TALON™ DISTALFIX™ SLN-Nail Surgical Technique

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

ODi’s patented Talon Technology is the proven foundation for development of the Talon™ DistalFix™ Proximal Femoral Nail System. Having proven the effectiveness of a lag screw with integrated deployable Talons, our design team looked to improve the nail itself, which has undergone little innovation since cephalomedullary devices became popular in the latter portions of the 20th century. Subtle differences do exist among nail designs currently available (i.e. material, radius of curvature, set screw mechanism, proximal bend, distal tip design). Our team looked at all aspects of proximal femur fractures—from patient considerations to surgeon and OR staff concerns—when developing the Talon™ DistalFix™ Proximal Femoral Nail System.

The Talon™ DistalFix™ Proximal Femoral Nail System features an advanced distal fixation method with patented Talon Technology, which eliminates the use of cortical locking screws. The integral Talons deploy from within the medullary canal, making the “free hand” technique of locking screw placement a thing of the past. Patient safety is brought to a new level with a minimally invasive surgical technique that requires fewer incisions and may reduce patient time under anesthesia. Another benefit of the DistalFix™ system is a reduction in radiation exposure to the patient, surgeon, and OR staff.

At ODi our design team was charged with a simple goal: improve patient care. To that end, they developed a state-of-the-art proximal femoral nail system that enhances safety at every level. Coupled with easy to use instruments, the Talon™ DistalFix™ Proximal Femoral Nail System puts ODi one step closer to achieving its goal of perfecting fixation.

Luis Vega, MD
Clinical Director
Orthopedic Designs North America, Inc.
SLN—Nail — Design Features

Self-tapping dual lead thread requires fewer turns for implantation

Lag screw Talons, deployable to a diameter of 28mm, engage the cortical bone of the femoral head/neck junction to improve rotational control and resistance to cutout and provide unmatched compression

Tapered lag screw anti-rotation flats, narrower towards the threads, allows intra-operative compression to be maintained post-operatively while still permitting dynamic sliding

Nail Talons, deployable to a diameter of 38mm, reduce operative time, radiation exposure, number of incisions, and potential complications associated with locking screw placement

### Lag Screw

- **Lengths:** 70mm—120mm (5mm increments)
- **Thread Diameter:** 11.0mm
- **Root Diameter:** 8.2mm

### Standard Nail

- **Length:** 220mm
- **Proximal Diameter:** 15.5mm
- **Distal Diameter:** 11mm
- **Angles:** 120°, 125°, 130°
- **Lateral Bend:** 4°

### Long Nails

- **Lengths:** 300mm—420mm (20mm increments)
- **Proximal Diameter:** 15.5mm
- **Distal Diameter:** 11mm
- **Angle:** 125°
- **Lateral Bend:** 4°
- **Radius of Curvature:** 2m
- **Anteversion:** 10°

ALL TALONS ARE FULLY RETRACTABLE

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

Indications

The Talon™ DistalFix™ Proximal Femoral Nail’s primary indications are for fixation/stabilization of stable and unstable fractures of the proximal femur including:

- Intertrochanteric fractures,
- Pertrochanteric fractures,
- High subtrochanteric fractures (without shaft extension)
- Combinations of these fractures.
- The long nail allows the additional indication of low subtrochanteric fractures.

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

Contraindications

- Active local infection
- Metal sensitivity or allergic reaction to foreign bodies
- Loss of bone stock or insufficient bone quality to support the device
- Obliterated medullary canal
- Comminuted fractures
- Fractures of the distal third
- Femoral neck fractures

Precautions

The Talon™ DistalFix™ Proximal Femoral Nail System has not been evaluated for safety and compatibility in the MR environment. The Talon™ DistalFix™ Proximal Femoral Nail System has not been tested for heating or migration in the MR environment.
Patient Positioning

The patient should be placed in the supine or lateral decubitus position according to surgeon preference on a fracture or other radiolucent table. Ensure you have ample space for the image intensifier for visualization of the proximal femur in both the AP and lateral planes. Centering the axis of rotation of the image intensifier on the femoral neck of the affected hip will ensure that AP and lateral views of the proximal femur can be easily obtained.

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

An attempt at a closed reduction should be made prior to prepping and draping the patient. Reduce the fracture as anatomically as possible.
Instruments for Accessing the Canal

- Tissue Protector
  SLN-T17

- Curved Entry Awl
  SLN-T16

- Guide Wire Obturator
  SLN-T32
  (Special Order Instrument)

- T-Handle Pin Puller
  (Universal Chuck)
  THN-T03

- Trocar Tip Guide Wire 3.0mm x 600mm
  SLN-T35

- Ball Tip Sheathed Guide Wire
  SLN-T41

- Proximal Reamer
  SLN-T19

- Exchange Tube
  SLN-T44
**Determine the Starting Point**

The entry point for the nail is in line with the medullary canal in the lateral view. This should be at the junction of the anterior one-third and posterior two-thirds of the greater trochanter. In the AP view, the 4˚ lateral bend of the proximal nail pushes the entry point slightly lateral to the tip of the greater trochanter.

**Accessing the Canal**

**Option 1—Standard Method:** Make a longitudinal incision proximal to the greater trochanter. Dissect down through the incision separating muscle fibers longitudinally until the greater trochanter can be palpated. Insert the Tissue Protector with Guide Wire Obturator (special order instrument) through the incision and down to the bone.

Pass a 3.0mm Trocar Tip Guide Wire through the Guide Wire Obturator and into the proximal femur either with a powered driver or universal chuck. The guide wire should be centered in the canal on the lateral view and intersect the center of the canal just beyond the lesser trochanter on the AP view. Confirm the position of the guide wire in both the AP and lateral planes. Withdraw the guide wire and reposition as necessary.
Accessing the Canal (continued)

Option 2—Percutaneous Method: With the 3.0mm Trocar Tip Guide Wire connected to either a powered driver or a universal chuck, puncture the skin proximal to the greater trochanter. Advance the guide wire until reaching the greater trochanter. Drive the guide wire through the starting point and into the proximal femur. Confirm the position of the guide wire in both the AP and lateral planes. Withdraw the guide wire and reposition as necessary.

With the guide wire in place, make a longitudinal incision through the puncture site. Follow the guide wire with the scalpel down to the greater trochanter, separating the muscle fibers longitudinally. Pass the Tissue Protector with Guide Wire Obturator (special order instrument) over the guide wire and through the incision down to the bone.

Option 3—Entry Awl Method: Make a longitudinal incision proximal to the greater trochanter. Dissect down through the incision separating muscle fibers longitudinally until the greater trochanter can be palpated. Insert the Curved Entry Awl through the incision and down to the bone. Rotate the awl back and forth to penetrate the bone, then pass a Ball Tip Sheathed Guide Wire through the awl with the universal chuck. If the trajectory of the wire is not correct, withdraw it and reposition as necessary.

Pass the Tissue Protector with Guide Wire Obturator (special order instrument) over the guide wire and through the incision down to the bone.
Proximal Reaming

Remove the Guide Wire Obturator from the Tissue Protector. Connect the cannulated Proximal Reamer to a powered driver and pass over the guide wire and through the Tissue Protector. Ream the proximal femur to the desired depth.

There are two corresponding sets of grooves on the cutter head and reamer shank that indicate depth. The grooves on the cutter head can be read radiographically as they pass into the greater trochanter. Optionally, the grooves on the shank can be read as they pass the proximal end of the tissue protector. These grooves correspond to the three End Cap sizes—flush, +5, and +10.

The minimum recommended reaming depth is to the first groove.

If the Trocar Tip Guide Wire was used to access the medullary canal, it should now be exchanged for the Ball Tip Sheathed Guide Wire by way of the disposable Exchange Tube. Optionally, the Guide Wire Introducer (special order instrument) can be used if a more rigid instrument is needed for wire exchanges.

Note: A traditional ball tip guide wire, without a sheath, is available for distal reaming if the sheathed version is not desired. The traditional ball tip guide wire, however, will not pass through the nail cannulation and will need to be exchanged for a smooth guide wire after distal reaming but prior to nail insertion.
Instruments for Preparing the Canal

Radiographic Talon Template
SLN-T09

Folding Nail Guide Wire Ruler
SLN-T37

Ball Tip Sheathed Guide Wire
SLN-T41

Tissue Protector
SLN-T17

Modular Flexible Reamer Shaft
SLN-T01

Modular Reamer Cutter Head
SLN-T02-XXX

Guide Wire Pusher
SLN-T40
**Determine Nail Length**

**Option 1—Wire Method:** With a Ball Tip Sheathed Guide Wire in the canal, place the Radiographic Talon Template on the thigh to determine the length of the longest nail recommended for the given patient. The Talons span a distance of 38mm across when fully deployed.

*The Radiographic Talon Template provides an approximation of maximum Talon deployment.* Position the template such that all four points reside in cortical bone. The distal edge of the template (opposite the graduations) indicates the tip of the nail. Withdraw or advance the guide wire until its tip is even with the distal edge of the template.

Open the Folding Nail–Guide Wire Ruler and slide it over the guide wire and through the Tissue Protector until the foot abuts the greater trochanter. Read the suggested nail length measurement at the end of the guide wire. This reading indicates the longest nail recommended for the given patient.

Note that this measurement is a direct reading to the distal tip of the guide wire. A fracture that is not properly reduced may result in an artificially high or low measurement. Actual nail length is determined by the surgeon.
Option 2—Radiographic Method:
Confirm that the fracture is well reduced and place the Radiographic Talon Template on the thigh to determine the length of the longest nail recommended for the given patient. The Talons span a distance of 38mm across when fully deployed. The Radiographic Talon Template provides an approximation of maximum Talon deployment.
Position the template such that all four points reside in cortical bone. The distal edge of the template indicates the tip of the nail. Move the image intensifier to the proximal femur and read the measurement radiographically at the tip of the greater trochanter.

The depth of insertion of the guide wire is not relevant in this method.

Note that a fracture which is not properly reduced may result in an artificially high or low measurement. Actual nail length is determined by the surgeon.
Distal Reaming (optional)

Using the image intensifier, ensure that fracture reduction has been maintained to this point. Place the 9mm Modular Cutter Head on the Flexible Reamer Shaft and pass over the guide wire. Advance the reamer with steady pressure to the desired depth.

Back the reamer out, using the Pin Pusher to keep the guide wire in place. Place the end of the guide wire in the dimple of the black cap of the Pin Pusher and withdraw the reamer until the drill contacts the cap. Then flip the Pin Pusher such that the wire portion passes through the cannulation of the drill/reamer shaft and continue withdrawing the reamer. Exchange the cutter head for the next largest size and repeat. If the guide wire sheath is removed with the reamer, advance it back down the canal prior to the next reamer pass.

It is recommended that reaming begin with the 9mm cutter head. The canal should be reamed to at least 1mm larger than the nail diameter of 11mm. Modular Cutter Heads range in size from 9mm to 13mm in 0.5mm increments. Step up in 1mm increments until chatter begins, then proceed in 0.5mm increments to minimize risk of thermal necrosis.

NOTE: DISTAL REAMING SHOULD ALWAYS BE DONE WITH THE GUIDE WIRE SHEATH IN PLACE OR OVER A TRADITIONAL BALL TIP GUIDE WIRE.
Instruments for Nail Assembly and Insertion

Guide Handle  
SLN-T03-02

Guide Arm  
SLN-T03-01

Guide Arm Connector Screw  
SLN-T03-03

Nail-Guide Connector Screw  
SLN-T03-04

Guide Arm Lock  
SLN-T03-05

Lag Guide Pin Placement Aid  
SLN-T03-06

Handle-Arm Connector Screw  
SLN-T03-03

7mm Hex Driver  
SLN-T15

Ratcheting Axial Handle  
SLN-T04

Lag Guide Sleeve  
SLN-T23

Ball Tip Sheathed Guide Wire  
SLN-T41

Lag Alignment Plug with Drill Stop  
SLN-T31/SLN-T29

Slotted Slap Hammer  
SLN-T07  
(Special Order Instrument)

Impactor  
SLN-T45 or ODI-U03

Guide Wire Pusher  
SLN-T40
Assemble the Targeting Guide

Mate the radiolucent Guide Arm to the Guide Handle with the Handle-Arm Connector Screw and tighten using the 7mm Hex Driver (shown with the Torque-Limiting T-Handle). This connection should be as tight as possible.

Place the Lag Guide Pin Placement Aid into the channel grooves at the top of the Guide Arm and verify they pass through the Guide Handle.

Insert the Guide Arm Lock into the bottom of the Guide Arm and engage the screw. Do not tighten at this time.

The 7mm Hex Driver may feature a flexible section. See Page 38 for proper usage.

Note, text on Guide Arm shown in white for effect.
Attach the Nail

Mate the desired nail to the guide assembly with the Nail–Guide Connector Screw and secure using the 7mm Hex Driver (shown with the Torque-Limiting T-Handle). Take care to align the corresponding reference lines on the nail and Guide Handle. This connection should be as tight as possible.

Verify proper alignment of the nail and guide assembly by inserting the Lag Guide Sleeve through the corresponding targeting hole in the Guide Arm. Advance the guide sleeve to contact the nail and tighten the Guide Arm Lock. Insert the Lag Alignment Plug and make sure that it passes through the nail properly. If misaligned, confirm the sleeve is passing through the appropriate hole in Guide Arm. If so, loosen the connection between the handle and the nail. Align the nail with the aid of the Lag Alignment Plug and re-tighten the connection between nail and handle.

Once well aligned, loosen the Guide Arm Lock and remove the Guide Sleeve and Lag Alignment Plug in preparation for nail insertion.
NOTE: PRIOR TO NAIL INSERTION, REMOVE THE SHEATH FROM THE GUIDE WIRE. THE INNER WIRE WILL PASS THROUGH THE NAIL. USE THE PIN PUSHER TO KEEP THE INNER WIRE IN PLACE DURING SHEATH REMOVAL. IF A TRADITIONAL BALL TIP GUIDE WIRE WAS USED, IT MUST BE EXCHANGED FOR A SMOOTH GUIDE WIRE PRIOR TO NAIL INSERTION.

Pass the nail over the guide wire and through the incision. Hold the targeting arm vertically as you enter the proximal femur. While applying gentle pressure, advance the nail down the femur while rotating the targeting arm down. This maneuver will aid in inserting the nail.

An Impactor can be attached to the Guide Handle and struck with the Slotted Slap Hammer (special order instrument), if necessary. If considerable resistance is encountered, remove the nail and enlarge the canal through distal reaming.

NOTE: DO NOT DIRECTLY STRIKE THE GUIDE ARM WITH THE SLAP HAMMER OR ANY OTHER MALLET.

With the nail inserted, remove the guide wire.
Instruments for Preparing the Femoral Head

- Lag Guide Sleeve
  SLN-T23

- Lag Guide Pin Obturator
  SLN-T22

- Knob Wrench
  SLN-T11

- Lag Guide Pin 2.4mm x 550mm
  SLN-T42

- Lag Screw Guide Pin Ruler
  SLN-T18

- Lag Drill
  SLN-T28

- Lag Drill Stop
  SLN-T29

- Guide Wire Pusher
  SLN-T40
Place the Guide Pin

With the image intensifier positioned for an AP view, use a straight edge to approximate the necessary nail insertion depth for a guide pin to be slightly inferior of center. Adjust the nail depth accordingly then remove the Impactor, if attached. Insert the Lag Guide Pin Obturator into the Lag Guide Sleeve, introduce the assembly through the corresponding hole in the Guide Arm, and advance to the level of the skin. Make a small stab incision at the tip of the assembly and pass through the skin. Continue to advance the guide sleeve and obturator until the tip contacts the lateral cortex of the femur. Verify radiographically that the sleeve is in contact with the femoral cortex and tighten the Guide Arm Lock. The Knob Wrench or 7mm Hex Driver can be used to tighten the Guide Arm Lock, if necessary.

**NOTE:** THE GUIDE ARM LOCK MUST BE TIGHTLY SECURED SO AS NOT TO MOVE DURING THE CASE.

**Note:** The position of the Guide Arm Lock may prevent passage of the guide sleeve. Passage may be obstructed if the screw is engaged too much or not enough. For unobstructed passage, position the Guide Arm Lock so that it is flush with, or slightly protruding from, the end of the Guide Arm. The sectioned view shows the holes unobstructed in this position.
Position the image intensifier for a lateral view of the proximal femur and extend the Lag Guide Pin Placement Aid (a.k.a. goal posts). The goal posts will aid in establishing the correct version for the nail without trial and error. When a good lateral view is obtained, rotate the Guide Arm until the goal posts overlap and appear as one—this is the true trajectory of a pin placed with the arm in that orientation.

Insert the 2.4mm x 550mm Lag Guide Pin through the Obturator. Apply steady pressure to advance the guide pin through the lateral cortex of the femur. The ideal position of the guide pin is slightly inferior of center on the AP view and centered on the lateral view. The pin should be advanced into the subchondral bone of the femoral head to within 3–6mm of the joint space radiographically.

**NOTE:** THE POSITION OF THE GUIDE PIN IS OF CRITICAL IMPORTANCE, AS IT WILL DETERMINE THE ULTIMATE POSITION OF THE LAG SCREW. REPOSITION IF NECESSARY.
Measure Guide Pin Depth

Withdraw the Lag Guide Pin Obturator slightly and place the foot of the Lag Screw Guide Pin Ruler against the green knob of the Lag Guide Sleeve, saddling the obturator shaft. Read the depth of the guide pin (approximately 105mm in this illustration).

NOTE: THE RULER IS CALIBRATED TO THE TIP OF THE GUIDE PIN. ACTUAL DRILLING DEPTH AND LAG SCREW SIZE ARE AT THE DISCRETION OF THE SURGEON.

Drill for Lag Screw

Connect the Lag Drill to a powered driver and set the Lag Drill Stop to the desired depth by way of the reference window. The drill stop can be oriented in either direction. Confirm that the Guide Arm Lock is tightly secured.

Remove the obturator from the sleeve and pass the Lag Drill over the guide pin. Advance the Lag Drill with gentle pressure. As the Drill Stop approaches the knob of the sleeve, monitor the lag drill’s depth radiographically with the image intensifier. The drilling depth set with the Drill Stop is reached when the Drill Stop contacts the guide sleeve. Drilling depth is at the discretion of the surgeon and may be stopped short of the depth set by the Drill Stop.

Use the Pin Pusher to ensure the guide pin remains in the femoral head when removing the Lag Drill.
Instruments for Nail Talon Deployment

Torque Limiting Handle
SLN-T05

Lag Alignment Plug with Drill Stop
SLN-T31/SLN-T29

Nail Talon Driver—Short, Rigid
SLN-T20-S-R

Nail Talon Driver
SLN-T20-L-R or ODI-U09
Place the Lag Alignment Plug

Set the Lag Alignment Plug insertion depth by way of its drill stop. The depth setting should correspond with the depth drilled in the previous step. The stop can be oriented in either direction. Pass the Lag Alignment Plug over the guide pin and through the sleeve. The plug will pass through the lag screw hole in the nail and maintain the nail’s position as the distal nail Talons are deployed. Advance the plug until the drill stop contacts the sleeve.

Once inserted, rotate the T-handle until it is parallel with the Guide Arm. This will orient the slots in the plug to allow passage of the Nail Talon Deployment Driver.

Remove the guide pin to allow passage of the Nail Talon Deployment Driver.
Deploy Nail Talons

Attach the Nail Talon Deployment Driver to the Torque-Limiting Handle and pass the deployment driver down the nail. The guide pin must be removed to allow passage down the nail. If the driver will not advance, withdraw the plug slightly until it does. Advance the driver until engaging the distal nail Talons.

The Nail Talon Deployment Driver may feature a flexible section. See Page 38 for proper usage.

Turn the driver clockwise to deploy the Talons.

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

A consistent low resistance/torque should be felt during deployment until the cortex is reached. A sudden increase in resistance/torque marks cortical contact. For long nails, monitor the deployment progress with the image intensifier positioned for a lateral view of the distal femur once cortical contact is made. Continue deploying until the torque limiting handle trips or you are radiographically indicated to stop (i.e. excessive cortical penetration).

The extent of Talon deployment varies by location in the femur—less in the shaft than in the metaphysis.

TALONS SHOULD NEVER BE DEPLOYED USING A POWERED DRIVER.
Instruments for Lag Screw Insertion and Lag Screw Talon Deployment

- Lag Driver
  SLN–T30
- Lag Driver Compression Knob
  SLN–T30–03
- Lag Driver Connector Screw
  SLN–T24
- 5mm Hex Driver
  SLN–T14
- T-Handle Pin Puller (Universal Chuck)
  THN–T03
- Torque Limiting Handle
  SLN–T05
- Ratcheting Axial Handle
  SLN–T04
- Lag Talon Deployment Driver
  SLN–T12
- Knob Wrench
  SLN–T11
Connect the Lag Screw and Lag Driver

Pass the Lag Driver Connector Screw through the Lag Driver. Mate the chosen lag screw with the driver and secure by tightening the connector screw.

Set the Lag Driver Compression Knob

The Lag Driver Compression Knob sets the relative depth at which the lag screw will be placed. If the lag screw size matches the depth that was drilled (i.e. drilled to 95mm and are placing a 95mm lag screw), the indicator would be set to “0”.

If a smaller lag screw than what was drilled is being used, so as to be able to apply compression across the fracture, the indicator should be set to the difference between the depth drilled and lag screw size chosen (i.e. if 100mm was drilled and a 95mm lag screw is being used, the indicator should be set at “+5” [100mm−95mm]).
Insert the Lag Screw

Pass the lag screw and driver assembly over the guide pin and through the sleeve. Slide the assembly until resistance is met. Advance the lag screw by turning the driver clockwise and applying steady pressure. Once the lag screw threads engage the bone, the assembly should advance itself with continued turning. When the Lag Driver Compression Knob contacts the sleeve the lag screw is fully inserted.

Note that in order to align the anti-rotation flats of the lag screw with the integrated set screw, the Lag Driver handle must be PARALLEL or PERPENDICULAR to the Guide Arm.

Verify the final lag screw position radiographically.

Remove the guide pin with the T-Handle Pin Puller (universal chuck).
Engage the Set Screw

With the Lag Driver handle positioned parallel or perpendicular to the targeting arm, connect the 5mm Hex Driver to the Torque-Limiting Handle. Introduce the 5mm Hex Driver through the proximal end of the nail to adjust the integrated set screw. Turn the driver clockwise until it contacts the lag screw. Do not aggressively tighten at this time.

The 5mm Hex Driver may feature a flexible shaft. See Page 38 for proper usage.

Deploy Lag Screw Talons

Connect the Lag Talon Deployment Driver to the Ratcheting Axial Handle and introduce it through the Lag Driver until contact is made with the Talons. Do not thrust the driver in forcibly as this may damage the threads. Turn the driver clockwise to deploy the Talons. Deployment begins once resistance is felt and full deployment requires approximately 15 complete turns of the driver.

NOTE: TALONS NEED NOT BE FULLY DEPLOYED. AT SURGEON’S DISCRETION, DEPLOYMENT CAN BE STOPPED AT ANY TIME. TALONS ARE DESIGNED TO PENETRATE THE CORTICAL BONE AT THE JUNCTION OF THE FEMORAL HEAD AND NECK. CARE SHOULD BE TAKEN TO AVOID PENETRATION OF THE TALONS THROUGH THE WEIGHT-BEARING SURFACE OF THE FEMORAL HEAD. TALONS SHOULD NEVER BE DEPLOYED USING A POWERED DRIVER.
Apply Compression (optional)

RELEASE TRACTION ON THE LEG PRIOR TO APPLYING COMPRESSION ACROSS THE FRACTURE.

To apply interfragmentary compression, first disengage the set screw by turning the 5mm Hex Driver 1/4 turn counter-clockwise (1). This will allow the lag screw to slide but not rotate.

With the set screw disengaged, use the Knob Wrench to rotate the Lag Driver Compression Knob clockwise (2). As the compression knob turns, the Lag Screw/Lag Driver assembly is pulled back, thus closing any gap and applying compression.

If the Lag Driver Compression Knob was set to “0”, then 5mm of compression can be applied. If it was set to “+5”, then 10mm of compression can be applied. If set to “+10”, 15mm of compression can be applied.

Monitor compression with the image intensifier. Over-compressing may lead to Talon deformation.
Set the Lag Screw Fixation Type

Whether compression is applied or not, the type of lag screw fixation—fixed or sliding—must be set by means of the Set Screw.

**Option 1—Fixed:** The fixed lag screw position does not allow for rotation or sliding. It is achieved by turning the 5mm Hex Driver clockwise until the Set Screw is fully tightened against the lag screw anti-rotation flat.

**Option 2—Sliding:** The sliding lag screw position allows free lateral sliding of the lag screw while preventing rotation. The design of the anti-rotation flats is such that the Set Screw prevents medial migration of the lag screw. This also means that any intra-operative compression that is applied can be maintained post-operatively while preserving the ability to further compress as the patient bears weight. To position the Set Screw to allow for sliding, turn the 5mm Hex Driver clockwise until a firm stop is felt. This firm stop is the set screw contacting the lag screw flat. This contact between the set screw and lag screw will allow lateral sliding with weight bearing, but will prevent the lag screw from translating medially.
Release Lag Screw and Remove Sleeve

With the fixation set, release the lag screw from the Lag Driver by turning the Lag Driver Connector Screw counterclockwise. Use the 5mm Hex Driver, if necessary. Withdraw the Lag Driver from the sleeve.

Loosen the Guide Arm Lock and remove the sleeve. Use the 7mm Hex Driver (shown) or Knob Wrench to release the Guide Arm Lock, if necessary.
Remove the Targeting Guide

With the 7mm Hex Driver connected to the Ratcheting Axial Handle, insert the driver into the Guide Handle and turn counterclockwise to loosen the Nail–Handle Connector Screw, releasing the nail from the targeting guide.

Insert End Cap (optional)

Secure the End Cap onto the 5mm Hex Driver. The 5mm Hex Driver is designed to lock on to the End Cap ensuring it does not disengage from the driver. Pass the End Cap through the incision and mate it to the proximal end of the nail. Turn the driver clockwise to tighten the End Cap in place.
Instruments for Explantation

- Lag Talon Retractor Driver
  SLN–T13
- Lag Driver
  SLN–T30
- Lag Driver Connector Screw
  SLN–T24
- Ratcheting Axial Handle
  SLN–T04
- 5mm Hex Driver
  SLN–T14
- Lag Alignment Plug
  with Drill Stop
  SLN–T31/SLN–T29
- Lag Guide Pin 2.4mm x 550mm
  SLN–T42
- Slotted Slap Hammer
  SLN–T07
  (Special Order Instrument)
- Torque Limiting Handle
  SLN–T05
- Nail Talon Driver
  SLN–T20–L–R or ODI–U09
- Nail Talon Driver—Short, Rigid
  SLN–T20–S–R
- Impactor/Extractor
  SLN–T27
- Impactor/Extractor
  SLN–T27
**Attach the Lag Driver**

Pass a 2.4mm x 550mm Lag Guide Pin through the lag screw to clear any debris. Use the guide pin to direct the Lag Driver and Lag Driver Connector Screw to the end of the lag screw. Mate the Lag Driver to the lag screw.

Remove the Lag Guide Pin.

---

**Retract Lag Screw Talons**

Connect the Lag Talon Retractor Driver to the Ratcheting Axial Handle. With the Lag Driver connected to the lag screw, pass the Lag Talon Retractor Driver through the Lag Driver and engage the threads in the lag screw by turning in a clockwise direction. Continue to turn clockwise until the talons are fully retracted, approximately 24 full turns.

Alternatively, Talons can be retracted using either the Deployment Driver or a 3.0mm pin. Insert the Deployment Driver or pin into the lag screw (thread in driver 2 turns). Lightly tap with a mallet to retract the Talons.

Confirm complete Talon retraction radiographically.
Remove End Cap & Disengage Set Screw

Attach the 5mm Hex Driver to the Ratcheting Axial Handle. Engage the End Cap and turn counterclockwise to remove.

Take care not to lose the End Cap in the soft tissue.

Engage the Set Screw and turn counterclockwise two full turns to clear the lag screw.

Remove Lag Screw

Turn the Lag Driver counterclockwise to remove the lag screw.
Retract Distal Nail Talons

Select the Lag Alignment Plug and pass it through the lag screw hole in the nail. The T-handle must be oriented in the coronal plane (i.e. parallel to the floor) to allow passage of the Nail Talon Deployment Driver. The plug will prevent nail rotation while retracting the distal nail Talons.

Attach a rigid Nail Talon Deployment Driver to the Torque Limiting Handle and pass the driver down the nail until it engages the distal nail Talons. Turn the handle counterclockwise to retract the Talons. If fully deployed, it will take approximately 18 full turns for complete retraction.

Confirm complete Talon retraction radiographically.

Remove Nail

Select the Impactor/Extractor and thread it on to the proximal end of the nail by turning it clockwise until fully engaged. If necessary, pass a guide wire down the nail and use it to guide the Impactor/Extractor to the nail head.

Use the Slotted Slap Hammer (special order instrument) to extract the nail, as needed.
Proper Flex Shaft Usage

The Nail Talon Deployment Driver, 5mm Hex Driver, and 7mm Hex Driver are available, upon request, with an integral flexible section. That flexible section can deliver enough torque to trip the Torque-Limiting Handle when held STRAIGHT. The more the shaft is flexed, the less torque it can deliver before permanently deforming.

IT IS IMPERATIVE FOR THE CONTINUED FUNCTIONALITY OF THE INSTRUMENT THAT THE SHAFT BE RETURNED TO A STRAIGHT ORIENTATION WHEN SIGNIFICANT RESISTANCE IS FELT.

LOW TORQUE / MINIMAL RESISTANCE

HIGH TORQUE / SIGNIFICANT RESISTANCE

ALL DRIVERS FEATURING A FLEXIBLE SHAFT SECTION ARE AVAILABLE IN A RIGID VERSION.
### TALON DISTALFIX™ SLN—Nail — Implants

<table>
<thead>
<tr>
<th>Catalog Number</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>SLN-011-070</td>
<td>Lag Screw — Ø11mm x 70mm</td>
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<tr>
<td>SLN-011-075</td>
<td>Lag Screw — Ø11mm x 75mm</td>
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<tr>
<td>SLN-011-080</td>
<td>Lag Screw — Ø11mm x 80mm</td>
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<td>SLN-011-085</td>
<td>Lag Screw — Ø11mm x 85mm</td>
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<td>Lag Screw — Ø11mm x 120mm</td>
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<tr>
<td>SLN-155-000</td>
<td>End Cap — Ø15.5mm x Flush</td>
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<td>SLN-155-005</td>
<td>End Cap — Ø15.5mm x 5mm</td>
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<td>SLN-155-010</td>
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<td>SLN-120-220</td>
<td>Short Nail — 220mm x 120° Universal</td>
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<td>Radiographic Talon Template</td>
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<td>SLN-T11</td>
<td>Knob Wrench</td>
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<td>SLN-T12</td>
<td>Lag Talon Deployment Driver</td>
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<td>Lag Talon Retractor Driver</td>
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## TALON DISTALFIX™ SLN-Nail — Instruments

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<td>Guide Wire Introducer (Special Order)</td>
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<td>Lag Guide Sleeve</td>
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<td>Lag Alignment Plug</td>
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<td>Guide Wire Obturator (Special Order)</td>
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## TALON DISTALFIX™ SLN-Nail — Instruments

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<td>SLN-T41</td>
<td>Ball Tip Sheathed Guide Wire</td>
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<td>SLN-T44</td>
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<td>T-Handle Pin Puller (Universal Chuck)</td>
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<td>SLN-T50</td>
<td>Instrument Tray</td>
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Important Medical Information

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

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

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

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

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

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

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

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

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

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

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

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

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

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

10. Implants are provided sterile and should be stored unopened in their protective packaging. Inspect packages for damage prior to surgery. Instruments should be cleaned between each surgical procedure in accordance with AAMI-TIR12 2010 or similar method. Prior to use instruments should be steam sterilized after removal of any non-autoclavable protective packaging and labeling, using the following parameters:

<table>
<thead>
<tr>
<th>Method</th>
<th>Cycle</th>
<th>Temperature</th>
<th>Exposure Time</th>
<th>Minimum Dry Time*</th>
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<tbody>
<tr>
<td>Steam</td>
<td>Gravity</td>
<td>250°F (121°C)</td>
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<td>Steam</td>
<td>Gravity</td>
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<td>Steam</td>
<td>Prevacuum</td>
<td>270°F (132°C)</td>
<td>10 minutes</td>
<td>30 minutes</td>
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*Refers to in chamber dry time. Please note that dry times may vary due to differences in the user's packaging materials, environmental conditions, steam quality, device materials, total mass, sterilizer performance and varying cool down time. The user should employ verifiable methods (e.g. visual inspections) to confirm adequate drying. It is the user's responsibility to validate the appropriate drying time with the sterilization equipment and sterilization load used.

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

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Tampa, FL 33610 USA
Phone: (888) 635-8535       Fax: (888) 632-8047
www.odi-na.com

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