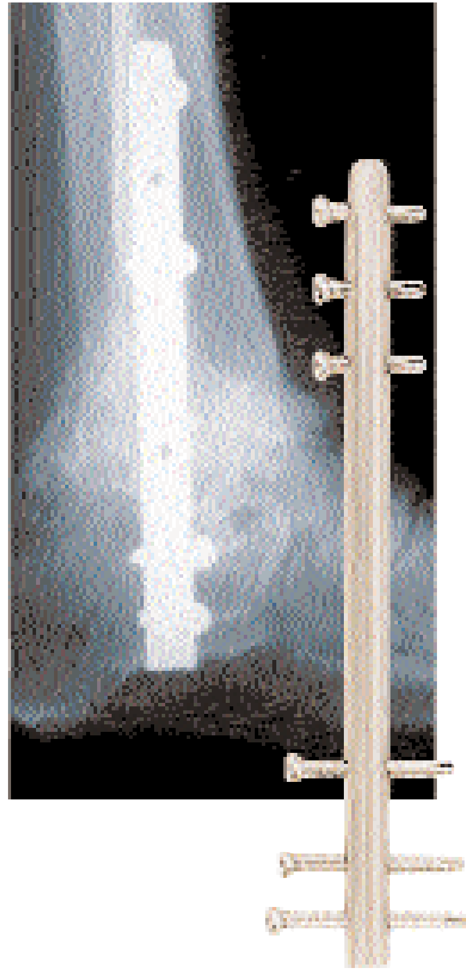
S M I T H & N E P H E W

REVISION™ NAIL



SURGICAL TECHNIQUE

ReVision Nail

contributions by

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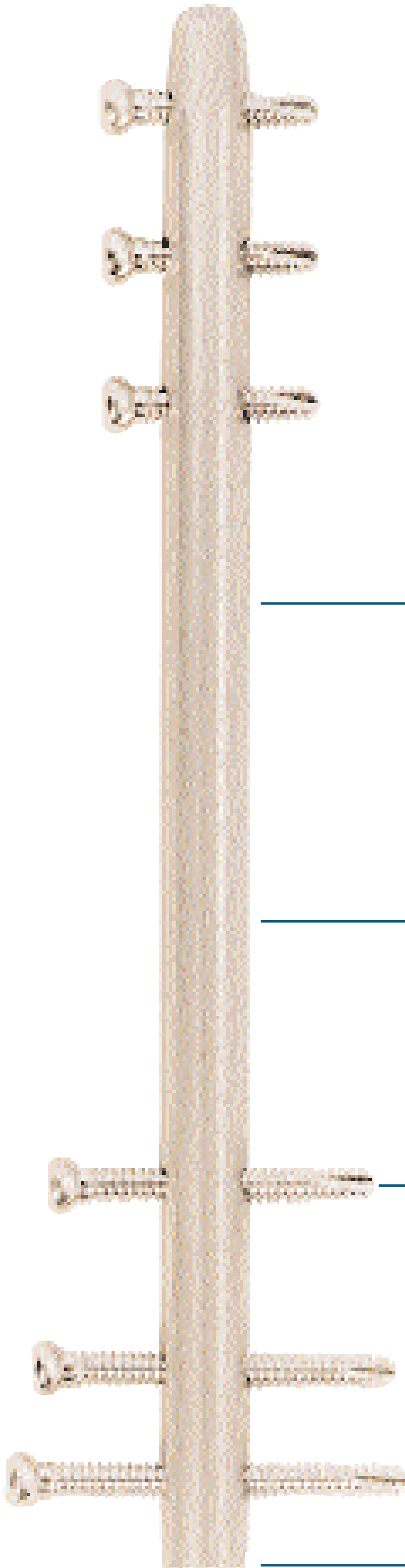
Nota Bene: The technique description herein is made available to the healthcare professional to illustrate the authors' suggested treatment for the uncomplicated procedure. In the final analysis, the preferred treatment is that which addresses the needs of the specific patient.

The following statement is required by the U.S. FDA.
WARNING: This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.



REVISION NAIL

- *Sterile-packed implants*
- *Stackable sterilization case system*
- *Shared instruments and screws with Russell-Taylor® (R-T) Nail System*
- *Standard and radiolucent targeting system*
- *Sterile-packed ReVision Nail Disposable Target Pak available which includes radiolucent drill guide, drill bits, guide pin, and trocars*

Available in 11, 12, and 13 mm diameters and 15, 18, and 21 cm lengths

Stainless steel, cannulated, closed section design

Interlocked with R-T 5.0 mm locking screws or 5.0/6.4 mm step screws

Positive lock keyway

Introduction

The ReVision Nail System was developed to obtain tibiotalocalcaneal arthrodesis in patients with posttraumatic arthritis, severe end stage degenerative arthritis, rheumatoid arthritis, Charcot arthropathy, and failed ankle fusions with subtalar involvement. Retrograde insertion of an intramedullary nail into the calcaneus may be a desirable option for severely deformed ankle and hindfoot problems.

Preoperative Planning

This procedure is performed under either general, spinal, or epidural anesthesia. It is an inpatient procedure requiring the use of intraoperative fluoroscopy and usual admission for two to three nights. The transmalleolar and posterior approaches will be discussed as options for the fusion. In both approaches, a thigh tourniquet is used to maintain hemostasis.

Advantages to the transmalleolar approach are good visualization of the medial and lateral aspects of the ankle joint and familiarity of the approach to the surgeon. An added benefit is the removed malleoli often provides enough cancellous bone to avoid an iliac crest bone graft and narrows the ankle for improved cosmesis. Nevertheless, the iliac crest should be prepared in case a more extensive graft is necessary. A disadvantage to the transmalleolar approach is that the site may already be scarred with atrophic tissue which could pose some difficulty with healing. Secondly, extensive bone loss or an avascular talus could affect the success rate of a fusion of the ankle and subtalar joints. Using this approach in these cases, the options are limited. One option is to remove most of the body of the talus and fuse the calcaneus to the tibia however, this can produce severe shortening of the foot.

The posterior approach has several advantages. First it avoids the medial and lateral aspects of the ankle, thus allowing healthy skin for the surgical approach. Second, a wide surgical exposure is easily obtained and a massive intra- and extraarticular bone graft recipient site prepared. Another advantage is the ability to maintain height by removing the body of the talus and leaving its medial, lateral, or anterior walls. The posterior approach is particularly applicable for patients with AVN (avascular necrosis) of the talus or when removing a total ankle with significant bone loss. The disadvantages of the posterior approach are first, the fear of skin breakdown while operating through the posterior skin near the Achilles tendon region. A second disadvantage is the difficulty in reaching the anterior ankle joint if there are anterior spurs holding the ankle in equinus. This can be accomplished with careful dissection but the transmalleolar approach may be better for this specific case. In general, the surgeon should choose the approach that is most familiar and appropriate for the patient.

Preoperative radiographs:

- Standing A-P, lateral, and oblique views of the ankle and foot.
- CT with coronal cuts through hindfoot may be helpful in evaluating involvement of ankle and subtalar joints.
- Occasionally, an MRI scan will be used to evaluate the vascularity of the talus.

Preoperative planning for foot positioning:

- Use contralateral extremity as a guide, particularly to view the amount of external rotation.

The Transmalleolar Approach

The patient is positioned supine with a lateral bump under the ipsilateral hip on the operating table with a radiolucent foot piece. A lateral incision is made approximately 6 cm proximal to the ankle joint extending distally in a curvilinear fashion to the base of the fourth metatarsal *(Figure 1)*. The distal fibula and lateral malleolus are dissected free, and the distal 3 cm of the fibula is excised using a power saw in an oblique fashion (≈45°) *(Figure 2)*. Once the fibula has been excised, the ankle and subtalar joints are easily visualized. An anterior medial incision is then made over the medial malleolus *(Figure 3)*. The medial malleolus is dissected free and excised to narrow the ankle while protecting the posterior tibial tendon and neurovascular structures. Cancellous bone from the malleoli is morselized to be used as bone graft. If the ankle and hindfoot are not severely malaligned from previous trauma, the articular cartilage from the ankle and subtalar joints is denuded leaving the natural shape of the joints intact. This allows the surgeon to manipulate the ankle and subtalar joint into a neutral position.

The surgeon should take great care to place the forefoot plantigrade to the floor so that it will not be in varus or supination prior to fixation. If the ankle is severely malaligned preoperatively, then a sagittal saw can be used to make flat cuts on the distal tibia and talus to obtain correct varus/valgus and dorsiflexion/plantarflexion alignment. After all of the cartilage has been removed from both joints, the surfaces are shingled with a small osteotome and drilled with a 2 mm drill bit to penetrate any remaining subchondral bone plate.

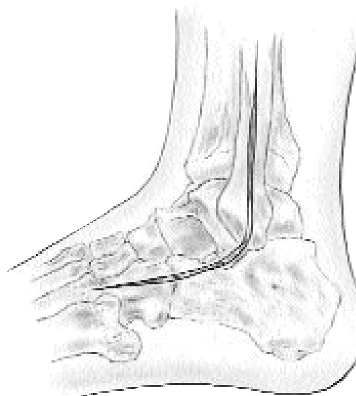


Figure 1

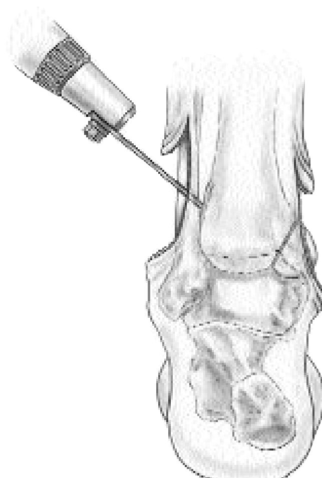


Figure 2

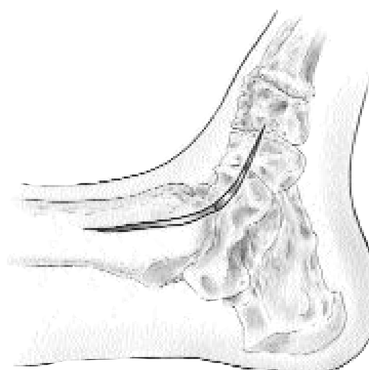


Figure 3

The Posterior Approach

In the prone position, the ipsilateral posterior iliac crest and extremity are sterilely prepared and draped. An extensive corticocancellous bone graft is harvested from the posterior iliac crest in a standard fashion and morselized for later use. A posteromedial, curvilinear incision is made along the medial border of the Achilles tendon. A full-thickness skin and subcutaneous flap is created and extreme care is used in retraction of the skin edges. The Achilles tendon is split in the coronal plane, transecting the proximal cut posteriorly and the distal cut anteriorly. The deep fascia of the posterior compartment is opened staying lateral to the midline and the flexor hallucis longus is elevated from its origin off the fibula and interosseous membrane to expose the posterior ankle and subtalar joints *(Figure 4)*. Dissection is performed lateral to medial subperiosteally to protect the neurovascular structures.

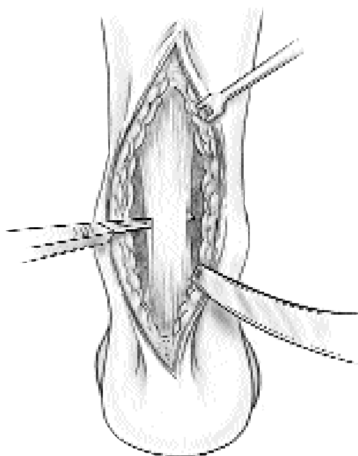


Figure 4

The superior portion of the cortex of the posterior aspect of the calcaneus and the posterior cortex of the tibia are removed to begin a recipient site for the extraarticular portion of the bone graft. All retained hardware is removed as needed and a large trough is created from the tibia to the calcaneus, through the body of the talus *(Figure 5)*. The trough in the tibia is extended all the way to the anterior cortex. Care is taken not to extend the trough too far proximally which may later compromise interlocking of the nail. Height is maintained by preserving the medial and/or lateral column as well as the anterior portion of the talus. One or both malleoli may be carefully removed to facilitate correction of any translational or varus/valgus deformities.

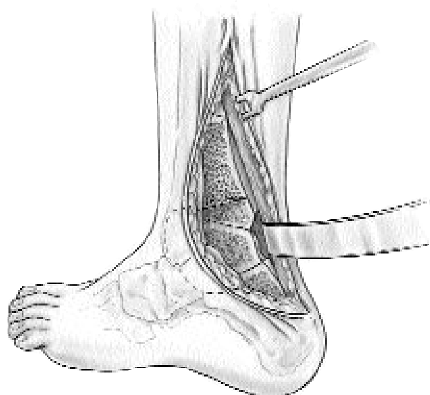


Figure 5

The hindfoot is placed in approximately 5º of valgus neutral dorsiflexion with approximately 5º of external rotation. Great care should be taken to place the forefoot plantigrade to the floor to avoid a varus malunion.

Nail Insertion and Interlocking

Once all the bony surfaces have been prepared and aligned, a 3 cm transverse or longitudinal incision is made on the plantar aspect of the heel. A hemostat is used to bluntly spread the soft tissues and open the plantar fascia down to the bone of the calcaneus. An imaginary line in the longitudinal axis of the foot from the second toe to the center of the heel will place the starting portal in approximately the correct position in the medial/lateral plane. This point is also approximately at the middle and distal third of the heel fat pad *(Figure 6)*. While holding the foot in the appropriate position and palpating the anterior tibial crest, the 3.2 mm x 385 mm tip threaded guide pin (7111-8015) can be inserted from the plantar aspect of the calcaneus across the subtalar and ankle joints *(Figure 7)*. The black drill sleeve (11-2086) may be used as a tissue protector when performing this step. Image intensification should be used to confirm that the pin is very close to the center of the tibia. If it is not centered, there is a risk of driving the nail into the cortex of the tibia and causing malalignment of the foot. There is also a danger of cracking the tibial cortex if the guide pin is not centered correctly. Insert the protective sleeve (7111-8011) over the guide pin, seat it against the calcaneus, and use the 9 mm cannulated reamer (11-2003) over the guide pin and advance to the tibial canal *(Figure 8)*.

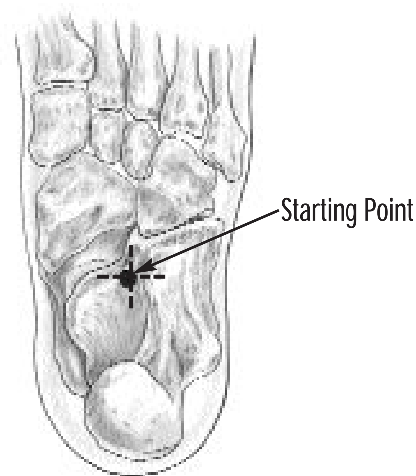


Figure 6

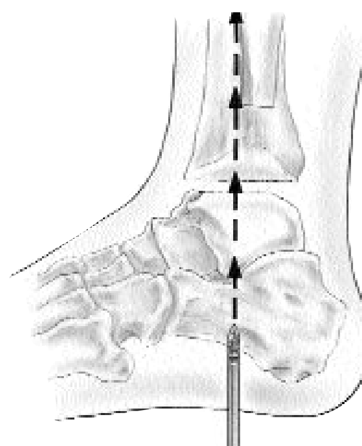


Figure 7

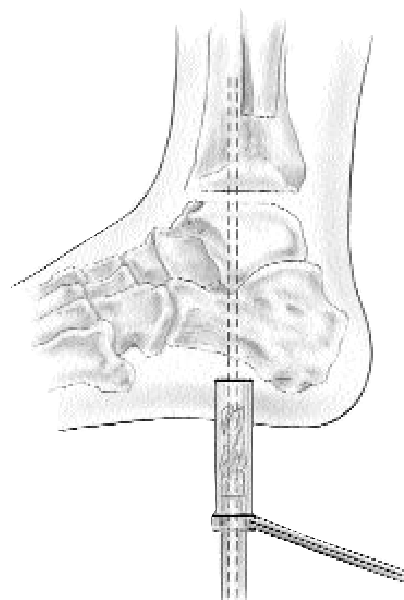


Figure 8

Figure 9

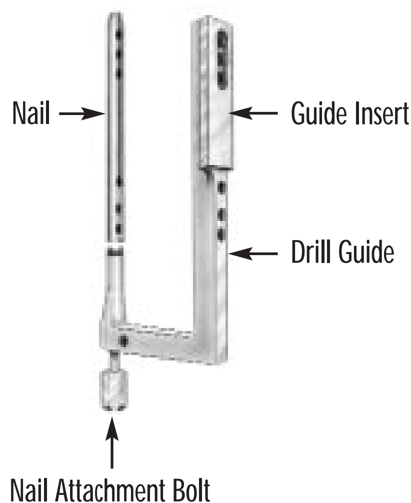


Figure 10

Further reaming can be performed over the guide pin, using the straight cannulated reamers (7111-8007 through 7111-8010) in a step-wise fashion to prepare a passage for the nail. **NOTE: Use a Jacob's Chuck to connect the reamers to power or the appropriate power adaptor *(Figure 9)*.** The depth markings on the reamers should be read against the protective sleeve. Under-reaming the calcaneus 0.5 mm smaller than the selected nail may allow for more stable fixation and possible compression when passing the nail. This typically works quite well with the posterior approach. However, with the transmalleolar approach or with significantly sclerotic bone, the nail tends to distract the fusion and the calcaneus may need to be overreamed 0.5 mm larger than the selected nail diameter. The reamers may be used manually by attaching the quick release T-handle (7111-8014 or 11-6011). (The standard Russell-Taylor flexible reamers may also be used over a ball tipped guide pin.) The foot should be maintained in the appropriate neutral position and intraoperative fluoroscopy utilized to confirm this position.

The selected nail should be assembled to either the radiolucent drill guide (7111-8002) or the metal drill guide (7111-8016) with the nail attachment bolt (7111-8003). Use the 11/16" open end wrench (11-0564) to tighten the bolt and then attach the supine driver (11-2024) to the bolt on the drill guide. Place the appropriate length guide insert (7111-8004 through 7111-8006) over the proximal end of the drill guide until it is fully seated *(Figure 10)*. Confirm the drill guide alignment by inserting the alignment rod (11-5503) through the guide and the nail.

Advance the nail by hand over the guide pin across the subtalar and ankle joints into the medullary canal of the tibia. **NOTE: Never directly strike the drill guides.** The distal end of the nail should be flush to the plantar cortex of the calcaneus and the location of the screw holes should be visualized in relation to the depth of the nail using image intensification *(Figure 11)*. There is a notch on the drill guide to aid in visualizing the connection with the nail on the image intensifier. The alignment stylus (7111-8017) may be inserted in the hole near the barrel of the drill guide to help visualize dorsiflexion/plantarflexion alignment. Correct foot positioning and location of screw holes with respect to bone structures should again be confirmed prior to interlocking.

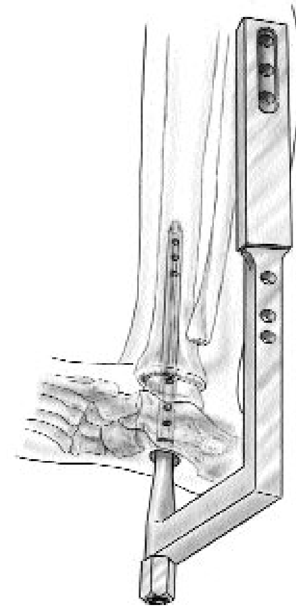


Figure 11

There are six screw holes in all size nails for interlocking: three distal and three proximal. All self-tapping locking screws are placed percutaneously by predrilling and inserting the screw through drill sleeves (11-2012, 11-2086, or 11-2056) and are placed lateral to medial *(Figure 12)*. **Prior to drilling, the guide should be rotated anteriorly enough so the proximal locking screws will miss the fibula.** Insert a percutaneous knife with a #10 blade through the hole in the drill guide to determine the proper location of the incision. Insert the 8.0 mm green drill sleeve (11-2012) and the 4.0 mm gold drill sleeve (11-2056) through the most distal hole in the drill guide. Place both sleeves against the cortex.

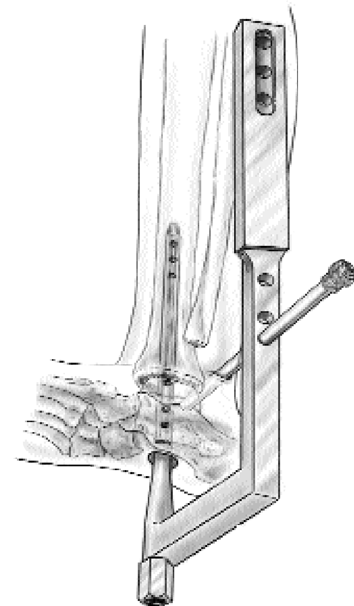


Figure 12

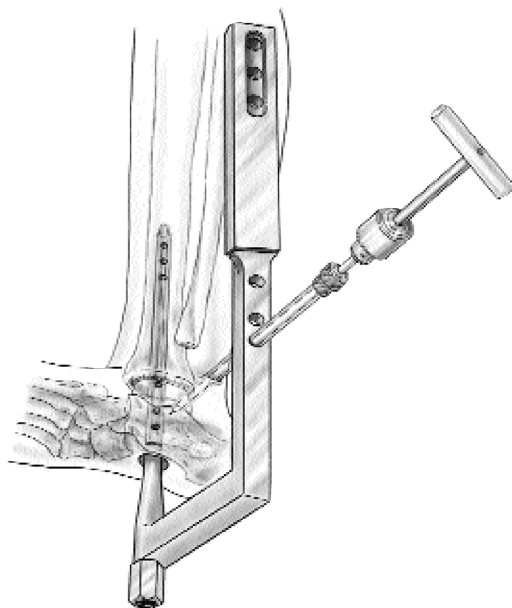


Figure 13

Using the T-Handle Jacob's Chuck (11-0257) to hold the 4.0 mm disposable trocar pin (11-2004), insert the trocar through the gold sleeve to dimple the bone. It is important to dimple the bone to prevent the drill bit from "walking," which is a major cause of targeting problems *(Figure 13)*. Using a 4.0 mm twist drill (11-2049) through the gold sleeve, drill through both cortices. In case of osteoporotic bone, use the 3.5 mm black drill sleeve and the 3.2 mm guide pin to make a path for the 5.0 mm screw. Take depth measurements reading the drill calibrations against the top of the gold sleeve. Withdraw the twist drill and gold sleeve. To confirm locking screw length, use the screw length gauge (11-5058) against the top of the green sleeve *(Figure 14)*.

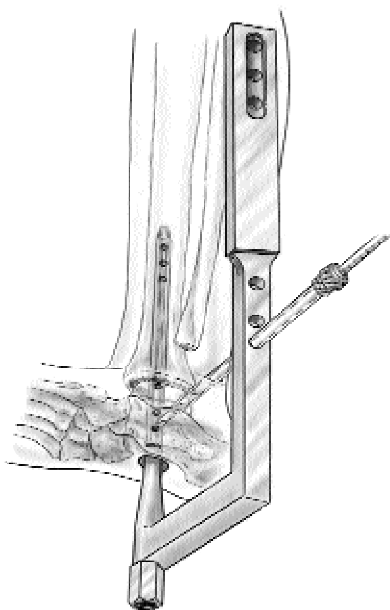


Figure 14

Assemble the hexdriver shaft (11-5059) into the quick-release T-handle and insert the selected screw through the green sleeve. Repeat the procedure, using a second set of drill sleeves for the remaining screws *(Figure 15)*. After the calcaneal screws are placed, it is optional to gently tap the supine driver on the drill guide for compression across the subtalar and ankle joints. Just prior to this, morselized bone graft can be placed across the subtalar and ankle joints. This morselized graft can then be impacted by gently malleting the end of the supine driver. **NOTE: Never directly strike the drill guides.**

After inserting all locking screws, remove the hexdriver and drill guide. Irrigate all wounds copiously with sterile solution and close in a routine fashion. An intraoperative drain may be placed in the lateral aspect of the ankle using a small, round, silastic drain connected to a bulb-type suction device. Adaptic® is placed over the wounds, at which time a sterile, bulky, compressive Robert Jones dressing is applied with a stirrup splint. This is secured with either a plaster splint or a fiberglass short-leg cast. The pneumatic tourniquet is deflated after application of the compressive dressing. Permanent intra-operative radiographs should be obtained prior to reversal of the anesthesia.

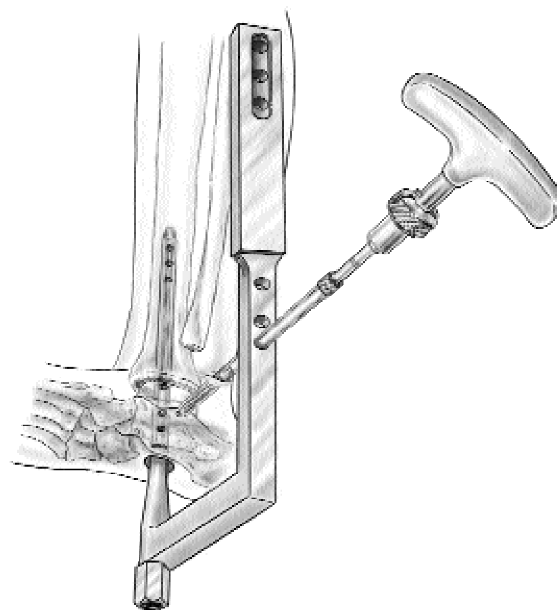


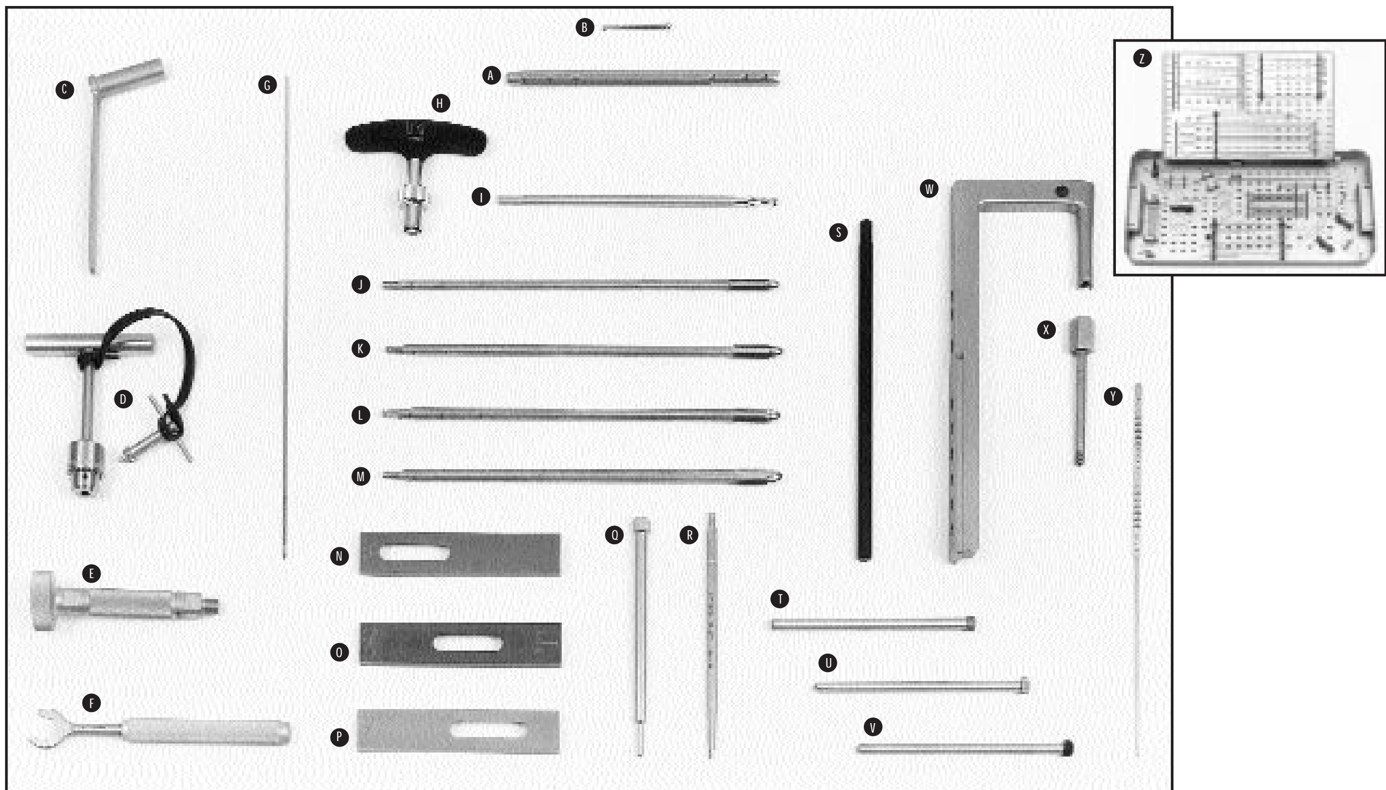
Figure 15

Postoperative Care

On the third or fourth postoperative day, the dressing is removed and a short-leg, nonweightbearing cast or cast boot is applied. Nonweightbearing is maintained until radiographic evidence of consolidation is noted, usually at 6 to 8 weeks. A walking cast can then be utilized for an additional 4 to 8 weeks. Occasionally, a removable fracture boot may be worn instead of, or subsequent to, the walking cast. A compression stocking may be fitted with a cushioned heel and a rocker-bottom sole. **CAUTION: Intramedullary nails are neither intended to carry the full load of the patient acutely, nor intended to carry a significant portion of the load for extended periods of time. All patients should be cautioned against significant weightbearing prior to good callus formation. For this reason, patients who are obese and/or noncompliant, as well as patients who could be predisposed to delayed or nonunions, must have auxiliary support. Additional postoperative precautions should be taken when the fracture line occurs within 5 cm of the nail's screw hole, as this situation places greater stress on the nail at the location of the transverse screw hole.**

Nail Removal

It is not recommended to remove the nail unless deep infection occurs or if the patient is symptomatic. If removal is required, dissect the plantar soft tissue to expose the distal end of the nail. Retract and protect the lateral plantar artery and nerve. Clear away any tissue or bone that may have grown into the threads in the end of the nail. Reattach the drill guide bolt to the nail using the 11/16" wrench. The supine driver may be attached to the drill guide bolt if desired. Make stab wounds over the original incisions and remove the 5.0 mm locking screws with the hexdriver and quick release T-handle. Once all the screws have been removed, extract the nail from the foot. Close in the usual manner.



ReVision Implant Set

Cat. No. 7112-9000

(All implants are sterile packed.)

	Cat. No.	Description	Set Qty.
A	7112-9001	ReVision Nail 11 mm x 15 cm	2
	7112-9002	ReVision Nail 11 mm x 18 cm	2
	7112-9003	ReVision Nail 11 mm x 21 cm	1
	7112-9004	ReVision Nail 12 mm x 15 cm	2
	7112-9005	ReVision Nail 12 mm x 18 cm	2
	7112-9006	ReVision Nail 12 mm x 21 cm	1
	7112-9007	ReVision Nail 13 mm x 15 cm	2
	7112-9008	ReVision Nail 13 mm x 18 cm	1
	7112-9009	ReVision Nail 13 mm x 21 cm	1
B	12-2303	5.0 mm Locking Screw - 20 mm	6
	12-2280	5.0 mm Locking Screw - 25 mm	6
	12-2281	5.0 mm Locking Screw - 30 mm	6
	12-2282	5.0 mm Locking Screw - 35 mm	6
	12-2283	5.0 mm Locking Screw - 40 mm	6
	12-2284	5.0 mm Locking Screw - 45 mm	4
	12-2285	5.0 mm Locking Screw - 50 mm	4
	12-2286	5.0 mm Locking Screw - 55 mm	4
	12-2287	5.0 mm Locking Screw - 60 mm	4
	Available Separately		
	12-2288	5.0 mm Locking Screw - 65 mm	0
	12-2276	5.0 mm Locking Screw - 70 mm	0
	12-2277	5.0 mm Locking Screw - 75 mm	0
	12-2278	5.0 mm Locking Screw - 80 mm	0
	12-2279	5.0 mm Locking Screw - 85 mm	0
	12-2289	5.0 mm Locking Screw - 90 mm	0

Disposable Pak:

7111-8018 ReVision Nail Disposable Target Pak (not shown)
(Includes 7111-8002 radiolucent drill guide, 7111-8015 3.2 mm guide pin, 11-2049 4.0 mm twist drill [2], 11-2004 4.0 mm trocar [2])

ReVision Instrument Set

Cat. No. 7111-8000

(Instruments can be ordered as a set or individually using the following catalog numbers.)

	Cat. No.	Description	Set Qty.
C	7111-8011	Protective Sleeve	1
D	11-0257	T-Handle Jacob's Chuck	1
E	11-2024	Supine Driver	1
F	11-0564	11/16" Open End Wrench	2
G	7111-8015	3.2 x 385 mm Guide Pin w/Threaded Tip (Sterile Packed)	3
I	11-2003	9.0 mm Cannulated Reamer	1
J	7111-8007	Straight Cannulated Reamer - 10.5 mm	1
K	7111-8008	Straight Cannulated Reamer - 11.5 mm	1
L	7111-8009	Straight Cannulated Reamer - 12.5 mm	1
M	7111-8010	Straight Cannulated Reamer - 13.5 mm	1
N	7111-8004	15 cm Guide Inserts	1
O	7111-8005	18 cm Guide Inserts	1
P	7111-8006	21 cm Guide Inserts	1
Q	11-5503	Alignment Rod	1
R	11-5059	Hexdriver Shaft for 5.0 mm Screws	1
S	7111-8017	Alignment Stylus	1
T	11-2012	8.0 mm Drill Sleeve (green)	2
U	11-2086	3.5 mm Drill Sleeve (black)	1
V	11-2056	4.0 mm Drill Sleeve (gold)	2
W	7111-8016	Metal Drill Guide	1
X	7111-8003	ReVision Drill Guide Bolt	1
Y	11-5058	Screw Length Gauge	1
Z	7111-8001	ReVision Nail Instrument Sterilization Case	1
	Not Shown:		
	11-2004	4.0 mm Trocar Pin (Sterile Packed)	3
	7111-8014	Quick-Release Ratchet T-Handle	1
	11-2049	4.0 mm Twist Drill (Sterile Packed)	6
	Available Separately		
H	11-6011	Quick-Release T-Handle	
	7111-8002	Radiolucent Drill Guide (Sterile Packed)	

IMPORTANT MEDICAL INFORMATION
Warnings and Precautions
INTRAMEDULLARY NAIL SYSTEM

SPECIAL NOTE

The Intramedullary Nail System consists of interlocking intramedullary nails and interlocking fusion nails and pins. Intramedullary nails contain holes proximally and distally to accept locking screws. Components are available in many styles and sizes and are manufactured from various types of metals. The component material is provided on the outside carton label. Use only components made from the same material together. Do not mix dissimilar metals or components from different manufacturers. Refer to manufacturer literature for specific product information. All implantable devices are designed for single use only.

Intramedullary Interlocking Nails are provided with a variety of screw placement options based on surgical approach, antegrade or retrograde, and indications.

Interlocking Fusion Nails indicated for joint arthrodesis have screw holes for locking on either side of the joint being fused. The locking screws reduce the likelihood of shortening and rotation of the fusion site.

INDICATIONS

The general principles of patient selection and sound surgical judgment apply to the intramedullary nailing procedure. The size and shape of the long bones present limiting restrictions on the size and strength of implants.

Indications for interlocking intramedullary nails include simple long bone fractures; severely comminuted, spiral, large oblique and segmental fractures; nonunions and malunions; polytrauma and multiple fractures; prophylactic nailing of impending pathologic fractures; reconstruction following tumor resection and grafting; supracondylar fractures; bone lengthening and shortening. Interlocking intramedullary nails are indicated for fixation of fractures that occur in and between the proximal and distal third of the long bones being treated.

In addition to the indications for interlocking intramedullary nails, devices that contain holes/slots proximally to accept screws that thread into the femoral head for compression and rotational stability are indicated for the following: subtrochanteric fractures with lesser trochanteric involvement; ipsilateral femoral shaft/neck fractures; and intertrochanteric fractures.

In addition to the indications for interlocking intramedullary nails, devices that utilize a retrograde femoral surgical approach are indicated for the following: severely comminuted supracondylar fractures with or without difficult intra-articular extension; fractures that require opening the knee joint to stabilize the femoral condylar segment; fractures above total knee implants.

Indications for the **ReVision Nail** include the following: degeneration, deformity, or trauma of both the tibiotalar and talocalcaneal articulations in the hindfoot; tibiocalcaneal arthrodesis; combined arthrodesis of the ankle and subtalar joints; avascular necrosis of the ankle and subtalar joints; failed total ankle replacement with subtalar intrusion; failed ankle arthrodesis with insufficient talar body; rheumatoid arthritis; severe deformity secondary to untreated talipes equinovarus or neuromuscular disease; and severe pilon fractures with trauma to the subtalar joint.

Knee Fusion Nails are intended for intramedullary knee arthrodesis.

Contraindications

1. These systems should not be used in crossing open epiphyseal plates.
2. Insufficient quantity or quality of bone, obliterated medullary canal or conditions which tend to retard healing; also, blood supply limitations, previous infections, etc.
3. Active infection.
4. The presence of a previously inserted fracture fixation device.
5. Preexisting bone deformity.
6. Hypovolemia, hypothermia and coagulopathy.
7. Mental conditions that preclude cooperation with the rehabilitation regimen.
8. The forearm nail should not be used in children who have not reached skeletal maturity.

WARNINGS

1. This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.
2. Intramedullary nails are neither intended to carry the full load of the patient acutely, nor intended to carry a significant portion of the load for extended periods of time.
3. The correct selection of device components is extremely important. The appropriate type and size should be selected for the patient. Failure to use the largest possible components or improper positioning may result in loosening, bending, cracking, or fracture of the device or bone or both.
4. Do not mix dissimilar metals. Use only stainless steel screws with stainless steel devices, and Ti-6Al-4V screws with Ti-6Al-4V devices.

PRECAUTIONS

1. Use care in handling and storage of implant components. Cutting, sharply bending or scratching the surface can significantly reduce the strength and fatigue resistance of the implant system. This, in turn, could induce cracks and/or noninternal stresses that could lead to fracture of the implants.
2. Surgical technique information is available upon request. The surgeon should be familiar with the devices, instruments and surgical technique prior to surgery.
3. The use of locking screws is necessary for strength and compatibility. Please refer to the surgical technique or product catalog for information on the correct size of screws for each nail.
4. The patient should be advised that a second, more minor procedure for the removal of implants is usually necessary.
5. While the surgeon must make the final decision regarding implant removal, wherever possible and practical for the individual patient, fixation devices should be removed once their service as an aid to healing is accomplished. In the absence of a bursa or pain, removal of the implant in elderly or debilitated patients is not suggested.
6. Postoperative instructions to patients and appropriate nursing care are critical. Early weight bearing substantially increases implant loading and increases the risk of loosening, bending or breaking the device. Early weight bearing should only be considered where there are stable fractures with good bone-to-bone contact. Patients who are obese and/or noncompliant, as well as patients who could be pre-disposed to delayed or non-union, must have auxiliary support. The implant may be exchanged for a larger, stronger nail subsequent to the management of soft tissue injuries.
7. Even after full healing, the patient should be cautioned that refracture is more likely with the implant in place and soon after its removal, rather than later, when voids in the bone left by implant removal have been filled in completely.
8. Patients should be cautioned against unassisted activity that requires walking or lifting.
9. Postoperative care and physical therapy should be structured to prevent loading of the operative extremity until stability is evident.
10. Additional postoperative precautions should be taken when the fracture line occurs within 5 cm of the nail's screw hole, as this situation places greater stress on the nail at the location of the transverse screw hole.

POSSIBLE ADVERSE EFFECTS

1. Loosening, bending, cracking or fracture of the implant components.
2. Limb shortening or loss of anatomic position with nonunion or malunion with rotation or angulation may occur.
3. Infections, both deep and superficial, have been reported.
4. Irritational injury of soft tissues, including impingement syndrome.
5. Supracondylar fractures from retrograde nailing.
6. Tissue reactions which include macrophage and foreign body reactions adjacent to implants.
7. Although rare, metal sensitivity reactions and/or allergic reactions to foreign materials have been reported in patients.

PACKAGING AND LABELING

Components should only be accepted if received by the hospital or surgeon with the factory packaging and labeling intact.

STERILIZATION/RESTERILIZATION

Most implants are supplied sterile and have been packaged in protective trays. The method of sterilization is noted on the package label. All radiation sterilized components have been exposed to 25 kiloGrays of gamma radiation. If not specifically labeled sterile, the implants and instruments are supplied non-sterile and must be sterilized prior to use. Inspect packages for punctures or other damage prior to surgery.

Metal components may be initially sterilized or resterilized, if necessary, by steam autoclaving in appropriate protective wrapping, after removal of all original packaging and labeling. Protect the devices, particularly mating surfaces, from contact with metal or other hard objects which could damage the product. The following process parameters are recommended for these devices:

- Prevacuum Cycle: 4 pulses (Maximum = 26.0 psig [2.8 bars] & Minimum = 10.0 inHg [339 millibars]) with a minimum dwell time of 4 minutes at 270°F to 275°F (132°C to 135°C), followed by a 1 minute purge and at least 15 minutes of vacuum drying at 10 inHg (339 millibars) minimum.
- Gravity Cycle: 270°F to 275°F (132°C to 135°C) with a minimum dwell time at temperature of 15 minutes, followed by a 1 minute purge and at least 15 minutes of vacuum drying at 10 inHg (339 millibars) minimum.

Smith & Nephew does not recommend the use of low temperature gravity cycles or flash sterilization on implants.

INFORMATION

For further information, please contact Customer Service at (800) 238-7538 for calls within the continental USA and (901) 396-2121 for all international calls.

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

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The following statement is required by the U.S. FDA.
WARNING: This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

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