ORTHOPEDIC DESIGNS
NORTH AMERICA, INC.

TALON™ DISTALFIX™

Antegrade/Retrograde

Femoral Nail

Surgical Technique

Table of Contents

Note: This publication is provided to set forth a suggested surgical procedure. The physician should tailor this procedure to the specific needs of the patient.

Talon™ DistalFix™ Antegrade/Retrograde Femoral Nail System

Device Description

The Talon™ DistalFix™ Antegrade/Retrograde Femoral Nail System is used for fixation and stabilization of fractures of the femur until bony union can occur. The Talon™ DistalFix™ Antegrade/Retrograde Femoral Nail may be inserted into the femoral canal using either an antegrade or retrograde surgical approach. The system consists of the following parts:

- A femoral nail with proximal cortical locking screw holes and distal deployable integral talons to achieve distal fixation from within the intramedullary canal. The distal talons may be retracted for removal of the intramedullary nail if and when it is necessary.
- Cortical locking screws are provided separately. The cortical locking screws are provided for proximal fixation if desired. The cortical locking screws are available in a variety of lengths and styles. This includes a “universal” cortical screw featuring a reduced minor diameter at the tip which provides increased purchase in cancellous bone.
- A proximal end cap is provided separately in a variety of lengths. The end cap prevents bony ingrowth and preserves the threads which may be used for attachment of instrumentation during removal of the nail.

Implants are constructed of titanium alloy (Ti-6AL-4V-ELI). Patient contacting portions of the instrumentation are constructed of stainless steel (304, 316 or 17-4) and nitinol.

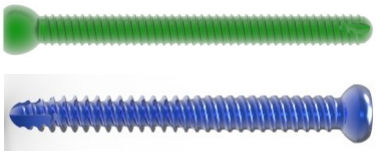
Talon™ DistalFix™ Antegrade/Retrograde Femoral Nail System

Nails

- Head Diameter: 13mm
- Shaft Diameters: 10, 11, 12mm
- Lengths: 280mm-420mm
  (20mm increments)
- Radius of Curvature: 1.5m
- Compression Range: 10mm
- Maximum Talon Span: 38mm

Cortical Screws

- Head Diameter: 8mm
- Thread Diameter: 5mm
- Single Core Diameter: 4.3mm
- Dual Core Diameter: 3.4mm/4.3mm
- Lengths: 30mm-120mm
  (5mm increments)
- Self-tapping design
- Internal thread secures screw to 5mm Hex Driver



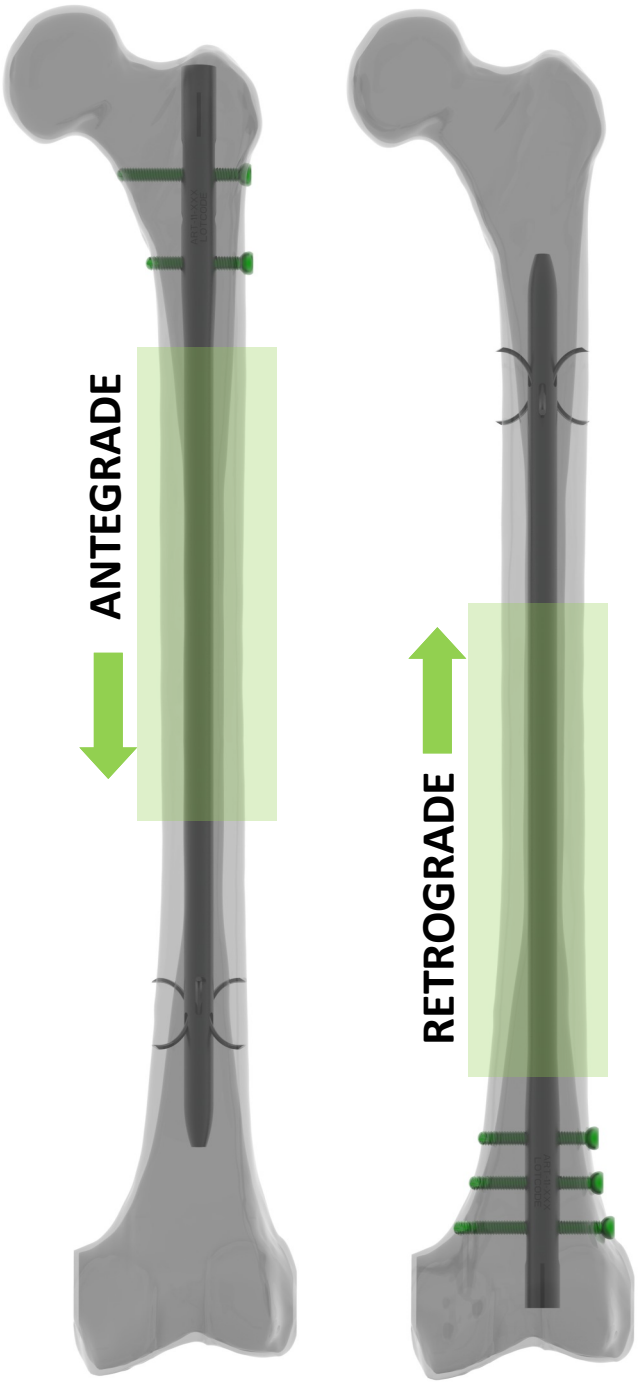
End Caps

- Lengths: Flush-35mm
  (5mm increments)
- Smooth lead-in section aligns end cap with head of nail
- Internal thread secures cap to 5mm Hex Driver

ALL TALONS ARE FULLY RETRACTABLE

U.S. Patents: 5,976,139 - 6,183,474 - 6,648,889 - 6,695,844 - 8,491,584

Indications



The Talon™ DistalFix™ Antegrade/Retrograde Nail's primary indications are for fixation/ stabilization of stable and unstable fractures of the femur including:

- Femoral shaft fractures
- Ipsilateral femur fractures
- Supracondylar fractures including those with intra-articular extension
- Osteoporotic fractures
- Pathologic/impending pathologic fractures
- Malunions/nonunions

The device is intended to stabilize fragments of the fracture until bony union can occur.

Relative Contraindications

The following conditions may present an increased risk of implant failure. It is not meant to be comprehensive. Physicians should use their clinical judgment when determining the appropriate implant and approach for a given patient.

- Active local infection
- Material sensitivity
- Loss of bone stock/insufficient bone quality to support the device
- Cognitive and/or physical impairment that would lead to unacceptable risk of fixation failure
- Obesity

Special Considerations

- Talons perform best when deployed into the cortical bone of the femoral shaft. Care should be taken to avoid deploying Talons in areas where the cortex is flaring (i.e. metaphysis). This may mean selecting a shorter implant.
- Screws Warning: The cortical screws are not approved for screw attachment or fixation to the posterior element (pedicles) of the cervical, thoracic or lumbar spine.

MRI Safety Information

The Talon™ DistalFix™ Antegrade/Retrograde Femoral 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 the Talon™ DistalFix™ Antegrade/Retrograde Femoral 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

The patient should be placed in the supine or lateral decubitus (not shown) position according to surgeon preference on a fracture or other radiolucent table (Fig.1). Ensure you have ample space for the image intensifier for visualization of the entire femur in both the AP and lateral planes. On a fracture table, this can be accomplished by abducting the unaffected leg while flexing the leg at the hip and knee (Fig. 2).

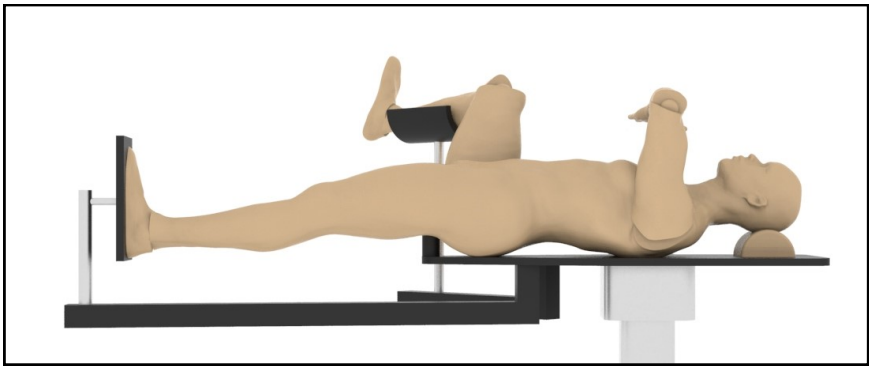


Fig. 1

Traction should be applied to the affected leg and it should be placed in slight adduction. If the leg cannot be adducted, the torso can be abducted 10-15° towards the unaffected leg. This will place the piriformis fossa and femoral shaft in a more accessible position.

An attempt at a closed reduction should be made prior to prepping and draping the patient. Reduce the fracture as anatomically as possible under image intensification.

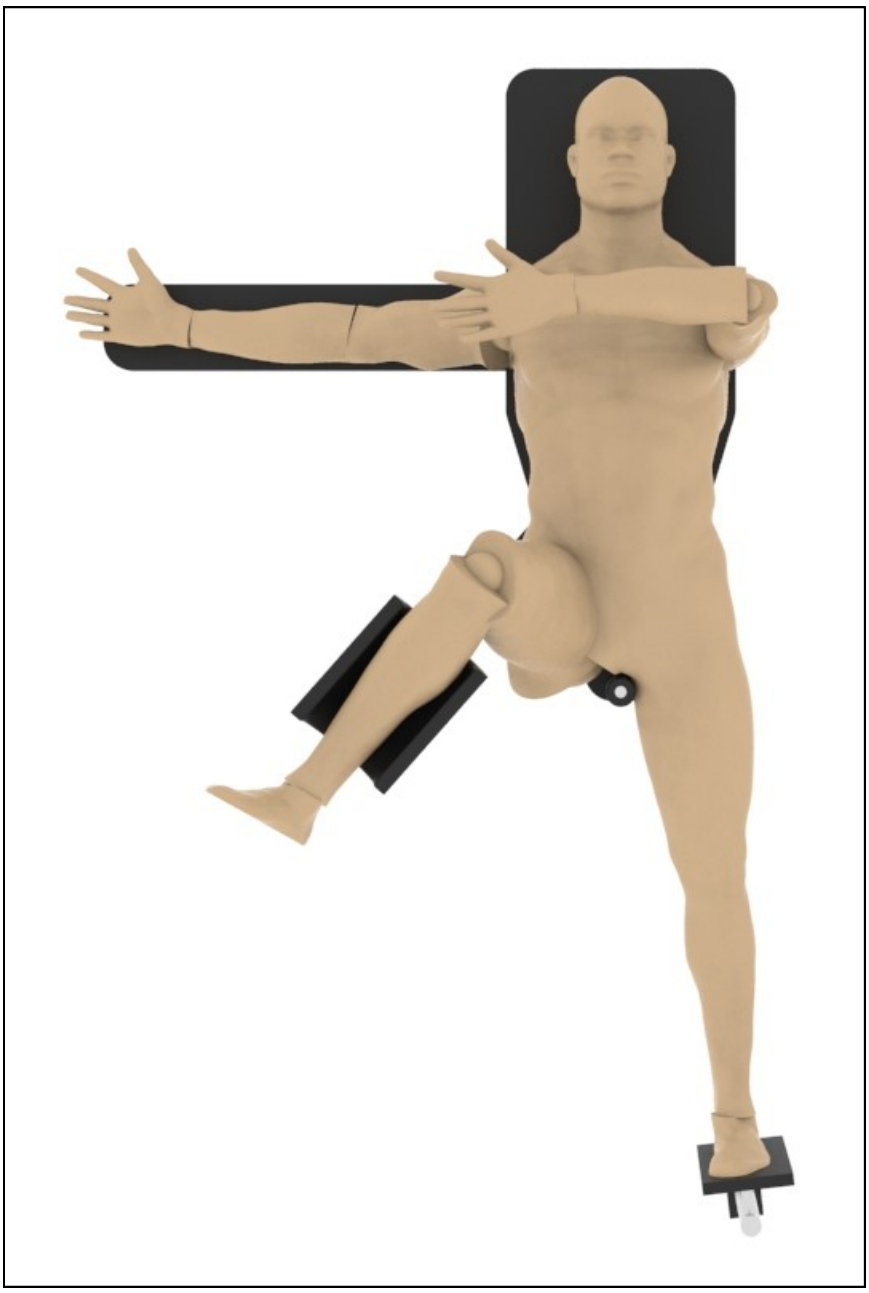


Fig. 2

Opening the Proximal Femur

Palpate the greater trochanter. A longitudinal incision should be made proximal to the tip of the greater trochanter. Divide the gluteus medius muscle in line with its fibers and dissect down until the proximal femur is reached.

The entry point for the Talon™ DistalFix™ A/R Femoral Nail is in line with the medullary canal in both the AP and lateral views. This point should coincide with the piriformis fossa (Fig. 3), but can vary depending on the patient's anatomy.

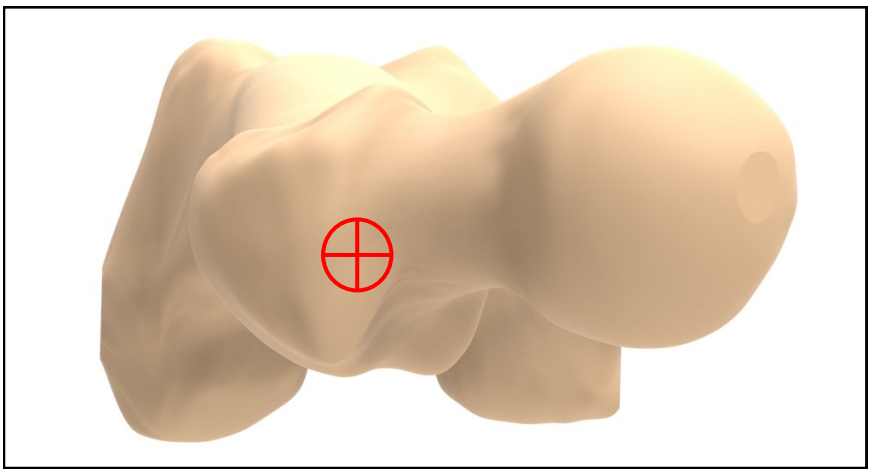


Fig. 3

Advance the 3.0mm x 600mm Trocar Tip Guide Wire (SLN-T35) through the starting point with a powered driver. Confirm its position in the AP (Fig. 4) and lateral (Fig. 5) planes. Proper position is critical. Withdraw wire and reposition as necessary.

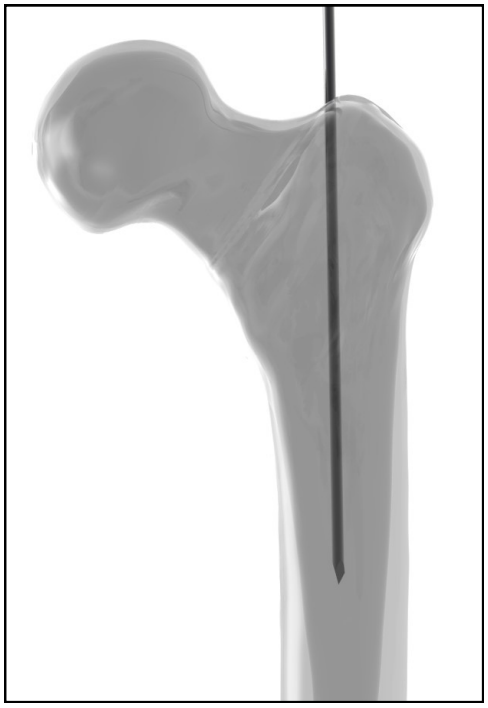


Fig. 4

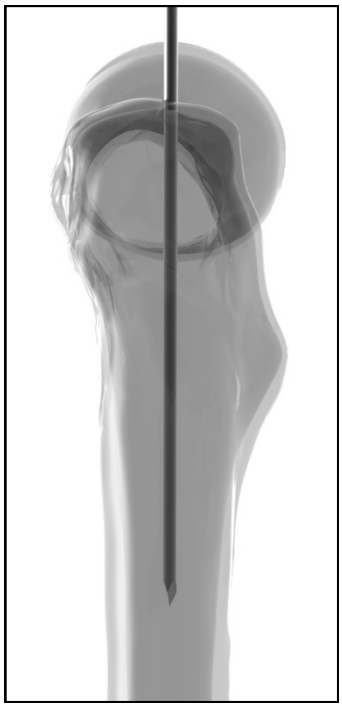


Fig. 5

With the wire in the desired position, open the proximal femur. The femur can be opened via one of two methods.

Method One: Cannulated Awl

Pass the 14mm Cannulated Awl (ODI-F02) over the guide wire to the level of the bone (Fig. 6). Use gentle twisting motions to advance the awl into the proximal femur. Take care not to displace the fracture or plunge the awl through the fracture site.

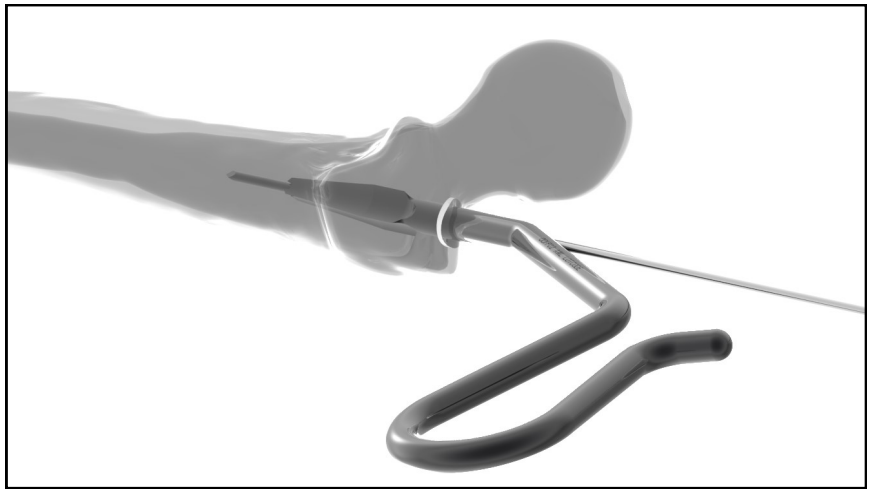


Fig. 6

Opening the Proximal Femur (cont.)

Method Two: Entry Reamer

Pass the 14mm Entry Reamer (ODI-F03) and Tissue Protector (ODI-F01) over the guide wire to the level of the bone. Use a powered driver to advance the entry reamer into the proximal femur.

Monitor the reaming depth via the image intensifier. There are four grooves on the cutting blades that represent the location of the cortical screw holes on the head of the nail (Fig. 7). Ream until the desired screw position(s) is reached. The end of the nail is denoted by the step between the reamer shank and cutting blades.

After opening the proximal femur, remove the trocar tip guide wire and replace it with the Ball Tip Sheathed Guide Wire (SLN-T41) (Fig. 8). Advance the sheathed wire across the fracture and down the femur.

Enlarge the medullary canal through distal reaming beginning with a 9mm cutter head. It is recommended that the canal be reamed 1mm greater than the diameter of the desired nail. Ream the canal to a minimum of 11mm (the smallest nail has a distal diameter of 10mm). If no resistance is felt after reaming to 11mm, continue reaming for the next size nail. Repeat this process, as needed, to a maximum of 13mm.

Once the canal has been reamed to the appropriate size, remove the sheath from the wire.

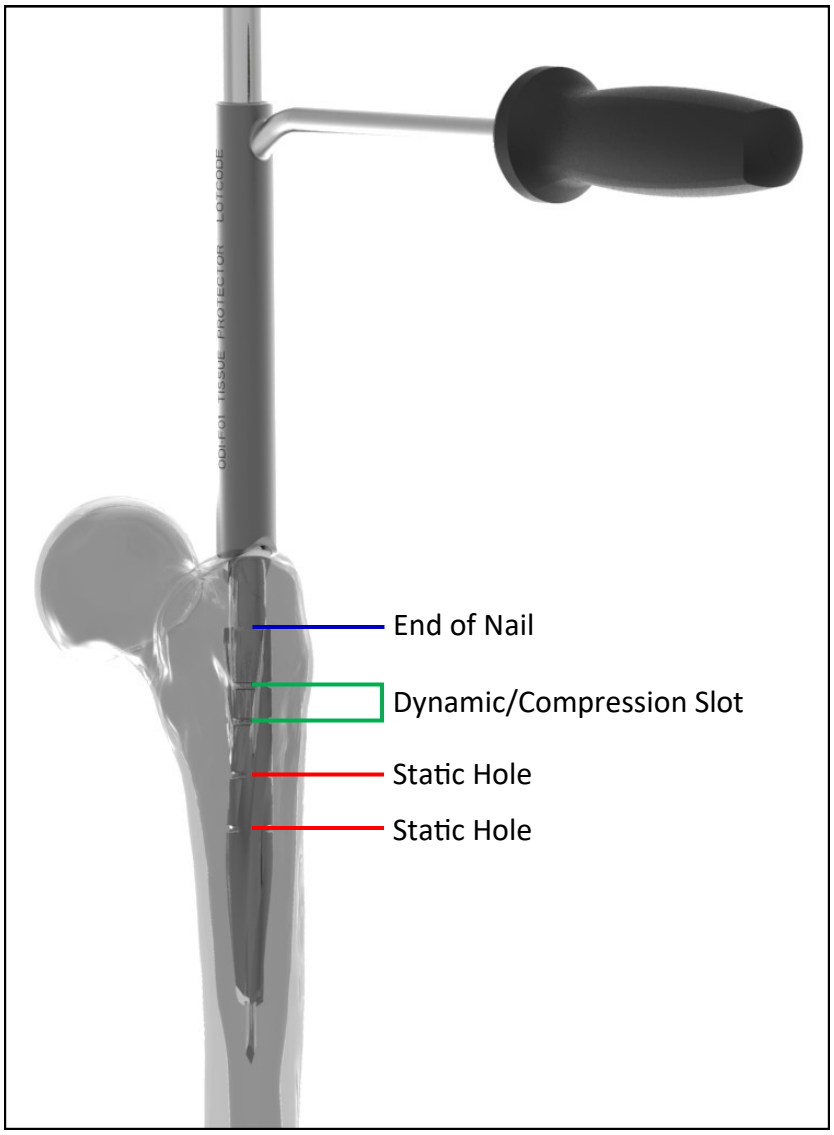


Fig. 7

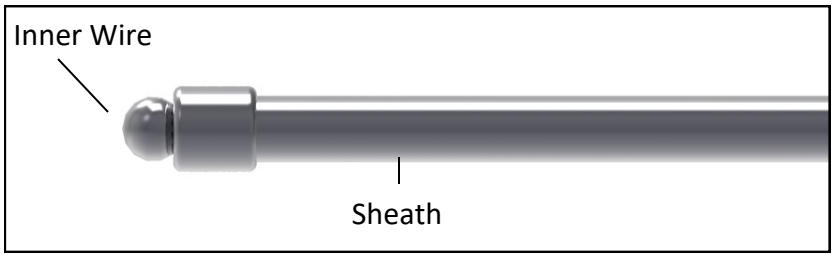


Fig. 8

Selection of the appropriate size implant—diameter and length—is of critical importance. Nail diameter can be determined through intra-medullary reaming following the steps described in the previous page. Nail length can be determined via one of two methods—measuring off the guide wire or radiographically.

Method One: Measuring the Wire

Open the Folding Guide Wire Ruler (ODI-F05) and pass it over the guide wire. The ruler has four pairs of notches that correspond to the screw hole positions on the head of the nail, as well as several slots that correspond to the head of the nail (long slot) and the depth of the head of the nail relative to the surface of the bone (small slots). Introduce the ruler into the proximal femur and position it according to the desired screw location(s) (Fig. 9). Note the depth of the end of the nail.

Place the Radiographic Ruler (ODI-F04) on the patient's thigh and position the image intensifier for an AP view of the distal femur. Adjust the template until the four points appear well into the cortical bone (Fig. 10). Avoid the metaphyseal flare. With the template in position, adjust the guide wire until its tip is even with that of the template (Fig. 11). Read the suggested nail length off the back of the wire (Fig. 12).

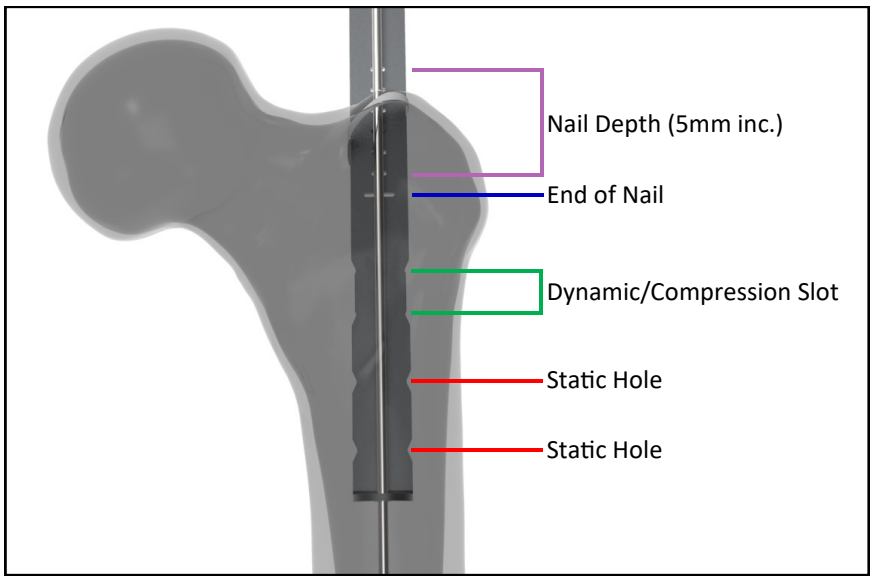


Fig. 9

Fig. 10

Fig. 11

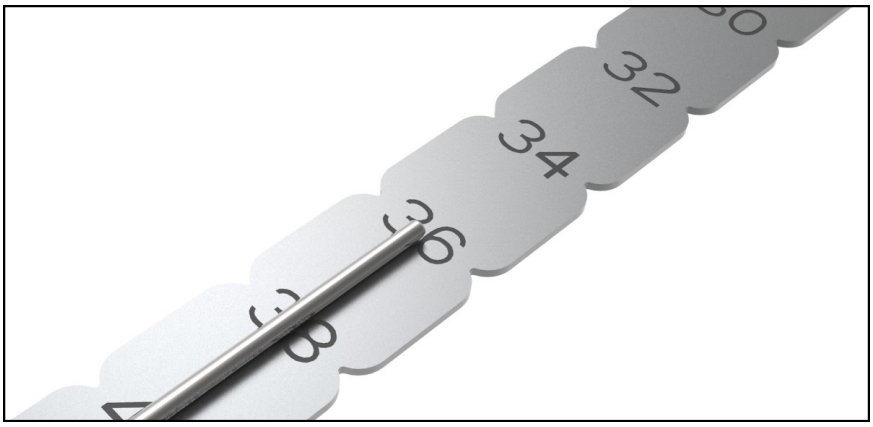


Fig. 12

Nail Selection (cont.)

Method Two: Radiographically

Position the Folding Guide Wire Ruler (ODI-F05) and the Radiographic Ruler (ODI-F04) as described in Method One. Do not adjust the guide wire. Position the image intensifier over the proximal femur. Roll the image intensifier past the AP plane so that the guide wire ruler can be seen behind the Talon template. Read radiographically the suggested length to the slot corresponding to the end of the nail (long slot) (Fig. 13).

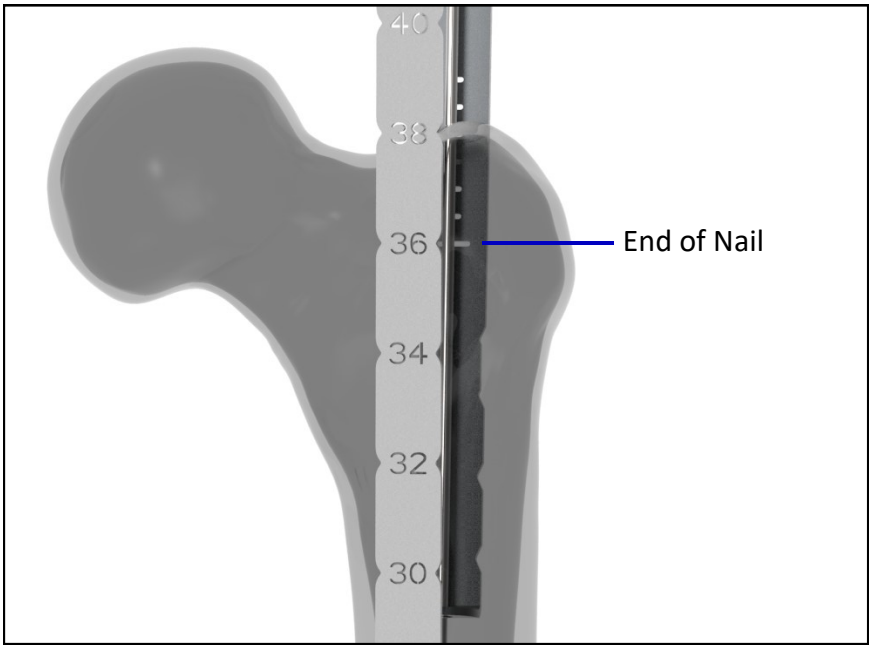


Fig. 13

Nail Insertion

Mate the chosen nail with the Guide Handle (ODI-F08). Take care to align the reference mark on the nail head with the appropriate corresponding mark on the handle (Fig. 14 & 15).

LA/RR: **L A**ntegrade / **R R**etrograde

RA/LR: **R A**ntegrade / **L R**etrograde

Secure the nail to the handle with the Nail-Handle Screw (ODI-F09) using the 7mm Hex Driver (ODI-U08) and Torque-Limiting T-Handle (ODI-U07) (Fig. 16). Ensure the screw is tightly secured by turning the T-handle until the torque limit is reached.

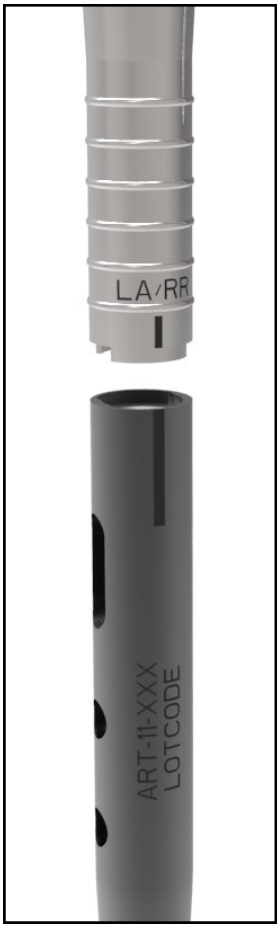


Fig. 14

Fig. 15

Fig. 16

Nail Insertion (cont.)

If not already done, remove the sheath leaving the inner wire in place. The sheath will not pass through the nail.

Pass the nail over the wire and into the femur. Apply steady pressure and use small oscillating motions to advance the nail (Fig. 17). Monitor passage of the nail across the fracture site radiographically. Rings on the guide handle indicate insertion depth. Insert the nail to the depth noted during nail selection.

An Impactor (ODI-U03) can be used to aid in seating the nail (Fig. 17 Inset). Never strike the guide handle directly. If excessive resistance is encountered, remove the nail, replace the sheath, and further enlarge the medullary canal through reaming. If significant impaction is required to seat the nail, confirm the tightness of the nail-handle connector screw before continuing.

Once the nail is fully seated, confirm the reduction of the fracture in both the AP and lateral planes. If satisfied, remove the guide wire.

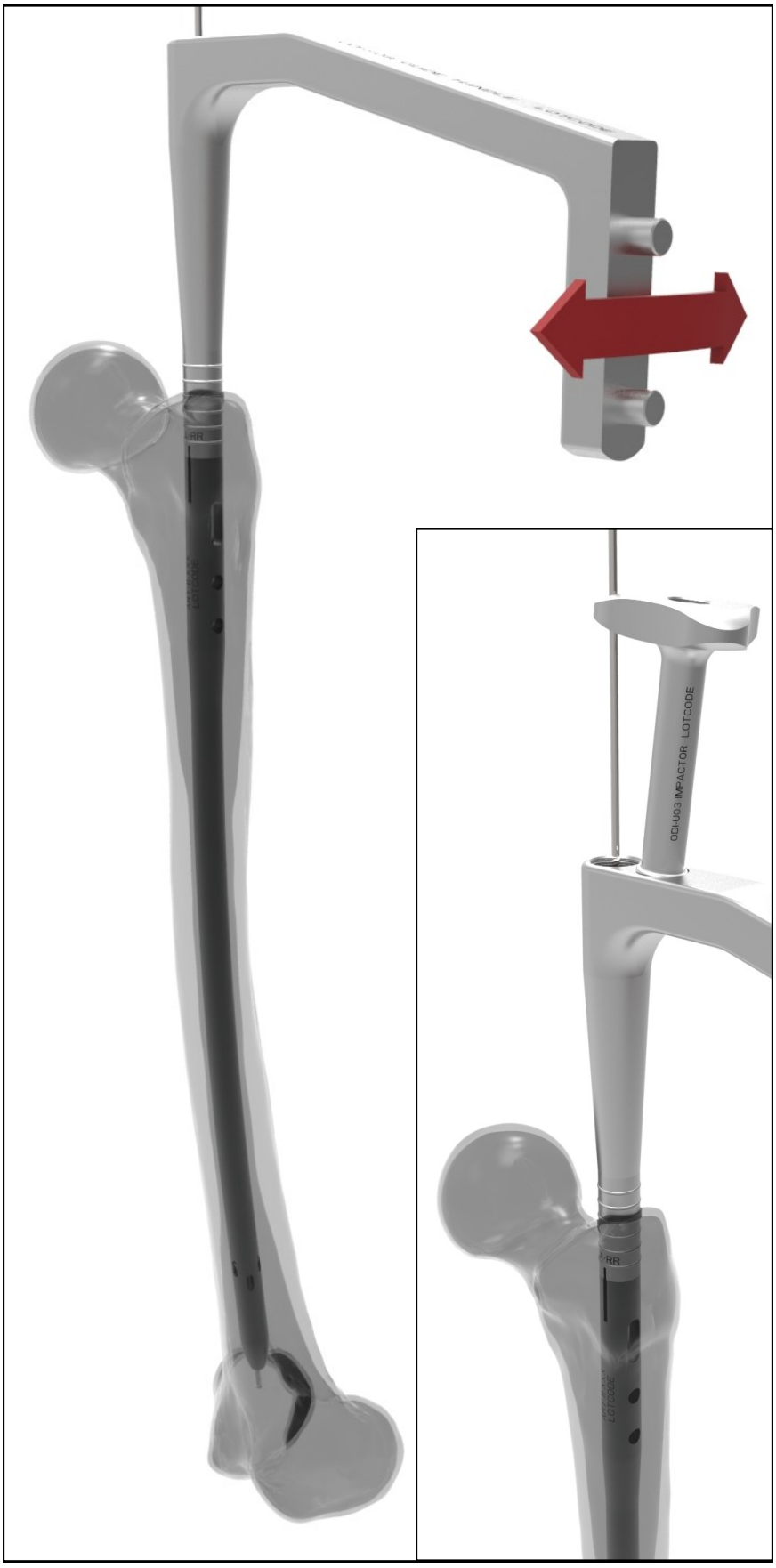


Fig. 17

Talon Deployment

Attach the Talon Driver (ODI-U09) to the Torque-Limiting T-Handle (ODI-U07) and pass the driver down the cannulation of the nail. Turn the driver clockwise to deploy the Talons (Fig. 18). Approximately 18 complete turns of the handle will take the Talons from the original position within the nail (Fig. 19) to fully deployed (Fig. 20).

NOTE: TALONS NEED NOT BE FULLY DEPLOYED. AT SURGEON'S DISCRETION, DEPLOYMENT CAN BE STOPPED AT ANY TIME. TALONS ARE DESIGNED TO PENETRATE THE CORTICAL BONE. CARE SHOULD BE TAKEN TO AVOID EXCESSIVE PERFORATION *THROUGH* THE CORTICAL BONE AND INTO SOFT TISSUE.

A consistent low resistance/torque should be felt during deployment until the cortex is reached. A sudden increase in resistance/torque marks cortical contact. Monitor the deployment progress with the image intensifier positioned for a lateral view of the distal femur once cortical contact is made (Fig. 21). Continue deploying until the torque -limiting handle trips or you are radio-graphically indicated to stop. If necessary, retract the Talons by turning the driver counterclockwise.

The extent of Talon deployment varies by location in the femur. Take care to avoid the metaphyseal flare.

Fig. 18

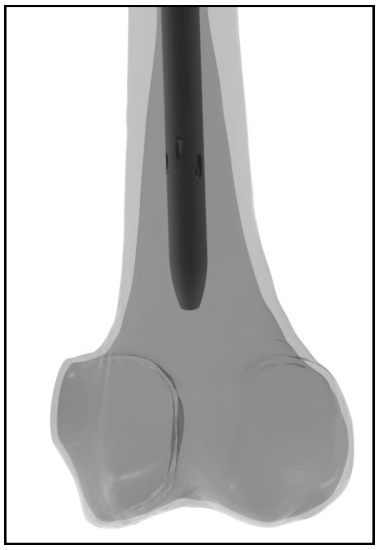


Fig. 19

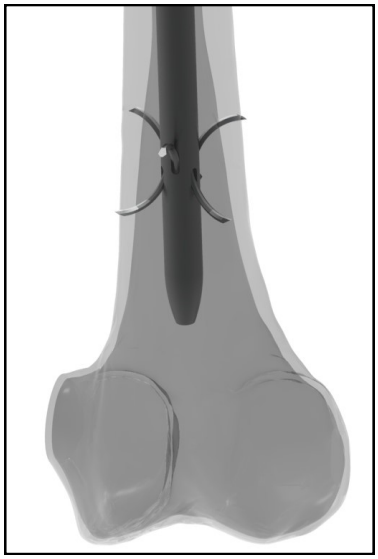


Fig. 20

Fig. 21

TALONS SHOULD NEVER BE DEPLOYED USING A POWERED DRIVER.

Attach the Guide Arm (ODI-F12) to the Guide Handle (ODI-F08) and tighten the Guide Arm-Handle Connector Screw (ODI-U11) (Fig. 22). The technique for placing cortical screws is identical for all screw hole positions. The procedure for placing a screw with the intent of applying compression will be demonstrated.

Insert the triple sleeve assembly—Screw Sleeve (ODI-F13), Drill Sleeve (ODI-F14), and Trocar (ODI-F15)—through the hole in the Guide Arm labeled “DYN/COMP”. Make a small incision in the skin and advance the sleeves to the cortical surface (Fig. 23). Apply pressure with the Trocar to create a dimple in the lateral cortex.

Remove the Trocar and pass the calibrated 4.2mm Cortical Drill (ODI-F16) through the Drill Sleeve. Drill through both cortices (Fig. 24).

Read the drilled depth directly from the graduations on the drill (Fig. 25). Apply pressure to the Drill Sleeve to ensure it is in contact with the cortex. This will yield the most accurate measurement. Graduations are calibrated to the tip of the drill and coincide with the available screw lengths.

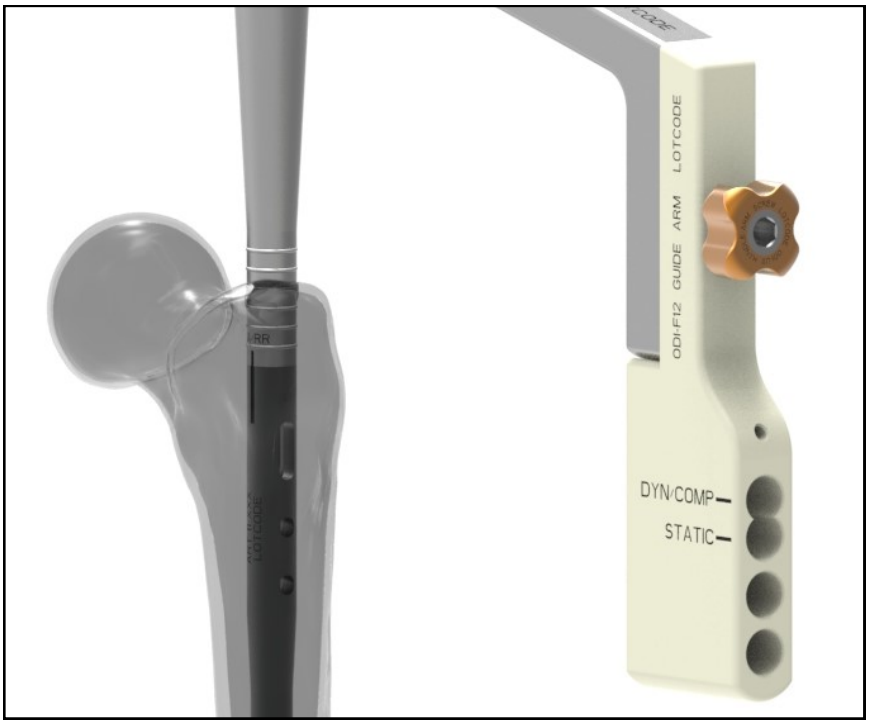


Fig. 22

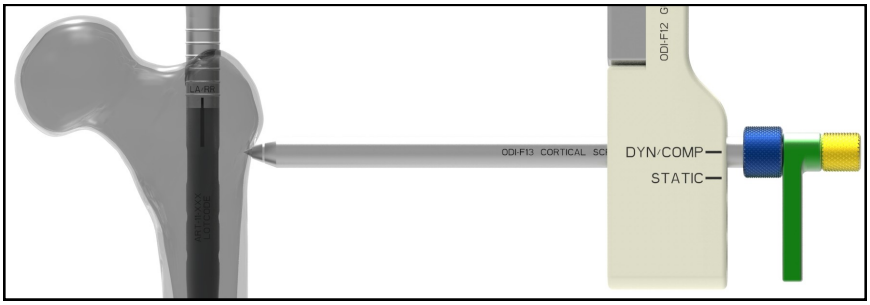


Fig. 23

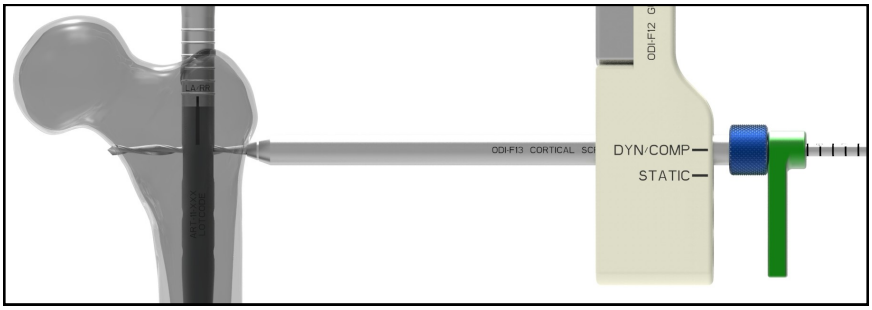


Fig. 24

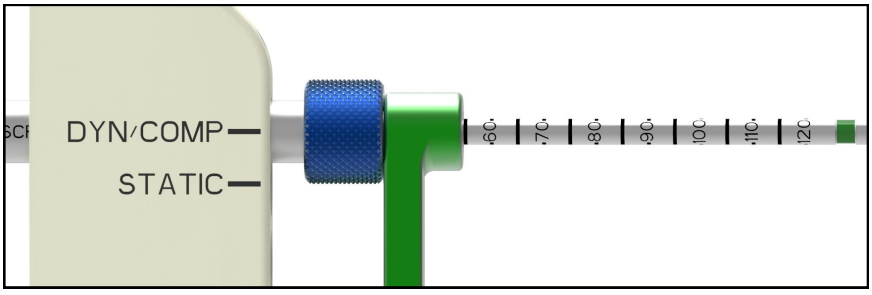


Fig. 25

Proximal Locking (cont.)

Mate the chosen cortical screw with the 5mm Hex Driver (ODI-U01) and secure with the 5mm Driver Connector Screw (ODI-U02) (Fig. 26).

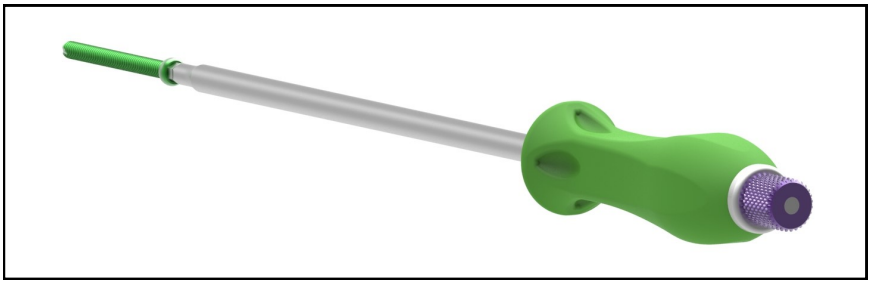


Fig. 26

Remove the Drill Sleeve and pass the cortical screw/driver assembly through the Screw Sleeve and into the bone (Fig. 27). Advance the screw until the screw head is seated against the lateral cortex. Do not over tighten as this may lead to the screw stripping. Release the cortical screw from the hex driver by turning the connector screw counterclockwise. Remove the Screw Sleeve from the Guide Arm.

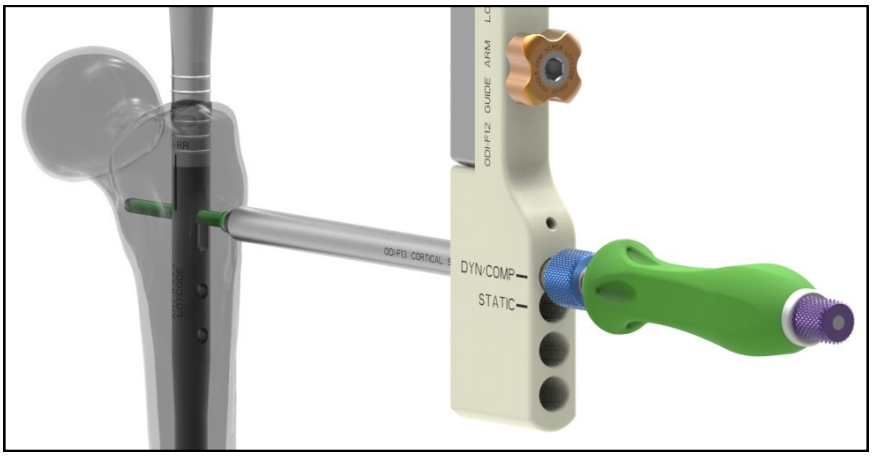


Fig. 27

To apply compression, connect the Compressor (ODI-F10) to the Ratcheting Axial Handle (ODI-U05) and insert through the Guide Handle. Turn clockwise to engage the threads and apply compression (Fig. 28). During compression, the distal fragment will be drawn towards the proximal fragment. Up to 10mm of compression can be applied (Fig. 29). Monitor compression with the image intensifier. Do not over-compress as this may cause the cortical screw to fail. **The Talon™ DistalFix™ A/R Femoral nail is not meant to be backslapped against the deployed Talons to achieve compression.**

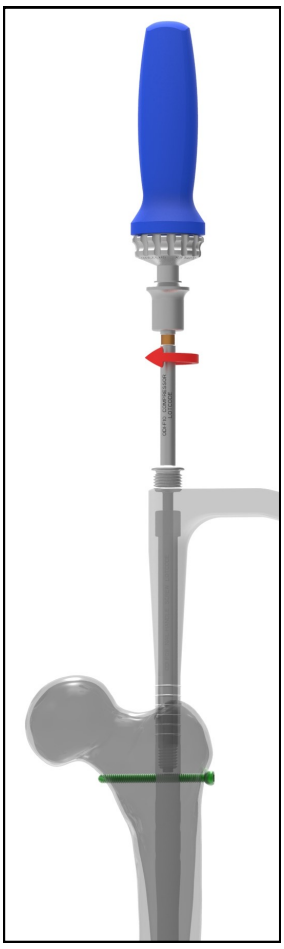


Fig. 28

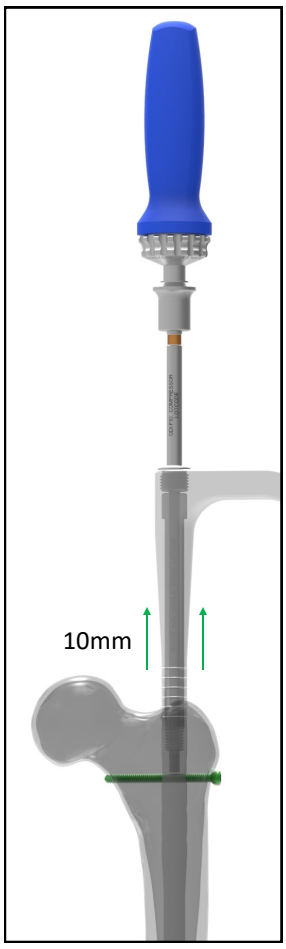


Fig. 29

Fig. 30

Place a second screw in one of the static holes *prior* to removing the Compressor to ensure the applied compression is maintained (Fig. 30) .

Common locking configurations are as follows:

Static (Fig. 31)

Dynamic (Fig. 32)

Static, with the option to dynamize the nail secondarily (Fig. 33)

Compression (Fig. 34)

All cortical screws can be placed following the steps described in the preceding pages under the heading Proximal Locking.

A third screw can be used, as needed, for additional stability.

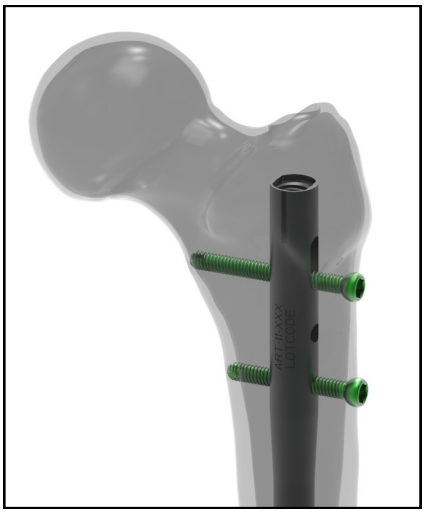


Fig. 31

Fig. 32

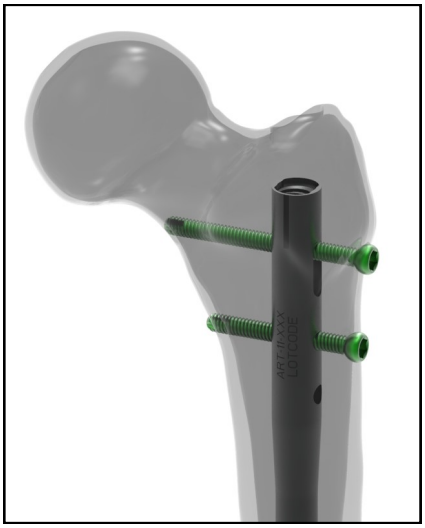


Fig. 33

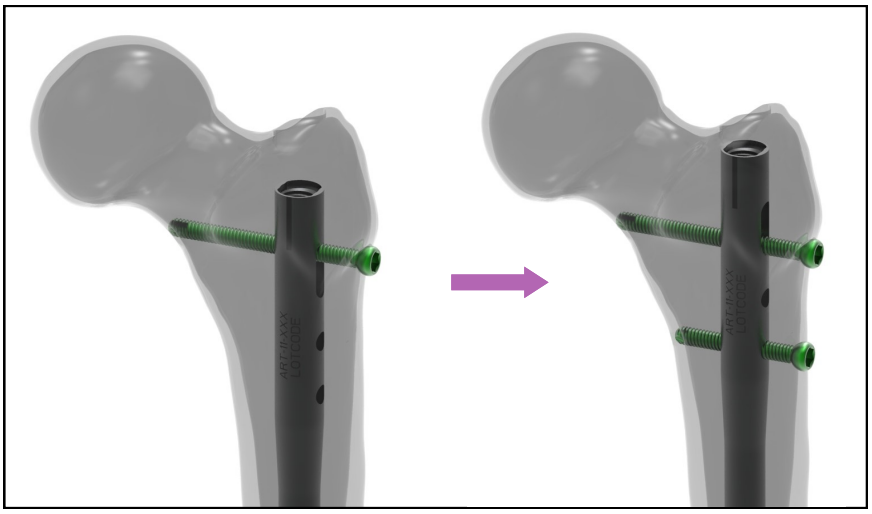


Fig. 34

End Cap Placement

Note the position of the head of the nail after cortical screw placement (Fig. 35). The depth of the nail may have changed if compression was applied.

Confirm the final implant position—proximally and distally—with the image intensifier in both the AP and lateral planes. If satisfied, use the 7mm Hex Driver (ODI-U08) to loosen the Nail-Handle Screw (ODI-F09) and remove the Guide Handle (ODI-F08).

Mate the chosen end cap with the 5mm Hex Driver (ODI-U01) and secure with the 5mm Driver Connector Screw (ODI-U02) (Fig. 36). The connector screw will ensure the end cap is not lost in the soft tissue.

Bring the end cap to the head of the nail—the smooth lead-in segment should help orient the end cap with the head of the nail. Turn the driver clockwise to engage the cap (Fig. 37). When fully engaged, release the end cap from the driver by turning the connector screw counterclockwise.

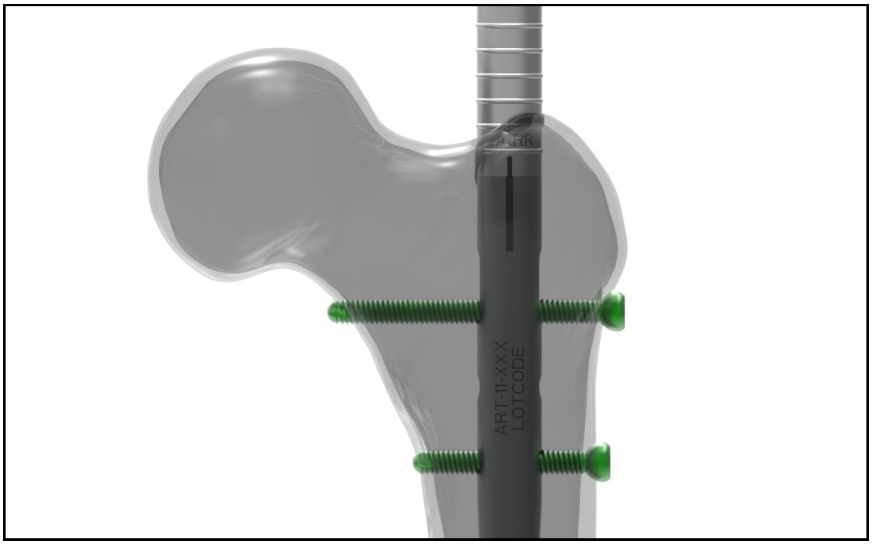


Fig. 35

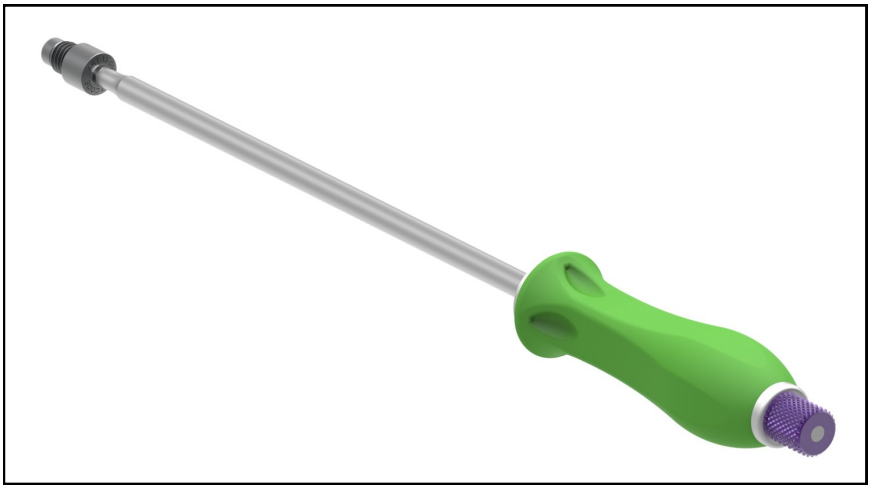


Fig. 36

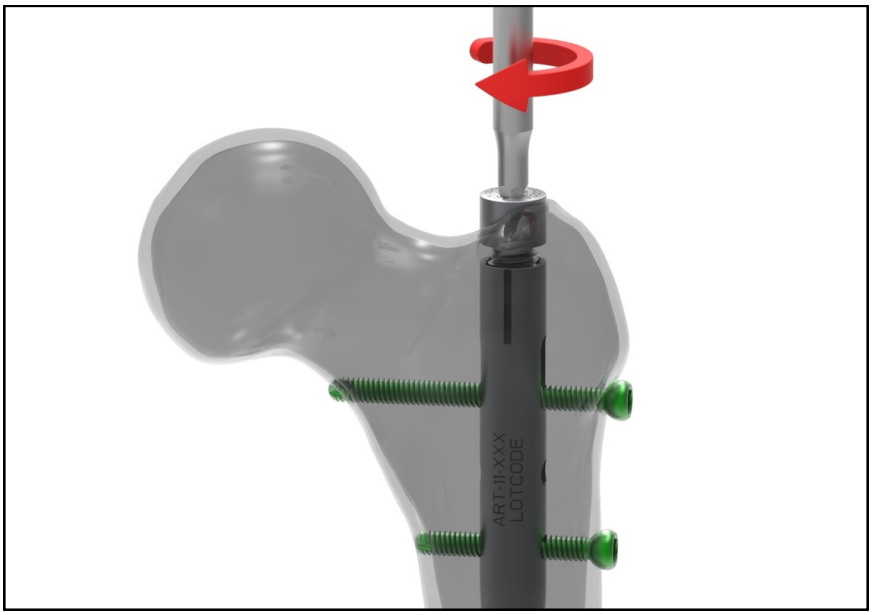


Fig. 37

Patient Positioning

The patient should be placed in the supine position according to surgeon preference on a radiolucent table (Fig.38). Flex the hip and knee of the affected limb 30-40°. A leg roll positioned below the flexed knee may aid in proper reduction and stabilization of the fracture. Ensure you have ample space for the image intensifier for visualization of the entire femur in both the AP and lateral planes.

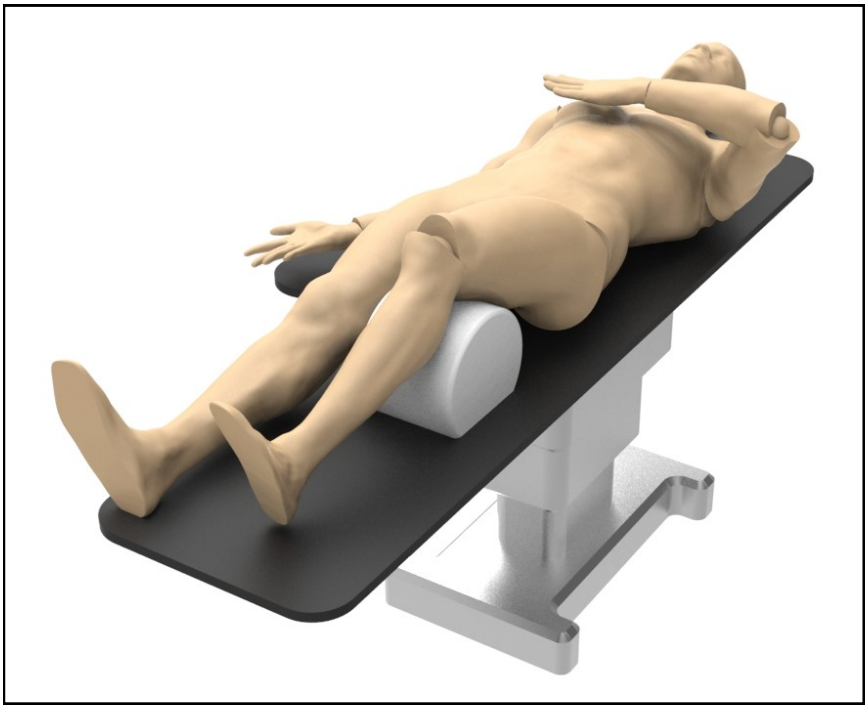


Fig. 38

An attempt at a closed reduction should be made prior to prepping and draping the patient. Reduce the fracture as anatomically as possible under image intensification.

If intra-articular fractures are present, use interfragmentary screws to stabilize them prior to nail placement. Take care to avoid the path of the nail when placing interfragmentary screws.

A midline skin incision extending from the inferior pole of the patella to the tibial tubercle should be made. Afterwards, a medial parapatellar capsular incision should be made to open the joint and expose the articular surface of the distal femur (Fig. 39).

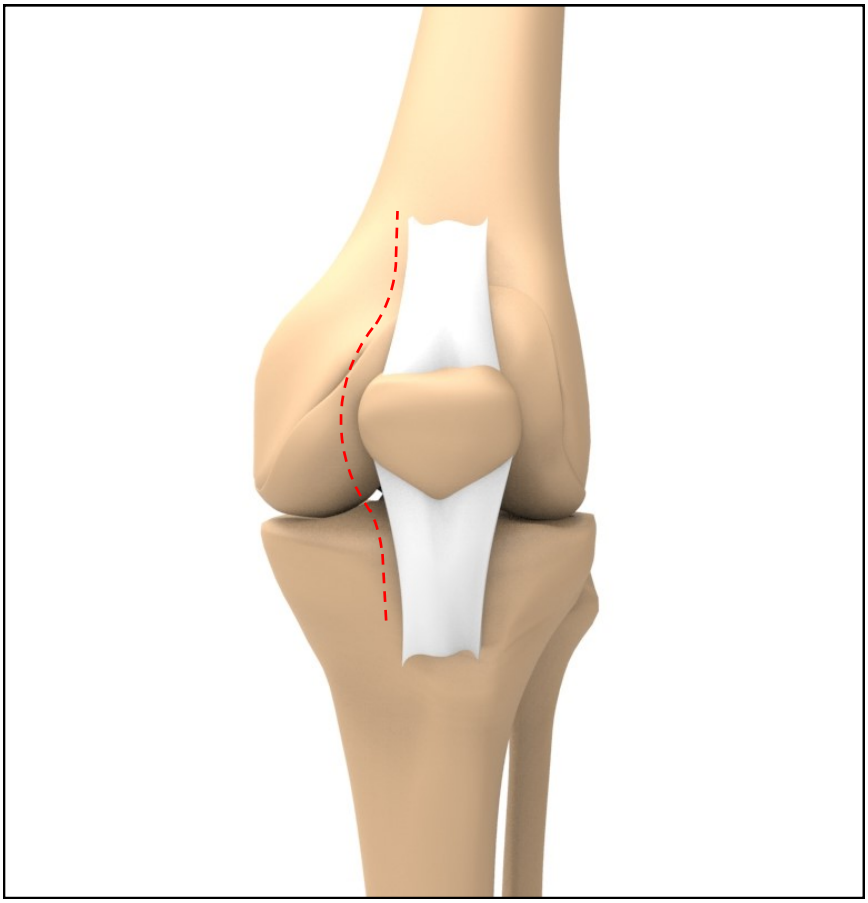


Fig. 39

Opening the Distal Femur

The entry point for the Talon™ DistalFix™ A/R Femoral Nail is in line with the medullary canal in both the AP and lateral views. This point should be at the top of the inter-condylar notch, slightly anterior and lateral to the femoral origin of the posterior cruciate ligament (Fig. 40), but can vary depending on the patient's anatomy.

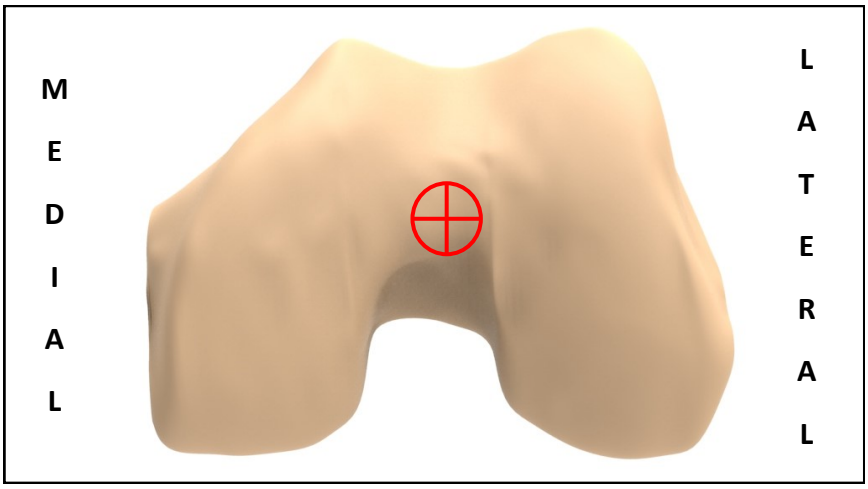


Fig. 40

Advance the 3.0mm x 600mm Trocar Tip Guide Wire (SLN-T35) through the starting point with a powered driver. Confirm its position in the AP (Fig. 41) and lateral (Fig. 42) planes. Proper position is critical. Withdraw wire and reposition as necessary.

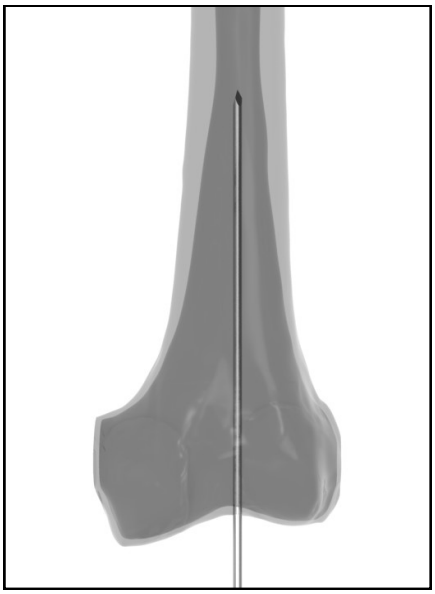


Fig. 41

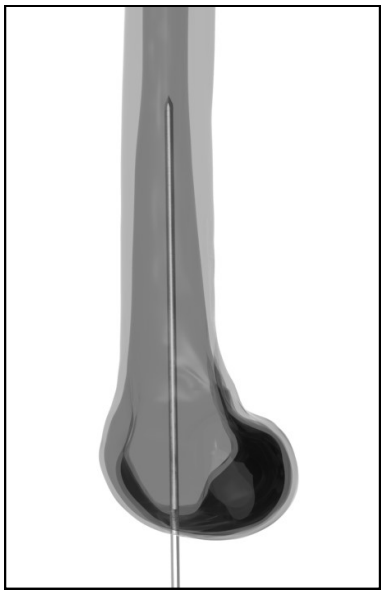


Fig. 42

With the wire in the desired position, open the proximal femur. The femur can be opened via one of two methods.

Method One: Cannulated Awl

Pass the 14mm Cannulated Awl (ODI-F02) over the guide wire to the level of the bone. Use gentle twisting motions to advance the awl into the distal femur. Take care not to displace the fracture or plunge the awl through the fracture site.

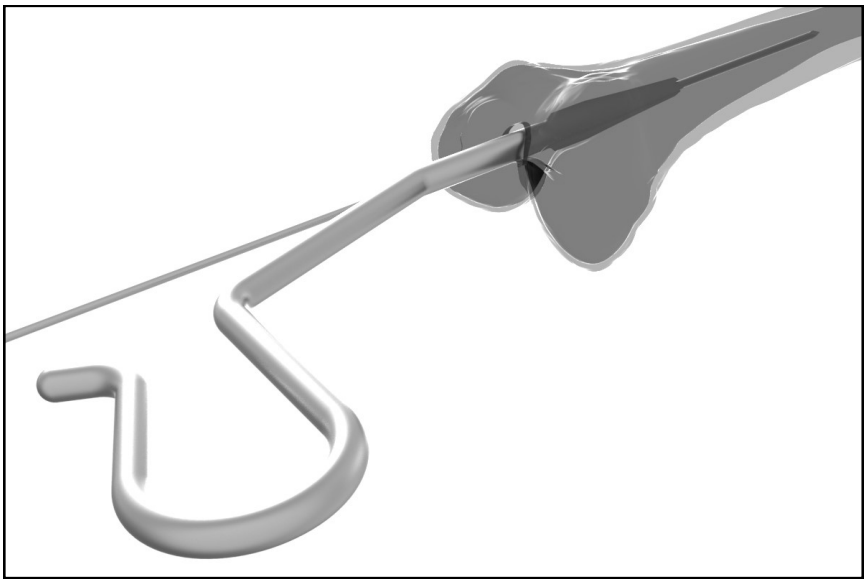


Fig. 43

Opening the Distal Femur (cont.)

Method Two: Entry Reamer

Pass the 14mm Entry Reamer (ODI-F03) connected to a powered driver and Tissue Protector (ODI-F01) over the guide wire.

Monitor the reaming depth via the image intensifier. There are four grooves on the cutting blades that represent the location of the cortical screw holes on the head of the nail (Fig. 44). Ream until the desired screw position(s) is reached. The end of the nail is denoted by the step between the reamer shank and cutting blades. Take care to position the nail head deep enough with respect to the articular surface to allow for compression/ dynamization.

Replace the trocar tip guide wire with the Ball Tip Sheathed Guide Wire (SLN-T41) (Fig. 45). Advance the sheathed wire across the fracture and up the femur.

Enlarge the medullary canal through distal reaming beginning with a 9mm cutter head. It is recommended that the canal be reamed 1mm greater than the diameter of the desired nail. Ream the canal to a minimum of 11mm (the smallest nail has a distal diameter of 10mm). If no resistance is felt after reaming to 11mm, continue reaming for the next size nail. Repeat this process, as needed, to a maximum of 13mm.

Once the canal has been reamed to the appropriate size, remove the sheath from the wire.

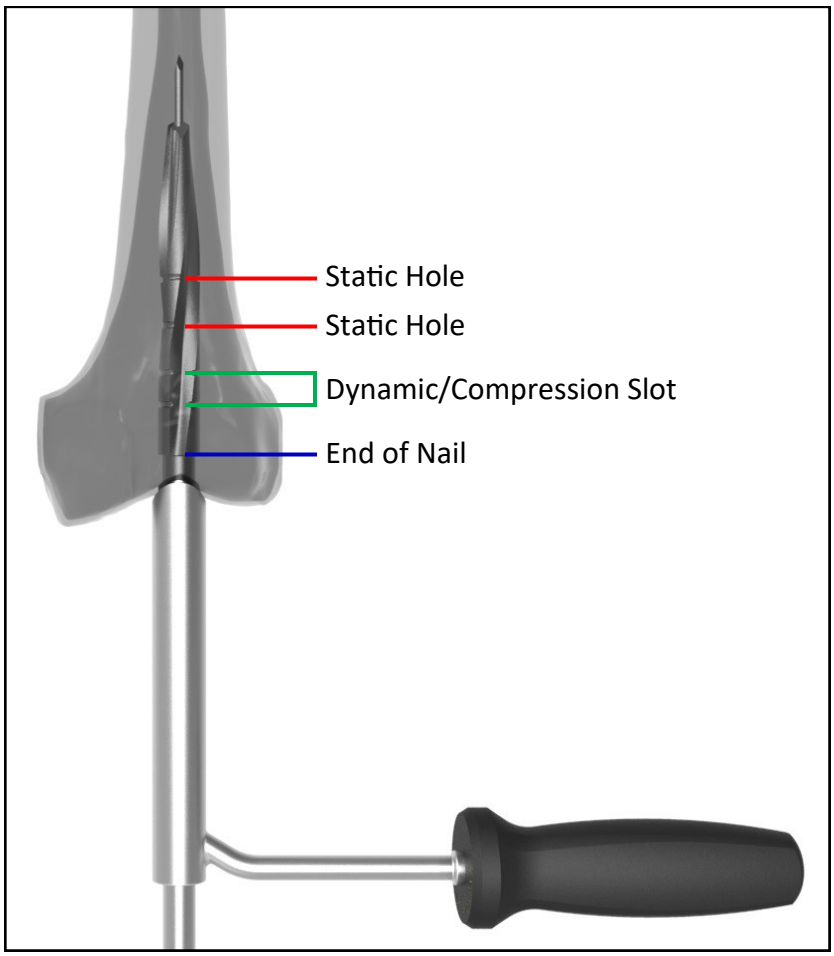


Fig. 44

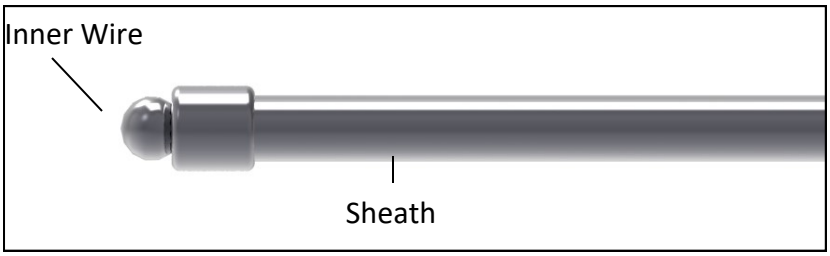


Fig. 45

Selection of the appropriate size implant—diameter and length—is of critical importance. Nail diameter can be determined through intra-medullary reaming following the steps described in the previous page. Nail length can be determined via one of two methods—measuring off the guide wire or radiographically.

Method One: Measuring the Wire

Open the Folding Guide Wire Ruler (ODI-F05) and pass it over the guide wire. The ruler has four pairs of notches that correspond to the screw hole positions on the head of the nail, as well as several slots that correspond to the head of the nail (long slot) and the depth of the head of the nail relative to the surface of the bone (small slots). Introduce the ruler into the distal femur and position it according to the desired screw location(s) (Fig. 46). Allow space for compression/dynamization, as needed. Note depth of nail head.

Place the Radiographic Ruler (ODI-F04) on the patient's thigh and position the image intensifier for an AP view of the proximal femur. Adjust the template until the four points appear well into the cortical bone (Fig. 47). Avoid the metaphyseal flare. With the template in position, adjust the guide wire until its tip is even with that of the template (Fig. 48). Suggested nail length can be read off the back of the wire (Fig. 49).

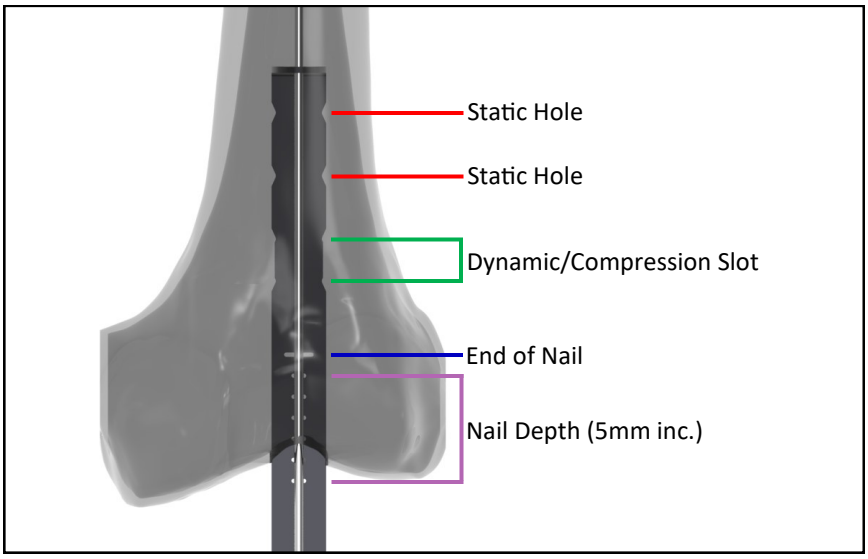


Fig. 46

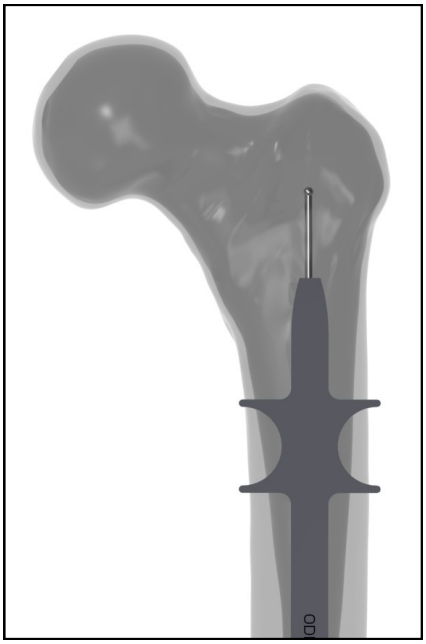


Fig. 47

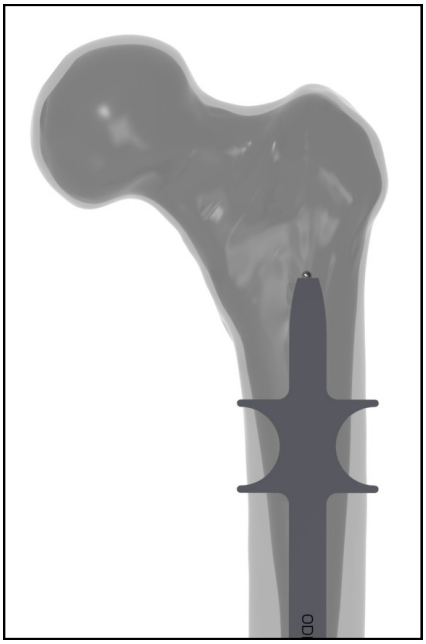


Fig. 48

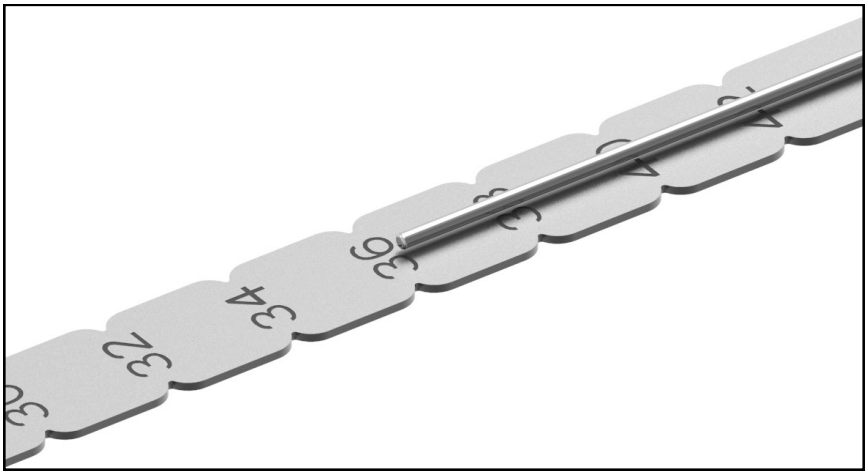


Fig. 49

Nail Selection (cont.)

Method Two: Radiographically

Position the Folding Guide Wire Ruler (ODI-F05) and the Radiographic Ruler (ODI-F04) as described in Method One. Do not adjust the guide wire. Position the image intensifier over the distal femur. Roll the image intensifier past the AP plane so that the guide wire ruler can be seen behind the Talon template. Read radiographically the suggested length to the slot corresponding to the end of the nail (long slot) (Fig. 50).

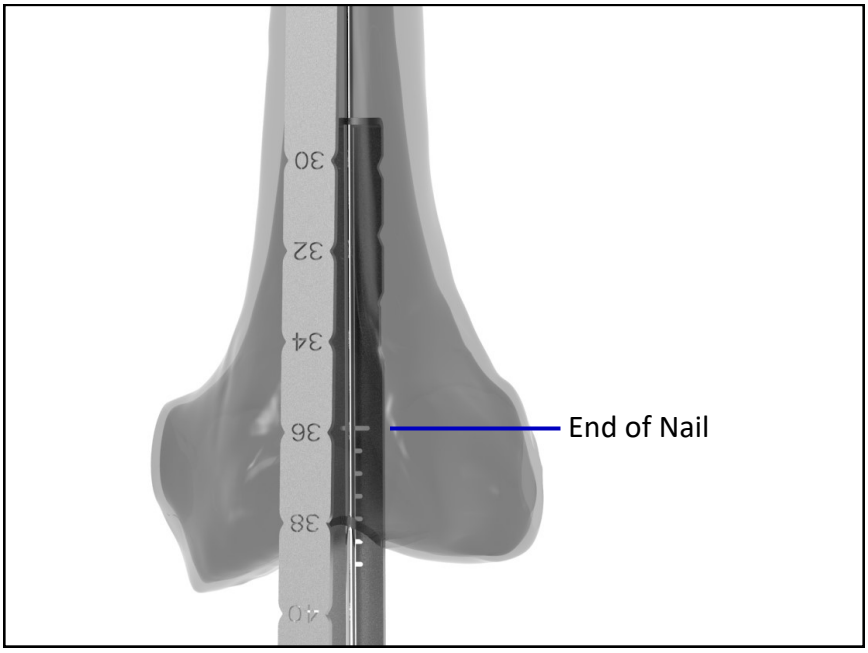


Fig. 50

Nail Insertion

Mate the chosen nail with the Guide Handle (ODI-F08). Take care to align the reference mark on the nail head with the appropriate corresponding mark on the handle (Fig. 51 & 52).

LA/RR: **L A**ntegrade / **R R**etrograde

RA/LR: **R A**ntegrade / **L R**etrograde

Secure the nail to the handle with the Nail-Handle Screw (ODI-F09) using the 7mm Hex Driver (ODI-U08) and Torque-Limiting T-Handle (ODI-U07) (Fig. 53). Ensure the screw is tightly secured by turning the T-handle until the torque limit is reached.

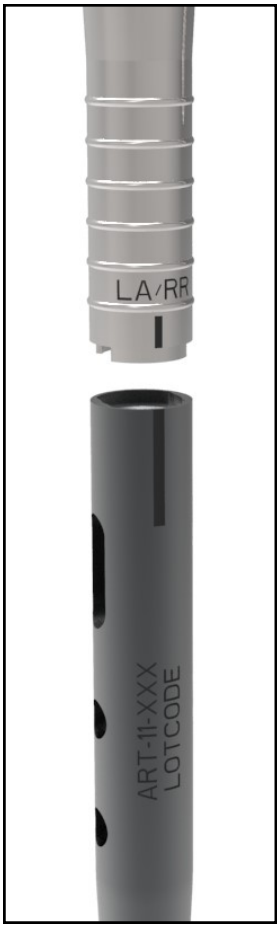


Fig. 51

Fig. 52

Fig. 53

RETROGRADE TECHNIQUE

If not already done, remove the sheath leaving the inner wire in place. The sheath will not pass through the nail.

Pass the nail over the wire and into the femur. Apply steady pressure and use small oscillating motions to advance the nail (Fig. 54). Monitor passage of the nail across the fracture site radiographically. Rings on the guide handle indicate insertion depth. Insert the nail to the depth noted during nail selection.

An Impactor (ODI-U03) can be used to aid in seating the nail (Fig. 54 Inset). Never strike the guide handle directly. If excessive resistance is encountered, remove the nail, replace the sheath, and further enlarge the medullary canal through reaming. If significant impaction is required to seat the nail, confirm the tightness of the nail-handle connector screw before continuing.

Once the nail is fully seated, confirm the reduction of the fracture in both the AP and lateral planes. If satisfied, remove the guide wire.

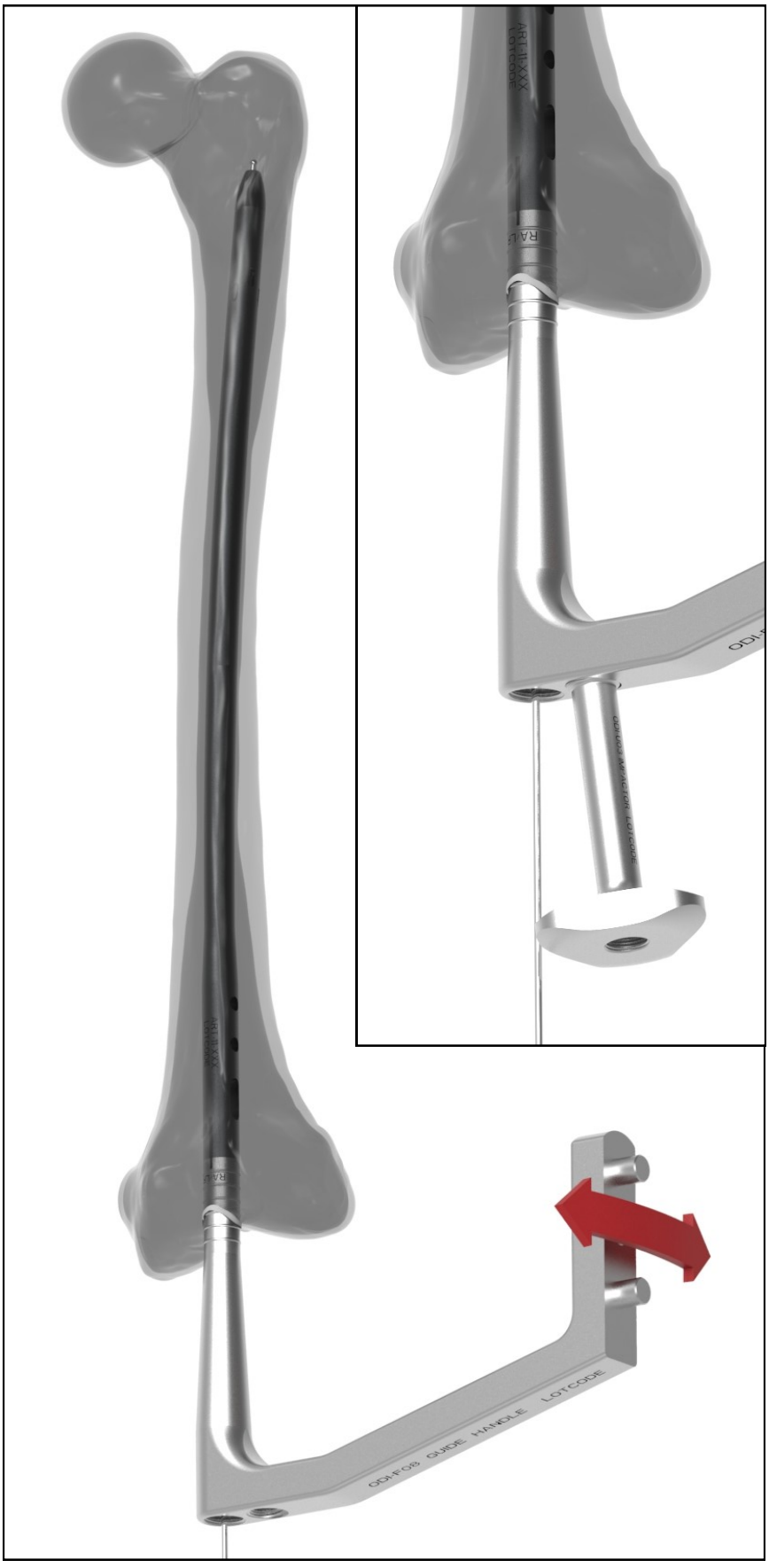


Fig. 54

Talon Deployment

Attach the Talon Driver (ODI-U09) to the Torque-Limiting T-Handle (ODI-U07) and pass the driver down the cannulation of the nail. Turn the driver clockwise to deploy the Talons (Fig. 55). Approximately 18 complete turns of the handle will take the Talons from the original position within the nail (Fig. 56) to fully deployed (Fig. 57).

NOTE: TALONS NEED NOT BE FULLY DEPLOYED. AT SURGEON'S DISCRETION, DEPLOYMENT CAN BE STOPPED AT ANY TIME. TALONS ARE DESIGNED TO PENETRATE THE CORTICAL BONE. CARE SHOULD BE TAKEN TO AVOID EXCESSIVE PERFORATION *THROUGH* THE CORTICAL BONE AND INTO SOFT TISSUE.

A consistent low resistance/torque should be felt during deployment until the cortex is reached. A sudden increase in resistance/torque marks cortical contact. Monitor the deployment progress with the image intensifier positioned for a lateral view of the proximal femur once cortical contact is made (Fig. 58). Continue deploying until the torque-limiting handle trips or you are radio-graphically indicated to stop. If necessary, retract the Talons by turning the driver counterclockwise.

The extent of Talon deployment varies by location in the femur. Take care to avoid the metaphyseal flare.

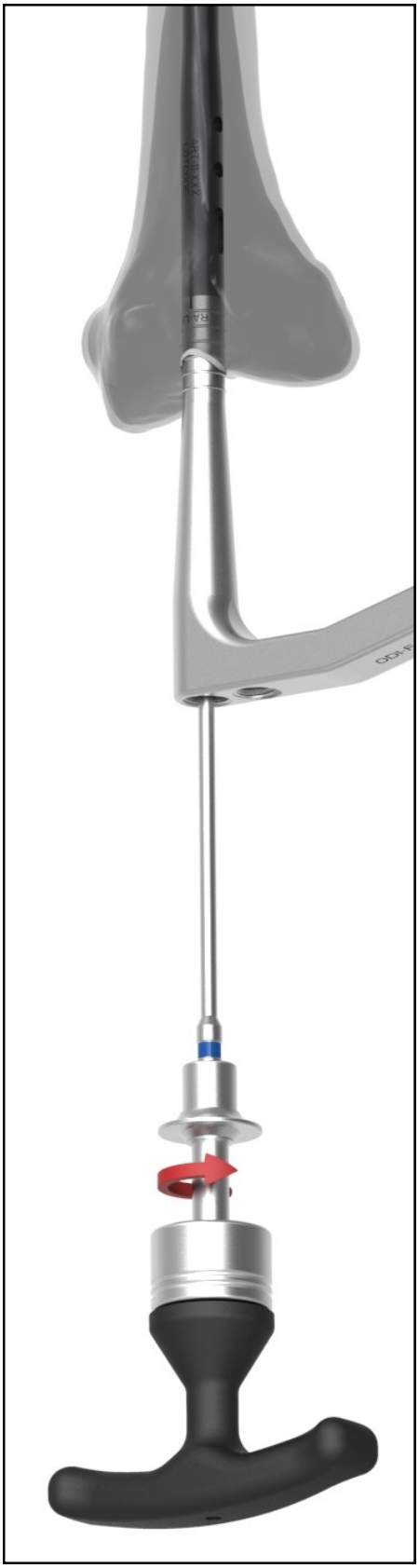


Fig. 55

Fig. 56

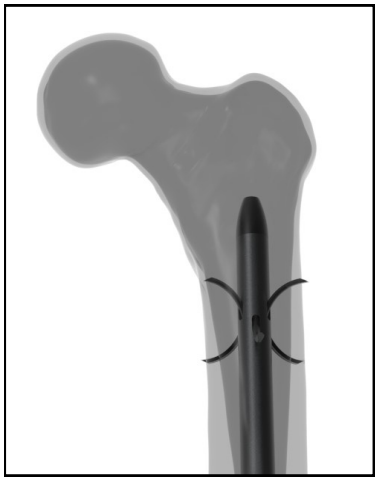


Fig. 57

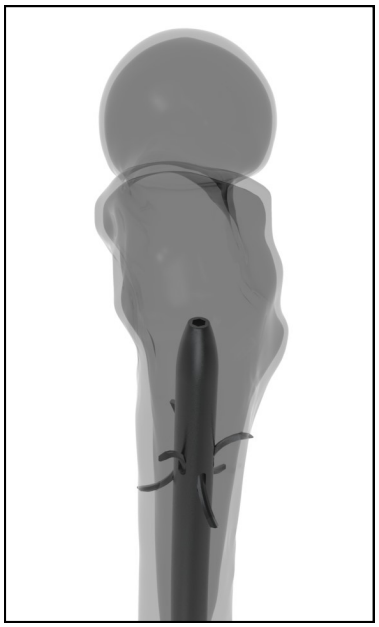


Fig. 58

TALONS SHOULD NEVER BE DEPLOYED USING A POWERED DRIVER.

Attach the Guide Arm (ODI-F12) to the Guide Handle (ODI-F08) and tighten the Guide Arm-Handle Connector Screw (ODI-U11) (Fig. 59). The technique for placing cortical screws is identical for all screw hole positions. The procedure for placing a screw with the intent of applying compression will be demonstrated.

Insert the triple sleeve assembly—Screw Sleeve (ODI-F13), Drill Sleeve (ODI-F14), and Trocar (ODI-F15)—through the hole in the Guide Arm labeled “DYN/COMP”. Make a small incision in the skin and advance the sleeves to the cortical surface (Fig. 60). Apply pressure with the Trocar to create a dimple in the lateral cortex.

Remove the Trocar and pass the calibrated 4.2mm Cortical Drill (ODI-F16) through the Drill Sleeve. Drill through both cortices (Fig. 61).

Read the drilled depth directly from the graduations on the drill (Fig. 62). Apply pressure to the Drill Sleeve to ensure it is in contact with the cortex. This will yield the most accurate measurement. Graduations are calibrated to the tip of the drill and coincide with the available screw lengths.

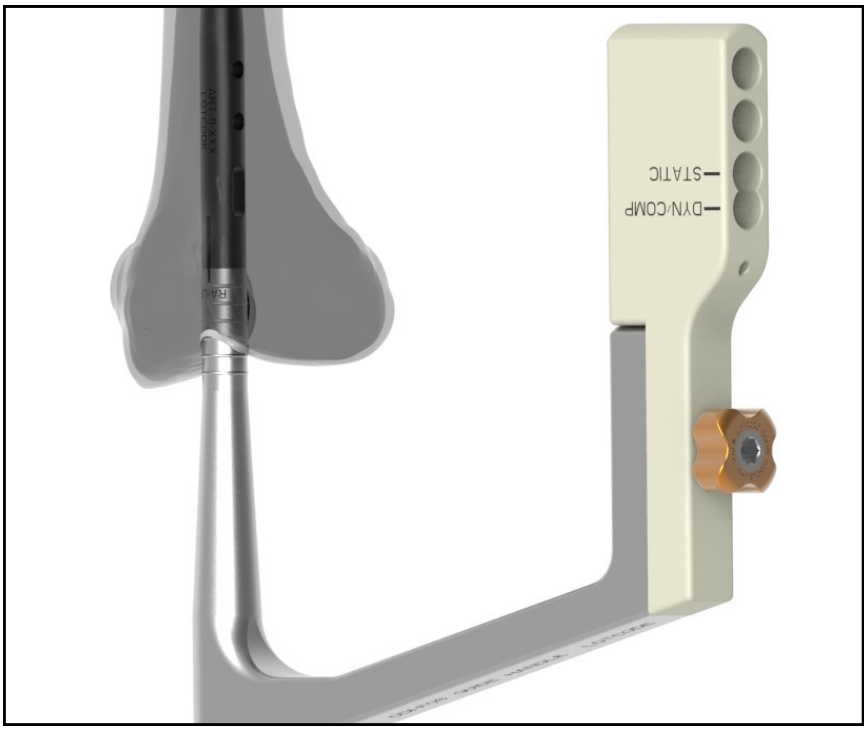


Fig. 59

Fig. 60

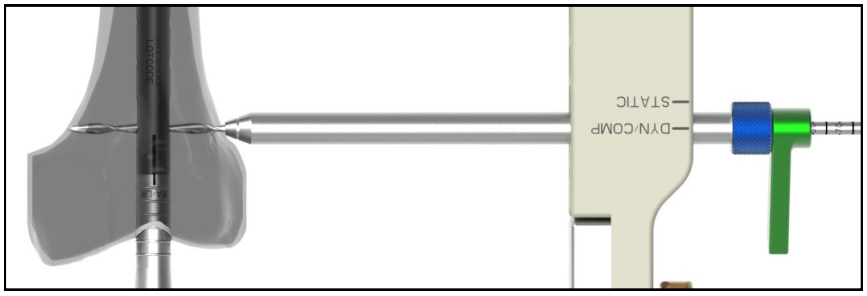


Fig. 61

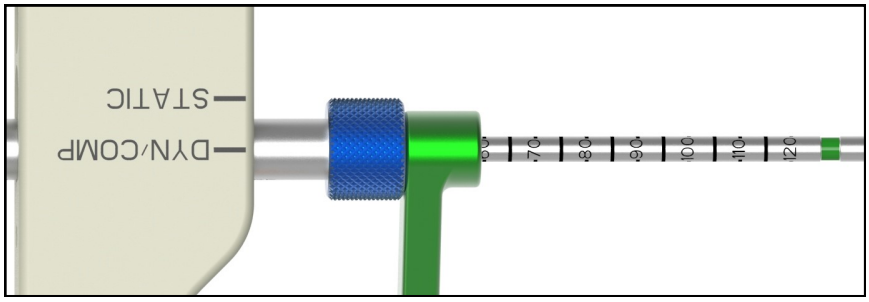


Fig. 62

Proximal Locking (cont.)

Mate the chosen cortical screw with the 5mm Hex Driver (ODI-U01) and secure with the 5mm Driver Connector Screw (ODI-U02) (Fig. 63).

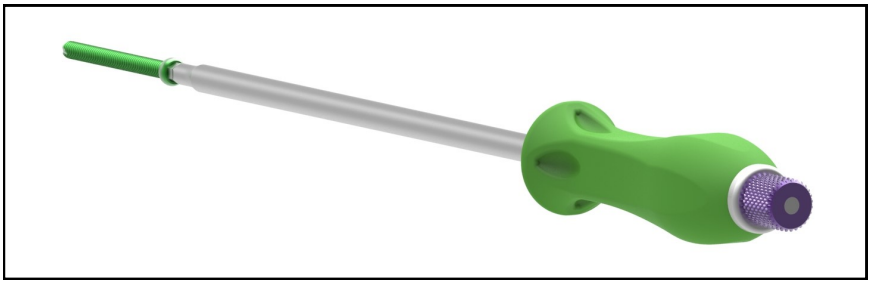


Fig. 63

Remove the Drill Sleeve and pass the cortical screw/driver assembly through the Screw Sleeve and into the bone (Fig. 64). Advance the screw until the screw head is seated against the lateral cortex. Do not over tighten as this may lead to the screw stripping. Release the cortical screw from the hex driver by turning the connector screw counterclockwise. Remove the Screw Sleeve from the Guide Arm.

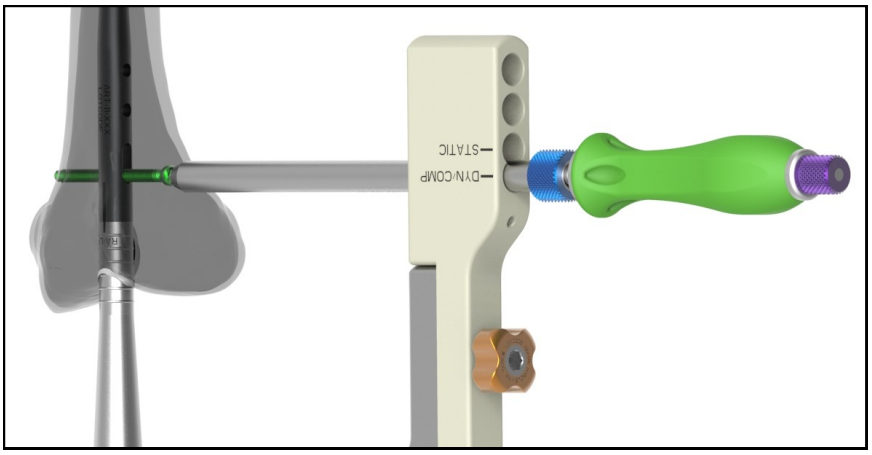


Fig. 64

To apply compression, connect the Compressor (ODI-F10) to the Ratcheting Axial Handle (ODI-U05) and insert through the Guide Handle. Turn clockwise to engage the threads and apply compression (Fig. 65). During compression, the distal fragment will be drawn towards the proximal fragment. Up to 10mm of compression can be applied (Fig. 66). Monitor compression with the image intensifier. Do not over-compress as this may cause the cortical screw to fail. **The Talon™ DistalFix™ A/R Femoral nail is not meant to be backslapped against the deployed Talons to achieve compression.**

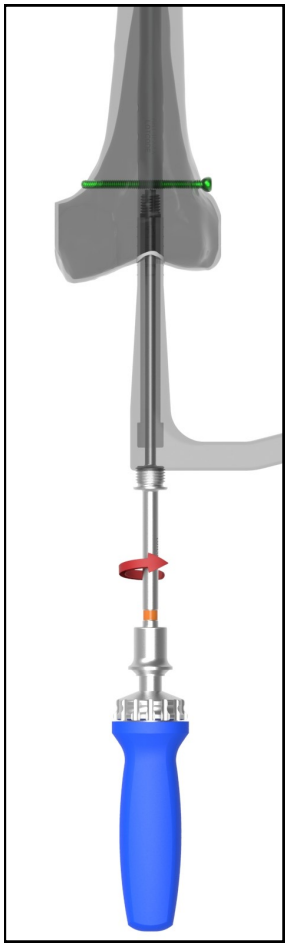


Fig. 65

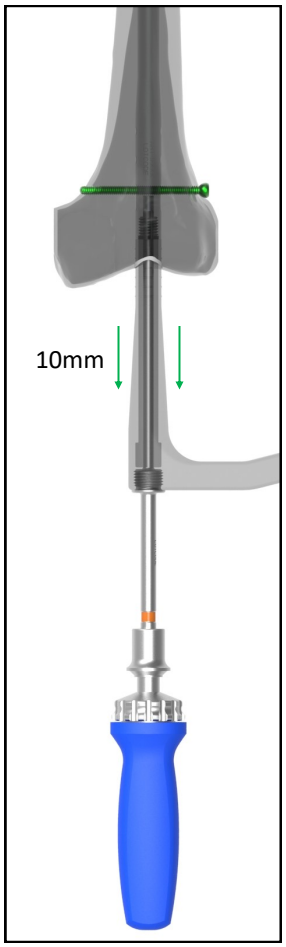


Fig. 66

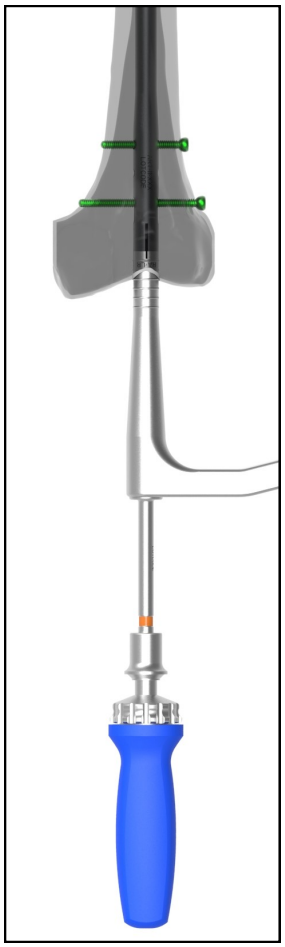


Fig. 67

Place a second screw in one of the static holes *prior* to removing the Compressor to ensure the applied compression is maintained (Fig. 67) .

RETROGRADE TECHNIQUE

Common locking configurations are as follows:

Static (Figs. 68 & 69)

Dynamic (Fig. 70)

Static, with the option to dynamize the nail secondarily (Fig. 71)

Compression (Fig. 72)

All cortical screws can be placed following the steps described in the preceding pages under the heading Proximal Locking.

A third screw can be used, as needed, for additional stability.

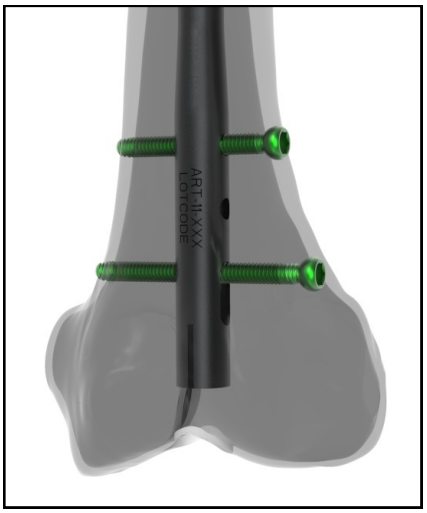


Fig. 68

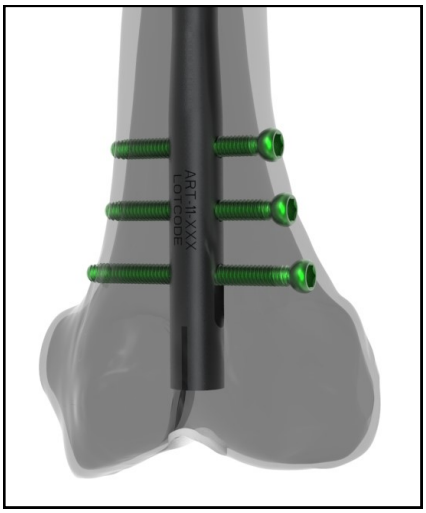


Fig. 69

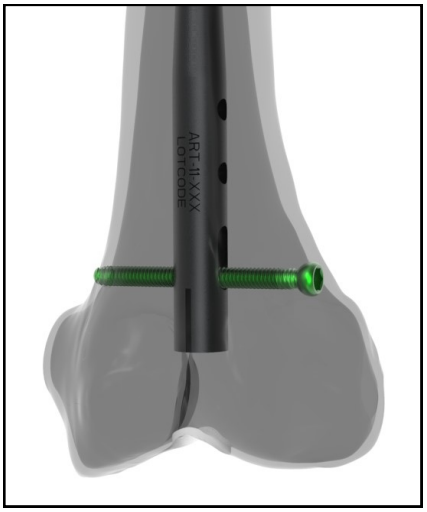


Fig. 70

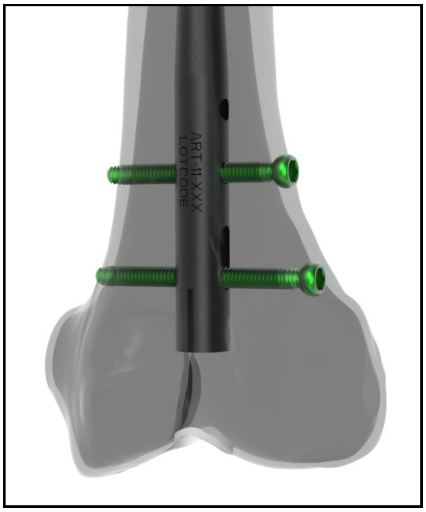


Fig. 71

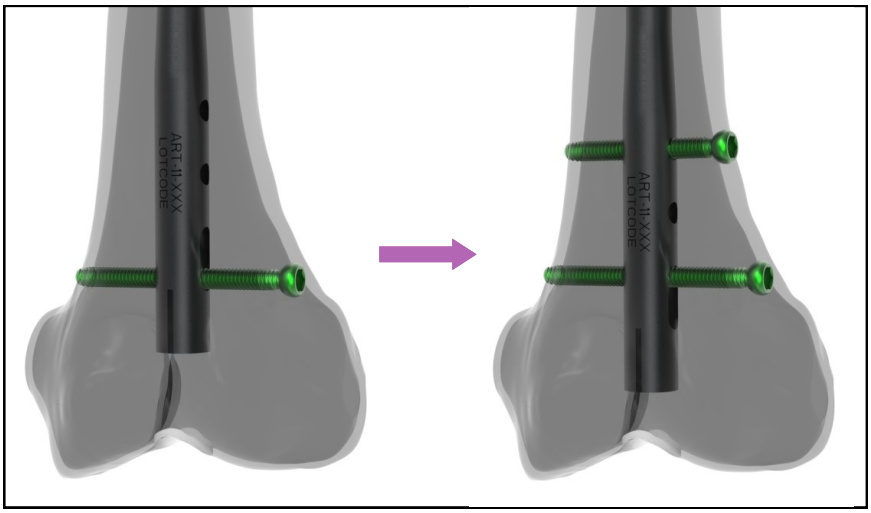


Fig. 72

End Cap Placement

Note the position of the head of the nail after cortical screw placement (Fig. 73). The depth of the nail may have changed if compression was applied.

Confirm the final implant position—proximally and distally—with the image intensifier in both the AP and lateral planes. If satisfied, use the 7mm Hex Driver (ODI-U08) to loosen the Nail-Handle Screw (ODI-F09) and remove the Guide Handle (ODI-F08).

Mate the chosen end cap with the 5mm Hex Driver (ODI-U01) and secure with the 5mm Driver Connector Screw (ODI-U02) (Fig. 74). The connector screw will ensure the end cap is not lost in the soft tissue.

Bring the end cap to the head of the nail—the smooth lead-in segment should help orient the end cap with the head of the nail. Turn the driver clockwise to engage the cap (Fig. 75). When fully engaged, release the end cap from the driver by turning the connector screw counterclockwise.

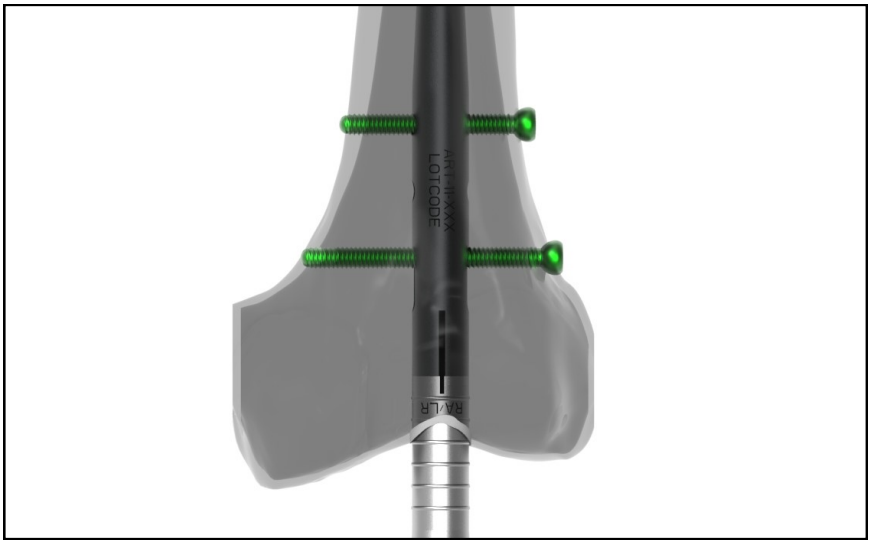


Fig. 73

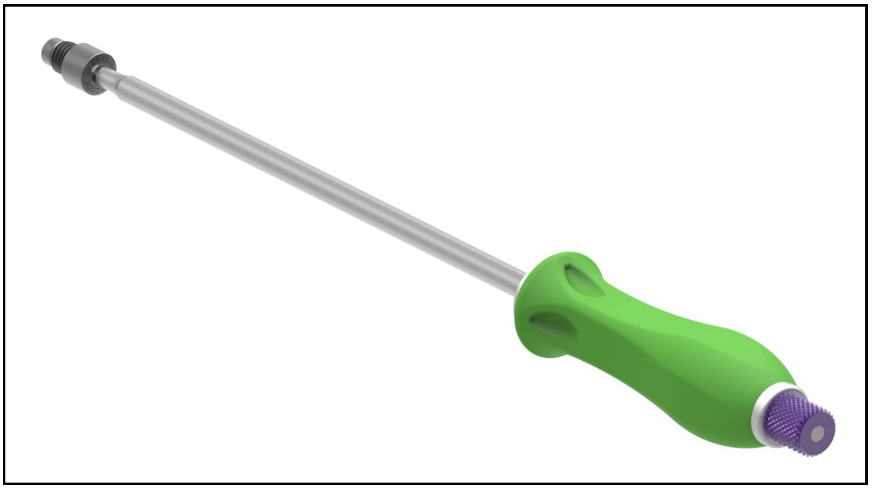


Fig. 74

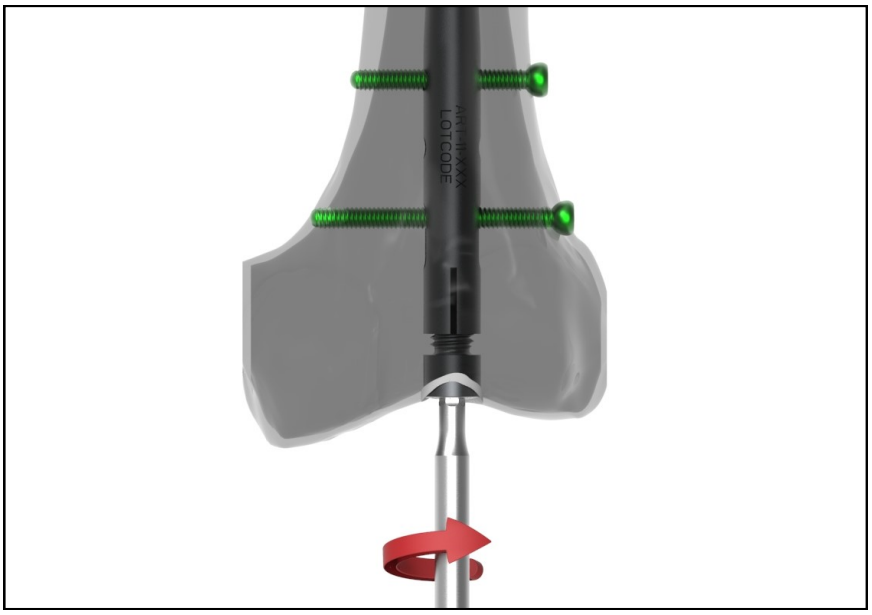


Fig. 75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LOTCODE

Implant Removal—Optional

Implant removal is an elective procedure. The steps for removing a Talon™ DistalFix™ A/R Femoral Nail are the same regardless of the orientation of the nail—antegrade or retrograde. The removal of a retrograde nail is depicted.

Clear any debris that may have grown into the hex socket of the end cap. Remove the end cap with the 5mm Hex Driver (ODI-U01) (Fig. 76). The 5mm Hex Driver Connector Screw (ODI-U02) can be used to secure the driver to the end cap, ensuring it does not fall off the driver in the soft tissue.

Clear any debris that may have grown into the hex socket of the cortical screws. Remove cortical screws with the 5mm Hex Driver (ODI-U01) and 5mm Hex Driver Connector Screw (ODI-U02) (Fig. 77).

Be sure to remove all screws before proceeding (Fig. 78).

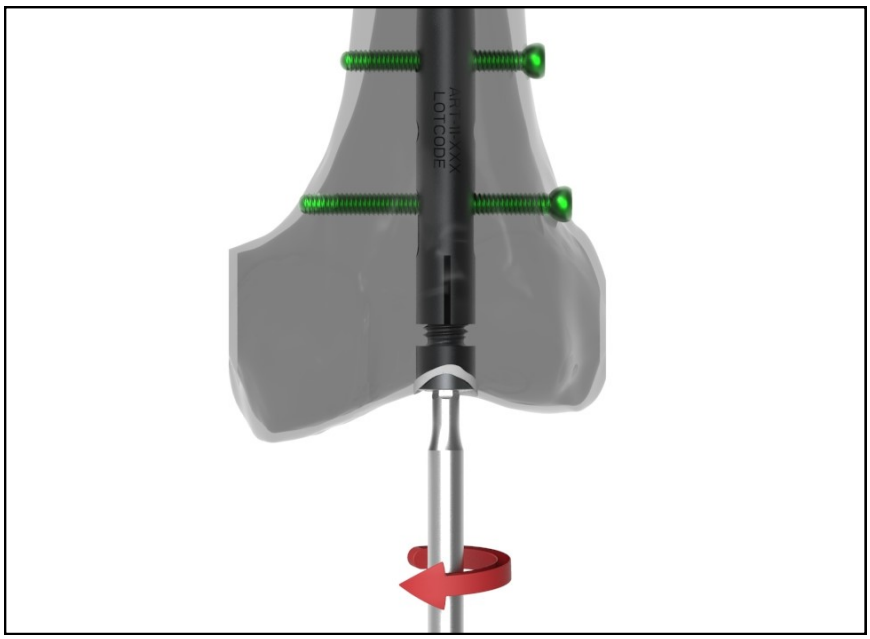


Fig. 76

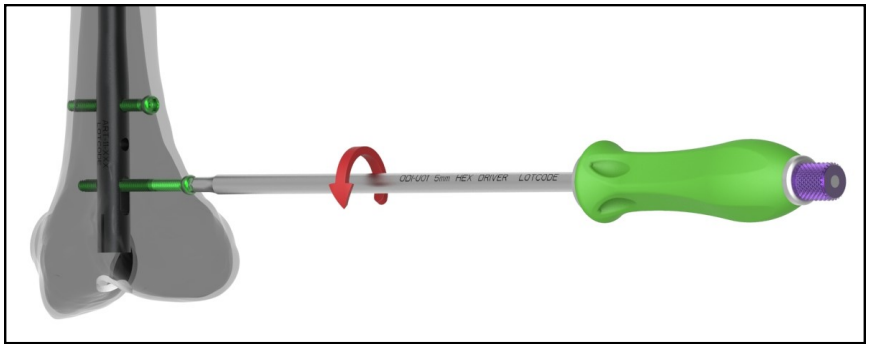


Fig. 77

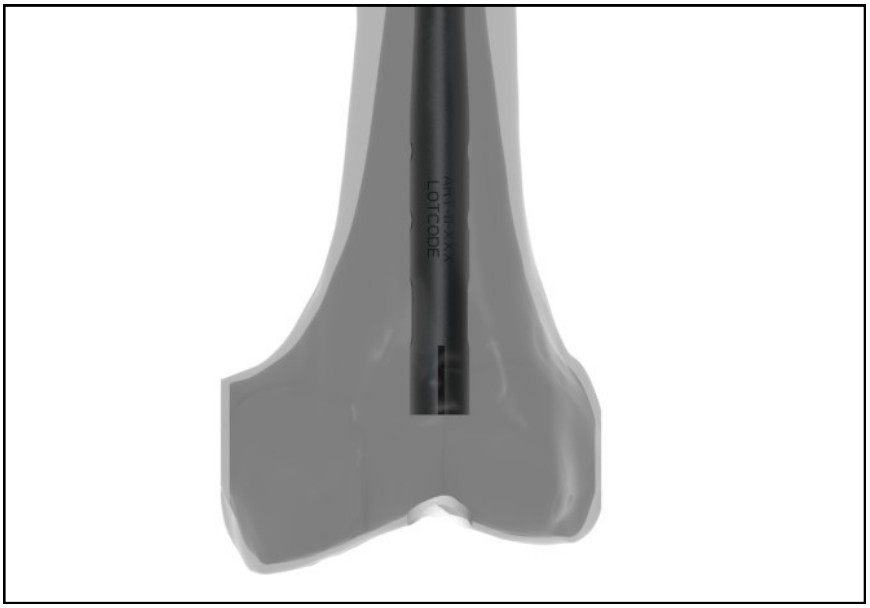


Fig. 78

MISCELLANEOUS

Implant Removal—Optional (cont.)

Connect the Talon Driver (ODI-U09) to the Torque-Limiting T-Handle (ODI-U07). Pass the driver down the nail and engage the Talon mechanism. Ensure the driver is fully seated in the mechanism before turning. Turn counterclockwise to retract the Talons (Fig. 79).

Confirm radiographically that the Talons are fully retracted (Fig. 80). Remove the Talon Driver.

Pass the Extractor (ODI-F06) through the Slide Hammer (ODI-U04) and connect the Extractor to the head of the nail. (Connection of the Extractor can be simplified by first inserting a guide wire through the nail cannulation). Extract the nail via gentle blows of the Slide Hammer against the Extractor (Fig. 81).

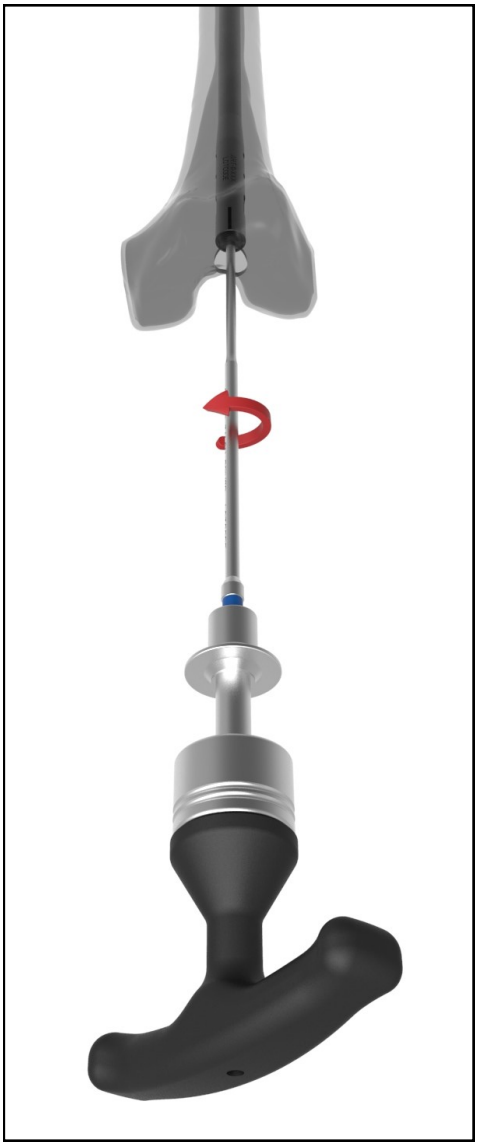


Fig. 79

Fig. 80

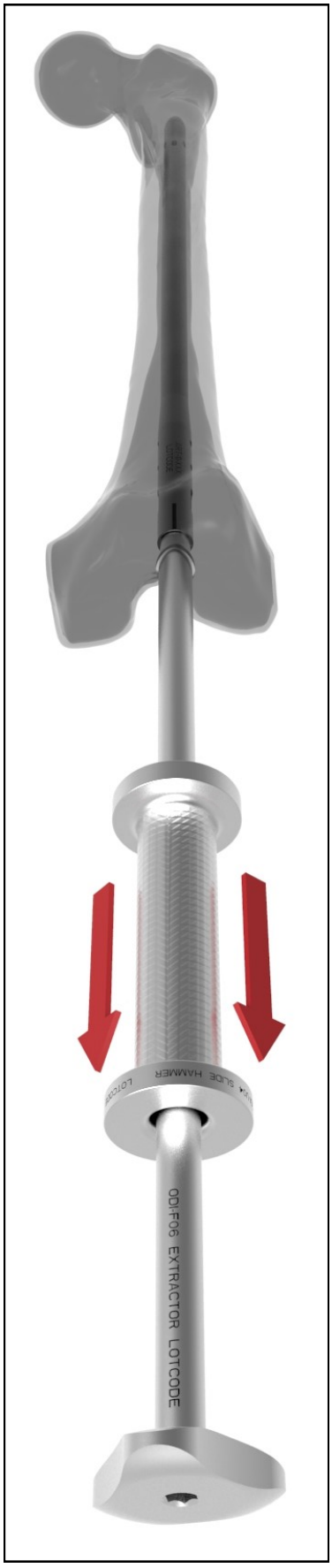


Fig. 81

MISCELLANEOUS

Implant Catalog

Nails

LENGTH (mm)	10mm DIAMETER
280	ART-10-280
300	ART-10-300
320	ART-10-320
340	ART-10-340
360	ART-10-360
380	ART-10-380
400	ART-10-400
420	ART-10-420

LENGTH (mm)	11mm DIAMETER
280	ART-11-280
300	ART-11-300
320	ART-11-320
340	ART-11-340
360	ART-11-360
380	ART-11-380
400	ART-11-400
420	ART-11-420

LENGTH (mm)	12mm DIAMETER
280	ART-12-280
300	ART-12-300
320	ART-12-320
340	ART-12-340
360	ART-12-360
380	ART-12-380
400	ART-12-400
420	ART-12-420

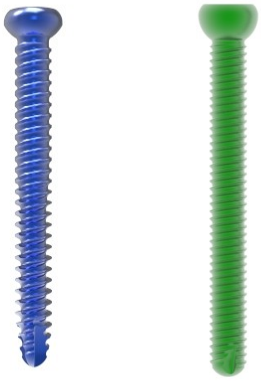
MISCELLANEOUS

End Caps

LENGTH (mm)	13mm DIAMETER
0	ART-13-C00
5	ART-13-C05
10	ART-13-C10
15	ART-13-C15
20	ART-13-C20
25	ART-13-C25
30	ART-13-C30
35	ART-13-C35

Universal Cortical Locking Screws

LENGTH (mm)	5mm DIAMETER
30	ART-U-5-030
35	ART-U-5-035
40	ART-U-5-040
45	ART-U-5-045
50	ART-U-5-050
55	ART-U-5-055
60	ART-U-5-060
65	ART-U-5-065
70	ART-U-5-070
75	ART-U-5-075
80	ART-U-5-080
85	ART-U-5-085
90	ART-U-5-090
95	ART-U-5-095
100	ART-U-5-100
105	ART-U-5-105
110	ART-U-5-110
115	ART-U-5-115
120	ART-U-5-120



Cortical Locking Screws

LENGTH (mm)	5mm DIAMETER
30	ART-5-030
35	ART-5-035
40	ART-5-040
45	ART-5-045
50	ART-5-050
55	ART-5-055
60	ART-5-060
65	ART-5-065
70	ART-5-070
75	ART-5-075
80	ART-5-080
85	ART-5-085
90	ART-5-090
95	ART-5-095
100	ART-5-100
105	ART-5-105
110	ART-5-110
115	ART-5-115
120	ART-5-120

Instrument Catalog—Reusable Instruments

ODI-F01—TISSUE PROTECTOR

ODI-F02—ENTRY AWL

ODI-F03—ENTRY REAMER

ODI-F04—RADIOGRAPHIC RULER

ODI-F05—GUIDE WIRE RULER

ODI-F06—EXTRACTOR

MISCELLANEOUS

Instrument Catalog - Reusable Instruments

ODI-F08—GUIDE HANDLE

ODI-F09—NAIL / HANDLE SCREW

ODI-F10—COMPRESSOR

ODI-F12—GUIDE ARM

ODI-F13—SCREW SLEEVE

ODI-F14—DRILL SLEEVE

ODI-F15—TROCAR

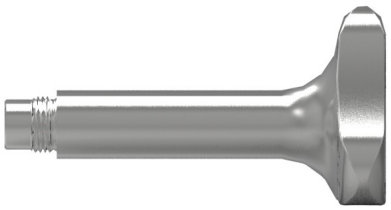
ODI-F16—DRILL

MISCELLANEOUS

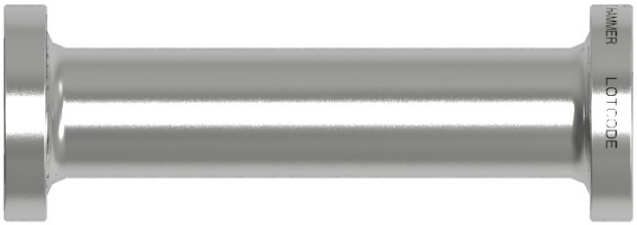
Instrument Catalog—Reusable Instruments

ODI-U01—5mm DRIVER

ODI-U02—5mm DRIVER CONNECTOR SCREW



ODI-U03—IMPACTOR



ODI-U04—SLIDE HAMMER

ODI-U05—RATCHETING AXIAL HANDLE

ODI-U07—TORQUE LIMITING T-HANDLE

ODI-U08—7mm DRIVER

ODI-U09—TALON DRIVER

MISCELLANEOUS

Instrument Catalog - Reusable Instruments

ODI-U11—HANDLE / ARM SCREW

ODI-F100—INSTRUMENT CASE

Instrument Catalog - Disposables

SLN-T33—3.0mm X 900mm TROCAR TIP GUIDE WIRE

SLN-T34—3.0mm X 900mm ROUND TIP GUIDE WIRE

SLN-T35—3.0mm X 600mm TROCAR TIP GUIDE WIRE

SLN-T36—3.0mm X 600mm ROUND TIP GUIDE WIRE

SLN-T41—3.0mm X 900mm BALL TIP SHEATHED GUIDE WIRE

Notes

Important Medical Information

The use of surgical implants provides the orthopedic surgeon a means of bone fixation and helps generally in the management of fractures and reconstructive surgeries. These implants are intended as an aid to normal healing, and are not intended to replace normal body structure or bear the weight of the body in the presence of incomplete bone healing. Delayed unions or nonunions, in the presence of load bearing or weight bearing, might eventually cause the implant to break, due to metal fatigue. All metal surgical implants are subject to repeated stress in use, which can result in metal fatigue.

1. NO PARTIAL WEIGHT BEARING OR NONWEIGHT BEARING DEVICE CAN BE EXPECTED TO WITHSTAND THE UNSUPPORTED STRESSES OF FULL WEIGHT BEARING. Until firm bone union is achieved, the patient should employ adequate external support and restrict physical activities which would place stress upon the implant or allow movement at the fracture site and delay healing.

   Failure to immobilize a delayed union or nonunion of bone will result in excessive and repeated stresses, which are transmitted by the body to any temporary internal fixation device, prior to the healing of the fracture. Due to normal metal fatigue, these stresses can cause eventual bending or breakage of the device. Therefore, it is important that immobilization of the fracture is maintained until firm bony union (confirmed by clinical and roentgenographic examination) is established.

   Special precautions are necessary if a temporary internal fixation device is used to treat unstable fractures. These fractures are more difficult to reduce and result in unusually strong unbalanced muscle forces, which cause greater stress to be transmitted to the temporary internal fixation device than with other types of femoral fractures. These stresses increase the possibility of implant bending or breakage.

   NOTE: Postoperative care is extremely important. The patient must be warned that noncompliance with postoperative instruction could lead to breakage of the implant, requiring revision surgery to remove the device.

2. CORRECT SELECTION OF THE IMPLANT IS EXTREMELY IMPORTANT. The potential for success in fracture fixation is increased by the selection of the proper size, shape and design of the implants. The size and shape of the human bone presents limiting restrictions on the size and strength of the implants.

3. Preoperative and operative procedures, including knowledge of surgical techniques, good reduction, and proper selection and placement of the implant are important considerations in the successful utilization of temporary internal fixation devices. See the specific surgical technique for surgical procedure.

4. In evaluating patients for orthopedic appliance application, the patient's weight, occupation, activity level, mental condition, foreign body sensitivity, and any degenerative diseases are of extreme importance to the eventual success of the procedure. These conditions must be evaluated as part of the preoperative planning.

5. CORRECT HANDLING OF IMPLANTS IS EXTREMELY IMPORTANT. The device should not be bent sharply, reverse bent, notched or scratched. All of these operations can produce defects in the surface finish and internal stress concentrations, which may become the focal point for eventual failure of the appliance.

   If metal screws, wire bands or other metallic devices are to be used together with a particular temporary internal fixation device, all such devices should be manufactured from materials having similar composition, to avoid the possibility of galvanic corrosion or other metallic reactions.

6. NO METALLIC SURGICAL IMPLANT SHOULD BE REUSED. Any metal implant, once used, should be discarded. Even though it appears undamaged, stresses from prior use may create small defects and internal stress patterns which may lead to fatigue failure.

7. Detailed written instructions on the use and limitations of the device should be given to the patient. If partial weight bearing is recommended or required prior to firm bony union, the patient must be warned that bending or breakage of the device are complications which may occur as a result of weight bearing or muscle activity. An active patient, debilitated or demented patient, who cannot properly use weight support devices, may be particularly at risk during postoperative rehabilitation.

8. REMOVAL OF THE DEVICE. While the surgeon must make the final decision on implant removal, it is the position of the Orthopedic Surgical Manufacturers Association that, whenever possible and practical for the individual patient, fixation devices should be removed once their service as an aid to healing is accomplished, particularly in younger more active patients.

9. SCREWS WARNING. This device is not approved for screw attachment or fixation to the posterior element (pedicles) of the cervical, thoracic, or lumbar spine.

10. Implants that are provided sterile should be stored unopened in their protective packaging. Inspect packages for damage prior to surgery. Products not labeled as sterile are non-sterile.

    Instruments should be cleaned between each surgical procedure. Orthopedic Designs North America recommends using the validated cleaning instructions provided in “Instructions for Use: Reusable Orthopedic Surgical Instruments” (7019).

    Prior to use, instruments and non-sterile implants should be steam sterilized after removal of any non-autoclavable protective packaging and labeling. Instruments and non-sterile implants should be sterilized using only FDA-cleared sterilization barriers (e.g. pouches, wraps or containers). The following process parameters are validated by Orthopedic Designs North America and recommended for sterilization and/or resterilization:

Method	Cycle	Temperature	Exposure Time	Minimum Dry Time*
Steam	Gravity	250°F (121°C)	30 minutes	30 minutes
Steam	Gravity	270°F (132°C)	15 minutes	30 minutes
Steam	Prevacuum	270°F (132°C)	10 minutes	30 minutes

*Refers to in chamber dry time. Please note that dry times may vary due to differences in the user’s packaging materials, environmental conditions, steam quality, device materials, total mass, sterilizer performance and varying cool down time. The user should employ verifiable methods (e.g. visual inspections) to confirm adequate drying. It is the user’s responsibility to validate the appropriate drying time with the sterilization equipment and sterilization load used.

CAUTION: Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.

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The symbols glossary is provided electronically at:

WWW.ODI-NA.COM/SYMBOLS-GLOSSARY

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