ENGLISH / INSTRUCTIONS FOR USE

FuseRight PIP Fusion Reamers

FOR FIXATION OF HAND AND FOOT PIP JOINTS

DESCRIPTION AND ACTIONS

FuseRight 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 **FuseRight Instrumentation** Kit includes the male and female reamers and a wire pass drill.

FuseRight has a history of safe medical use, and it has been shown to be effective in laboratory and clinical testing and use.

FuseRight is delivered as a non-sterile set within two plastic bubbles, each containing one instrument. Each instrument requires sterilization prior to use.

INDICATIONS

FuseRight is indicated for:

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 **FuseRight,** 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

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

INFORMATION FOR USE

1. A tourniquet is suggested during the surgical procedure. The MTP (metatarsal-phalangeal) joint is preferably approached with an oblique incision, approximately 1-1.5 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.

2. 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.
3. The PIP joint is acutely flexed to expose the proximal phalanx head, and the neck is grasped by the surgeon with a forcep, stabilizing the phalanx. While protecting the soft tissues, a 0.0625 in. k-wire is then used to drill 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).
4. The male FuseRight 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.
5. 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.
   The base of the middle phalanx is then exposed with a closed adson forcep placed by the assistant under the planter surface of the middle phalanx, lifting the phalanx above the previously reamed peg to avoid inadvertent injury during receptacle reaming. The soft tissues are again protected.
6. The 0.0625 in. k-wire is again used to drill 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.
7. The female FuseRight 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.
8. A 1.6 mm (0.0625 in.) Kirschner wire (threaded* or smooth), or 1.5 mm bio-absorbable pin is driven first retrograde out the end of the toe from the middle phalanx receptacle hole. 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 (if a smooth wire is used, it may be driven across the MTP joint if toe deviation is present or for surgeon preference).*
9. The pin is trimmed and/or bent and capped, and the tourniquet is released. Hemostasis is achieved, and the wounds are re-approximated with interrupted 4-0 or 5-0 skin 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.
10. 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 appropriate intervals 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.

*The technique for use of a threaded 1.6 mm Kirschner wire is identical to that described in step 9, but requires that the direction of rotation of the driver be appropriately applied for advancement of the pin in the desired direction. Crossing the MTP joint with a threaded or absorbable pin is not recommended. Threaded pins are not bent following insertion, and are removed in the office at 4-6 weeks with a needle driver clamp placed axially on the end of the pin to allow for a rotational "unscrewing" of the pin. This is typically painless, but can be painful at the final 2-3 threads. The clamp is usually removed once easy rotation of the pin is felt, and the final removal is much less painful with finger rotation of the pin.

Surgical Considerations and reminders
As for other methods of internal fixation:

- Perioperative antibiotics are recommended.
- Use proper local, regional or general anaesthesia.
- Maintain aseptic conditions during procedure.
- Proper exposure using standard surgical procedure.
- Arteries and nerves should be preserved by careful dissection.
- On the basis of surgeon's decision radiographs are taken before wound closure.
- Meticulous hemostasis and complete primary skin closure over the implant are essential.
- X-ray control can be used for alignment/reduction evaluation.

Surgical Technique

Postoperative Reminders

- Use appropriate additional immobilization (e.g. suitable cast, brace, surgical shoe and/or crutches) during bone healing.
- Provide the patient with detailed instructions for postoperative care.
- The surgical site stability will determine the nature of postoperative weight bearing and rehabilitation regimen.
- X-ray, CT or MRI control can be used to evaluate bone healing.

PRECAUTIONS AND WARNINGS

- **FuseRight instrumentation** is supplied as a re-usable and must be cleaned for debris/tissue and sterilized after each use
- **FuseRight** can be used *for up to a maximum of 15 (fifteen) uses*. After 8 (eight) uses, cutting edges and flutes must be monitored at each use for dullness / overheating and replaced immediately as needed.
- Specialized **FuseRight** instruments are available and must be used to assure the accurate implantation of **FuseRight**

- The surgeon should choose the correct devices, method of application and surgical procedure prior to performing the surgery. Incorrect selection, placement, positioning, or fixation can cause subsequent undesirable results.
- Soft tissues must be carefully retracted and protected during use of the reaming devices. Skin or soft tissue burn, or contact injury, can occur if tissue comes in contact with the rotating device.
- Dense bone can generate heat during the use of the device and may require continuous or intermittent irrigation with saline solution to keep the prepared bone cool during reaming. A gentle axial bouncing of the reamer during use can also reduce heat generation.
- Care must be used during assembly of the reamed phalanges to avoid bending force applied to the reamed peg to reduce the risk of breakage or fracture of the reamed elements.
- Appropriate consideration for immobilization should be used in applications involving diaphyseal or weight bearing cancellous bone.
- Please follow our included guidelines for re-sterilization

SPECIAL PATIENT POPULATIONS
The effect of the **FuseRight** upon the healing of physeal cartilage has not been tested clinically.

ADVERSE EFFECTS
Complications are similar to those with any method of internal fixation:
- Infections, both deep and superficial related to surgery performed.
- Allergic and other responses to anaesthetic agents and device materials.
- Neurovascular injuries can occur due to surgical trauma.
- Internal repair using the **FuseRight** (as for other similar fixation devices) may be associated with transient local fluid accumulation or sinus formation.

CAUTION
Federal law (USA) restricts this device to sale by, or on the order of, a licensed physician.

STERILITY
FuseRight instruments are delivered non-sterile, and must be STERILIZED BEFORE ANY USE, including the initial use.

STORAGE
Store at room temperature (15 to 30°C or 59 to 86°F) and at a normal relative humidity.

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Sticker Symbols:

Symbol	Meaning

REF	Catalogue number
LOT	Lot Number
	See Instructions for Use
	Monitor bur/blade and distal handpiece temperature
	Irrigate surgical site to reduce heat
	Read instructions for use
Rx Only	U.S. Federal law restricts this device to sale, distribution, or use by or on the order of a physician