Integra™

Panta® – Panta® XL
Arthrodesis Nail System
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**Design rationale PANTA®**

The talo-tibio-calcaneal arthrodesis is characterized by its challenging technique. The use of a retrograde nail is part of the therapeutic option that allows:

- Re-alignment of the foot on the weight-bearing axis.
- Correction of coronal and saggital plane deformities.
- Rotational stability.
- Axial compression.

The Panta® nail system has been designed to best achieve these targets through:

- Precise and radiolucent instrumentation.
- A unique system to apply compression balanced with multi-planar screw fixation — in the tibia, the talus and the calcaneus — and enhanced calcaneal fixation to optimize stability and alignment of the arthrodesis.

**Indications**

The PANTA® and PANTA® XL nails are intended for use in tibiotalocalcaneal arthrodesis and treatment of trauma to the hindfoot and distal tibia. Depending on the particular patient factors, indications may include:

- Post-traumatic and degenerative arthritis involving both ankle and subtalar joints.
- Rheumatoid arthritis.
- Revision of failed ankle arthrodesis with subtalar involvement or with insufficient talar body.
- Revision of failed total ankle arthroplasty with subtalar intrusion.
- Talar deficiency conditions (requiring a tibiocalcaneal arthrodesis).
- Avascular necrosis of the talus.
- Neuroarthropathy or neuropathic ankle deformity.
- Severe deformity as a result of talipes equinovarus, cerebral vascular accident, paralysis or other neuromuscular disease.
- Severe pilon fractures with trauma to the subtalar joint.

**Design rationale PANTA® XL**

Incorporated features are longer lengths and a conical extremity shape designed to reduce stress at the proximal tip of the nail.

Another feature is the addition of nail autodynamisation. The proximal edge of the slot maintains compression while allowing dynamisation with postoperative weight bearing, providing continuous compression.
**Implant description**

The PANTA® and PANTA® XL nails are available in 14 sizes. All nails are color coded for easy size identification.

Bony fixation is achieved using two tibial screws, two calcaneal screws and one (optional) talar screw.

Two kinds of screws are available:

- Fully threaded screws (FTS) with cortical thread over the entire length providing increased bony fixation.

- Partially Threaded Screw (PTS) with cortical threads on extremities only providing more resistance.

Screws length is available from 20mm to 110mm in 5mm increments.

An end cap may be inserted into the distal nail threads to prevent tissue ingrowth and facilitate future nail removal.

The nail, cross locking screws and end cap are manufactured from titanium alloy: Ti-6Al-4V ELI, ISO 5832-3, ASTM F136.

### The PANTA® – PANTA® XL nails color code

<table>
<thead>
<tr>
<th>Diameter</th>
<th>L. 150 mm</th>
<th>L. 180 mm</th>
<th>L. 210 mm</th>
<th>L. 240 mm</th>
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<tr>
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<tr>
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### FULLY THREADED SCREWS
- Cortical threads on the entire length.
- The thread provides more grip.
- The head avoids a too deep insertion of the screw in the bone.

### PARTIALLY THREADED SCREWS
- Cortical threads on the extremities only.
- The smooth part provides more resistance.
- The headless design enables the implant being totally embedded.
Instrument description

Instrument rationale
The instrumentation for the PANTA® and PANTA® XL nails is designed to achieve unique compression across the ankle and subtalar joints.

The patented compression/targeting device incorporates the following features:

- A combination of a radiolucent targeting frame to allow optimal placement of the calcaneal screws.
- A dual armed targeting device to allow medial or lateral tibial and talar screw placement and equal application of compression.
- A simple design conforming to natural hindfoot anatomy (calcaneus and ankle joint).
- A threaded compression mechanism to provide increased mechanical advantage and enhanced bony apposition.

Application of compression through the bone rather than through the soft tissue allowing more effective, direct and controllable alignment of the arthodesis sites.

Compression system
The patented compression/targeting device consists of a radiolucent frame and metallic support that are assembled together.

Compression rods are used to stabilize the device to the bone and offer the compression.

Applying compression
When the compression wheel is turned clockwise, the metallic support slides out, applying compression.

Up to 12mm of compression can be applied, direct and controllable alignment of the arthodesis sites.
NEWDEAL as the manufacturer of this device, does not practice medicine and does not recommend this or any other surgical technique for use on a specific patient. The surgeon who performs any implant procedure is responsible for determining and using the appropriate techniques for implanting the device in each patient.

This technique has been developed with the help of James W. Brodsky, MD (PANTA® Nail) and Beat Hintermann, PhD (PANTA XL Nail).

**Surgical technique**

1. **Patient positioning**
   The patient is placed supine with the foot close to the end of the table to facilitate the procedure.

2. **Preparation of the joint surfaces**
   A range of surgical approaches and incisions can be utilized including anterior, anterolateral or lateral approaches to the tibiotalar joint and subtalar joint.

   Single or separate incisions can be utilized depending upon the particular characteristics of the case.

   The essential issue is to achieve satisfactory preparation of the bone surfaces for arthrodesis and satisfactory alignment of the limb through the arthrodesis sites.

3. **Incision**
   A plantar incision is made to prepare for insertion of the nail and support device assembly. This may be a longitudinal or transverse incision.

   Care must be taken to protect the plantar neurovascular structures, both in the dissection and during the procedure, as these structures are at risk.
4. First Drilling

1. Assemble the plantar protection sleeves:
   - A – internal 3.2mm (519 028)
   - B – central 9mm (519 029)
   - C – external 13.5mm (519 030)

2. The guide wire insertion point should be slightly lateral to accommodate the lateral offset of the calcaneus relative to the medullary canal of the tibia.

3. Appropriate tibial alignment is critical.

4. Introduce the 3.2mm diameter guide wire through the protection sleeves. Use the 400mm (519 032) or the 600mm (519 034 or 519 034S) guide wire depending on surgeon preference.

5. Advance through the calcaneus and the talus using fluoroscopy to control the position in both the anteroposterior and mediolateral planes.

6. Confirm the alignment of the calcaneus and talus and the anatomic axis of the tibia.

7. Advance the guide wire into the tibia.

8. Laser marks on the guide wire may assist in the approximate length of the final implant. The final length determination is made based on the final reamer depth described in the next step.

5. Canal enlargement

1. Change to the central protection sleeve B (519029), by removing the internal sleeve A (519028).

2. The 9mm central protection sleeve has a built in stop for the 7mm and 9mm drills. The nail insertion point is enlarged by inserting the 7mm drill (519 007) until it contacts the back (plantar) side of the sleeve. Insert the 9mm drill (519 009) to further enlarge the opening.
6. Reaming and nail choice

1. Remove the central protection sleeve B (519029). Attach the reamers to power using the cannulated quick coupling (519020: optional).

2. For nail diameter 11 to 13mm, start reaming with the 10.5mm diameter reamer (519014) on all the chosen length (150 or 180mm) then use progressively all the reamers from diameter 11mm to the diameter that perfectly fits the tibial diaphysis. In case of very fragile bone, start reaming with the 10mm diameter reamer (519010: optional). The final diameter of the reamer should be 0.5mm larger than the final implant (see table below).

**SPECIFIC FOR PANTA® XL NAIL**

After each reaming with classical reamers (519011 to 519017) sequentially ream with the conical reamers 539020, 539021, 539022, 539023. e.g.: for a Panta® XL 11mm dia. nail insertion, ream with the standard 11mm diameter reamer, then with 11.5mm diameter reamer.

Finish the reaming with the 11.5mm diameter conical reamer (539020).

The final length of the implant is determined at this stage.

Check insertion with biplanar fluoroscopy and control the insertion depth using the position of the appropriate laser mark (150mm, 180mm, 210mm or 240mm) relative to the back surface of the outer sleeve.

Then proceed sequentially to the selected diameter of the nail.

Refer to corresponding table for PANTA® and Panta® XL nail

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<th>Nail diameter – Nail length</th>
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<td>11 mm • 150 mm</td>
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<td>12 mm • 150 mm</td>
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<td>-</td>
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<tr>
<td>13.5 mm</td>
<td>13 mm • 150 mm</td>
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SPECIFIC FOR 10 MM DIA. PANTA® NAIL

For the distal part of the 10mm diameter Panta® nail, start reaming with the 10.5mm diameter reamer (519014) then continue reaming only with the 11 + 11.5mm diameter reamer (519011) and do not go past the talus. (drilling length: 70mm). The new generation 11 & 11.5mm diameter reamers (519011 & 519015) have a «D10» marking (Fig. 6.2). Ream until this mark is at the level of the back surface of the outer sleeve (519030).
Check the reamer under fluoroscopy in the anteroposterior and mediolateral planes to verify satisfactory position within the medullary canal.

7. Nail insertion

Based on surgeon’s preference, step 7 can be performed one of two ways (7a or 7b).

7a. Nail insertion with support device

The guide wire has to be removed.

Open the final implant and remove the end cap.

**HINT**

- Insert the nail fixation axis.
- Engage the nail on the thread.
- Position the nail on the three support teeth.
- Finalize assembly.

1. Assemble the toothed wheel (519 121) to the nail fixation axis (519 120).

2. Introduce the assembly through the support device (519 110).

Position the implant on the nail fixation axis by aligning it with the three teeth on the support device.

This ensures the proper orientation of the screw holes.

Lock the implant to the support device by tightening the toothed wheel.

3. Remove the guide wire.

Holding the alignment of the arthrodesis, manually insert the nail assembly under fluoroscopic control.

**WARNING**

Do not discard the end cap.

(If the end cap is accidentally discarded or dropped, sterile packaged replacement end caps are available)

**WARNING**

Special care should be taken when handling the nail fixation axis (A). It is not attached to the support device and may fall out of the sterile field if accidentally dropped.

**WARNING**

To avoid the nail to toggle on the targeting device assembly, it must be properly tightened with the nail fixation axis (519120).
7b. Nail insertion and guide wire removal
Open the final implant and remove the end cap.

1. Insert the implant 2/3 of the way over the guide wire. Remove the guide wire.

2. Assemble the toothed wheel (519 121) to the nail fixation axis (519 120). Introduce the assembly through the support device (519 110).

3. Position the fixation axis by aligning it with the three teeth on the support device. This ensures the proper orientation of the screw holes. Attach support device to the implant by tightening the toothed wheel.

4. Complete insertion of the assembly.

8. Nail positionning

1. The arthrodesis sites must be satisfactorily aligned under direct vision as well as radiographically.

2. The arthrodesis sites are manually compressed.

3. The final position of the nail/support device assembly is determined based on multiple factors:
   – The anatomy of the arthrodesis,
   – Osseous structures,
   – The position of the proximal interlocking screw holes relative to position of the fibula (for example, if the tibial screws are placed from lateral to medial, the rod is rotated slightly to move the screw holes anterior to the fibula).

4. After final positioning ensure that the distal end of the nail is flush with the plantar cortex of the calcaneus.

A visual verification of the height is made under fluoroscopy by ensuring that the groove is inside of the calcaneus.

**WARNING**
Do not discard the end cap. (If the endcap is accidentally discarded or dropped, sterile packaged replacement end caps are available.)

**WARNING**
Special care should be exercised when handling the nail fixation axis (A). It is not attached to the support device and may fall out of the sterile field if dropped.

**HINT**
The vertical axis of the support device should appear to be pointed approximately to the head of the first metatarsus.

**HINT**
The groove between the axis and the distal end of the nail should be at or slightly above the plantar cortex.
9. Calcaneal pre-drilling

It is important to check that the nail fixation axis is properly tightened with the nail to avoid any misalignment with screws.

For easy identification, instruments concerning calcanea contain blue dots. They also correspond to the appropriate insertion holes on the support device.

1. Assemble the 4.3mm short drill guide (519 179) with the 7 mm short soft tissue protector (519 184). Place the soft tissue protector on the skin to precisely determine the incision point. Make the incision.

2. Insert the trocar awl (519 040) through the protection sleeves and into the posterior cortex of the calcaneus to prepare the bone for drilling.

10. Calcaneal drilling (1/2)

It is important to check that the nail fixation axis is properly tightened with the nail to avoid any misalignment with screws.

Using the 4.3mm short drill (519 003) drill the proximal hole.

Control the drill depth using fluoroscopy.

The surgeon may read the screw length from the calibrated drill bit (read from top of the guide).

The drill guides must contact the cortex to provide the accurate screw depth.

Read step 12 for measurement method.

Leave drill in place.
11. Calcaneal drilling (2/2)

It is important to check that the nail fixation axis is properly tightened with the nail to avoid any misalignment with screws.

Drill the distal hole with the 4.3mm long drill (519 006).

Control the depth with fluoroscopy.

The surgeon may read depth directly on drill bit.

12. Measurement method

Two depth measurement methods may be used to determine the correct screw length. If the graduated drill bit is used the inner sleeve must be in contact with the bone.

HINT
The graduated drill bit indicates the length of screw to be used. To get an accurate measurement from the drill, the inner sleeve must be in contact with the cortex. When the inner sleeves do not contact the cortex, the depth gauge should be used to verify the depth measurement.

HINT
When the short drill guide (519 179) do not contact the cortex. The medium soft tissue protector (519 183), the long drill guide (519 178) and the drills (519 002 & 008) are used instead of the regular ones.
13. Calcaneus fixation

1. Remove the distal drill after reading the length of the screw on the bit. Remove the drill guide, leaving the soft tissue protector in place.

   Assemble the hexagonal screwdriver tip with AO attachment (519 290) to the power drill.

2. Screws are inserted by hand or partially by power and then completed by hand.
   Screw insertion should be done using fluoroscopic control in perpendicular planes throughout the procedure.

3. Repeat these steps for the proximal screw.
   Control the insertion depth using fluoroscopy.

### SPECIFIC PARTIALLY THREADED SCREWS

For partially threaded screws only, use the tap (539 015) to prepare the head of the partially threaded screw in the bone. Screw down slightly up to the right laser mark (C7, C15 or C30 / M7, M15 or M30 depending on the used sleeves), corresponding to the screw head length. Then unscrew slightly the tap.

<table>
<thead>
<tr>
<th>Screw ref.</th>
<th>Screw length</th>
<th>Head length</th>
<th>Corresponding laser mark</th>
</tr>
</thead>
<tbody>
<tr>
<td>511 020 &gt; 511 040</td>
<td>20 &gt; 40 mm</td>
<td>7 mm</td>
<td>C7</td>
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<tr>
<td>511 045 &gt; 511 060</td>
<td>45 &gt; 60 mm</td>
<td>15 mm</td>
<td>C15</td>
</tr>
<tr>
<td>511 065 &gt; 511 110</td>
<td>65 &gt; 110 mm</td>
<td>30 mm</td>
<td>C30</td>
</tr>
</tbody>
</table>

**HINT**

When the “C” laser mark (or “M” with the use of the medium soft tissue protector 519 183) on the shaft of the screwdrivers is flush with the back face of the Soft Tissue Protector, the head of the screw is flush with the sleeve extremity.
14. Compression device

1. Remove the toothed wheel and put on the compression wheel (519 135) with the compression device (519 130). If one of the teflon rings (519 133) is missing, replace it with one of the extra rings in the instrument set.

2. Insert the compression device into the support device (the Newdeal® laser markings and the mm scale should face anteriorly; this will ensure that the scale can be read easily when the patient is in the supine position).

3. Zero out the compression wheel by turning it counterclockwise (so that the millimeter scale on the medial and lateral sides is no longer visible).

Recheck nail position under fluoroscopy.
15. Incisions for rods
For easy identification, instruments concerning compression rods contain green dots. They also correspond to the appropriate insertion holes on the support device.

Position two drill guides (519 181) on each side of the green dotted holes. Holes will be selected based on the final length of the implant (150mm, 180mm, 210mm and 240mm).

Make the incisions.

16. Proximal drilling
It is important to check that the nail fixation axis is properly tightened with the nail to avoid any misalignment with screws.

1. At this stage, the position of the foot with the tibia should be controlled and aligned at its final position.

Drill from the medial side if there is concern about hitting the fibula from the tibial side or drill through the fibula if a lateral approach is preferred.

Drill the proximal hole up to the second drill guide using the 5 mm diameter drill (519 005).

Leave it in place.

17. Distal drilling
It is important to check that the nail fixation axis is properly tightened with the nail to avoid any misalignment with screws.

Drill from the medial side if there is concern about hitting the fibula from the tibial side or drill through the fibula if a lateral approach is preferred.

Drill the distal hole with the second 5mm drill bit up to the coaxial drill guide.

18. Distal rod insertion
Remove the distal drill and introduce the compression rod using the T-handle.
19. Proximal rod insertion

1. Remove the proximal drill bit and insert the second compression rod using the T-handle.

2. Ensure that each rod is secured within both the medial and the lateral sleeves that pass through each arm of the compression device.

Remove the T-handle attachment.

20. Compression

Gently apply compression by turning the compression wheel clockwise. Up to 12mm of compression may be applied.

The compression can be visualized at any point using fluoroscopy.

Stop when desired compression is reached.

WARNING
Avoid over-compressing the arthrodesis sites! This may have adverse effects and impede removal of the compression rods.
21. Tibial screws incision
For easy identification, instruments concerning tibial and talus screws contain yellow dots. They also correspond to the appropriate insertion holes on the support device.

1. Assemble the long soft tissue protectors (519 185) (yellow dotted) with the long 4.3mm drill guides (519 180). Position the protector/sleeve assembly in the compression device according to the length of the nail to determine incision height. The screws can be placed from medial to lateral or lateral to medial in the tibia. The advantage of medial-to-lateral is that the insertion process passes through less soft tissue. The advantage of lateral-to-medial screw placement is greater soft tissue protection over the screw head. Make incision.

2. Insert the assembly into the yellow holes until the drill guide contacts the tibial cortex. The guide must contact the cortex to provide an accurate measurement of screw length when using the calibrated scale on the drill. Fluoroscopy is used to control the proper contact of the drill guide and the bone.

22. Tibial drilling
Drill from the medial side if there is concern about hitting the fibula from the tibial side or drill through the fibula if a lateral approach is preferred.

1. Use the proximal drill (519 004) for pre-drilling the proximal interlocking screws. Leave the drill bit in the guide.

2. Using the second 4.3 mm drill bit, drill the distal hole.

23. Tibial screws measurement
Read the screw length either from the calibrated drill bit (read from top of sleeve) or with the depth gauge (519 160).
See instructions for measurement Step 12.

HINT
The graduated drill bit indicates the length of screw to be used.
24. Tibial screws insertion

1. Remove the distal drill bit and its protection sleeve.

**SPECIFIC TO PARTIALLY THREADED SCREWS**
For partially threaded screws only, use the tap (539 015) to prepare the head of the partially threaded screw in the bone. It should be screwed down slightly up to the right laser mark (T7 or T15), corresponding to the screw head length. Then unscrew slightly the tap.

<table>
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<tr>
<th>Screw ref.</th>
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<th>Head length</th>
<th>Lasermark</th>
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<td>20 &gt; 40 mm</td>
<td>7 mm</td>
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</tr>
<tr>
<td>511 045 &gt; 511 060</td>
<td>45 &gt; 60 mm</td>
<td>15 mm</td>
<td>T15</td>
</tr>
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</table>

**HINT**
The “T” laser mark on the shaft flush with the soft tissue protector indicates that the head of the screw is flush with the bone.

2. Assemble the hexagonal screwdriver tip (519 290) to the power drill.

**SPECIFIC FOR PANTA® XL NAIL**
Only use the partially threaded screw (PTS) (ref. 511 020 to 511 110).

The screws may be inserted by hand or by power. Check each step of the screw insertion as noted above using fluoroscopy in perpendicular AP and lateral planes.

3. Remove proximal drill bit.

4. Proceed as described for the distal screw. Finalize locking manually with the screwdriver.
25. Talar screw (OPTIONAL)
An optional talar screw may be implanted after final fixation.

1. Assemble the long 4.3 mm drill guide (519 180) and the soft tissue protector (519 185), previously used for tibial screw preparation, and use the yellow color coded drill (519 004) to prepare the screw hole.

2. Control depth directly using the calibrated scale on the drill or with the depth gauge (519 160). Read the screw length from the calibrated drill bit (read from top of sleeve). See step 20 for measurement method.

3. Assemble the hexagonal screwdriver tip (519 290) to the power drill. The screw may be inserted by hand or partially by power and then completed by hand.

Check each step of the screw insertion as noted above using fluoroscopy in perpendicular AP and lateral planes.
26. Support device removal
Release the compression device several turns counterclockwise on the wheel to ease the tension on the compression rods. Removing the sleeves will further release the tension and facilitate removal of the compression rods.

1. Using the T-handle (519 021), remove all the compression rods (519 175), then drill guides and soft tissue protectors.

2. Reattach the toothed wheel to the nail fixation axis and unscrew it to release the compression device from the implant.

3. Remove the compression device (519 130) and the nail fixation axis (519 120) toothed wheel (519 121). In the same time, hold the support device ref (519 110) in place.

27. Guided end cap insertion

1. With the screwdriver (519 295) insert the end cap (500 001) in distal part of the Panta nail through the support device ref (519 110).

SPECIFIC TO PARTIALLY THREADED SCREWS
For Panta® and Panta® XL nails with partially threaded screws, use the end cap (510 005) with the screwdriver (519 295). The distal screw is locked by the end cap. The 510 004 can be inserted manually (out of the support device).

WARNING
Care should be taken to prevent the end cap from falling into the soft tissues.

28. Post operative recommandations
2 months of immobilization in a cast or stable walker-boot to get the fusion between the bones healed.

Partial weight bearing and after 6 weeks full weight bearing.

When a bone graft was used to fill bony defects a much longer healing time can be expected (up to 9 months).

Then weight bearing up to surgeons discretion.
## References

### Panta® Nails (sterile)

<table>
<thead>
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### Panta® XL Nails (sterile)

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<td>(optional) Short drill for calcaneus screws used with medium drill guide dia. 4.3 mm</td>
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<tr>
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<td>519 175</td>
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### Partially threaded screw (PTS) dia. 5 mm (sterile)

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<tbody>
<tr>
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### Fully threaded screw (FTS) dia. 5 mm (sterile)

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<td>501 027</td>
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## Instrumentation set

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<td>Cannulated drill dia. 9mm</td>
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<td>519 010 to 519 017</td>
<td>Reamers dia. 10mm to dia. 13.5mm (x7)</td>
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<td>3</td>
<td>519 020</td>
<td>Quick Coupling (optional)</td>
</tr>
<tr>
<td>4</td>
<td>519 028</td>
<td>Internal protection sleeve dia. 3.2 mm</td>
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<td>4</td>
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<td>External protection sleeve dia. 13.5mm</td>
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<td>5</td>
<td>519 032</td>
<td>Guide wire dia. 3.2 mm, L. 400 mm</td>
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<td>539 020 to 539 023</td>
<td>Conical Reamers dia. 10.5mm to dia. 13.5mm (x4) for Panta® XL nail</td>
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<tr>
<td>7</td>
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<td>Conical Reamer holder X2 (to be hang on the basis 519 910) for Panta® XL nail</td>
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<td>519 034 &amp; 519 034S</td>
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### Basis - Upper level

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<tr>
<td>6</td>
<td>519 003</td>
<td>Short drills dia. 4.3mm for calcaneus screws</td>
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<tr>
<td>7</td>
<td>519 004</td>
<td>Drill dia. 4.3mm for tibial screws (x2)</td>
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<td>519 006</td>
<td>Long drill dia. 4.3mm for calcaneus screws</td>
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<td>519 021</td>
<td>T-handle with AO attachment</td>
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<td>519 040</td>
<td>Trocar awl</td>
</tr>
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<td>11</td>
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<td>Support device</td>
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<td>519 160</td>
<td>Depth gauge</td>
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<td>519 175</td>
<td>Compression rods (x4)</td>
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<td>Short soft tissue protector dia. 7mm (x2)</td>
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<td>519 185</td>
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<td>519 295</td>
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### Basis - Lower level

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<td>Toothed wheel</td>
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<tr>
<td>21</td>
<td>519 130</td>
<td>Compression device</td>
</tr>
<tr>
<td>22</td>
<td>519 133</td>
<td>Teflon rings (x2)</td>
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<td>Compression wheel</td>
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<td>519 179</td>
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<td>Long drill guide dia. 4.3mm (x2)</td>
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<td>519 290</td>
<td>Hexagonal screwdriver tip dia. 3.5mm</td>
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<td>27</td>
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<td>Tap dia. 6.5mm</td>
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Instructions for use

INTRAMEDULLARY NAIL SINGLE USE

In the event of preoperative sterilization relative to medical devices and the amputation, this product must be handled and implanted by WELL-TRAINED AND QUALIFIED PERSONS, AWARE OF THESE DIRECTIONS FOR USE.

1 - Indications

The PANTA® Ankle Nail system consists of an interlocking fusion nail, interlocking screws and an cap. The PANTA® Ankle Nail is available in various diameters and lengths. The use of an interlocking fusion nail makes holes for locking on either side of the joint being fused.

These devices do not contain phalates unless this is indicated on the label.

2 - Indications

The PANTA® Ankle Nail system is intended for use in bilateral/ankle arthrodesis and treatment of trauma to the hindfoot and distal tibia. Examples include:

- Post-traumatic and degenerative arthritis involving both ankle and subtalar joints
- Rheumatoid arthritis
- Revision of failed ankle arthrodesis with subtalar involvement or with insufficient talus.
- Revision of failed total ankle arthroplasty with subtalar involvement
- Talar deficiency conditions (requiring a bilocular arthrodesis)
- Avascular necrosis of the talus
- Neoaisthepsy or neuropathic ankle deformity
- Soft tissue coverage as a result of a large ulcer, equinovarus, cerebral vascular accident, paralyse or other neurovascular disease
- Severe prior fracture with trauma to the subtalar joint.

3 - Contraindications

The implant should not be used in a patient who has currently, or who has a history of:

- Lack of general physical condition
- Active local or systemic infection
- Severe cardiovascular disease
- Severe neurological disease
- Severe deformity as a result of talipes equinovarus, cerebral vascular accident, paralysis or other neuromuscular disease
- Severe prior fracture with trauma to the subtalar joint.
- Insufficient quantity or quality of bone to permit stabilization of the arthrodesis
- Severe peripheral vascular disease
- Loss of fixation in bone
- Limb shortening or loss of anatomical position with malunion or rotation or angulation
- Deep or superficial infection
- Intertaloidal and radiological necrosis of the bone
- Sensitivity or other reaction to the device material
- Tissue reactions which include macrophage and foreign body reactions adjacent to implant.
- Pain, discomfort, or abnormal sensations due to the presence of the implant
- Hematoma or thrombosis
- Interference risks during medical imaging

The patient should be encouraged to receive prompt medical attention for any infection that could occur, whether at the operated-member level or elsewhere in the body.

4 - Warnings

Serious post-operative complications may occur from the use of the implant in who:

- Lacks good general physical condition
- Has immunological responses, sensitization, or hypersensitivity to foreign materials
- Systemic metabolic disorders

These implants are intended as a guide to normal healing and are not intended to replace normal body structure or bear the weight of the body in the presence of inremovable bone defect. Defected unions or nonunions in the presence of load bearing or weight bearing might eventually cause the implant to break due to meta fatigue.

5 - Precautions for use

Physician must determine if implant is appropriate for patients who have any of the following conditions:

- Drug and/or alcohol and/or smoke addiction and/or abuse
- Infections disease; malaria
- Local bone tumors;
- Compromised wound healing;
- Obesity;
- Demonstrated psychological instability, displayed a lack of understanding, motivation, or attitude;
- Unwillingness to accept the possibility of multiple surgeries for revision or re-operation;
- Lacks an understanding that a metallic implant is not as strong as normal healthy bone;
- Lacks bone density, bone loss, or excessive demand placed on it;
- Lacks an understanding that their preoperative capacity may not be fully recovered even after successful implantation;
- Knowledge of surgical techniques, proper reduction, selection and placement of implants, and post-operative patient management are considerations essential to a successful outcome.

Criteria for patient selection are the responsibility of the surgeon. Information concerning the patient and the bone to be treated should be taken into consideration by the selection process. Recognition of the appropriate indications and contraindications and the selection of the proper surgical procedures and techniques determined to be best for the responsibility of the surgeon. Each surgeon must evaluate the appropriateness of the procedure and instruments used during the procedure.
SURGICAL TECHNIQUE REMOVAL KIT

Integra™

Panta® – Panta® XL
Arthrodesis Nail System
NEWDEAL, as the manufacturer of this device, does not practice medicine and does not recommend this or any other surgical technique for use on a specific patient. The surgeon who performs any implant procedure is responsible for determining and using the appropriate techniques for implanting the device in each patient.

**Surgical technique**

1. **End Cap unscrewing**
   Remove the end cap using the screwdriver (309 645). The protection sleeve (119 552) may be used to find the nail extremity.

   A fluoroscopy control can be useful during this step.

2. **Calcaneal screws removal**
   Calcaneal screws (501 020 to 501 110 or 511 020 to 511 110) have to be removed first. Protection sleeves (119 552) may be used to locate the screw head. Using the screwdriver (309 645) remove both screws.

   In case of talar screw presence, remove it.

   Insert the « T » handle (519 210) into the nail. The sharp extremity enables to find out the cannula.

   Protection sleeve may be used.

3. **Tibial screws removal**
   As for the calcaneal screws, the tibial screws (501 020 to 501 110 or 511 020 to 511 110) have to be removed using the screwdriver.
4. Nail removal with the « T » handle
Break possible bony bridge by turning the «T» handle.

Then pull the «T» handle to remove the nail.

4 bis. Nail extraction with the sliding hammer
In case of hard bone, the sliding hammer might be used. Attach the sliding hammer to the «T» handle while holding the assembly.

Slide the hammer in axial until the bony bridges are broken and the nail extracted.
In accordance with the directive 93/42/EEC relative to medical devices, every product must be handled by well-trained and qualified persons. Awareness of these directions for use. These instruments are intended for use in surgery, and should be used only for the intended use of associated Newdeal® products. None of the instruments should be implanted. Only medical professionals who are thoroughly familiar with the instrument’s function, application, and use should use them in surgery. Only a surgeon qualified to perform the orthopedic surgery required by the particular patient should use the surgical instruments. Unless labelled for single use, this instrument may be re-used. However, active superabrasive tools should not be reused. Improper maintenance, handling, or poor cleaning procedures can render the instrument unsuitable for its intended purpose, or even dangerous to the patient or surgeon. Products are sold either sterile or non-sterile.

Packaging (product sold STERILE only) Instruments manufactured by Newdeal and sold sterile have been sterilized by gamma radiation or using ethylene oxide (ETO). The sterilization method is specified on the packaging. Components sterilized by radiation are exposed to a minimum of 25 kGy of gamma irradiation. The products considered to be non-sterile can be (re)sterilized unpacked before use, in compliance with current regulations.

Check packaging and labeling integrity before use. The sterilization is guaranteed as long as the packaging has not been damaged (film scratched, label missing, questionable packaging), and before the end of the sterility validity.

Do not use any product for which the packaging has been opened or damaged outside the operating theatre.

Instruments should be packaged under sterile conditions (sterile storage and transportation). This means that all instruments and their accessories should be: appropriate for sterilization and packaging (sterile), at the correct temperature and humidity (dry), at the correct storage period (sterile), and stored in a manner that prevents damage.

Recommendations for (re)sterilization: Instruments sterilized in an autoclave, are considered for reuse if they can be re-cleaned and disinfected. Instruments sterilized using ETO are not considered for reuse. Newdeal recommends to use the instruments as indicated by the manufacturer of the hospital’s equipment.

Handling and reprocessing (NON-STERILE product or considered to be) Check the integrity of the packaging and labeling before opening the package. Remove all the products from their packaging prior to sterilization. All products should be cleaned, decontaminated, and sterilized before use. Always use the instruments as recommended by the manufacturer of the hospital’s equipment.

- Preparation: Double instruments (as internal screwdriver and associated external screwdriver) should be separated prior to cleaning.
- Cleaning: Cleaning can be performed manually, automatically or ultrasonically in accordance with the specifications designated by the manufacturer of the hospital’s equipment.
- Manual cleaning: Manual cleaning consists of using alkaline-free cleansers (neutral or alkaline), applied with a soft brush, taking special care to threaded parts and parts difficult to reach. Certain solutions such as those containing bleach or formaldehyde may damage the devices, and they must not be used. Use of metallic brushes or other abrasive products is also forbidden. Cleaning should be immediately followed by profusely rinsing with deionized water. Check that water flows out with no remaining parts.
- Automatic cleaning: Automatic cleaning is performed in a cleaning/drying cycle using machine neutral cleansers, with a cleaning cycle of 3 minutes minimum and a rinsing cycle of 3 minutes. Check the complete removal of visible dirt, especially in the cannulated parts of the instrument. The instrument’s exterior must remain dry. Check that water flows out with no remaining parts.
- Drying: 40 minutes minimum, followed by a 20 minutes “cracked*” phase to allow the instrument to return to a period of 20 minutes in which the sterilizer door is opened approximately 6 inches (15 cm) while the tray remains inside. These sterilization parameters assume that all instruments have been properly decontaminated prior to sterilization. The parameters are validated to sterilize superabrasive tools as stated in the tray markings. If other instruments are added to the tray or to the sterilizer, the recommended parameters may not be valid and new cycle parameters may need to be validated by the user. The autoclave must be properly installed, maintained, and calibrated.
- Other sterilization methods and cycles may also be used. However, individuals or hospitals not using the recommended method are advised to validate the alternative method using appropriate laboratory techniques. ISO-sterilization of cold-sterilization techniques are not recommended.

- Examination: Instruments must always be examined by the user prior to use in surgery. Examination should be thorough, and in particular should take into account the presence of any cracks, bends, or distortions, and that all components of the instrument are complete.

- NeXdeal instruments are designed for use on the inside of surgical instruments. NeXdeal instruments should not be used without the appropriate corresponding NeXdeal K-wire inside the cannulated parts.

- Minimize the tissue contact to avoid possibility of burns.

- The active surgical instrument must not be used for any purpose other than its intended use in the orthopedic surgical procedure.

- The active surgical instrument must not be modified.

- Resharpening of active surgical instrument should not be performed under any circumstances.

- Contact with other metal objects could cause damage to the active surgical instrument and may necessitate replacement.

- Newdeal informs the surgeon that repeated uses of the active surgical instrument can lead to incidents which would compromise the surgical technique or the results of the procedure.

- Newdeal does not practice medicine and does not recommend any specific surgical technique.

- It is the surgeon’s responsibility to select the appropriate surgical technique and instruments for each individual patient, in accordance with the surgeon’s practice, experience, training, standard of care and knowledge of the relevant medical literature. Newdeal is not responsible for selection of the appropriate surgical technique to be used for an individual patient.

- Criteria for patient selection are the responsibility of the surgeon. The surgeon should discuss with the patient prior to surgery possible risks, precautions, warnings, consequences, complications, and adverse reactions associated with the surgical procedure and device being implanted in the surgical procedure. The surgeon should refer to the instructions for use accompanying the device.

- Information contained within this document should be taken into consideration during the selection process. Recognition of the appropriate indications and contraindications and the selection of the proper surgical procedures and techniques determined to be best for the patient are the responsibility of the surgeon.

- Each surgeon must evaluate the appropriateness of the procedure and instruments used during the procedure based on his or her own training and experience.

- Information: Should any information regarding the products or their uses be required, please contact your representative or distributor or directly contact the manufacturer. Surgical technique: Panta® – Panta® XL

# Panta® Nail removal kit description
1 219 209 Sliding hammer
2 219 210 Handle extractor
3 309 645 Screwdriver Hex Dia 3.5mm
4 119 552 Protection sleeve
5 919 950 Container including the following components:
- Lid (not shown)
- Basis
- 996 100
Bibliography – Not exhaustive list

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The Journal of Foot and Ankle Surgery • Volume 23, n° 11:992-995 • 2002

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Foot and Ankle International • Volume 22, n° 9:731-733 • 2001

Tibiotalocalcaneal arthrodesis
Foot and Ankle International • Volume 21, n° 10:804-808 • 2000

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Stress fractures and tibial cortical hypertrophy after tibiotalocalcaneal arthrodesis with an intramedullary nail
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Ankle arthrodesis in rheumatoid arthritis using an intramedullary nail with fins
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Berend M, Glisson R, Nunley J
A biomechanical comparison of intramedullary nail and crossed lag screw fixation for tibiotalocalcaneal arthrodesis
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Pinzur M, Kelikian A
Charcot Ankle Fusion with a Retrograde Locked Intramedullary Nail
Foot and Ankle International • Volume 18, n° 11:699-704 • 1997

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