Phoenix Retrograde Femoral Nail System

Featuring CoreLock Technology

- Each nail features CoreLock Technology, a preassembled embedded locking mechanism that allows four distal screws to be mechanically locked to provide enhanced distal femoral fixation.

- Distal screws can be removed without disengaging the embedded setscrew since the holes within the setscrew are grooved.
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Introduction

The Phoenix Retrograde Femoral Nail System features CoreLock Technology, a preassembled, embedded locking mechanism that allows the four distal screws (2 transverse and 2 oblique) to be mechanically locked to provide enhanced distal femoral fixation. This universal retrograde femoral nail is composed of titanium alloy that incorporates a 1.8m radius of curvature and a 5° distal bend, that is initiated at 45mm from the driving end. Nails are available in outer diameters of 9mm, 10.5mm, 12mm and 13.5mm for applications in a wide variety of patients in lengths of 240mm-460mm in 20mm increments. Additionally, the system features a strong, lightweight Radiolucent Targeting Arm that permits radiographic visualization in multiple planes and allows for accurate transverse and/or oblique targeting. With its easy to use color-coded instrumentation conveniently contained in a single tray and its innovative implant design, the Phoenix Retrograde Femoral Nail System is designed to address both patient and surgeon needs.

This material represents the surgical technique utilized by Michael S. Sirkin, M.D., Cory A. Collinge, M.D. and Kenneth J. Koval, M.D. Biomet does not practice medicine. The treating surgeon is responsible for determining the appropriate treatment, technique(s), and product(s) for each individual patient.
Indications and Contraindications

INDICATIONS

Phoenix Femoral Nail System
These devices are to be implanted into the femur for alignment, stabilization and fixation of fractures caused by trauma or disease, and the fixation of femurs that have been surgically prepared (osteotomy) for correction of deformity, and for arthrodesis.

CONTRAINDICATIONS

1. Infection.
2. Patient conditions including blood supply limitations, and insufficient quantity or quality of bone.
3. Patients with mental or neurologic conditions who are unwilling or incapable of following postoperative care instructions.
4. Foreign body sensitivity. Where material sensitivity is suspected, testing is to be completed prior to implantation of the device.
Design Features

NOTE: Views are not to scale and should be used for reference only.
The Phoenix Retrograde Femoral Nail features CoreLock Technology, a preassembled embedded locking mechanism that allows the four distal screws to be mechanically locked to provide enhanced distal femoral fixation.

Since the holes within the embedded setscrew are grooved, distal screw removal can be achieved without disengaging the embedded setscrew.

Nail diameters and length:
- 9mm, 10.5mm, 12mm and 13.5mm
- Offered in lengths ranging from 240mm - 460mm (20mm increments)
- Distal diameter for 9mm, 10.5mm, and 12mm nails is 12mm
- Distal diameter for 13.5mm nail is 13.5mm
5mm Double-Lead Thread Screws
- Composed of Titanium Alloy
- Features a double-lead thread design for quick insertion
- Self-tapping tip
- Interior of 5mm cortical screw head is threaded for secure retention to inserter
- Threads are close to screw head and screw tip for better bicortical purchase
- Color-coded light green

5mm Screw Lengths:
- 20mm – 60mm (Available in 2mm increments)
- 65mm – 110mm (Available in 5mm increments)

End Caps
3.5mm Inserter Connector retains head of end cap to facilitate easier insertion. End Caps offered in 0mm, 5mm, 10mm, 15mm and 20mm sizes.
Surgical Technique

Step 1. Patient Positioning And Preparation

Place the patient supine on a radiographic surgical table. Support the affected limb with a radiolucent triangle to a 45 degree angle. Underside of table should be free to navigate a C-arm freely distally and proximally up to the intertrochanteric region for AP and lateral x-rays. Try to reduce the fracture as best as possible before starting procedure. Distraction may be maintained by a distraction device. Alternatively, hang the affected limb over the end of the surgical table and place the unaffected limb and a support device out 45 degrees from the midline. Prior to nail insertion, intra-articular fragments should be reduced and secured with interfragmentary screw fixation. While securing the fragments, care should be taken to keep in mind the path of the nail.

Step 2. Incision

Incise a 3-4cm midline incision from the inferior border to the patella. Next, perform a medial parapatella capsular incision and retract the patellar tendon laterally. Articular cartilage should be visualized to allow for irrigation and removal of reaming debris. Alternatively, the patella tendon can be split.
Step 3. Entry Point

The entry point is located in the intercondylar notch anterior and lateral to the femoral attachment of the posterior cruciate ligament.

Insert the Entry Trocar (Catalog #14-442098) into the Working Channel Soft Tissue Sleeve (Catalog #41029). A 3.2mm x 460mm COCR Threaded Tip Guide Wire (Catalog #14-441054) is placed through the trocar assembly and advanced into the distal femoral metaphysis, verified with AP and lateral radiographs. Remove the Entry Trocar.

AP view of guide wire inserted

Lateral view of guide wire inserted
Surgical Technique (Continued)

Step 4. Opening The Medullary Canal

Alternatively, a Curved Cannulated Awl (Catalog #41026) attached to a Modular T-Handle, Non-Ratcheting (Catalog #29407) can be used to obtain the entrance portal.

If desired, the 4.3mm Trocar Interlock (Catalog #14-442014) can be inserted through the cannulation of the Curved Cannulated Awl, to provide an impact surface and help prevent penetration of bone debris into the awl.

Advance the 12.2mm One-Step Reamer (Catalog #14-442002) through the Working Channel Soft Tissue Sleeve, over the Threaded Tip Guide Wire to enlarge the entry side and drill until entering the canal.

NOTE: The one-step reamer has a groove on the cutting flutes to indicate, under radiographic visualization, the proper depth to accommodate the distal outer diameter of the nail.
Step 5. Fracture Reduction And Guide Wire Placement

Fracture reduction is performed manually, with use of radiograph images to aide with positioning. If the canal is to be reamed, a 3.0mm x 98cm Bead Tip Guide Wire (Catalog #27922) is inserted into the intramedullary canal and advanced past the fracture site, into the proximal femur. Confirm position of Guide Wire to be center – center in the AP and lateral views.

To help facilitate Guide Wire passage through the fracture site, the Keyless Chuck T-Handle (Catalog #14-442078) can be used.
In the case of a non-union, where the path to the canal is blocked and unlikely to advance a guide wire or entry reamer across the fracture site, a Pseudarthrosis Pin Straight (Catalog #14-442073) or Curved (Catalog #14-442074) can be used to create an opening for the passage of a guide wire for canal reaming.

In the event of a difficult fracture reduction, the 8.5mm Fracture Reducer (Bowed) (Catalog #14-442068) can be used to facilitate Guide Wire insertion and fracture reduction. In patients with tight canals, reaming to 9.5mm may help facilitate passage of reducer.
Step 6. Determining Nail Length

A second Guide Wire of equal length can be used to measure the length of the medullary canal or a Medullary Canal and Length Estimator (Catalog #14-442075) can be used to determine nail diameter and length. The appropriate nail length should be inserted passed Blumensaat’s Line and usually approximating 1cm proximal to the lesser trochanter. The 98cm Telescoping Nail Measuring Gage (Catalog #14-440067) is placed over the 3.0 Bead Tip Guide Wire with the foot resting on the articular surface. With the Guide Wire resting in the desired proximal femur, the telescoping tube is extended to the end of the Guide Wire. To measure nail length, a direct reading can be made at the junction of the two tubes. The nail should be countersunk to prevent any impingement. The nail length chosen should be at least 1cm shorter than the measured medullary canal to allow countersinking of the nail.
Step 7. Intramedullary Reaming

Upon attaching the 8mm diameter Modular Reamer Head to the Flexible Nitinol Reamer Shaft (52cm-Catalog #27940), begin reaming over the Bead Tip Guide Wire in 0.5mm increments to a size 1-1.5mm greater than the diameter of the nail to be inserted.

During medullary canal reaming, the Wire Pusher (Catalog #41027) can be used to help retain the Bead Tip Guide Wire during reamer extraction.

NOTE: Since the 3.0mm Bead Tip Guide Wire will pass through all Phoenix Retrograde Femoral Nail diameter cannulas, an exchange technique is not required.
Step 8. Nail Assembly

Position the Driver Nose (Catalog #14-442019) anterior (marked on nose) and align the arrows on the Driver Nose and nail. Insert the Connecting Bolt (Catalog #14-442021) through the Driver Nose and tighten with the Connecting Bolt Driver (Catalog #14-442088). Attach the Retrograde Femoral Nail Targeting Arm (Catalog #14-442020) to the Driver Nose assembly and secure with a Thumb Screw (Catalog #14-442059) to verify target accuracy. Insert a Soft Tissue Guide (Catalog #14-442012) and 4.3mm Drill Sleeve (Catalog #14-442013) into the associated oblique and transverse targeting arm slot and pass a 4.3mm x 365mm Calibrated Drill Bit (Catalog #27961) through the assembly. Upon confirming accurate trajectories, remove the Targeting Arm and guides, if desired.
Surgical Technique (Continued)

Step 9. Nail Insertion

Insert the retrograde nail assembly over the Bead Tip Guide Wire and advance into the medullary canal to the desired depth. If needed, the Slotted Mallet (Catalog #14-442053) can be used by lightly tapping the Driver Nose to seat the nail.

It is recommended to attach the Targeting Arm to the Driver Nose once the retrograde nail has been completely seated into the canal, to avoid potential loosening.

NOTE: Do not strike the Targeting Arm directly with the Slotted Mallet. This could damage the Targeting Arm and cause misalignment.

The fracture should be adequately reduced and out to length during the insertion of the nail and should be monitored with radiographic images. The Bead Tip Guide Wire is removed after the nail passes the fracture site. The nail should be countersunk past Blumensaat’s Line on a lateral x-ray to the level indicated by the groove on the Driver Nose. Final nail positioning should be checked in both AP and lateral radiographs to ensure proper alignment.

NOTE: Be certain to make sure Targeting Arm connections are securely connected, prior to distal locking.

NOTE: Grooves on the Driver Nose help indicate depth when countersinking.
Step 10. Distal Locking

Assemble the 4.3mm Trocar (Catalog #14-442014), 4.3mm Drill Sleeve (Catalog # 14-442013) and Soft Tissue Sleeve (Catalog #14-442012) together and insert through the desired transverse or oblique targeting arm slot. Advance the assembly to bone, determine and mark the entry point. Remove the Trocar and advance the assembly to the near cortex. Secure the assembly to the Targeting Arm with a Sleeve Locking Setscrew (Catalog #14-442056). Insert the 4.3mm Calibrated Drill Bit (Catalog #27961) through the Drill Sleeve to perforate the medial cortex. Appropriate screw length is measured off the Calibrated Drill Bit, at the end of the Drill Sleeve. Alternatively, the Screw Depth Gauge (Catalog #14-442081) can be used to determine and verify the length of the screw.
Attach the 3.5mm Inserter Connector, Long (Catalog #14-441043) through the cannula of the either the Straight or T-Handle and connect the 3.5mm Inserter, Long (Catalog #14-441044). Retain the screw to the threaded hex tip of the Inserter Connector and turn the knob in a clockwise fashion. Insert the screw through the Soft Tissue Guide and into bone. Repeat the locking procedure to insert additional screws.

The line marked “Femoral” on the 3.5mm Inserter, Long indicates when the screw head is fully seated (Ensure the Soft Tissue Sleeve is firmly against bone).

When distal screw insertion is complete, insert the 4mm Hex Driver through the Driver Nose into the distal aspect of the nail and turn in a clockwise motion to lock the distal screws with the preassembled, embedded setscrew/locking mechanism. When complete, remove the hex driver and targeting arm assembly.

NOTE: For final tightening 5mm screws, the 3.5mm Solid Inserter-Long (Catalog #14-441051) or the 3.5mm Solid Inserter-Short (Catalog #14-441052) should be used.
Step 11. Proximal Locking

Proximal locking is accomplished in the AP plane by using a free-hand technique or using the Biomet Radiolucent Targeting Device. For free-hand technique, align the C-Arm with the desired locking hole in the nail, such that the hole appears a perfect circle. A knife blade is placed on the skin, with the incision point verified with radiographic image and a 1cm incision is made over the hole in the nail. The tip of the 4.5mm Crowe Point Twist Drill (Catalog #14-442095) appears as a solid circle in the center of the screw hole. Proceed to drill both cortices. The position of the drill bit is confirmed with radiographic image in both the AP and ML planes. To determine the length of the screw, overlay the drill bit with the 4.5mm Drill Measuring Sleeve (Catalog #14-442096) and read the screw measurement at the end of the drill bit.
Surgical Technique (Continued)

Attach the 3.5mm Inserter Connector, Short (Catalog #14-441045) through the cannula of either the Straight or T-Handle and connect the 3.5mm Inserter, Short (Catalog #14-441046). Retain the screw to the threaded hex tip of the Inserter Connector and turn the knob in a clockwise fashion. Insert the screw into bone and repeat the locking procedure to insert the second screw if desired.

NOTE: For final tightening 5mm screws, the 3.5mm Solid Inserter-Long (Catalog #14-441051) or the 3.5mm Solid Inserter-Short (Catalog #14-441052) should be used.
**End Cap Insertion**

If desired, one of five different profile end caps ranging from 0mm to 20mm (available in 5mm increments) can be inserted into the distal end the Phoenix Retrograde Femoral Nail to prevent bony in-growth. Retain the end cap to the Inserter Connector assembly and insert into the distal end of the nail.

NOTE: For final tightening end caps, the 3.5mm Solid Inserter-Long (Catalog #14-441051) or the 3.5mm Solid Inserter-Short (Catalog #14-441052) should be used.
Nail Removal

Remove the end cap if implanted and all but one of the locking screws with the 3.5mm Inserter Connector. Leaving one screw in the nail helps to prevent nail rotation when connecting the nail extractor to the nail. Alternatively, if all screws have been removed, a 4.3mm Drill Bit can be placed through any of the removed screw holes if rotation of the nail occurs during connection of the nail extractor. The 3.5mm Hex Screw Extractor (Catalog#14-442084) may be used to remove 5mm screws.

Insert a Threaded Tip Guide Wire into the end of the nail to help guide the extractor to the distal portion of the nail. Attach the 3/4” Driver (Catalog #14-442066) to the Modular T-Handle (Catalog #29407). Attach the driver assembly to the Nail Extractor Tap (Catalog #14-441048) and thread the assembly into the nail. A tight interference fit should be achieved. The extractor is meant to cross-thread into the distal portion of the nail. Thread the Slap Hammer Shaft (Catalog #29448) into the Nail Extractor Tap and remove the remaining screw or drill bit. Extract the nail with a backslapping motion using the Slotted Mallet.

NOTE: Since the holes within the embedded setscrew are grooved, distal screw removal can be achieved without disengaging the embedded setscrew.
## Product Ordering Information

### 9mm Retrograde Femoral Nails

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<td>Retrograde Femoral Nail Instrument Tray (empty)</td>
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*Stryker is a registered trademark of the Stryker Corp.

* Available sterile packed
**INDICATIONS**
Phoenix Femoral Nail System
These devices are to be implanted into the femur for alignment, stabilization and fixation of fractures caused by trauma or disease, and the fixation of femurs that have been surgically prepared (osteotomy) for correction of deformity, and for arthrodesis.

**CONTRAINDICATIONS**
1. Infection.
2. Patient conditions including blood supply limitations, and insufficient quantity or quality of bone.
3. Patients with mental or neurologic conditions who are unwilling or incapable of following postoperative care instructions.
4. Foreign body sensitivity. Where material sensitivity is suspected, testing is to be completed prior to implantation of the device.

Additional contraindications for Phoenix Ankle Arthrodesis Nail System:
1. Dysvascular limb.
2. Severe longitudinal deformity.
3. Insufficient plantar heel pad.
4. Where an isolated ankle or subtalar fusion can be performed.
At Biomet, engineering excellence is our heritage and our passion. For over 35 years, through various divisions worldwide, we have applied the most advanced engineering and manufacturing technology to the development of highly durable systems for a wide variety of surgical applications.

Phoenix Retrograde Femoral Nail System
Featuring CoreLock Technology

To learn more about this product, contact your local Biomet Sales Representative today.