

SEINE™

Retrograde
Femur Nailing System

Surgical Technique



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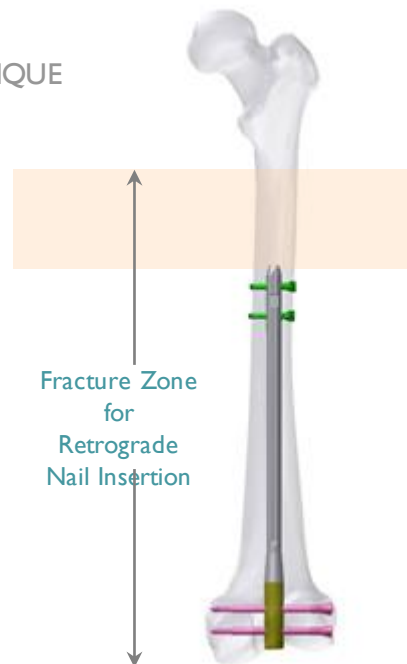
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Warning

The contents of this manual are intended to be only a guide and are not intended to set a standard of care. Instruction by a surgeon experienced in handling these instruments is highly recommended.

INTRODUCTION

The SEINE™ Retrograde Femur Nailing System addresses the spectrum of femoral fractures ranging from the distal femur to the shaft, using an intracondylar insertion point. The system features a minimal invasive technique and biomechanical stability allow early functional exercise. It also provides an accurate and fast mechanical aiming device for proximal and distal locking.



Features and Benefits

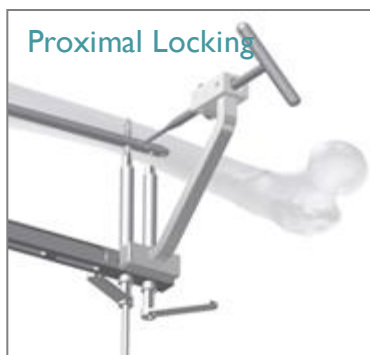
- Minimal invasive technique and biomechanical stability allow early functional exercise.
- Accurate and fast mechanical aiming device for proximal and distal locking.
- A locking screw of a smooth shank configuration is much stronger for a given diameter than a fully threaded screw.
- All of the implants are available in Titanium Alloy and Stainless Steel.
- The nails and locking screws are color coded for easy identification.

Indications

The primary indications are for femoral shaft fractures including segmental, severely comminuted, spiral, large, and oblique fractures, and nonunions and malunions.

Supracondylar fractures with or without difficult intracondylar extension, fractures that require opening the knee joint to stabilize the femoral condylar segment, and fractures above a total knee implant may be treated with the retrograde nail.

It may also be used in the treatment of femoral reconstruction following tumor resection and grafting and in impending pathologic fractures of the shaft or distal femur.



SURGICAL TECHNIQUE

I Position Patient and Reduce Fracture

Place the patient in the supine position on a radiolucent table. The leg should be draped free and fluoroscopic control in both planes should be possible. The femur is positioned horizontally on the table with the knee flexed 40°- 50° to provide adequate access. A rolled towel may be used at the distal end of the femur to prevent recurvatum of the distal fragment (Figure 1).



Figure 1

Whenever possible, femoral fractures should be stabilized within the first 24 hours following injury, provided the patient's condition will allow it. Do not start surgery unless the fracture is well reduced.

2 Determine Nail Length and Diameter

Thorough evaluation of pre-operative radiographs of the affected extremity is critical.

The retrograde nail length is determined by measuring the distance between a point 5 mm – 10 mm proximal to the Intercondylar Notch to a point at a level of the Lesser Trochanter.



Figure 2

The diameter of the retrograde nail should match the isthmus in the lateral X-Ray projection.

3 Approach and Determine Entry Point

Make a 4-6 cm medial para-patellar incision and retract the patellar tendon and fat pad to the lateral side.

The entry point is located at the intercondylar notch, anterior 2mm to the insertion of the posterior cruciate ligament in lateral view. The point of entry should be in line with the long axis of the femoral shaft in both the AP and coronal planes (Figure 2).

With fractures extending into the joint, the intra-articular fracture should be reduced anatomically and stabilized using posteriorly placed lag screws, prior to opening the intercondylar notch.

4 Open the Entry Portal

Under the radiological monitor, the **Pointed Awl** (MOI 0200003) is placed at the entry point and then advanced with a rotational action to open the medullary canal (Figure 3).



Figure 3

The **Rigid Reamer 13.0 mm** (MOI 1400001) is now used to further open the metaphyseal bone of the femoral condyles after the awl is removed (Figure 4).

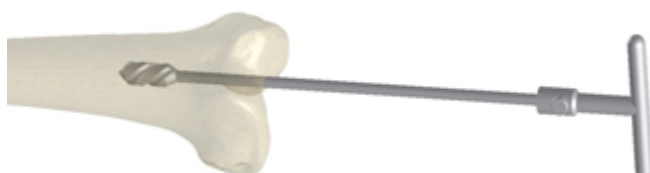


Figure 4

5 Insert Guide Wire

The entry point for the nail is in line with the medullary canal in the AP and lateral views. Insert the **Guide Wire with Ball Tip 2.5 mm** (MOI 1400007) through the incision to the proximal fragment, up to the level of the lesser trochanter.

6 Ream the Canal

In some cases, reaming of the shaft may be necessary. Use the cannulated **Flexible Reamers** (MOI 0100043 and MOI 1400000B) to do so. Insert the flexible reamer over the guide wire. Pass the fracture zone and position the reamer in the centre of medullary cavity end (Figure 5). Reaming may be carried out in 1 mm increments until the cortex of the isthmus is reached. Ream to a width 1 mm greater than the proposal nail.



Figure 5

7 Assemble the Insertion Instruments

Guide the cannulated **Nail Holding Screw** (MOI 1400012) through the **Insertion Handle** (MOI 1400017). Check that the wings are engaged in the nail and tighten firmly with the **Allen Wrench SW5.0** (MOI 0100023) (Figure 6).



Figure 6

8 Insert the Nail

The nail is now passed over the guide wire, using a twisting motion to advance the nail. Ideally, the nail should be inserted by hand (Figure 7), but gentle tapping by **Sliding Hammer** (MOI I400015) may be necessary (Figure 8). Ensure that the distal end of the nail is 5-7 mm below the surface of the intercondylar notch, so that it will not protrude into the knee joint.

The guide wire must now be removed. The use of image intensification is recommended when passing the fracture.



Figure 7



Figure 8

9 Distal Locking

Distal locking is usually performed first from the lateral side. Two small stab incisions are made at the level of the holes in the insertion handle, and extended down to the bone with blunt dissection. Two **Protection Sleeves 10.0/8.2 mm** (MOI I400006) are inserted into the holes in the insertion handle and pushed in turn down to the bone using the straight **Trocar 8.0 mm** (MOI 0200005) (Figure 9).

Insert the **Drill Sleeve 8.0/4.2 mm** (MOI I400005) into the protection sleeve and make sure that the drill sleeve is pressed firmly to the cortex. Drill through both cortices with the **Drill Bit 4.0 mm** (MOI 0100003). Confirm the drill bit position using the image intensifier and then set the drill stop on the drill bit. Stop the drill immediately after penetrating the far cortex (Figure 10).



Figure 9

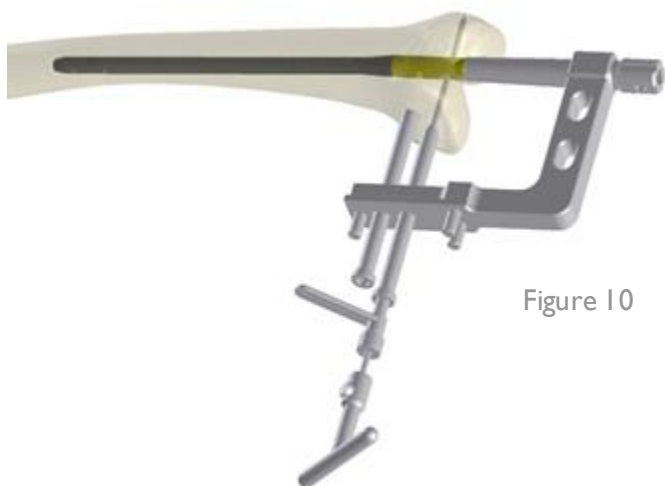


Figure 10

9 Distal Locking (Continued)

Remove the drill sleeve, use the **Depth Gauge for Locking Screws** (MOI 0200008) to measure through the protection sleeve using standard depth gauge technique. The locking screw length is estimated carefully, so that the tip of the screw will just penetrate the second cortex (Figure 11).

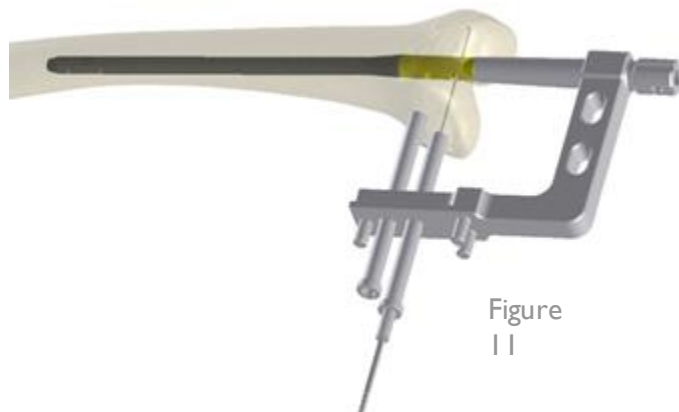


Figure 11

Remove the depth gauge. Insert the **Drill Sleeve 8.0/5.2 mm** (MOI 1400004) into the protection sleeve and make sure that the drill sleeve is pressed firmly to the cortex. Drill through the proximal cortex with the **Drill Bit 5.0 mm** (MOI 0100002) and stop 15-20 mm before the second cortex (Figure 12).

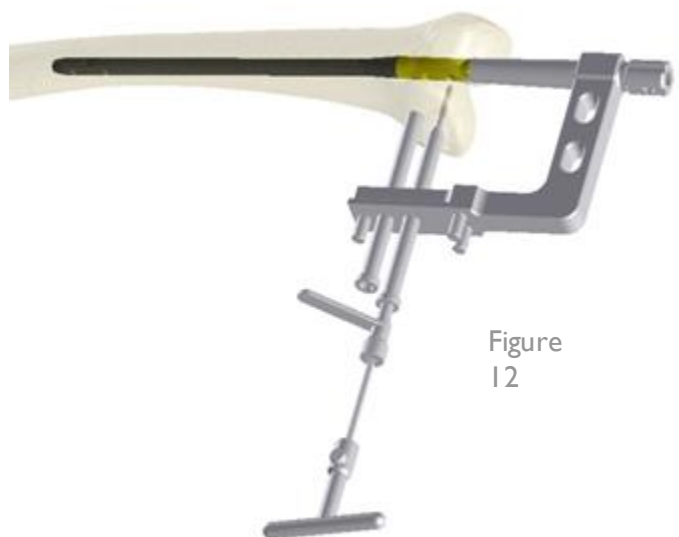


Figure 12

The drill bit and drill sleeve are removed. The **T-Handled Tap 6.5 mm** (MOI 1400010) is inserted into the Protection Sleeve to tap the proximal cortex (Figure 13).

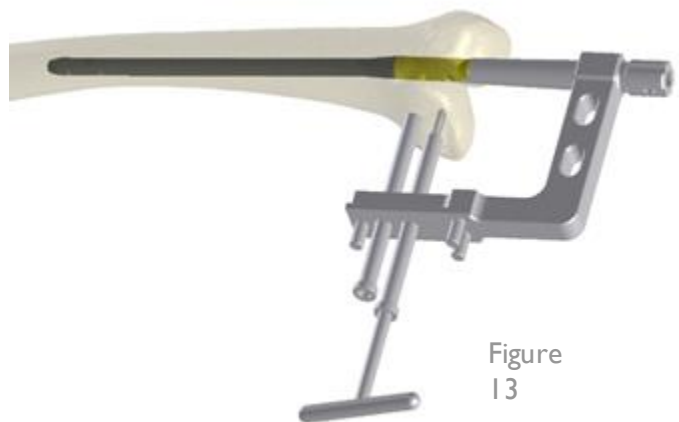


Figure 13

9 Distal Locking (Continued)

A **Locking Screw 5.0 mm** of correct length is now inserted into the protection sleeve, pushed through the bone with the **T-Handled Screwdriver SW3.5 (MOI 0200007)** until its thread engages the lateral cortex, and screwed into place as described for distal locking (Figure 14).

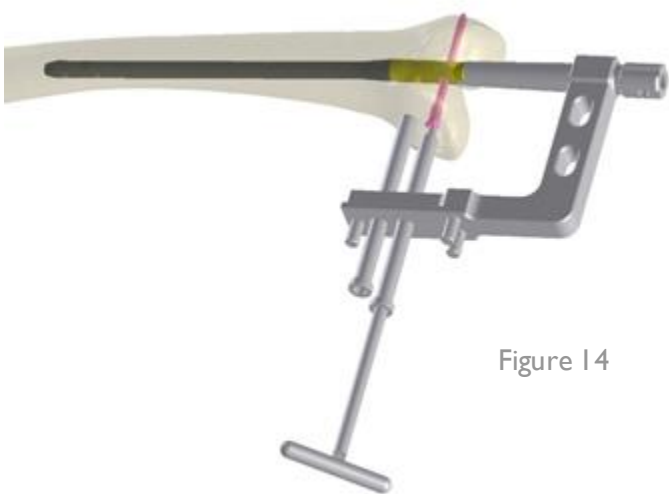


Figure 14

Repeat the above procedures to insert the second distal Locking Screw 5.0 mm (Figure 15).

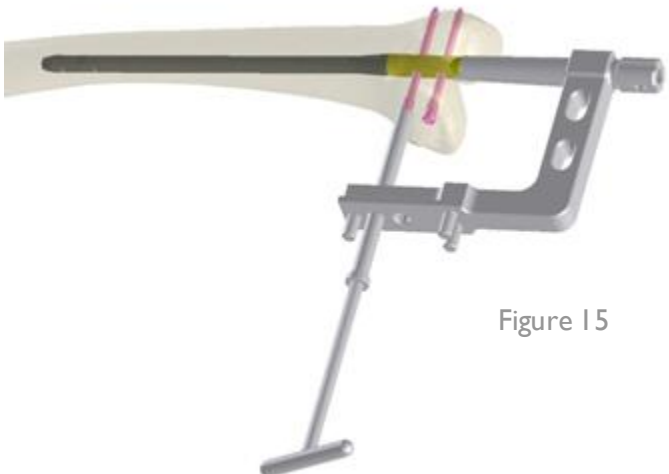


Figure 15

10 Proximal Locking

The insertion handle must be positioned laterally for proximal locking. The **Guide Bar (MOI 1400008)** is connected with the Insertion Handle. The number corresponding to the selected nail length lines up with the **Locking Block (MOI 1400018)**. The Guide Bar is then locked firmly into place using **Hex Wrench (MOI 0200001)** (Figure 16).

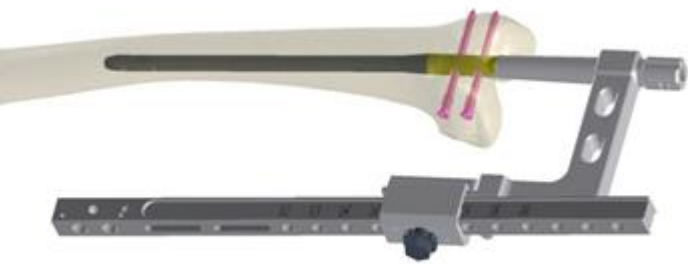


Figure 16

The **Distal Outrigger (MOI 1400009)** is now attached on the Guide Bar and tightened firmly (Figure 17).

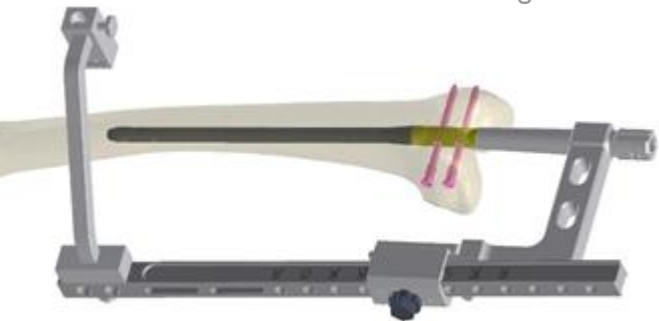


Figure 17

10 Proximal Locking (Continued)

Insert the **Protection Sleeve 10.0/8.2 mm** (MOI 1400006) into the outrigger and position it over the centre of the femur, make a 15 mm incision at this point and extend it down to the deep fascia. Split the muscles longitudinally down to the bone. Insert the **Trocar 8.0 mm** into the protection sleeve and push the two together down to the bone. Tighten the small screw to fix the protection sleeve.

Withdraw the trocar 8.0 mm and insert the **Drill Sleeve 8.0/5.2 mm** into the protection sleeve (Figure 18).

The **Drill Bit 5.0 mm** is inserted down to the bone, using gentle pressure to keep the point in contact with the cortex. The anterior cortex only is then drilled (Figure 19).

The drill bit is removed and the **T-Handled Reamer 5.0 mm** (MOI 1400003) is inserted. The hole in the bone is cleared by turning the reamer, until its tip can be heard and felt touching the nail. Tapping the nail to confirm contact may be helpful. The reamer is then removed (Figure 20).

Withdraw the **Protection Sleeve 10.0/8.2 mm**, **Drill Sleeve 8.0/5.2 mm** and **T-Handled Reamer 5.0 mm**. Insert the **Stabilizing Rod Sleeve 10.0/8.0 mm** (MOI 1400016) into the outrigger and tighten the small screw to fix the sleeve (Figure 21).

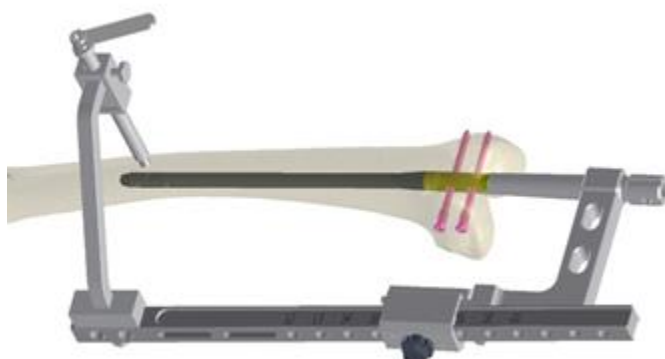


Figure 18

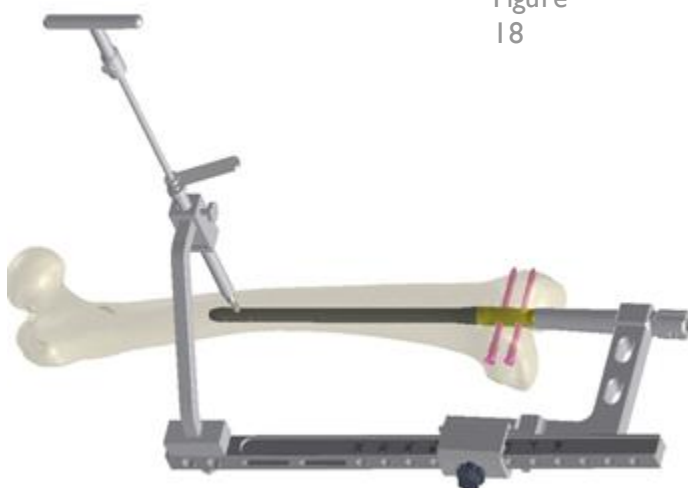


Figure 19

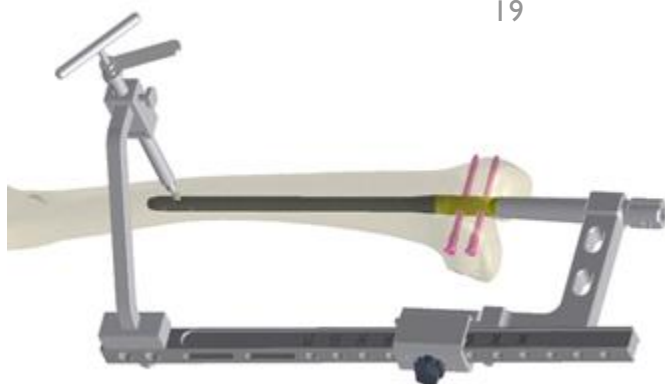


Figure 20

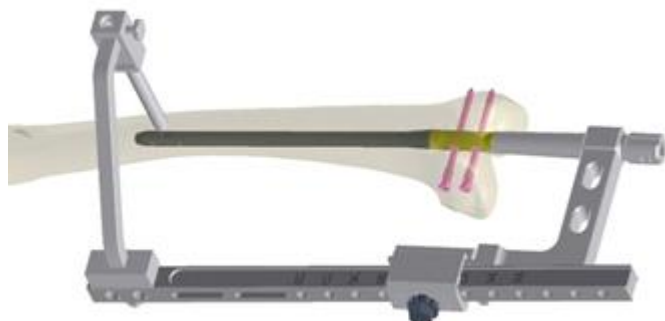


Figure 21

10 Proximal Locking (Continued)

The **T-Handled Stabilizing Rod** (MOI 1400014) is inserted through the Stabilizing Rod Sleeve and the hole in the anterior femoral cortex, down to the nail, contact being confirmed by tapping its tip on to the nail. Press the T-Handled Stabilizing Rod slightly, and the **U-Shaped Block** (MOI 1400013) is now attached so that the fork fits into the groove in the shaft of the T-Handled Stabilizing Rod (Figure 22).

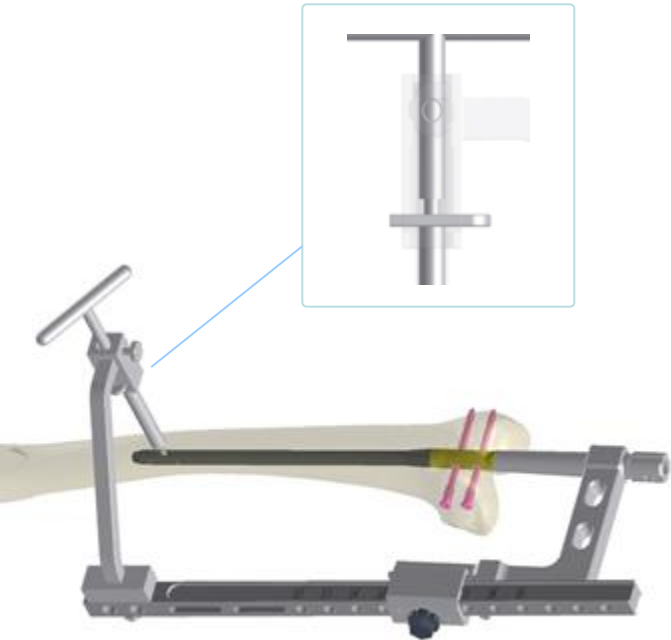


Figure 22

The handle of the Stabilizing Rod is now held so that its tip is in contact with the nail. The surgeon maintains this contact throughout. A Protection Sleeve 10.0/8.2 mm is inserted through one of the holes in the Guide Bar and, through a stab incision, advanced down to the bone with the aid of the Trocar 8.0 mm (Figure 23).

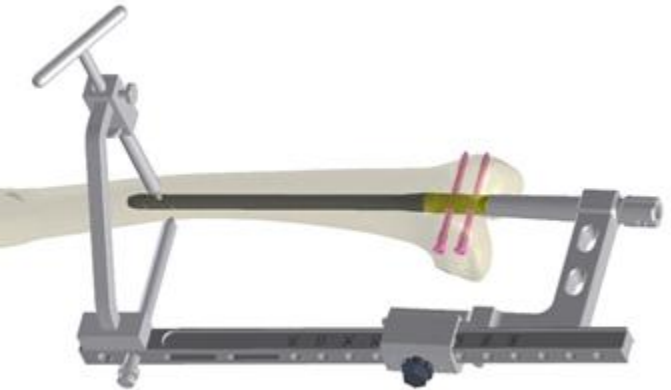


Figure 23

A Drill Sleeve 8.0/4.2 mm is now inserted into the Protection Sleeve, and tapped gently to engage its tip in the bone. The surgeon grips the T-handle of the Stabilizing Rod, to keep its tip against the nail, and maintains this position throughout the drilling procedure. The Drill Bit 4.0 mm is used to drill both cortices (Figure 24).

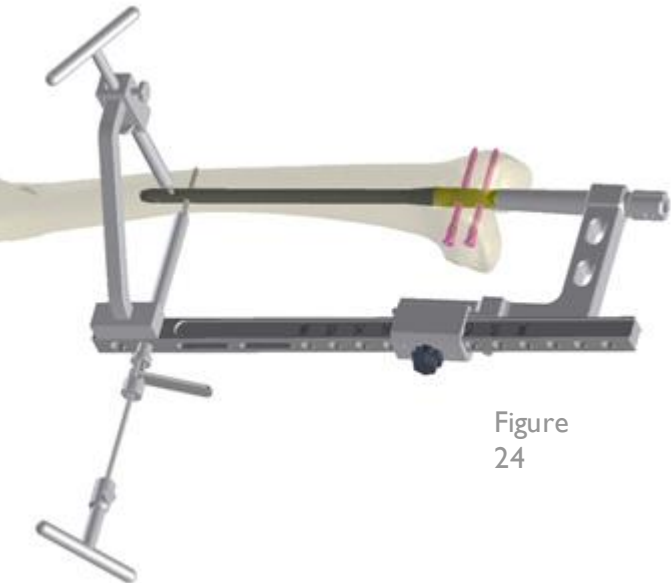


Figure 24

10 Proximal Locking (Continued)

Remove the drill bit and drill sleeve, and insert the **L-Position Rod** (MOI 0200029). This L-Position Rod has now stabilized the position of the guide bar (Figure 25). Do not drill the second hole until the L-Position Rod is in position.

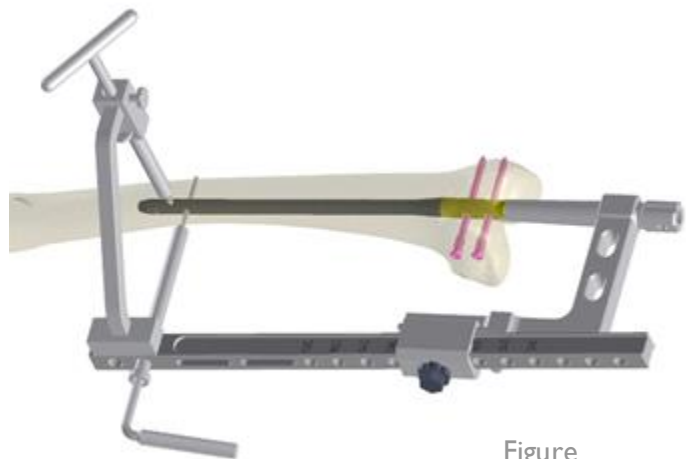


Figure 25

Advance the second Protection Sleeve 10.0/8.2 mm and drill the second hole in the same way (Figure 26).

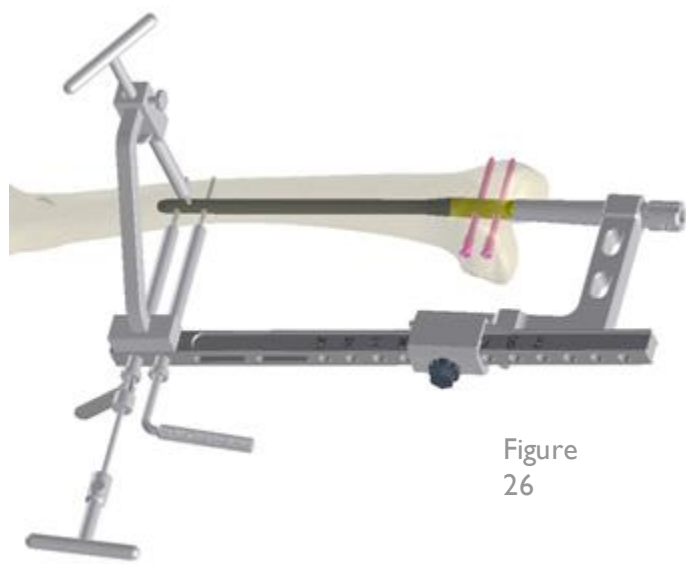


Figure 26

Tap the second hole using T-Handled Tap 6.0 mm (Figure 27).

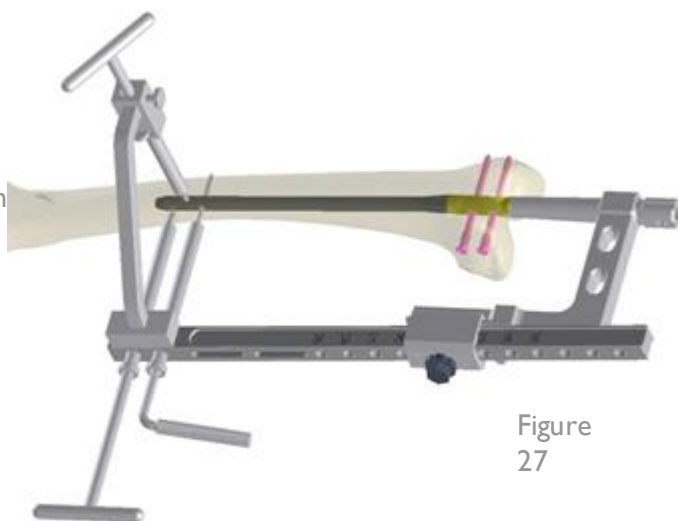


Figure 27

10 Proximal Locking (Continued)

Use Depth Gauge to measure the screw length. A Locking Screw 4.0 mm of correct length is now inserted into the second protection sleeve, pushed through the bone with the T-Handled Screwdriver SW3.5 until its thread engages the lateral cortex, and screwed into place as described for proximal locking (Figure 28).

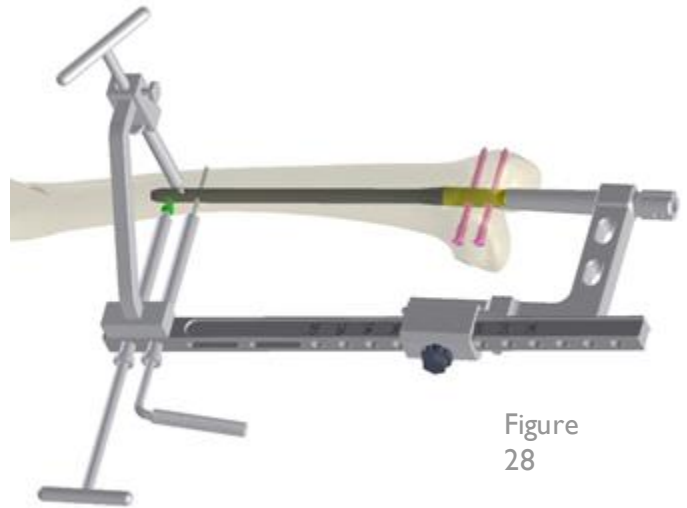


Figure 28

Remove the L-Position Rod from the first protection sleeve, and repeat this procedure to insert the second proximal locking screw 4.0 mm (Figure 29).

A check is now carried out with the Image Intensifier or by X-ray to confirm that both screws have passed through the nail and that reduction has been maintained. The stabilizing rod, protection sleeve and distal outrigger are removed.

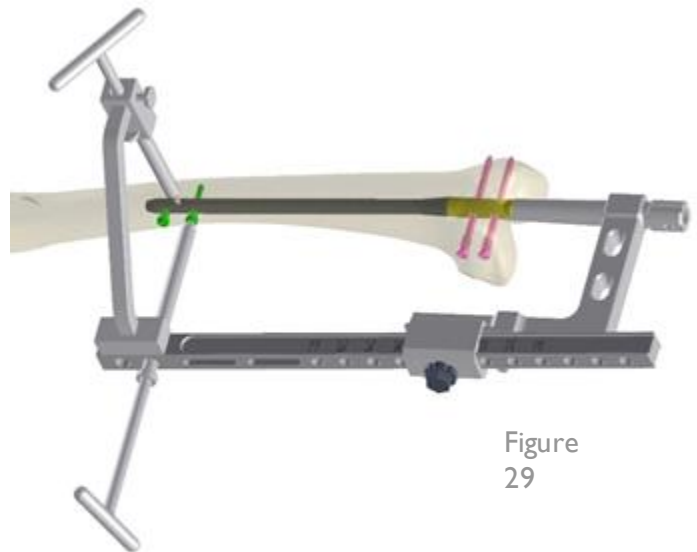


Figure 29

11 Final Check

Before removing the handle from the nail, it is important to check all of the locking screws for correct insertion, both in the AP and lateral planes, either by image intensification or X-ray films, ensuring that all pass through the nail and penetrate the distal cortex. These X-rays can also be used to confirm that the base of each screw head is firmly positioned against the surface of the cortex.

12 Insert the End Cap

The Guide Bar and Insertion Handle are removed. The nail End Cap can be inserted with T-Handled Screwdriver SW3.5. The nail end cap must be securely tightened, and Avoiding protrusion into the joint (Figure 30).



Figure 30

IMPLANT REMOVAL

Nail removal may normally be carried out after 18-24 months provided there is radiological evidence of union.

The distal end of the nail is exposed through a small incision. It may be necessary to clear some new bone from the end of the nail. The nail end cap is removed with the T-Handled Screwdriver SW3.5.

The **Connector for Nail Extraction** (MOI 1400019) is screwed fully on to the nail and locked firmly by Hex Wrench. It is important to avoid crossing the thread in the nail.

The locking screws are now all removed. The **Locking Screw Extractor** (MOI 0200025) is inserted down to the head of the Locking Screw 4.0 mm, and is turned counterclockwise. The T-Handled Screwdriver SW3.5 is used to remove the Locking Screw 5.0 mm.

Thread the Sliding Hammer into the Connector for Nail Extraction. The nail is then removed by reverse hammering (Figure 3 I).



Figure 3 I

IMPLANT INFORMATION

Locking Screw 5.0 mm, for Retrograde Femur Nail



REF (SS)	REF (TIT)	DIA (mm)	LEN (mm)
MOI 11503060	MOI 31503060	5.0	60
MOI 11503065	MOI 31503065	5.0	65
MOI 11503070	MOI 31503070	5.0	70
MOI 11503075	MOI 31503075	5.0	75
MOI 11503080	MOI 31503080	5.0	80
MOI 11503085	MOI 31503085	5.0	85
MOI 11503090	MOI 31503090	5.0	90
MOI 11503095	MOI 31503095	5.0	95
MOI 11503100	MOI 31503100	5.0	100

Locking Screw 4.0 mm



REF (SS)	REF (TIT)	DIA (mm)	LEN (mm)
MOI 11501030	MOI 31501030	4.0	30
MOI 11501035	MOI 31501035	4.0	35
MOI 11501040	MOI 31501040	4.0	40
MOI 11501045	MOI 31501045	4.0	45
MOI 11501050	MOI 31501050	4.0	50
MOI 11501055	MOI 31501055	4.0	55
MOI 11501060	MOI 31501060	4.0	60
MOI 11501065	MOI 31501065	4.0	65
MOI 11501070	MOI 31501070	4.0	70

End Cap, for SEINE™ Retrograde Femur Nail



REF (SS)	REF (TIT)	SIZE (mm)
MOI 11704000	MOI 31704000	2

IMPLANT INFORMATION

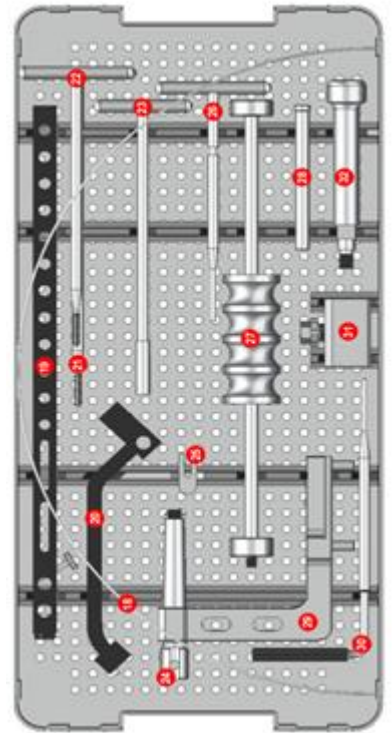
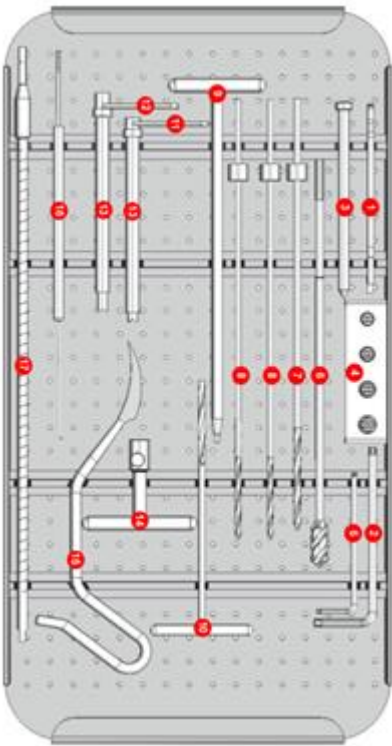


REF (SS)	REF (TIT)	DIA (mm)	LEN (mm)
MOI 11316200	MOI 31316200	9.0	200
MOI 11316220	MOI 31316220	9.0	220
MOI 11316240	MOI 31316240	9.0	240
MOI 11316260	MOI 31316260	9.0	260
MOI 11316280	MOI 31316280	9.0	280
MOI 11316300	MOI 31316300	9.0	300
MOI 11316320	MOI 31316320	9.0	320
MOI 11316340	MOI 31316340	9.0	340
MOI 11316360	MOI 31316360	9.0	360
MOI 11317200	MOI 31317200	10.0	200
MOI 11317220	MOI 31317220	10.0	220
MOI 11317240	MOI 31317240	10.0	240
MOI 11317260	MOI 31317260	10.0	260
MOI 11317280	MOI 31317280	10.0	280
MOI 11317300	MOI 31317300	10.0	300
MOI 11317320	MOI 31317320	10.0	320
MOI 11317340	MOI 31317340	10.0	340
MOI 11317360	MOI 31317360	10.0	360
MOI 11318200	MOI 31318200	11.0	200
MOI 11318220	MOI 31318220	11.0	220
MOI 11318240	MOI 31318240	11.0	240
MOI 11318260	MOI 31318260	11.0	260
MOI 11318280	MOI 31318280	11.0	280
MOI 11318300	MOI 31318300	11.0	300
MOI 11318320	MOI 31318320	11.0	320
MOI 11318340	MOI 31318340	11.0	340
MOI 11318360	MOI 31318360	11.0	360
MOI 11339200	MOI 31339200	12.0	200
MOI 11339220	MOI 31339220	12.0	220
MOI 11339240	MOI 31339240	12.0	240
MOI 11339260	MOI 31339260	12.0	260
MOI 11339280	MOI 31339280	12.0	280
MOI 11339300	MOI 31339300	12.0	300
MOI 11339320	MOI 31339320	12.0	320
MOI 11339340	MOI 31339340	12.0	340
MOI 11339360	MOI 31339360	12.0	360

INSTRUMENTS INFORMATION

SEINE™ Retrograde Femur Nailing System Basic Instrument

Set (MOI SEINE-01)



REF	DESCRIPTION	UNITS
1 MOI 0200001	Hex Wrench, Open	1
2 MOI 0100023	Allen Wrench SW5.0	1
3 MOI 0200005	Trocars 8.0 mm	1
4 MOI 1400000B	Replaceable Reamer Heads, 9/10/11/12 mm	1
5 MOI 0100025	Allen Wrench SW3.0	1
6 MOI 1400001	Rigid Reamer 13.0 mm	1
7 MOI 1400002	Drill Bit 5.0mm, with Drill Stop	1
8 MOI 0100003	Drill Bit 4.0 mm with Drill Stop	2
9 MOI 0200007	T-Handled Screwdriver SW3.5	1
10 MOI 1400003	T-Handled Reamer 5.0 mm, for Stabilizing Rod	1
11 MOI 1400004	Drill Sleeve 8.0/5.2 mm, for Stabilizing Rod	1
12 MOI 1400005	Drill Sleeve 8.0/4.2 mm, for Locking Screw	1
13 MOI 1400006	Protection Sleeve 10.0/8.2 mm	2
14 MOI 0200010	Quick Coupling T-Handle	1
15 MOI 0201003	Pointed Awl	1
16 MOI 0200008	Depth Gauge for Locking Screw	1
17 MOI 0100043	Flexible Reamer Shaft	1
18 MOI 1400007	Guide Wire with Ball Tip 2.5 mm	1
19 MOI 1400008	Guide Bar	1
20 MOI 1400009	Distal Outrigger	1
21 MOI 1400010	T-Handled Tap 6.5 mm	1
22 MOI 1400011	T-Handled Tap 6.0 mm	1
23 MOI 0200025	Locking Screw Extractor	1
24 MOI 1400012	Nail Holding Screw	1
25 MOI 1400013	U-Shaped Block, for Stabilizing Rod	1
26 MOI 1400014	T-Handled Stabilizing Rod	1
27 MOI 1400015	Sliding Hammer	1
28 MOI 1400016	Stabilizing Rod Sleeve 10.0/8.0 mm	1
29 MOI 1400017	Insertion Handle	1
30 MOI 0200029	L-Position Rod	1
31 MOI 1400018	Locking Block	1
32 MOI 1400019	Connector for Nail Extraction	1
* MOI 1400020C	Trays and Container	1



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