# SECURE
## Intramedullary Nail System

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**AM** SURGICAL, INC.

## Introduction

The A.M. Surgical, Inc. *SECURE* Intramedullary Nail System is a sterile, single-use, implantable nail used for fractures of the long bones of the hand including the metacarpals and the proximal and middle phalanges, and the metatarsal bones of the foot. The *SECURE* nail is made from a single piece of implantable grade stainless steel. The nail comes packaged and pre-sterile in a Tyvek Pouch (autoclavable tools can be purchased separately). The nail comes in multiple sizes to match different size long bones in the hand and feet. The curved tip at the distal end of the nail facilitates insertion and stabilizes rotation within the bone. The head of the nail at the proximal end is designed to work with surgical clamps for easy insertion and removal. The nail is intended to be removed after healing is complete.

## Contents of the Package

- Self-contained, sterilized IM nail.

## Indications

- Fractures of the shaft and neck that are angulated and/or unstable
- Multiple fractures of the metacarpal shaft and neck
- Mildly comminuted, transverse, oblique, and spiral fractures of the shaft
- Unstable soft tissue envelope

## Contraindications

- Highly comminuted fractures
- Irreducible fractures
- Fractures with insufficient size for fixation

## Training

For safe and effective use, surgeons must possess a thorough knowledge and understanding of hand anatomy.

**Rx Only** — Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

## PROCEDURE SETUP

### Instrumentation

The following instrumentation is recommended for the SECURE Intramedullary Nail System procedure:

- A.M. Surgical SECURE Intramedullary Nail
- A.M. Surgical Awl
- A.M. Surgical Clamp
- Mini C-arm
- Basic small hand tray
- Mallet and tamp
- 15 blade scalpel

### Positioning and Preparation

The patient is placed in the supine position on the operating table. A forearm tourniquet is used and the arm is draped in the usual sterile manner. A bolster is placed beneath the hand.

### Anesthesia

Local anesthesia is recommended for the procedure.

## OPERATIVE TECHNIQUE

### Radiologic Assessment of SECURE Nail Size

- The SECURE IM Nail size is determined by placing the nail over the suspected metacarpal and examined via fluoroscopy *(Figure 1)*

- The nail should be 3-5 mm shorter than the metacarpal *(Figure 2)*

- Measurement of the medullary canal should be made to confirm that a 1.6 mm nail shaft size will fit into the cavity

### Incision and Exposure

- After appropriate preparation and draping, a 1-2 cm longitudinal incision is made at the base of the suspected metacarpal *(Figure 3)*

- The carpometacarpal (CMC) joint is exposed

- Extensor tendons are retracted, making sure any dorsal branches of the radial and ulnar nerve are protected

### Access to the Medullary Canal

- An awl is used to penetrate 3-5 cm through the dorsal cortex of the base of the metacarpal *(Figure 4)*

- Fluoroscopic images should be taken to ascertain that the awl is in the medullary canal *(Figure 5)*

- Once confirmed, the awl is gently removed

### Delivery of the IM Nail

- The proper sized SECURE IM Nail is driven through the fenestration into the medullary canal by grabbing the head of the nail with the clamp and gently twisting *(Figure 6 & 7)*



FIG 1



FIG 2



FIG 3



FIG 4



FIG 5



FIG 6



FIG 7
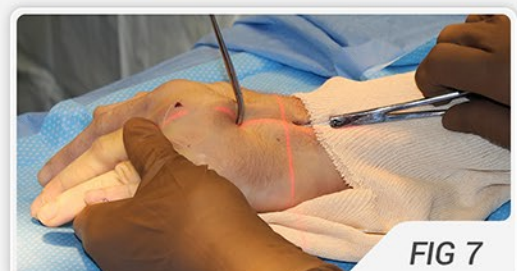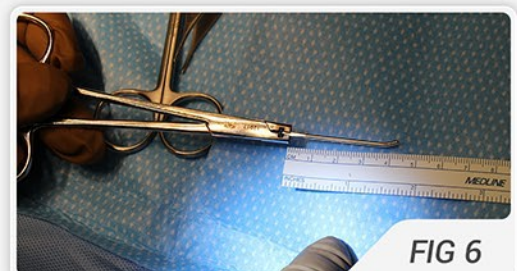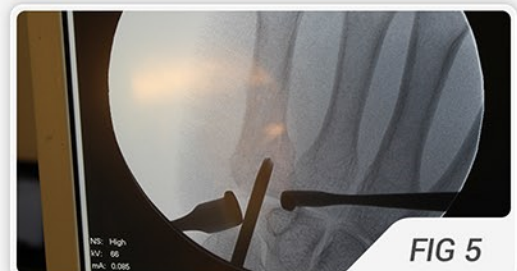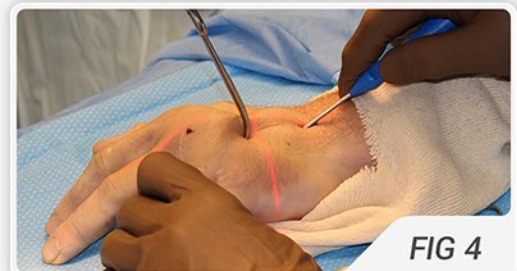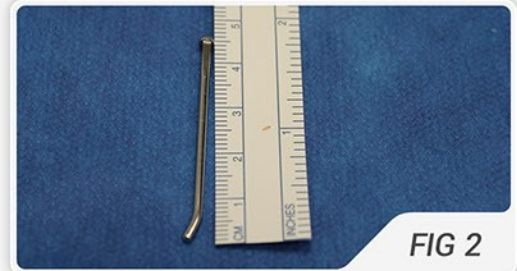
- The nail is further passed into the cavity as the surgeon observes the process via fluoroscopy *(Figure 8)*
- Reduce the fracture prior to driving the nail across the fracture site

### Seat the SECURE IM Nail

- Using a tamp, drive the head of the nail as close to the base of the metacarpal as possible *(Figure 9)*
- Do not penetrate the metaphyseal end of the bone
- Bury the proximal head of the nail beneath soft tissue and irrigate the wound *(Figure 10 & 11)*

### Radiologic Confirmation

- AP, lateral, and oblique radiological images are taken to ensure acceptable reduction *(Figure 12)*

### Closure

- The wound is closed with running 5-0 nylon subcuticular closure *(Figure 13)*
- A Steri-Strip is placed over the sutures
- An ulnar gutter splint is placed around the hand *(Figure 14)*

### Post-op Instructions

- Strict, non-weight bearing for 6 weeks
- Patient is placed in a custom orthosis
- Full AROM/PROM outside of splint
- Suture is removed at follow-up

### Removal Instructions

- Nail is removed at 6-8 weeks post-op with a clamp


FIG 8


FIG 9


FIG 10


FIG 11


FIG 12


FIG 13


FIG 14
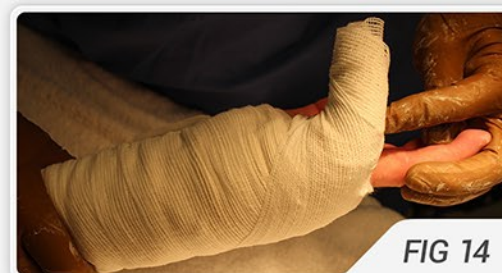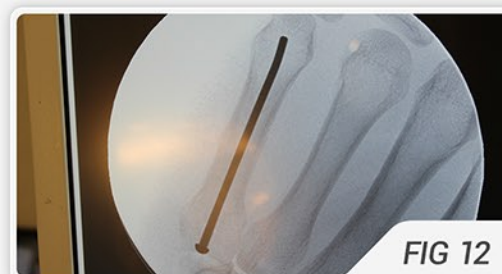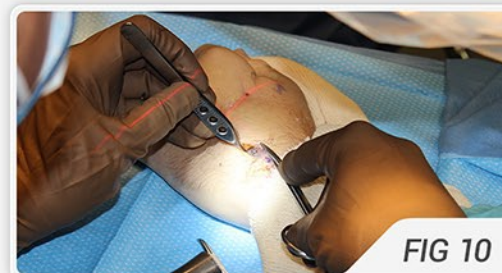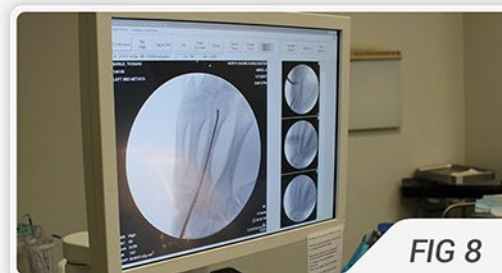
## Disposables

### SECURE IM Nail - Sterile Packaged

| | |
|---|---|
| #8960-40K | 40mm x 1.6mm IM Nail • (5 Pack) |
| #8960-45K | 45mm x 1.6mm IM Nail • (5 Pack) |
| #8960-50K | 50mm x 1.6mm IM Nail • (5 Pack) |
| #8960-55K | 55mm x 1.6mm IM Nail • (5 Pack) |
| #8960-60K | 60mm x 1.6mm IM Nail • (5 Pack) |
| #8960-K | 1.6mm IM Nail Starter Pack • (one of each size) |

## Instrumentation

○ #8900 • A.M. Surgical Clamp

○ #8900-20 • A.M. Surgical Awl

## Warnings

○ Contents are sterile unless package is opened or damaged. DO NOT RESTERILIZE. For single use only. Discard any open, unused product. Do not use after the expiration date.

○ It is the surgeon's responsibility to be familiar with the appropriate surgical technique prior to use of the device.

○ Weight bearing or other unsupported stress may not be tolerated until healing is complete.

○ Read these instructions prior to use.

## Precautions

○ U.S. Federal Law restricts this device to sale by or on the order of the physician.

○ Prior to use, inspect the product package for signs of damage or tampering. Do not use If damaged.

## MRI Safety Information

**SECURE** has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of **SECURE** in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

## Warranty

For single-use only. This product is warranted to be free from defects in material and workmanships. Do not reuse.
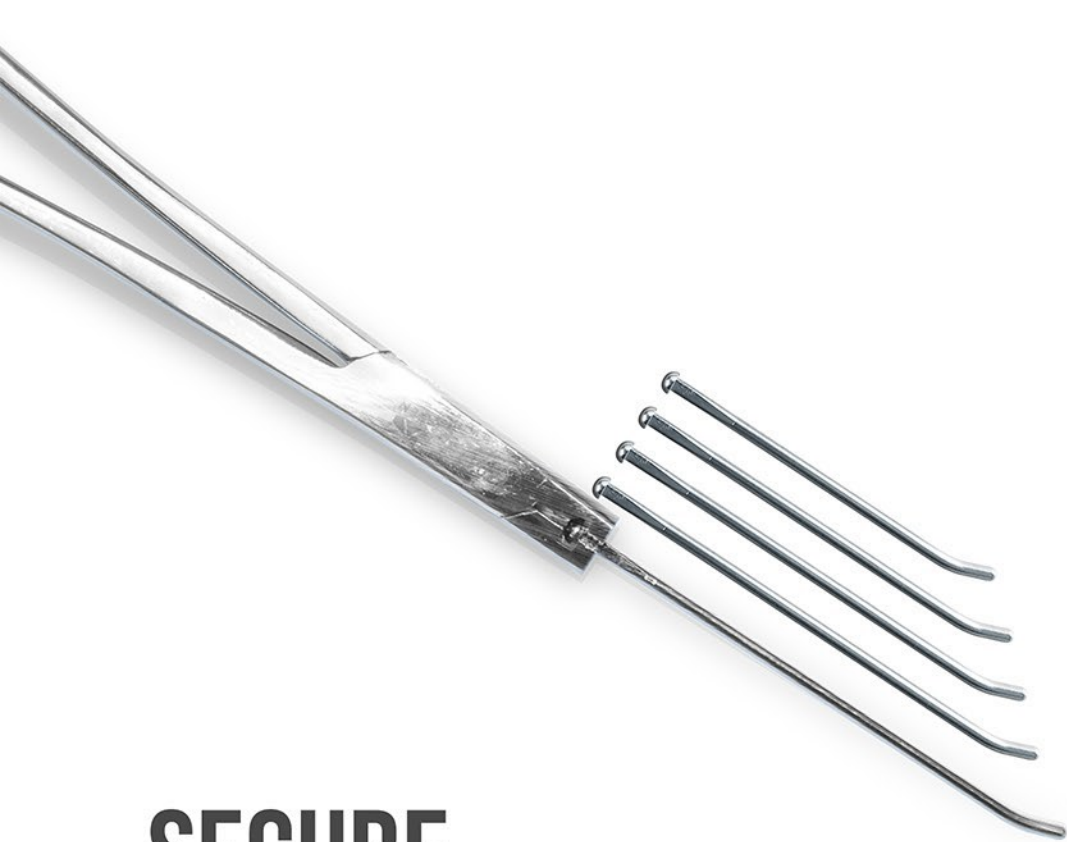
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