Surgical Technique

Syncera®
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ATLAS◇ HFN

Hip Fracture Nail

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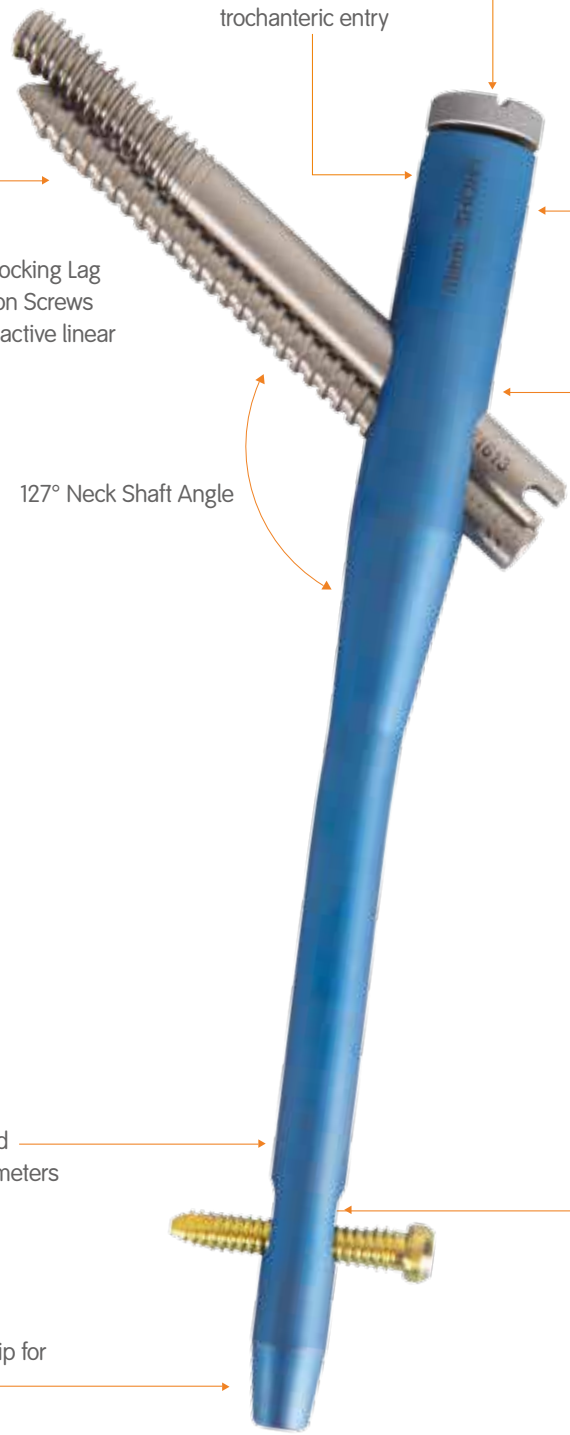
Nota Bene
The technique description herein is made available to the healthcare professional to illustrate the author's suggested treatment for the uncomplicated procedure. In the final analysis, the preferred treatment is that which addresses the needs of the specific patient.

Design Features



5° lateral offset for minimally invasive trochanteric entry

Set screw allows for creation of a fixed angle device or facilitates postoperative sliding

Integrated Interlocking Lag and Compression Screws for stability and active linear compression

Small proximal diameter 15.24mm preserves the gluteus medius tendon and the lateral wall of the greater trochanter

127° Neck Shaft Angle

12° of built-in femoral neck anteversion (long nail) for optimal screw position in the femoral neck and head

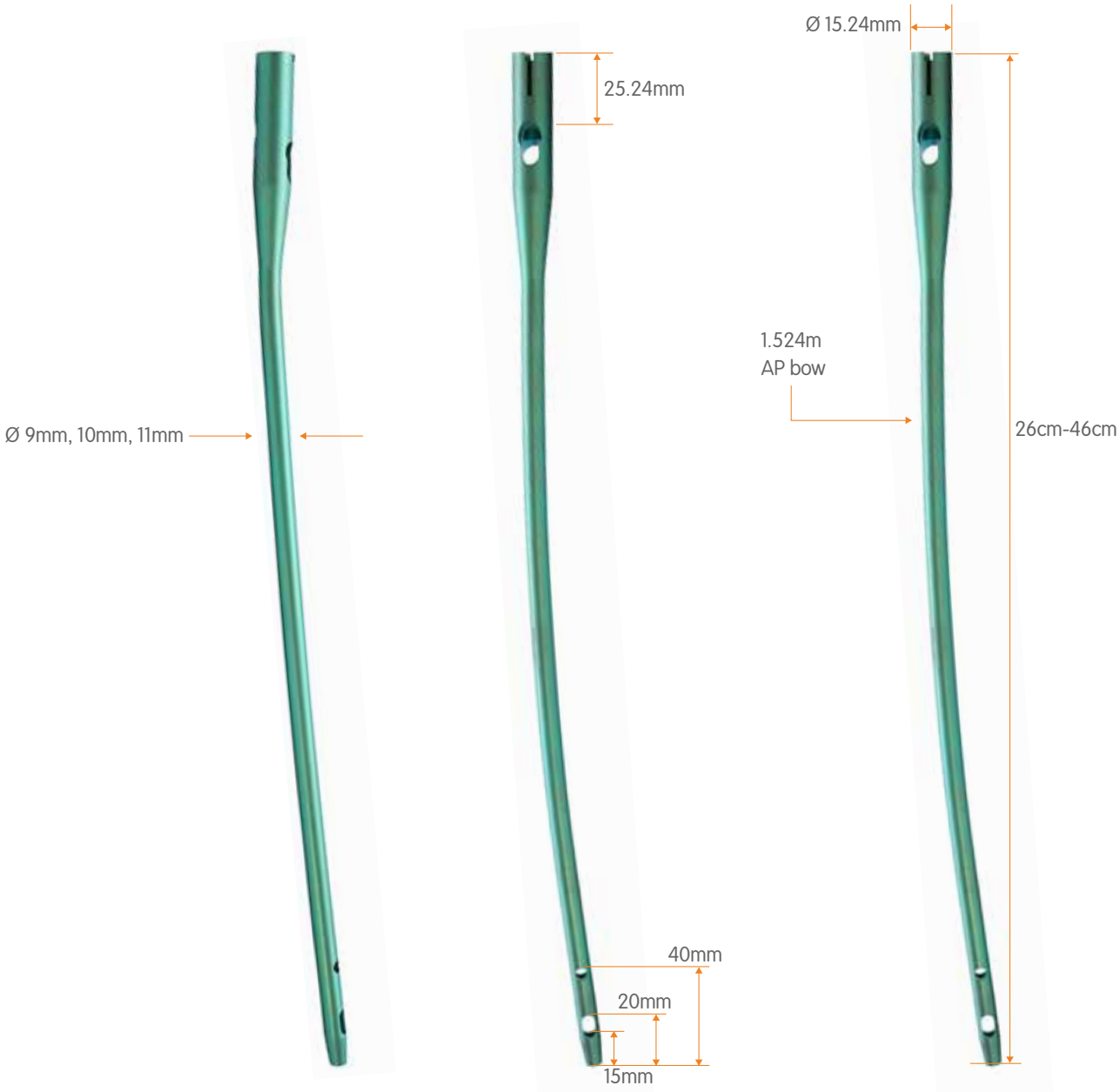
9mm, 10mm and 11mm distal diameters

Distal locking slot allows static or dynamic locking using standard 4.5mm diameter or 5.0mm diameter Internal Hex Captured Locking Screws

Bevelled distal tip for ease of entry

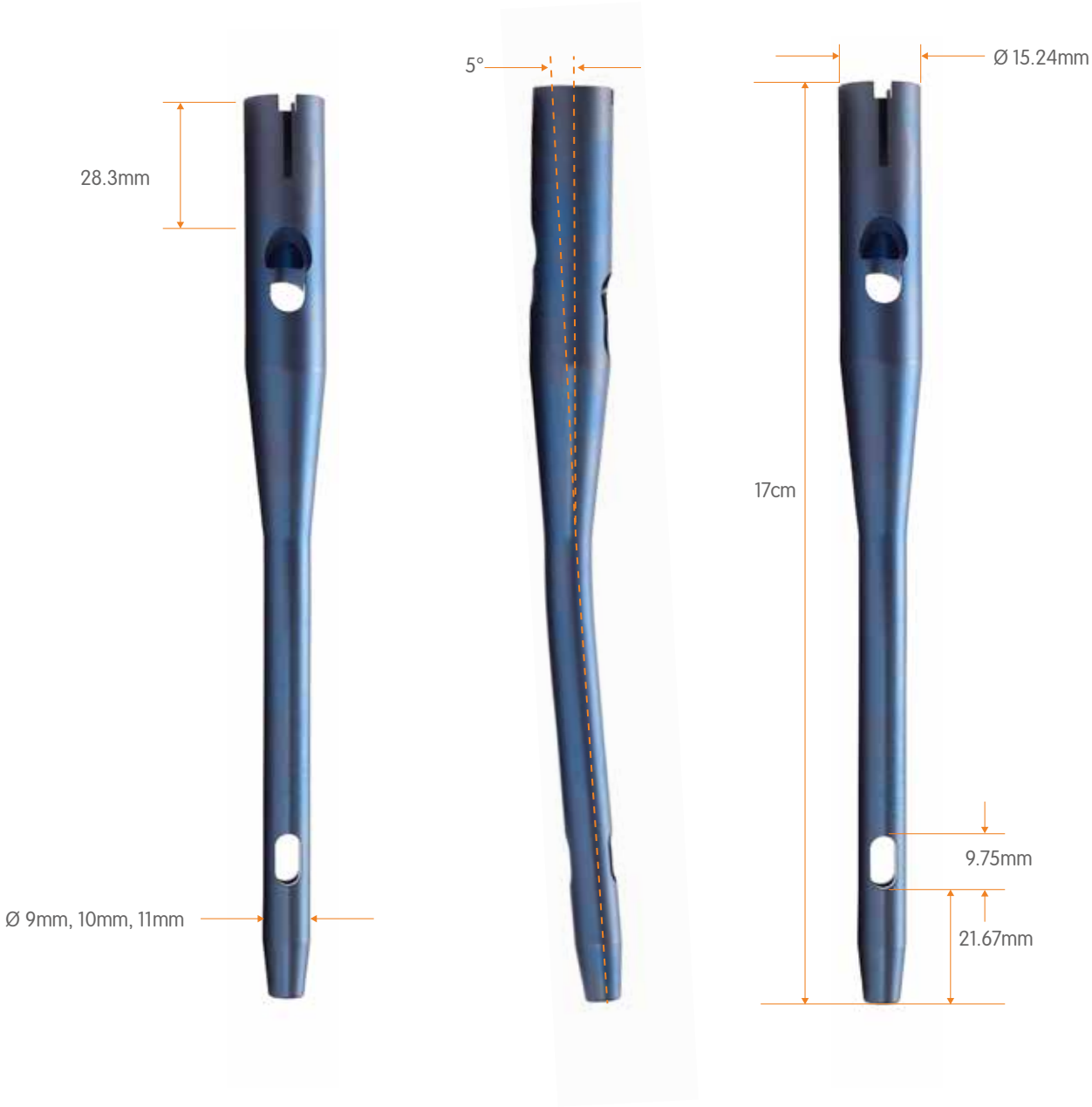
Implant Specifications

ATLAS° HFN (Long Nails)



Note *These views are not to scale and should be used as a pictorial representation only.*

ATLAS° HFN (Short Nails)



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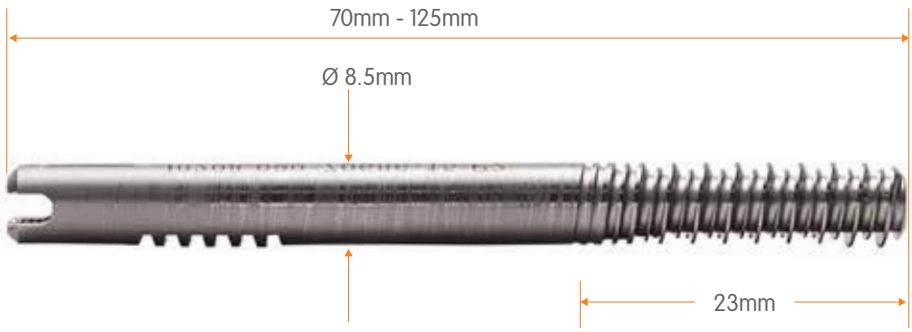
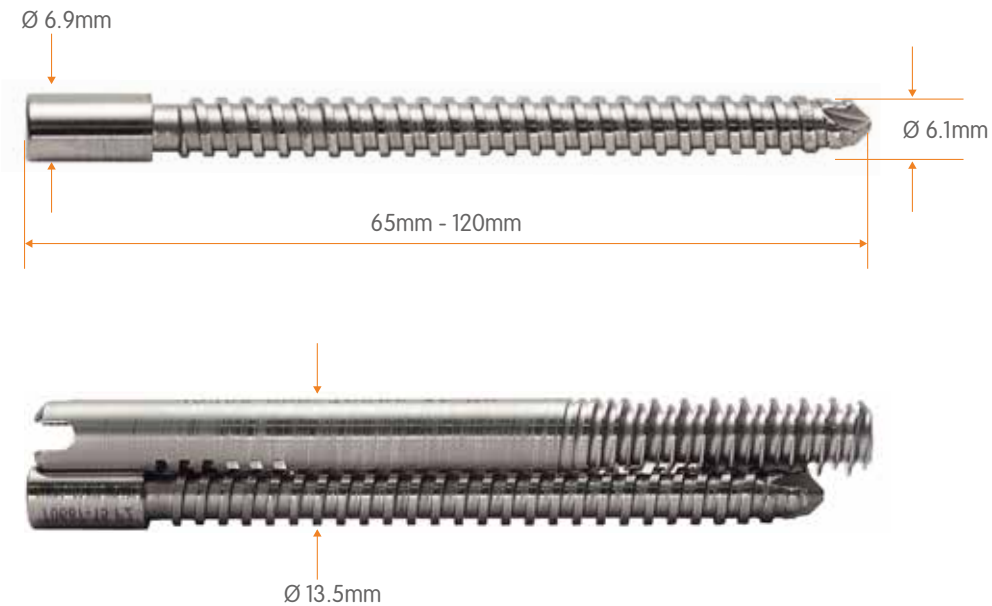
ATLAS◇ HFN

Lag Screws



Minor diameter tapers from Ø 8.5mm - 5.5mm

Compression Screws



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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 information 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.

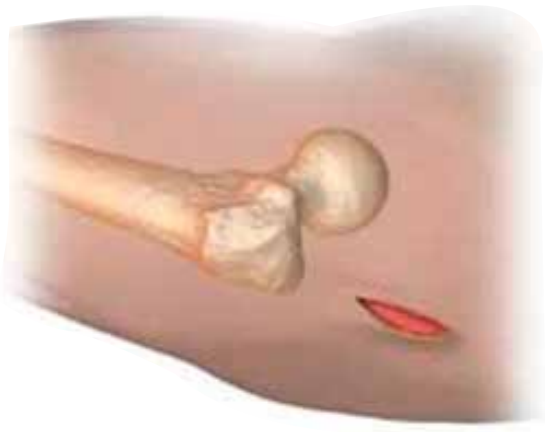
The torso may be abducted 10°–15° to allow for clear access to the intramedullary canal. Check the affected limb for length and rotation by comparison to the unaffected limb. Rotate the C-Arm to ensure optimal AP and lateral visualization of the proximal femur.

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.*

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 intramedullary canal in the lateral plane.

Entry Portal Acquisition

Insert the entry portal instrument through the incision down to bone. Attach a 3.2mm x 343mm brad point tip threaded guide pin 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 curved awl to locate the medial face of the greater trochanter and check its position with AP and lateral views.

Note *Ensure correct guide pin insertion into the intramedullary canal to reduce risk of perforation and distal targeting error in short nails.*

Following fluoroscopic confirmation of correct guide pin placement, attach the 16mm cannulated entry reamer to power and slide over the guide pin. Adjust the angle of the reamer assembly to the desired trajectory and advance the reamer till the laser marking on it coincides with the proximal end of the entry portal tube. 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.

Note *In the instance of hard bone, it may be necessary to pass the reamer more than once.*

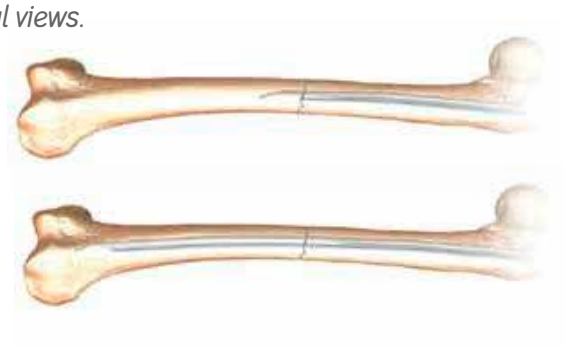
Intramedullary Reaming

Fracture Reduction

Insert the back end of the ball tip guide rod into the keyless chuck and tighten the locking screw. Introduce the ball tip guide rod 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 rod across the fracture site. Pass the ball tip guide rod down to the desired depth. It is valuable to pass the guide rod 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 rod should be center-center within the distal femur in the AP and lateral views.

Optional

Connect the reducer with quick connect T-handle 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 ball tip guide rod. Pass the ball tip guide rod 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 rod is in position, loosen the keyless chuck locking screw and remove the reducer, if used, from the intramedullary canal. Slide the obturator into the back of the T-handle during extraction in order to maintain guide rod position within the canal.

Implant Measurement (Long Nails)

Under fluoroscopy, use the length gauge to measure the required length of the nail and select the appropriate size.

Intramedullary Reaming (Only for Long Nail Insertion)

Preparing the Canal

Beginning with the 9.0mm 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 rod position is maintained throughout the reaming process by inserting the obturator 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 rod 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 center of the distal femoral fragment at the level of the physeal scar.

*Instruments are not provided in the ATLAS® HFN Set

Nail Insertion

Nail Assembly

Connect the guide bolt wrench to the quick connect T-handle. Attach the drill guide to the nail with the locking bolt and tighten using the assembled guide bolt wrench. Ensure the marking on the nail is aligned with the marking on the drill guide.

Insert the lag screw outer sleeve into the drill guide and manually lock it into position using the knob provided on the drill guide. Verify targeting accuracy by passing the lag screw drill through the assembly. An incorrectly attached nail will not target. Remove the lag screw drill sleeve for insertion.

Insertion

Orient the drill guide handle in line with the lateral femoral cortex and manually advance the nail into the proximal femur.

Note *Do not definitively seat the nail until proper AP alignment and femoral neck anteversion has been confirmed.*

For long nails, 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 Impactor-Long to the drill guide handle for impaction of the nail into the femur. Light hammer blows may be necessary when implanting long nails.

Note *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 to pass the reamer into the intramedullary canal again before inserting the nail.*

Insertion Depth

To confirm nail insertion depth, orient the C-Arm in the AP plane and slowly advance the nail. With the C-Arm in the AP plane, use the 3.2mm guide pin to ensure alignment with the center of the femoral neck and head.

The compression screw sits beneath the lag screw in the integrated screw formation. Ensure that the lag screw is positioned optimally (centre of the femoral head) and that there is sufficient space between the lag screw position and the calcar to accommodate the compression screw. Definitively seat the nail to the desired position using the slotted hammer.

Remove the Impactor from the drill guide handle and the 3.0mm ball tip guide rod from the intramedullary canal if used.

Note *After definitively seating the nail, confirm that the nail and drill guide handle are securely connected as hammering can loosen the guide bolt.*

Proximal Locking Overview

Integrated Interlocking Screws

1. Insert the 3.2mm x 343mm brad point tip threaded guide pin and advance to the desired position in the femoral head. Carefully confirm the position of the guide pin in both the AP and lateral planes using fluoroscopy
2. Measure for the lag screw
3. Drill the lateral cortex with the 5.0mm compression screw starter drill
4. Drill with the 6.2mm compression screw drill to the desired length
5. Insert the anti-rotation bar
6. Drill over the guide pin with the lag drill to the desired length
7. Insert the integrated interlocking lag screw
8. Remove the anti-rotation bar
9. Insert the integrated interlocking compression screw
10. Engage the set screw (optional)

Note *The ATLAS® HFN will only accommodate the integrated lag and compression screws. Stand alone lag screws or compressions screws cannot be used.*

Proximal Locking

Lag Screw Drill Sleeve Insertion

Make an incision at the site of lag screw entry and insert the lag Screw outer sleeve into the drill guide until it locks. Pass the guide pin sleeve through the assembly down to the bone. Gently tap the guide pin sleeve using the slotted hammer until the sleeve's trocar end is inside the bone (up to 5mm).

Note *The lag screw outer sleeve does not have to be on the bone.*

Lag Screw Guide Pin Insertion

Insert the 3.2mm x 343mm brad point tip threaded guide pin (under fluoroscopy) through the guide pin sleeve to the desired position in the femoral neck and head.

Confirm guide pin position in both the AP and lateral planes. The guide pin should be center-center in both views with a tip-apex distance of less than 25mm[1].

Lag Screw Measurement

Slide the lag screw length gauge over the 3.2mm guide pin to the back of the guide pin sleeve. Lag screw length measurement is taken from the calibrations at the end of the guide pin.

Note *The lag screw length gauge measures the length of a lag screw from the tip of the 3.2mm guide pin to the guide pin sleeve tip. Incorrect seating of the guide pin sleeve tip in the bone will result in incorrect measurement.*

1 The Value of the Tip-Apex distance in predicting failure of fixation of peritrochanteric fractures of the hip. MR Baumgaertner, SL Curtin, DM Lindskog and JM Keggi. The Journal of Bone and Joint Surgery of America, 77: pp.1058-1064, 1995.

Integrated Interlocking Screw Insertion

Confirm guide pin position. Attach the 5.0mm compression screw starter drill to power and insert into the Lag screw outer sleeve through the slot that is beneath the 3.2mm guide pin. Advance the starter drill under power until it abuts the back end of the lag screw outer sleeve.

Attach the 6.2mm compression screw drill to power and insert through the lag screw outer sleeve into the hole created by the starter drill. Advance the compression screw drill to a depth, 5mm less than the measurement taken for the lag screw from the guide pin. The mark on the compression screw drill should be flush with the back of the lag screw outer sleeve.

Remove the 6.2mm compression screw drill and manually insert the anti-rotation bar into the same hole. If the anti-rotation bar meets with resistance upon insertion, remove it and re-drill with the compression screw drill. The handle on the anti-rotation bar should align with the nail and the lateral cortex of the femur so that the flat surface of the anti-rotation bar is pointed towards the head of the patient.

Integrated Interlocking Screw Insertion

Confirm guide pin position and remove the guide pin sleeve. Attach the lag screw drill to power and insert into the lag screw outer sleeve over the 3.2mm guide pin. Drill to the depth measured for the lag screw. The measurement used should be flush with the back of the lag screw outer sleeve. Re-confirm guide pin position under fluoroscopy.

Note *In the instance of hard bone, it may be necessary to use the lag screw tap prior to lag screw insertion.*

Integrated Interlocking Screw Insertion

No Compression

Select a lag screw equal in length to the drilled depth.

Example	Drilling depth	85mm
	Compression required	0mm
	Lag Screw length	85mm

Align the back end of the appropriate length interlocking lag screw with the lag screw driver. Thread the retaining rod into the lag screw and tighten. Insert the assembly into the lag screw outer sleeve over the 3.2mm guide pin.

Advance the lag screw manually until the “0mm” mark on the lag screwdriver is flush with the back of the lag screw outer sleeve and the T-handle is perpendicular to the drill guide. At final seating, the laser line on the T-Handle must align with that of the drill sleeve and must be perpendicular to the drill guide assembly. The groove on the under-surface of the lag screwdriver must be oriented towards the patient's feet in order to allow removal of the anti-rotation Bar and proper insertion of the compression Screw.

Remove the anti-rotation bar and attach the corresponding compression screw (80mm) to the compression screw hexdriver. If the anti-rotation bar does not withdraw easily, adjust the lag screwdriver to a position perpendicular to the handle on the anti-rotation bar. Attach the T-handle to the screw hexdriver and insert the assembly into the lag screw outer sleeve beneath the lag screw driver. Advance the compression screw until the laser line on the hexdriver is flush with the back of the lag screw drill sleeve.

Note *Key for retaining rod can be used to unscrew the retaining rod in the lag and compression screw hexdriver.*

The Lag screw should always be paired with a compression screw that is 5mm shorter unless there is a requirement to use the 35mm compression screw.

Integrated Interlocking Screw Insertion

With Compression

Select a lag screw equal in length to the drilled depth minus the desired amount of compression.

Example	Drilling depth	85mm
	Compression required	5mm
	Lag Screw length	80mm

Align the back end of the appropriate length Integrated interlocking lag screw with the lag screwdriver. Thread the retaining rod into the lag screw and tighten. Insert the assembly into the lag screw outer sleeve over the 3.2mm guide pin.

Advance the lag screw manually until the “5mm” mark on the screwdriver is flush with the back of the lag screw outer sleeve, corresponding to the desired amount of compression. At final seating, the laser line on the T-handle must align with that of the drill sleeve and must be perpendicular to the drill guide assembly. The groove on the under-surface of the lag screwdriver must be oriented towards the patient’s feet in order to remove the anti-rotation bar and allow for proper insertion of the compression screw. Release any traction on the affected limb to allow for fracture compression.

Remove the anti-rotation bar and attach the corresponding compression screw (75mm) to the compression screw hexdriver. If the ani-rotation bar does not withdraw easily, adjust the lag screwdriver to a position perpendicular to the handle on the anti-rotation bar. Attach the T-handle to the screw hexdriver and insert the assembly into the lag screw outer sleeve beneath the lag screwdriver. Advance the compression screw until the line on the hexdriver is flush with the back of the lag screw outer sleeve.

Compression is achieved by advancing the compression screw assembly clockwise until the “0mm” mark on the lag screwdriver is visible. As the head of the compression screw abuts against the nail, the gear mechanism of the integrated interlocking screws will allow for compression with further advancement of the screw. It is recommended to stop compression when the “0mm” mark appears.

Note *It is not possible to exceed 10mm of compression due to the built in safety block on the compression screwdriver.*

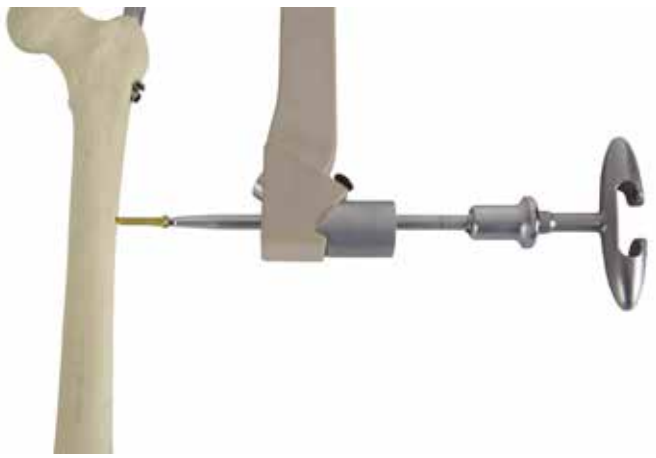
Distal Locking (Short Nails)

Short Nails: 170mm

Remove the lag screw outer sleeve from the drill guide and reconfirm fracture reduction via intra-operative radiographic imaging. Make a small incision at the site of distal screw entry and insert the distal sleeve guide block into the drill guide until it locks in place. Insert the 9.0mm distal drill sleeve through the desired slot on the drill sleeve guide block and drop down to bone. Drill both cortices with the 4.0mm pilot drill.

Measure for screw length using either the calibrations on the 4.0mm pilot drill or the screw length gauge. Attach the appropriate length 4.5mm or 5.0mm titanium locking screw to the hexdriver and insert through the 9.0mm drill sleeve. Attach the T-handle to the hexdriver and tighten the locking screw by hand.

Note *The 4.5mm titanium locking screws are intended for use with the 9.0mm diameter nails whereas the 5.0mm titanium locking screws are intended for use with the 10mm and 11mm diameter nails.*



Distal Locking (Long Nails)

Long Nails: 260-460mm

Distal locking is performed in the lateral plane using a free-hand technique. Reconfirm fracture reduction and align the C-Arm over the desired locking hole. Obtain a “perfect circle” image of the locking hole and use a blunt object to approximate the location of the locking hole by dimpling the skin.

Make a stab incision at the site of screw entry. Insert the 4.0mm Drill bit down to bone, and position it in the exact center of the perfect circles on fluoroscopic images. Once the position and trajectory of the drill have been confirmed fluoroscopically, carefully drill both cortices.

Measure for screw length using the depth gauge. Insert the appropriate length, 4.5mm or 5.0mm titanium locking screw using hexdriver and T-handle. Use one or two distal locking screws depending on the location of the fracture (distal fractures require use of two distal locking screws), the quality of the bone (use of two distal locking screws is recommended for significantly osteoporotic bone) and surgeon preference.

Set Screw Insertion

Set Screw Insertion

Remove the drill guide by unlocking the locking bolt using the assembly of guide bolt wrench and T-handle. Attach the set screw to the assembly of hexdriver and the T-handle. Advance the set screw till it engages with the top of the nail.

The Integrated Interlocking Screws are incapable of excessive medial migration and/or rotation within the nail, but can still slide to allow further uncontrolled postoperative compression.

To facilitate sliding, do not lock the set screw on top of the nail. Full engagement of the set screw with the lag screw converts the construct into a fixed angle device.

Closure

Obtain Final AP and lateral radiographic images to confirm implant position and fracture reduction. Wound closure is performed using a standard technique.

Implant Removal: Optional

Set Screw removal
Insert the hexdriver into the top of the nail until it engages with the hex head of the set screw, and then engage the retaining rod. Attach the T-handle to the back of the hexdriver and turn counterclockwise to fully disengage the set screw from the lag screw.

Integrated Interlocking Screw removal
Start with the removal of the compression screw. Insert the compression screw hexdriver into the back of the compression screw and engage the retaining rod. Attach the T-handle to the back of the hexdriver and remove using counterclockwise turns of the assembly.

Under fluoroscopy, insert a 3.2mm x 343mm brad point tip threaded guide pin into the back of the integrated interlocking lag screw. Slide the lag screwdriver over the guide pin and engage it with the back of the lag screw. Thread the retaining rod into the lag screw and remove using counterclockwise turns of the assembly.

Distal Screw removal
Insert the hexdriver into the distal screw and engage the retaining rod. Attach the T-handle to the back of the hexdriver and remove the distal screw using counterclockwise turns of the assembly.

Open nail extraction technique
Remove all but one of the titanium locking screws in the distal end using the hexdriver and T-handle. Thread the nail extractor into the impactor and introduce the extraction assembly into the top of the nail until it engages with the threads in the nail. Remove the final titanium locking screw and extract the nail with a back-slapping motion using the slotted hammer.

Catalog Information

ATLAS◇ HFN Integrated Interlocking Screws

Lag Screws

Minor diameter tapers from 8.5mm-5.5mm

Catalogue No	Description
I0208.070	ATLAS HFN 70MM Lag Screw
I0208.075	ATLAS HFN 75MM Lag Screw
I0208.080	ATLAS HFN 80MM Lag Screw
I0208.085	ATLAS HFN 85MM Lag Screw
I0208.090	ATLAS HFN 90MM Lag Screw
I0208.095	ATLAS HFN 95MM Lag Screw
I0208.100	ATLAS HFN 100MM Lag Screw
I0208.105	ATLAS HFN 105MM Lag Screw
I0208.110	ATLAS HFN 110MM Lag Screw
I0208.115	ATLAS HFN 115MM Lag Screw
I0208.120	ATLAS HFN 120MM Lag Screw
I0208.125	ATLAS HFN 125MM Lag Screw

Compression Screws

Catalogue No	Description
I0209.065	ATLAS HFN Compression Screw 65MM
I0209.070	ATLAS HFN Compression Screw 70MM
I0209.075	ATLAS HFN Compression Screw 75MM
I0209.080	ATLAS HFN Compression Screw 80MM
I0209.085	ATLAS HFN Compression Screw 85MM
I0209.090	ATLAS HFN Compression Screw 90MM
I0209.095	ATLAS HFN Compression Screw 95MM
I0209.100	ATLAS HFN Compression Screw 100MM
I0209.105	ATLAS HFN Compression Screw 105MM
I0209.110	ATLAS HFN Compression Screw 110MM
I0209.115	ATLAS HFN Compression Screw 115MM
I0209.120	ATLAS HFN Compression Screw 120MM

ATLAS HFN Nail Cap Set Screws

Catalogue No	Description
I0301.00	ATLAS HFN 0MM Nail Cap Set Screw
I0301.05	ATLAS HFN 5MM Nail Cap Set Screw
I0301.10	ATLAS HFN 10MM Nail Cap Set Screw

ATLAS◇ Titanium Locking Screws

Catalogue No	Description
I0210.4520	ATLAS Titanium Locking Screw 4.5MM X 20MM
I0210.4523	ATLAS Titanium Locking Screw 4.5MM X 22.5MM
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

Catalogue No	Description
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◇ HFN Short Nails

Catalogue No	Description
I0137.0917	ATLAS HFN Universal, Short, 9MM X 17CM
I0137.1017	ATLAS HFN Universal, Short, 10MM X 17CM
I0137.1117	ATLAS HFN Universal, Short, 11MM X 17CM

Note *Only 127° neck angle option is provided in all nails.*

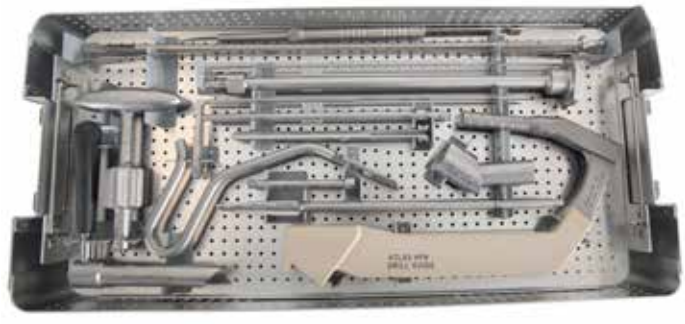
ATLAS◇ HFN Long Nails

Catalogue No	Description
I0139.0926	ATLAS HFN 9MM Long, Right - 26CM
I0139.0928	ATLAS HFN 9MM Long, Right - 28CM
I0139.0930	ATLAS HFN 9MM Long, Right - 30CM
I0139.0932	ATLAS HFN 9MM Long, Right - 32CM
I0139.0934	ATLAS HFN 9MM Long, Right - 34CM
I0139.0936	ATLAS HFN 9MM Long, Right - 36CM
I0139.0938	ATLAS HFN 9MM Long, Right - 38CM
I0139.0940	ATLAS HFN 9MM Long, Right - 40CM
I0139.0942	ATLAS HFN 9MM Long, Right - 42CM
I0139.0944	ATLAS HFN 9MM Long, Right - 44CM
I0139.0946	ATLAS HFN 9MM Long, Right - 46CM
I0138.0926	ATLAS HFN 9MM Long, Left - 26CM
I0138.0928	ATLAS HFN 9MM Long, Left - 28CM
I0138.0930	ATLAS HFN 9MM Long, Left - 30CM
I0138.0932	ATLAS HFN 9MM Long, Left - 32CM
I0138.0934	ATLAS HFN 9MM Long, Left - 34CM
I0138.0936	ATLAS HFN 9MM Long, Left - 36CM
I0138.0938	ATLAS HFN 9MM Long, Left - 38CM
I0138.0940	ATLAS HFN 9MM Long, Left - 40CM
I0138.0942	ATLAS HFN 9MM Long, Left - 42CM
I0138.0944	ATLAS HFN 9MM Long, Left - 44CM
I0138.0946	ATLAS HFN 9MM Long, Left - 46CM
I0139.1026	ATLAS HFN 10MM Long, Right - 26CM
I0139.1028	ATLAS HFN 10MM Long, Right - 28CM
I0139.1030	ATLAS HFN 10MM Long, Right - 30CM
I0139.1032	ATLAS HFN 10MM Long, Right - 32CM
I0139.1034	ATLAS HFN 10MM Long, Right - 34CM
I0139.1036	ATLAS HFN 10MM Long, Right - 36CM
I0139.1038	ATLAS HFN 10MM Long, Right - 38CM
I0139.1040	ATLAS HFN 10MM Long, Right - 40CM
I0139.1042	ATLAS HFN 10MM Long, Right - 42CM
I0139.1044	ATLAS HFN 10MM Long, Right - 44CM
I0139.1046	ATLAS HFN 10MM Long, Right - 46CM
I0138.1026	ATLAS HFN 10MM Long, Left - 26CM
I0138.1028	ATLAS HFN 10MM Long, Left - 28CM
I0138.1030	ATLAS HFN 10MM Long, Left - 30CM
I0138.1032	ATLAS HFN 10MM Long, Left - 32CM
I0138.1034	ATLAS HFN 10MM Long, Left - 34CM
I0138.1036	ATLAS HFN 10MM Long, Left - 36CM
I0138.1038	ATLAS HFN 10MM Long, Left - 38CM

Catalogue No	Description
I0138.1040	ATLAS HFN 10MM Long, Left - 40CM
I0138.1042	ATLAS HFN 10MM Long, Left - 42CM
I0138.1044	ATLAS HFN 10MM Long, Left - 44CM
I0138.1046	ATLAS HFN 10MM Long, Left - 46CM
I0139.1126	ATLAS HFN 11MM Long, Right - 26CM
I0139.1128	ATLAS HFN 11MM Long, Right - 28CM
I0139.1130	ATLAS HFN 11MM Long, Right - 30CM
I0139.1132	ATLAS HFN 11MM Long, Right - 32CM
I0139.1134	ATLAS HFN 11MM Long, Right - 34CM
I0139.1136	ATLAS HFN 11MM Long, Right - 36CM
I0139.1138	ATLAS HFN 11MM Long, Right - 38CM
I0139.1140	ATLAS HFN 11MM Long, Right - 40CM
I0139.1142	ATLAS HFN 11MM Long, Right - 42CM
I0139.1144	ATLAS HFN 11MM Long, Right - 44CM
I0139.1146	ATLAS HFN 11MM Long, Right - 46CM
I0138.1126	ATLAS HFN 11MM Long, Left - 26CM
I0138.1128	ATLAS HFN 11MM Long, Left - 28CM
I0138.1130	ATLAS HFN 11MM Long, Left - 30CM
I0138.1132	ATLAS HFN 11MM Long, Left - 32CM
I0138.1134	ATLAS HFN 11MM Long, Left - 34CM
I0138.1136	ATLAS HFN 11MM Long, Left - 36CM
I0138.1138	ATLAS HFN 11MM Long, Left - 38CM
I0138.1140	ATLAS HFN 11MM Long, Left - 40CM
I0138.1142	ATLAS HFN 11MM Long, Left - 42CM
I0138.1144	ATLAS HFN 11MM Long, Left - 44CM
I0138.1146	ATLAS HFN 11MM Long, Left - 46CM

Note *Only 127° neck angle option is provided in all nails.*

ATLAS◇ HFN Instrument Set listing



Catalogue No	Description
I0537.00	ATLAS Obturator
I0538.00	ATLAS Large Extractor
I0539.00	ATLAS HFN Lag Screw Length Gauge
I0569.00	ATLAS HFN Proximal Reamer
I0541.00	ATLAS HFN Drill Guide
I0543.00	ATLAS HFN Locking Bolt
I0544.00	ATLAS HFN Distal Sleeve Guide Block
I0545.00	ATLAS HFN Lag Screw Outer Sleeve
I0546.00	ATLAS HFN Guide Pin Sleeve
I0547.32	ATLAS Guide Pin 3.2
I0548.00	ATLAS HFN Anti Rotation Bar Assembly
I0549.00	ATLAS HFN Lag Screw Drill
I0550.00	ATLAS HFN Proximal Locking Lag Screw Tap
I0551.00	ATLAS HFN Lag Screw Driver
I0552.00	ATLAS HFN Compression Screw Starter Drill
I0553.00	ATLAS HFN Compression Screw Drill
I0554.00	ATLAS HFN Compression Screw Driver Assembly
I0555.48	ATLAS Hex Driver, 4.75 A/F
I0556.90	ATLAS HFN 9mm Distal Drill Sleeve
I0558.40	ATLAS HFN 4mm Pilot Drill
I0559.00	ATLAS HFN Entry Portal Sleeve
I0560.00	Quick Connect T-Handle
I0561.00	ATLAS Reducer
I0562.00	ATLAS HFN Guide Bolt Wrench
I0563.00	ATLAS Impactor-Long
I0564.00	ATLAS Slotted Hammer
I0565.00	ATLAS HFN Keyless Chuck
I0566.00	ATLAS HFN Curved Cannulated Awl
I0567.00	ATLAS Length Gauge
I0568.00	ATLAS HFN Screw Length Gauge
I0506.05	ATLAS Distal Depth Gauge
I0522.402	ATLAS Drill Bit Q.C. Dia. 4.0mm, Length 225mm
I0570.00	ATLAS Key for Retaining Rod
D0101.2301	Atlas HFN Instrument Case
D0102.2001	Atlas HFN Instrument Tray

Instructions for use on ATLAS◇ HFN Hip Fracture Nail

For use by an Accredited Orthopaedic Surgeon only

Device Description:

Atlas HFN is an intramedullary interlocking nail with corresponding screws designed to address hip fractures. It consists of interlocking intramedullary nails in long and short configurations, lag screw, compression screw, distal locking screw and nail cap set screw. HF nails contain proximal and distal holes to accept locking screws. The integrated lag and compression screws provide stability, strength and active compression. The Atlas HF Nail and screws are made from titanium Ti-6Al-4V material.

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 are essential to safe and effective fracture treatment. See NOTES, INDICATIONS, CONTRAINDICATIONS, and PREOPERATIVE PLANNING below.
2. HF nails are NOT substitutes for skeletal healing, and proper follow-up care is essential to safe and effective use. See WARNINGS, POSTOPERATIVE CARE and POSSIBLE ADVERSE EFFECTS below.
3. Metallic surgical implants are NEVER TO BE REUSED (single use).

Notes:

Metallic surgical implants are intended to be used as aids to normal fracture healing. Such implants are NOT replacements for skeletal structures. 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 the following information and should 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:

ATLAS HFN is indicated for fractures of the femur including:

1. Simple shaft fractures
2. Comminuted shaft fractures
3. Spiral shaft fractures
4. Long oblique shaft fractures and segmental shaft fractures
5. Intertrochanteric fractures (see contraindications)
6. Ipsilateral femoral shaft/neck fractures
7. Intracapsular fractures; nonunions and malunions
8. Polytrauma and multiple fractures
9. Prophylactic nailing of impending pathologic fractures
10. Sub-trochanteric fracture only indicated for long nails and without the option of single lag screw
11. Reconstruction, following tumor resection and grafting
12. Bone lengthening and shortening

Contraindications:

1. Atlas HFN 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.
8. The Short HFN is contraindicated for sub-trochanteric, complex intertrochanteric and femoral neck fractures.

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: Proper size of implant must be selected to insure effective treatment of patients. The following factors should be considered:
   - A patient's size, strength, skeletal characteristics, skeletal health, and general health. Overweight or musculoskeletally deficient or unhealthy patients may create greater loads on implants that may lead to breakage or other failure of the implants.
   - A patient's activity level during the time the implant is in the patient's body, including such factors as whether the patient's occupation or typical activities include running, heavy lifting, impact loading, or the like.
   - Whether a patient has a degenerative or progressive disease that delays or prevents healing, and consequently decreases the effective life of the implant.
   - If a patient is suspected of having material or foreign body sensitivities, appropriate testing should be accomplished prior to implantation.
   - Mental conditions or substance abuse problems that may prevent a patient from understanding or following directions or observing precautions.
3. 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.
4. 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.
5. 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 or improper positioning 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 non 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 Atlas HF Titanium screws with Atlas HF Titanium 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 the device. Early weight bearing should only be considered where there are stable fractures with good bone-to-bone contact. Patients who are obese and/or noncompliant, as well as patients who could be pre-disposed to delayed or non-union, should have auxiliary support. The implant may be exchanged for a larger, stronger nail subsequent to the management of soft tissue injuries. 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 structured to prevent loading of the operative extremity until stability is evident. Additional postoperative precautions should be taken when the fracture line occurs within 5cm of the nail's screw hole, as this places greater stress on the nail at the location of the transverse screw hole.
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. It is suggested 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 HF 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, have been reported in similar intra-medullar nails.
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. Damage to the femoral capital epiphysis due to trauma during surgery or improper position or length of compression screws and guide wires.
8. 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.
9. Although rare, metal sensitivity reactions and/or allergic reactions to foreign materials have been reported in patients.

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 below direction.

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:

If packaging of a metal component appears to be damaged and the metal component is to be used, the metal component should be cleaned prior to re-sterilization as follows:

- Use deionized, or distilled, warm (room temperature) water for soaking, cleaning and rinsing. Disassemble as appropriate. Soak soiled products for a minimum of 10 minutes. For non-ceramic coated components: immerse and hand wash with a neutral pH or mild detergent. 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. Do not stack devices.

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 bloodborne 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	Rx only	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@adlermediequip.com**

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