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 patient.

WARNING: This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.
PATIENT PREPARATION

1. Position the patient supine. Place a sterile bolster (leg roll) or use a leg positioner under the thigh and flex the knee for positioning. Check the axial alignment by stretching a “bovie” cord through the middle of the patella to the second toe. The cord should bisect the middle of the tibial plateau and talar dome in the A/P view when the leg is straight. Adjust the leg for rotation and length by comparison with the uninjured leg and by visualizing the fracture configuration. Insertion alignment can be slightly proximal to the fibular neck, but below the articular surface of the knee to avoid meniscular damage. A slightly lateralized entry portal is optimal (Figure 1).

ENTRY PORTAL

2. Make a 3 cm incision medial to the patellar tendon. Rotate the barrel of the Entry Tool (7163-1114) until the “K” is seen, then place the Entry Tool with Honeycomb Insert through the incision to bone (Figure 2). Adjust to align the Entry Tool with the axial line of the tibial shaft in the A/P and lateral image views. Attach the 3.2 Tip-Threaded Guide Wire (7163-1190) to power using the Mini-Connector (7163-1186). Insert the Guide Wire when the axial alignment is acceptable and centered along the tibia. The target zone should be just lateral to the medial tibia tubrical. The Entry Tool may be backed out as needed to confirm that the pilot hole is started correctly. Insert the wire approximately 3 cm in depth. Once proper placement of the Guide Wire has been established, the “honeycomb” insert should be removed (Figure 3).
Attach suction to the Entry Tool to assist in blood evacuation and minimize aerosolisation of blood to operative team. Attach the 12.5 mm Entry Reamer (7163-1116) to power and insert over the Guide Wire (7163-1190) to ream the proximal portion of the tibia. The reamer should be inserted such that it is reaming the anterior cortex and not directed toward the posterior cortex. The Entry Portal Tool functions as a soft tissue protector. The reamer should be advanced to the medullary canal of the tibia, approximately 4-5 cm. Confirm the position of the reamer under lateral X-ray views as well. Remove the flexible 12.5 mm Entry Reamer and Guide Wire (*Figure 4*).
FRACTURE REDUCTION

4 Snap the T-Handle (7163-1172) onto the Reducer (7163-1124) (Figure 5). Insert the Reducer (7163-1124) through the Entry Tool and advance into the distal medullary canal to reduce the fracture (Figure 6). Attach the Gripper (7163-1100) to the Ball-Tipped Guide Rod (7163-1126) and introduce it into the medullary canal through the Reducer and Entry Portal Tool (Figure 7 and 7 Inset). The Guide Rod can be positioned by rotating the Reducer while placing the rod into the medullary canal. Remove the Gripper from the guide rod to allow for removal of the Reducer. When Guide Rod is in place, remove the Reducer.
CANAL PREPARATION

5 Canal preparation is dependent on surgical decision. If reaming is planned, use progressive reamers through the Entry Tool. Unreamed nails are selected based on preoperative planning, but should be of sufficient size to provide translational fill of the intramedullary canal in mid-diaphysis. The Flex Reamer Extender (7163-1130) is available to extend the reamer shaft for nails longer than 42 cm. If reaming is selected, proceed to sequentially ream the tibial shaft beginning with the 9 mm reamer head. Sequentially ream in half millimeter increments to 0.5 mm to 1.0 mm larger than the selected nails size (Figure 8).

NAIL SELECTION

6 Determine nail diameter from image intensifier, templating as necessary from reaming, or sounding the canal. Never insert a nail that has a larger diameter than the last reamer used. Confirm placement of the guide rod at the desired portion of the distal tibia metaphysis and then insert the Ruler (7163-1128) over the exposed end of the guide rod pushing the end down to the level where the top of the nail will stop. Confirm the position on the image intensifier at the other end of the nail length gauge (Figure 9). Leave the Guide Rod in place. Exchange of the ball-tipped Guide Rod is not necessary. Note: Make provisions for countersinking the tibial nail to minimize impingement problems at the knee. Allow for reduction of the fracture, if dynamization is required.
7. Attach the Knee Guide (7163-1142) to the Drill Guide (7163-1134). The Drill Guide is keyed so that the Knee Guide will only fit one way. Secure the Knee Guide to the Drill Guide by tightening the “knurled knob” by hand. Final tightening can also be accomplished by placing the end of the Guide Bolt Wrench (7163-1140) into the holes in the knurled knob. Insert Quick Bolt (7163-1138) in the Drill Guide to secure nail. The Quick Bolt will also be used to rotate Drill Guide 180° as needed for lateral oblique screw insertion. Alternatively, the Knee Guide may be assembled to the Drill Guide after the nail is inserted (Figure 10).

8. Advance the nail over the Guide Rod and carefully pass the fracture. Countersink the nail approximately 2-5 mm into the tibia proximally (Figure 11A and Figure 11B). Confirm rotation as is appropriate. Remove the Guide Rod.
5.0 mm (GOLD) screws are to be used with 10 mm, 11.5 mm, and 13 mm Knee Implants.

4.5 mm (GREY) screws are to be used with 8.5 mm Knee Implants which are indicated for use in the TIBIAL MODE ONLY.

9. **Proximal Screws: Transverse and Medial Oblique Placement** — Insert the Gold Outer Drill Sleeve (7163-1152) through the proximal holes. Make a skin incision and insert the sleeve to bone. It is recommended that the oblique screw holes be pre-drilled in the proximal tibia, as the bone and the screw are not perpendicular to each other.

A. **PRE-DRILLING TECHNIQUE** — The Silver Inner Drill Sleeve (7163-1156) is introduced through the Gold Outer Drill Sleeve (7163-1152). Attach the Long Pilot Drill (7163-1110) to power using the Mini-Connector (7163-1186). Insert the Long Pilot Drill through both cortices (Figure 12). The length measurements are taken from the calibrations off the drill in relation to the end of the drill sleeve. The appropriate length screw is selected and attached to the Screwdriver. The Drill and Silver Inner Drill Sleeve are removed. Attach Screwdriver to power or use manual T-Handle (7163-1172) or Straight Screwdriver Handle (7163-1163) and place screws in bone through the Gold Outer Drill Sleeve. The Screwdriver contains a laser-marked ring. This ring should be stopped short of the Gold Outer Drill Sleeve to prevent final seating of the screw by power. Final tightening of the screws should always be under manual control using the T-Handle (7163-1172) or Straight Screwdriver Handle (7163-1163) (Figure 13).
B. SCREW LENGTH GAUGE — After predrilling through both cortices as outlined above, remove the Silver Inner Drill Sleeve, leaving the Gold Outer sleeve in place. Use the Screw Length Gauge (7163-1170) through the Gold Outer Drill Sleeve (7163-1152) from the far cortex to measure for proper length screw (Figure 14). An alternative option in measuring for screw length is the Direct Measuring Gauge (7163-1189) used without the Drill Sleeve. The appropriate length screw is selected and attached to the Medium (7163-1166) or Long (7163-1164) Screwdriver. Attach Screwdriver to power or use manual T-handle (7163-1172) or Straight Screwdriver Handle (7163-1163) and place screws in bone. The Screwdriver contains a laser-marked ring. This ring should be stopped short of the Gold Outer Drill Sleeve to prevent final seating of the screw by power. Final tightening of the screws should always be under manual control using the T-Handle (7163-1172) or Straight Screwdriver Handle (7163-1163) (Figure 15).

NOTE: Once screw is seated, simply insert the Screwdriver Release Handle (7163-1208) into the cannulation of the T-Handle and turn counterclockwise. The Screwdriver Release Handle releases the screw from the screwdriver without the need to remove the T-Handle or Straight Screwdriver (Figure 16).
10 Continue with the placement of the medial oblique screw by following the predrilling technique (Figure 17).

11 Proximal Lateral Oblique Screw Placement — For insertion of the lateral oblique screw, the Quick Bolt (7163-1138) is loosened and back-turned two complete revolutions. This allows the Knee Guide to be lifted and rotated 180°. After rotating the Knee Guide, retighten with the Quick Bolt, making sure the key is engaged. The guide is now in correct position for placement of the lateral oblique screw. Predrilling may be particularly advantageous and recommended in the oblique holes when drilling through the Knee Guide. This can be done by following the predrill technique previously outlined on pages 7 and 8 (Figures 18 and 19).
Distal Screws: The freehand technique is used. First, the rotation is confirmed with the tibia to be satisfactory. Next, the image intensifier is used to obtain perfect circles radiographically on the medial view or the anterior view. There are four screw hole options in the standard Knee Nail sizes and three screw hole options with the 8.5 mm Knee Tibial Nails.

A. PREDRILLING TECHNIQUE — After perfect circles are confirmed, a stab incision is made over the holes and the Long Pilot Drill (7163-1110) is inserted through both cortices. The Mini-Connector (7163-1186) can be used to conveniently connect the drill to power. Remove the Mini-Connector and push the Silver Inner Drill Sleeve (7163-1156) to bone over the drill. The appropriate length measurement is taken from the drill calibrations in relation to the top of the Silver Inner Drill Sleeve (Figure 20). An alternative option in measuring for screw length is the Direct Measuring Gauge (7163-1189) used without the Drill Sleeve. The appropriate length screw is selected and attached to the Screwdriver. Remove the Drill and Silver Inner Drill Sleeve. Attach Screwdriver to power or use manual T-Handle (7163-1172) or Straight Screwdriver Handle (7163-1163) place screws in bone. The Screwdriver contains a laser-marked ring. This ring should be stopped short of the Gold Outer Drill Sleeve to prevent final seating of the screw by power. It is recommended that final tightening of the screw should always be under manual control using the T-Handle (7163-1172) or Straight Screwdriver Handle (7163-1163).
B. SCREW LENGTH GAUGE — After predrilling through both cortices as outlined above, insert the Gold Outer Drill Sleeve (7163-1152) to bone and use the Screw Length Gauge (7163-1170) through the Gold Outer Drill Sleeve from the far cortex to measure for proper screw length (Figure 21). An alternative option in measuring for screw length is the Direct Measuring Gauge (7163-1189) used without the Drill Sleeve. The appropriate length screw is selected and attached to the Screwdriver. Attach Screwdriver to power or use manual T-handle (7163-1172) or Straight Screwdriver Handle (7163-1163) and place screws in bone. The Screwdriver contains a laser-marked ring. This ring should be stopped short of the Gold Outer Drill Sleeve to prevent final seating of the screw by power. It is recommended that final tightening of the screw should always be under manual control.

C. (OPTIONAL) POWER TECHNIQUE — The distal interlocking technique can be performed without a guide by the freehand method. Measure for screw length with the Ruler (7163-1128) under imaging. This can be done by placing the Ruler on top of the leg and shooting an image. Count the number of grooves between the edge of the Ruler and the far cortex. The grooves are 5 mm apart. The Ruler should be placed against the edge of the near cortex for the best measurement. The screw length should be adjusted 3 to 5 mm larger for magnification error correction to assure that the far cortex is reached. After “perfect circles” are confirmed, the proper length screw is attached to the Screwdriver. Attach Screwdriver to power and place screws in bone (Figure 22). It is recommended that final tightening of the screw should always be under manual control using the T-Handle (7163-1172) or Straight Screwdriver Handle (7163-1163) (Figure 23 and 23 Inset).
D. TARGETER — The Targeter (7163-1174) may be used to assist in placing additional distal screws after the first screw has been inserted. Be sure to use the Short Screwdriver (7163-1168) when placing the first screw in bone as outlined in the above options. Leave the Short Screwdriver attached to the first screw in the bone. Choose whether you will be “statically” or “dynamically” locking the implant. Place the appropriate labeled hole on the Targeter over the Screwdriver and push to skin (Figure 24). Make sure that the Targeter can freely rotate. The Long Screwdriver (7163-1164) can also be attached to the side of the Targeter. It acts as a handle to stabilize the Targeter, as well as an aid in reducing exposure of the hand during imaging. Use the C-Arm to rotationally locate the second hole. Once the position is found, place the Short Drill (7163-1112) through the wire hole on the Targeter and into bone to maintain position. The Mini-Connector (7163-1186) provides a convenient attachment of the drill to power. Make an incision at the tip of the barrel for the second screw and insert the Silver Inner Drill Sleeve and Targeter to bone. Use of the standard predrill technique or power technique can be used to finish screw placement. The Targeter can be used for both M/L and A/P placement of the second screw. When using the Targeter for A/P locking, the slot marked “dynamic” should be used for the second screw (Figure 25 and 25 Inset).

NOTE: Once screw is seated, simply insert the Screwdriver Release Handle (7163-1208) into the cannulation of the T-Handle and turn counterclockwise. The Screwdriver Release Handle releases the screw from the screwdriver without the need to remove the T-Handle (Figure 26).
Final position of the fracture is confirmed. Following completion of nailing and interlocking screw placement, the Knee Guide and Drill Guide are disassembled by backing off the Quick Bolt. Irrigate incision with saline and close in a standard fashion (Figure 27).
The TriGen Instrument Set offers two extractors for nail explanation. When removing a TriGen nail, the Large Extractor (7163-1178) is always used. For nails other than TriGen, the Large Extractor is designed to remove diameters greater than 10 mm. The Small Nail Extractor (7163-1176) is designed for 10 mm diameters or smaller nails. These two nail extractors are designed to remove virtually any nail.

**STANDARD TECHNIQUE FOR LARGE OR SMALL EXTRACTOR**

1. Patient is placed in correct position on a radiolucent table for imaging.
2. Make a 1 cm to 2 cm incision in approximately the same location as the original incision used to place the nail.
3. Place the 3.2 mm Tip Threaded Guide Wire (7163-1190) into the top of the nail.
4. Insert the 12.5 mm Entry Reamer (7163-1116) to the top of the nail and use to clear debris and overgrowth.
5. After debris has been cleared, remove the guide wire and Entry Reamer and assemble the Impactor to the appropriate extractor.
6. The extractor is placed through the incision down to the top of the nail and screwed into the nail using slight, downward pressure. Be sure to check alignment of the extractor and nail to make assembly easier.
7. After the Extractor is tightened to the nail, the Guide Bolt Wrench (7163-1140) is placed into the hole on the Impactor (7163-1185) handle to provide additional leverage.
8. Remove all locking screws.
9. The Slotted Hammer (7163-1150) is then placed on the Impactor and used to back slap the nail out of the bone.

**OPTIONAL CANNULATED TECHNIQUE**

**FOR LARGE EXTRACTOR ONLY**

Most useful when removing antegrade femoral nails

1. Patient is placed lateral decubitus on a radiolucent table for imaging.
2. Remove all locking screws.
3. Make a 1 cm to 2 cm incision in approximately the same location as the original incision used to place the nail.
4. Place the 3.2 mm Tip Threaded Guide Wire (7163-1190) into the top of the nail.
5. Insert the 12.5 mm Entry Reamer (7163-1116) over the guide wire to the top of the nail and use to clear debris and overgrowth.
6. Once the debris is cleared, remove the Entry Reamer, leaving the 3.2mm Tip Threaded Guide Wire in place.
7. Assemble the One-Piece Impactor (7163-1185) to the Large Extractor.
8. The Large Extractor is placed over the wire and guided to the top of the nail. The Extractor is screwed into the nail using slight downward pressure.
9. After the extractor is tightened to the nail, the Guide Bolt Wrench (7163-1140) is placed into the hole on the Impactor (7163-1185) handle to provide additional leverage.
10. The Slotted Hammer (7163-1150) is then placed on the hammer and used to back slap the nail and 3.2 mm guide wire out of the bone.
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**4.5 MM CAPTURED SCREW**

(Grey) For 8.5 mm Implants Only

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**5.0 MM CAPTURED SCREW**

(Gold) For 10 mm, 11.5 mm & 13 mm Implants

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Long Pilot Drill  
Cat. No. 7163-1110

Short Pilot Drill  
Cat. No. 7163-1112

Entry Tool  
Cat. No. 7163-1114

12.5 mm Entry Reamer  
Cat. No. 7163-1116

14 mm Channel Reamer  
Cat. No. 7163-1118

Entry Reamer Connector  
Cat. No. 7163-1120

Obturator  
Cat. No. 7163-1122

Reducer  
Cat. No. 7163-1124

3.0 mm X 1000 mm Ball Tip Guide Rod  
Cat. No. 7163-1126

Ruler  
Cat. No. 7163-1128

Flex Reamer Extender  
Cat. No. 7163-1130

Skin Protector  
Cat. No. 7163-1132
Drill Guide
Cat. No. 7163-1134

Guide Bolt
Cat. No. 7163-1136

Quick Bolt
Cat. No. 7163-1138

Guide Bolt Wrench
Cat. No. 7163-1140

Knee Guide
Cat. No. 7163-1142

Hip Guide
Cat. No. 7163-1144

8.5 mm FAN Guide
Cat. No. 7163-1146

One Piece Impactor
Cat. No. 7163-1185

Hammer
Cat. No. 7163-1150

Gold Outer Drill Sleeve
Cat. No. 7163-1152

Silver Inner Drill Sleeve
Cat. No. 7163-1156

Supracondylar Guide
Cat. No. 7163-1158

6.4 mm Drill
Cat. No. 7163-1160

6.4 mm Tap
Cat. No. 7163-1162
Long Screwdriver  
Cat. No. 7163-1164

Medium Screwdriver  
Cat. No. 7163-1166

Short Screwdriver  
Cat. No. 7163-1168

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Screw Length Gauge  
Cat. No. 7163-1170

Direct Measuring Gauge  
Cat. No. 7163-1189

T-Handle (Zimmer-Hall)  
Cat. No. 7163-1172

Straight Screwdriver Handle  
Cat. No. 7163-1163

Targeter  
Cat. No. 7163-1174

Small Extractor  
Cat. No. 7163-1176

Large Extractor  
Cat. No. 7163-1178

Small AO Adapter  
Cat. No. 7163-1184
Mini Connector  
Cat. No. 7163-1186

Tip Threaded Guide Wire  
Cat. No. 7163-1190

Flex Reamer Shaft  
Cat. No. 7163-1192

Screwdriver Release Handle  
Cat. No. 7163-1208

Pilot Nose Reamer Heads

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Instrument Case Set
Cat. No. 7163-1200
Consists of: 7112-9400 Large Outer Case; 7112-9402 Lid for Outer Case; 7163-1199; and 7163-1201

TriGen Instrument Tray 1
Cat. No. 7163-1199

TriGen Instrument Tray 2
Cat. No. 7163-1201

FAN Case – Left
Cat. No. 7163-1202

FAN Case – Right
Cat. No. 7163-1203

Knee Nail Case
Cat. No. 7163-1204

FAN Case – 13 mm Nails
Cat. No. 7163-1206

Large Outer Case 4.8”
Cat. No. 7112-9400

Small Outer Case 2.4”
Not Shown
Cat. No. 7112-9401

Lid for Outer Case
Shown with Case
Cat. No. 7112-9402

Screw Caddy
Cat. No. 7163-1180
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, long 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 trochanter 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 tibial and talocalcaneal articulations in the hindfoot; tibiocalcaneal arthrodesis; combined arthrodesis of the ankle and sub-talar joints; avascular necrosis of the ankle and sub-talar joints; failed total ankle replacement with sub-talar 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 sub-talar 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. Preeexisting 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 catalogue 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. Irritationary 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 a minimum of 25 kGy 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), 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.