ST SURGICAL TECHNIQUE

MEDSHAPE® DYNANAIL MINI®
ACTIVE, ADAPTIVE HEALING FOR MEDIAL COLUMN FUSION
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DJO® is a manufacturer of orthopedic implants and does not practice medicine. This surgical technique was prepared in conjunction with licensed health care professionals and is presented to demonstrate the surgical techniques utilized by Kent Ellington, MD (Charlotte, NC). The treating surgeon is responsible for determining the appropriate treatment, technique(s), and product(s) for each individual patient.

See package insert for complete list of potential adverse effects, contraindications, warnings and precautions.

A workshop training is recommended prior to performing your first surgery. All non-sterile devices must be cleaned and sterilized before use.

Multi-component instruments must be disassembled for cleaning. Please refer to the corresponding assembly/disassembly instructions, if applicable. Please remember that the compatibility of different product systems has not been tested unless specified otherwise in the product labeling.

The surgeon must discuss all relevant risks including the finite lifetime of the device with the patient.
WHY DYNA NAIL MINI® FOR MEDIAL COLUMN FUSION?

Midfoot reconstruction procedures represent a significant clinical challenge, particularly in Charcot neuropathic patients given the compromised bone healing capacity and poor bone quality inherent to the condition. Internal beaming devices are often used in surgery to fixate the corrected deformity and promote fusion, but current beams have reported high nonunion and complication rates, often resulting in amputation.

The DynaNail Mini® Fusion System in extended lengths was designed for use in midfoot reconstruction procedures and features patented and proven superelastic Internal NiTiNOL Compressive Element technology now miniaturized to accommodate smaller bone anatomy. Unlike traditional beaming devices that lose compression within 1 mm of bone resorption, the DynaNail Mini is the only internal fusion device that maintains active compression post-surgery in response to bone resorption or settling. The Nail Implant is available in multiple length offerings, with the amount of available post-operative NiTiNOL compression increasing with Implant length up to almost 6 mm. In addition, manual compression can be applied during the surgery to further tightly appose the fusion surfaces.

The DynaNail Mini is provided with the NiTiNOL Element pre-stretched and pre-loaded on a disposable Nail Guide. Two Transverse Headless Screws in the talus and metatarsal are then placed to allow for improved rotational stability and decrease the risk of implant migration. The system also features a rigid, radiolucent carbon fiber-filled polyether ether ketone (PEEK) Targeting Frame that is used to precisely position the Nail Implant across the joints and accurately drill and place the Screws.

INDICATIONS
DYNANAIL MINI® FUSION SYSTEM
The DynaNail Mini® Fusion System is indicated for:
• Fracture fixation.
• Osteotomies.
• Reconstruction procedures.
• Non-unions.
• Fusions of large bones in the foot and ankle.

CONTRAINDICATIONS
DYNANAIL MINI FUSION SYSTEM
The DynaNail Mini Fusion System is contraindicated for:
• Patients with an active local or systemic infection.
• Patients with an active soft tissue infection or osteomyelitis of foot and ankle.
• Patients with severe peripheral vascular disease.
• Patients with an obliterated medullary canal or other conditions that tend to retard healing, such as blood supply limitations or previous infections.
• Skeletally immature patients where the implant would cross open epiphyseal plates.
• Patients with a dysvascular limb.
• Patients with an insufficient quantity or quality of bone to permit fusion of the joints or stabilization of the arthrodesis.
• Patients with conditions that restrict their ability or willingness to follow post-operative instructions during the healing process.
• Patients with suspected foreign body sensitivity, or documented metal allergy or intolerance. Where material sensitivity is suspected, appropriate tests should be conducted and sensitivity ruled out prior to implantation.
### TECHNICAL SPECIFICATIONS

#### NAIL IMPLANT
Available in 7 mm diameter and 110 - 140 mm lengths in 10 mm increments.

![Diagram of MedShape® DynaNail Mini®](image)

#### HEADLESS SCREW
- Length: 14 mm - 40 mm, available in 2 mm increments
- 3 mm Hex Drive

![Diagram of Headless Screw](image)

#### END CAP
- 2 mm Hex Drive
- Available in +3 and +6 mm Head heights

### AMOUNT OF POST-OPERATIVE COMPRESSION BY IMPLANT LENGTH

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ACCESSORY INSTRUMENTATION
The DynaNail Mini® Targeting Frame is made of high-strength, rigid carbon fiber PEEK to provide accurate drill targeting and placement of screws along with excellent visibility of the surgical site under fluoroscopy.

Frame Operational Features

1. Retention Knob: Turn clockwise to secure the Nail Implant onto the Targeting Frame.

2. Targeting Frame: Use to insert the Nail Implant and provide accurate placement of transverse Headless Screws.


5. Step Numbers: Indicate order of steps involving the Targeting Frame.
The DynaNail Mini® Fusion System maintains active compression using its proprietary internal NiTiNOL Compressive Element that automatically responds to changes in loading due to bone resorption or settling. The unloading of the Compressive Element can be visualized on fluoroscopy via translation of the screw holes in the Sliding Element through the slot in the Outer Body. This is best visualized on anterior-posterior radiographs.

**OUT OF THE PACKAGE**
The DynaNail Mini is provided with the NiTiNOL Compressive Element pre-stretched and pre-loaded on the disposable Nail Guide.

**IMMEDIATE POST-SURGERY**
Once the Targeting Frame is removed, the Compressive Element is now in its stretched, activated position with the metatarsal Screw oriented in the distal end of the slot and the Sliding Element extending distally from the Nail Body.

**WEEKS TO MONTHS POST-SURGERY**
As the compressive element unloads (i.e. recovers its stretched length) in response to bone resorption or settling, the metatarsal Screw will progressively shift proximally. The Compressive Element has completely unloaded when the metatarsal Screw is at the proximal end of the slot and the transparent region is no longer visible.
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The following is a general overview of the DynaNail Mini® Medial Column Fusion Surgical Technique intended to be used as an easy reference. A more detailed surgical technique including technical tips and pearls is described in the following pages.

Numbers in brackets in bold correspond to the numbers marked on the frame and are intended to be used as a guide for the order of steps taken with the DynaNail Mini Targeting Frame.

1. Insert Guidewire.
2. Ream entry canal to the diameter size of the selected Nail.
3. Determine Nail length using Implant Trial.
4. Assemble Targeting Frame and attach Nail Implant.
5. Insert Nail Implant into reamed canal.
6. Drill and insert Headless Screw across the talus. [1]
8. Drill and insert Headless Screw across the first metatarsal. [3]
1. SURGICAL APPROACH

With the foot in a neutral plantigrade position, make a medial incision along the axis of the medial column to expose the medial column joints. Identify and avoid the tibialis anterior tendon during the procedure. Perform osteotomies as needed to correct any deformities and properly align the foot. Utilize K-wires to provisionally fixate the foot in the proper neutral plantigrade position during the procedure, if necessary.

2. JOINT PREPARATION

Instruments used:

1. Fenestration Drill, 2.5 mm (24)
2. Soft Tissue Protector (23)

Joints should be resected and prepared. Debride the tarsometatarsal (TMT), naviculocuneiform (NC) and talonavicular (TN) joints until there is exposed bleeding subchondral bone. Leave the overall contours of the bones intact. Once all cartilage is removed, use a sharp osteotome to “fish-scale” the facets. The 2.5 mm Fenestration Drill can be used to aid in creating bleeding bone and feathering the joint surface (FIGURE 1). Assure that the bleeding bone surfaces are in apposition before proceeding. Place any graft material if desired.
GENERAL PROCEDURAL STEPS WHEN PERFORMING BOTH MEDIAL COLUMN AND SUBTALAR FUSIONS
When performing both the medial column and subtalar procedures, it is recommended to follow the below steps.

**Step 1**
Insert the Guidewire for the subtalar procedure. On the lateral view, aim the Guidewire anterior to the fibula and toward the anterior third of the talar body.

On A-P fluoroscopy, the Guidewire should be slightly biased lateral in the talus to leave space for the medial column Guidewire.

**Step 2**
Insert the Guidewire for the medial column procedure. Refer to p. 12 for further instruction.

Check Guidewire placement in all three planes for proper placement and foot alignment before proceeding to the reaming step. The subtalar and medial column Guidewires in the talus should be positioned a far enough distance apart to accommodate for the diameter of the selected Reamer.

**Step 3**
Insert the Nail Implant for the subtalar procedure. Follow the DynaNail Mini® Subtalar Surgical Technique Guide for detailed steps.

**Step 4**
Insert the Nail Implant for the medial column procedure. Refer to p. 18 for further instruction.
3. PLACE THE GUIDEWIRE

Instruments used:

1. Guidewire, 2.4 mm x 229 mm (10)

Expose the 1st metatarsal head by making a dorsal incision. Plantarflex the 1st metatarsal phalangeal (MTP) joint and insert the 2.4 mm Guidewire into the articular surface of the 1st metatarsal head into the medial column. Advance the Guidewire into the 1st metatarsal intramedullary canal and follow the canal trajectory through the cuneiform, navicular, and into the talus (FIGURE 2). Use fluoroscopy while advancing the Guidewire until the tip of the wire is in the desired implant position in the talus.

**TIP:**
- Insert the Guidewire slightly above the center of metatarsal head.
- The Guidewire should not penetrate the posterior cortex of the talus. It is recommended to keep the Guidewire behind the halfway point of the talar body.

**GUIDEWIRE PLACEMENT TIP:**
- On the lateral view, aim the Guidewire through the center of the intramedullary canal toward the talar head.
- On the A-P view, ensure that the Guidewire follows the intramedullary canal of the 1st metatarsal, cuneiform, navicular, and talus. Be careful to NOT breach the medial cortex.
3. OPTIONAL: MEASURE GUIDEWIRE DEPTH

Instruments used:

1. Guidewire Depth Gauge (28)

Place the Guidewire Depth Gauge onto the Guidewire and rest firmly against the metatarsal head (FIGURE 3). Read the length from the end of the Guidewire.
4. REAMING ENTRY CANAL

Instruments used:

1. Soft Tissue Protector (23)
2. Cannulated Drill/Reamers, 5 mm - 8.5 mm (11-15)

Place the Soft Tissue Protector over the Guidewire against the distal aspect of the first metatarsal. If desired, the 5 mm Cannulated Drill may first be used to gain entry through the metatarsal. Then, select the Cannulated Reamer that is the same size as the selected Nail diameter and insert over the Guidewire into the Soft Tissue Protector. Drill over the path of the Guidewire until the proximal tip of the Drill nears the end of the Guidewire (FIGURE 4).

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**TIP:**

Use fluoroscopy while reaming to ensure that the Cannulated Drill or Reamer is not advanced further than the Guidewire and there is sufficient cortex remaining to avoid damaging the bone due to over reaming.

---

**FIGURE 4**
5A. DETERMINING NAIL IMPLANT LENGTH

Option 1

Instruments used:

1. Cannulated Drill/Reamers, 5 mm - 8.5 mm (11-15)

Lasermarks on the Reamer may be read off the back of the Soft Tissue Protector to get an initial length estimate (FIGURE 5). Subtract 40 mm from the lasermark reading to determine the necessary Nail Implant length.

TIP:

Select a Nail length that is at least 10 mm shorter than the tunnel depth to allow the Implant to be inserted sub-flush and to accommodate for manual compression.
5B. DETERMINING NAIL IMPLANT LENGTH
Option 2 (Recommended)

Instruments used:

1. Implant Trial, 110 - 140 mm (17)

Remove the Drill and insert the Implant Trial into the reamed tunnel (FIGURE 6).

**TIP:**
If the Implant Trial is inserted over the Guidewire, the size marks may not be visible. In such cases, remove the Guidewire. If necessary, the Guidewire can be reinserted through the Implant Trial after Implant Length is determined.

Ensure that the proximal screw hole of the Implant Trial is aligned with the talar neck (A). Use the etched lines on the distal end of the Implant Trial to determine the appropriate position of the distal end of the Implant in the metatarsal. The numbers on the Implant Trial correspond with the notch below and indicate the associated Nail length (i.e. "13" = 130 mm) (B).

**TIP:**
Select a Nail Implant length that is at least 10 mm shorter than the tunnel depth to allow the Nail Implant to be inserted sub-flush and to accommodate for manual compression.
6. IMPLANT ATTACHMENT

Instruments used:

1. Targeting Frame (5)
2. Retention Knob (6)
3. Bone Apposition Sleeve (7)
4. Compression Knob (8)
5. DynaNail Mini® Implant

Attach the pre-stretched DynaNail Mini Implant Assembly onto the Targeting Frame and turn the Retention Knob clockwise to securely tighten. Thread the Bone Apposition Sleeve onto the Compression Knob by turning counter-clockwise until it stops (A). With the Bone Apposition Sleeve oriented up, advance the Manual Compression Knob over the DynaNail Mini Assembly and down past the ball bearing until it clicks into place (FIGURE 7).

TIP:

Before inserting the Nail Implant, check the drill targeting by inserting the Guide Sleeve, Drill Guide, and 4 mm Drill into the appropriate hole in the Targeting Frame and advance the Drill until it passes through the proximal screw hole in the Nail Implant.

FIGURE 7
7. IMPLANT INSERTION

Instruments used:

1. Targeting Frame (5-8)

Insert the DynaNail Mini® implant into the reamed canal such that the Arm of the Targeting Frame is on the medial side of the foot (FIGURE 8). If necessary, lightly mallet on the Retention Knob to help advance the implant. Do NOT mallet on any other part of the Targeting Frame besides the Retention Knob.

**TIP:**
Check DynaNail Mini Implant positioning on A-P and lateral fluoroscopy before proceeding to the next step.

**IMPLANT PLACEMENT TIP:**
On lateral fluoroscopy, ensure that the proximal screw hole aligns with the talar neck. The distal end of the DynaNail Mini Implant should be at least 10 mm sub-flush in the 1st metatarsal to accommodate the internal Compressive Element and manual compression. The distal end of the Nail can be visualized as a translucent area in the Nail Connection Guide on lateral fluoroscopy.
8. PROVISIONAL FIXATION OF FRAME

Instruments used:

1. Steinmann Pin, 2 mm x 9" (qty 2) (9)

Provisionally fixate the Targeting Frame by drilling two Steinmann Pins through the small holes in the Targeting Frame anterior and posterior to the intended hole for drilling the talar screw hole (FIGURE 9).
9. DRILLING FOR TRANSVERSE TALAR SCREW

Instruments used:

1. 6.5 mm Guide Sleeve (20)
2. 4.0 mm Drill Guide (21)
3. 4.0 mm Transverse Screw Drill (18)

Insert the 6.5 mm Guide Sleeve into the appropriate hole on the Targeting Frame corresponding to the selected Nail Implant length. Make an incision where the Guide Sleeve contacts the skin.

Insert the 4.0 mm Drill Guide into the Guide Sleeve. Do NOT rest the Drill Guide on the bone as this may alter the drilling trajectory.

Insert the 4.0 mm Transverse Screw Drill through the Drill Guide and drill through the proximal screw hole of the Nail Implant to the lateral cortex (FIGURE 10). Use A-P fluoroscopy to ensure full drill depth has been reached. Advance the Drill Guide against the bone prior to the next step.

**TIP:**

Do NOT advance the Drill tip beyond the lateral cortex such that the drill extends past the taper. The end of the Headless Screw is tapered and will lose purchase on the far cortex if over drilled.
10. MEASURING SCREW LENGTH

Instruments used:

1. Screw Depth Gauge (19)

There are two methods for determining the appropriate screw length:

Option 1
With the Drill Guide abutted to the bone, read the lasermarks on the Drill off the back of the Drill Guide (FIGURE 11).

TIP:
Use A-P fluoroscopy to confirm the Drill has reached the lateral cortex before reading the lasermarks.

Option 2
The Screw Depth Gauge may be inserted through the Drill Guide (FIGURE 12). Ensure the Drill Guide is abutted against the bone and the Depth Gauge hooked to the lateral cortex of the talus (A). Then read the lasermarks on the Depth Gauge off the back of the Drill Guide (B).
11. TRANSVERSE TALAR SCREW INSERTION

Instruments used:

1. 3.0 mm Hex Driver (3)
2. Blue-Handle Ratchet Driver (4)
3. Headless Screw

Attach the 3.0 mm Hex Driver to the Blue-Handle Ratchet Driver. Remove the 4.0 mm Drill and Drill Guide from the Guide Sleeve. Place the Headless Screw onto the 3.0 mm Hex Driver and insert into the Guide Sleeve (FIGURE 13).

The Headless Screw does not provide any tactile feedback to indicate when it is fully inserted. When the lasermarking on the Hex Driver approaches the back of the Guide Sleeve, use A-P fluoroscopy while advancing the final turns, ensuring the Screw tip does not extend beyond the lateral cortex of the talus. Remove the Hex Driver and Guide Sleeve from the Targeting Frame.

**TIP:**

Do NOT use power for screw insertion.
12. APPLY MANUAL COMPRESSION

Ensure the incision is big enough for the Bone Apposition Sleeve to butt against the bone before applying manual compression. To apply manual compression, turn the Manual Compression Knob clockwise in the direction indicated by the arrows on the Knob (FIGURE 14).

The approximate amount of manual compression applied can be determined by reading the laser markings on the Bone Apposition Sleeve of the Targeting Frame (A) and taking the difference before and after applying manual compression.

**NOTE:**

The Manual Compression Knob will disengage from the Targeting Frame once the distal end of the Nail Implant has reached the posterior cortex of the talus to prevent the Nail Implant from being positioned outside the bone.
13. METATARSAL SCREW DRILLING

Instruments used:

1. 6.5 mm Guide Sleeve (20)
2. 4.0 mm Drill Guide (21)
3. 4.0 mm Transverse Screw Drill (18)
4. 3.0 mm Hex Driver (3)
5. Blue-Handle Ratchet Driver (4)
6. Headless Screw

Insert the 6.5 mm Guide Sleeve and 4 mm Drill Guide into the distal hole on the Targeting Frame. Follow the same technique outlined in Steps 9 – 11 to drill a pilot hole and determine proper screw length (FIGURE 15).

Insert a 4.0 mm Headless Screw using the 3.0 mm Hex Driver ensuring the Screw is bicortical but not breaching past the lateral cortex of the 1st metatarsal (A). Remove the Guide Sleeve.
14. RELEASE NAIL
Instruments used:

1. 2.0 mm Hex Driver (2)
2. Blue-Handled Ratchet Driver (4)

Load the 2.0 mm Hex Driver onto the Blue-Handle Ratchet Driver and insert through the Retention Knob attaching to the Connection Screw (FIGURE 16). Turn the 2.0 mm Hex Driver counter-clockwise to release the Connection Screw from the Sliding Element (A) and activate the NiTiNOL Compressive Element.
15. ADD ENDCAP

Instruments used:

1. 2 mm T-Handle Driver (1)
2. End Cap

Select the desired End Cap size and place onto the end of the 2.0 mm T-Handle Driver (FIGURE 17). Thread the End Cap into the distal end of the Sliding Element in the Nail Implant (A) until finger tight.
15. FINAL ASSESSMENT
Check final positioning of nail using both A-P and lateral fluoroscopy.

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<td>2600-05-0003</td>
<td>END CAP, +3MM OFFSET</td>
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<td>2600-05-0006</td>
<td>END CAP, +6MM OFFSET</td>
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