ACUMED®

POLARUS® LOCKING HUMERAL ROD

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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.

For over a decade, the Polarus Humeral Rod System has provided an excellent means of fixing proximal humerus fractures.

Acumed's goal when designing Polarus was to provide the surgeon with excellent fracture stability through a minimally invasive procedure. When the Polarus was designed, proximal humeral fractures were said to be the last 'unsolved' fracture in orthopedics. Acumed provided the first innovative solution to address these fractures that were once difficult to treat.

CONTENTS

The Polarus Locking Humeral Rod provides excellent fixation for 2-, 3-, and some 4-part fractures of the proximal humerus. A minimally invasive surgical technique and straightforward, accurate targeting procedure minimizes O.R. time – a benefit for both the patient and the surgeon.

Polarus is a cannulated intramedullary humeral rod that features a tapered profile with a patented spiral array of proximal screws. Multi-planar fixation acts as a scaffold, restoring the proper anatomic alignment of the humerus through a percutaneous approach.

The Polarus Locking Humeral Rod System is contained in a comprehensive, well-organized tray with all of the instruments needed to implant the rod. Calibrated drills ensure proper screw sizing and eliminate extra surgical steps. Straightforward assembly of the targeting guide saves frustration and valuable O.R. time.

Acumed incorporated many features into the Polarus Locking Humeral Rod for proper fracture alignment, maximum fixation, and to ease the surgical technique.

Patented Spiral Array of Locking Screws provide multi-planar fracture fixation in the humeral head.

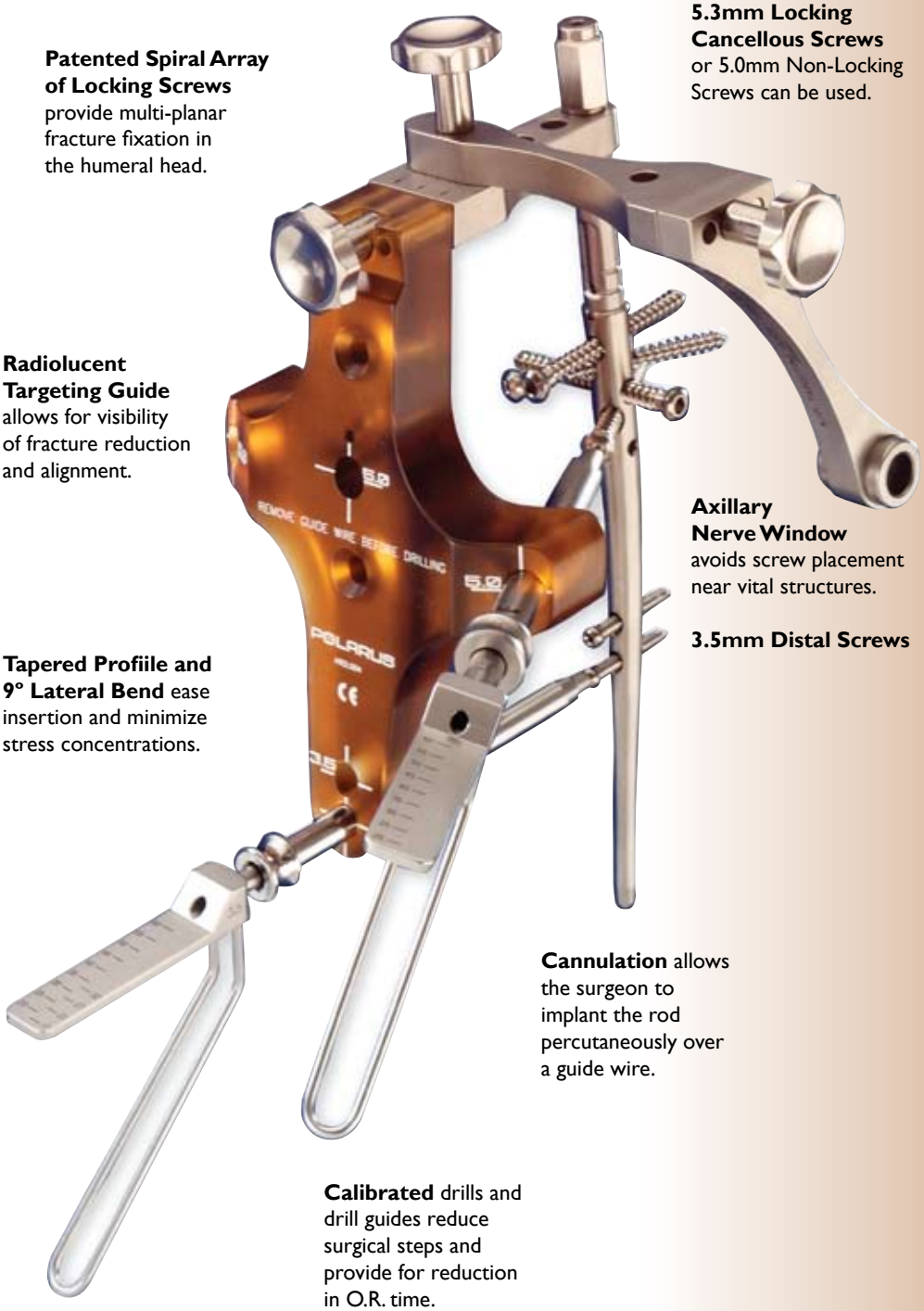
5.3mm Locking Cancellous Screws or 5.0mm Non-Locking Screws can be used.

Radiolucent Targeting Guide allows for visibility of fracture reduction and alignment.

Axillary Nerve Window avoids screw placement near vital structures.

3.5mm Distal Screws

Tapered Profiile and 9° Lateral Bend ease insertion and minimize stress concentrations.



Cannulation allows the surgeon to implant the rod percutaneously over a guide wire.

Calibrated drills and drill guides reduce surgical steps and provide for reduction in O.R. time.

Minimally Invasive

Fracture Stability

Anatomic Restoration

MINIMALLY INVASIVE

The Polarus Locking Humeral Rod may be inserted utilizing a minimally invasive approach. Patient morbidity is reduced and overall rehabilitation is lessened, providing a quicker return to normal daily activity. Minimal soft tissue dissection and a small exposure site reduces valuable O.R. time.

The Polarus is cannulated to both ease insertion and ensure proper implant positioning. The cannulated instrumentation allows creation of the rod insertion site through a small incision. A guide wire insertion device aids in passing the guide wire into the humeral canal. Laser marks on the guide wire and an x-ray template enable the surgeon to pinpoint screw location, indicating whether the Polarus Locking Rod is ideal for the fracture pattern.

Unlike plates, intramedullary rods do not pose a threat to damage of the periosteum. Removal of the Polarus Locking Humeral Rod may also be performed percutaneously.

A minimally invasive procedure reduces overall patient scarring and reduces O.R. time.

The cannulated Polarus Locking Rod is inserted over a guide wire to both ensure proper positioning and ease implant insertion.

CASE STUDY

Indication:
Severely displaced four part-fracture-dislocation of the proximal humerus associated with multiple injuries.

History:
Passenger in high-speed vehicle collision. Other injuries included a closed fracture of femur, a contralateral humeral shaft fracture and a significant head injury. No cardiovascular or abdominal injuries.

Treatment:
Open reduction of the fracture using an anterior approach preserving the remaining soft tissue attachments and stabilization using a Polarus Locking intramedullary rod.

Comments:
Decision made to perform ORIF rather than hemiarthroplasty because of patients age and expected full recovery. In addition, soft tissue remained attached to lesser tuberosity and metaphysis.

Results:
Excellent reduction achieved with stable fixation allowing rehabilitation. Union of fracture at three months. No evidence of delayed complications or osteonecrosis evident at nine months.

Patient's Age and Gender:
Female Age 21

Surgeon's Name and Address:
Mr. D. Potter FRCS (Orth)
Northern General Hospital
Sheffield, United Kingdom

FRACTURE STABILITY

The Polarus Locking Humeral Rod features a patented spiral array of screws, providing maximum fracture

stability. The screws are positioned and angled to treat the most common fracture patterns and to ensure that the proximal screws are in the best quality bone in the humeral head. The low profile, locking screws have deep cancellous threads for excellent stability in the soft bone of the humeral head. A triple-lead thread allows the screw to engage the rod and lock smoothly.

A Polarus Cap is included in the system to lock the most proximal screw in a fixed angle if a non-locking screw is chosen. The Polarus Cap also prevents bony ingrowth, easing the technique if implant removal is required.

The Polarus Locking Humeral Rod features two 3.5mm bi-cortical distal screws for a strong construct both proximally and distally. A proximal suture hole is included for tension banding severe open fractures.

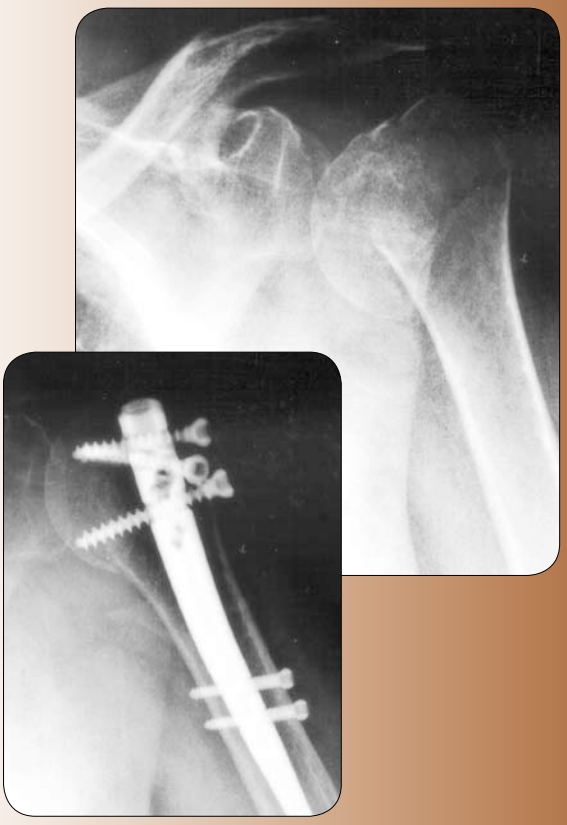
ANATOMIC RESTORATION

The Polarus Locking Humeral Rod properly restores the patient's anatomy by combining proper rod and screw placement with an anatomic bend and taper that accommodates implant insertion.

With Polarus, both the proximal and distal screws are strategically placed to avoid the axillary nerve and other key vessels that wrap around the humerus. The rod may be rotated up to 20° to maximize fixation or to avoid key anatomic structures.

The innovative targeting guide system is designed to ensure that the Polarus Locking Humeral Rod is buried to the appropriate depth. This prevents the rod from sitting proud, resulting in rotator cuff injury.

The Polarus features a 9° lateral bend to aid with insertion and a tapered tip to reduce distal stress concentrations in the humerus.



SURGICAL TECHNIQUE

This section offers Acumed's suggested method for implanting the Polarus Locking 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 fluoroscopy 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.

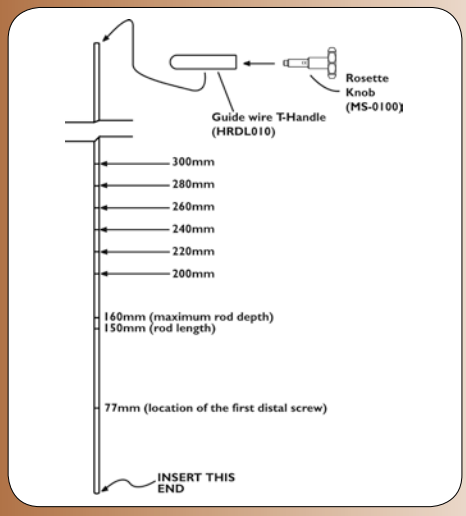
If an anteriolateral approach is indicated, a 3-5cm incision is made at the anteriolateral aspect of the acromium extending parallel to the fibers of the deltoid. The supraspinatus tendon is then split in the direction of the fibers to expose the proximal humerus posterior to the biceps tendon. It is important not to detach 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 guide wire. 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 base plate 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 5-10mm 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 fluoroscopy, 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

5.3mm locking screws or 5.0mm non-locking screws may be inserted proximally utilizing the 5.0mm cannula, probe and drill guide. If using an A/P screw, target it first in order to avoid 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 to assist with targeting accuracy. 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 and up to the bone surface. Before drilling, be sure the guide wire is removed. Use fluoroscopy 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 locking proximal screws as required.

Step 8: Secure and Target Distal Fraction

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 cortices, 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 4: 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 fluoroscopy. 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 fluoroscopy 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 Polaris 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.

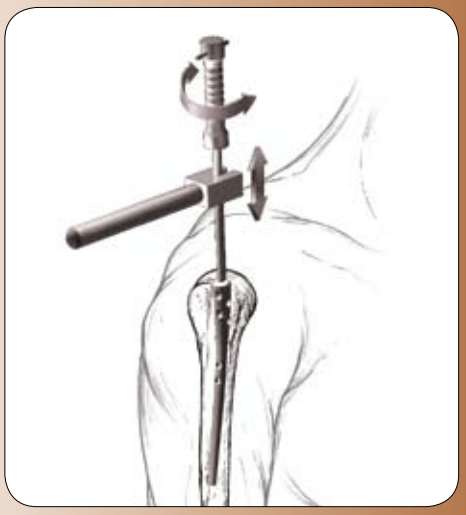
Step 11: Repair Rotator Cuff

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 Vicrylr 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.



CLINICAL STUDIES

"A locked intramedullary nail can provide a valuable means of fixation for difficult displaced fractures of the proximal humerus in both young and old patients. The higher functional scores obtained in patients aged more than 60 years is encouraging."

Bhamra, et al., "Fixation of proximal humeral fractures with the Polarus nail," J of Shoulder & Elbow Surgery, January 2001

"Polarus rod fixation is found to be a reliable method of dealing with common, as well as complex humeral head and neck fractures, yielding an excellent method of fixation with few complications."

Jerome V. Ciullo, AAOS Annual Meeting, March, 2000

"We feel that the implant is a very useful addition to the management of a rather difficult fracture. Nail insertion and locking did not entail open reduction in any of the cases, making the entire procedure minimally invasive. In our opinion, it has alleviated pain and suffering in patients who have often been treated in slings or collar and cuff or undergone major open surgery. It has enabled the old, a group in which this type of injury is common, to resume earlier joint movement and return to independent existence."

A.O. Adedapo & J.O. Ikpeme, "The results of internal fixation of three- and four-part proximal humeral fractures with the Polarus nail," Injury: International Journal of the Care of the Injured, July, 2000

"(The Polarus Humeral Rod) provided a stronger more stable, and durable fixation option than did percutaneous pin fixation for large-fragment multi-part proximal humeral fractures with minimal comminution."

Donna L. Wheeler and Mark R. Colville "Biomechanical Comparison of Intramedullary and Percutaneous Pin Fixation for Proximal Humeral Fracture Fixation," JOT April, 1997

SHOULDER SOLUTIONS

By offering a comprehensive group of unique products, Acumed strives to provide the surgeon with a complete solution for a wide variety of proximal humeral fracture types and patients.

Polarus PHP
An anatomically contoured, locking proximal humeral plate.

Polarus Plus Humeral Rod
Lengths from 200mm to 280mm for fractures that extend distally.

Polarus Modular Shoulder
Unique implant and targeting guide provide anatomic restoration.

Polarus Locking Humeral Rod	
Polarus Locking Humeral Rod	HR-L1115-S

Polarus 5.3mm Locking Screws	
5.3mm x 25.0mm Locking Screw	HCA-L5325-S
5.3mm x 30.0mm Locking Screw	HCA-L5330-S
5.3mm x 35.0mm Locking Screw	HCA-L5335-S
5.3mm x 40.0mm Locking Screw	HCA-L5340-S
5.3mm x 45.0mm Locking Screw	HCA-L5345-S

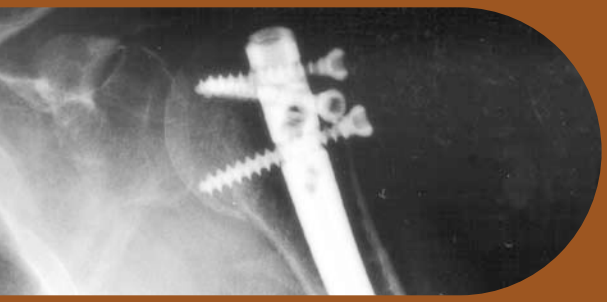
Polarus 5.0mm Cancellous Screws	
5.0mm x 20.0mm Cancellous Screw	HCA5200-S
5.0mm x 25.0mm Cancellous Screw	HCA5250-S
5.0mm x 30.0mm Cancellous Screw	HCA5300-S
5.0mm x 32.5mm Cancellous Screw	HCA5325-S
5.0mm x 35.0mm Cancellous Screw	HCA5350-S
5.0mm x 37.5mm Cancellous Screw	HCA5375-S
5.0mm x 40.0mm Cancellous Screw	HCA5400-S
5.0mm x 45.0mm Cancellous Screw	HCA5450-S
.3mm x 45.0mm Locking Screw	HCA5500-S
.3mm x 45.0mm Locking Screw	HCA5550-S

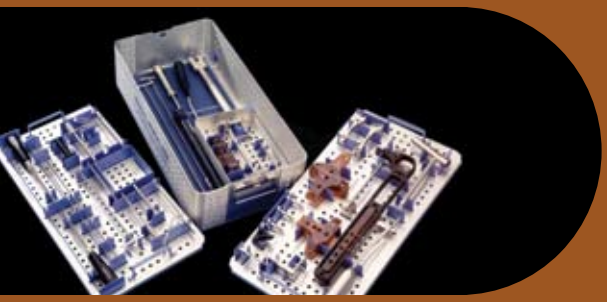
Polarus Cap	HR-0001-S
Polarus Cap with Insertion Assy.	HR-0050-S

Polarus 3.5mm Cortical Screws	
3.5mm x 17.5mm Cortical Screw	HCO3175-S
3.5mm x 20.0mm Cortical Screw	HCO3200-S
3.5mm x 22.5mm Cortical Screw	HCO3225-S
3.5mm x 25.0mm Cortical Screw	HCO3250-S
3.5mm x 27.5mm Cortical Screw	HCO3275-S
3.5mm x 30.0mm Cortical Screw	HCO3300-S
3.5mm x 32.5mm Cortical Screw	HCO3325-S
3.5mm x 35.0mm Cortical Screw	HCO3350-S
3.5mm x 40.0mm Cortical Screw	HCO3400-S
3.5mm x 45.0mm Cortical Screw	HCO3450-S
3.5mm x 50.0mm Cortical Screw	HCO3500-S
3.5mm x 55.0mm Cortical Screw	HCO3550-S
3.5mm x 60.0mm Cortical Screw	HCO3600-S

3.5mm Washer for Cortical Screws	HCO35WA

Polarus Instrumentation	
Polarus X-Ray Template	FHUM-05
2.0mm x 20” Guide Wire Stainless Steel	WS-2020
2.8mm Tap Drill	HR-D105
Short Polarus Plus 2.8 Drill	HRSD105
2.5 Solid Hex Driver Assembly	HD-2500
3.5 Solid Hex Driver Assembly	HD-3500
Polarus Witness Hole Drill	HR-3106





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