ATLAS◇ FFN

Femoral Fracture Nail

Surgical Technique

ADLER®

Nota Bene

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

ATLAS◇ FFN Femoral Fracture Nail

Table of Contents

Indications

The ATLAS◇ Femoral Fracture Nail is indicated for fractures of the femur, including intertrochanteric, basi/ transcervical femoral neck fractures and subtrochanteric fractures, ipsilateral femoral neck/shaft fractures, stable and unstable shaft fractures, segmental fractures, nonunions and malunions, polytrauma, reconstructions following tumor resection and bone lengthening and shortening

ATLAS◇ FFN Design Features

Nail Cap:

- 0mm, 5mm & 10mm

Screws:

- 6.4mm Recon screws (Length range – 65mm to 125mm)
- 5mm screws (gold – from 20mm to 80mm in 2.5mm increments & 80mm to 110mm in 5mm increments) for 10, 11.5 & 13mm nails
- 4.5mm (green – from 25mm to 65mm in 5mm increments) for 9mm nails

Nail length range:

- 30cm to 50cm

- 5° lateral offset for minimally invasive trochanteric entry
- 12° of built-in femoral neck ante-version
- Neck shaft angle of 130 degrees
- 2 ML distal locking options including one dynamic slot

Distal nail diameters:

- 9, 10, 11.5 & 13mm

ATLAS◇ FFN

Surgical Technique

Preoperative Considerations

The technique description below is provided as an educational tool.

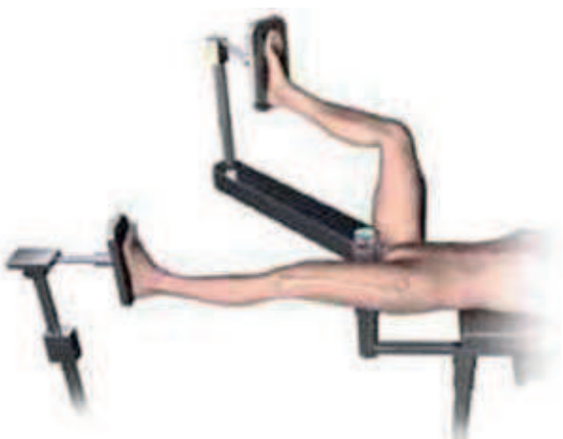
When making final determinations in product usage and technique execution, it is the responsibility of operating medical professionals to exercise their judgment and rely on their own medical training and experience.

Prior to performing this technique, or utilizing any product referenced herein, please conduct a thorough review of each product's indications, contraindications, warnings, precautions and instructions as detailed in the instructions for use (IFU) provided in the surgical technique.

Patient Positioning

- Place the patient in the supine or lateral decubitus position on a fracture table according to surgeon preference and/or fracture pattern. The foot of the affected limb is placed in a foot holder or a skeletal traction pin is inserted through the calcaneus, proximal tibial metaphysis or distal femoral metaphysis to achieve traction. The unaffected limb is extended at the hip and positioned down and away from the affected limb or is placed up in a leg holder. Alternatively, the procedure can be performed in the lateral position on a standard radiolucent table without traction attachments.

- The injured leg may be adducted 10°–15° relative to the torso to allow for clear access to the intramedullary canal. Check the affected limb for length and rotation by comparison to the unaffected limb. Rotate the C-Arm to ensure optimal AP and lateral visualization of the proximal femur.



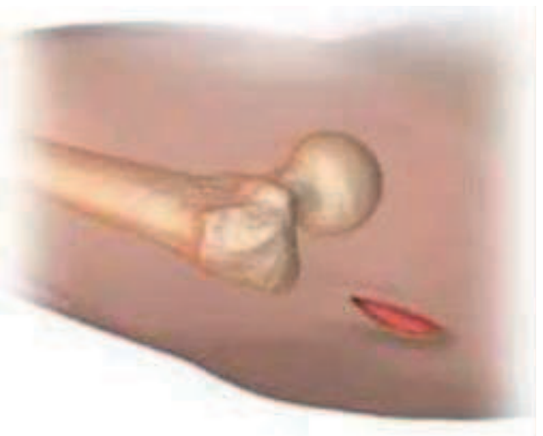
Note:

- If using a radiolucent table, a distraction device may be helpful in reducing the fracture. Demonstrating the ability to reduce the fracture under fluoroscopic control after positioning on the table but prior to preparing and draping the patient is recommended. This allows for adjustments in patient position that are necessary to achieve an adequate reduction of the fracture.
- Mating instrument should connect properly with driving instrument

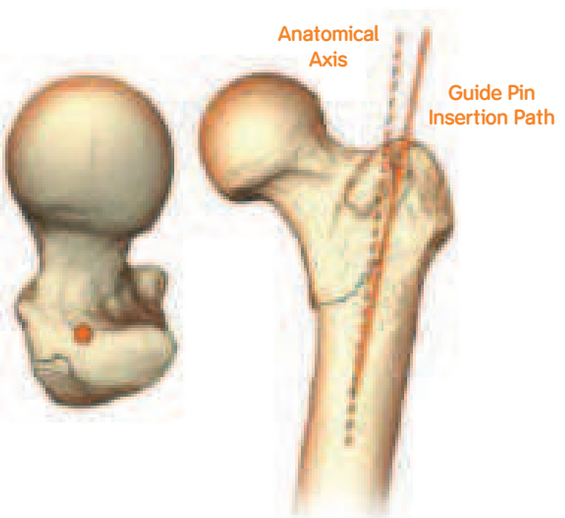
Opening the Proximal Femur

Incision and Entry Point

- A longitudinal incision is made proximal to the greater trochanter. Carry the incision through the fascia and palpate the tip of the greater trochanter.



- The optimal entry point is located on the medial face of the greater trochanter, 5° lateral to the anatomical axis in the AP plane and in-line with the center of the femoral neck in the lateral plane.

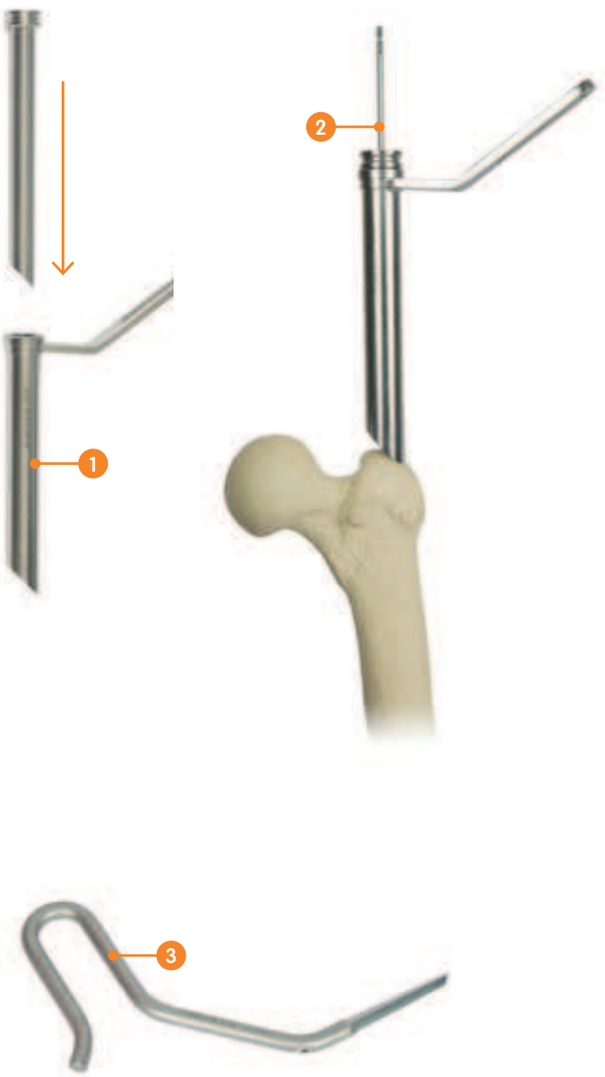


Entry Portal Acquisition

- Position the **Entry Protection Sleeve (I0505.2015)** 1 such that handle faces lateral femoral cortex.
- Insert the entry drill sleeve through the incision down to bone. Attach a **3.2mm ATLAS° Guide Pin (I0547.32)** 2 to power and insert it 2-3cm into the trochanteric region.
- Avoid over-insertion of the guide pin as this can establish a false trajectory and lead to fracture mal-alignment. Confirm guide pin placement in the AP and lateral planes.
- Alternatively, use the cannulated **ATLAS Curved Cannulated Awl (I0566.00)** 3 to locate the medial face of the greater trochanter and check its position with AP and lateral views.

Caution:

- Incorrect Guide Wire entry point may affect correct implant placement.
- Ensure that the power tool chuck is fully tightened before use.



Entry Portal Acquisition

- Following fluoroscopic confirmation of correct guide pin placement, attach the **14mm Cannulated Proximal Entry Reamer (I0569.02)** 1 to power and slide over the **3.2mm ATLAS° Guide Pin (I0547.32)**.

- Adjust the angle of the reamer assembly to the desired trajectory and when the entry reamer is used through the entry protection sleeve, the 'stopper' on the reamer will prevent it from advancing more than 5cm.

- For hip fractures and proximal femoral fractures, ensure that the fracture remains reduced throughout the process of advancing the reamer to prevent malreduction with nail insertion.

- Confirm the reamer assembly's final position and fracture reduction in both the AP and lateral planes. Remove the reamer assembly and guide pin.

Caution: Reaming with the Proximal Entry Reamer without use of the Protection Sleeve may lead to cortical perforation.

Fracture Reduction

- Insert the back end of the **Ball Tip Guide Wire** into the **ATLAS® Keyless Chuck (I0565.00)** 1 and tighten the locking screw. Introduce the **ATLAS Ball Tip Guide Wire (C1501.3010)** 2 into the intramedullary canal through the entry portal sleeve.

- Fracture reduction must be achieved by closed manipulation under fluoroscopic control prior to passing the guide wire across the fracture site.

- Pass the ball tip guide wire down to the desired depth. It is valuable to pass the guide wire to the level of the physeal scar in the distal femur to reduce the risk of it being withdrawn beyond the fracture site during the reaming process. The guide wire should be center-center within the distal femur in the AP and lateral views

Caution: Nailing Guide wire may abrade skin in obese patients. In such patients it is advised to:

- Plan a skin incision slightly more than proximal
- Re-adjust patient position, adduct the ipsilateral leg further making a so called “banana“ position of the patient
- Use of tissue protector is essential in such situations

Fracture Reduction

Optional

- Connect the reducer with **Quick Connect T-handle (I0560.00)** 1 and introduce it into the intramedullary canal. The reducer will allow the surgeon to manipulate the proximal fragment to achieve a closed fracture reduction for subtrochanteric and femoral shaft fractures, and allow passage of the **ATLAS° Ball Tip Guide Wire (C1501.3010)** 2.

- Pass the ball tip guide wire through the back of the T-handle and insert to the desired depth (typically to the level of the distal femur physeal scar) using the reducer's curved tip to avoid any areas of comminution. The guide rod should be centered within the distal femur in both the AP and lateral views.

- Once the guide wire is in position, loosen the **ATLAS Keyless Chuck (I0565.00)** 3 locking screw and remove the reducer, if used, from the intramedullary canal. Slide the **ATLAS Obturator (I0537.00)** into the back of the T-handle during extraction in order to maintain guide wire position within the canal.

Note: The Reducer may be too large to use if the patient has a small diameter intramedullary canal. If this is the case, reduce the fracture manually.

Nail Selection

- Under fluoroscopy, use the length gauge to measure the require length of the nail and select the appropriate diameter. Never insert a nail that has a larger diameter than the last reamer used.

- The **ATLAS° Length Gauge (I0567.00)** 1 enables selection of the desired nail length with the help of the image intensifier.

Caution:

- Make sure calibration cut-outs are clear and not clogged with any foreign material that may prevent clear visibility on fluoroscopy.
- Prior to Nail insertion, if any third-party Reaming Guide Wire / Reaming system has been used, the same may need to be exchanged with a **Nailing Guide Wire.** An **Exchange Tube (I0525.00)** 2 has been included in the instrument set for this purpose.
- Make provision in the nail length for countersinking the femoral nail to minimize impingement problems at the femur and / or to allow for reduction of the fracture, if fracture dynamization is required.
- Improper implant selection or technique may lead to inadequate fixation or soft tissue problems and may contribute to early implant failure.

Canal Preparation / Reaming

- Beginning with the 8.0mm end cutting reamer head and flexible reamer shaft, ream the intramedullary canal sequentially in half millimeter increments to a size 1-1.5mm larger than the desired nail diameter. Be certain to maintain the fracture in a reduced position throughout the reaming process to ensure final proper alignment of fracture fragments.

- Ensure guide wire position is maintained throughout the reaming process by inserting the **ATLAS° Obturator (I0537.00)** into the back of the reamer unit during retraction. Continue to confirm guide rod position throughout reaming. Periodically move the reamer back and forth in the canal to clear debris from the cutting flutes. If the guide wire is ever inadvertently withdrawn beyond the level of the fracture site during the reaming process, reinsert it to the appropriate depth by repeating the technique originally used to achieve its proper position in the centre of the distal femoral fragment at the level of the physeal scar. The **Tissue Protector (C2411.00)** may be used during flexible reaming to avoid soft tissue damage.

- Proximal diameter of the nail is 13mm therefore, post canal preparation, proximal femur should be over reamed with the help of flexible reamers up to 14mm diameter to accommodate proximal dia. of the nail during insertion.

Note:

- Flexible Reamers are not included in the ATLAS FFN instrument set.
- The Syncera ATLAS Flexible Reamer Set is compatible with the **Ball Tip Guide Wire (C1501.3010)**

Caution:

- The **Ball Tip Guide Wire (C1501.3010)** is compatible with FFN nails as a Nailing Wire and does not require Guide Wire Exchange.
- If any other Reaming System is used, the operating surgeon should verify compatibility for reaming and nailing steps as needed.
- Correct size selection and sharp cutting edges are important to ensure reaming without causing intramedullary canal damage through thermal necrosis.
- If a guide wire tip is bent intra-operatively to facilitate reduction, the extent of bending should be checked for easy passage through the exchange tube prior to using the bent tip wire for fracture reduction.
- Re-used Guide Wires that may be kinked/bent may cause significant problems during reaming. Re-use of Guide Wires is prohibited.
- Exercise caution while using flexible reamers. Accidentally hitting the “reverse” or anti-clockwise function of the Power System can cause the Flexible Shaft to uncoil in the medullary canal
- Last reamer used should be 1 - 1.5mm larger than nail size to be used .

Nail Assembly

- Connect the **ATLAS° Guide Bolt Wrench (I0562.00)** 1 to the **Quick Connect T-handle (I0560.00)** 2. Attach the **ATLAS FFN Drill Guide (I0574.00)** 3 to the nail with the locking bolt and tighten using the assembled guide bolt wrench.

- Ensure the correct anterior bow before connecting the nail to the drill guide. The orientation mark at the proximal end on the anterior aspect of the nail serves as a guide.

Verifying Target Accuracy

- Slide the **9.0mm ATLAS Outer Drill Sleeve (I0556.901)** 4 into any of 130 degree locking option through FFN drill guide. Verify targeting accuracy by passing the screw drill through the assembly. An incorrectly attached nail will not target.

Caution:

- Ensure that the Locking Bolt is securely tightened with the help of Guide Bolt Wrench to the Nail threads before impaction to prevent damage of Locking Bolt/Nail threads bending or breakage.
- Ensure that the Guide Wire is not kinked or bent prior to introducing the Nail into the canal.
- If excessive impaction is found to be needed, withdraw the Nail, ream the canal to the next larger size of reamer and attempt to introduce the nail again. Excessive impaction without adequate canal preparation may cause nail bending or breakage during insertion.

Nail Insertion

- Begin insertion with the drill guide handle in line with the anterior cortex of the femur. As the nail taper reaches the isthmus of the canal, rotate handle laterally to align with the lateral cortex.

Optional

- Attach the **ATLAS° Impactor-Long (I0563.00)** to the drill guide handle for impaction of the nail with the help of **Slotted Hammer (I0564.00)** into the femur.

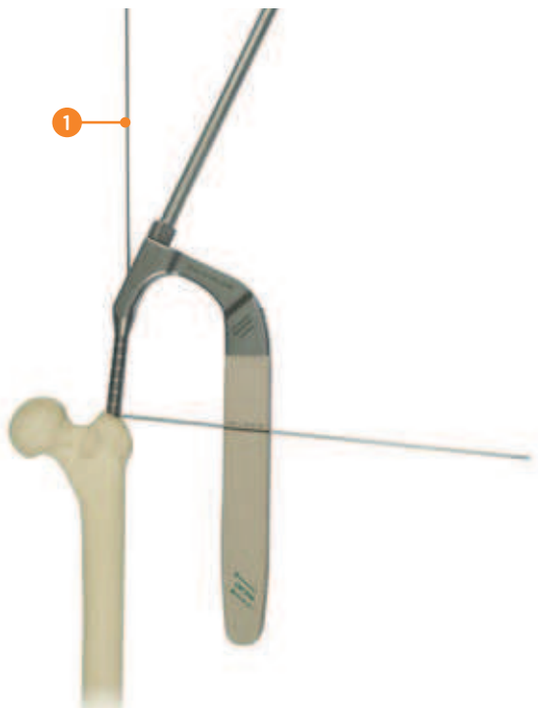
Caution:

- It is advised that nail should be inserted manually till it crosses the fracture and up to about 2 inches beyond fracture site. Flex the knee and abduct the limb to achieve correct position. This should be the preferred technique as it minimizes risk of iatrogenic fracture during nail insertion.
- In the instance of hard bone, initial passage of the nail may prove difficult. In this case, it may be necessary to remove the nail and ream the canal with the next size of reamer before attempting to re-insert the nail manually. The use of excessive/misdirected impaction force may lead to an iatrogenic fracture or cause instrument damage leading to surgical delays.
- Ensure that the Impactor threads are securely tightened to the Drill Guide to avoid thread damage.
- Insert the nail to the desired depth. Verify fracture reduction as the nail crosses the fracture site, paying close attention to rotation, length, alignment, distraction and shortening. After nail insertion, confirm that the nail and drill guide are securely connected as hammering can loosen the locking bolt.
- Impaction using Hammer after the nail has crossed the fracture site should be done with great care.
- For distal third fractures, the placement of nail is not very tight in the IM canal. It is advised to insert third locking screw distally in AP direction, third hole to be proximal to current locking holes.
- Direct hammering on the drill guide without attaching the impactor is prohibited.

Insertion Depth

Proximal insertion depth

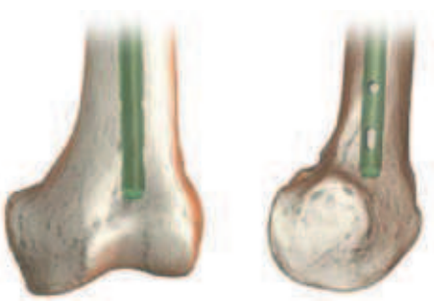
- To confirm nail proximal insertion depth, orient the C-Arm in the AP plane and pass a **3.2mm ATLAS° Guide Pin (I0547.32)** 1 through the FFN drill guide to check proximal end of the nail.



Confirm distal nail position

- Verify center-center placement of the nail in the distal femoral metaphysis in both the AP and lateral planes

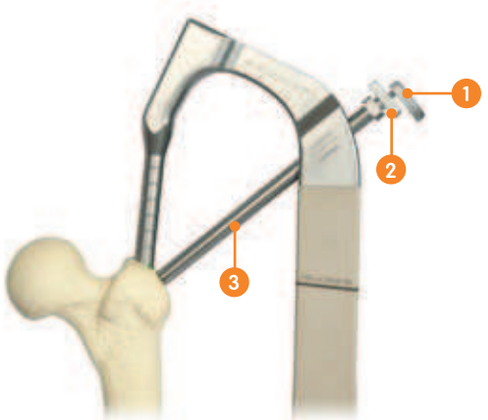
- Remove the Impactor from the **Drill Guide Handle** and the 2.8mm **Ball Tip Guide Wire** from the intramedullary canal if used



Caution: After definitively seating the nail, confirm that the Nail and Drill Guide are securely connected as impaction forces while inserting the nail may have loosened the Locking Bolt and may affect targeting accuracy.

Proximal Locking - Standard Femoral Locking

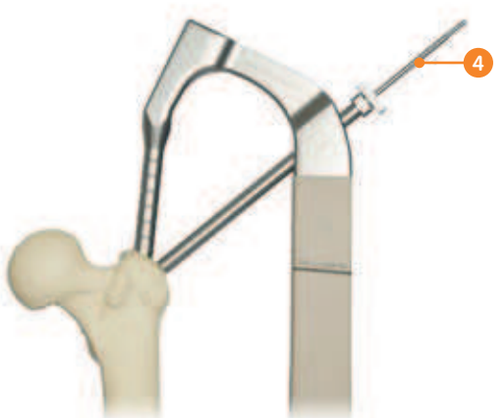
ATLAS® FFN provides an option of either Standard Femoral Locking with a single 5mm locking screw or Recon Locking with two 6.4mm recon screws.



Standard Femoral Locking

- Slide the **4.0mm Trocar (I0577.40)** 1 into the **4.0mm Trocar Sleeve (I0575.9040)** 2 and insert into **9.0mm Outer Drill Sleeve (I0556.901)** 3. This 9.0mm drill sleeve should pass through the standard Locking option on ATLAS FFN drill guide.

- Slight resistance may be encountered while inserting Drill Sleeves either into the Drill Guide or into smaller sized sleeves. This is normal as the sleeve is designed to be self-retaining in the Outer Sleeve. Rotating the Drill Sleeve back and forth will ease insertion.



- Make a small incision at the site of screw entry and insert the trocar/ sleeve assembly through the hole on the drill guide and down to the bone.

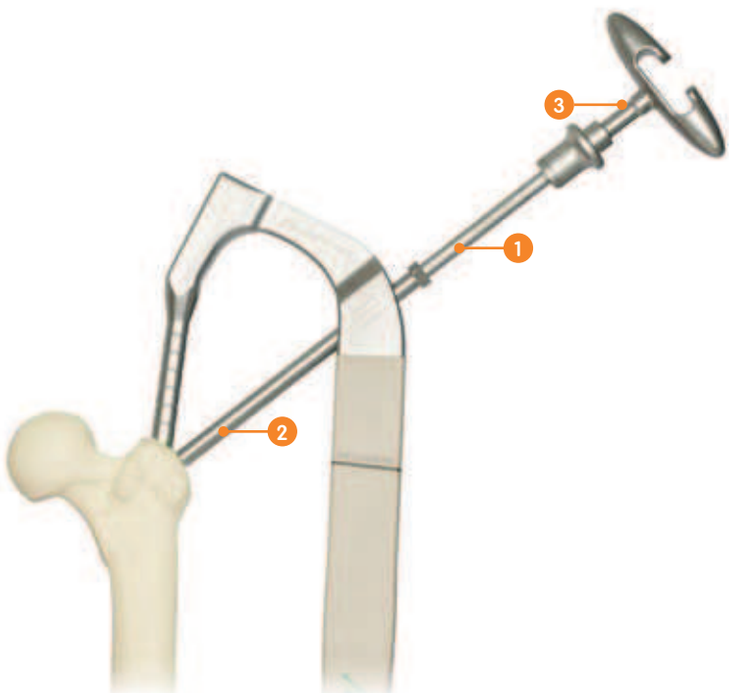
- Attach the **4.0mm Long Pilot Drill (I0572.4002)** 4 to power. Remove the 4.0mm Trocar from the drill sleeve assembly. Drill through both cortices.

- Measure for screw length using either the calibrations on the 4.0mm Long Pilot Drill or by removing the Drill Sleeve Trocar and using the **ATLAS Depth Gauge (I0506.06)** 5.

Caution:

- Ensure to withdraw the Guide Wire from the Nail before commencing proximal locking operations. Failure to do so will result in breakage of the drill bit, possible damage to the nail and instruments and significant surgical delay.
- The 4.0mm Trocar Sleeve must contact the lateral cortex to ensure accurate locking screw length measurement using either the 4mm calibrated drill bit or the Depth Gauge
- Ensure markings on Drill Bit/Depth Gauge are legible to prevent accidental selection of an incorrect screw length and thereby compromised fixation or surgical delay.

- Attach the appropriate length 5.0mm locking screw to the end of the **ATLAS° Hex Driver (I0555.48)** 1.
- Use power to insert the screw through the **9.0mm Drill Sleeve (I0556.901)** 2 until the laser-etched ring on the hexdriver reaches the back of the drill sleeve.
- Attach the **Quick Connect T-handle (I0560.00** 3 to the hexdriver and tighten the locking screw by hand.
- Post tightening the locking screw, **ATLAS Key for Retaining Rod (I0570.00)** should be used for releasing the screw from the driver.



Proximal Locking - Reconstruction Locking

Recon Locking

- After confirming nail insertion depth and femoral neck anteversion, make two small incisions at the site of screw entry through the 130 degree FFN screw options.

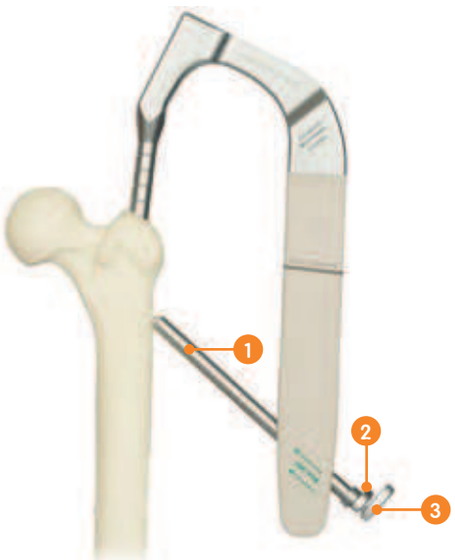
- Insert a **9.0mm Drill Sleeve (I0556.901)** 1, **4.0mm Trocar Drill Sleeve (I0575.9040)** 2, and **4.0mm Trocar (I0577.40)** 3 into the inferior most recon locking hole on the **ATLAS FFN Drill Guide** and down to the bone. Repeat the process for the superior locking hole.

- Remove the **4.0mm Trocar (I0577.40)** along with the **Trocar Sleeve (I0575.9040)** from inferior trocar assembly. Attach the **4.0mm Long Pilot Drill (I0572.4002)** 4 to power.

- Drill to the desired depth in the femoral neck and head.

- Measure for screw length using the calibrations on the 4.0mm Long Pilot Drill.

Caution: Due care needs to be exercised while drilling for the Recon screws to avoid perforating the femoral head.



- Remove the 4.0mm drill and Drill Sleeve from the 9.0mm Drill Sleeve. Attach the **ATLAS° Drill Bit 6.4mm (I0573.64)** 1 to power and drill to the depth measured for the 6.4mm recon locking screw.

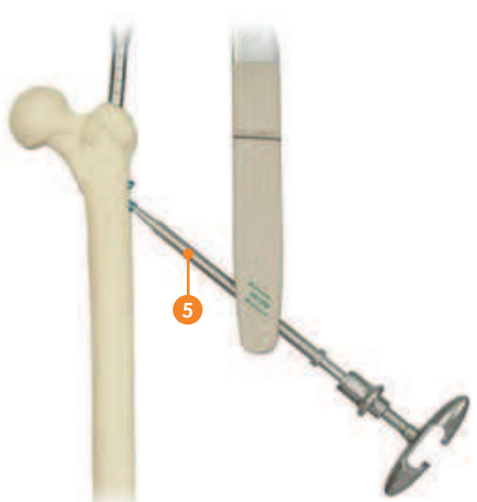
- Use the **ATLAS Tap 6.4mm (I0576.64)** before the final screw insertion (step is optional). The calibration on the drill will be flush with the back of the Drill Sleeve.

- Monitor all drilling under fluoroscopy in order to avoid perforating the femoral head. Attach the appropriate length 6.4mm recon locking screw to the **ATLAS Hex Driver (I0555.48)** 2 and **Quick Connect T-handle (I0560.00)** 3. Remove the inferior 6.4mm Step Drill.

- Insert the locking screw through the **9.0mm Drill Sleeve (I05w56.901)** 4. Do not tighten definitively.

- Repeat the process to insert the superior recon locking screw as mentioned above. Release any traction and tighten both locking screws definitively using the ATLAS Hex driver and quick connect T-handle.

- Post tightening the Recon screw, **ATLAS Key for Retaining Rod (I0570.00)** 5 should be used for releasing the screw from the driver.



Caution:

- Ensure guidewire is withdrawn before drilling for proximal locking. Otherwise drill bit could break.
- Due care needs to be exercised while drilling for the recon screws to avoid perforating the femoral head.

Distal Locking

- There are two distal locking options in ATLAS® FFN.
- The freehand technique is used. First, ensure that tibial rotation is satisfactory.
- Next, the image intensifier is used to obtain perfect circles radiographically on the distal tibial medial view or the anterior view. After perfect circles are confirmed, a stab incision is made over the holes and the **4.0mm Short Pilot Drill (I0572.4001)/ Long Pilot Drill (I0572.4002)** is inserted on power through both cortices.
- The **ATLAS Depth Gauge (I0506.06)** is used to determine screw length.
- The selected screw is attached to the **Short Hex Driver (I0555.481)/ATLAS Hex Driver, (I0555.48)** 1. Attach the Screwdriver to power or use the **Quick Connect T-handle (I0560.00)** 2 to place the screws in bone.
- It is recommended that final tightening of the screw should always be done manually using the Quick Connect T-Handle.
- Post tightening the locking screw, **ATLAS Key for Retaining Rod (I0570.00)** 3 should be used for releasing the screw from the driver.

Caution:

- Make sure that screw length is gauged correctly as it may result in soft tissue irritation.
- Do not use excessive force to insert a distal locking screw if resistance is encountered. Re-check the trajectory of the drilled hole and the position of the distal hole in the nail before proceeding.
- In the advent of an unexpected broken screw, removal is essential to avoid secondary fracture & allow easy nail removal.
- Care should be taken while selecting correct screw diameter and inserting the screw into the implanted nail as the use of an oversized screw or incorrectly targeted screw may result in damage to the nail and the assembly.
- If planning for nail dynamization, nail length selection should take into account the distal travel of the nail during dynamization.
- Nicking the nail hole with the drill bit during free hand drilling may weaken the nail and increase the risk of early implant failure.
- Optional: Include a 3mm Stienmann Pin (very sharp, long tip) to support distal locking.

Nail Cap Insertion

- A Nail Cap can be used to prevent bone ingrowth to enable easy nail removal and/or to extend nail length in cases of excessive countersinking.

- After final nail seating and completion of proximal and distal locking, detach the Drill Guide Assembly by unscrewing the **ATLAS° Guide Bolt (I0543.00)** with the help of **ATLAS Guide Bolt Wrench (I0562.00)**.

- Attach the selected Nail Cap to the **ATLAS Hexdriver (I0555.48)** 2, couple the assembly with the **Quick Connect T-handle (I0560.00)** 2 and thread the Nail Cap into the proximal end of the implanted Nail.

- 0mm, 5mm & 10mm nail end caps are available for appropriate selection based on requirement.

Caution:

- Ensure perfect engagement with Hex Driver shaft Hex and retaining rod threads.
- Avoid cross-threading the Nail Cap during insertion to avoid problems during removal.

Nail Extraction - Standard Technique

Standard Technique

- Remove the nail cap or nail cap set screw if implanted and all of the distal locking screws with the **ATLAS® Hexdriver (I0555.48)**/T-handle assembly. Remove all of the proximal locking screws except for one in the same manner.

- Thread the **ATLAS Impactor-Long (I0563.00)** into the back of the disposable **ATLAS Large Extractor (I0538.00)** 1 and then thread the assembly into the top of the nail. Remove the remaining proximal locking screw and then extract the nail with a back-slapping motion using the **ATLAS Slotted Hammer (I0564.00)**.

Caution:

- Nails implanted for a long duration may have damages, cracks or nicks due to fatigue or mis-targeting during implantation.
- Exercise care during the back-slapping operation with the slotted hammer to prevent nail or extractor breakage during extraction and consequent delay.

Nail Extraction - Percutaneous Technique

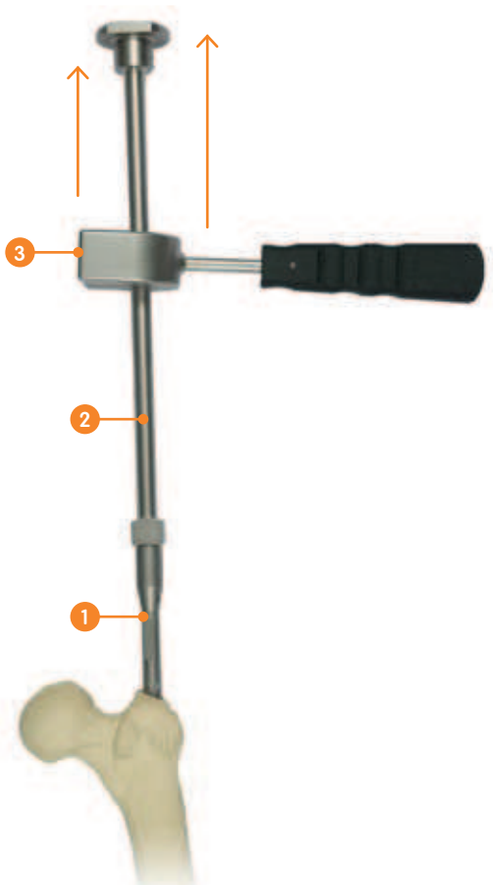
Percutaneous Technique

- After prepping and draping, remove any distal screws and all but one proximal screw from the nail, leaving the screw closest to the driving end of the nail. Under fluoroscopy, percutaneously place an ATLAS® Guide Pin 3.2 into the threaded end of the nail. If a cap is on the nail, an incision must be made and the cap removed. A mallet may be used to insert this guide pin, but usually power equipment can be used for percutaneous placement.

- When the guide pin is in the nail, make a one inch incision around the pin and advance the **Proximal Entry Reamer (I0569.01)** over the pin to remove the tissue and ingrowth overlying the nail. Note that the tip of the reamer is straight for approximately 1/2 an inch before flaring out. It is this portion of the reamer that enters the nail. After reaming, remove the Reamer and the Guide Pin.

- Thread the **ATLAS Large Extractor (I0538.00)** 1 to the proximal threads of the nail. Use the Hex Driver (I0555.48) shaft as a tommy bar to securely tighten the Large Extractor onto the Nail threads.

- Thread the **ATLAS Impactor Long (I0563.00)** 2 onto the threads of the Large Extractor to form the complete assembly to extract the nail. Once this is done, remove the last locking screw. Support the lower part of the assembly while back-slapping the Long Impactor using the ATLAS Slotted Hammer 3 to extract the nail from bone.



Note:

- Use extreme caution not to exert any side loads on the impactor-extractor assembly.
- Excessive pulling and pushing on the end of the impactor handle could result in pre-mature failure of the extraction device.
- Recommended usage for extractor: 7-10 times.

ATLAS◇ FFN

Catalog Information

ATLAS FFN Implants Catalog
ATLAS FFN Screws Catalog
ATLAS FFN Instrumentation Catalog

ATLAS® FFN Implants Catalog

ATLAS FFN 9mm diameter Nails – Left

I0142.0930	ATLAS FFN Left 9mm X 30cm
I0142.0932	ATLAS FFN Left 9mm X 32cm
I0142.0934	ATLAS FFN Left 9mm X 34cm
I0142.0936	ATLAS FFN Left 9mm X 36cm
I0142.0938	ATLAS FFN Left 9mm X 38cm
I0142.0940	ATLAS FFN Left 9mm X 40cm
I0142.0942	ATLAS FFN Left 9mm X 42cm
I0142.0944	ATLAS FFN Left 9mm X 44cm
I0142.0946	ATLAS FFN Left 9mm X 46cm
I0142.0948	ATLAS FFN Left 9mm X 48cm
I0142.0950	ATLAS FFN Left 9mm X 50cm

ATLAS FFN 9mm diameter Nails – Right

I0143.0930	ATLAS FFN Right 9mm X 30cm
I0143.0932	ATLAS FFN Right 9mm X 32cm
I0143.0934	ATLAS FFN Right 9mm X 34cm
I0143.0936	ATLAS FFN Right 9mm X 36cm
I0143.0938	ATLAS FFN Right 9mm X 38cm
I0143.0940	ATLAS FFN Right 9mm X 40cm
I0143.0942	ATLAS FFN Right 9mm X 42cm
I0143.0944	ATLAS FFN Right 9mm X 44cm
I0143.0946	ATLAS FFN Right 9mm X 46cm
I0143.0948	ATLAS FFN Right 9mm X 48cm
I0143.0950	ATLAS FFN Right 9mm X 50cm

ATLAS FFN 10mm diameter Nails – Left

I0142.1030	ATLAS FFN Left 10mm X 30cm
I0142.1032	ATLAS FFN Left 10mm X 32cm
I0142.1034	ATLAS FFN Left 10mm X 34cm
I0142.1036	ATLAS FFN Left 10mm X 36cm
I0142.1038	ATLAS FFN Left 10mm X 38cm
I0142.1040	ATLAS FFN Left 10mm X 40cm
I0142.1042	ATLAS FFN Left 10mm X 42cm
I0142.1044	ATLAS FFN Left 10mm X 44cm
I0142.1046	ATLAS FFN Left 10mm X 46cm
I0142.1048	ATLAS FFN Left 10mm X 48cm
I0142.1050	ATLAS FFN Left 10mm X 50cm

ATLAS FFN 10mm diameter Nails – Right

I0143.1030	ATLAS FFN Right 10mm X 30cm
I0143.1032	ATLAS FFN Right 10mm X 32cm
I0143.1034	ATLAS FFN Right 10mm X 34cm
I0143.1036	ATLAS FFN Right 10mm X 36cm
I0143.1038	ATLAS FFN Right 10mm X 38cm
I0143.1040	ATLAS FFN Right 10mm X 40cm
I0143.1042	ATLAS FFN Right 10mm X 42cm
I0143.1044	ATLAS FFN Right 10mm X 44cm
I0143.1046	ATLAS FFN Right 10mm X 46cm
I0143.1048	ATLAS FFN Right 10mm X 48cm
I0143.1050	ATLAS FFN Right 10mm X 50cm

ATLAS FFN 11.5mm diameter Nails – Left

I0142.1130	ATLAS FFN Left 11.5mm X 30cm
I0142.1132	ATLAS FFN Left 11.5mm X 32cm
I0142.1134	ATLAS FFN Left 11.5mm X 34cm
I0142.1136	ATLAS FFN Left 11.5mm X 36cm
I0142.1138	ATLAS FFN Left 11.5mm X 38cm
I0142.1140	ATLAS FFN Left 11.5mm X 40cm
I0142.1142	ATLAS FFN Left 11.5mm X 42cm
I0142.1144	ATLAS FFN Left 11.5mm X 44cm
I0142.1146	ATLAS FFN Left 11.5mm X 46cm
I0142.1148	ATLAS FFN Left 11.5mm X 48cm
I0142.1150	ATLAS FFN Left 11.5mm X 50cm

ATLAS FFN 11.5mm diameter Nails – Right

I0143.1130	ATLAS FFN Right 11.5mm X 30cm
I0143.1132	ATLAS FFN Right 11.5mm X 32cm
I0143.1134	ATLAS FFN Right 11.5mm X 34cm
I0143.1136	ATLAS FFN Right 11.5mm X 36cm
I0143.1138	ATLAS FFN Right 11.5mm X 38cm
I0143.1140	ATLAS FFN Right 11.5mm X 40cm
I0143.1142	ATLAS FFN Right 11.5mm X 42cm
I0143.1144	ATLAS FFN Right 11.5mm X 44cm
I0143.1146	ATLAS FFN Right 11.5mm X 46cm
I0143.1148	ATLAS FFN Right 11.5mm X 48cm
I0143.1150	ATLAS FFN Right 11.5mm X 50cm

ATLAS◇ FFN Implants Catalog

ATLAS FFN 13mm diameter Nails – Left

I0142.1330	ATLAS FFN Left 13mm X 30cm
I0142.1332	ATLAS FFN Left 13mm X 32cm
I0142.1334	ATLAS FFN Left 13mm X 34cm
I0142.1336	ATLAS FFN Left 13mm X 36cm
I0142.1338	ATLAS FFN Left 13mm X 38cm
I0142.1340	ATLAS FFN Left 13mm X 40cm
I0142.1342	ATLAS FFN Left 13mm X 42cm
I0142.1344	ATLAS FFN Left 13mm X 44cm
I0142.1346	ATLAS FFN Left 13mm X 46cm
I0142.1348	ATLAS FFN Left 13mm X 48cm
I0142.1350	ATLAS FFN Left 13mm X 50cm

ATLAS FFN 13mm diameter Nails – Right

I0143.1330	ATLAS FFN Right 13mm X 30cm
I0143.1332	ATLAS FFN Right 13mm X 32cm
I0143.1334	ATLAS FFN Right 13mm X 34cm
I0143.1336	ATLAS FFN Right 13mm X 36cm
I0143.1338	ATLAS FFN Right 13mm X 38cm
I0143.1340	ATLAS FFN Right 13mm X 40cm
I0143.1342	ATLAS FFN Right 13mm X 42cm
I0143.1344	ATLAS FFN Right 13mm X 44cm
I0143.1346	ATLAS FFN Right 13mm X 46cm
I0143.1348	ATLAS FFN Right 13mm X 48cm
I0143.1350	ATLAS FFN Right 13mm X 50cm

ATLAS◇ FFN Screws Catalog

ATLAS Titanium Locking Screw 5.0mm

I0211.5020	ATLAS Titanium Locking Screw 5.0mm X 20mm
I0211.5023	ATLAS Titanium Locking Screw 5.0mm X 22.5mm
I0211.5025	ATLAS Titanium Locking Screw 5.0mm X 25mm
I0211.5027	ATLAS Titanium Locking Screw 5.0mm X 27.5mm
I0211.5030	ATLAS Titanium Locking Screw 5.0mm X 30mm
I0211.5033	ATLAS Titanium Locking Screw 5.0mm X 32.5mm
I0211.5035	ATLAS Titanium Locking Screw 5.0mm X 35mm
I0211.5038	ATLAS Titanium Locking Screw 5.0mm X 37.5mm
I0211.5040	ATLAS Titanium Locking Screw 5.0mm X 40mm
I0211.5043	ATLAS Titanium Locking Screw 5.0mm X 42.5mm
I0211.5045	ATLAS Titanium Locking Screw 5.0mm X 45mm
I0211.5048	ATLAS Titanium Locking Screw 5.0mm X 47.5mm
I0211.5050	ATLAS Titanium Locking Screw 5.0mm X 50mm
I0211.5053	ATLAS Titanium Locking Screw 5.0mm X 52.5mm
I0211.5055	ATLAS Titanium Locking Screw 5.0mm X 55mm
I0211.5058	ATLAS Titanium Locking Screw 5.0mm X 57.5mm
I0211.5060	ATLAS Titanium Locking Screw 5.0mm X 60mm
I0211.5063	ATLAS Titanium Locking Screw 5.0mm X 62.5mm
I0211.5065	ATLAS Titanium Locking Screw 5.0mm X 65mm
I0211.5068	ATLAS Titanium Locking Screw 5.0mm X 67.5mm
I0211.5070	ATLAS Titanium Locking Screw 5.0mm X 70mm
I0211.5073	ATLAS Titanium Locking Screw 5.0mm X 72.5mm
I0211.5075	ATLAS Titanium Locking Screw 5.0mm X 75mm
I0211.5078	ATLAS Titanium Locking Screw 5.0mm X 77.5mm
I0211.5080	ATLAS Titanium Locking Screw 5.0mm X 80mm
I0211.5085	ATLAS Titanium Locking Screw 5.0mm X 85mm
I0211.5090	ATLAS Titanium Locking Screw 5.0mm X 90mm
I0211.5095	ATLAS Titanium Locking Screw 5.0mm X 95mm
I0211.5100	ATLAS Titanium Locking Screw 5.0mm X 100mm
I0211.5105	ATLAS Titanium Locking Screw 5.0mm X 105mm
I0211.5110	ATLAS Titanium Locking Screw 5.0mm X 110mm

ATLAS Titanium Locking Screw 4.5mm

I0210.4525	ATLAS Titanium Locking Screw 4.5mm X 25mm
I0210.4528	ATLAS Titanium Locking Screw 4.5mm X 27.5mm
I0210.4530	ATLAS Titanium Locking Screw 4.5mm X 30mm
I0210.4533	ATLAS Titanium Locking Screw 4.5mm X 32.5mm
I0210.4535	ATLAS Titanium Locking Screw 4.5mm X 35mm
I0210.4538	ATLAS Titanium Locking Screw 4.5mm X 37.5mm
I0210.4540	ATLAS Titanium Locking Screw 4.5mm X 40mm
I0210.4543	ATLAS Titanium Locking Screw 4.5mm X 42.5mm
I0210.4545	ATLAS Titanium Locking Screw 4.5mm X 45mm
I0210.4548	ATLAS Titanium Locking Screw 4.5mm X 47.5mm
I0210.4550	ATLAS Titanium Locking Screw 4.5mm X 50mm
I0210.4553	ATLAS Titanium Locking Screw 4.5mm X 52.5mm
I0210.4555	ATLAS Titanium Locking Screw 4.5mm X 55mm
I0210.4558	ATLAS Titanium Locking Screw 4.5mm X 57.5mm
I0210.4560	ATLAS Titanium Locking Screw 4.5mm X 60mm
I0210.4563	ATLAS Titanium Locking Screw 4.5mm X 62.5mm
I0210.4565	ATLAS Titanium Locking Screw 4.5mm X 65mm

ATLAS FFN Nail Caps

I0303.00	ATLAS TFN Nail Cap, 0mm
I0303.05	ATLAS TFN Nail Cap, 5mm
I0303.10	ATLAS TFN Nail Cap, 10mm

ATLAS FFN Screw 6.4mm

I0211.6465	ATLAS FFN, 6.4mm x 65mm
I0211.6470	ATLAS FFN, 6.4mm x 70mm
I0211.6475	ATLAS FFN, 6.4mm x 75mm
I0211.6480	ATLAS FFN, 6.4mm x 80mm
I0211.6485	ATLAS FFN, 6.4mm x 85mm
I0211.6490	ATLAS FFN, 6.4mm x 90mm
I0211.6495	ATLAS FFN, 6.4mm x 95mm
I0211.6500	ATLAS FFN, 6.4mm x 100mm
I0211.6505	ATLAS FFN, 6.4mm x 105mm
I0211.6510	ATLAS FFN, 6.4mm x 110mm
I0211.6515	ATLAS FFN, 6.4mm x 115mm
I0211.6520	ATLAS FFN, 6.4mm x 120mm
I0211.6525	ATLAS FFN, 6.4mm x 125mm

ATLAS◇ FFN Instrumentation Catalog

Cat. No.	ATLAS FFN Part Name (Catalog)
I0555.48	ATLAS Hex Driver, 4.75 A/F
I0505.1532	Entry Drill Sleeve 15.5/3.2
I0505.2015	Entry Protection Sleeve 20/15.5
I0547.32	ATLAS Guide Pin 3.2
I0569.02	14mm Cannulated Proximal Entry Reamer
C2411.00	Tissue Protector, Adler
I0543.00	ATLAS HFN Locking Bolt
I0562.00	ATLAS HFN Guide Bolt Wrench
I0556.901	Outer Drill Sleeve, 9mm
I0506.06	ATLAS Depth Gauge
I0566.00	ATLAS HFN Curved Cannulated Awl
I0560.00	Quick Connect T-Handle
I0561.00	ATLAS Reducer
I0537.00	ATLAS Obturator
I0567.00	ATLAS Length Gauge
C1501.3010	ATLAS Ball Tip Guide Wire 2.8 x 1000
I0525.00	Exchange Tube
I0538.00	ATLAS Large Extractor
I0563.00	ATLAS Impactor-Long
I0564.00	ATLAS Slotted Hammer
I0565.00	ATLAS HFN Keyless Chuck
I0570.00	ATLAS Key for Retaining Rod
I0572.4002	4.0mm Long Pilot Drill
I0572.4001	4.0mm Short Pilot Drill
I0573.64	ATLAS Drill Bit 6.4mm
I0574.00	ATLAS FFN Drill Guide
I0575.9040	ATLAS Trocar Sleeve, 4mm
I0576.64	ATLAS Tap 6.4mm
I0577.40	ATLAS Trocar 4mm
I0555.481	ATLAS Short Hex Driver, 4.75 A/F
D0207.05	Screw Holding Forceps

ATLAS FFN Instrument Set	
D0101.2604	ATLAS FFN Instrument Case
D0102.3001	ATLAS FFN Instrument Tray
D0101.2605	ATLAS FFN Implant case
D0102.3002	ATLAS FFN Implant Case Middle Tray
D0102.3003	ATLAS FFN Implant Case Upper Tray
D0102.3004	ATLAS FFN, Screw Caddy

Instructions for use for ATLAS◇ FFN Femoral Fracture Nail

For use by an Accredited Orthopaedic Surgeon only

Device Description:
The ATLAS FFN (Femoral Fracture Nail) system is designed to handle femoral fracture indications in diameters of 9mm, 10mm, 11.5mm, and 13mm in length range from 30cm to 50cm. It consists of femoral nails in the preceding length and diameter sizes, Reconstruction screws, locking screws for femoral & distal locking, and nails caps to accommodate the prescribed fixation technique. The system includes instrumentation trays, which house the instrument set that, are needed for installation and removal of the implantable assembly. Implants are provided non-sterile, to be sterilized before use by suitable process as recommended in the "Section – Sterilization Instructions" of this document. Implant trays are provided for ease of handling & sterilization of implants. The ATLAS FF Nails, Screws and Caps are made from titanium - vanadium alloy Ti6Al4V material complying to ISO 5832 - 3.

Summary:
Operating surgeons should be aware of the following aspects related to the use of metallic implants.

1. Proper size, length, side and type selection, as well as proper handling and use of the intramedullary nails is essential for safe and effective fracture treatment. See NOTES, INDICATIONS, CONTRAINDICATIONS, and PREOPERATIVE PLANNING below.
2. FFN system is NOT a substitute for skeletal healing, and proper operative technique and follow-up care is essential to enable desired outcomes See WARNINGS, POSTOPERATIVE CARE and POSSIBLE ADVERSE EFFECTS below.
3. Metallic surgical implants are NEVER TO BE REUSED (single use).

Notes:
Healing of fractures treated with metallic surgical implants must be confirmed prior to permitting weight bearing on the bones. Weight bearing on bones that have failed to heal or healed partially or improperly can cause stress and fatigue in metallic surgical implants with consequent breakage or failure of the implants. Surgeons should consider this and inform patients of pertinent information relevant to the patients' health and safety. The general principles of patient selection and sound surgical judgment apply to the intramedullary nailing procedure. The size and shape of the long bones present limiting restrictions on the size and strength of implants.

Indications:
The ATLAS◇ Femoral Fracture Nail system is indicated for fractures of the femur including intertrochanteric, basi/trans-cervical femoral neck fractures and subtrochanteric fractures, ipsilateral femoral neck/shaft fractures, stable and unstable shaft fractures, segmental fractures, Comminuted shaft fractures, Spiral shaft fracture, Long oblique shaft fractures nonunions and malunions, polytrauma, reconstructions following tumor resection and bone lengthening and shortening.

Contraindications:

1. ATLAS◇ Femoral Fracture Nail system should not be used in crossing open epiphyseal plates.
2. Insufficient quantity or quality of bone obliterated medullary canal or conditions which tend to retard healing, blood supply limitations, previous infections etc.
3. Active infection.
4. Any hardware that would preclude use of nails.
5. Congenital or acquired bony deformity.
6. Hypovolemia, hypothermia and coagulopathy.
7. Mental conditions that preclude cooperation with the rehabilitation regimen.

Preoperative Planning:

1. Surgical Technique: 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.
2. Implant Selection: The surgeon must exercise appropriate caution and judgement in the selection and use of these devices. Selection of the proper size, shape and design of the complete set of Implants and Instruments is a crucial parameter for success of the operative procedure which should be ensured by the operating surgeon. All Implants, Instruments and its sub-assemblies should be checked for intact packaging on receipt. All implants and instruments must be carefully checked for completeness and should be carefully inspected for compatible dimensions.
3. 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 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.
4. 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 manufacturer's instructions. In no case should an implant be sharply or reverse bent, notched, gouged, reamed, scratched or cut.
5. Component Compatibility: Components such as nails, screws are available in many styles and sizes and are manufactured from various types of metals. 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.
6. Implant Removal: The patient should be advised that a second procedure for the removal of implants may be necessary.

Warnings:

1. The correct selection of device components is extremely important. The appropriate size should be selected for the patient. Failure to use the largest possible components, improper positioning or the use of excessive forces during implantation may result in loosening, bending, cracking, or fracture of the device or bone or both.
2. Because of unbalanced muscle forces, sub-trochanteric fractures and osteotomies place extreme loads on implants, substantially reducing the chance of fracture healing with bending or breaking implant components. Additional precautions and internal or external supports should be utilized to enhance the stability of the fracture and to minimize internal stress loading of the implant and broken bone until solid bony union is evident by radiograph. Supplementary procedures such as bone graft or medial displacement osteotomy may also be considered.
3. The length of time for none or limited weight bearing should be correspondingly increased until solid bony union occurs.
4. The threads of an implanted screw should not engage the fracture line. The screw threads should be firmly fixed in bone and the screw should be long enough to permit telescopic sliding in the event of resorption of the fracture surface.
5. Do not mix dissimilar metals. Use only FFN screws and caps with FFN Nails.

Postoperative Care:

1. 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 of 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 delay or non-union, should have auxiliary support. PATIENTS AND NURSING CARE PROVIDERS SHOULD BE ADVISED OF THESE RISKS.
2. Care Subsequent to Bony Union: Even after bony union, the patient should be cautioned that a fracture is more likely with the implant in place and soon after its removal, rather than later, when voids in the bone left by implant removal have been filled in completely. Patients should be cautioned against unassisted activity that requires walking or lifting. Postoperative care and physical therapy should be exercised to prevent loading of the operative extremity until stability is evident. Additional postoperative precautions should be taken when the fracture line occurs within 5 cm of any locking holes provided in the nail. This would typically include distal most proximal locking hole and the proximal most distal locking hole. Greater stress is placed on the nail at these hole locations in these situations.
3. Patients should be directed to seek medical opinion before entering potentially adverse environments that could affect the performance of the implant, such as electromagnetic or magnetic fields, including a magnetic resonance environment.
4. Implant Removal: The operating surgeon will make final recommendations regarding removal of implants, considering all facts and circumstances. Adler suggests that whenever possible, and after bony union is observed that implants be removed. Removal is particularly advisable for younger and more active patients. In the absence of a bursa or pain, removal of the implant in elderly or debilitated patients is not recommended. If the implant components are not removed subsequent to completion of their intended use, the following complications may ensue.
   - Corrosion combined with localized pain or tissue reaction.
   - Migration of position of the implant, resulting in injury.
   - Bending, loosening or breakage of implant components, which may make removal more difficult or even impractical.
   - Possibly increased risk of infection.
   - Bone loss due to stress shielding.
   - Pain, discomfort or abnormal sensations felt by the patient due to the presence of the device.

Magnetic Resonance Imaging (MRI) Safety:
ATLAS◇ Femoral Fracture Nail System has not been evaluated for safety and compatibility in the MR environment. This System has not been tested for heating or migration in the MR environment.

No Reuse:
Metallic surgical implants are NEVER TO BE REUSED. Stresses and fractures, even though not noticeable by visual inspection, may have been created during implantation. Single use devices should not be reused due to risks of breakage, failure or patient infection.

Possible Adverse Effects:

1. Loosening, bending, cracking or fracture of the implant components.
2. Infections, both deep and superficial.
3. Limb shortening or loss of anatomic position with nonunion or malunion with rotation or angulation.
4. Penetration of a guide screw into the pelvis can occur.
5. Leg length discrepancies and subsequent patient limp may occur.
6. Tissue reactions which include macrophage and foreign body reactions adjacent to implants can occur.
7. Vascular disorders including thrombophlebitis, pulmonary emboli, wound hematomas, and avascular necrosis of the femoral head may result from the surgery and concomitant use of internal fixation devices.
8. Although rare, metal sensitivity reactions and/or allergic reactions to foreign materials have been reported in patients.
9. Implant Migration.

Packaging and Labeling:
Components should only be accepted if received by the hospital or surgeon with the factory packaging and labeling intact. Implant components supplied in non-sterile condition are packed in unwoven polyethylene and are indicated as 

on the label, which must be properly sterilized by suitable method prior to surgery as indicated in the instructions below
The set of instruments used for the surgery must be carefully checked for completeness and individual instruments must be inspected for functionality and absence of damage prior to surgery.

Sterilization Instructions:
Remove all original packaging and labeling inserts prior to sterilization. It is important that adequate cleaning be carried out prior to sterilization.
DO NOT REUSE implant components or single use disposable instruments.

Recommended steam sterilization cycle parameters-

- Dynamic Air Removal (Prevacuum) Steam Cycle: 132°C (270°F) for 4 minutes or 135°C (275°F) for 3 minutes and a minimum vacuum drying time of 30 minutes.
- Gravity Displacement Steam Cycle: 132°C (270°F) for 30 minutes and a minimum vacuum drying time of 30 minutes.
- Flash Steam Cycle (Reusable instruments only): Exposure temperature: 132°C (270°F) for 10 minutes in a Gravity Displacement Cycle or 4 minutes in a Dynamic Air Removal (Prevacuum) Cycle.
- United Kingdom Steam Cycle: 134°C for 3 minutes and a minimum vacuum drying time of 30 minutes.(Note: Sterilization evacuation and pulsing should be carried out in accordance with HTM 2010.)

Containment devices should be wrapped with an approved central supply wrap (CSR) or placed in an approved reusable rigid container for sterilization. All sterilization wraps may not be approved for all cycle types. Check with manufacturer for approvals.

Cleaning:
Use deionized, or distilled, warm (room temperature) water for soaking, cleaning and rinsing. Scrub with a soft bristle brush paying close attention to threads and hard to reach areas. If product is cannulated, insert a soft nylon brush into cannula. Rinse all components immediately and thoroughly after washing. Immediately dry product. Inspect all products prior to sterilization and storage.

Storage Conditions:
Store in dry place. Protect devices from exposure to direct sunlight, radioactive sources and rains.

Retrieval and Analysis of Removed Implants:
The most important part of surgical implant retrieval is preventing damage that would render scientific examination useless. Special care should be given to protect the implant from damage during handling and shipment. Follow internal hospital procedures for the retrieval and analysis of implants removed during surgery. When handling removed implants, use precautions to prevent spread of blood borne pathogens.

Symbols Used in IFUs, Labels and Packaging Materials:

Symbol	Definition	Symbol	Definition	Symbol	Definition
	Single use (Do not re-use)		Batch Number		CE Logo conformity to MDD 93/42/EEC
	Date of Manufacture YYYY-MM-DD		Manufactured by		Use by Date (Date of Expiry) YYYY-MM-DD
	European Authorised Representative		Do not re-sterilize		Do not use if package is opened or damaged
	Caution: check for specific warnings or precautions		Consult instructions for use		Non Sterile
	Keep away from heat /sunlight and radioactive sources	REF:	Code Number / Part No.		Avoid moisture or water contact
	Recycle		To be sold only against prescription		

Further information:
For further information concerning use of these devices, please check with Adler Customer Service at the address given herein or e-mail to info@adler-healthcare.com

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