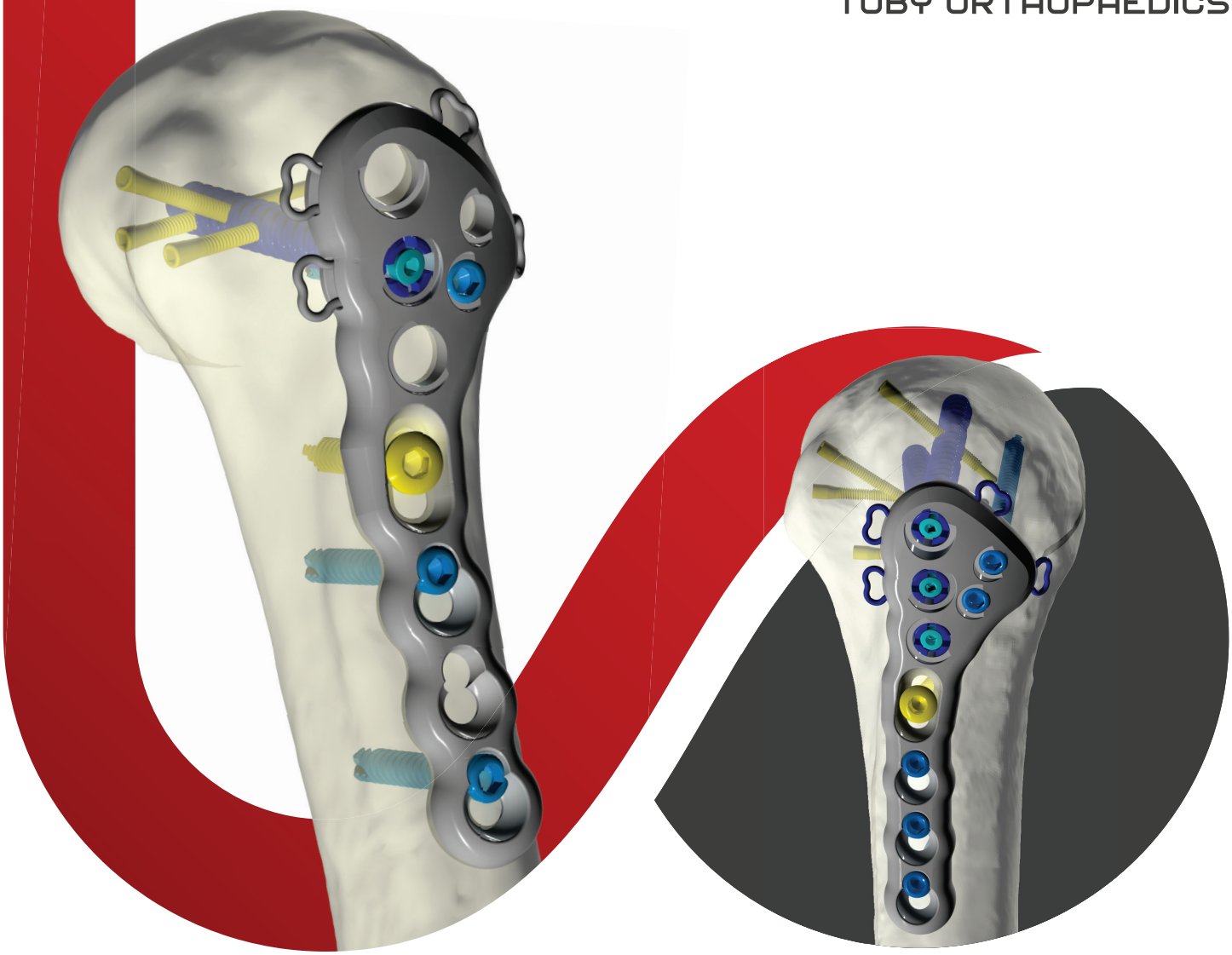
TOBY ORTHOPAEDICS



PANTERA

PROXIMAL HUMERUS FRACTURE FIXATION PLATE SYSTEM

SURGICAL TECHNIQUE GUIDE

INTENDED USE

The PANTERA Proximal Humerus Fracture Fixation plate system is intended for the internal fixation of bone fragments about the proximal humerus and indicates unique features for enhanced fization of soft bone.

INDICATED USE

PANTERA is indicated for fractures with significant fragmentation of the head where reconstructuion is not possible.

CONTRAINDICATIONS

- Proximal humerus fractures with significant fragmentation of the head where reconstruction is not possible
- Proximal humerus fractures for which there is a likelihood of development of clinically relevant avascular necrosis of the fracture.

ADVERSE EFFECTS

- Postoperative pain (shoulder)
- Screw perforation into glenohumeral joint
- Numbness
- Postoperative disconfort
- Inflamation
- Humeral head collapse/fracuture due aseptic necrosis after the fracture healed
- General infection
- Avascular necrosis

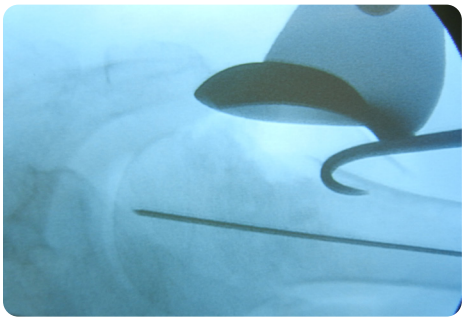
⚠ **Cautions**

- Before use, inspect the product packaging to ensure it shows no signs of damage, tampering, or contamination. Use the oldest products first (first-in, first-out inventory practice). When not in use, store the clean and disinfected PANTERA Plate System inside the Sterilization Tray in a cool, dry place, away from direct sunlight.
- Instruments should be disassembled for cleaning and inspection when appropriate. Refer to PANTERA Cleaning and Sterilization (Document 50000057). Carefully remove any debris, tissue, or bone fragments to ensure proper performance. Because PANTERA instrumentation is subjected to repeated stresses from impaction, bone contact, cleaning, and sterilization, it does not have an infinite functional life. Reusable instruments must be inspected before each use and replaced if damaged, worn, or not functioning properly. Devices that have reached the end of their service life must be disposed of in accordance with institutional procedures.
- Dispose of contaminated implants and instruments in accordance with established healthcare facility protocols for handling contaminated or biohazardous materials.
- Personal Protective Equipment (PPE) must always be worn when handling contaminated or potentially contaminated devices. Universal precautions for infection control must be strictly followed to reduce the risk of bloodborne pathogen transmission. Exercise caution when handling sharp or cutting devices.
- Implants must never be reused. Prior stresses from previous use may create imperfections that could lead to device failure. Implantable devices must be protected from scratches, nicks, or dents that may create stress concentrations and result in failure.

- Exercise caution to avoid damage to the vasculature of bone fragments during implantation.
- Avoid penetrating the joint during drilling. It is advisable to drill to a depth that remains 5 mm to 10 mm from the subchondral bone of the joint surface to minimize the risk of joint penetration.
- The patient should be cautioned, preferably in writing, regarding the use, limitations, and possible adverse effects of the device.
- Select Post Screw and Locking Cortical Screw that terminate 5 mm to 10 mm from the subchondral bone of the joint surface to minimize the risk of penetration. The Depth Gauge and Screw Caddy measuring instruments have ± accuracy tolerances, and the CE scale has an accuracy of ± 2 mm.
- Ensure that the notches on the Cross Elements Guide are properly aligned with the corresponding notches on the Post Screw. Failure to do so may result in improper placement of the Cross Element.
- Exercise care to avoid damage to the suture clips. Excessive force or bending of the suture clip(s), whether with instruments or suture wire, may degrade clip performance. It is advisable to use no larger than #2 braided surgical suture to avoid clip damage.
- Avoid measurement errors when selecting the size of the Post Screw, by using the drill bit scale to determine length.
- Reduce the risk of Cross Element migration by maintaining a distance of 5 mm to 10 mm from the far cortex when drilling the pilot hole.
- Use caution when selecting implantable components for patients with severe osteoporosis, as the risk of plate and screw migration may be increased.
- For additional cautions, refer to PANTERA Instructions for Use (Document 60000010).
- For additional cleaning and sterilization instructions, refer to PANTERA Cleaning and Sterilization Instructions (Document 50000057).
- The PANTERA System implants have been evaluated for MR safety. Non-clinical testing under worst-case conditions has demonstrated that the implants are MR Conditional. A patient with a Toby Orthopaedics PANTERA Humerus Bone Plate implant may be safely scanned only under specified MR conditions. Failure to follow these conditions may result in patient injury.

Name / Identification of device	Toby Orthopaedics PANTERA Proximal Humerus Fraction Fixation Plate System
Nominal Value (s) of Statid Magnetic Field [T]	1.5 T or 3 T
Maximum Spatial Field Gradient [T/m and guass/cm]	30 T/m (300 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil type	Whole Body transmit coil, Head RF transmit-receive coil
Maximum Whole Body SAR [W/kg.]	2.0 W/kg (Normal Operating Mode)
Limits of Scan Duration	2.0 W/kg. whole body average SAR for 30 minutes of continous RF (a sequence or back to back series without breaks), followed by an additional 15-minute scan.
MRI Image Artifact	The presence of this implant may produce an image artificat of 19 min.
Note: If a specific parameter is not listed, no conditions are associated with that parameter.	

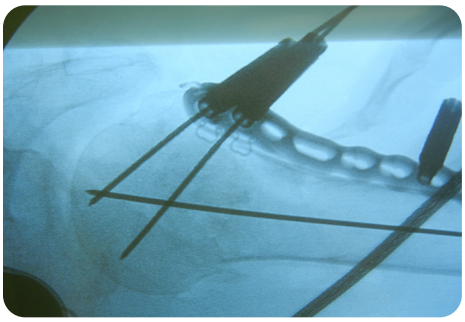
SURGICAL SEQUENCE



01

Preliminary Reduction and Temporary Fixation

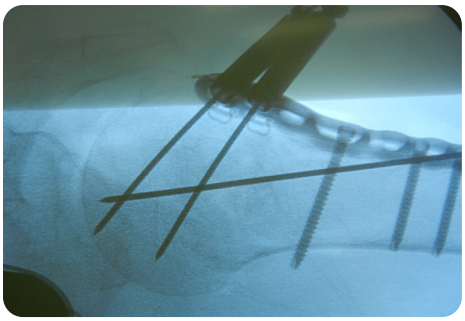
- Perform fracture reduction
- Provisionally stabilize using K-wire



02

Plate Positioning and Fixation

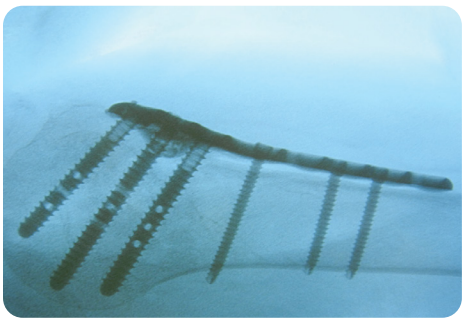
- Position the plate in the proximal region of the humerus
- Verify height and alignment under fluoroscopic control
- Provisionally fix as necessary



03

Diaphyseal Fixation

- Insert the appropriate diaphyseal screws
- Confirm alignment and construct stability



04

Humeral Head Fixation

- Insertion of Post Screws
- Placement of the Posterior Locking Screw
- Placement of Cross Element screws
- Application of Post Cap Screws (optional)

PATIENT POSITIONING

Recommended Position

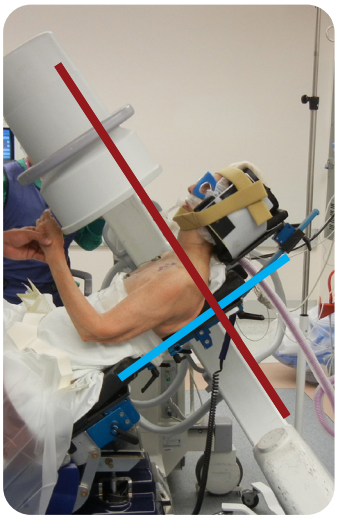
The beach chair position is recommended.
Imaging equipment may be introduced from the contralateral side.

Radiographic Control

Orthogonal views are required to confirm reduction and fixation.

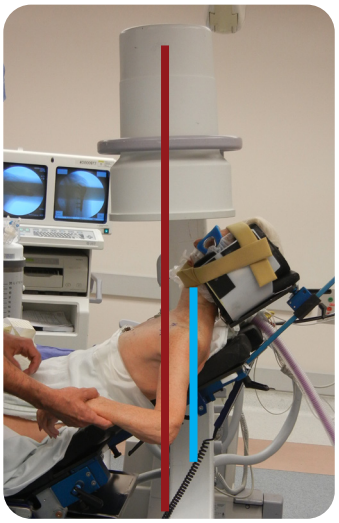
AP View

Position the C-arm axis perpendicular to the coronal plane of the proximal humerus.

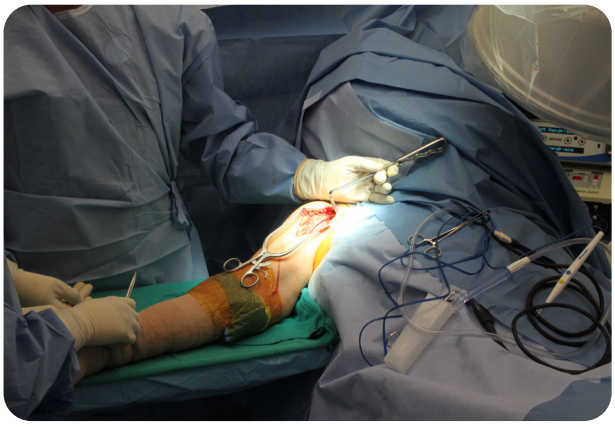


Axillary View

An axillary view of the proximal humerus is obtained by rotating the C-arm 45° vertically and extending the shoulder 45° in the opposite direction, minimizing arm and equipment manipulation.



UPPER EXTREMITY POSITIONING



The forearm may be supported on a Mayo stand to facilitate manipulation.

The shoulder may be placed in abduction to reduce tension on the deltoid muscle.

A deltopectoral approach is recommended.

01 PRELIMINARY REDUCTION AND TEMPORARY FIXATION

Expose and debride the fracture site.

Avoid devitalizing soft tissue attached to the fragments whenever possible.

Evacuate the hematoma by suction.

Restore the anatomic relationship between the articular surface and the humeral shaft, ensuring proper angular alignment and retroversion.

Reduce the tuberosities to their anatomic positions.

Sutures may be passed through comminuted bone fragments to facilitate reduction.

The metaphyseal defect may be filled with appropriate allograft or bone substitute.

Preliminary reduction may be maintained with K-wires.

⚠ **Caution**
Exercise care to avoid damage to the vasculature of the bone fragments.

02 PLATE POSITIONING AND FIXATION

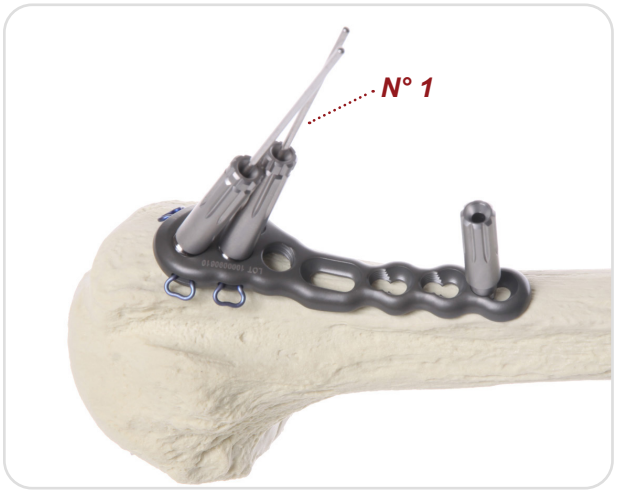
Assemble two Post Drill Guides with their corresponding Post Drill Guide Sleeves, preferably in the proximal holes.

This allows drilling and placement of a compression screw in the oblong hole with minimal interference.

Assemble the 2.5mm Locking Screw Drill Guide in the most distal hole of the plate.
This facilitates handling and positioning of the plate during initial placement.

Identify the proper position of the plate.

It should be placed immediately posterior to the intertubercular groove and approximately 1.5 to 2.0 cm distal to the insertion of the supraspinatus to avoid impingement with the acromion.

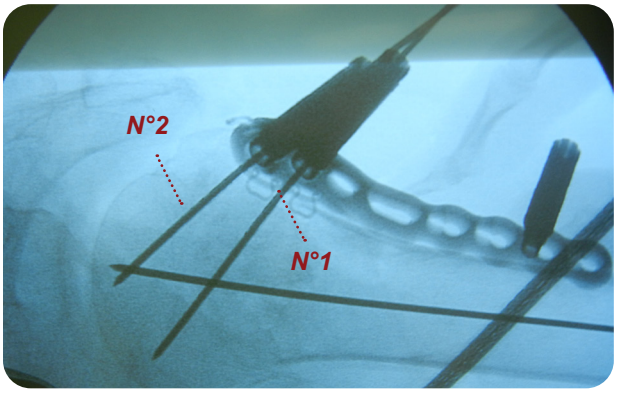


With the plate positioned, insert K-wires through each of the two Post Drill Guide Sleeves and confirm preliminary plate position under fluoroscopy.

Very important, the K-wire (No. 1), corresponding to the central Post, must be placed along the midline of the humeral head.

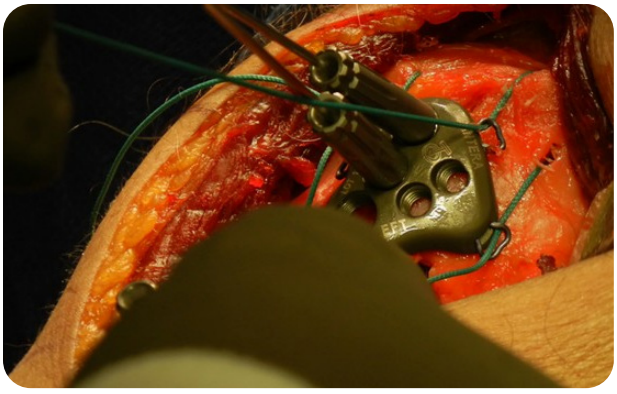
This serves as the primary reference point for plate positioning.

Note: When using extended-length plates (120–220 mm), take full advantage of the K-wire hole design features to assist with preliminary positioning.



A second wire (No. 2) confirms plate position and provides divergent plate-to-bone stability, allowing continuation of fine reduction.

Anteroposterior and lateral views must confirm correct plate positioning.



Take full advantage of the Suture Clips to assist with reduction and fixation of comminuted tuberosity fragments.

Position the comminuted greater tuberosity beneath the proximal and posterior buttress of the plate.

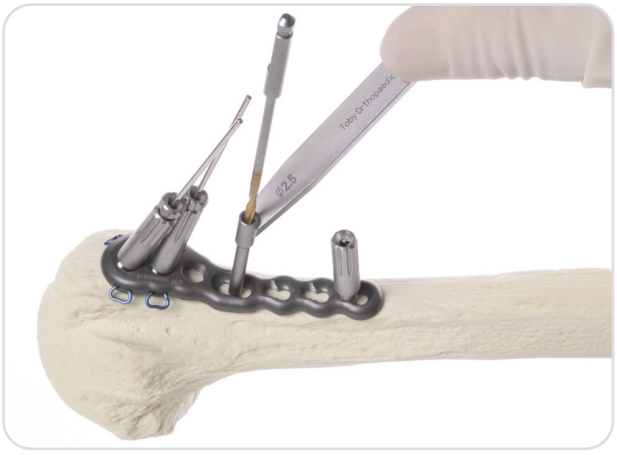
⚠ Caution
Avoid excessive force or bending of the suture clips, as this may compromise performance. Use no larger than #2 braided surgical suture.

Avoid having a prematurely placed screw interfere with fracture reduction.

Fixation of the plate to the shaft, as described in Step 3, may assist in completing reduction of the humeral head and tuberosities to the shaft.

This technique is commonly referred to as “buttress reduction” or “buttress plating.”

03 DIAPHYSEAL FIXATION



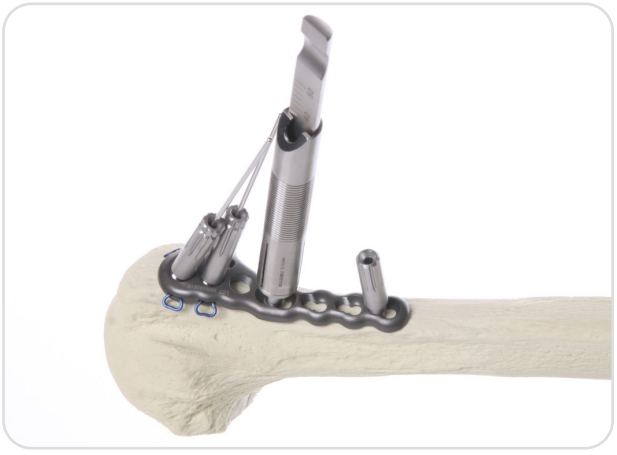
Secure the plate to the humeral shaft fragment using a 3.5 mm Cortical Screw inserted through the oblong hole of the plate with the T10 Driver.
This may assist in fracture reduction (buttress reduction).

If plate positioning is not optimal, remove the K-wires and loosen the 3.5 mm Cortical Screw.
Adjust as needed, reinsert the K-wires, and retighten the screw.

Fully insert the 2.5/3.5 mm Drill Guide (tissue protector) into the plate and ensure it is fully seated. Maintain proper positioning throughout drilling to prevent device damage and patient injury.

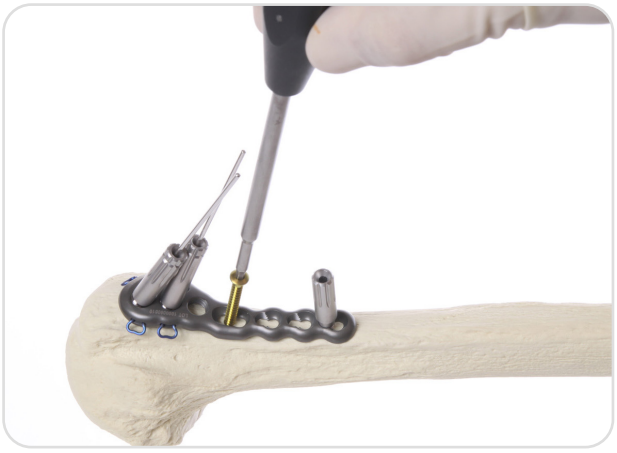
Using the 2.5 mm Drill Bit, drill into the humeral neck through the center of the oblong hole or an adjacent hole.

⚠ **Caution**
Avoid excessive manipulation of the drill bit or the application of excessive force, as this may result in device damage or patient injury.



Use the Depth Gauge to determine the appropriate 3.5mm Cortical Screw length.

The Depth Gauge measuring instrument has an accuracy of ± 1 mm.



Secure the plate to the humeral shaft fragment using a 3.5 mm Cortical Screw inserted through the oblong hole of the plate with the T10 Driver.
This may assist in fracture reduction (buttress reduction).

If plate positioning is not optimal, remove the K-wires and loosen the 3.5 mm Cortical Screw.

Adjust as needed and retighten the screw once alignment is confirmed.

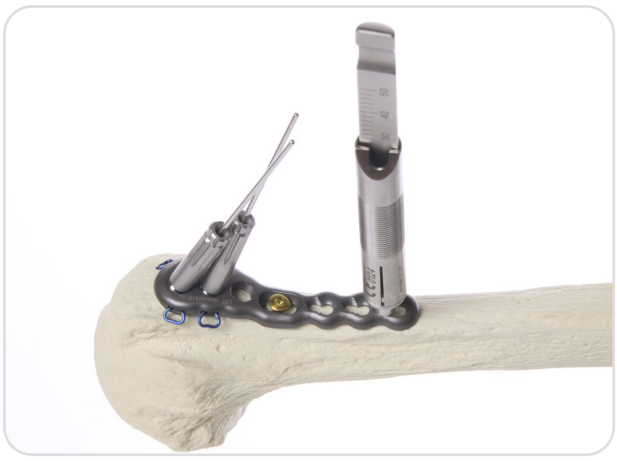
If a medial calcar fracture is present, use a hole distal to the oblong hole to initiate diaphyseal fixation and achieve the desired buttress reduction.

The calcar fragment may then be lagged to the construct through the oblong screw hole (calcar reduction hole).

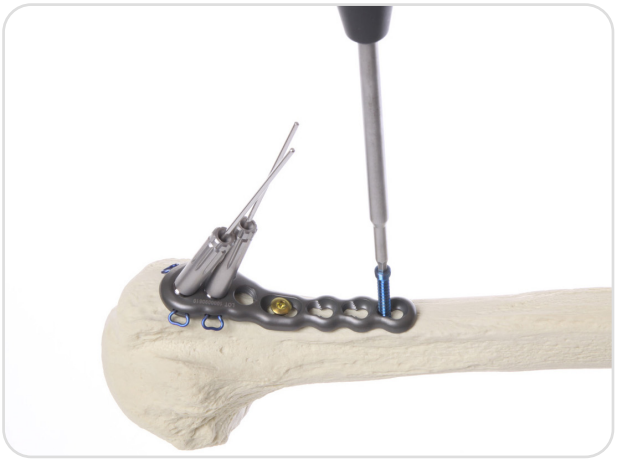
At least one 3.5mm Cortical Locking Screw must be placed in one of the distal holes of the plate.

Thread the 2.5mm Locking Screw Drill Guide into the selected distal hole.

Using the 2.5 mm Drill Bit, drill through the Locking Screw Drill Guide into the bone.



Use the Depth Gauge to determine the appropriate 3.5mm Cortical Locking Screw length.



Insert the 3.5 mm Cortical Locking Screw into the threaded hole of the plate using the T10 Driver.

Repeat as necessary in the remaining distal holes.

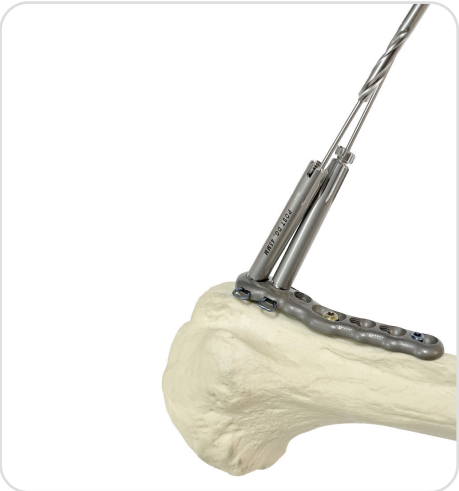
Alternatively, 3.5 mm Cortical Screw may be used. In this case, insert the screw into the non-threaded portion of the plate hole.

04 HUMERAL HEAD FIXATION

Once optimal fracture reduction, including the tuberosities, and proper plate positioning with distal fixation are achieved, proceed with definitive proximal fixation.

Using the 4.0 mm Cannulated Drill Bit, drill for the 5.2 mm Cannulated Post Screw as shown.

> ⚠ **Caution**
> Avoid articular penetration. Drill to a depth that remains 5–10 mm from the subchondral bone to minimize the risk of joint surface penetration.



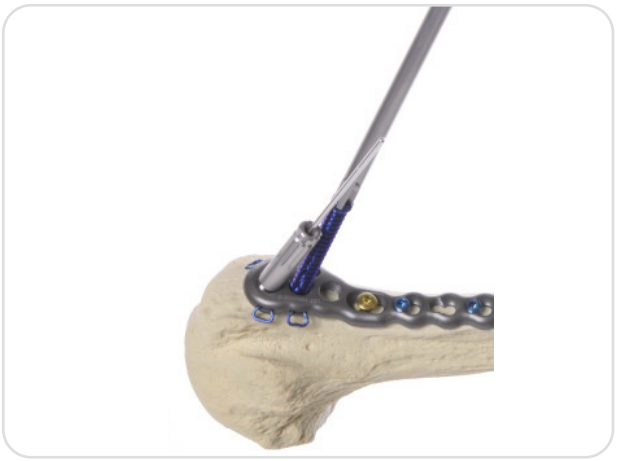
With the 4.0 mm Cannulated Drill Bit fully seated, determine the appropriate screw length by reading the measurement directly from the integrated scale. Select the shorter length if in doubt.

Remove the 4.0 mm Cannulated Drill Bit while maintaining the K-wire in position.

Using the Cannulated Cruciform Driver, remove the Post Drill Guide Sleeve only, keeping the K-wire in place to guide insertion of the 5.2 mm Cannulated Post Screw.

Integrated scale on the 4.0 mm Cannulated Drill Bit for screw length determination.

Note: If there is any uncertainty regarding the required post screw length, use the Depth Gauge to confirm the measurement. Remove the Post Drill Guide before using the Depth Gauge, and perform the measurement under fluoroscopic guidance.



Use the Cannulated Cruciform Driver to remove the Post Screw Drill Guide, leaving the K-wire in place.

Insert the 5.2 mm Cannulated Post over the K-wire, through the plate, and into the humeral head using the Cannulated Cruciform Driver.

⚠ Caution
Do not overtighten the 5.2 mm Cannulated Post. Seat the Post flush with the plate to allow for final adjustments.

Instrument Alignment

The Cannulated Cruciform Driver features laser markings that correspond to matching features in the Post head.

These markings indicate the orientation of the parallel cross screw holes on the Post and the Cross Element Guide.

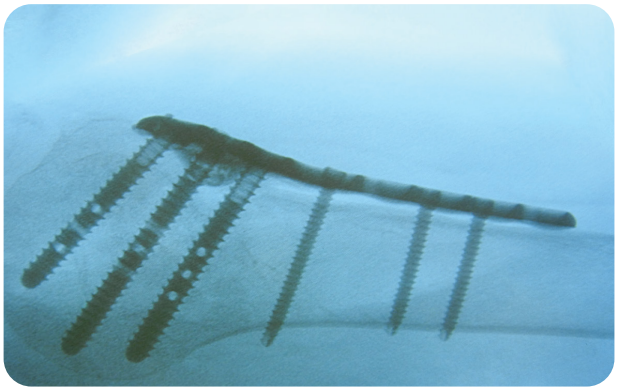
Proper alignment is required for Cross Element Screw installation, when indicated.

Advance the 5.2 mm Cannulated Post over the corresponding K-wire, maintaining alignment with the pre-drilled hole.

The laser markings along the shaft correspond to the thick limb of the asymmetric cross on the instrument tip.

When inserting the 5.2 mm Post Screw, leave the screw in a preferred final position with the thick limb of the cross oriented anterior–posterior (not superior–inferior).

This orientation allows the Cross Element Guide to be assembled more easily onto the Post.



Confirm proper implantation with intraoperative fluoroscopy.

Repeat as needed to fill all three 5.2 mm Cannulated Post Screw holes.

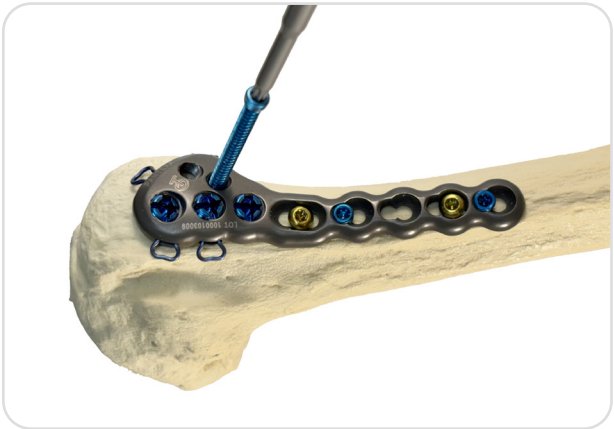
POSTERIOR LOCKING SCREWS

Thread the Locking Screw Drill Guide into a proximal plate hole.

Drill with the 2.5 mm Drill Bit for the 3.5 mm Cortical Locking Screw.

Use the Depth Gauge to determine the appropriate screw length.

⚠ Caution
Avoid articular penetration. Select a screw length that remains 5–10 mm from the subchondral bone to minimize the risk of joint surface penetration.

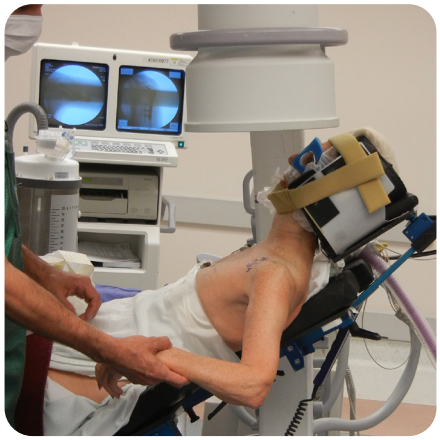


Insert the 3.5 mm Cortical Locking Screw into the threaded hole of the plate and confirm placement with intraoperative fluoroscopy.

Repeat this process until both proximal holes are filled.

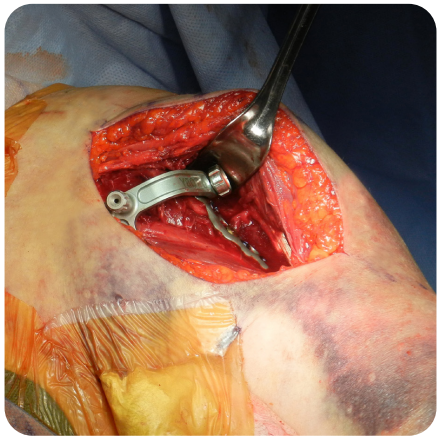
APPLICATION OF CROSS ELEMENT SCREW

At surgeon discretion, Cross Element Scew may be applied at this point.



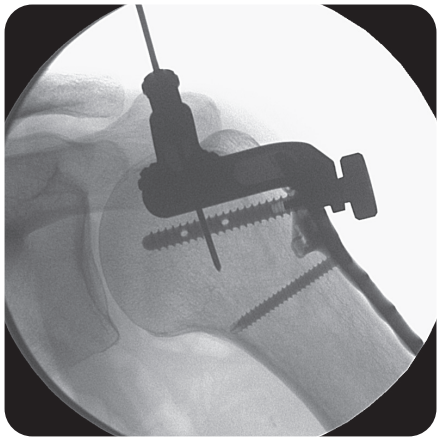
PATIENT POSITIONING

Application of the Cross Element Guide and Cross Elements is simplified with the shoulder in slight extension abduction and slight external rotation.



GUIDE PLACEMENT

The Cross Element Guide is placed over the humeral head to guide the insertion.

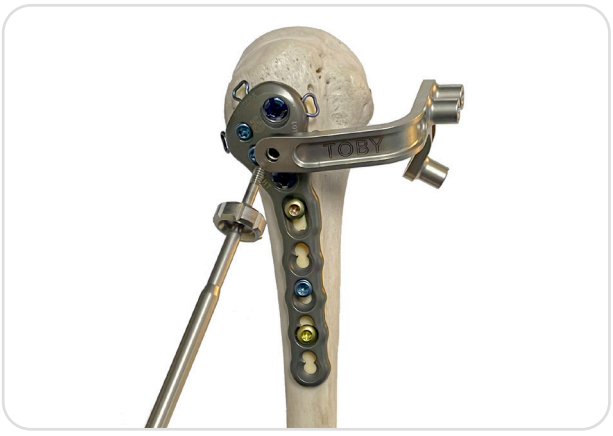


FLUOROSCOPIC CONTROL

Use fluoroscopy to confirm proper positioning and trajectory of the screw.

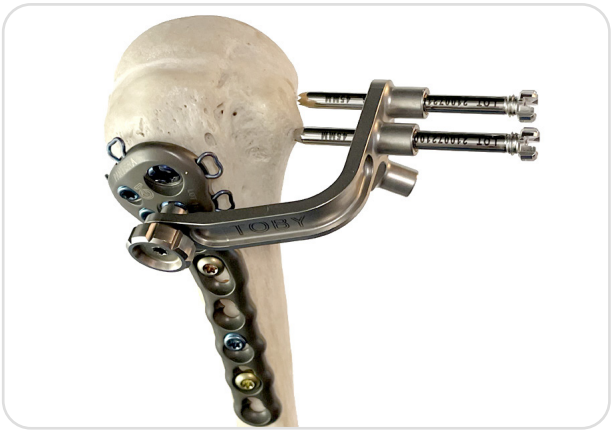
Align the Cross Element Guide with one of the Post Screw.

⚠ **Caution**
Ensure the notches on the Cross Element Guide are fully aligned with the corresponding notches in the Post Screw. Failure to align these features may result in improper placement of the Cross Element Screw.



Secure the Cross Element Guide by threading the Cross Element Guide Reatainer.

Tighten the Retainer with the T10 driver until it fully engages and locks into position.



Insert two Post Drill Guide Sleeves into the selected positions on the Cross element Guide.

⚠ **Caution**
Do not push the Post Drill Guide Sleeves throught the cortical bone.

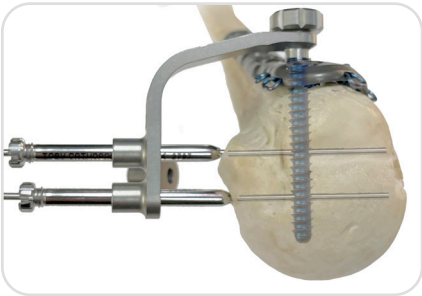
Use the serrated tip of the sleeves, together with the Cannulated Cruciform Driver, to clear soft tissue and expose the cortical bone.

This facilitates smooth and precise placement of the Cross Element Screws.

Insert two K-wires through the Post Guide Sleeves, passing through the bone and Post Screw to prevent unintended rotation of the guide during placement of the Cross Element Screw.

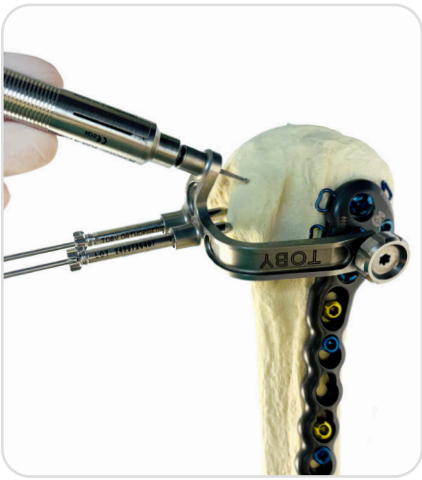
Confirm positioning with fluoroscopy and make any necessary adjustments using anteroposterior and lateral or axillary views.

The Cross Element Screw is introduced through the lesser tuberosity along an extracapsular, extra-articular trajectory to help resist humeral head collapse.



Advance the K-wire three to four times to create a well-defined pilot hole for the Cross Element.

⚠ Caution
To avoid joint penetration, maintain a distance of 5–10 mm from the far cortex when drilling the pilot hole.



Remove one K-wire and its corresponding Post Guide Sleeve to proceed with drilling for the Cross Element Screw..

Insert the Depth Gauge into the Cross Element Guide hole vacated by the Post Guide Sleeve.

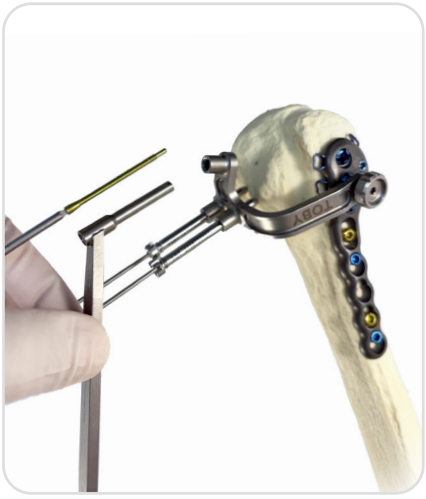
⚠ Caution
Do not advance the tip of the Depth Gauge into the bone. Advance the Depth Gauge only until it contacts the humeral head cortex.

Leave the second K-wire (in the remaining Guide Sleeve) in place to stabilize the construct before installing the first Cross Element Screw.

Select the appropriate Cross Element Screw length using the “Cross Element Screw Scale” on the cylindrical surface of the Depth Gauge.

Available lengths: 20 mm, 25 mm, 30 mm, and 35 mm.

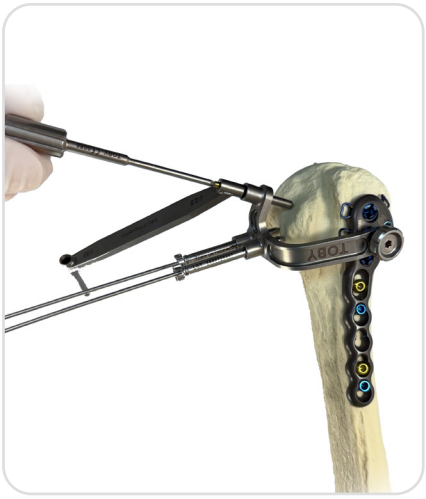
If the measurement falls between sizes, select the shorter length. The Depth Gauge accuracy is ± 2 mm.



Use the 2.5 mm / 3.5 mm Drill Guide directly in the Cross Element Guide hole to insert the Cross Element Screw.

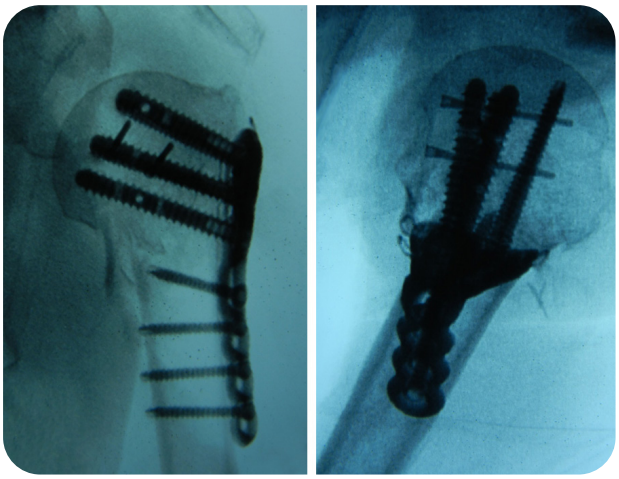
Ensure the head of the Cross Element Screw is seated below the surface of the humeral head.

Repeat this step as needed, up to three times per Post, to complete the available articulation holes for the Cross Elements.



The number of Cross Element Screws used is at the surgeon's discretion.

These screws provide fixation of the lesser tuberosity and additional mechanical support to the humeral head.

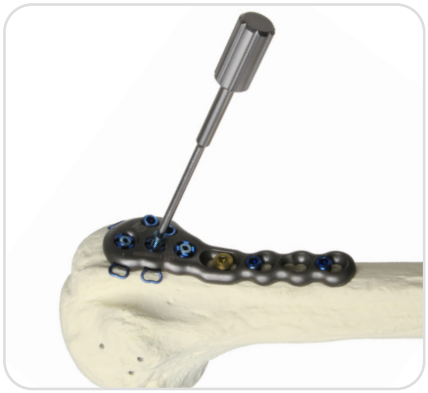


FINAL CONTROL

Assess fixation and final implant placement using fluoroscopy and make any necessary adjustments.

Use anteroposterior and lateral or axillary views.

APPLICATION OF POST CAP SCREW (OPTIONAL)

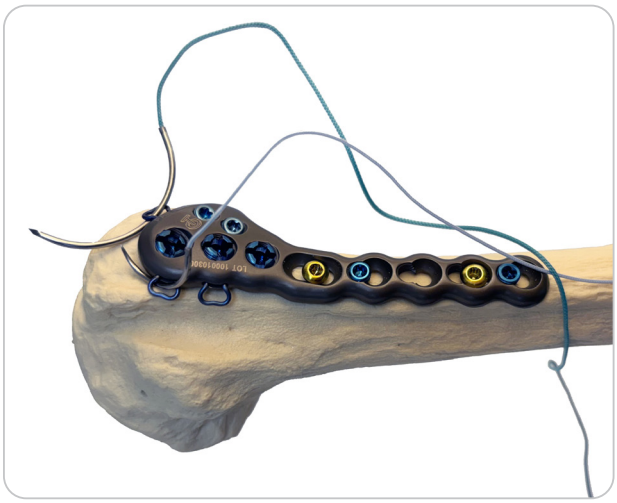


Thread the Post Cap Screw into the center of the Post head using the Precision Square Driver.

> ⚠ **Caution**
> Minimal torque is required to seat the Post Cap Screw.

Repeat for each installed Post Screw.

SUTURE CLIPS



Suture Clips may be used for:

- Management of comminuted tuberosity fragments
- Repair of soft tissue injuries
- Reinforcement of the rotator cuff

The Clips provide additional tuberosity fixation and contribute to construct stability.

The design allows passage of multiple sutures, including high-strength sutures up to #2 braided surgical suture.

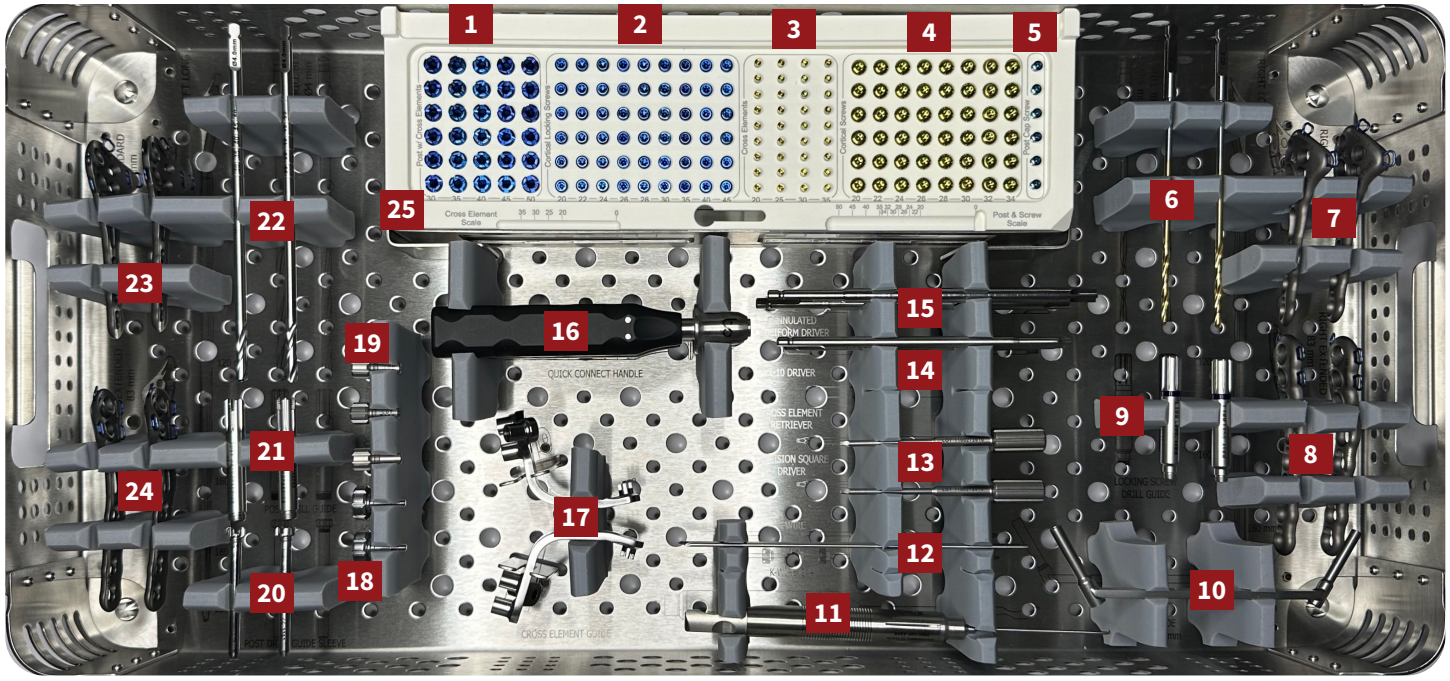
Rotator cuff repair may be performed once fracture fixation has been completed.

WOUND CLOSURE

Close the wound using standard surgical closure technique. Place a drain if clinically indicated.

PANTERA SYSTEM – TRAY CONFIGURATION

Components and Included Instrumentation



No.	Catalogue Ref.	Description
1	TO-52-CP-xx	5.2mm Canulated Post Screw, 30-50 mm
2	TO-35-T10-CLS-xx	3.5mm T10 Cortical Locking Screw, 20-45 mm
3	TO-20-CE-xx	2.0mm Cross Element, 20-35 mm
4	TO-35-T10-CS-xx	3.5mm T10 Cortical Screw, 20-34 mm
5	TO-PH-PCS	Post Cap Screw
6	TO-DB25-110	2.5mm Drill Bit x 110 mm
7	TO-PHP-R73	PANTERA Plate, Right, 73 mm
8	TO-PHP-R83	PANTERA Plate, Right , 83 mm
9	TO-25-LSDG-45	2.5mm Locking Screw Drill Guide, 45 mm
10	TO-DG-2535	2.5/3.5 mm Drill Guide
11	TO-PH-DG-50	Depth Gauge, 50 mm
12	TO-KW-16-130	K-wire, 1.6mm x 130 mm
13	TO-DRI-PSQ	Precision Square Driver

No.	Catalogue Ref.	Description
14	TO-DRI-10P	T10 Driver
15	TO-DRI-CQCCR	Cannulated Cruciform Driver
16	TO-DRI-S-CQCH	Cannulated Universal Handle
17	TO-FIX-CEG	Cross Element Guide
18	TO-FIX-CEGR	Cross Element Guide Retainer
19	TO-FIX-CEGS	Discontinued (Not Supplied)
20	TO-PH-PDGS-45	Post Drill Guide Sleeve, 45 mm
21	TO-PH-PDG-45	Post Drill Guide, 45 mm
22	TO-CDB40-130	Cannulated Drill Bit 4.0 mm x 130 mm
23	TO-PHP-L73	PANTERA Plate, Left, 73 mm
24	TO-PHP-L83	PANTERA Plate, Left, 83 mm
25	TO-PANTERA-SC	PANTERA Screw Caddie

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EU REP

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Ireland

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Federal law restricts this device to sale by or on the order of a Physician.
This surgical technique is intended as an educational tool to assist a properly licensed medical professional in the usage of Toby Orthopaedics products and is not meant to replace professional judgment as to product usage and technique.
Prior to use, medical professionals should consult the product's Instructions for Use and rely on their own training and experience.

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Surgical Technique Guide
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