ortemiz

OIC Cephalomedullary Hip Nail
Surgical Technique Guide

ortemiz

Table of Contents

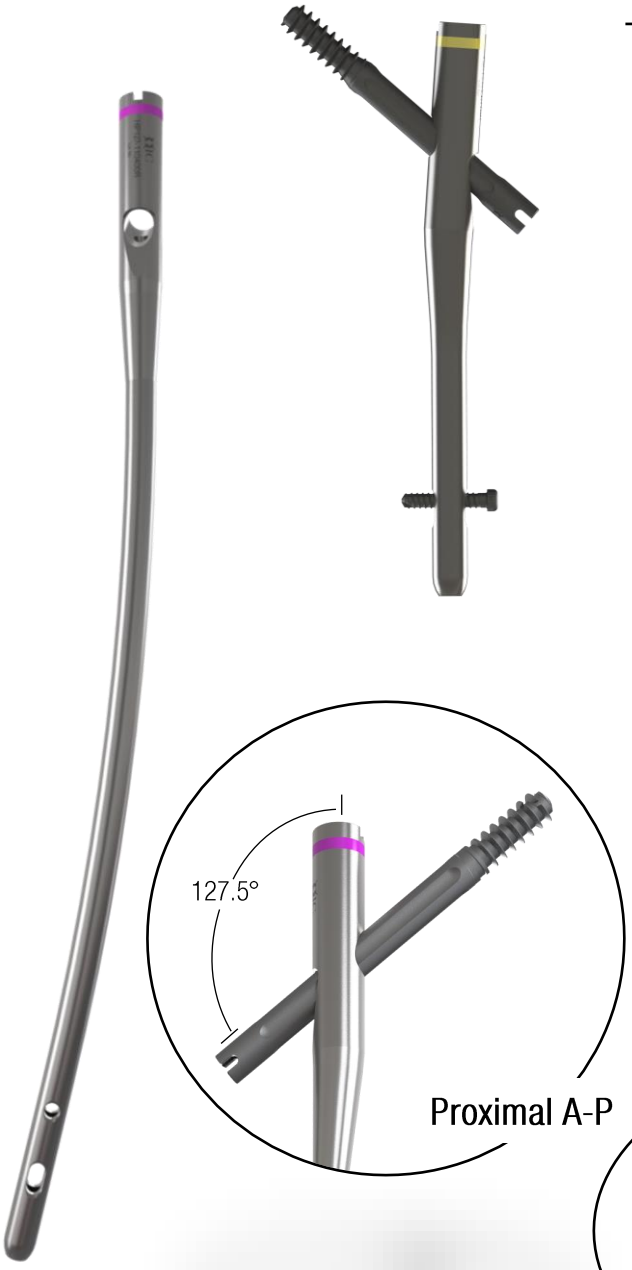
The technique description herein is made available to the healthcare professional to illustrate the author's suggested treatment for the uncomplicated procedure. In the final analysis, the preferred treatment is that which addresses the specific needs of the patient.

System Features

INTRODUCTION

The OIC Cephalopmedullary Hip Nail is a cost-effective product that incorporates the design features of modern hip nails to obtain optimal clinical results with minimal surgical time. Instruments are designed to be intuitive and are used in conjunction with all the nails in OIC's portfolio, flattening the technique learning curve.

DESIGN FEATURES



OIC Hip Nail	
Characteristics	**Values**
Metallurgy	Titanium Alloy (Ti6AL4V)
Proximal Diameter	15.5mm
Distal Diameter	Neutral: 10mm Right and Left: 11mm
Lengths	Neutral: 180mm; 210mm Left and Right: 320-440mm, 20mm increments
Cross-Section	Circular
Lag Screw Angle	127.5°
Lag Screw Diameter	10.5mm
Lag Screw Lengths	70-120mm
Cross-Lock Screw Diameter	5mm
Cross-Lock Screw Lengths	25-100mm
Degree of Proximal M/L Bend	4°
Proximal M/L Bend Location	67.5mm
Radius of Antecurvature	1.0m

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
- The short intertrochanteric nail is contraindicated for complex intertrochanteric and femoral neck fractures.

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 Cephalomedullary Hip 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 Cephalomedullary Hip 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. In most intertrochanteric fractures this requires internal rotation, however 5% reduce with traction and external rotation. Reduction should be confirmed with both AP and Lateral fluoroscopic images. In some cases, closed reduction of the fracture is not possible, but many percutaneous reduction techniques exist. A ball spike pusher (01-IM53), bone hook and cobb elevator should all be available, especially for subtrochanteric fractures. It is imperative for surgeons to understand that cephallomedullary nail do not reduce fractures. The fracture must be reduced before the nail is inserted and reduction must be held during the reaming process. In reverse obliquity or comminuted extended fracture patterns, use of cables prior to nailing may be needed.

FIG 1

INCISION AND PIN PLACEMENT

After sterile preparation and draping, the 3.2mm Guide Pin (32-400) is used to locate the tip of the greater trochanter at the junction of the anterior 1/3 and posterior 2/3 on both AP and lateral views **FIG 1**. A 2cm incision is then made around the pin.

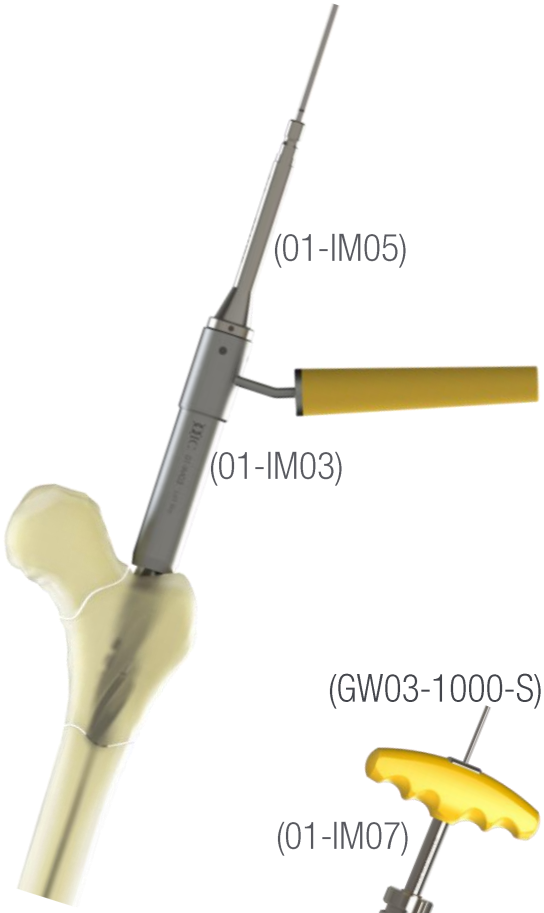


FIG 2

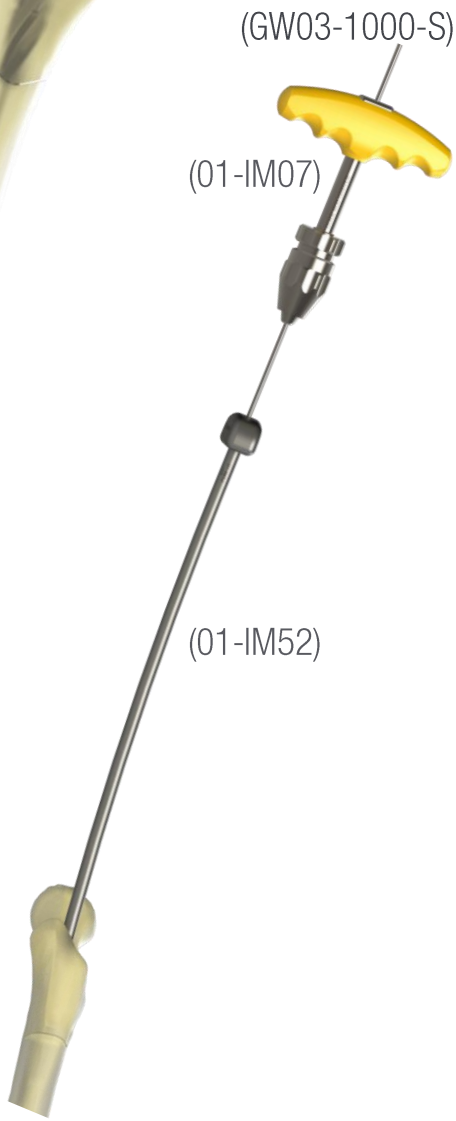


FIG 3

PREPARATION OF MEDULLARY CANAL

Pass the 16mm Proximal Entry Reamer (01-IM05) over the Guide Pin and through the 16mm Tissue Protector (01-IM03) to gain access to the medullary canal FIG 2. This should be taken down to the level of the lesser trochanter to allow for easy passage of the nail.

CAUTION: Without appropriate attention, the reamer can shift laterally and destroy the lateral cortex. Reaming under fluoroscopic guidance and rigorous technique will prevent this complication.

Additional Reaming – The Ball Tip Guide Rod (GW03-1000-S) is then attached to the Guide Rod Gripper (01-IM07) and passed across the fracture site into a center-center position in the knee. The Reduction Tool (01-IM52) can be used to facilitate passage and positioning FIG 3. This should be confirmed on both AP and Lateral fluoroscopic images to ensure correct placement. Anterior positioning can cause cortical break and result periprosthetic fracture or intra-articular hardware placement. 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. 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 or pull out the guide rod during reaming. The fracture should be held reduced during reaming to prevent eccentric reduction.

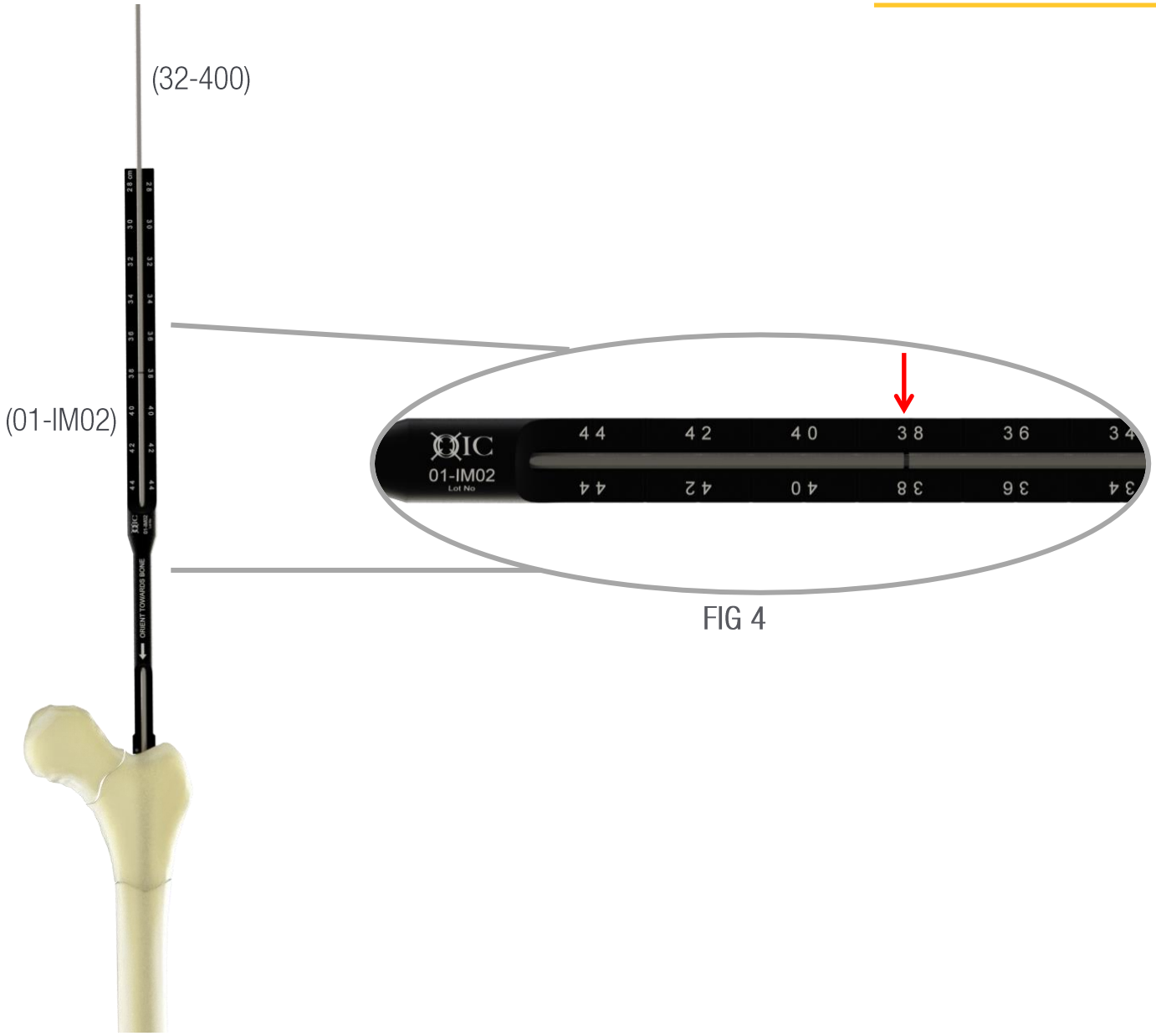


FIG 4

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 (GW03-1000-S) up to level of the greater trochanter and the measurement is read FIG 4. 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.

ASSEMBLING THE TARGETING GUIDE AND NAIL

To assemble the guide, align the pins on the Hip Drop (01-IM22) to the holes in the Femur Handle (01-IM21) FIG 5. Tighten the thumb screw to complete the assembly. Attach the selected nail to the targeting guide by securing it with the Femur Guide Bolt (01-IM24) FIG 6 and tightening it with the Guide Bolt Driver (01-IM29) FIG 7. 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. Ensure that the Lag Screw Tissue Protector (01-IM40) aligns with the lag screw hole in the nail. This alignment is imperative to allow for proper lag screw insertion.

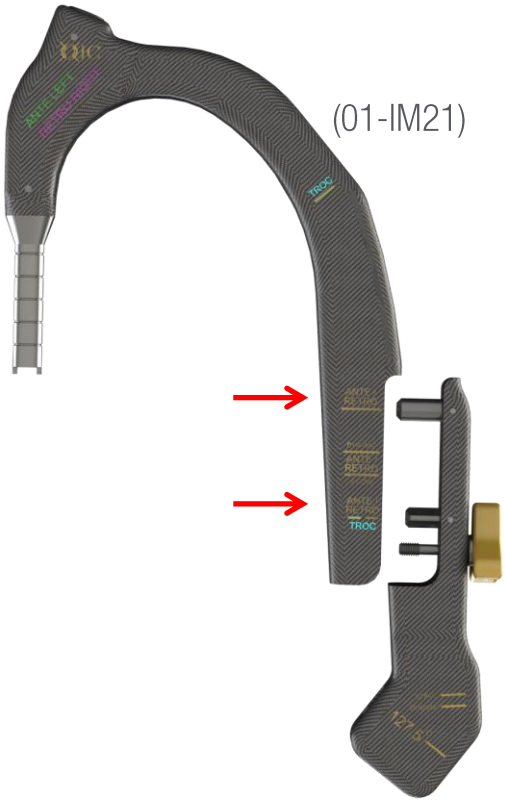


FIG 5

FIG 6

FIG 7

NAIL INSERTION

Introduce the attached nail and targeting guide over the Guide Rod. Insert the nail by hand with care taken to watch the anterior bow of the nail. 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 8. To avoid damage to the carbon fiber guide, only hit the metal Impactor (01-IM30) . Ideal nail depth is determined by the desired position of the lag screw.

Remove the Guide Rod.

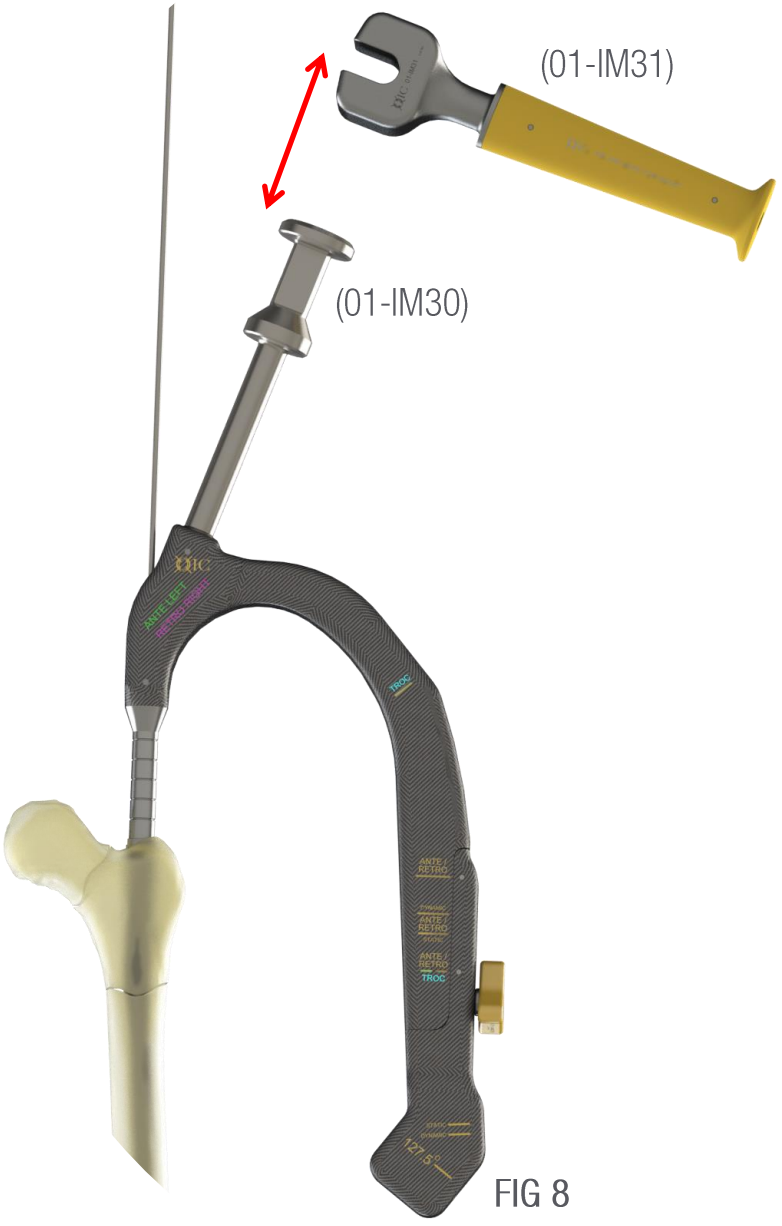


FIG 8

LAG SCREW INSERTION

Insert the Guide Pin Sleeve (01-IM41) into the Lag Screw Tissue Protector (01-IM40) and advance the assembly through the targeting drop and soft tissue until it reaches the outer cortex of the lateral femur. Place a Guide Pin (32-400) through the Guide Pin Sleeve and achieve a center-center position in the femoral head FIG 9. Also confirm that the guide pin is centered in the lag screw hole of the nail. Both AP and Lateral fluoroscopic images should be utilized to confirm placement.

CAUTION: Care should be taken not to perforate articular surface with the guide pin.

Once ideal pin position has been obtained, lag screw measurement can be determined in two ways:

1) Sliding the Lag Screw Depth Gauge (01-IM42) over pin FIG 10.
2) Using calibration marks on Guide Pin FIG 11.

NOTE: Measurement device and pin measures from the tip of the pin.

FIG 9

FIG 10 (01-IM42)

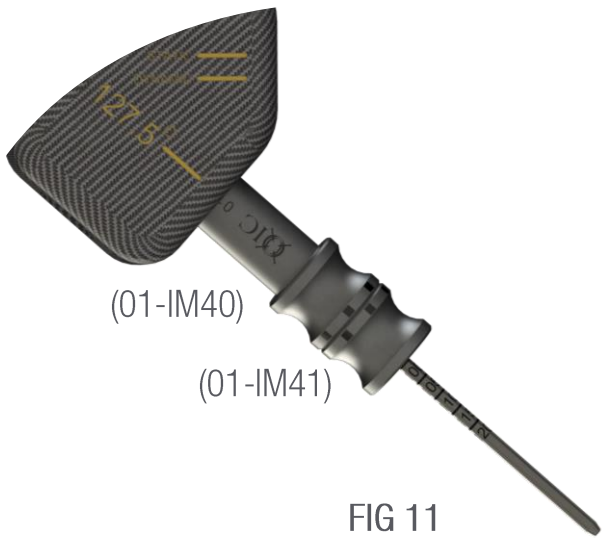


FIG 11

Assemble the Lag Screw Reamer (01-IM43) by depressing the button and sliding the collar over the shaft **FIG 12**. Stop at the correct lag screw measurement. In **FIG 13** if the lag screw measurement is 100mm, the number "100" should be displayed directly below the collar. Ensure that the button is no longer depressed, locking the collar in place **FIG 14**.

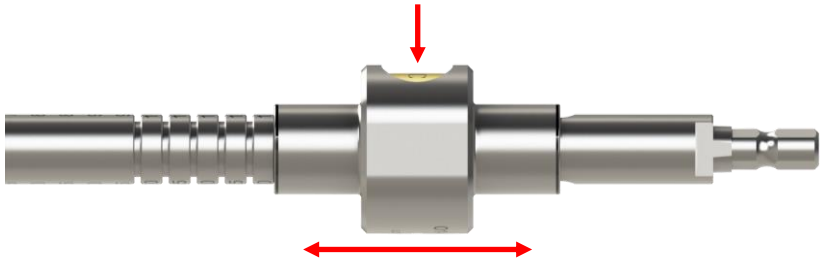


FIG 12

FIG 13

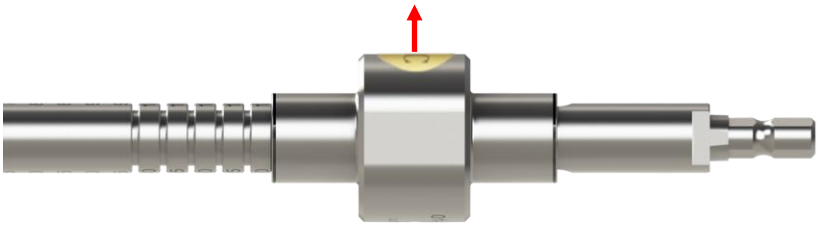


FIG 14

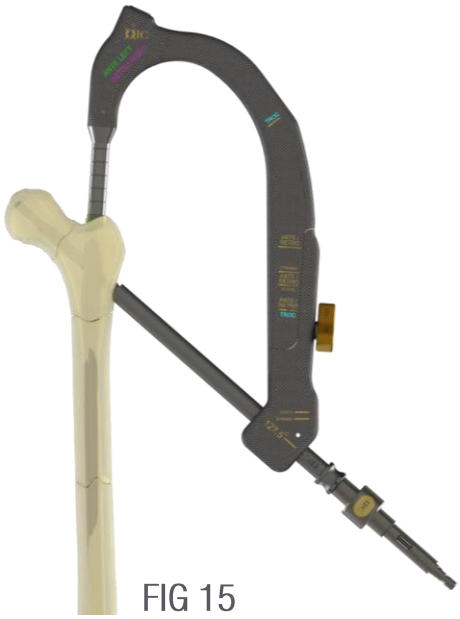


FIG 15

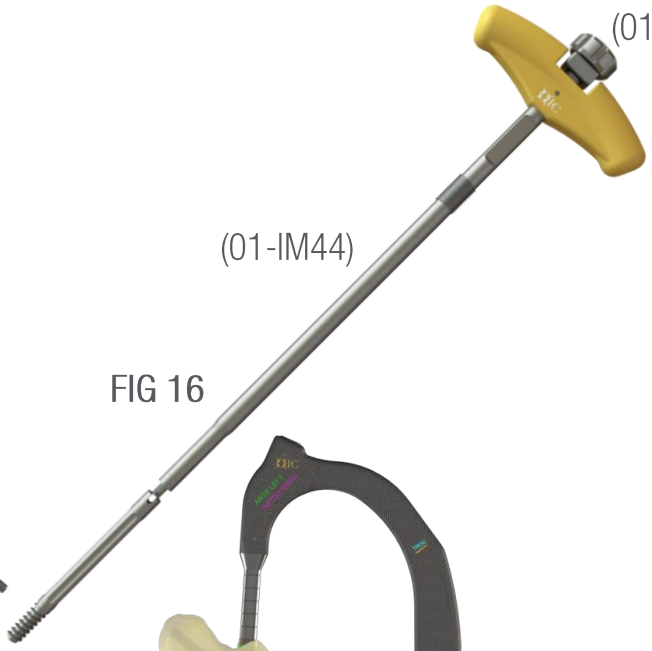


FIG 16

FIG 17

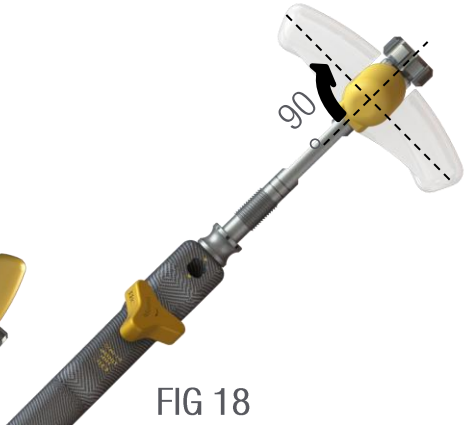


FIG 18

Remove the Guide Pin Sleeve and ream over the Guide Pin until reamer bottoms out on Lag Screw Tissue Protector **FIG 15**.

CAUTION: To avoid reaming too far, reaming should always be done under fluoroscopic guidance.

Assemble the Lag Screw (HLG-105XX) onto the Lag Screw Inserter (01-IM44 and 01-IM45) **FIG 16**. Insert the Lag Screw under fluoroscopic guidance over the Guide Pin **FIG 17**. Once the Lag Screw has been inserted to the appropriate depth, the Lag Screw Inserter Handle must be parallel or perpendicular to the targeting device to facilitate set screw locking **FIG 18**.

NOTE: In more dense bone, the femoral head can be rotated during reduction and care should be taken to maintain reduction during insertion.

LAG SCREW COMPRESSION (OPTIONAL)

If compression is desired, attach the Compression Dial (01-IM46) onto Lag Screw Inserter FIG 19. Arrow on side of Compression Dial should point toward the Targeting Guide. Compression is obtained by turning the Compression Dial clockwise against the Lag Screw Tissue Protector. Compression Dial markings on Lag Screw Inserter, shown in FIG 20, should be used FOR REFERENCE only.

CAUTION: Perform compression under fluoroscopic guidance to monitor amount of desired compression and avoid Lag Screw pullout.

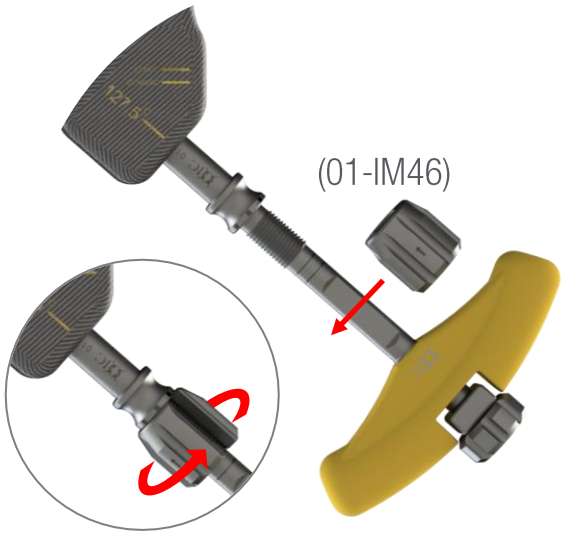


FIG 19

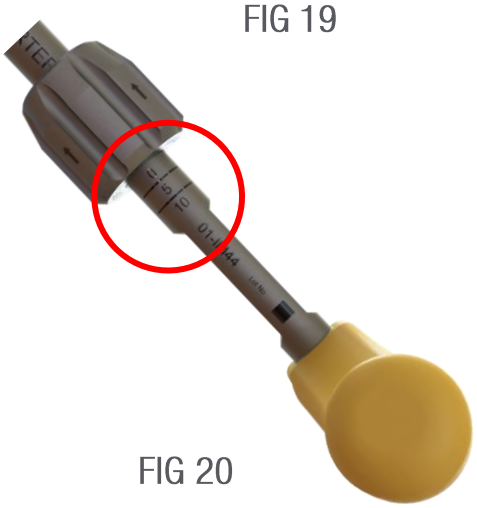


FIG 20

LOCK SET SCREW

Attach the Set Screwdriver (01-IM47) to the AO Connect Handle (01-IM49) and insert into the nail through the Targeting Guide and tighten the set screw to engage the nail and lock the Lag Screw FIG 21. If the operative surgeon desires sliding of the Lag Screw, the set screw can be unscrewed ¼ turn.

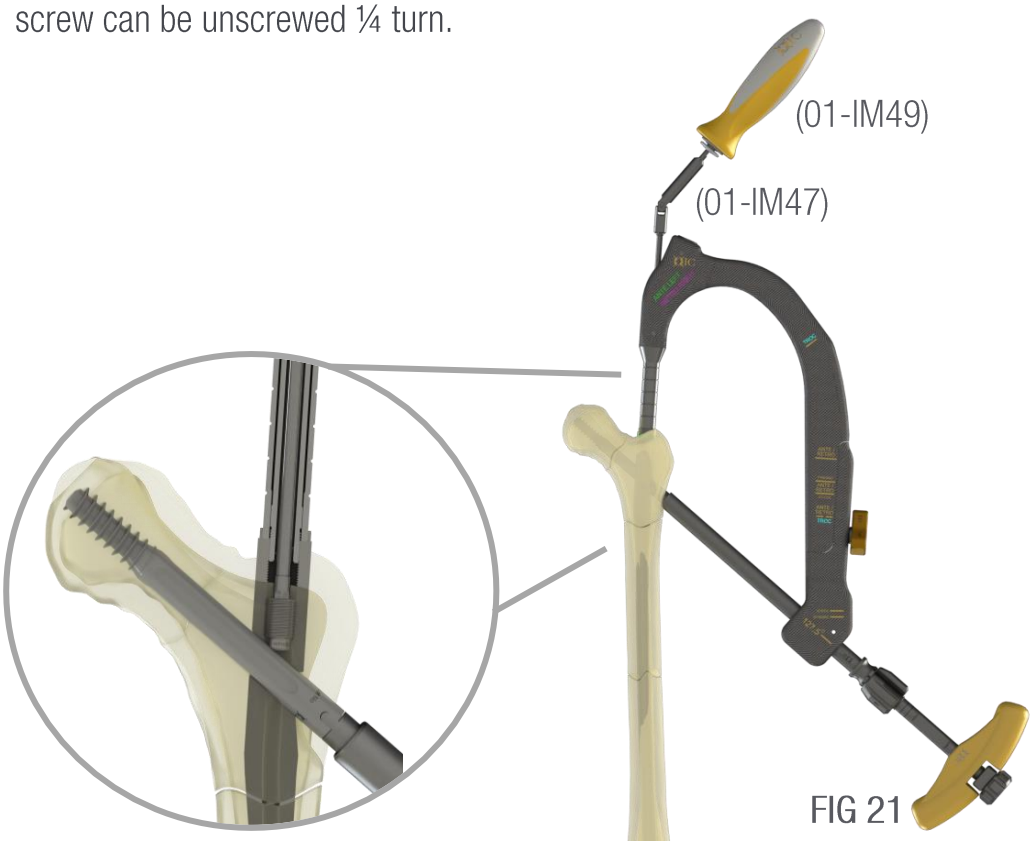


FIG 21

FIG 22

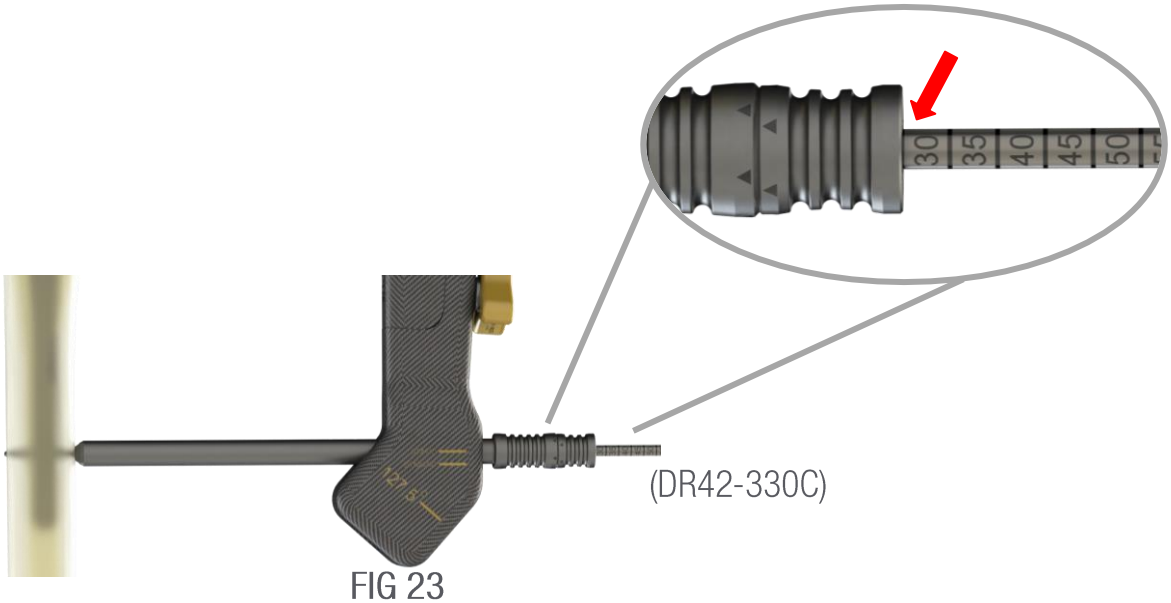
(01-IM32)
(01-IM33)
(01-IM34)

DISTAL CROSS LOCK SCREW

Distal cross locking is recommended for rotationally unstable or comminuted fracture patterns. The OIC Hip Nail has several distal screw locking options.

Short Nail – If a short nail is chosen, the distal Cross Lock Screws (NLB-5XXX) can be inserted with the targeting jig. Either the static or dynamic screw slot can be selected depending on surgeon preference. The triple sleeve (01-IM32, 01-IM33, 01-IM34) is assembled and placed through the Hip Drop FIG 22. A small incision is made to allow insertion of the sleeve through the soft tissue against the bone. The Trocar (01-IM33) is then removed and long 4.2mm Calibrated Drill Bit (DR42-330C) is utilized under fluoroscopic guidance. Screw length can be determined by noting the laser etched measurements on the drill against the Drill Sleeve (01-IM32) FIG 23. The Drill Sleeve is then removed and the screw is inserted using the Long 3.5mm Screw Driver (01-IM35) via the Tissue Protector Sleeve (01-IM34). 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.



(DR42-330C)

FIG 23

Surgical Technique

Long Nails – In Long Nail options, the distal Cross Lock Screws must be inserted using standard free hand techniques. Either one or two screws can be used based on surgeon preference. 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). Screw length is measured using the Depth Gauge (01-IM51) FIG 24.

The screw is inserted using the short 3.5mm Hex Driver (01-IM50) FIG 25.

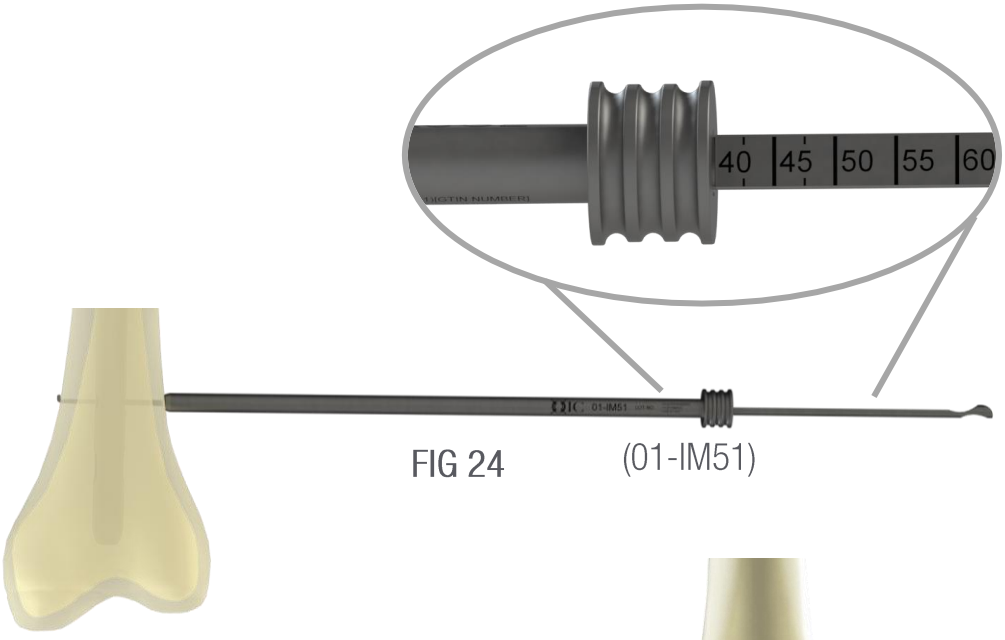


FIG 24 (01-IM51)

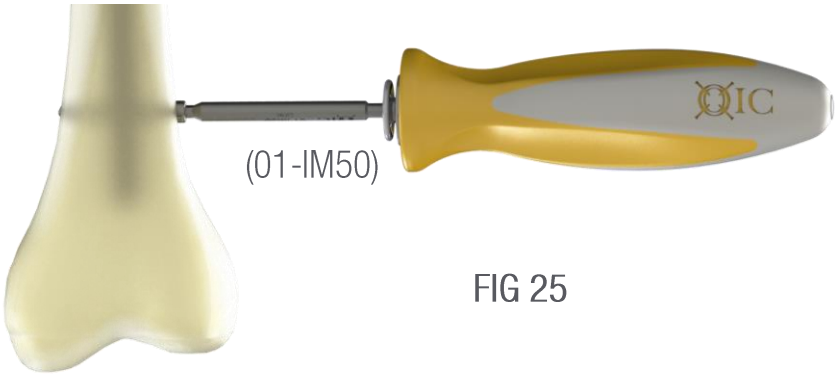


FIG 25

POST OPERATIVE MANAGEMENT

Weight bearing status is left to the surgeon's discretion. In most cases, for stable fractures with good bony contact full weightbearing is instituted immediately. For comminuted fracture patterns, partial weightbearing may be utilized for 6 to 8 weeks.

NAIL EXTRACTION

At times nail extraction is indicated and can be accomplished via previous incisions. Remove the distal Cross Lock Screw(s). Insert the guide pin into the lag screw. If bony overgrowth has occurred this should be removed with a curette or osteotomes. Disengage and remove the set screw via the proximal end of the nail.

NOTE: The set screw needs to be fully removed in order to fully engage the extraction bolt.

Insert the Femur Nail Extraction Bolt (01-IM57) into the proximal end of the nail FIG 26. Once solid connection has been established, remove the Lag Screw with the Lag Screw Inserter over the Guide Pin by turning counterclockwise. Screw the Impactor (01-IM30) onto the Extraction Bolt and remove the nail by back-slapping with the Slotted Mallet FIG 27. If more back-slapping distance is needed to remove the nail, the Long Impactor (01-IM58) can be utilized.

NOTE: The Long Impactor is located in the OIC Nail Extraction Set.

FIG 26

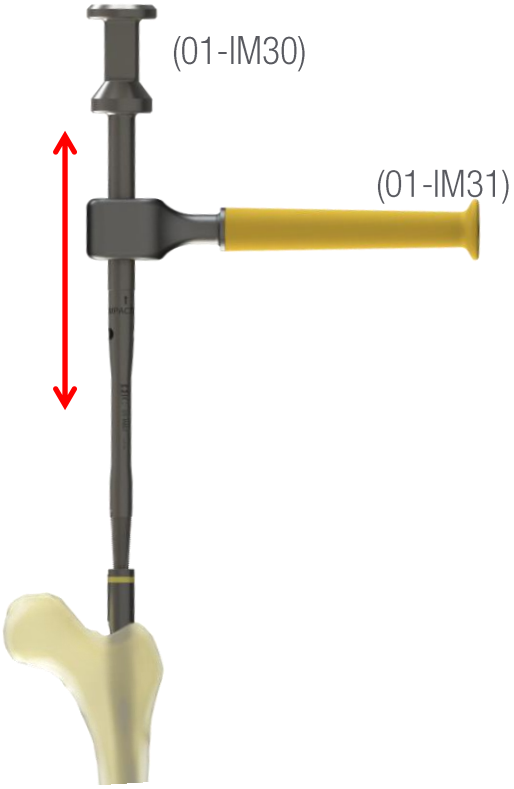
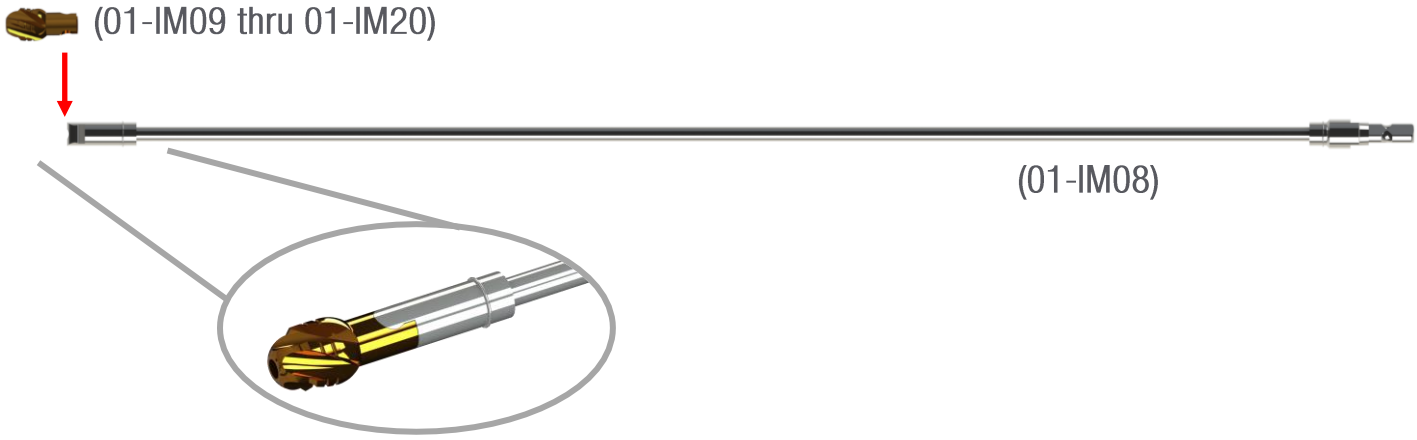


FIG 27

Assembly and Disassembly

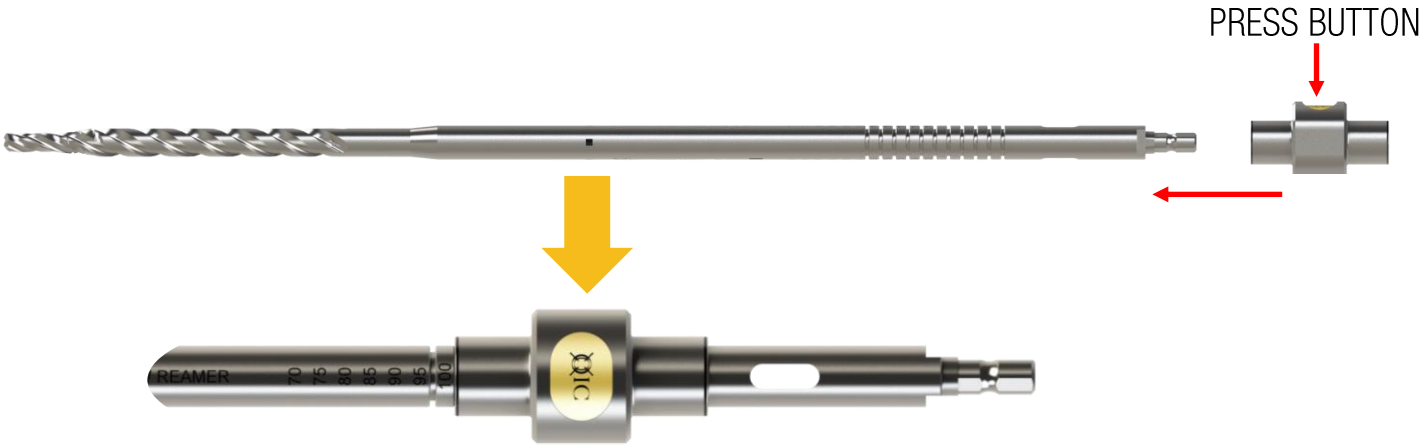
FLEXIBLE REAMER SHAFT ASSEMBLY



DRILL TISSUE PROTECTOR ASSEMBLY

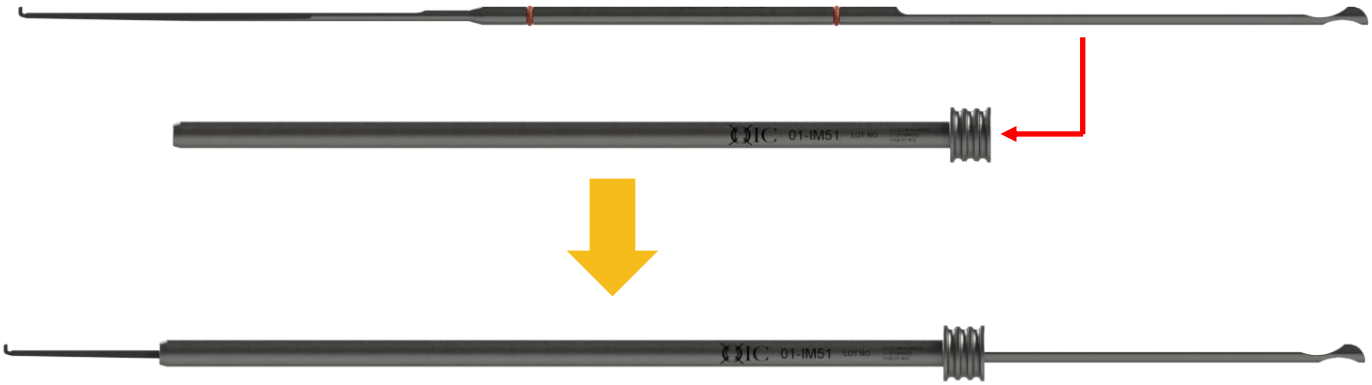
Assembly and Disassembly

01-IM43: LAG SCREW REAMER



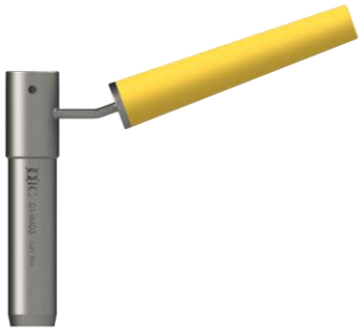
BUTTON SHOULD CLICK INTO DESIRED LOCKED POSITION

01-IM51: SCREW GAUGE



Reusable Instruments

Catalog Information

01-IM02	Nail Measuring Gauge	
01-IM03	16mm Tissue Protector	
01-IM05	16mm 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-IM22	127.5° Carbon Fiber Drop	
01-IM24	Hip and Femur Guide Bolt	
01-IM29	Guide Bolt Driver	
01-IM30	Impactor	
01-IM31	Slotted mallet	
01-IM32	Tissue protector Sleeve	
01-IM33	Trocar	
01-IM34	Drill Sleeve	

Reusable Instruments (Cont.)

Catalog Information

01-IM37	3.5mm Long Screw Driver	
01-IM40	Lag Screw Tissue Protector	
01-IM41	Guide Pin Sleeve	
01-IM42	Lag Screw Depth Gauge	
01-IM43	Lag Screw Reamer	
01-IM44	Lag Screw Inserter	
01-IM45	Lag Screw Locking Shaft	
01-IM46	Compression Dial	
01-IM47	Set Screw Driver	
01-IM49	AO Connect Handle	

Reusable Instruments (Cont.)

Catalog Information

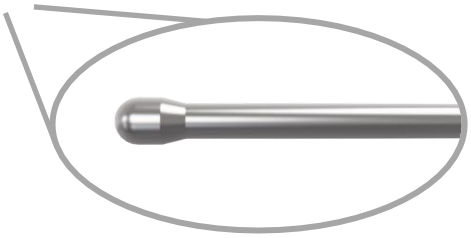
01-IM50	3.5mm Short Screw Driver
01-IM51	Screw Gauge
01-IM52	Fracture Reduction Tool
01-IM53	Ball Spike Pusher
01-IM56	Obturator
01-IM57	Femur Nail Extraction Bolt
01-IM58	Long Impactor

(Located in OIC Extraction Set)

Disposable Instruments

Catalog Information

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



Implants

Catalog Information

SHORT HIP NAIL	
PART #	DIAMETER x LENGTH
HIP127-100180	10mm x 180mm

INTERMEDIATE HIP NAIL	
PART #	DIAMETER x LENGTH
HIP127-100210	10mm x 210mm

LONG HIP NAILS (LEFT AND RIGHT)			
PART #	DIAMETER x LENGTH	PART #	DIAMETER x LENGTH
HIP127-110320L HIP127-110320R	11mm x 320mm	HIP127-110400L HIP127-110400R	11mm x 400mm
HIP127-110340L HIP127-110340R	11mm x 340mm	HIP127-110420L HIP127-110420R	11mm x 420mm
HIP127-110360L HIP127-110360R	11mm x 360mm	HIP127-110440L HIP127-110440R	11mm x 440mm
HIP127-110380L HIP127-110380R	11mm x 380mm		

Implants (Cont.)

Catalog Information

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

LAG SCREWS			
PART #	DIAMETER x LENGTH	PART #	DIAMETER x LENGTH
HLG-10570	10mm x 70mm	HLG-105100	10mm x 100mm
HLG-10575	10mm x 75mm	HLG-105105	10mm x 105mm
HLG-10580	10mm x 80mm	HLG-105110	10mm x 110mm
HLG-10585	10mm x 85mm	HLG-105115	10mm x 115mm
HLG-10590	10mm x 90mm	HLG-105120	10mm x 120mm
HLG-10595	10mm x 95mm		

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

ortemiz

Pragati Maidan, Nadupuru, Visakhapatnam,
Andhra Pradesh 530032.