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DigiFuse™ Cannulated Intramedullary Fusion System Instructions for Use

Description

The METASURG® DigiFuse™ Implant is a one-piece threaded device made of titanium intended to be implanted into the medullary bone of the lesser toes. The implant is offered in 4 variations consisting of the combination of 2.0mm and 2.5mm threads and 0° and 10° blades. Available implants and instrumentation are packaged as a single system and are also available separately as individual components.

The system includes instruments (guide pins, broach, insertion / removal drivers) to facilitate the placement of the implants.

The implants are constructed from implant grade titanium alloy (Ti 6Al-4V ELI) per ASTM F-136.

Clinical Indications

The METASURG® DigiFuse™ implant is indicated for the fixation of osteotomies and reconstruction of the lesser phalanges during procedures to correct deformities of the toes and fingers.

- Hammer toe deformity
- Claw toe deformity
- Mallet toe deformity
- Other deformities of the feet and hands

The METASURG® DigiFuse™ implants and guide wires are intended for single use only.

Contraindications

Use of the METASURG® DigiFuse™ implant is contraindicated in cases of active or suspected infection or in patients who are immunocompromised; in patients previously sensitized to titanium; in patients with inadequate bone stock; or in patients with certain metabolic diseases; in patients with high levels of activity; in patients who are not able to comply with post-operative treatment protocols.

Possible Adverse Effects

The following are specific adverse effects which should be understood by the surgeon and explained to the patient. These do not include all adverse effects which can occur with surgery in general, but are important considerations particular to metallic internal fixation devices. General surgical risks should be explained to the patient prior to surgery.

1. Infection.
2. Pain, discomfort or abnormal sensations due to the presence of the implant.
3. Metal sensitivity or allergic reaction to a foreign body.
4. Migration of the implant: loosening of the implant.
5. Delayed wound healing or deep wound infection resulting in possible removal of the implant.
6. Fracture of the implant due to non-compliance to post operative regimen, improper implant selection or non-union.

Warnings

1. Re-operation to remove or replace the implants may be required at any time due to medical reasons or device failure. If corrective action is not taken, complications may occur.
2. Plates and screws, wires, or other appliances of dissimilar metals should not be used together in or near the implant site.
3. Instruments, guide pins, and implants are to be treated as sharps.
4. The METASURG® DigiFuse™ Implant has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating or migration in the MR environment.

Maintaining Device Effectiveness

1. The surgeon should have specific training, experience, and thorough familiarity with the use of DigiFuse™ implant devices.
2. The implants are not intended to endure excessive abnormal functional stresses.
3. All METASURG® DigiFuse™ implants and instruments may be required for each surgery. Failure to use dedicated, unique METASURG® instruments and implants for every step of the implantation technique may compromise the integrity of the implanted device, leading to premature device failure and subsequent patient injury. Failed devices may require reoperation and removal.
4. Carefully inspect the implants prior to use. Inspect the instruments before and after each procedure to assure they are in proper operating condition. Instruments which are faulty, damaged or suspect should not be used. They should be replaced or sent to METASURG® for disposition and repair.
5. METASURG® recommends the use of METASURG® products in a sterile environment.
6. For best results and to ensure proper working condition, after cleaning the Ratchet Handle (DF-1500) a non silicone lubricant should be used per the manufacturer's instructions.

Instructions for Use – METASURG DigiFuse Implant

1. Perform an incision, of the surgeon's choice, over the proximal interphalangeal (PIP) joint. Reflect the soft tissues surrounding the PIP joint to completely expose it for resection. Determine at this point if the 0° or 10° plantar correction implant will be utilized. Any resection cuts at this point should be made to reflect the eventual use of the corresponding chosen implant as it relates to plantar correction. Complete the resection of the PIP joint in preparation for PIP joint fusion.
2. Using the included K-Wire (DW-2590), drive the wire into the center of the proximal phalanx. Ensuring that the location of k-wire is correct. A mini C-arm may be useful at this point if there is uncertainty as to the location and depth of the wire.
3. After the k-wire is correctly placed, select the appropriate sized implant based on the size of the proximal phalanx and previously selected plantar correction. Place the distal end of the threaded portion of the

implant over the k-wire and push the implant up to the resection site. Slide the appropriate driver (0° or 10° driver as marked on the driver itself), that matches the selected implant, over the k-wire and engage the barbed end of the implant. Turn the screw into the proximal phalanx until the threaded portion of the implant is completely or near completely recessed into the phalanx and the dorsal mark on the driver is aligned correctly with the patient anatomy. Remove the k-wire when the implant is in an acceptable position.

4. Depending on the density of bone stock, it may be beneficial to use the included k-wire to drill a hole in the middle phalanx where the broached hole will be placed. Position the tip of the broach on the middle phalanx in the correct orientation (over the previously drilled hole – optional) and insert the broach while holding the middle phalanx to secure it. The broach should be inserted until the shoulder contacts the resected portion of the middle phalanx.
5. Manually distract the middle phalanx and place the broached hole, in the middle phalanx, over the barbed end of the implant that is protruding from the proximal phalanx using care to align the broached hole with the implant blade. Using firm pressure press the middle phalanx onto the barbed end until the resected surfaces of the middle and proximal phalanx meet. Once the implant is fully seated, check manually for retention.
6. Verification can be confirmed by utilizing a mini C-arm (or equivalent) in multiple axes.
7. Close the incisions with the suture material of choice. Post operative care is according to surgeon preference and should follow protocol for fusions of a similar nature.

Sterility

The METASURG® DigiFuse™ implants and instruments are packaged **non-sterile** and must be sterilized prior to surgical use.

Sterility Type: Pre-Vacuum Steam Sterilization
Exposure Temp: 270° F (132° C)
Exposure Time: 4 minutes
Dry Time: 20 Minutes
Configuration: Wrapped

Sterility Type: Gravity Steam Sterilization
Exposure Temp: 270° F (132° C)
Exposure Time: 15 Minutes
Dry Time: 20 Minutes
Configuration: Wrapped

Caution:

- **Federal (United States) law restricts this device for sale by or on the order of a medical practitioner licensed to do so.**
- **Do not attempt a surgical procedure with faulty, damaged or suspect METASURG® instruments or implants. Inspect all components preoperatively to assure utility.**



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