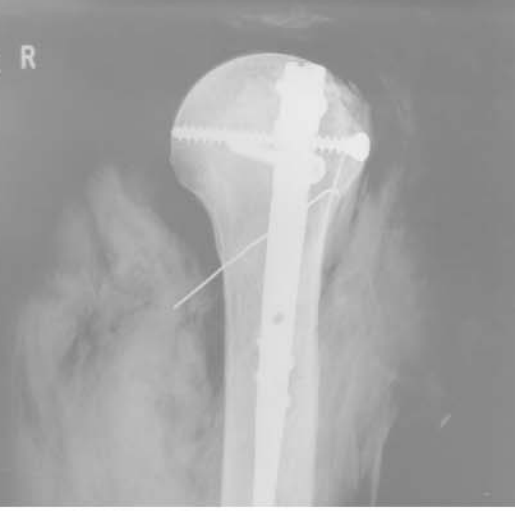
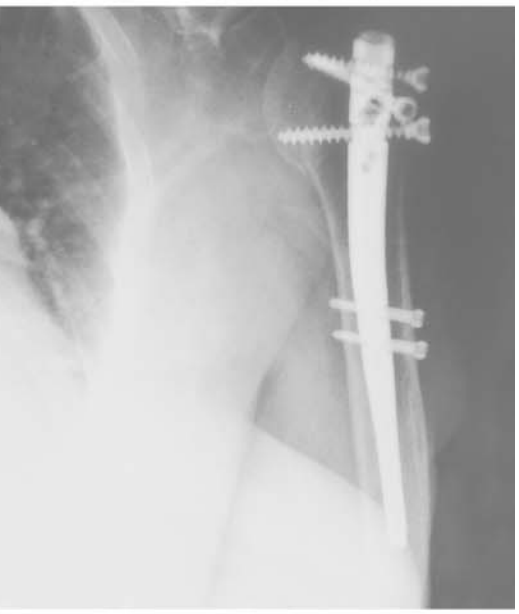
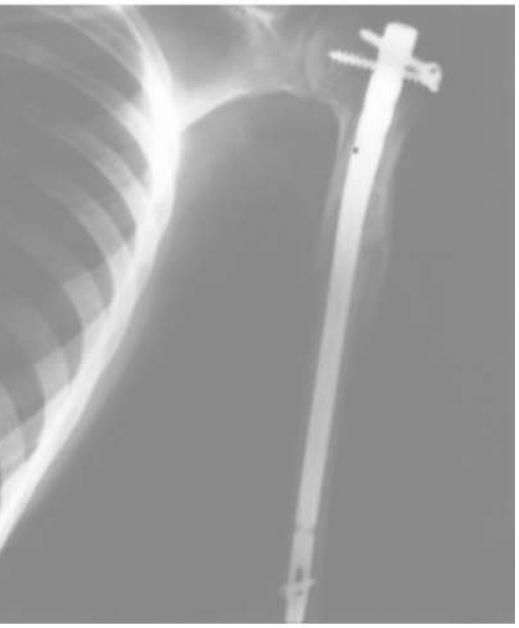
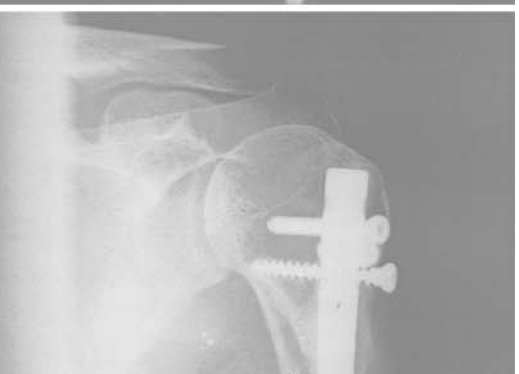






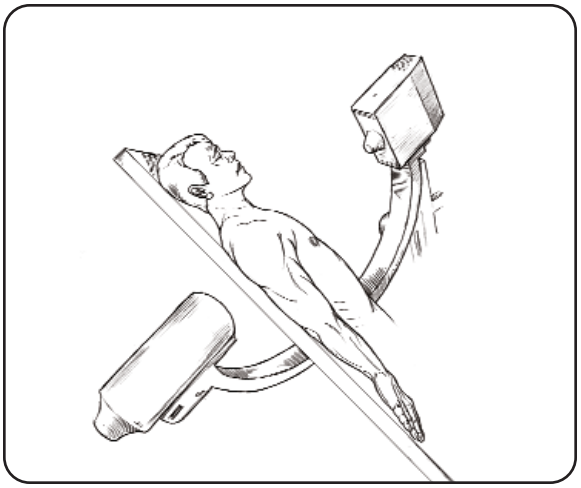


POLARUS®
HUMERAL ROD

Surgical Technique

ACUMED®

This section offers Acumed's suggested method for implanting the Polarus Humeral Rod.
For specific questions not addressed here, please contact your local Acumed representative or Acumed at 888 627-9957.

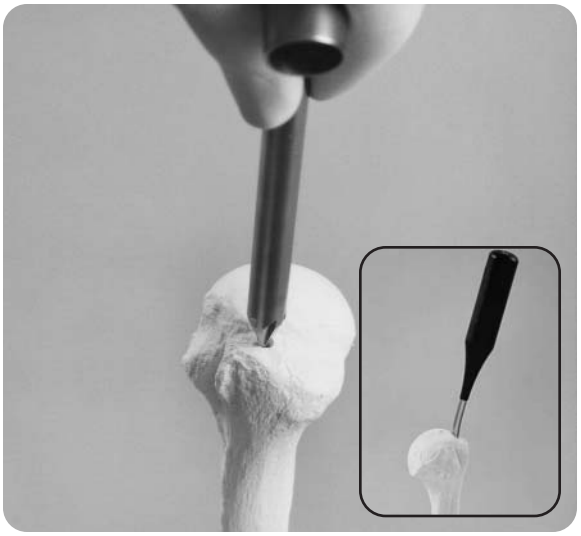


Step 1: Patient Positioning and Surgical Exposure

The patient may be placed either supine or in a beach chair position so that flouroscopy can be used to allow intraoperative assessments of fracture reduction, implant insertion and a thorough evaluation of the final implant position.

Utilizing a radiolucent table, position the shoulder off the edge of the table, or place a pad beneath the scapula to elevate the shoulder. There should be enough table clearance to externally rotate the humerus without the screw targeting guide contacting the table.

If an anterolateral approach is indicated, a 3-5cm incision is made at the anterolateral aspect of the acromium extending parallel to the fibers of the deltoid. The supraspinatus tendon is then split in the direction of the fibers to expose the proximal humerus posterior to the biceps tendon. It is important not to detatch the insertion of the tendon.

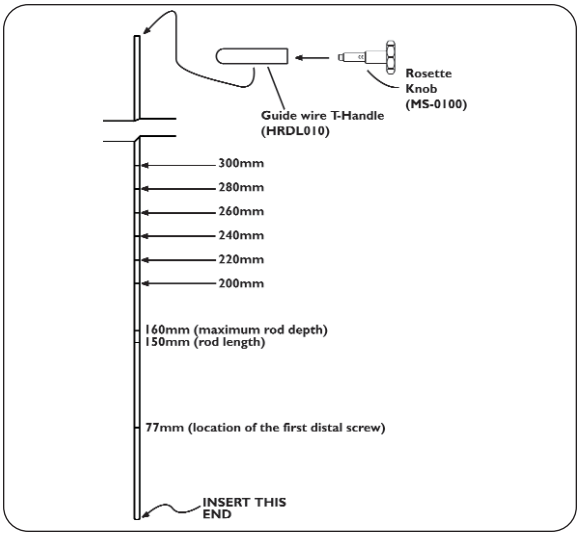


Step 2: Cortex Perforation

The implant insertion point is located approximately 1.0-1.5cm posterior to the bicipital groove, just medial to the greater tuberosity. For three-part fractures, care should be taken to make the starting point at the junction of the articular surface and the greater tuberosity. The tip of the awl (MS-0200) should be carefully buried no deeper than 3cm below the bone surface to create an entry hole 11mm in diameter.

If the fracture runs through the insertion site, it may be necessary to create a starting hole at the edge of the fragments with a burr or rongeur. An optional technique is to perforate the cortex with the 2.8mm drill and then pass the wire down into the canal. The canal is then prepared with the bud drill (Step 4).

If difficulty is experienced passing the guide wire into the canal, a guide wire passer (PA-1000) is available in the system to aid with inserting the guide wire past the fracture site.



Step 3: Insert Guide Wire

Assemble the "T" handle (HRDL010) onto the guide wire (WS-2020) as shown, paying particular attention to the orientation of the depth markings along the length of the wire.

The guide wire position should be verified with images in both the A/P and oblique planes to ensure that the guide wire is inside the humerus and has not exited through the fracture site.

An optional trocar-tipped guide wire (WN-2020ST) is available to aid wire insertion. A drill bit may also be used in the proximal fragment as a joystick to aid fracture reduction and realignment. The drill should be positioned to avoid interference with both the rod and targeting guide during insertion.

Step 4: Canal Preparation

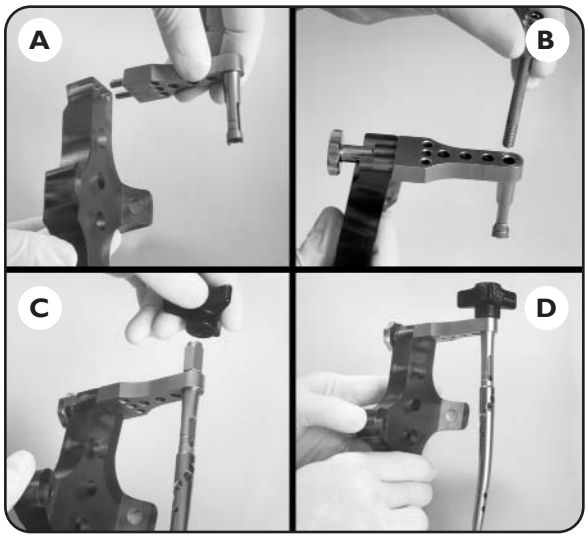
The proximal canal may be prepared by using an 11mm cannulated bud drill over the guidewire. Drill with the 11mm bud drill (DRB1115) to a depth of approximately 50-60mm to allow the rod to pass into the canal.

An alternate technique for preparing the canal is to use the broach (HR-B115). Insert the broach to the level of the last cutting tooth. Note that the lateral side of the broach is marked with the word "LATERAL" on the proximal end of the handle.

Step 5: Assemble the Targeting Guide

A) Attach targeting guide base plate (HRDL007) to lateral targeting guide (HRDL004), securing with a rosette knob (MS-0100). **B)** Insert locking bolt (HRDL001) into position. **C)** Assemble implant onto targeting guide base plate, aligning the two reference marks on the implant and targeting guide base plate. **D)** Tighten rod into position with the provided finger wrench (MS-0611). When assembled properly, the rod should curve toward the lateral targeting guide.

Optional: If A/P screw is to be used, assemble outrigger arm (HRDL005) onto targeting guide baseplate and secure with a rosette knob, For left humerus, as pictured in Step 7, the outrigger points to the left of the targeting guide. Attach and lock AP targeting guide (HRDL008) into position using a rosette knob.

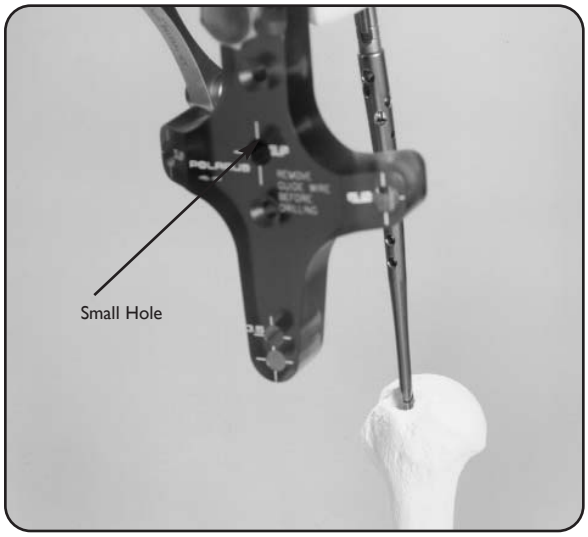


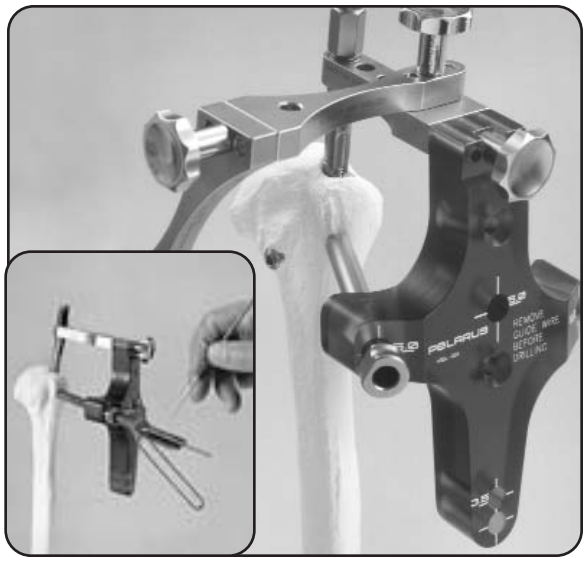
Step 6: Implant Insertion

Insert the rod over the guide wire and verify that the proximal end of the rod is 5 to 10mm below the cortex to avoid any possible impingement with the rotator cuff. Note that the rod should be inserted with hand pressure.

Once proper depth is achieved, the rod and targeting guide may be rotated up to 20° to both align the screws with the bone fragments and to avoid the biceps tendon. To avoid injury to the axillary nerve, do not insert the rod more than 1cm deep relative to the cortex. Etched marks on the barrel are a reference for the surgeon that the rod is either 5mm or 10mm below the cortex. The depth of the rod may also be verified by inserting a drill (HR-D105) through the small hole located just above the center hole on the targeting guide. Under flouroscopy, the drill will point to the top of the Polarus rod. It is important that the c-arm is exactly parallel to the arm to obtain an accurate image of implant depth.

Remove the Guide Wire prior to drilling.



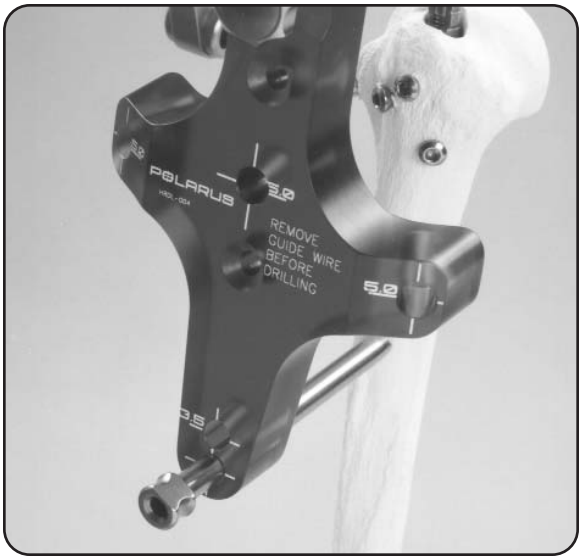


Step 7: Proximal Screw Placement

If using an A/P screw, target it first in order to aviod the biceps tendon.

Choose the desired screw position and insert the 5.0mm cannula (HR-5101) and probe (HR-5102) through the targeting guide and through a stab incision over the target site. Lightly tap the probe to create a small indentation in the bone. Only light tapping should be used on the probe to avoid damaging the lateral cortex. Using the probe prior to drilling assists with targeting accuracy.

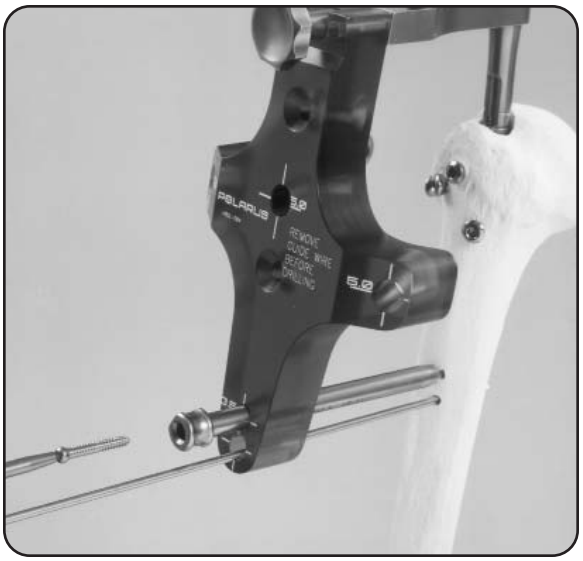
Remove the probe and insert the 5.0mm drill guide (HR-5104) through the cannula and up to the bone surface. Before drilling, be sure the guide wire is removed. Use flouroscopy to check that the drill is at the desired depth and that the drill bit has not penetrated the articular surface. At this time, the screw size may be read from the scale on the 5.0mm drill guide. If the screw size reading is between sizes, round down to the shorter size. When the groove on the driver shaft aligns with the end of the cannula, the screw is fully seated against the bone. Repeat these steps to install additional proximal screws as reqiuired. Note that all screws in the system are self-tapping.



Step 8: Secure and Target Distal Fragment

Insert the 3.5mm cannula (HR-3101) and probe (HR-3102) into the most distal hole in the targeting guide. Lightly tap the probe against the bone to create a dimple. The 3.5mm drill guide (HR-3104) is then inserted through the cannula. Using the long drill (HR-D105), drill through both cortices. Leaving the long drill through the rod and both corticies, remove the drill guide and cannula. The drill will help to preserve the positioning of the distal fragment.

Place cannula into the other distal hole and dimple the bone. Replace probe with the witness hole drill (HR-3106) to perforate the lateral cortex. Importance is placed on using the witness hole drill because it prevents walking of the primary drill and creates a glide hole for the wider distal screw diameter. Use long drill (HR-D105) to drill through both cortices, 1-2mm through the far cortex.



Step 9: Insert Distal Screws

Insert a 3.5mm screw into the most proximal of the distal holes with the 2.5mm hex driver (HD-2500). Verify the screw position under flouroscopy. The screw should not extend past the medial cortex by more than 1.0mm. Remove the "placeholder" drill from distal hole and perforate the lateral cortex with the witness hole drill. Insert second 3.5mm screw.

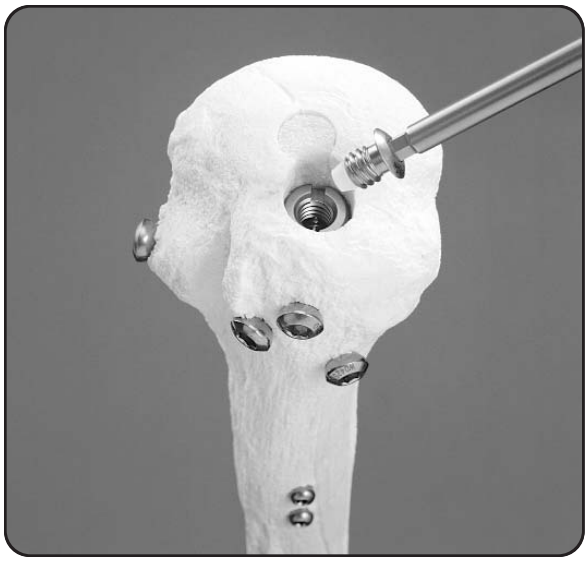
It is important to lock the distal humerus in the correct amount of retroversion relative to the humeral head. The fracture can be rotated under flouroscopy until the fractures are restored to their anatomical positioning. If a good A/P image of the humeral head is viewed, the forearm can be locked at approximately 30° of external rotation.

Step 10: Insert Polarus Cap

Place the cap assembly onto the 3.5mm driver and insert into the top of the rod. Advance the cap until the polyethylene fully engages the threads of the most proximal cancellous screw holding it into position. When fully advanced the cap is flush with the top of the rod, adding only 1.5mm to the total implant height.

Note: A Polarus Cap with an insertion device (HR-0050-S) is available in the system. If using the standard Polarus Cap (HR-0001-S), care should be taken to ensure that the cap remains connected to the driver during installation. One tip is to tie a piece of suture under the top of the cap and hold onto the end of the suture while inserting the cap into the Polarus implant.

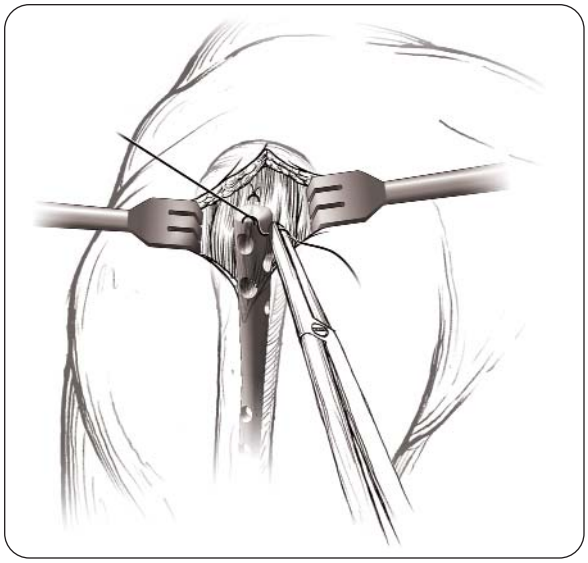
To prevent possible cross-threading of the cap upon insertion, thread the cap in a counter clockwise direction for the first few turns, then turn the cap clockwise until fully seated into the top of the Polarus rod.



Step 11: Repair Rotator Cuff

It is vital to close the rotator cuff after insertion of the rod. Number 2 Ethibond or a permanent suture is utilized to close the rotator cuff. Generally, two figure-8 sutures are used to close the small longitudinal incision of the rotator cuff. After this the deltoid is closed. The wound is then closed in layers with the deltoid closed with number one Vye-krill and the skin is closed in standard fashion.

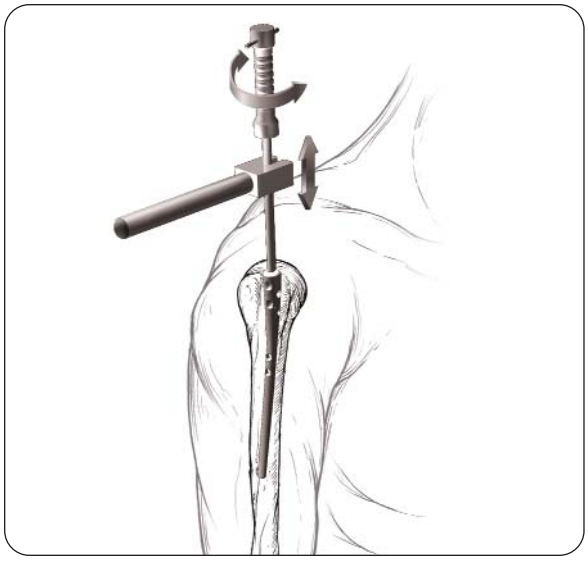
For a post-op protocol, please turn to Page 11.



Implant Removal

If it is desirable to remove the implant, approach the proximal end of the rod in the same manner as when implanting it. Locate the screws under image and remove the proximal screws. Use the tip of the removal instrument (HRDR001) to core out any ingrown tissue. Screw the removal instrument into the rod. The threaded portion of the removal tool has cutting flutes that will remove bone as it is inserted. The tip will fit into the cannulated hole to prevent cross threading. Note that the removal tool will not point straight down the humeral shaft, but will angle laterally about 10°.

Screw in the removal instrument until it stops. Do not use the hammer (HRDR002) yet. Locate and remove the distal screws. Failure to do so could result in breaking the screws, rod, or removal tool. After verifying that the screws have been removed, slip the forked end of the removal hammer over the shaft of the tool and break the rod loose.



This section offers Acumed's suggested method for implanting the Polarus Plus Humeral Rod.
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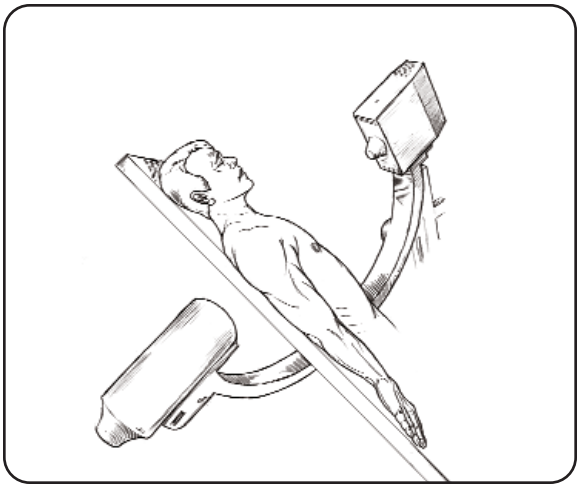

Step 1: Patient Positioning and Surgical Exposure

The patient may be placed either supine or in a beach chair position so that flouroscopy can be used to allow intraoperative assessments of fracture reduction, implant insertion and a thorough evaluation of the final implant position.

Utilizing a radiolucent table, position the shoulder off the edge of the table, or place a pad beneath the scapula to elevate the shoulder. There should be enough table clearance to externally rotate the humerus without the screw targeting guide contacting the table.

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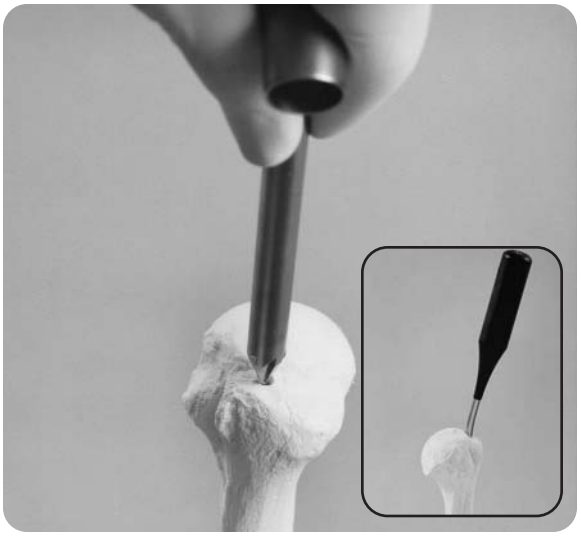
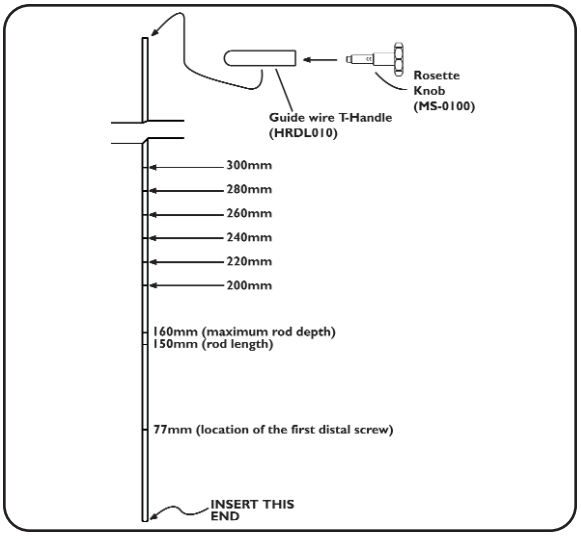


Step 2: Cortex Perforation

The implant insertion point is located approximately 1.0-1.5cm posterior to the bicipital groove, just medial to the greater tuberosity. For three-part fractures, care should be taken to make the starting point at the junction of the articular surface and the greater tuberosity. The tip of the awl (MS-0200) should be carefully buried no deeper than 3cm below the bone surface to create an entry hole 11mm in diameter.

If the fracture runs through the insertion site, it may be necessary to create a starting hole at the edge of the fragments with a burr or rongeur. An optional technique is to perforate the cortex with the 2.8mm drill and then pass the wire down into the canal. The canal is then prepared with the bud drill (Step 4).

If difficulty is experienced passing the guide wire into the canal, a guide wire passer (PA-1000) is available in the system to aid with inserting the guide wire past the fracture site.



Step 3: Insert Guide Wire

Assemble the "T" handle (HRDL010) onto the guide wire (WS-2020) as shown, paying particular attention to the orientation of the depth markings along the length of the wire.

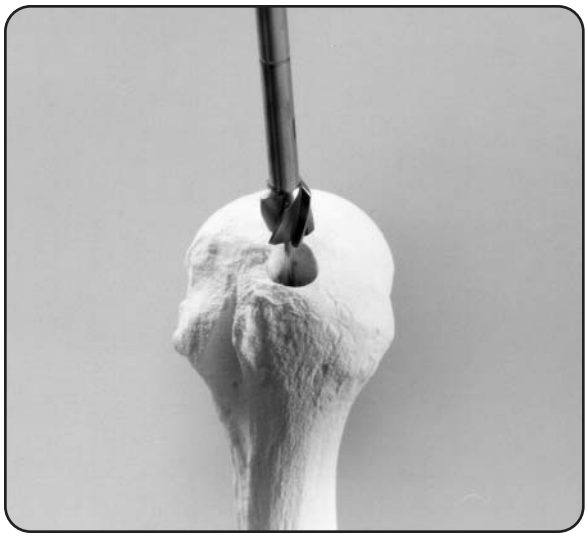
The guide wire position should be verified with images in both the A/P and oblique planes to ensure that the guide wire is inside the humerus and has not exited through the fracture site.

An optional trocar-tipped guide wire (WN-2020ST) is available to aid wire insertion. A drill bit may also be used in the proximal fragment as a joystick to aid fracture reduction and realignment. The drill should be positioned to avoid interference with both the rod and targeting guide during insertion.

Step 4: Canal Preparation

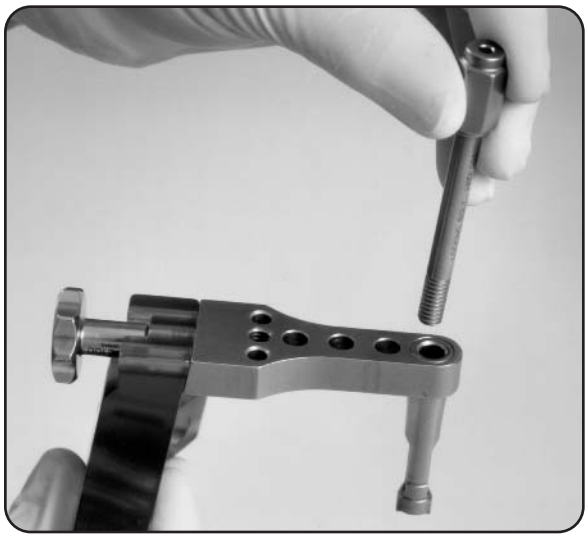
The proximal canal may be prepared by using an 11mm cannulated bud drill over the guidewire. Drill with the 11mm bud drill (DRB1115) to a depth of approximately 50-60mm to allow the rod to pass into the canal.

An alternate technique for preparing the canal is to use the broach (HR-B115). Insert the broach to the level of the last cutting tooth. Note that the lateral side of the broach is marked with the word "LATERAL" on the proximal end of the handle.



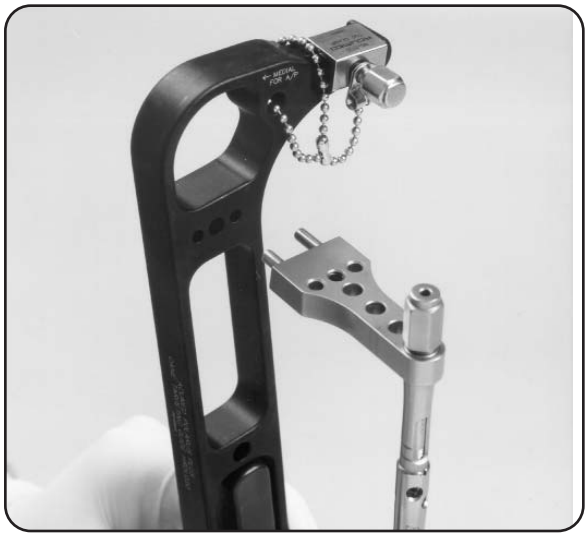
Step 5: Assemble the Targeting Guide

Attach targeting guide base plate (HRDL009) to lateral targeting guide (HRDL004), securing with a rosette knob (MS-0100). Insert locking bolt (HRDL001) into position and assemble implant onto targeting guide base plate, aligning the two reference marks on the implant and targeting guide base plate. Tighten rod into position with the provided finger wrench (MS-0611). When assembled properly, the rod should curve toward the lateral targeting guide.



Step 6: Targeting the Distal Holes with the Cane

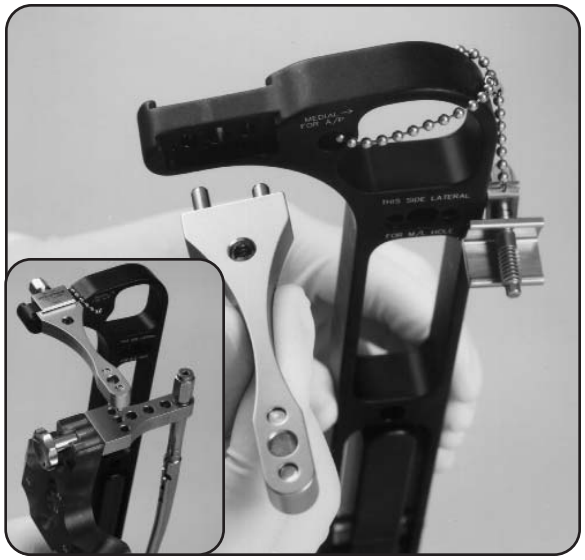
If the Polarus Plus Cane distal targeting device is used, it will need to be pre-targeted to the rod to ensure accurate targeting. The cane is designed to target either the A/P distal slot or the M/L distal hole in the Polarus Plus implant. Whether the A/P or M/L hole is used is based on the preference of the surgeon.



Step 6-a: Cane Pre-Targeting for M/L Hole

For M/L targeting, attach targeting guide base plate (HRDL009) to cane (HRDL020) laterally, securing with a rosette knob (MS-0100). The rosette knob slips into the recessed portion on the opposite side of the cane and should be tightened securely (see small photo).

Pre-target the cane to the rod by inserting the 3.5mm hex driver (HD-3500) into the adjustment screw, located just below the 200mm mark on the distal end of the cane. Adjust until the guide lines up with the M/L hole in the rod.



Step 6-b: Cane Pre-Targeting for the A/P Hole

For A/P targeting, attach the outrigger extension arm (HRDL005) to the proximal end of the cane as required for a left or right shoulder. Secure outrigger extension arm with the stabilizing "toe clamp" and locking bolt attached to the chain assembly. Attach the outrigger extension arm to the targeting guide baseplate (HRDL007) with a rosette knob (MS-0100). Be sure that the rosette knob is tightened securely to ensure proper functioning of the cane.

Pre-target the cane to the rod by inserting the 3.5mm hex driver (HD-3500) into the adjustment screw (as shown above), located just below the 200mm mark on the distal end of the cane. Adjust until the guide lines up with the A/P slot in the rod.

Note: When attached properly, the curve of cane always matches the curve of the rod.

Step 7: Implant Insertion and Fragment Positioning

Insert the rod over the guidewire and verify that the proximal end of the rod is 5-10mm below the cortex to avoid any possible impingement with the rotator cuff. Note that the rod should be inserted with hand pressure.

Once proper depth is achieved, the rod and targeting guide may be rotated up to 20° to both align the screws with the bone fragments and to aviod the biceps tendon. To avoid injury to the axillary nerve, do not insert the rod more than 1cm deep relative to the cortex. Etched marks on the barrel are a reference for the surgeon that the rod is either 5mm or 10mm below the cortex.

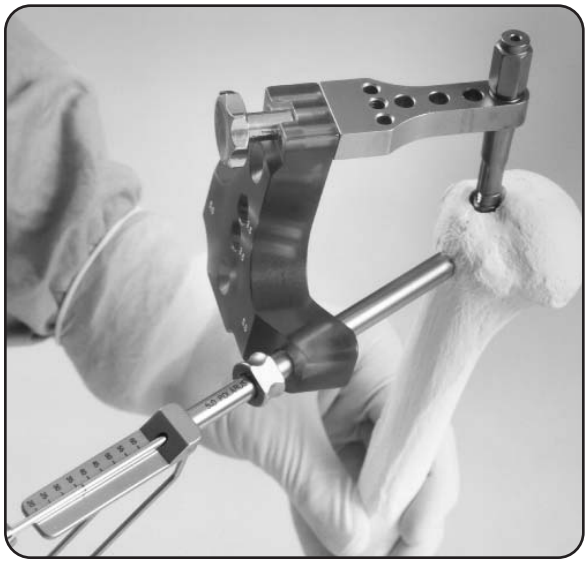
The depth of the rod may also be verified by inserting a drill (HR-D105) through the small hole located just above the center hole on the targeting guide. It is important that the c-arm is exactly parallel to the arm to obtain an accurate image of implant depth.

Remove the Guide Wire prior to drilling.

Step 8: 5.0mm Proximal Screw Placement

Choose the desired screw position and insert the 5.0mm cannula (HR-5101) and probe (HR-5102) through either of the 5.0mm target locations through a stab incision over the target site. Lightly tap the probe to create a small indentation in the bone. Only light tapping should be used on the probe to avoid damaging the lateral cortex.

Remove the probe and insert the 5.0mm drill guide (HR-5104) through the cannula up to the bone surface. Before drilling, be sure the guide wire is removed. Use flouroscopy to check that the drill (HR-D105) is at the desired depth and that the drill bit has not penetrated the articular surface. At this time, the screw size may be read from the scale on the drill guide. If the screw size reading is between sizes, round down to the shorter size. When the groove on the driver shaft aligns with the end of the cannula, the screw is fully seated against the bone. Repeat these steps for targeting the second 5.0mm proximal screw. Note that all screws in the system are self-tapping.

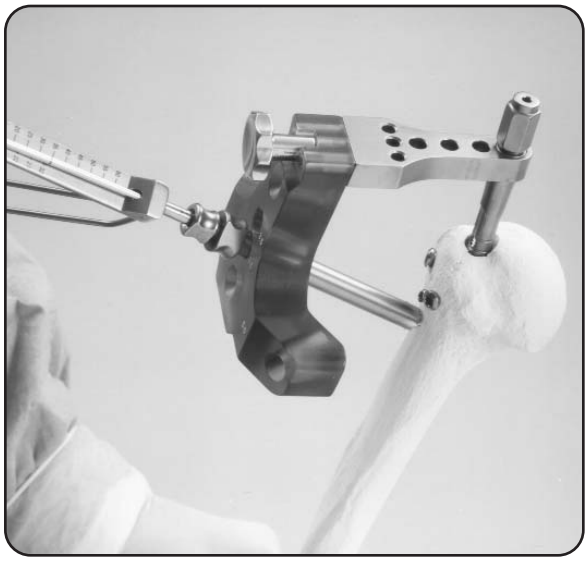


Step 9: 3.5mm Proximal Screw Placement

Insert the 5.0mm cannula (HR-5101) through the most proximal 3.5mm targeting positions. Insert the 3.5mm cannula (HR-3101) through the 5.0mm cannula. Use the probe (HR-5102) to dimple the bone, insert the 3.5mm drill guide, and drill 1-2mm through far cortex. Use flouroscopy to check that the drill (HR-D105) is at the desired depth. At this time, the screw size may be read from the scale on the drill guide. If the screw size reading is between sizes, round down to the shorter size. Insert the screw. When the groove on the driver shaft aligns with the end of the cannula, the screw is fully seated against the bone.

For patients with soft bone, a 3.5mm washer is available (HCO-35WA). After drilling, remove the 3.5mm drill guide and 3.5mm cannula. Insert the screw and washer through the 5.0mm cannula.

Repeat these steps for targeting the second 3.5mm proximal screw.



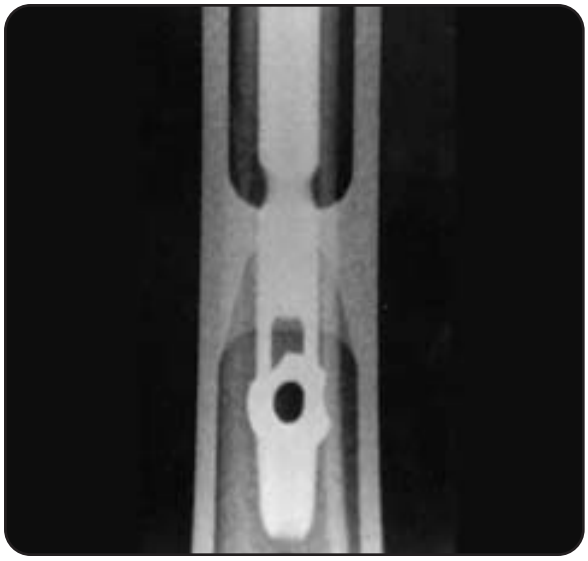
Step 10: Ensure Proper Targeting with the Cane

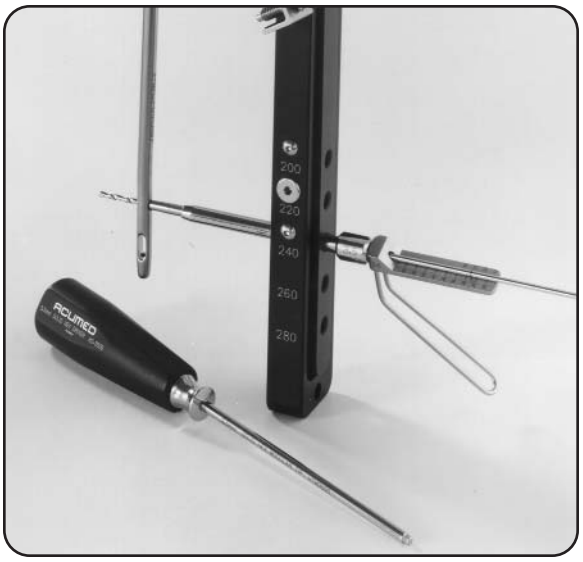
In addition to pre-targeting the cane, there are several key tips to ensure proper targeting of the distal screws:

1. Ensure that all rosette knobs and locking bolts are tight in order to maintain a secure interface between the hardware pieces.

2. Throughout the procedure, avoid side pressure on the patient's arm or the Cane to maintain accuracy when targeting the distal screw holes.

3. For intraoperative visualization of the distal targeting hole, the C-Arm must be positioned in a direct axial view down the 3.5mm cannula. When positioned properly, concentric circles will be seen if the device is targeted correctly. If an oval shape appears, this means that a distal adjustment to the cane is necessary to align the holes until concentric circles are visualized. Depending on which approach (A/P or M/L) is used, the arm may have to be rotated into the desired position to obtain the x-ray image. The C-Arm should be parallel to the cane when obtaining the x-ray image.





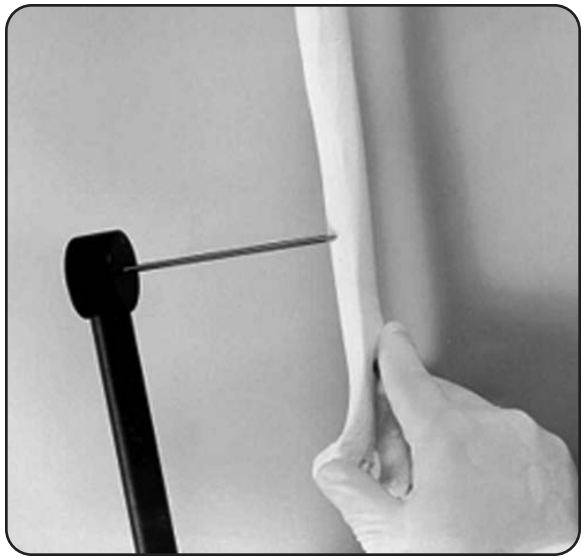
Step 11: Insert Distal Screws

When accurate positioning is achieved, use the witness hole drill (HR-3106) first to open the near cortex to assist in accurate screw placement.

Use the primary drill (HR-D105) to perforate the far cortex. Use the 3.5mm drill guide (HR-3104) to establish correct screw length.

Install the appropriate screw length with or without the washer (HCO-35WA).

It is important to lock the distal humerus in the correct amount of retroversion relative to the humeral head. The fracture can be rotated under flouroscopy until the fractures are restored to their anatomical positioning. If a good A/P image of the humeral head is viewed, the forearm can be locked at approximately 30° of external rotation.



Optional: Freehand Targeting of the Distal Screws

If freehand targeting of the distal screws is preferred, locate the distal screw hole flouroscopically. Care should be taken to avoid damaging the radial nerve when making the incision for the distal interlocking screws when the M/L approach is used. Careful spreading of tissue and retraction down to the bone will minimize injury to the nerve and improve visibility of the screw insertion site.

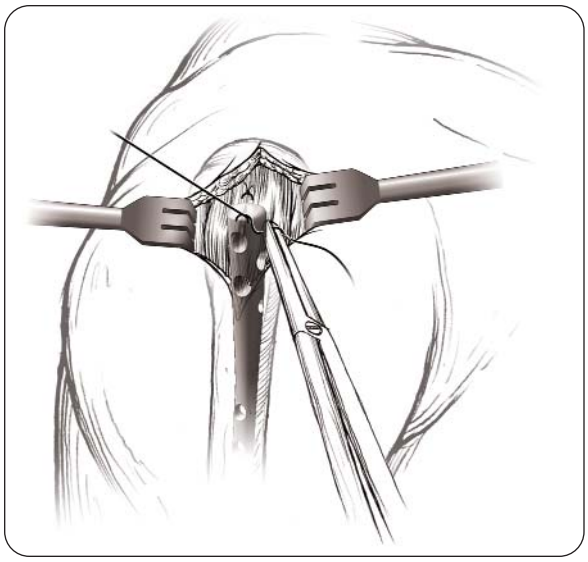
Using a C-Arm and the freehand targeting guide (MS-0210), find the center of the distal hole. Stand up the freehand guide and tap it to create a starting dimple. Drill first with the witness hole drill (HR-3106) to open the near cortex to aid in accurate screw placement. Place the 3.5mm drill (HR-D105) in the dimple and drill parallel with the C-Arm beam. Use the 3.5mm drill guide (HR-3104) to determine screw length. Install the appropriate screw length with or without the washer (HCO-35WA).

Step 12: Insert Polarus Cap

Place the cap assembly onto the 3.5mm driver and insert into the top of the rod. Advance the cap until the polyethylene fully engages the threads of the most proximal cancellous screw holding it into position. When fully advanced the cap is flush with the top of the rod, adding only 1.5mm to the total implant height.

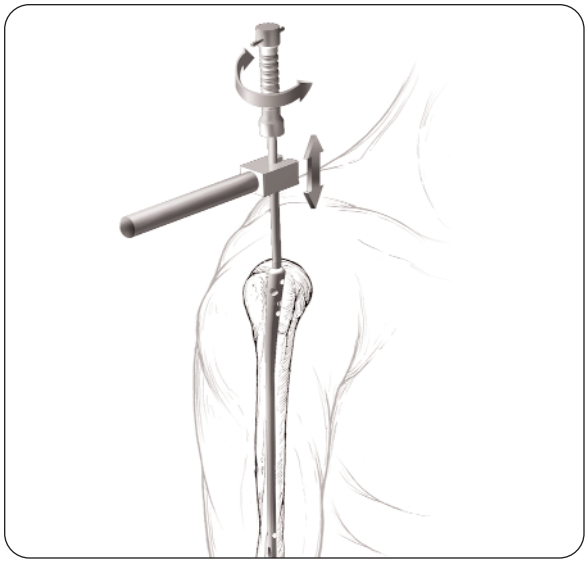
Note: A Polarus Cap with an insertion device (HR-0050-S) is available in the system. If using the standard Polarus Cap (HR-0001-S), care should be taken to ensure that the cap remains connected to the driver during installation. One tip is to tie a piece of suture under the top of the cap and hold onto the end of the suture while inserting the cap into the Polarus implant.

To prevent possible cross-threading of the cap upon insertion, thread the cap in a counter clockwise direction for the first few turns, then turn the cap clockwise until fully seated into the top of the Polarus rod.



Step 13: Repair Rotator Cuff

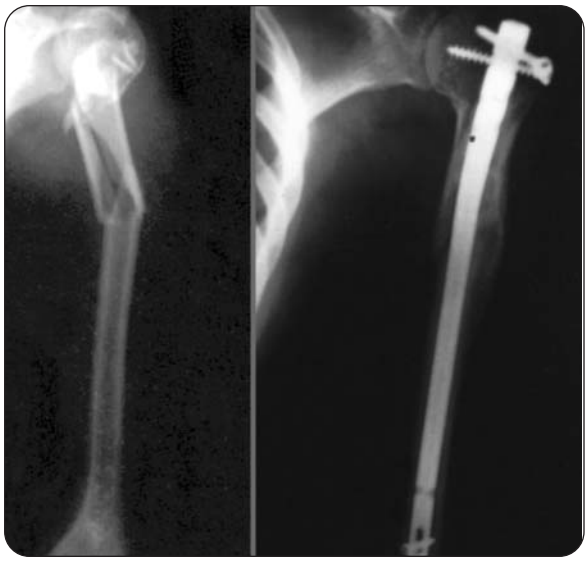
It is vital to close the rotator cuff after insertion of the rod. Number 2 Ethibond or a permanent suture is utilized to close the rotator cuff. Generally, two figure-8 sutures are used to close the small longitudinal incision of the rotator cuff. After this the deltoid is closed. The wound is then closed in layers with the deltoid closed with number one Vye-krill and the skin is closed in standard fashion.



Implant Removal

If it is desirable to remove the implant, approach the proximal end of the rod in the same manner as when implanting it. Locate the screws under image and remove the proximal screws. Use the tip of the removal instrument (HRDR001) to core out any ingrown tissue. Screw the removal instrument into the rod. The threaded portion of the removal tool has cutting flutes that will remove bone as it is inserted. The tip will fit into the cannulated hole to prevent cross threading. Note that the removal tool will not point straight down the humeral shaft, but will angle laterally about 10°.

Screw in the removal instrument until it stops. Do not use the hammer (HRDR002) yet. Locate and remove the distal screws. Failure to do so could result in breaking the screws, rod, or removal tool. After verifying that the screws have been removed, slip the forked end of the removal hammer over the shaft of the tool and break the rod loose.



Post-Op Protocol

Post-operatively, the patient is placed in an arm sling and a Markane Pain Pump may be placed in the sub-acromial space to help with post-operative pain relief. The patient is started on pendulum motion exercises at one to two weeks, a passive motion program for two to six weeks, and active strengthening at six weeks when evident signs of healing are seen.

DESCRIPTION: Acumed® intramedullary rods and screws are designed to provide fixation of humeral, forearm, and fibula fractures while they heal.

INFORMATION FOR USE: Physiological dimensions limit the sizes of implant appliances. The surgeon must select the type and size that best meets the patient's requirements for close adaptation and firm seating with adequate support.

INDICATIONS: Polarus Rods address fracture fixation of the humerus.

CONTRAINDICATIONS: Active or latent infection. Osteoporosis, insufficient quantity or quality of bone/soft tissue. Material sensitivity. If suspected, tests are to be performed prior to implantation. Sepsis. Patients who are unwilling or incapable of following postoperative care instructions. This device is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

WARNINGS: For safe and effective use of this implant, the surgeon must be thoroughly familiar with the implant, the method of application, instruments, and the recommended surgical technique for this device. The device is not designed to withstand the stress of weight bearing, load bearing, or excessive activity. Device breakage or damage can occur when the implant is subjected to increased loading associated with delayed union, nonunion, or incomplete healing. Improper insertion of the device during implantation can increase the possibility of loosening and migration. The patient must be cautioned, preferably in writing, about the use, limitations, and possible adverse effects of this implant including the possibility of the device failing as a result of loose fixation and/or loosening, stress, excessive activity, or weight bearing or load bearing, particularly if the implant experiences increased loads due to delayed union, nonunion, or incomplete healing. The patient must be warned that failure to follow postoperative care instructions can cause the implant and/or treatment to fail.

PRECAUTIONS: An implant shall never be reused. Previous stresses may have created imperfections which can lead to device failure. Instruments shall be inspected for wear or damage prior to usage. Protect implant appliances against scratching and nicking. Such stress concentrations can lead to failure.

ADVERSE EFFECTS: Fracture of the implant due to excessive activity, prolonged loading upon the device, incomplete healing, or excessive force exerted on the implant during insertion. Implant migration and/or loosening. Metal sensitivity or histological or allergic reaction resulting from implantation of a foreign material. Pain, discomfort, or abnormal sensations due to the presence of an implant. Nerve damage resulting from surgical trauma. Necrosis of bone or bone
resorption. Necrosis of tissue or inadequate healing.

STERILITY: This product is provided presterile and was exposed to a minimum dose of 25.0 kGy gamma irradiation. With the exception of the Polarus Cap, resterilization of the other rods and screws of this product line may only be performed if the original sterile package has been opened in error using one of the following methods. For a gravity displacement autoclave, set at 250 °F (121 °C) for 30 min. For a prevacuum autoclave, set at 270 °F (132 °C) for 4 min, or at 273 °F - 279 °F (134 °C to 137 °C) for 3 min. Please consider your equipment manufacturer's written instructions for the specific sterilizer and load configuration being used and current AORN standards and recommended practices.

STORAGE INSTRUCTIONS:
Store in a cool dry place, and keep away from direct sunlight. Prior to use, inspect product package for signs of tampering, damage, or water contamination. Use oldest lots first.

CAUTION: Federal Law (USA) restricts this product to sale by or on the order of a physician or hospital.

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