Titanium Knee Fusion Nail
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Indications

Historically, knee arthrodesis has been used as one alternative form of treatment for knee arthritis. It should be considered in monarticular arthritis, most commonly secondary to trauma. A more common indication for knee arthrodesis, however, is following failed total knee arthroplasty. This may be secondary to infection, mechanical problems in the knee, or loss of the extensor mechanism. If the arthrodesis is being performed following an infection, this may be done as a one or two stage procedure.

Preoperative X-ray Evaluation

It is necessary to obtain long X-rays of the entire limb to assess the two most critical features regarding nail selection: nail length and nail diameter. Using an X-ray marker, long X-rays of the hip (that include the hip, knee, and ankle on A-P) are obtained. Laterals of the femur and tibia are also obtained as well as a lateral of the knee.

The nail should extend from the tip of the greater trochanter to within 2-6 cm from the plafond of the ankle. If the arthrodesis is being performed following a failed total knee arthroplasty, the thickness of the femoral and tibial components and any bone defects that will be resected needs to be subtracted.

Magnification needs to be determined by the radiographic marker and the appropriate adjustment in measurement should be made. The Knee Fusion Nail comes in 55-90cm lengths (in 5cm increments). Additional lengths can be special ordered.

Canal diameter should also be determined preoperatively. Again, using the X-ray marker, the diameter of the femur and tibia at the isthmus should be obtained. The tibia usually has the smaller canal diameter. Cortical thickness may allow for a certain amount of reaming to increase the canal size for the nail. The Knee Fusion Nail comes in 11.5mm and 13mm diameters.

Preoperative Planning

The following surgical technique is for knee arthrodesis following a failed total knee arthroplasty. Modifications would be necessary for arthrodesis for other reasons.

The patient is positioned supine on an operating table. A fluoroscopic board is necessary to allow fluoroscopy from the hip to the ankle. A sand bad or a stack of linen should be placed under the ipsilateral pelvis to raise the greater trochanter into better position for visualization.

The involved extremity is prepped and draped to allow access to the greater trochanter all the way down to the foot. The foot needs to be visible to help with rotational alignments.
Titanium Knee Fusion Nail
Design Features

Product Overview
• Titanium
• Cannulated Nails
• Lengths: 55cm-90cm (increments of 5cm)
• Interlock with TRIGEN 5.0mm Internal Hex Captured Locking Screws
• Use with TRIGEN Instruments

Unique five-hole proximal locking configuration allows femoral or recon locking modes in one nail

Straight proximal profile for ease of insertion through the piriformis fossa

12° of built-in femoral neck anteversion for optimal proximal screw position

Hybrid proximal-distal AP Bow transition: 1.5m-2.5m

Static and dynamic distal locking configuration using 5.0mm TRIGEN Internal Hex Captured Locking Screws

130° Femoral and Recon screw angles
Surgical Technique

Opening the Proximal Femur

Incision and Entry Point

Assemble the Honeycomb (7167-4075), Entry Handle (7167-4092) and Entry Portal Tube (7167-4060). The pieces will lock in place securely at either 0° or 180°.

A longitudinal incision is made proximal to the greater trochanter. Carry the incision through to the fascia and palpate the tip of the greater trochanter.

The entry point for the FAN is through the piriformis fossa, in-line with the intramedullary canal in the AP and the lateral. The entry point is slightly posterior in the lateral although this varies with patient anatomy.
Surgical Technique

Entry Portal Acquisition

Insert the Entry Portal instrumentation through the incision down to bone. Attach a 3.2mm x 343mm Tip Threaded Guide Pin (7167-4029) to power via the Mini Connector (7163-1186) and insert 2-3 cm. Confirm guide pin placement in the AP and lateral planes.

Following guide pin placement, remove the Honeycomb from the Entry Portal Tube along with any additionally inserted guide pins. Insert the 12.5mm Entry Reamer (7163-1116) into the 14mm Channel Reamer (7163-1023) until it clicks and attach to power. Advance the assembly through the Entry Portal Instrumentation 2-3cm. Evaluate reamer position before proceeding.

Adjust the trajectory of the reamer assembly if desired and advance to the positive stop on the Entry Portal Tube. The channel reamer will stop just below the level of the lesser trochanter. If the Entry Portal Instrumentation is not used, the channel reamer must still be advanced to the same point. Confirm the reamer assembly’s final position in both the AP and lateral planes. Detach and remove the 12.5mm Entry Reamer from the 14mm Channel Reamer.

Note: The Channel Reamer and Entry Portal Instrumentation will serve as a soft tissue protector.
Surgical Technique

Alternative Technique:
Entry Portal Acquisition

Attach the T-Handle (7167-4076) to the Cannulated Awl (7167-4000) and insert the 3.2mm Trocar (7167-4074) into the back of the assembly. Introduce the awl into the proximal femur at the designated entry point until it is below the level of the lesser trochanter*. Remove the 3.2mm Trocar and pass a 3.0mm Ball Tip Guide Rod (7163-1626) into the back of the T-Handle. Remove the awl from the proximal femur.

The region of the proximal femur extending to the lesser trochanter must be enlarged to 14mm in order to accommodate the proximal geometry of a 10mm, 11.5mm or 13mm TAN/FAN nail. If inserting a 14.5mm or 16mm FAN, the proximal femur must be reamed to 17.5mm.

Note: Intramedullary reamers should be used to prepare the proximal femur if the 14mm Channel Reamer is not used**.

*The entry point for the Cannulated Awl will differ depending on whether a TAN or FAN is being implanted.
**The largest Reamer Head that the TRIGEN™ Base Instrument Tray can hold is 16mm. Larger sizes are available in SculptOR Reamer System (7111-8330).
Instruments for Fracture Reduction and Intramedullary Reaming

Entry Portal Tube
Cat. No. 7167-4060

Entry Portal Handle
Cat. No. 7167-4092

T-Handle
Cat. No. 7167-4076

14mm Channel Reamer
Cat. No. 7163-1023

Gripper
Cat. No. 7167-4080

Obturator
Cat. No. 7167-4078

Reamer Heads
Cat. No. 7111-8231 to 7111-8256*

Reamer Shaft
Cat. No. 7111-8200

3.0mm x 1000mm Ball Tip Guide Rod
Cat. No. 7163-1626

Note: Images on this page are not shown to scale
Surgical Technique

Introduce the Reducer into the intramedullary canal through the channel reamer and Entry Portal Instrumentation.

A ball-tip guide wire is passed down the medullary canal to just above the knee. The smooth end, not the ball-tip end, is introduced to facilitate reaming from the knee. This is left in place while the knee is being exposed.

A sterile tourniquet is applied to the leg. Make an incision over the knee at approximately the same location as prior surgery. A medial parapatellar incision is made and the knee joint is entered. Cultures are obtained as needed.

Prior to removal of the total knee components, a long ruler is placed anteriorly over the distal femur and proximal tibia. Using an osteotome or an electrocautery, a line is drawn superficially in the anterior tibial shaft and in the anterior femoral shaft along the line of this ruler. This line will be used later to determine rotational alignment when inserting the nail. This line should be preserved and not removed with bone cuts or resection of the tibial or femoral implants.

Using osteotomes and the appropriate total knee instrumentation, all of the total knee components are extracted. Usually, there is debris and erosion of the bone that has to be curetted and cleaned. As much bone as possible should be preserved. If the patella is in good condition, it can also be preserved to be used as a bone graft. Otherwise, a patellectomy may be performed.

The distal femur and proximal tibia may need to be recut. This can be done with standard intramedullary knee resection guides for total knee prostheses or with the Smith & Nephew intramedullary cutting guides. A minimal amount of bone should be resected.
Surgical Technique

After removal of all of the total knee components, the cement, and after cutting the proximal tibia and distal femur, the intramedullary canals should be reamed from the knee. This should be done over the guide wire that has already been inserted. The femur and tibia should be over-reamed by 1 to 2mm, depending on the diameter of the isthmus in both the tibia and femur. **Reaming should be done with the tourniquet removed.**

Nail length can be confirmed at the time of surgery using fluoroscopy. A marker can be placed over the greater trochanter and over the distal tibia where the tip of the nail should be driven. The distance can then be measured correctly with the tibia and femur opposed.

The appropriate length and diameter nail should then be inserted in the entry portal of the femur. The guide wire is not needed for this step.

*Note: For reamers larger than 12.5mm, the Channel Reamer must be removed before reaming.*

The nail should be inserted in about 45° of internal rotation. This position provides both some flexion as well as some valgus to the limb. The nail should be carefully driven down the femoral shaft without excessive force. Look for signs of impending incarceration or fracture. As the tip of the nail exits the femur, the tibia is reduced on the femur with the rotational alignment achieved by recreating the “marker line” that was placed in the anterior femoral and anterior tibial cortices. The nail is then carefully driven across the knee into the proximal tibia. The knee is reduced and the bone ends are opposed and the nail is sufficiently positioned in the tibia where the tip of the nail is distal to the isthmus of the canal and proximal to the ankle joint.

Any defects or gaps noted in the region of the knee should be compressed or filled. Small segments of bone may be removed from the distal femur to improve contact medially or laterally. Bone grafts should be used to fill any gaps in place if the knee is not actively infected at the time of arthrodesis. The patella may also be used as bone graft.

*Note: Images on this page are not shown to scale*
Instruments for Nail Assembly and Insertion

- Percutaneous Drill Guide
  Cat No. 7163-1021

- AP Alignment Tower
  Cat No. 7163-1025

- Percutaneous Guide Bolt
  Cat No. 7163-1024

- AP Alignment Arm
  Cat No. 7163-1015

- T-Handle
  Cat No. 7167-4076

- Slotted Hammer
  Cat No. 7167-4082

- Guide Bolt Wrench
  Cat No. 7163-1140

- Impactor*
  Cat No. 7167-4081

- 9.0mm Drill Sleeve
  Cat No. 7163-1152

- 4.0mm Trocar Drill Sleeve
  Cat No. 7163-1026

- 6.4mm Step Drill
  Cat No. 7163-1035

- Radiolucent Drop
  Cat No. 7163-1022

- 4.0mm Long Pilot Drill**
  Cat No. 7163-1110

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* The Impactor (7167-4081) is interchangeable with the One-Piece Impactor (7163-1185)
** 4.0mm AO Long Drill (7163-1121) is interchangeable with 4.0mm Long Pilot Drill (7163-1110)
Surgical Technique

Nail Assembly

Attach the Percutaneous Drill Guide (7163-1021) to the nail with the Percutaneous Guide Bolt (7163-1024) and tighten with the Guide Bolt Wrench (7163-1140) and T-Handle.

The nail is correctly aligned when:

1. The apex of the nail's AP bow point anterior
2. The three proximal locking holes on the lateral side of the nail mirror image depicted on the underside of the drill guide.
Surgical Technique

The nail is correctly aligned when:

1. The apex of the nail’s AP bow point anterior
2. The three proximal locking holes on the lateral side of the nail mirror image depicted on the underside of the drill guide

Verifying Targeting Accuracy

Attach the Radiolucent Drop (7163-1022) to the drill guide to verify targeting accuracy. The drop is etched with color-coded markings to allow for accurate nail-drill guide assembly.

1. Femoral locking mode: Insert a 9.0mm Drill Sleeve (7163-1152) and 4.0mm Trocar Drill Sleeve (7163-1026) into the Percutaneous Drill Guide. Pass a 4.0mm Long Pilot Drill (7163-1110)* through the drill sleeves and nail.

2. Recon locking mode: Insert a 9.0mm Drill Sleeve into the appropriately color-coded locking hole on the Radiolucent Drop. Pass a 6.4mm Step Drill (7163-1160) through the drill sleeve and nail.

An incorrectly attached nail will not target. With targeting accuracy confirmed, remove the drop and any drill sleeves.

* 4.0mm AO Long Drill (7163-1121) is interchangeable with 4.0mm Long Pilot Drill (7163-1110)
Surgical Technique

Insertion

Orient the drill guide assembly in the AP plane and manually insert the nail into the intramedullary canal as far as possible*. If necessary, attach the Impactor (7167-4081) to the drill guide and advance the nail over the guide rod using light blows from the Slotted Hammer (7167-4082). Insert the nail to the desired depth.

**Note** If excessive force is required to implant the nail, it may be necessary to ream the intramedullary canal conditionally.

Insertion Depth

**Proximal**

Insert the nail until its driving end is at or below the top of the greater trochanter. Each gauge on the insertion barrel represents a 10mm depth interval.
Surgical Technique

1. **Femoral locking mode**: Attach the AP Alignment Tower (7163-1025) to the drill guide and slide the back end of the AP Alignment Arm (7163-1015) into the tower. Under fluoroscopy, the center portion of the alignment arm indicates the path of the 5.0mm locking screw through the trochanteric region.

2. **Recon locking mode**: Attach the alignment tower to the drop and slide the back end of the alignment arm into the tower. Under fluoroscopy, the parallel slots and threaded screw tips of the alignment arm indicate the position of both 6.4mm recon locking screws in the femoral neck and head.
Instruments for Proximal Locking

- Percutaneous Drill Guide
  Cat No. 7163-1021

- 4.0mm Trocar Drill Sleeve
  Cat No. 7163-1026

- 4.0mm Trocar
  Cat No. 7163-1191

- 9.0mm Drill Sleeve
  Cat No. 7163-1152

- Depth Screw Gauge
  Cat No. 7163-1189

- Radiolucent Drop
  Cat No. 7163-1022

- T-Handle
  Cat No. 7163-4076

- Screwdriver Release
  Cat No. 7163-4084

- Medium Hex Driver
  Cat No. 7163-1066

- Long Hex Driver*
  Cat No. 7163-1070

- Mini Connector
  Cat No. 7163-1186

- 4.0mm Long Pilot Drill**
  Cat No. 7163-1110

- 6.4mm Step Drill
  Cat No. 7163-1035

- 6.4mm Tap
  Cat No. 7163-1036

* Not included in the TRIGEN Base Instrument Set (7167-4012)
**4.0mm AO Long Drill (7163-1121) is interchangeable with 4.0mm Long Pilot Drill (7163-1110)
Surgical Technique

Proximal Locking

**Standard Femoral Locking**
Slide the 4.0mm Trocar (7163-1191) into the 4.0mm Drill Sleeve Trocar (7163-1026) and insert into a 9.0mm Drill Sleeve. Make a small incision at the site of the screw entry and insert the trocar/sleeve assembly through the hole on the drill guide and down to bone. Attach the 4.0mm Long Pilot Drill* to power via the Mini Connector, remove the trocar from the drill sleeve assembly and drill both cortices.

Measure for screw length using either the calibrations on the 4.0mm Long Pilot Drill or by removing the Drill Sleeve Trocar and using the Screw Depth Gauge (7163-1189).

**Note** The 4.0mm Drill Sleeve Trocar must be against the lateral cortex for accurate locking screw length measurement.

Attach the appropriate length 5.0mm locking screw to the end of the Medium Hexdriver (7163-1066) and insert through the 9.0mm Drill Sleeve on power until the laser etched ring on the hexdriver reaches the back of the drill sleeve. Attach the T-Handle to the hexdriver and tighten the locking screw by hand.

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*4.0mm AO Long Drill (7163-1121) is interchangeable with 4.0mm Long Pilot Drill (7163-1110)
Surgical Technique

**Standard Femoral Locking**
After confirming nail insertion depth and femoral neck anteversion, make two small incisions at the site of screw entry. Insert a 9.0mm Drill Sleeve, 4.0mm Drill Sleeve Trocar, and 4.0mm Trocar into the inferior-most recon locking hole on the Radiolucent Drop and down to bone. Repeat the process for the superior locking hole.

Remove the 4.0mm Trocar from the inferior trocar/sleeve assembly. Attach the 4.0mm Long Pilot Drill to power via the Mini Connector and drill to the desired depth in the femoral neck and head. Leave the 4.0mm drill in place and repeat the process for the superior trocar/sleeve assembly. Measure for screw length using the calibrations on the 4.0mm Long Pilot Drill.

**Note** The 4.0mm Drill Sleeve Trocar must be against the lateral cortex for accurate locking screw measurement.

Remove the 4.0mm drill and drill sleeve trocar from the inferior 9.0mm Drill Sleeve. Attach the 6.4mm Step Drill to power and drill to the depth measured for the 6.4mm recon locking screw. The calibration on the drill will be flush with the back of the drill sleeve. Leave the step drill in place and repeat the process for the superior locking screw.

**Note** It is recommended to monitor all drilling under fluoroscopy to avoid penetration of the acetabulum.

Attach the appropriate length 6.4mm recon locking screw to the Medium Hexdriver and T-Handle. Remove the inferior 6.4mm Step Drill and insert the locking screw through the 9.0mm Drill Sleeve. Do not tighten definitively. Repeat the process for the superior Recon locking screw using the Long Hexdriver (7163-1070)* and T-Handle. Release any traction and tighten both locking screws definitively.

*Not included in the TRIGEN® Base Instrument Set (7167-4012)
Distal Locking

Distal locking is typically approached from the medial side using a free hand technique. Confirm fracture reduction and align the C-Arm in either the AP or lateral position depending on which locking screw is to be inserted. Obtain a "perfect circle" image of the locking hole and use a blunt object to approximate the location of the locking hole by dimpling the skin.

Make a stab incision at the site, insert the 4.0mm Short Drill*, and drill both cortices. Measure for screw length using the Screw Depth Gauge. Alternatively, leave the 4.0mm Short Drill* in place, insert the Screw Length Sleeve down to bone, and read the exposed calibrations off the drill. Insert the appropriate length screw using the T-Handle/Hexdriver assembly.
Instruments for Implant Removal

Medium Hexdriver
Cat No. 7163-1066

12.5mm Entry Reamer
Cat No. 7163-1116

Impactor
Cat No. 7163-1116

Slotted Hammer
Cat No. 7163-4082

Mini Connector
Cat No. 7163-1186

Disposable Nail Extractor
Cat No. 7163-1320

One Piece Impactor*
Cat No. 7163-1185

T-Handle
Cat No. 7163-4076

3.0mm x 100mm Ball Tip Guide Rod
Cat No. 7163-1626

3.2mm x 343mm Tip Threaded Guide Pin
Cat No. 7163-4029

*The One Piece Impactor is found in the original TRIGEN® Instrument Set (7163-1326)
Surgical Technique

Implant Removal: Optional

**Open Nail Extraction**
Remove the nail cap if implanted and all but one of the locking screws using the Medium Hexdriver and T-Handle. Thread the Disposable Nail Extractor (7163-1320) into the Impactor or One Piece Impactor (7163-1185)* and introduce the extraction assembly into the top of the nail. Remove the final locking screw(s) and extract the nail with a back-slapping motion using the Slotted Hammer.

**Percutaneous Nail Extraction Technique**
This technique assumes the absence of a nail cap. Attach a 3.2mm x 343mm Tip Threaded Guide Pin to power via the Mini Connector and insert into the top of the nail under fluoroscopy. This may also be performed manually.

Attach the 12.5mm Entry Reamer to power. Make a one inch incision around the guide pin and advance the entry reamer over the guide pin and into the top of the nail to remove bony in-growth. Nail extraction follows the previously described technique.

**Note** The tip of the entry reamer is straight for approximately one inch before flaring out. It is this portion of the entry reamer that enters the top of the nail.

*The One Piece Impactor is found in the original TRIGEN* Instrument Set (7163-1326)
Surgical Technique

Guided Rod Jamming Technique
This technique assumes the absence of a nail cap. Under fluoroscopy, insert a 3.2mm x 343mm Tip Threaded Guide Pin into the top of the nail under power or manually.

Attach the 12.5mm Entry Reamer to power. Make a one inch incision around the guide pin and advance the entry reamer over the guide pin and into the top of the nail to remove bony in-growth. Nail extraction follows the previously described technique.

Guide Rods

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Additional Removal Items

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*Available sterile. For nail removal only, do not use for nail insertion.
**Located in Russell-Taylor Extraction Kit (Set #7508) available through Loaners
### Catalog Information

**IMPLANTS**

**Loaner Services Kit# 009236**

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## 5.0mm Internal Hex Captured Screws (Gold)

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<td>7164-2325</td>
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Note: Images on this page are not shown to scale
**SPECIAL NOTE**
The Intramedullary Nail System consists of interlocking intramedullary nails, and interlocking fusion nails, and pins. Intramedullary nails contain holes proximally and distally to accept locking screws. Components are available in many styles and sizes and are manufactured from various types of metals. The component material is provided on the outside carton label. Use only components made from the same material together. Do not mix dissimilar metals or components from different manufacturers. Refer to manufacturer literature for specific product information. All implantable devices are designed for single use only.

**INDICATIONS**
The general principles of patient selection and sound surgical judgment apply to the intramedullary nailing procedure. The size and shape of the long bones present limiting restrictions on the size and strength of implants.

**PRECAUTIONS**
Interlocking Fusion Nails indicated for joint arthrodesis have screw holes for locking on either side of the joint being fused. The locking screws reduce the likelihood of shortening and rotation of the fusion site.

**WARNINGS**
2. Surgical technique information is available upon request. The surgeon should be familiar with the devices, instruments and surgical technique prior to surgery. The use of locking screws is necessary for strength and compatibility. Please refer to the surgical technique or product catalogue for information on the correct size of screws for each nail. The patient should be advised that a second more minor procedure for the removal of implants is usually necessary.

3. While the surgeon must make the final decision regarding implant removal, wherever possible and practical for the individual patient, fixation devices should be removed once their service as an aid to healing is accomplished. In the absence of a bursa or pain, removal of the implant in elderly or debilitated patients is not suggested.

**STEREILIZATION/RESTERILIZATION**
Most implants are supplied sterile and have been packaged in protective trays. The method of sterilization is noted on the package label. All radiation sterilized components have been exposed to a minimum of 25 kiloGray of gamma radiation. If not specifically labeled sterile, the implants and instruments are supplied non-sterile and must be sterilized prior to use. Inspect packages for punctures or other damage prior to surgery. Metal components may be initially sterilized or resterilized, if necessary, by steam autoclaving in appropriate protective wrapping, after removal of all original packaging and sterilization on implants.

**INFORMATION**
For further information, please contact Customer Service at (800) 238-7538 for calls within the continental USA and (908) 396-2121 for all international calls. Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.