ZIMMER BIOMET
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A.L.P.S.® Proximal Humerus Plating System

Surgical Technique

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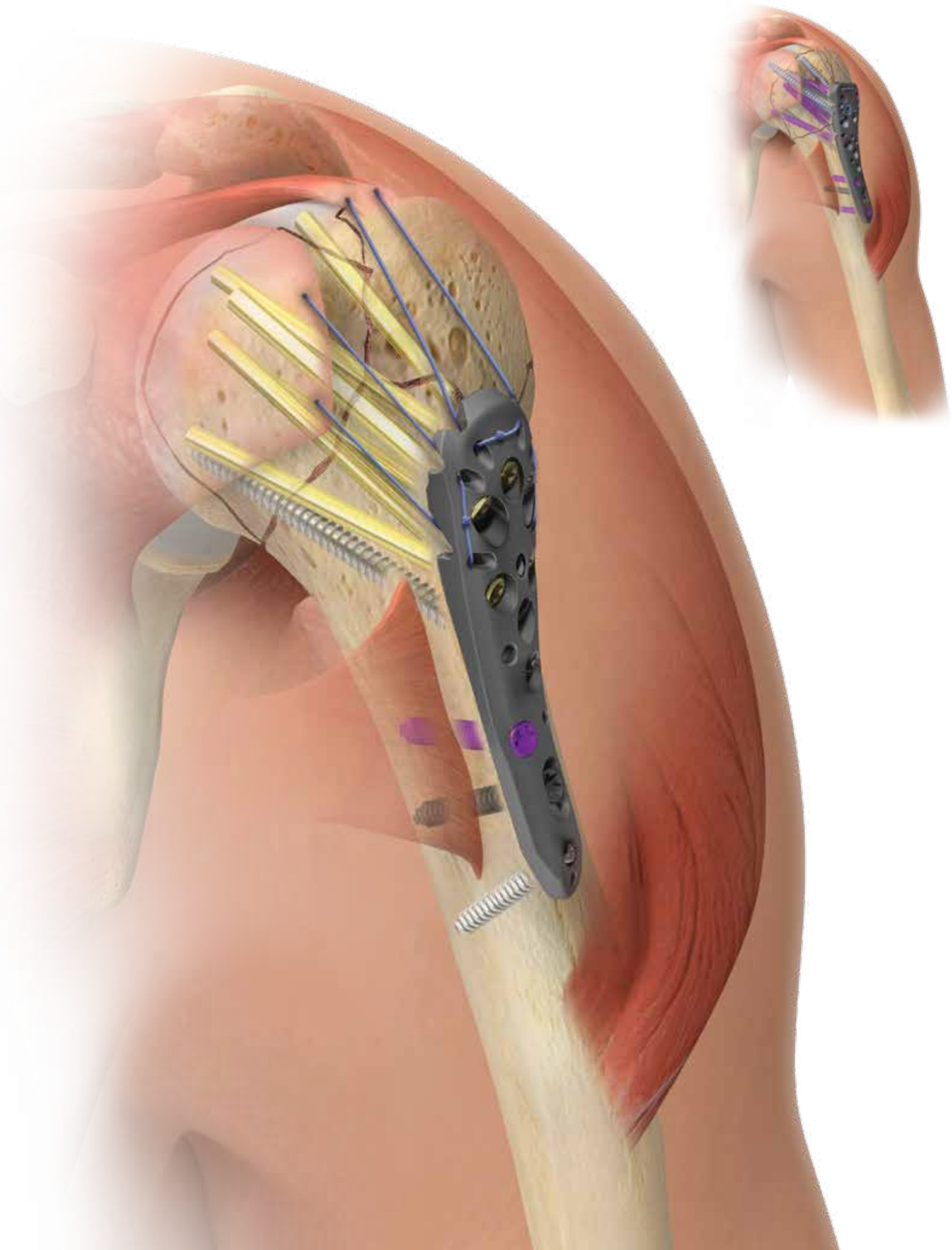


Introduction

The A.L.P.S. Proximal Humerus Plating System is an integral part of the Zimmer Biomet continuum of care for shoulder treatment. Zimmer Biomet offers a diverse portfolio of options for the life-cycle of patients, from sports-related injuries to fracture fixation to shoulder replacement. It features the next generation in humeral plating, offering the surgeon 2 plating options based on preference and fracture pattern.

The A.L.P.S. Proximal Humerus Plating System takes full advantage of the principle of Spatial Subchondral Support, which was successfully used in its predecessors, the S$^{3®}$ Proximal Humerus Plating System and the DVR® Anatomic Volar Plating System.

The A.L.P.S. Proximal Humerus Plating System is designed to provide intraoperative flexibility and efficiency to the surgical team. The A.L.P.S. Proximal Humerus Plating System is designed to minimize the risk of some of the complications commonly associated with treating proximal humerus fractures by its design to:

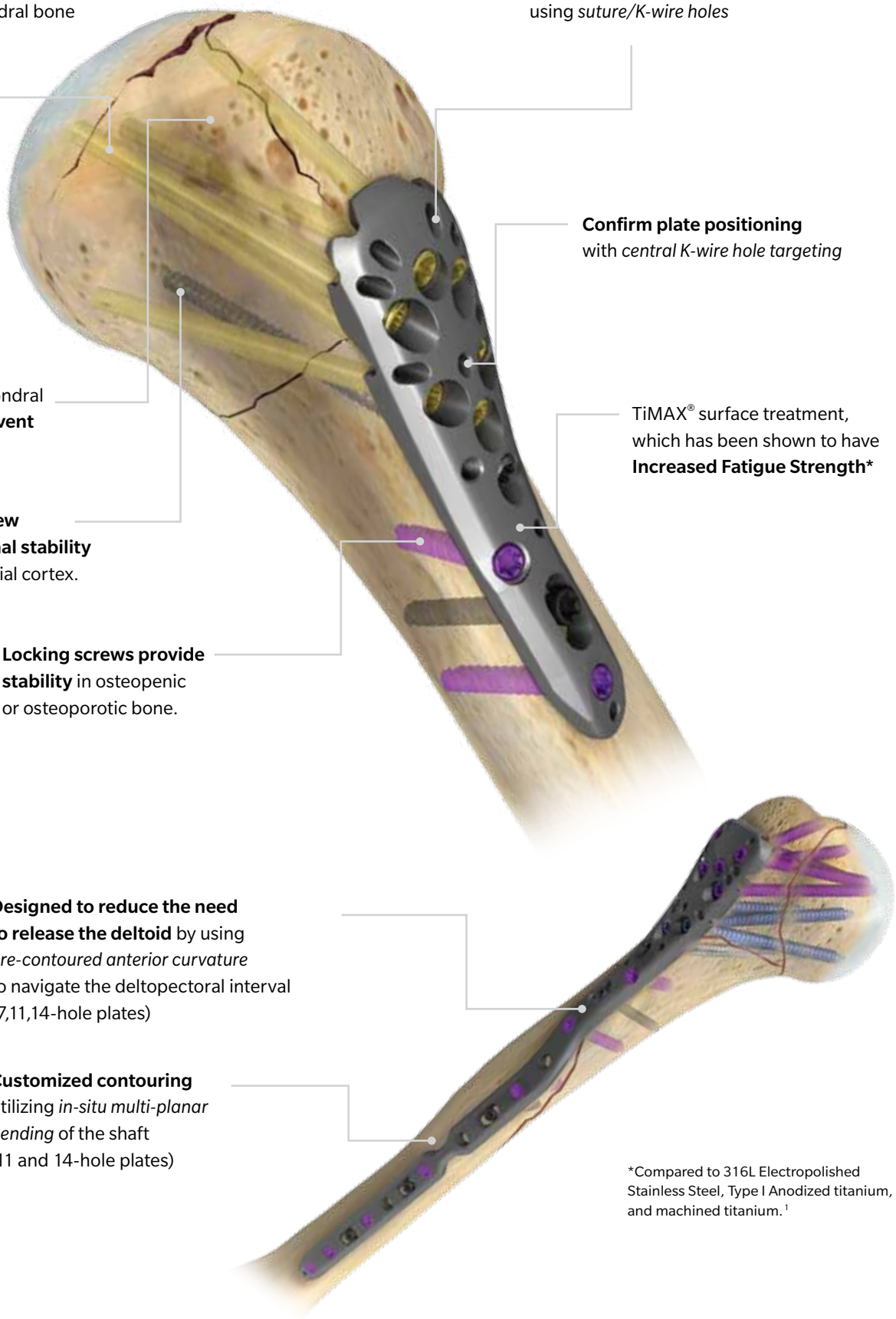
- **Minimize varus collapse** by creating an internal subchondral support system of diverging and converging locking screws around the anatomic 135° neck-shaft angle of the humerus. **Medial calcar** screw provides additional fixation in the inferior medial cortex
- **Minimize articular surface screw penetration** by using pegs with smooth blunt ends that engage the subchondral bone with blunt fixation
- **Minimize subacromial impingement** by sitting 2 cm distal to the greater tuberosity (Low Plate only)

The A.L.P.S. Proximal Humerus Plating System features **A.L.P.S. Technology** which utilizes:

- Pre-loaded, disposable F.A.S.T. Guide Inserts help the surgeon to drill accurately, and reduce intraoperative assembly to save OR time.
- **Tapered triple-lead locking screws** and **dual threaded pegs** facilitate easy removal
- **Cobalt chrome multi-directional locking screws** allow for up to a 25° cone of angulation
- Anatomic plates that can be **contoured in-situ** for optimal fit (11 & 14-hole plates only)

Designed to help minimize the risk of articular surface penetration by using *Smooth Blunt Locking Pegs* to engage subchondral bone

Temporary stabilization of the fracture and suture capture of the tuberosities using *suture/K-wire holes*



Confirm plate positioning with *central K-wire hole targeting*

The spatial subchondral support helps **prevent varus collapse.**

TiMAX® surface treatment, which has been shown to have **Increased Fatigue Strength***

Medial calcar screw provides additional stability in the inferior medial cortex.

Locking screws provide stability in osteopenic or osteoporotic bone.

Designed to reduce the need to release the deltoid by using *pre-contoured anterior curvature* to navigate the deltopectoral interval (7,11,14-hole plates)

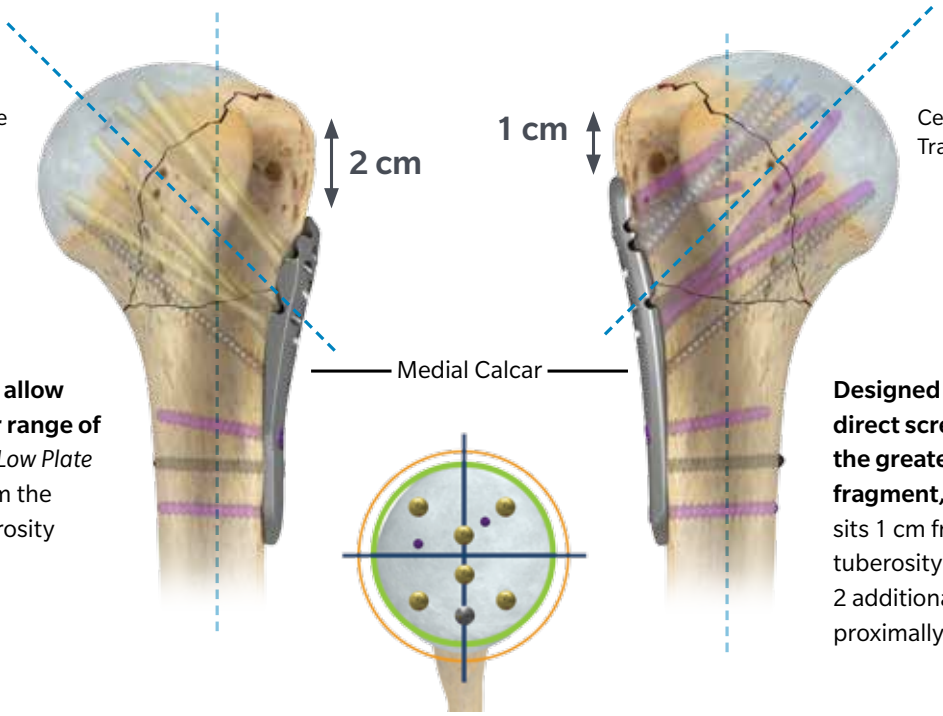
Customized contouring utilizing *in-situ multi-planar bending* of the shaft (11 and 14-hole plates)

*Compared to 316L Electropolished Stainless Steel, Type I Anodized titanium, and machined titanium.[1]

Unique Features

Designed to minimize varus collapse using *converging and diverging peg trajectories* that create an internal subchondral support system through range of motion.

Plate Options



Designed to allow for a greater range of motion, the *Low Plate* sits 2 cm from the greater tuberosity

Designed to achieve direct screw fixation of the greater tuberosity fragment, the *High Plate* sits 1 cm from the greater tuberosity and offers 2 additional screw holes proximally

Screw Options

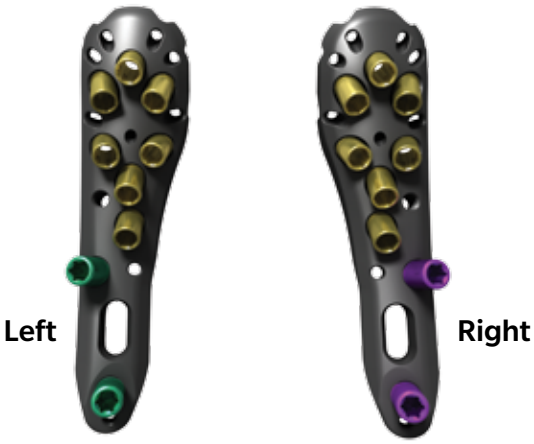
Optimal fixation achieved with *tapered, triple lead locking and low profile non-locking screw options*

25° cone of angulation using *cobalt chrome multi-directional locking screws (MDS)* that lock into the plate by creating their own threads

One Driver Simplicity
T15 driver used for all screws and pegs

F.A.S.T. Guide Inserts

Facilitate accurate drilling and easy plate identification with *pre-loaded F.A.S.T. Guide inserts* – Lime = Left, Rose = Right (shaft holes)



Gold F.A.S.T. Guide Inserts indicate the proximal holes that can utilize *locking peg fixation*

Figure 1

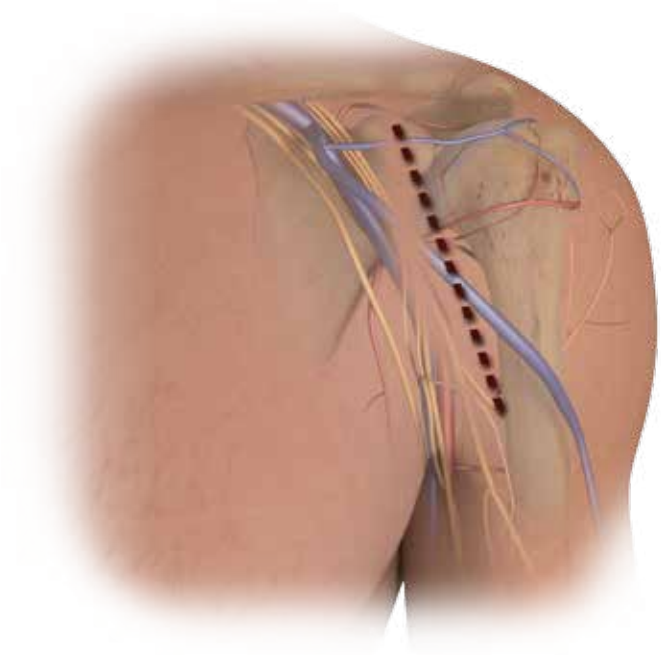


Figure 2

Step 1: Approach

Patient and Fluoroscopy Positioning

Proper patient positioning and fluoroscopy is critical to ensure the fracture can be adequately visualized. For the purposes of this technique, the deltopectoral approach is performed in a 45° beach chair orientation (Figure 1). The arm of the fluoroscopy machine can come in from the top or side, depending on surgeon preference.

Note: An alternative patient position is supine using a radiolucent arm table.

Exposure

Locate and mark the corocoid process and the axis of the humeral shaft and begin your 12–14 cm incision laterally between these two landmarks , in the standard deltopectoral approach (Figure 2). Care is taken to ensure that the incision is not crossing the anterior axillary fold. The deltopectorial interval is developed and the cephalic vein is retracted laterally or medially.

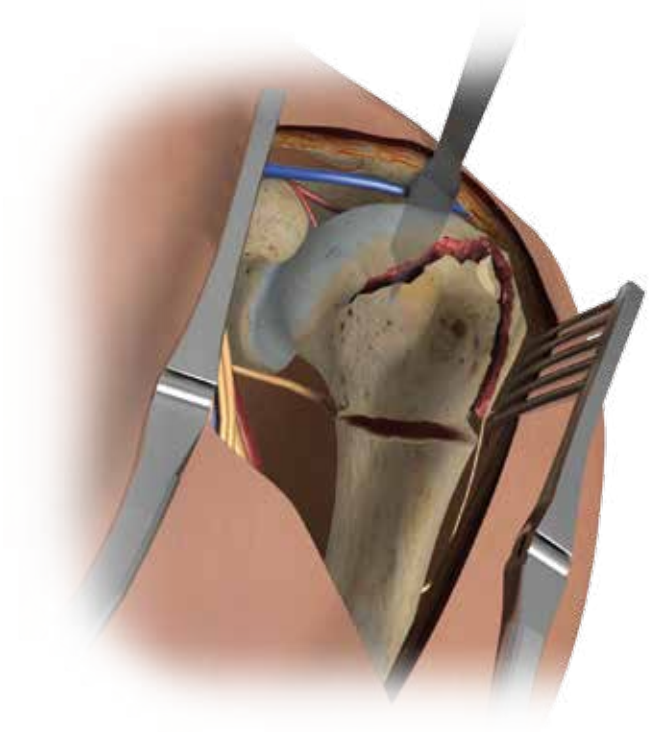


Figure 3

Managing Biceps Tendon and Deltoid

Retract the coracobrachialis medially and the deltoid laterally, taking care not to injure the axillary and musculocutaneous nerves. Identify the pectoralis insertion at the floor of the deltopectoral interval. If necessary, release the proximal third of the pectoralis tendon for better exposure. Develop the subacromial space and mobilize the proximal deltoid with deltoid retractor if desired (Figure 3).

Note: The biceps tendon is kept intact throughout the procedure for rotational alignment and plate positioning and then may be released/tenodesed after implant fixation.

Note: The 7, 11 and 14 hole plates are designed to curve anteriorly between the deltoid pectoralis interval, to help minimize release of the deltoid insertion.

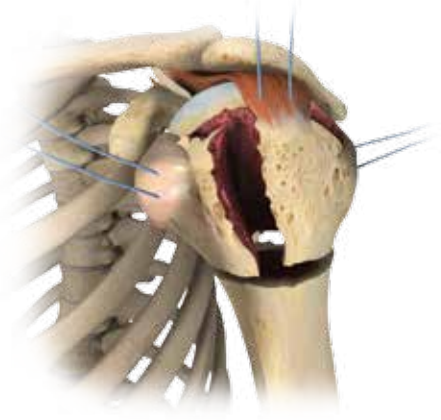


Figure 4

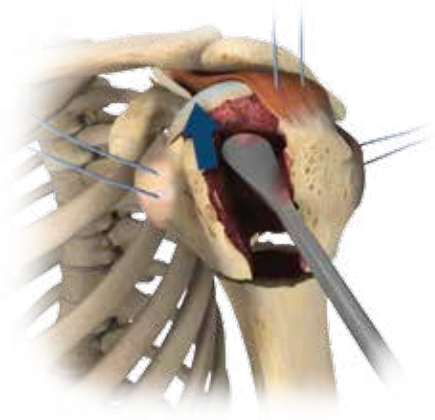


Figure 5

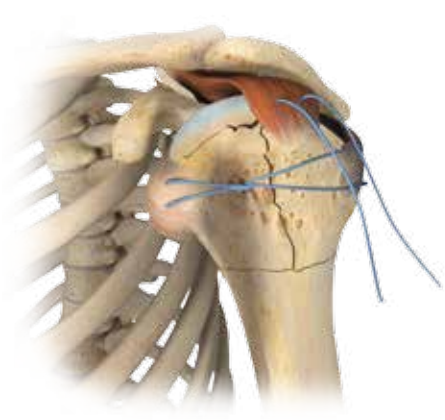


Figure 6

Step 2: Achieve Initial Reduction

Reduce the humeral head fragments using traction, manipulation or your preferred technique:

- Place sutures in to the osseotendinous junction of the rotator cuff to reduce the tuberosities (Figure 4).
- Insert a blunt elevator into the fracture to reduce the head and recreate the natural 135° neck-shaft angle and correct apex anterior angulation (Figure 5)
- Make a 2-part fracture by tying the head and tuberosities together, then reducing to the shaft (Figure 6)
- Insert crossing K-wires from anterior to posterior to hold the reduction, and then confirm proper reduction using fluoroscopy.

Note: K-wires may also be used through the suture holes around the proximal edge of the plate for provisional fixation and reduction assistance.

Note: Zimmer Biomet bone grafting or osteoconductive agents may be considered for bony voids or gaps that are not intrinsic to the stability of the bony structure.

Low Plate High Plate

Figure 7

Low Plate High Plate

Figure 8

Step 3: Plate Selection

Based on surgeon preference, choose the plate style that is most suited for the fracture. The low plate is designed to minimize the risk of subacromial impingement, whereas the high plate is designed to offer additional screw fixation of the greater tuberosity fragment (Figure 7). Both plate styles provide medial calcar and spatial subchondral support of the humeral head.

Note: Patients with larger anatomy may require the plate to sit more distal. Patients with smaller anatomy may require a more proximal plate position.

Step 4: Plate Positioning

Visual Positioning

Select the appropriate length plate (3, 4, 7, 11 or 14 hole). Choose a right or left plate utilizing F.A.S.T. Guide color identification in shaft holes (Figure 8):

- Left plates = Lime-colored
- Right plates = Rose-colored

Align the plate immediately lateral to the bicipital groove (Figure 7). To determine the appropriate placement on the greater tuberosity:

- Low plate = approximately 2 cm distal to the greater tuberosity
- High plate = approximately 1 cm distal to the greater tuberosity

Figure 11

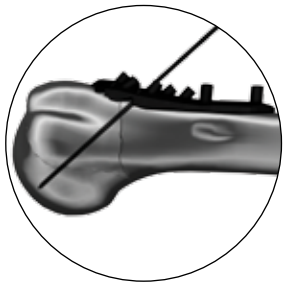


Figure 12

Figure 13

Figure 14

K-wire Targeting

Central K-wire Hole

This primary targeting method allows for symmetrical peg or screw distribution in all four quadrants of the humeral head.

- Drill the 2.0 mm K-wire (KW20SS) through the central K-wire hole on the proximal portion of the plate (Figure 11)
- Using fluoroscopy, confirm the K-wire is centrally located in both anterior-posterior and lateral planes (Figure 12)
- If it is off-axis, remove the K-wire and re-drill until the center is reached

Alternate Targeting through Medial Calcar Screw Hole

This targeting method may be preferred if there is comminution in the medial calcar that necessitates peg or screw support.

- Insert the 2.0 mm K-wire Adapter (110017541) into the F.A.S.T. Guide of the medial calcar screw position (Figure 13)
- Drill the K-wire through the adapter into the medial calcar screw hole to estimate the distance from the medial wall of the calcar
- Using fluoroscopy, confirm that the K-wire is 2-4 mm proximal to the medial wall of the calcar (Figure 14)

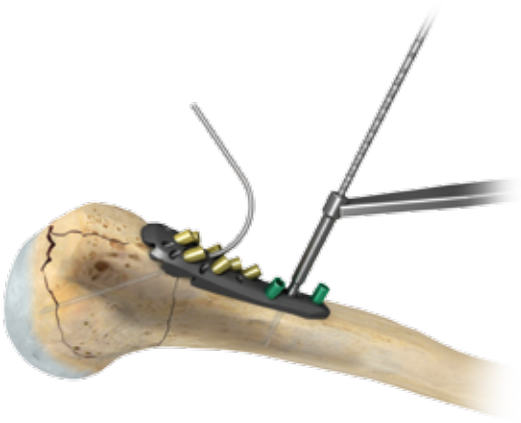


Figure 15

Figure 16

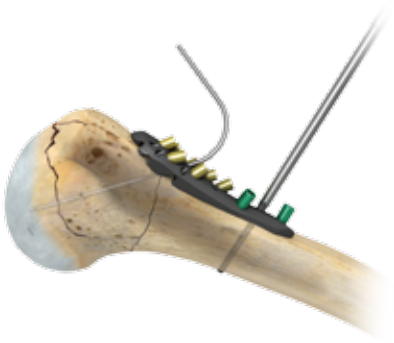


Figure 17

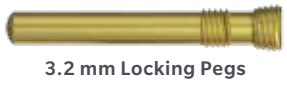
Step 5: Distal Provisional Screw Insertion

Drill through the proximal oblong hole in the shaft of the plate using the 2.7 mm Calibrated Drill Bit (214227070) through the 2.7 mm end of the Soft Tissue Guide (110017533) (Figure 15).

Determine the required non-locking screw length using the Shoulder Plate Depth Gauge (110017535) (Figure 16). Insert the 3.5 mm T15 Low Profile Non-Locking screw in the oblong hole in the shaft of plate (1100177XX) using the T15 Driver and Ratcheting Screwdriver Handle (214124000) (Figure 17).

Note: Do not fully tighten the screw to allow for later plate adjustments.

Note: K-wires may also be used in the shaft or to provide additional provisional fixation.



3.2 mm Locking Pegs

3.5 mm Locking Cortical Screws

4.0 mm Locking Cancellous Screws

3.5 Low Profile Non-Locking Screw

3.5 mm Locking Multi-Directional Screws (MDS)

Figure 18

Figure 19

Step 6: Proximal Peg or Screw Insertion

Peg or Screw Options

Select the appropriate screw based on bone quality or surgeon preference (Figure 18).

Recommended Peg/Screw Order

It is recommended that the medial calcar screw or peg is inserted first. However, if a K-wire is already in place and being used for provisional fixation, proceed to the next hole.

Color Coded Instrumentation

The instrumentation has been color-coded for easy identification (Figure 19):

- Gold = 3.2 mm Gold Locking Pegs (Gold 3.2 mm F.A.S.T. Guide Inserts indicate the positions that are recommended to be used with pegs)
- Silver = 3.5 mm Locking Cortical Screws, 3.5 mm Low Profile Non-Locking Screws, 4.0 mm Locking Cancellous Screws and 3.5 mm Locking MDS

Note: Prior to drilling, the K-wire(s) should be bent to avoid drill bit obstruction.

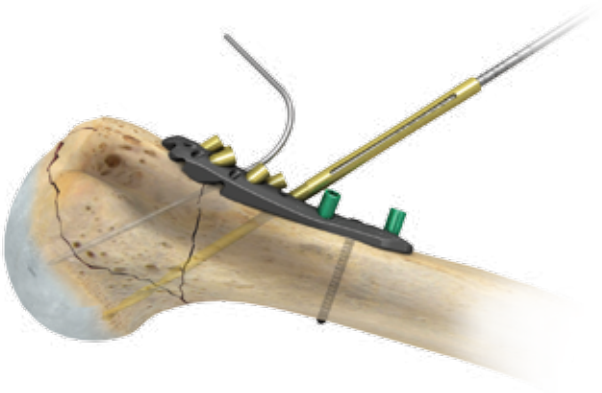


Figure 20

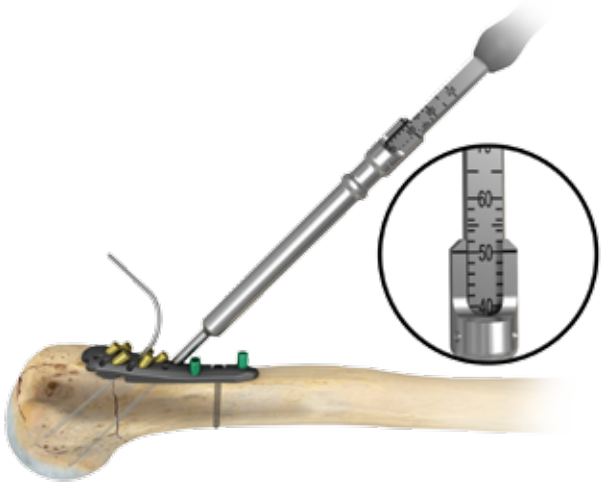


Figure 22

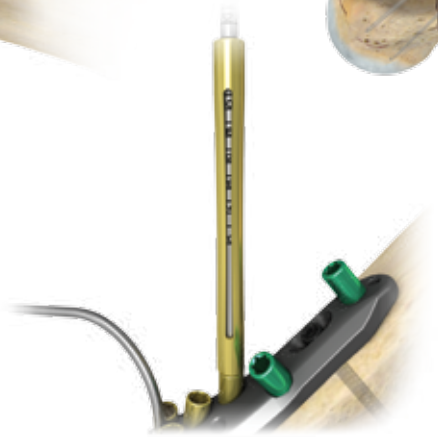


Figure 21

3.2 mm Locking Pegs

Drilling

- Preload gold 3.2 mm Drill Sleeve (110017561) on to the 3.2 mm Calibrated Drill Bit (110017537)
- Drill through gold F.A.S.T. Guide Insert
- Before removing 3.2 mm Drill Bit, slide drill sleeve against the F.A.S.T. Guide Insert (Figure 20)

IMPORTANT: Regardless of peg or screw type, drill cautiously to avoid perforation through the far cortex. Using fluoroscopic guidance, advance drill until resistance is felt from subchondral bone.

Determine Peg Length

- Remove 3.2 mm Drill Bit from F.A.S.T. Guide Insert
- Read measurement from proximal end of the gold 3.2 mm Drill Sleeve (Figure 21)

Note: If a second measurement is required, use the Shoulder Plate Depth Gauge to measure directly off the plate (Figure 22).

Note: Manual drilling can be used to help reduce the likelihood of perforating the subchondral bone.

- Attach the 3.2 mm Drill Bit to the 2 Nm Torque Limiting Handle (214118001)
- Advance the drill through the F.A.S.T. Guide Insert, stopping when resistance is felt from subchondral bone (Figure 20)

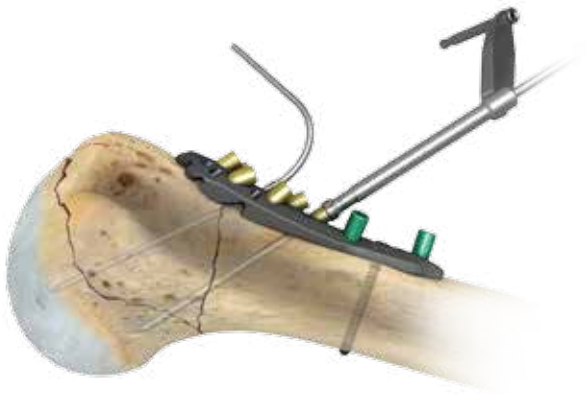


Figure 23

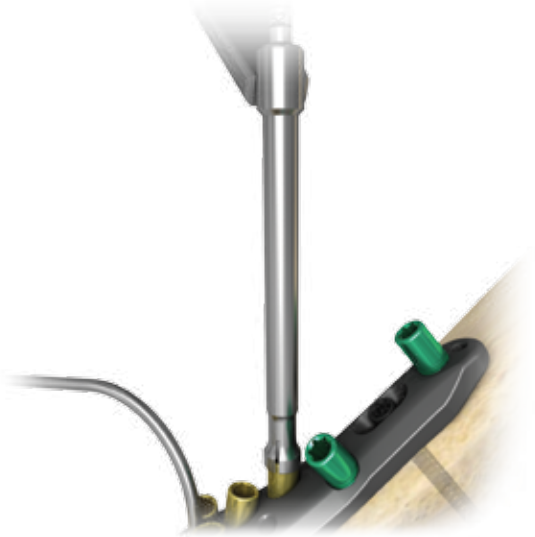


Figure 24

3.5 mm Locking Cortical and 4.0 mm Locking Cancellous Screws

If screws are preferred over pegs in the proximal holes with gold F.A.S.T. Guide Inserts, follow these steps.

Drilling

- Apply end labeled "2.7 mm F.A.S.T. GUIDE" of the 2.7 mm Soft Tissue/Drill Guide (110017533) over the gold F.A.S.T. Guide Insert
- Ensure that Guide is fully seated on to F.A.S.T. Guide Insert before drilling.
- Using the 2.7 mm Calibrated Drill Bit (214227070), drill through the Drill Guide and gold F.A.S.T. Guide Insert (Figure 23)

Determine Screw Length

- Before removing the 2.7 mm Drill Bit, read measurement from proximal end of the 2.7 mm Soft Tissue/Drill Guide (Figure 24)
- Remove the drill bit from the F.A.S.T. Guide Insert

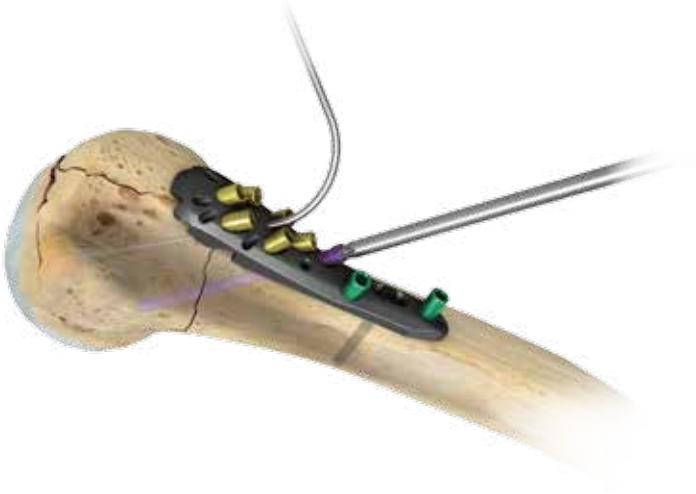


Figure 25

3.5 mm Locking Cortical Screws

3.5 Low Profile Non-Locking Screws

3.5 mm Locking Multi-Directional Screws (MDS)

Figure 26

Peg or Screw Insertion

Attach the T15 driver to the pink 2 Nm Torque Limiting Handle (214118001). If F.A.S.T. Guide Insert is still attached to plate, remove and discard. Insert the appropriate size peg or screw with the same driver (Figure 25).

Note: If the drill perforated the subchondral bone, use a shorter peg or screw to help ensure that it is not in the joint.

Step 7: Distal Screw Insertion

The two most proximal shaft screw holes are pre-loaded with color-coded F.A.S.T. Guide Inserts in order to help with plate identification. The most distal holes in the 4, 7, 11 and 14-hole plates are not pre-loaded with F.A.S.T. Guide Inserts in order to facilitate submuscular insertion.

Screw Options

Select the appropriate screw based on bone quality or surgeon preference (Figure 26).

Note: The 11 and 14-hole plates can be contoured in-situ using the Long Plate Benders (212000005). See Appendix B for instructions on how to use the benders.

Figure 27

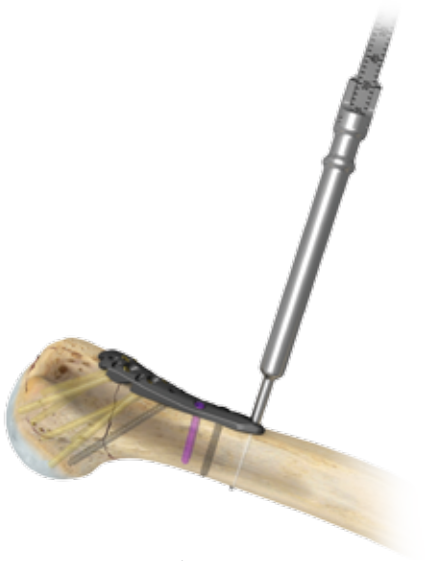


Figure 29

Figure 28

Holes with F.A.S.T. Guide Technology:

Drilling

- Before drilling, ensure the silver 2.7 mm Measuring Drill Sleeve (110017661) is pre-loaded onto the 2.7 mm Calibrated Drill Bit
- Drill through the F.A.S.T. Guide Insert (Figure 27)
- Before removing 2.7 mm Drill Bit, slide Drill Sleeve against the F.A.S.T. Guide Insert

Determine Screw Length

- Remove 2.7 mm Drill Bit from F.A.S.T. Guide Insert
- Read measurement from proximal end of the silver 2.7 mm Drill Sleeve (Figure 27)

Holes without F.A.S.T. Guide Technology :

Drilling

- Before drilling, insert the 2.7 mm Locking Drill Guide (110017559) into the locking hole
- Using the 2.7 mm Calibrated Drill Bit, drill through the Drill Guide (Figure 28)

Determine Screw Length

- Before removing the Drill Bit, read measurement from proximal end of the 2.7 mm Locking Drill Guide

Note: If a second measurement is required, use the Shoulder Plate Depth Gauge to measure directly off the plate (Figure 29).

Figure 30

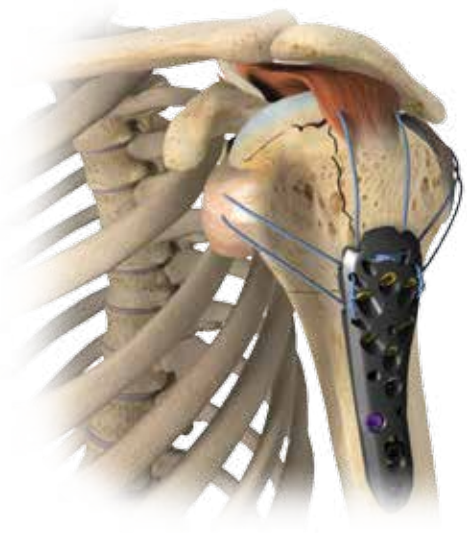


Figure 31

Screw Insertion

In holes with F.A.S.T. Guides Inserts, remove F.A.S.T. Guide Insert using the T15 driver and discard. In holes without F.A.S.T. Guide Inserts, remove the 2.7 mm Locking Drill Guide manually or using the T15 driver. Insert the appropriate size 3.5 mm locking or non-locking screw with the same driver (Figure 30).

Step 8: Repair Tuberosities

In order to counteract deforming forces and limit tuberosity displacement, secure the tuberosities to the plate by first passing the needles through the cuff insertion and then through the suture attachment holes in the plate (Figure 31).

Figure 32

Step 9: Closure

Using fluoroscopic guidance, check that reduction has been achieved and confirm there are no screws or pegs in the joint. Suggested soft tissue considerations after implantation:

- Perform Biceps Tenodesis, if indicated
- If the pectoralis major or deltoid insertions were released, repair by suturing to soft tissue, bone or each other
- Irrigate the wound and perform routine incision closure using intracutaneous sutures (Figure 32)

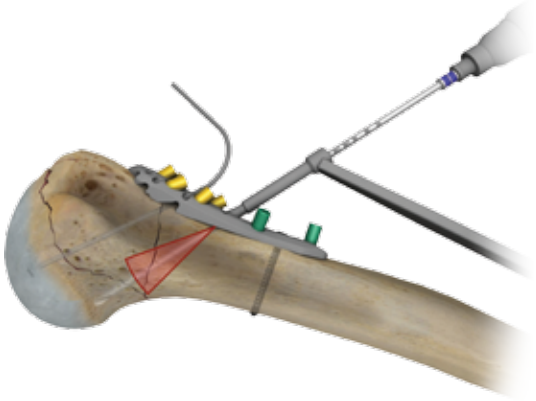


Figure 33

Figure 34

Figure 35

Appendix A: Instructions for inserting Multi-Directional Screws

Drilling

- Remove F.A.S.T. Guide Insert using the T15 Driver
- Using end labeled "2.7 mm" of the 2.7 mm Soft Tissue/Drill Guide, determine 25° cone of angulation
- Drill through the guide with the 2.7 mm Calibrated Drill Bit (Figure 33)

Important: Drill cautiously to avoid perforation through the far cortex. Using fluoroscopic guidance, advance drill until resistance is felt from subchondral bone (Figure 34).

Determine Screw Length

Measure directly off the surface of the threaded hole using the Shoulder Plate Depth Gauge (110017535) (Figure 35)

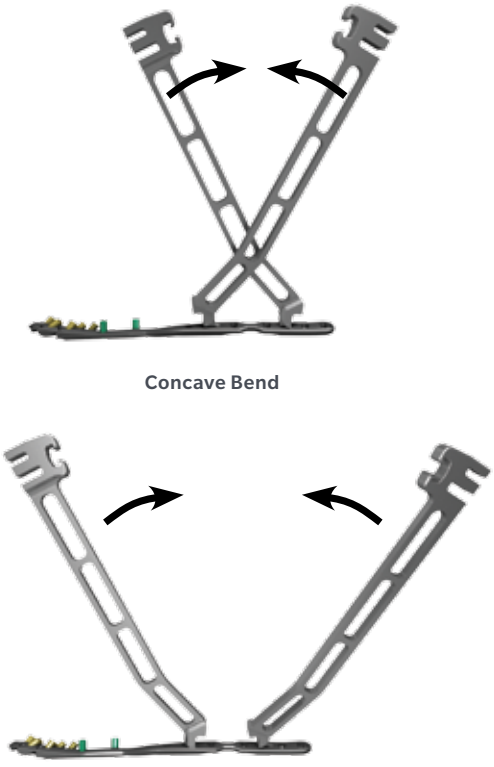
Screw Insertion

Attach the T15 driver to the pink 2 Nm Torque Limiting Handle. Insert the appropriate size screw with the same driver.

Note: Stop driving the MDS once the head is flush with the plate.

Bender "Feet"

Figure 36



Concave Bend

Convex Bend

Figure 37

Appendix B:
Plate Contouring using the Benders

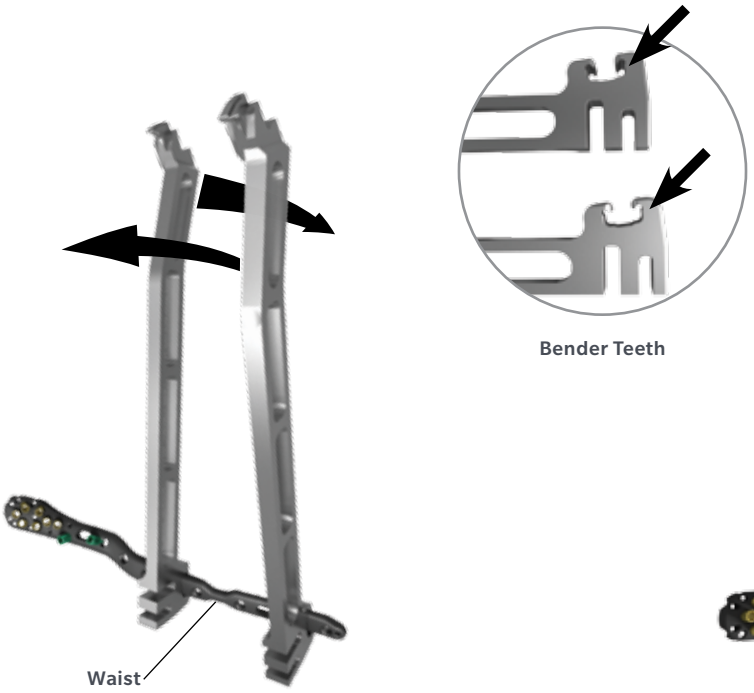
Concave/Convex Contouring
(for the 11 & 14-hole plates only)

Using the "feet" of the benders the plates can be contoured to conform to the patient's unique anatomic needs (Figure 36). The foot of the bender is placed inside the slotted section of the plate and engaged on the underside of the plate. The benders can be used either facing or opposing each other to create concave or convex bends (Figure 37).

Note: The 11/14-hole plates are designed to fit the anatomy of the humerus, but additional contours can be made due to anatomic variations of the diaphysis. Recommended maximum bending angles:

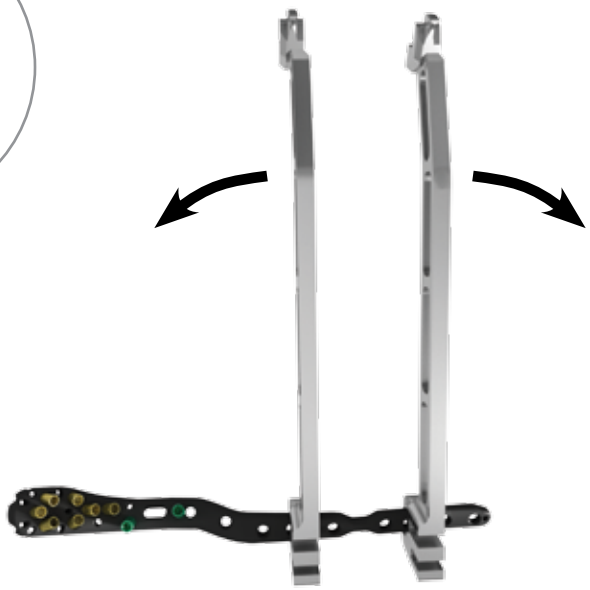
Concave/Convex: 10 degrees
Axial: 12 degrees
Planar: 8 degrees

Note: When creating convex bends there must be at least one empty slot in-between benders to ensure there is no thread deformation of the locking hole.



Axial Bend

Figure 38



Planar Bend

Figure39

Axial Contouring

Using the "teeth" of the benders the plates can be contoured in the axial direction. Insert bender teeth over the waist and slide benders over thicker part of plate shaft. Rotate benders away from each other to impart twist (Figure 38).

Planar Contouring

To apply planar bend, use the "teeth" of the benders. Insert bender teeth over the waist and slide benders over thicker part of plate shaft. Pull benders away from one another to impart planar bend (Figure 39).

Implants

Proximal Humerus Plating System Low Plates

Product	Description	Size	Part Number (Non-Sterile)
	**Proximal Humerus Low Plate Left 3 Hole**	73 mm	110030100
	**Proximal Humerus Low Plate Left 4 Hole**	83 mm	110030101
	**Proximal Humerus Low Plate Left 7 Hole**	133 mm	110030102
	**Proximal Humerus Low Plate Left 11 Hole**	190 mm	110030103
	**Proximal Humerus Low Plate Left 14 Hole**	227 mm	110030104
	**Proximal Humerus Low Plate Right 3 Hole**	73 mm	110030200
	**Proximal Humerus Low Plate Right 4 Hole**	83 mm	110030201
	**Proximal Humerus Low Plate Right 7 Hole**	133 mm	110030202
	**Proximal Humerus Low Plate Right 11 Hole**	190 mm	110030203
	**Proximal Humerus Low Plate Right 14 Hole**	227 mm	110030204

Proximal Humerus Plating System High Plates

Product	Description	Size	Part Number (Non-Sterile)
	**Proximal Humerus Hi Plate Left 3 Hole**	80 mm	110030300
	**Proximal Humerus Hi Plate Left 4 Hole**	90 mm	110030301
	**Proximal Humerus Hi Plate Left 7 Hole**	140 mm	110030302
	**Proximal Humerus Hi Plate Left 11 Hole**	197 mm	110030303
	**Proximal Humerus Hi Plate Left 14 Hole**	234 mm	110030304
	**Proximal Humerus Hi Plate Right 3 Hole**	80 mm	110030400
	**Proximal Humerus Hi Plate Right 4 Hole**	90 mm	110030401
	**Proximal Humerus Hi Plate Right 7 Hole**	140 mm	110030402
	**Proximal Humerus Hi Plate Right 11 Hole**	197 mm	110030403
	**Proximal Humerus Hi Plate Right 14 Hole**	234 mm	110030404

Pegs and Screws

3.2 mm Locking Pegs

Product	Part Number (Non-Sterile)	Size
	110025320	20 mm
	110025322	22 mm
	110025324	24 mm
	110025326	26 mm
	110025328	28 mm
	110025330	30 mm
	110025332	32 mm
	110025334	34 mm
	110025336	36 mm
	110025338	38 mm
	110025340	40 mm
	110025342	42 mm
	110025344	44 mm
	110025346	46 mm
	110025348	48 mm
	110025350	50 mm
	110025352	52 mm
	110025354	54 mm
	110025356	56 mm
	110025358	58 mm
	110025360	60 mm
	110025365	65 mm
	110025370	70 mm

3.5 mm T15 Multi-Directional Locking Screws

Product	Part Number (Non-Sterile)	Size
	110018020	20 mm
	110018022	22 mm
	110018024	24 mm
	110018026	26 mm
	110018028	28 mm
	110018030	30 mm
	110018032	32 mm
	110018034	34 mm
	110018036	36 mm
	110018038	38 mm
	110018040	40 mm
	110018042	42 mm
	110018044	44 mm
	110018046	46 mm
	110018048	48 mm
	110018050	50 mm
	110018052	52 mm
	110018054	54 mm
	110018056	56 mm
	110018058	58 mm
	110018060	60 mm
	110018065	65 mm
	110018070	70 mm

3.5 mm Cortical Locking Screws

Product	Part Number (Non-Sterile)	Size
	816135020	20 mm
	816135022	22 mm
	816135024	24 mm
	816135026	26 mm
	816135028	28 mm
	816135030	30 mm
	816135032	32 mm
	816135034	34 mm
	816135036	36 mm
	816135038	38 mm
	816135040	40 mm
	816135042	42 mm
	816135044	44 mm
	816135046	46 mm
	816135048	48 mm
	816135050	50 mm
	816135052	52 mm
	816135054	54 mm
	816135056	56 mm
	816135058	58 mm
	816135060	60 mm
	816135065	65 mm
	816135070	70 mm

4.0 mm Cancellous Locking Screws

Product	Part Number (Non-Sterile)	Size
	816140020	20 mm
	816140022	22 mm
	816140024	24 mm
	816140026	26 mm
	816140028	28 mm
	816140030	30 mm
	816140032	32 mm
	816140034	34 mm
	816140036	36 mm
	816140038	38 mm
	816140040	40 mm
	816140042	42 mm
	816140044	44 mm
	816140046	46 mm
	816140048	48 mm
	816140050	50 mm
	816140055	55 mm
	816140060	60 mm
	816140065	65 mm
	816140070	70 mm

3.5 mm T15 Low Profile Non-Locking Screws

Product	Part Number (Non-Sterile)	Size
	110017720	20 mm
	110017722	22 mm
	110017724	24 mm
	110017726	26 mm
	110017728	28 mm
	110017730	30 mm
	110017732	32 mm
	110017734	34 mm
	110017736	36 mm
	110017738	38 mm
	110017740	40 mm
	110017742	42 mm
	110017744	44 mm
	110017746	46 mm
	110017748	48 mm
	110017750	50 mm
	110017752	52 mm
	110017754	54 mm
	110017756	56 mm
	110017758	58 mm
	110017760	60 mm
	110017765	65 mm
	110017770	70 mm

Instruments

Instruments

Part Number	Description
110017562	**T-15 Driver**
110017559	**2.7 mm Locking Drill Guide**
110017533	**2.7 mm Soft Tissue Drill Guide**
110017661	**2.7 mm Measuring Drill Sleeve**
214118001	**Small Torque Limiting Driver**
110017535	**Shoulder Plate Depth Gauge**
110017561	**3.2 mm Measuring Drill Sleeve**
110017541	**2.0 mm K-Wire Adapter Long**
214124000	**Ratchet Screwdriver Handle**
212000005	**Long Plate Bender W/2 Slots**
231218020	**Torque Limiting Power Adapter**
110017572	**T15 Tapered Driver Short**
110017641	**2.0 mm K-Wire Adapter Short**
110017635	**Shoulder Plate Depth Gauge Hook (Replacement)**

Disposables

Part Number (Non-Sterile)	Description
214227070	**2.7 mm x 160 mm Calibrated Drill Bit**
110017537	**3.2 mm Calibrated Drill Bit**
KW20SS	**2.0 mm x 152 mm K-Wire (6 in)**

Tray

Part Number	Description
110018101	**PHP System Case & Tray**

INDICATIONS

The Biomet A.L.P.S. Proximal Humeral Plating System is indicated for fixation of fractures and fracture dislocations, fusions, osteotomies and non-unions of the humerus, particularly in osteopenic bone.

Patient selection factors to be considered include:

1. Need for alignment and stabilization of bone fractures
2. Ability and willingness of the patient to follow postoperative care instructions until healing is complete
3. A good nutritional state of the patient.

CONTRAINDICATIONS

1. Active infection.
2. Patient conditions including blood supply limitations, and insufficient quantity or quality of bone.
3. Patients with mental or neurologic conditions who are unwilling or incapable of following postoperative care instructions or materials.
4. Foreign body sensitivity. Where material sensitivity is suspected, testing is to be completed prior to implantation of the device.

Notes

References

1. Data on file at Biomet. Test # DVA-107504-DVER. Mechanical testing is not necessarily indicative of clinical performance.

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