

A&U MED[®]



*Locking Proximal
Humeral Plate*

POLARUS[®] PHP[™]

POLARUS[®] PHP[™] LOCKING PROXIMAL HUMERAL PLATE

Since 1988 Acumed has been designing solutions to the demanding situations facing orthopedic surgeons, hospitals and their patients. Our strategy has been to know the indication, design a solution to fit, and deliver quality products and instruments.

In a continuing effort to advance orthopedics, Acumed is pleased to introduce the Polarus PHP Locking Proximal Humeral Plate. The plate has numerous features that contribute to overall stability in the proximal humerus, ultimately benefiting the patient.

The launch of the Polarus PHP Locking Proximal Humeral Plate completes the Polarus family of innovative products. When combined with the Polarus Humeral Rod and the Polarus Modular Shoulder System, Acumed offers a comprehensive group of unique products designed specifically for the treatment of proximal humeral fractures.

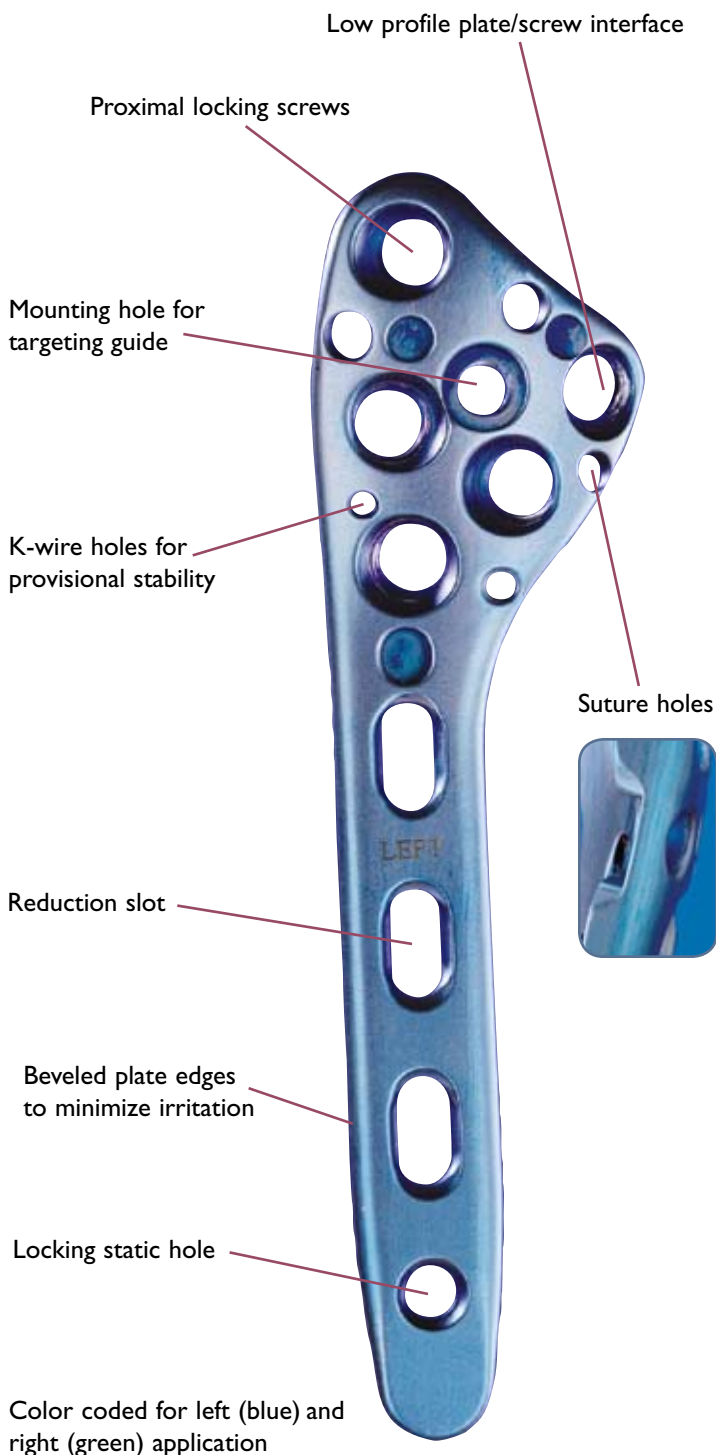


With the Polarus PHP Locking Proximal Humeral Plate, Acumed has designed an advanced solution for repairing fractures of the proximal humerus. The plate and instrumentation contain numerous features that help to maximize surgical outcome and address the issues faced with other plating systems.

Acumed's goal was to design a plate that incorporated a locking construct with an anatomical size and contour that best accommodates the patient. When designing the Polarus PHP, Acumed recognized that the humeral anatomy differs from patient to patient. To maximize stability in the humeral head, the proximal screws needed to be precisely angled to capture and secure the fracture fragments.

The design and placement of the Polarus PHP minimizes impingement and soft tissue irritation for the patient. Acumed's unique instrumentation is designed to improve the overall surgical technique and maximize surgical outcome.

Acumed incorporated many features into the Polarus Proximal Humeral Plate to properly reduce the fracture, maximize fixation, and ease the surgical technique.



Color coded for left (blue) and right (green) application

Titanium

Enhanced Screw Angulation enables the surgeon to maximize purchase in the humeral head. The improved screw placement, when combined with locking screws, create a solid and stable construct.



Anatomical Plate Design matches the anatomy of the patient with little or no bending. The Polarus PHP may also act as a guide or template for restoring the patient's original anatomy when reconstructing a highly comminuted fracture.



Advanced Instrumentation includes a simplified targeting guide that accurately and quickly targets the screw holes in the plate.





Acumed's goal, when creating the Polarus PHP Proximal Humeral Plate, was to design a plate system that closely replicated the anatomical contours of the proximal humerus. Prior to designing the plate, our cadaveric research showed that the anatomic curvature of the proximal humerus is different in large and small patients. The curvature between the metaphysis and the diaphysis is greater on large patients. The surface area of the greater tuberosity decreases on smaller patients. Acumed recognized these differences and designed a plate to accommodate the patient's anatomy to minimize impingement, provide fracture support, and ensure accurate reduction.

Small and large plates are included in the Polarus PHP System. The Polarus PHP plates are contoured to match the anatomical slope of the proximal humerus and the curvature of the tuberosities. The placement and shape of the plate minimize soft tissue irritation, resulting in a better outcome for the patient.

The length for both large and small plates was determined by the location of the deltoid attachment. Minimal, if any, release of the deltoid is required.



The Polarus PHP Plates are color coordinated for quick identification. Blue plates are left and green plates are right. The color coding system is consistent with other Acumed plate systems.

SCREW TRAJECTORY

The Polarus PHP Locking Proximal Humeral Plate features a unique proximal screw trajectory to maximize fixation in the humeral head. When determining the placement and trajectory of the screws, Acumed's goal was to capture the best bone available in the humeral head for maximum stability and pull out strength.

When determining the location of quality cancellous bone, Acumed referred to a recent biomechanical study of humeral bone strength. Maximum bone quality was observed in the medial and lateral aspects of the proximal humerus and near the bicipital groove. The authors felt that plates should be designed to allow anchorage into these regions¹. The Polarus PHP screws are angled to capture the quality cancellous bone identified by the study.

Acumed provides surgeons with the option to use locking or non-locking screws. Each proximal hole in the Polarus PHP is threaded to accept 4.5mm locking buttress screws. The plate also accepts Acumed's 5.0mm non-locking cancellous screws proximally to aid with fracture reduction. Each screw traverses the proximal humerus at a different angle, maximizing pull out strength and improving overall plate stability. The plate is secured distally with 3.5mm bi-cortical screws.

1. Pierre Hepp, MD, et al. *Where Should Implants be Anchored in the Humeral Head?* Clinical Orthopedics and Related Research, No. 414, pp. 139-147.



A combination of 4.5mm locking and 5.0mm screws maximize stability in the humeral head.



The Polarus PHP System provides:

- 4.5mm Locking Buttress Screw for fixation in the humeral head
- 5.0mm Cancellous Screw for fixation in the humeral head
- 3.5mm Bi-cortical Screw for fixation in the humeral shaft
- 3.5mm Locking Screw for fixation in the humeral shaft

ADVANCED INSTRUMENTATION

In addition to the innovative features of the Polarus PHP Proximal Humerus Plate, Acumed designed the instrumentation for ease of use by reducing the steps of traditional techniques and saving valuable O.R. time.



The Polarus PHP System features a unique targeting guide where only one drill guide/depth gauge is required to measure screw length, significantly reducing procedure steps.

Color coded implants and instrumentation allow for quick identification, saving both time and frustration during surgery.

A custom Verbrugge Clamp was designed for the Polarus PHP System to assist in provisional stabilization of the plate. The Verbrugge Clamp pivots without having to be released, giving the surgeon the ability to position the clamp in an accommodating location while it is being used.



Color coded implants and instrumentation allow for quick identification of the proper drill, drill guide and screw, saving O.R. time.

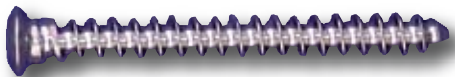


Adjustable Verbrugge Clamp designed specifically for the Polarus PHP allows for provisional plate fixation.

4.5mm Screw Cut-out Testing

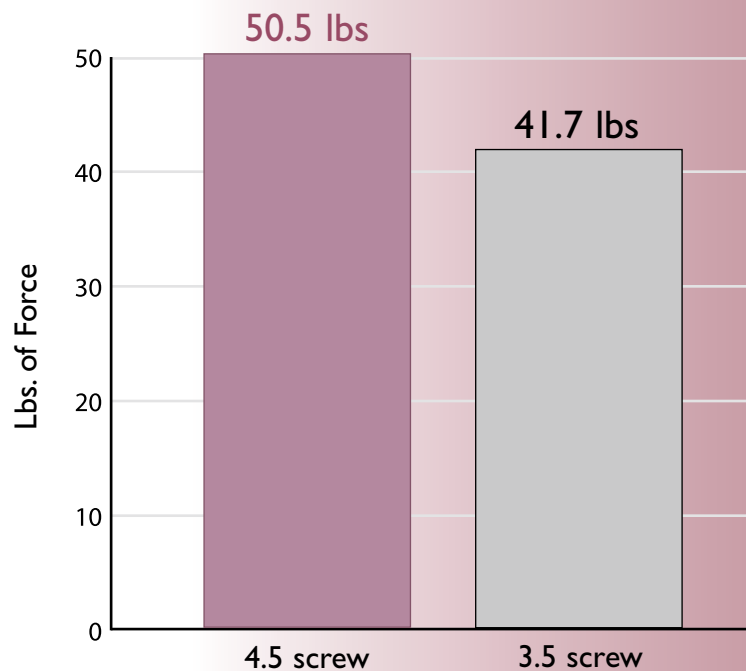


3.5mm Screw Cut-out Testing



Acumed has selected 4.5mm locking buttress screws for the proximal aspect of the PHP. Testing was done comparing 3.5mm screws with 4.5mm screws. With just a 1mm increase in screw diameter an almost 30% increase in cutout resistance occurs. Combining this increase in screw diameter with angling them toward the best bone in the humeral head, a stable proximal construct can be achieved.

Cut-out Test Results



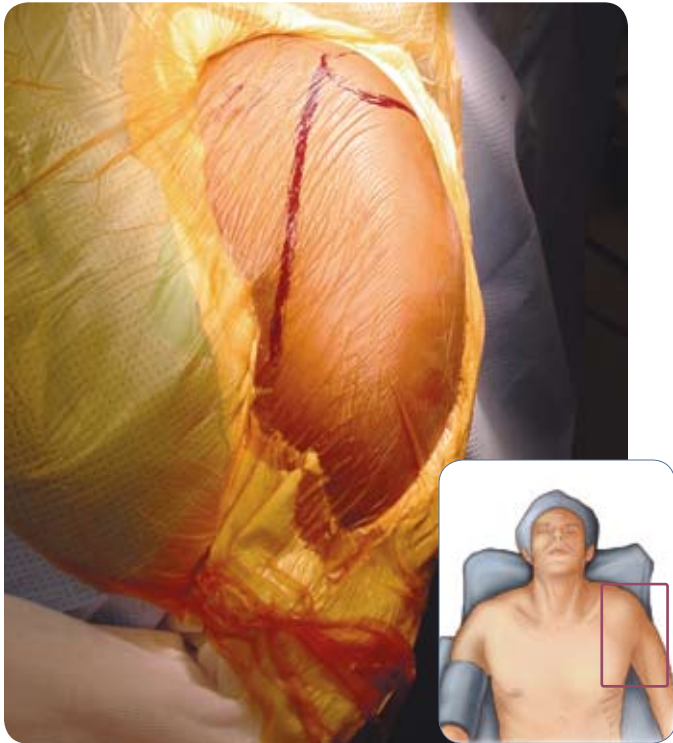
PHP Tray

The instrumentation system gives the surgeon a comprehensive set of instruments to implant the plate. The system features a number of clamps, retractors, and soft tissue protectors, in addition to the drivers, drills and targeting device. Acumed's goal is to have one self-contained kit with everything needed for a case, eliminating the hassle of opening other instrumentation sets for additional components.

SURGICAL TECHNIQUE

by William Geissler, MD

This section offers Acumed's suggested method for implanting the Polarus PHP™ Proximal Humeral Plate. For specific questions not addressed here, please contact your local Acumed representative or contact Acumed directly either at 888 627-9957 or on the web at www.acumed.net.



Step 1

The patient is placed in a beach chair position and the arm is draped to aid with fracture reduction. Create an entry site for access to the proximal humerus through a 10mm standard deltoid-pectoral incision made obliquely, in line with the deltoid-pectoral interval. As an alternative, the incision may be made in a more longitudinal direction, starting at the level of the acromioclavicular joint and extending distally. This approach may potentially be more cosmetic for the patient.

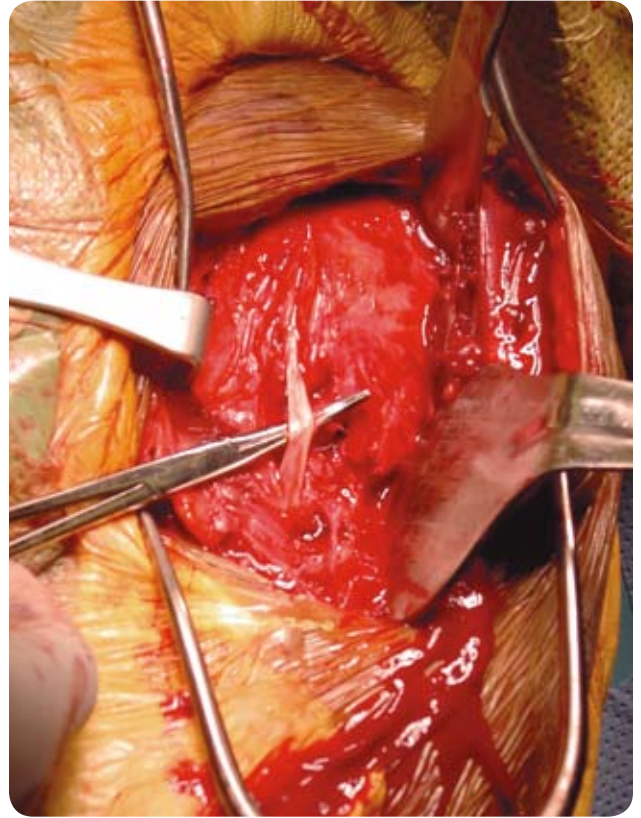


Step 2

Sharply dissect down to the level of the fascia and elevate the skin flaps. Identify the cephalic vein and develop the interval between the deltoid and the pectoralis. Retract the cephalic vein laterally and the pectoralis major medially.

Step 3

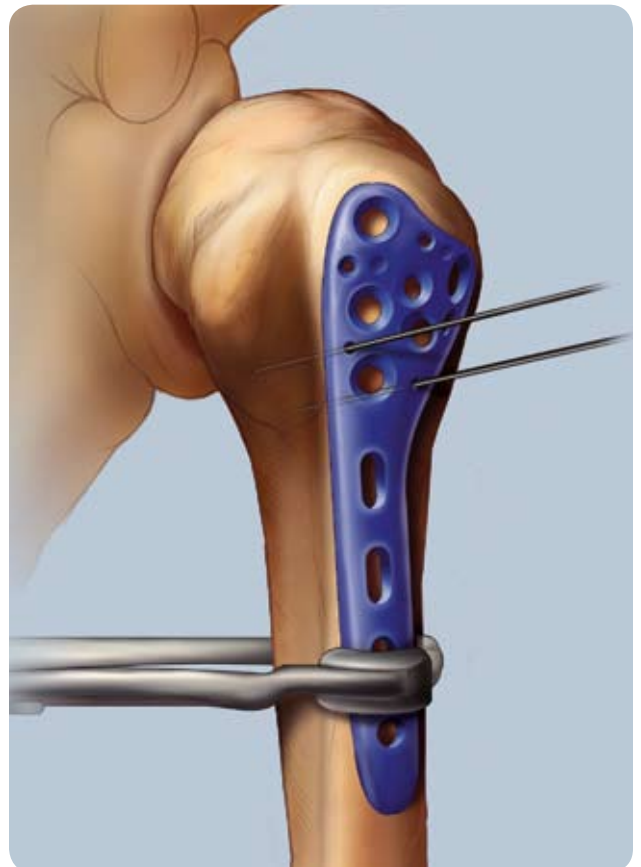
Release the fascia along the lateral border of the coracobrachialis and retract it medially to expose the proximal humerus with the subscapularis tendon attachment. To help facilitate reduction and improve fracture visualization, release the superior one-third of the pectoralis major from the shaft. It is important to place a finger underneath the pectoralis major as it is being released to protect the biceps tendon, which lies directly underneath.



Step 4

Place the Polarus PHP 3 to 5mm posterior to the bicipital groove and approximately 5mm inferior to the top of the greater tuberosity. Confirm fracture reduction and plate height fluoroscopically. When proper reduction and positioning are obtained, provisionally secure the plate to the bone with the custom PHP Verbrugge clamp. K-Wires may be inserted through the proximal K-Wire holes and into the humeral head for provisional fixation.

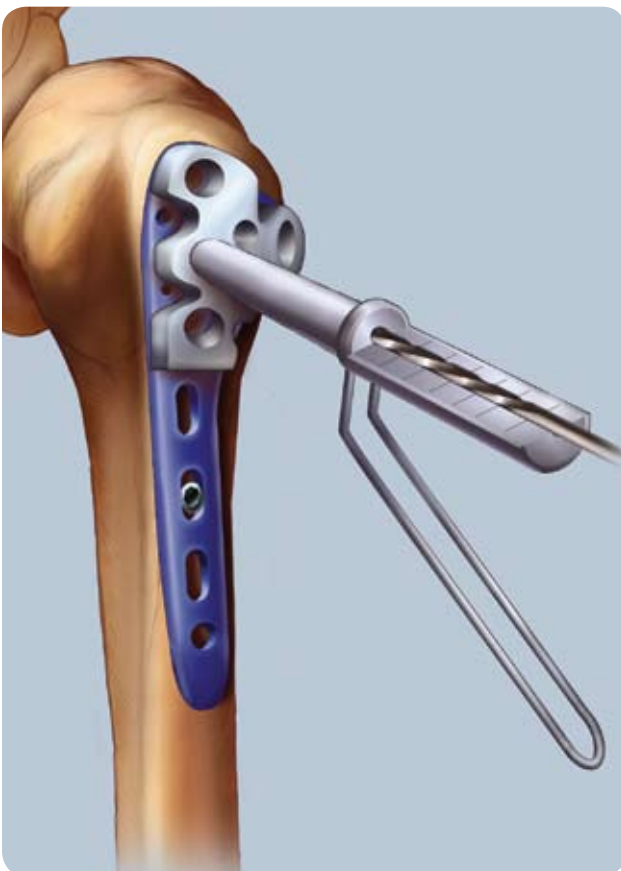
*Sutures may be added at this time to improve construct stability. Due to the design of the three suture holes, the sutures may be added upon completion of plate application.





Step 5

Insert a 3.5mm bicortical screw to secure the plate to the shaft. The screw may be inserted through any slot in the plate distal to the fracture. Use the 2.8mm drill guide and the short 2.8mm drill; determine screw length with the depth gauge. Using the 2.5mm hex driver, insert the 3.5mm cortical screw. The clamp may now be removed.



Step 6

Select the appropriate targeting guide and secure it to the plate with the targeting guide locking screw. The first proximal screw inserted may be a 5.0mm non-locking cancellous screw. This helps draw the plate to the bone affirming reduction and a low-profile plate-to-bone interface.

Insert the drill guide into one of the proximal holes of the plate. All proximal holes accept the 5.0mm cancellous screws, however, the first screw inserted is usually the center hole that borders the bicipital groove in the large plate and the most inferior hole in the small plate. Use the 2.8mm drill either under power or by hand. Determine screw length by aligning the laser mark on the drill with the scale on the back of the drill guide. For accurate measurement, be sure the drill guide is fully seated into the targeting guide.

Step 7

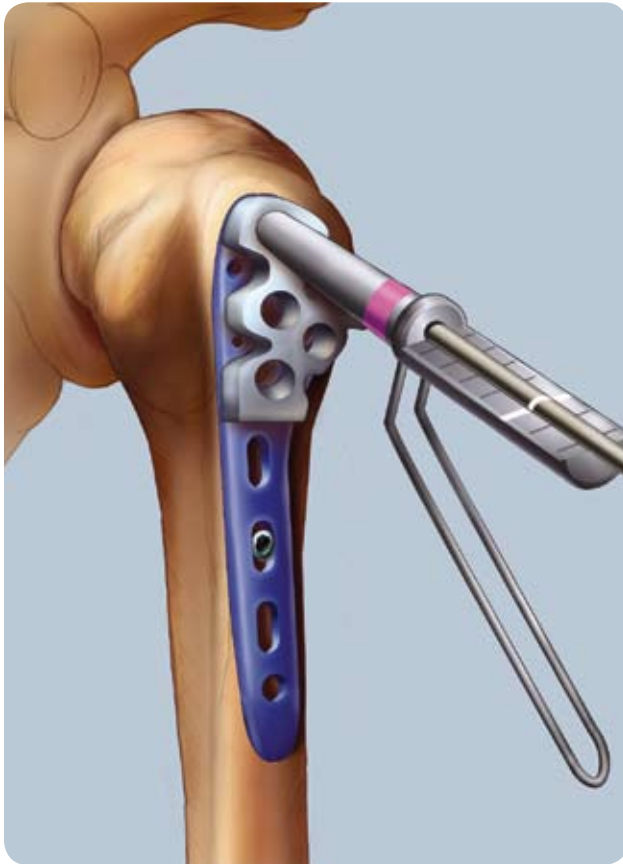
Remove the drill and drill guide and insert a 5.0mm non-locking cancellous screw through the targeting guide and plate.



Step 8

Insert the first proximal locking screw through one of the top holes of the targeting guide. These holes most frequently utilize locking screws because of their converging screw angles. Insert the fuchsia-banded clearance drill to open the near cortex of the proximal humerus.





Step 9

Insert the fuchsia-banded drill guide into one of the top two proximal holes. Note that all of the proximal holes accept locking screws. Use the fuchsia-banded drill either under power or by hand. Determine screw length by aligning the laser mark on the drill with the scale on the back of the drill guide. For accurate measurement, be sure the drill guide is fully seated into the targeting guide.



Step 10

Remove the drill and drill guide and insert a fuchsia 4.5mm locking buttress screw through the targeting guide and plate. Prior to inserting the locking screws be sure to confirm that the fracture is reduced anatomically. The locking buttress screws do not produce a lag effect that draws the plate and bone together.

Step 11

Using the same process, insert the remaining proximal 4.5mm locking buttress screws.

In osteoporotic bone, the non-locking 5.0mm cancellous screw may be replaced with a 4.5mm locking buttress screw.

Insert the remaining distal 3.5mm bicortical screws as previously described.

Note: A blue 3.5mm locking screw (COL-3xxO) may be placed in the distal hole of the plate. The locking drill guide (MS-LDG35) must be used prior to drilling. Screw length is measured with the standard depth gauge (MS-9020).



Step 12

Close the wound in layers with a subarticular stitch and place a drain for early post-operative recovery.

Postop Protocol

Passive range of motion exercises are initiated for the first four weeks, then active assisted for two weeks. Active range of motion and strengthening are started at approximately six weeks post-operatively when fracture healing is evident on radiographs.



ORDERING INFORMATION

Proximal Humeral Plates

Large Left Proximal Humeral Plate	PL-PHGL
Large Right Proximal Humeral Plate	PL-PHGR
Small Left Proximal Humeral Plate	PL-PHSL
Small Right Proximal Humeral Plate	PL-PHSR

4.5mm Locking Buttress Screws

4.5mm x 25mm Locking Buttress Screw	CA-PHB25
4.5mm x 27.5mm Locking Buttress Screw	CA-PHB275
4.5mm x 30mm Locking Buttress Screw	CA-PHB30
4.5mm x 32.5mm Locking Buttress Screw	CA-PHB325
4.5mm x 35mm Locking Buttress Screw	CA-PHB35
4.5mm x 37.5mm Locking Buttress Screw	CA-PHB375
4.5mm x 40mm Locking Buttress Screw	CA-PHB40
4.5mm x 45mm Locking Buttress Screw	CA-PHB45
4.5mm x 50mm Locking Buttress Screw	CA-PHB50
4.5mm x 55mm Locking Buttress Screw	CA-PHB55

5.0mm Cancellous Screws

5.0mm x 25mm Cancellous Screw	HCA-5125
5.0mm x 27.5mm Cancellous Screw	HCA-5127
5.0mm x 30mm Cancellous Screw	HCA-5130
5.0mm x 32.5mm Cancellous Screw	HCA-5132
5.0mm x 35mm Cancellous Screw	HCA-5135
5.0mm x 37.5mm Cancellous Screw	HCA-5137
5.0mm x 40mm Cancellous Screw	HCA-5140
5.0mm x 45mm Cancellous Screw	HCA-5145
5.0mm x 50mm Cancellous Screw	HCA-5150
5.0mm x 55mm Cancellous Screw	HCA-5155

3.5mm Cortical Screws

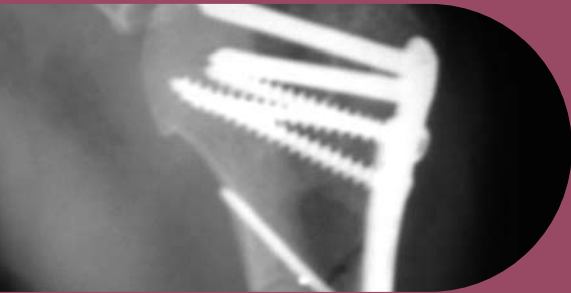
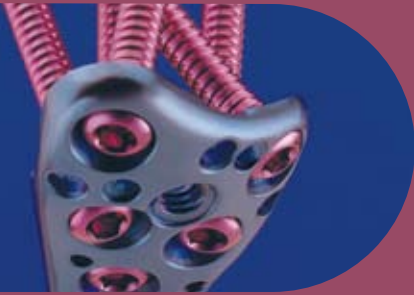
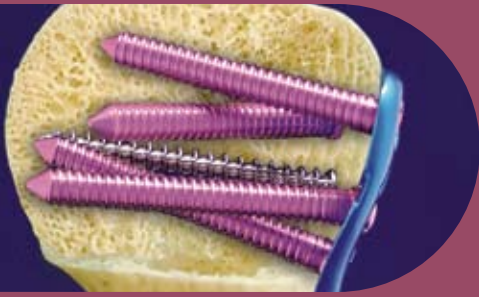
3.5mm x 20mm Cortical Screw	CO-3200
3.5mm x 22.5mm Cortical Screw	CO-3225
3.5mm x 25mm Cortical Screw	CO-3250
3.5mm x 27.5mm Cortical Screw	CO-3275
3.5mm x 30mm Cortical Screw	CO-3300
3.5mm x 32.5mm Cortical Screw	CO-3325
3.5mm x 35mm Cortical Screw	CO-3350
3.5mm x 40mm Cortical Screw	CO-3400
3.5mm x 45mm Cortical Screw	CO-3450
3.5mm x 50mm Cortical Screw	CO-3500
3.5mm x 55mm Cortical Screw	CO-3550

3.5mm Locking Cortical Screws

3.5mm x 20mm Locking Cortical Screw	COL-3200
3.5mm x 22.5mm Locking Cortical Screw	COL-3225
3.5mm x 25mm Locking Cortical Screw	COL-3250
3.5mm x 27.5mm Locking Cortical Screw	COL-3275
3.5mm x 30mm Locking Cortical Screw	COL-3300

Instruments

2.8mm Cancellous Drill	MS-PH28
4.6mm Cancellous Drill	MS-PH46
2.8mm Quick Release Drill	MS-DC28
3.5mm Quick Release Drill	MS-DC35
0.062" x 9" Guide Wire	WS-1609ST
0.078" x 9" Guide Wire	WS-2009ST



ACUMED®

5885 N.W. Cornelius Pass Road
Hillsboro, OR 97124-9370

(888) 627-9957
www.acumed.net

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