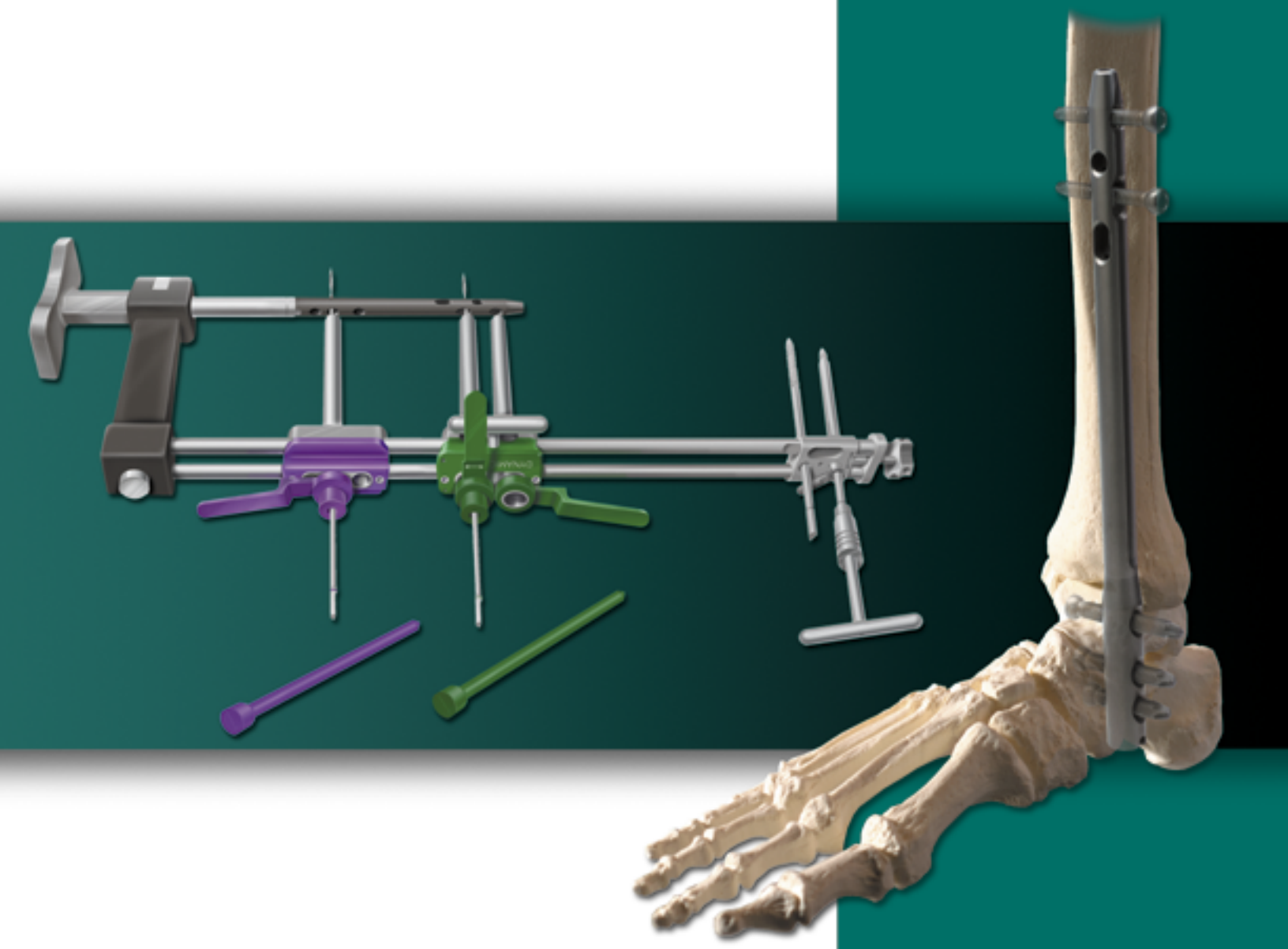
Tibiotalocalcaneal Fusion Using the VersaNail™

Surgical Technique



DePuy ACE
a Johnson & Johnson company

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All Operative Features in One *Versa*tile Nailing System from Primary to Salvage!

Implant Versatility

- Lateral-medial or posterior-anterior distal screw orientation options
- Three anatomically-ideal distal hole choices
- Both a proximal static hole and dynamic slot
- Wide range of sterile nail sizes and end cap styles
- Increased fatigue strength of TiMAX™ allows for the unique versatile design

Instrumentation Versatility

- Push button release allows targeting arm to rotate and lock with ease in 90 degree positions around the foot
- Adjustable targeting device provides:
  - Proximal nail length setting options
  - Intraoperative fine tuning of targeting carriage
  - Controlled proximal dynamization
- Intraoperative axial compression (10 mm)
- Color-coded instrumentation for ease-of-use in the OR

Design Rationale

The VersaNail System, developed to address ankle arthrodesis, offers versatile implants that are optimal for the anatomy of the foot. The VersaNail's easy-to-use instrumentation provides a wide range of operative features in one system.

Intramedullary (IM) Nails

Due to the advantageous properties of the material, all implants are manufactured from 6Al-4V ELI grade, proprietary type II anodized (TiMAX) titanium alloy. This material offers a lower modulus of elasticity, increased fatigue strength over stainless steel and decreased risk for patient metal sensitivity. Based on market experience, the nail sizes for the system were created in 10 and 12 mm proximal diameters and 150, 200 and 250 mm lengths (300 mm special order). Both the 10 and 12 mm diameter options have a 12 mm distal end, allowing larger screw diameters for this region of increased anatomic stresses. Therefore, only the 10 mm nail incorporates a tapered design, occurring just proximal to the distal hole construct.

The distal end of the nail accommodates three 5.5 mm-diameter fully-threaded cortical screws. The distal holes are grouped to ideally place the two most distal screws in the calcaneus and the third screw in the main body of the talus. Dual calcaneal screws eliminate significant rotation, preventing the calcaneus from "rocking" on the nail during weight-bearing. The talus, fixed between the calcaneus and the distal tibia, requires one screw for sufficient rigidity.

The proximal end of the nail uses 4.5 mm-diameter fully-threaded cortical screws, which can be locked statically or in a dynamic mode. The dynamic slot allows 5 mm of axial movement while maintaining rotational control. The nail offers a dual construct of one dynamic slot and one round hole at the proximal nail end in both the lateral and anteroposterior planes. Thus, regardless of whether the distal end of the nail is placed lateral-medial or posterior-anterior, the proximal screws can be placed from medial to lateral through the nail.

End Caps

To provide surgical options, three end cap designs are available in this system. In addition to a nonimpinging design, two impinging end caps capture the first- or second-most distal 5.5 mm locking screw to prevent screw migration. All end caps sit flush to the end of the nail and protect the internal threads from tissue ingrowth.

Screws

The self-tapping screws have an enlarged core diameter for increased static and fatigue strength. The resultant design provides a smaller outside diameter with comparable strength characteristics to larger diameter screws. Additional 5.5 mm distal screw sizes were created to accommodate the very short calcaneal bridges in the lateral-medial orientation and longer distances through the body of the calcaneus for the posterior-anterior approach.

Instrumentation and Cases

A dedicated instrumentation set takes full advantage of the versatility of the implants. The color-coded compression targeting device rotates completely around the nail and locks in 90 degree increments at the push of a button. This characteristic facilitates targeting and insertion of the locking screws in lateral-medial, posterior-anterior and medial-lateral planes. The proximal carriage slides and locks into six distinct positions, depending upon the selected nail length and the distal screw orientation, and can be repositioned intraoperatively for fine adjustment. The targeting device includes an external fixation compression feature to assist in alignment of the screw holes and to provide up to 10 mm of axial compression across the fusion site. The distal and proximal instrumentation are color-coded for ease of identification and use. The calibrated drills have a trocar tip to minimize the drill from "walking" on the cortical surfaces. The single instrument case is designed with color-coded instrument outlines and organized by procedural steps to assist the OR staff.

Introduction

Surgical technique written in conjunction with Paul S. Cooper, MD, Associate Professor, Department of Orthopaedic Surgery, Georgetown University Medical Center, Washington, D.C.

The following are some of the surgical indications and contraindications for the DePuy ACE VersaNail for tibiotalocalcaneal fusion:

This product could be used if the following conditions are present:

- Revision of failed ankle arthrodesis
- Talar deficiency conditions (requiring a tibiocalcaneal arthrodesis)
- Post-traumatic or primary arthrosis involving both ankle and subtalar joints
- Rheumatoid hindfoot with severe deformity
- Avascular necrosis of the talus
- Failed total ankle arthroplasty from aseptic conditions
- Neuropathic ankle deformity

This product should not be used if the following conditions are present:

- Intact asymptomatic subtalar joint
- Significant tibial malalignment (less than 10 degrees in either the sagittal or coronal plane)
- Active soft tissue infection/osteomyelitis of lower limb
- Severe peripheral vascular disease

Please see the package insert for a complete list of indications and contraindications.

Preoperative Planning

Initial evaluation consists of both clinical and radiographic confirmation of ankle and hindfoot arthrosis and deformity consistent with patient's symptoms. Clinical assessment includes a thorough evaluation of the quality and viability of the soft tissues about the surgical site, vascular status and presence of neuropathy. If the source of the pain is in question, use diagnostic intra-articular injections in the ankle or subtalar joints to confirm the location. Radiographic evaluation of the ankle includes a weight-bearing anteroposterior, mortise and lateral series. A lateral hindfoot and Broden's view are useful in evaluating the subtalar and transverse tarsal joints. A tibiocalcaneal view demonstrating the overall alignment helps to determine the deformity apex in the coronal plane. Confirm appropriate VersaNail implant size with the use of the preoperative X-ray template (Cat. No. 8207-10-999).

Note: 150 mm nails are typically utilized in post-traumatic and talar-deficient cases. In Charcot deformities or other neuropathic conditions, use of 200 or 250 mm length rods that extend proximal to the isthmus are recommended.

Surgical Technique

Patient Positioning

Select either **L/M** (gray box) or **P/A** (yellow box) Distal Approach

Lateral-Medial (L/M) Distal Approach

Place the patient in a supine position on a fluoroscopy table with a well-padded tourniquet on the upper thigh. Place a roll under the ipsilateral buttocks to maintain a neutral rotational position of the knee and lower limb. In cases where rotary deformities of the lower limb exist, prepare and drape the contralateral limb as well. Prepare the entire foot and ankle up to the thigh tourniquet and drape the limb free to allow intraoperative assessment of lower limb alignment. Position a standard or minifluoroscopy unit on the operative side to obtain both full length anteroposterior and lateral studies of the lower limb. Inflate the tourniquet following exsanguination with an Esmarch bandage.

Posterior-Anterior (P/A) Distal Approach

Place the patient in a decubitus (lateral) position on a bean bag with the operative limb facing up. Prepare and drape the leg above the knee. Apply a thigh tourniquet. Ensure the leg externally rotates sufficiently to provide access for all medial applied portions of the surgical procedure (anteromedial and lateral ankle joint preparation, compression application and proximal screw placement). Position a standard or minifluoroscopy unit on the operative side to obtain both full length anteroposterior and lateral studies of the lower limb.

Surgical Procedure For Lateral Transmalleolar Approach Joint Exposure and Preparation

To expose both the lateral ankle and subtalar joints, make a 10 cm curvilinear incision over the distal 6-8 cm of the fibula that extends inferior and anterior over the sinus tarsi *[Figure 1]*.

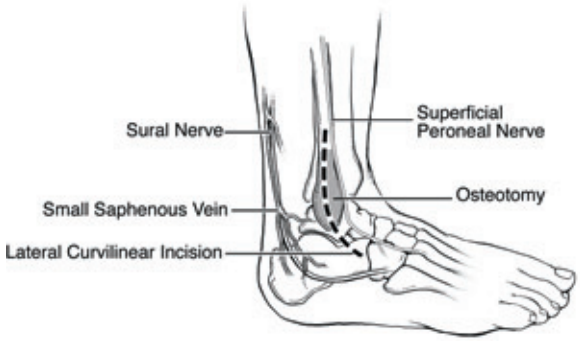


Figure 1

This is an internervus plane between the superficial peroneal nerve anteriorly and the sural nerve posteriorly. Free the distal fibula of surrounding soft tissue. Using a sagittal saw to apply a beveled cut, resect the fibula obliquely at a 45 degree angle 3-4 cm above the ankle joint. Morselize the excised fibula on a back table with a rongeur or bone mill for use as bone graft later in the procedure.

Make a second 3 cm longitudinal incision along the anteromedial aspect of the ankle joint, medial to the tibialis anterior tendon, and expose the medial ankle joint *[Figure 2]*.

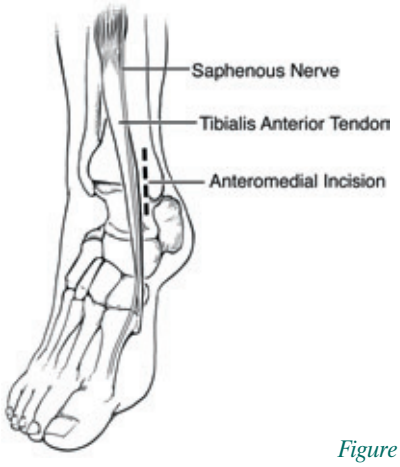


Figure 2

Mobilize the ankle joint with a Cobb elevator and then place a lamina spreader in the medial joint for distraction. Denude the lateral half of the articular surfaces of the tibiotalar joint and then reposition the lamina spreader in the lateral wound to allow distraction of the medial tibiotalar joint to complete the debridement *[Figure 3]*.

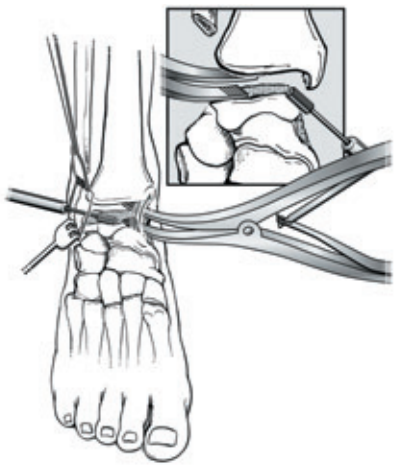


Figure 3

Maintaining the contour of the ankle joint in cases without severe deformity will enhance the fusion and provide better alignment. Debride 1 cm from the medial gutter by resecting 5 mm from both the medial talar dome and the medial malleolus.

When completed, the talus should translate medially by 1 cm *[Figure 4]***. This is a critical step in assuring the talus and calcaneus are centered with the tibial canal on rod insertion to reduce the risk of damage to the lateral plantar nerve.** Utilize the Pe.R.I.™ Tongs (optional Cat. Nos. 1919 to 1922) to hold the medial translation of the foot.

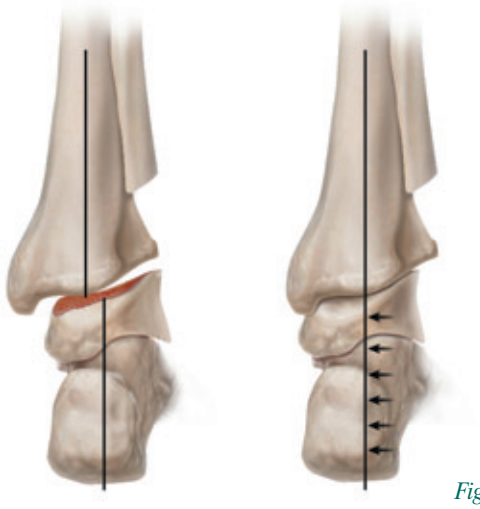


Figure 4

Denude the articular surfaces with either curettes or a high-speed motorized burr *[Figure 3]*. Refrain from excessive burring of sclerotic areas on the joint surfaces, which will lead to large bony gaps and decrease the contact area for successful arthrodesis. Use iced saline to irrigate while burring to help prevent heat necrosis of the bone. In cases of extensive joint destruction, use a sagittal saw or osteotome to create parallel transverse tibial and talar surfaces. Use a 3.5 mm drill bit with a drill guide (optional Cat. No. 13543) to create vascular channels to facilitate arthrodesis while preserving bone stock. Next, resect the soft tissue within the sinus tarsi with a single lamina spreader. Denude the posterior facet of the subtalar joint in a similar fashion *[Figure 4]*.

In the presence of deformity in the sagittal or coronal plane involving the tibiotalar or talocalcaneal joints, an osteotomy may be necessary to correct the malalignment. This may require a full transmalleolar resection to obtain flush surfaces for sufficient contact at the ankle joint level. However, avoid complete resection of the medial malleolus if possible to reduce injury to the deltoid artery. In cases of excessive bone loss, which would result in greater than 2 cm of residual limb shortening, insert an intercalary femoral head bone block allograft into the defect. Augment with either autogenous cancellous graft or a platelet derived substitute.

Ankle Positioning and Temporary Stabilization

Once the joints have been adequately prepared, position the foot with neutral ankle dorsi-plantar flexion, 5 degrees external rotation in relationship to the tibial crest and 5 degrees of hindfoot valgus while maintaining a plantigrade foot *[Figure 5]*. In addition, translate the talus medially in relation to the central axis of the tibia. Avoid excessive posterior translation, which will place the rod too anterior in the talus and calcaneus, compromising fixation.

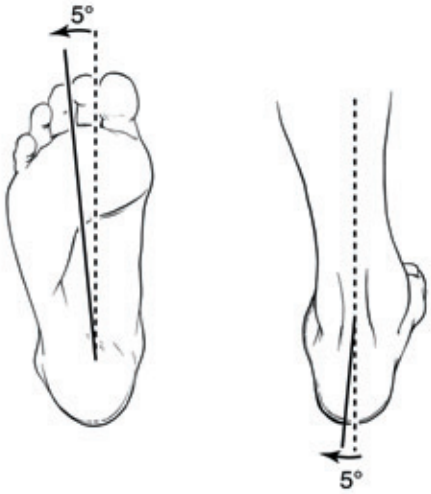


Figure 5

Temporarily stabilize the joint in the desired position using 9 in. guide pins anteriorly, taking care to avoid obstructing the center body of the talus and intramedullary canal of the tibia *[Figure 6]*. A temporary spanning external fixator can also be applied medially instead of guide pins with the distal pins in the calcaneus and talus offset from the central canal and with the proximal pins distal to the locking screw site in the medial tibia.

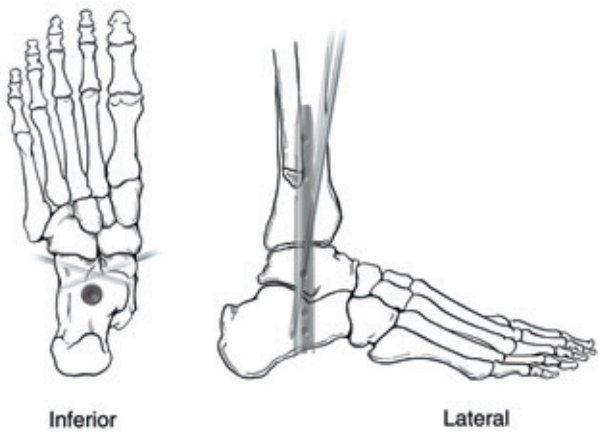


Figure 6

Plantar Exposure

Position the C-arm to obtain a true lateral view of the distal tibia and hindfoot. Place a 14 in. guide pin (Cat. No. 14012-14) 1-2 cm distal from the subcalcaneal fat pad to locate the starting point for nail insertion. The starting point will vary based upon the patient's foot pattern, with a cavus foot pattern starting more proximally and a planovalgus foot more distally. Individual variations in the starting point can be extreme and should be determined primarily on the lateral fluoroscopic view.

Make a 3-4 cm longitudinal incision midline on the plantar foot of the heel pad *[Figure 7]*. Bluntly dissect through the plantar fascia. Using a small Cobb elevator, dissect through the soft tissue to the plantar os calcis. Gently retract the neurovascular bundle (involving the lateral plantar nerve and artery) medially with a narrow small Hohmann retractor and introduce the entry guide (Cat. No. 8207-09-000) into the wound over the placed guide pin. Seat the teeth of the entry guide longitudinally on the plantar cortex of the calcaneus with gentle taps of a mallet.

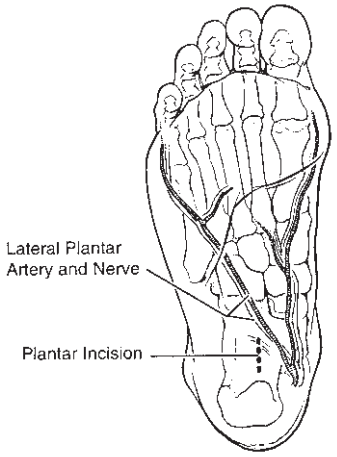


Figure 7

Distal Entry Portal Preparation - Guide Pin Insertion

Use a power driver to insert and seat the 14 in. threaded guide pin (Cat. No. 14012-14) through the entry guide, from the plantar calcaneus through to the distal tibial medullary canal. Confirm using both anteroposterior and lateral fluoroscopy that the pin is in line with the anatomic tibial axis.

Place the cannulated awl (Cat. No. 8207-01-000), without the awl trocar (Cat. No. 8207-02-000), over the guide pin and through the entry guide *[Figure 8]*.

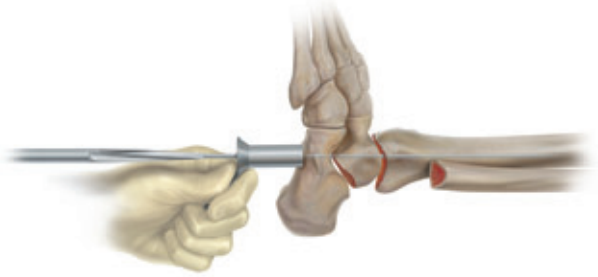


Figure 8

Manually ream up to the level of the distal metaphysis of the tibia *[Figure 9]*. Confirm proper cannulated awl position under fluoroscopy.

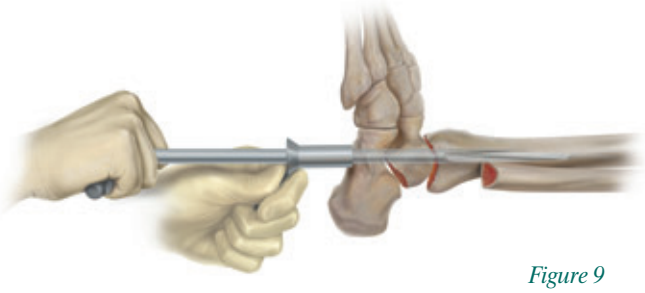


Figure 9

Note: In cases of sclerotic bone, the additional option of a power 8.5 mm cannulated entry reamer (Cat. No. 8207-11-000) may be preferred.

Alternative Entry Portal Option: Use the cannulated awl and awl trocar together as a single step to create the entry portal. Advance the locked cannulated awl and awl trocar assembly under fluoroscopy into the distal tibial intramedullary canal.

Proximal Flexible Reaming

Leaving the entry guide in place, remove the cannulated awl, trocar, guide pin or cannulated entry reamer. Insert the 38 in. ball nose guide wire (Cat. No. 8092-30-038) using the guide wire grip (Cat. No. 1291) into the proximal tibia under fluoroscopy *[Figure 10]*. Use both anteroposterior and lateral fluoroscopy to document that the ball nose guide wire remains centrally located in the tibia.

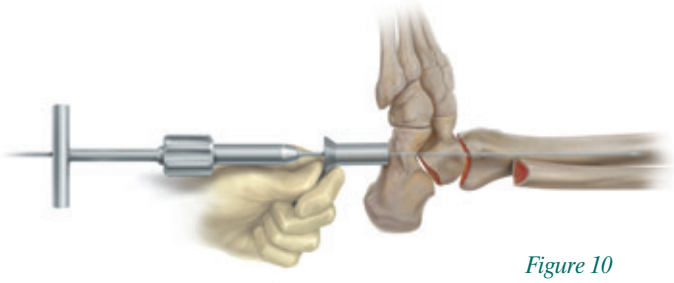


Figure 10

Place a 9 mm diameter flexible reamer over the ball nose guide wire and advance it through the entry guide into the tibial intramedullary canal *[Figure 11]*.

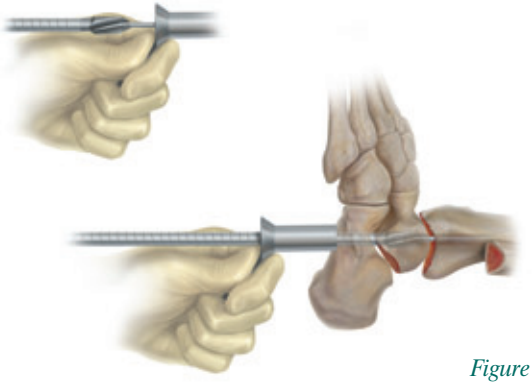


Figure 11

Increase reamer diameter sequentially in 0.5 mm increments until the final diameter of the portal is a minimum of 0.5 mm greater than the proximal diameter of the nail. If the length of the rod extends past the tibial diaphysis, ream to 1 mm greater than the rods proximal diameter to avoid risk of tibial fracture upon rod insertion.

Note for reaming: Monitor the foot position during reaming to ensure proper hindfoot alignment is maintained. There is a tendency for the foot to fall into plantar flexion during reaming, which will result in ankle equinus upon nail insertion.

Remove the flexible reamer and ball nose guide wire while leaving the entry guide in place. Insert a driving guide wire (Cat. No. 8092-32-238) into the tibial intramedullary canal using fluoroscopy to confirm proper placement.

Nail Selection and Compression Targeting Device Assembly

With the ankle prepared and aligned properly, select the appropriate size VersaNail implant using the radiographic trial sizer (Cat. No. 8207-08-000). Under fluoroscopy, the trial sizer will demonstrate the 150, 200 and 250 mm nail length, as well as the distal hole locations.

Place the appropriate size nail on the compression targeting device (Cat. No. 8207-05-000). Use the hammer pad (Cat. No. 8207-06-000) to secure the nail to the targeting device using the 3/4 in. wrench (Cat. No. 1186) *[Figure 12]*.

Figure 12

Prior to nail insertion, perform a test for proper targeting alignment by passing drill bits through the targeting device and nail holes *[Figure 13]*. However, proximal alignment verification will not be possible if distal P/A orientation is anticipated, since the P/A grouping of proximal nail holes will be 90 degrees off the drill bit path.

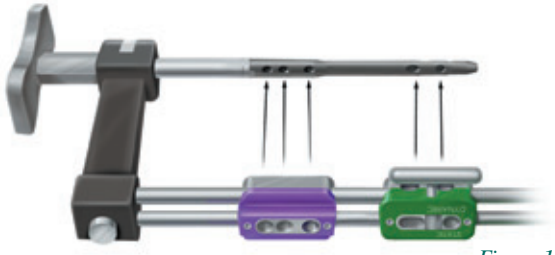


Figure 13

Insertion of Compression Targeting Device Assembly

Under fluoroscopy, advance the nail assembly manually over the driving guide wire until resistance is felt and then remove the guide wire *[Figure 14]*.

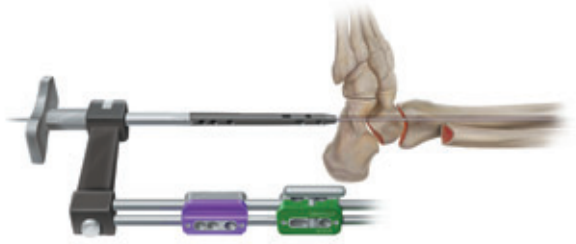


Figure 14

Continue to insert the nail assembly under fluoroscopy by striking the hammer pad with a large mallet, taking care to keep the foot manually positioned in neutral dorsiflexion *[Figure 15]*. If excessive resistance is felt, re-address proximal reaming as necessary to avoid tibial shaft fracture. **Never directly hit the targeting device.**

Figure 15

If hindfoot alignment is compromised while inserting the nail, remove the nail. Increase the diameter of the canal by incrementally reaming until proper alignment can be maintained with nail insertion. Generally, each millimeter of increased reaming will allow for approximately 2-3 degrees of correction. Take caution to avoid oblique insertion of the nail near the tibial isthmus to reduce the potential risk of a fracture at the proximal to the tip of the nail upon insertion. If a fracture does occur, exchange with a longer length nail.

Final Nail Seating

Determine final nail seating using fluoroscopy to view the placement of the three distal holes in the calcaneus and talus respectively.

Determine Final Nail Seating for **L/M** (gray box) or **P/A** (yellow box) Distal Option.

L/M Distal Approach

Ideally, place the two most distal holes in the calcaneus and the third in the talus *[Figure 16]*. Critical landmarks for the L/M orientation would place the second distal screw hole in the sustentaculum tali.

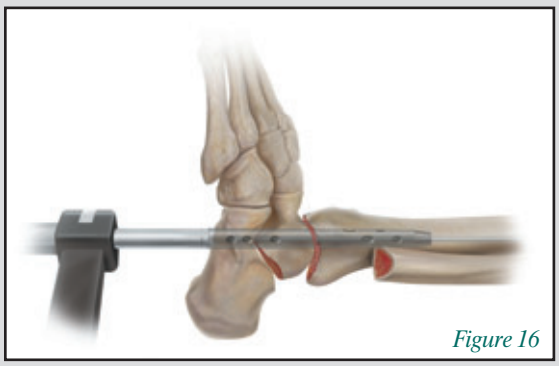


Figure 16

P/A Distal Approach

The ideal P/A orientation seating places the proximal screw through the longitudinal axis of the talar body. If the talus is absent, center the middle and plantar screws in the calcaneal body. The P/A approach should actually be a posterolateral to anteromedial (~ 15-20 degrees off the sagittal midline) such that the distal screws are directed in the longitudinal plane of the talus to assure optimal fixation *[Figure 17]*.

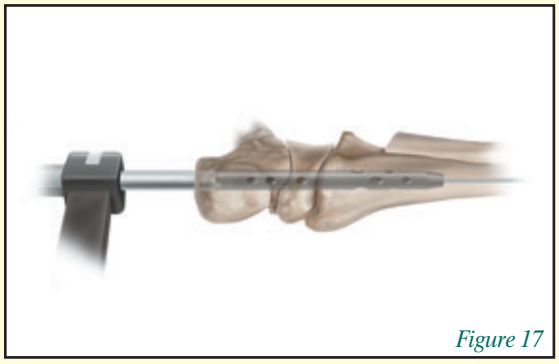


Figure 17

Ideally, the distal end of the nail should be flush or recessed within the cortex of the os calcis. Particularly in pes planus feet, the lower calcaneal pitch angle may leave the end of the nail slightly proud (usually greater than 5 mm). This is acceptable, as long as the nail is not seated proud as compared to the plantar calcaneal weight-bearing surface.

Once the nail is properly seated, add bone graft by tamping it into any larger defects. Bone graft options include: morselized fibula, ipsilateral proximal tibia, iliac crest and/or synthetic bone substitute. These bone graft materials may be combined with platelet rich plasma (Symphony™ PCS) to facilitate graft fixation and to optimize conditions for bone healing.

Distal Locking with 5.5 mm Screws

(purple instrumentation)

Select **L/M** (gray box) or **P/A** (yellow box) Distal Screw Placement.

L/M Distal Screw Placement

Once the nail is properly seated, place distal 5.5 mm cortical screws using the purple instrumentation. Before proceeding, take a moment to **verify that the targeting device directly below the nail is notched at the L/M position** such that the distal nail holes will accept the drill bits *[Figure 18]* .

Figure 18

Thread the purple trocar (Cat. No. 8207-55-002) into the purple sheath (Cat. No. 8207-55-001) *[Figure 19]*. Insert the sheath and trocar assembly through the first desired distal screw hole in the purple carriage on the targeting device. Retract the soft tissues (including the peroneal tendons) posteriorly and inferiorly, and insert the trocar against the lateral wall of the os calcis.

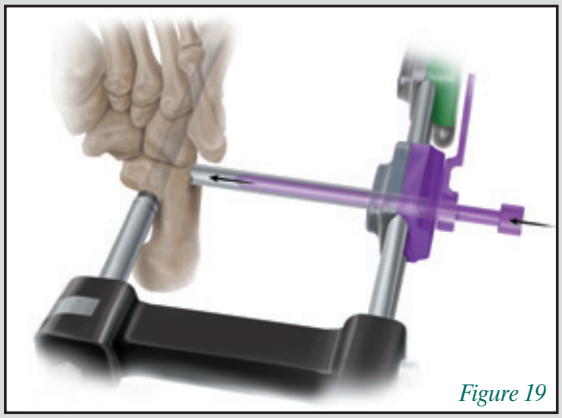


Figure 19

L/M Distal Screw Placement, continued

Unscrew the trocar from the sheath and replace it with the purple 4.4 mm drill sleeve (Cat. No. 8207-55-003), screw the sleeve down into the sheath. Insert the 4.4 mm diameter depth twist drill with trocar tip (Cat. No. 8207-55-004) into the drill sleeve and sheath assembly and drill through the lateral cortex, through the nail hole and into the medial cortex *[Figure 20]*. Determine the proper length 5.5 mm screw by reading the calibration mark off the drill at the back of the drill sleeve. A depth gauge (Cat. No. 8207-07-000) can also be used to determine proper screw length.

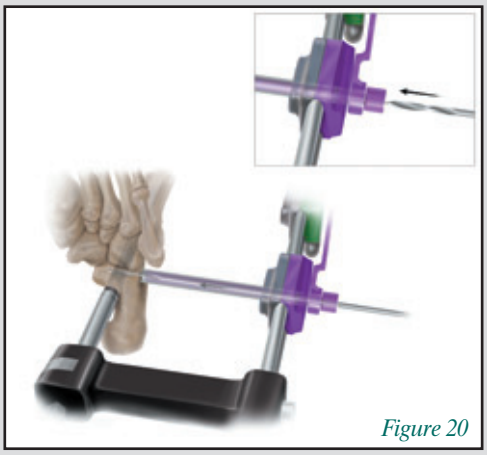


Figure 20

Remove the drill sleeve and drill. Using the T-handle screwdriver (Cat. No. 1250), place the appropriate length 5.5 mm diameter self-tapping cortical screw through the purple sheath, and advance it into the predrilled hole, through the nail, and seat it firmly against the lateral wall *[Figure 21]*. Reposition the sheath and trocar assembly and repeat the technique as described above for the remaining distal screw holes.

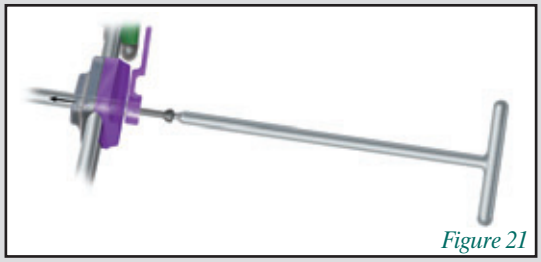


Figure 21

Under fluoroscopy, verify proper placement of the distal screws in anteroposterior and lateral views *[Figure 22]*.

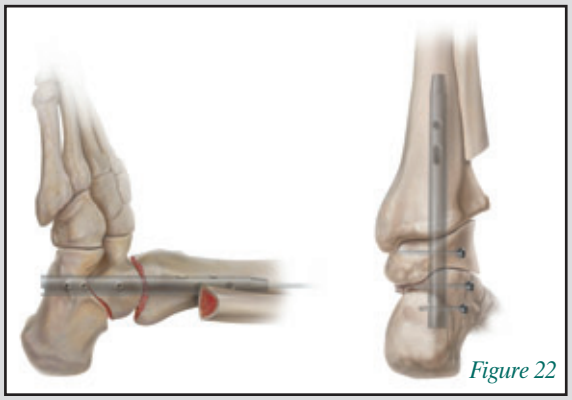


Figure 22

P/A Distal Screw Placement

In cases of poor bone quality or where a pantalar arthrodesis is considered, the P/A approach for distal 5.5 mm cortical screws may be ideal.

Note: The notch on the compression targeting device must read L/M regardless of the distal screw option selected (L/M or P/A) *[Figure 23]*. If this is not observed, the distal nail holes will be at 90 degrees from the targeting attempts.

Figure 23

Nail orientation should be posterolateral to anteromedial (~ 15-20 degrees off the sagittal midline). This plane directs the distal screws through the long axis of the talus to assure optimal fixation. Use lateral fluoroscopy to confirm centering of the most proximal screw in the talar body. If the talus is absent, center the middle and distal plantar screws in the calcaneal body. Following compression, place the most proximal screw into the distal tibia for added fixation. If pantalar arthrodesis is planned, the length of screws should factor fixation across the talonavicular joint. Use an optional power screwdriver attachment (Cat. No. 2631) to aid in screw insertion for the longer screws required in the P/A option.

Follow the same sequence of events for screw placement described in the L/M Distal Screw Placement Section (pages 13-14).

Under fluoroscopy, verify proper placement of the distal screws in lateral and P/A views *[Figure 24]*.

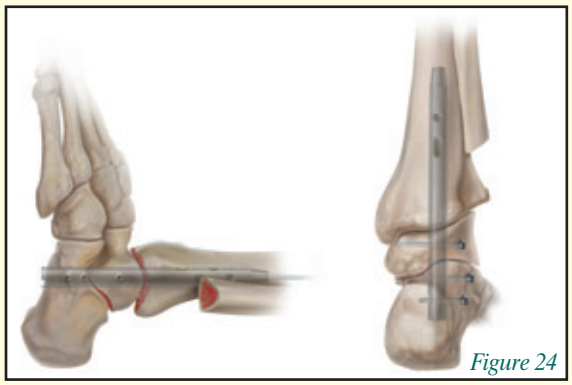


Figure 24

Apply Manual Compression

Once distal screws are placed and bone graft has been added to the joint spaces, apply manual compression by striking the bottom of the hammer pad two or three times *[Figure 25]*.

Figure 25

Rotation of Targeting Device to Medial Side of Limb

With the distal 5.5 mm screws in place, disengage the long arm of the targeting device by depressing the push button on the "elbow" of the compression targeting device *[Figure 26]*.

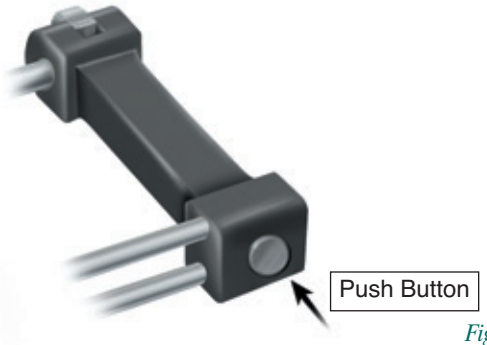


Figure 26

Swing the long arm of the targeting device to the medial side of the leg until it locks/engages in place. The targeting arm will swing 180 degrees if distal screws were placed L/M and 90 degrees if the P/A orientation was selected *[Figure 27]*.

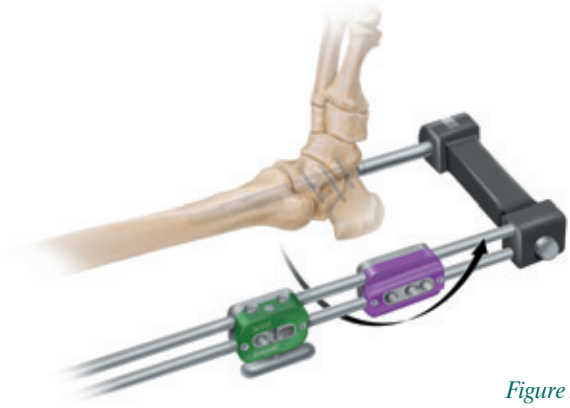


Figure 27

Note: Once the targeting arm is on the medial side of the limb, the notch on the end of the targeting device will read either L/M or P/A. Confirm the green 4.5 mm carriage and the notch on the base of the targeting arm both read the same, either L/M or P/A.

Pin Insertion for Applying Compression and Targeting Device Stabilization

Prior to compression pin insertion, fully extend the compression knob in a counter-clockwise direction *[Figure 28]*. Assess for rotation of the limb prior to pin placement since there is a tendency for internal rotation to occur.

Figure 28

Make a stab wound at the distal hole in the proximal compression pin carriage. Insert both the pin sheath (Cat. No. 8207-10-000) and pin trocar (Cat. No. 8207-10-001) through the targeting device to the bone.

Remove the pin trocar and place the first self-drilling and self-tapping pin (Cat. No. 8107-10-000) through the pin sheath either by hand using the T-handle quick couple attachment (Cat. No. 8210-69-000) or under power. Use fluoroscopy to prevent the pin tip from penetrating soft tissues upon exit from the second cortex. Obtain the second pin sheath and previous pin trocar and repeat for the most proximal hole through the pin guide of the compression targeting device *[Figure 29]*.

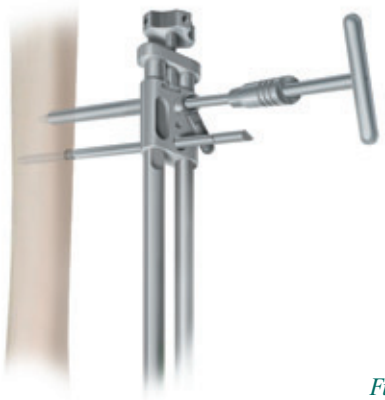


Figure 29

To prevent varus misalignment upon compression, insert the pins perpendicular to the tibial cortex, while keeping the targeting arm parallel to the tibia. Use the optional stabilizing stake (Cat. No. 8207-05-100) and dual pin stabilizer (Cat. No. 8207-05-200) to aid in obtaining a rigid construct for compression. Screw the stabilizing stake into the center hole of the pin carriage. Lock down the pin stabilizer to the back of the pin sheaths, which are seated flush on the bone. The final assembly should not allow the targeting device to slide on the pins.

Applying Compression

Achieve axial compression across the tibiotalar joint by inserting tommy bars (Cat. No. 8282-20-000) into the holes in the compression knob and turning clockwise. Use the calibration window in the pin carriage to apply as much as 10 mm of compression *[Figure 30]*. Each hash mark in the calibration window denotes ~ 1 mm of compression.

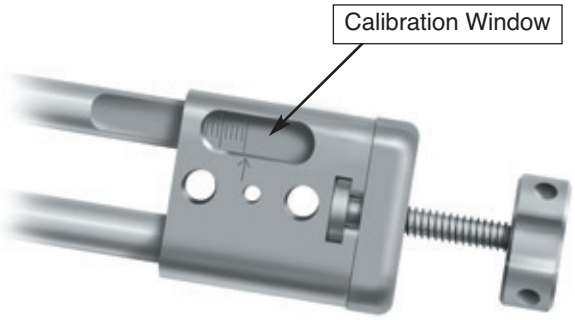


Figure 30

Proximal Medial-Lateral Cross-locking with 4.5 mm Screws

(green instrumentation)

Verify that the green carriage on the compression targeting device is located in the appropriate L/M or P/A position and locked with the knob parallel to the long arm of the targeting device *[Figure 31]*.

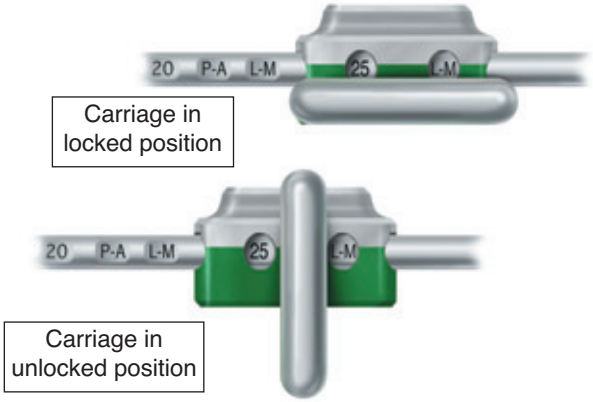


Figure 31

The green carriage can be unlocked and repositioned under fluoroscopic guidance if minor adjustments are necessary.

Dynamic Proximal Cross-locking

Thread the green trocar (Cat. No. 8207-45-002) into the green dynamic sheath (Cat. No. 8207-45-005). Position the trocar and dynamic sheath assembly through the distal slot in the green carriage of the targeting device **with the sheath handle pointed over the locking knob** *[Figure 32]*. Push the assembly through the slot and against the surface of the skin. Make a longitudinal incision approximately 3 mm in length to correspond with the trocar insertion point. After blunt dissection, retract the soft tissue and advance the trocar to seat against the medial tibial cortex.

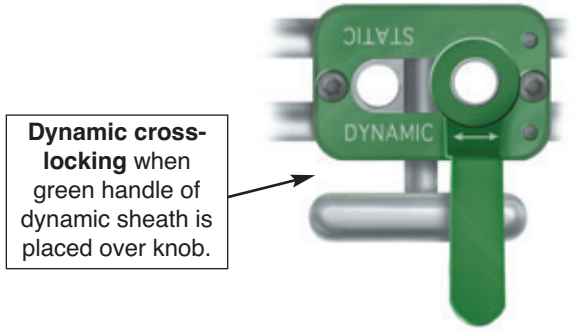


Figure 32

Unscrew the trocar and replace it by screwing in the 3.8 mm drill sleeve (Cat. No. 8207-45-003). Drill through the medial cortex of the tibia, nail hole and lateral cortex using the 3.8 mm diameter depth twist drill with trocar tip (Cat. No. 8207-45-004) under anteroposterior fluoroscopic guidance. Determine the proper length of the 4.5 mm screw by reading the calibration mark off the drill at the back of the drill sleeve. The depth gauge (Cat. No. 8207-07-000) can also be used to determine proper screw length.

Unscrew and remove the drill sleeve and drill from the sheath. Using the T-handle screwdriver (Cat. No. 1250), place the appropriate length 4.5 mm diameter self-tapping cortical screw through the sheath and into the bone while maintaining compression and rotational alignment. Advance the screws through the nail to capture the lateral cortex until the head of the screw is seated firmly against the surface of the bone. Using the static sheath (Cat. No. 8207-45-001), place a second 4.5 mm screw in the remaining proximal hole to initially static lock the nail. Delayed dynamization may be performed at a later date with the removal of the proximal static screw.

Static Proximal Cross-locking

This option is similar to the dynamic proximal cross-locking technique, **except** the trocar and dynamic sheath assembly are placed through the distal slot in the green carriage **with the sheath handle pointed away from the locking knob.**

Final Assessment/Closure

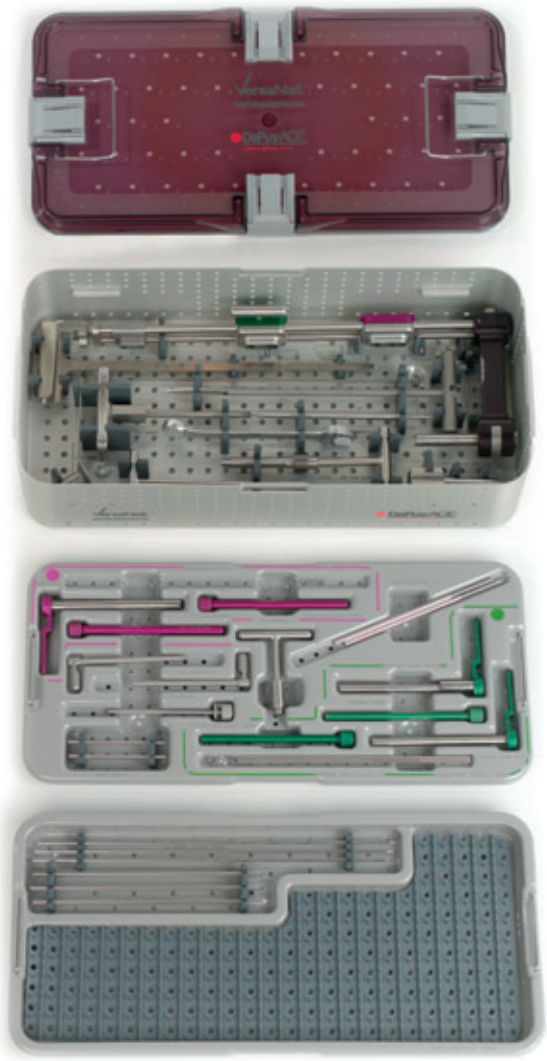
View the full length of the tibia and hindfoot under anteroposterior and lateral fluoroscopy to assess proper nail alignment, screw placement and for evidence of iatrogenic tibial diaphyseal fracture. Upon satisfactory assessment, remove the compression pins and compression targeting device using the wrench. Place an end cap in the distal end of the nail until it is fully engaged. An end cap is recommended particularly in cases where the tip of the nail is seated deep to the plantar cortex of the os calcis or where added fixation between the nail and screw is needed. Let down the tourniquet and obtain hemostasis. A layered closure over a drain placed in the lateral wound is recommended. Temporarily apply a soft dressing with cotton and U-splint for five to seven days depending upon the expected risk of wound necrosis.

Postoperative

Place the patient on the first return visit in a windowed (for incision access) short leg cast. The patient should remain non-weight-bearing for six weeks or until there is early radiographic evidence of consolidation at the arthrodesis sites. Place the patient in a short leg walking cast for an additional four to six weeks or until the fusion is complete. Once healed, place the patient in a solid ankle, cushioned-heel shoe with a rocker sole attachment.

Nail Removal

Make an incision and bluntly dissect to the head of each cortical locking screw. Insert the T-handle screwdriver into the hex of each screw and remove. Make an incision through the plantar side of the foot at the approximate location of the nail, and using the same screwdriver, remove the endcap from the end of the nail. Thread the hammer pad into the nail. Administer gentle taps with a mallet on the underside of the pad. Additionally, use the optional assembly of the solid extraction rod, impactor and slap hammer (Cat. No. 1098, 1095 and 1096, respectively) with the end of the nail for extraction.



VersaNail Instrument Case, Cat. No. 8299-23-000

VersaNail Product Ordering Information

Ordering Information

VersaNail implants are available in 10 and 12 mm diameters and in 150, 200 and 250 mm lengths. Cortical screws are available in 4.5 mm diameter (proximal) with lengths ranging from 18-60 mm (in 2 to 4 mm increments) and in 5.5 mm diameter (distal) with lengths ranging from 25-120 mm (in 5 mm increments).

VersaNail Implants (Sterile Only)

Cat. No.	Description
8007-00-001	End Cap Nonimpinging
8007-00-000	End Cap Impinging
8007-00-200	End Cap Second Hole Impinging
8007-10-015	VersaNail 10 mm x 150 mm
8007-10-020	VersaNail 10 mm x 200 mm
8007-10-025	VersaNail 10 mm x 250 mm
8007-12-015	VersaNail 12 mm x 150 mm
8007-12-020	VersaNail 12 mm x 200 mm
8007-12-025	VersaNail 12 mm x 250 mm

Special Order

8007-10-030	VersaNail 10 mm x 300 mm
8007-12-030	VersaNail 12 mm x 300 mm

- 300 mm length nails would require freehand proximal screw placement.
- 300 mm length nails will be too long to utilize the compression guide on the targeting device.

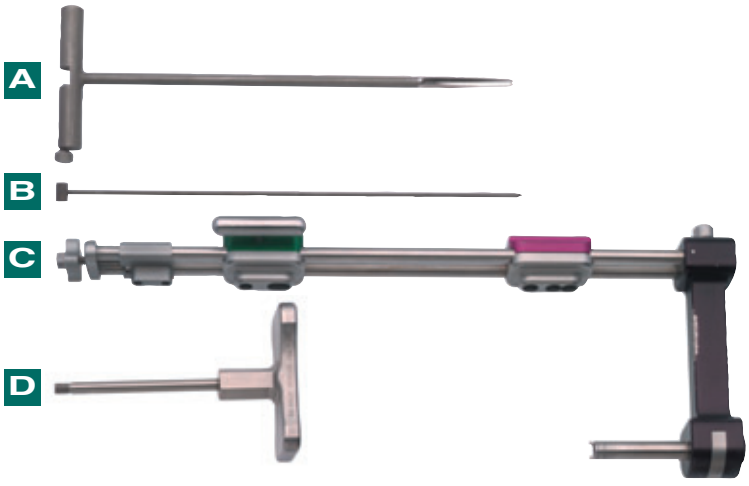
Modular Screw System

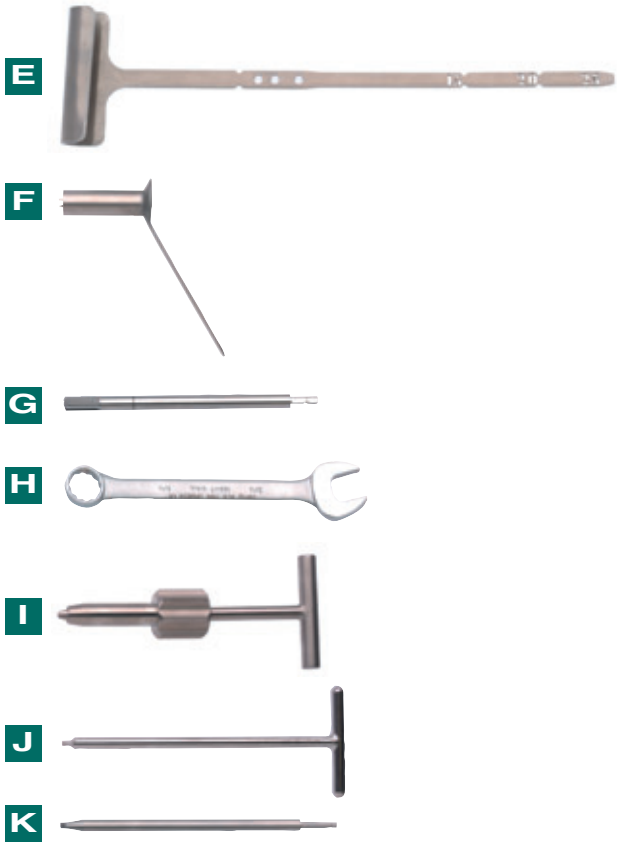
VersaNail Instrument Case and DePuy ACE Modular Screw System (For Nonsterile Screws)

Cat. No.	Description
8299-23-000	VersaNail Instrument Case (Lid, Base, Targeting Tray, Ancillary Tray)
8299-10-500	Outer Modular Screw Case
8299-10-045	4.5 mm Cortical Screw Module
8299-10-055	5.5 mm Cortical Screw Module
13571	Screw Forceps
14022-18/60	Nonsterile 4.5 mm Fully Threaded Cortical Screws
1515-25/120	Nonsterile 5.5 mm Fully Threaded Cortical Screws
8299-10-111	Accessory Module

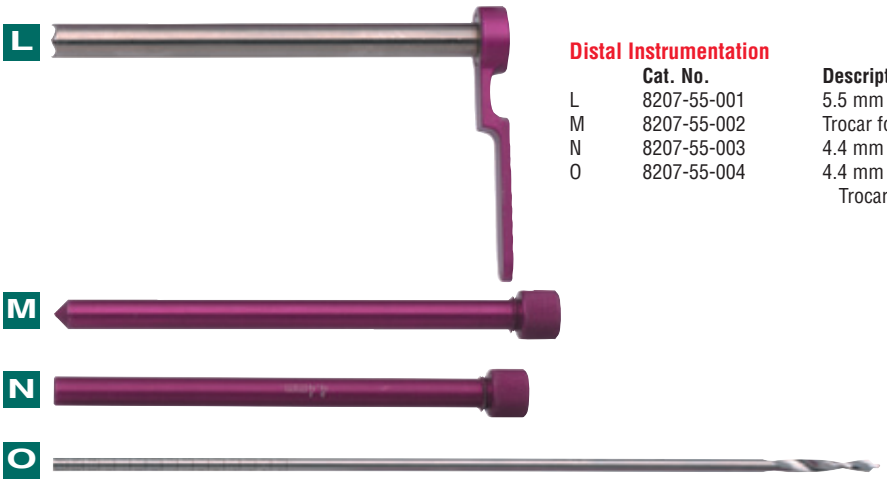
General Instrumentation

	Cat. No.	Description	Misc.
A	8207-01-000	Cannulated Awl	1 in Case
B	8207-02-000	Awl Trocar	1 in Case
C	8207-05-000	Compression Targeting Device	1 in Case
D	8207-06-000	Hammer Pad, Small	1 in Case
N/A	8207-07-000	Depth Gauge	Space in Case
E	8207-08-000	VersaNail Trial Sizer	1 in Case
F	8207-09-000	Entry Guide	1 in Case
G	8207-11-000	Entry Reamer, Cannulated 8.5 mm	1 in Case
H	1186	3/4 in. Wrench	1 in Case
I	1291	Guide Wire Grip	1 in Case
J	1250	T-handle Screwdriver	1 in Case
K	2631	Power Screwdriver Attachment	1 in Case



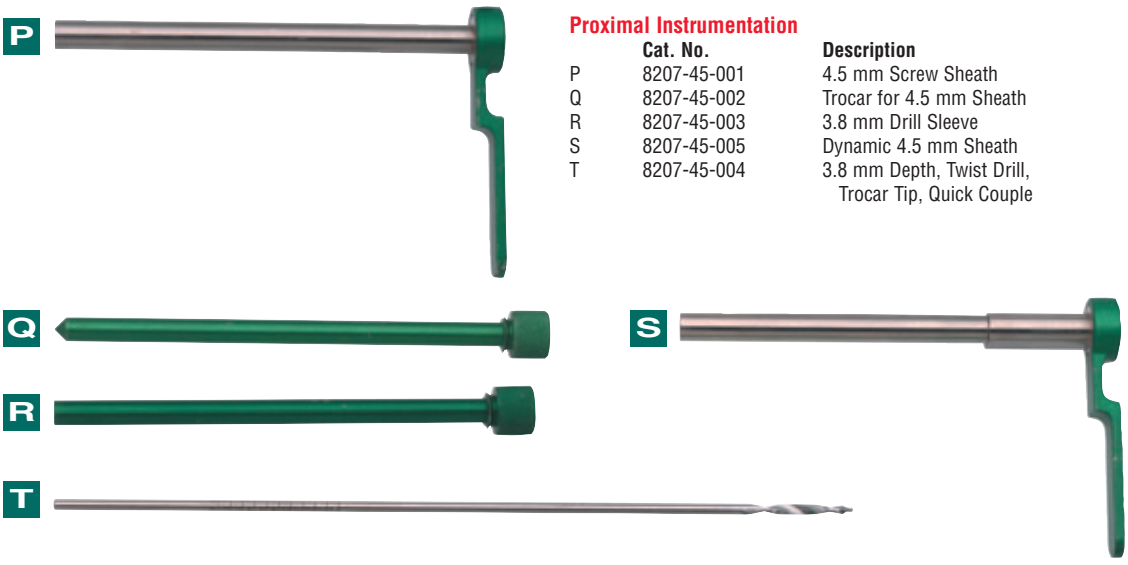


VersaNail Product Ordering Information



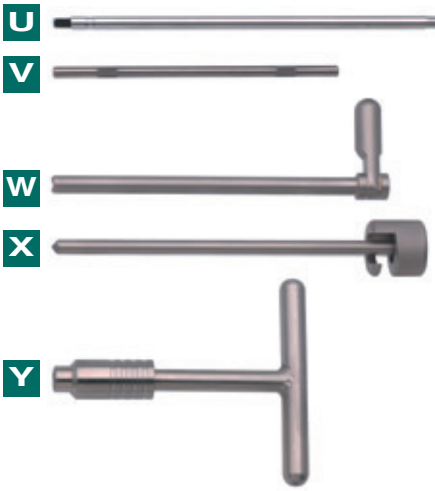
Distal Instrumentation

	Cat. No.	Description	Misc.
L	8207-55-001	5.5 mm Screw Sheath	1 in Case
M	8207-55-002	Trocar for 5.5 mm Sheath	1 in Case
N	8207-55-003	4.4 mm Drill Sleeve	1 in Case
O	8207-55-004	4.4 mm Depth, Twist Drill, Trocar Tip, Quick Couple	Disposable



Proximal Instrumentation

	Cat. No.	Description	Misc.
P	8207-45-001	4.5 mm Screw Sheath	1 in Case
Q	8207-45-002	Trocar for 4.5 mm Sheath	1 in Case
R	8207-45-003	3.8 mm Drill Sleeve	1 in Case
S	8207-45-005	Dynamic 4.5 mm Sheath	1 in Case
T	8207-45-004	3.8 mm Depth, Twist Drill, Trocar Tip, Quick Couple	Disposable



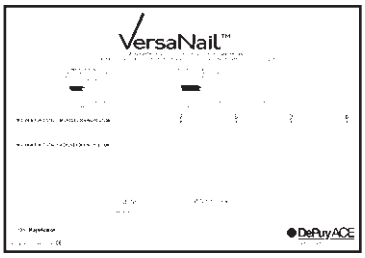
Compression Pin Instruments

	Cat. No.	Description	Misc.
U	8107-10-000	Pin Self-drilling/Self-tapping, Stainless Steel, Nonsterile, Quick Couple	Disposable
V	8282-20-000	Tommy Bar	2 in Case
W	8207-10-000	Pin Sheath	2 in Case
X	8207-10-001	Pin Trocar	1 in Case
Y	8210-69-000	T-handle, Quick Couple	1 in Case
N/A	8207-05-100	Stabilizing Stake	1 in Case
N/A	8207-05-200	Dual Pin Stabilizer	1 in Case

VersaNail Product Ordering Information

Disposables

Cat. No.	Description	Misc.
8207-10-999	X-ray Template	Order Per Surgery
8092-30-038	Ball Nose Guide Wire 3 mm x 38 in., Sterile	Order 1 Per Surgery
8092-32-238	Nail Driving Guide Wire, Sterile	Order 1 Per Surgery
14012-14	Guide Pin, 3.2 mm x 14 in., Three Pack, Nonsterile	Order 1 Per Surgery
8207-55-004	4.4 mm Depth Twist Drill, Trocar Tip, Quick Couple	Order 1-2 Per Surgery
8207-45-004	3.8 mm Depth Twist Drill, Trocar Tip, Quick Couple	Order 1-2 Per Surgery
8107-10-000	Pin Self-drilling/Self-tapping Stainless Steel, Nonsterile, Quick Couple	Order 2 Per Surgery
--------	9 in. Guide Pins/Steinmann Pins (any type)	Space in Case



X-ray Template, Cat. No. 8207-10-999

Optional

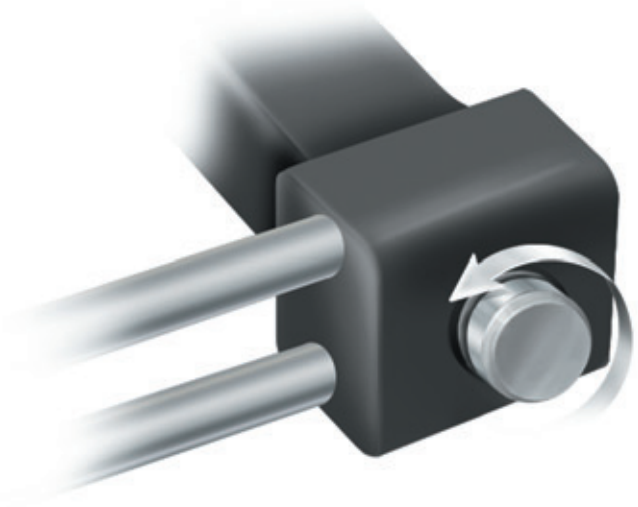
Cat. No.	Description	Misc.
13543	3.5/4.0 mm Drill Guide (tissue protection)	Space in Case
2104-12/20-000	Flexible Reamers (9 to 13mm)	No Tray Space
1919/22	Pe.R.I. Tongs	Separate Set
1095	Impactor Rod	In A.R.T. Retrograde Femoral Set
1096	Sliding Hammer	In A.R.T. Retrograde Femoral Set
1098	Solid Extraction Rod	In A.R.T. Retrograde Femoral Set

General Cleaning Note:
This system has many narrow cannulated items. Take care to adequately clean each one.

Compression Targeting Arm Cleaning:

Arm Disassembly: Rotate the push button knob counter-clockwise until the circular line on the button becomes visible (do not unscrew completely). Depress the push button knob deeply and remove the nail adaptor stem from the black handle of the device.

Arm Reassembly: Depress the push button while inserting the nail adaptor stem from the outside of the device. The nail stem must seat completely against the black handle surface. Rotate the nail stem until it clicks into position. Screw in the push button knob clockwise until it seats into position.



Note: This system was not designed to have targeting carriages dissembled.

The targeting device was not designed to withstand any impaction by a mallet. When striking the assembly, only impact the surface of the hammer pad.

Case Study

The patient is a 55-year-old woman who presented with symptomatic pseudarthrosis following three attempts for (a) arthrodesis including screw fixation *[Figures 33 and 34]* and (b) external fixator with implantable bone stimulator *[Figure 35]*. Preoperative clinical assessment and radiographs (c) *[Figures 36 through 39]* demonstrate gross instability with extensive talar bone loss. At six months following tibiotalocalcaneal intramedullary rodding (d), successful arthrodesis was observed *[Figures 40 and 41]*.

a) Screw fixation

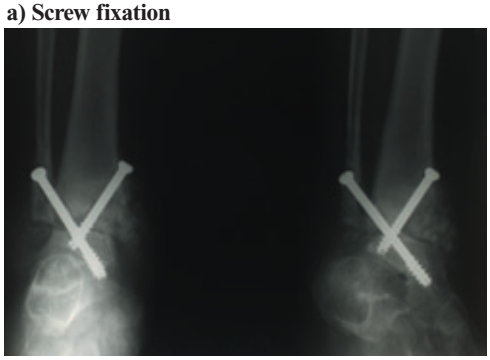


Figure 33

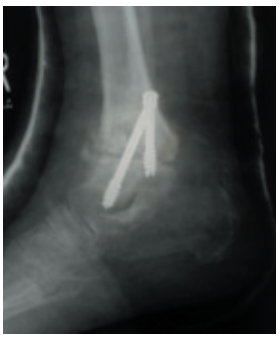


Figure 34

b) External fixator with implantable bone simulator

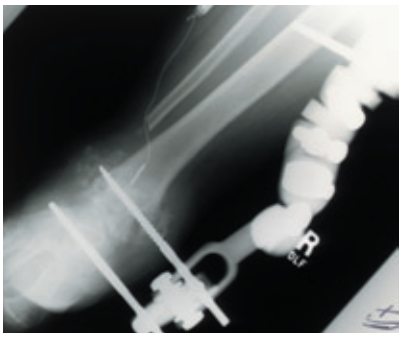


Figure 35

c) Preoperative foot

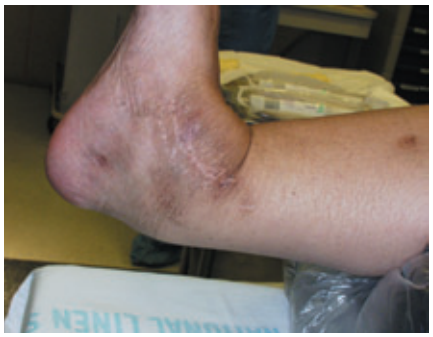


Figure 36

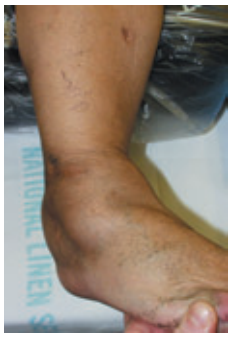


Figure 37

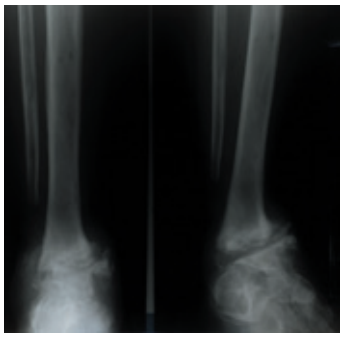


Figure 38

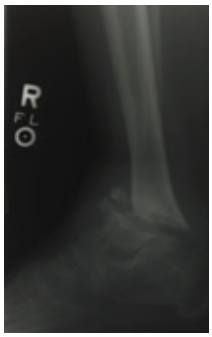


Figure 39

d) Postoperative foot

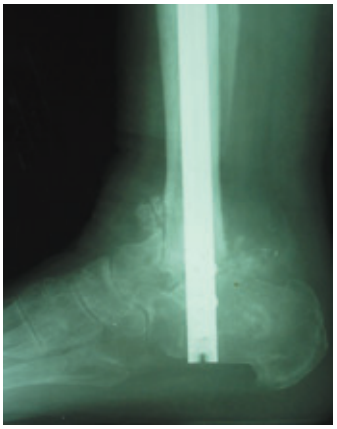


Figure 40

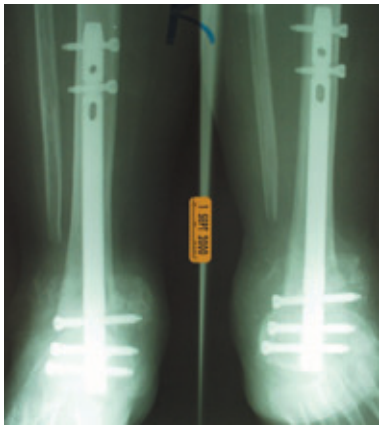


Figure 41

Intramedullary Nails

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

Indications: Intramedullary nails provide the orthopaedic surgeon a means of bone fixation and help generally in the management of fractures and reconstructive surgery.

Contraindications: The use of intramedullary nails is contraindicated in: cases with active local or systemic infection; cases where the nail would cross open epiphyseal plates in skeletally immature patients; cases with insufficient quantity or quality of bone to permit stabilization of the fracture; cases of obliterated medullary canal or other conditions which tend to retard healing such as blood supply limitations, previous infections etc.; conditions that restrict the patient's ability or willingness to follow postoperative instructions during the healing process; cases of material sensitivity. The following are additional contraindications for retrograde femoral nailing: a history of septic arthritis of the knee; knee extension contracture with inability to attain at least 45 degrees of flexion.

Warnings and Precautions: 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.

Adverse Events: The following are the most frequent adverse events after intramedullary nailing: loosening, bending, cracking or fracture of the nail; loss of fixation in bone; loss of anatomic position with nonunion or malunion with rotation or angulation; deep or superficial infection; sensitivity or other reaction to the device material.

REFERENCES
1. Semlitsch, M.F., et al. "Joint Replacement components made of hot-forged and surface-treated Ti-6Al-7Nb alloy." International Conference on Titanium Products and Applications, 1990.
2. Benjamin, David, "Properties and selection; stainless steels, tool materials and special-purpose metals." Metals Handbook, ninth edition, vol. 3, American Society for Metals, Metals Park, OH, 1990: 34, 378, 379, 388 and 389.

Color illustrations by Lisa Clark.

CAUTION: Federal Law (USA) restricts these devices to sale by or on the order of a physician.
Consult package insert for complete product information.
For more information about DePuy ACE products, visit our web site at **www.depuyace.com**.

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