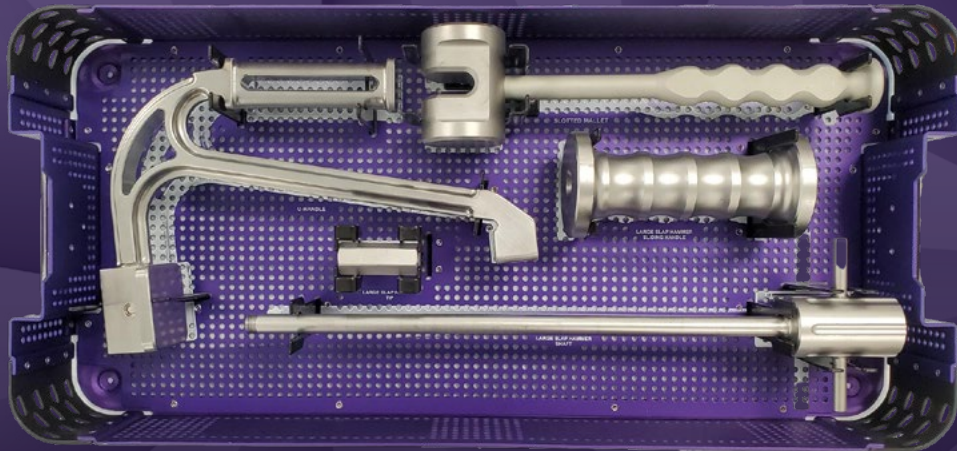
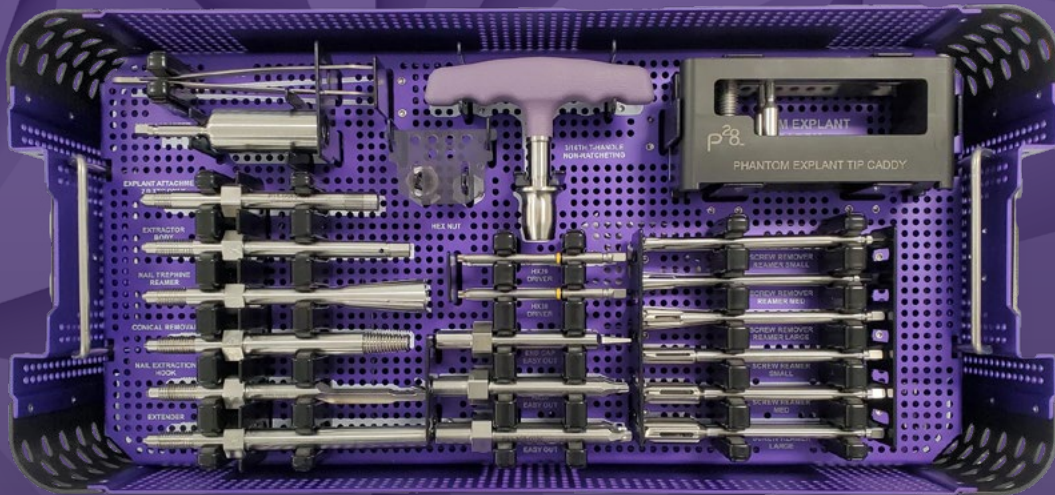

SURGICAL TECHNIQUE GUIDE

Phantom® Explant System



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FEATURED INSTRUMENTATION



Long TTC Explant Attachment



Cross Thread Explant Attachment



ActivCore Inner Nail Explant Attachment



Conical Explant Attachment



Nail Extraction Hook



Nail Trepine Reamer



Extender



Extractor Body



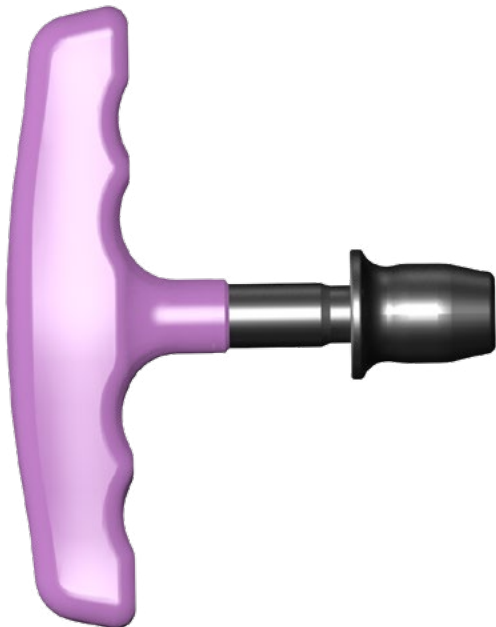
End Cap Easy Out



Screw Easy Out
TX-20



Screw Easy Out
TX-30

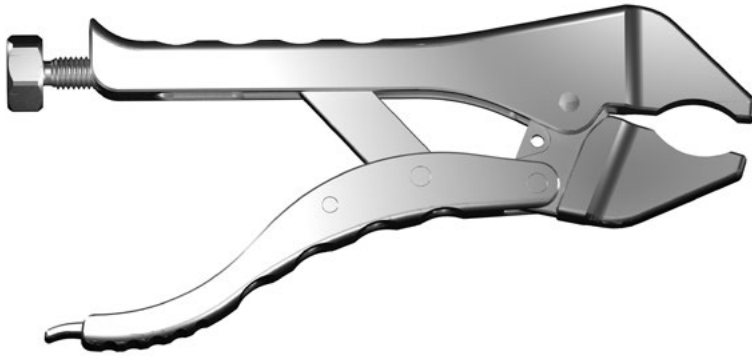


Non-Ratcheting
T-handle



T-handle
Hex Adaptor

FEATURED INSTRUMENTATION



Pliers



17 mm Nut



17 mm Wrench



8 mm Wrench



U Handle



Slotted Mallet



Slaphammer Shaft



Slaphammer Sliding Weight



Slaphammer Tip



Slaphammer Assembled

NAIL EXPLANT OPTIONS



OPTION	TTC	ACTIVCORE
1	Long Explant Attachment (Direct Nail Thread Engagement)[Page 8]	N/A
2	N/A	ActivCore Inner Nail Explant Attachment (Direct Nail Inner Core Thread Engagement) [Page 9]
3	Cross Thread Explant Attachment (Cross Threads into Nail) [Page 10]	Cross Thread Explant Attachment (Cross Threads into Nail) [Page 10]
4	Conical Explant Attachment (Cross Threads into Nail) [Page 11]	Conical Explant Attachment (Cross Threads into Nail) [Page 11]
5	Nail Extraction Hook (Hooks into distal slot of Nail) [Page 12]	Nail Extraction Hook (Hooks into distal slot of Nail) [Page 12]
6	Nail Trephine Reamer (Removes portion of calcaneus and interfaces with external portion of the Nail) [Page 13]	Nail Trephine Reamer (Removes portion of calcaneus and interfaces with external portion of the Nail) [Page 13]

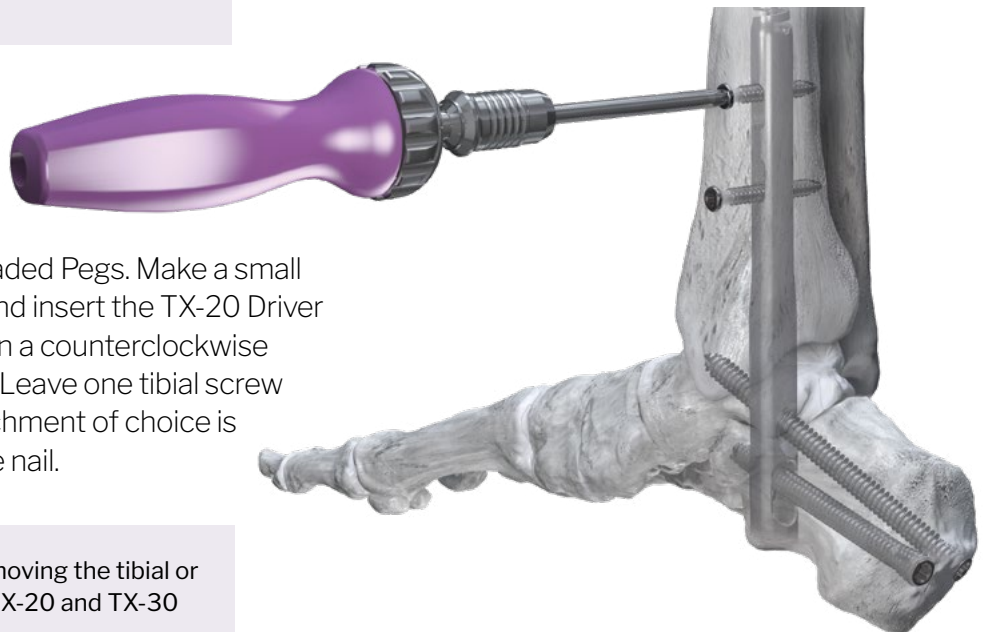
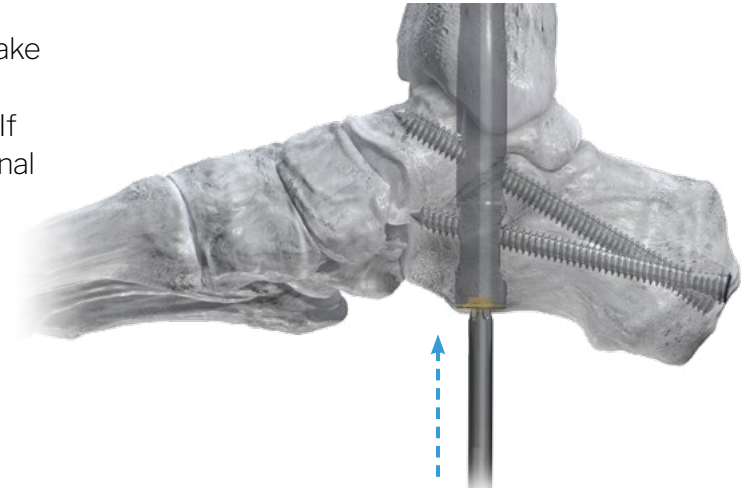
IMPLANT REMOVAL – BOTH NAILS SURGICAL APPROACH

NOTE: It is recommended to clean out the plantar nail threads with a forceps and saline to remove in growth and soft tissue before attempting to insert explant attachment.

Attach the TX-30 Driver to the appropriate Handle. Using fluoroscopy, locate the plantar insertion point of the Nail, and make a small incision. If an end cap was implanted, insert the TX-30 Driver into the end cap and rotate counterclockwise to remove. If no end cap was implanted, insert the TX-30 Driver into the Internal Compression Screw and rotate counterclockwise to remove.

NOTE: If the surgeon is having difficulty removing the end cap, use the provided end cap easy out.

NOTE: If compression screw is not able to be removed, advance screw superiorly to maximum depth after removing calcaneal crossing screws.



Using fluoroscopy, locate the Tibial Threaded Pegs. Make a small incision at each Threaded Peg location and insert the TX-20 Driver into the head of the Threaded Peg. Turn in a counterclockwise direction until Threaded Peg is removed. Leave one tibial screw engaged in the nail until the explant attachment of choice is connected with the inferior portion of the nail.

NOTE: If the surgeon is having difficulty removing the tibial or calcaneal threaded pegs, use the provided TX-20 and TX-30 easy outs.

Utilizing the same TX-30 Driver and Handle construct as described above, remove the Subtalar Threaded Peg and Calcaneal Threaded Peg. Confirm removal of all Threaded Pegs, using fluoroscopy prior to attempting to remove the Phantom[®] TTC Nail.

Continue with implant removal with the chosen explant attachment per surgeon preference.



IMPLANT REMOVAL – BOTH NAILS

TIBIAL/CALCANEAL THREADED PEG AND END CAP REMOVAL

EASY OUTS

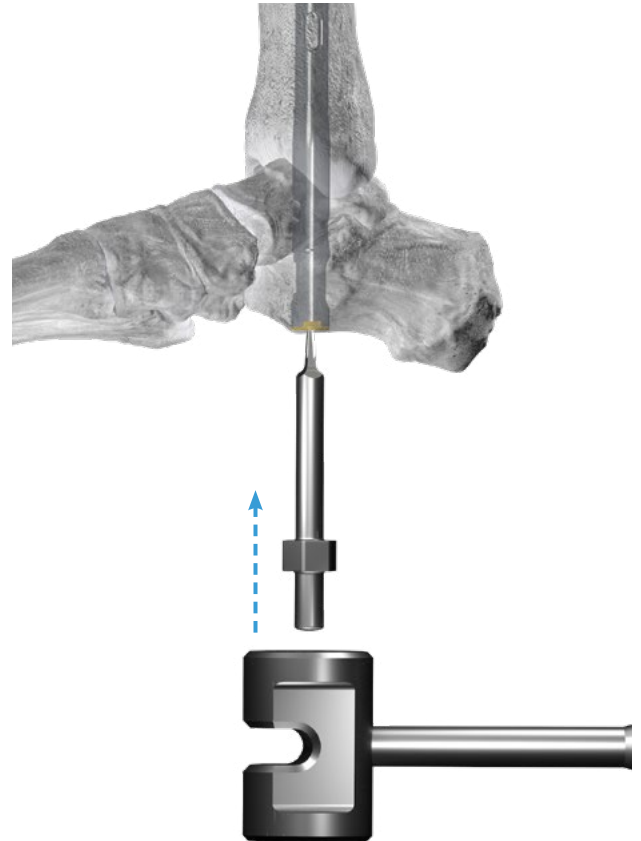
If there are issues removing any of the tibial threaded pegs, calcaneal threaded pegs, or the end cap in the nail. Easy outs are provided to expedite removal.

PART TO BE REMOVED	EASY OUT TO USE
Tibial Threaded Peg	TX-20 Easy Out
Subtalar/Calcaneal Threaded Peg	TX-30 Easy Out
End Cap	End Cap Easy Out TX-30 Easy Out

Align the easy out with the hex feature of the pegs or end cap and tap into the peg or end cap with a mallet.

After firmly seating the easy out in the peg/end cap, use the provided 17 mm wrench or T-handle with the hex adaptor to turn the easy out/peg counterclockwise.

Continue turning it counterclockwise until the peg is fully removed.



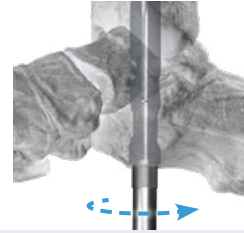
IMPLANT REMOVAL – TTC NAIL ONLY

OPTION 1: LONG EXPLANT ATTACHMENT

Thread the long explant attachment into the end of the nail until secure.



NOTE: If the surgeon is still having difficulty threading in the attachment, proceed to the cross thread tip removal option.



NOTE: Confirm using fluoroscopy that the long explant attachment has advanced into the calcaneal slots of the nail.

Assemble the Slaphammer by sliding the weight down the shaft and threading the tip onto the end.

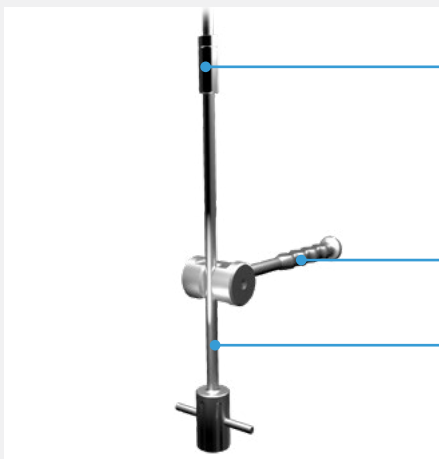
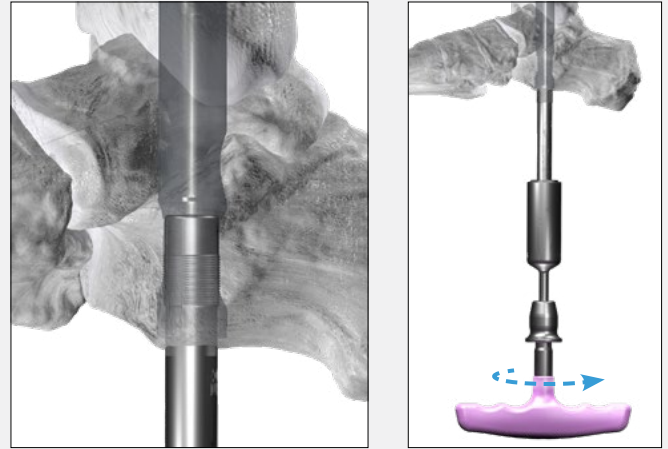


Thread the Slaphammer onto the extractor body. Upon being securely attached, remove any remaining tibial or calcaneal threaded pegs. Use the sliding weight of the Slaphammer to back the nail out of the foot in an inferior direction until the Nail is removed.

NOTE: If preferred, the extractor body can be used with the U handle as shown on page 9.

NOTE: If necessary, the sliding weight of the Slaphammer can be removed so that the slotted mallet can be used with the shaft of the Slaphammer instead.

NOTE: If necessary, the provided T-handle and Hex adaptor can be used to provide more force to thread the explant attachment into the end of the nail.



Slotted Mallet

Slaphammer Tip

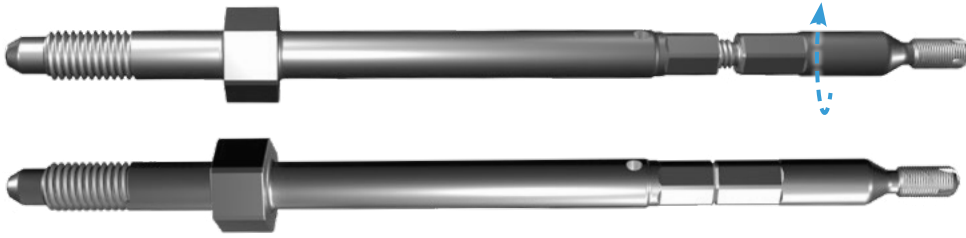
Slaphammer Shaft

Slaphammer Weight

IMPLANT REMOVAL – ACTIVCORE NAIL ONLY

OPTION 2: ACTIVCORE INNER NAIL EXPLANT ATTACHMENT

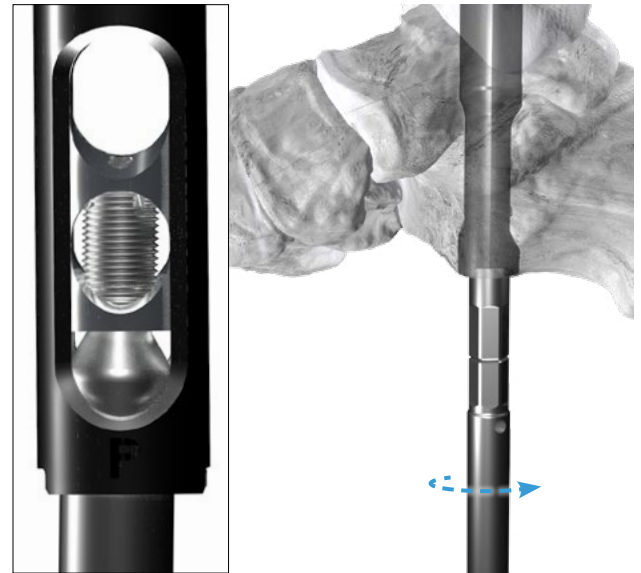
Thread the ActivCore Inner Nail explant attachment into the extractor body until secure. The 8 mm wrench can be used to secure it as well.



Thread the constructed explant attachment into the inner nail until secure. Do not go past hand tightness when securing in the nail, as excessive force may break extractor tip or inner nail. Advance the tip until it bottoms out inside the nail or until it is visible inside the most distal calc hole of the nail.

NOTE: If the surgeon is still having difficulty, proceed to option 3 (Cross Thread Tip) on page 10.

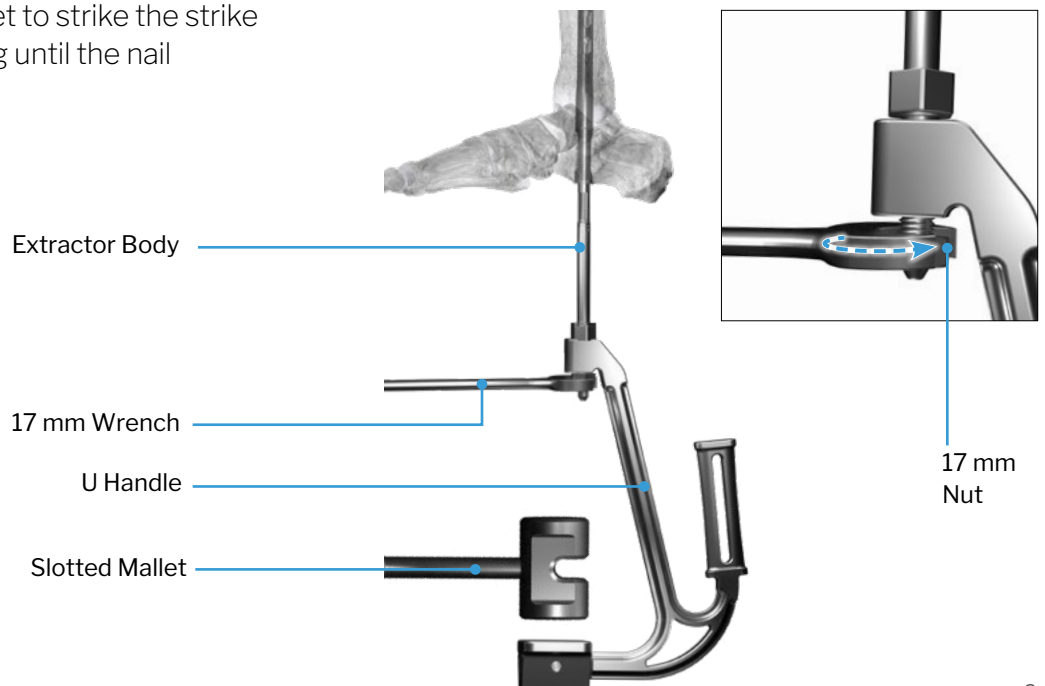
NOTE: Threading into the inner nail can help compress the proximal coil and can disrupt boney ongrowth that may be present.



Place the extractor body through the hole on the U handle and secure with the 17 mm nut and provided wrench.

After securing, remove any remaining tibial or calcaneal threaded pegs. Use the provided mallet to strike the strike plate of the U handle. Continue striking until the nail is removed.

NOTE: If preferred, the extractor body can be used with the Slaphammer as shown previously.



IMPLANT REMOVAL – BOTH NAILS

OPTION 3: CROSS THREAD EXPLANT ATTACHMENT

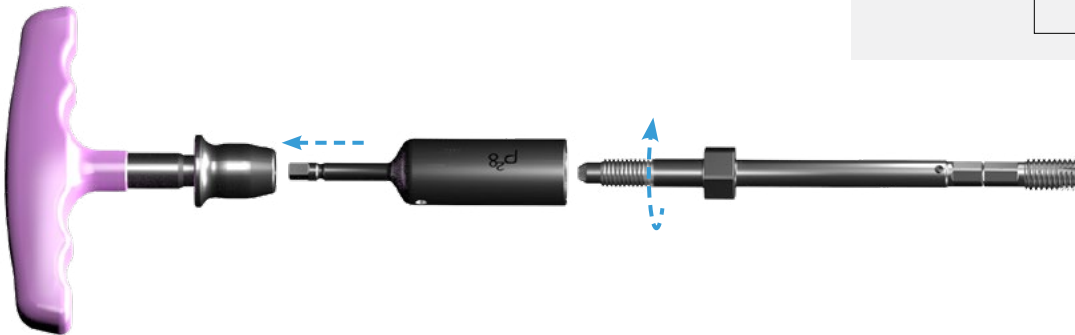
Thread the Cross Thread Explant attachment onto the end of the extractor body.



Thread the extractor body onto the Slaphammer. Use the Slaphammer construct or use the extractor construct and the provided T-handle and Hex adaptor to thread the tip into the nail. Engage 1-2 threads and continue spinning until squealing is heard to confirm the threads have been engaged.

NOTE: If the surgeon is still having difficulty, proceed to option 4 (Conical Explant Tip) on page 11.

NOTE: For best engagement confirm 2 complete threads have been engaged before attempting to remove the nail.

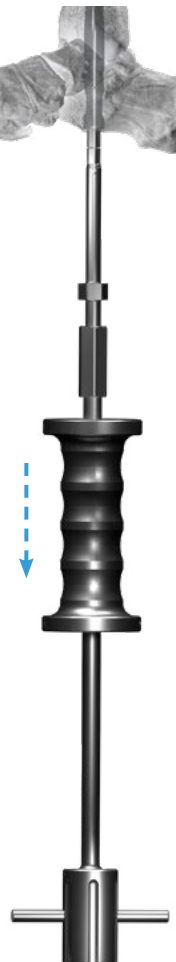


Assemble the Slaphammer by sliding the weight down the shaft and threading the tip onto the end. Thread the Slaphammer onto the extractor body.

Remove any remaining tibial or calcaneal threaded pegs. Use the sliding mechanism of the Slaphammer to back the nail out of the foot in an inferior direction until the Nail is removed.

NOTE: If preferred, the extractor body can be used with the U handle as shown previously.

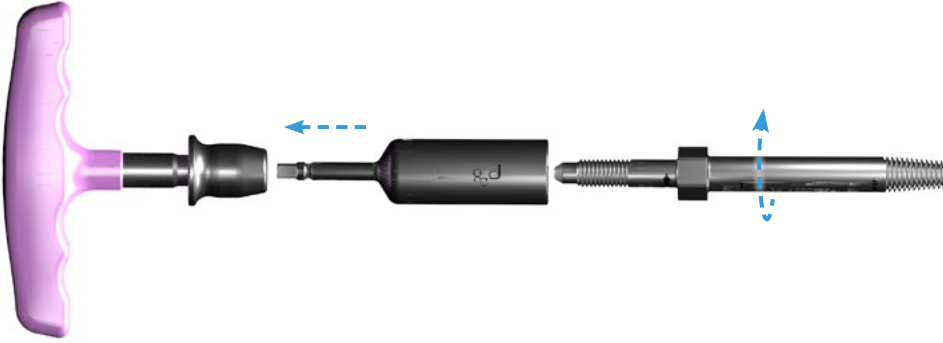
NOTE: If necessary, the sliding weight of the Slaphammer can be removed so that the slotted mallet can be used with the shaft of the Slaphammer instead.



IMPLANT REMOVAL – BOTH NAILS

OPTION 4: CONICAL EXPLANT ATTACHMENT

Thread the Conical Explant attachment onto the Slaphammer. Use the Slaphammer construct or use the Conical Explant attachment with the provided T-handle and Hex adaptor to thread the tip into the nail in a counterclockwise direction. Continue spinning counterclockwise until squealing is heard to confirm the threads have been engaged.



NOTE: If the surgeon is still having difficulty, proceed to option 5 (Nail Extraction Hook).

NOTE: For best engagement confirm 2 complete threads have been engaged before attempting to remove the nail.

Assemble the Slaphammer by sliding the weight down the shaft and threading the tip onto the end. Thread the Slaphammer onto the threaded end of the Conical Explant attachment.

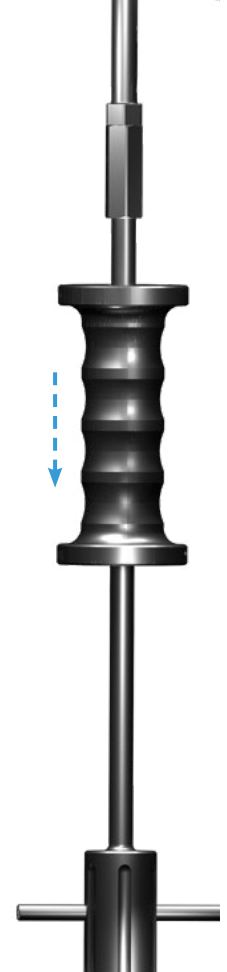
Use a wrench to provide counter torque while attaching Slaphammer or U Handle to prevent tip from loosening from implant during final assembly.

Remove any remaining tibial or calcaneal threaded pegs. Use the sliding mechanism of the Slaphammer to back the nail out of the foot in an inferior direction until the Nail is removed.

NOTE: If preferred, the extractor body can be used with the U handle as shown previously.



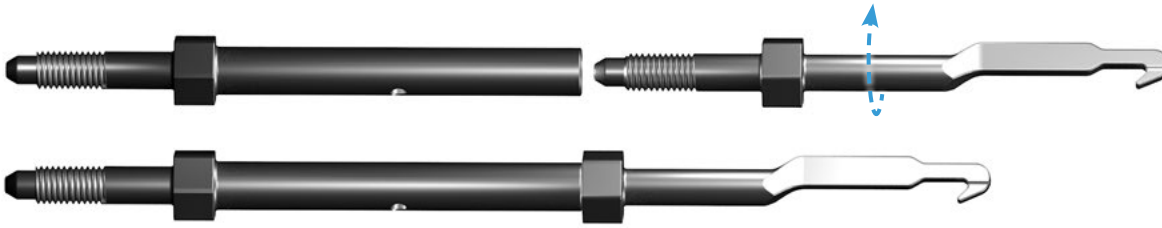
NOTE: If necessary, the sliding weight of the Slaphammer can be removed so that the slotted mallet can be used with the shaft of the Slaphammer instead as shown on page 8.



IMPLANT REMOVAL – BOTH NAILS

OPTION 5: NAIL EXTRACTION HOOK

Optional: Thread the Nail Extraction Hook attachment onto the end of the extender.



Thread the extender or the extraction hook directly onto the Slaphammer. Use the Slaphammer construct or use the Nail Extraction Hook and the provided T-handle and Hex adaptor to place the hook into the nail. Aim the hook posteriorly and grab one of the distal slots in the nail.

It may be necessary to clean out bone around the calcaneal slot of the nail to engage the hook into the nail.

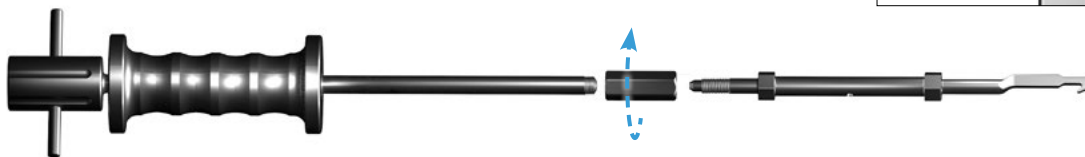
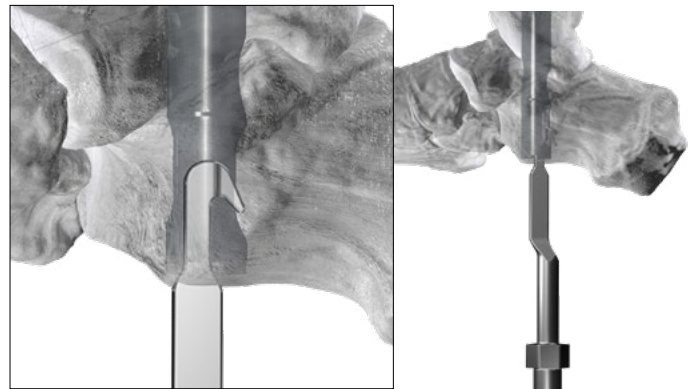
NOTE: If the surgeon is still having difficulty, proceed to option 6 (Nail Trephine Reamer).

NOTE: Use of the extender is optional and only needs to be used when more distance is needed between the bottom of the fat pad of the foot and the removal device (Slaphammer or U Handle).

NOTE: The hook can grab the calcaneal slot of the nail from outside the nail as well.

Assemble the Slaphammer by sliding the weight down the shaft and threading the tip onto the end. Thread the Slaphammer onto the extractor body.

Remove any remaining tibial or calcaneal threaded pegs. Use the sliding mechanism of the Slaphammer to back the nail out of the foot in an inferior direction until the Nail is removed.



NOTE: If preferred, the extractor body can be used with the U handle as shown previously.

NOTE: If necessary, the sliding weight of the Slaphammer can be removed so that the slotted mallet can be used with the shaft of the Slaphammer instead as shown on page 8.



IMPLANT REMOVAL – BOTH NAILS

OPTION 6: NAIL TREPHINE REAMER

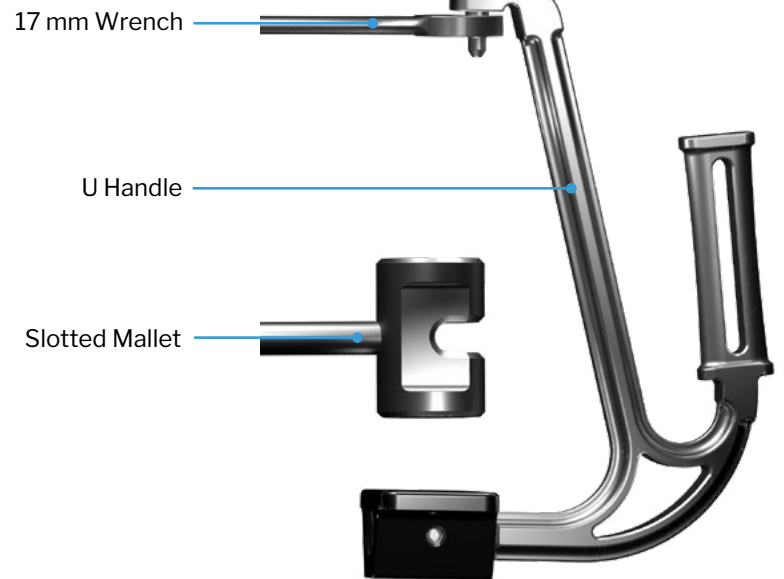
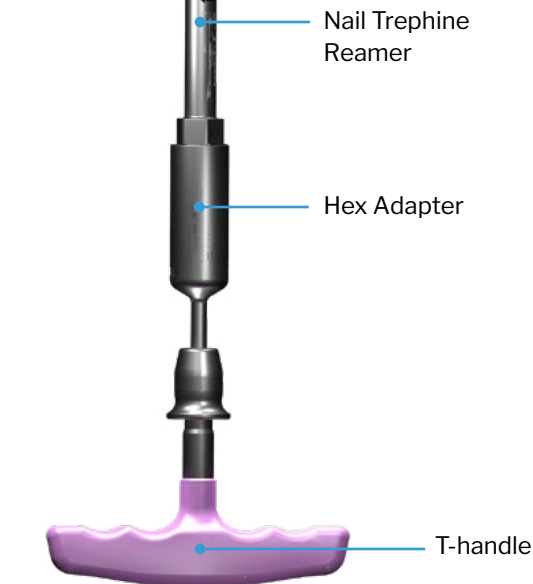
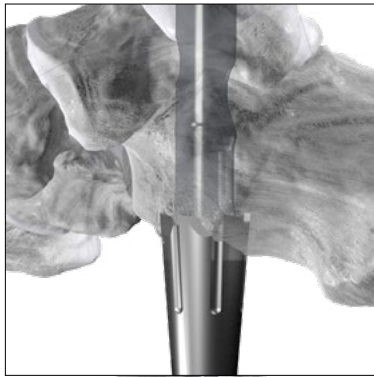
Thread the Nail Trephine Reamer onto the Slaphammer. Use the Slaphammer construct or use the Nail Trephine Reamer with provided T-handle and Hex adaptor to cut through the calcaneus and into the Nail with the trephine. Continue spinning until squealing is heard to confirm the threads have been engaged.

Place the threaded end of the Nail Trephine Reamer through the hole on the U handle and secure with the 17 mm nut and provided wrench.

After securing, remove any remaining tibial or calcaneal threaded pegs. Use the provided mallet to strike the strike plate of the U handle. Continue striking until the nail is removed.

NOTE: This option will remove a portion of the calcaneus around the nail.

NOTE: If preferred, the extractor body can be used with the Slaphammer, as shown previously.



Refer to www.paragon28.com/ifus for the complete and most current instructions for use document.

INDICATIONS FOR USE

The Phantom® Hindfoot TTC/TC Nail System is indicated for tibiotalocalcaneal arthrodesis (fusion) and to provide stabilization of the hindfoot and ankle including the transverse tarsal joints coupling the mid-foot to the hindfoot. Examples of specific indications include:

- Post-traumatic or degenerative arthritis
- Previously infected arthrosis
- Revision of failed ankle arthrodesis
- Revision of failed total ankle arthroplasty
- Talar deficiency conditions such as avascular necrosis of the talus (requiring tibiocalcaneal arthrodesis)
- Neuromuscular deformity or other neuromuscular disease with severe deformity or instability of the ankle
- Rheumatoid arthritis
- Osteoarthritis
- Nonunions or pseudarthrosis of hindfoot and distal tibia
- Trauma (severe or malunited tibial pilon fracture)
- Charcot foot (neuroarthropathy)
- Severe end-stage degenerative arthritis
- Instability and skeletal defects after tumor resection
- Pantalar arthrodesis
- Severe foot/ankle deformity

CONTRAINDICATIONS

The Paragon 28® Phantom® Hindfoot TTC/TC Nail System implants are not designed or sold for any use except as indicated. Use of the Phantom® Hindfoot TTC/TC Nail System is contraindicated in the following situations:

- Active, suspected or latent infection in the affected area
- Patients who are physiologically or psychologically inadequate
- Corpulence; an overweight or corpulent patient can strain the implant to such a degree that stabilization or implant failure can occur
- Patients previously sensitized to titanium
- Longitudinal splits, fractures, or deformities
- Insufficient quantity or quality of bone to permit stabilization, conditions that retard healing (not including pathological fractures) and conditions causing poor blood supply
- Open epiphyseal plates
- Patients with an insufficient plantar fat pad
- Patients with an intact asymptomatic subtalar joint
- Patients with significant tibial malalignment (>10 degrees in either sagittal or coronal plane)
- In patients where there is a possibility for conservative treatment
- Indications not included in the **INDICATIONS FOR USE**

POTENTIAL COMPLICATIONS AND ADVERSE REACTIONS

In any surgical procedure, the potential for complications and adverse reactions exist. The risks and complications with these implants include:

- Loosening, deformation or fracture of the implant
- Acute post-operative infections and late infections with possible sepsis
- Migration, subluxation of the implant with resulting reduction in range of movement
- Fractures resulting from unilateral joint loading
- Thrombosis and embolism
- Wound hematoma and delayed wound healing
- Temporary and protracted functional neurological perturbation
- Tissue reactions as a result of allergy or foreign body reaction to dislodged particles
- Corrosion with localized reaction and pain
- Pain, a feeling of malaise or abnormal sensations due to the implant used
- Bone loss due to stress shielding
- Loss of fixation in bone attributable to nonunion, osteoporosis and/or markedly unstable comminuted fractures
- Nonunion or malunion with rotation or angulation resulting in limb shortening or loss of anatomic positioning
- Irritation of soft tissues, including impingement syndrome

All possible complications listed here are not typical of Paragon 28®, Inc. products but are in principle observed with any implant. Promptly inform Paragon 28®, Inc. as soon as complications occur in connection with the implants or surgical instruments used. In the event of premature failure of an implant in which a causal relationship with its geometry, surface quality or mechanical stability is suspected, please provide Paragon 28®, Inc. with the explant(s) in a cleaned, disinfected and sterile condition. Paragon 28®, Inc. cannot accept any other returns of used implants. The surgeon is held liable for complications associated with inadequate asepsis, inadequate preparation of the osseous implant bed in the case of implants, incorrect indication or surgical technique or incorrect patient information and consequent incorrect patient behavior.

WARNINGS AND PRECAUTIONS

- Re-operation to remove or replace implants may be required at any time due to medical reasons or device failure. If corrective action is not taken, complications may occur.
- Use of an undersized implant in areas of high functional stresses may lead to implant fracture and failure.
- Implants, wires, or other appliances of dissimilar metals should not be used together in or near the implant site.
- The implants and guide wires are intended for single use only.
- Instruments, guide wires and screws are to be treated as sharps.
- Do not use other manufacturer's instruments or implants in conjunction with the Phantom® Hindfoot TTC/TC Nail System
- Do not resterilize the Phantom® Hindfoot TTC/TC Nail

MRI SAFETY INFORMATION


A patient with the Paragon 28® Phantom® Hindfoot TTC/TC Nail System may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.

Name/Identification of device	Paragon 28® Phantom® Hindfoot TTC/TC Nail System
Nominal value(s) of Static Magnetic Field [T]	1.5 T or 3 T
Maximum Spatial Field Gradient [T/m and gauss/cm]	30 T/m (3000 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Whole body transmit coil, Head RF transmit-receive coil
Maximum Whole Body SAW [W/kg]	2.0 W/kg (Normal Operating Mode)
Limits on Scan Duration	All anatomical regions can be safely scanned under the following conditions: 1.0 W/kg whole body average SAR for 40 minutes of continuous RF (a sequence or back to back series/scan without breaks) with a 20 minute cooling period for an hour long scanning session
	Scanning of the knees and all anatomy superior to the knees can be safely scanned under the following conditions: 2.0 W/kg whole body average SAR for 60 minutes of continuous RF (a sequence or back to back series/scan without breaks)
If information about a specific parameter is not included, there are no conditions associated with that parameter.	

PHANTOM[®]
HINDFOOT TTC/TC SYSTEM

PHANTOM
ACTIVCORE[™] NAIL SYSTEM

PATENTED, DESIGNED & EXCLUSIVELY DISTRIBUTED BY


Exclusively foot & ankle **28**[®]
Paragon

P31-STG-0003 Rev B [01-30-2024]

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Patents: www.paragon28.com/patents

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DISCLAIMER

The purpose of the Phantom[®] Explant Surgical Technique Guide is to demonstrate the optionality and functionality of the Phantom[®] Explant System. Although variations in placement and use of the Phantom[®] Explant System can be performed, the fixation options demonstrated in this technique were chosen to demonstrate the functionality of the system and for simplicity of explanation. Other uses for the Phantom[®] Explant System can be employed, appropriate for the size of the device. Federal law (U.S.A.) restricts this device to sale and use by, or on order of, a physician.

www.Paragon28.com