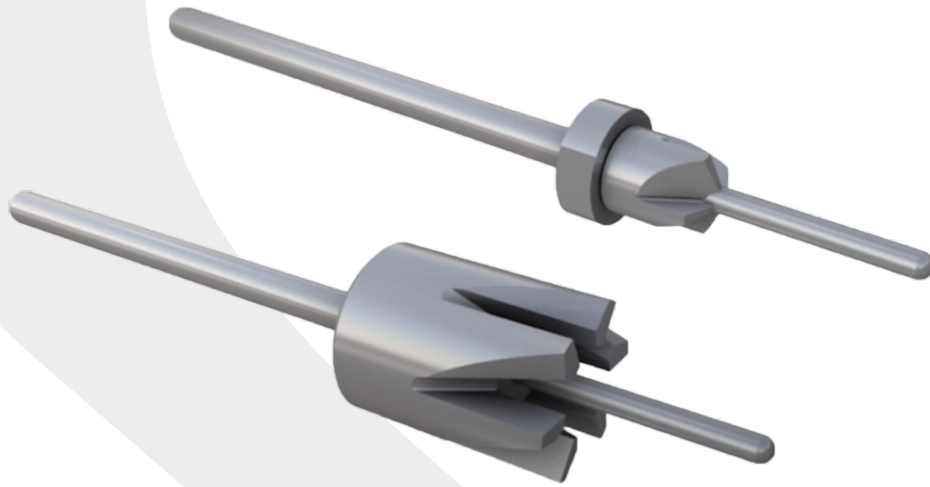


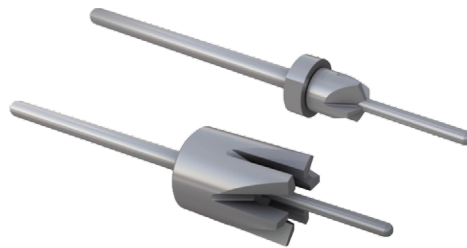
FuzeRight

Peg & Hole Reamers



DESCRIPTION OF THE MEDICAL DEVICE

FuzeRight is constructed of 17-4 Stainless steel having a long history of safe medical use. Two reamers act on opposing sides of the PIP joint to create a stable peg and hole solution for correcting hammer toe and other PIP deformities. The FuzeRight Instrumentation Kit includes the male and female reamers. FuzeRight has a history of safe medical use, and it has been shown to be effective in laboratory and clinical testing and use. FuzeRight is delivered as a single-use, non-sterile set of one male and one female reamer. Each instrument requires sterilization prior to use.



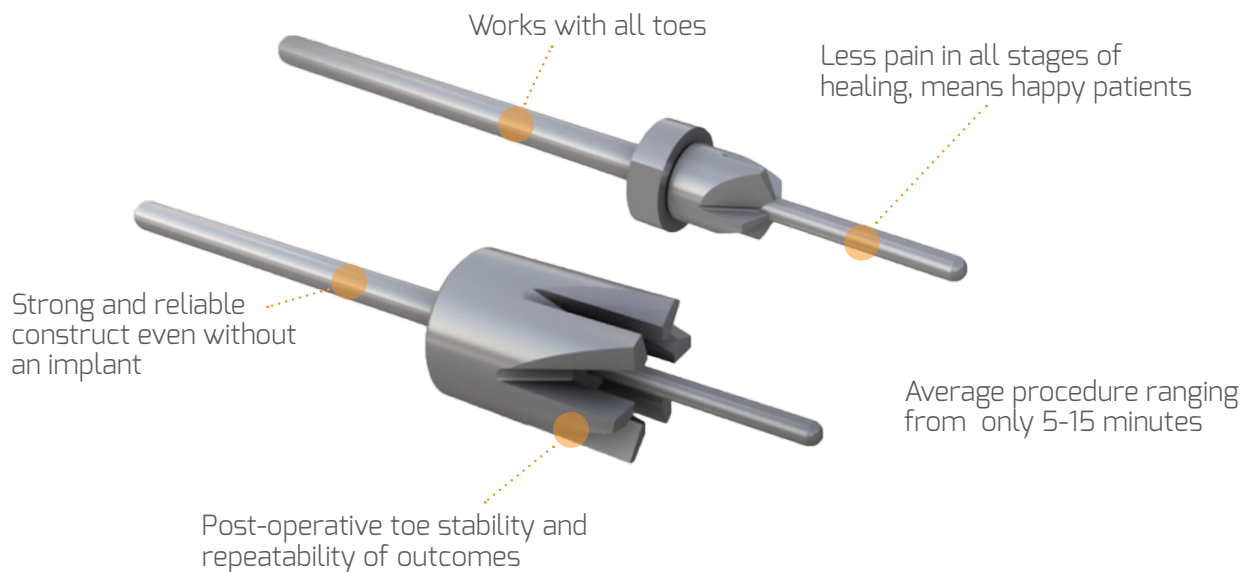
INDICATIONS FOR USE

1. Any Proximal Interphalangeal (PIP) joint deformity.
2. Classic hammer toe deformity.
3. Minimal transverse plane deviation (varus/valgus), associated with a rigid flexion contracture of the PIP joint.
4. A revision hammer toe procedure in the setting of non-union or malunion after a prior intervention. Using FuzeRight, the toe may be salvaged and stabilized; reliably resisting deformation at the PIP joint over time.
5. Any Rigid or flexible PIP joint deformity with early dislocation or subluxation of the Metatarso-Phalangeal (MTP) joint as a component of overall toe reconstruction when accompanied by appropriate MTP realignment procedures.

CONTRAINDICATIONS

- High-load bearing applications.
- Situations where internal fixation is otherwise contraindicated, e.g., active or potential infection and where patient compliance is not expected.
- Inadequate bone stock as determined by pre-operative x-ray evaluation (relative contraindication).

Ease-of-Use & Comfort



FAQs

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?

The kit is provided sterile packed consisting of one male reamer, one female reamer, and two k-wires.

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 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.

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.

What mm is the toe shortened?

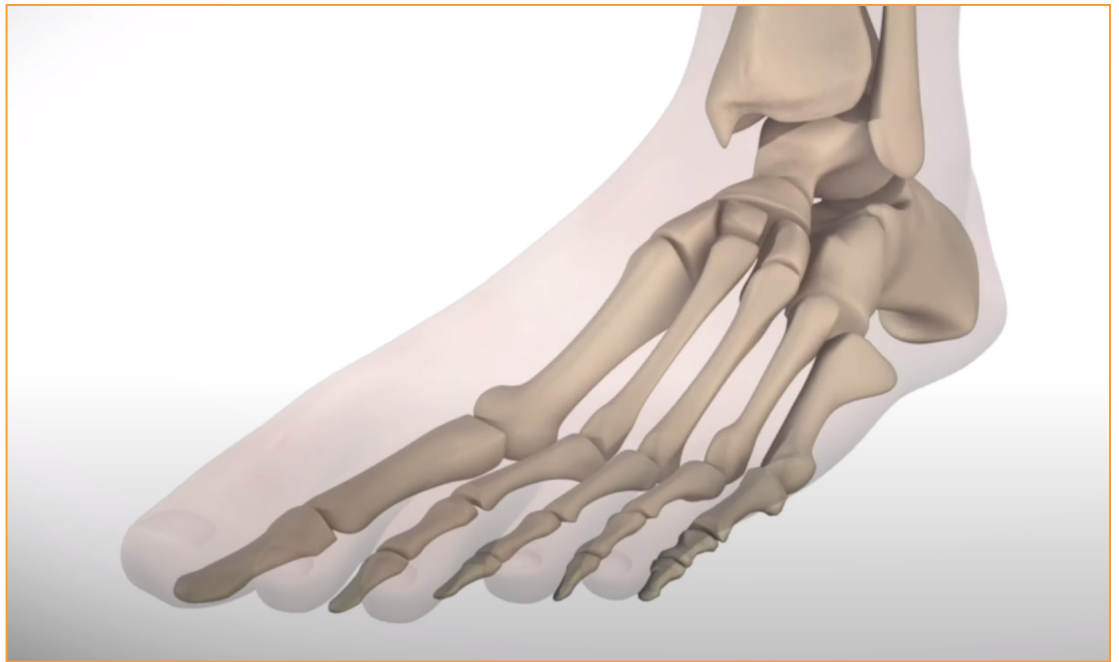
2-4 millimeters.

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.

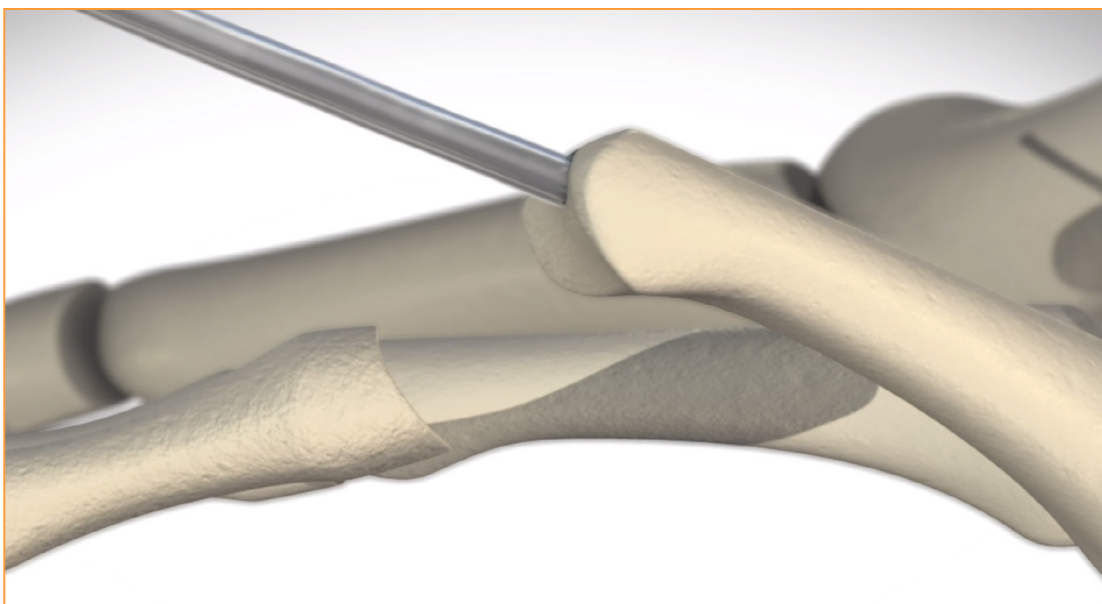
Can I cross the MPJ?

Yes, Fuse Right allows the K-Wire to cross the MPJ when needed. Note that the pin will follow the path of the initial pilot hole.

**PRE-OP**

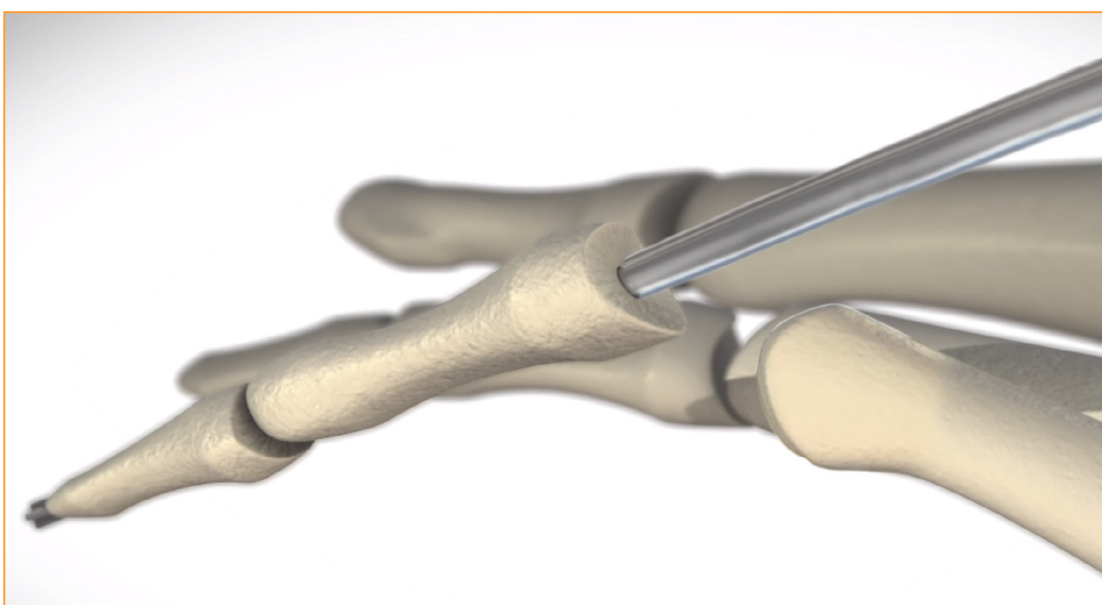
An ankle Esmark 4 inch bandage is used as a sterile tourniquet (a pneumatic ankle, calf or thigh tourniquet may also be used). The MTP (metatarso-phalangeal) joint is approached with an oblique incision, 1.5 cm in length. The Long and short extensor tendons are released transversely. The dorsal capsule, medial and lateral collateral ligaments are sharply released down to the plantar plate, leaving the plantar plate intact.

The PIP joint is approached with a longitudinal incision, 1.5 cm in length. The dorsal capsule is sharply delineated and then a transverse capsulotomy is performed, sharply releasing the dorsal capsule and the collateral ligaments. The plantar capsule is then elevated from off the base of the middle phalanx and the head of the proximal phalanx. Excess dorsal capsule and extensor hood is excised down to the level of planned peg length to clear the surgical area.



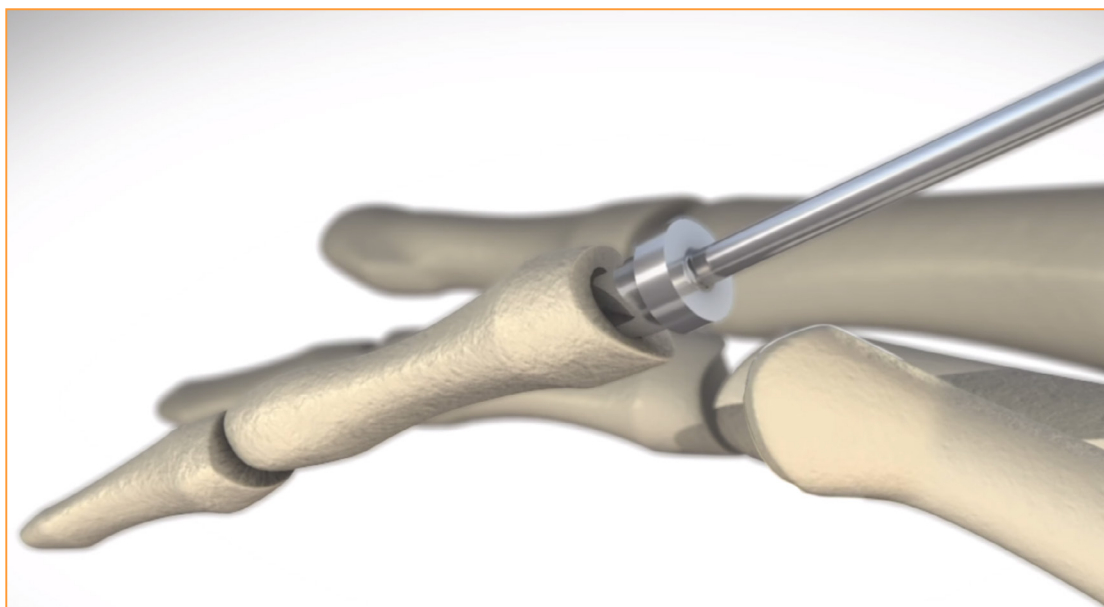
1

The PIP joint is acutely flexed to expose the proximal phalanx head, and the head is grasped by the surgeon with a forcep, stabilizing the phalanx. An assistant protects the soft tissues with narrow 2-prong skin hook retractors. Using a K-Wire create an axial guide hole beginning at the inter-condylar notch, at the sagittal midline, drilling down the center of the medullary canal, ending at the base of the phalanx (the MTP joint is not penetrated).

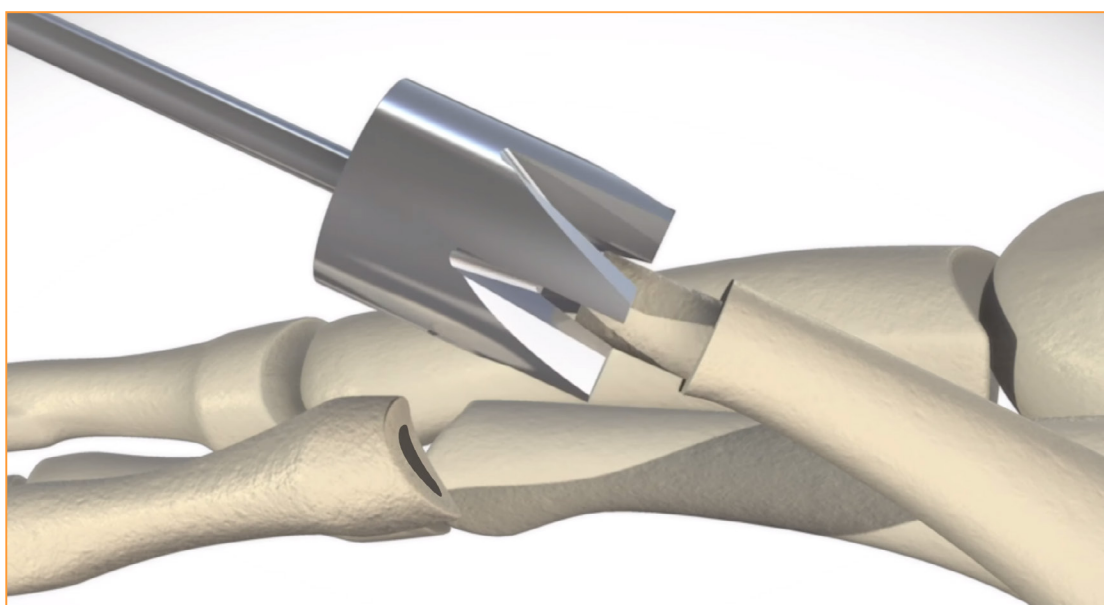


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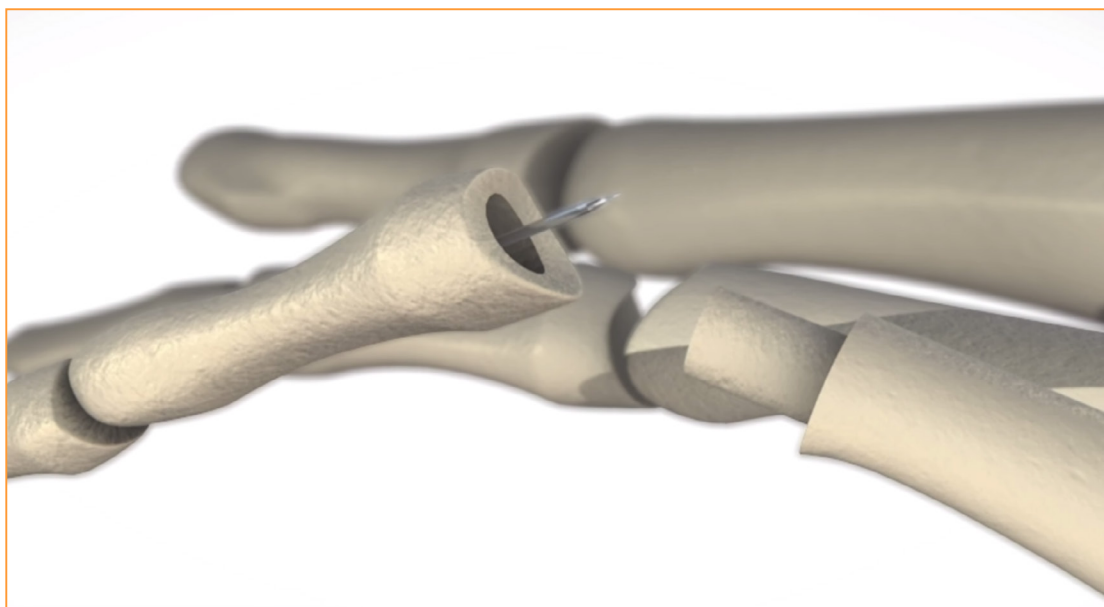
The base of the middle phalanx is then exposed. The soft tissues are again retracted for visualization and protection with skin hooks. Using a K-wire create an axial guide hole beginning at the center of the articular surface of the middle phalanx with the DIP joint held in an extended position, drilling across the middle phalanx, the DIP joint and across the distal phalanx.

**3**

The female FuzeRight reamer guide post is then inserted into the pre-drilled hole in the middle phalanx and the receptacle is reamed, again using care to avoid heating of the bone with a gentle bouncing axial motion until the reamer has reached its end point. Light saline irrigation can be helpful for reducing heat generation. The joint is further irrigated to wash away any debris.

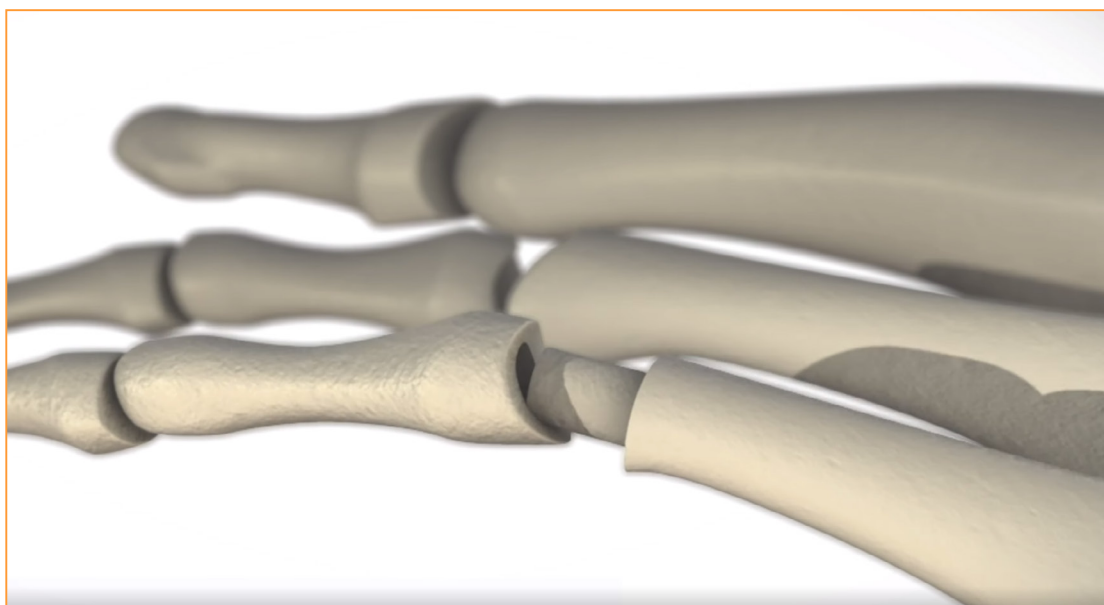
**4**

The male FuzeRight reamer guide post is then inserted into the pre-drilled hole and the peg is reamed, using care to avoid heating of the bone with a gentle bouncing axial motion until the reamer has reached its end point. Light saline irrigation can be helpful for reducing heat generation. A small rongeur is then used to resect any residual bone or soft tissue remaining around the base of the reamed peg to allow for a flush connection of the fusion site.



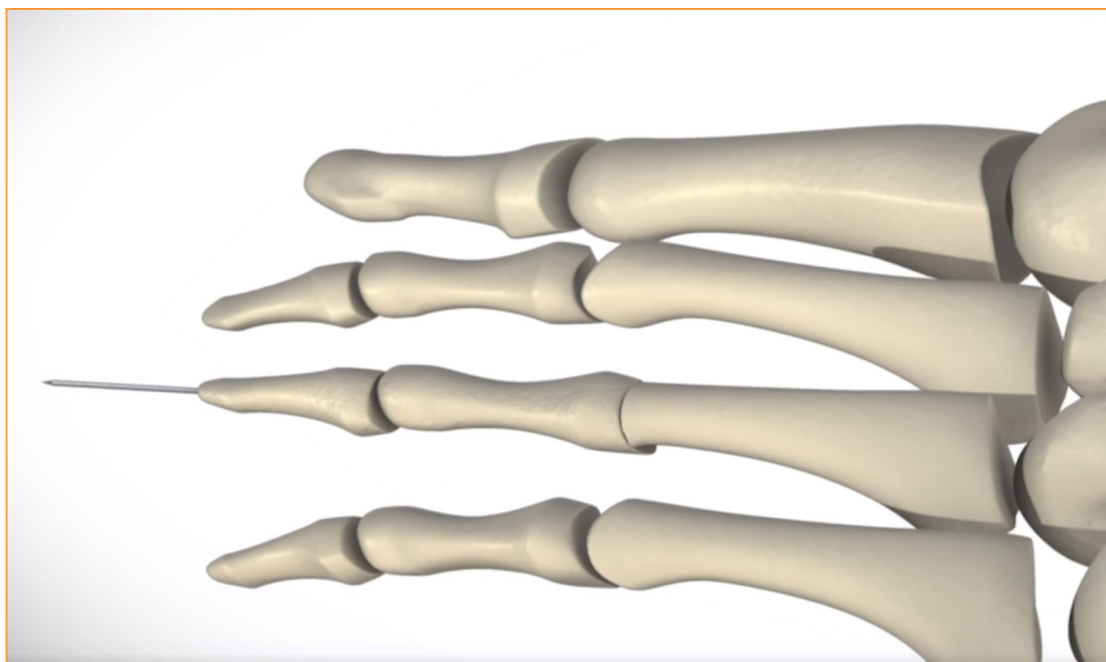
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A 1.6 mm K-wire is driven first retrograde out the end of the toe from the middle phalanx receptacle hole.



6

The fusion peg is then gently inserted into the receptacle using a mild distraction force on the toe while extending the PIP joint. The fusion site is gently compressed together, and while the surgeon holds the fusion in a secure position, an assistant drills the pin anterograde across the PIP joint and to the base of the proximal phalanx.

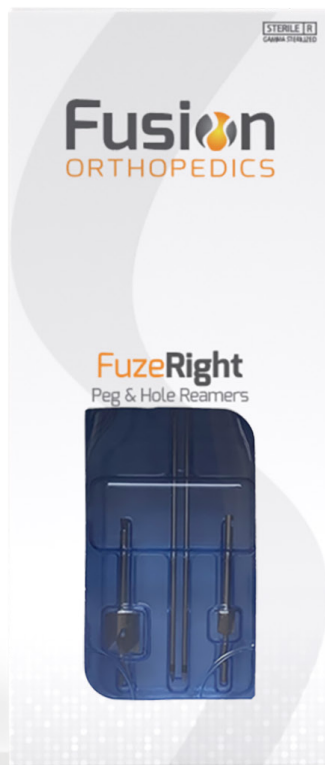


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The pin is trimmed and/or bent and capped. The wounds are reapproximated with interrupted 4-0 or 5-0 nylon sutures. A forefoot dressing is then applied, and remains in place for the first week. A post-op surgical shoe is applied and used for at least 4 weeks after surgery.

POST-OP

The patient is instructed to walk with a foot-forward, flatfoot gait until the pin removal at 4 weeks post-operatively. If an absorbable pin is used, the surgical shoe and gait instructions remain the same to provide adequate protection for healing. Sutures are removed at 2 weeks, and forefoot x-rays (AP and lateral) are obtained at 2, 6 and 10 weeks post-operatively. Dressings are changed at 1 week, and then are fully removed after suture removal at 2 weeks, allowing the patient to shower on a daily basis.



Kits	Description	Sterile
	Peg and Hole Reaming Kit	HT-60-8000-S

A surgeon must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. Fusion Orthopedics does not dispense medical advice and recommends that surgeons be trained in the use of any particular product before using it in surgery. The information presented is intended to demonstrate the breadth of Fusion Orthopedics' product offerings. A surgeon must always refer to the package insert, product label, and instructions for use before using any Fusion Orthopedics product. Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your representative if you have questions about the availability of products in your area.

FDA Cleared

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Rev 1



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