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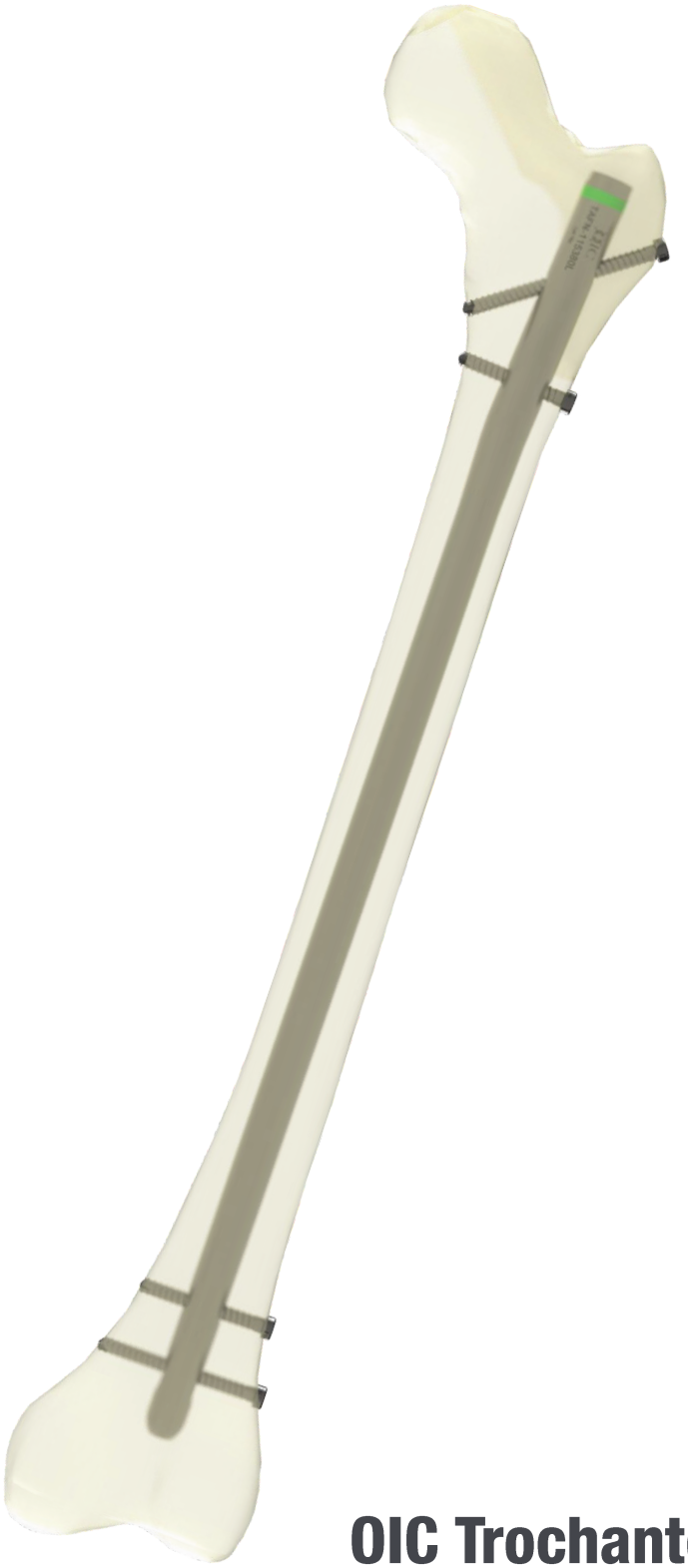

OIC Trochanteric Femur Nail
Surgical Technique Guide

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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.

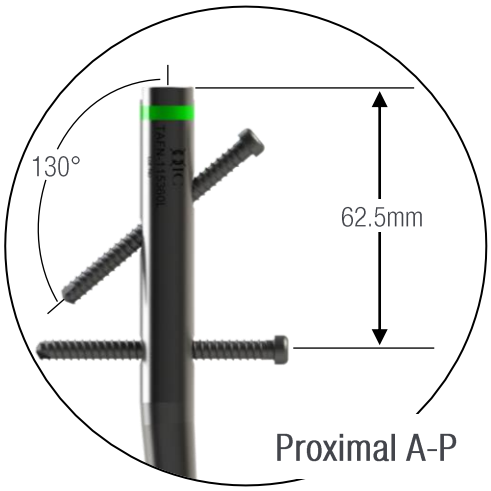
System Features

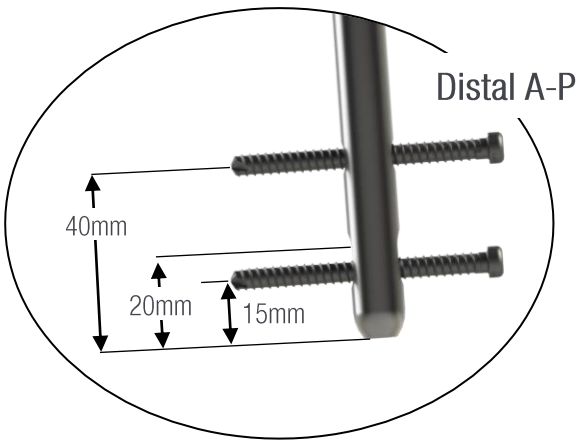
INTRODUCTION

The OIC Trochanteric femur nail (TAFN) is a cost-effective product that incorporates design features of modern femur nails that obtain consistent clinical results. Instrumentation is elegantly simple and tray layouts are thoughtfully designed to promote operational efficiencies from the back table.

DESIGN FEATURES

OIC Trochanteric Femur Nail	
Characteristics	**Value**
Metallurgy	Titanium Alloy (Ti6AL4V)
Proximal Diameter	13mm
Distal Diameter	10mm, 11.5mm, and 13mm
Lengths	320mm-440mm 20mm increments
Cross-section	Circular
Cross-lock Screw Diameter	5mm
Cross-lock Screw Lengths	25mm-100mm
Degree of Proximal M/L bend	4°
Proximal M/L Bend Location	77.5mm
Radius of Curvature	1.5m





Indications and Warnings

INDICATIONS FOR USE

The OIC Intramedullary Nail System is intended for surgical management of femoral and tibial fractures including open and closed fractures, pseudarthrosis and correction osteotomy, pathologic fractures, impending pathologic fractures, tumor resections, nonunions and malunions. The hip nails may be used for basilar neck, subtrochanteric and intertrochanteric fractures. The femoral nails may be used for fractures of the femur below the hip joint including ipsilateral femur fractures, fractures proximal to a total knee arthroplasty and supracondylar fractures, including those with intra-articular extension.

CONTRAINDICATIONS

- These systems should not be used in crossing open epiphyseal plates. Insufficient quantity or quality of bone, obliterated medullary canal or conditions which tend to retard healing, blood supply limitations, previous infections, etc.
- Active infection
- Any hardware that would preclude use of nails
- Congenital or acquired bony deformity
- Hypovolemia, hypothermia and coagulopathy
- Mental conditions that preclude cooperation with the rehabilitation regimen

Indications and Warnings

PREOPERATIVE PLANNING

Correct surgical technique is essential to a successful outcome. Proper reduction of fractures and proper placement of implants are necessary to effectively treat patients using metallic surgical implants. Please review the surgical technique for effective surgical procedures.

Implant Selection – A proper type and size of implant must be selected to insure effective treatment of patients. The following factors should be considered:

- A patient's size, strength, skeletal characteristics, skeletal health, and general health. Overweight or musculoskeletally deficient or unhealthy patients may create greater loads on implants that may lead to breakage or other failure of the implants.
- A patient's activity level during the time the implant is in the patient's body, including such factors as whether the patient's occupation or typical activities include running, heavy lifting, impact loading, or the like.
- Whether a patient has a degenerative or progressive disease that delays or prevents healing, and consequently decreases the effective life of the implant.
- If a patient is suspected of having material or foreign body sensitivities, appropriate testing should be accomplished prior to implantation.
- Mental conditions or substance abuse problems that may prevent a patient from understanding or following directions or observing precautions.

Implant Alterations – Unless an implant is designed to be physically altered, it should not be altered in any way. If the implant is designed to be altered, it should only be altered in accordance with OIC's instructions.

In no case should an implant be sharply or reverse bent, notched, gouged, reamed, scratched or cut.

Component Compatibility –Components such as intramedullary nails, screws, wires, pins, and the like are available in many styles and sizes and are manufactured from various types of metals. The component material is provided on the outside carton label. Use only components made from the same material together unless specifically approved by the manufacturer. Do not mix dissimilar metals or components from different manufacturers unless specifically approved by a manufacturer of the components. Refer to manufacturers' literature for specific product information.

Implant Removal – The patient should be advised that a second procedure for the removal of implants may be necessary.

Indications and Warnings

POSTOPERATIVE CARE

Care Prior to Bony Union – Immobilize and/or externally support skeletal structures that have been implanted with surgical metallic implants until skeletal union is observed. Early weight bearing substantially increases implant loading and increases the risk of loosening, bending or breaking the device. Early weight bearing should only be considered where there are stable fractures with good bone-to-bone contact. Patients who are obese and/or noncompliant, as well as patients who could be pre-disposed to delayed or non-union, should have auxiliary support. The implant may be exchanged for a larger, stronger nail subsequent to the management of soft tissue injuries.

ADVERSE EFFECTS

1. Loosening, bending, cracking or fracture of the implant components.
2. Limb shortening or loss of anatomic position with nonunion or malunion with rotation or angulation.
3. Infections, both deep and superficial.
4. Irritational injury of soft tissues, including impingement syndrome.
5. Supracondylar fractures from retrograde nailing.
6. Tissue reactions which include macrophage and foreign body reactions adjacent to implants.
7. Although rare, metal sensitivity reactions and/or allergic reactions to foreign materials have been reported in patients.
8. Restricted range of motion of the joint adjacent to the insertion point of the nail, usually transitory due to protruding nails.

MAGNETIC RESONANCE IMAGING (MRI) SAFETY

The OIC Trochanteric Femur 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 OIC Trochanteric Femur Nail 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.

PATIENT POSITIONING

Patient is placed supine on a fracture table. Care is taken to pad all bony prominences. Scissoring of the legs is recommended with the operative leg horizontal and non-operative leg angled down. A well leg holder for the non-operative leg can also be utilized but a slightly increased risk of compartment syndrome has been reported. The ipsilateral arm is placed over the chest and the body should be flexed slightly to the opposite side to facilitate access to the starting point. Slight adduction of the operative limb can be helpful. The image intensifier should be positioned so that AP and lateral views of the hip and knee can be easily obtained.

FRACTURE REDUCTION

The fracture is reduced by traction and reversal of the mechanism of injury. Reduction should be confirmed with both AP and Lateral fluoroscopic images. In some cases, closed reduction of the fracture is not possible and many percutaneous reduction techniques exist. A Ball Spike Pusher (01-IM53), bone hook and cobb elevator should all be available. It is imperative for all surgeons to understand that no nail reduces a fracture. The fracture must be reduced before the nail is inserted and reduction must be held during the reaming process.

INCISION AND PIN PLACEMENT

After sterile preparation and draping, a 3.2mm Guide Pin (32-400) is inserted just lateral to the tip of the greater trochanter and in line with the middle of the femoral neck. This should be confirmed on both AP and lateral views FIG 1 & 2. A 2 cm incision is then made around the wire.

FIG 1

FIG 2

PREPARATION OF MEDULLARY CANAL

Pass the 12.5mm Proximal Entry Reamer (01-IM06) over the Guide Pin and through the 16mm/12.5mm Tissue Protector assembly (01-IM03 and 01-IM04) to gain access to the intermedullary canal FIG 3. This should be taken down to the level of the lesser trochanter to allow for easy passage of the nail.

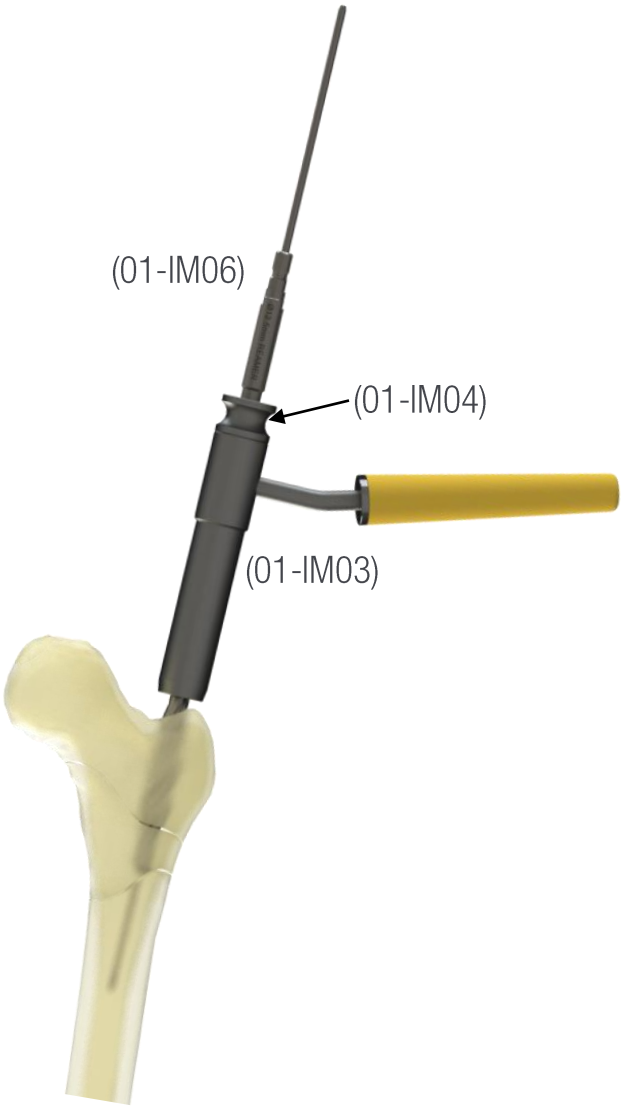


FIG 3

GUIDE ROD INSERTION AND REAMING

Guide Rod Insertion – The Ball Tip Guide Rod (GW03-1000S) is then attached to the guide Rod Gripper (01-IM07) and passed across the fracture site into a center-center position in the knee FIG 4. This should be confirmed on both AP and Lateral fluoroscopic images to ensure correct placement. Anterior positioning can cause cortical break and resultant periprosthetic fracture or intra-articular hardware placement.

NOTE: If the Guide Rod is unable to be passed across the fracture site, the Fracture Reduction Tool (01-IM52) can be utilized. Insert Fracture Reduction Tool, achieve reduction, and pass the Ball Tip Guide Rod into distal fragment FIG 5. The diameter of the Fracture Reduction Tool is 8.5mm. Reaming of the proximal fragment may be necessary.

Reaming – Reamers (01-IM09 thru 01-IM20) are then utilized with the Flexible Reamer Shaft (01-IM08) starting at 9mm and increasing by 0.5mm increments FIG 6. The canal should be reamed 1.5-2mm above the diameter of the nail. The Obturator (01-IM56) can be utilized to ensure Guide Rod placement during reaming.

CAUTION: Care should be taken during reaming not to lateralize the guide wire or pullout guide wire during reaming. The fracture should be held reduced during reaming to prevent eccentric reduction.

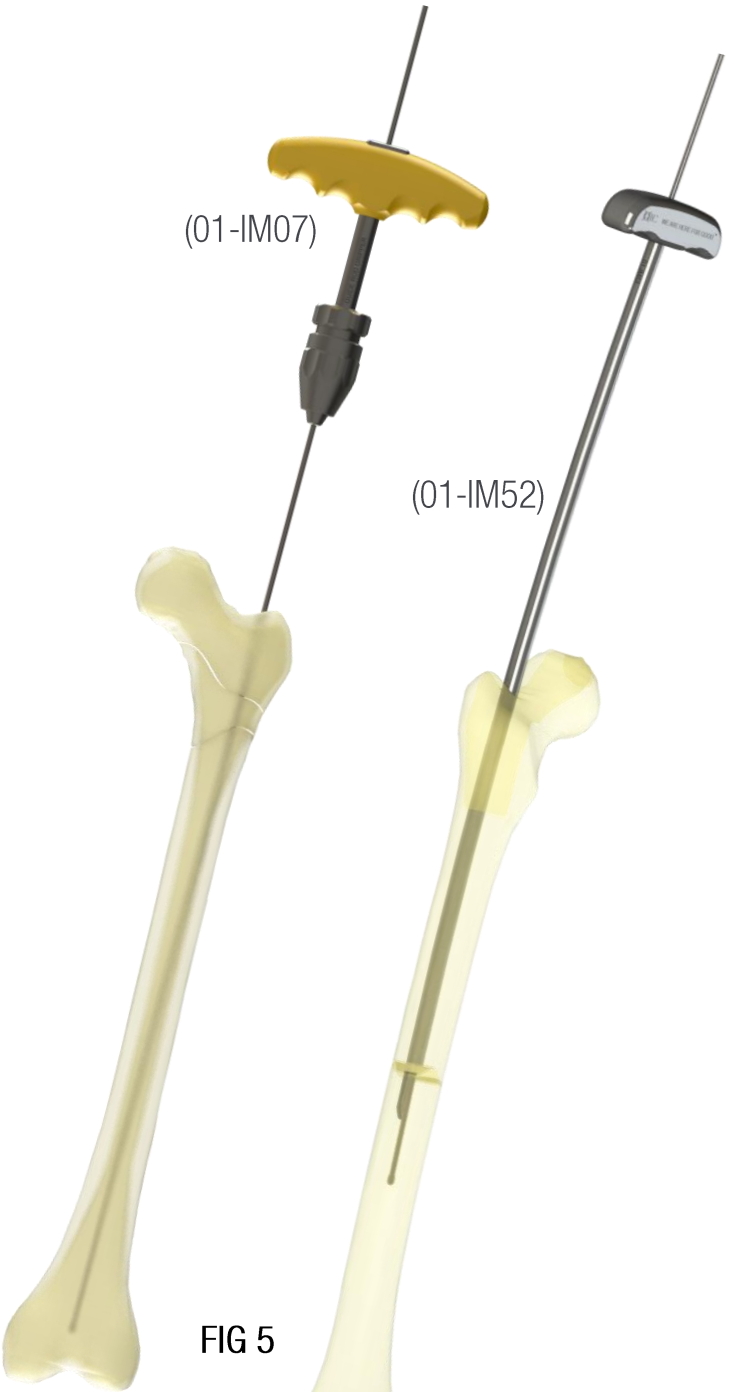


FIG 5

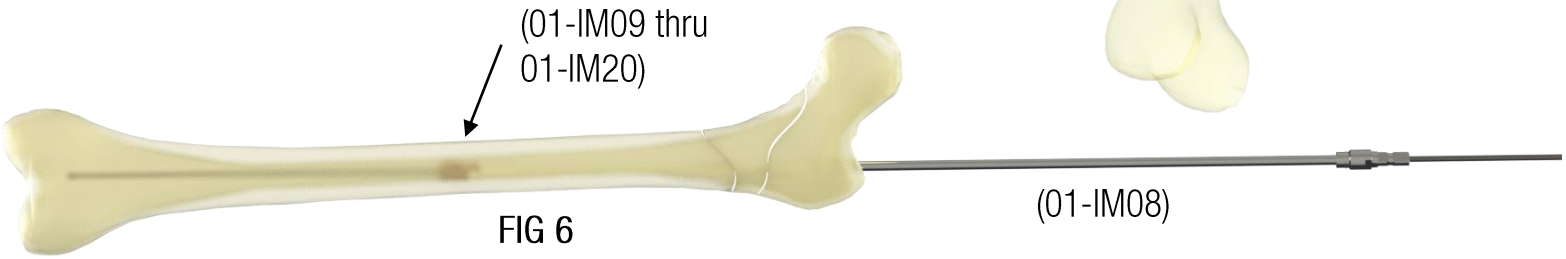


FIG 6

NAIL MEASUREMENT

Nail measurement can be done pre or post reaming. If measuring post reaming, care should be taken to ensure an accurate reading. The Nail Depth Gauge (01-IM02) is utilized to determine the appropriate nail length. The Gauge is passed over the Guide Rod up to level of the greater trochanter and the measurement is read FIG 7. The appropriate nail length is chosen by nearest 20mm.

CAUTION: An excessively long nail can lead to intra-articular hardware and a short nail can increase the possibility of periprosthetic fracture.

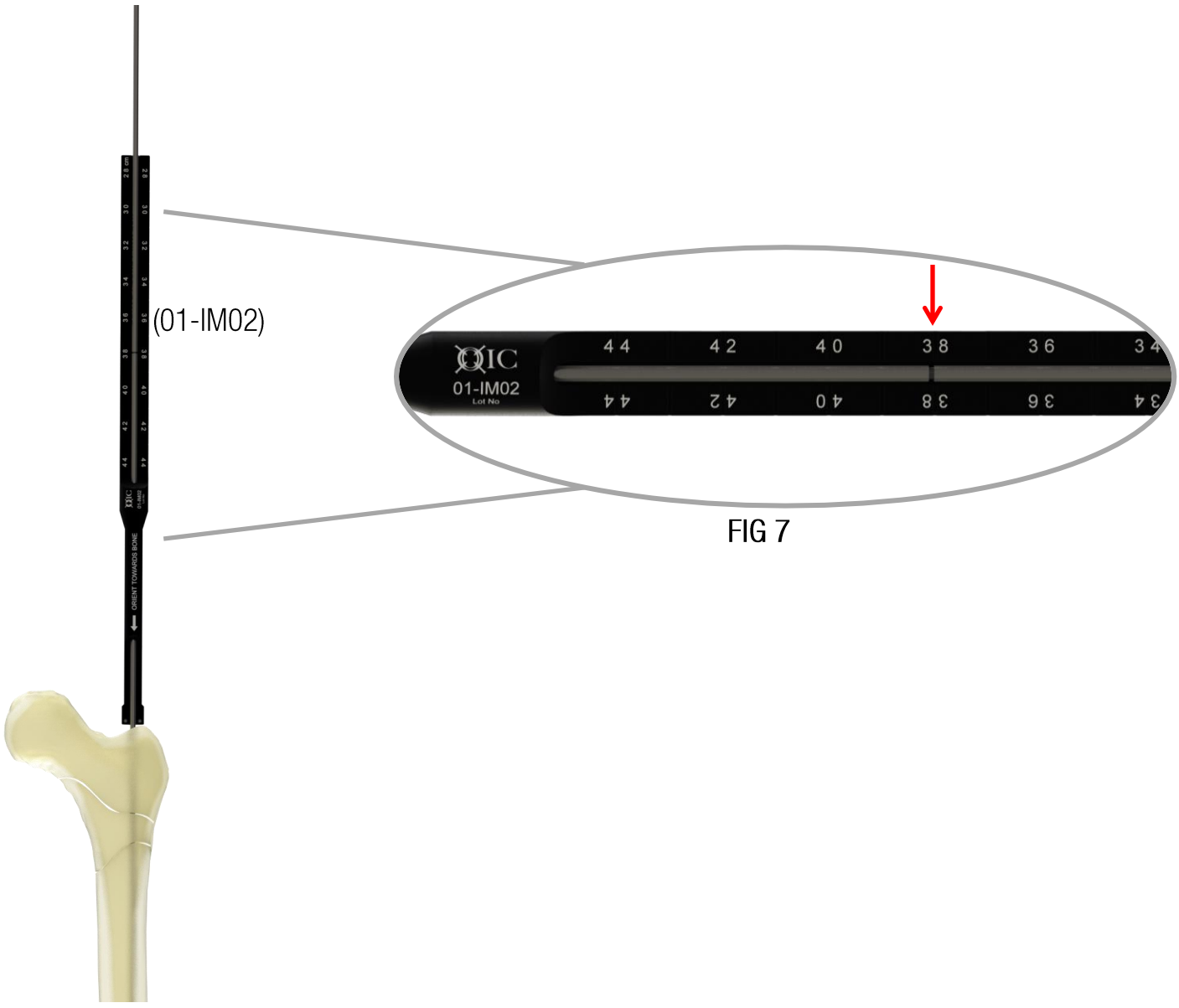


FIG 7

ASSEMBLING THE TARGETING GUIDE AND NAIL

Attach the selected nail to the Targeting Guide (01-IM21) by securing it with the Guide Bolt (01-IM24) FIG 8 and tightening it with the Guide Bolt Driver (01-IM29) FIG 9. Tangs on bolt and notches in nail are asymmetric to ensure nail is secured to aiming arm securely and properly and no cross threading occurs. Extra care should be taken to ensure that the nail is attached to the guide in the correct orientation.

NOTE: With the guide positioned laterally, double check that the curvature of the nail matches that of the femur.

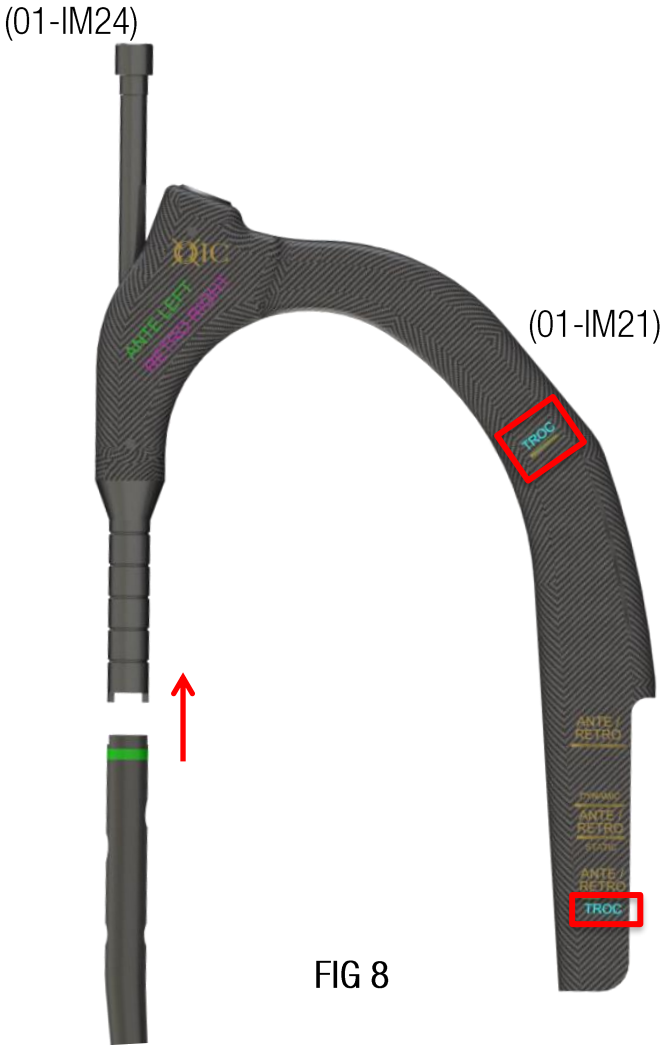


FIG 8

FIG 9

NAIL INSERTION

Introduce the attached nail and Targeting Guide over the Ball Tip Guide Rod. The nail should be inserted by hand over the Guide Rod into the proximal femur. In smaller diameter canals, nail passage may be facilitated by gently rotating the nail and targeting guide during advancement. In some cases, the nail can be advanced using the Slotted Mallet (01-IM31) FIG 10.

NOTE: To avoid damage to the carbon fiber, only hit the metal Impactor (01-IM30).

Remove the Ball Tip Guide Rod.

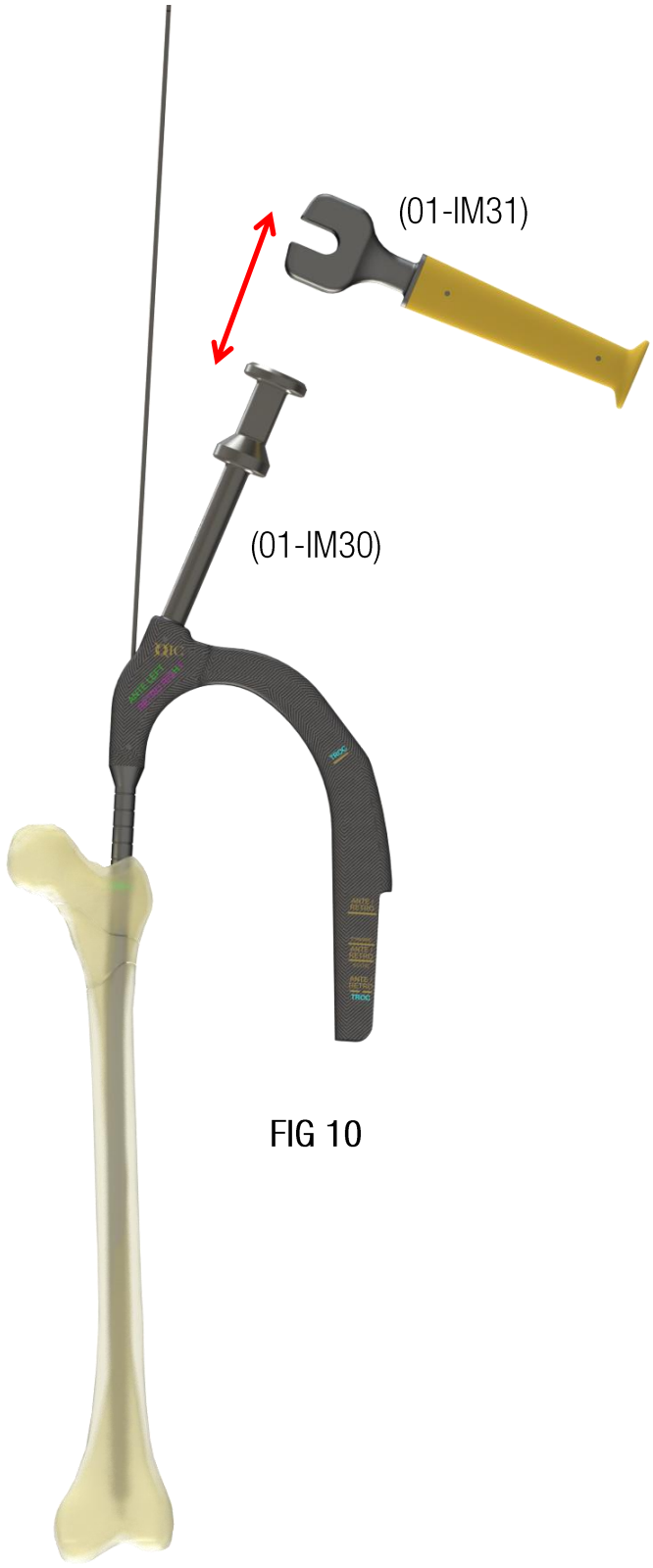


FIG 10

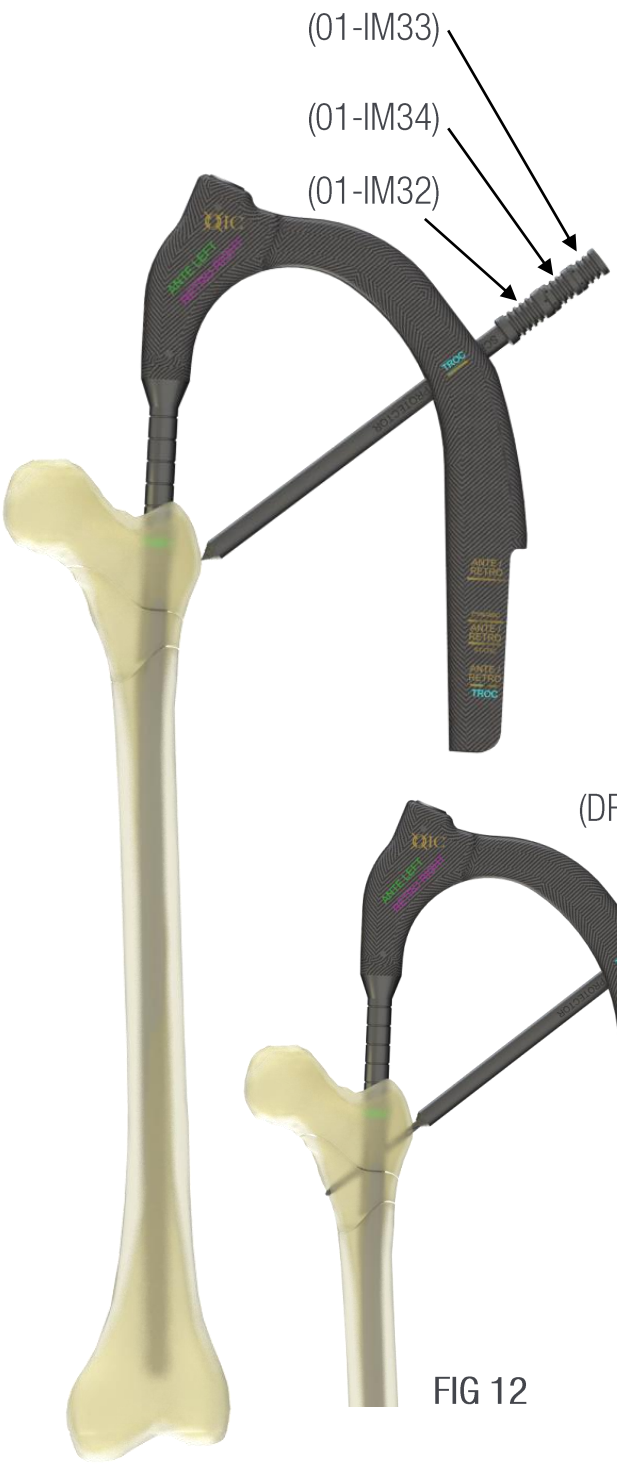


FIG 11

PROXIMAL CROSS LOCK SCREW

Either the static or dynamic screw slot can be selected depending on surgeon preference. The triple sleeve (01-IM32, 01-IM34, 01-IM33) is assembled and placed through the jig FIG 11. A small incision is made to allow insertion of the sleeve through the soft tissue against the bone. The long 4.2mm Calibrated Drill Bit (DR42-330C) is then utilized under fluoroscopic guidance. Screw length can be determined by noting the laser etched measurements on the drill against the Drill Sleeve FIG 12. The Drill Sleeve is then removed and the screw is inserted using the long 3.5mm Screw Driver (01-IM37) and AO Connect Handle (01-IM49) via the Screw Insertion Sleeve FIG 13. Screw length can be measured using the Depth Gauge (01-IM51).

NOTE: Measurements will only be accurate if the sleeve is against the outer cortex

FIG 12

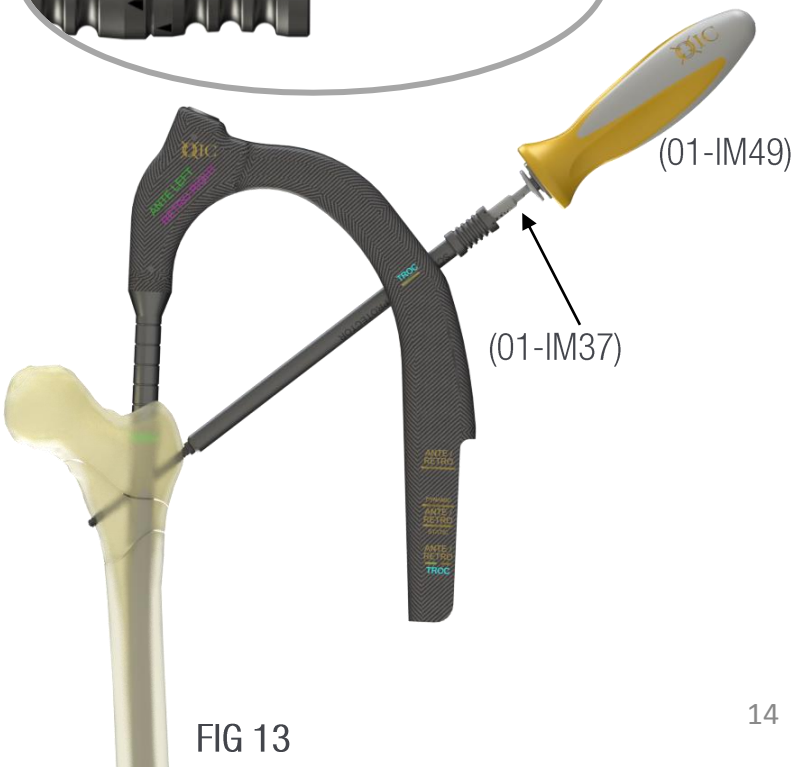


FIG 13

DISTAL CROSS LOCK SCREW

The most important step in this process is to ensure accurate position of the image intensifier so that “perfect circles” are visualized prior to drilling. The screw hole is drilled utilizing the short 4.2mm Drill Bit (DR42-155) FIG 14. Screw length can either be measured off the drill using the Measuring Gauge (01-IM35) or with the Depth Gauge (01-IM51) FIG 15.

The screw is inserted using the Short 3.5mm Hex Driver (01-IM50) FIG 16.

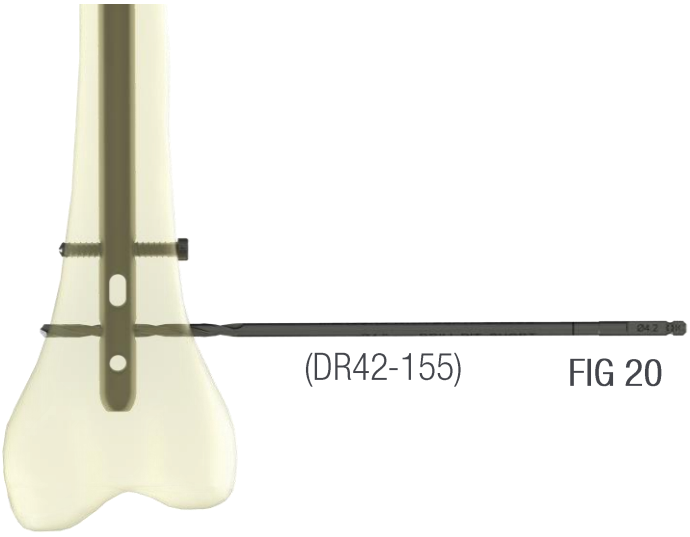


FIG 14

FIG 20

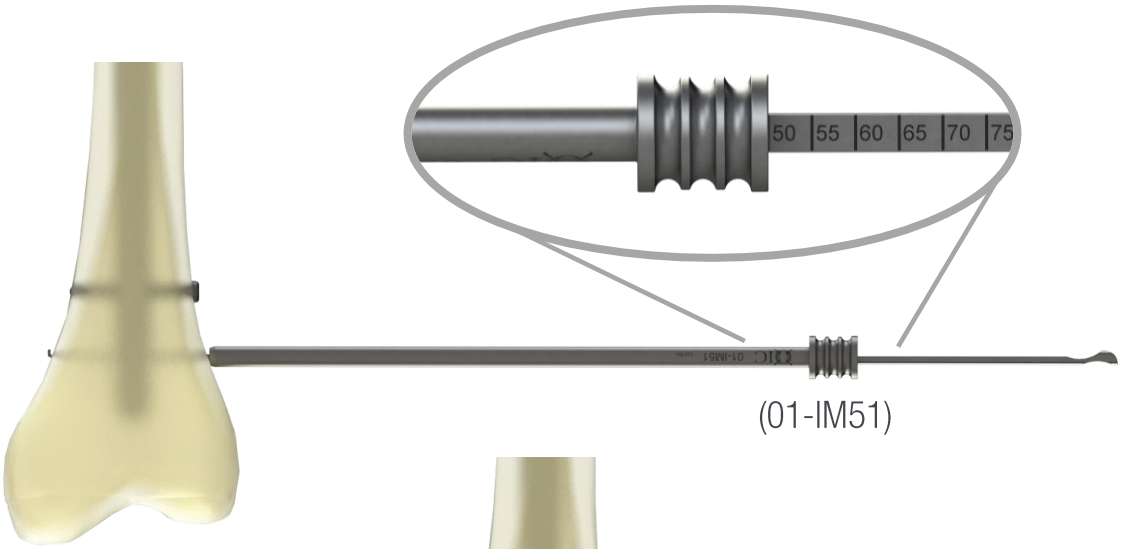


FIG 15

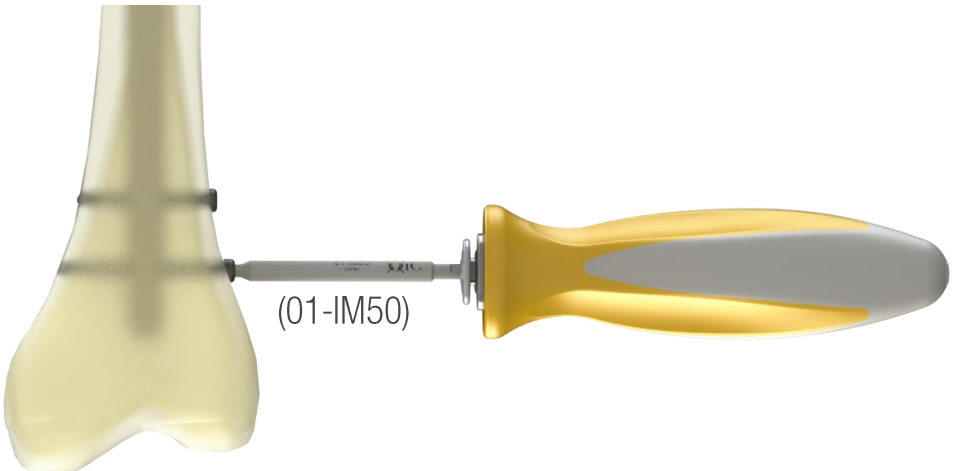


FIG 16

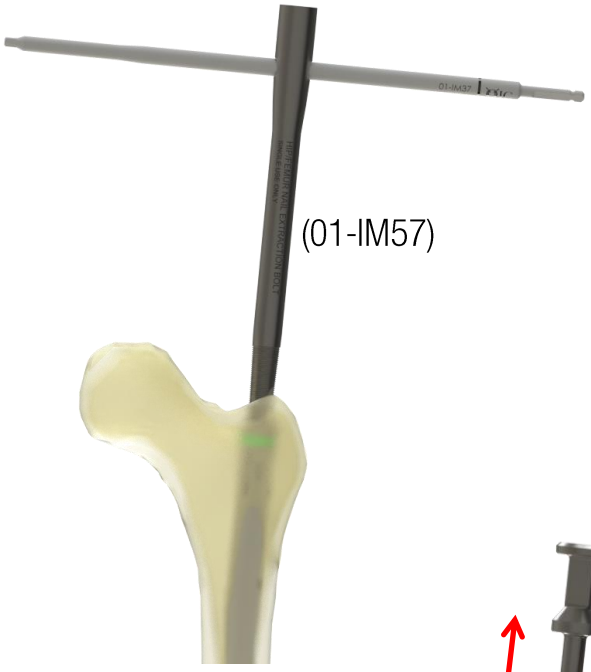


FIG 17

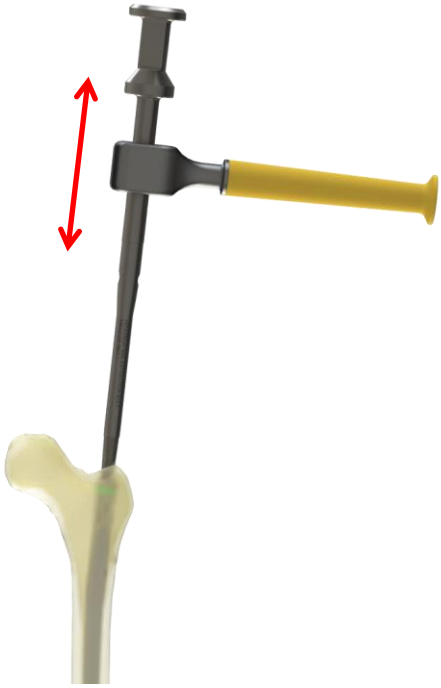


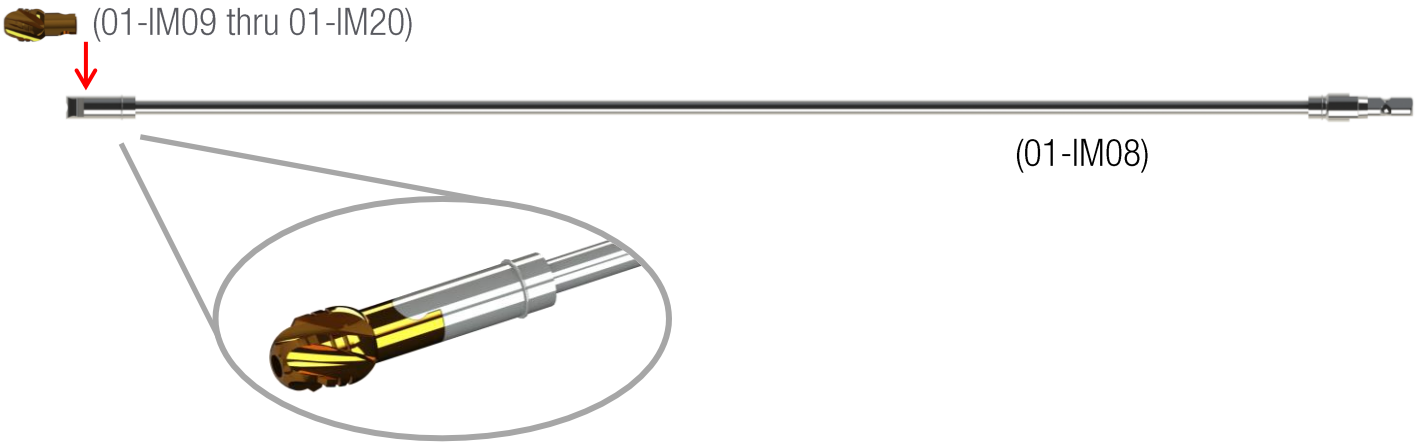
FIG 18

NAIL EXTRACTION

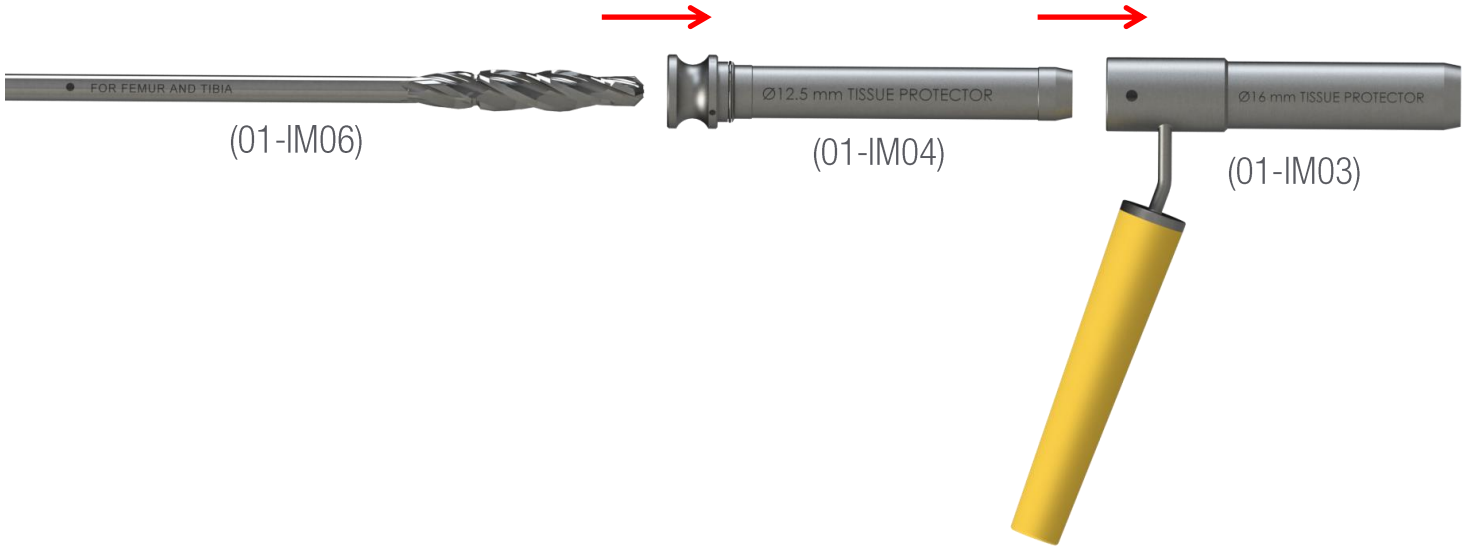
At times nail extraction is indicated and can be accomplished via previous incisions. Remove the distal Cross Lock Screw(s). If bony overgrowth has occurred this should be removed with a curette or osteotomes.

Insert the Femur Nail Extraction Bolt (01-IM57) into the proximal end of the nail FIG 17. Screw the Impactor (01-IM30) to the Extraction Bolt and remove the nail by back-slapping with the Slotted Hammer (01-IM31) FIG 18.

FLEXIBLE REAMER SHAFT ASSEMBLY



ENTRY REAMER TISSUE PROTECTOR ASSEMBLY

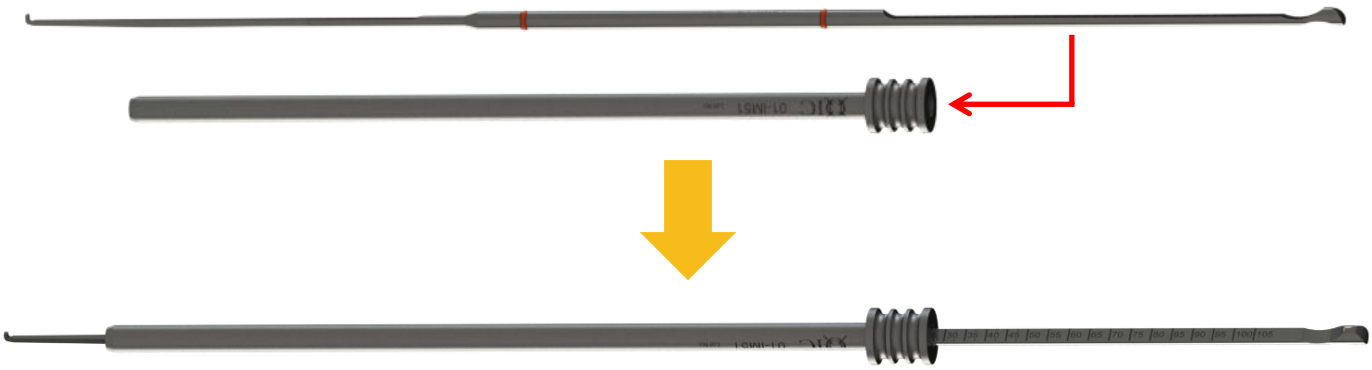


Assembly and Disassembly

TRIPLE SLEEVE ASSEMBLY

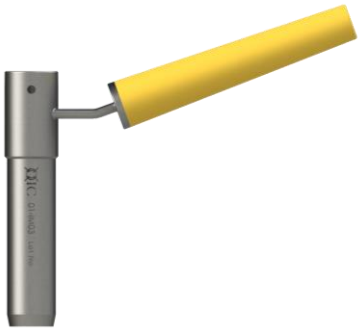
(01-IM33) (01-IM34) (01-IM32)

01-IM51: SCREW GAUGE



REUSABLE INSTRUMENTS

Catalog Information

01-IM02	Nail Measuring Gauge	
01-IM03	16mm Tissue Protector	
01-IM04	12.5mm Tissue Protector Sleeve	
01-IM06	12.5mm Proximal Reamer	
01-IM07	Guide Rod Gripper	
01-IM08	Flexible Reamer Shaft	
01-IM09 THRU 01-IM20	Reamer Heads	

REUSABLE INSTRUMENTS (Cont.)

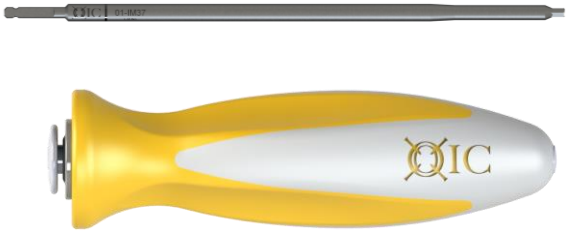
Catalog Information

01-IM21	Carbon Fiber Femur Handle	
01-IM24	Femur and Hip Guide Bolt	
01-IM29	Guide Bolt Driver	
01-IM30	Impactor	
01-IM31	Slotted Mallet	
01-IM32	Tissue Protector Sleeve	
01-IM33	Sleeve Trocar	
01-IM34	Drill Sleeve	

REUSABLE INSTRUMENTS (Cont.)

Catalog Information

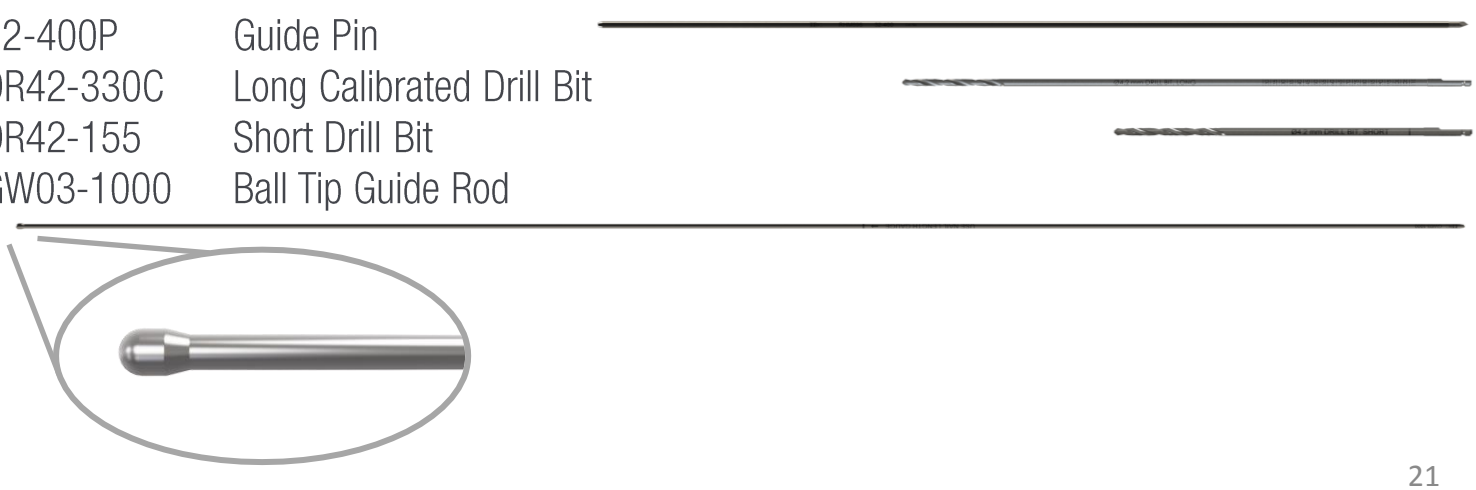
01-IM37	3.5mm Long Screw Driver
01-IM49	AO Connect Handle
01-IM50	3.5mm Short Screw Driver
01-IM51	Screw Gauge
01-IM52	Fracture Reduction Tool
01-IM53	Ball Spike Pusher
01-IM56	Obturator
01-IM57	Femur Nail Extraction Bolt
01-IM58	Long Impactor



(Located in OIC Extraction Set)

DISPOSABLE INSTRUMENTS

32-400P	Guide Pin
DR42-330C	Long Calibrated Drill Bit
DR42-155	Short Drill Bit
GW03-1000	Ball Tip Guide Rod



IMPLANTS

Catalog Information

TAFN Nails (Left and Right)

Part #	Diameter x Length	Part #	Diameter x Length	Part #	Diameter x Length
TAFN-100320L TAFN-100320R	10mm x 320mm	TAFN-115320L TAFN-115320R	11.5mm x 320mm	TAFN-130320L TAFN-130320R	13mm x 320mm
TAFN-100340L TAFN-100340R	10mm x 340mm	TAFN-115340L TAFN-115340R	11.5mm x 340mm	TAFN-130340L TAFN-130340R	13mm x 340mm
TAFN-100360L TAFN-100360R	10mm x 360mm	TAFN-115360L TAFN-115360R	11.5mm x 360mm	TAFN-130360L TAFN-130360R	13mm x 360mm
TAFN-100380L TAFN-100380R	10mm x 380mm	TAFN-115380L TAFN-115380R	11.5mm x 380mm	TAFN-130380L TAFN-130380R	13mm x 380mm
TAFN-100400L TAFN-100400R	10mm x 400mm	TAFN-115400L TAFN-115400R	11.5mm x 400mm	TAFN-130400L TAFN-130400R	13mm x 400mm
TAFN-100420L TAFN-100420R	10mm x 420mm	TAFN-115420L TAFN-115420R	11.5mm x 420mm	TAFN-130420L TAFN-130420R	13mm x 420mm
TAFN-100440L TAFN-100440R	10mm x 440mm	TAFN-115440L TAFN-115440R	11.5mm x 440mm	TAFN-130440L TAFN-130440R	13mm x 440mm

IMPLANTS

Catalog Information

Cross Lock Screws	
Part #	Diameter x Length
NLB-5025	5mm x 25mm
NLB-5027	5mm x 27.5mm
NLB-5030	5mm x 30mm
NLB-5032	5mm x 32.5mm
NLB-5035	5mm x 35mm
NLB-5037	5mm x 37.5mm
NLB-5040	5mm x 40mm
NLB-5042	5mm x 42.5mm
NLB-5045	5mm x 45mm
NLB-5047	5mm x 47.5mm
NLB-5050	5mm x 50mm
NLB-5055	5mm x 55mm
NLB-5060	5mm x 60mm
NLB-5065	5mm x 65mm
NLB-5070	5mm x 70mm
NLB-5075	5mm x 75mm
NLB-5080	5mm x 80mm
NLB-5085	5mm x 85mm
NLB-5090	5mm x 90mm
NLB-5095	5mm x 95mm
NLB-50100	5mm x 100mm

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

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Andhra Pradesh 530032.