



**OIC Femur Nail
Antegrade and Retrograde Approach
Surgical Technique Guide**

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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.

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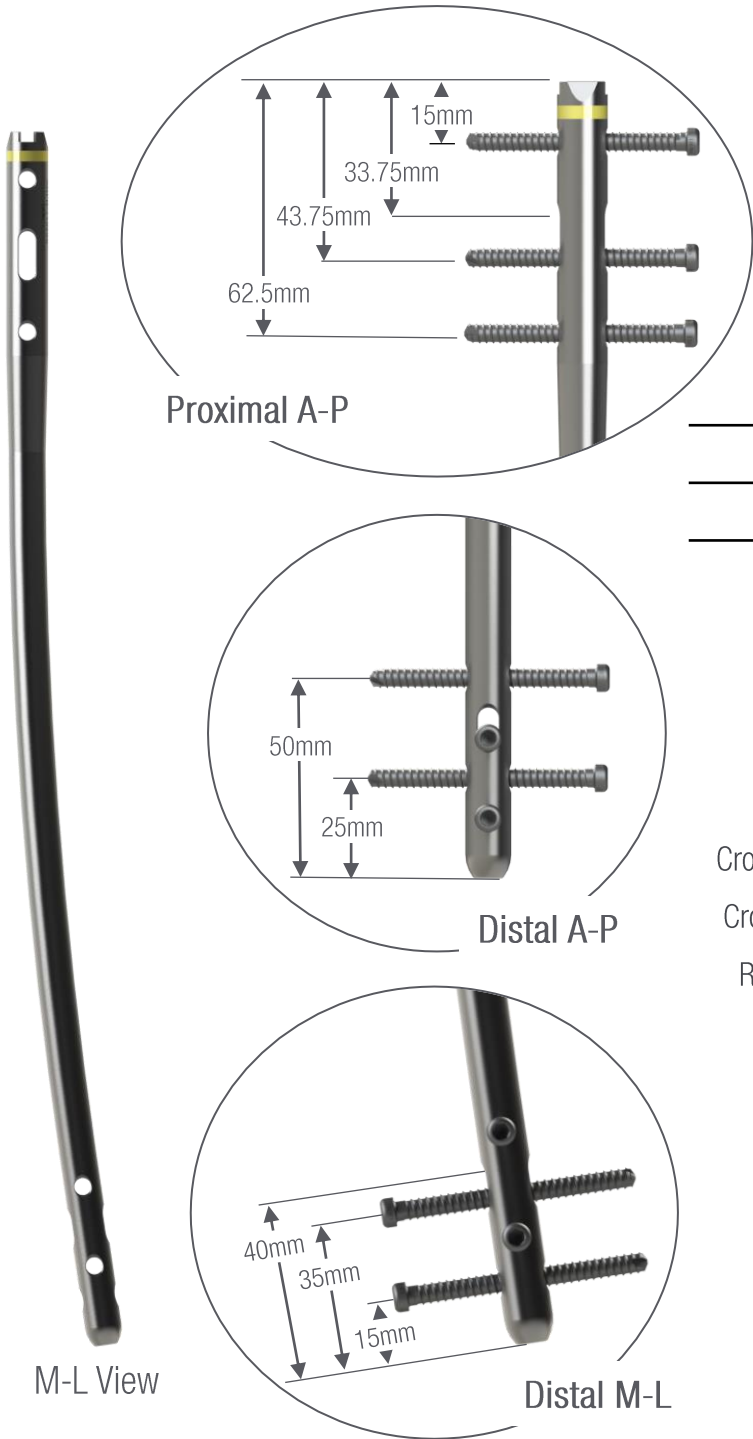
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The technique description herein is made available to the healthcare professional to illustrate the author’s suggested treatment for the uncomplicated procedure. In the final analysis, the preferred treatment is that which addresses the specific needs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

INTRODUCTION

The OIC Antegrade/Retrograde Femur Nail (ARFN) is a cost-effective product that incorporates the design features of modern femur nails to obtain consistent clinical results. Instruments share a similar platform to other OIC intramedullary nails.

DESIGN FEATURES



OIC Antegrade/Retrograde Femur Nail	
Characteristics	Value
Metallurgy	Titanium Alloy (Ti6AL4V)
Proximal Diameter	13mm
Distal Diameter	10mm, 11.5mm, 13mm
Lengths	300-440mm; 20mm increments
Cross-Section	Circular
Cross-Lock Screw Diameter	5mm
Cross-Lock Screw Lengths	25mm-100mm
Radius of Antecurvature	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 Femur Nail System 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 the OIC Femur Nail System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Surgical Technique – Antegrade Approach

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, the 3.2mm Guide Pin (32-400) is used to locate piriformis on both AP and lateral views FIG 1 & 2. A 2 cm incision is then made around the wire.

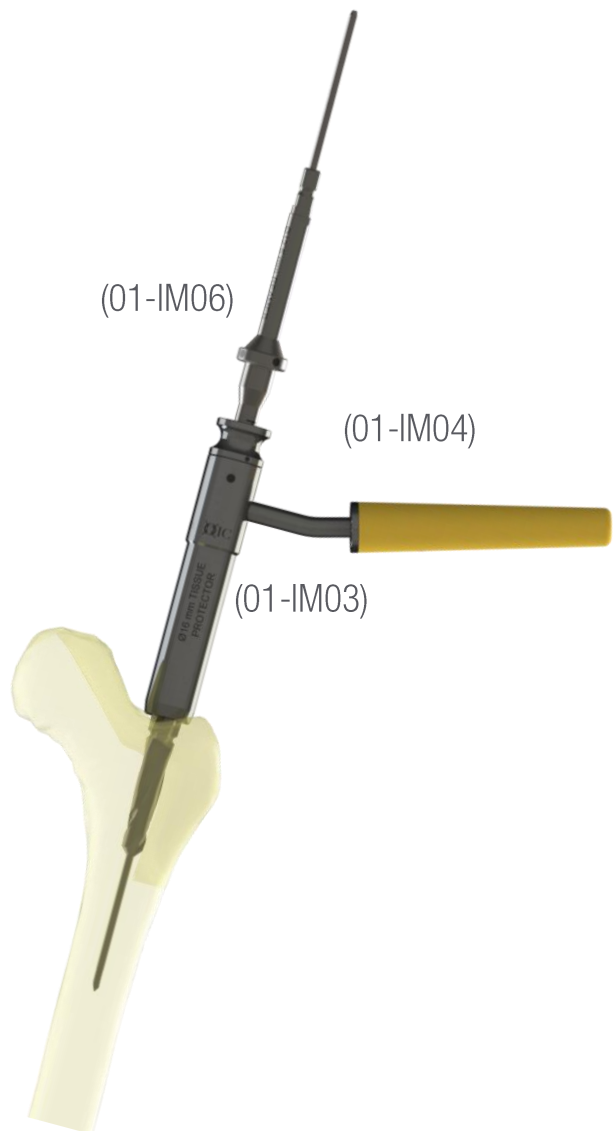


FIG 3

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 intramedullary canal **FIG 3**. This should be taken down to the level of the lesser trochanter to allow for easy passage of the nail.

Surgical Technique – Antegrade Approach

GUIDE ROD INSERTIONS AND REAMING

Guide Rod Insertion – 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 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 pull-out guide wire during reaming. The fracture should be held reduced during reaming to prevent eccentric reduction.



FIG 4

FIG 5



FIG 6

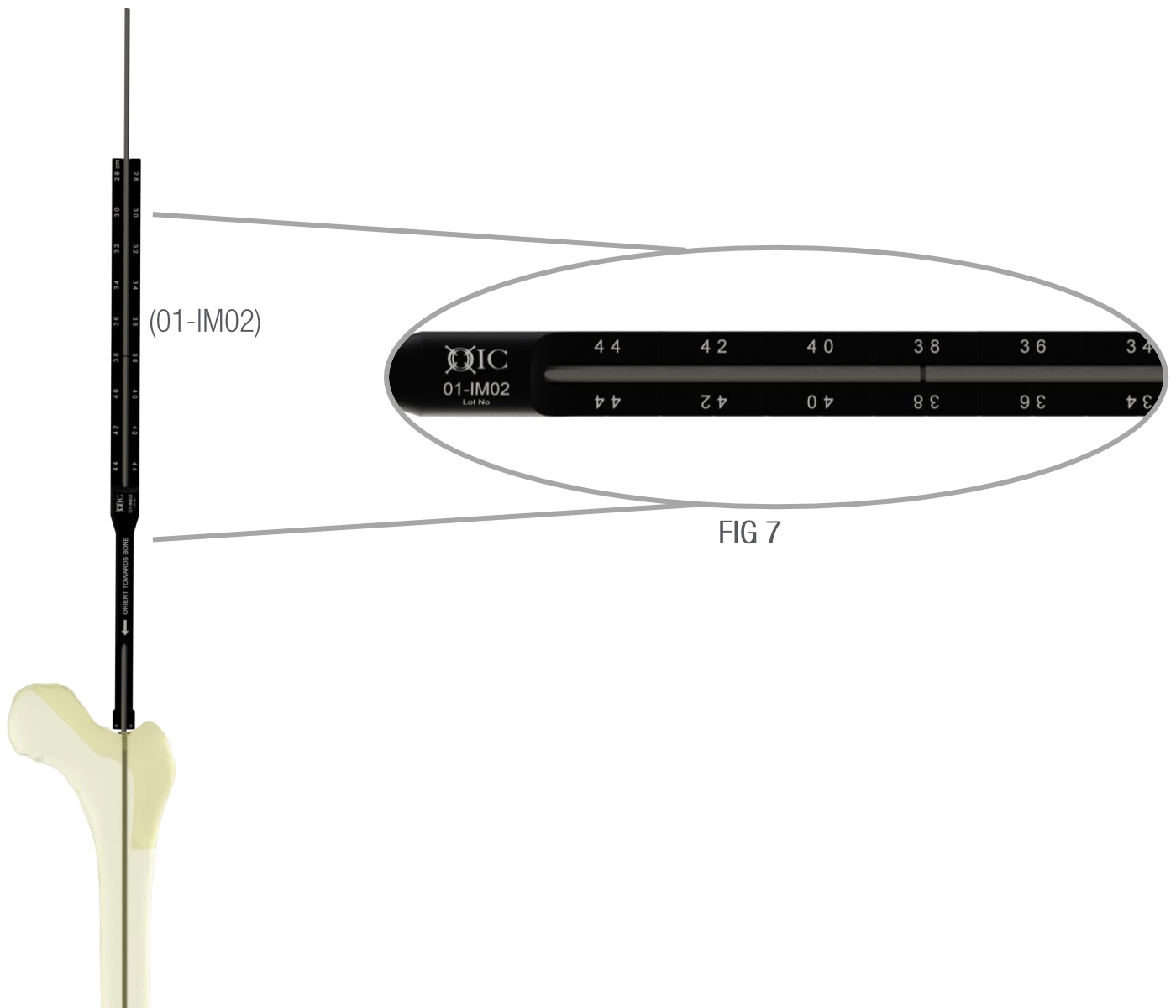
(01-IM08)

Surgical Technique – Antegrade Approach

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.



Surgical Technique – Antegrade Approach

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. Ensure that the notches fit well 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.

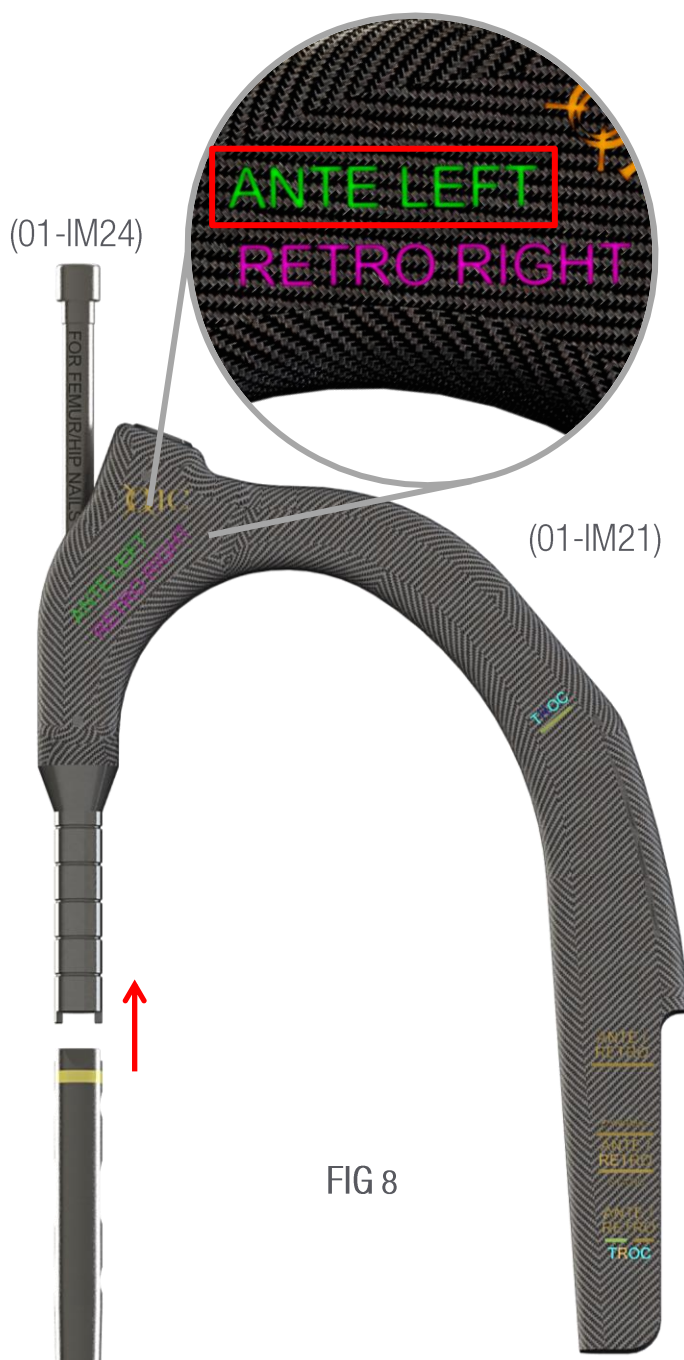


FIG 8

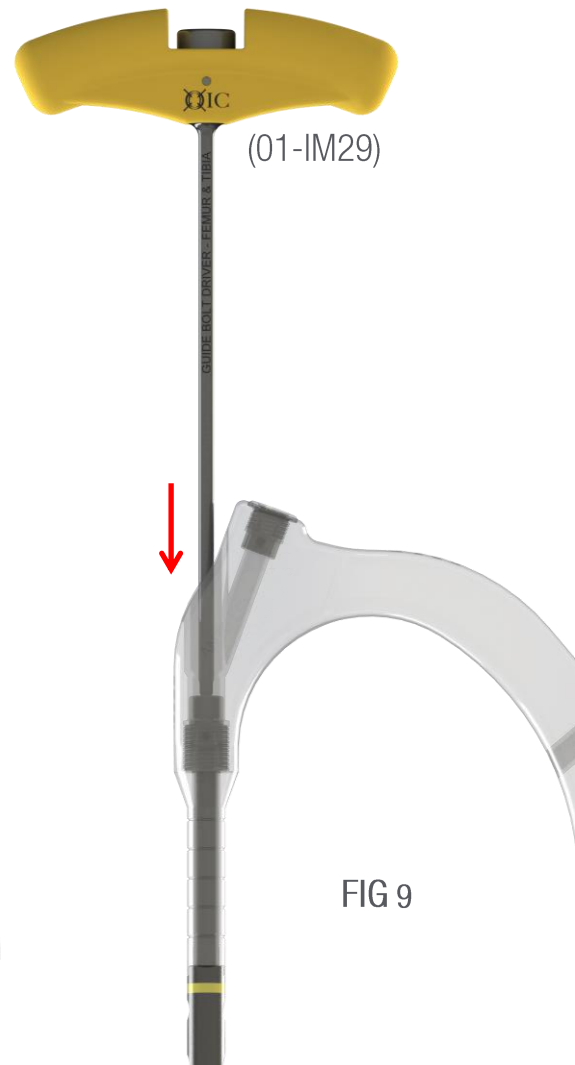


FIG 9

Surgical Technique – Antegrade Approach

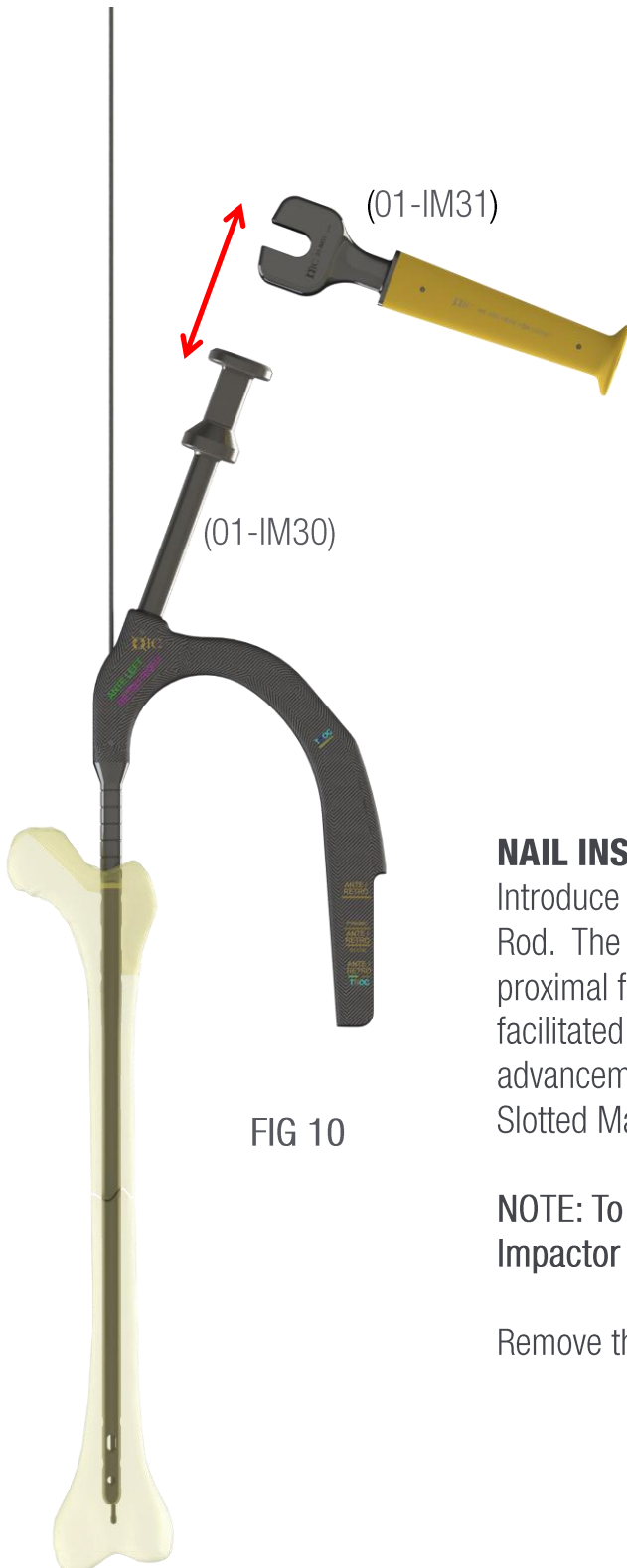


FIG 10

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.

Surgical Technique – Antegrade Approach

PROXIMAL CROSS LOCK SCREW

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 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 a Depth Gauge (01-IM51).

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

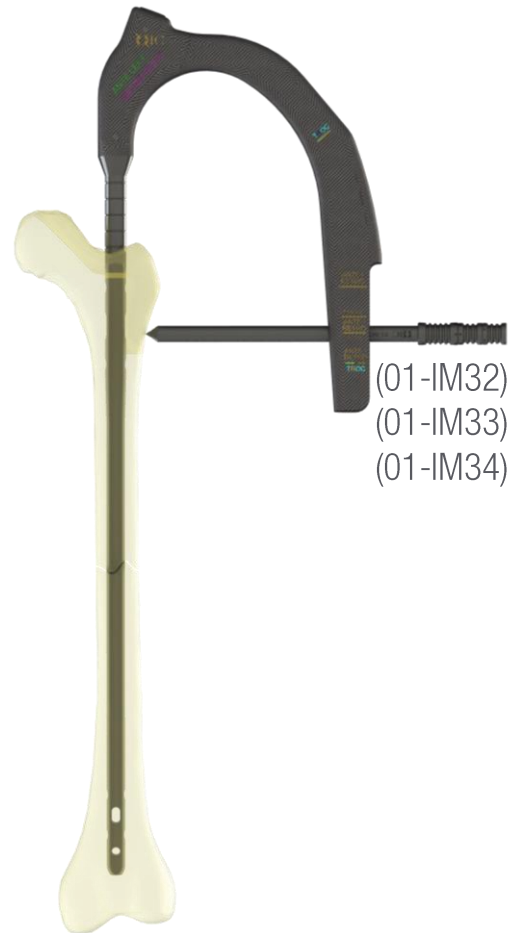


FIG 11

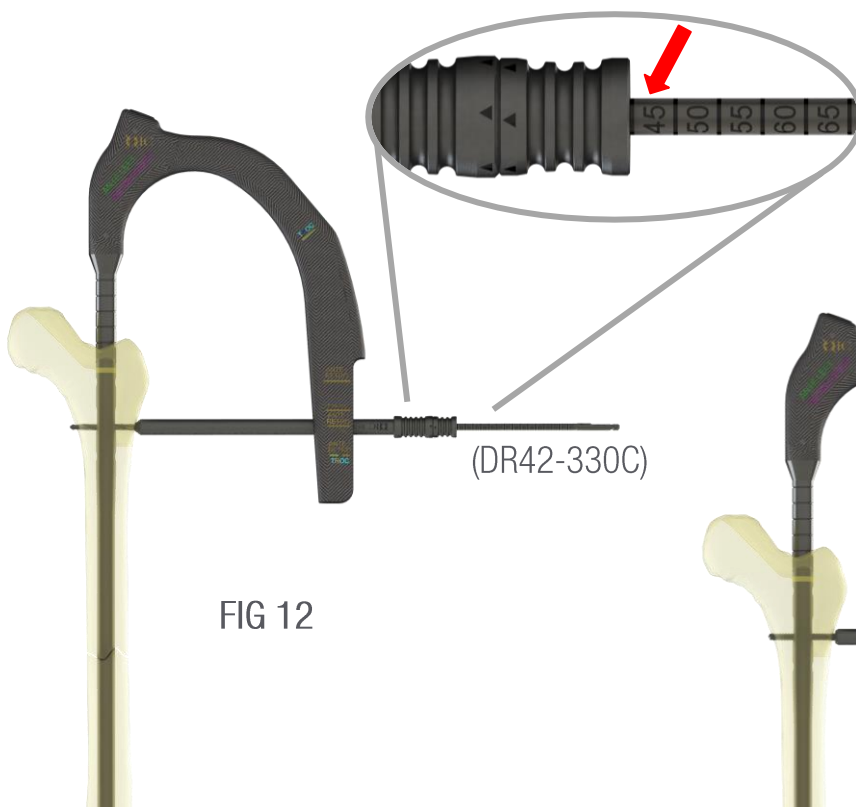


FIG 12

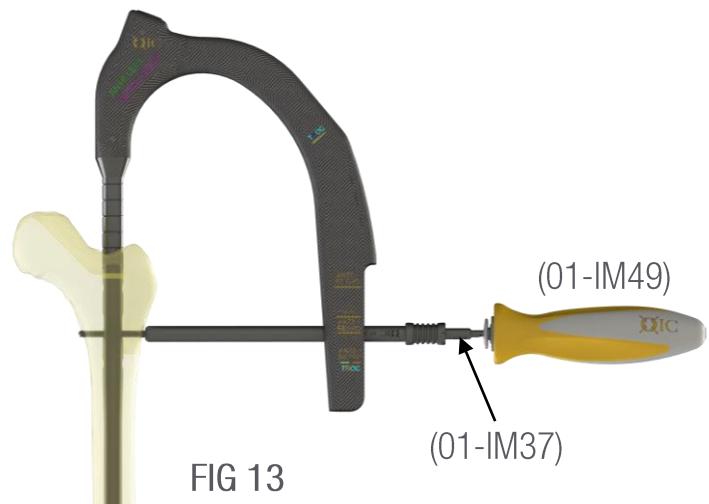


FIG 13

Surgical Technique – Antegrade Approach

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.

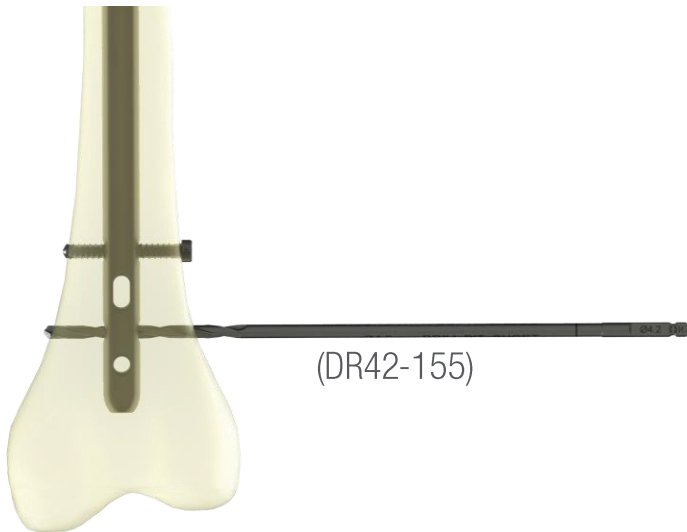


FIG 14

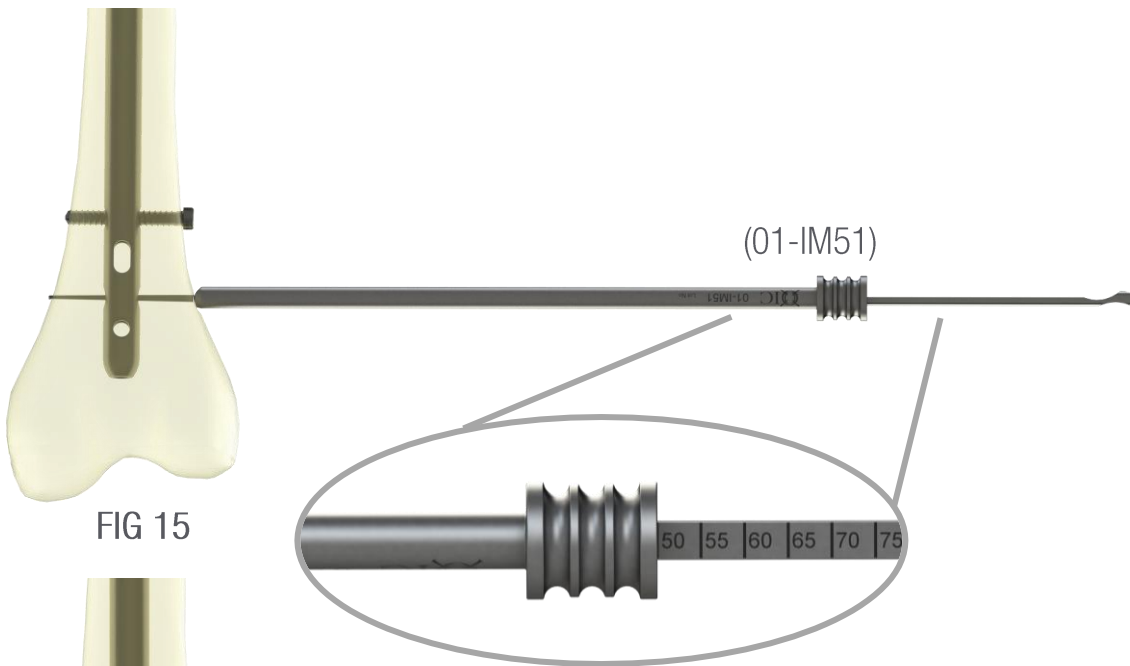


FIG 15

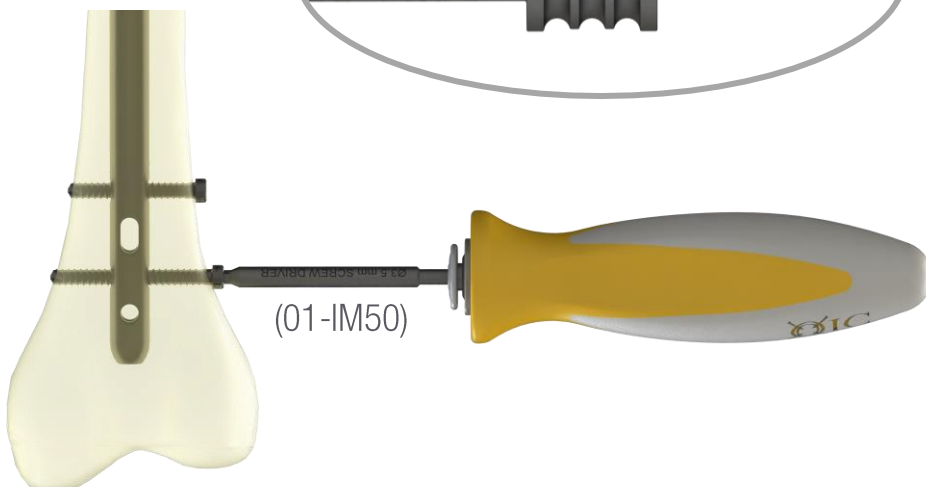


FIG 16

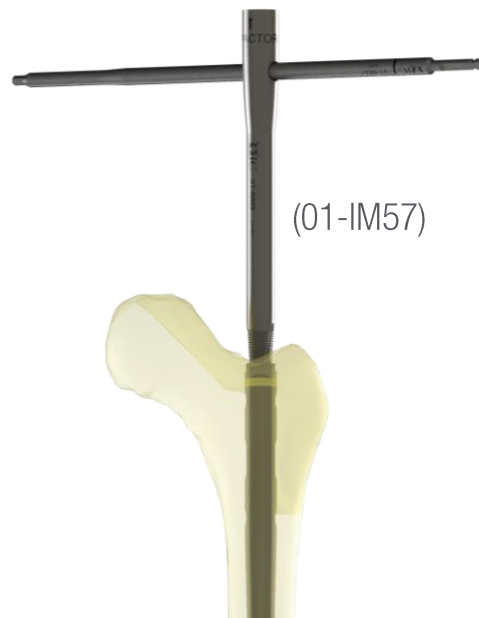


FIG 17



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.

Surgical Technique – Retrograde Approach

PATIENT POSITIONING

Patient is placed supine on a radiolucent table. Care is taken to pad all bony prominences. A triangle or bone foam can be utilized for positioning. 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. Unicortical Shantz pins or a Ball Spike Pusher (01-IM53) can be used for reduction assistance. If no holding help is available, use of an external fixator can be used as well.

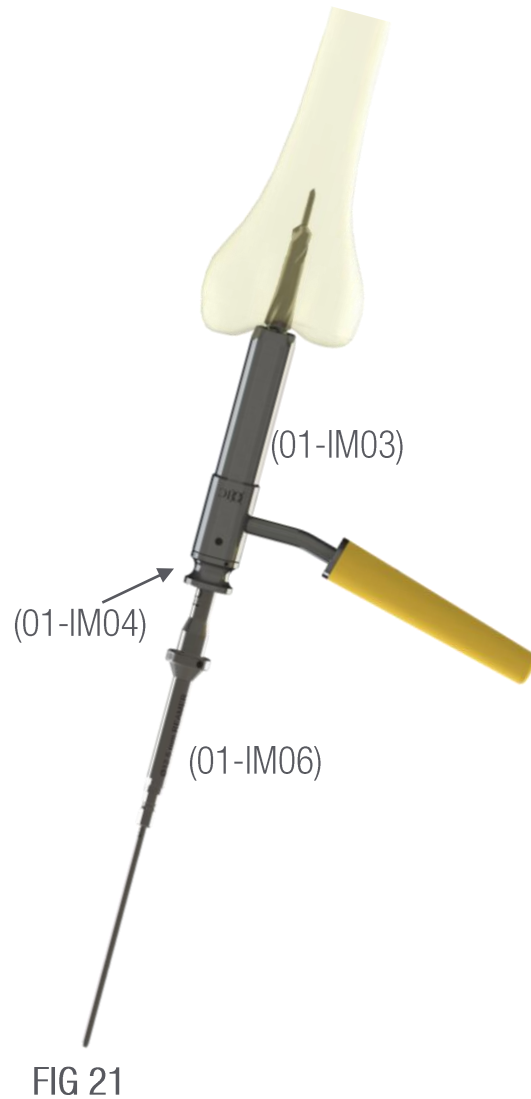
INCISION AND PIN PLACEMENT

After sterile preparation and draping, a 2 cm medial parapatellar incision is made. The 3.2mm Guide Pin (32-400P) is then placed into the middle of the intercondylar notch on the AP view and on the anterior tip of Blumensaat's line on the lateral view **FIG 19 & 20**. Posterior start point can lead to fracture mal-reduction and damage to the anterior cruciate ligament.



FIG 19

FIG 20



PREPARATION OF MEDULLARY CANAL

The entry portal can be made by the 12.5mm Entry Reamer (01-IM06) over a Guide Pin placed at the appropriate starting point. Care should be taken to direct the reamer into the intramedullary canal to avoid posterior penetration or varus/valgus deformity. The 16mm Tissue Protector (01-IM03) and 12.5mm Tissue Protector Sleeve (01-IM04) can be used to avoid inadvertent damage to the patella during reaming FIG 21.

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.

Surgical Technique – Retrograde Approach

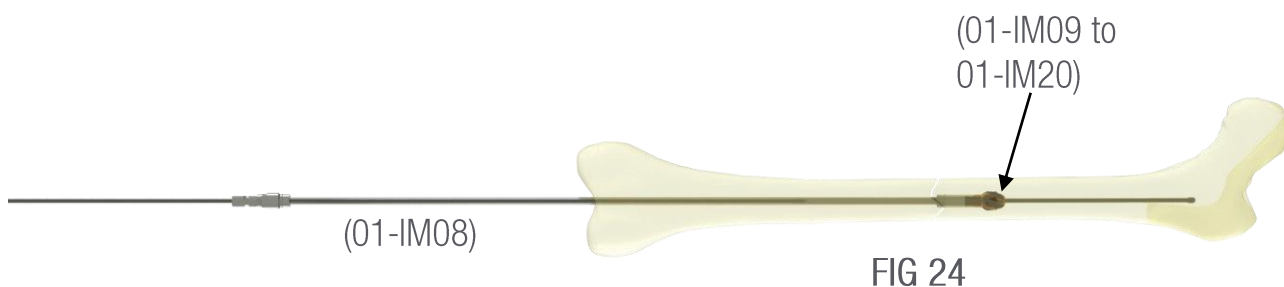
GUIDE ROD INSERTIONS AND REAMING

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 FIG 22. This should be confirmed on both AP and Lateral fluoroscopic images to ensure correct 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 Ball Tip Guide Rod into proximal fragment FIG 23. The diameter of the fracture reduction tool is 8.5mm. Reaming of the distal 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 24. 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 pull-out guide wire during reaming. The fracture should be held reduced during reaming to prevent eccentric reduction.

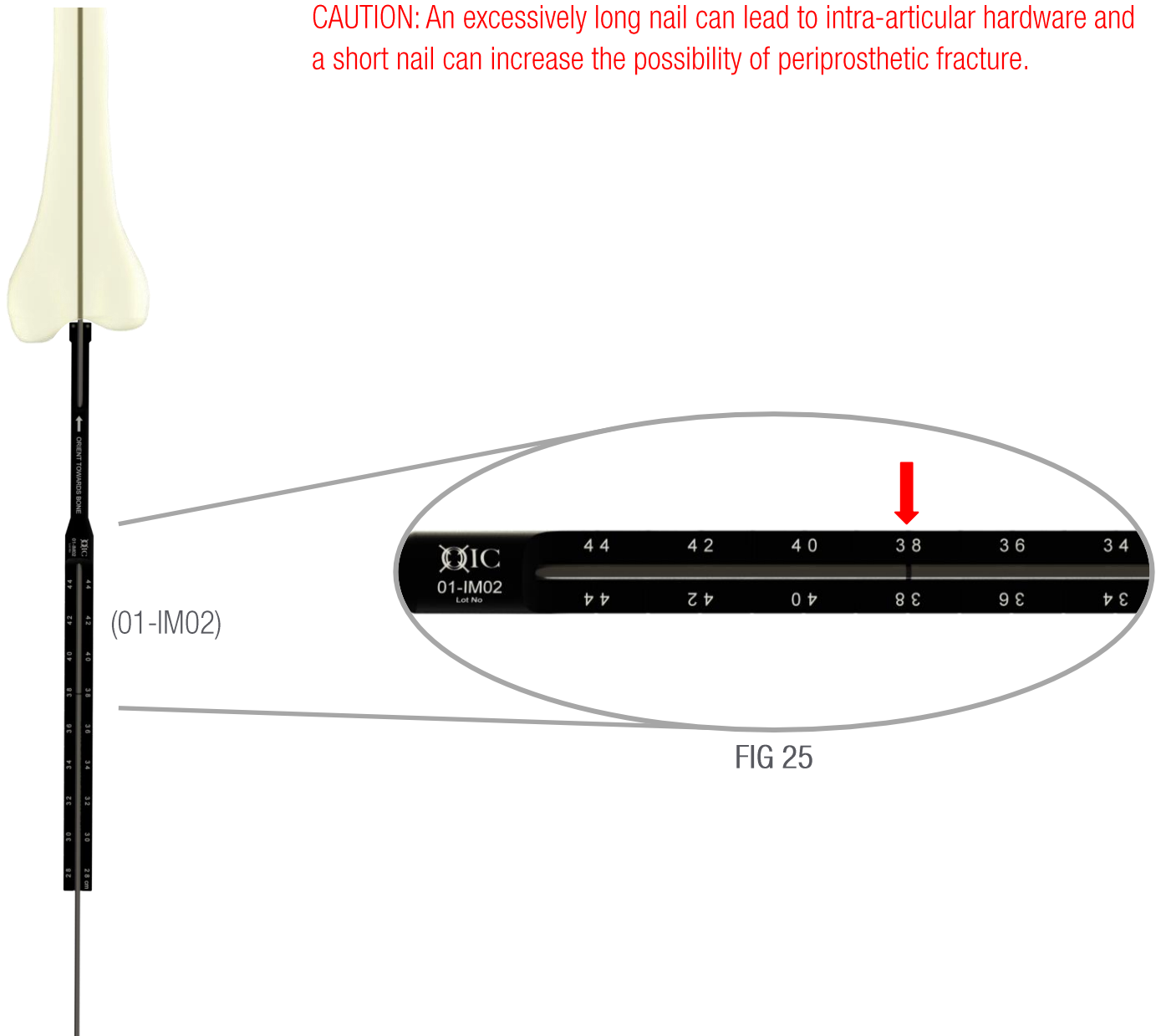


Surgical Technique – Retrograde Approach

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 Ball Tip Guide Rod (GW03-1000-S) up to level of the cortex and the measurement is read FIG 25. 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.



Surgical Technique – Retrograde Approach

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 26 and tightening it with the Guide Bolt Driver (01-IM29) FIG 27. Ensure that the notches fit well 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 26

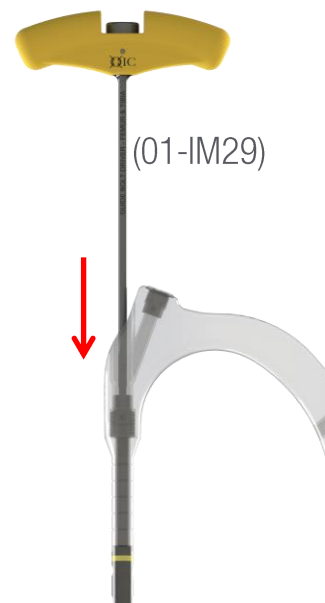


FIG 27

Surgical Technique – Retrograde Approach

NAIL INSERTION

Introduce the attached nail and targeting guide assembly over the Ball Tip Guide Rod. The nail should be inserted by hand over the wire into the distal femur. In smaller diameter canals, nail passage may be facilitated by gently rotating the nail and Targeting Guide during advancement. Ideal nail depth is to the level of the lesser trochanter. Do not leave the nail prominent in the knee. It should be 5mm below the articular surface. In some cases the nail can be advanced using the Slotted Mallet (01-IM31) FIG 28.

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

Remove the Ball Tip Guide Rod.

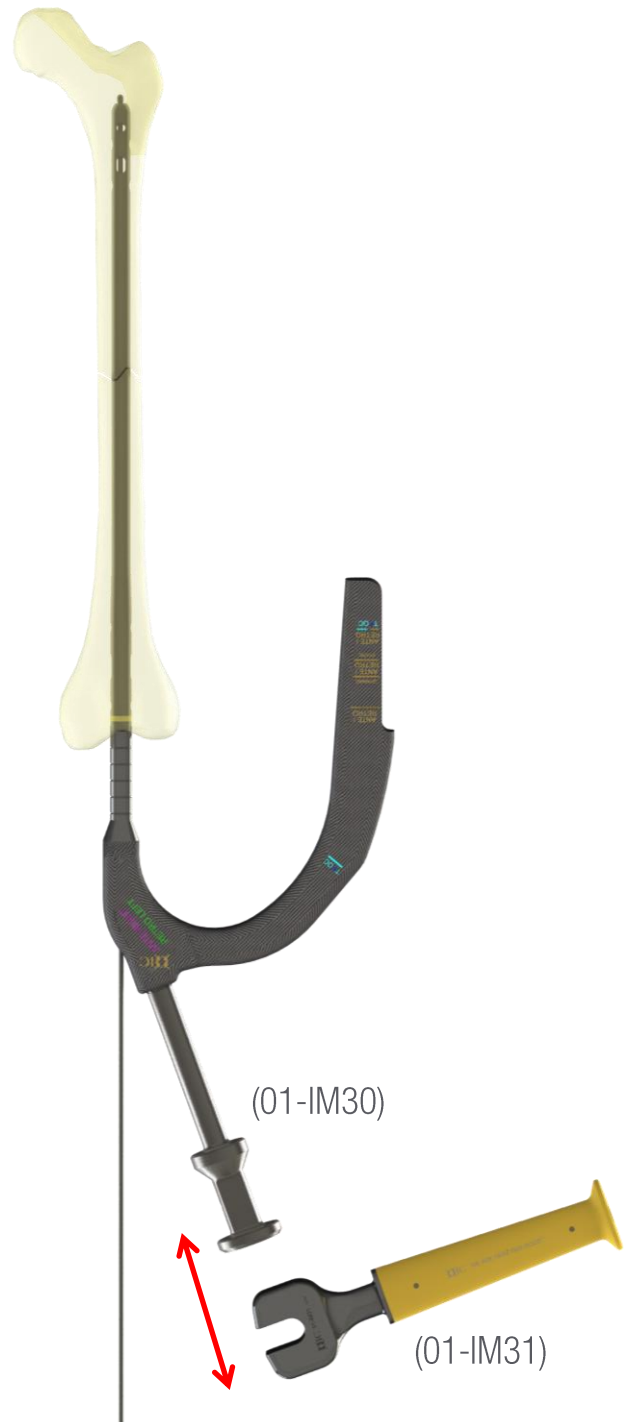


FIG 28

Surgical Technique – Retrograde Approach

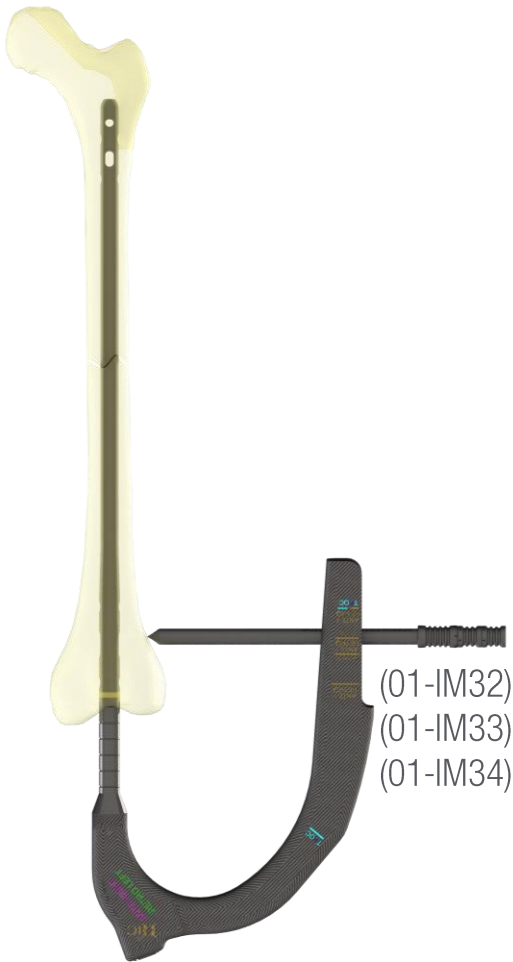


FIG 29

DISTAL CROSS LOCK SCREW

Four distal options are available and can be used at the surgeon's discretion. Both static and dynamic options exist. Each screw can be placed using the Tissue Protection Sleeve (01-IM32), the Drill Sleeve (01-IM34) and the Trocar (01-IM33) FIG 29. When the triple sleeve is advanced to the bone through a small incision, the Trocar is removed. The Calibrated Drill (DR42-330C) is placed through the drill sleeve and the screw length measured off the laser marked calibration lines FIG 30. The Drill Sleeve is then removed and the correctly sized screw inserted through the Tissue Protection Sleeve using the 3.5mm Long Screw Driver (01-IM37) and the AO Connect Handle (01-IM49) FIG 31. Screw length can be measured using a Depth Gauge (01-IM51).

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

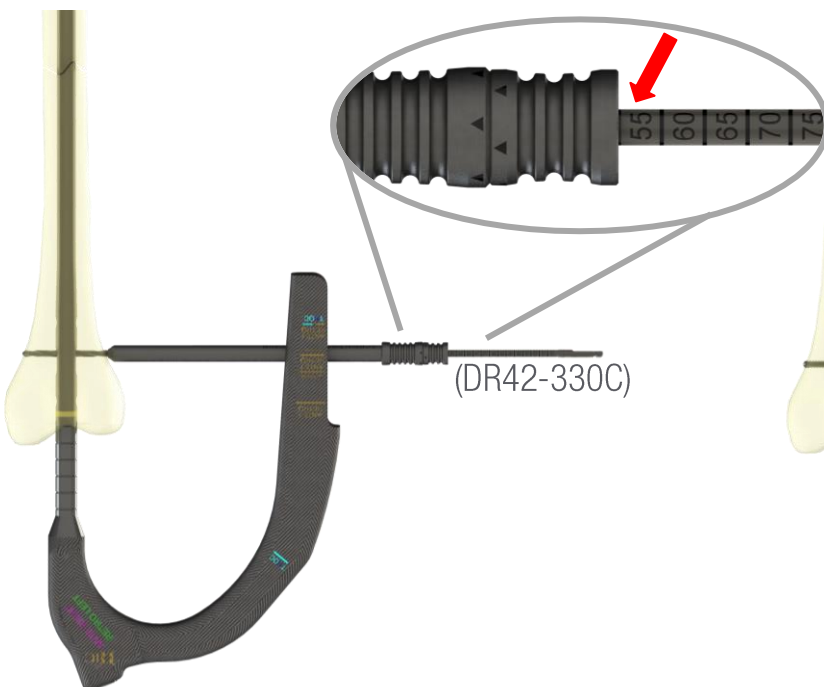


FIG 30

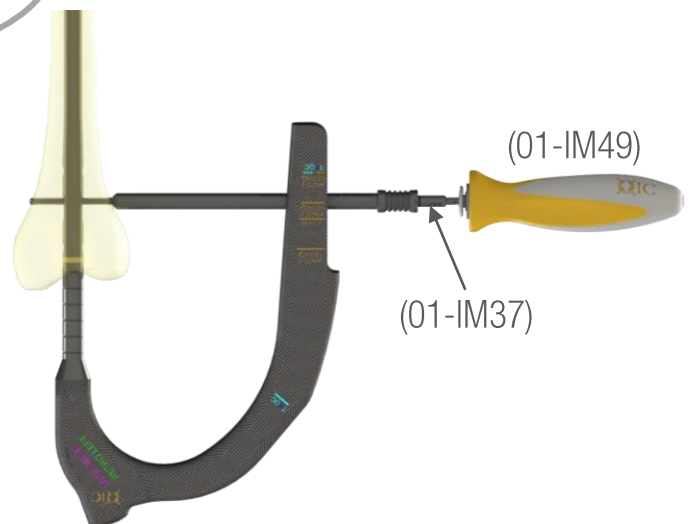
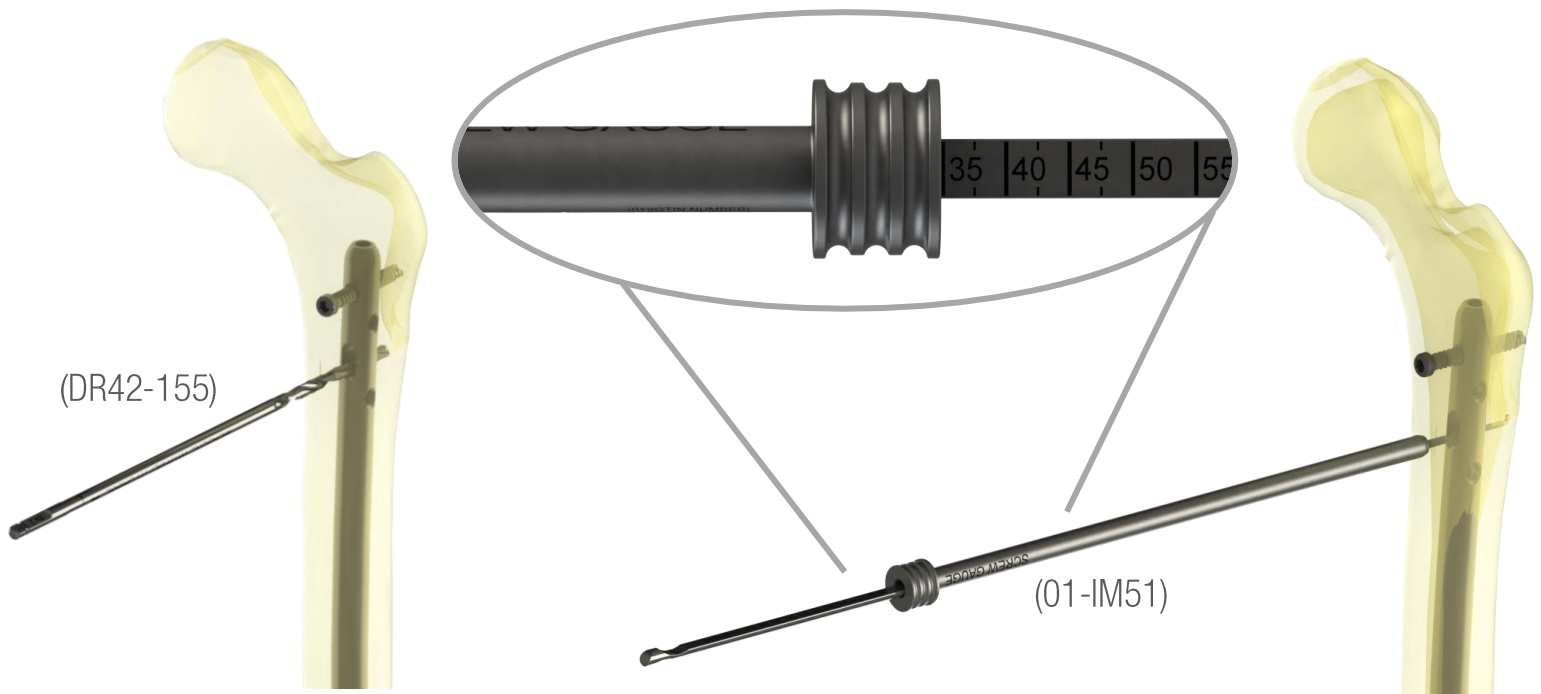


FIG 31

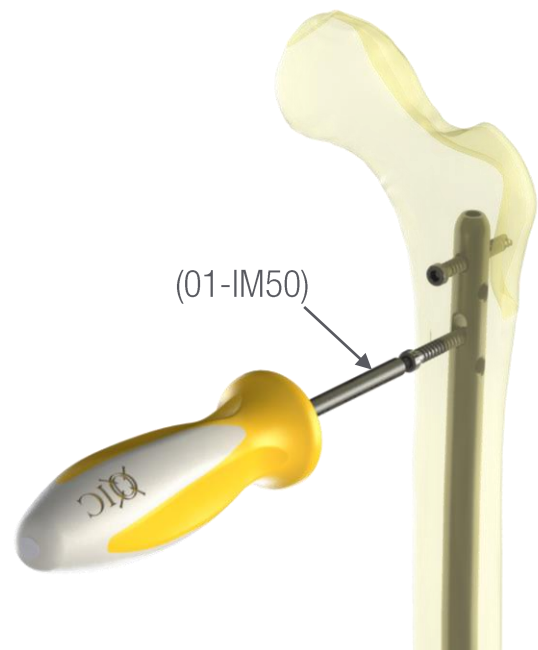
Surgical Technique – Retrograde Approach



PROXIMAL CROSS LOCK SCREW

Proximal cross lock screws are recommended for all fracture patterns and must be inserted utilizing the free hand technique. 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 32. Screw length can either be measured with the Standard Depth Gauge (01-IM51) FIG 33.

The screw is inserted using the Short 3.5mm Hex Driver (01-IM50) FIG 34.



Surgical Technique – Retrograde Approach

NAIL EXTRACTION

At times nail extraction is indicated and can be accomplished via previous incisions. Remove the 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 35**. Screw the Impactor (01-IM30) to the Extraction Bolt and remove the nail by back-slapping with the Slotted Mallet **FIG 36**. 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.



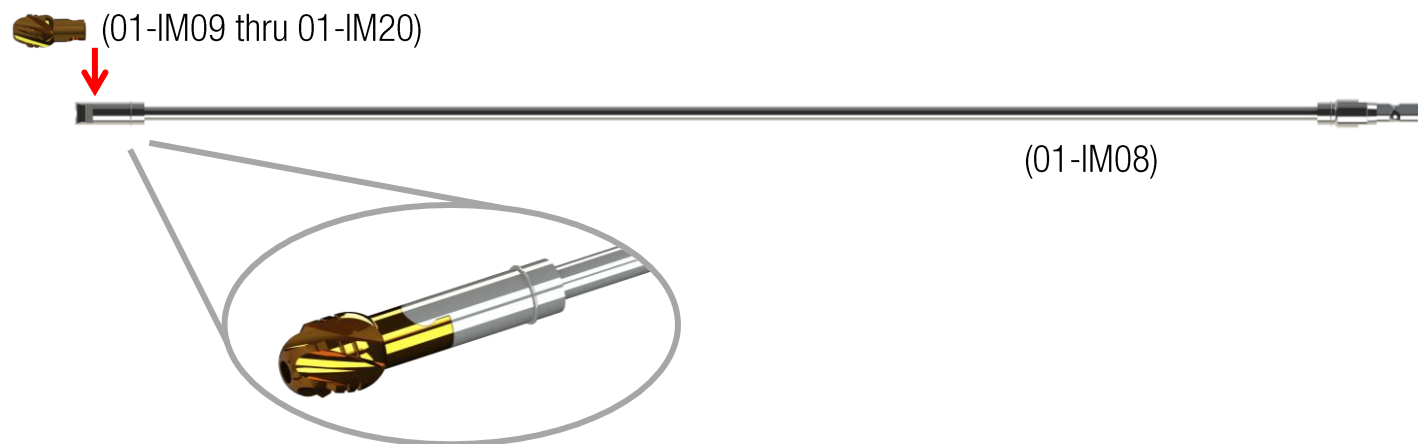
FIG 35



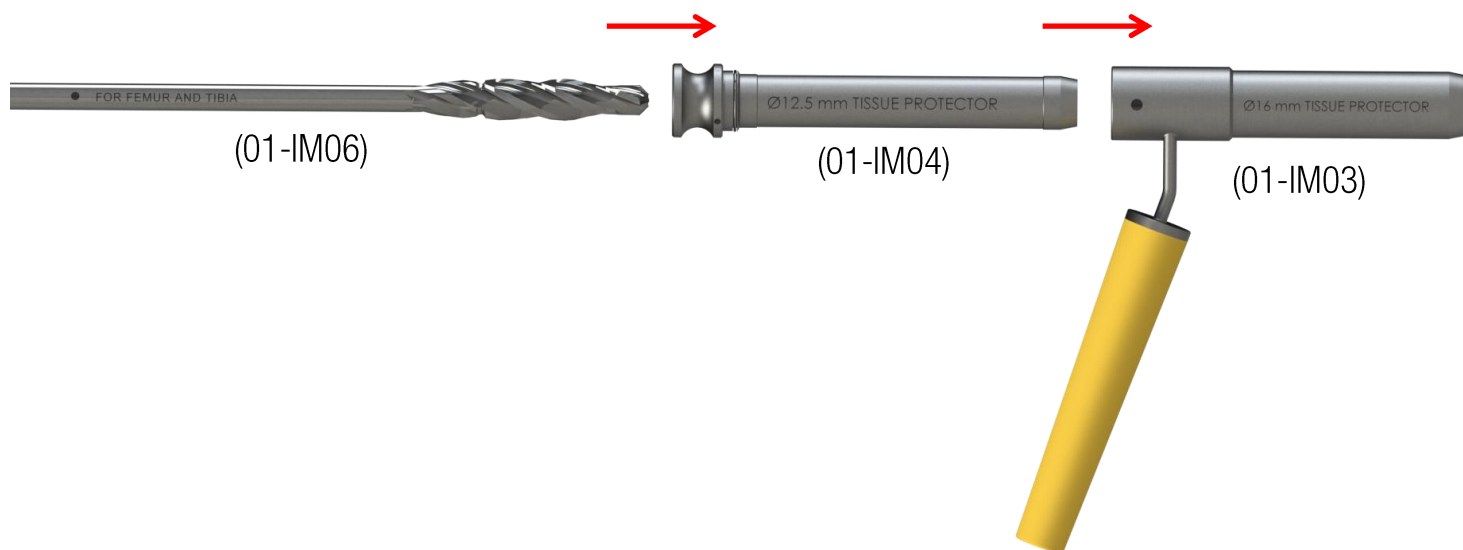
FIG 36

Assembly and Disassembly

FLEXIBLE REAMER SHAFT ASSEMBLY



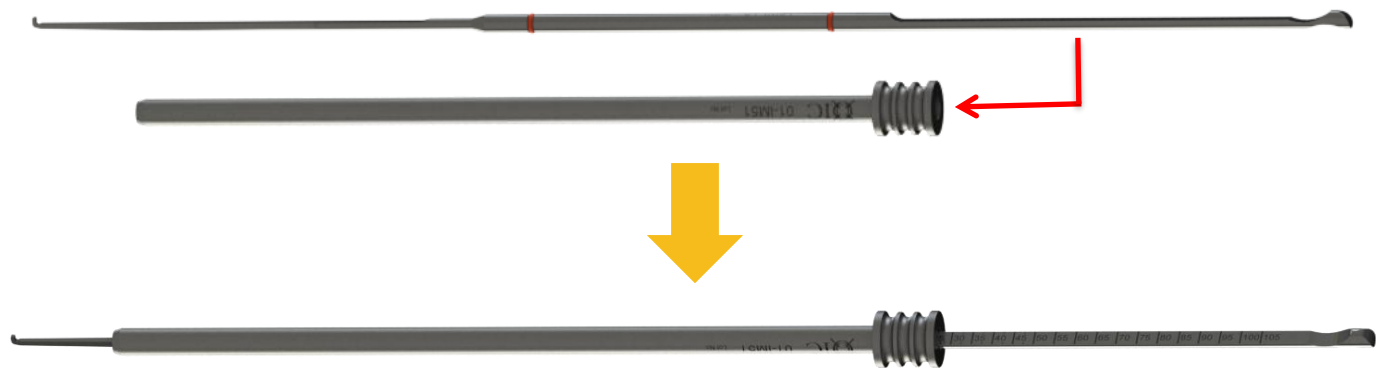
ENTRY REAMER TISSUE PROTECTOR ASSEMBLY



TRIPLE SLEEVE ASSEMBLY



01-IM51: SCREW GAUGE



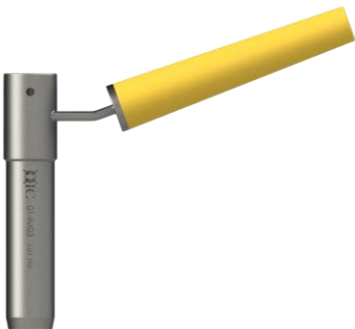
REUSABLE INSTRUMENTS

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 Reamer Heads
THRU
01-IM20



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 3.5 Short Screw Driver



01-IM51 Screw Gauge



01-IM52 Fracture Reduction Tool



01-IM53 Ball Spike Pusher



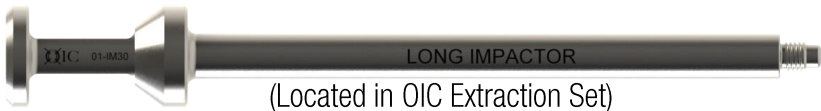
01-IM56 Obturator



01-IM57 Femur Nail Extraction Bolt



01-IM58 Long Impactor



DISPOSABLE INSTRUMENTS (SINGLE USE ONLY)

Catalog Information

32-400P

Guide Pin



DR42-330C

Long Calibrated Drill Bit



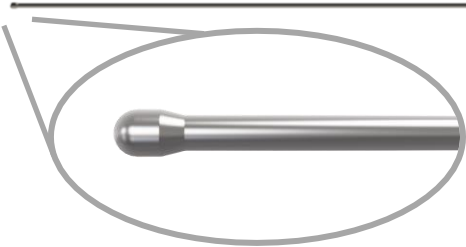
DR42-200

Short Drill Bit



GW03-1000-S

Ball Tip Guide Rod (sold separately)



IMPLANTS

Catalog Information

OIC ARFN NAILS

PART #	SHAFT DIA x LENGTH
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10.0mm Diameter

ARFN-100320	10mm x 320mm
ARFN-100340	10mm x 340mm
ARFN-100360	10mm x 360mm
ARFN-100380	10mm x 380mm
ARFN-100400	10mm x 400mm
ARFN-100420	10mm x 420mm
ARFN-100440	10mm x 440mm

11.5mm Diameter

ARFN-115320	11.5mm x 320mm
ARFN-115340	11.5mm x 340mm
ARFN-115360	11.5mm x 360mm
ARFN-115380	11.5mm x 380mm
ARFN-115400	11.5mm x 400mm
ARFN-115420	11.5mm x 420mm
ARFN-115440	11.5mm x 440mm

13.0mm Diameter

ARFN-130320	13mm x 320mm
ARFN-130340	13mm x 340mm
ARFN-130360	13mm x 360mm
ARFN-130380	13mm x 380mm
ARFN-130400	13mm x 400mm
ARFN-130420	13mm x 420mm
ARFN-130440	13mm x 440mm

CROSS LOCK SCREWS

PART #	SHAFT DIA x LENGTH
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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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