FLOW-NAIL™ WITH LAGLOCK™ SURGICAL TECHNIQUE GUIDE

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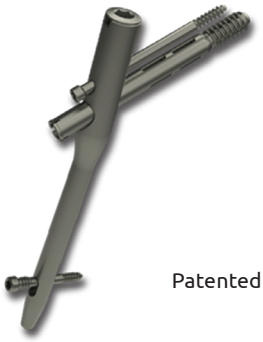

Patented

Intertrochanteric and subtrochanteric fractures are growing public health concerns in the aging population and account for significant mortality. However, proper operative fixation of these fractures could help decrease mortality. Precision delivery of bone void filler may improve surgical outcomes in patients.

This guide outlines the proper technique and steps required for the successful use of Flow-Nail and the precision delivery of bone void filler (BVF). The instructions also describe the Laglock static locking feature in detail for successful deployment after BVF delivery.

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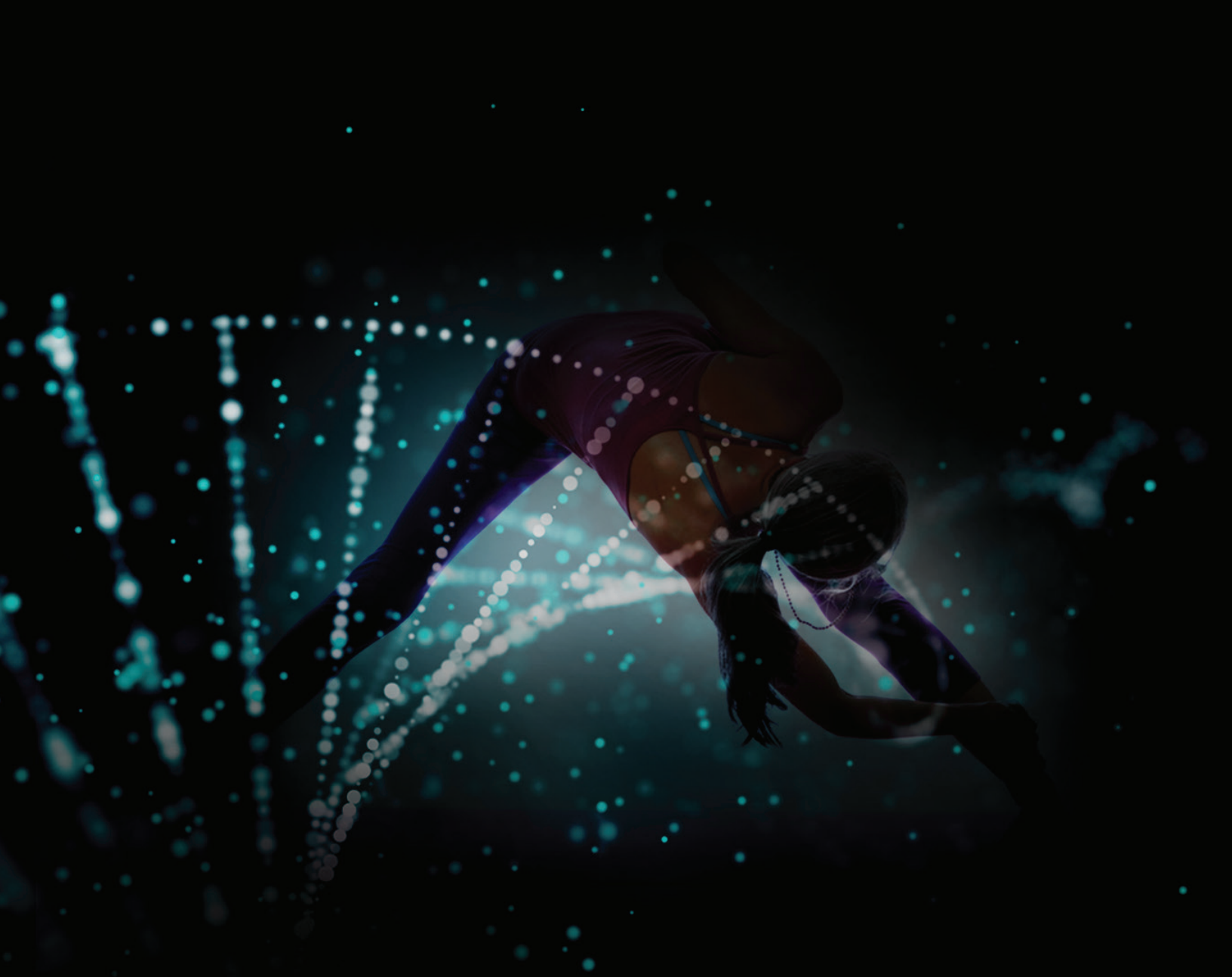

Flow-FX™

REIMAGINING THE SCIENCE OF SKELETAL HEALTH

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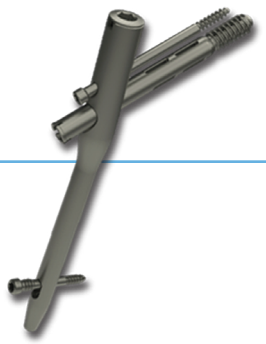


INTRAMEDULLARY FIXATION REVOLUTIONIZED WITH PRECISION DELIVERY OF BONE VOID FILLER AND SLIP-PROOF, STATIC LOCKING LAGLOCK FEATURE

Patented, 510K-cleared Flow-Nail offers exclusive advantages:

- Patented side port cannula delivers bone void filler through fenestrations while protecting the hip joint from unintended intrusion of biologic material
- Advanced delivery mechanism ensures precise placement of bone void filler to the implantation site, using manual low-pressure delivery
- Invented for fracture fixation, Flow-Nail gives the surgeon an option regarding standalone construct or supplementation with bone void filler
- Available in 125° and 130° neck angles with 180mm and 220mm lengths to allow for the treatment of the majority of fractures as a standalone device
- The Laglock lag screw creates a unique, patent-pending, static nail construct for challenging fractures. It withstands a 400-pound static load in line with the screw and 1 million cycles at 72nm fatigue tests.

IMPLANT OVERVIEW

Flow-Nail intramedullary fixation system includes primary components:

Cap

Nail Cap

Peg

Peg

Trochanteric Nail 10-11mm

125°, 180mm
125°, 220mm
130°, 180mm
130°, 220mm

Lag Screw (non-locking)

80-120mm in 5mm increments

Laglock Screw

80-120mm in 5mm increments

Cortical Screw

20-60mm in 2mm increments
60-80mm in 5mm increments

Anti-Rotation Screw

50-100mm in 10mm increments

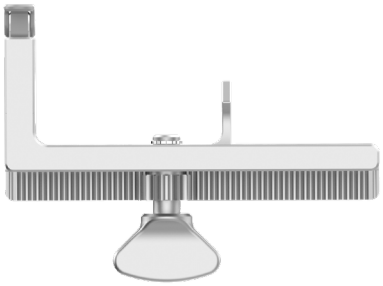
STANDARD INSTRUMENTS

The following instruments are typically used in intertrochanteric and subtrochanteric surgical fixation with Flow-Nail.

Lag Screw Length Gauge

Lag Screw Drill

Lag Screw Tap



Compression Device

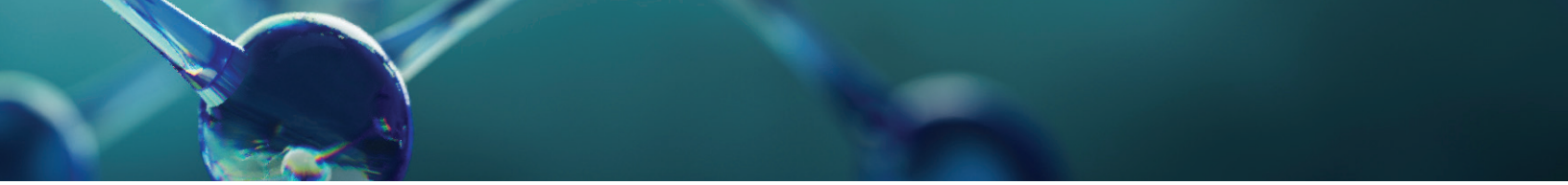
Lag Screw Driver Bolt

Cap Driver Bolt

Lag Screw Depth Stop

Multi-Driver with Depth Stop

Cap Driver



AR Screw Sheath

AR Screw Trocar

AR Screw Drill

Cortical Screw Sheath

Multi-Driver Screw Bolt

Cortical Screw Drill

Cortical Screw Trocar

Side Port Cannula

BVF Gauge

Side Port Cannula Plunger

Lag Screw Driver with Collet

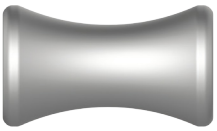
Cortical Screw Drill Guide

STANDARD INSTRUMENTS

T-Handle

Wrench

Slap Hammer Rod



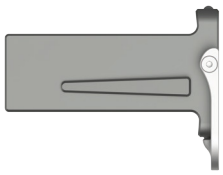
Slap Hammer Slider

Guidewire

Bolt Loosener

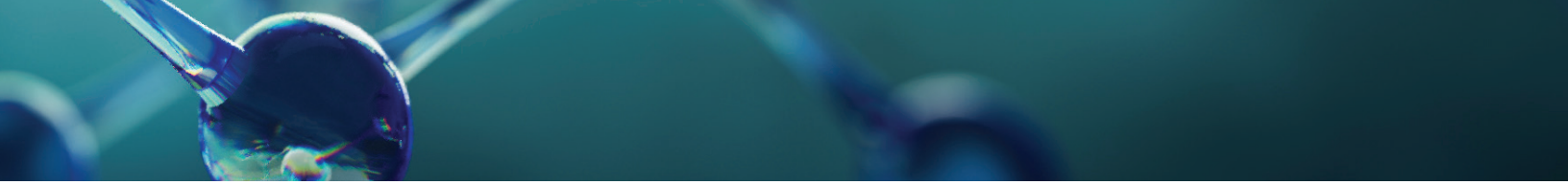
Adapter

IM Nail Jig



Jig Cartridge

Jig Bolt with Washer



Jig Bolt Driver

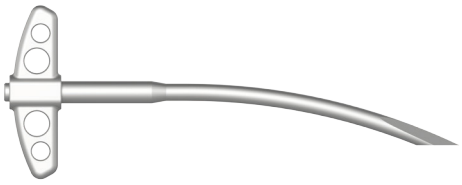
Reamer Sheath

Multi-Channel IM Guidewire Guide

IM Guidewire Trocar

IM Nail Reamer

AP Template



Cannulated Awl

Lag Screw Sheath

Lag Screw Guidewire Guide

Lag Screw Guidewire Trocar

The following is a step-by-step surgical guide that demonstrates the seamless integration of Flow-Nail in your surgical procedure.

Patient Positioning

Position the patient on a fracture table with the pressure areas well padded. Perform closed reduction under fluoroscopy as needed. Sterile prep per routine. Preoperative antibiotics recommended.

IM Nail Prep

1. Attach the correct diameter, angle and length nail to the jig.

- Fasten nail to jig using the IM jig bolt with integral lock washer, ensuring that the jig splines are aligned correctly and the jig bolt is tightened firmly.
- Depending on the angle of the nail to be used, insert the cartridge into the jig in either the 125- or 130-degree position.
- Orient the cartridge such that the lag screw hole is nearer the distal end of the jig and ensure that the cartridge ejector handle is positioned below the lag screw hole.

IM Nail Placement

2. Determine the incision location.

- Incise and dissect to the femoral cortex.
- The nail incision will be approximately 3cm long.
- Use the reamer sheath, guidewire guide and trocar, advance to cortical bone, remove trocar.

3. Drive guidewire into femoral canal.

- Use the reamer sheath, guidewire guide and trocar, advance to cortical bone, remove trocar.
- Position guidewire guide at entry point, slightly lateral to the tip of the trochanter.
- Remove the guidewire trocar and drive guidewire into femoral canal with fluoroscopic guidance.

IM Nail Placement *Cont'd*

4. Ream proximally for the nail, down to the lesser trochanter.

- Distal reaming is not required. Remove all instruments when complete.

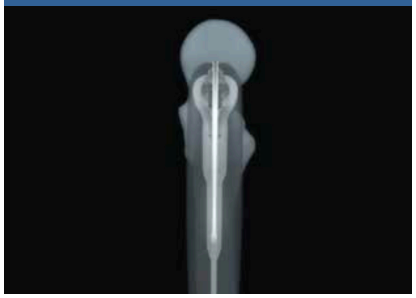
5. Reduce the fracture if open reduction is necessary.

- No fracture reduction tools are provided with the instrument set.

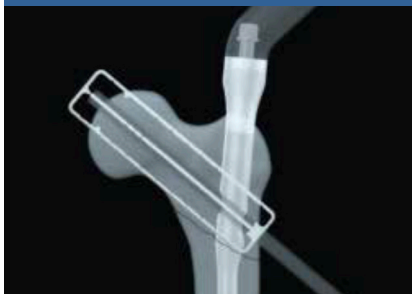
6. Insert the nail.

- Slide the nail into position in the femoral canal, using the AP template and the alignment aids integrated into the jig to determine proper position and orientation.
- The AP template is attached by sliding its foot into the correct slot (125° or 130°) on the jig and threading its fastener into the jig.
- The upper bar of the AP template corresponds to the AR screw channel in the Flow-Nail.

Simulated Lateral X-Ray



Simulated AP X-Ray



Lag Screw Prep

7. Incise for the lag screw.

- The incision will be approximately 3cm. For rotationally unstable fractures, the AR drill or guidewire may be used through the AR sheath for temporary fixation prior to lag screw placement.
- Ensure lag screw is in place prior to AR screw insertion.

8. Install the lag screw sheath/trocar into the jig.

- Run the lag screw sheath up to the bone and remove the trocar.

9. Insert lag screw guidewire into sheath and install the lag screw guidewire with fluoroscopic guidance on AP/Lateral.

- Drive the guidewire to within 5mm of the femoral head cortical bone.

10. Measure the lag screw length after ensuring that the guidewire guide is firmly pressed against the bone.

- Measure the distance from the top of the lag screw sheath to the end of the guidewire. Remove the guidewire guide and length gauge when complete. The guidewire stays in place. After the guidewire guide has been removed, the lag screw sheath can be advanced 5mm for firm cortical contact.

11. Drill over the guidewire for the lag screw with fluoroscopy.

- Set the drill stop on the step drill and drill up to the stop. Use caution when passing the drill through the nail.
- Use fluoroscopy to ensure guidewire doesn't advance during drilling.
- Remove the lag screw step drill. When removing the drill, the lag screw, guidewire guide trocar can be used to prevent guidewire from backing out.

12. Tap for the lag screw with fluoroscopy.

- Tap over the guidewire. The compressor has been designed to work with the tap as well as the lag screw.
- After compressing fracture through the tap with fluoroscopic observation, remeasure the screw length via length markings on the tap where it passes from the sheath or by remeasuring the guidewire.
- The compressor is powerful and care should be used with osteoporotic bone. When removing the tap, the lag screw trocar can be used to keep the guidewire in place.
- Remove tap.

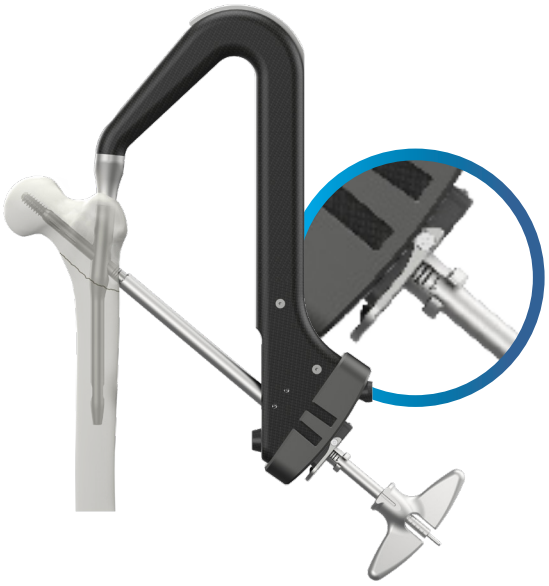
Lag Screw Placement

13. Assembling the Lag Screw Driver.

- Attach the correct length and configuration lag screw to the driver with the driver bolt.
- Choose a lag screw for dynamic fixation or a Laglock screw if static locking may be needed.
- Asymmetric driver tines ensure the screw attaches only in the correct orientation. The T-handle is also designed so that firm attachment to the lag driver is only achieved when the handle's flat surface aligns with the screws' delivery slots and Laglock.

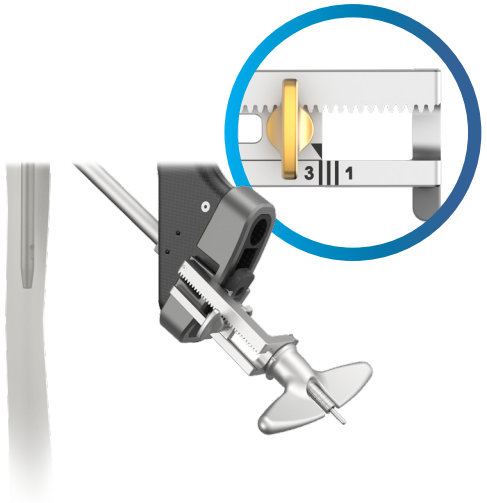
14. Insert the Lag Screw.

- Insert the lag screw over the guidewire with fluoroscopic guidance. Final correct orientation requires the flat surface of the T-handle to face the patient's foot.
- Correct positioning of the lag screw with Laglock can be judged in 2 ways. Depending on screw length, the proximal end of the screw has been marked with 1, 2 or 3 rings that correspond to rings on the driver shaft.
- When the correct number of rings are visible through the lag screw sheath cutout, with the desired ring abutting the cartridge, the screw is in the correct position for Laglock deployment.
- If the screw has been placed beyond the correct position due to fracture characteristics, the compressor can be used to compress the fracture and pull the screw back, aligning the Laglock.
- Proper position for Laglock deployment is achieved when the correct number of rings are seen in the lag screw sheath cutout or the compressor indicator is at the correct line marking.
- Compression can also be performed once the Laglock peg has been placed into its position (see step 19). Confirm that the T-handle flat surface faces the patient's foot. Remove the T-handle and guidewire.



15. Compressing the fracture

- Attach the compressor to surround the lag screw driver while resting on the jig/cartridge, gently distract the device under careful fluoroscopic observation to assess slippage.
- The three line markings on the compressor indicate correct positioning for Laglock deployment.
- If significant compression or lack of compression causes the Laglock to become mispositioned, screw replacement is advisable if locking is planned.
- There is a 5mm margin of error laterally from each marking for acceptable placement. For example, the third ring or line can be up to 5mm lateral to its desired position and the Laglock will still function. Compression can also be performed with the Laglock peg in its first position.



Lag Screw – Delivery of Bone Void Filler (BVF)

16. Prior to delivering BVF to the femoral head or fracture site, inject 3-4cc of radio-opaque contrast through the side port cannula to confirm that the hip joint has not been compromised.

- The side port cannula should be examined for structural integrity before use.

17. Attach the BVF gauge to the lag screw driver.

- Firm attachment is possible with only one orientation and results in the BVF gauge notch facing the foot aligned with the screw slots and Laglock.
- Set the gauge for the correct screw length via the markings on the side of the device.

18. Dispense the BVF, confirming location with fluoroscopy. Insert the BVF side port cannula into the BVF side port cannula gauge.

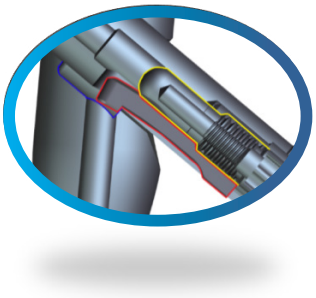
- Push the BVF side port cannula in until the tip of the cannula is at the end of the lag screw and confirm under fluoroscopy.
- Inject 4cc of radiopaque contrast to confirm the joint surface is intact. Dispense the BVF to desired area. The side port cannula indicator cutouts show the direction the side port is facing.
- The tip of the indicator shows the position of the side port inside the screw, allowing precision delivery along the course of the screw. Use the cannula plunger to deliver all of the material remaining inside the cannula. Cutout on the indicator shows the direction the side port faces.
- Remove the side port cannula and BVF gauge.

Note: BVF must be delivered prior to peg placement.

Locking the Laglock

19. Attach the Laglock peg to the multi-driver with the bolt and deploy the multi-driver depth stop.

- Attach a T-handle to the lag screw driver and a T-handle to the multi-driver. The multi-driver is used as the peg driver, AR driver and cortical screw driver. Secure the lag screw driver to the sheath by gently tightening the lag screw drive collet retention device and remove the lag screw driver bolt, keeping the driver firmly seating in the screw.
- Inserting the peg through the driver two full turns to abut the deployed multi-driver depth stop allows the compressor to be used at this point after the collet has been loosened if needed. As previously described, the markings on the compressor that correspond to the markings on the proximal screw indicate correct position of the screw for Laglock deployment.
- There is a 5mm margin of error laterally from each marking for acceptable placement. For example, the third ring or line can be up to 5mm lateral to its desired position and the Laglock will still function. Compression can also be performed with the Laglock peg in its first position.
- At this point, collapse the depth stop. Applying counter-torque to the lag screw, screw the Laglock peg in to full-stop which deploys the Laglock into the nail's Laglock pocket and prevents further construct collapse of more than a few mm. **This step requires that the screw be correctly oriented with Laglock pointing at the patient's foot (indicated by the flat surface of the T-handle facing the foot)**.
- Remove the various drivers/bolts and lag screw sheath once complete.



Anti-Rotation (AR) Screw Placement

20. Determine the incision location and incise.

- It may be necessary to enlarge the incision proximal to the lag screw sheath. Remove lag screw sheath if needed to facilitate the incision.

21. Drill for the anti-rotation screw using fluoroscopy for assistance.

- Advance the sheath to the femoral lateral cortex and remove the trocar.
- Replace with the drill. Use caution when passing the drill through the nail and take care not to over-penetrate the medial cortex to avoid joint penetration.
- Identify the screw length by reading the number on the drill where it passes out of the sheath. Remove the drill.

Insert the Anti-Rotation Screw

22. Attach AR screw to multi-driver with driver bolt.

- Attach the T-handle. Drive the AR screw manually to the desired depth and confirm with fluoroscopy.
- Remove the multi-driver/bolt, sheath and jig cartridge when complete. Note: AR screw length can be confirmed with the AR screw length gauge on the reverse side of the lag screw length gauge. The multi-driver is used as the peg driver, AR driver and cortical screw driver.

Distal Cortical Screw Placement

23. Cortical Screw Placement.

- Determine the incision location and incise.

24. Install the cortical screw sheath and trocar.

- Install the cortical screw sheath, drill guide, and trocar.
- Remove the trocar when the sheath is firmly on bone and insert the cortical screw drill.
  Note that the drill is a stepped drill to allow for the unique fixation of the cortical screw and the increased smooth diameter portion resting inside the nail.
- Advance drill 1-2mm beyond furthest cortex under fluoroscopic guidance. The stepped drill requires steady pressure for the step to drill the medial cortex as desired. Identify the screw length by the lengths shown at the top of the sheath between the wings of the drill guide. Cortical screw length can be confirmed with the length gauge on the reverse side of the lag screw length gauge.

25. Place the cortical screw.

- Remove the cortical drill guide.
- Attach the correct length cortical screw to the multi-driver. The cortical screw will not require threading until it passes through the nail. Remove the cortical screw sheath and driver when complete.

Cap and Close

26. Remove Jig.

- Drop a guidewire through the nail jig bolt and unfasten the jig bolt (with the bolt driver) from the nail, having the bolt remain captive to the jig.

27. Install the cap.

- Attach a cap to the cap driver using the cap driver bolt. Follow the guidewire to the nail and install the cap. Unfasten the cap driver bolt. Remove the cap driver and the guidewire.

28. Problem Solving.

1. If there is difficulty removing the cortical screw sheath from the jig, replace the trocar, insert a guidewire into hole in head of trocar for gripping assistance and remove sheath.
2. if any bolt heads become slippery or overtightened, insert the bolt loosener/T-handle into its lateral tip to remove.

29. Close with proper sutures or staples, and dress.

End of procedure

Nail Removal

- Repeat the lateral incisions and remove cortical screw, lag screw and AR screw. Specific removal order is up to the surgeon.
- To disengage the Laglock, the Laglock peg must be removed with counterclockwise rotation. If it's difficult to access, a 2.8 mm threaded K-wire will thread partially into the peg bolt threads and allow the multi-driver to be placed onto the peg over the K-wire.
- Once the peg has been removed, the lag screw driver can be used to remove the lag screw. The widest tine of the lag driver will face the foot of patient when fitting into screw if it was inserted per instructions. Counterclockwise rotation of the lag screw will force the Laglock into its retracted position if it has not fully retracted upon removing the peg. The appropriate bolts can be used inside the drivers to ensure positive attachment and ease of removal.

Flow-Nail™ with LagLock™

Trochanteric Nail

Instructions for Use

IFU-101 rev G

DESCRIPTION

The Flow-FX Flow-Nail is designed as a trochanteric nail system for fixation of stable and unstable proximal fractures of the femur and is composed of an intramedullary nail, sliding, fenestrated lag screw, anti-rotation screw, cortical screws and accompanying instruments. The Laglock™ system includes the modified lag screw and Flow-Nail designed to use as a static construct, limiting movement at the fracture site when needed.

The Flow-Nail can also be used for the delivery of bone void fillers.

INDICATIONS

The Flow-Nail is intended to treat stable and unstable proximal fractures of the femur including pertrochanteric, intertrochanteric, and high subtrochanteric fractures and combinations of these fractures. The Flow-Nail can also be used to deliver injectable bone void fillers to a surgical site.

MATERIALS

The Flow-Nail implant components are made of titanium alloy (Ti-6Al-4V) conforming to ASTM F136.

CONTRAINDICATIONS

- Insufficient quantity or quality of bone, conditions that retard healing (not including pathological fractures) and conditions causing poor blood supply or obliteration of the medullary canal or femoral neck and head.
- Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests should be made and sensitivity ruled out prior to implantation.
- Any active or suspected latent infection or marked local inflammation in or about the affected area.
- Compromised vascularity that would inhibit adequate blood supply to the fracture or the operative site.
- Material sensitivity documented or suspected.
- Obesity. An overweight or obese patient can produce loads on the implant that can lead to failure of the fixation of the device or to failure of the device itself.
- Patients having inadequate tissue coverage over the operative site.
- Implant utilization that would interfere with anatomical structures or physiological performance.
- Any mental or neuromuscular disorder which would create an unacceptable risk of fixation failure or complications in postoperative care.
- Other medical or surgical conditions which would preclude the potential benefit of surgery.

⚠ WARNINGS

- For professional use only.
- Do not use this system without fully reading the instructions for use.
- The surgeon should be familiar with the general principles and technique of intramedullary nails to treat stable and unstable proximal fractures of the femur including pertrochanteric, intertrochanteric, and high subtrochanteric fractures and combinations of these fractures and the Flow-Nail System.
- The surgeon should be familiar with the general principles and technique of delivering bone void filler using the Flow-Nail System.
- Surgeons should follow the surgical technique.
- Selection of the correct nail and lag screw length is very important. Determination of the alignment of the femoral neck and head should be performed using fluoroscopy and/or designated gauges.
- Use of contrast media in patients with a known contraindication to contrast.
- If delivery of a bone void filler is required in an area adjacent to a joint, injection of 4cc of radiopaque contrast through the side port cannula is recommended to confirm the integrity of the articular surface. If the articular surface is not intact, delivery of bone void filler in that area is not recommended.
- Patients should be cautioned against significant load bearing prior to good callus formation. Patients who are either noncompliant, or predisposed to delayed union or non-union, must have auxiliary support.
- Periodic X-rays are recommended for at least six months to detect any changes in position, nonunion, loosening, bending or cracking of components.
- Patients should be cautioned that even after complete healing there is a higher risk for re-fractures while the nail is in position.
- Postoperative care and physical therapy should be structured to prevent excessive loading of the operated extremity.
- All implants and all instruments are provided non-sterile. All non-sterile implants and instruments must be sterilized prior to surgery in accordance with the Sterilization Section.
- Screws and hardware from other device manufacturers should not be combined with the Flow-Nail System.
- Flow-Nail implants should only be used for delivery of bone void fillers that have been validated for use with the device.

⚠ PRECAUTIONS/INSPECTION

- The Flow-Nail implants, the trocar-tipped guidewire and the side port cannula for the application of bone void filler are one-time use. The side port cannula and trocar-tipped guidewire will be disposed of in accordance with local requirements. The implants are intended to remain in the patient.
- The Flow-Nail Instrument set, with exception of the side port cannula trocar-tipped guidewire, is intended to be reusable and will be cleaned and sterilized in accordance with the Sterilization Section.
- The side port cannula should be examined for structural integrity before use.
- Proper handling and storage of the system components is mandatory. Damage or alterations may produce stresses and cause defects, which could become the focal point for failure.
- All implants and instruments must be inspected prior to use for any damage. Do not use if damage exceeds normal standards for implants and instruments.

MRI SAFETY INFORMATION

The Flow-FX Flow-Nail has not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of the Flow-FX Flow-Nail in the MR environment is unkown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.

ADVERSE EFFECTS

The adverse events include but are not limited to:

- Implants may migrate, cause pain or stress shield bone even after a fracture has healed.
- Pain, discomfort, nerve or soft tissue damage etc.
- Metal sensitivity or allergies.
- Trauma.
- A pulmonary embolism may result from using this hardware with an injectable bone void filler.

STERILITY

Implants

The Flow-FX implants are provided non-sterile.

Instruments

The Flow-FX instruments, are provided non-sterile.

Scope

These cleaning instructions apply to the reusable manual orthopedic surgical instruments used to prepare the bone and implant the Flow-Nail Trochanteric Nail implant set. The side port cannula and the trocar-tipped guidewires are single-use instruments and should be discarded after each use.

⚠ WARNINGS AND LIMITATIONS

Automated cleaning may not be effective. A thorough, manual cleaning process is recommended.

Cleaning agents with chlorine or chloride as the active ingredient are corrosive to stainless steel and must not be used. Enzymatic and cleaning agents with neutral pH are recommended.

Repeated processing, according to these instructions, has minimal effect on Flow-Nail reusable manual instruments. End of life is normally determined by wear and damage due to use.

INSTRUCTIONS AT POINT OF USE

Separate any nested instruments and disassemble any instruments that can be disassembled without using tools. Please refer to the surgical tray graphics for the expected state of disassembly.

In addition, the BVF gauge (101-71) shall be separated into two parts for cleaning and reassembled for sterilization. The separation is accomplished by completing the following procedure.

1. Extend the collar until the set screw is adjacent the 90 notch position.
2. Rotate the collar further clockwise (to the left when viewed from the notch position) until the set screw engages the collar release slot and is unable to rotate further.
3. Slide the collar out of the device.
4. Reassembly is accomplished by reversing the removal process.

Remove excess body fluids and tissue with a disposable, non-shedding wipe and cover with a damp cloth or submerge in a basin of sterile water. Body fluids and tissue should not be allowed to dry on instruments prior to cleaning.

CONTAINMENT/TRANSPORTATION

Universal precautions for handling contaminated/ biohazardous materials should be observed.

Instruments should be cleaned within 30 minutes of use to minimize the potential for drying prior to cleaning.

MANUAL CLEANING PROCEDURE

1. Prepare neutral pH enzyme and cleaning agents at the use-dilution and temperature recommended by the manufacturer.
2. Completely submerge the instrument in enzyme solution and allow it to soak for 20 minutes. Use a soft-bristled brush to gently clean the device (paying close attention to all threads, crevices and other hard-to-clean areas) until all visible soil has been removed. Any instruments with lumens or cannulas should be cleaned with a long, narrow, soft-bristled brush (i.e., pipe cleaner brush). The enzyme solution should be changed when it becomes grossly contaminated.
3. Remove the device from the enzyme solution and rinse in purified water (from one or any combination of the following processes: ultra-filter, RO, DI and/or distilled) for a minimum of 3 minutes. Thoroughly flush lumens, holes and other difficult to reach areas.
4. Prepare the neutral pH cleaning (detergent) solution and place in a sonication unit.
5. Completely submerge device in cleaning solution and

sonicate for 10 minutes, preferably at 45-50 kHz.

6. Rinse instrument in purified water (from one or any combination of the following processes: ultra-filter, RO, DI and/or distilled) thoroughly for at least 3 minutes or until there is no sign of blood or soil in the rinse stream.
7. Repeat steps 5 and 6 with freshly prepared cleaning solution until the instruments are thoroughly clean.
8. Dry instrument with a clean, disposable, absorbent, non-shedding wipe.

AUTOMATED CLEANING PROCEDURE

Automated washer/disinfector systems are not recommended as the sole cleaning method for complex surgical instruments. These instruments should be cleaned following the manual cleaning procedure above. An automated system may be used as a follow-up method but is not required.

Automated washer/disinfector systems are recommended for cleaning the Flow-Nail implants. For effective automated cleaning of the implant tray, remove the tray cover, remove the removable tray and place it in a covered wire basket and expose the bottom layer of the tray.

DISINFECTION

Disinfection is only acceptable as an adjunct to full sterilization for reusable surgical instruments. See sterilization section below.

INSPECTION/FUNCTION TESTING

1. Carefully inspect each instrument to ensure that there is no visible contamination and that all visible blood and soil has been removed. If visible contamination is evident, repeat the Manual Cleaning Procedure above.
2. Visually inspect for damage and/or wear, corrosion, pitting, discoloration or separation of parts. If there is any evidence of damage, do not use the instrument.
3. Check the action of moving parts (such as hinges and box-locks) to ensure smooth operation throughout the intended range of motion.
4. Check instruments with long slender features (particularly rotating instruments) for distortion.
5. When instruments form part of a larger assembly, check that the devices assemble readily with mating components.

INSPECTION/FUNCTION TESTING FAILURE

If an instrument fails inspection or a functional test due to improper cleaning, repeat the cleaning procedure. If the instrument continues to fail after repeated cleanings, discard the instrument.

If an instrument fails inspection or a functional test due to wear or damage, discard the instrument.

MAINTENANCE

Lubricate hinges, threads and other moving parts with a commercial water-based, surgical-grade instrument lubricant (such as instrument milk) to reduce friction and wear.

PACKAGING

1. Individually – a standard polyethylene/Tyvek (or equivalent) sterilization pouch of the appropriate size may be used for single instruments. Ensure that the pack is large enough to contain the instrument without stressing the seals or tearing the packaging.
2. InSets — sets of instruments may be loaded into dedicated instrument trays or general purpose sterilization trays for sterilization. If applicable, use standard medical-grade steam sterilization wrap following the AAMI wrap method (ANSI/AAMI ST79-2010).

STERILIZATION

The following steam sterilization method should be performed:

PROCEDURE	FRACTIONATED VACUUM PROCEDURE
Exposure Time	4 minutes
Temperature	132°C
Drying Time (Implant Tray)	30 minutes
Drying Time (Instrument Tray)	45 minutes

STORAGE

1. Sterile, packaged instruments should be stored in a designated, limited access area that is well ventilated and provides protection from dust, moisture, insects, vermin, and temperature and humidity extremes.
2. Sterile instrument packages should be examined closely prior to opening to ensure that there has been no loss of package integrity.

STORAGE INSTRUCTIONS

Implants should be stored at room temperature.

⚠ CAUTION

Federal law restricts this device to sale by or on order of a physician.

MANUFACTURER:

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