



SURGICAL
TECHNIQUE

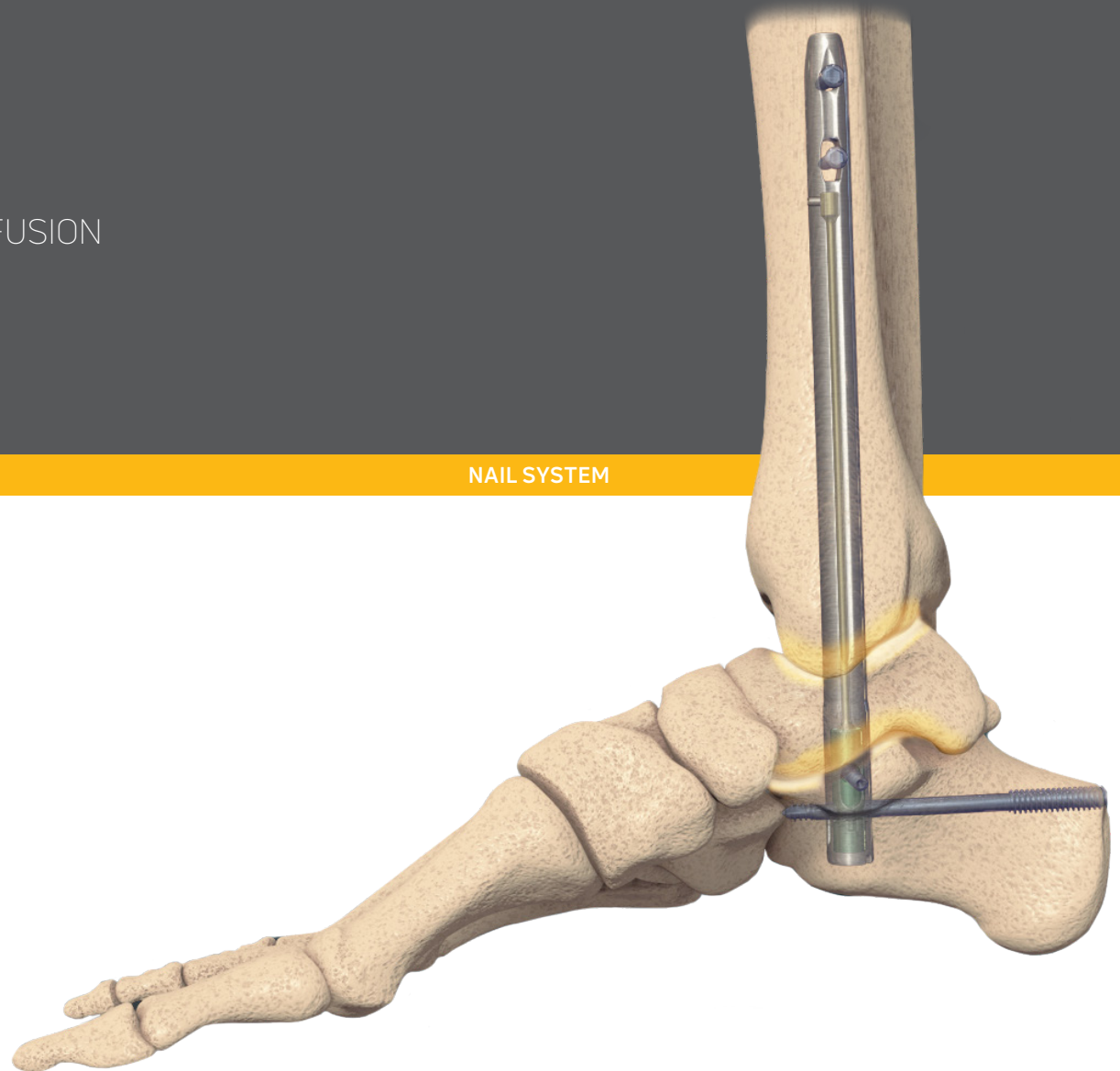


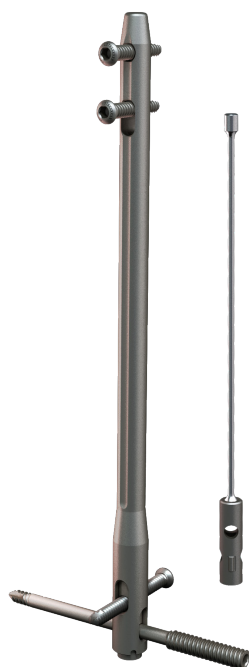
MEDSHAPE®

DYNANAIL®

ACTIVE, ADAPTIVE HEALING FOR TTC FUSION

NAIL SYSTEM





**THE ONLY
INTRAMEDULLARY
NAIL WITH THE
COMPRESSIVE POWER
OF AN EXTERNAL
FIXATOR**

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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. This brochure is presented to demonstrate the surgical techniques utilized by Thomas P. San Giovanni, M.D. 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 DYNANAIL® FOR TTC FUSION?

Tibiototalcalcaneal (TTC) fusion surgery is performed to relieve pain and correct severe foot deformity by achieving solid bony union, often the only remaining treatment option before limb amputation.

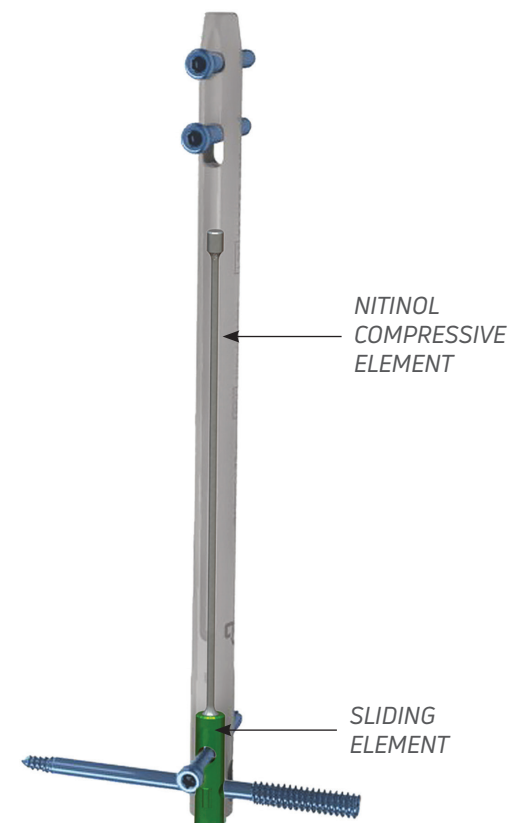
According to the Association for the Study of Internal Fixation principles, compression across a fusion site is important for promoting bone healing and achieving a solid union. Compression also provides stability by maximizing bone-to-bone contact and limiting micro-motion. External fixation frames allow for compression to be applied and adjusted during the course of treatment, but these systems are surgically complex, associated with poor patient compliance, and have a relatively high rate of pin tract infections. Intramedullary (IM) nails provide rigid, internal fixation and are less invasive and technically demanding to implant than external frames. Traditional IM nails apply external manual compression at the time of surgery, but compression is lost once the instrumentation is removed. Third-generation IM nails contain an internal compression mechanism that helps maintain compression after instrument removal; however, these nail systems lose compression over time post-surgery due to bone resorption and joint settling¹

The DynaNail TTC Fusion System is the only fusion approach that offers the compression-sustaining performance of an external fixator inside an intramedullary nail. Due to its proprietary Internal NiTiNOL Compressive Element, DynaNail provides sustained, active compression to the bones, maintaining them in close apposition while also providing immediate dynamization. Clinical results show this maintained active compression allows for faster fusion times in more challenging patient populations compared to other IM nails.²

The DynaNail TTC Fusion System is available in different diameters and lengths to accommodate varying patient anatomies. The Compressive Element is housed inside a rigid outer titanium body with a 7 mm locking End Cap. The system also features the DynaFrame™ CF Deployment System, a rigid, radiolucent carbon fiber-filled polyether ether ketone (PEEK) Targeting Device that is used to precisely position the Nail Implant across the joints, stretch the Compressive Element, and then accurately drill and place the screws. Housed in a single sterilization tray, the DynaFrame and accompanying instrumentation provides the surgeon with a simple, reliable surgical approach.

1. Yakacki et al. Pseudoelastic nailing for tibio-talo-calcaneal arthrodesis. *Expert Rev Med Devices*, 2011; 8(2):159-166.

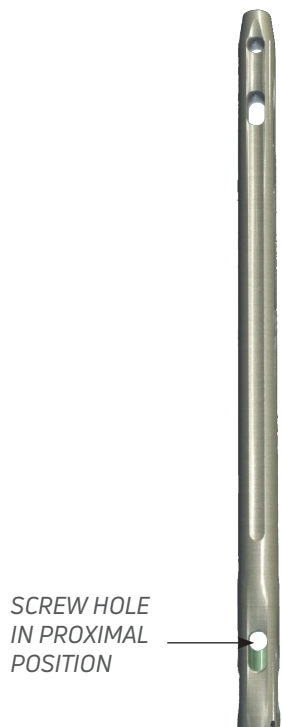
2. Steele JR, et al. Comparison of TTC Arthrodeses Using a Sustained Dynamic Compression Nail vs Nondynamized Nails. *Foot & Ankle Spec*, 2020; 13(3): 193-200.



The DynaNail® TTC Fusion System maintains active compression across the joints using its proprietary internal NiTiNOL Compressive Element that automatically responds to changes in loading due to bone resorption or settling. The stretching and 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.

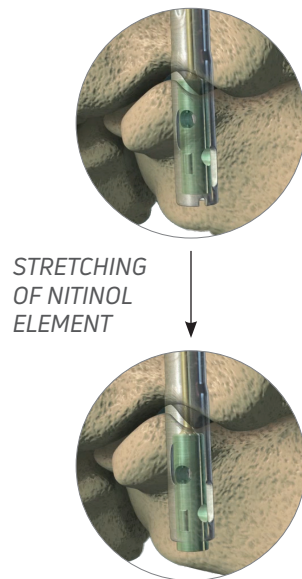
OUT OF THE PACKAGE

The Compressive Element is in its unstretched position with the calcaneal screw holes in the Sliding Element positioned proximal in the Nail Body slot.



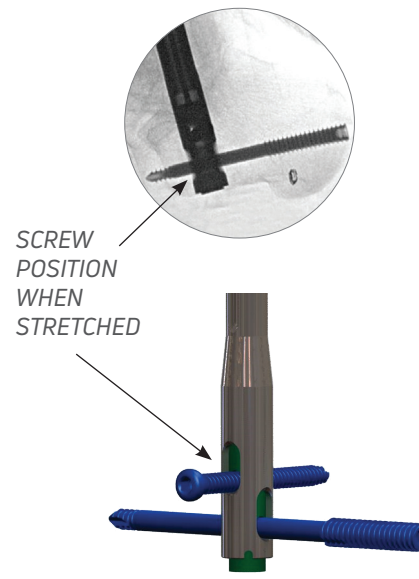
DURING SURGERY

The Compressive Element is stretched using the DynaFrame™ Deployment System, causing the calcaneal screw holes to shift distally in the Nail Body slot, a distance that corresponds to the amount of desired compression. While the DynaNail Frame holds the Compressive Element in the stretched position, screws are placed in the calcaneus and tibia.



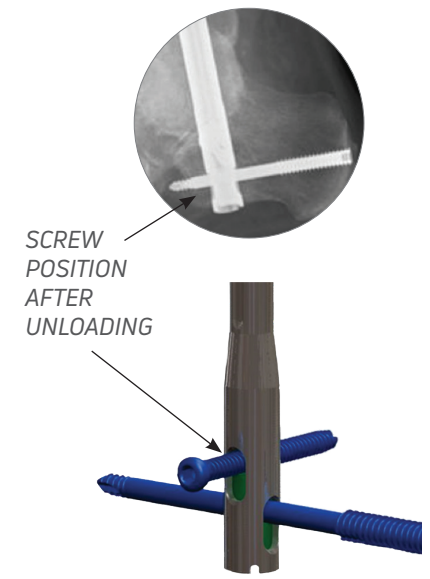
IMMEDIATE POST-SURGERY

Once the DynaFrame is removed, the Compressive Element is in its stretched activated position with the calcaneal screws oriented in the distal end of the slot and the Sliding Element extending plantarly from the Nail Body.

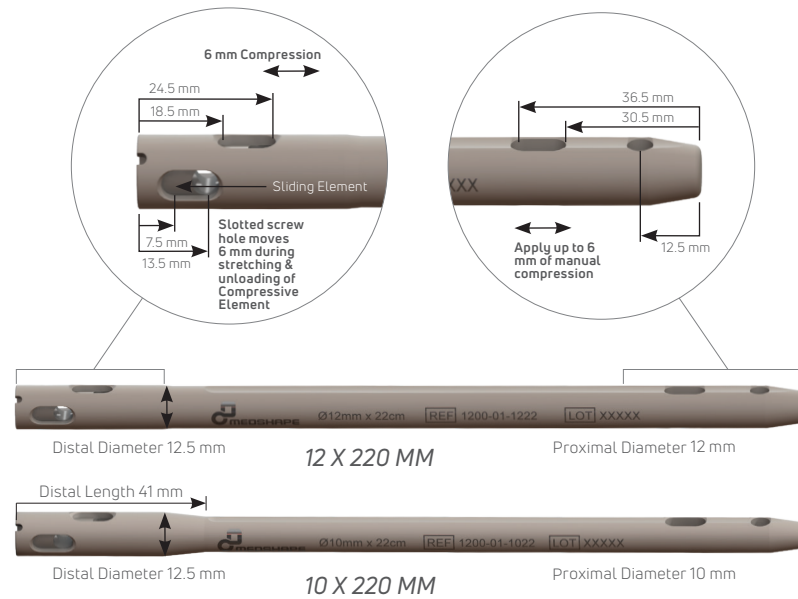


POST-OPERATIVELY

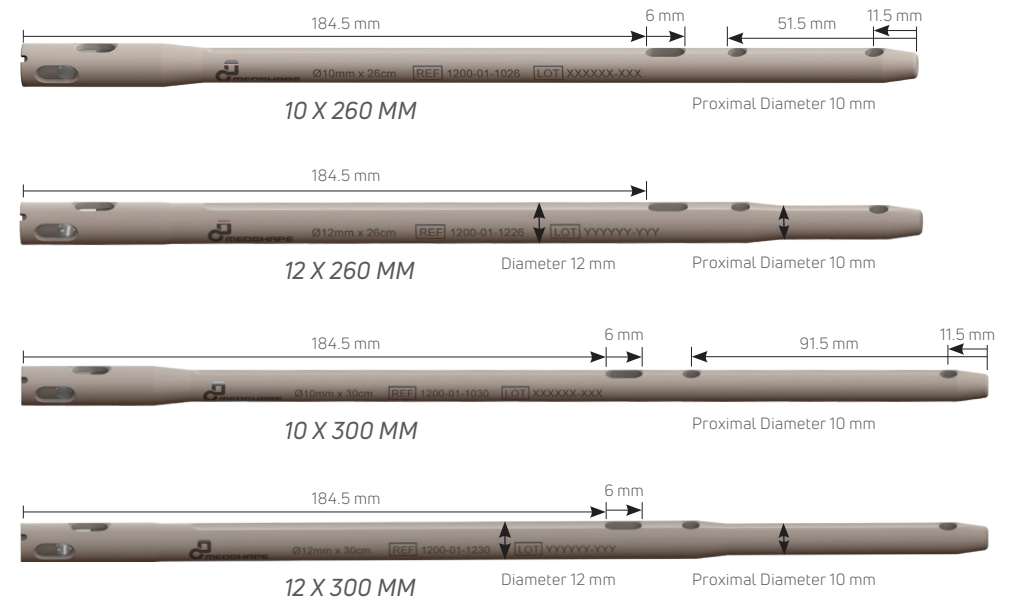
As the Compressive Element unloads (i.e., recovers its stretched length) in response to bone resorption or settling, the calcaneal screws will progressively shift proximally. The amount of unloading can be measured on radiograph by the position of the screws. The Compressive Element has completely unloaded back to its resting state when the calcaneal screws are at the proximal end of the slot.



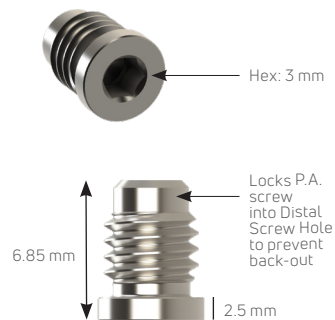
NAIL IMPLANT



DYNANAIL XL®



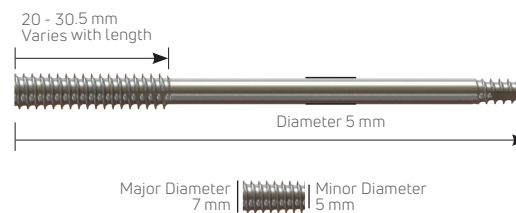
END CAP



SCREWS

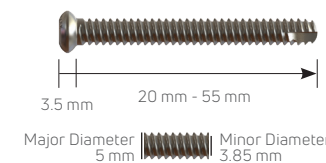
HEADLESS PA SCREWS

- Length: 60 mm - 110 mm, available in 5 mm increments
- 3.5 mm Hex Drive



LOW-PROFILE CORTICAL SCREWS

- Length: 20 mm - 55 mm, available in 5 mm increments (2.5 mm increments for 20-30 mm lengths)
- 3.5 mm Hex Drive



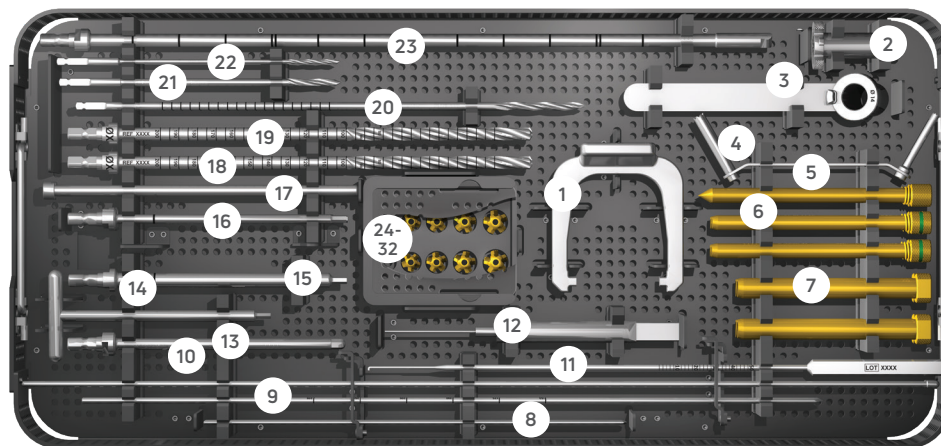
ACCESSORY INSTRUMENTATION

The DynaFrame™ CF Deployment System is made of high-strength, rigid carbon fiber polyether ether ketone (PEEK) to provide accurate drill targeting and placement of screws, along with excellent visibility under fluoroscopy.

FRAME OPERATIONAL FEATURES

- 1. Cam Lever:** Pull down to stretch the Compressive Element.
- 2. Stop Wheel:** Turn to set the desired length of Compressive Element stretch (0 - 6 mm).
- 3. Manual Compression Knob:** Rotate clockwise to apply external compression.
- 4. Deployment Base:** Use lasermarks to determine amount of manual compression applied (0 -6 mm).
- 5. Compression Tubes:** Contain slots to aid in targeting medial-lateral screws.
- 6. PA Targeting Arm:** Attach to compression tubes to provide accurate placement of PA screw.
- 7. Outer Tube Brace:** Provides additional rigidity to the DynaFrame
- 8. Step Numbers:** Indicates order of steps involving the DynaFrame™

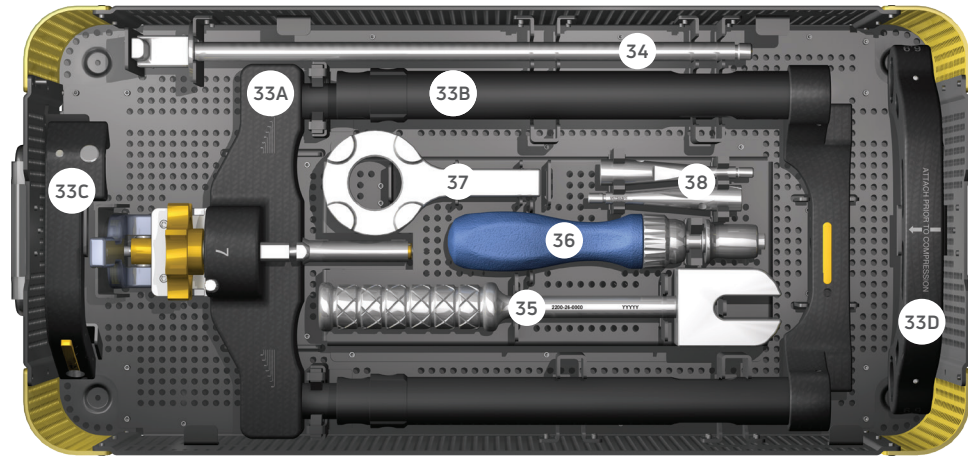




INSTRUMENT CASE, TOP TRAY

#	DESCRIPTION	PART #	QTY
1	ANVIL ATTACHMENT	2200-02-0000	1
2	3.3 MM PROTECTION SLEEVE	2200-04-0633	1
3	14 MM PROTECTION SLEEVE	2200-04-0140	1
4	2.5/4 MM DRILL GUIDE	2200-08-2540	1
5	TROCAR OBTURATOR	2200-15-0000	2
6	4 MM DRILL GUIDE	2200-08-0040	4
7	8 MM GUIDE SLEEVE	2200-08-0080	4
8	2.0 MM STEINMANN PIN	2200-19-0031	5
9	3.1 MM x 400 MM TROCAR-TIPPED GUIDEWIRE	2200-18-4031	2
10	3.1 MM x 500 MM BEAD-TIPPED GUIDEWIRE	2200-18-5031	2
11	DRILL GUIDE DEPTH GAUGE	2200-10-0000	1
12	FREE-HAND DEPTH GAUGE	86.2410	1
13	5 MM HEX DRIVER	2200-12-0050	1
14	3 MM HEX DRIVER, T-HANDLE	2200-13-0030	1
15	3.5 MM X Ø8 MM (WIDE) HEX DRIVER	2200-12-0135	1
16	3.5 MM HEX DRIVER	2200-12-0035	1

#	DESCRIPTION	PART #	QTY
17	M6 CONNECTION SCREW	2200-03-0000	2
18	9 MM CANNULATED DRILL	2200-05-0090	1
19	7 MM CANNULATED DRILL	2200-05-0070	1
20	4 MM DRILL	2200-09-0040	3
21	4 MM FREE-HAND DRILL	2200-09-0400	2
22	2.5 MM FENESTRATION DRILL	2200-09-0025	2
23	REAMER SHAFT	2200-23-0000	1
24	9 MM REAMER HEAD	2201-06-0090	1
25	10 MM REAMER HEAD	2201-06-0100	1
26	10.5 MM REAMER HEAD	2201-06-0105	1
27	11 MM REAMER HEAD	2201-06-0110	1
28	11.5 MM REAMER HEAD	2201-06-0115	1
29	12 MM REAMER HEAD	2201-06-0120	1
30	12.5 MM REAMER HEAD	2201-06-0125	1
31	13 MM REAMER HEAD	2201-06-0130	1
32	13.5 MM REAMER HEAD	2201-06-0135	1



INSTRUMENT CASE, BOTTOM TRAY

#	DESCRIPTION	PART #	QTY
33A	DEPLOYMENT BASE*		1
33B	MANUAL COMPRESSION ASSEMBLY*		1
33C	PA ATTACHMENT*		1
33D	OUTER TUBE BRACE		1
34	REMOVAL TOOL STRIKE PLATE	2200-24-0002	1
36	BLUE-HANDLE RATCHET DRIVER	2200-11-0001	1
37	HANDWHEEL WRENCH	2200-16-0000	1
38	REMOVAL TOOL ATTACHMENT	2200-24-0001	2

*Comprises the DynaFrame™ CM Deployment System

NOTE: Additional removal tools available upon request.

INDICATIONS

MEDSHAPE DYNANAIL® TTC FUSION SYSTEM

The MedShape DynaNail® TTC Fusion system is indicated for use in tibiototalcaneal (TTC) fusion procedures to treat the following conditions:

- Post-traumatic and degenerative arthritis
- Post-traumatic or primary arthrosis involving both ankle and subtalar joints
- Revision after total ankle arthrodesis with subtalar involvement
- Failed total ankle arthroplasty
- Non-union ankle arthrodesis
- Rheumatoid hindfoot
- Absent talus (requiring tibiocalcaneal arthrodesis)
- Avascular necrosis of the talus
- Neuroarthropathy or neuropathic ankle deformity
- Neuromuscular disease and severe deformity
- Osteoarthritis
- Charcot Foot
- Previously infected arthrosis with confirmed eradication of infection

CONTRAINDICATIONS

MEDSHAPE DYNANAIL® TTC FUSION SYSTEM

The MedShape DynaNail® TTC Fusion System is contraindicated where there is:

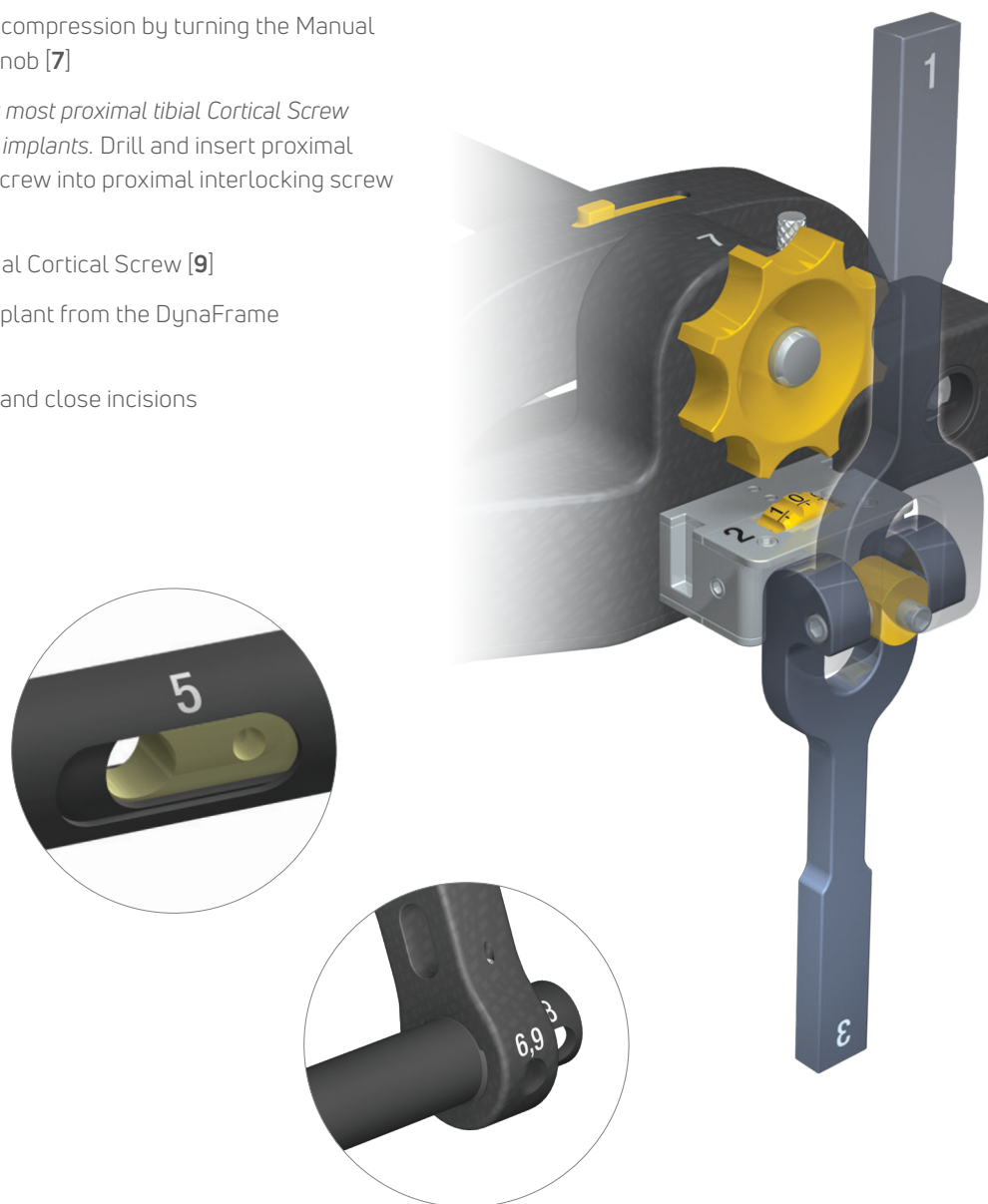
- An active local or systemic infection
- An active soft tissue infection or osteomyelitis of the foot and ankle
- An obliterated medullary canal or other conditions that tend to retard healing, such as blood supply limitations or previous infections
- An insufficient plantar pad
- Skeletal immaturity where the implant would cross open epiphyseal plates
- An intact asymptomatic subtalar joint
- Significant tibial malalignment (>10 degrees in either sagittal or coronal plane)
- A dysvascular limb
- Severe longitudinal deformity
- An insufficient quality or quantity of bone to permit fusion of the joints or stabilization of the arthrodesis
- Conditions that restrict a patient's ability or willingness to follow post-operative instructions during the healing process
- Foreign body sensitivity, suspected or documented metal allergy or intolerance. Where material sensitivity is suspected, appropriate tests should be conducted and sensitivity ruled out prior to implantation.

The following is a general overview of the DynaNail® 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 bold correspond to the numbers marked on the DynaFrame™ and are intended to be used as a guide for the order of steps to be taken.

- 1.** Assemble DynaFrame Assembly
- 2.** Insert Guidewire into tibial canal
- 3.** Drill entry tunnel with 7 mm and 9 mm Drills
- 4.** Ream to appropriate size using Reamer Shaft and Reamer Heads
- 5.** Load Nail Implant onto DynaFrame Assembly
- 6.** Insert Nail Implant into reamed tibial canal
- 7.** Stretch the Compressive Element by pulling down on Lever **[1]**
- 8.** Set the amount of compression by turning Stop Wheel **[2]**
- 9.** Return Lever by pulling up when finished **[3]**
- 10.** Attach Outer Tube Brace and PA Attachment
- 11.** Drill into the calcaneus and insert P-A Headless Screw **[4]**
- 12.** Drill into the calcaneus and insert L-M Cortical Screw **[5]**
- 13.** Drill medial-to-lateral into distal interlocking screw hole of the Nail Implant **[6]**

- 14.** Apply external compression by turning the Manual Compression Knob **[7]**
- 15.** (Optional) Insert most proximal tibial Cortical Screw in DynaNail XL® implants. Drill and insert proximal tibial Cortical Screw into proximal interlocking screw hole **[8]**
- 16.** Insert distal tibial Cortical Screw **[9]**
- 17.** Release Nail Implant from the DynaFrame Assembly
- 18.** Insert End Cap and close incisions



1. PATIENT POSITIONING

Place the patient in the supine or pseudo-lateral position with the foot at the terminal end of the table. Clear visualization to the plantar aspect of the foot is critical. Be sure to prep and drape above the knee to be able to assess limb rotation. If unaffected, assess contralateral limb for rotational alignment.

TIP: A trauma triangle with the apex padded or cushioned may be placed under the ankle for ease of drilling and placing screws.

2. JOINT PREPARATION

Instruments used:

1. Steinmann Pinn (8)*
2. 2.5 mm Fenestration Drill (Optional) (22)
3. 2.5 mm/4 mm Drill Guide (Optional) (4)

A range of surgical approaches and incisions may be utilized to access the tibiotalar and subtalar joint. The surgical approach chosen for joint prep and alignment is dependent upon factors such as the local anatomy, type of deformity, and surgeon preference.

Adequate joint preparation and alignment is a critical step for achieving a successful fusion. Denude any remaining cartilaginous surface, paying attention to any angular deformities in the tibiotalar and subtalar joints. The 2.5 mm Fenestration Drill with the 2.5 mm end of the 2.5 mm/4 mm Drill Guide may be used to aid in creating viable bleeding bone or feathering the joint surfaces (**FIGURE 1**). If any significant bone gaps are noted, they can be filled with either bone autograft or allograft per surgeon preference. Continue joint preparation until good bone-to-bone apposition is achieved at both joints. Meticulous attention should be paid for visual evidence of viable bone on each apposing surface. If in question, the tourniquet should be deflated to evaluate for punctuate bleeding.

Provisional fixation with smooth Steinmann Pins to maintain desired alignment may be performed at this time, paying close attention to all three planes (coronal, sagittal, and rotation). Typically, neutral to 7 degree valgus, neutral dorsiflexion-plantarflexion, and rotation comparable to the contralateral side is desired. Avoid varus or excessive valgus positioning. To avoid excessive valgus with a neutral ankle, it is recommended to translate the calcaneus medially under the talus. An excessive valgus or a too medial insertion point may affect the placement of the calcaneal PA Screw.

*(Number) represents corresponding position in Instrument Tray. Refer to pages 7-8.

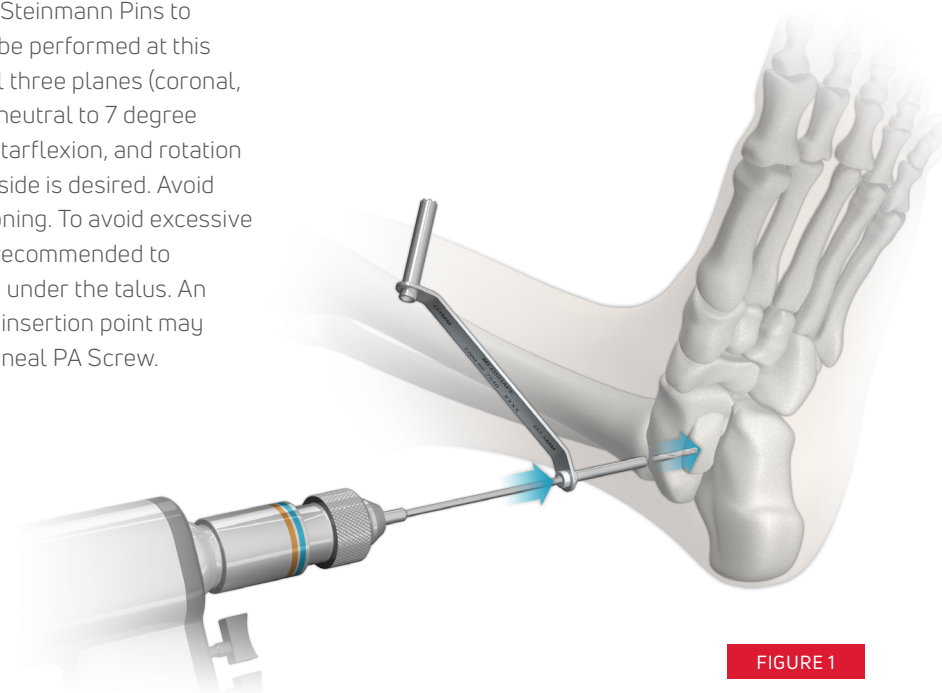


FIGURE 1

3. NAIL ENTRY SITE PREPARATION

Make a plantar incision at least 2 cm in length. The incision can be in the longitudinal or transverse direction, according to surgeon preference. Bluntly dissect the soft tissue down to the surface of the calcaneus (FIGURE 2). Extreme care must be taken to protect the plantar neurovascular structures throughout the procedure.

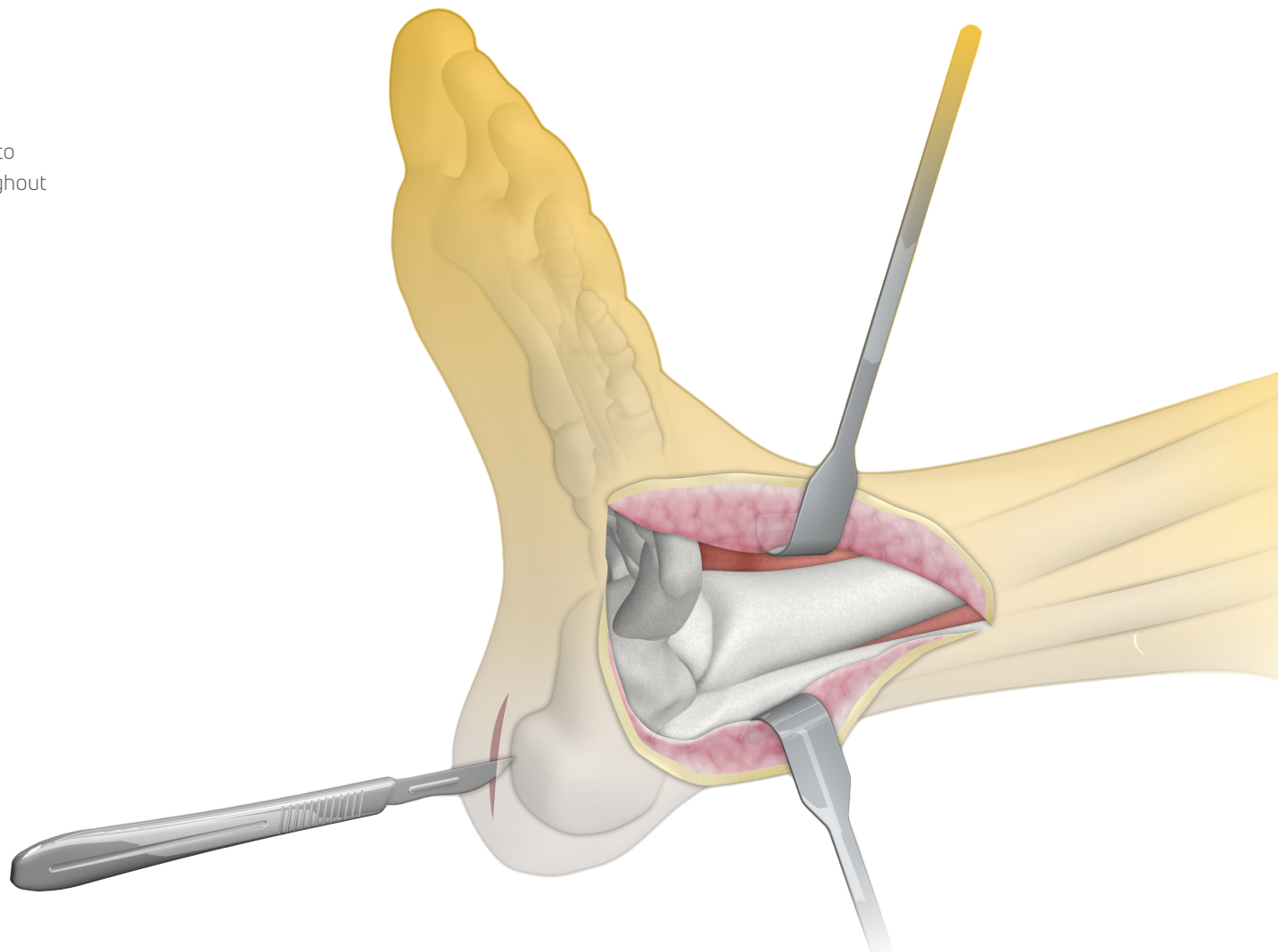


FIGURE 2

4. DYNAFRAME™ COMPONENT ASSEMBLY

Instruments used:

1. DynaFrame™ Assembly (33a & 33b)

To assemble the DynaFrame, slide the Manual Compression Tubes onto the Deployment Base (FIGURE 3). Push down on the gold latch on top of the Compression Tube arch to lock it in place (A). The DynaFrame is secured in place when the Manual Compression Assembly no longer slides and the latch pops up to its original position.

BEFORE loading the Nail Implant, be sure to check that:

- The numbered gold Stop Wheel is set to “0” and that the lever is in the upright position to allow the DynaNail® Implant to attach to the frame (B).
- The gold Manual Compression Knob is in the starting position by rotating it fully counter clockwise. This sets the Manual Compression Tubes to the “0” position (C).
- If the Stop Wheel is not set to zero: pull the lever down, turn the Stop Wheel to “0,” and return the lever to its upright position.



FIGURE 3

5. GUIDEWIRE INSERTION

Instruments used:

1. Trocar-Tipped Guidewire (9)
2. 14 mm Protection Sleeve (3)
3. 3.3 mm Protection Sleeve (2)

Assemble the 3.3 mm and 14 mm Protection Sleeves (A). Place the Protection Sleeve Assembly against the plantar surface of the calcaneus. Insert the Trocar-Tipped Guidewire (B) into the central hole of the 3.3 mm Protection Sleeve, taking care that the Guidewire tip is contacting the inferior aspect of the calcaneus. Drill the Guidewire through the calcaneus and talus into the tibial medullary canal (FIGURE 4). With the Protection Sleeve abutted against the bone, confirm proper depth has been reached by reading the lasermarks off the back of the 3.3 mm Protection Sleeve (C). If not satisfied with the initial Guidewire placement, a second Guidewire may be inserted through one of the adjacent holes in the 3.3 mm Protection Sleeve. When satisfied with the Guidewire placement, remove the 3.3 mm Protection Sleeve, leaving the Trocar-Tipped Guidewire in place.

TIP: Fluoroscopy should be utilized throughout the entire insertion process to ensure centered Guidewire placement in the tibial medullary canal on both the anterior and lateral views.

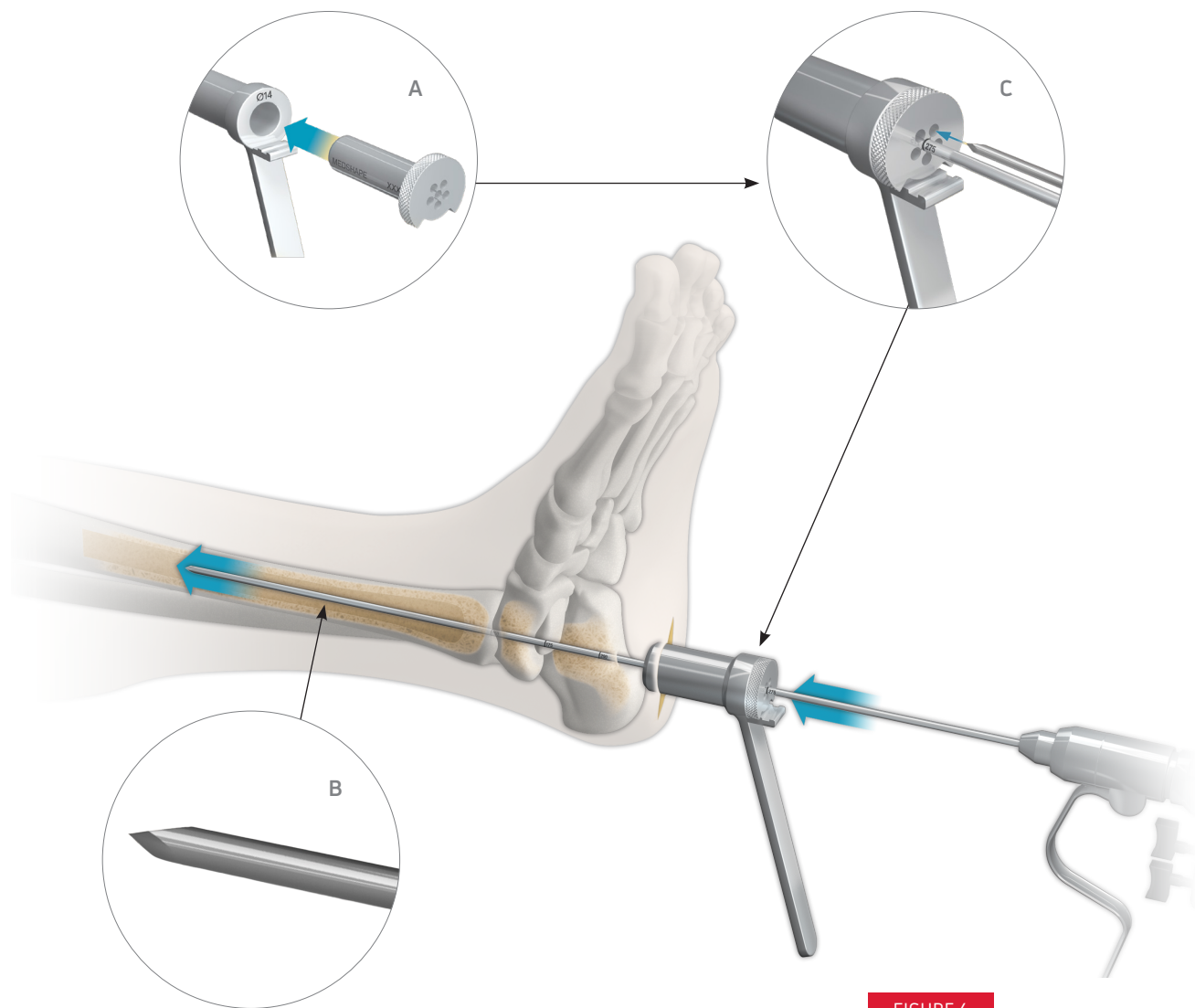


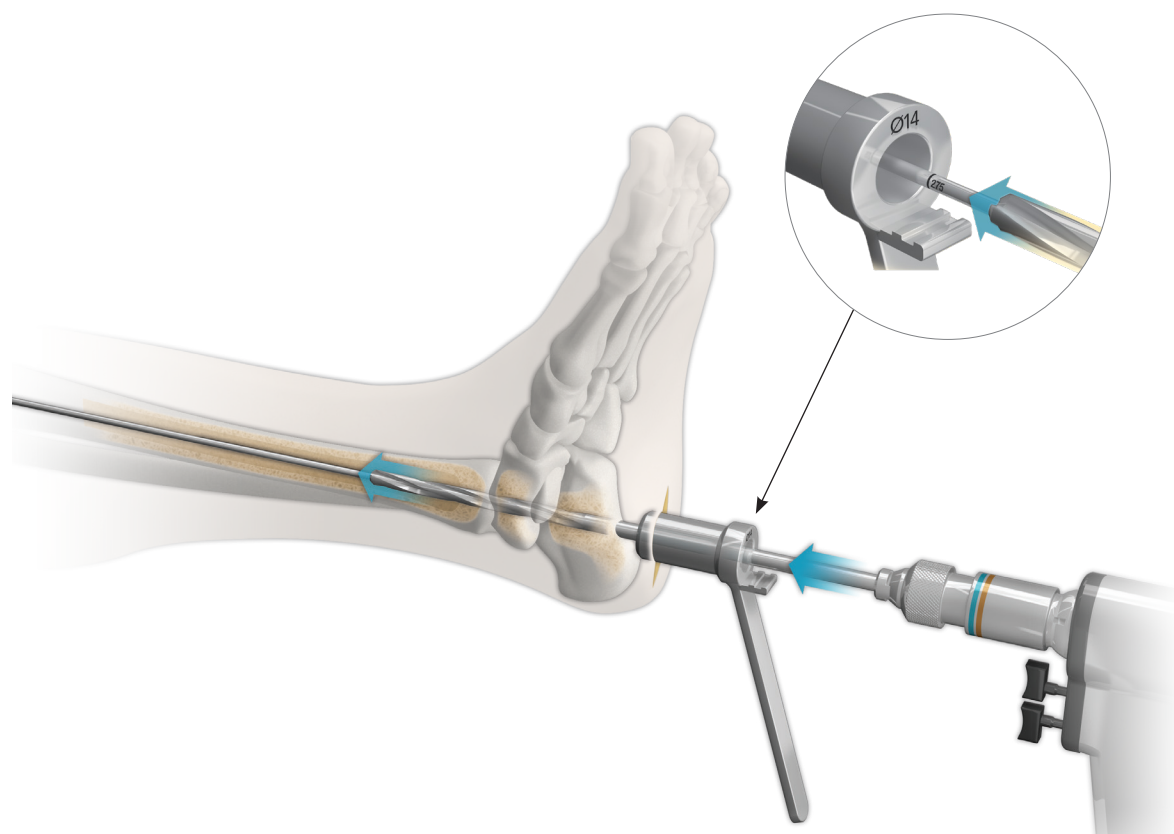
FIGURE 4

6. INITIAL DRILLING

Instruments used:

1. Trocar-Tipped Guidewire (9)
2. 14 mm Protection Sleeve (3)
3. 7 mm Cannulated Drill (19)
4. 9 mm Cannulated Drill (18)
5. Bead-Tipped Guidewire (10)

Using the 14 mm Protection Sleeve, insert the 7 mm Cannulated Drill over the Guidewire and drill into the medullary canal (**FIGURE 5**). The Trocar-Tipped Guidewire will come out when removing the 7 mm Drill. Replace the Trocar-Tipped Guidewire with the Bead-Tipped Guidewire. For the DynaNail XL® (260 and 300 mm lengths), the 800 mm Guidewire may be used to allow for additional reaming into the tibial canal. Reconfirm with fluoroscopy that the Bead-Tipped Guidewire is seated in the same position prior to proceeding with the 9 mm Drill. Repeat drilling using the 9 mm Cannulated Drill.



TIP:

- It is recommended to drill with the 7 mm Cannulated Drill to just beyond the tibiotalar joint, stopping at the metaphyseal level. Then, drill through the tibial canal using the 9 mm Cannulated Drill.
- A 2nd Bead-Tipped Guidewire can be inserted into the back of the drill and pushed against the inserted Bead-Tipped Guidewire ensuring it remains in place while pulling out the drill.
- Do NOT forget to replace the Trocar-Tipped Guidewire with the Bead-Tipped prior to reaming.

7. REAMING

Instruments used:

1. Bead-Tipped Guidewire (10)
2. 14 mm Protection Sleeve (3)
3. Reamer Shaft (23)
4. 9-13.5 mm Reamer Heads (24-32)

Place the 10 mm Reamer Head onto the Reamer Shaft (A). With the 14 mm Protection Sleeve still in place against the calcaneus, slide the Reamer assembly over the Bead-Tipped Guidewire. Ream into the tibial medullary canal to the depth recommended for the chosen DynaNail® length as determined from **TABLE 1** (as read off the 14 mm Protection Sleeve (B)). Once the recommended depth is reached, replace the 10 mm Reamer Head with the 10.5 mm Reamer Head and repeat.

Using fluoroscopy, continue progressively reaming in 0.5 mm increments until cortical contact is made within the tibia (**FIGURE 6**). It is recommended that the final reaming size be 1 - 1.5 mm larger than the selected DynaNail Implant diameter (**TABLE 2**). Use fluoroscopy as necessary to be sure the cortical wall is not compromised.

NOTE:

The distal end of the DynaNail Implant is larger than the proximal end (12.5 mm), requiring additional reaming on the distal side through both the calcaneus and talus (refer to **TABLE 2**).

TABLE 1: RECOMMENDED TUNNEL DEPTH

NAIL LENGTH (MM)	REAMING LENGTH (MM)
220	250
260	300
300	325

TABLE 2: RECOMMENDED TUNNEL DIAMETER

NAIL DIAMETER	PROXIMAL END OF NAIL		DISTAL END OF NAIL (TO A DEPTH OF 75 MM)	
	PROXIMAL DIAMETER (MM)	REAMING DIAMETER (MM)	DISTAL DIAMETER (MM)	REAMING DIAMETER (MM)
10 MM	10	11	12.5	13.5
12 MM	12	13	12.5	13.5

TIP:

- For easier accessibility, the Reamer Heads Caddy can be removed from the tray and placed closer to the operating table (C).
- The Reamer Heads are only retained on the Reamer Shaft by the Guidewire and can fall if not held onto the shaft until the reamer head is securely on the Guidewire.
- Be sure that the Protection Sleeve abuts the calcaneus to ensure accurate depth readings.

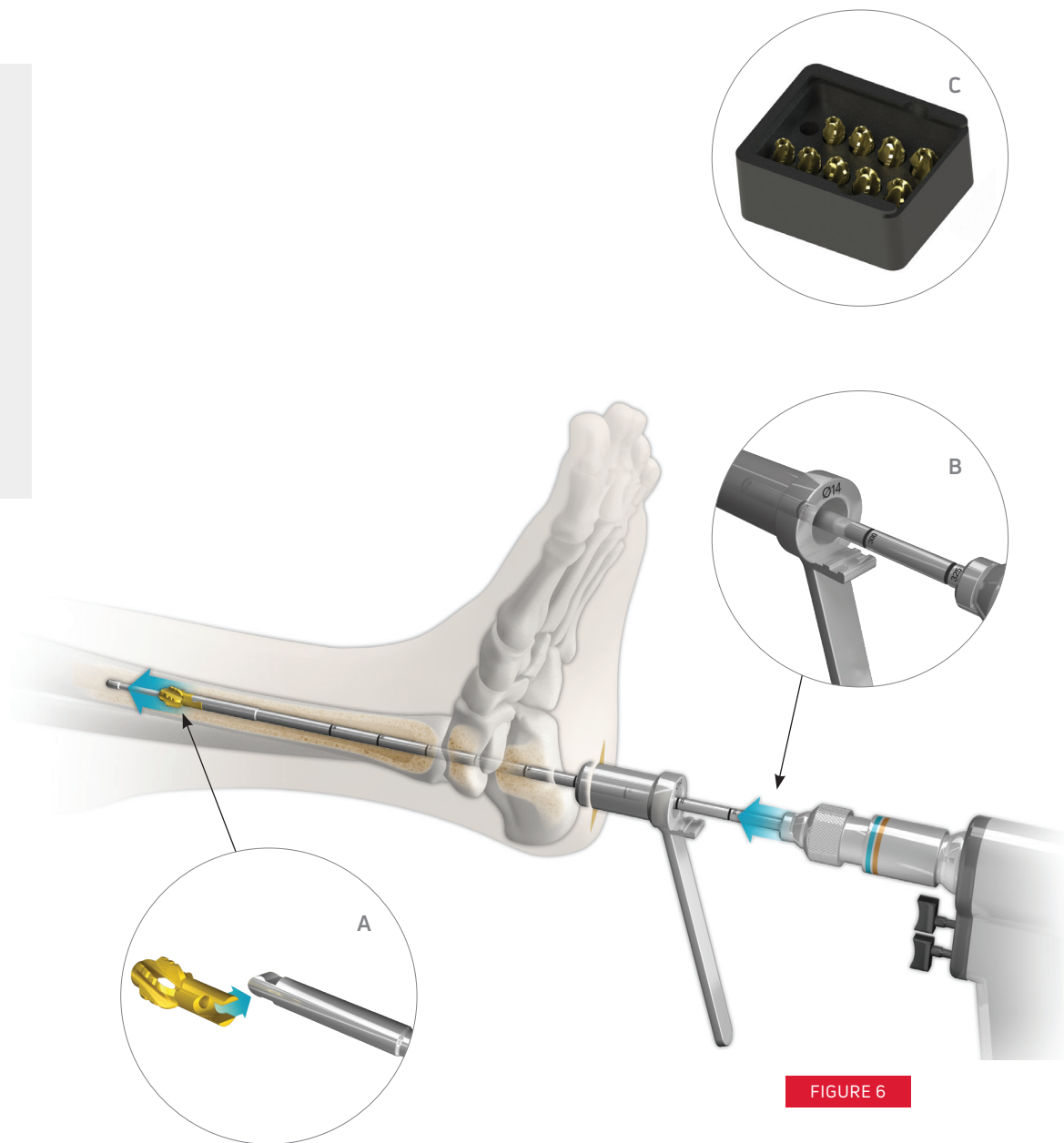


FIGURE 6

8. IMPLANT ATTACHMENT

Instruments used:

1. M6 Connection Screw (17)
2. 5 mm Hex Driver (13)
3. Blue-Handle Ratchet Driver (36)
4. DynaFrame™ Assembly (33a & 33b)

Insert the M6 Connection Screw through the inner cylinder of the DynaFrame Assembly (A). Attach the DynaNail® Implant onto the DynaFrame Assembly (FIGURE 7), taking care to correctly align the keyed slots on the Implant with the pegs on the DynaFrame Assembly (B). Attach the 5 mm Hex Driver onto the Blue-Handle Ratchet Driver (C) and use the Hex Driver to screw the M6 Connection Screw into the distal end of the DynaNail Implant until tight on the DynaFrame Assembly.

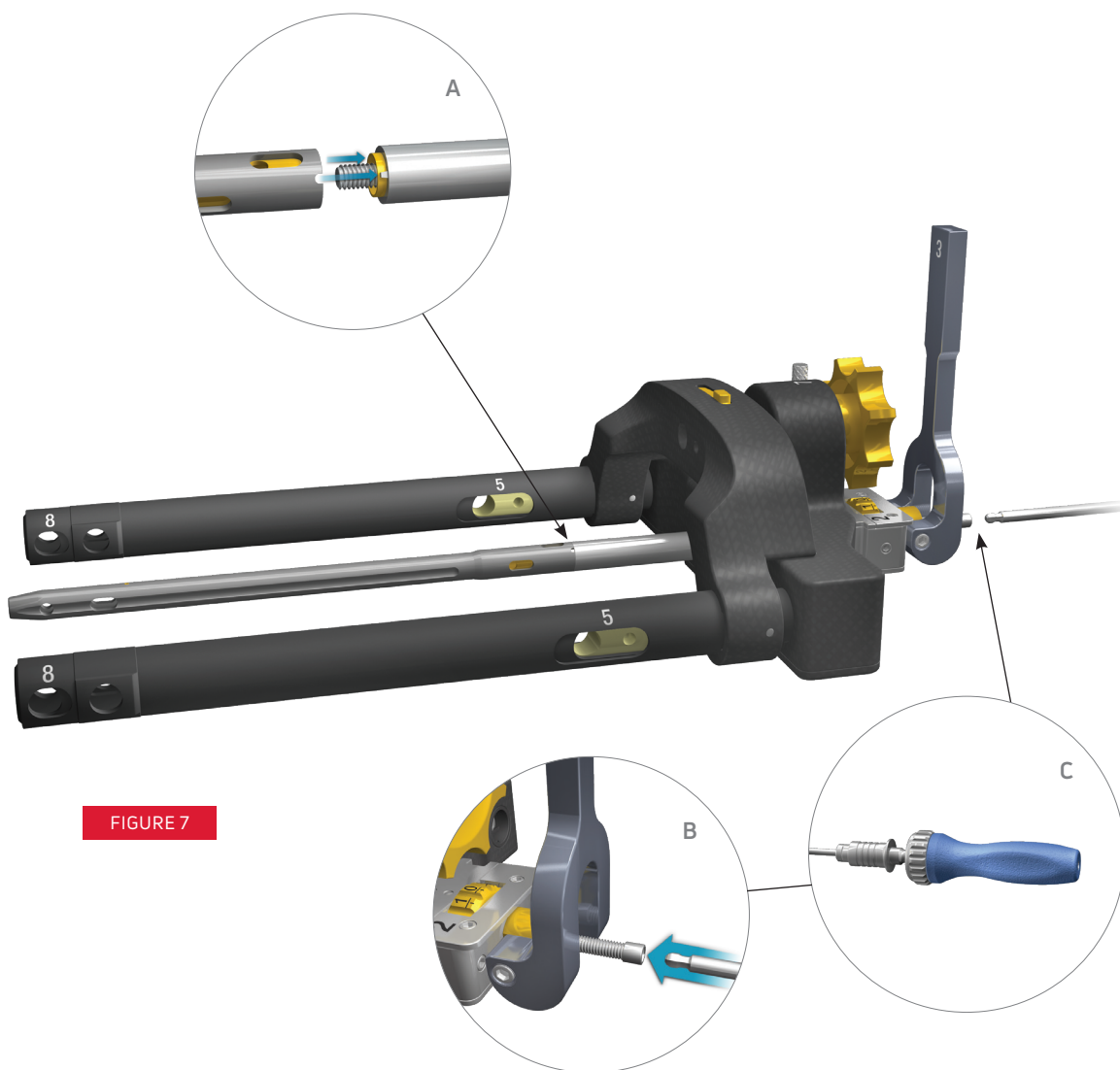


FIGURE 7

9. IMPLANT INSERTION

Instruments used:

1. Anvil Attachment (1)

Remove the Bead-Tipped Guidewire and insert the DynaNail® Implant into the medullary canal, rotating the DynaFrame™ Assembly to help advance the Implant.

(FIGURE 8)

TIP: Pay attention to rotation of the Nail Implant during insertion. Too medial of an entry point combined with internal rotation may affect the position and purchase of the calcaneal PA Screw.

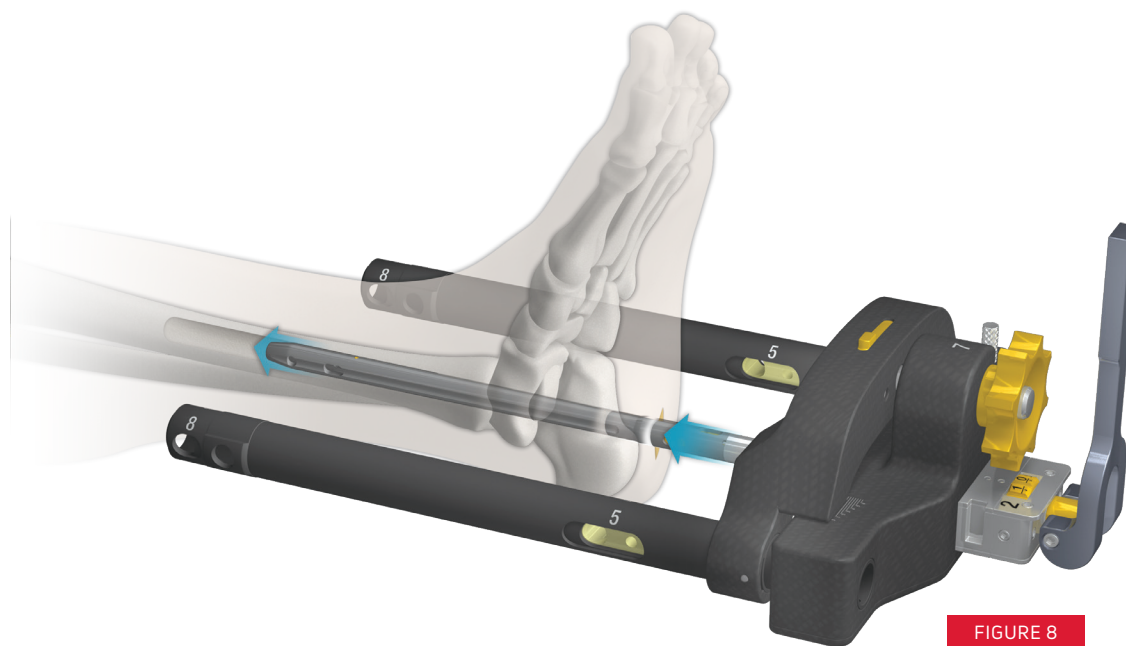


FIGURE 8

NAIL PLACEMENT GUIDELINES

Position the lateral-to-medial calcaneal screw hole as proximal as possible in the calcaneus (after the Compressive Element is stretched in the following step). In this proximal position, the lateral screw gains optimal purchase by targeting the longest possible screw in the widest part of the calcaneus. This proximal position also countersinks the DynaNail as far as possible within the calcaneus. Countersink the distal end of the DynaNail Implant 6 mm in the calcaneus (Refer to Figure 9). The Outer Body will translate distally up to 6 mm as the Compressive Element unloads post-operatively.



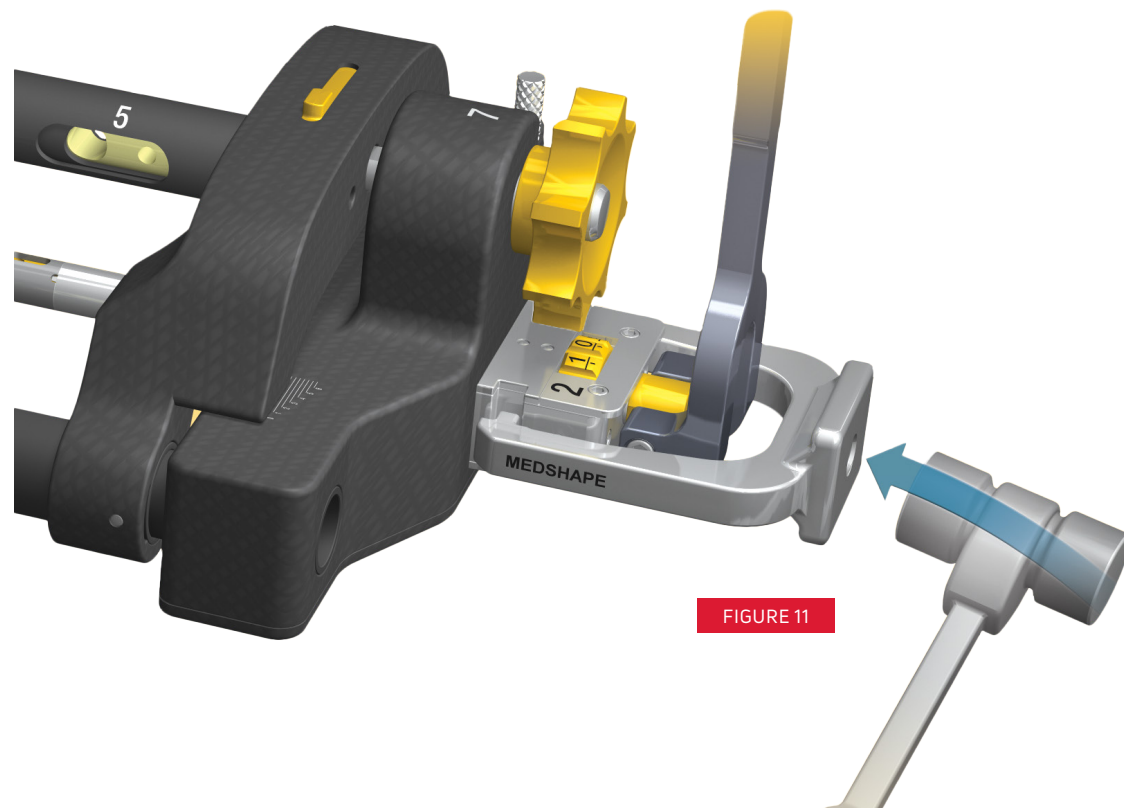
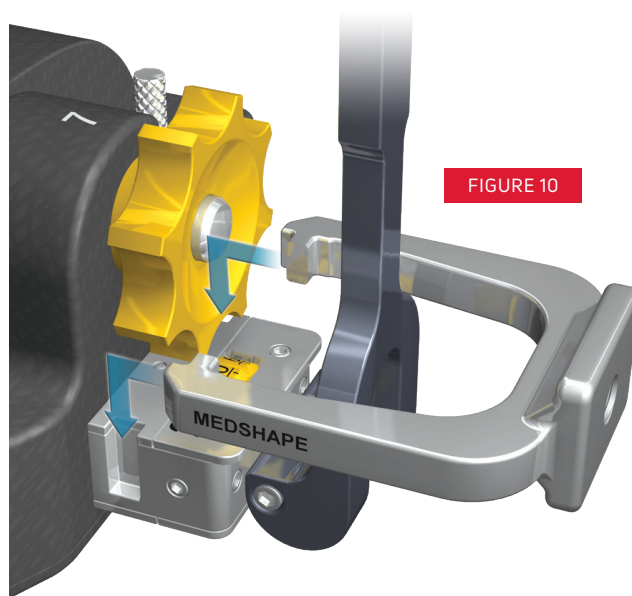
FIGURE 9

TIP: To achieve optimal lateral-to-medial screw positioning after the Compressive Element is stretched, insert the DynaNail Implant until the lateral-to-medial screw hole is aligned with the subtalar joint (refer to FIGURE 9). In this case when the Compressive Element is stretched to the maximum 6 mm (Step 10), this screw hole will translate distally by 6 mm, placing it in the optimal proximal position within the calcaneus.

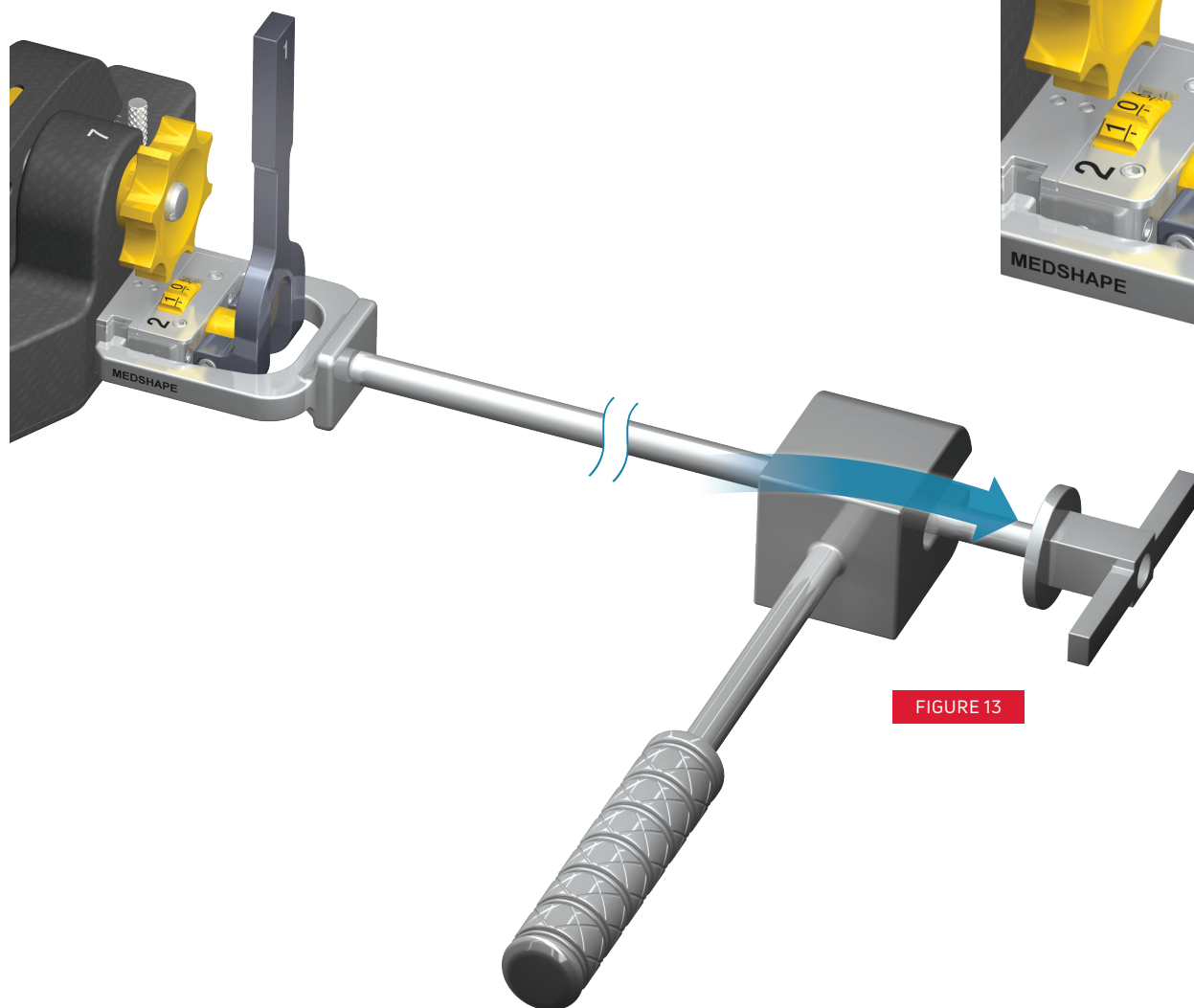
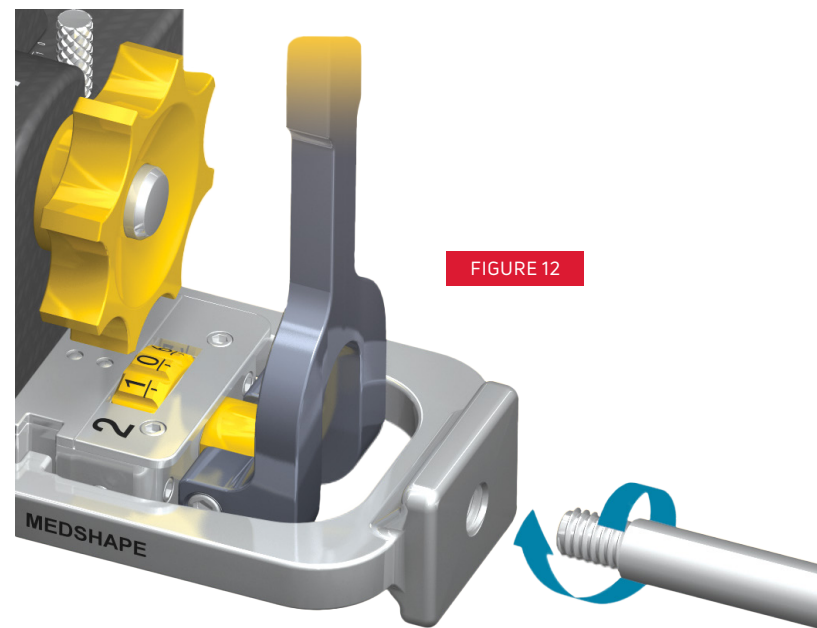
If additional force is required to advance the Nail Implant, slide the Anvil Attachment onto the DynaFrame® Assembly (FIGURE 10) and strike the Anvil with a mallet (FIGURE 11). The Anvil Attachment can be removed after the DynaNail® Implant is inserted.

TIP:

- Do NOT strike any other part of the frame besides the Anvil Attachment.
- Hold at least one side of the anvil down in the slot to ensure that it does not slip out and fall.



If the Nail Implant is inserted too far, the Removal Tool may be threaded into the Anvil attachment (**FIGURE 12**) and the Slap Hammer used to back out the Nail Implant (**FIGURE 13**).



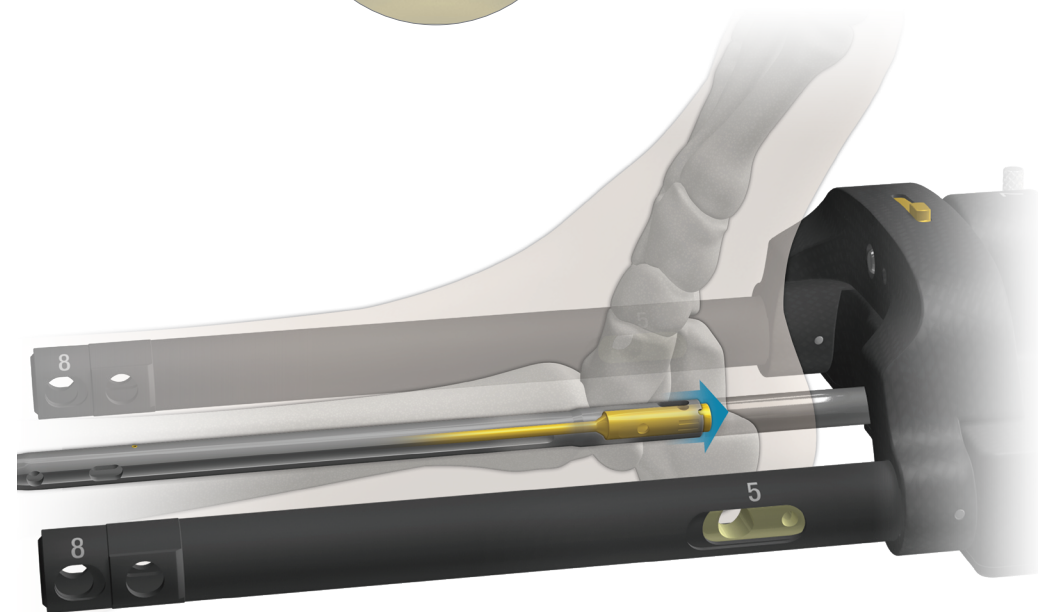
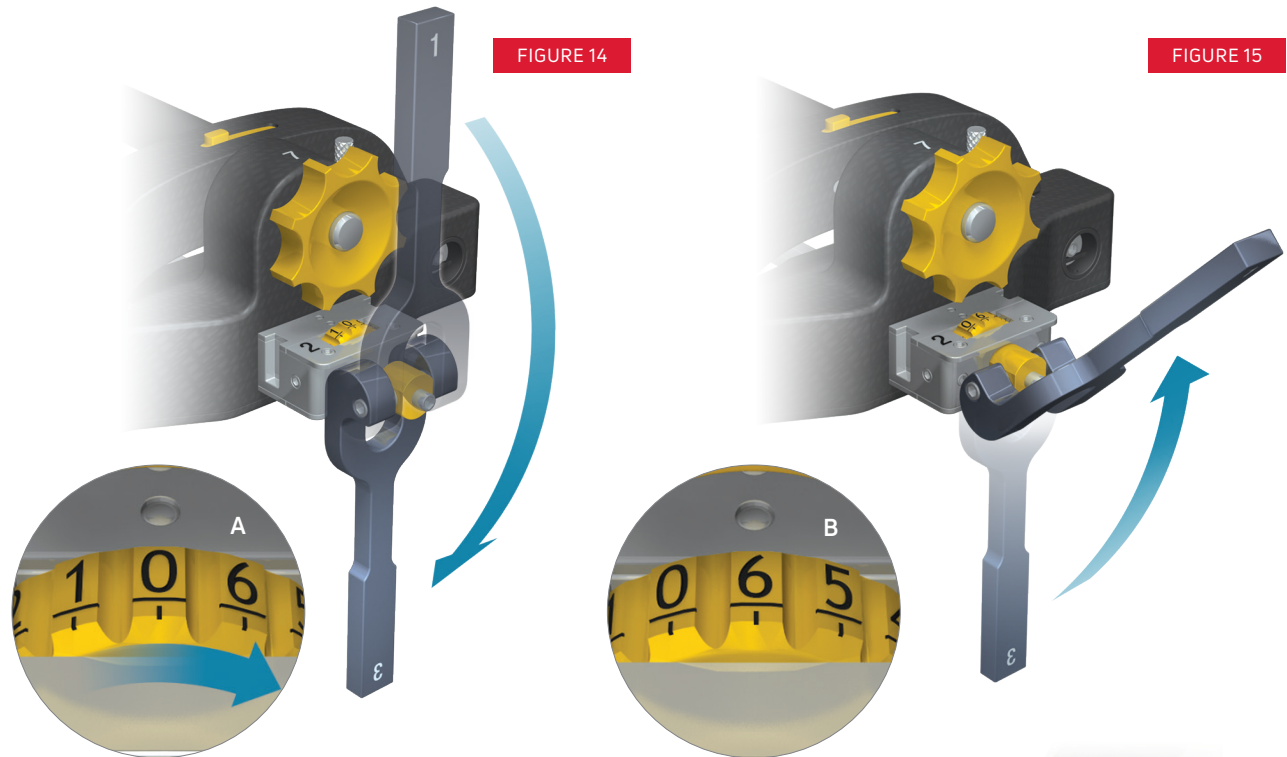
10. STRETCH COMPRESSIVE ELEMENT

Instruments used:

1. DynaFrame™ Assembly (33a & 33b)

Stretch the Compressive Element by pulling the lever into the full downward position (FIGURE 14). Use the Stop Wheel to set the desired amount of compression (up to 6 mm) from the Compressive Element (A,B). For example, setting the Stop Wheel to 6 signifies the Compressive Element is stretched by 6 mm and can therefore unload and maintain compression for up to 6 mm of bone resorption and/or settling.

Flip the lever back up into its relaxed position (FIGURE 15). Note the DynaNail's calcaneal screw holes have translated distally and are now in their final position. Confirm desired location of screw holes in the calcaneus under fuoroscopy before continuing (FIGURE 16).



11. HEADLESS PA SCREW PLACEMENT

Instruments used:

1. DynaFrame™ Assembly (33a & 33b)
2. PA Attachment (33c)
3. Outer Tube Brace (33d)
4. 8 mm Guide Sleeve (7)
5. 4 mm Drill Guide (6)
6. Trocar Obturator (5)
7. 4 mm Drill (20)
8. Wide 3.5 mm Hex Driver (15)
9. 3.5 mm Hex Driver (16)
10. Blue-Handle Ratchet Driver (36)
11. Headless PA Screw

Slide the Outer Tube Brace (A) onto the Manual Compression Tubes until it locks in place, ensuring the arrow markings are pointed towards the DynaFrame Assembly (FIGURE 17). Be sure that the holes in the Outer Tube Brace align with the holes in the Manual Compression Tubes.

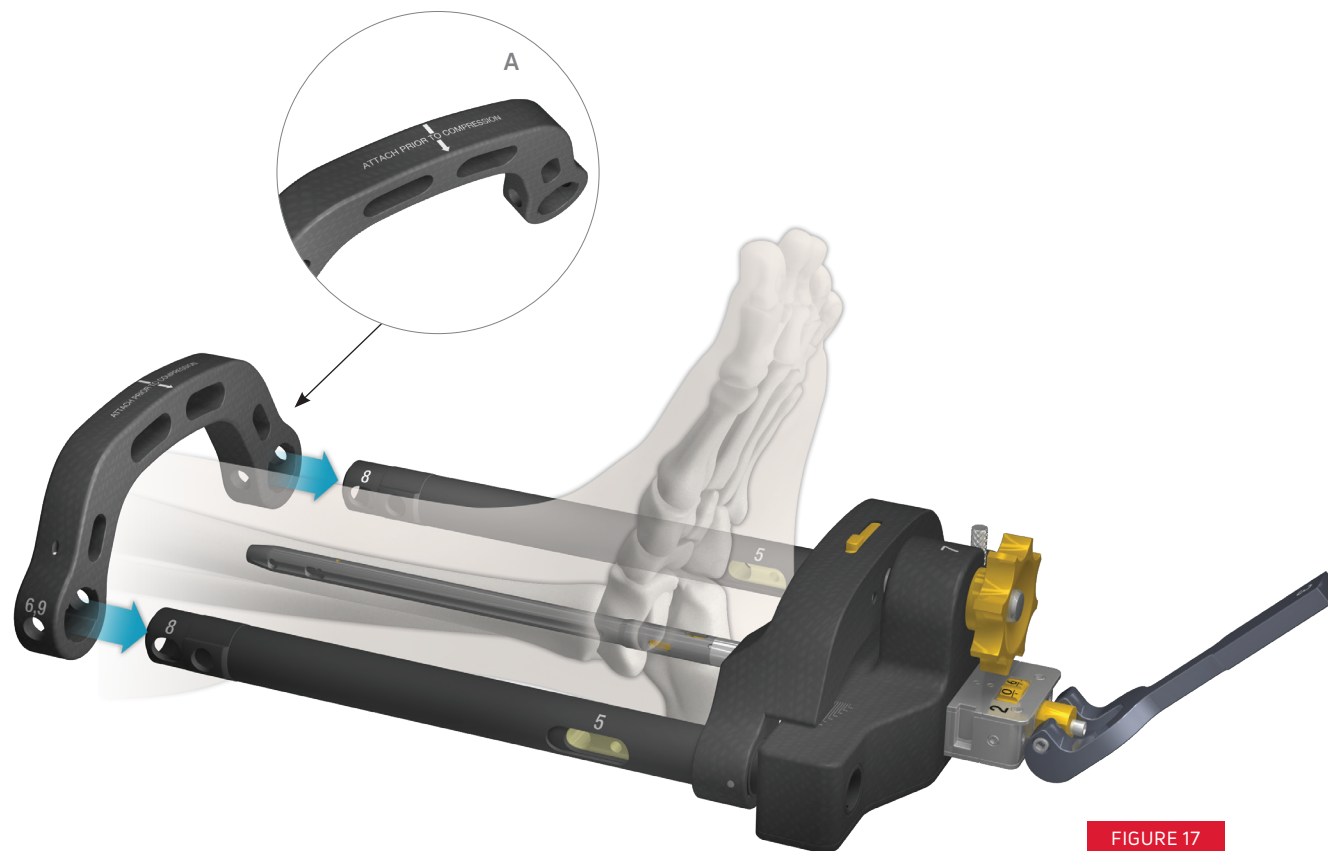


FIGURE 17

Attach the Posterior-Anterior (PA) Attachment to the right side of the DynaFrame™ Assembly (**FIGURE 18**). The Headless PA Screw should be aimed toward the calcaneocuboid (C-C) joint. If the calcaneus is deformed such that there is limited purchase for the Headless Screw, externally rotate the DynaFrame Assembly so that the PA Attachment targets towards the desired entry point.

TIP:

A trauma triangle can be used here to keep the foot elevated.

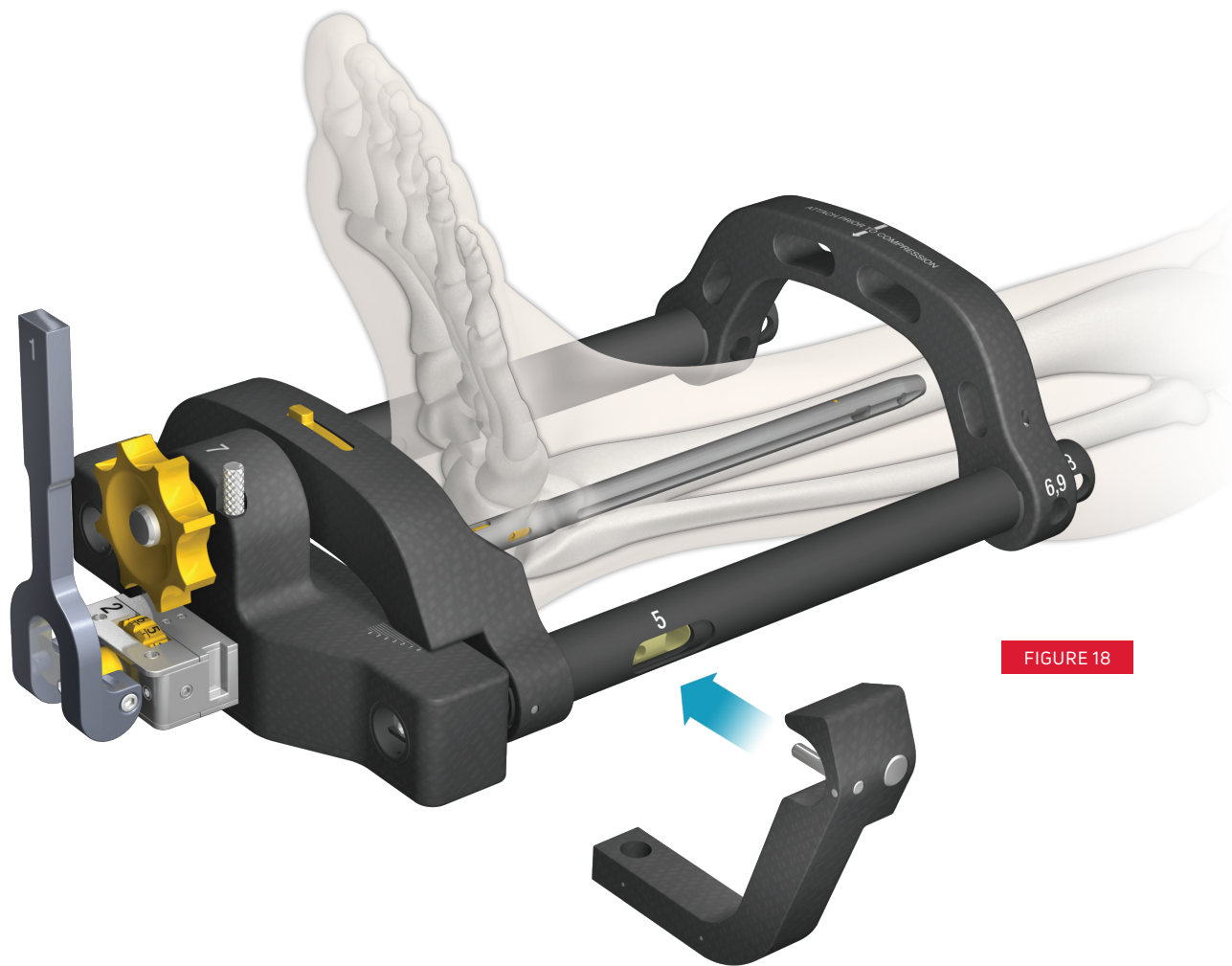


FIGURE 18

Thread the Trocar Obturator into the 8 mm Guide Sleeve (B). Depress the gold trigger on the PA Attachment to insert the Guide Sleeve/Trocar assembly. Make an incision at the Trocar tip and confirm that the Trocar is resting directly against the calcaneus (FIGURE 19).

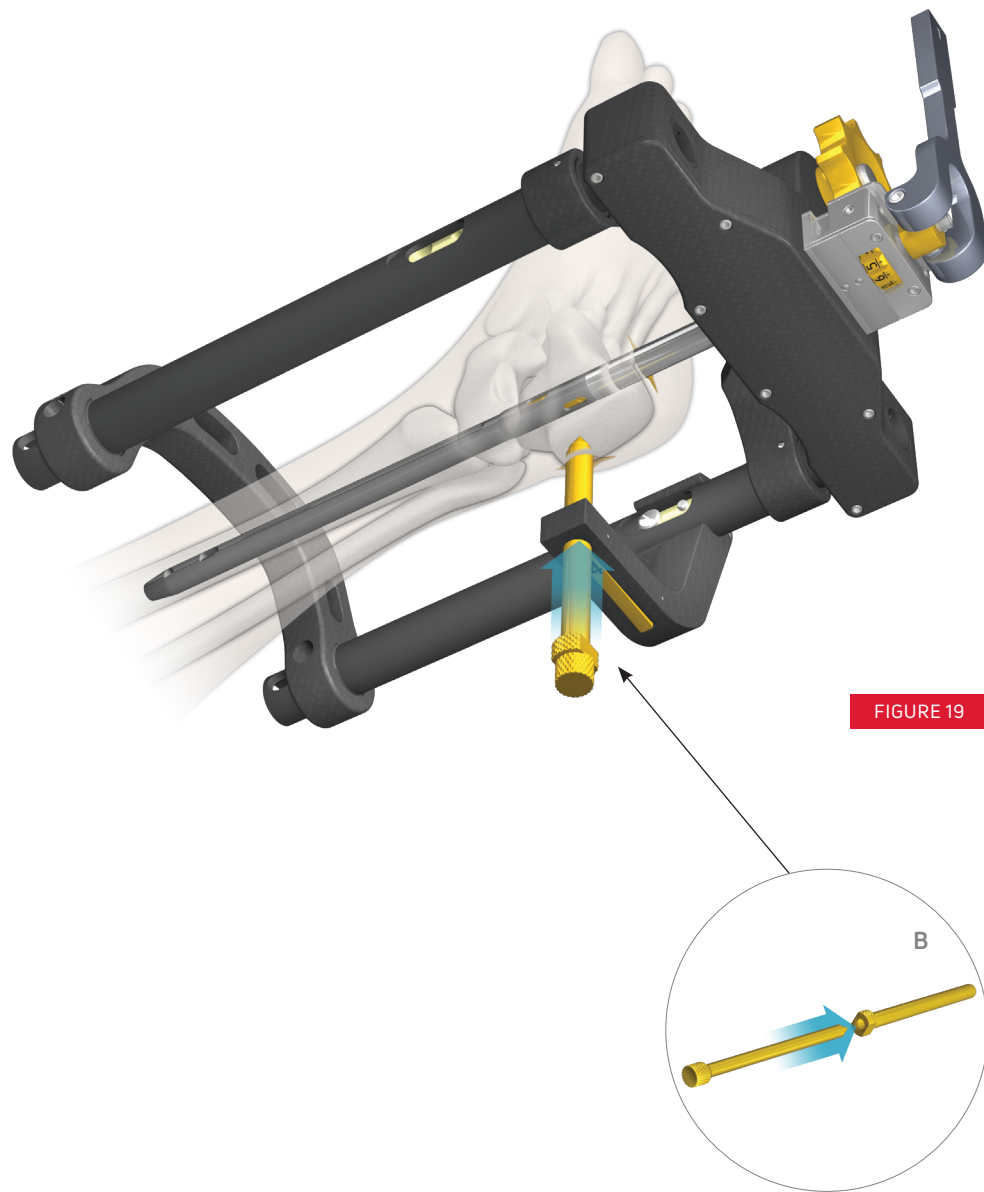


FIGURE 19

Leaving the Drill Guide Sleeve in place (**FIGURE 20**), replace the Trocar with the 4 mm Drill Guide (indicated with green stripe) (**C**).

TIP:

- Leave the Drill Guide just off the bone while drilling to ensure Drill Guide does not push back against the PA Attachment.
- If patient's leg must be lifted and not using a trauma triangle, hold the leg, NOT the DynaFrame™, to lift.

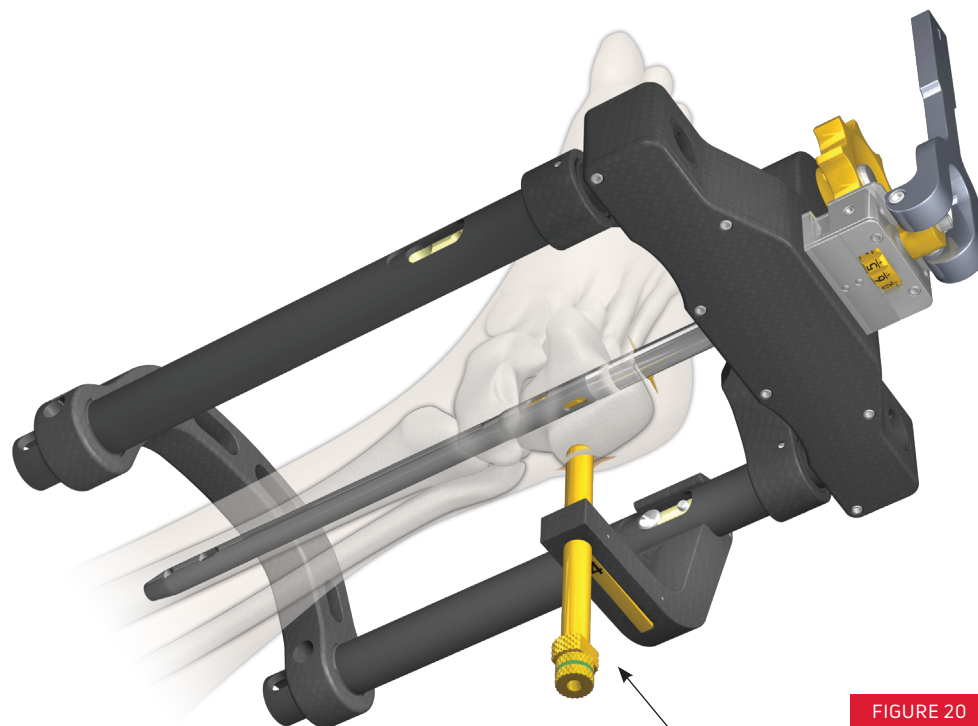
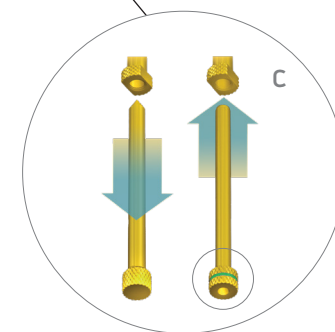


FIGURE 20



Insert the 4 mm Drill into the Drill Guide and drill to the desired depth (typically just proximal to the C-C joint) (FIGURE 21). Read the laser markings on the Drill relative to the back of the Drill Guide to determine the appropriate screw length (D).

TIP:

After drilling, advance the Drill Guide directly against the bone for accurate screw length measurement.

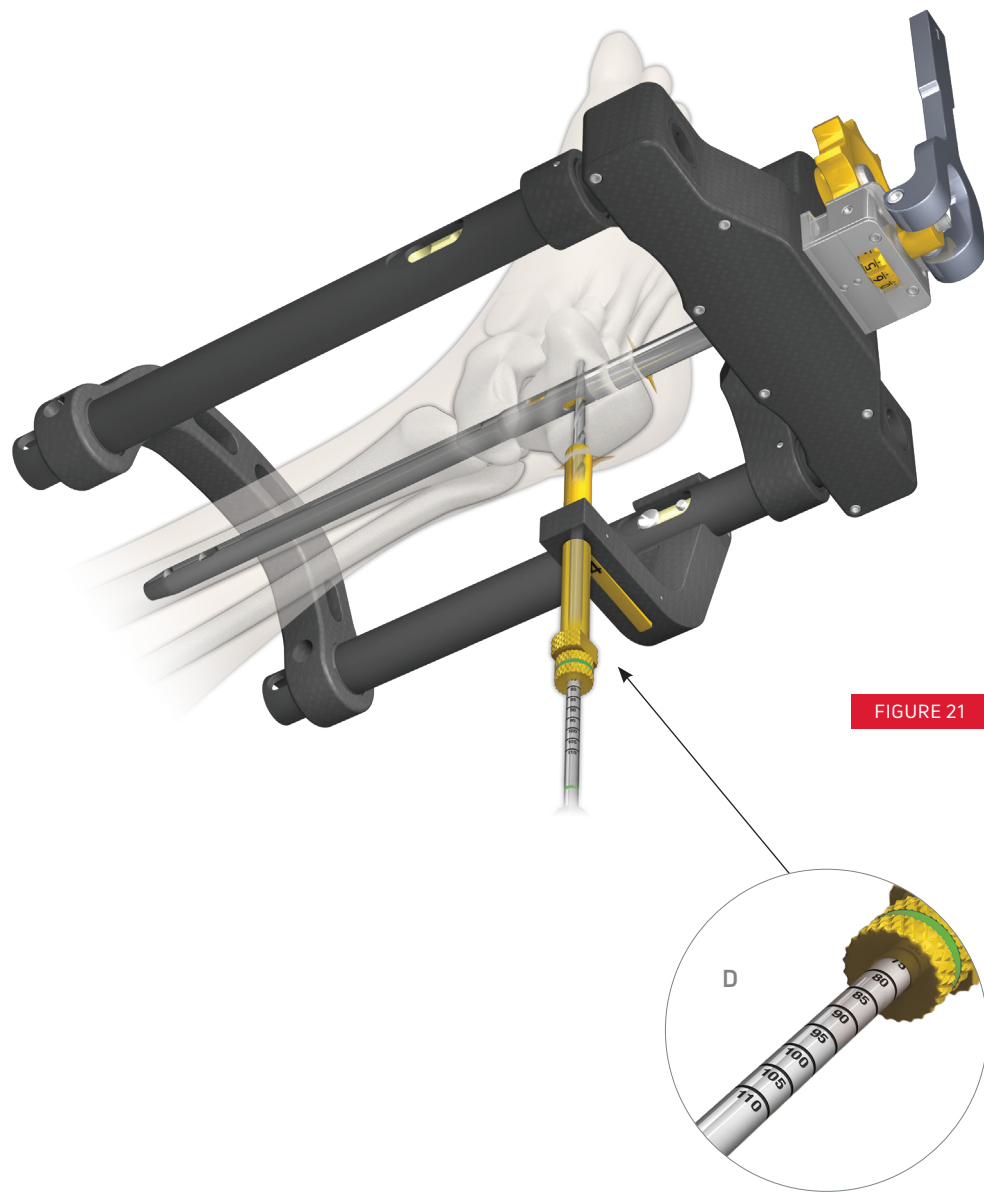


FIGURE 21

Attach the Wide 3.5 mm Hex Driver to a power drill and a second standard 3.5 mm Hex Driver to the Blue-Handle Ratchet Driver. Remove the 4 mm Drill and Drill Guide from the Guide Sleeve. Insert the Headless PA Screw through the Guide Sleeve using the Wide 3.5 mm Hex Driver loaded on the power drill until the screw has passed through the Nail Implant (FIGURE 22). Then switch to the Blue-Handle Ratchet Driver to continue to advance the screw until it is flush with the posterior calcaneus (E). Remove the Guide Sleeve from the PA Attachment. Remove the PA Attachment from the DynaFrame™ Assembly.

TIP:

- The Headless PA Screw does not provide tactile feedback to indicate when it is fully inserted. Use the laser line on the 3.5 mm Hex Driver to determine if the PA Screw is fully inserted.
- Use fluoroscopy while inserting both under power and manually to ensure the screw tip does not breach the C-C joint (FIGURE 23).

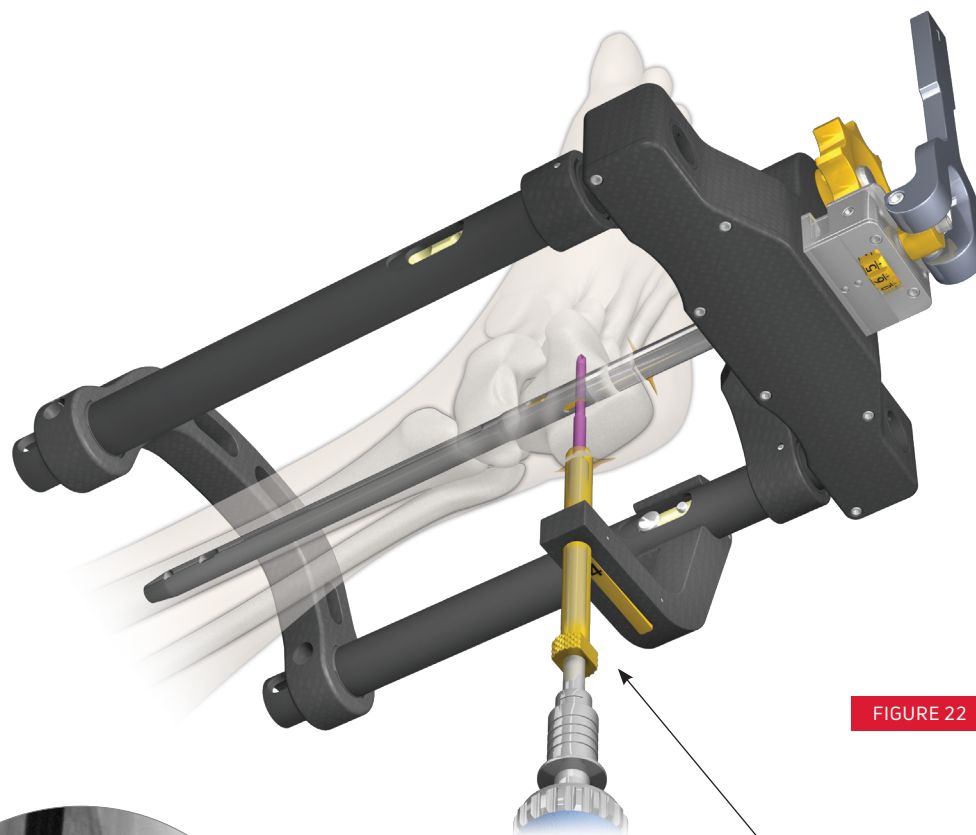


FIGURE 22

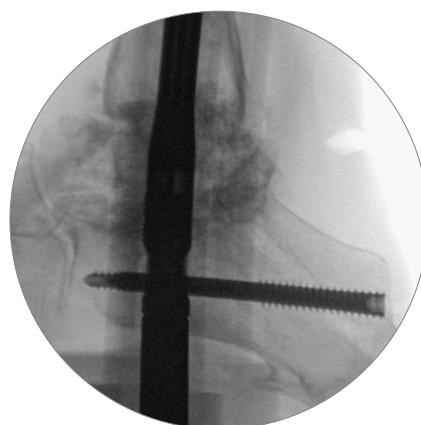
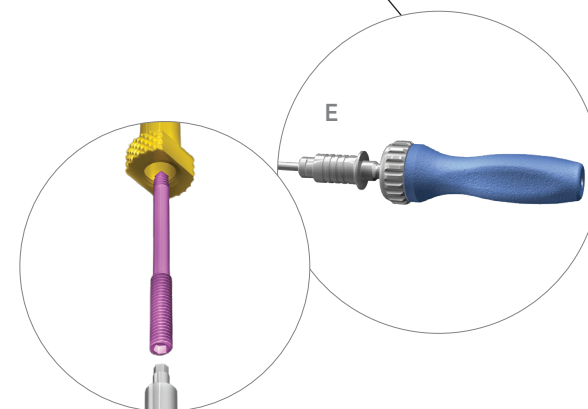


FIGURE 23



12. CALCANEAL L-M SCREW PLACEMENT

Instruments used:

1. 8 mm Guide Sleeve (7)
2. Trocar Obturator (5)
3. 4 mm Drill Guide (6)
4. 4 mm Drill (20)
5. Drill Guide Screw Depth Gauge (*Optional*) (11)
6. Wide 3.5 mm Hex Driver (15)
7. Blue-Handle Ratchet Driver (6)
8. Cortical Screw

Thread the Trocar into the 8 mm Guide Sleeve. Insert the 8 mm Guide Sleeve and Trocar assembly into the lateral side of the DynaFrame™ Assembly. Make an incision at the Trocar tip and abut the Trocar against the calcaneus. Distal retraction of the peroneal tendons can sometimes be done to allow direct contact of the Trocar against bone. Leaving the Guide Sleeve in place, replace the Trocar with the 4 mm Drill Guide (A). Ensuring the Drill Guide is NOT resting against the bone, drill bicortical with the 4 mm Drill and measure the screw length off the Drill Guide in the same manner as previously described in Step 11 (FIGURE 24). Alternatively, the Screw Depth Gauge can be used to determine screw length. Note that the Screw Depth Gauge must also be read off of the Drill Guide as it abuts the bone.

TIP: Due to the soft bone in the calcaneus, it might be difficult to determine whether the drill has breached the far cortex through tactile feedback. Assess drill depth using fluoroscopy.

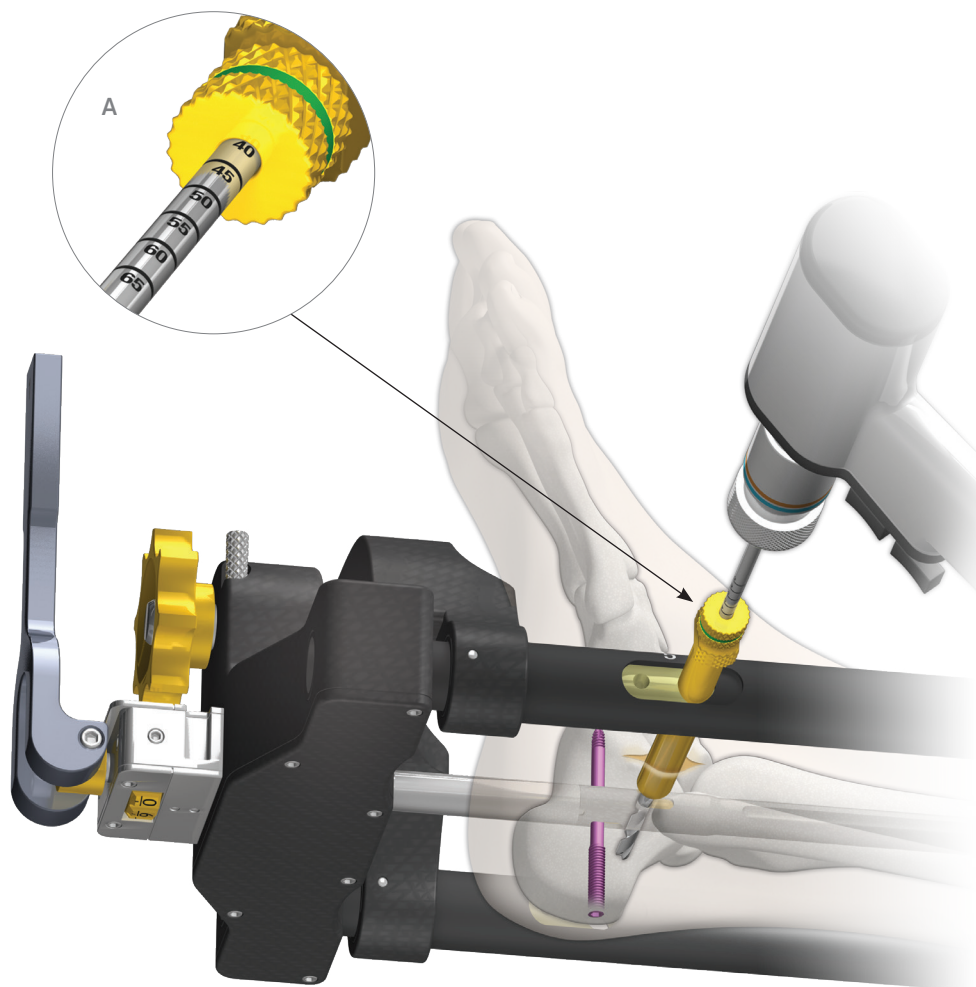


FIGURE 24

Remove the 4 mm Drill Guide from the Guide Sleeve (B). Insert the Cortical Screw through the 8 mm Guide Sleeve using the Wide 3.5 mm Hex Driver as described in Step 11 (FIGURE 25). Use fluoroscopy to determine when desired depth is reached and the screw is fully seated.

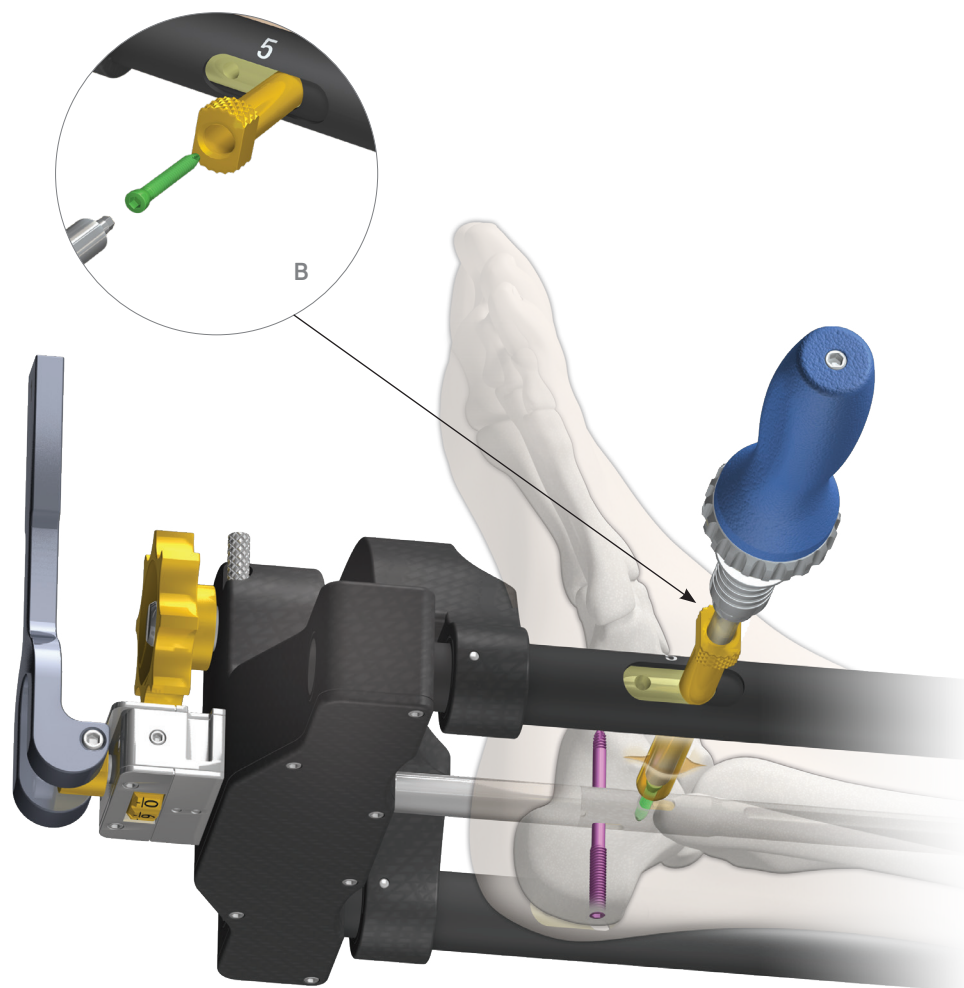


FIGURE 25

13. APPLY MANUAL COMPRESSION

Instruments used:

1. 8 mm Guide Sleeve (x2) (7)
2. 4 mm Drill Guide (x2) (6)
3. Trocar Obdurator (5)
4. 4 mm Drill (20)

Thread the Trocar into the 8 mm Guide Sleeve. Insert the 8 mm Guide Sleeve and Trocar assembly into the more distal tibial screw hole on the medial side of the DynaFrame™ Assembly (passing through the Outer Tube Brace). Make an incision at the Trocar tip and advance the Trocar down to bone. Leaving the Guide Sleeve in the DynaFrame Assembly, replace the Trocar with the 4 mm Drill Guide.

Drilling from the medial side, pass a fresh 4 mm Drill through the tibia and across the DynaFrame Assembly. Thread another 4 mm Drill Guide into a second 8 mm Guide Sleeve and insert the Guide assembly into the distal hole on the lateral side of the DynaFrame Assembly so that it abuts against the bone. Continue to insert the 4 mm Drill into the Drill Guide on the lateral side (FIGURE 26). Leave the drill in place and rotate the Manual Compression Knob clockwise to apply compression across the joint (A). The approximate amount of applied manual compression can be determined by reading the lasermarks on the DynaFrame Assembly (B). Leave the Drill in place while proceeding to Step 14.

NOTE:

If manual compression is not desired, proceed to the Quick Compress Technique on page 39 for tibial screw placement.

TIP:

- The 4 mm Drill Guide should be placed just off the bone to ensure that the DynaFrame Assembly is floating freely during drilling.
- Do NOT place the second 4 mm Drill Guide on lateral side of the DynaFrame (next step) until AFTER advancing the Drill through the Nail Implant. The fibula can interact with the lateral Drill Guide, which can push the DynaFrame Assembly out of alignment.
- If not using a trauma triangle, make sure the targeting tubes are not resting on any table or pillows. If using bumps or towels, move them to underneath ankle.

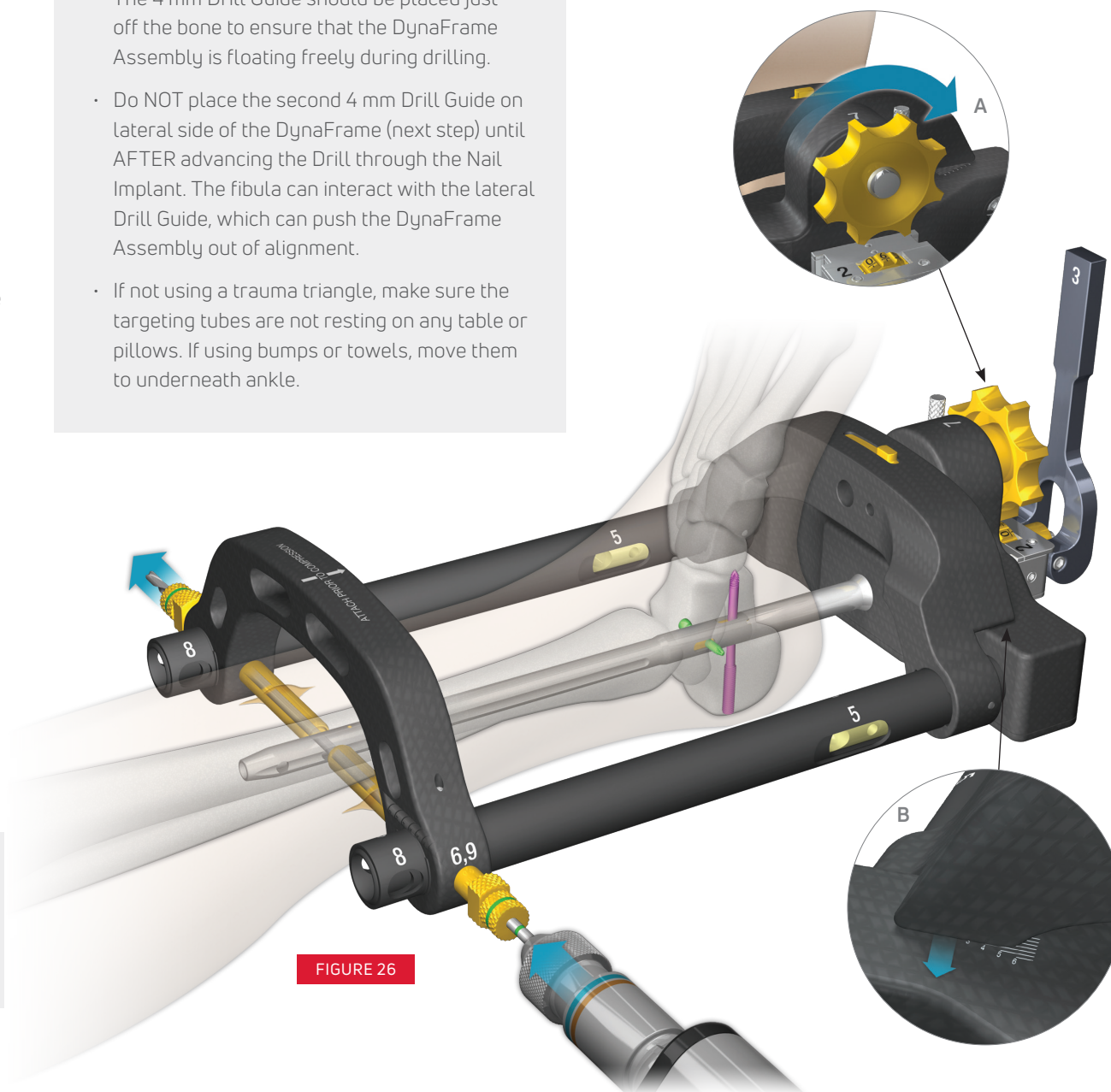


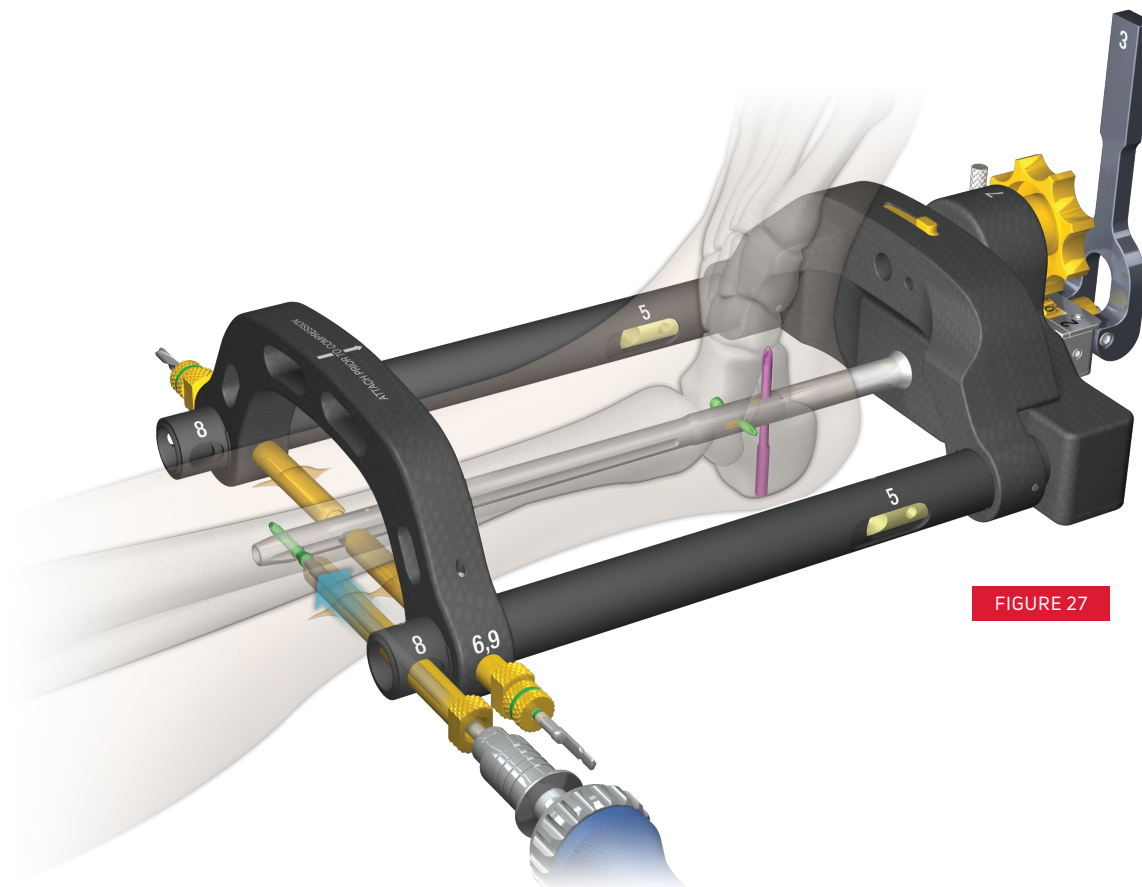
FIGURE 26

14. PROXIMAL TIBIAL SCREW PLACEMENT

Instruments used:

1. 8 mm Guide Sleeve (7)
2. Trocar Obturator (5)
3. 4 mm Drill Guide (6)
4. 4 mm Drill (20)
5. 3.5 mm Hex Driver (16)
6. Blue-Handle Ratchet Driver (36)
7. Cortical Screw

Thread the Trocar into a third 8 mm Guide Sleeve. Place the 8 mm Guide Sleeve and Trocar Assembly in the most proximal hole on the medial side of the DynaFrame™ Assembly. Make an incision at the Trocar tip and advance down to bone. Leaving the Guide Sleeve in place, replace the Trocar with the 4 mm Drill Guide. Drill using a fresh 4 mm Drill, determine appropriate Cortical Screw length, and insert Cortical Screw as described in Step 12 (FIGURE 27). Remove the 8 mm Guide Sleeve from the DynaFrame Assembly.



15. DISTAL TIBIAL SCREW PLACEMENT

Instruments used:

1. 3.5 mm Hex Driver (16)
2. Blue-Handle Ratchet Driver (36)
3. Cortical Screw

Relieve the compression on the 4 mm Drill by turning the Manual Compression Knob back counterclockwise until it rotates freely (A), but do not force the wheel back until it reads zero. Remove the 4 mm Drill. Determine the appropriate screw length and insert the Cortical Screw as described in Step 11 (FIGURE 28). Confirm screw placement, anatomic alignment, and apposition of fusion surfaces under fluoroscopy prior to removing DynaFrame™ Assembly (FIGURE 29).

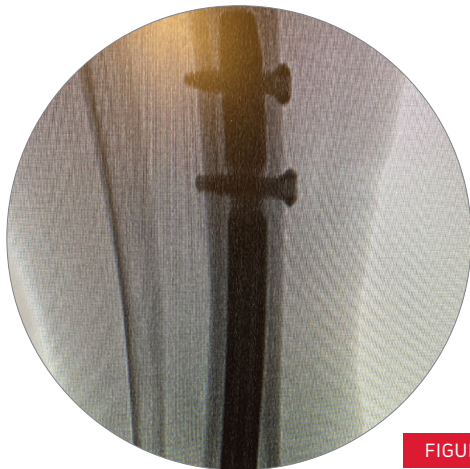


FIGURE 29

*Image courtesy
of Steve Behrens
(Hospital for Special
Surgery)*

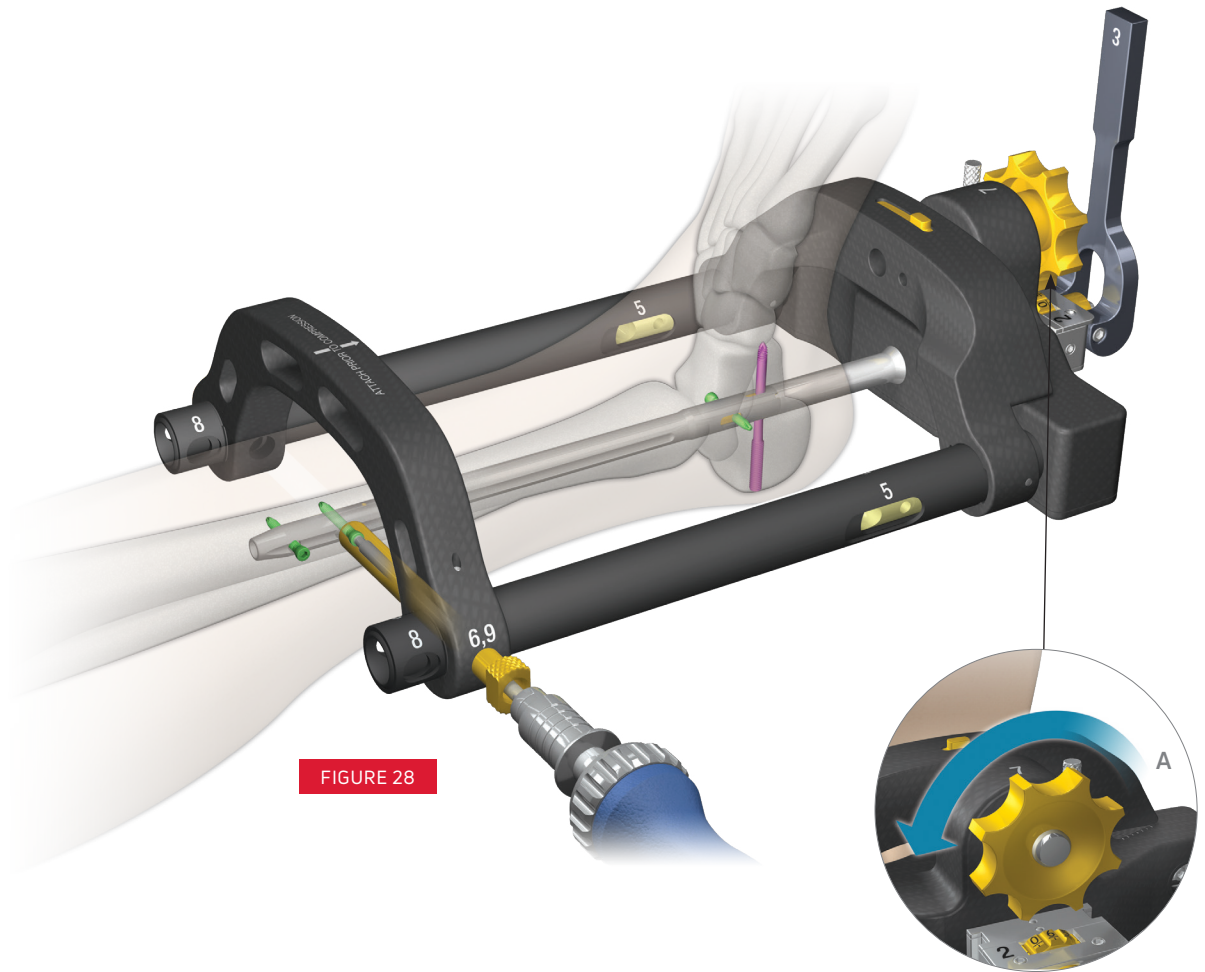


FIGURE 28

16. OPTIONAL: PROXIMAL TIBIAL SCREW PLACEMENT (FOR DYNANAIL XL® IMPLANTS ONLY)

Instruments used:

1. Cortical Screw
2. 4 mm Freehand Drill (21)
3. 2.5 mm /4 mm Drill Guide (4)
4. Free-Hand Depth Gauge (12)
5. 3.5 mm Hex Driver (16)
6. Blue-Handle Ratchet Driver (36)

For 260 mm and 300 mm length Nail Implants, a Cortical Screw may also be free-handed into the most proximal tibial screw hole. This screw can also be a substitute for the tibial Cortical Screw described in Step 15. Drill using the 4 mm Free-Hand Drill (FIGURE 30) in the most proximal tibial screw hole using perfect circles technique under fluoroscopy. Determine the appropriate screw length by inserting the Free-Hand Depth Gauge (FIGURE 31). Insert the Cortical Screw as described in Step 12 (FIGURE 32). Use fluoroscopy to determine when desired depth is reached and the screw is fully seated.

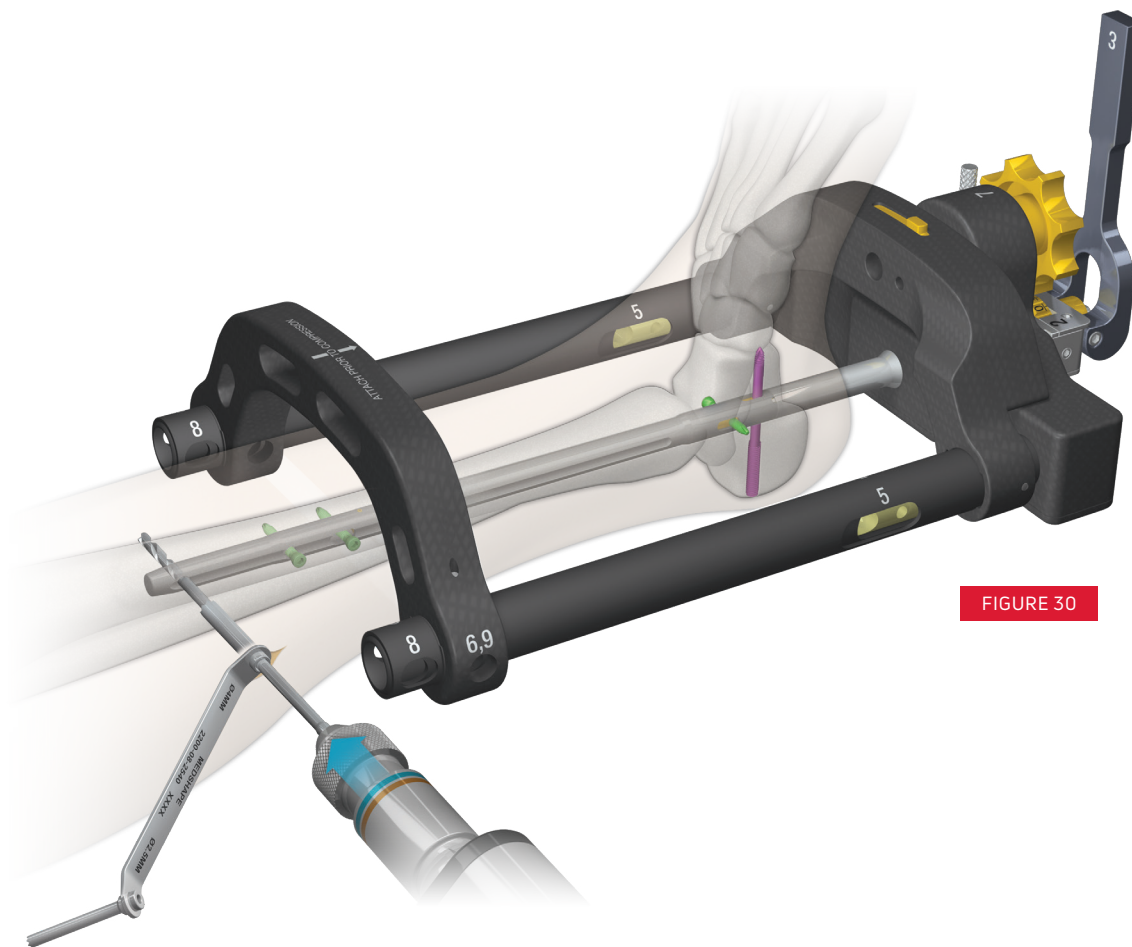


FIGURE 30

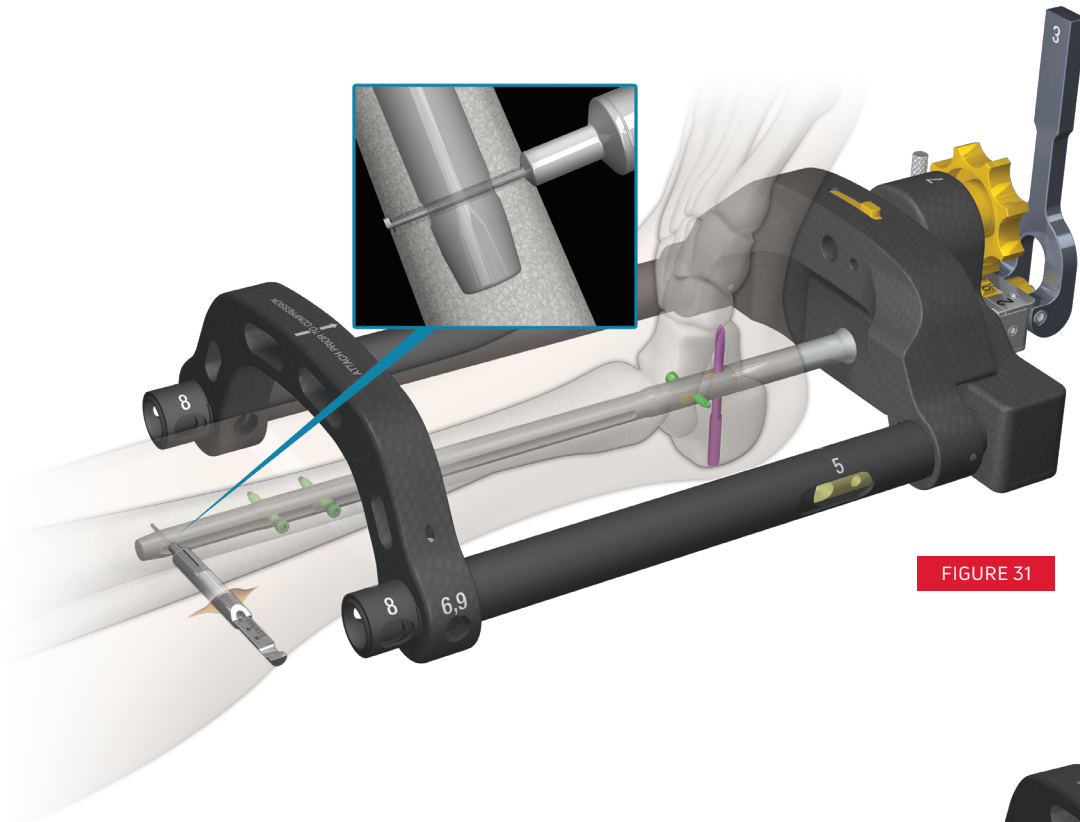


FIGURE 31

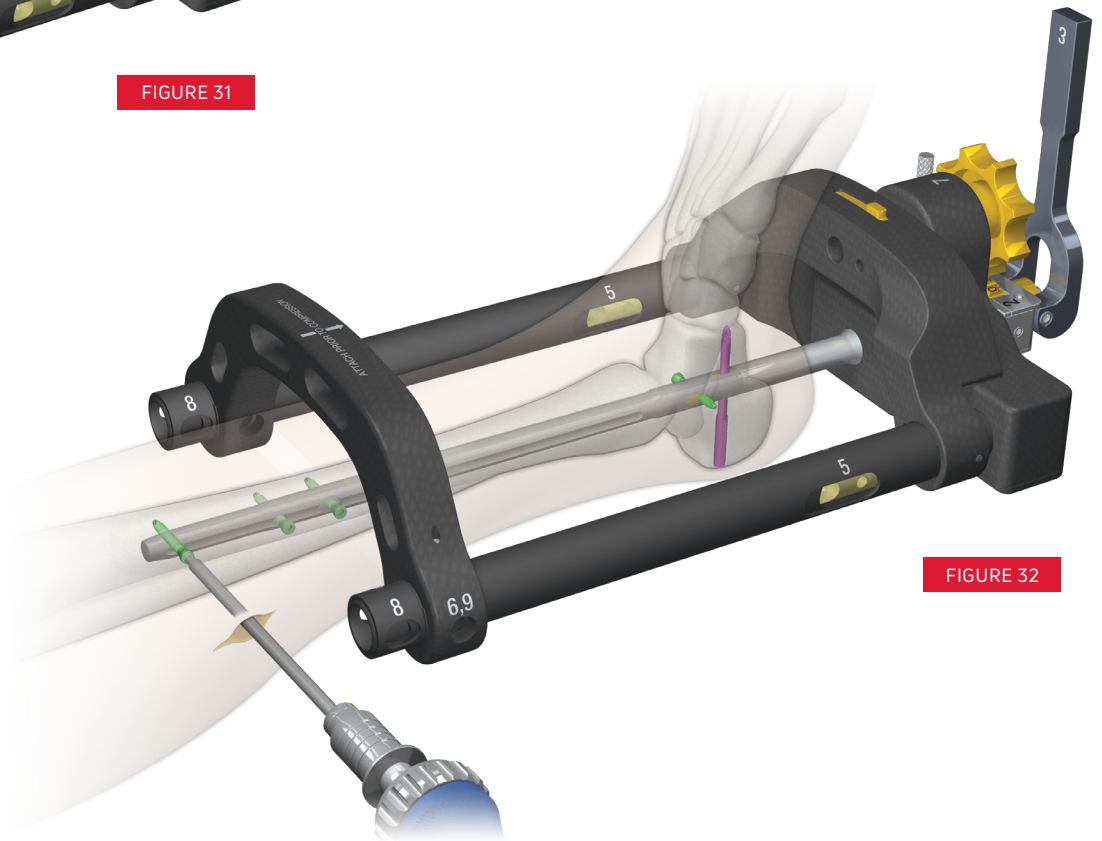


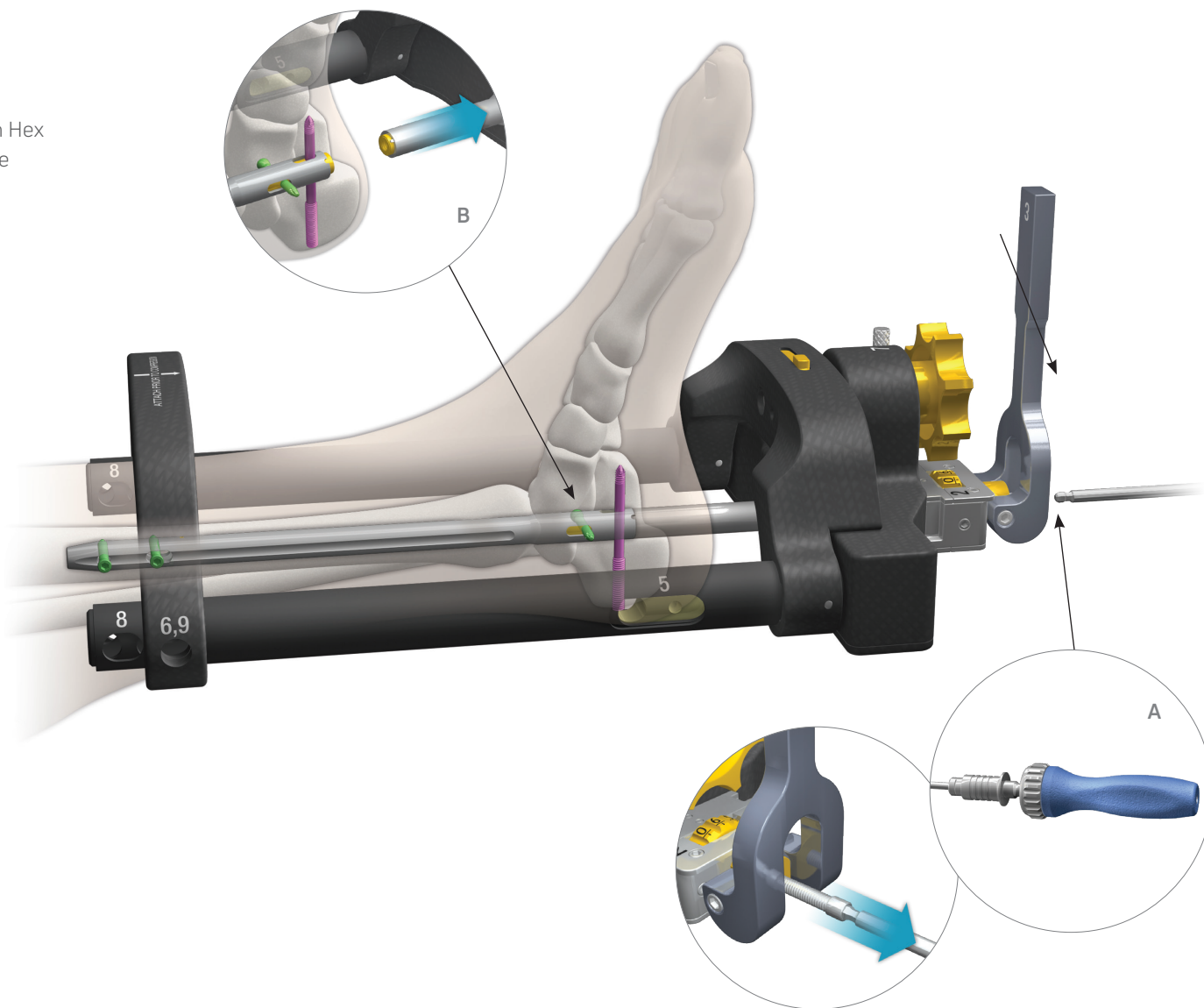
FIGURE 32

17. RELEASE NAIL

Instruments used:

1. 5 mm Hex Driver (13)
2. Blue-Handle Ratchet Driver (36)

Unscrew the M6 Connection Screw using the 5 mm Hex Driver (A), releasing the DynaNail® Implant from the DynaFrame™ Assembly (B).



18. ADD END CAP

Instruments used:

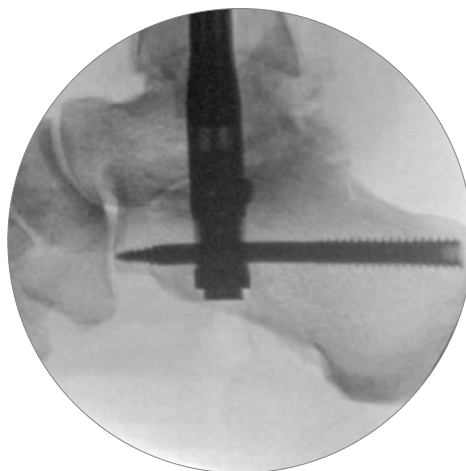
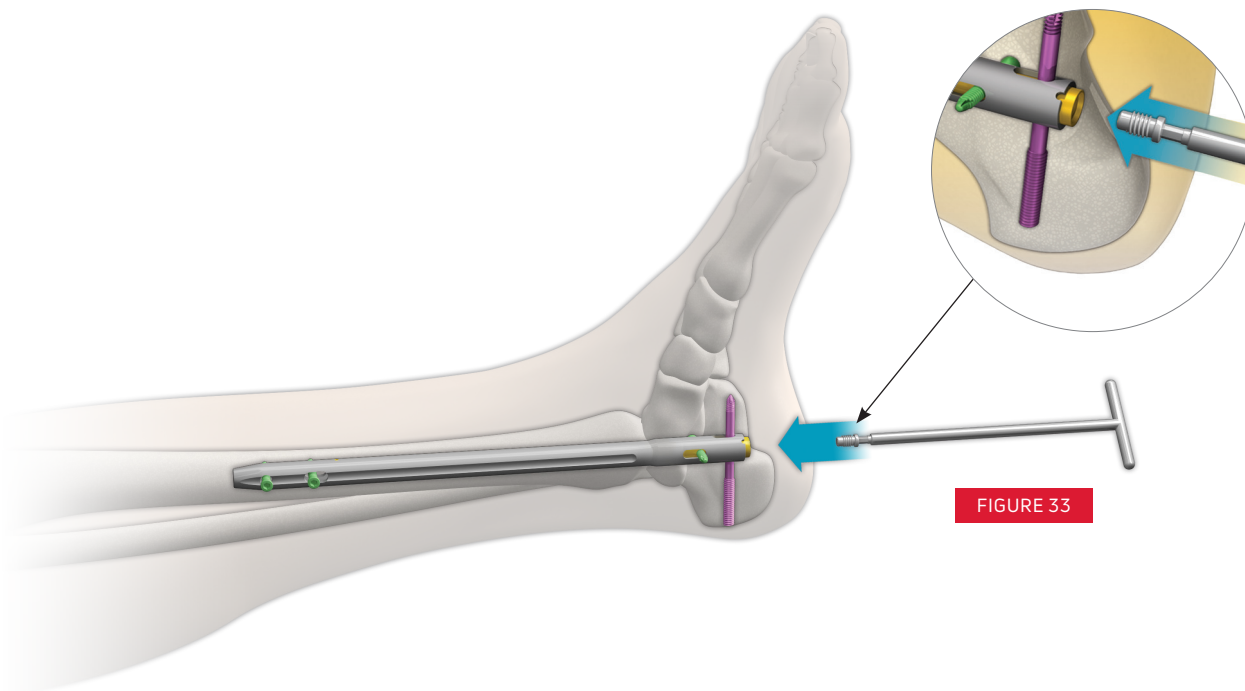
1. 3 mm Hex Driver, T-Handle (14)
2. End Cap

Thread the End Cap into the distal end of the DynaNail® Implant using the 3 mm T-Handle Hex Driver (**FIGURE 33**).

Close incisions per surgeon preference.

NOTE:

The End Cap locks the PA Screw into the distal calcaneal screw hole, preventing back out.



NOTE:

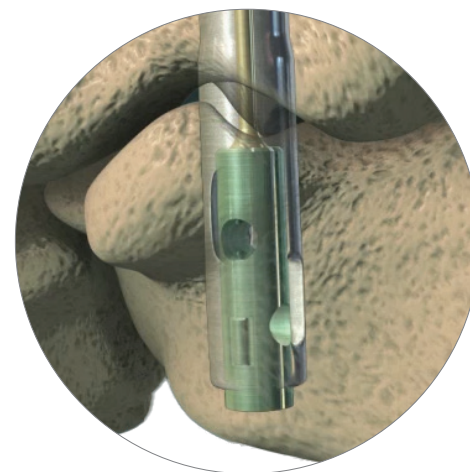
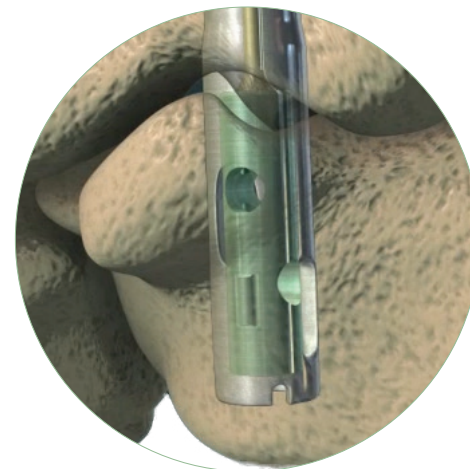
On the final fluoroscopy shot, note the distal position of the Calcaneal Screws in the Sliding Element slots and the Sliding Element protruding plantar from Outer Nail Body, indicating the Compressive Element is in its stretched, activated state.

If a surgeon would like to bypass external manual compression, the following steps may replace Steps 13-16 described previously. Depending upon the choice of tibial screw placement, this alternate technique also allows for additional dynamization even after full recovery of the Compressive Element.

While the Compressive Element will provide post-operative compression, applying manual compression helps ensure the joints are tightly compressed intra-operatively so that the Compressive Element does not recover until resorption occurs post-surgery. Therefore, it is recommended that this alternate technique only be adopted when the joints appear visually compressed intra-operatively. Indications include if a surgeon wants to avoid the lateral plantar neurovascular bundle, reduce the risk of a stress riser at the screw when drilling in the tibia, or drill only one tibial screw hole instead of two. Patients with large bony defects who might receive a bulk allograft or are immunocompromised with poor bone healing capacity might not be suitable for this technique.

NOTE:

Though not using the Manual Compression feature, the Compression Wheel must still be "zeroed" in order to properly load the Nail Implant.



13B. COMPRESS ARTHRODESIS SITE

Instruments used:

1. Anvil Attachment (1)

Slide the Anvil Attachment onto the DynaFrame™ Assembly (**FIGURE 34**) and strike the Anvil with a mallet to apply compression to the arthrodesis site.

TIP: Do NOT strike any other part of the DynaFrame besides the Anvil Attachment.

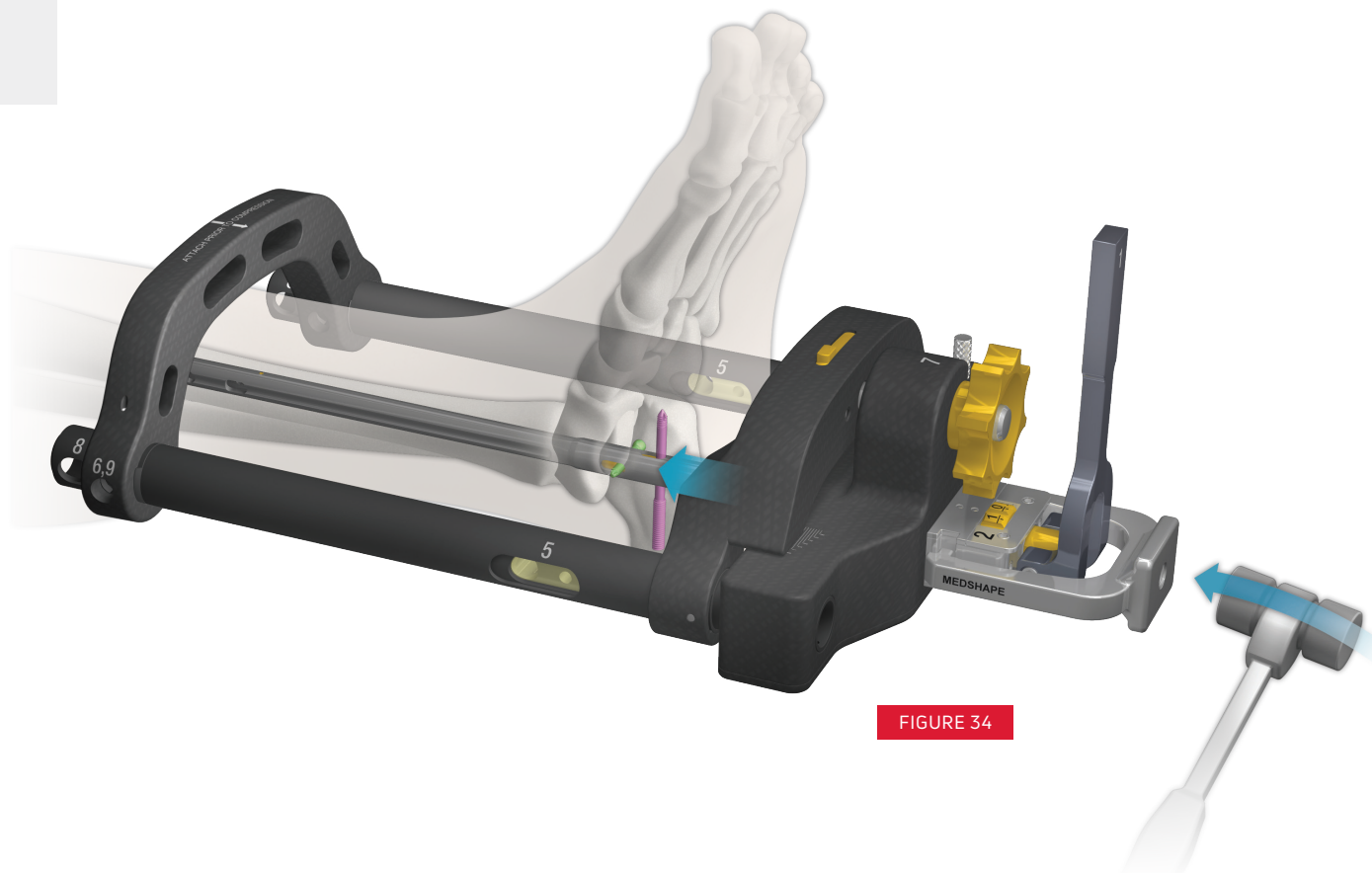


FIGURE 34

14B. DISTAL TIBIAL SCREW PLACEMENT

Instruments used:

1. Cortical Screw
2. 4 mm Drill (20)
3. 4 mm Drill Guide (6)
4. 8 mm Guide Sleeve (7)

If automatic dynamization is desired, drill a hole from the medial side into the distal tibial oblong slot of the DynaNail® Implant until the Drill has breached the lateral side of the tibia (**FIGURE 35**). Insert a Cortical Screw as described in Step 12 (**FIGURE 36**).

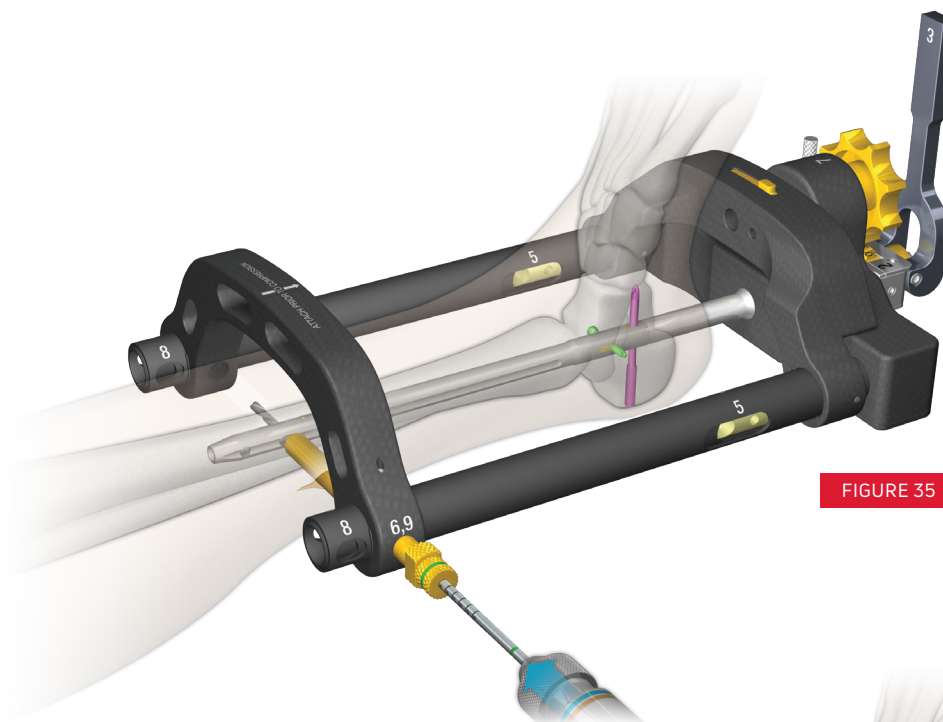


FIGURE 35

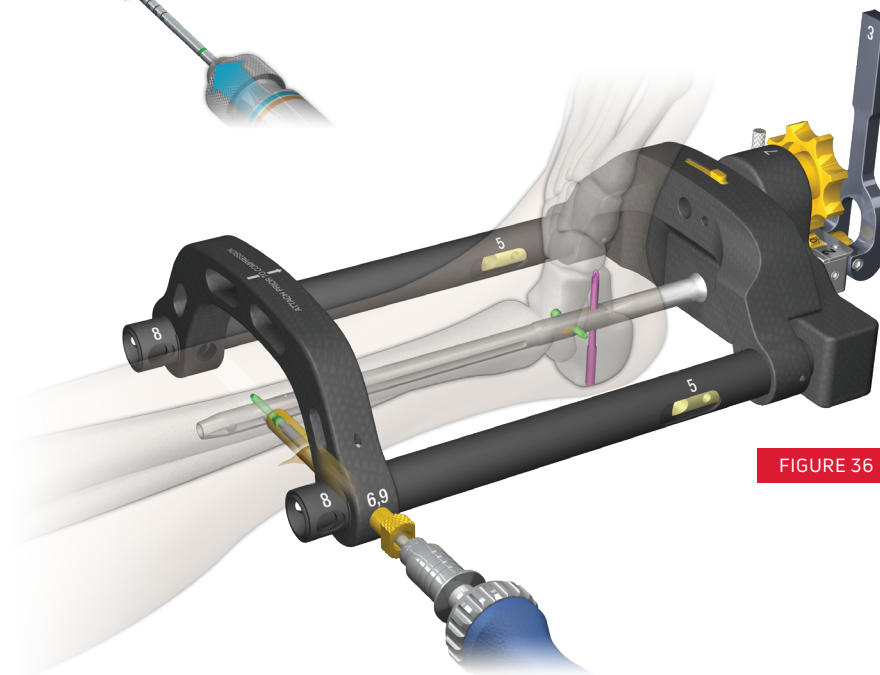
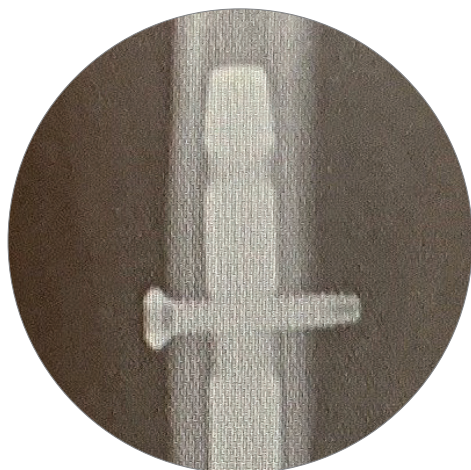


FIGURE 36

15B. OPTIONAL: PROXIMAL TIBIAL SCREW PLACEMENT

If static locking is desired, drill a hole into one of the proximal tibial screw holes of the DynaNail® Implant (FIGURE 37) and insert a Cortical Screw as described in Step 12 (FIGURE 38). This step may replace Step 15b such that there is only one screw in the proximal tibial hole, if so desired.

Proceed to step 17 in the original technique to finish the procedure.

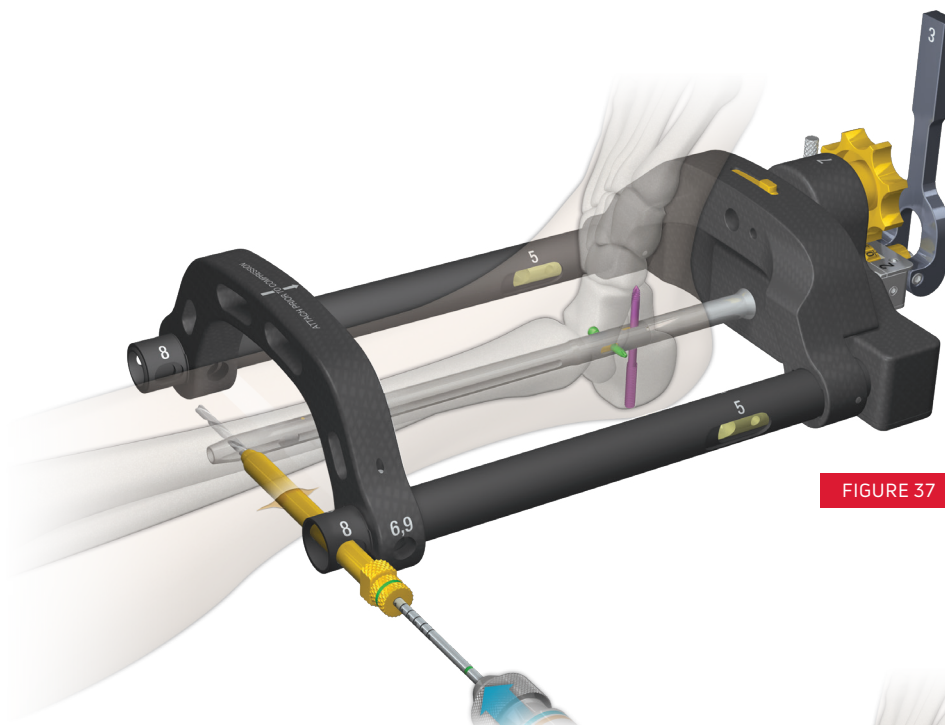


FIGURE 37

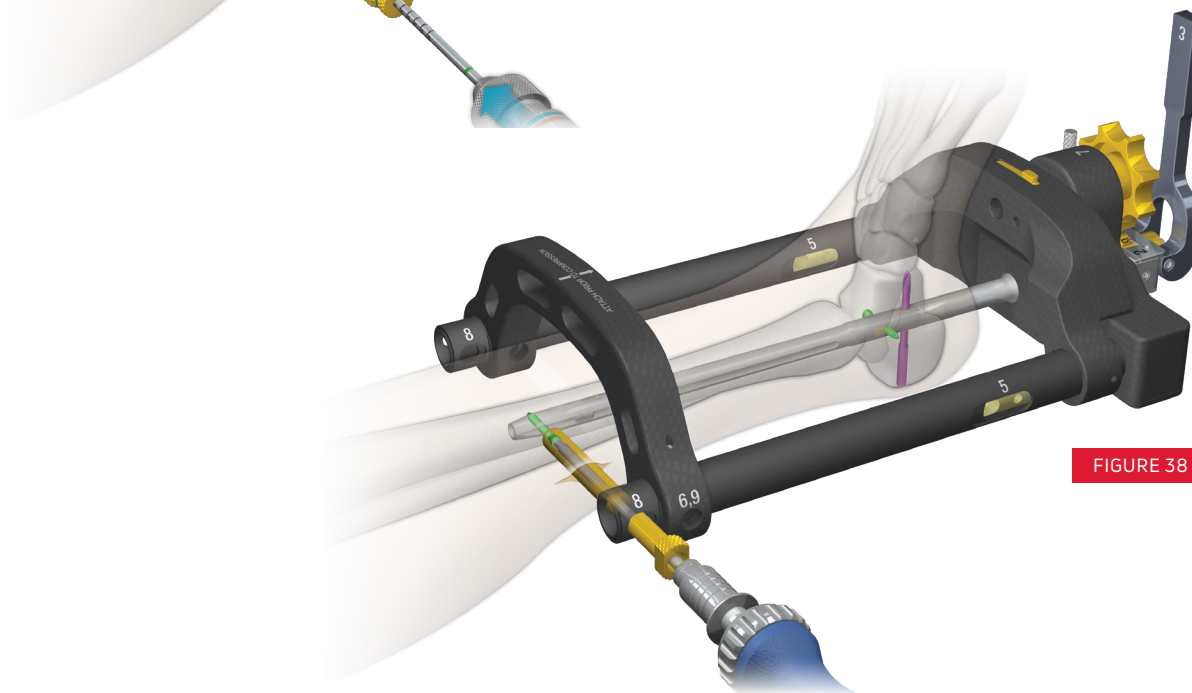


FIGURE 38

DYNANAIL® IMPLANTS

PART #	DESCRIPTION
1200-01-1022	DYNANAIL, 10 MM X 22 CM
1200-01-1222	DYNANAIL, 12 MM X 22 CM
1200-01-1026	DYNANAIL XL, 10 MM X 26 CM
1200-01-1226	DYNANAIL XL, 12 MM X 26 CM
1200-01-1030	DYNANAIL XL, 10 MM X 30 CM
1200-01-1230	DYNANAIL XL, 12 MM X 30 CM
1200-02-5020	HEADED CORTICAL SCREW, 5.0 MM X 20 MM
1200-02-5022	HEADED CORTICAL SCREW, 5.0 MM X 22.5 MM
1200-02-5025	HEADED CORTICAL SCREW, 5.0 MM X 25 MM
1200-02-5027	HEADED CORTICAL SCREW, 5.0 MM X 27.5 MM
1200-02-5030	HEADED CORTICAL SCREW, 5.0 MM X 30 MM
1200-02-5035	HEADED CORTICAL SCREW, 5.0 MM X 35 MM
1200-02-5040	HEADED CORTICAL SCREW, 5.0 MM X 40 MM
1200-02-5045	HEADED CORTICAL SCREW, 5.0 MM X 45 MM
1200-02-5050	HEADED CORTICAL SCREW, 5.0 MM X 50 MM
1200-02-5055	HEADED CORTICAL SCREW, 5.0 MM X 55 MM

PART #	DESCRIPTION
1200-03-5060	HEADLESS PA SCREW, 5.0 MM X 60 MM
1200-03-5065	HEADLESS PA SCREW, 5.0 MM X 65 MM
1200-03-5070	HEADLESS PA SCREW, 5.0 MM X 70 MM
1200-03-5075	HEADLESS PA SCREW, 5.0 MM X 75 MM
1200-03-5080	HEADLESS PA SCREW, 5.0 MM X 80 MM
1200-03-5085	HEADLESS PA SCREW, 5.0 MM X 85 MM
1200-03-5090	HEADLESS PA SCREW, 5.0 MM X 90 MM
1200-03-5095	HEADLESS PA SCREW, 5.0 MM X 95 MM
1200-03-5100	HEADLESS PA SCREW, 5.0 MM X 100 MM
1200-03-5105	HEADLESS PA SCREW, 5.0 MM X 105 MM
1200-03-5110	HEADLESS PA SCREW, 5.0 MM X 110 MM
1200-04-0000	END CAP

DYNANAIL® SINGLE-USE INSTRUMENTS

PART #	DESCRIPTION
2200-09-0040	4 MM DRILL
2200-18-4031	TROCAR TIPPED GUIDEWIRE (3.1 MM x 400 MM)
2200-18-5031	BEAD TIPPED GUIDEWIRE (3.1 MM x 500 MM)
2200-19-0020	STEINMAN PINS, 2 MM X 9"
2201-09-0025	2.5 MM X 15 CM DRILL
2201-09-0040	4 MM X 15 CM DRILL



T 800.456.8696 D 512.832.9500 F 512.834.6300
1575 Northside Dr NW | Suite 440 | Atlanta, GA 30318 | U.S.A.
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