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OIC Intramedullary Screw System

Threaded Metacarpal Nail Surgical Technique Guide

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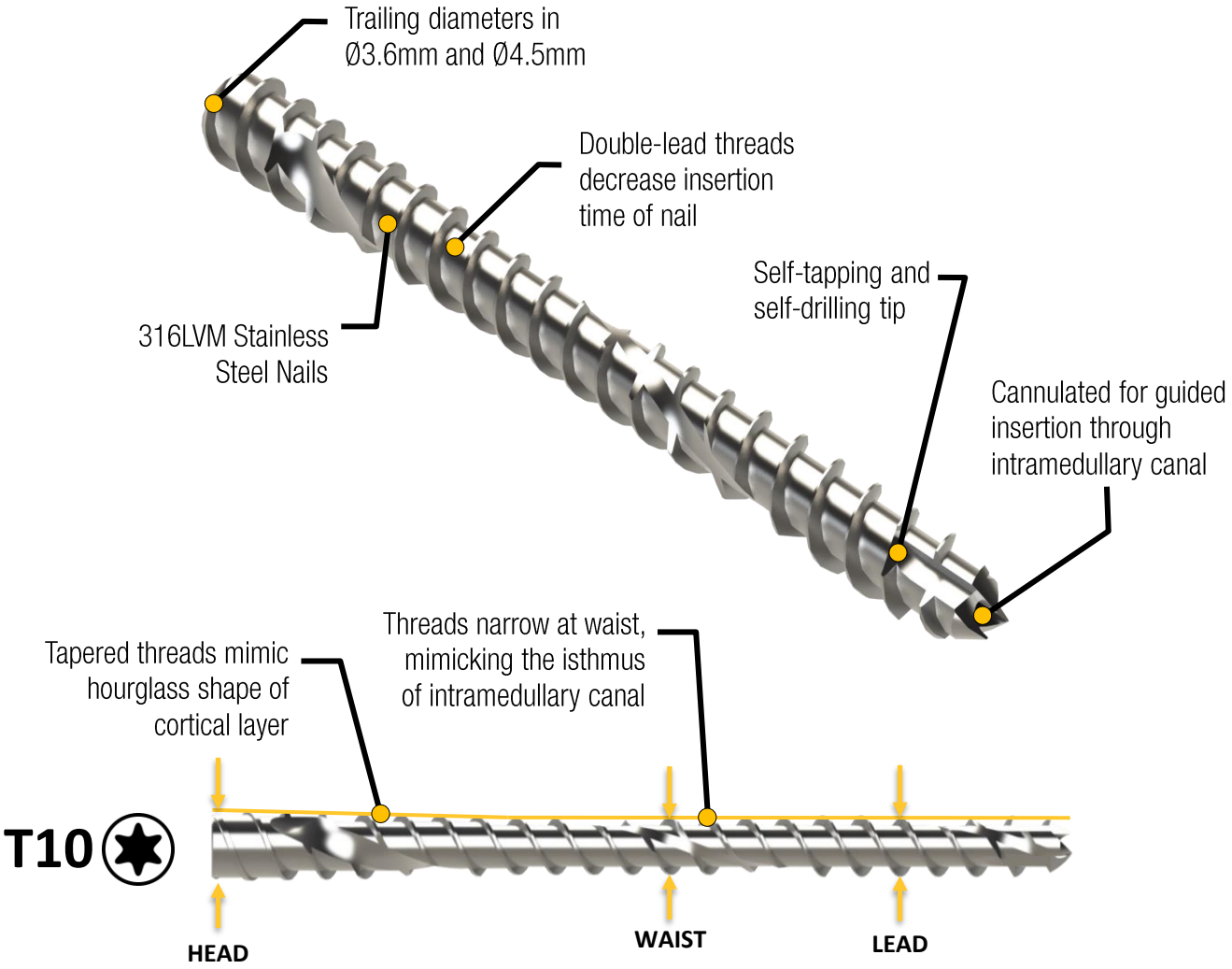
Table of Contents

The technique description herein is made available to the healthcare professional to illustrate the author's suggested treatment for the uncomplicated procedure. In the final analysis, the preferred treatment is that which addresses the specific needs of the patient.

Threaded Metacarpal Nail

The OIC Threaded Metacarpal Nail provides a minimally invasive approach to metacarpal fixation. The Threaded Metacarpal Nail features a low insertion torque and minimal compression. Fully-threaded design helps fully stabilize fracture patterns, providing rigid fixation of the metacarpal.



Nail	Lengths	Head	Waist	Lead	Drill
3.6 MCN-36XX	**35-60mm**	**Ø3.6mm**	**Ø3.0mm**	**Ø3.2mm**	**Ø2.6** DR26-09C
4.5 MCN-45XX	**40-80mm**	**Ø4.5mm**	**Ø3.7mm**	**Ø4.0mm**	**Ø3.3** DR33-110C

Indications and Warnings

INDICATIONS FOR USE

The OIC Intramedullary Screw System is indicated for the fixation of intra-articular and extra-articular fractures, mal-unions, non-unions or osteotomies of small bones and small bone fragments, as well as arthrodesis of small joints. The device is intended for use in adults.

Contraindications

- Sensitivity to implant material
- Active or latent infection
- Osteoporosis
- Insufficient quantity or quality of bone/soft tissue
- Conditions which tend to retard healing such as blood supply limitations, previous infections, etc.
- Insufficient quantity or quality of bone to permit stabilization of the fracture complex and/or fusion of the joints
- Conditions that restrict the patient's ability or willingness to follow postoperative instructions during the healing process
- Cases with malignant primary or metastatic tumors which preclude adequate bone support or nail fixations, unless supplemental fixation or stabilization methods are utilized
- Adolescents whose growth plates have not fused or if the implanted nail will cross the growth plate

WARNINGS AND PRECAUTIONS

For safe and effective use of this implant, the surgeon must be thoroughly familiar with the implant, the method of application, instruments, and the recommended surgical technique for this device. The device is not designed to withstand the stress of weight bearing or excessive activity. Device breakage or damage can occur when the implant is subjected to increased loading associated with delayed union, nonunion, or incomplete healing. Improper insertion of the device during implantation can increase the possibility of loosening and migration. The patient must be cautioned, preferably in writing, about the use, limitation, and possible adverse effects of this implant including the possibility of the device failing as a result of loose fixation, stress, excessive activity, or weight bearing, particularly if the implant experiences increased loads due to delayed union, nonunion, or incomplete healing.

The patient must be warned that failure to follow postoperative care instructions can cause the implant and/or treatment to fail. Osteoporotic patients are also at risk for loss of fixation and construct failure due to the poor quality of their bone.

Once applied, the implant should never be reused. Although it may appear undamaged, previous stresses may have created imperfections that could reduce its service life.

Indications and Warnings

Even with anatomic reduction, lack of fracture gap and appropriate construct creation, initial weight bearing restrictions are indicated. In order to prevent loss of correction and premature nail failure, it is recommended that partial weight bearing be instituted for 6-12 weeks followed by advancement to full weight bearing only when radiographs confirm significant callus and bony healing.

Instruments shall be inspected for wear or damage prior to usage.

Protect implant appliances against scratching and nicking, which may cause stress concentrations leading to failure. In no case should an implant be sharply or reverse bent, notched, gouged, reamed, scratched or cut.

All implant materials for the Threaded Intramedullary Nail System are implant grade stainless steel. This material is not ferromagnetic, susceptible to aging, nor will steam sterilization have an effect on the materials' properties. The instruments are made from stainless steel and aluminum.

MAGNETIC RESONANCE IMAGING (MRI) SAFETY

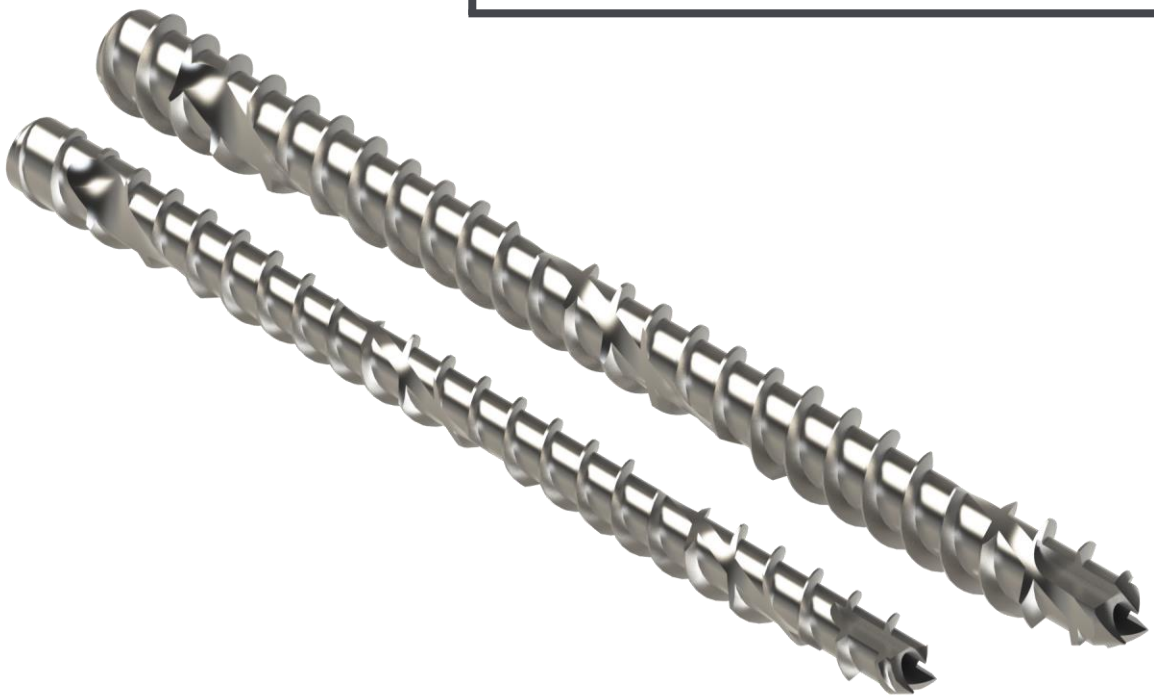
The OIC Threaded Intramedullary Nail has not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of threaded nails in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.

ADVERSE EFFECTS

Fracture of the implant due to excessive activity, prolonged loading upon the device, incomplete healing, or excessive force exerted on the implant during insertion. Implant migration and/or loosening. Metal sensitivity or histological or allergic reaction resulting from implantation of a foreign material. Pain, discomfort, or abnormal sensations due to the presence of an implant. Nerve damage resulting from surgical trauma. Necrosis of bone or bone resorption. Necrosis of tissue or inadequate healing.

SURGICAL TECHNIQUE

Ø3.6mm/Ø4.5mm Threaded Nails



1 Fracture Reduction and Exposure

Fracture fragments should be reduced utilizing standard reduction techniques. Make a stab incision at the entry point of the metacarpal head, with the dorsal third of metacarpal head exposed.

2 Guidewire Insertion

With the fracture reduced, place a Ø1.15mm guidewire (KW115-150) through the dorsal third of the metacarpal until the tip of the wire is up to the proximal cortex **FIG 1**.

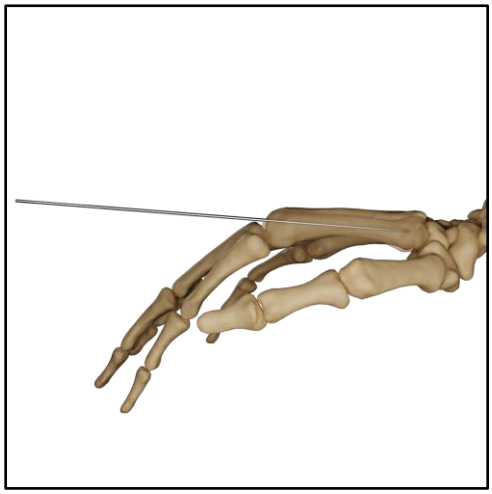


Figure 1

3 Implant Selection

Nail length and diameter can be determined using the metacarpal nail depth gauge (01-IMS01). Insert the depth gauge next to the guidewire till the depth gauge tip is in contact with the metacarpal head **FIG 2**. Read the measurement shown at the end of the guidewire. In cases where tendons obstruct the metacarpal head, the tip of the depth gauge may be used to gently push aside the tendon. The tip of the depth gauge may then be placed adjacent to the guidewire past the tendon.

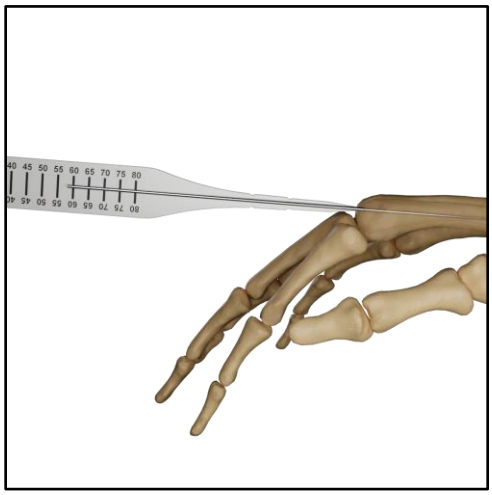
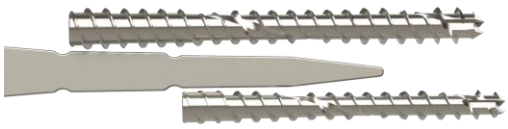


Figure 2



Note: The tip of the depth gauge matches the taper and width of the nail threads and may be used to visualize nail fit by placing the depth gauge on the dorsum of the metacarpal under fluoroscopy.

Note: It may be appropriate to round down or subtract 5mm from the measured result to ensure the nail rests under the articular surface.

4 Drill

Using the appropriate cannulated drill (DR26-090C for Ø3.6 nails or DR33-110C for Ø4.5 nails), drill over the guidewire to the desired depth **FIG 3**. Depth markings on the drill may be used to determine nail length and monitor drill depth. The drill should be used over the entire length of the desired nail.

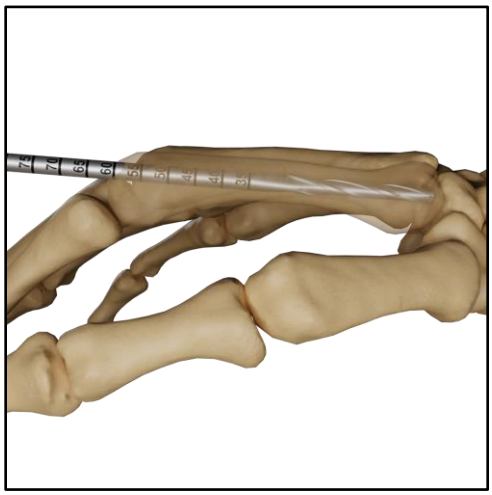


Figure 3

5 Implant Insertion

Insert the desired nail (MCN-36XX or MCN-45XX) over the guidewire using the cannulated T10 driver (01-IMS02). Insert the nail to the desired depth **FIG 4**.

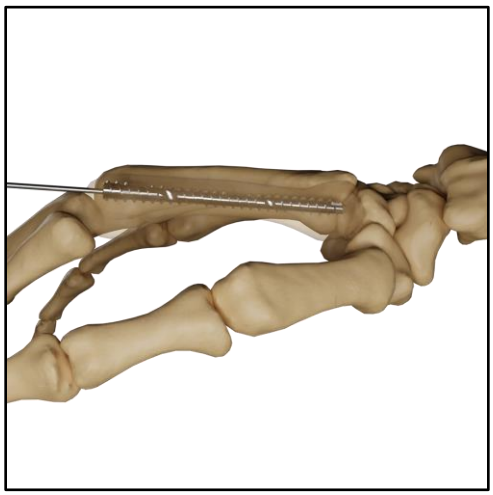


Figure 4

6 Wound Closure and Post-Op Protocol

Confirm reduction and nail positioning under fluoroscopic imaging. Layered wound closure is recommended. Weight and load bearing are left to the surgeon discretion.

7 Optional: Implant Removal

If the nail requires removal, re-open or use a stab incision at the metacarpal head. It may be necessary to use the nail's respective drill bits (DR26-090C or DR33-110C), to ream out an entry hole to the T10 socket. Using the cannulated T10 driver (01-IMS02), carefully remove the nail.

Implants – Threaded Metacarpal Nails

Ø3.6mm Threaded Metacarpal Nail	
Part No.	Description
MCN-3635	Ø3.6mm x 35mm
MCN-3640	Ø3.6mm x 40mm
MCN-3645	Ø3.6mm x 45mm
MCN-3650	Ø3.6mm x 50mm
MCN-3655	Ø3.6mm x 55mm
MCN-3660	Ø3.6mm x 60mm

Ø4.5mm Threaded Metacarpal Nail	
Part No.	Description
MCN-4540	Ø4.5mm x 40mm
MCN-4545	Ø4.5mm x 45mm
MCN-4550	Ø4.5mm x 50mm
MCN-4555	Ø4.5mm x 55mm
MCN-4560	Ø4.5mm x 60mm
MCN-4570	Ø4.5mm x 70mm
MCN-4580	Ø4.5mm x 80mm

Disposable Instruments

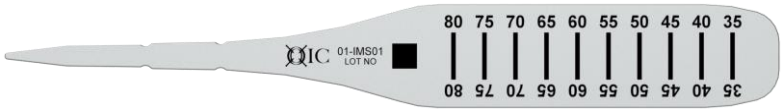
KW115-150 Ø1.15mm K-Wire

DR26-090C Ø2.6mm x 90mm Cannulated Drill Bit

DR33-110C Ø3.3mm x 110mm Cannulated Drill Bit

Reusable Instruments

01-IMS01 Metacarpal Nail Depth Gauge



01-IMS02 Cannulated T10 Driver

CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN

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