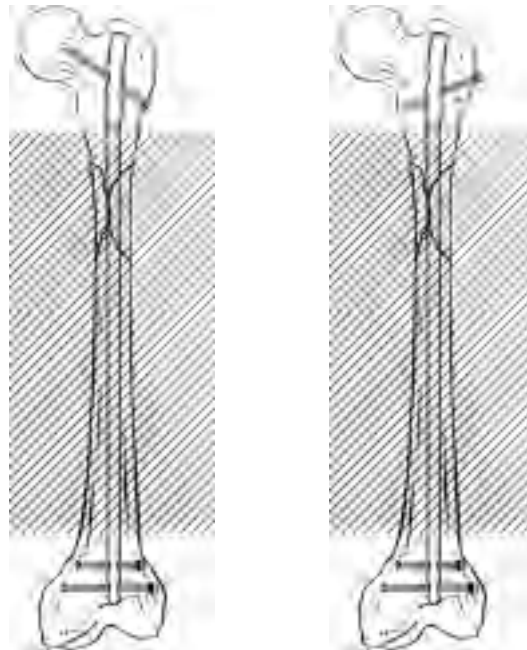


TRIGEN[®] IM NAIL SYSTEM

SURGICAL TECHNIQUE

8.5 MM FEMORAL ANTEGRADE NAIL (FAN[®])

As Described By
Thomas A. Russell, M.D.
and
Roy W. Sanders, M.D.



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 Patient is placed supine with unaffected limb extended below the affected limb and trunk. The affected limb is adducted. Flex the affected hip 15°. Apply traction through a skeletal pin or the foot with the fracture table foot holder. Adjust the affected limb for length and rotation by comparison with the unaffected limb. Rotation is further checked by rotating the arm to align the femoral neck anteversion and then making the appropriate correction by foot, usually in 0-15° of external rotation. Decubitus position may also be used with the fracture table, in this situation because of the change of position of the femoral head, the leg is usually internally rotated 10-15°. This is best checked by visualizing the femoral anteversion proximally and matching it with correct rotation at the knee (*Figure 1*).

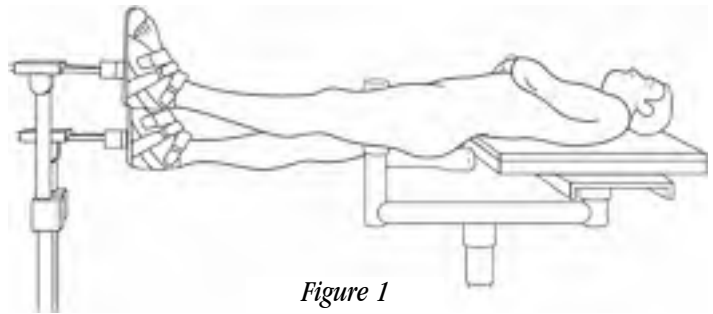


Figure 1

2 Make a small 2-3 cm incision just lateral and above the apex of the greater trochanter. Angle this incision posteriorly at its proximal end. Carry the incision through the fascia. Palpate the greater trochanter (*Figure 2*).



Figure 2

ENTRY PORTAL

3 Assemble the Entry Tool and Honeycomb Insert (7163-1114). The Entry Tool can be set for the appropriate limb by pulling back on the suction port and allowing it to snap back into place. This allows blood flow to quickly exit the tool. Attach suction to the Entry Tool to assist in blood evacuation and minimize aerosolisation of blood to operative team (*Figure 3*).

4 Place the Entry Tool with Honeycomb Insert (7163-1114) through the incision to bone. Adjust to align the Entry Tool with the axial line of the femoral shaft in the A/P and lateral image views. This may require placing pressure on the Entry Tool to align the Tip Threaded

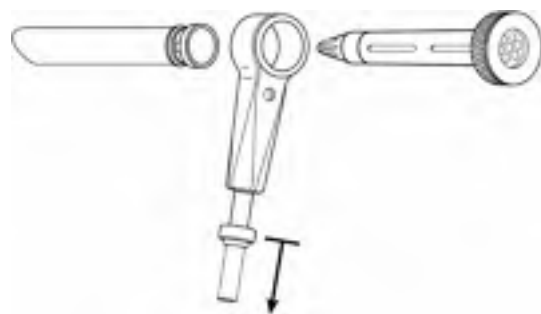


Figure 3

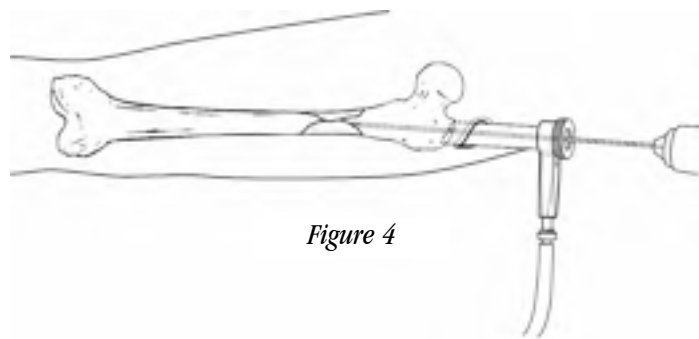


Figure 4



Figure 5

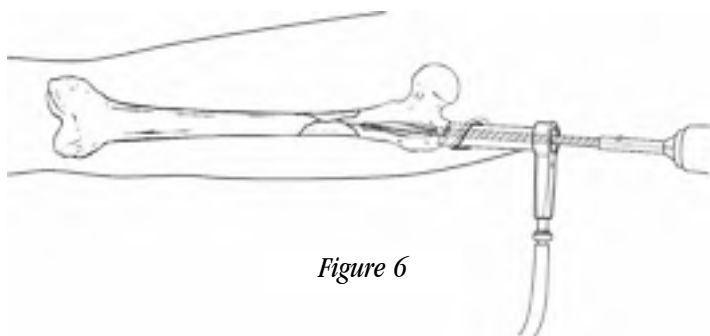


Figure 6

Guide Wire (7163-1190) with the axial line of the femur. Insert the Guide Wire when the axial line and drill alignment is acceptable. A second 3.2 mm wire can be used to further define the correct entry portal. In this way, the position in the trochanter is maintained should the first pilot drill be removed or repositioned. The Guide Wire will snap fit into the Mini-Connector (7163-1186), which easily connects to any drill with a “Hall” connector. Once proper placement of the Guide Wire has been established, the “honeycomb” insert should be removed. (Figure 4).

5 Attach the 12.5mm Entry Reamer (7163-1116) to power to ream the proximal section of the femur through the Entry Tool (Figure 5). Adjust the Entry Reamer over the Guide Wire and ream the proximal portion of the femur until the reamer reaches the intersection of the canal just below the lesser trochanter. The Entry Reamer enlarges the proximal femur 1.0 mm over the diameter of the head of the nail to 12.5 mm. Remove the 12.5 mm Entry Reamer and Guide Wire, keeping the Entry Tool in place (Figure 6).

FRACTURE REDUCTION

6 Snap the T-Handle (7163-1172) onto the Reducer (7163-1124) (*Figure 7*). Place the Reducer through the Entry Tool to reduce the fracture (*Figure 8*). Once the Reducer is in the medullary canal and has captured the distal fragment, the 3.0 mm Ball-Tipped Guide Rod (7163-1126) is inserted through the Reducer into the distal femur in the region of the old postulus scar (*Figure 9*). The Gripper (7163-1100) is useful in holding onto the Guide Rod during insertion and removal (*Figure 9 Inset*).

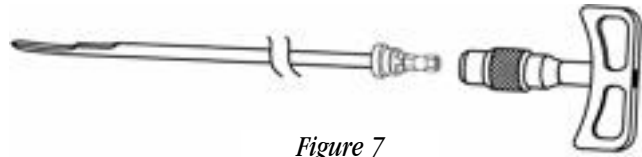


Figure 7

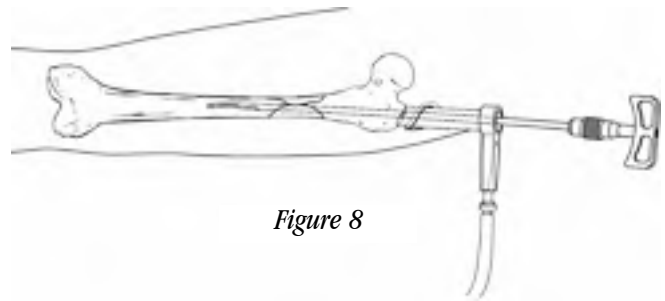


Figure 8

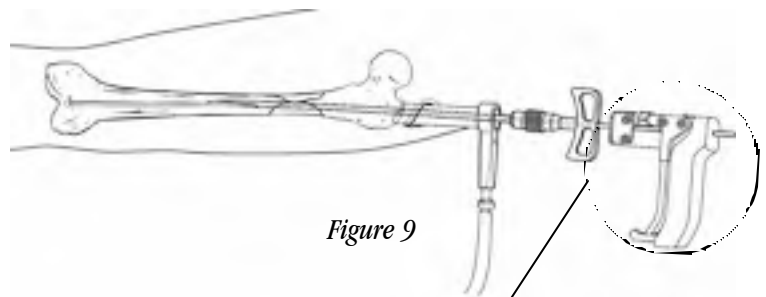


Figure 9

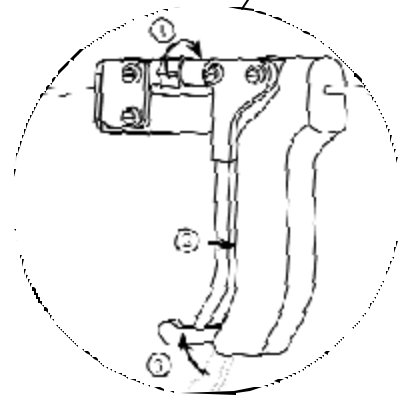


Figure 9 Inset

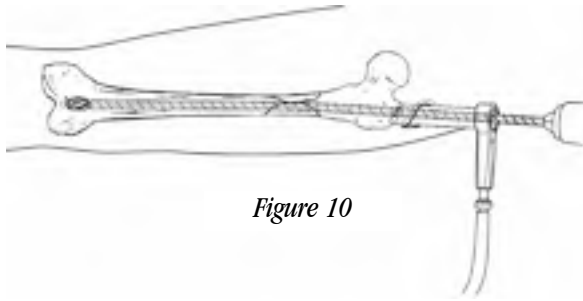


Figure 10

CANAL PREPARATION

7 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 the mid-diaphysis. Once the Guide Rod is in place, remove the Reducer. Proceed to sequentially ream the femoral shaft to .5 to 1.0 mm or more above the chosen nail diameter through the Entry Tool. For more curved femoral shafts, .5 to 1.0 mm of over reaming may be beneficial. In patients that are very long, the Flex Reamer Extender (7163-1130) may be added to extend the shaft of the flexible reamer for very distal fractures or nails longer than 42 cm (Figure 10).

NAIL SELECTION

8 Determine nail diameter from image intensifier or templating. Never insert a nail that has a larger diameter than the last reamer used.

9 Position the tip of the guide rod at the desired level of the tip of the nail considering fracture patterns and locking screw positioning. Measure the nail length by positioning the open end of the Ruler (7163-1128) over the exposed end of the guide rod pushing the end down to the level of bone through the Entry Tool. Confirm the position on the image intensifier. Read the nail length from the calibrations exposed at the other end of the Ruler. Leave the guide rod in place for placement of the nail. Exchange of the ball-tipped guide rod is not necessary (Figure 11).

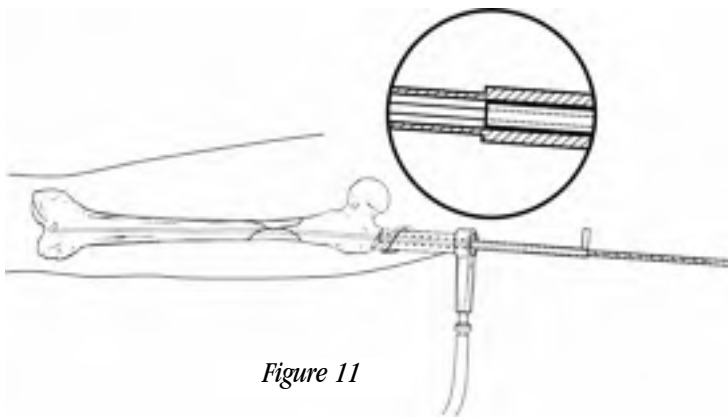


Figure 11

DRILL GUIDE ASSEMBLY

FEMORAL MODE

10 Insert the Guide Bolt (7163-1136) into the Drill Guide (7163-1134) and use the Guide Bolt Wrench (7163-1140) to secure the bolt to the nail. Connect the 8.5 mm FAN Guide (7163-1146) to the Drill Guide. The guide is keyed so that it will only fit one way. Tighten the knurled knob by hand until snug. Use the end of the Guide Bolt Wrench (7163-1140) to finish tightening the guide in place. Check the alignment of the guide to the screw holes by passing the Medium Screwdriver (7163-1166) through the Gold Outer Drill Sleeve (7163-1152) up into the holes of the nail. Screw the Impactor onto the top of the Drill Guide to drive the nail into the medullary canal (*Figure 12*). Insert the Skin Protector (7163-1132) in the incision parallel to the Entry Tool. The Skin Protector will assist in maintaining control of the surrounding tissues and provide continued access to the bone. Remove the Entry Tool. Advance the nail over the guide rod and carefully past the fracture. Remove the guide rod after the nail is inserted and before inserting the locking screws (*Figure 13*).

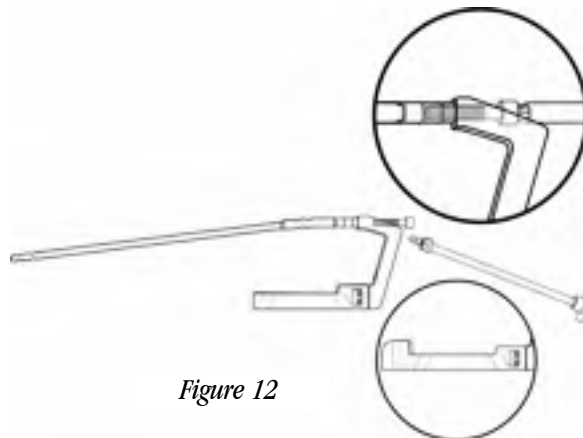


Figure 12

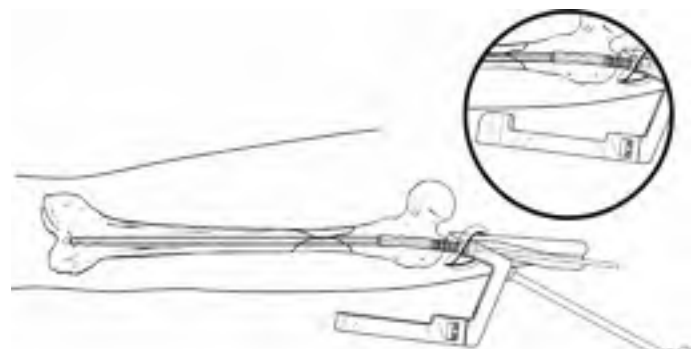


Figure 13

INTERLOCKING FOR FEMORAL MODE

4.5 mm (GREY) screws are to be used with 8.5 mm FAN Implants.

11 Proximal Screw: To place one screw into the femoral head or one transversely, the following options are available (*Figure 14*):

A. PREDRILLING TECHNIQUE — Make a stab incision at the entry hole and push the Gold Outer Drill Sleeve (7163-1152) through the drill guide hole until it is touching the lateral cortex. Introduce the Silver Inner Drill Sleeve (7163-1156) through the Gold Outer Drill Sleeve. Attach the Long Pilot Drill (7163-1110) to power using the Mini-Connector (7163-1186). Drill to, but not through the opposite cortex and measure for proper length. The length

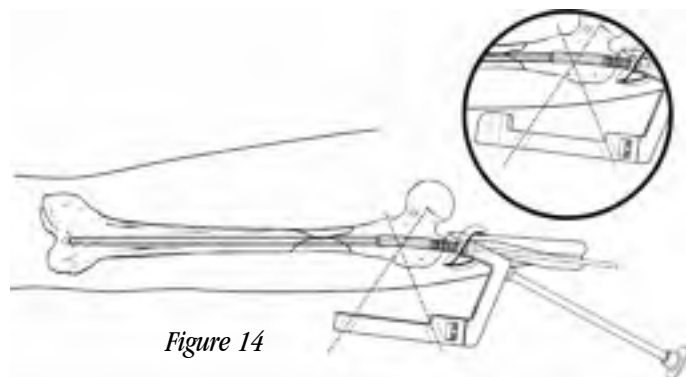


Figure 14

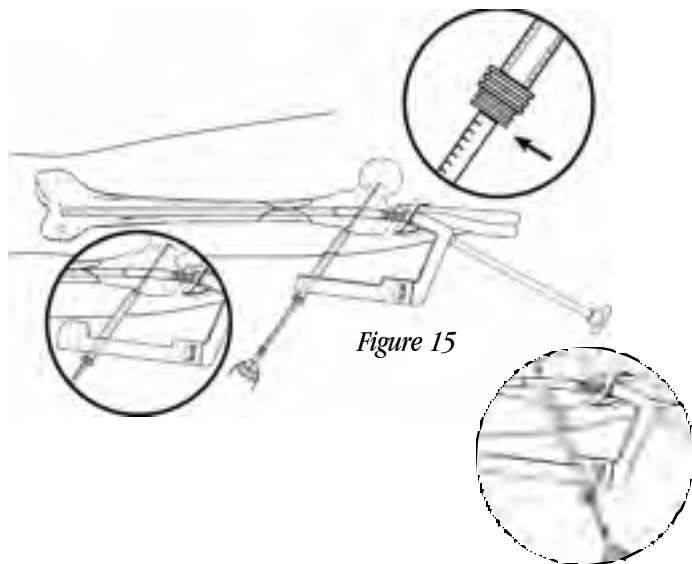


Figure 15

measurements are taken from the calibrations off the drill in relation to the end of the Silver Inner Drill Sleeve. The appropriate length 4.5 mm screw (GREY) is selected and attached to the Screwdriver (*Figure 15*). The drill and Silver Inner Drill Sleeve are removed and the screw is inserted through the Gold Outer Drill Sleeve. Attach Screwdriver to power or use manual T-Handle (7163-1172) and place screw 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 4.5 mm screw should always be under manual control using the T-Handle (7163-1172) or Straight Screwdriver Handle (7163-1163) (*Figure 16*).

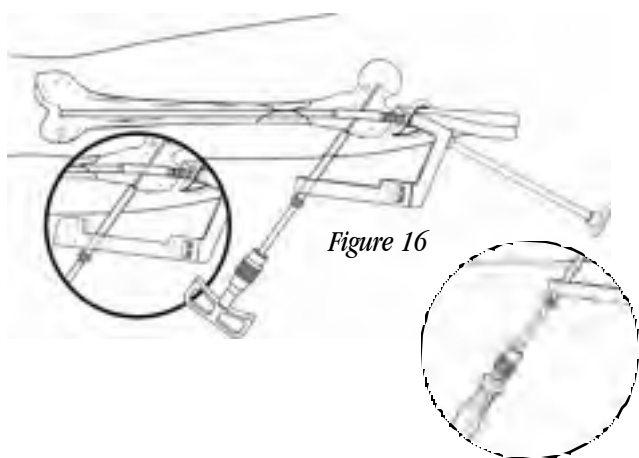


Figure 16

B. SCREW LENGTH GAUGE — Pre-drill through both cortices. Insert the Screw Length Gauge (7163-1170) through the Gold Outer Drill Sleeve (7163-1152) from the far cortex to measure for proper length (*Figure 17*). The appropriate length 4.5 mm screw (GREY) is selected and attached to the Screwdriver. Attach

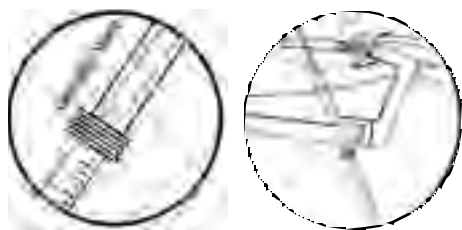


Figure 17

Screwdriver handle to power or use manual T-handle (7163-1172) 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 4.5 mm screw should always be under manual control using the T-Handle (7163-1172) or Straight Screwdriver Handle (7163-1163) (Figure 18).

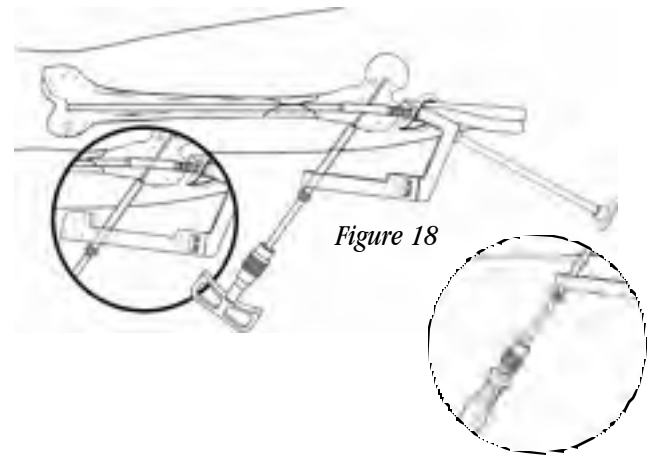


Figure 18

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 (see Figure 19).

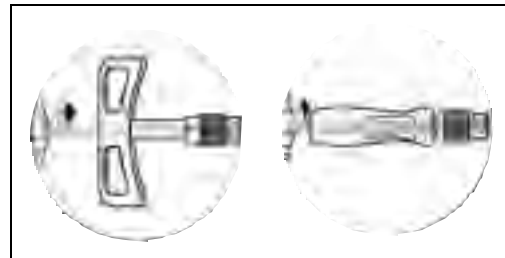


Figure 19

12 Distal Screws: Perform distal locking with the Cole Radiolucent Drill or Freehand Technique. The Freehand technique is used with the C-Arm placed medial to the patient, allowing for proper image of the femur. Make adjustments to the C-Arm until perfect circles are visualized. Make a stab incision over the holes of the image and then one of the following techniques may be used.

A. PREDRILLING TECHNIQUE — After perfect circles are confirmed, a stab incision is made over the holes. Confirm the alignment and attach the Short Drill (7163-1117) to power using the Mini-Connector (7163-1186). Insert the drill through both cortices. Remove the Mini-Connector and push the Silver Inner Drill Sleeve (7163-1156) to bone over the drill. The length measurements are taken from the calibrations off the drill in relation the Silver Inner Drill Sleeve to bone (Figure 20). The appropriate length 4.5 mm screw (GREY) is selected and attached to the Screwdriver. Remove the Long Drill and Silver Inner Drill Sleeve. Attach Screwdriver handle to power or use manual T-handle (7163-1172) or Straight Screwdriver Handle (7163-1163) and place screws in bone. It is recommended that final tightening of the 4.5 mm screw should always be under manual control using the T-Handle (7163-1172) or Straight Screwdriver

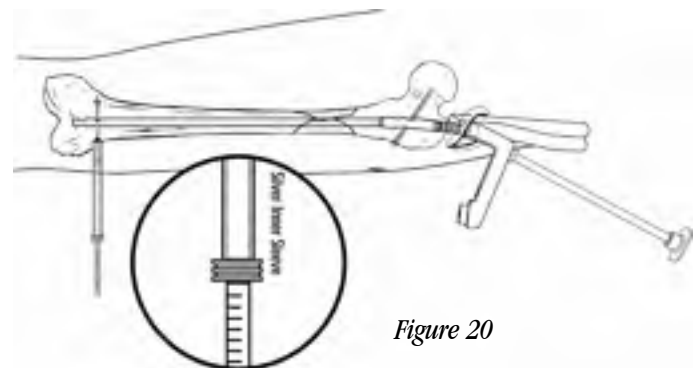


Figure 20

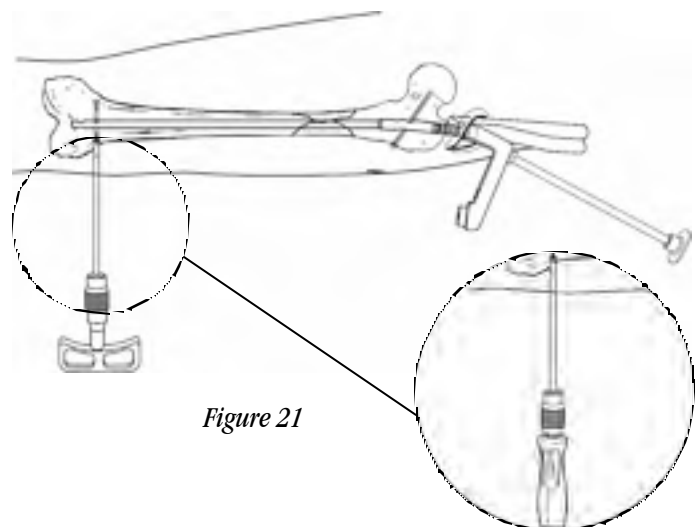


Figure 21

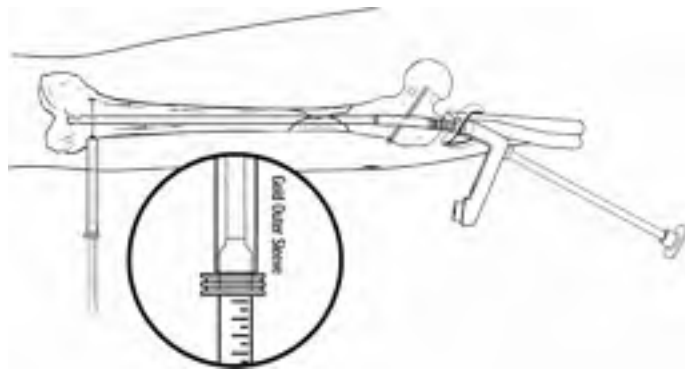


Figure 22

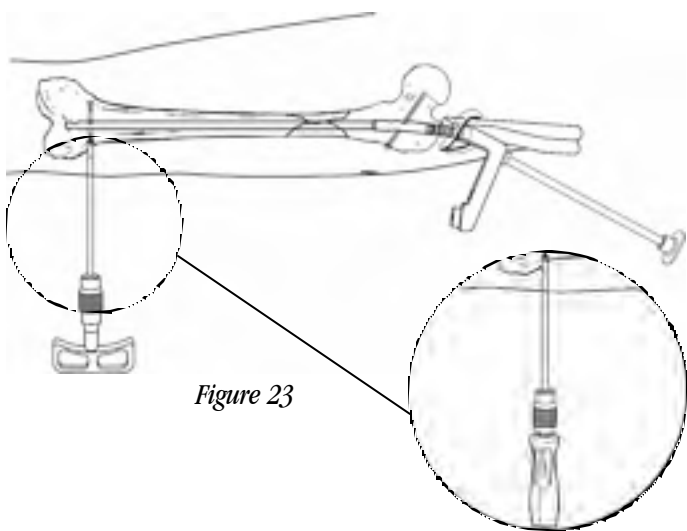


Figure 23

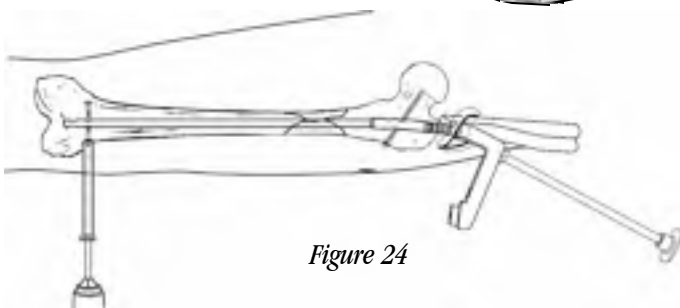


Figure 24

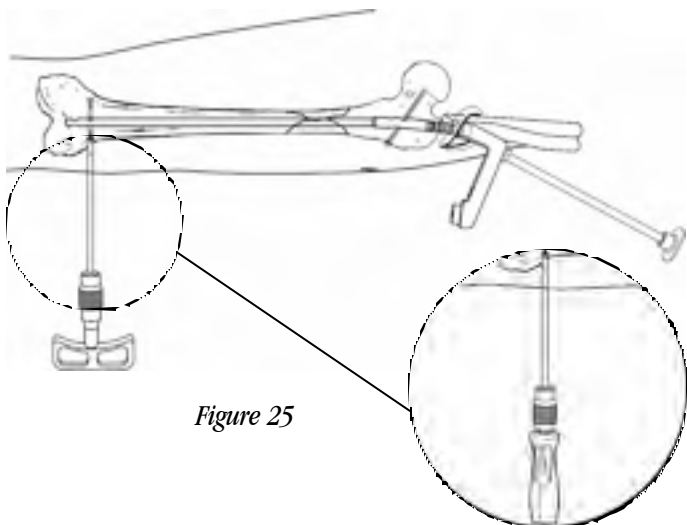


Figure 25

Handle (7163-1163) (Figure 21).

B. SCREW LENGTH GAUGE — Pre-drilling through both cortices. Insert the Gold Outer Drill Sleeve (7163-1152) to bone. Insert the Screw Length Gauge (7163-1170) through the Gold Outer Drill Sleeve from the far cortex to measure for proper 4.5 mm screw (GREY) length (Figure 22). An alternative option in measuring for screw length is the Direct Measuring Gauge (7163-1189) used without the drill sleeve. The appropriate length 4.5 mm screw (GREY) is selected and attached to the Screwdriver. Attach Screwdriver handle to power or use manual T-handle (7163-1172) or Straight Screwdriver Handle (7163-1163) and place screws in bone. It is recommended that final tightening of the 4.5 mm screw should always be under manual control using the T-Handle (7163-1172) or Straight Screwdriver Handle (7163-1163) (Figure 23).

C. (OPTIONAL) POWER TECHNIQUE — The distal interlocking technique can be performed without a guide by the freehand method. This can be done by placing the Ruler (7163-1128) on top of the leg and taking a C-arm 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 3-5 mm longer for magnification error correction to ensure that the far cortex is reached. The proper length 4.5mm screw (GREY) is attached to the Screwdriver. After “perfect circles” are confirmed, insert the screw into bone through the Gold Outer Drill Sleeve (7163-1152) using power. 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 (Figure 24). It is recommended that final tightening of the 4.5 mm screw should always be under manual control using the T-Handle (7163-1172) or Straight Screwdriver Handle (7163-1163) (Figure 25).

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 Medium Screwdriver (7163-1166) when placing the first screw in bone as outlined in the above options. Leave the Medium 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, making sure that the Targeter can freely rotate (*Figure 26*). The Short Screwdriver (7163-1168) 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 a 3.2 mm Tip Threaded Guide Wire (7163-1190) 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 (*Figure 27*). Use of the standard pre-drill technique or power technique can be used to finish screw placement (*Figure 28*). The optional power technique can also be used for the second screw by removing the 4.0 mm drill sleeve.

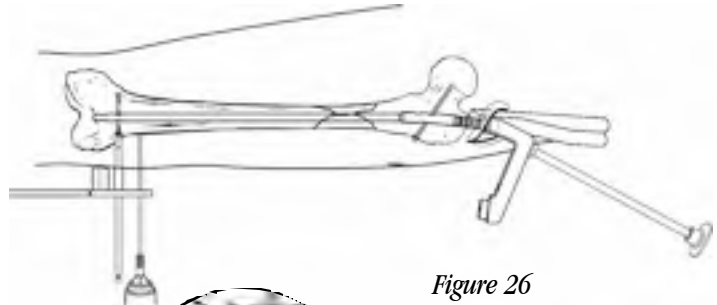


Figure 26

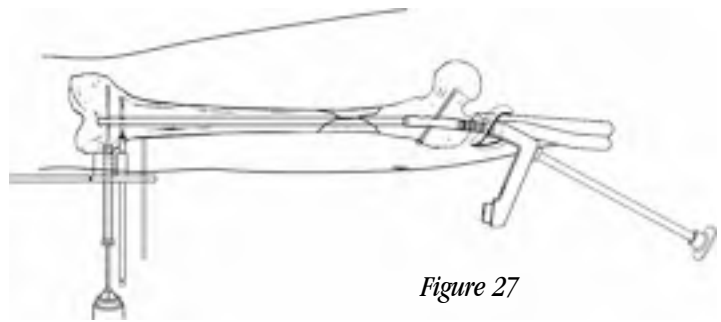


Figure 27

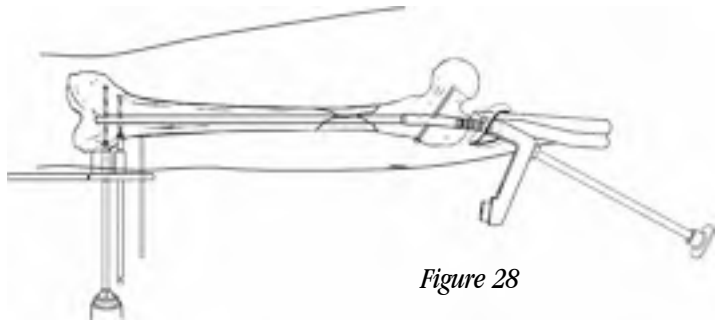


Figure 28

CLOSURE

13 On the completion procedure, the proximal guide is removed with the Guide Bolt Wrench (7163-1140), wounds are irrigated and closed in a standard fashion (*Figure 29*).



Figure 29

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

Standard Technique for Large or Small Extractor

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, when removing a femoral nail inserted in the antegrade position. Otherwise, the 3.2 mm Guide Wire is not needed.
5. Insert the 12.5 mm Entry Reamer (7163-1116) to the top of the nail and use to clear debris and overgrowth.
6. After debris has been cleared, remove the guide wire and Entry Reamer and assemble the Impactor to the appropriate extractor.
7. 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.
8. 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.
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 cannulated 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.

CATALOG INFORMATION — NAILS

8.5 MM FAN

(Grey)

Cat. No.	Length
7163-6124	24 cm
7163-6126	26 cm
7163-6128	28 cm
7163-6130	30 cm
7163-6132	32 cm
7163-6134	34 cm
7163-6136	36 cm
7163-6138	38 cm
7163-6140	40 cm



CATALOG INFORMATION — SCREWS

4.5 MM CAPTURED SCREW

(Grey) For 8.5 mm Implants Only

Cat. No.	Length
7163-2120	20 mm
7163-2125	25 mm
7163-2130	30 mm
7163-2135	35 mm
7163-2140	40 mm
7163-2145	45 mm
7163-2150	50 mm
7163-2155	55 mm
7163-2160	60 mm
7163-2165	65 mm



CATALOG INFORMATION — INSTRUMENTATION

Gripper

Cat. No. 7163-1100



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



CATALOG INFORMATION — INSTRUMENTATION

Long Screwdriver

Cat. No. 7163-1164



Medium Screwdriver

Cat. No. 7163-1166



Short Screwdriver

Cat. No. 7163-1168



Screwdriver Replacement Bars

Cat. No.	Description
7163-1165	Large
7163-1167	Medium
7163-1169	Short



Screw Length Gauge

Cat. No. 7163-1170



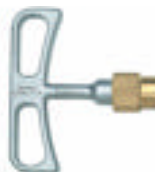
Direct Measuring Gauge

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

Cat. No.	Description
7111-8233	9.5 mm Head
7111-8234	10.0 mm Head
7111-8235	10.5 mm Head
7111-8236	11.0 mm Head
7111-8237	11.5 mm Head
7111-8238	12.0 mm Head
7111-8239	12.5 mm Head
7111-8240	13.0 mm Head
7111-8241	13.5 mm Head
7111-8242	14.0 mm Head



CATALOG INFORMATION — INSTRUMENT/IMPLANT TRAYS

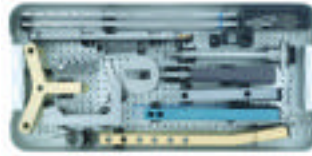
Instrument Case Set

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



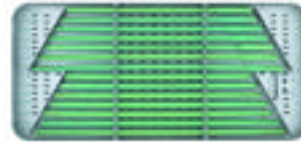
TriGen Instrument Tray 2

Cat. No. 7163-1201



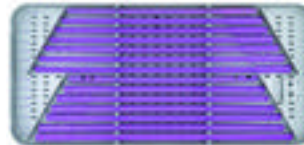
FAN Case – Left

Cat. No. 7163-1202



FAN Case – Right

Cat. No. 7163-1203



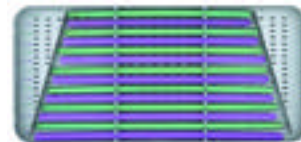
Knee Nail Case

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



IMPORTANT MEDICAL INFORMATION

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; tibio-calcaneal 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. 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 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. 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 a minimum of 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.

