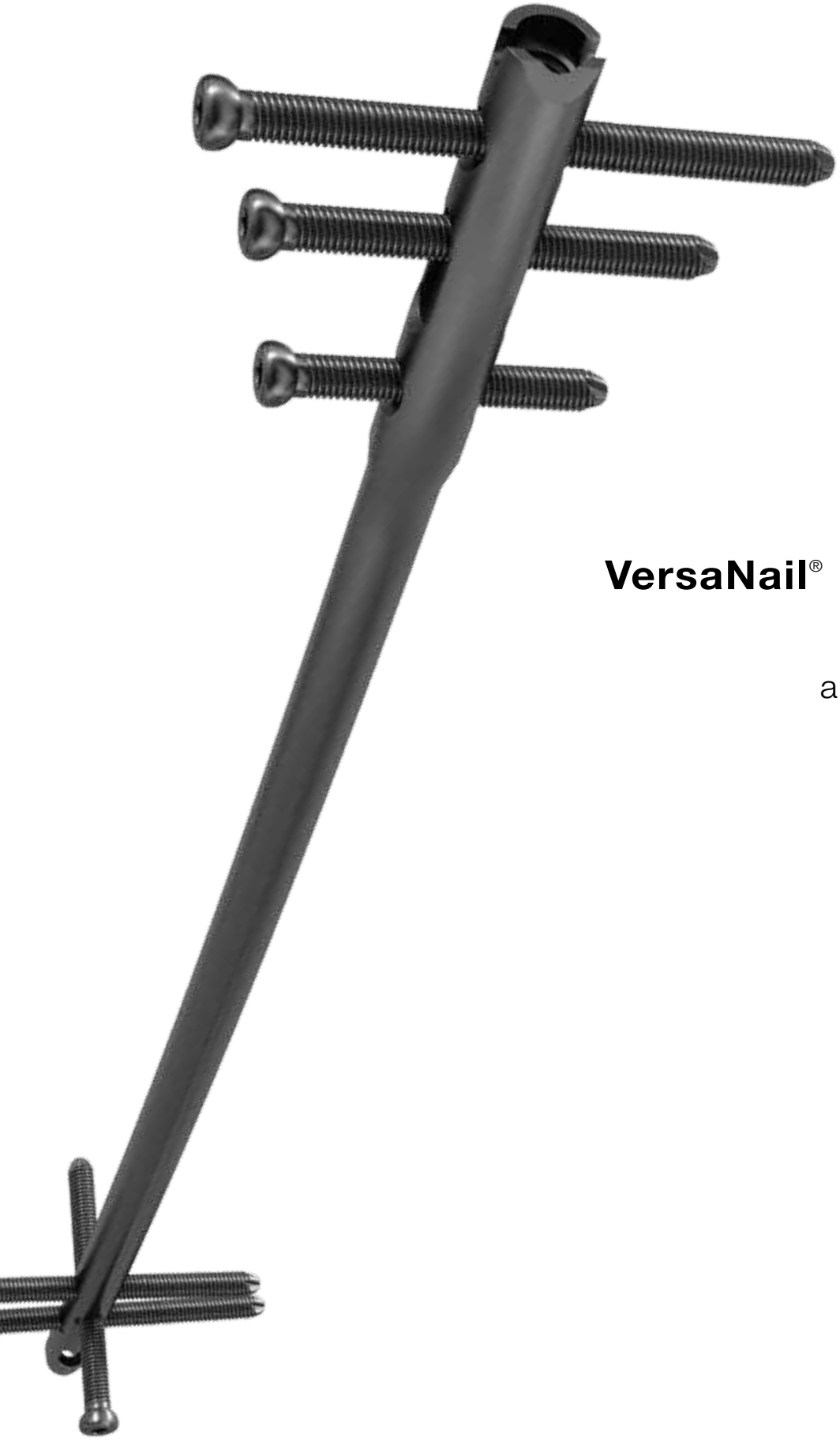


VersaNail® Femoral Universal

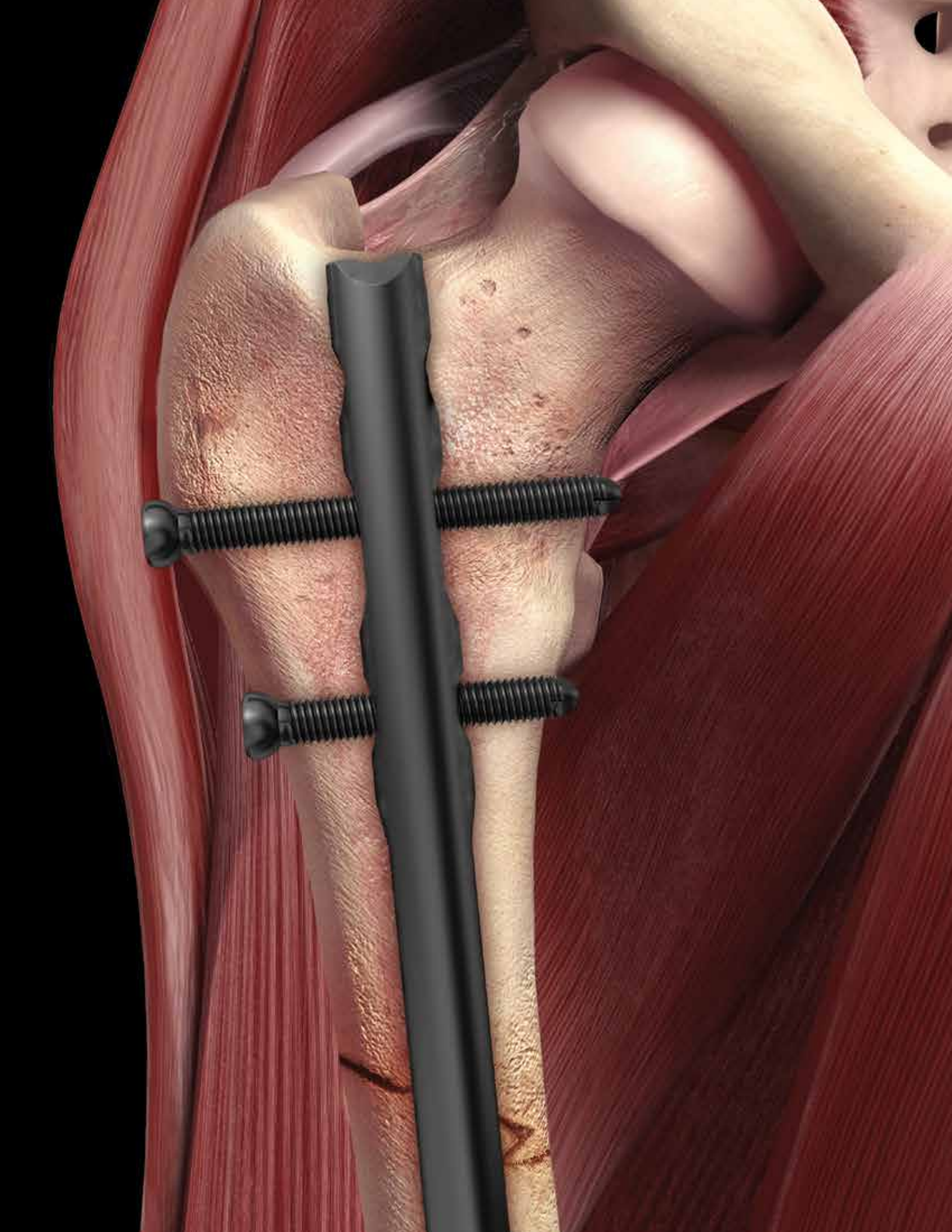
Product Rationale and Surgical Technique

BIOMET® TRAUMA

VersaNail® Femoral Universal

Contents

Note: This brochure presents a surgical technique available for use with the Biomet VersaNail® Platform instruments and implants. Surgeons may need to make modifications as appropriate in their own surgical technique with these devices depending on individual patient requirements.



VersaNail® Femoral Universal

One Implant Designed for the Efficient Treatment of a Range of Femur Fractures

- Anatomically designed for treatment of both antegrade and retrograde applications
- The intuitive, universal instrumentation system enables efficiency in the OR
- Universal design to aid inventory management

The VersaNail® Femoral Universal Nail is part of a long bone nailing system that offers a complete portfolio of implants and instruments based on a single, standardized technology platform. The Femoral Universal Nail System from the VersaNail Platform offers options to treat a range of femoral fractures using either an antegrade or retrograde approach with one implant. The VersaNail Platform instrumentation system is designed for intuitive assembly and ease-of-use by OR staff and surgeons, enabling a simpler and more efficient procedure. The instrumentation is designed to provide intra-operative options including entry portals, reduction tools and color-coded screw placement, while being standardized to maintain commonality across the platform.

VersaNail® Femoral Universal

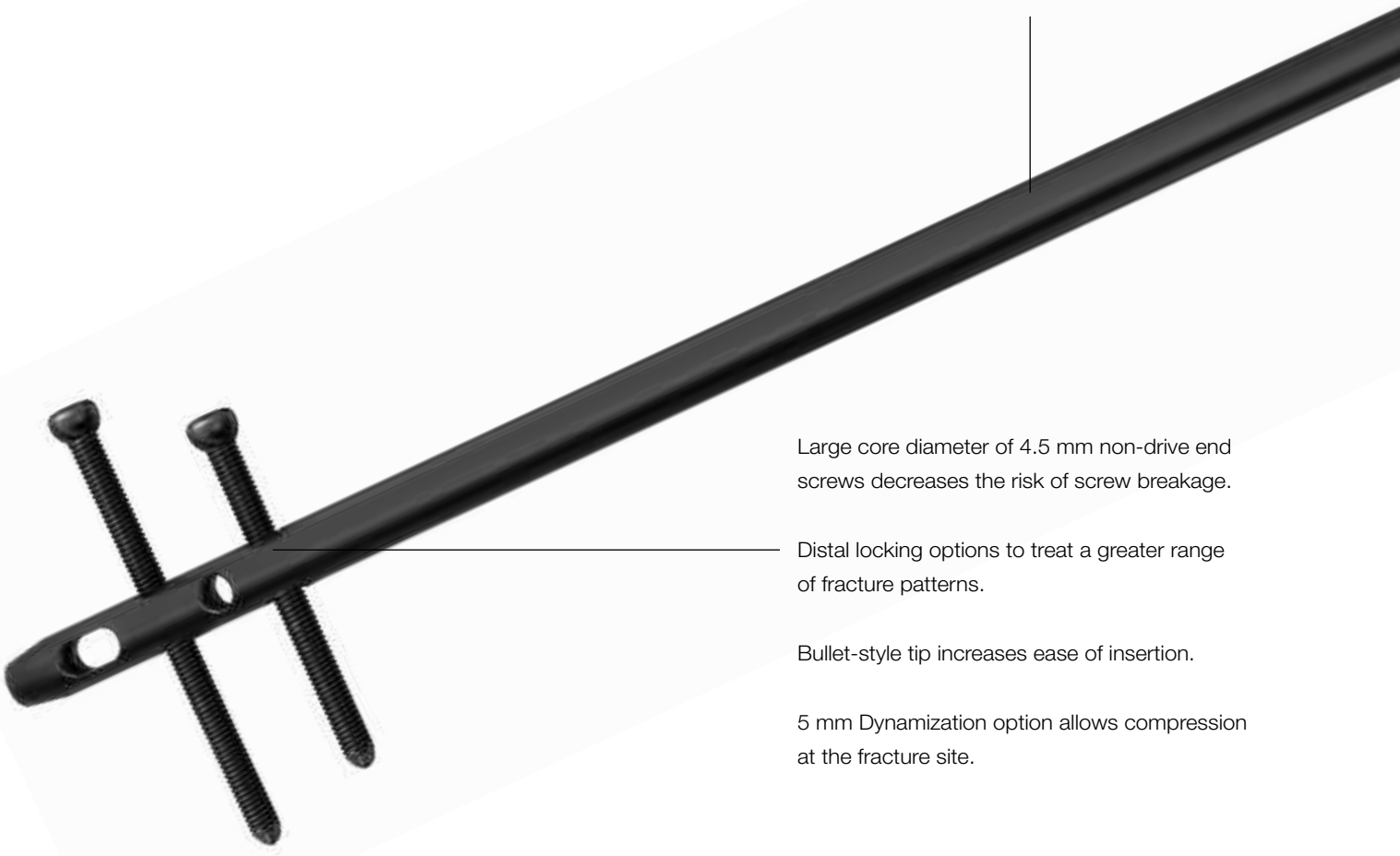
The Femoral Universal Nail is designed to treat:

- Femoral shaft fractures
- Proximal or mid-shaft femoral non-unions and malunions
- Pathologic fractures in osteoporotic bone of the diaphyseal area
- Revision procedures

Universal design allows one nail for either antegrade or retrograde application to treat right- or left-sided fractures.

Enlarged nail cannulation accepts the ball nose guide wire, eliminating the need for an exchange tube.

2.2 meter radius of curvature accommodates the anterior bow of the femur.



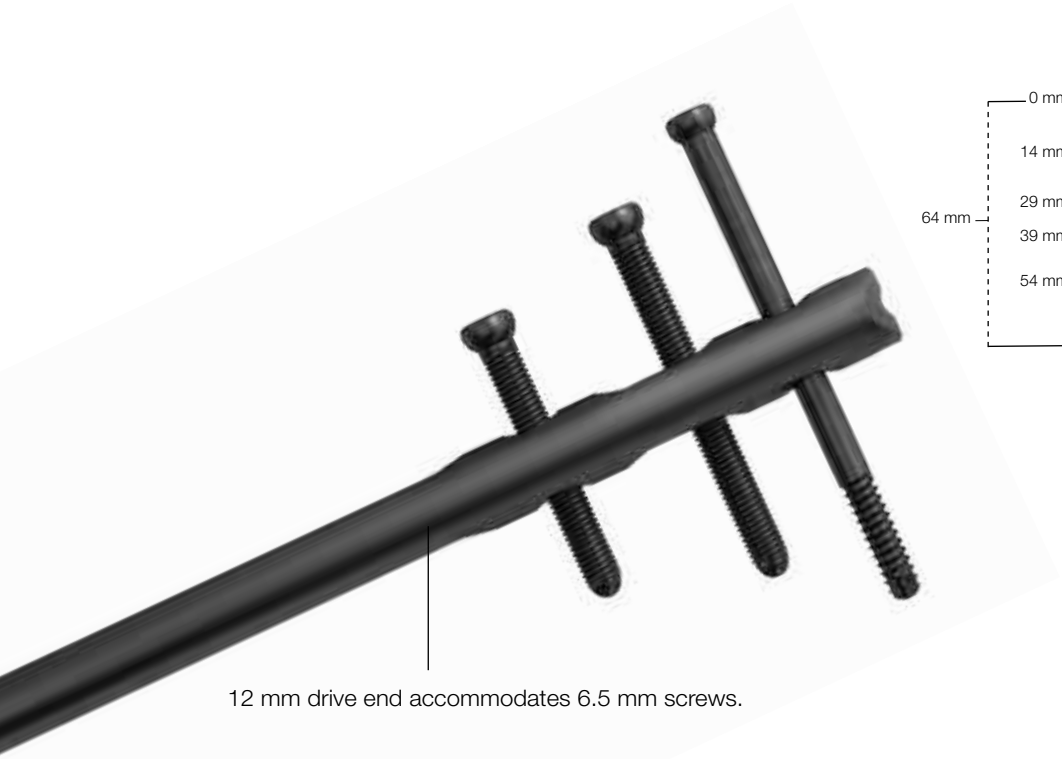
Large core diameter of 4.5 mm non-drive end screws decreases the risk of screw breakage.

Distal locking options to treat a greater range of fracture patterns.

Bullet-style tip increases ease of insertion.

5 mm Dynamization option allows compression at the fracture site.

The VersaNail Platform instrumentation system is designed to be intuitive, enabling a simpler and more efficient procedure. The VersaNail Platform's modular nature facilitates the use of common instruments across all VersaNail nailing systems, reducing confusion among the OR staff. For example, VersaNail Platform jigs look and function the same way, and common instruments (such as awls, entry portals, guide wires, nail length gauge, locking instrumentation and screw caddies) can be used across all VersaNail Platform nailing systems.



12 mm drive end accommodates 6.5 mm screws.

Large core diameter of 6.5 mm screws decreases risk for screw breakage.

10 mm Dynamization option allows compression at the fracture site.

Multiple locking options for optimum implant stability

The Femoral Universal Nail hole configurations provide a number of locking possibilities.
The Femoral Universal Nail is locked with 6.5 mm screws on the drive end and 4.5 mm screws on the non-drive end.

The locking instrumentation is color-coded for ease of use:

Color	Screw Size	Drill Bit Size
Black	6.5 mm Cortical	5.3 mm
Gold	6.5 mm Cancellous	6.5 mm/4.8 mm Step Drill
Silver	3.2 mm Guide Pin Sleeve	
Green	4.5 mm Cortical	3.8 mm

Antegrade Entry and Canal Preparation

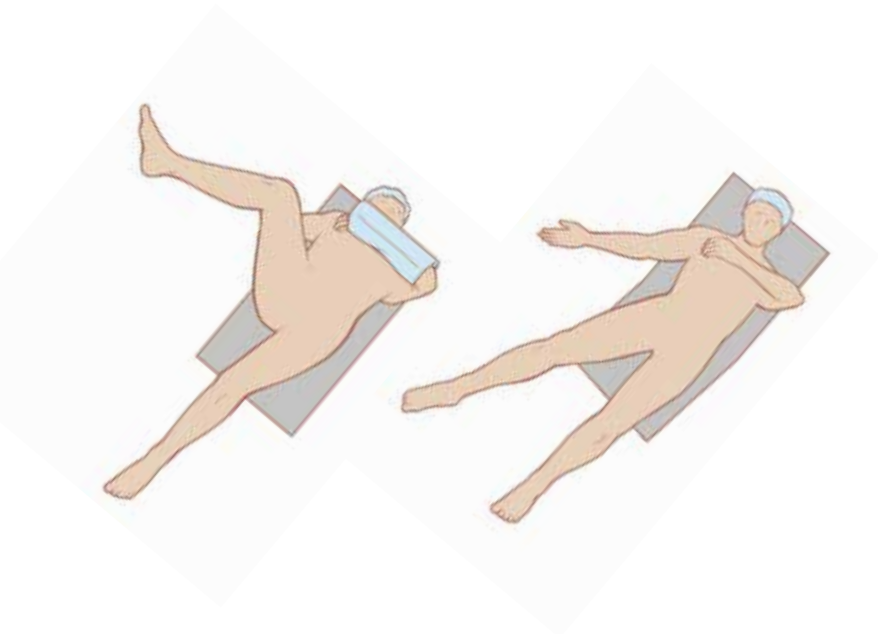


Figure 1

Figure 2

Patient Positioning

Place the patient in the supine position on a fracture or radiolucent imaging table (Figure 1). Lateral access to the proximal femur is required. The affected leg must be adducted and the trunk secured and bent toward the opposite side. The contralateral leg may be flexed at the hip or scissored below the affected leg.

Entry Site and Surgical Approach

Identify the entry site, which is in the piriformis fossa. The ideal entry point is adjacent to the greater trochanter at the lateral edge of the piriformis fossa.

Initiate the entry site with a 3.2 mm guide pin through a stab incision proximal to the trochanteric region, in line with the femoral axis. Confirm correct entry location and guide pin placement radio-graphically with A/P and lateral views (Figure 2). The guide pin placement should be in line with the center of the femoral canal in both views.

Figure 3

Figure 4

Once the ideal entry point has been achieved, an appropriate incision can be made. Extend the entry incision 1-2 cm (Figure 3).

The Entry Portal Sheath (2810-13-005) and Trocar (2810-13-004) can be advanced over the guide pin down to the piriformis fossa. Parallel guide holes allow for accurate adjustment of pin positioning. Remove the trocar from the entry portal, keeping the guide pin in place.The entry portal sheath may be left in place to protect soft tissues during canal entry and reaming (Figure 4).

Antegrade Entry and Canal Preparation

Figure 5

Figure 6

Figure 7

Entry Site and Surgical Approach (cont.)

Canal access can be obtained using either a Cannulated Entry Reamer or Cannulated Awl (2810-01-005). Both 12 mm (2810-13-001) and 13 mm (2810-13-002) entry reamers are available depending on surgeon preference. The proximal nail diameter is 12 mm for all nail sizes equal to or less than 12 mm, and 13 mm to 15 mm nails have a proximal diameter equal to the nail diameter. Use A/P and lateral fluoroscopic views to confirm accurate placement (Figures 5 and 6). Use the awl or entry reamer to open the proximal femur in the piriformis fossa.

Note: If utilizing the cannulated entry reamer, the length of the distal portion of the reamer is enlarged and matches the length of the drive end portion of the nail. Fluoroscopically verify the entry reamer has been inserted to the proper depth that will correspond with the depth of the nail.

Once access to the femoral canal has been gained, place the ball nose guide wire into the entry site utilizing the pistol-style Guide Wire Gripper (2810-01-001) (Figure 7). If preferred, a T-handle Guide Wire Gripper (2810-01-002) is also available as an option.

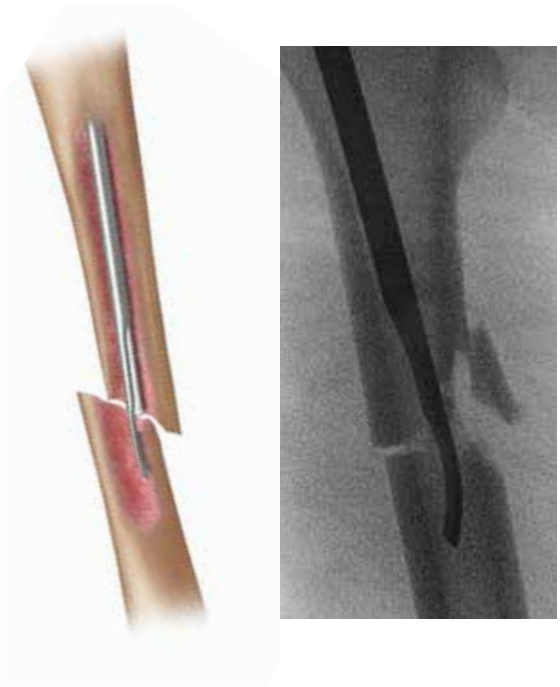


Figure 8

Figure 9

Fracture Reduction

Once access to the femoral canal has been gained, obtain appropriate anatomic reduction in order to restore length, alignment and rotation of the injured limb. Reduction can be achieved through the surgeon's preferred method such as traction and/or an external fixator. To aid in manipulating the fracture fragments and passing the Ball Nose Guide wire, large (7.5 mm diameter, 2810-01-007) and small (6.5 mm diameter, 2810-01-008) reduction tools are available (Figure 8).

Insert the reduction tool into the medullary canal, past the fracture site. Once the fracture is aligned, pass the Ball Nose Guide Wire, available in both 80 cm (2810-01-080) and 100 cm (2810-01-100) lengths, across the fracture site. Remove the reduction tool.

Canal Preparation

Achieve proper alignment of the fracture prior to reaming and maintain it throughout the reaming process to avoid eccentric reaming. Initiate reaming by placing the VersaNail Flexible Reamers over the 3.0 mm ball nose guide wire (Figure 9). Ream the medullary canal in millimeter increments until cortical bone is reached and half-millimeter increments thereafter. Surgeon preference should dictate the actual extent of intramedullary reaming. Monitor the reaming procedure using image intensification to avoid eccentric or excessive cortical reaming.

Antegrade Nail Insertion

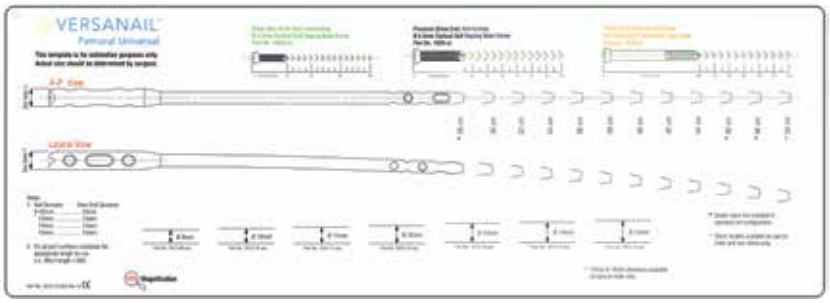


Figure 10

Figure 11

Nail Size Selection

An X-ray template (2810-13-025) including 10 percent magnification is available to determine nail size preoperatively (Figure 10).

Nail Diameter Selection

Generally, a nail diameter 1 mm to 1.5 mm less than the final reamer diameter is chosen. Femoral Universal Nails are available in 1 mm increments from 9 mm to 15 mm diameters.

Nail Length Selection

With the tip of the ball nose guide wire at the level of the desired depth of nail insertion, slide or snap the Nail Length Gauge (2810-01-031) onto the ball nose guide wire until the nose contacts the bone, ensuring the tip does not fall into the existing entry canal, which could result in an inaccurate measurement (Figure 11).

Figure 12

Figure 13

To obtain the appropriate nail length, read the measurement mark on the nail length gauge that is closest to the beginning of the black transition area on the guide wire (Figure 12). If a nail of the exact measured length is not available, choose a shorter nail of the next closest available length. A direct measurement can also be taken of the uninjured extremity using either radiographs with magnification markers, or directly on the uninjured limb.

Nail/Jig Assembly

Place the nail on the femoral insertion handle in the correct orientation. The nail should be oriented on the femoral insertion handle such that the anterior bow of the nail is in line with the anterior bow of the femur and the jig is lateral to the nail. Secure the nail to the femoral insertion handle by inserting the Femoral Jig Bolt (2810-13-008) through the cannulation of the nose and tightening with the Jig Bolt Driver (2810-13-006) and T-handle (2810-01-004) (Figure 13).

Antegrade Nail Insertion

Figure 14

Figure 15

Figure 16

Nail Insertion

Once proper reduction has been achieved, insert the nail over the 3 mm ball nose guide wire into the medullary canal (Figure 14). It is important not to strike the femoral insertion handle directly.

Attach the Hammer Pad (2810-13-011) to the insertion handle (Figure 15). Ensure that the hammer pad is tightened thoroughly prior to impaction. Avoid excessive force when inserting the nail. If the nail jams in the medullary canal, extract it and choose the next-smaller diameter nail or enlarge the canal appropriately.

Note: The femoral insertion handle is marked with three grooves (Figure 16). The groove closest to the nail is an indicator for the nail/insertion handle junction. A K-wire can be inserted lateral to medial through the target arm if additional identification of the nail/ insertion handle junction is needed. The middle groove is marked 5 mm from the top of the nail and the groove farthest from the nail is marked 15 mm from the top of the nail. Ensure the nail is seated to proper depth for planned dynamization.

Confirm fracture reduction and ensure appropriate nail insertion depth proximally and distally with biplanar fluoroscopy. Remove the ball nose guide wire.

Antegrade Locking

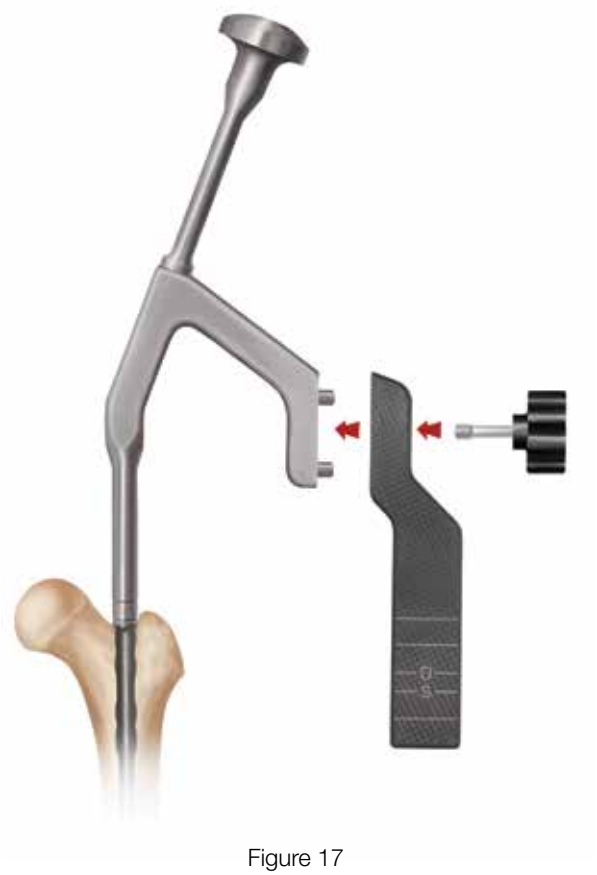


Figure 17

Dynamization

A dynamic slot has been incorporated in the drive end and non-drive end of the nail. The drive end slot has a 10 mm range of dynamization. The non-drive end slot has a 5 mm range of dynamization. If dynamization is planned, countersink the nail to the appropriate depth to avoid backing out of the nail into the proximal soft tissues. Lock the M/L slot in the dynamic mode. Delayed dynamization may be performed at a later date with the removal of the static screws.

Universal Target Arm Assembly

Attach the radiolucent Universal Target Arm (2810-13-009) onto the insertion handle, using the Target Arm Attachment Bolt (2810-13-026) and hand tighten (Figure 17). Ensure the target arm is properly secured to the insertion handle for excellent targeting.

Locking

Prior to locking both proximally and distally, check femoral length and rotational alignment. The nail can be locked either distally or proximally first, depending on surgeon preference.

Antegrade Locking

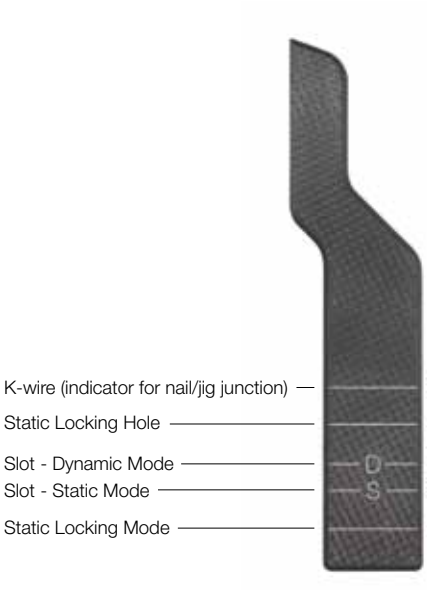


Figure 18

Figure 19

Figure 20

Proximal Locking

The universal target arm is marked to identify which locking option is being targeted (Figure 18).

Place 6.5 mm cortical locking screws using the black instrumentation (Figure 19).

Place the 6.5 mm Screw Sheath (2810-13-020) and Trocar (2810-13-021) through the appropriate holes in the jig's targeting arm to locate the incision site (Figure 20). Make a stab incision and advance the sheath and trocar to the bone. Soft tissue dissection should be completed sharp and precise to clear a path for the sheath. Undue soft tissue tension against the sheath can cause misdirect drilling.

Figure 21

Figure 22

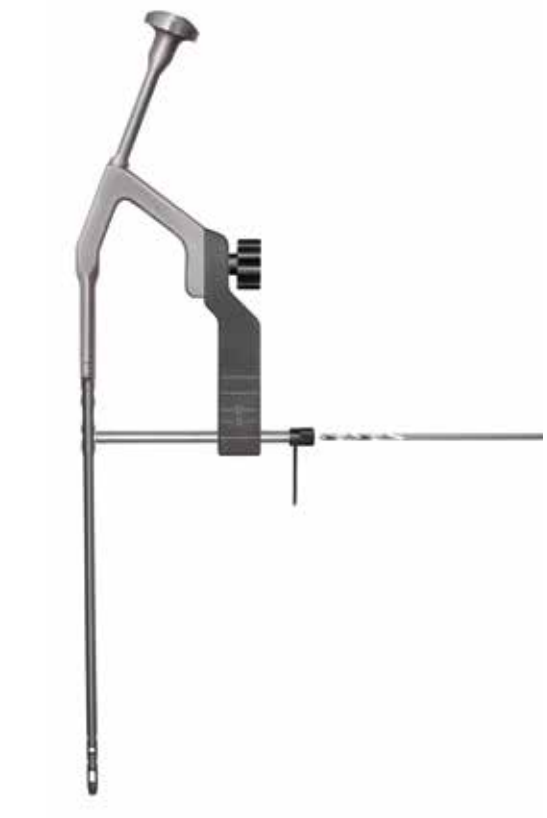


Figure 23

Note: A 3.2 mm x 17.5 in Guide Pin (9030-03-004) and 3.2 mm Pin Guide Sleeve (2810-13-018) can be used to verify screw position prior to drilling (Figure 21).

Remove the trocar and replace it with the 5.3 mm Drill Sleeve (2810-13-022) (Figure 22).

Utilizing the 5.3 mm Drill Bit (2810-13-153) drill through the drill sleeve and sheath until the far cortex is penetrated (Figure 23).

Antegrade Locking

Figure 24

Figure 25

Proximal Locking (cont.)

Read the calibration on the drill bit that lines up with the drill sleeve to determine the screw length (Figure 24).

Ensure the drill sleeve is on bone and read the calibration on the drill bit at the end of the drill sleeve to determine the appropriate screw length (Figure 24). If penetrating the far cortex prior to taking the reading, use the screw length indicated on the drill bit at the screw depth measurement line. If you are not penetrating the far cortex prior to taking the reading, add 5 mm in length to the screw length reading.

If further screw length is required, or if the locking hole has been initiated with a guide pin, a 6.5 mm Screw Depth Gauge (2810-13-035) is available to read screw length off of the 3.2 mm x 17.5 in guide pin (Figure 25).

Figure 26

Figure 27

Verify fluoroscopically to assure the proper screw length selection. Remove the drill sleeve. Using the 6.5 mm Screwdriver Shaft (2810-13-024), insert the 6.5 mm cortical screw through the sheath. The etch mark on the screwdriver corresponds with the screw sheath to indicate when the screw is fully seated (Figure 26).

Use caution as the most proximal screw position could be in femoral neck, depending on the depth of the nail.

Repeat above steps for additional screw placement.

Distal Locking

Place 4.5 mm cortical locking screws using the green instrumentation (Figure 27).

Antegrade Locking

Figure 28

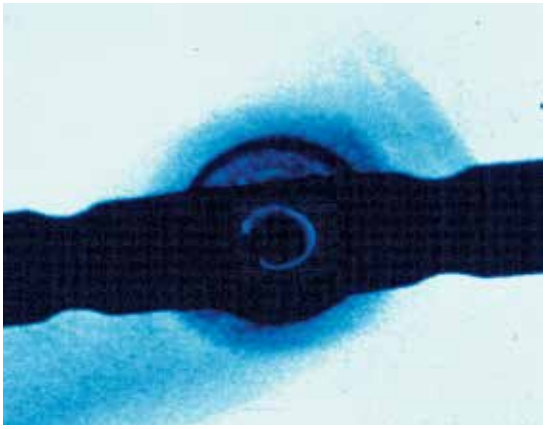


Figure 29

Distal Locking (cont.)

Use fluoroscopy to conduct freehand locking utilizing a familiar freehand technique. A Black Radiolucent Wand (2810-12-016) is available to aid in freehand locking (Figure 28).

Accurate C-arm position is confirmed when the distal nail hole appears to be a perfect circle. Once correct placement has been verified fluoroscopically, make a stab wound in direct alignment with the distal hole (Figure 29).

A compensation factor is built into the measurement of the screw depth gauge (for the screw head and cutting flutes), and the calibrated drills (for the screw head only).

If penetrating the far cortex prior to taking the reading, use the screw length indicated on the drill bit at the screw depth measurement line. If you are not penetrating the far cortex prior to taking the reading, add 5 mm in length to the screw length reading.

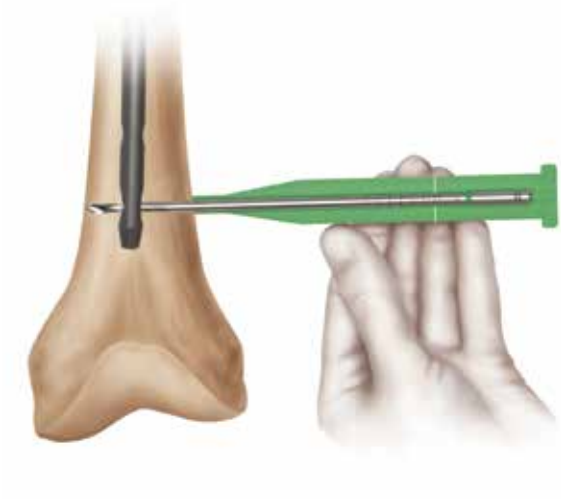


Figure 30

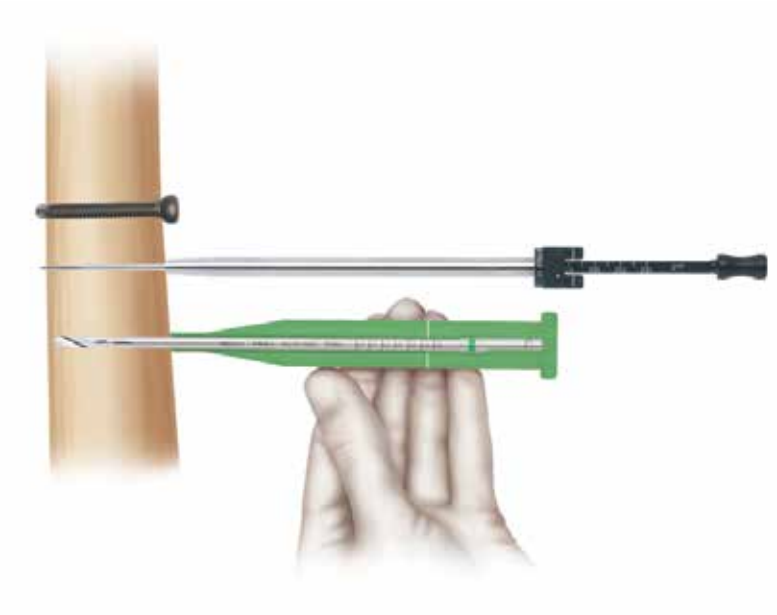


Figure 31

Using the 3.8 mm Drill Bit (6 in: 2810-12-138 or 8 in: 2810-13-138), drill until the second cortex is reached or penetrated. Verify the drill bit position fluoroscopically prior to taking any measurements. Place the green 4.5 mm Screw Length Gauge (2810-01-032) onto the calibrated drill bit and advance down to the bone. Read the calibration on the drill bit that corresponds to the measurement line indicated on the screw length gauge (Figure 30). A Screw Depth Gauge (2810-01-017) is also provided for further screw length verification. For an accurate reading, take care to ensure the 4.5 mm screw length gauge or screw depth gauge sheath is fully seated on the bone. Remove the drill bit and advance the 4.5 mm screw. Repeat above steps for additional screw placement. The SolidLok® Screwdriver (2810-01-020 and 2810-01-021) can be utilized to capture the screw while passing it through soft tissue during screw placement.

Determining Screw Length

The screw size indicates the total measurement from the tip to the screw head. The calibrated drills and the screw depth gauges have a compensation factor built into the measurement such that the reading should indicate the exact size screw to achieve bi-cortical purchase. To ensure a proper reading, the screw depth gauge and drill sleeves must be touching bone. Fluoroscopy is recommended to verify the correct screw length (Figure 31).

Retrograde Entry and Canal Preparation

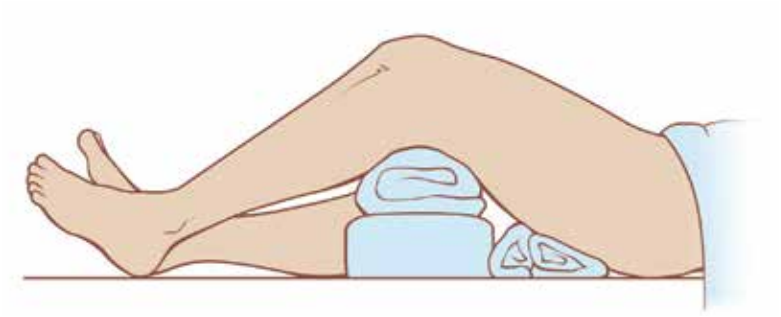


Figure 32

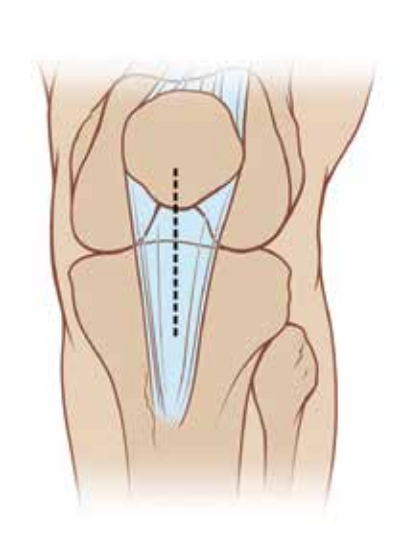


Figure 33

Patient Positioning

Place the patient in the supine position on a fracture or radiolucent imaging table (Figure 32). Place the knee in approximately 45 degrees of flexion. Use manual traction, a femoral distractor or an external fixator to reduce severely displaced fractures and maintain length. Special attention is needed to maintain proper length when using a retrograde approach to treat a comminuted fracture.

Entry Site and Surgical Approach

Identify the entry site, which is above the intercondylar notch (Figure 33).

Figure 34

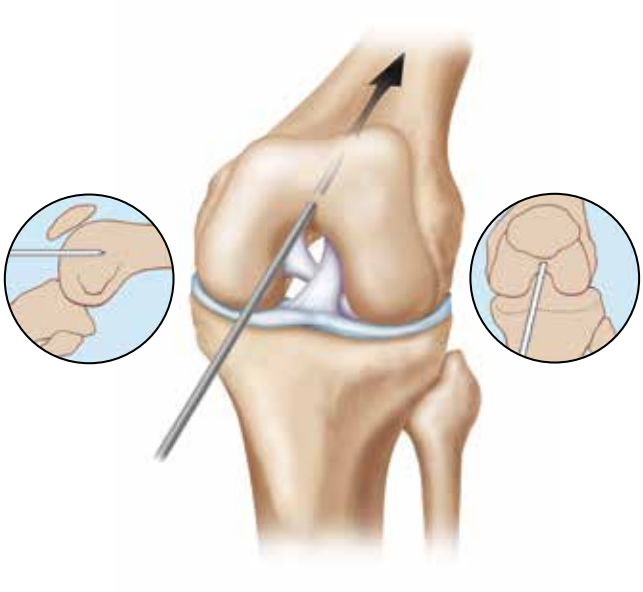


Figure 35

Approach the distal femur through a midline longitudinal incision between the patella and the tibial tubercle (Figure 34). Obtain access to the intercondylar notch by splitting the tendon longitudinally or displacing the tendon laterally.

Alternative approach: Approach the distal femur through a longitudinal incision from the superior pole of the patella to the tibial tubercle, placed along the medial border of the patellar tendon. Expose the intercondylar notch by using retractors to reflect the patellar tendon laterally or perform the procedure percutaneously.

Place the guide pin in the center of the intercondylar notch approximately 1 cm anterior to the posterior cruciate ligament and confirm accurate guide pin placement in two planes fluoroscopically prior to reaming. The guide pin placement should be in line with the center of the femoral canal in both views (Figure 35).

Retrograde Entry and Canal Preparation

Figure 36

Figure 37

Entry Site and Surgical Approach (cont.)

Canal access can be obtained using either a Cannulated Entry Reamer or Cannulated Awl (2810-01-005) (Figures 36 and 37). Both 12 mm (2810-13-001) and 13 mm (2810-13-002) entry reamers are available depending on surgeon preference. The distal (drive end) nail diameter is 12 mm for all nail sizes equal to or less than 12 mm, and 13 mm to 15 mm nails have a distal diameter equal to the nail diameter. Use A/P and lateral fluoroscopic views to confirm accurate placement. Use the awl or entry reamer to open the distal femur in the intercondylar notch. As an option, an Entry Portal Sleeve (2810-12-001) is available for soft tissue protection, as great care must be taken to protect the undersurface of the patella.

Note: If utilizing the cannulated entry reamer, the length of the distal portion of the reamer is enlarged and matches the length of the drive end portion of the nail. Fluoroscopically verify the entry reamer has been inserted to the proper depth that will correspond with the depth of the nail.

Figure 38

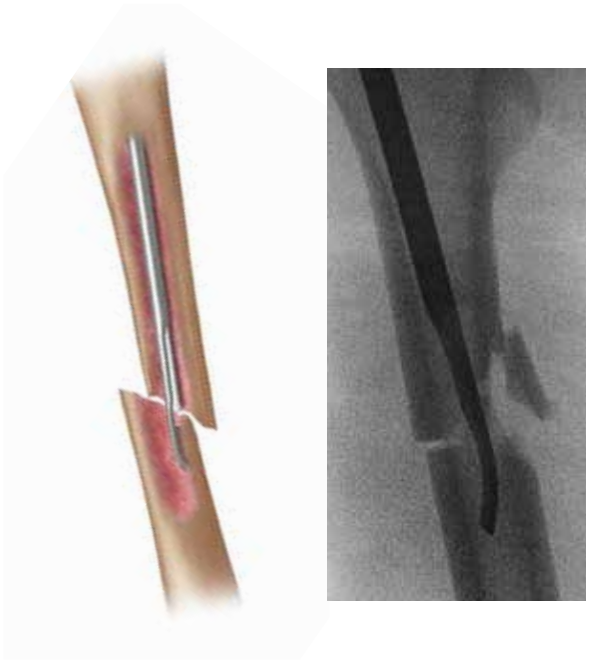


Figure 39

Once access to the femoral canal has been gained, place the ball nose guide wire into the entry site utilizing the pistol-style Guide Wire Gripper (2810-01-001) (Figure 38). If preferred, a T-handle Guide Wire Gripper (2810-01-002) is also available as an option.

Fracture Reduction

Obtain appropriate anatomic reduction in order to restore length, alignment and rotation of the injured limb. Reduction can be achieved through the surgeon's preferred method such as traction and/or an external fixator. To aid in manipulating the fracture fragments and passing the Ball Nose Guide Wire, large (7.5 mm diameter, 2810-01-007) and small (6.5 mm diameter, 2810-01-008) reduction tools are available (Figure 39). Insert the reduction tool into the medullary canal, past the fracture site. Once the fracture is aligned, pass the Ball Nose Guide Wire, available in both 80 cm (2810-01-080) and 100 cm (2810-01-100) lengths, across the fracture site. Remove the reduction tool.

Retrograde Nail Insertion

Figure 40

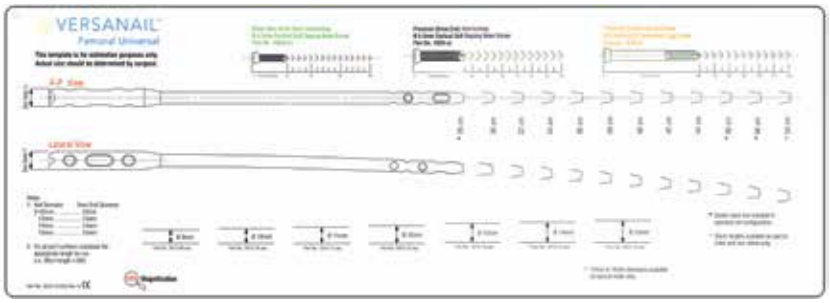


Figure 41

Canal Preparation

Achieve proper alignment of the fracture prior to reaming and maintain it throughout the reaming process to avoid eccentric reaming. Initiate reaming by placing the VersaNail Flexible Reamers over the 3.0 mm Ball Nose Guide Wire (Figure 40). Ream the medullary canal in millimeter increments until cortical bone is reached and half-millimeter increments thereafter. Surgeon preference should dictate the actual extent of intramedullary reaming. Monitor the reaming procedure using image intensification to avoid eccentric or excessive cortical reaming.

Nail Size Selection

An X-ray Template (2810-13-025) including 10 percent magnification is available to determine nail size preoperatively (Figure 41).

Figure 42

Nail Diameter Selection

Generally, a nail diameter 1 mm less than the final reamer diameter is chosen. Femoral Universal Nails are available in 1 mm increments from 9 mm to 15 mm diameters.

Nail Length Selection

With the tip of the ball nose guide wire at the level of the desired depth of nail insertion, slide or snap the Nail Length Gauge (2810-01-031) onto the ball nose guide wire until the nose contacts the bone, ensuring the tip does not fall into the existing entry canal, which could result in an inaccurate measurement (Figure 42).

Retrograde Nail Insertion

Figure 43

Figure 44

Nail Length Selection (cont.)

To obtain the appropriate nail length read the measurement mark on the nail length gauge that is closest to the beginning of the black transition area on the guide wire (Figure 43). The selected nail length must be at least 5 mm less than the measured length to allow for the required recessing of the drive end of the nail, ensuring that the nail will not protrude into the patellofemoral joint. If the dynamization mode is to be used at the drive end of the nail, nail length should be further appropriately shortened. If a nail of the exact measured length is not available, choose a shorter nail of the next closest available length. A direct measurement can also be taken of the uninjured extremity using either radiographs with magnification markers, or directly on the uninjured limb.

Nail/Jig Assembly

Place the nail on the femoral insertion handle in the correct orientation. The nail should be oriented on the femoral insertion handle such that the anterior bow of the nail is in line with the anterior bow of the femur and the jig is lateral to the nail. Secure the nail to the femoral insertion handle by inserting the Femoral Jig Bolt (2810-13-008) through the cannulation of the nose and tightening with the Jig Bolt Driver (2810-13-006) and T-handle (2810-01-004) (Figure 44).

Figure 45

Figure 46

Nail Insertion

Once proper reduction has been achieved, insert the nail over the 3 mm ball nose guide wire into the medullary canal (Figure 45). It is important not to strike the femoral insertion handle directly.

Attach the Hammer Pad (2810-13-011) to the insertion handle (Figure 46). Ensure that the hammer pad is tightened thoroughly prior to impaction. Avoid excessive force when inserting the nail. If the nail jams in the medullary canal, extract it and choose the next-smaller diameter nail or enlarge the canal appropriately.

Retrograde Nail Insertion

Figure 47

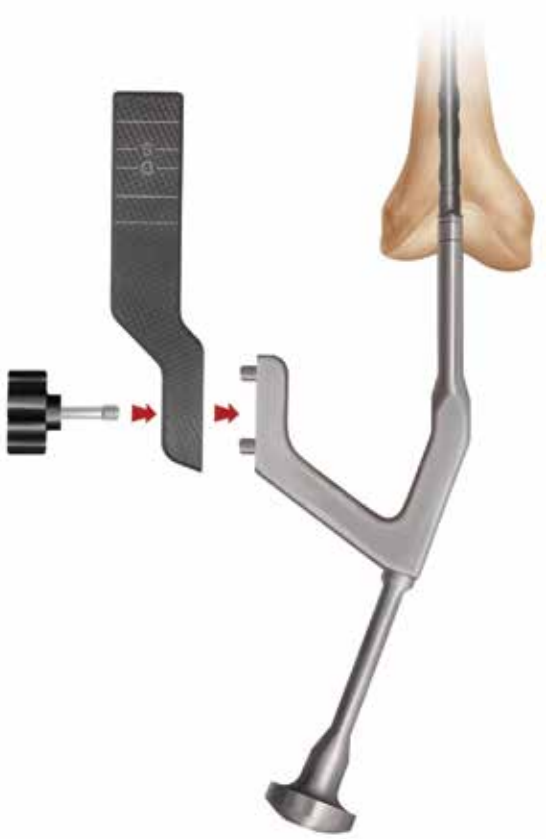


Figure 48

Nail Insertion (cont.)

Note: The femoral insertion handle is marked with three grooves (Figure 47). The groove closest to the nail is an indicator for the nail/insertion handle junction. A K-wire can be inserted lateral to medial through the target arm if additional identification of the nail/insertion handle junction is needed. The middle groove is marked 5 mm from the top of the nail and the groove farthest from the nail is marked 15 mm from the top of the nail. Ensure the nail is seated to proper depth for planned dynamization.

Confirm fracture reduction and ensure appropriate nail insertion depth proximally and distally with biplanar fluoroscopy. Remove the ball nose guide wire.

Dynamization

A dynamic slot has been incorporated in the drive end and non-drive end of the nail. The drive end slot has a 10 mm range of dynamization. The non-drive end slot has a 5 mm range of dynamization. If dynamization is planned, countersink the nail to the appropriate depth to avoid backing out of the nail. Lock the M/L slot in the dynamic mode. Delayed dynamization may be performed at a later date with the removal of the static screws.

Universal Target Arm Assembly

Attach the radiolucent Universal Target Arm (2810-13-009) onto the insertion handle, using the Target Arm Attachment Bolt (2810-13-026) and hand tighten. Ensure the target arm is properly secured to the insertion handle for excellent targeting (Figure 48).

Retrograde Locking

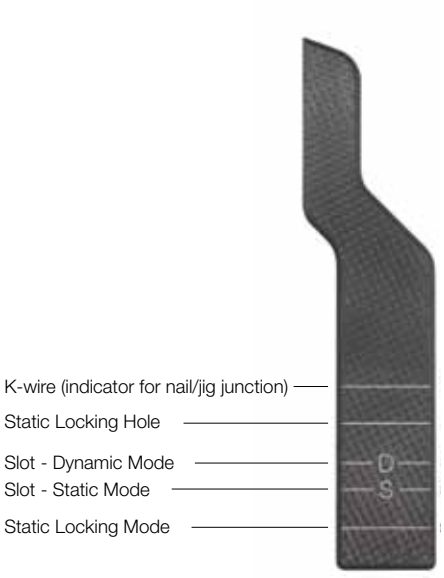


Figure 49

Figure 50

Figure 51

Locking

Prior to locking both proximally and distally, check femoral length and rotational alignment. The nail can be locked either distally or proximally first, depending on surgeon preference.

Distal Locking

The universal target arm is marked to identify which drive end locking option is being targeted (Figure 49).

Place 6.5 mm cortical locking screws using the black instrumentation (Figure 50).

Note: Depending on surgeon preference, a 6.5 mm lag screw is also available for distal locking. If a lag locking technique is preferred, place the 6.5 mm cancellous lag screw using the gold instrumentation.

Place the 6.5 mm Screw Sheath (2810-13-020) and Trocar (2810-13-021) through the appropriate holes in the jig's targeting arm to locate the incision site (Figure 51). Make a stab incision and advance the sheath and trocar to the bone. Soft tissue dissection should be completed sharp and precise to clear a path for the sheath. Undue soft tissue tension against the sheath can cause misdirect drilling.

Retrograde Locking

Figure 52

Figure 53

Figure 54

Distal Locking (cont.)

Note: A 3.2 mm x 17.5 in Guide Pin (9030-03-004) and 3.2 mm Pin Guide Sleeve (2810-13-018) can be used to verify screw position prior to drilling (Figure 52).

Remove the trocar and replace it with the 5.3 mm Drill Sleeve (2810-13-022) (Figure 53).

Utilizing the 5.3 mm Drill Bit (2810-13-153) drill through the drill sleeve and sheath until the far cortex is penetrated (Figure 54).

Figure 55

Figure 56

Read the calibration on the drill bit that lines up with the drill sleeve to determine the screw length (figure 55).

Ensure the drill sleeve is on bone and read the calibration on the drill bit at the end of the drill sleeve to determine the appropriate screw length (Figure 55). If penetrating the far cortex prior to taking the reading, use the screw length indicated on the drill bit at the screw depth measurement line. If you are not penetrating the far cortex prior to taking the reading, add 5 mm in length to the screw length reading.

If further screw length is required, or if the locking hole has been initiated with a guide pin, a 6.5 mm Screw Depth Gauge (2810-13-035) is available to read screw length off of the 3.2 mm x 17.5 in guide pin (Figure 56).

Retrograde Locking

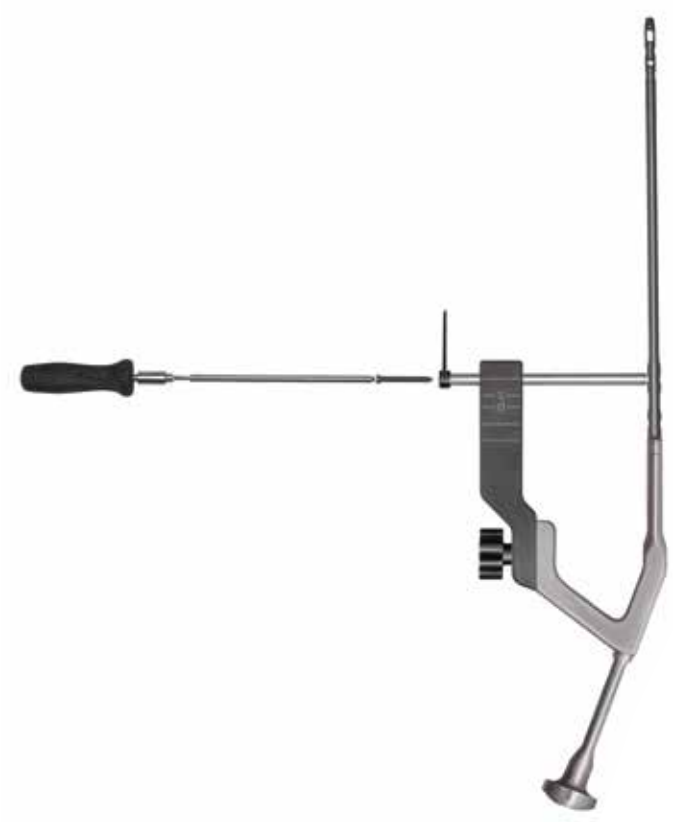


Figure 57

Figure 58

Distal Locking (cont.)

Verify fluoroscopically to assure the proper screw length selection. Remove the drill sleeve. Using the 6.5 mm Screwdriver Shaft (2810-13-024), insert the 6.5 mm cortical screw through the sheath (Figure 57). The etch mark on the screwdriver corresponds with the screw sheath to indicate when the screw is fully seated.

Repeat above steps for additional screw placement.

Proximal Locking

Place 4.5 mm cortical locking screws using the green instrumentation (Figure 58).

Figure 59

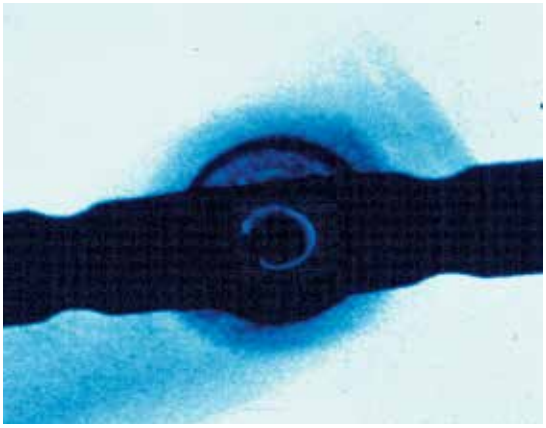


Figure 60

Use fluoroscopy to conduct freehand locking utilizing a familiar freehand technique. A black Radiolucent Wand (2810-12-016) is available to aid in freehand locking (Figure 59).

Accurate C-arm position is confirmed when the distal nail hole appears to be a perfect circle (Figure 60). Once correct placement has been verified fluoro-scopically, make a stab wound in direct alignment with the distal hole.

Retrograde Locking

A compensation factor is built into the measurement of the screw depth gauge (for the screw head and cutting flutes), and the calibrated drills (for the screw head only).

If penetrating the far cortex prior to taking the reading, use the screw length indicated on the drill bit at the screw depth measurement line.
If you are not penetrating the far cortex prior to taking the reading, add 5 mm in length to the screw length reading.

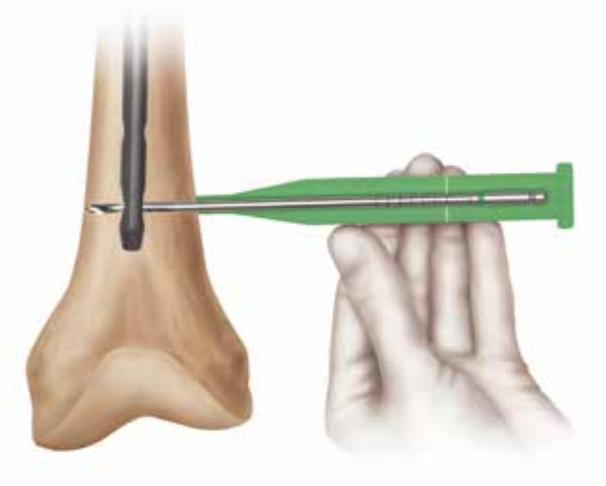


Figure 61

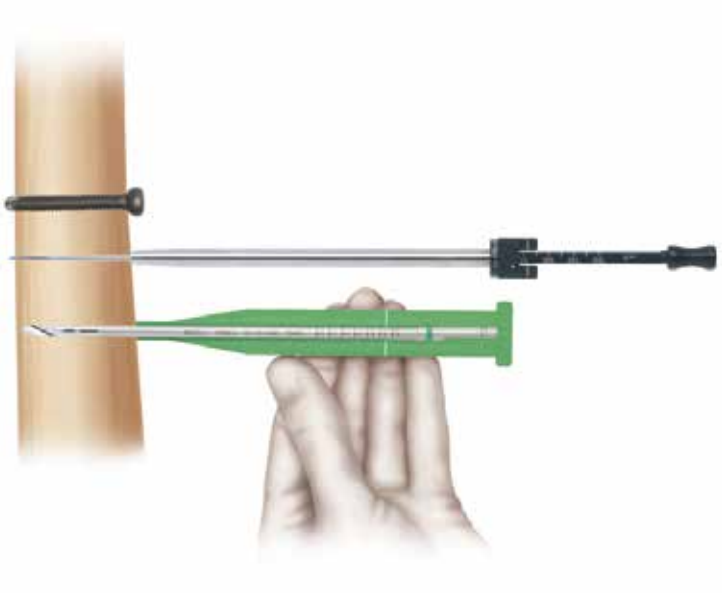


Figure 62

Proximal Locking

Using the 3.8 mm Drill Bit (6 in: 2810-12-138 or 8 in: 2810-13-138), drill until the second cortex is reached or penetrated. Verify the drill bit position fluoroscopically prior to taking any measurements (Figure 61). Place the green 4.5 mm Screw Length Gauge (2810-01-032) onto the calibrated drill bit and advance down to the bone. Read the calibration on the drill bit that corresponds to the measurement line indicated on the screw length gauge. A Screw Depth Gauge (2810-01-017) is also provided for further screw length verification. For an accurate reading, take care to ensure the 4.5 mm screw length gauge or screw depth gauge sheath is fully seated on the bone. Remove the drill bit and advance the 4.5 mm screw. Repeat above steps for additional screw placement. The SolidLok Screwdriver (2810-01-020 and 2810-01-021) can be utilized to capture the screw while passing it through soft tissue during screw placement.

Determining Screw Length

The screw size indicates the total measurement from the tip to the screw head. The calibrated drills and the screw depth gauges have a compensation factor built into the measurement such that the reading should indicate the exact size screw to achieve bi-cortical purchase. To ensure a proper reading, the screw depth gauge and drill sleeves must be touching bone. Fluoroscopy is recommended to verify the correct screw length (Figure 62).

End Cap Placement and Nail Removal

Figure 63

Figure 64

End Cap Placement

Impinging and non-impinging cannulated end caps are provided in the system to both prevent bony ingrowth and add length when needed (Figure 63).

End caps have a double hex of 5 mm and 3.5 mm and are cannulated to accept a 3.2 mm guide pin. Place the end cap into the end of the nail with the 4.5/5.5 mm Screwdriver (2810-01-015) or the SolidLok Screwdriver (2810-01-020 and 2810-01-021) (Figure 64). If the end cap will be placed using a 3.2 mm guide pin, place the end cap with the 5 mm Hex Driver (2810-01-037). Irrigate the joint to ensure that no debris remains. Close the wound.

End Cap Placement and Nail Removal

Figure 65

Figure 66

Figure 67

Nail Removal

If the surgeon deems it appropriate to remove the nail, a Cannulated Extractor Bolt (2810-01-023), used with 3/4 in Hex Driver (2810-01-027) and T-handle Hudson (2810-01-004), is provided to aid in nail extraction (Figure 65).

Locate the top of the nail through an appropriate incision. Remove the end cap. End caps have a double hex of 5 mm and 3.5 mm and are cannulated to accept a 3.2 mm guide pin. If using the guide pin method, insert the 3.2 mm guide pin and remove the end cap using the cannulated 5 mm Hex Driver (2810-01-037), which is connected to the T-handle Hudson (2810-01-004) (Figure 66).

The SolidLok® Locking Screwdriver (2810-01-020 and 2810-01-021) is also available to aid in removing the end cap, if not utilizing a guide pin. Insert the SolidLok screwdriver into the Hex Tip (2810-01-019) and tighten the handle to lock the end cap's hex tip into the inner end cap's 3.5 mm hex (Figure 67). The end cap can also be removed with a standard 3.5 mm hex screwdriver.

Make the appropriate incisions and remove all locking screws. Remove all overgrown bone around the nail's proximal aspect to avoid iatrogenic fracture during nail extraction.

Figure 68

Figure 69

Figure 70

Once locking screws are removed, drive a 3.2 mm guide pin into the cannulation in the nail's proximal section. Insert the extractor bolt over the 3.2 mm guide pin and thread it into the nail (Figure 68).

Then thread the impactor rod into the extractor bolt and use either the slotted mallet or sliding hammer to remove the nail (Figure 69).

If nail removal is unobtainable utilizing the standard extractor bolt, a Conical Nail Extractor Bolt (2810-01-022) is available for removal cases where the nail threads are difficult to engage (Figure 70). This instrument is designed to work with various nail thread/cannulation designs.

Note: Nail thread/cannulation condition may limit the purchase amount that can be gained using the conical extractor bolt.

VersaNail® Femoral Universal Ordering Information

CATALOG NUMBER	DESCRIPTION
Femoral Universal Nail 9 mm 28-50 cm	
1813-09-280	9 mm x 28 cm
1813-09-300	9 mm x 30 cm
1813-09-320	9 mm x 32 cm
1813-09-340	9 mm x 34 cm
1813-09-360	9 mm x 36 cm
1813-09-380	9 mm x 38 cm
1813-09-400	9 mm x 40 cm
1813-09-420	9 mm x 42 cm
1813-09-440	9 mm x 44 cm
1813-09-460	9 mm x 46 cm
1813-09-480	9 mm x 48 cm
1813-09-500	9 mm x 50 cm
Femoral Universal Nail 10 mm 28-50 cm	
1813-10-280	10 mm x 28 cm
1813-10-300	10 mm x 30 cm
1813-10-320	10 mm x 32 cm
1813-10-340	10 mm x 34 cm
1813-10-360	10 mm x 36 cm
1813-10-380	10 mm x 38 cm
1813-10-400	10 mm x 40 cm
1813-10-420	10 mm x 42 cm
1813-10-440	10 mm x 44 cm
1813-10-460	10 mm x 46 cm
1813-10-480	10 mm x 48 cm
1813-10-500	10 mm x 50 cm
Femoral Universal Nail 11 mm 28-50 cm	
1813-11-280	11 mm x 28 cm
1813-11-300	11 mm x 30 cm
1813-11-320	11 mm x 32 cm
1813-11-340	11 mm x 34 cm
1813-11-360	11 mm x 36 cm
1813-11-380	11 mm x 38 cm
1813-11-400	11 mm x 40 cm
1813-11-420	11 mm x 42 cm
1813-11-440	11 mm x 44 cm
1813-11-460	11 mm x 46 cm
1813-11-480	11 mm x 48 cm
1813-11-500	11 mm x 50 cm
Femoral Universal Nail 12 mm 28-50 cm	
1813-12-280	12 mm x 28 cm
1813-12-300	12 mm x 30 cm
1813-12-320	12 mm x 32 cm
1813-12-340	12 mm x 34 cm
1813-12-360	12 mm x 36 cm
1813-12-380	12 mm x 38 cm
1813-12-400	12 mm x 40 cm
1813-12-420	12 mm x 42 cm
1813-12-440	12 mm x 44 cm
1813-12-460	12 mm x 46 cm
1813-12-480	12 mm x 48 cm
1813-12-500	12 mm x 50 cm

Femoral Universal Nail 13 mm 28-50 cm	
1813-13-280	13 mm x 28 cm
1813-13-300	13 mm x 30 cm
1813-13-320	13 mm x 32 cm
1813-13-340	13 mm x 34 cm
1813-13-360	13 mm x 36 cm
1813-13-380	13 mm x 38 cm
1813-13-400	13 mm x 40 cm
1813-13-420	13 mm x 42 cm
1813-13-440	13 mm x 44 cm
1813-13-460	13 mm x 46 cm
1813-13-480	13 mm x 48 cm
1813-13-500	13 mm x 50 cm
Femoral Universal Nail 14 mm 28-50 cm (Special Order Only)	
1813-14-280	14 mm x 28 cm
1813-14-300	14 mm x 30 cm
1813-14-320	14 mm x 32 cm
1813-14-340	14 mm x 34 cm
1813-14-360	14 mm x 36 cm
1813-14-380	14 mm x 38 cm
1813-14-400	14 mm x 40 cm
1813-14-420	14 mm x 42 cm
1813-14-440	14 mm x 44 cm
1813-14-460	14 mm x 46 cm
1813-14-480	14 mm x 48 cm
1813-14-500	14 mm x 50 cm
Femoral Universal Nail 15 mm 28-50 cm (Special Order Only)	
1813-15-280	15 mm x 28 cm
1813-15-300	15 mm x 30 cm
1813-15-320	15 mm x 32 cm
1813-15-340	15 mm x 34 cm
1813-15-360	15 mm x 36 cm
1813-15-380	15 mm x 38 cm
1813-15-400	15 mm x 40 cm
1813-15-420	15 mm x 42 cm
1813-15-440	15 mm x 44 cm
1813-15-460	15 mm x 46 cm
1813-15-480	15 mm x 48 cm
1813-15-500	15 mm x 50 cm
End Caps	
1813-00-005	End Cap Universal 5 mm
1813-00-010	End Cap Universal 10 mm
1813-00-015	End Cap Universal 15 mm
1813-00-002	End Cap Universal Impinging
1813-00-001	End Cap Universal Flush

6.5 mm Self Tapping Cortical Screws Full Thread (Drive End)	
1020-40	40 mm Length
1020-45	45 mm Length
1020-50	50 mm Length
1020-55	55 mm Length
1020-60	60 mm Length
1020-65	65 mm Length
1020-70	70 mm Length
1020-75	75 mm Length
1020-80	80 mm Length
1020-85	85 mm Length
1020-90	90 mm Length
1020-95	95 mm Length
1020-100	100 mm Length
8050-65-105	105 mm Length
8050-65-110	110 mm Length
8050-65-115	115 mm Length
8050-65-120	120 mm Length
6.5 mm Solid Cancellous Lag Screws (Drive End)	
1030-60	60 mm Length
1030-65	65 mm Length
1030-70	70 mm Length
1030-75	75 mm Length
1030-80	80 mm Length
1030-85	85 mm Length
1030-90	90 mm Length
1030-95	95 mm Length
1030-100	100 mm Length
1030-105	105 mm Length
1030-110	110 mm Length
1030-115	115 mm Length
1030-120	120 mm Length
4.5 mm Self Tapping Cortical Screws Full Thread (Non-Drive End)	
14022-24	24 mm Length
14022-28	28 mm Length
14022-32	32 mm Length
14022-36	36 mm Length
14022-40	40 mm Length
14022-44	44 mm Length
14022-48	48 mm Length
14022-52	52 mm Length
14022-56	56 mm Length
14022-60	60 mm Length
14022-65	65 mm Length
14022-70	70 mm Length
14022-75	75 mm Length
14022-80	80 mm Length
(4.5 mm screws available in 2 mm increments up to 60 mm)	

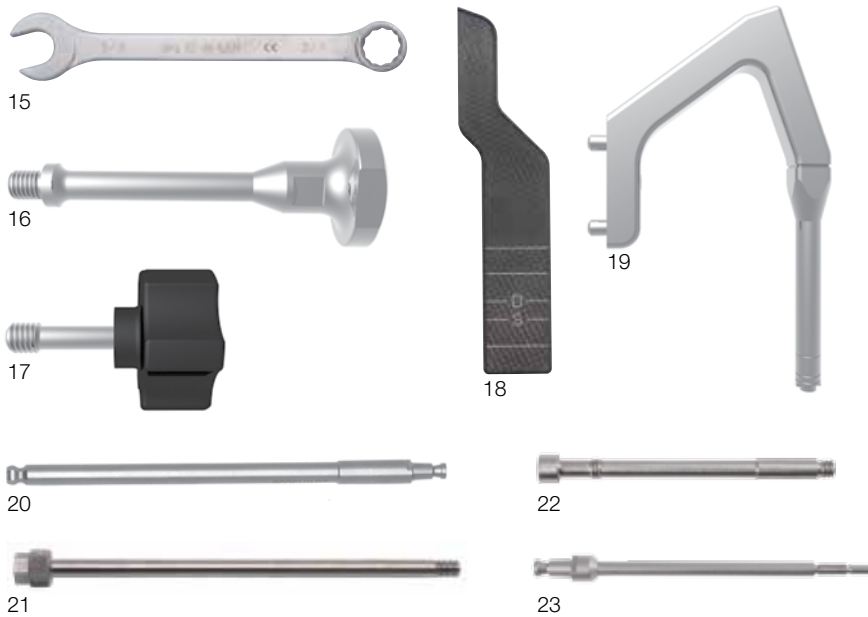
Indicates outlier size not included in standard set configuration.

Indicates special orders only. Not an inventory item. Packaged non-sterile only.

Sterile packaged.

General		
2810-01-001	Pistol Guidewire Gripper	1
2810-01-002	T-Handle Guidewire Gripper (optional)	2
2810-01-003	Slotted Mallet	3
2810-01-004	T-Handle Hudson	4
1096	Sliding Hammer	5

Canal Prep		
2810-01-007	Long Reduction Tool	6
2810-01-008	Short Reduction Tool	7
2810-01-005	Curved Cannulated Awl	8
2810-13-004	Entry Portal Trocar	9
2810-13-005	Long Entry Portal	10
2810-13-002	13 mm Entry Reamer, Femur	11
2810-13-001	12 mm Entry Reamer, Femur	12
2810-01-025	Awl Stylus	13
2810-01-026	Guidewire Pusher	14

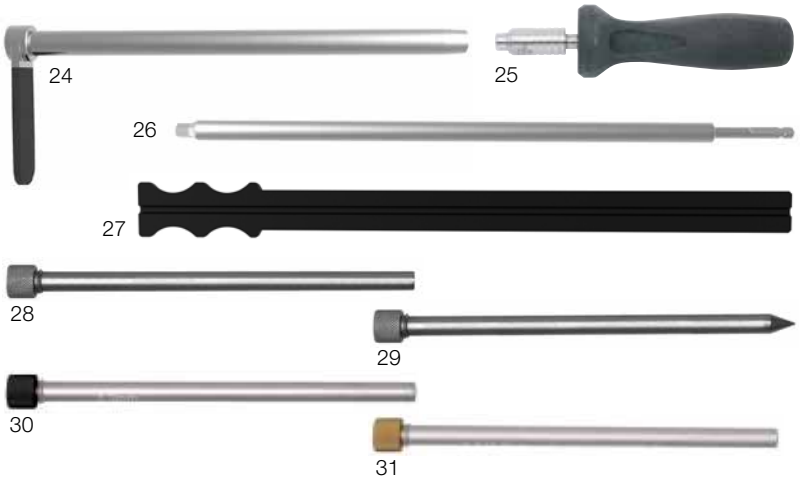


Nail Insertion		
1186	3/4 in Combination Wrench	15
2810-13-011	Hammer Pad Femur	16
2810-13-026	Target Arm Attachment Bolt	17
2810-13-009	Universal Target Arm	18
2810-13-007	Femoral Insertion Handle	19
2810-13-006	Jig Bolt Driver, 8 mm	20
1095	Impactor Rod/Extraction	21
2810-13-047	Fem Univ Compression Bolt	22
2810-13-046	Compression Rod	23

VersaNail® Femoral Universal Ordering Information

Promixal Locking

2810-13-020	6.5 mm Screw Sheath	24
2141-49-000	AO Quick Couple Screwdriver	25
2810-13-024	6.5 mm Screwdriver Shaft	26
2810-13-035	6.5 mm Screw Depth Gauge	27
2810-13-018	3.2 mm Guide Pin Sleeve - Silver	28
2810-13-021	6.5 mm Screw Trocar	29
2810-13-022	5.3 mm Drill Sleeve - Black	30
2810-13-023	6.5/4.8 mm Step Drill Sleeve - Gold	31



Distal Locking

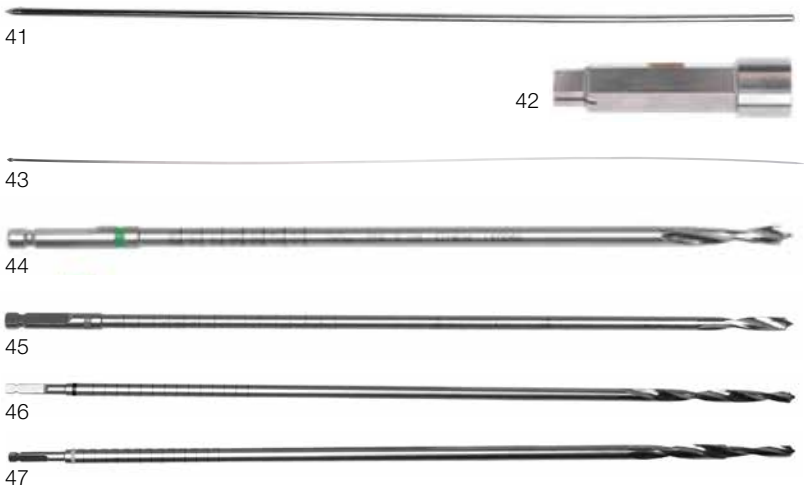
2810-01-032	4.5 mm Screw Length Gauge	32
2810-12-016	Freehand Distal Targ. Dev. Universal - Black	33
2810-01-020	SolidLok Screwdriver Handle	34
2810-01-015	4.5/5.5 mm Screwdriver Shaft	35
2810-01-017	Screw Depth Gauge	36
2810-01-021	SolidLok Driver Inner Shaft	37

Nail Removal

2810-01-023	Extractor Bolt, Tibia/Femur	38
2810-01-022	Conical Extractor Tool	39
2810-01-027	3/4 in Hex Driver	40

Disposables

14012-14	3.2 mm x 14 in Short Threaded Guide Pin	
9030-03-004	3.2 mm x 17 1/2 in Threaded Guide Pin	41
2810-01-019	SolidLok Hex Tip, 3.5 mm	42
2810-01-080	Ball Nose Guide Wire 80 cm	43
2810-01-100	Ball Nose Guide Wire 100 cm	43
2810-12-138	3.8 mm Drill Bit 6 in, Non-sterile	44
2810-13-138	3.8 mm Drill Bit 8 in, Non-sterile	45
2810-13-153	5.3 mm Drill Bit, Non-sterile	46
2810-13-165	6.5/4.8 mm Step Drill Bit, Non-sterile	47



48

49

50 Outer Case

51

52

Cases & Trays

2810-13-030	Femoral Tray Entry & Jigs	48
2810-13-031	Femoral Tray Locking & Extraction	49
8299-10-500	Modular Screw System Outer Case	50
8299-10-065	6.5 mm Screw Module	51
8299-10-045	4.5 mm Cort Screw Module	52

53

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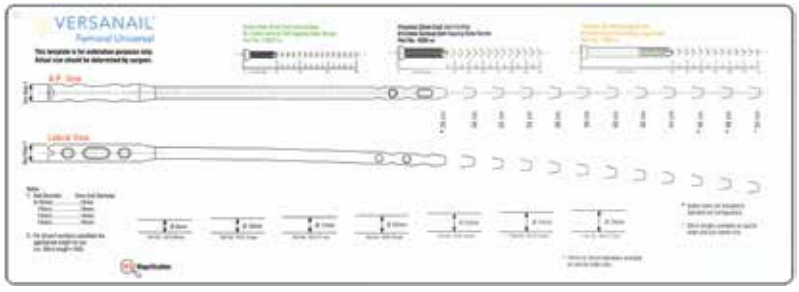

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Nail Measurement

1245	Radiographic Ruler	53
2810-01-031	Nail Length Gauge, 14 mm	54
2810-13-025	VersaNail Femoral Universal Template	55

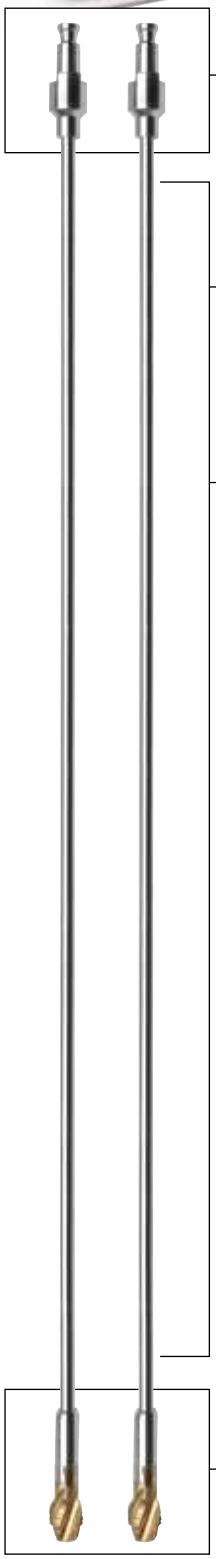
56

Endcap Placement

2810-01-037	5.0 mm Hex Driver, Long	56

VersaNail® Femoral Universal Ordering Information

Flexible Reaming System



Coupling design is simple,long established and easy to clean (AO and/or HUDSON).

Excellent cleanability - Nitinol (Nickel-Titanium) alloy allows for a smooth cannulated shaft that provides the required flexibility without the cleaning problems associated with coil-cut or spring shaft designs.

Small shaft diameters allow debris to be removed and transported up to the open proximal end of the medullary canal.

Deep cutting flutes allow debris to be moved proximally away from the reamer head, maintaining cutting edge efficiency.

Sharp side cutting edges are designed to remove bone without generating a substantial increase in temperature.

Surface coating titanium nitride (TiNi) will keep cutting edge sharper longer.

Ellipsoidal head shape allows the cutting edge to remove bone gradually and transport debris away, while bone chipping design decreases the size of debris, reducing canal pressure.

Reverse cutting feature minimizes the potential for the reamer to catch in the medullary canal.

Monobloc Reamer Hudson

Cat. No.	Diameter
2810-02-060	6.0 mm
2810-02-065	6.5 mm
2810-02-070	7.0 mm
2810-02-075	7.5 mm
2810-02-080	8.0 mm
2810-02-085	8.5 mm
2810-02-090	9.0 mm
2810-02-095	9.5 mm
2810-02-100	10.0 mm
2810-02-105	10.5 mm
2810-02-110	11.0 mm
2810-02-115	11.5 mm
2810-02-120	12.0 mm
2810-02-125	12.5 mm
2810-02-130	13.0 mm

Modular Reamer Head

Cat. No.	Diameter
2810-04-090	9.0 mm
2810-04-095	9.5 mm
2810-04-100	10.0 mm
2810-04-105	10.5 mm
2810-04-110	11.0 mm
2810-04-115	11.5 mm
2810-04-120	12.0 mm
2810-04-125	12.5 mm
2810-04-130	13.0 mm
2810-04-135	13.5 mm
2810-04-140	14.0 mm
2810-04-145	14.5 mm
2810-04-150	15.0 mm
2810-04-155	15.5 mm
2810-04-160	16.0 mm
2810-04-165	16.5 mm
2810-04-170	17.0 mm
2810-04-175	17.5 mm
2810-04-180	18.0 mm
2810-04-185	18.5 mm
2810-04-190	19.0 mm
2810-04-195	19.5 mm
2810-04-200	20.0 mm
2810-04-205	20.5 mm
2810-04-210	21.0 mm
2810-04-215	21.5 mm
2810-04-220	22.0 mm

Nitinol Modular Reamer Shaft Hudson

Cat. No.	Length
2810-02-400	400 mm
2810-02-470	470 mm

Reamer Extension

Cat. No.	Length
2810-02-015	150 mm

Ball Nose Guide Wires

Cat. No.	Length
3.0 mm (use with 8.0-22.0 mm Reamers)	
2810-01-080	800 mm
2810-01-100	1000 mm
2.0 mm (use with 6.0-7.5 mm Reamers)	
2810-17-006	700 mm

Flexible Reamer Case

2810-02-016

Notes

Notes

Screws, Plates, Intramedullary Nails, Compression Hip Screws, Pins and Wires

Important:

This Essential Product Information does not include all of the information necessary for selection and use of a device. Please see full labeling for all necessary information.

Indications:

The use of metallic surgical appliances (screws, plates, intramedullary nails, compression hip screws, pins and wires) provides the orthopaedic surgeon a means of bone fixation and helps generally in the management of fractures and reconstructive surgeries. These implants are intended as a guide 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 subjected to repeated stress in use, which can result in metal fatigue.

Contraindications:

Screws, plates, intramedullary nails, compression hip screws, pins and wires are contraindicated in: active infection, conditions which tend to retard healing such as blood supply limitations, previous infections, insufficient quantity or quality of bone to permit stabilization of the fracture complex, conditions that restrict the patient's ability or willingness to follow postoperative instructions during the healing process, foreign body sensitivity, and cases where the implant(s) would cross open epiphyseal plates in skeletally immature patients.

Additional Contraindication for Orthopaedic Screws and Plates only: Cases with malignant primary or metastatic tumors which preclude adequate bone support or screw fixations, unless supplemental fixation or stabilization methods are utilized.

Additional Contraindication for Retrograde Femoral Nailing:

A history of septic arthritis of the knee and knee extension contracture with inability to attain at least 45º of flexion.

Additional Contraindications for Compression Hip Screws only:

Inadequate implant support due to the lack of medial buttress.

Warnings and Precautions:

Bone screws and pins are intended for partial weight bearing and non-weight bearing applications. These components cannot be expected to withstand the unsupported stresses of full weight bearing.

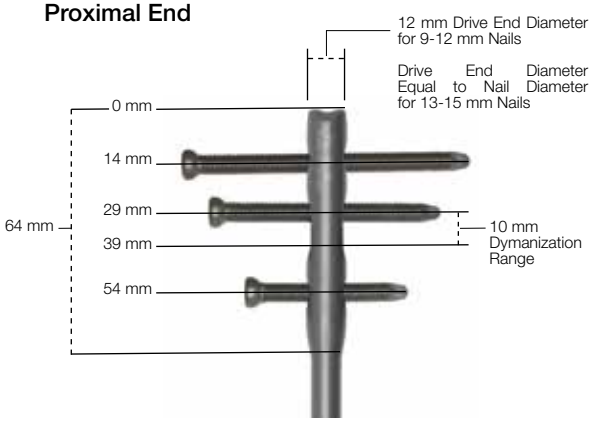
Adverse Events:

The following are the most frequent adverse events after fixation with orthopaedic screws, plates, intramedullary nails, compression hip screws, pins and wires: loosening, bending, cracking or fracture of the components or loss of fixation in bone attributable to nonunion, osteoporosis, markedly unstable comminuted fractures; loss of anatomic position with nonunion or malunion with rotation or angulation; infection and allergies and adverse reactions to the device material. Surgeons should take care when targeting and drilling for the proximal screws in any tibial nail with oblique proximal screws. Care should be taken as the drill bit is advanced to penetrate the far cortex. Advancing the drill bit too far in this area may cause injury to the deep peroneal nerve. Fluoroscopy should be used to verify correct positioning of the drill bit.

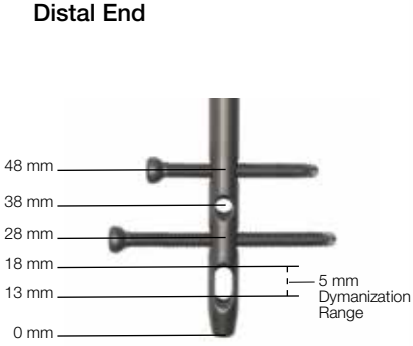
Additional Adverse Events for Compression Hip Screw only:

Screw cutout of the femoral head (usually associated with osteoporotic bone).

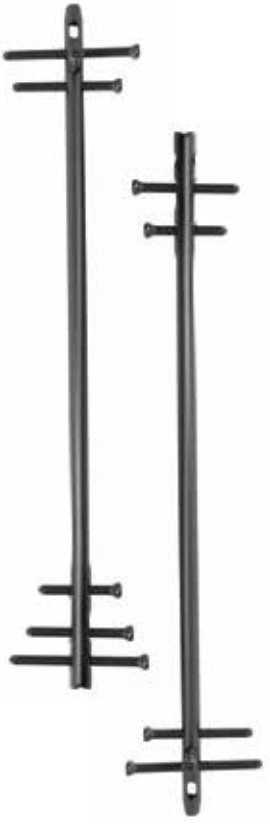
Proximal End



Distal End



Locking Options



For product information see package insert and Biomet's website.

Biomet does not practice medicine and does not recommend any particular orthopaedic implant or surgical technique and is not responsible for the kind of treatment selected for a specific patient. The surgeon who performs any implant procedure is responsible for determining and utilizing the appropriate techniques for implanting prosthesis in each individual patient.

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