Warning
This description alone does not provide sufficient background for direct use of DePuy Synthes products. Instruction by a surgeon experienced in handling these products is highly recommended.

Processing, Reprocessing, Care and Maintenance
For general guidelines, function control and dismantling of multi-part instruments, as well as processing guidelines for implants, please contact your local sales representative or refer to:
http://emea.depuysynthes.com/hcp/reprocessing-care-maintenance
For general information about reprocessing, care and maintenance of Synthes reusable devices, instrument trays and cases, as well as processing of Synthes non-sterile implants, please consult the Important Information leaflet (SE_023827) or refer to:
http://emea.depuysynthes.com/hcp/reprocessing-care-maintenance
# Table of Contents

**Product Description**  
2

**Use of the Image Intensifier**  
4

**Surgical Technique – S.U.N. Tibia**  
5
- Indications  
5
- Positioning of the patient  
6
- Determining the point of insertion  
7
- Opening of the medullary cavity  
8
- Reaming of the medullary cavity  
8
- Mounting the insertion instrument and aiming device  
9
- Insertion of the S.U.N. Tibia  
10
- Removal of the conical bolt  
11
- Distal locking  
12
- Proximal locking  
18

**Surgical Technique – S.U.N. Femur**  
20
- Indications  
20
- Positioning of the patient  
21
- Correct point of insertion  
23
- Opening of the medullary cavity  
23
- Reaming of the medullary cavity  
24
- Mounting the insertion instrument and aiming device  
25
- Insertion of the S.U.N Femur  
26
- Removal of the conical bolt  
27
- Distal locking  
28
- Proximal locking  
29

**Implant Removal**  
31
- Removal of the locking bolts  
31
- Loosening of a jammed conical bolt  
33

**Product Information**  
34
- Instruments  
34
- Implants  
35
- Simplified universal Nails S.U.N. for Tibia  
36
- Simplified universal Nails S.U.N. for Femur  
37

**MRI Information**  
38
**Product Description**

**Tibia and Femur**

**Optimal load transmission** during insertion and extraction of the nail due to the special thread design. The constant diameter of the thread allows the same instruments to be used for all nail diameters in the tibia, whereas different insertion instruments are applied in the femur depending on the nail diameter.

**Right and left application** made possible by the transverse locking bolt feature.

**Proximal Locking:** Choice of two round holes for static locking (only one hole for femur) secures the rotational and axial stability. A dynamic hole allows axial suitable dynamisation.

Wall thickness of 1.25mm causes as a closed tube an optimum on stability.

**Anatomical design**

**Tibia:** The AO/ASIF curvature of 11° in the upper third of the S.U.N. allows for easy insertion and good anatomical fit.

**Femur:** The 1.5m radius of the S.U.N. corresponds closely with the average anatomical curvature of the femur.

**Secure distal locking** through two medial/lateral holes.
Looking bolts

Locking
- High strength (4.3mm core diameter)
- No tapping necessary
- Easy locking technique

1. Kind to soft tissue with low profile head
2. Secure fit in the nail due to special low profile thread
3. High strength with 4.3mm core diameter over the full length of the bolt
4. Easy insertion due to slightly rounded trocar point
In both closed and locking nail techniques an image intensifier is required. It enables controlled penetration of the fracture zone with the guide wire, the medullary reamers and the medullary nail. In locked nailing, the image intensifier is additionally used for placing the distal locking bolts. Correct positioning of the image intensifier is extremely important for positioning the distal locking holes.

If the patient is in a lateral position, the radiation source of the image converter should be below the leg, if the patient is in supine position, it should be opposite the surgeon. This arrangement allows the direction finder (A, shown in figure) to correct to the divergence of the X-rays.

The distance between the receiver of the image converter and the medial or the lateral side of the tibia should be as large as possible. (This distance should be sufficient to enable the process of drilling of the distal locking holes to be carried out under image control). The monitor should be placed facing the surgeon, and the image intensifier set up so as to give a real (not mirror) image of the operative field. This will help to reduce radiation exposure. When positioning the image intensifier, care should be taken to ensure that the C-arm can be swivel and adjusted freely. The receiver of the image intensifier should have a sterile cover.
Surgical Technique – S.U.N. Tibia

Indications

Fractures with bony support (stable fracture in the middle third of the tibia)

1. transverse fractures
2. short oblique fractures
3. pseudarthroses

Fractures without bony support (unstable fractures in 60% of the tibial length)

4. fractures near the metaphysis
5. long torsional fractures
6. segmental fractures
7. comminuted fractures
8. fractures with bone defects

The S.U.N. must be locked with locking bolts to achieve rotational and axial stability of the fracture.
Positioning of the patient

The reduction of the fracture can be carried out using open or closed techniques. For open reduction, the fracture must be exposed. **Closed reduction** is carried out by means of an extension table under image intensification and is **preferable to open reduction**. For both techniques, the large distractor can be used to facilitate reduction (see product information on the «Large Distractor»).

**Positioning on a standard table**

The operating table used must be radiolucent. The injured leg is bent at the knee so that the tibia is in a upright position. Here a leg holder can be useful. Care should be taken that the table is low enough.

**Positioning on a fracture table**

The patient is placed in the supine position, with the knee of the injured leg bent to an angle of 90 degrees and the lower leg extended downwards. Place the foot in cushioned shoe or use a calcaneus wire extension. When locking distally, the wire extension must be used as the shoe extends too far proximally.

The uninjured leg is flexed.

Free movement of the C-arm should be ensured. It is important that the C-arm can be swivelled from the A-P direction into the lateral direction. Fracture reduction (including rotational correction) should be carried out before sterile draping as this is difficult to achieve during the operation. Good cushioning of the popliteal fossa is also important, with care being taken to ensure that most of the pressure acts against the thigh.
Determining the point of insertion

Correct siting of the insertion point of the nail is important if a trouble-free introduction of the nail is to be ensured. The insertion point should be sited as far as proximally possible but on no account in the knee joint.

It is important that the site of entry is aligned directly with the centre of the medullary cavity, i.e., slightly medial to the tibial tuberosity.
Opening of the medullary cavity

A longitudinal incision is made over the patellar ligament beginning at the anterior patella pole going 5cm downwards. The patellar ligament is divided medially. If necessary, it can also be moved laterally. First, the 4mm centering pin (no. 351.060) has to be drilled in by hand. The correct angle of inclination is determined by a universal nail held along the anterior edge of the tibial plateau. Then the cannulated cutter (no. 351.240) is inserted over the centering pin and with it a cylindrical bone fragment is cut out by hand. Due to the fact that the instrument also cuts at the sides of its sharp edge, the patellar ligament should be protected by the protection sleeve (no. 351.260).

Insertion of the reaming rod

The 2.5mm SynReam reaming rod (352.032) with olive is advanced under image control through the fracture zone into the malleolar region. The slight bend of the reaming rod facilitates the passage through the individual fragments. The holding forceps (no. 351.780) serve to check the rotation of the bent reaming rod.

Reaming of the medullary cavity

Refer to the SynReam surgical technique 036.000.808.

When using the S.U.N. the last reaming operation should always be carried out with a reamer whose diameter is 0.5–1.0mm larger than the diameter of the nail.
Mounting the insertion instrument and aiming device

**Insertion handle**
The insertion handle mounted on the proximal end of the nail is used to guide the medullary nail during insertion. The same insertion handle serves as an aiming device for placing the proximal locking screws. On removal of the conical bolt, the insertion handle must be held firmly to avoid rotation of the nail (see page 11).

1. The S.U.N. is advanced over the guide rod and is pushed as far as possible by hand into the tibia.

2. The insertion handle A is placed on the nail so that the tabs of the insertion handle clicks into the corresponding notches of the nail. The insertion handle points to medial.

3. The conical bolt B is pushed through the mounted insertion handle and screwed into the proximal end of the nail.

4. Tighten the conical bolt B slightly and mount the locking nut C which is tightened with the pin wrench.

5. Screw the curved driving piece D with mounted driving head E onto the conical bolt B. When assembling conical bolts and curved driving piece ensure that the knurled nut F is adjusted to leave a 2 to 3mm gap between the rear threads of the conical bolt and the striker receptacle of the curved driving piece. It must be positioned in such a way that it neutralizes the direction of the forces caused by the curve of the closed Nail of the S.U.N.

**Note:** Insertion can also be carried out using the cannulated guide rod and ram (mounting see page 26).
Insertion of the S.U.N. Tibia

With measured blows using the 700 g hammer, drive the medullary nail into the tibia. The rotation of the medullary nail can be checked during the process of insertion using the insertion handle. If there is a tendency for rotation, the handle can be rotated laterally by a simple manoeuvre for improved guidance and control of rotation or counter-torsion. Next open the locking nut then detach the insertion handle from the notches of the nail. Rotate the insertion handle by 180 degrees and tighten the locking nut again.

If the nail does not penetrate further into the medullary cavity with each blow, the nail is removed once more and the medullary cavity is reamed further by 0.5 to 1.0mm.

The penetration of the fracture zone with the medullary nail can be carried out under image control. When the nail is fully driven in, the curved driving piece and the guide rod are removed.

For proximal locking the insertion handle, the conical bolt, and the locking nut remain mounted on the medullary nail.
Removal of the conical bolt

1. Loosen the nut C by half a turn.

2. Hold the insertion handle A firmly...

3. … and detach the conical bolt B with the combination wrench or socket wrench.

Non-observance of this instruction can lead to a cross-threading of the conical bolt in the nail. Any attempt to remove the conical bolt by force can lead to a total jamming of the bolt. Should jamming occur, loosen the conical bolt with the combination wrench and locking pliers (see also page 33). If the insertion handle is used to resist the torque on removal of the conical bolt, jamming can be prevented. The tabs of the handle articulate with the notches of the proximal end of the medullary nail, and thus prevent distortion of the nail. The conical bolt can thus be removed without any problems.

Key:
M = Removal moment of the conical bolt
X = Resisting moment through the insertion handle
Distal locking

1. Position the image intensifier as far as the X-ray axis corresponds to the hole axis of the locking hole.

The positioning is carried out at the proximal hole of the two distal locking holes unless this hole is too near to the fracture. This position is achieved by swivelling and tilting the C-arm. **The image must be congruent with the surgical field as seen by the surgeon, i.e., the right hole in the surgical field must also be the right hole on the screen.**

When the two axes correspond, the locking hole will appear completely round on the screen. At this adjustment the proximal hole should be positioned in the middle of the lower half of the screen.

2. The cutaneous incision is carried out under image control. Place an incision about 4cm long over the two distal holes down to the bone surface.
3. The distal aiming device, with inserted aiming trocar (no. 355.640), is pushed through the incision onto the bone surface.

4. Slightly tilt the distal aiming device under image intensification as far as the dot is in the centre of the circle of the direction finder. Without changing direction, the distal aiming device is moved over the bone surface up to the dot of the aiming trocar appearing in the centre of the locking hole. The direction finder keeps the protection sleeve of the distal aiming device aligned with the beam axis.
5. The distal aiming device is pushed firmly against the bone surface. Remove the aiming trocar and replace it with the drill sleeve 8.0/4.5 (no. 355.710). Check once more the position of the direction finder. If the direction finder is correctly aligned, the locking hole in the nail appears round through the drill sleeve 8.0/4.5 (no. 335.710) on the monitor.

6. A 4.0mm drill hole is now made through both cortices. Use the 4.0/4.5mm drill bit (no. 355.900). The drilling direction is adjusted using the direction finder as a guide and should be checked during drilling.
The image intensifier is not required for the following steps.

7. Remove the drill sleeve 8.0/4.5 (no. 355.710) and measure the length of the required locking bolt through the aiming device. The locking bolt must be chosen 2mm longer than the measured length. This ensures a good purchase for the locking bolt in the far cortex.

8. Insert and tighten the tibial fixation bolt (no. 355.670). This anchors the distal aiming device to the bone.
9. The screwdriver is inserted into one of the two hexagonal screws on the side of the distal aiming device (no. 355.620).

**Note:** The direction finder must turn freely around the protection sleeve.

For the next step the image intensifier must be used.

10. Under image intensification, the direction finder is turned around the protection sleeve with the screwdriver until the metal guide on the direction finder is located parallel to the nail. This position is fixed by tightening the hexagonal screw on the direction finder. After removal of the screwdriver the correct position of the direction finder should be checked.

For the remaining steps the image intensifier is not needed.

11. The protection sleeve 11.0/8.0 (no. 355.700), with the trocar in place, is inserted through the direction finder onto the bone. Replace the trocar with the drill sleeve 8.0/4.5 (no. 355.710) and drill a 4mm hole through both cortices with the drill bit 4.0/4.5mm (no. 355.900). After removal of the drill sleeve 8.0/4.5 (no. 355.710), determine the bolt length by using the depth gauge.
12. Insert the corresponding locking bolt through the protection sleeve 11.0/8.0 (no. 355.700). Locking bolts should be 2mm longer than the measured length, in order to gain a good purchase in the far cortex.

13. Leave the protection sleeve 11.0/8.0 (no. 355.700) in place, and remove the fixation bolt from the first hole. Insert the appropriate locking bolt. Remove the distal aiming device.
**Proximal locking of the tibia**

1. The insertion handle is used to locate the proximal locking bolts.

Through the holes of the insertion handle, all bolts can be placed without the need of image intensification.

2. The protection sleeve 11.0/8.0mm (no. 355.700) together with the trocar is inserted through the corresponding drill hole and pushed down to the bone through an approx. 2cm skin incision.
3. Insert the drill sleeve 8.0/4.5 (no. 355.710) and drill through both cortices with the 4.0/4.5mm drill bit (no. 355.900).

4. Remove the drill sleeve 8.0/4.5 (no. 355.710). Measure the length for the suitable locking bolts. The locking bolt should be 2mm longer than the measured length.

5. Screw in the corresponding locking bolt through the protection sleeve 11.0/8.0 (no. 355.700). If a further proximal hole is to be occupied, repeat steps 2 to 5.
Surgical Technique – S.U.N. Femur

Indications

Fractures with bony support (stable fracture in the middle third of the femur)

1. transverse fractures
2. short oblique fractures
3. pseudarthroses

Fractures without bony support (unstable fracture in 60% of the femoral length)

4. fractures near the metaphysis
5. long torsional fractures
6. segmental fractures
7. comminuted fractures
8. fractures with bone defects

The S.U.N. must be locked with locking bolts to achieve rotational and axial stability of the fracture.
Positioning of the patient

Reduction of the fracture may be carried out using open or closed techniques.

**Closed reduction** must be carried out under image control. This technique is preferable to open reduction.

The large distractor may also be used for both techniques (see product information on the large distractor).

Medullary nailing can be performed with the patient in the supine or lateral position.

**Lateral positioning on fracture table**

A fracture table with long cantilevers is used. The patient is placed in a lateral decubitus position. The pelvis is held exactly vertical by pelvic supports on both sides of the table. The patient is slid downwards on the table until the perineum rests on a well cushioned perineal post. In male patients check that the genitals are freely mobile.

**Supine positioning on fracture table**

With the patient in the supine position, the leg of the injured femur is allowed to hang with the knee fixed 90 degrees. The patient’s pelvis should lie flat on the table to ensure the correct rotational alignment of the femur. Rotation cannot be corrected. If possible, slightly adduct the injured leg at the hip.
Lateral positioning on a standard table
The operating table must be radiolucent. The patient is placed in a lateral position (a vacuum mattress may be helpful for this purpose). the injured leg is flexed forward at an angle of about 45 degrees, with the knee bent at an angle of 90 degrees, and the foot is placed over the uninjured leg. The large distractor is used to aid reduction and correct rotational alignment.

Supine positioning on a standard table
The operating table must be radiolucent. The patient is placed in a supine position. To allow access to the proximal femur, the uninjured leg is abducted as far as possible, and the injured leg is adducted. The large distractor can be used to aid reduction and to correct rotational alignment (see product information on the large distractor).
Correct point of insertion

The choice of the correct point of insertion is important in use of the S.U.N.
Investigations on the geometry of the medullary cavity have shown that the ideal point of insertion for the Simplified Universal Nail S.U.N. is directly in the piriform fossa. Rotation of the S.U.N. is thus prevented.

Opening of the medullary cavity

1 An incision is carried out from the trochanter major to proximal. The centering pin is clamped into the cannulated cutter in such a way that the tip protrudes about 5cm (Tighten the screw with hexagonal recess by means of the screwdriver). The tip of the centering pin is set onto the femur at the level of the point of insertion (cf. above). By rotating the centering pin, the cutting edge is brought down onto the bone. Control axial alignment of the centering pin to the medullary cavity on the image intensifier. (When treating very proximal fractures, it is more favourable to insert the 4mm centering pin (no. 351.060) with the universal chuck, and to subsequently mount the cannulated cutter on the inserted centering pin).
2 When the direction of the centering pin related to the medullary cavity is correct, opening is carried out by pushing and simultaneously rotating the cannulated cutter at a minimum angle of 180 degrees. Remove the cannulated cutter and the centering pin.

**Introduction of the reaming rod**

The 2.5mm SynReam reaming rod (352.032) with olive is pushed forward through the fracture zone into the condyle massif under image intensifier control. Slight bending and twinsting of the end of the reaming rod allows free passage through individual fragments. The holding forceps (no. 351.780) serve to check the rotation of the bent reaming rod.

**Reaming of the medullary cavity**

Refer to the SynReam surgical technique 036.000.808.

The diameter of the last reamer has to be 1.0 – 1.5mm larger than the diameter of the nail.
Mounting the insertion instrument and aiming device

The insertion handle mounted on the proximal end of the nail serves to guide the medullary nail during insertion. The same insertion handle serves as an aiming device for placing the proximal locking bolts. For the removal of the conical bolt, the insertion handle must be used as a counter stay (see page 27).

1. The S.U.N. is passed over the guide rod and pushed by hand as far as possible into the femur.
2. The conical bolt B is screwed into the proximal end of the nail, and the insertion handle A is mounted.
3. Tighten the conical bolt B with the combination wrench and apply the locking nut C which is then tightened with the pin wrench.
4. Push the cannulated guide rod (no. 355.220) over the 4mm guide rod, and screw it onto the proximal end of the conical bolt.
5. To prevent the guide rod from «backing out», the holding rod D is inserted into the cannulated guide rod.
Insertion of the S.U.N. Femur

Insert the nail into the femur with measured blows of the ram. Rotation of the nail during insertion is checked by the insertion handle. By fixing the holding rod into the cannulated guide rod, a backing out of the 4mm guide rod can be avoided.

If the nail does not penetrate further into the medullary cavity with each blow, the medullary nail is removed once more and the medullary cavity is reamed further by 0.5 to 1.0mm.

The penetration of the fracture zone should be carried out under image intensifier control. When the nail has been completely inserted, the cannulated guide rod and the 4mm guide rod are removed.

Note: Take care not to trap fingers during hammering.

For proximal locking the conical bolt, the insertion handle and the locking nut remain mounted at the proximal end of the medullary nail.
Removal of the conical bolt

1. Loosen the nut C by half a turn.

2. Hold the insertion handle A firmly...

3. … and detach the conical bolt B with a combination wrench or socket wrench.

Non-observance of this instruction can lead to a cross-threading of the conical bolt in the nail.
Any attempt to remove the conical bolt by force can lead to total jamming of the bolt. Should jamming occur, loosen the conical bolt with the combination wrench and locking pliers (see also page 33). If the insertion handle is used to resist the torque on removal of the conical bolt, jamming can be prevented.
The tabs of the handle articulate with the notches of the proximal end of the nail, and thus prevent distortion of the nail. The conical bolt can thus be removed without any problems.

Key:
M = Removal moment of the conical bolt
X = Resisting moment through the insertion handle
Distal Locking

Distal locking of the femur is carried out as distal locking of the S.U.N. Tibia.
Please refer to page no. 12 to 17.
Proximal Locking

1. The insertion handle is used for the placement of the proximal locking bolts. Through the holes of the insertion handle, both locking bolts can be placed without image intensification.

2. Depending on the fracture situation, the protection sleeve 11.0/8.0 (no. 355.700), together with the trocar (no. 355.750) is inserted through one of the two positioning holes, through the 2cm incision and pushed onto the bone. Remove the trocar. The protection sleeve remains in place until the bolt is completely inserted.
3. Insert the drill sleeve 8.0/4.5 (no. 355.710) and drill both cortices with the 4.0/4.5mm drill bit (no. 355.900).

4. Remove the drill sleeve 8.0/4.5 (no. 355.710). Measure the length of the drill hole. The locking bolt must be 2mm longer than the measured length.

5. The locking bolt is screwed in through the protection sleeve 11.0/8.0 (no. 355.700). If both proximal holes are to be occupied, repeat steps 2 to 5.
Implant Removal

Removal of the locking bolts

The large holding sleeve contained in the instrument set allows easy removal of the locking bolt after healing of the fracture.

1. Large holding sleeve
2. Quick release coupling
3. Large hexagonal screwdriver

Note: The large holding sleeve (no. 314.280) fits only to the large hexagonal screwdriver (no. 314.270).

1. Push the holding sleeve over the screwdriver shaft as far as it clicks into place.

2. Introduce the screwdriver into the hexagonal recess of the locking bolt.
3. Push the holding sleeve forward up to the stop; the locking bolt is now fixed and the holding sleeve connected to the screwdriver.

4. Remove the locking bolt. The locking bolt is released by pulling back the holding sleeve.

5. Remove the holding sleeve:
   Push the holding sleeve forward up to the stop, hold the holding sleeve firmly on the end near to the handle. Push the quick release coupling in the direction of the handle. At the same time push the holding sleeve in the direction of the screwdriver tip and remove it.
Loosening of a jammed conical bolt

Jamming can occur by mistaken use of the short conical bolt contained in the AO/ASIF universal nail instrument set. As the insertion handle cannot be used over the conical bolts, the removal of these bolts can be very difficult. If this situation should occur, the S.U.N. should be driven out approximately 5 cm. The proximal end of the nail must then be held with a locking wrench. During the loosening of the conical threaded bolt, the locking wrench serves as a torque resistor. This method should only be used in emergency cases.
Product Information

Instruments

The S.U.N. Tibia and Femur are used with the instrument sets of the universal nailing system

You need:
– the Reaming Instrument Set,
– the Insertion Instrument Set,
– the Locking Instrument Set.

Please refer to the SYNTHES® catalogue for ordering information.
Thread diameter: 4,9mm  
Fully threaded  
Drill bit for threaded hole: 4,0mm  
Core diameter: 4,3mm  
Hexagonal socket: 3,5mm  
Head diameter: 8,0mm

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To ensure safe hold in the far cortex, a locking bolt 2mm longer than measured has to be chosen to allow for the trocar tip.
### Simplified universal Nails S.U.N. for Tibia

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Simplified universal Nails S.U.N. for Femur

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Torque, Displacement and Image Artifacts according to ASTM F 2213-06, ASTM F 2052-06e1 and ASTM F2119-07

Non-clinical testing of worst case scenario in a 3 T MRI system did not reveal any relevant torque or displacement of the construct for an experimentally measured local spatial gradient of the magnetic field of 3.69 T/m. The largest image artifact extended approximately 169 mm from the construct when scanned using the Gradient Echo (GE). Testing was conducted on a 3 T MRI system.

Radio-Frequency-(RF-)induced heating according to ASTM F2182-11a

Non-clinical electromagnetic and thermal testing of worst case scenario lead to peak temperature rise of 9.5 °C with an average temperature rise of 6.6 °C (1.5 T) and a peak temperature rise of 5.9 °C (3 T) under MRI Conditions using RF Coils [whole body averaged specific absorption rate (SAR) of 2 W/kg for 6 minutes (1.5 T) and for 15 minutes (3 T)].

Precautions: The above mentioned test relies on non-clinical testing. The actual temperature rise in the patient will depend on a variety of factors beyond the SAR and time of RF application. Thus, it is recommended to pay particular attention to the following points:

- It is recommended to thoroughly monitor patients undergoing MR scanning for perceived temperature and/or pain sensations.
- Patients with impaired thermo regulation or temperature sensation should be excluded from MR scanning procedures.
- Generally it is recommended to use a MR system with low field strength in the presence of conductive implants. The employed specific absorption rate (SAR) should be reduced as far as possible.
- Using the ventilation system may further contribute to reduce temperature increase in the body.