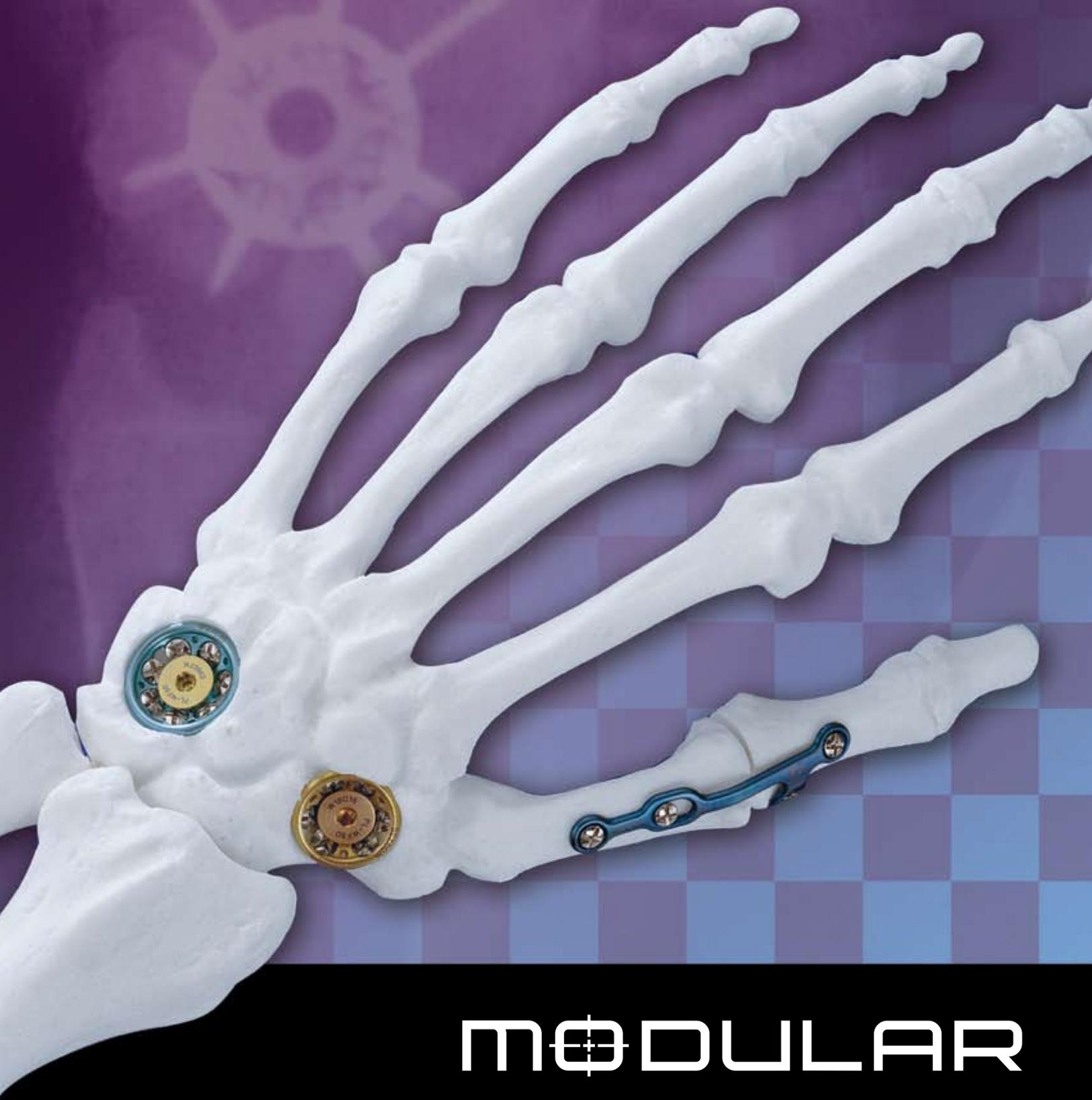


A&U MED[®]



MODULAR HAND SYSTEM

MODULAR HAND SYSTEM

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. The Modular Hand System is an extension of this philosophy.

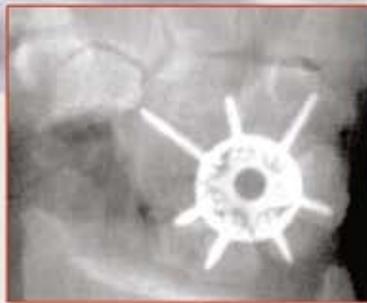
Designed to address specific indications throughout the hand, from the carpals to the phalanges, the Modular Hand System offers the surgeon innovative fixation solutions. Ultimately encompassing both fracture and fusion fixation, the system is contained in a modular tray that allows for customization and expansion as future innovative products are introduced.

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The Hub Cap™

The Hub Cap Limited Wrist Fusion Plate was designed to provide outstanding fixation and a straightforward technique. As a targeted solution for four-corner and other limited wrist fusions, the plate offers the kind of innovations upon which Acumed has built its reputation.



Four-corner fusions have been used with a high degree of success over the past 20 years to treat SLAC, SNAC and other arthritic conditions in the wrist.



Up to seven 2.1mm or 2.7mm screws secure the plate to the Capitate, Lunate, Hamate, and Triquetrum. The screws are kept in place with the optional screw cover that threads into the center of the plate.

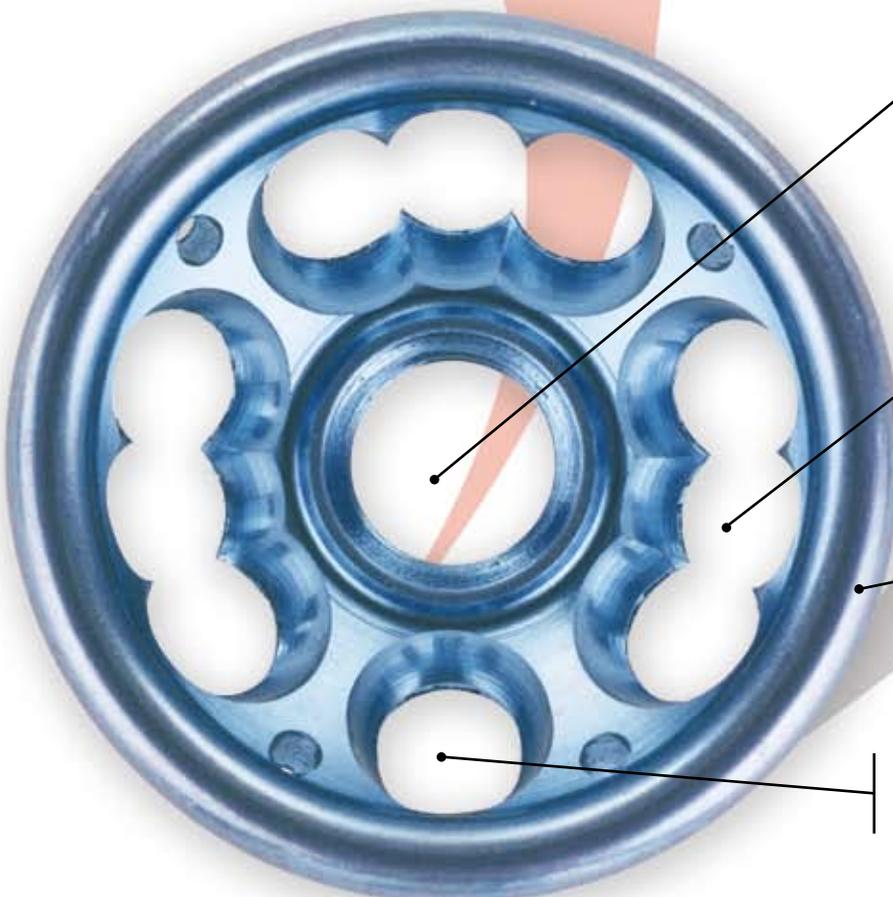
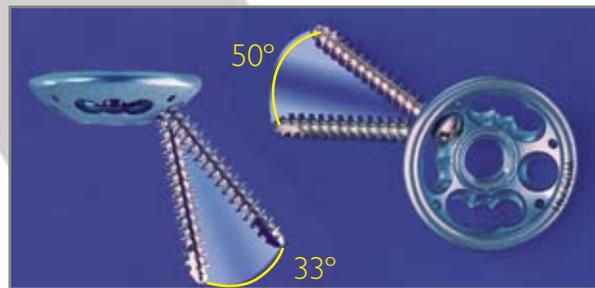


Plating is an alternative to challenging screw fixation procedures or problems with instability and long periods of immobilization when using K-wires.

Variable Screw Placement is facilitated by the screw-plate interface and scalloped design which allows for maximized purchase in the four carpals. The enhanced screw placement, when combined with Acumed's 2.7mm or 2.1mm screws, makes for a solid construct that fits the patient.

Provisional Stability During Insertion is achieved through both the K-wire holes and the Hub Cap Plate Post. Creating early stability ensures accurate screw placement and eliminates plate tilt, or dishing, which could lead to prominence of the plate above the dorsal surface of the carpals.

Advanced Instrumentation includes a dual purpose reamer that captures and contains bone debris as it creates the spherical depression to prepare the fusion site for the Hub Cap. A unique bone graft harvester designed specifically for use on the distal radius is also included in the system.



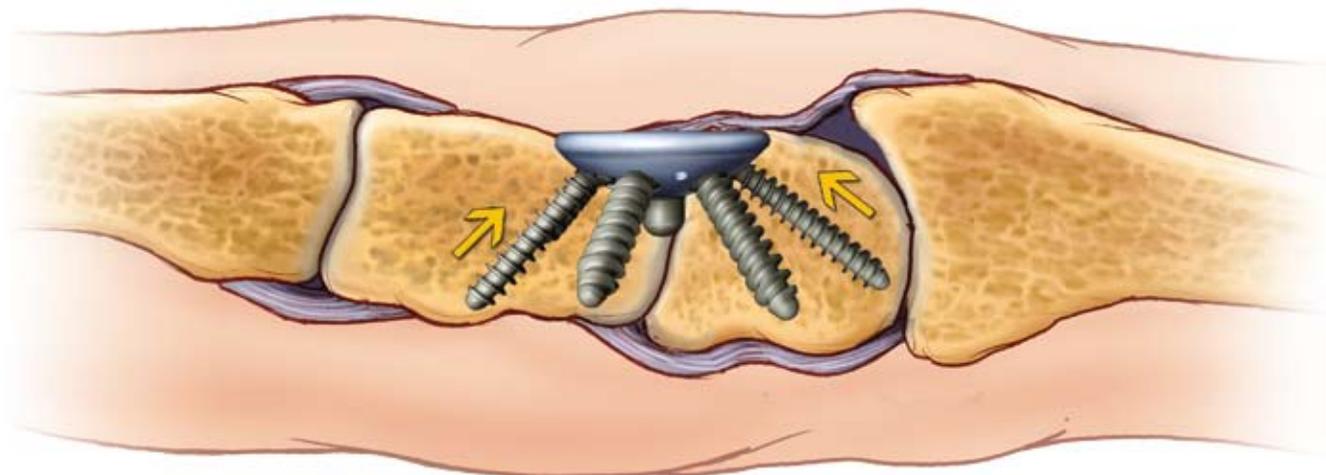
Center Hole enables using the Plate Post for provisional stability, removing it to pack bone graft, and preserving screw position with a screw cover — all at the surgeon's discretion.

Scalloped Holes enable placement of either 1 or 2 screws into each carpal, based on surgeon preference.

Rounded and Polished Crown allows tendons to glide naturally over the top of the titanium plate, while a grit blasted underside promotes bony ongrowth.

Single Hole provides a dedicated starting point that facilitates accurate placement of the remaining screws.

THE HUB CAP™



Enhanced Screw Angulation

The Hub Cap's enhanced variable screw angulation allows maximum purchase into each carpal bone. When combined with the Plate Post, the screws work together to draw the carpals toward a central hub. In addition, the post keeps the plate in proper positioning while inserting the screws, protecting the soft tissues.



Proper Plate Placement

The Hub Cap's advanced reamer utilizes laser lines to indicate proper reaming depth. The plate sits at or below the surface of the carpals to prevent soft tissue irritation. The maximized screw length and variable angled screws, combined with the benefits of the Plate Post and reamer, create a stable four-corner carpal fusion.

MINIHUB 4-C STT FUSION PLATES

The Mini Hub 4-C and Mini Hub STT Limited Wrist Fusion Plates, provide all the same features that have made the Hub Cap a success: excellent screw placement, provisional stability, rounded and polished crown, grit blasted underside, screw cover, and Acumed's advanced instrumentation.



The Mini Hub 4-C

The Mini Hub 4-C (4-Corner) is designed specifically for four-corner fusions in smaller patients. It offers seven-screw fixation, a dedicated starting hole, and provisional fixation just like the Hub Cap, but with a diameter that fits a smaller anatomy.



The Mini Hub STT

The Mini Hub STT (3-Corner) is the only plate that offers nine different options for up to six screws placed in three bone fusions. This combined with the provisional fixation of the plate post and K-wires makes for a streamlined procedure that produces solid results.

Advanced instrumentation makes for a straightforward procedure.

The Mini Hub 4-C and STT plates share the reamer shaft with the larger Hub Cap, but uses a smaller reamer head and sleeve that match their smaller diameter. Like the Hub Cap, this reamer head collects the reamed material and is disposable, offering a sharp cutting edge with every surgery.



Alternative Plate Placements

CMC Fusion

The Mini Hub STT plate is a great solution for fusions of the Carpometacarpal joint in cases of arthritis or chronic instability.



SC Fusion

Both the Mini Hub 4-C and STT plates offer excellent fixation for a Scaphocapitate fusion.



SLC Fusion

The Mini Hub STT plate provides a straightforward solution for Scapholunacapitate fusions.



MCP FUSION PLATE

The Acumed MCP Fusion Plate is the first plate specifically designed for fusions of the 1st MCP joint of the thumb. Whether the indication is arthritis or chronic instability of the MCP or CMC joint, this plate offers excellent stability and enables early rehabilitation. Sharing its instrumentation and screws with the Hub Cap makes for a familiar procedure and a simple prep in the O.R.

Precontoured Plate Design

helps to create desired flexion, maximizes screw placement, and minimizes O.R. time spent bending plates.

Low Profile Plate and Screw Design

minimizes soft tissue irritation, which is especially important in this area with little tissue coverage.

Highly Polished and Rounded

surfaces allow the tendons of the thumb to glide across the plate without irritation or adhesion.

Designed in conjunction with Dr. Miguel Pirela-Cruz, M.D.

Chair of the Department of Orthopedic Surgery at the Texas Tech University School of Medicine in El Paso, Texas.



SYSTEM FEATURES

Designed to address specific indications throughout the hand, from the carpals to the phalanges, the Modular Hand System offers innovative fixation solutions. Ultimately encompassing both fracture and fusion fixation, the system is contained in a modular tray allowing for customization and expansion as future products are introduced.

Current plates, as well as future additions to the system, use the same screws and instruments, making it highly flexible and surgeon friendly.

Instrumentation in the Modular Hand System includes Acumed's cannulated Small Joint Reamers for phalangeal fusions. The reamers not only streamline the procedure reducing O.R. time, but they produce joint surfaces that are congruent and promote a strong union. The unique cutting flutes clear bone debris as the reamer is advanced. Gauges are included with the reamers to ensure accurate sizing. Reamer sizes include 14mm and 16mm concave and convex, and the cannulation ensures accuracy with each surgery.

The Hub Cap drill guide allows both fixed and 45° variable angle drilling. All instruments are quick release, and the appropriate drills are included with each screw diameter to ensure accuracy during the procedure. The plates are color-coded for quick identification; MCP Right is Green, MCP Left is Blue, the Hub Cap is Light Blue, Mini Hub 4-C is fuchsia, and the Mini Hub STT is Gold.



Modular Tray Design allows for future expansion. Corresponding drills and screws are housed in their own modular tray to eliminate possible confusion in the O.R.



Small Joint Reamers streamline fusion procedures and provide congruent joint surfaces. The reamers are cannulated for accurate placement.



Color Coded implants for quick identification.

HUB CAP™ SURGICAL TECHNIQUE

by Miguel Pirela Cruz, M.D.

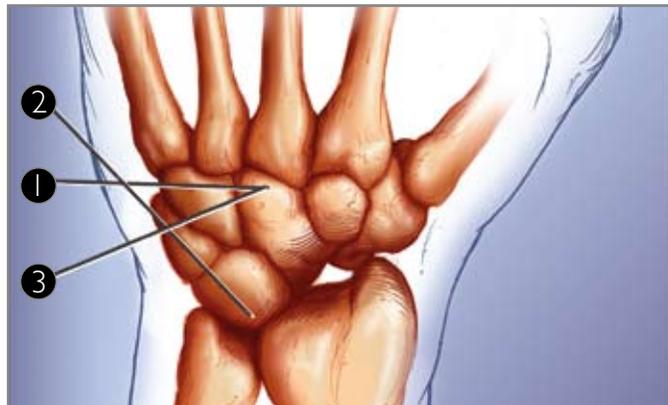
This section offers Acumed's suggested method for implanting the Hub Cap Limited Wrist Fusion Plate from the Acumed Modular Hand System. For specific questions not addressed here, please contact your local Acumed representative or Acumed by phone at 888 627-9957 or on the web at www.acumed.net.



Step 1: Create an entry site.

Create an entry site central to the dorsal wrist, taking care to avoid the radial and ulnar nerves. Either a dorsal midline longitudinal or T-incision may be used.

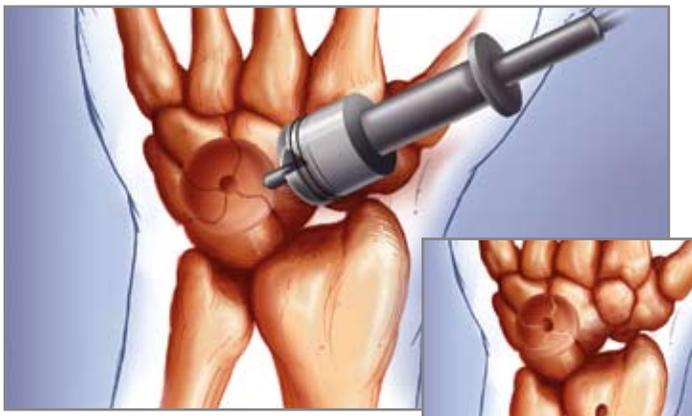
In cases where scaphoidectomy is called for, care should be taken to protect the extrinsic ligaments while removing the scaphoid. Radial styloidectomy may be required as well.



Step 2: Fix carpals with K-wires.

After exposing the capitate, lunate, hamate, and triquetrum, denude the cartilage between the four bones involved in the fusion. Provisionally fix the bones with .045" K-wires as volar as possible. Suggested order for K-wires: 1) Hamate to Capitate, 2) Triquetrum to Lunate, 3) Triquetrum to Capitate.

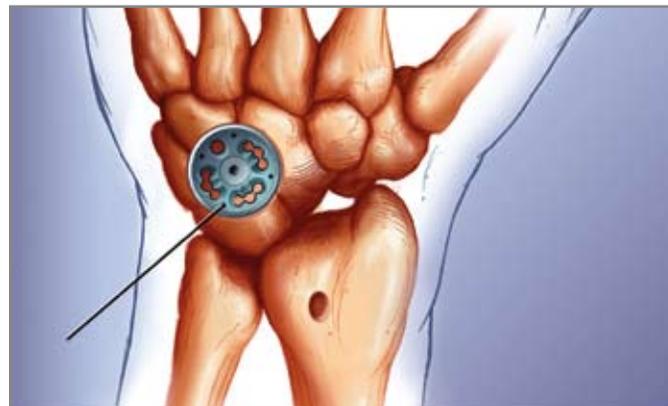
Neutral alignment along the capitulunate axis is crucial for obtaining unimpinged flexion once the wrist has fused. A K-wire joystick may be used to aid in the dorsal rotation of the lunate.



Step 3: Ream the carpals and pack the fusion site with autograft.

Center the reamer (PL-SR40) over the junction of the four carpals, targeting the center with the guide tip of the reamer. If using the Mini Hub 4-C, use the Mini Hub 4-C/STT Reamer Assembly (PL-SR30). Under power; ream until the dorsal surface of the carpals lies between the two lines on the reamer head. This, along with placing the plate into the recess to check for prominence, ensures a sufficient plate depth below the dorsal surface of the carpals.

The reamer will capture bone debris as it cuts, keeping the fusion site clear and providing a possible source of bone graft material. The bone graft harvester (PL-BG07) from the system may also be used to harvest autogenous bone from the distal radius or iliac crest. Pack the autograft into the reamed depression targeting the joint surfaces to be fused.



Step 4: Target the hamate and fix the plate with a K-wire.

Install the Plate Post (PL-WF50) into the center of the Hub Cap with the 2.5mm hex driver (HPC-0025). Place the Hub Cap into the depression and target the hamate with the single screw hole. Ensure that the placement of this first screw maximizes subsequent screw placement in the three other bones. When targeting, keep in mind that Acumed recommends a total of seven screws for this procedure: one in the single hole, and two for each of the scalloped slots, placed in the outer holes.

Fix the plate provisionally with a .035" K-wire(s) opposite the hamate to ensure its position. The K-wire(s) and Plate Post provide multiple points of provisional stabilization, securing the plate's position during drilling and screw insertion.



Step 5: Drill the hamate.

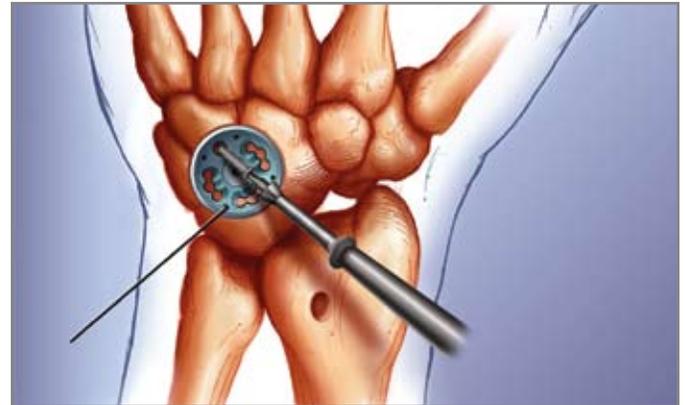
Using either end of the drill guide (PL-2127), drill into the hamate and measure depth. Holes should be drilled to within 2mm of the far cortex. Avoid bicortical drilling. Acumed recommends a total of seven screws for this procedure: one in the single hole, and two for each of the scalloped slots, placed in the outer holes.

Screw placement ranges:

Single hole: 50° vertical and 40° horizontal

Scalloped slot: 33° vertical and 50° horizontal

Tip: While 2.1mm screws (CO-F21XX) are available, Acumed recommends using the 2.7mm screws (CO-F27XX) and the accompanying drills and taps within the system. 2.1mm screws require a 1.5mm drill (MS-DC15). 2.7mm screws require a 2.0mm drill (MS-DC5020).

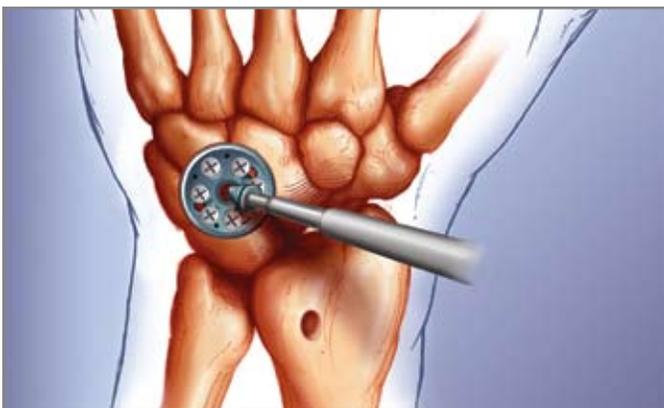


Step 6: Insert hamate screw and target lunate.

Measure drill depth and determine screw length with the depth gauge (MS-1030). Insert the first screw with the cruciform screw driver (MS-2213). Use the longest screws possible for maximum fixation. After inserting first screw, target lunate for next screw, drill, and insert. With two screws and the Plate Post as fixation, the plate is now stable enough to remove the .035" K-wire(s) that had been used to provisionally stabilize the plate.

Tip: In the case that a rescue solution is needed:

1. Redrill at a different angle
2. Place a 3rd screw into the middle scallop
3. Secure the screw with the screw cap (PL-WF60)
4. If using a 2.1mm screw, replace with a 2.7mm screw



Step 7: Insert remaining screws and remove plate post.

Using the same process, drill and insert screws into the remaining holes. Tighten all of the screws to ensure compression of the joint surfaces and promote fusion of the carpals.

Recommended screw insertion order is: 1) Hamate, 2) Lunate, 3) Capitate, 4) Triquetrum. Fill the remaining holes in any order.

The Plate Post may then be removed with the 2.5mm hex driver (HPC-0025) contained in the system, allowing autograft to be packed in the central plate hole.



Step 8: Assess final fixation.

View fixation under fluoroscopy to ensure proper placement and test range of motion. Optional: Secure screws and autograft with the screw cover (PL-WF60) by inserting it into the central plate hole.

Post-Op Protocol

After closure, place arm in a bulky volar splint that immobilizes the wrist in a neutral position and elbow at 90°, yet enables early movement of the fingers. In approximately one week, remove sutures and replace medium splint with a removable short arm splint to allow an early range of motion and rehabilitation. Splint should be used for three to four weeks. Periodic radiographs should be taken to check fusion of the four carpals. Normal activities may be resumed after fusion is determined to be successful.

STT FUSION SURGICAL TECHNIQUE

By John W. Deitrich, M.D.

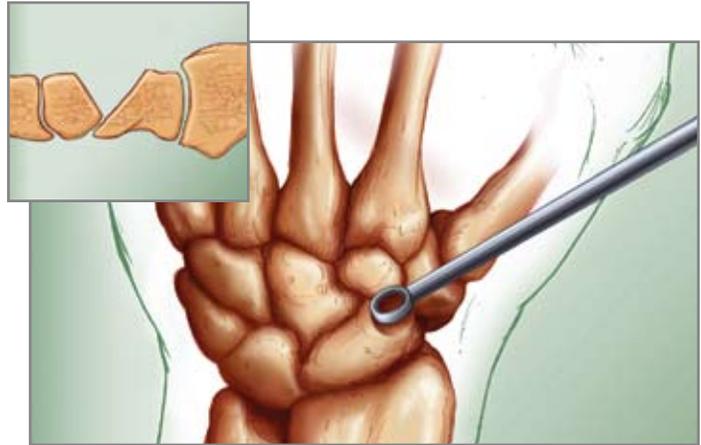
This section offers Acumed's suggested method for implanting the MCP Fusion Plate from the Acumed Modular Hand System. For specific questions not addressed here, please contact your local Acumed representative or Acumed by phone at 888 627-9957 or on the web at www.acumed.net.



Step 1: Exposure.

A dorsal approach to the scaphotrapezium-trapezoid (STT) joint is utilized. A longitudinal and curvilinear incision is made just radial to Lister's tubercle and extends distally. The incision can be extended proximally to allow access to the distal radius for supplemental bone graft.

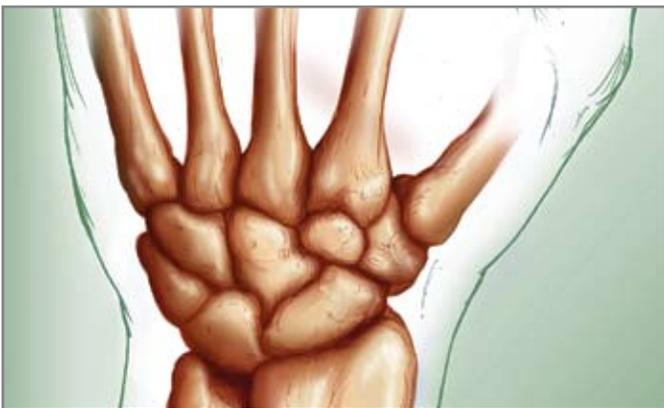
With this approach, it is important to avoid branches of the radial sensory nerve, lateral antebrachial cutaneous nerve, the deep branch of the radial artery and the extensor pollicis longus tendon.



Step 2: Prepare the joints for fusion.

The articular cartilage between the STT joints is removed in a V-shaped fashion. This is accomplished by removing more bone/cartilage dorsally while the volar attachment of these joints is left intact.

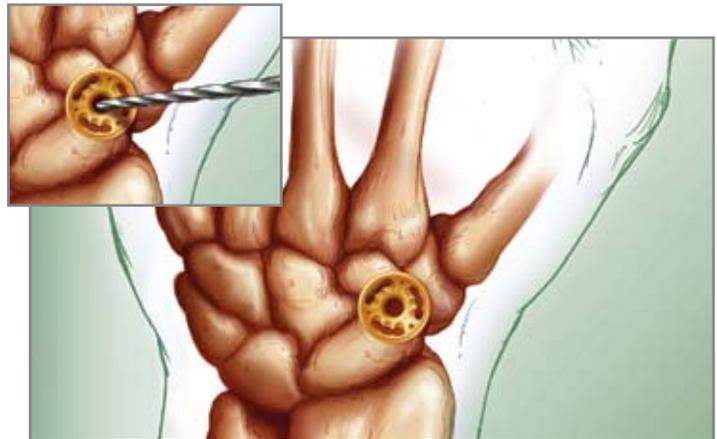
Supplemental bone graft is then packed and tamped into the interstices of the fusion site. The bone graft harvester from the system (PL-BG07) may be used to harvest autograft. This 7mm drill simultaneously harvests and morsellizes the bone.



Step 3: Fix carpals with K-wires.

The position of the fusion is now determined. Usually, any palmar flexion of the scaphoid needs to be corrected.

Preliminary fixation of the carpals is accomplished using .045" or .059" K-wires found in the Modular Hand System. The wrist is then put through a range of motion to see the impact this has on flexion, extension and radial and ulnar deviation. If significant impairment in the range of motion in any of these directions is noted, the K-wire fixation is readjusted.



Step 4: Provisional plate placement.

Correct placement of the Mini Hub STT is critical. Incorrect placement of the plate can impede range of motion and may not allow adequate screw placement. Care must be taken that the ulnar aspect of the plate does not abut the capitate. Before inserting the Plate Post (PL-WF50), the Mini Hub STT (PL-WF33) is placed at the fusion site. The placement is adjusted so that maximum coverage of all three bones is assured. The center of the plate is then marked with a small drill or burr to guide the Mini Hub 4-C/STT Reamer Assembly (PL-SR30).

Prepare the Mini Hub STT for insertion by threading the Hub Cap Plate Post (PL-WF50) into the center hole.

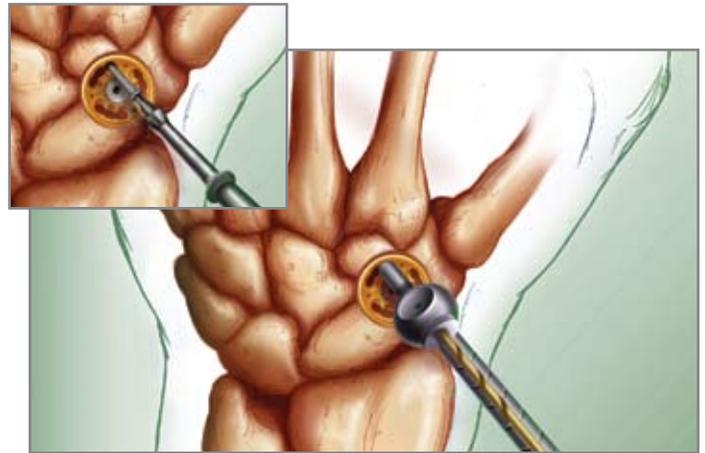
NOTE: To get two screws into each of the three bones, the outside holes of the scallops must be used.



Step 5: Prepare the site for the Mini Hub STT.

When using the Mini Hub STT it is essential that the Mini Reamer Assembly (PL-SR30) be used. If the Mini Reamer is not pre-assembled, remove the Standard Reamer Head (PL-SR39) using the blue triangular wrench (PL-SR41). Thread the Mini Reamer Head (PL-SR29) onto the shaft until finger tight. **DO NOT TIGHTEN WITH THE FINGER WRENCH.**

The reamer drill tip is now placed at the location marked in Step 4. Under power, or by hand, the three carpal bones are reamed until the first laser mark on the reamer is buried in all three bones. This, along with placing the plate into the recess to check for prominence, ensures a sufficient plate depth below the dorsal surface of the carpals.



Step 6: Plate placement and screw insertion.

Insert the plate, confirm proper depth, and rotate to target the three carpal bones. If two screws cannot be placed in all three bones, the trapezoid, which is the most stable, may be secured with only one screw.

Drill the first hole in the trapezoid with the 2.0mm drill (MS-DC5020) through the freehand end of the drill guide (PL-2127). Measure drill depth with the depth gauge (MS-1030). A 2.7mm screw (CO-F27XX) is inserted with the cruciform screw driver (MS-2213), but not fully tightened. Place the second screw opposite the first, most often in the radial aspect of the scaphoid, and tighten these two screws alternately to seat the plate. The remaining screws are then placed with two screws in the scaphoid, two in the trapezium and at least one in the trapezoid.

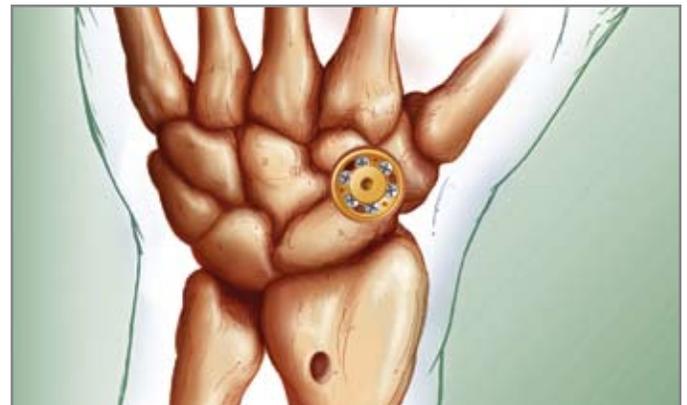


Step 7: View, post removal, cover insertion and closure.

Once all screws are placed, the construct is viewed from multiple angles under fluoroscopy to ensure that no screws enter into the first CMC joint or interfere with the SC articulation.

The Hub Cap Plate Post (PL-WF50) is now removed allowing bone graft to be packed in the central hole of the plate. The optional Hub Cap Screw Cover (PL-WF60) may be threaded into the central hole to hold the screws and bone graft in position.

The wound is then closed in standard fashion with closure of the capsule overlaying the plate. The retinaculum and skin are closed in the manner preferred by the individual surgeon.



Post-op Protocol:

Post-op the patient is placed in a thumb spica splint.

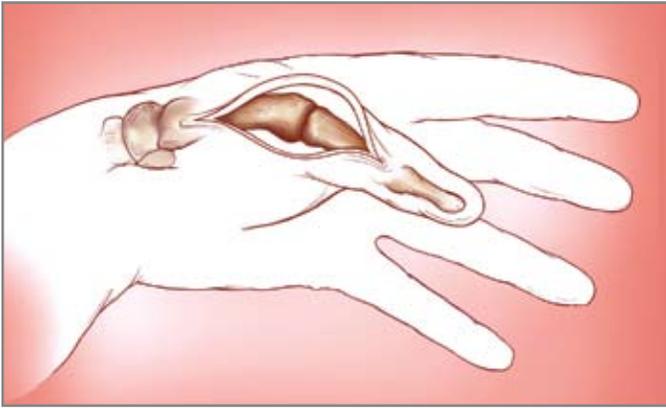
At approximately two weeks the patient is placed in a thumb spica cast. Radiographic union usually occurs between eight to twelve weeks. Use of an external bone stimulator during this time can be a significant adjunct to insure union. Should there be any question of whether union has occurred a CT scan can be obtained.

Once the surgeon feels union has been accomplished, the patient can begin mobilization. The use of a removable splint as well as occupational therapy is highly recommended to achieve a functional range of motion and grip strength.

MCP FUSION SURGICAL TECHNIQUE

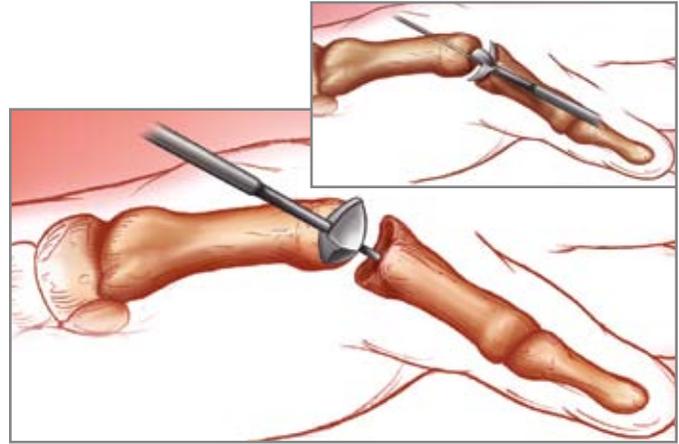
by Miguel Pirela Cruz, M.D.

This section offers Acumed's suggested method for implanting the MCP Fusion Plate from the Acumed Modular Hand System. For specific questions not addressed here, please contact your local Acumed representative or Acumed by phone at 888 627-9957 or on the web at www.acumed.net.



Step 1: Create entry site.

Create an entry site using a dorsal midline approach to the metacarpophalangeal joint. Continue the dissection sharply on the radial and ulnar aspects of the joint, excising the collateral ligaments and creating exposure to the joint.



Step 2: Decorticate joint surfaces.

Drive a .059" K-wire from the system through each bone to act as a guide for the reamers. While the wire for the proximal phalanx should be driven centrally, the wire for the metacarpal should be driven obliquely at an angle equal to the desired angle of flexion. This should begin centrally and exit through the dorsal midline of the metacarpal.

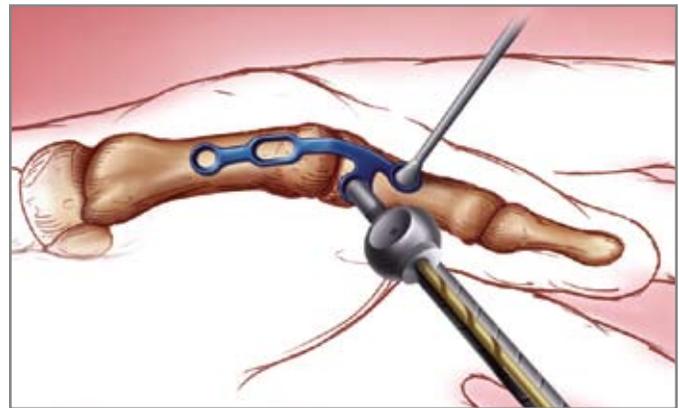
Decorticate the articular surfaces of the joint using the cannulated concave/convex reamers within the system. This creates a complementary surface for the fusion with minimal shortening of the thumb. Prior to reaming, the ligaments should be released completely to maximize access and minimize any risk to the soft tissues.



Step 3: Secure plate to proximal phalanx.

If necessary, contour plate to desired angle of flexion. The plate comes precontoured with a 25° angle.

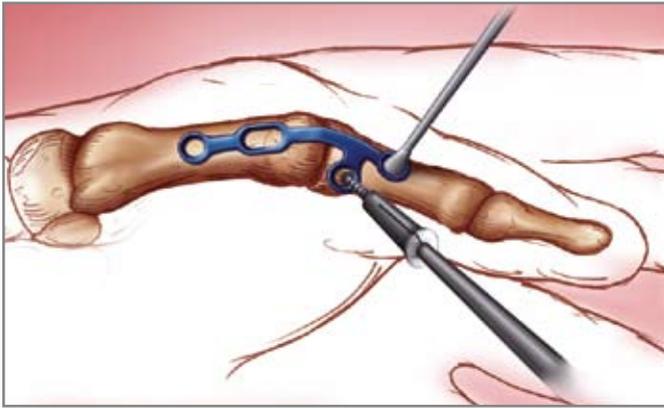
Secure the plate to the proximal phalanx using the Plate Tack (PL-PTACK) in the most distal hole and check flexion.



Step 4: Drill the first hole.

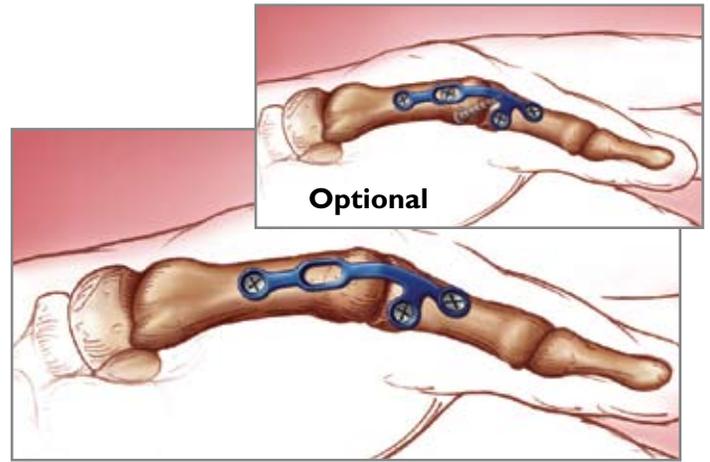
Using the freehand end of the drill guide (PL-2127), drill the proximal phalangeal hole of the plate. Measure the depth of the hole with the depth gauge (MS-1030) and note the appropriate screw size that will sufficiently engage both cortices.

Tip: 2.1mm (CO-F21XX) screws require a 1.5mm drill (MS-DC15). 2.7mm screws (CO-F27XX) require a 2.0mm drill (MS-DC5020).



Step 5: Insert the first screw. Repeat process for second.

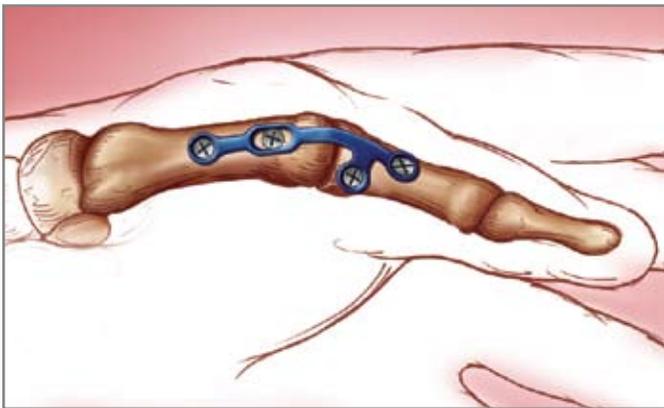
Insert the appropriate screw through the plate with the cruciform screw driver (MS-2213) and into the bone. Remove the Plate Tack. Repeat the drill and insertion process for the distal hole.



Step 6: Compress the joint, drill holes, and insert screws.

While maintaining compression across the MCP joint, place the proximal portion of the plate along the radial side of the metacarpal. Drill and measure as before, inserting the proximal screw and then the distal.

Option: If greater compression is desired, a compression screw may be inserted obliquely from the medial side of the metacarpal across the fusion site and into the proximal phalanx.



Step 7: Pack the fusion site with autograft.

After securing the plate to the metacarpal, insert a small amount of bone graft into the vicinity of the fusion mass. Ensure that the interphalangeal joint of the thumb is unrestricted in its motion and repair the extensor tendons. After closing, a sterile dressing and a protective dorsal splint are applied.



Post-op Protocol:

In approximately one week the patient is placed in a thumb spica splint and referred to therapy. In therapy, a strong emphasis is placed on an early range of motion for both the interphalangeal and carpometacarpal joints. The thumb spica splint is discontinued in four to six weeks after the patient is relatively comfortable.

ORDERING INFORMATION

Implants (Titanium)

| | |
|---------|---|
| PL-WF40 | Hub Cap™ Limited Wrist Fusion Plate |
| PL-WF44 | Mini Hub 4-C Limited Wrist Fusion Plate |
| PL-WF33 | Mini Hub STT Limited Wrist Fusion Plate |
| PL-WF50 | Hub Cap Plate Post |
| PL-WF60 | Hub Cap Screw Cover |
| PL-MCPL | MCP Fusion Plate - Left |
| PL-MCPR | MCP Fusion Plate - Right |



Screws (Titanium)

| | |
|----------|-------------------------|
| CO-F2106 | 2.1mm x 6mm Bone Screw |
| CO-F2108 | 2.1mm x 8mm Bone Screw |
| CO-F2110 | 2.1mm x 10mm Bone Screw |
| CO-F2112 | 2.1mm x 12mm Bone Screw |
| CO-F2114 | 2.1mm x 14mm Bone Screw |
| CO-F2116 | 2.1mm x 16mm Bone Screw |
| CO-F2706 | 2.7mm x 6mm Bone Screw |
| CO-F2708 | 2.7mm x 8mm Bone Screw |
| CO-F2710 | 2.7mm x 10mm Bone Screw |
| CO-F2712 | 2.7mm x 12mm Bone Screw |
| CO-F2714 | 2.7mm x 14mm Bone Screw |
| CO-F2716 | 2.7mm x 16mm Bone Screw |



Instrumentation

| | |
|-----------|---------------------------------------|
| WF-0000 | Tray Set & Instruments (No Implants) |
| PL-SR39 | Hub Cap Reamer Replacement Head |
| PL-SR40 | Hub Cap Reamer Assembly |
| PL-SR29 | Mini Hub 4-C/STT Reamer Head Spare |
| PL-SR30 | Mini Hub 4-C/STT Reamer Head Assembly |
| PL-SR41 | Hub Cap Reamer Head Wrench |
| PL-BG07 | Bone Graft Harvester |
| MTP-F014 | 14mm Concave Joint Reamer |
| MTP-M014 | 14mm Convex Joint Reamer |
| MTP-F016 | 16mm Concave Joint Reamer |
| MTP-M016 | 16mm Convex Joint Reamer |
| PL-2127 | 2.1/2.7mm Drill Guide Assembly |
| MS-DC15 | 1.5mm Quick Release Drill |
| MS-DC5020 | 2.0mm Quick Release Drill |
| MS-1210 | Quick Release Handle |
| HPC-0025 | 2.5mm Quick Release Driver |
| PL-PTACK | Plate Tack |
| MS-2213 | Cruciform Driver Tip |
| MS-47959 | Cruciform Driver Sleeve |
| MS-2210 | Cruciform Driver Handle |
| WS-0906ST | .035" Guide Wire Stainless Steel |
| WS-1106ST | .045" Guide Wire Stainless Steel |
| WS-1505ST | .059" Guide Wire Stainless Steel |





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Patent pending.

MHS00-01-A

Effective: 11/2008