

# Instructions for Use - Warnings and Precautions

## HammerLock™ Intramedullary Nitinol Implant System

### I. General

The HammerLock™ Intramedullary Nitinol Implant System gives the surgeon a means of intramedullary bone fixation and helps in the management of reconstructive surgery.

### II. Basic Structure

The devices of the HammerLock™ Intramedullary Nitinol Implant System are made of biocompatible Nitinol and possess shape memory and superelastic properties. The HammerLock™ is a one-piece Nitinol device with legs that deflect outward in the medullary cavity and towards each other resulting in implant stabilization and compression.

### III. Indications For Use

- Small bone reconstruction and fusion such as in the phalanges of the fingers and toes.

### IV. Contraindications

- Pathologic conditions of bone such as osteopenia which would impair the ability to securely fix the implant.
- Foreign body sensitivity to metals including nickel. Where material sensitivity is suspected, appropriate tests should be made prior to implantation.

### V. Warnings

- The HammerLock™ cannot be expected to replace normal healthy bone or withstand the stress placed upon the device by full or partial weight bearing or load bearing in the presence of nonunion, delayed union or incomplete healing. Therefore, it is important that immobilization of the treatment site using routine methods (casting, splints, etc...) be maintained until bone healing has occurred (4-6 weeks).
- Reduction of the site should be achieved and maintained after implanting the device. The compressive force of the HammerLock™ implant should not be relied upon to achieve closure or reduction of a fracture line.
- The HammerLock™ Intramedullary Nitinol Implant System has not been evaluated for safety and compatibility in the MR environment. The device has not been tested for heating or migration in the MR environment.
- Any additional processing or reprocessing of this implant may affect the shape memory properties of the nitinol, changing or otherwise reducing the effectiveness of the implant.

### VI. Clinical Use Considerations

- HammerLock™ implants are provided for use where intramedullary fixation with multiaxial stabilization is desired.

### VII. Clinical Use Examples

- Interphalangeal arthrodesis of the hand and foot.

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### VIII. Instructions

1. After site preparation and resections, prepare the medullary canals with the broach. If necessary, use the drill to create a pilot hole and/or the reamer to resect the articular cartilage.
2. Remove the implant from the freezer and deliver to the operating room within 10 minutes. Remove implant from sterile packaging and use the supplied forceps to disengage the implant from the polyethylene storage block. Note: After removal from the implant packaging, device should be fully implanted within a total of 4 minutes to prevent premature activation (a maximum of 2 minutes for the proximal end and 2 minutes for the distal end).
3. Insert the exposed proximal end of the implant into the proximal fragment until the retaining block makes contact with the bone.
4. Open the forceps to expose the distal end of the implant. While flexing/distracting the joint, insert the distal end of the implant into the distal fragment and fully reduce.
5. Ensure desired alignment and reduction while the implant is activating.

### IX. Removal

Expose the site and distract the bony segments to expose one portion of the implant. Using forceps, remove the remaining portion of the implant. If the implant is solidly connected, create a dorsal window to expose and remove the distal and/or proximal portion of the implant.

### X. Care and Caution

- Ancillary equipment should be sterilized by a gravity feed autoclave cycle at 121°C (250°F) for 30 minutes. Alternatively, a pre-vac autoclave cycle of 135°C (275°F) for 4 minutes is acceptable. A drying cycle of 15 minutes is recommended. These recommended cycle times presuppose properly maintained autoclave equipment used with due diligence by the operator. Inspect each item prior to use. Do not use if there is any indication of cracks or crazing.
- Inspect the sterile pouches used for the implants prior to use. Sterilization cannot be assured and plate should not be used if pouch or seal is damaged.
- HammerLock™ implants may be stored at room temperature, however, they must be placed in a freezer for a minimum of 30 minutes prior to removing from the polyethylene block.