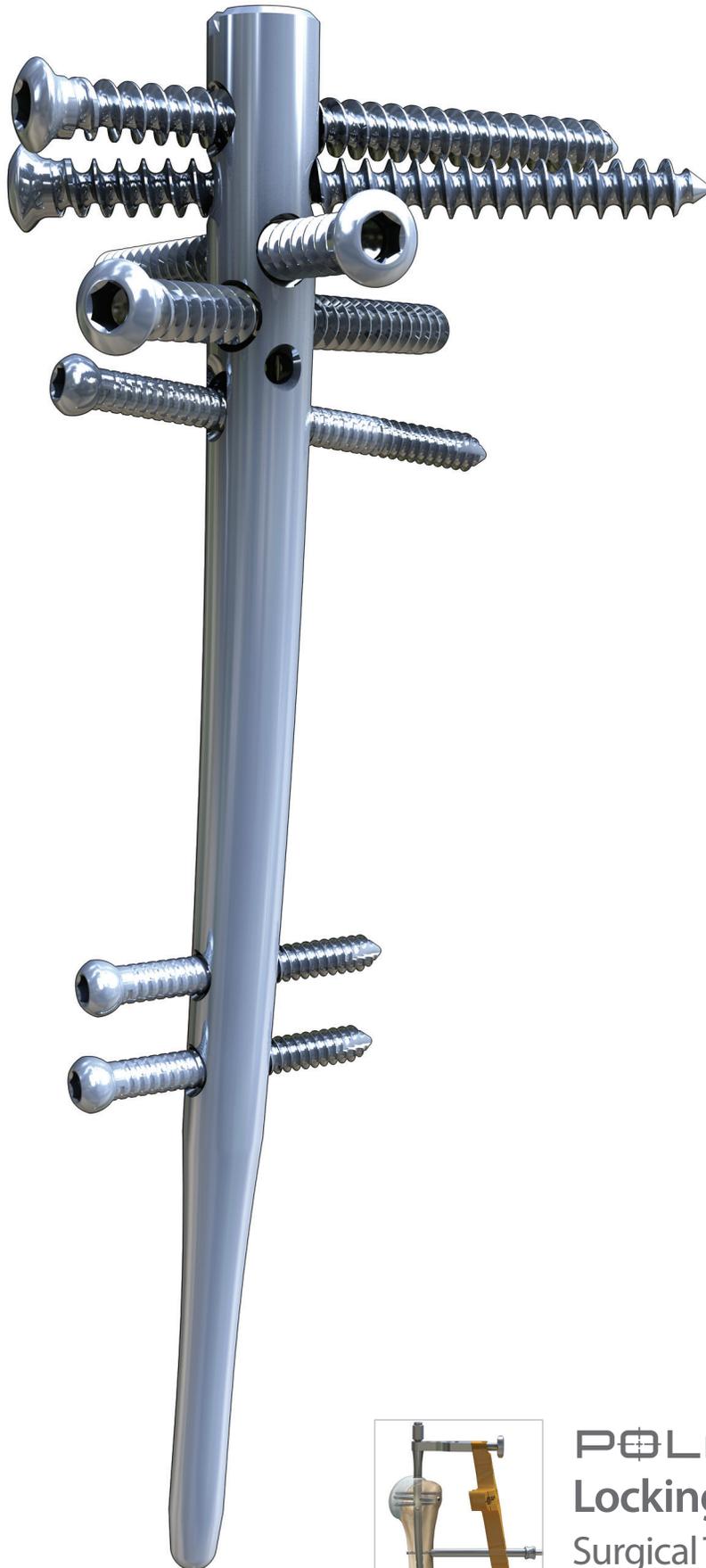


ACUMED®



POLARUS® 2
Locking Humeral Rod
Surgical Technique

Polarus® 2 Locking Humeral Rod Surgical Technique

The Polarus® 2 Locking Humeral Rod is designed to provide fixation for 2-, 3-, and some 4-part fractures of the proximal humerus through a minimally invasive surgical technique.

Polarus® 2 is a cannulated intramedullary humeral rod that features a tapered profile with a spiral array of proximal screws designed to target the best quality bone. Multi-planar fixation acts as a scaffold, this aids fracture reduction and realignment. One of the additional values of intramedullary rodding compared to competing technologies is its percutaneous approach, designed to minimize soft tissue disruption and support periosteum healing. The Polarus® 2 Locking Humeral Rod System is contained in a comprehensive tray including all of the instruments needed to implant the rod and calibrated drills meant to ensure proper screw sizing and eliminate extra surgical steps.

Cleared Indications:

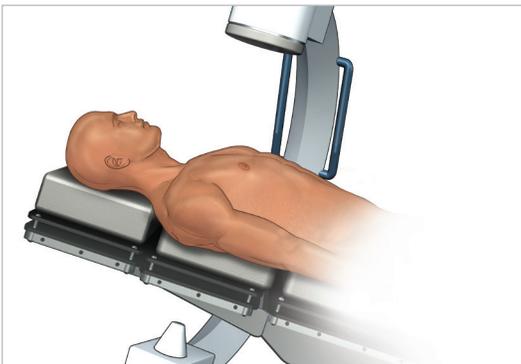
2-, 3-, and some 4-part fractures of the proximal humerus

Minimally Invasive
Fracture Stability
Anatomic Restoration

- Cannulation allows the surgeon to implant the rod percutaneously over a guide wire
- Calibrated drills and drill guides
- Tapered Profile and 4° Lateral Bend
- Radiolucent Targeting Guide
- Spiral Array of Locking Screws provides multi-planar fracture fixation in the humeral head
- 5.3 mm Locking Cancellous Screws or 5.0 mm Non-Locking Screws are both compatible with the rod
- Axillary Nerve Window is designed to reduce the risk of screw placement near vital structures
- 3.5 mm Distal Screws

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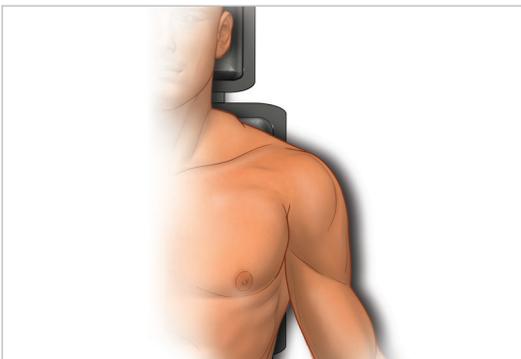
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1 PATIENT POSITIONING AND SURGICAL EXPOSURE

The patient may be placed either supine or in a beach chair position to aid fluoroscopy use. A bolster may be used to elevate the shoulder and gain exposure.

If an anterolateral approach is indicated, a 3.0-5.0 cm incision is made at the anterolateral aspect of the acromion 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.



2 CORTEX PERFORATION AND GUIDE WIRE INSERTION

The implant insertion point is located approximately 1.0-1.5 cm posterior to the bicipital groove, just medial to the greater tuberosity and just lateral to the articulating surface of the humeral head. The cannulated awl (HR-0200) should be used to perforate the cortex and create an entry hole 10 mm in diameter. Extra care should be taken to ensure the tip is buried no deeper than the groove line on the cannulated awl below the bone surface.

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.

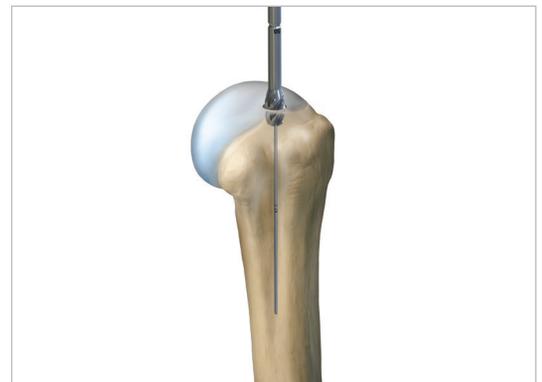
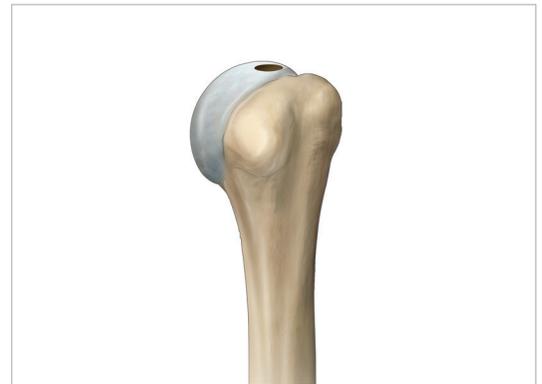
While using the cannulated awl, pass the guide wire (WS-2020) through the awl and into the humeral canal. A guide wire passer (PA-1000) and guide wire "T" handle (HRDL010) coupled with a rosette knob (MS-0100) are available to aid insertion.

ALTERNATE TECHNIQUE USING POWER

An optional technique is to perforate the cortex with the 2.8 mm drill (HR-D105) and then pass the guide wire (WS-2020) down the canal. The proximal canal can then be prepared using power with the 10.0 mm bud drill (DRB1015). To aid in guide wire insertion, a guide wire passer (PA-1000) and guide wire "T" handle (HRDL010) are available in the system.

With either standard or power technique, fluoroscopy should be used in both the A/P and oblique planes to ensure the guide wire has not exited the humerus through the fracture site. Note: The length markings on the guide wire to assist in verifying the depth of the final implant.

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.



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3 OPTIONAL FURTHER CANAL PREPARATION

The proximal canal may be prepared by using a 10.0 mm cannulated bud drill over the guide wire. Drill with the 10.0 mm bud drill (DRB1015) to a depth of approximately 50-60 mm to allow the rod to pass into the canal. The first groove on the 10.0 mm bud drill indicates a depth of 50 mm.



4 ASSEMBLE THE TARGETING GUIDE (FOR ROD HRA-1055-S)

If you are utilizing rod number HRA-1055-S Polarus® 2-4 degrees (10.0 mm x 5.5 mm X150 mm Standard Rod) use the following steps:

- Attach targeting guide base plate (HRDL007) to Polarus® 2-4 degrees lateral targeting guide (HRDL025), securing with a rosette knob (MS-0100).
- Insert locking bolt (HRDL001) into position.
- Assemble implant onto targeting guide base plate, aligning the two reference marks on the implant and targeting guide base plate. Ensure implant is the correct rod number (HRA-1055-S).
- Tighten rod into position with the provided finger wrench (MS-0611). When assembled properly, the rod should curve toward the lateral targeting guide.



ALTERNATE TECHNIQUE FOR ROD WITH A/P SCREW (HR-4D1055-S):

If you are utilizing rod number HR-4D1055-S Polarus® 2-4 degrees with A/P use the following steps:

- Attach targeting guide base plate (HRDL007) to Polarus® 2-4 degrees with AP lateral targeting guide (HRDL024), securing with a rosette knob (MS-0100).
- Insert locking bolt (HRDL001) into position.
- Assemble implant onto targeting guide base plate, aligning the two reference marks on the implant and targeting guide base plate. Ensure implant is the correct rod number (HR-4D1055-S).
- Tighten rod into position with the provided finger wrench (MS-0611). When assembled properly, the rod should curve toward the lateral targeting guide.
- Optional: Assemble outrigger arm (HRDL005) onto targeting guide base plate and secure with a rosette knob. Attach the AP targeting guide (HRDL028) to the outrigger arm using a rosette knob. Outrigger should be constructed to facilitate anterior to posterior approach according to the fracture pattern addressed.



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5 IMPLANT INSERTION

Insert the rod over the guide wire and verify that the proximal end of the rod is 5-10 mm 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 10.0 mm below the cortex. Groove marks on the targeting base plate can be used to verify a depth between 5 and 10 mm below the cortical surface.

The depth of the rod may also be verified by inserting a 2.8 mm tap drill (HR-D105) through the small hole (arrowed on the picture) located just above the center hole on the targeting guide. Depth can be verified using fluoroscopy; it is important that the c-arm is exactly parallel to the arm to obtain an accurate image of implant depth.

Remember to remove the guide wire prior to drilling.



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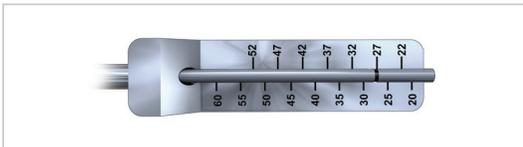
6 PROXIMAL SCREW PLACEMENT

5.3 mm locking screws (HCA-L53XX-S) or 5.0 mm nonlocking screws (HCA5XXX-S) may be inserted proximally utilizing the 5.0 mm cannula (HR-5101), probe (HR-5102) and drill guide (HR-5104). If using an A/P screw (using rod HR-4D1055), target the A/P screw hole first in order to avoid the biceps tendon.

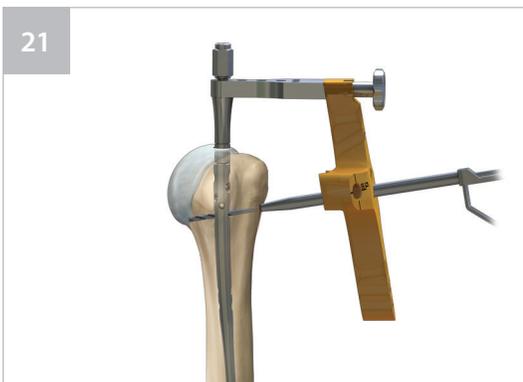
Choose the desired screw position and create a 2-4 mm stab incision in the skin. Insert the 5.0 mm cannula and probe through the targeting guide. Lightly tap the probe to create a small indentation in the bone to assist with targeting accuracy. Only light tapping should be used on the probe to avoid damaging the lateral cortex. Remove the probe and insert the 5.0 mm drill guide (HR-5102) 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. Using the depth measurements on the 5.0 mm drill guide, the proper screw length can be determined. If the length reading is between sizes, round down to the shorter screw length.

Use the black-handled 3.5 mm hex driver (HD-3500) to insert the screw into the rod. 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 required.

The Polarus® 2 Rod offers two different angles (see images 20 & 21) for additional support in the medial calcar region. These screw trajectories can be targeted using the targeting guide holes with the '3.5 mm' indication. Use the 3.5 mm drill guide (HR-3104) coupled with the 2.8 mm drill (HR-D105). Once measuring for correct length, the correct 3.5 mm cancellous screw (HCO3XXX-S) can be inserted.



Note that the system includes washers designed to increase the capture of good quality bone. These washers are available under part number: HR-WC50-S.

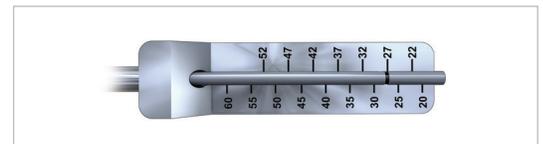
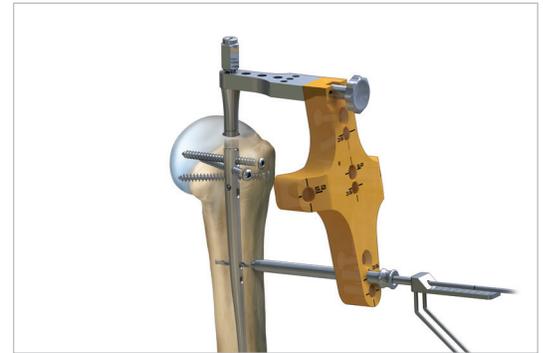


7 TARGET DISTAL HOLES AND SECURE HUMERAL SHAFT

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.

Insert the 3.5 mm 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 similar to Step 6. The 3.5 mm drill guide (HR-3104) is then inserted through the cannula. Using the 2.8 mm tap 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 the primary drill from walking and creates a glide hole for the wider distal screw diameter. Use the 2.8 mm tap drill (HR-D105) to drill through both cortices to a depth of, 1-2 mm through the far cortex.

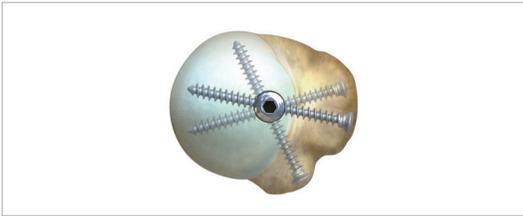


8 INSERT DISTAL SCREWS

Insert a 3.5 mm screw into the most proximal of the distal holes with the 2.5 mm hex driver (HD-2500). Verify the screw position under fluoroscopy. The screw should not extend past the medial cortex by more than 1 mm. Remove the “provisional” drill from distal hole and perforate the near cortex with the witness hole drill. Insert second 3.5 mm distal screw.



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9 INSERT POLARUS® ROD CAP

The Polarus® 2 Rod features 3 different cap height options. Caps are available in 2 mm (HR-0001-S), 4 mm (HR-0024-S), and 8 mm (HR-0028-S) options. Cap height should be chosen based upon the depth of the implant to provide best height while remaining below the articular surface. Place the cap assembly onto the 3.5 mm 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.

It may be helpful 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® 2 implant in order to keep the cap and driver assembled. 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® 2 Rod.

10 REPAIR ROTATOR CUFF

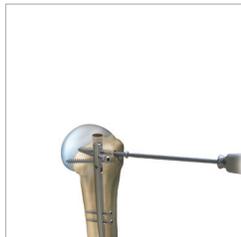
It is vital to close the incision in the rotator cuff after rod insertion. Using two figure-of-8 suture patterns, with either number 2 Ethibond or other permanent suture, the small longitudinal incision in the rotator cuff is closed. The deltoid muscle is closed with number 1 Vicryl, followed by 2/0 Vicryl to other superficial soft tissue layers. A subcuticular skin suture is strongly recommended.

IMPLANT REMOVAL

If the implant requires removal, approach the proximal end of the rod in the same manner as when implanting it. Locate the screws under fluoroscopy and remove the proximal screws. (Note, it may be helpful to leave in the distal screws, or most distal proximal screw, to prevent pushing the rod further down the humeral canal.) Remove the Polarus® Cap with the 3.5 mm hex driver.

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 in the rod to help prevent cross threading. Note that the removal tool will not point straight down the humeral shaft, but will angle laterally about 10°. Advance the removal instrument into the proximal end of the Polarus® 2 Rod until it is fully seated.

Before using the removal hammer (HRDR002), locate and remove any remaining screws. Failure to do so could result in breaking the screws, rod, and/or the 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 slap the rod out of the canal. Repair of the rotator cuff and deltoid should follow similar to Step 10.



Ordering Information

Instruments

10.0 mm Bud Drill	DRB1015
2.5 mm Solid Hex Driver Assembly	HD-2500
3.5 mm Solid Hex Driver Assembly	HD-3500
Polarus® 2 Cortical Awl	HR-0200
3.5 mm Targeting cannula	HR-3101
3.5 mm Targeting probe	HR-3102
3.5 mm drill guide / depth gauge	HR-3104
Witness Hole Drill	HR-3106
5.0 mm Targeting Cannula	HR-5101
5.0 mm Probe	HR-5102
5.0 mm Polarus® Drill Guide	HR-5104
Driver Assistant Cannula	HR-5135
2.8 mm Tap Drill (2)	HR-D105
Rod Locking Bolt	HRDL001
Outrigger Extension Arm	HRDL005
Targeting guide base plate assembly	HRDL007
Guide Wire "T" Handle	HRDL010
Polarus® 2 - 4 Deg with A/P Lat. Tgt Gd.	HRDL024
Polarus® 2 - 4Deg Lateral Targeting Guide	HRDL025
Polarus® Removal Hammer	HRDR002
Rosette Knob	MS-0100
Polarus® 5.0 mm Screw Gage	HR-SG50
Polarus® Removal Instrument	HRDR001
.078" X 20" Guide Wire	WS-2020
Polarus® Guide Wire Passer	PA-1000
Locking Bolt Finger Wrench	MS-0611
3.5 mm Cortical Screw Tap	HR-3107
Polarus® Shortened Tap Drill (2)	HRSD105
Polarus® Plus Lateral Targeting Guide	HRDL009
11 mm x 150 mm Polarus® Humeral Rod Broach Assy	HR-B115
7.3 mm T-handle Reamer	RMT7340
8.3 mm T-handle Reamer	RMT8340
Freehand Targeting Guide	MS-0210
Polarus® Instrument Tray	MS-9000
Polarus® Plus Distal Targeting Guide	HRDL020
AP Lateral Targeting Guide Arm	HRDL028

Rods

2 - 4 deg. 10 mm x 5.5 mm x 150 mm Std. Rod	HRA-1055-S
2 - 4 deg., 10 mm x 5.5 mm x 150 mm A/P Rod	HR-4D1055-S
8 mm X 200 mm Polarus® Plus Humeral	HR-0820-S
8 mm X 220 mm Polarus® Plus Humeral	HR-0822-S
8 mm X 240 mm Polarus® Plus Humeral	HR-0824-S
8 mm X 260 mm Polarus® Plus Humeral	HR-0826-S
8 mm X 280 mm Polarus® Plus Humeral	HR-0828-S

Caps & Washers

Polarus® Cap Screw Assembly	HR-0001-S
4 mm Polarus® Cap Screw Assembly	HR-0024-S
8 mm Polarus® Cap Screw Assembly	HR-0028-S
Circular 5.0 mm Washer, Cleated	HR-WC50-S

5.3 mm Screws

5.3 mm x 20 mm Cancellous Locking Screw	HCA-L5320-S
5.3 mm x 22.5 mm Cancellous Locking	HCA-L5322-S
5.3 mm x 25 mm Cancellous Locking Screw	HCA-L5325-S
5.3 mm x 27.5 mm Cancellous Locking	HCA-L5327-S
5.3 mm x 30 mm Cancellous Locking Screw	HCA-L5330-S
5.3 mm x 32.5 mm Cancellous Locking	HCA-L5332-S
5.3 mm x 35 mm Cancellous Locking Screw	HCA-L5335-S
5.3 mm x 37.5 mm Cancellous Locking	HCA-L5337-S
5.3 mm x 40 mm Cancellous Locking Screw	HCA-L5340-S
5.3 mm x 42.5 mm Cancellous Locking	HCA-L5342-S
5.3 mm x 45 mm Cancellous Locking Screw	HCA-L5345-S
5.3 mm x 47.5 mm Cancellous Locking	HCA-L5347-S

5.0 mm Screws

5.0 mm X 25.0 mm Cancellous Screw	HCA5250-S
5.0 mm X 27.5 mm Cancellous Screw	HCA5275-S
5.0 mm X 30.0 mm Cancellous Screw	HCA5300-S
5.0 mm X 32.5 mm Cancellous Screw	HCA5325-S
5.0 mm X 35.0 mm Cancellous Screw	HCA5350-S
5.0 mm X 37.5 mm Cancellous Screw	HCA5375-S
5.0 mm X 40.0 mm Cancellous Screw	HCA5400-S
5.0 mm X 42.5 mm Cancellous Screw	HCA5425-S
5.0 mm X 45.0 mm Cancellous Screw	HCA5450-S
5.0 mm x 47.5 mm Cancellous Screw	HCA5475-S

Ordering Information

3.5 mm Screws

3.5 mm X 17.5 mm Cortical Screw	HCO3175-S
3.5 mm X 20.0 mm Cortical Screw	HCO3200-S
3.5 mm X 22.5 mm Cortical Screw	HCO3225-S
3.5 mm X 25.0 mm Cortical Screw	HCO3250-S
3.5 mm X 27.5 mm Cortical Screw	HCO3275-S
3.5 mm X 30.0 mm Cortical Screw	HCO3300-S
3.5 mm X 32.5 mm Cortical Screw	HCO3325-S
3.5 mm X 35.0 mm Cortical Screw	HCO3350-S
3.5 mm X 40.0 mm Cortical Screw	HCO3400-S
3.5 mm X 45.0 mm Cortical Screw	HCO3450-S

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