75 % remaining circumferential cortex to have reliable stability

The K-Wire typically exits and remains partially (1 cm) outside the end of the toe. I'll bend it if it's smooth, or cut and cap a threaded pin. One of the potential benefits of Fuse Right, is that it creates such a stable fusion, that if you *don't* want to use K-Wires, you have at least a stable fusion construct in most cases, and with adequate dressings around the foot, even without that K-Wire, the stability of the fusion is significant. As with the use of an absorbable pin, the healing occurs without the need to remove the pin later. Not using a k-wire or an absorbable pin will work, especially with good bone stock. However, The K-wire or a pin adds significant stability to the final construct and should be usually recommended.

The reamer can be safely used for between 8 to 15 procedures. The stainless steel alloy used in production is fully sterilizable and reusable. Surgical center reuse is an individual decision but generally not recommended.

I see fibrous non-unions about 8% of the time, the majority of which are asymptomatic. Arthroplasty, or flat cut fusion, results in fibrous non-union much more frequently.

If used as an alternative to toe fusion implants, Fuse Right has the potential to significantly reduce costs and thus increase ASC and hospital profits. The only thing that has any form of comparison is Pro-Toe (in terms of price), and the lowest I've seen prices driven down for an implant is \$400 for one implant plus a \$100 kit. That is \$500 for the first toe and \$ 400 thereafter. My experience is that surgeons will average between 1 and 2 hammertoe procedures per surgery... I would say about 1.6 hammertoes per time on average.

Also, there is moderate controversy over the use of fusion implants... Some surgeons routinely utilize them, others philosophically avoid them in PIP fusion surgery (advocating flat cut and k-wire as the only reasonable option). , We feel that Fuse Right meets the needs and expectations of both groups of surgeon preferences with the stability of an implant and improved outcomes over flatcut techniques. This special niche makes Fuse Right a potentially market-changing disruptive technology.