Femoral Fracture Nail Retrograde - Ti
Surgical Technique

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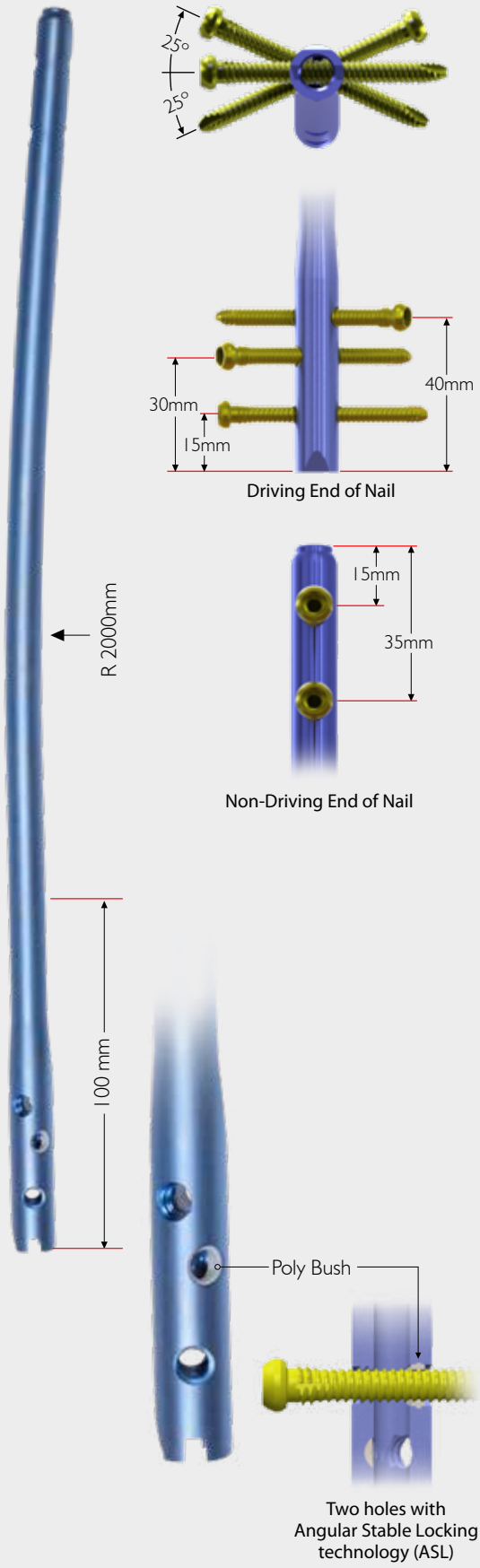
Indications for Use

The Atlas® Femoral Fracture Nail Retrograde is indicated for fractures of the femur including stable and unstable distal metaphyseal fractures, diaphyseal fractures, intra-articular fractures, peri-prosthetic fractures, non-unions, mal-unions and for the prophylactic nailing of impending pathological fractures.



ATLAS Ti Femoral Fracture Nail Retrograde - Specifications

Material	Ti6Al4V
Diameters	10.0mm & 11.5mm
Lengths	28cm - 44cm
Nail Colour	Blue
Distal Diameter Driving End	12.0mm
Proximal Diameter Non-Driving End	10.0mm & 11.5mm
Locking Bolt Threads	M8 x 1
Screw Diameter	5.0mm
Screw Colour	Gold
Screw Lengths	20mm - 110mm
Screw Socket	Hex 4.75mm
Sterilization	Radiation
Distal Locking Driving End	
Static Lock Locations/Orientations	15mm/ML Can be Locked with TFN/FFN Nail Cap 30mm/25° Threaded with bushing 40mm/25° Threaded with bushing
Proximal Locking Non-Driving End	
Static Lock Locations/Orientations	15mm/AP 35mm/AP
AP Bow Radius	2000mm
AP Bow Location	Starts 100mm from Driving End

ATLAS® Ti FFN Retrograde, Sterile

Code No.		Length cm
Ø 10mm	Ø 11mm	
I0146.1028s	I0147.1128s	28
I0146.1030s	I0147.1130s	30
I0146.1032s	I0147.1132s	32
I0146.1034s	I0147.1134s	34
I0146.1036s	I0147.1136s	36
I0146.1038s	I0147.1138s	38
I0146.1040s	I0147.1140s	40
I0146.1042*	I0147.1142*	42
I0146.1044*	I0147.1144*	44

*42 cm & 44 cm are supplied Non-Sterile

ATLAS Ti TFN/FFN Closing Cap

Code No.	Length mm
I0303.00	0
I0303.05	5
I0303.10	10

ATLAS® Ti Locking Screw Ø5.0mm

Code No. Ø 5.0mm Color: Gold	Length mm
I0211.5020	20.0
I0211.5023	22.5
I0211.5025	25.0
I0211.5028	27.5
I0211.5030	30.0
I0211.5033	32.5
I0211.5035	35.0
I0211.5038	37.5
I0211.5040	40.0
I0211.5043	42.5
I0211.5045	45.0
I0211.5048	47.5
I0211.5050	50.0
I0211.5053	52.5
I0211.5055	55.0
I0211.5058	57.5
I0211.5060	60.0
I0211.5063	62.5
I0211.5065	65.0
I0211.5068	67.5
I0211.5070	70.0
I0211.5073	72.5
I0211.5075	75.0
I0211.5078	77.5
I0211.5080	80.0
I0211.5085	85.0
I0211.5090	90.0
I0211.5095	95.0
I0211.5100	100.0
I0211.5105	105.0
I0211.5110	110.0

Illustrations not to scale. Specifications subject to change without notice.

Surgical Technique

Patient Positioning

Position the patient supine on a radiolucent table. Flex the affected limb approximately 45° over a posterior support to assist with fracture reduction. Check for length and rotation by comparison to the unaffected limb.

Rotate the C-Arm to ensure optimal AP and lateral visualization of the entire femur. The C-Arm should be able to freely access the femur up to and including the intertrochanteric area. A distraction device may also be applied to obtain and/or maintain traction.

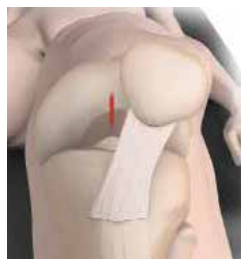
Intra-articular fracture components should be addressed with interfragmentary screw fixation prior to nail insertion. Care should be taken to place the screws in the anterior and posterior aspect of the distal femur and safely out of the nail's intended path.

Note: Cannulated screw guide pins allow for confirmation of definitive screw placement prior to fracture fixation and nail insertion.

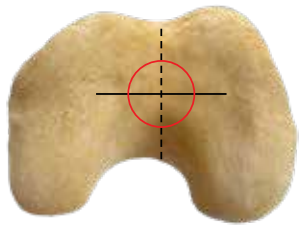
Incision and Entry Point

Assemble the Atlas® Multiple Hole Sleeve (I0582.1332) and Atlas® Protection Sleeve 16/13 (I0582.1613). The pieces will lock in place securely at either 0° or 180°.

A 3-4 cm midline incision is made followed by a medial parapatellar capsular incision to expose the intercondylar notch. Gently retract the patellar tendon laterally.



The entry point is located within the intercondylar notch just anterior and lateral to the femoral attachment of the posterior cruciate ligament.



Surgical Technique - continued

Instruments for Opening the Distal Femur

Atlas®
Hollow Open Awl, Inner Part
I0587.01

Atlas®
Multiple Hole Sleeve, 13/3.2
I0582.1332

Atlas®
Guide Pin, 3.2 x 400
I0581.3240

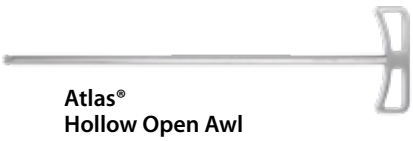
Atlas®
Guide Pin, 3.2 x 300
I0581.3230

Atlas®
Driving End Cannulated Drill, 12.8/3.2
I0583.1232

Atlas®
Flexible Driving End Cannulated Drill, 12.8/3.2
I0584.1232

Atlas®
Protection Sleeve, 16/13
I0582.1613

Atlas®
Coupling Adaptor
I0586.00



Atlas®
Hollow Open Awl
I0587.00

Atlas®
Q. C. T-Handle
I0585.00

Surgical Technique - continued

Entry Portal Acquisition

insert 3.2mm Atlas® Guide Pin (I0581.3230 or I0581.3240) into the distal femoral metaphysis to a depth of 6-8cm. The Protection Sleeve Instrumentation serves as a soft tissue protector.

In the instance of suboptimal Guide Pin insertion, rotate the Atlas® Multiple Hole Sleeve (I0582.1332) within the Atlas® Protection Sleeve 16/13 (I0582.1613) to the desired location and insert another 3.2mm Guide Pin.

The Guide Pin should be in-line with the femoral axis in the AP view and anterior to Blumensaat's Line in the lateral.

Surgical Technique - continued

Entry Portal

After definitive Atlas® Guide Pin (I0581.3230 or I0581.3240) placement, remove the Atlas® Multiple Hole Sleeve (I0582.1332) from the Atlas® Protection Sleeve 16/13 (I0582.1613) along with any additionally inserted Guide Pins and attach the Atlas® Driving End Cannulated Drill, 12.8/3.2 (I0583.1232) to power Atlas® Q. C. T-Handle (I0585.00). Advance over the Guide Pin through the Protection Sleeve to a depth of 6-8cm.

Check position via radiographic imaging and then remove the Atlas® Driving End Cannulated Drill, 12.8/3.2 (I0583.1232) and 3.2mm Guide Pin.

Alternative Technique Entry Portal

Insert the Atlas® Hollow Open Awl (I0587.00) into the distal femur to a depth of 6-8cm. Introduce the Atlas® Hollow Open Awl, Inner Part (I0587.01) into the back of the assembly prior to insertion in order to prevent awl slippage and accumulation of cortical bone within the cannulation.

Atlas®
Hollow Open Awl, Inner Part
I0587.01

Atlas®
Hollow Open Awl
I0587.00

Instruments for Fracture Reduction & Reaming

Atlas®
Protection Sleeve, 16/13
I0582.1613

Atlas®
Q. C. T-Handle
I0585.00

Atlas®
Ball Guide Wire Measurer
I0591.00

Atlas®
Guide Wire Holder
I0589.00

Atlas®
Reduction Rod
I0588.00

Atlas®
Flexible Reamer, 9mm
I0592.09

Atlas®
Flexible Reamer, 10mm
I0592.10

Atlas®
Flexible Reamer, 11mm
I0592.11

Atlas®
Flexible Reamer, 12mm
I0592.12

Atlas®
Flexible Reamer, 13mm
I0592.13

Atlas®
Ball Tip Guide Wire
4 x 1000mm
I0590.4100

Surgical Technique - continued

Fracture Reduction

Insert the back end of the 4.0 mm Ball Tip Guide Wire (I0590.4100) into the front of the Atlas® Guide Wire Holder (I0589.00) and gently close the trigger-grip. Connect the Atlas® Reduction Rod (I0588.00) to the T-Handle.

Advance the Reduction Rod into the intramedullary canal and use the curved tip to direct the 4.0 mm Ball Tip Guide Wire past the fracture into the region of the proximal femur. The Guide Wire should be center-center in the AP and lateral views.

The Guide Wire should be center-center in the AP and lateral views.

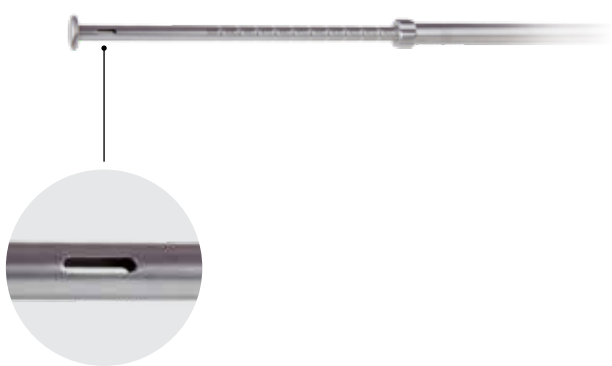
Reduction Rod Removal

Once the Guide Wire is at the desired depth, detach the Guide Wire Holder and remove the Reduction Rod from the femoral canal.

Implant Measurement

After Reduction Rod removal, re-confirm Guide Wire placement within the proximal femur and slide the Atlas® Ball Guide Wire Measurer (I0591.00) over the Guide Wire to the desired depth. The metal tip of the Ball Guide Wire Measurer denotes the driving end of the Atlas® FFN Retrograde Femoral Fracture Nail.

Confirm Guide Wire position in the window at the opposite end of the Ball Guide Wire Measurer as shown in order to ensure accurate implant measurement. Push down on the top of Ball Guide Wire Measurer until contact is made with the 4.0mm Ball Tip Guide Wire. Implant length is read from the exposed calibrations at the end of the Ball Guide Wire Measurer.



Note: Implant length selection should take into consideration the fact that the nail must be countersunk past the articular surface of the distal femur.

Note: Confirm that the Ball Guide Wire Measurer opens easily. Adjust the thumb-wheel connection at the end to allow for free movement.

Surgical Technique - continued

Reamed Technique

Intra-operative measurement will determine nail size. Beginning with the Atlas® Flexible Reamer, 9mm (I0592.09), ream the intramedullary canal sequentially in 1mm increments to a size 1-1.5mm larger than the selected nail size.

Continue reaming to confirm Guide Wire placement in the proximal femur throughout reaming. Periodically move the reamer back and forth in the canal to clear debris from the cutting flutes.

Instruments for Nail Assembly & Insertion.

Atlas®
Universal Wrench
I0597.00

Atlas®
DF Aiming Device
I0602.00

Atlas®
DF Drill Guide
I0593.02

Atlas®
Coupling Adaptor
I0586.00

Atlas®
Locking Screw Sleeve
11/8.6
I0602.1186

Atlas®
Drill Sleeve
8.6/4.3
I0603.8643

Atlas®
Nail Connection Rod
I0598.00

Atlas®
Drill Bit 4.3/300
I0605.4330

Atlas®
Open Wrench 11mm A/F
I0599.11

Atlas®
Wrench for
Connection Rod
I0596.00

Atlas®
DF Connection Bolt,
6.5 mm A/F
I0602.01

Atlas®
Trocar 4.3mm
I0604.43

Atlas®
Sliding Hammer
I0611.00

Atlas®
Limitation Wrench
4.3mm, 3mm A/F
I0606.431

Atlas®
Q. C. T-Handle
I0585.00

Atlas®
Limitation
4.3mm, 3mm A/F
I0606.43

Atlas®
Aiming Device, Bolt
I0601.01

Nail Assembly

Attach the Atlas® DF Drill Guide (I0593.02) to the nail with the Atlas® DF Connection Bolt, 6.5 mm A/F (I0602.01) and tighten with the Atlas® Universal Wrench (I0597.00) or Atlas® Wrench for Connection Rod (I0596.00) and T-Handle. The nail is correctly aligned when:

1. The line on the insertion barrel matches the line on the back of the nail.

2. The "A" on the nail matches the bevel of the insertion barrel.

3. The apex of the nail's AP Bow and the Drill Guide itself are oriented anterior.

The bevel on the front of the nail marks the connection to the Drill Guide and can be seen in the lateral view as a means for determining distal insertion depth.

Attach the Atlas® DF Aiming Device (I0602.00) to the Drill Guide and verify targeting accuracy by inserting a Atlas® Locking Screw Sleeve 11/8.6 (I0602.1186) and Atlas® Drill Sleeve 8.6/4.3 (I0603.8643) into the Aiming Device and passing a Atlas® Drill Bit 4.3/300 (I0605.4330) through the assembly. An incorrectly attached nail will not target.

Surgical Technique - continued

Nail Insertion

Remove the Aiming Device and attach the Atlas® Nail Connection Rod (I0598.00) to the Drill Guide. Orient the Drill Guide assembly in the AP position and advance the nail over the Guide Wire by light blows from the Atlas® Sliding Hammer (I0611.00) to the desired depth.

Additional reaming of the intramedullary canal may be necessary if excessive force is required to insert the nail.

Verify fracture reduction as the nail crosses the fracture site paying close attention to rotation, length, alignment, distraction and/or shortening. Check final nail position in both the AP and lateral views for correct alignment.

Check Nail Depth

Distal (Driving End)

In the AP and lateral views, confirm nail position within the distal femur. The notch at the nail/Drill Guide junction will be visible in the lateral. Each gauge on the insertion barrel represents a 5mm depth interval.

Proximal (Non-Driving End)

In the AP view, confirm that the nail has been inserted to the desired depth. Femoral fractures should be treated with the longest nail possible in order to reduce the likelihood of stress risers. Remove the Guide Wire once the nail has been fully seated and attach the Aiming Device.

Note: Following nail insertion, confirm that the nail and Drill Guide are securely connected as hammering can loosen the Connection Bolt.

Instruments for Standard Locking

Atlas®
DF Aiming Device
I0602.00

Atlas®
Drill Sleeve 4.3 mm
I0603.43

Atlas®
T-Locking Screwdriver, 4.75 mm
I0608.475

Atlas®
Drill Sleeve 8.6/4.3
I0603.8643

Atlas®
Drill Bit 4.3 x 150
I0610.4315

Atlas®
Locking Screw Sleeve, 11/8.6
I0602.1186

Atlas®
Drill Bit 4.3/300
I0605.4330

Atlas®
Depth Gauge for Driving End, SP/DF
I0607.00

Atlas®
Depth Gauge for Non-Driving End, SP/DF
I0607.01

Atlas®
Q. C. T-Handle
I0585.00

Surgical Technique - continued

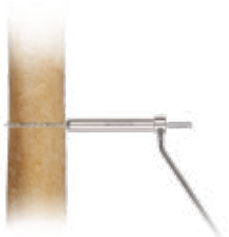
Locking Screw Measurement

There are four (4) methods:

1. Atlas® Locking Screw Sleeve 11/8.6 (I0602.1186), Atlas® Drill Sleeve 8.6/4.3 (I0603.8643) and Drill Bit 4.3 x 300 (I0605.4330).

2. Locking Screw Sleeve 11/8.6 and Atlas® Depth Gauge for Driving End, SP/DF (I0607.00).

3. Atlas® Drill Sleeve 4.3 mm (I0603.43) and Atlas® Drill Bit 4.3 x 150 (I0610.4315)



4. Atlas® Depth Gauge for Non-Driving End, SP/DF (I0607.01).

Surgical Technique - continued

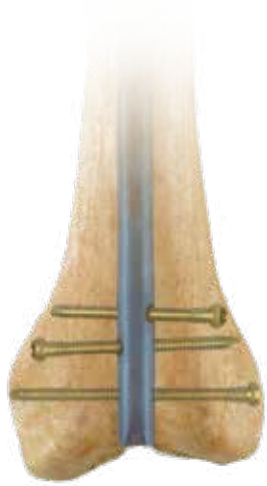
Locking Screw Insertion

Distal (Driving End) locking options include three (3) statically locked threaded holes that are targeted through the Aiming Device.

Proximal (Non-Driving End) locking options include two (2) statically locked, non-threaded AP holes.

Gold 5.0mm locking screws are compatible with 10mm and 11.5mm diameter nails.

Note: The Drill Bit 4.3 X 150 (I0610.4315) may be used to drill for a gold 5.0mm locking screw in the instance of hard cortical bone. Its 4.7-4.3mm width transition facilitates easier screw insertion without compromising purchase.



Distal (Driving End) Locking

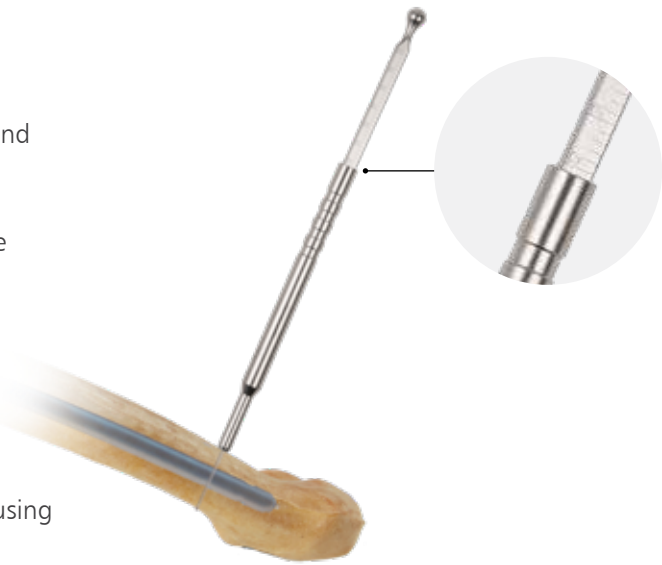
Make a small incision at the site of screw entry and insert the Locking Screw Sleeve 11/8.6 and Drill Sleeve 8.6/4.3 through the static slot on the Aiming Device down to bone. Drill both cortices with the Drill Bit 4.3 x 300.

Measure for screw length using either the calibrations on the Drill Bit 4.3 x 300 or by removing the Drill Sleeve 8.6/4.3 and using the Depth Gauge for Driving End, SP/DF. Attach the appropriate length screw to the end of the Atlas® T-Locking Screwdriver 4.75mm (I0608.475) and insert through the Locking Screw Sleeve 11/8.6 on power until the laser etched ring on the T-Locking Screwdriver reached the back of the Drill Sleeve. Attach the Quick Coupling T-Handle to the T-Locking Screwdriver and tighten the screw by hand.

Proximal (Non-Driving End) Locking

Proximal locking is performed in the AP plane using a free-hand technique. Confirm fracture reduction and align the C-Arm over the desired locking hole. Obtain a "perfect circle" image of the locking hole and use a blunt object to approximate the location of the locking hole by dimpling the skin.

Make a stab incision at the site, insert the Drill Bit 4.3 x 300, and drill both cortices. Measure for screw length using the Depth Gauge for Non-Driving End, SP/DF. Alternatively, leave the Drill Bit 4.3 x 300 in place, insert the Drill Sleeve 4.3mm down to bone, and read the exposed calibrations off the drill. Insert the appropriate length screw using the T-Locking Screwdriver assembly.



Surgical Technique - continued

Atlas® Nail Cap Insertion, Optional

Remove the Drill Guide/Aiming Device assembly. Attach the selected Nail Cap to the Atlas® End Cap Holder A/F 4.75 (I0608.00) assembly and insert into the end of the nail. Use Atlas® T-Locking Screwdriver 4.75 A/F (I0608.475) or Atlas® Screwdriver 4.75 A/F (I0609.475) for final tightening.

Note: The Atlas® Nail Cap does not engage with the most distal (Driving End) locking screws to create a fixed angle construct.

Note: If cross-threading occurs, rotate the Nail Cap counterclockwise until its threads line up with those of the nail. Proceed with insertion until tight.

Nail Cap Insertion Instruments

Atlas®
Screwdriver 4.75 A/F
I0609.475

Atlas®
End Cap Holder A/F 4.75
I0608.00

ATLAS® Ti TFN/FFN Closing Cap

Instruments for Implant Removal

Atlas®
Guide Pin, 3.2 x 300
I0581.3230

Atlas®
Nail Extractor
I0600.00

Atlas®
Guide Pin, 3.2 x 400
I0581.3240

Atlas®
Open Wrench 11mm A/F
I0599.11

Atlas®
Driving End Cannulated Drill, 12.8/3.2
I0583.1232

Atlas®
Screwdriver 4.75 A/F
I0609.475

Atlas®
Driving End Flexible Cannulated Drill, 12.8/3.2
I0584.1232

Atlas®
Sliding Hammer
I0611.00

Atlas®
Coupling Adaptor
I0586.00

Atlas®
Q. C. T-Handle
I0585.00

Nail Extraction, Optional

Standard Technique

Remove the Nail Cap if implanted and all of the proximal (non-driving end) locking screws with the Screwdriver 4.75 A/F (I0609.475)/ Quick Coupling T-Handle (I0585.00)/ Coupling Adaptor (I0586.00) assembly. Remove all of the distal locking screws except for one in the same manner.

Thread the Nail Extractor (I0600.00) with the help of open wrench 11mm A/F (I0599.11) into the end of the nail. Remove the remaining distal (driving end) locking screw and then extract the nail with a back-slapping motion using the Sliding Hammer (I0611.00).

Percutaneous Technique

This technique assumes the absence of a Nail Cap. Remove all proximal (non-driving end) locking screws and all but one of the distal (driving end) locking screws as previously described. Under fluoroscopy, insert a Guide Pin 3.2mm into the end of the nail on power or by hand. Make a 2cm incision around the Pin and advance the Driving End Cannulated Drill 12.8/3.2 over the Pin and into the end of the nail to remove any bony in-growth.

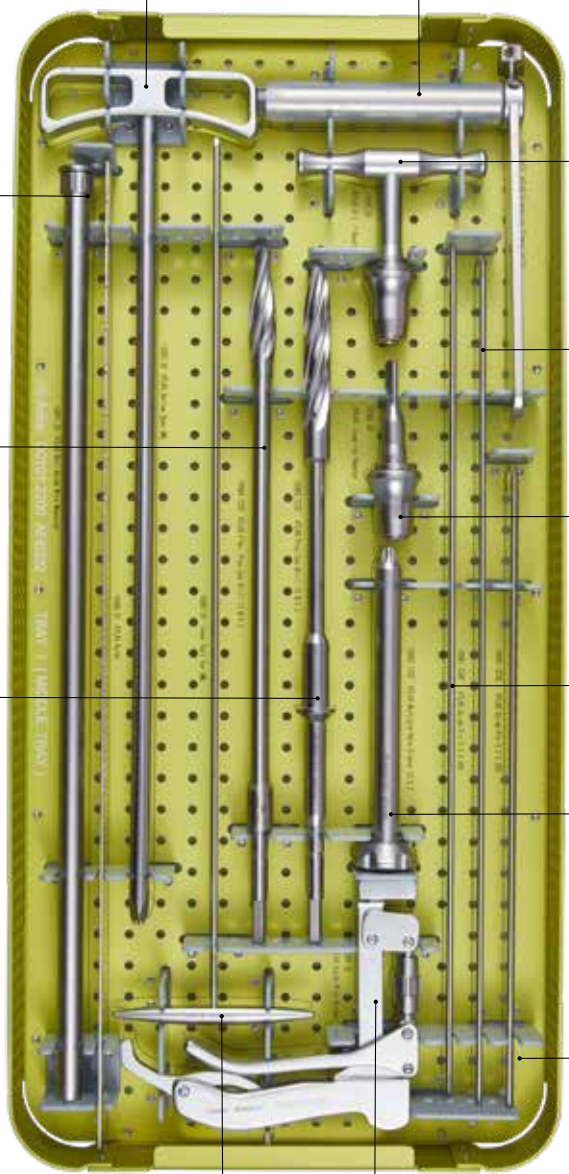
Thread the Nail Extractor (I0600.00) into the end of the nail. Remove the remaining distal (driving end) locking screw and then extract the nail with a backslapping motion.

Note: The tip of the Driving End Cannulated Drill 12.8/3.2 is straight for approximately 1cm before flaring out. It is this portion of the Driving End Cannulated Drill 12.8/3.2 that enters the top of the nail.

Catalogue Information

Instrument Set

Instruments for Femoral Fracture Nail Retrograde - Ti



Atlas®
Hollow Open Awl
I0587.00

Atlas®
Ball Guide Wire Measurer
I0591.00

Atlas®
Flexible Driving End
Cannulated Drill, 12.8/3.2
I0584.1232

Atlas®
Driving End
Cannulated Drill, 12.8/3.2
I0583.1232

Atlas®
Hollow Open Awl, Inner Part
I0587.01

Atlas®
Protection Sleeve,
16/13
I0582.1613

Atlas®
Q. C. T-Handle
I0585.00

Atlas®
Guide Pin, 3.2 x 400
I0581.3240

Atlas®
Coupling Adaptor
I0586.00

Atlas® Ruler
I0580.01

Atlas®
Multiple Hole Sleeve,
13/3.2
I0582.1332

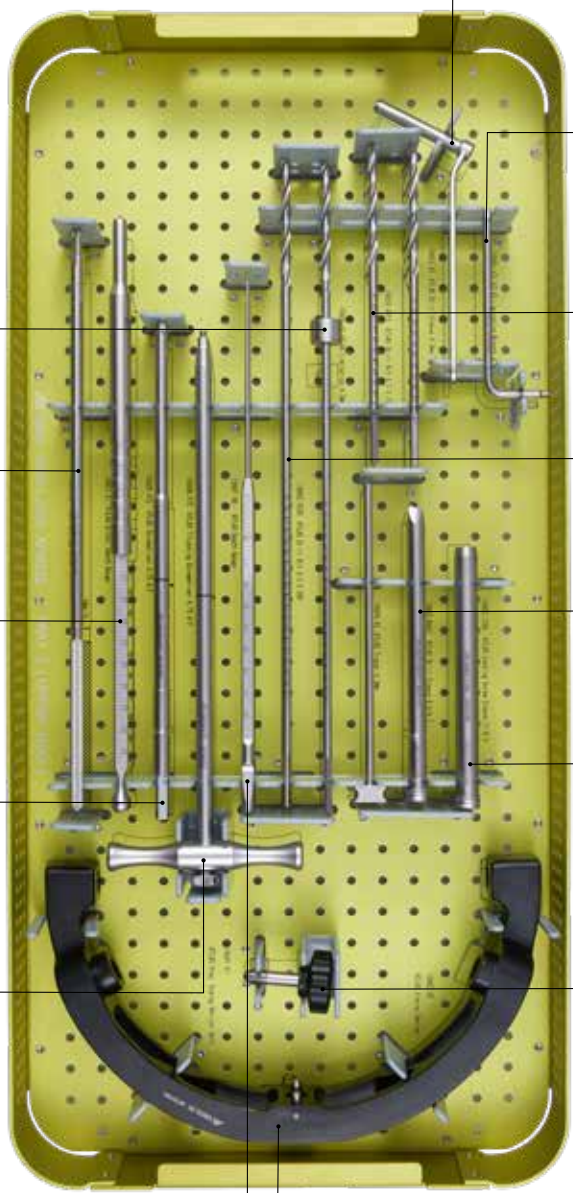
Atlas®
Guide Pin, 3.2 x 300
I0581.3230

Atlas®
Guide Wire Holder
I0589.00

Catalogue Information - continued

Instrument Set

Instruments for Femoral Fracture Nail Retrograde - Ti, continued



Atlas®
Drill Sleeve 4.3 mm
I0603.43

Atlas®
Limitation Wrench 4.3mm, 3mm A/F
I0606.431

Atlas®
Drill Bit 4.3 x 150
I0610.4315

Atlas®
Drill Bit 4.3/300
I0605.4330

Atlas®
Drill Sleeve 8.6/4.3
I0603.8643

Atlas®
Locking Screw Sleeve, 11/8.6
I0602.1186

Atlas®
Aiming Device, Bolt
I0601.01

Atlas®
Limitation 4.3 mm, 3mm A/F
I0606.43

Atlas®
End Cap Holder A/F 4.75
I0608.00

Atlas®
Depth Gauge for Non-Driving End, SP/DF
I0607.01

Atlas®
Screwdriver 4.75 A/F
I0609.475

Atlas®
T-Locking Screwdriver, 4.75 mm
I0608.475

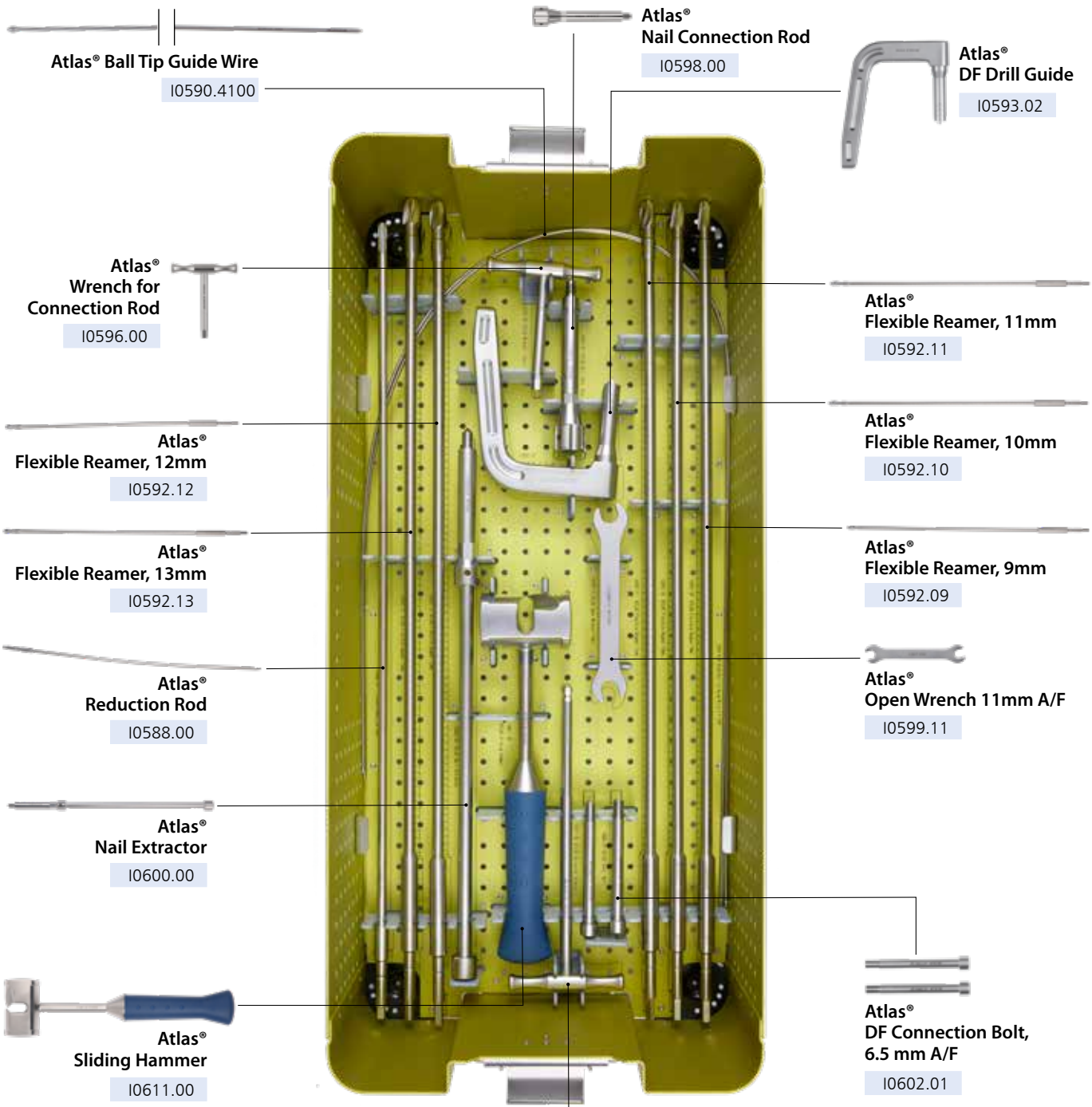
Atlas®
Depth Gauge for Driving End, SP/DF
I0607.00

Atlas®
DF Aiming Device
I0602.00

Catalogue Information - continued

Instrument Set

Instruments for Femoral Fracture Nail Retrograde - Ti, continued



Important Information on ATLAS® Femoral Fracture Nail Retrograde.
For use by an Accredited Orthopedic Surgeon only.

Device Description:

The ATLAS® FFN (Femur Fracture Nail) Retrograde is designed to handle femur fracture indications in diameters 10mm, 11mm in length range from 28cm to 44cm. It consists of femur nails in the preceding length and diameter sizes, locking screw, and nail cap screw. The ATLAS® FFN Retrograde system includes implantable nails and screws, which are provided in a variety of lengths and types to accommodate the prescribed fixation technique. The system includes instrumentation trays, which house the instrument that are needed for installation and removal of the implantable assembly. The Atlas FFN Retrograde, Screws and Caps are made from titanium-vanadium alloy Ti-6Al-4V material complying to ASTM F136/ISO 5832-3, Nail consist of UHMWPE Bush.

The ATLAS® FFN (Femur Fracture Nail) Retrograde is supplied in sterile condition for length 28CM to 40CM & for length 42CM to 44CM Supplied in non-sterile condition. Locking screw & Nail Cap Screw supplied in non sterile condition.

Summary:

Operating surgeons should be aware of the following aspects related to the use of metallic implants.

1. Proper size, length, side and type selection, as well as proper handling and use of the TFN Suprapatellar are essential to safe and effective fracture treatment. See NOTES, INDICATIONS, CONTRAINDICATIONS, and PREOPERATIVE PLANNING below.
2. FFN Retrograde are NOT substitutes for skeletal healing, and proper follow-up care is essential to safe and effective use. See WARNINGS, POSTOPERATIVE CARE and POSSIBLE ADVERSE EFFECTS below.
3. Metallic surgical implants are NEVER TO BE REUSED (single use).

Notes:

Metallic surgical implants are intended to be used as aids to normal fracture healing. Such implants are NOT replacements for skeletal structures. Healing of fractures treated with metallic surgical implants must be confirmed prior to permitting weight bearing on the bones. Weight bearing on bones that have failed to heal or healed partially or improperly can cause stress and fatigue in metallic surgical implants with consequent breakage or failure of the implants. Surgeons should consider the following information and should inform patients of pertinent information relevant to the patients' health and safety. 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:

The ATLAS® FFN Retrograde is indicated for shaft fractures of the femur including stable and unstable distal metaphyseal fractures, diaphyseal fractures, intra-articular fractures, periprosthetic fractures. It may also be used for nonunions, malunions, prophylactic nailing of impending pathological fractures.

Contraindications:

ATLAS® FFN Retrograde should not be used in:

1. Crossing open epiphyseal plates.
2. Insufficient quantity or quality of bone obliterated medullary canal or conditions which tend to retard healing, blood supply limitations, previous infections, etc.
3. Active infection.
4. Any hardware that would preclude use of nails.
5. Congenital or acquired bony deformity.
6. Hypovolemia, hypothermia, and coagulopathy.
7. Mental conditions that preclude cooperation with the rehabilitation regimen.

Preoperative Planning:

1. Surgical Technique: Correct surgical technique is essential to a successful outcome. Proper reduction of fractures and proper placement of implants are necessary to effectively treat patients using metallic surgical implants.
2. Implant Selection: Selection of the proper size, shape and design of the complete set of Implants and Instruments is a crucial parameter for success of the operative procedure and to insure effective treatment of patients that must be ensured by the operative surgeon. All Implants, Instruments and its sub-assemblies should be checked for intact packaging on receipt. All implants and instruments must be carefully checked for completeness and should be carefully inspected for compatible dimensions.
3. The following factors should be considered:

- A patient's size, strength, skeletal characteristics, skeletal health, and general health. Overweight or musculoskeletally deficient or unhealthy patients may create greater loads on implants that may lead to breakage or other failure of the implants.
- A patient's activity level during the time the implant is in the patient's body, including such factors as whether the patient's occupation or typical activities include running, heavy lifting, impact loading, or the like.
- Whether a patient has a degenerative or progressive disease that delays or prevents healing, and consequently decreases the effective life of the implant.
- If a patient is suspected of having material or foreign body sensitivities, appropriate testing should be accomplished prior to implantation.
- Mental conditions or substance abuse problems that may prevent a patient from understanding or following directions or observing precautions.

4. Implant Alterations: Unless an implant is designed to be physically altered, it should not be altered in any way. If the implant is designed to be altered, it should only be altered in accordance with manufacturer's instructions. In no case should an implant be sharply or reverse bent, notched, gouged, reamed, scratched or cut.
5. Component Compatibility: Components such as nails, screws are available in many styles and sizes and are manufactured from various types of metals. Use only components made from the same material together unless specifically approved by the manufacturer. Do not mix dissimilar metals or components from different manufacturers unless specifically approved by a manufacturer of the components. Refer to manufacturers' literature for specific product information.
6. Implant Removal: The patient should be advised that a second procedure for the removal of implants may be necessary.

Warnings:

1. The correct selection of device components is extremely important. The appropriate size should be selected for the patient. Failure to use largest possible components or improper positioning or the use of excessive forces during implantation may result in loosening, bending, cracking, or fracture of the device or bone or both.
2. The length of time for non or limited weight bearing should be correspondingly increased until solid bony union occurs.
3. The threads of an implanted screw should not engage the fracture line. The screw threads should be firmly fixed in bone and the screw should be long enough to permit telescopic sliding in the event of resorption of the fracture surface.
4. Do not mix dissimilar metals. Use only ATLAS® TF Titanium screws with ATLAS® FFN Retrograde Titanium Nails.
5. Implant guiding devices such as guide pins, guide wires etc. should not be re-used to prevent potential damage to the implants, inaccurate measurements and other possible errors.

Postoperative Care:

1. Care Prior to Bony Union: Immobilize and/or externally support skeletal structures that have been implanted with surgical metallic implants until skeletal union is observed. Early weight bearing substantially increases implant loading and increases the risk of loosening, bending or breaking of 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, should have auxiliary support. The implant may be exchanged for a larger, stronger nail subsequent to the management of soft tissue injuries. PATIENTS AND NURSING CARE PROVIDERS SHOULD BE ADVISED OF THESE RISKS.
2. Care Subsequent to Bony Union: Even after bony union, the patient should be cautioned that a fracture 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. Patients should be cautioned against unassisted activity that requires walking or lifting. Postoperative care and physical therapy should be structured to prevent loading of the operative extremity until stability is evident. Additional postoperative precautions should be taken when the fracture line occurs within 5 cm of any locking holes provided in the nail. This would typically include distal most proximal locking hole and the proximal most distal locking hole. Greater stress is placed on the nail at these hole locations in these situations.
3. Patients should be directed to seek medical opinion before entering potentially adverse environments that could affect the performance of the implant, such as electromagnetic or magnetic fields, including a magnetic resonance environment.
4. Implant Removal: The operating surgeon will make final recommendations regarding removal of implants, considering all facts and circumstances. Adler suggests that whenever possible, and after bony union is observed that implants be removed. Removal is particularly advisable for younger and more active patients. In the absence of a bursa or pain, removal of the implant in elderly or debilitated patients is not recommended. If the implant components are not removed subsequent to completion of their intended use, the following complications may ensue.

- Corrosion combined with localized pain or tissue reaction.
- Migration of position of the implant, resulting in injury.
- Bending, loosening or breakage of implant components, which may make removal more difficult or even impractical.
- Possibly increased risk of infection.
- Bone loss due to stress shielding.
- Pain, discomfort or abnormal sensations felt by the patient due to the presence of the device.

.**Magnetic Resonance Imaging (MRI) Safety:**

ATLAS® FFN Retrograde System has not been evaluated for safety and compatibility in the MR environment. This system has not been tested for heating or migration in the MR environment.

No Reuse:

Metallic surgical implants are NEVER TO BE REUSED. Stresses and fractures, even though not noticeable by visual inspection, may have been created during implantation. Single use devices should not be reused due to risks of breakage, failure or patient infection.

Possible Adverse Effects:

1. Loosening, bending, cracking or fracture of the implant components.
2. Infections, both deep and superficial.
3. Limb shortening or loss of anatomic position with nonunion or malunion with rotation or angulation.
4. Leg length discrepancies and subsequent patient limp may occur.
5. Tissue reactions which include macrophage and foreign body reactions adjacent to implants can occur.
6. Although rare, metal sensitivity reactions and/or allergic reactions to foreign materials have been reported in patients.
7. Vascular disorders including thrombophlebitis, pulmonary emboli, wound hematomas may result from the surgery and concomitant use of internal fixation devices.
8. Implant Migration related to loss of fixation or poor fracture reduction.
9. Screw Back-out.
10. Pain at the surgical site as a normal consequence of the operative procedure.

Packaging and Labeling:

Components should only be accepted if received by the hospital or surgeon with the factory packaging and labeling intact. Implant components supplied in sterile condition are packed in Double Blister with lid and are indicated as STERILE R on the label which must be properly sterilized by GAMMA Irradiation method. Also, Implant components supplied in non-sterile condition are packed in unwoven polyethylene and are indicated as NON STERILE on the label which must be properly sterilized by suitable method prior to surgery as indicated below. The set of instruments used for the surgery must be carefully checked for completeness and individual instruments must be inspected for functionality and absence of damage prior to surgery.

Sterilization Instructions:

ATLAS® FFN Retrograde are sterilized by gamma irradiation. The components of system are supplied in sterile to a Sterility Assurance Level (SAL) of 10-6. The method of sterilization is noted on the package label. The component of system supplied in non- sterile condition; Remove all original packaging and labeling inserts prior to sterilization. It is important that adequate cleaning be carried out prior to sterilization.

Sterility and Handling for components of system supplied in sterile condition:

- Correct handling of the implants prior to and during surgery is decisive for the success of surgical procedure. Implant components supplied in pre-sterile condition are individually packed and correspondingly labeled, as gamma irradiation sterilized (gamma sterilization, 25 kGy min).
- Prior to opening a sterile packed implant, verify that the package is undamaged and shows no signs of tampering, the "sterile" sticker that seals the outer box is intact, the sterility indicator button is of the right color indicating a properly sterilized implant (red in case of Gamma Irradiation) and that the implant is within the sterility period indicated on the label.
- Ensure that the surfaces of the implants are not damaged under any circumstance. Under no circumstance should the implants be used that have been damaged, surgically implanted or removed.

Recommended steam sterilization cycle parameters for components of system supplied in non-sterile condition:

- Dynamic Air Removal (Prevacuum) Steam Cycle: 132°C (270°F) for 4 minutes and a minimum vacuum drying time of 30 minutes.

Containment devices should be wrapped with an approved central supply wrap (CSR) or placed in an approved reusable rigid container for sterilization. All sterilization wraps may not be approved for all cycle types. Check with manufacturer for approvals.

Storage Conditions:

Store in dry place. Protect devices from exposure to direct sunlight, radioactive sources and rains. Do not stack devices.

Important Information:

The operative surgeon is responsible for carrying out the surgical procedure correctly and must have mastered the acknowledged updated and latest operating techniques related to the type of surgery being performed, in theory and practice. Complications due to incorrect diagnosis and operating technique and limitations of the method of treatment or lack of aseptic conditions are not the responsibility of the manufacturer.

In addition to physiotherapy and muscle training, it is the responsibility of the operating surgeon to educate the patient about the limitations of metallic implants and precautions to be followed to avoid unnecessary stresses to the implant.

Detailed instructions must be given to the patient concerning the use and limitations of the implanted device. If partial weight bearing is required or recommended, the patient must be warned that loosening, bending and / or breakage of the device are complications which may occur due to early or excessive weight bearing or muscular activity. The patient should be warned to avoid falls or sudden jolts of any nature. If the patient is demented, debilitated or otherwise unable to use crutches or other supporting devices, the risk of loosening, bending and / or breakage may be increased. The patient must be made aware of this fact.

Any retrieved implant / External Fixator component should be treated in such a manner so as to render further use / re-use of the components, impossible. Used implants / External Fixator Component that appear undamaged may have internal and external defects caused through accumulated stresses while in use. Reuse of implant components predisposes such components to premature failure.

Implant components from one manufacturer should not be used with those of another.

Further information:

For further information concerning use of these devices, please check with Adler Customer Service at the address given herein or e-mail to ***adler-customer.care@adler-healthcare.com.***

Manufactured & marketed by
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