



# Table of contents

Introduction	1
TRIGEN° Humeral Nail Specifications	2

#### Surgical Technique

Patient positioning	3
Establish the incision and entry portal	4
Place the Entry Cuff Guard and Guide Pin	5
Prepare the proximal section	6
Reduce the fracture	6
Measuring the implant length	7
Additional limited reaming	7
Nail Drill Guide assembly	8
Nail insertion	9
Final version adjustment	9
Distal locking screws for TRIGEN Proximal 16cm Humeral Nails	10
Proximal locking screws	11
Anterior locking screw	12
Distal locking screws	14
Closure	15
Catalog information	16

#### Nota Bene

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 judgment, for each of their patients. For more information on the product, including its Indications for Use, contraindications, cleaning, sterilization and product safety information, please refer to the product's label and the Instructions for Use (IFU) for the product.

# Introduction

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 proximal locking options to help maintain fracture stability, the TRIGEN Humeral Nail System offers an effective intramedullary nail for humeral fracture management.<sup>1-4</sup>

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 help to maintain fracture stability<sup>1-4</sup>
- Threaded screw holes with PPE bushings are designed to maximise the amount of thread purchase and provide adequate fixation
- Short and long straight and bent nails to address multiple indications
- Bent and straight nail options allow you to choose the entry portal<sup>1-3,5</sup>
- Trapezoidal nail profile is designed for rotational stability
- Nails and Nail Drill Guide are keyed to ensure proper orientation of the nail on the drill guide

# TRIGEN° Humeral Nail specifications





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



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



Threaded screw holes with PPE bushings are designed to maximise the amount of thread purchase and provide adequate fixation

# 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.
- 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.
- 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).



Figure 2



# 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 (71751100) 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 (71751101) 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 (71751147) or Trocar (71751136) to the Mini Connector with Handle (71751133).
- 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.



Figure 4

# Prepare the proximal section

- Insert the Straight Entry Reamer (71751103) 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 (71751141) through a Cannulated Awl (71751102) 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 (71751105) 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 (71751146) through the Straight Reducer (Figure 8).
- 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 (71751145) as needed to ensure the Guide Rod stays in place (Figure 9).













## Measure the implant length

- 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 (71751126) 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 (71118220 to 71118230) 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.



Figure 10







Figure 12

# Nail Drill Guide assembly

- 1. Once the implant has been selected, use the Humeral Nail Guide Bolt (71751108) to attach the Nail Drill Guide (71751129) 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).
- 2. Tighten the Humeral Nail Guide Bolt using the Guide Bolt Wrench (71751134).
- 3. Attach the Impactor (71751133) to the Humeral Nail Guide Bolt.
- 4. Attach the Proximal Drop (71751131) 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 (71751128) and 3.2mm Silver Inner Drill Sleeve (71751116) into the drop and passing a 3.2mm Long Graduated Two-Flute Drill (71751149) through the assembly.

Note An incorrectly attached nail will not target.



Figure 13

## 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.

- 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 (71751129).
- 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 (71751130) 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<sup>°</sup> 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.
- 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 (71751139) can be used through the Humeral Gold Outer Drill Sleeve to measure for distal locking screws (Figure 20).
- Select the appropriate length 4.0mm Self-Tapping Cortical Screw and attach it to the 3.5mm Hex Driver (71751140).
- 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.





Figure 20



# 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.

- 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.





Figure 28





#### 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

- Use the Screw Length Sleeve (110238) 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, attached 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 (71751144), the Proximal Nail Trephine (71751143) and the Extractor (71751142) 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 (71751133) into the back of the Extractor (71751142).
- 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.

# Catalog information





### TRIGEN° Instrument Set Set No. 71751150

Cat. Item	Description	Qty	Cat. Item	Description	Qty
71751133	Impactor	1	71751147	3.2mm Tip Threaded Guide Pin	1
71751149	3.2mm Long Graduated	1	71751103	Straight Entry Reamer	1
	Two-Flute Drill		71751126	Ruler	1
71751139	Screw Depth Gauge	1	71751136	Trocar	1
71751140	3.5mm Hex Driver	1	71751102	Cannulated Awl	1
71751108	Humeral Nail Guide Bolt	1	71751141	Straight Ratcheting Driver	1
71751129	Nail Drill Guide	1	71751137	Mini Connector with Handle	1
71751131	Proximal Drop	1	71751143	Proximal Nail Trephine	1
71751134	Guide Bolt Wrench	1	71751144	Screw Head Trephine	1
71751135	Small Hammer	1	71751104	Humeral Broach	1
110238	Screw Length Sleeve	1	71751142	Extractor	1
71751130	Anterior Stylus	1	7163-1187	Trinkle Connector	1
71751128	Gold Outer Sleeve	1	7163-1186	Mini Connector	1
71751116	3.2mm Silver Inner Drill Sleeve	1	71751153	AO Mini Connector	1
71751105	Straight Reducer	1	71751100	Entry Cuff Guard	1
71751145	Obturator	1			



#### **TRIGEN Flex Reamer Cassette** Set No. 71751156

Cat. No.	Description	Qty
71118220	6.0mm Fixed Endcutting RMR	1
71118222	7.0mm Fixed Endcutting RMR	1
71118224	8.0mm Fixed Endcutting RMR	1
71118226	9.0mm Fixed Endcutting RMR	1
71118228	10mm Fixed Endcutting RMR	1
71118230	11.0mm Fixed Endcutting RMR	1

# Implants

TRIGEN Humeral Nail Cap (Not Shown) Cat. No. 71760000

#### TRIGEN Proximal Straight Humeral Nail

Cat. Item	Size	Length	
71760816	8/7mm	16cm	
			- 0
			- 1
			U
TRIGEN Pro	ximal Ber	nt Humer	al Nail
<b>C L U L U L</b>	<b>.</b> .		

Cat. Item	Size	Length
71770816	8/7mm	16cm

#### TRIGEN Long Bent Humeral Nail

Cat. Item	Size	Length
71770818	8/7mm	18cm
71770820	8/7mm	20cm
71770822	8/7mm	22cm
71770824	8/7mm	24cm
71770826	8/7mm	26cm
71770828	8/7mm	28cm
71770830	8/7mm	30cm
71770918	9/7.5mm	18cm
71770920	9/7.5mm	20cm
71770922	9/7.5mm	22cm
71770924	9/7.5mm	24cm
71770926	9/7.5mm	26cm
71770928	9/7.5mm	28cm
71770930	9/7.5mm	30cm
71771018	10/8.5mm	18cm
71771020	10/8.5mm	20cm
71771022	10/8.5mm	22cm
71771024	10/8.5mm	24cm
71771026	10/8.5mm	26cm
71771028	10/8.5mm	28cm
71771030	10/8.5mm	30cm

#### 5.0mm Self-Tapping Cancellous Screw

Cat. Item	Length
71755024	24mm
71755026	26mm
71755028	28mm
71755030	30mm
71755032	32mm
71755034	34mm
71755036	36mm
71755038	38mm
71755040	40mm
71755042	42mm
71755044	44mm
71755046	46mm
71755048	48mm
71755050	50mm
71755052	52mm
71755054	54mm
71755056	56mm
71755058	58mm
71755060	60mm
71755062	62mm
71755064	64mm

#### 4.0mm Self-Tapping Cortical Screw

Cat. Item	Length
71754020	20mm
71754022	22mm
71754024	24mm
71754026	26mm
71754028	28mm
71754030	30mm
71754032	32mm
71754034	34mm
71754036	36mm
71754038	38mm
71754040	40mm
71754042	42mm
71754044	44mm
71754046	46mm
71754048	48mm
71754050	50mm
71754052	52mm
71754054	54mm
71754056	56mm
71754058	58mm
71754060	60mm



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