Nota Bene
The technique description herein is made available to the healthcare professional to illustrate a suggested treatment for the uncomplicated procedure. In the final analysis, the preferred treatment is that which addresses the needs of the patient.
The following technique is for informational and educational purposes only. It is not intended to serve as medical advice. It is the responsibility of treating physicians to determine and utilize the appropriate products and techniques, according to their own clinical judgement, for each of their patients. For more information on the TRIGEN® Humeral Nail System, including its indications for use, contraindications, and product safety information, please refer to the product’s label, the Instructions for Use packaged with the product, and, if using the TRIGEN SURESHOT™ Distal Targeting System, the TRIGEN SURESHOT Distal Targeting System User Manual.

The TRIGEN Humeral Nail System is indicated for proximal and/or diaphyseal fractures of the humerus, non-unions, malalignments, pathological humeral fractures, and impending pathological fractures. With multiplanar screws that are threaded into the nail and designed to inhibit proximal screw back-out, and effective, simple instrumentation designed to help protect soft tissues, the TRIGEN® Humeral Nail System offers an effective intramedullary nail for humeral fracture management.

The Humeral Nail System can be used with or without the SURESHOT Distal Targeting System. If using the SURESHOT Distal Targeting System, be sure to read and understand the TRIGEN SURESHOT Distal Targeting System User Manual. Only trained operators are allowed to use the TRIGEN SURESHOT Distal Targeting System.

Features of the TRIGEN Humeral Nail System
- Four multiplanar proximal locks designed to improve fracture stability
- Threaded screw holes and polyethylene bushings designed to enhance fixation and prevent screw back-out
- Short and long straight and bent nails to address multiple indications
- 4° lateral bend in bent nails to facilitate portal entry
- Trapezoidal nail profile designed to provide enhanced rotational stability
- Nails and Nail Drill Guide are keyed to ensure proper orientation of the nail on the drill guide
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.

Indications for interlocking intramedullary nails include simple long bone fractures; severely comminuted, spiral, large oblique and segmental fractures; nonunions and malunions; polytrauma and multiple fractures; prophylactic nailing of impending pathologic fractures; reconstruction following tumor resection and grafting; supracondylar fractures; bone lengthening and shortening.

Interlocking intramedullary nails are indicated for fixation of fractures that occur in and between the proximal and distal third of the long bones being treated.

In addition to the indications for interlocking intramedullary nails, devices that contain holes/slots proximally to accept screws that thread into the femoral head for compression and rotational stability (e.g. Femoral Antegrade Nail, Trochanteric Antegrade Nail and Femoral/Recon Antegrade Nail) are indicated for the following: subtrochanteric fractures, intertrochanteric fractures, and ipsilateral femoral shaft/neck fractures.

In addition to the indications for interlocking intramedullary nails, devices that use a retrograde femoral surgical approach (e.g. Knee Nail, Retrograde and Supracondylar Nails) are indicated for the following: comminuted supracondylar fractures with or without intraarticular extension; fractures that require opening the knee joint to stabilize the femoral condylar segment; fractures above total knee implants (peri-prosthetic fractures).

Contraindications

1. These systems should not be used in crossing open epiphyseal plates.
2. Insufficient quantity or quality of bone, obliterated medullary canal or conditions which tend to retard healing, blood supply limitations, previous infections, etc.
3. Active infection.
4. Any hardware that would preclude use of nails.
5. Congenital or acquired bony deformity.
6. Hypovolemia, hypothermia and coagulopathy.
7. Mental conditions that preclude cooperation with the rehabilitation regimen.
8. The forearm nail should not be used in children who have not reached skeletal maturity.
9. The ENDER Nail is contraindicated for the younger and/or more active patient, where open reduction techniques provide firm fixation without a substantially increased risk of mortality or morbidity.
10. The Short Intertrochanteric Nail is contraindicated for complex intertrochanteric and femoral neck fractures.
TRIGEN° Humeral Nail specifications

Proximal Bent Nail
8/7mm x 16cm

Proximal Straight Nail
8/7mm x 16cm

Long Bent Nail
8/7mm, 9/7.5mm, 10/8.5mm diameter; 18cm – 28cm lengths, by 2cm increments

5.0mm Cancellous Proximal Locking Screws; 24mm – 64mm lengths, 2mm increments

4.0mm Cortical Distal Locking Screws; 20mm – 40mm lengths, 2mm increments

Proximal locking holes have innovative threaded design. Screws thread into the nail to help prevent screw back-out.
Surgical Technique

Patient positioning

**Supine position**

1. Position the patient supine (Figure 1).
2. Tilt the patient on the fluoroimage table so that the humerus can be extended posteriorly.
   
   **Note** The C-arm can be positioned either superior to the shoulder or, if the C-arm modus is large enough, opposite the shoulder.

**Beach chair position**

1. Position the patient in a slight “beach-chair” position.
   
   **Note** Allow the arm of the semi-recumbent patient to hang near the trunk so that its weight helps reposition the humeral head anterior to the acromion.
2. Place the C-arm above the head of the table at 30°, extending distally over the patient’s shoulder. This allows an anteroposterior view of the humerus.
3. Place the arm in the reverse pushing position to clear the entry point, which is anatomically located at the superior margin of the articular surface, just medial to the greater tuberosity.
4. Once the correct positioning and imaging are assured, prepare and drape the shoulder and arm.
Establish the incision and entry portal

The recommended incision approach for antegrade humeral nailing is the lateral deltoid splitting incision (Figure 2). For complete fractures or nonunions, a traditional deltopectoral approach may be used.

1. Make a 2 – 3cm incision from the edge of the acromion to the edge of the humeral head, anterolateral to the tip of the acromion.
2. Divide the deltoid down to the sub-deltoid bursa, and then retract the deltoid.
3. Visualize the rotator cuff insertion into the greater tuberosity.
4. Palpate the biceps tendon anteriorly.
5. Incise the rotator cuff supraspinatus tendon 15 – 20mm in line with its fibers, exposing the humeral head.
6. Insert a suture into the rotator cuff interval to retract the rotator cuff and facilitate its repair following insertion of the nail.

Central portal (straight proximal nail)

If using a straight proximal nail, establish the central entry portal at the apex of the humeral head and centered midway between the biceps groove anteriorly and the posterior humeral head (Figure 3a).

Lateral portal

Establish a lateral entry portal just medial to the tendon insertion and centered midway between the biceps groove anteriorly and the posterior humeral head (Figure 3b).
Place the Entry Cuff Guard and Guide Pin

1. Divide the rotator cuff to expose the superior portion of the humeral head.

2. Use the Entry Cuff Guard (7175-1100) protective device to retract the soft tissue of the rotator cuff for visualization of the bone. (Figure 4)

   **Note** The Cuff Guard provides a visual working channel, while protecting the rotator cuff and soft tissue during the procedure.

   **Note** The Disposable Cuff Guard (7175-1101) may be used to protect the rotator cuff while preparing the humerus for the nail. The Nail can be inserted through the Disposable Cuff Guard. A Drill Guide comes packaged with the Disposable Cuff Guard to facilitate the placement of the guide pin in the precise position desired.

3. Attach the 3.2mm Tip Threaded Guide Pin (7175-1147) or Trocar (7175-1136) to the Mini Connector with Handle (7175-1133).

4. Avoiding the rotator cuff insertion, introduce the guide pin or trocar through the Cuff Guard and into the superior margin of the humeral head, just medial to the greater tuberosity.

5. Verify by oblique pictures that guide pin placement is aligned in the medullary canal at 45° with internal and external rotation of the shoulder.
Prepare the proximal section

1. Insert the Straight Entry Reamer (7175-1103) over the 3.2mm Tip Threaded Guide Pin or the Trocar through the Entry Cuff Guard and/or the Disposable Cuff Guard to prepare the humerus for the proximal section of the nail (Figure 5).

2. Ream until the cutting teeth are just below the articular surface of the humeral head.

   Note The depth indicator on the reamer should be level with the top of the Cuff Guard.

   Alternatively, insert a Straight Ratcheting Driver (7175-1141) through a Cannulated Awl (7175-1102) to ream the humeral head.

Reduce the fracture

1. Remove the Straight Entry Reamer and 3.2mm Tip Threaded Guide Pin or Trocar.

2. Insert the Straight Reducer (7175-1105) and attached Straight Ratcheting Driver (Figure 6), with the slot oriented toward the lateral cortex.

3. Reduce the fracture.

   Note Place the tip of the Straight Reducer just above the medial cortex to help reduce the fracture (Figure 7).

4. To maintain reduction, introduce the 2.0mm Graduated Ball Tip Guide Rod (7175-1146) through the Straight Reducer (Figure 8).

5. Center the Guide Rod 1 – 2cm proximal to the olecranon fossa in the distal end of the humerus.

6. Once the Guide Rod is in place, carefully remove the Straight Reducer, using the Obturator (7175-1145) as needed to ensure the Guide Rod stays in place (Figure 9).
Measure the implant length

1. When measuring the length of the implant needed, ensure that the distal tip of the 2.0mm Graduated Ball Tip Guide Rod is located at the desired position of the distal tip of the nail.

2. Slide the Ruler (7175-1126) over the proximal end of the 2.0mm Graduated Ball Tip Guide Rod and advance the open end of the Ruler to the location where the proximal portion of the implant will be seated, just below the articular surface of the proximal humerus (Figure 10).

3. Read the nail length from the calibrations exposed at the other end of the Ruler.

   **Note** Ensure the nail will be slightly countersunk.

   **Note** The 2.0mm Graduated Ball Tip Guide Rod has graduated markings and can be used to determine required implant length. The Straight Reducer can also be used to determine implant length using the markings on the reducer shaft. Both options are used to directly measure to the articular surface.

Additional limited reaming

Additional limited reaming is necessary for Proximal Nails longer than 8mm x 16cm. Once the appropriate nail length has been determined, perform additional limited reaming in order to avoid nail incarceration and distraction at the fracture site during insertion of the nail.

1. Begin with the 6.0mm Fixed End Cutting Reamer (7111-8220 to 7111-8230) and insert it over the 2.0mm Graduated Ball Tip Guide Rod (Figure 11).

2. Ream the intramedullary canal sequentially.

   **Note** Be careful not to shift the guide rod distally during reaming.

   **Note** Never insert a nail that has a larger diameter than the last reamer used.

It is recommended that templating be used in all cases to estimate the size of the implant needed (Figure 12). The diameter of the last reamer used will help determine the diameter of the implant needed.

Keep in mind that all of the nail sizes taper, and that the canal should be reamed to 1mm larger than the implant diameter.
Nail Drill Guide assembly

1. Once the implant has been selected, use the Humeral Nail Guide Bolt (7175-1108) to attach the Nail Drill Guide (7175-1129) to the nail. The Nail and Nail Drill Guide are keyed to ensure proper orientation of the nail on the Nail Drill Guide (Figure 13).


3. Attach the Impactor (7175-1133) to the Humeral Nail Guide Bolt.

4. Attach the Proximal Drop (7175-1131) to the lateral arm of the Nail Drill Guide to complete the assembly. Tighten the Proximal Drop to the Guide using the knurled knob.

5. Use the Proximal Drop to target the proximal screws on all Humeral Nails, as well as the distal screws on the 16cm Humeral Nails.

   **Note** To target distal locking screws for the 18cm or longer Humeral Nails, use either the TRIGEN® SURESHOT® Distal Targeting System or a freehand technique. If using the TRIGEN SURESHOT Distal Targeting System, refer to the User Manual for Field Accuracy Check instructions.

6. Verify targeting accuracy by inserting a Humeral Gold Outer Drill Sleeve (7175-1128) and 3.2mm Silver Inner Drill Sleeve (7175-1116) into the drop and passing a 3.2mm Long Graduated Two-Flute Drill (7175-1149) through the assembly.

   **Note** An incorrectly attached nail will not target.
Nail insertion

When inserting the nail, be sure to insert the nail with the correct amount of retroversion and depth in order to maximize locking screw fixation while avoiding critical soft tissues such as the biceps tendon and axillary and radial nerves.

1. Insert the nail over the 2.0mm Graduated Ball Tip Guide Rod and through the Entry Cuff Guard (Figure 14) until the lateral ledge on the drill guide is above the lateral cortex and the nail is seated just below the articular surface (Figure 15). The lateral arm of the drill guide should be oriented with approximately 30-35° of Adjustments to this version can be made so that the anterior arm of the drill guide is in line with the lesser tuberosity, avoiding alignment with the bicipital groove.

2. Remove the Guide Rod from the top of the Nail Drill Guide (7175-1129).

3. Confirm that the fracture is fully compacted and not distracted.

Final version adjustment

Final version adjustment to the nail can be performed prior to proximal locking screw insertion by attaching the Anterior Stylus (7175-1130) to the anterior arm of the Nail Drill Guide (Figure 16).

Insert the Trocar through the Anterior Stylus and position the nail so that the Trocar can be inserted into the lesser tuberosity at the location of the anterior locking hole (Figures 17 and 18). Leave the Trocar in place to maintain fracture reduction and rotational stability during the insertion of the proximal lateral screws.

Note This step ensures that the proximal anterior and proximal anterolateral locking screws will not be inserted into the bicipital groove, which could injure the biceps tendon.
Distal locking screws for TRIGEN®
Proximal 16cm Humeral Nails

Note The Proximal Drop targets the distal holes for the 16cm nails only. When targeting nails longer than 16cm, use the freehand technique or the TRIGEN SURESHOT® Distal Targeting System.

1. Connect the Proximal Drop to the lateral arm of the Nail Drill Guide.
2. Place the 3.2mm Silver Inner Drill Sleeve into the Humeral Gold Outer Drill Sleeve.
3. Insert the sleeve unit into the targeting hole in the Proximal Drop which corresponds to the superior M/L (mediolateral) distal locking hole in the nail.
4. While applying compression at the condyles of the elbow to reduce shaft fractures as needed, make a stab incision and push the sleeve unit down to the bone (Figure 19).

Note The Trocar, in combination with the drill sleeve unit, may be used to dimple the cortex.

5. Drill through both cortices using the 3.2mm Long Graduated Two-Flute Drill.
6. A length measurement can be taken from the calibrations on the drill against the 3.2mm Silver Inner Drill Sleeve, or the Screw Depth Gauge (7175-1139) can be used through the Humeral Gold Outer Drill Sleeve to measure for distal locking screws (Figure 20).
7. Select the appropriate length 4.0mm Self-Tapping Cortical Screw and attach it to the 3.5mm Hex Driver (7175-1140).
8. Insert the screw through the Humeral Gold Outer Drill Sleeve using the 3.5mm Hex Driver (Figure 21). The head of the screw should be nearly seated when the laser-marked ring on the Hex Driver is even with the Humeral Gold Outer Drill Sleeve.
9. Use the Straight Ratcheting Driver to manually tighten the screw (Figure 22).

Note Always perform final tightening of the screw manually using the Straight Ratcheting Driver.
10. Repeat this process for the inferior distal screw.
Proximal locking screws

Caution To avoid damage to the axillary nerve, do not countersink the proximal locking screws below the level of the humeral head.

16cm nails

Anterolateral locking screw

In order to avoid impingement of the biceps tendon, begin with the proximal anterolateral locking screw.

1. Place the 3.2mm Silver Inner Drill Sleeve into the Humeral Gold Outer Drill Sleeve.
2. Insert the sleeve unit into the Proximal Drop (Figure 23).
3. Insert the Trocar into the sleeve unit to determine the exact location for the insertion of the locking screw (Figure 24).

Note If the Trocar tip indicates that the proximal anterolateral screw is in line with the bicipital groove, reorient the nail to avoid impingement.

4. Once proper alignment has been achieved, make a stab incision and push the sleeve unit down to the bone.
5. Use the Trocar to dimple the cortex and then remove the Trocar from the sleeve unit.
6. Use the 3.2mm Graduated Two-Flute Drill to drill through the near cortex, stopping at the articular surface of the far cortex.
7. Take the length measurement from the calibrations on the drill or the Screw Depth Gauge (Figure 25).

Note The 3.2mm Silver Inner Drill Sleeve must be removed from the Humeral Gold Outer Drill Sleeve in order to use the Screw Depth Gauge.
8. Remove the 3.2mm Silver Inner Drill Sleeve and insert the 3.5mm Hex Driver with the appropriate length 5.0mm Cancellous Screw (Figure 26) attached. The head of the screw should be nearly seated when the laser-marked ring on the 3.5mm Hex Driver is even with the Humeral Gold Outer Drill Sleeve.

Note To avoid over insertion of the screw in soft bone, always perform final seating of the screw under manual control using the Straight Ratcheting Driver.
9. Insert the remaining two proximal locking screws.
Anterior locking screw

1. To target the proximal anterior locking hole, remove the Anterior Stylus.

2. Attach the Proximal Drop on the anterior arm of the Nail Drill Guide.
   
   **Note** Locate the biceps tendon prior to placing the anterior screw.

3. Insert the 3.2mm Silver Inner Drill Sleeve into the Humeral Gold Outer Drill Sleeve.

4. Insert the sleeve unit into the hole marked “Anterior” on the Proximal Drop (Figure 27).

5. Insert the Trocar into the sleeve unit to determine the exact location for the insertion of the anterior screw.
   
   **Note** If the Trocar tip indicates that the anterior screw is in line with the bicipital groove, reorient the nail to avoid impingement.

6. Once proper alignment has been achieved, make a stab incision and push the sleeve unit down to the bone.

7. Use the Trocar to dimple the cortex and then remove the Trocar from the sleeve unit.

8. Use the 3.2mm Graduated Two-Flute Drill to drill through the near cortex, stopping at the articular surface of the far cortex.

9. Take the length measurement from the calibrations on the drill or the Screw Depth Gauge (Figure 28).
   
   **Note** The 3.2mm Silver Inner Drill Sleeve must be removed from the Humeral Gold Outer Drill Sleeve in order to use the Screw Depth Gauge.

10. Remove the 3.2mm Silver Inner Drill Sleeve and insert the 3.5mm Hex Driver with the appropriate length 5.0mm Cancellous Screw attached. (Figure 29) The head of the screw should be nearly seated when the laser marked ring on the 3.5mm Hex Driver is even with the Humeral Gold Outer Drill Sleeve (Figure 30).

   **Note** To avoid over insertion of the screw in soft bone, final seating of the screw should always be done under manual control using the Straight Ratcheting Driver.

11. Insert the remaining two proximal locking screws.
18cm or longer nails

Freehand locking

Always use the freehand technique to lock anterolateral or anterior nails 18cm or longer. Alternatively, 18cm or longer nails may be locked using the TRIGEN® SURESHOT® Distal Targeting System. If using the SURESHOT Distal Targeting System, be sure to read and understand the TRIGEN SURESHOT Distal Targeting System User Manual.
Distal locking screws

16cm nails

1. Use the Screw Length Sleeve (11-0238) with the 3.2mm Graduated Two-Flute Drill to drill for the A/P (anteroposterial) distal locks.

2. Measure the screw depth length using the graduations on the drill against the Screw Length Sleeve. Alternatively, use the Screw Depth Gauge to determine the appropriate screw length.

3. Once the appropriate length 4.0mm Self-Tapping Cortical Screw is selected, attach the screw to the 3.5mm Hex Driver.

4. Insert the screw through the Humeral Gold Outer Drill Sleeve using the 3.5mm Hex Driver.

5. Manually tighten the screw until the head is flush with the bone.

   **Note** Always perform final screw tightening manually using the Straight Ratcheting Driver.

6. Repeat this process for the inferior distal screw.

18cm or longer Nails

Freehand locking

Always use the freehand technique to perform distal locking on nails 18cm and longer. Alternatively, 18cm or longer nails may be locked using the TRIGEN® SURESHOT® Imaging System. If using the SURESHOT Distal Targeting System, be sure to read and understand the TRIGEN SURESHOT Distal Targeting System User Manual.
Closure

16cm nails
1. Close the wound in layers.
   Note Use non-resorbable sutures in the rotator cuff repair.
2. Close the remainder of the wound as preferred.

To remove the nail
The Screw Head Trephine (7175-1144), the Proximal Nail Trephine (7175-1143) and the Extractor (7175-1142) are included in the instrument set to facilitate nail removal.

Standard technique
1. Use the 3.5mm Hex Driver to remove all of the distal locking screws, and all but one of the proximal locking screws.
2. Thread the Impactor (7175-1133) into the back of the Extractor (7175-1142).
3. Thread the assembly into the top of the nail.
4. Remove the remaining proximal locking screw.
5. Use the Slotted Hammer with a back-slapping motion to extract the nail.
TRIGEN® Instrument Set
Set No. 7175-1150

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TRIGEN® Flex Reamer Cassette
Set No. 7175-1156

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# Implants

## TRIGEN® Humeral Nail Implant Set
Set No. 7175-0703

## TRIGEN Humeral Nail Cap
(Not Shown)
Cat No. 7176-0000

## TRIGEN Proximal Straight Humeral Nail

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## 5.0mm Self-Tapping Cancellous Screw

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## 4.0mm Self-Tapping Cortical Screw

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Supporting healthcare professionals for over 150 years

**Caution:** U.S. Federal law restricts these devices to sale by or on the order of a physician.