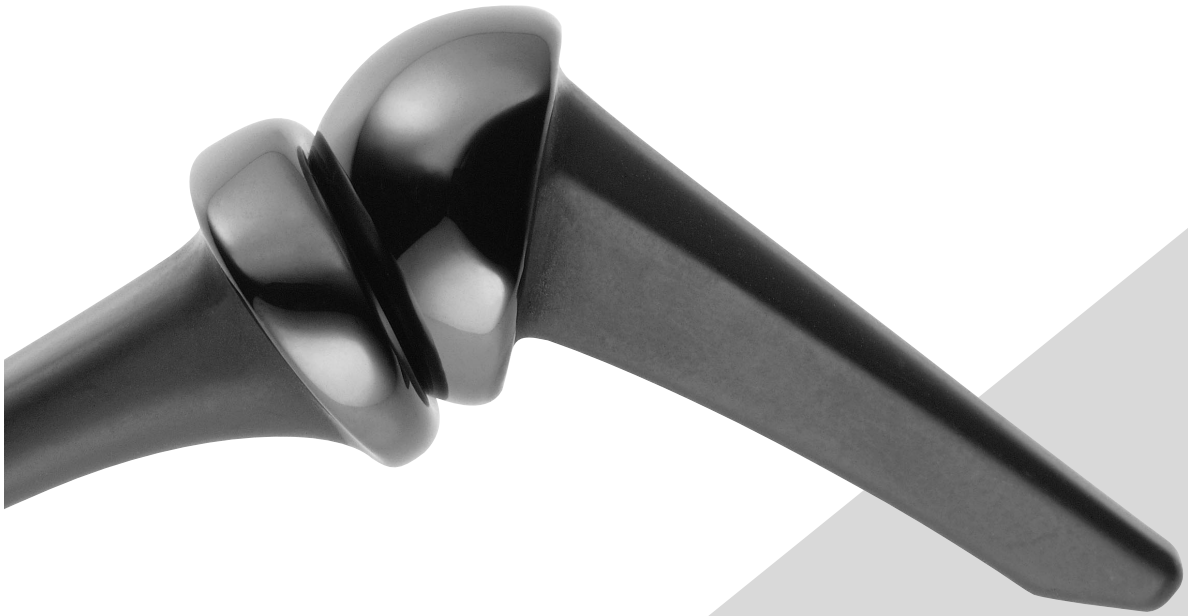
Ascension® MCP

surgical technique



surgical technique Ascension® MCP PyroCarbon Total Joint

Ascension Orthopedics

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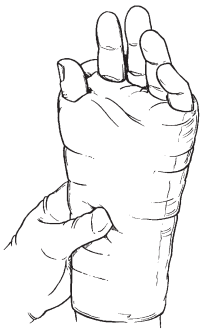
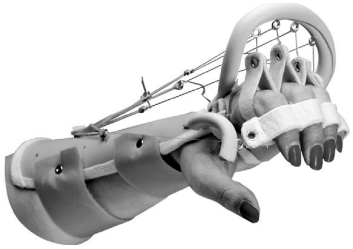
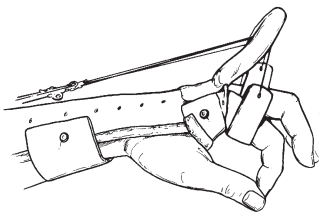






2.0 Introduction

This manual describes the sequence of techniques and instruments used to implant the Ascension® MCP (**FIGURE 2.1**). The surgical technique and instruments have been developed to assist in achieving correct surgical placement. Successful use of this implant depends on the proper patient selection, surgical technique, and post-operative therapy. The post-operative rehabilitation protocol is described in a separate brochure, but is essential to a good surgical outcome.

If questions arise, or a Post-Operative Therapy Protocol brochure is needed, please contact **Ascension Orthopedics** at **877-370-5001 (toll-free)** or e-mail us at **customerservice@ascensionortho.com.**

FIGURE 2.1 – Ascension® MCP

Metacarpal Component (PROXIMAL)

Phalangeal Component (DISTAL)

3.0 Ascension® MCP Implants

The Ascension® MCP is a metacarpophalangeal total joint replacement consisting of separate proximal and distal components. The proximal component replaces the metacarpal head and the distal component replaces the base of the proximal phalanx. It is available in five sizes (**FIGURE 3.1**). Intramedullary stems stabilize both components. Components are implanted using a press-fit technique. Guided osteotomies are made first to the metacarpal head and then the phalangeal base. Next the medullary canals are progressively broached to the desired size. The phalanx is broached first because it generally determines the sizing of the implant. Trial implants are then inserted, and the joint is reduced. Once the trial reduction is satisfactory, the trial implants are removed, and the final implants are impacted into place.

FIGURE 3.1

SIZE	CATALOG NUMBER
10	MCP-100-10
20	MCP-100-20
30	MCP-100-30
40	MCP-100-40
50	MCP-100-50

4.0 Instrumentation for MCP Arthroplasty

FIGURE 4.1 — INS-100-00 Ascension® MCP Instrument Set

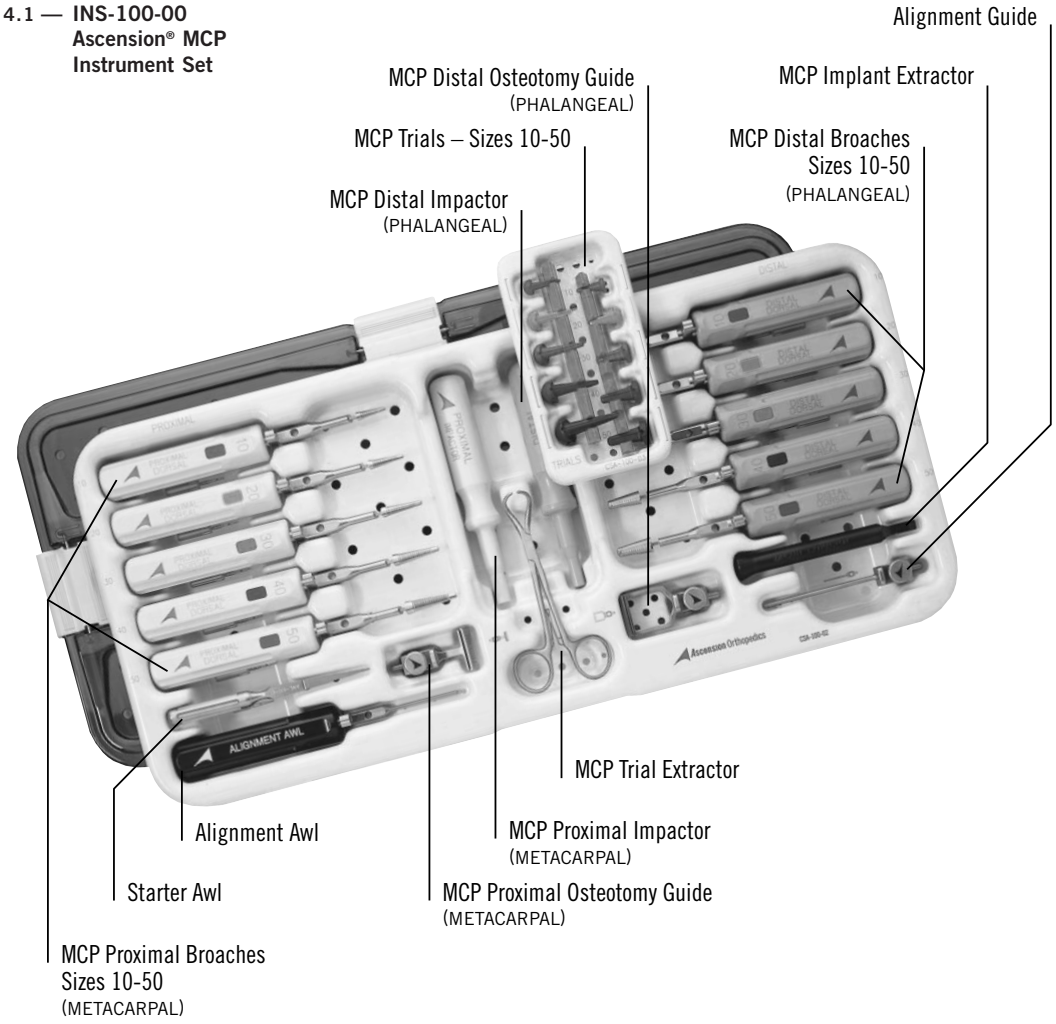
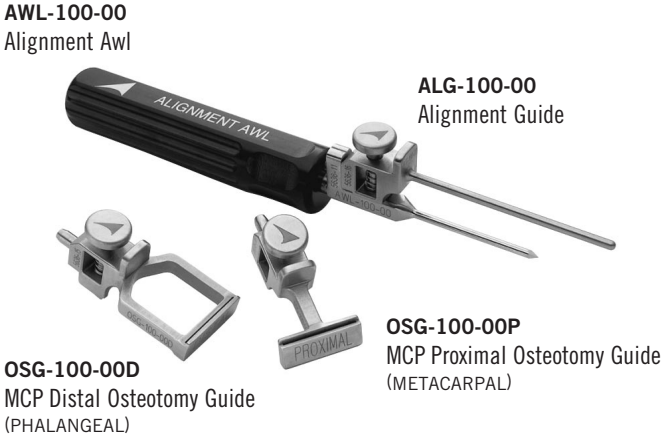


FIGURE 4.2 — Alignment Awl, Alignment Guide and Osteotomy Guides

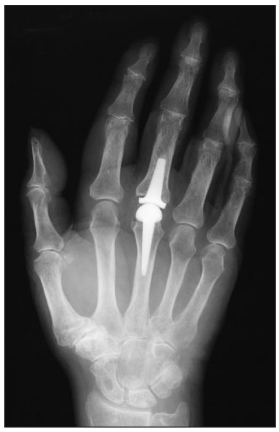


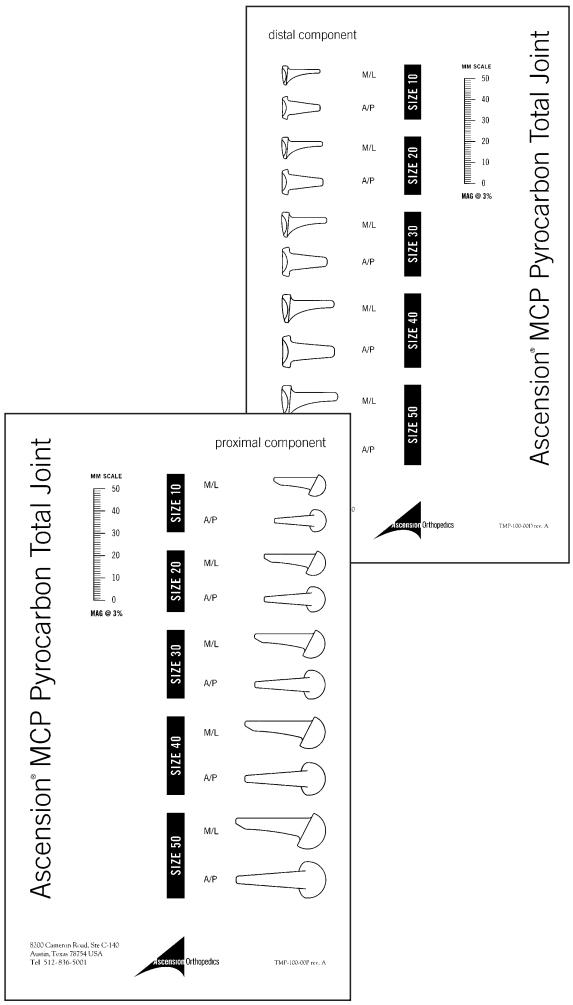
5.0 Pre-Operative Assessment

Ascension® MCP implant arthroplasty is appropriate for use in patients with osteo- and posttraumatic arthritis with nearly normal soft tissue envelopes. In patients with rheumatoid arthritis, soft tissue imbalance may be more severe, and the surgeon must determine that correction of volar subluxation deformities and ulnar deviation deformities can be achieved with standard MCP reconstruction techniques. Standard AP, lateral and oblique x-rays can be used to template the size of the implant likely to be required at surgery (**FIGURE 5.1**). The templates are 3% magnified approximating the standard magnification of most routine x-ray techniques. Note that digital (electronic) x-ray magnification may be quite variable and the surgeon should consult with the x-ray technician/radiologist to assure usefulness of the templates.

The largest Ascension® MCP (Size 50) implant should be large enough for the largest hand (**FIGURE 3.1**). The smallest implant (Size 10) however, may be too large in patients with juvenile rheumatoid arthritis and alternative treatment options should be considered in these cases. In patients with severe intercarpal supination and radial deviation of the wrist, ulnar deviation of the digits may not be correctable with soft tissue surgery, and in these instances, it is recommended that corrective wrist surgery be performed first at a separate setting.

FIGURE 5.1 — X-ray Templates





6.0 Surgical Technique

6.1 Initial Incision and Joint Exposure

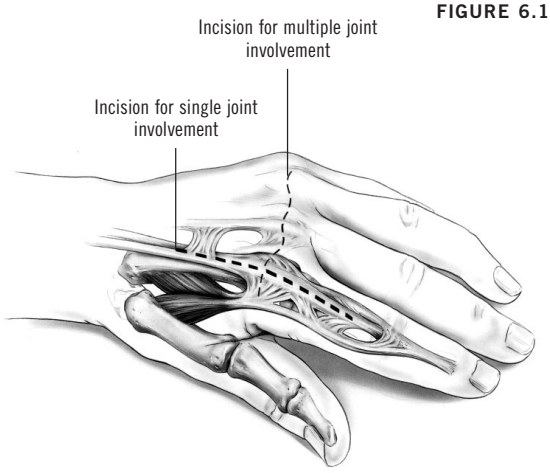
For single joint involvement:

A longitudinal incision is made over the dorsum of the metacarpophalangeal (MCP) joint (**FIGURE 6.1.1**).

For multiple joint involvement:

A curving transverse incision across the dorsum of the MCPs is recommended when multiple joints are involved (**FIGURE 6.1.1**). The extensor hood is incised on the radial side of the central tendon or through its center if no dislocation/subluxation of the tendon is present. Attempts are made to dissect the extensor tendon free from the joint capsule radially and ulnarly. This may not be possible in advanced disease. The capsule is split longitudinally and dissected to expose the joint, preserving the capsule as much as possible for later repair. The dissection should be continued so that the dorsal base of the proximal phalanx and the metacarpal head with the collateral ligament origins are visualized.

FIGURE 6.1.1



6.2 Opening the Metacarpal Medullary Canal

The starter awl is used to make the initial puncture of the metacarpal head (**FIGURE 6.2.1**). This puncture should be placed volar to the dorsal surface of the metacarpal head a distance one-third the sagittal height of the head and centered across the width of the head (**FIGURE 6.2.2**). The resulting puncture should be aligned with the long axis of the metacarpal's medullary canal.

FIGURE 6.2.1

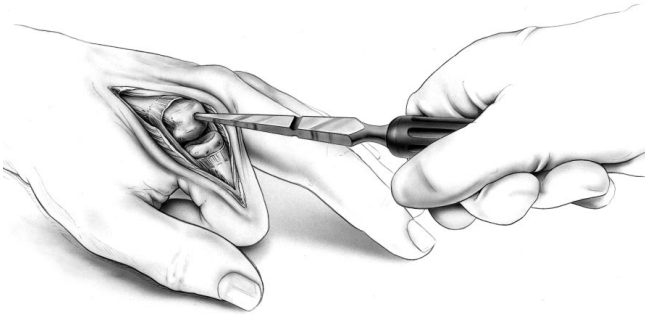
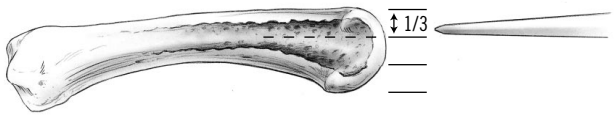


FIGURE 6.2.2



6.3 Establishing Metacarpal Medullary Canal Alignment

Attach the alignment guide to the alignment awl, (**FIGURE 4.2**) insert the alignment awl into the puncture (**FIGURE 6.3.1**) and advance it into the medullary canal one-half to two-thirds the length of the metacarpal (**FIGURE 6.3.2**). With the alignment guide mounted on the alignment awl it is possible to sight between the guide rod and the dorsal surface of the metacarpal. The alignment guide should be parallel to the dorsal surface of the metacarpal and in line with the long axis of the bone.

FIGURE 6.3.1

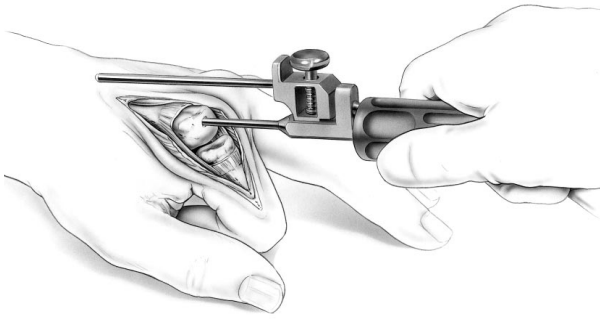
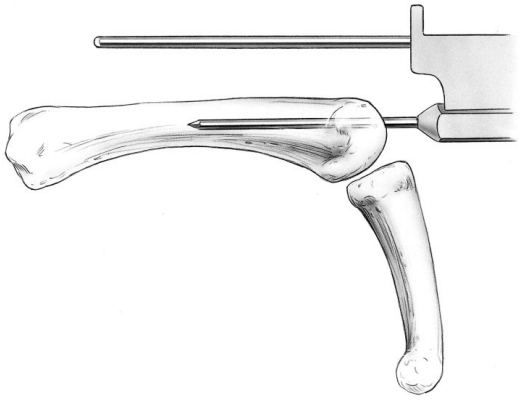


FIGURE 6.3.2



6.4 Metacarpal Osteotomy

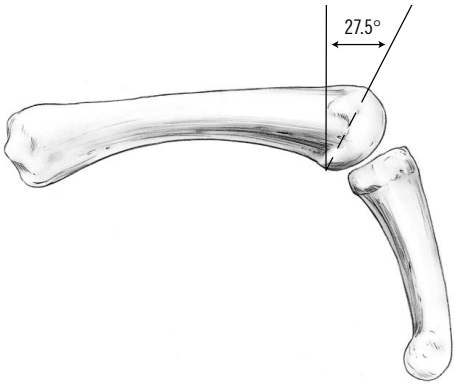
The metacarpal head osteotomy is made in two steps:

Step 1: A guided partial osteotomy is made using the proximal osteotomy guide mounted on the alignment awl.

Step 2: The osteotomy is completed free hand by following the previously established osteotomy plane.

Attach the proximal osteotomy guide (**FIGURE 4.2**) on the alignment awl along the previously established medullary axis. The osteotomy guide is advanced until the cutting plane of the guide is positioned 1.0 to 2.0 mm distal to the dorsal attachments of the collateral ligaments. The osteotomy guide provides a 27.5° distal tilt from vertical (**FIGURE 6.4.1**). Rotational alignment of the osteotomy guide is achieved when the volar surface of the guide is parallel to the dorsal surface of the metacarpal bone.

FIGURE 6.4.1



6.4 Metacarpal Osteotomy
CONTINUED

NOTE:

It is strongly recommended that, initially, a conservative osteotomy be made and then altered later. This allows for joint space adjustment during the fitting of the trial implants (see section 6.10). A conservative osteotomy is considered generally to be at least 1.5mm distal to the dorsal attachments of the collateral ligaments.

SPECIAL THIN BLADE REQUIREMENTS:

It is strongly recommended when performing the osteotomy that a small oscillating saw blade be used (7mm x 29.5mm x 0.4mm).

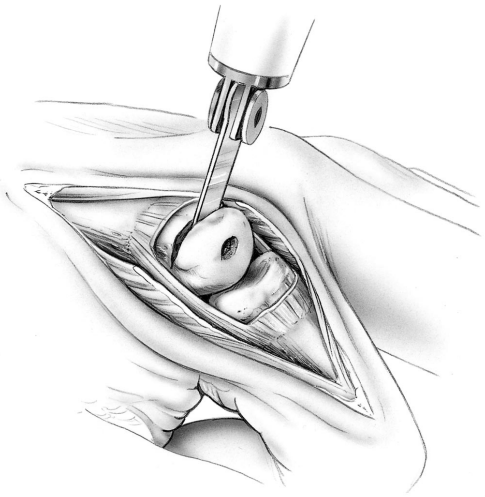
With the metacarpal cutting guide held steady the cut is performed by passing the saw blade of a small sagittal saw through the blade slot of the cutting guide (**FIGURE 6.4.2**). **The collateral ligaments' integrity should be retained as far as possible.** Because of the presence of the intramedullary rod of the alignment awl only a partial (dorsal) osteotomy can be performed with the cutting guide in place.

Completing the Osteotomy

Remove the alignment awl and complete the osteotomy by following the plane established by the guided cut (**FIGURE 6.4.3**).

FIGURE 6.4.2

FIGURE 6.4.3



6.5 Opening the Phalangeal Medullary Canal

With the joint flexed, the starter awl is used to make the initial puncture of the proximal phalangeal base (**FIGURE 6.5.1**).

CAUTION:

The joint must be flexed to avoid damage (by impingement) to the dorsal edge of the metacarpal osteotomy (**FIGURE 6.5.2**).

This puncture should be placed volar to the dorsal surface of the proximal phalanx a distance one-third the sagittal height of the proximal phalangeal base and centered across the width of the base. The resulting puncture should be aligned with the long axis of the proximal phalangeal's medullary canal (**FIGURE 6.5.2**).

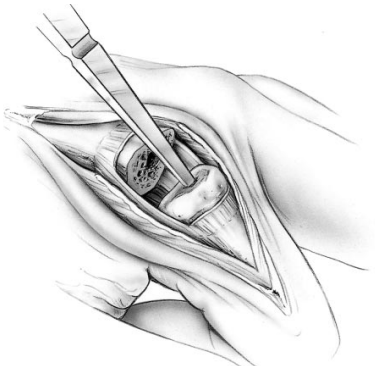


FIGURE 6.5.1

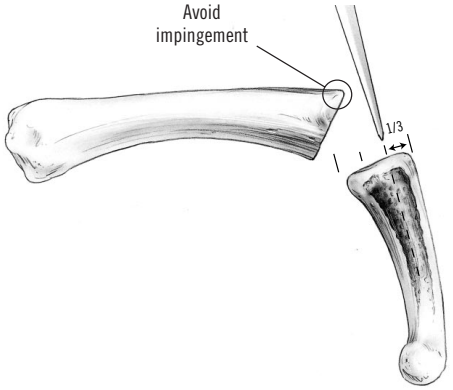


FIGURE 6.5.2

6.6 Establishing Phalangeal Medullary Canal Alignment

With the joint flexed, insert the alignment awl in the puncture and advance it into the phalangeal medullary canal one-half to two-thirds the length of the phalanx (**FIGURE 6.6.1**).

CAUTION:

The joint must be flexed to avoid damage (by impingement) to the dorsal edge of the metacarpal osteotomy (**FIGURE 6.6.2**).

With the alignment guide mounted on the alignment awl it is possible to sight between the guide rod and the dorsal surface of the phalanx. The alignment guide should be parallel to the dorsal surface of the phalanx and in line with the long axis of the bone.

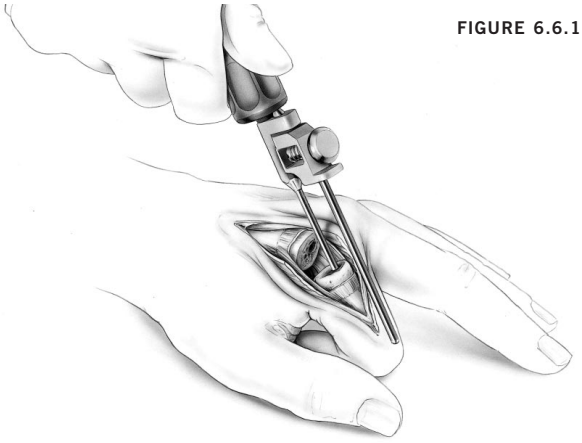


FIGURE 6.6.1

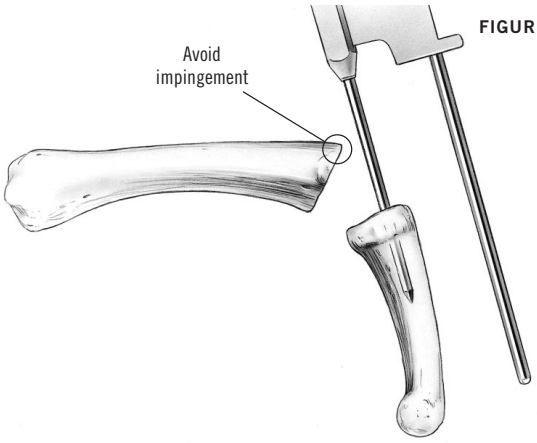


FIGURE 6.6.2

6.7 Phalangeal Osteotomy

The phalangeal base osteotomy is made in two steps:

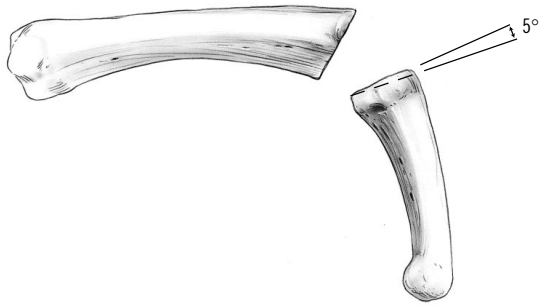
Step 1: A guided partial osteotomy is made using the distal osteotomy guide mounted on the alignment awl.

Step 2: The osteotomy is completed free hand by following the previously established osteotomy plane.

CAUTION:

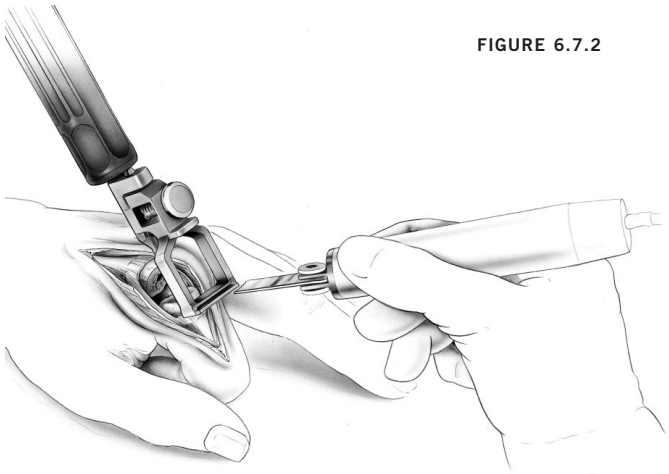
The joint must be flexed to avoid damage (by impingement) to the dorsal edge of the metacarpal osteotomy (**FIGURE 6.7.1**).

FIGURE 6.7.1



Attach the distal osteotomy guide on the alignment awl and reinsert the awl along the previously established medullary axis. The osteotomy guide is advanced until the cutting plane of the guide is positioned 0.5 to 1.0 mm distal to the dorsal edge of the proximal phalanx. Note that the osteotomy guide is tilted 5° distally from vertical (**FIGURE 6.7.1**).

FIGURE 6.7.2

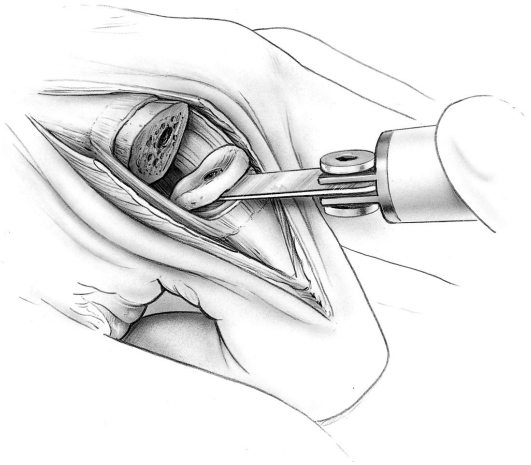


Rotational alignment of osteotomy guide is achieved when the volar surface of the guide is parallel to the dorsal surface of the phalanx.

NOTE:

It is strongly recommended that, initially, a conservative osteotomy be elected to allow the osteotomy level to be altered later. This allows for joint space adjustment during the fitting of the trial implants (see section 6.10). A conservative osteotomy generally removes only the joint's articular surface.

FIGURE 6.7.3



With the osteotomy guide held steady the cut is performed by passing the saw blade of a small sagittal saw through the blade slot of the osteotomy guide (**FIGURE 6.7.2**). **The collateral ligaments' integrity should be retained as far as possible.** Because of the presence of the intramedullary rod of the alignment awl, only a partial osteotomy can be performed with the osteotomy guide in place. The dorsal portion of the osteotomy can be completed with the guide in place.

Completing the Osteotomy

Remove the alignment awl and complete the osteotomy by following the plane established by the guided cut (**FIGURE 6.7.3**).

6.8 Phalangeal Medullary Canal Broaching

Broaches are provided in five color-coded sizes that correspond to color-coded trial and final implant sizes (**FIGURE 4.1**).

CAUTION:

The size of the phalangeal medullary canal is generally the limiting factor in implant size determination. Use clinical judgment and the x-ray templates to assess implant sizing.

Do not mismatch proximal and distal component sizes. For example, a size 10 proximal component should be matched with only a size 10 distal component. The wear behavior of mismatched proximal and distal component size combinations has not been evaluated, and is unknown.

Initially, the phalangeal opening is expanded and shaped with the starter awl. Then the size 10 distal broach is inserted along the previously established medullary axis (**FIGURE 6.8.1**). Rotational alignment of the broach is achieved when the dorsal surface of the broach is parallel to the dorsal surface of the phalangeal bone. Use of a side-cutting burr may be necessary to assist in proper seating of the broaches.

The alignment guide mounted on the broach should be parallel to the dorsal surface of the phalanx and in line with the long axis of the bone. Broaching continues until the seating plane of the broach is flush to 1mm deeper than the osteotomy (**FIGURE 6.8.2**). During broaching, assess fit and movement resistance. If a larger size is needed, repeat the broaching process with the next larger size broach until the largest size possible can be inserted and properly seated.

CAUTION:

The joint must be flexed to avoid damage (by impingement) to the dorsal edge of the metacarpal osteotomy (**FIGURE 6.8.2**).

FIGURE 6.8.1

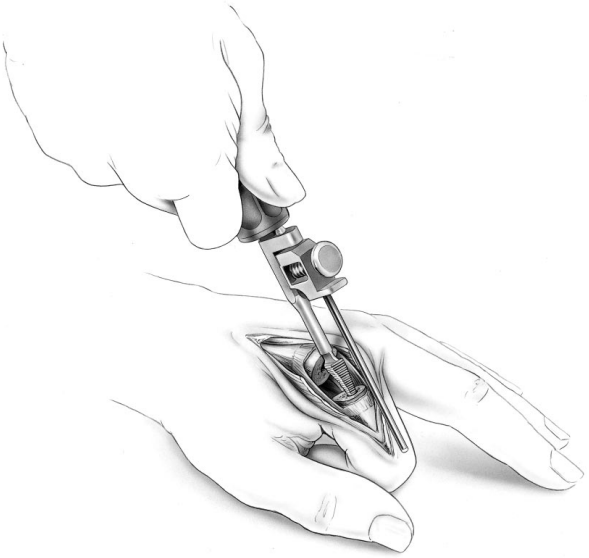
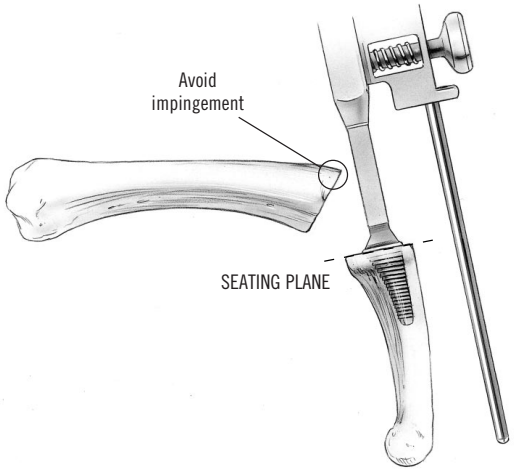


FIGURE 6.8.2



6.9 Metacarpal Medullary Canal Broaching

Generally the sizing from the phalangeal broaching process is used to determine metacarpal broach size selection. Broaches are provided in five color-coded sizes that correspond to color-coded trial and final implant sizes (**FIGURE 4.1**).

CAUTION:

The size of the phalangeal medullary canal is generally the limiting factor in implant size determination. Use clinical judgment to assess implant sizing.

Do not mismatch proximal and distal component sizes. For example, a size 10 proximal component should be matched with only a size 10 distal component. The wear behavior of mismatched proximal and distal component size combinations has not been evaluated, and is unknown.

Start with the size 10 proximal broach working up to the broach determined from the phalangeal broaching process (**FIGURE 6.9.1**). Insert the broach along the previously established medullary axis. Rotational alignment of the broach is achieved when the dorsal surface of the broach is parallel to the dorsal surface of the bone. The alignment guide mounted on the broach should be parallel to the dorsal surface of the metacarpal and in line with the long axis of the bone. Broaching continues until the seating plane of the broach is 1mm deeper than the osteotomy (**FIGURE 6.9.2**). During broaching, assess fit and movement resistance. Repeat the broaching process with the next larger size broach until the same size as the largest phalangeal broach is used. Do not mismatch proximal and distal component sizes. For example, a size 10 proximal component should be matched with only a size 10 distal component. The wear behavior of mismatched proximal and distal component size combinations has not been evaluated, and is unknown.

CAUTION:

The joint must be flexed to avoid damage (by impingement) to the dorsal edge of the proximal phalanx osteotomy (**FIGURE 6.9.2**).

FIGURE 6.9.1

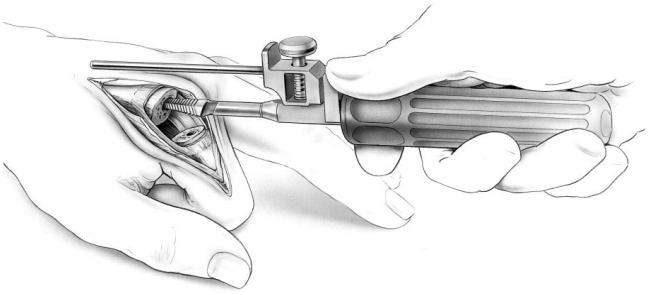
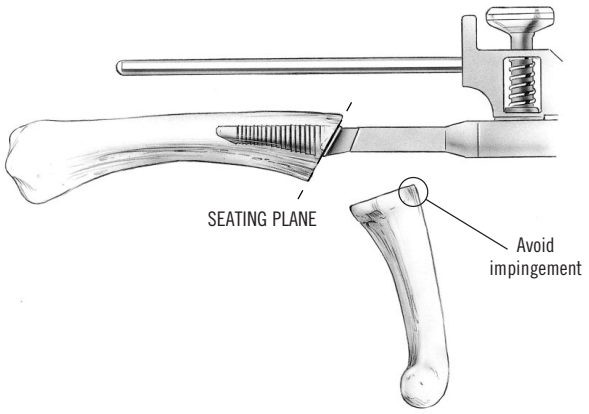


FIGURE 6.9.2



6.10 Trial Insertion and Reduction

With the joint flexed, insert and lightly impact the appropriate size (color-coded) distal trial implant with the distal impactor until the collar of the trial is flush with the phalangeal osteotomy (**FIGURE 6.10.1**). With the joint flexed, impact the appropriate size (color-coded) proximal trial with the proximal impactor until the collar of the trial seats against the metacarpal osteotomy (**FIGURE 6.10.2**). Reduce the joint and assess stability, joint laxity, and range of motion. Full extension of the joint should be possible.

NOTE:

To improve extension or relieve tension, increase the depth of the osteotomies to increase the joint space. Generally the metacarpal osteotomy should be adjusted first. The osteotomy guide is mounted on the appropriate broach and reinserted in the canal to make an adjustment cut. Remove bone in small increments to avoid joint laxity or instability. Reinsert the trials. Reduce the joint and assess stability, joint laxity, and range of motion.

NOTE:

The color-coded plastic trials produce a slightly looser fit with more friction than the final pyrocarbon components.

FIGURE 6.10.1

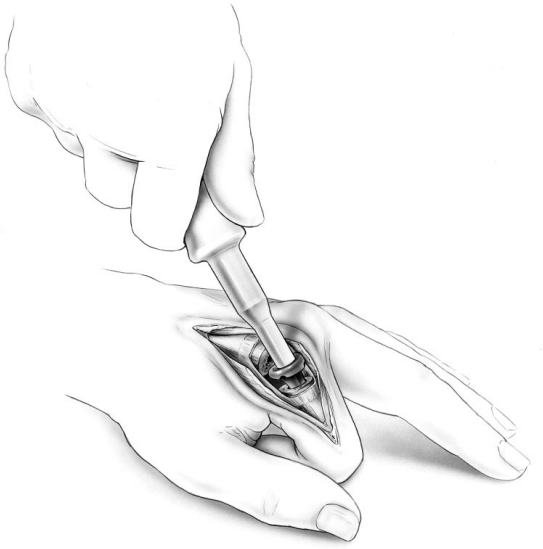
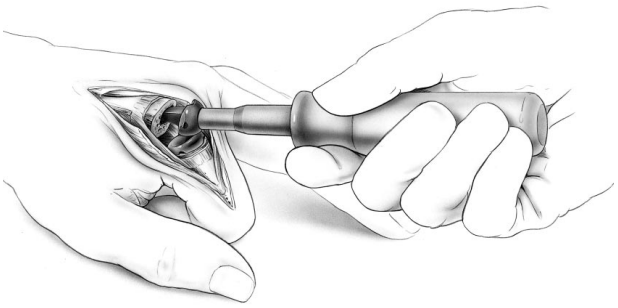


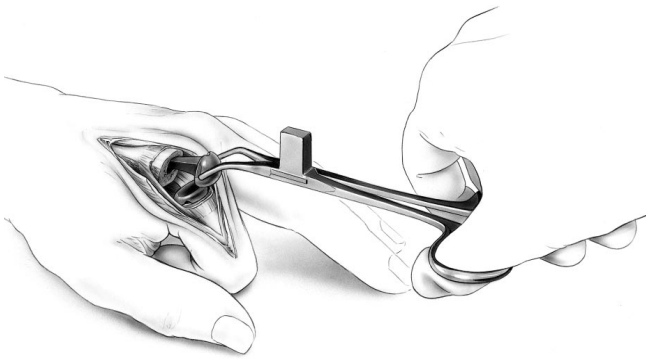
FIGURE 6.10.2



6.11 Removal of Trial Components

Use the trial extractor to remove the trials (proximal trial first), by inserting the two tongs of the extractor in the holes on the lateral sides of the trial heads (**FIGURE 6.11.1**).

FIGURE 6.11.1



6.12 Implantation of Ascension® MCP Components

With the joint flexed, insert and impact the appropriate size distal component with the distal impactor until the collar of the component is flush with the phalangeal osteotomy. Care must be taken to assure the correct axial rotation of the component by verifying that the dorsal surface of the component is parallel to the dorsal surface of the proximal phalanx.

WARNING:

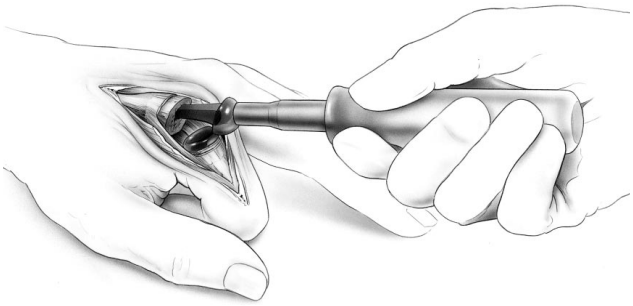
Do not modify the Ascension® MCP implant in any manner. Reshaping the implant using cutters, grinders, burrs, or other means will damage the structural integrity of the device and could result in implant fracture and/or particulate debris.

Do not mismatch proximal and distal component sizes. For example, a size 10 proximal component should be matched with only a size 10 distal component. The wear behavior of mismatched proximal and distal component size combinations has not been evaluated, and is unknown.

Do not grasp the Ascension® MCP implant with metal instruments, or instruments with teeth, serrations, or sharp edges. Implants should be handled only with instrumentation provided by Ascension Orthopedics. Ascension® MCP implants are made of pyrocarbon, which is a ceramic-like material. Mishandling implants could cause surface damage and reduce their strength, and could result in implant fracture and/or particulate debris.

Do not use Ascension® MCP components in combination with proximal and distal components from other products. The wear behavior of Ascension® MCP components against proximal and distal components from other products has not been evaluated, and could damage the structural integrity of the device and result in implant fracture and/or particulate debris.

FIGURE 6.12.1



With the joint flexed, insert and impact the mating proximal component with the proximal impactor until the collar of the component is flush with the metacarpal osteotomy (**FIGURE 6.12.1**).

6.13 Final Reduction and Soft Tissue Closure

Reduce the joint and recheck stability, joint axial alignment and range of motion (ROM) of the pyrocarbon components, which should mimic the performance of the trial components. Full digit extension should be possible. Check intrinsic tightness and release as necessary. As in all MCP surgery the goal is to centralize the extensor mechanism and imbricate it radially to prevent ulnar deviation of the digits. In addition to this implant surgery, the soft tissue envelope should be "tightened" to prevent volar subluxation/dislocation of the implant. To achieve this a capsular repair is attempted, if possible, to provide support. The collateral ligaments may be repaired as necessary (infrequent). The intrinsic tendons are released following implant reduction as appropriate and may be transferred according to the surgeon's preference (rarely needed). The extensor tendon must be centralized and snug which can usually be accomplished by "pants over vest" imbrication of the radial hood. It may be necessary to incise the hood on both sides of the central tendon, repair the ulnar hood to the radial hood, and suture the central tendon to the middle of the repaired hood to achieve a proper correction of severe ulnar dislocation (of the central tendon). Occasionally, the central tendon can be advanced and sutured into the dorsal base of the phalanx to increase stability of the implant against volar subluxation. At the conclusion of closure and application of the dressing, x-rays are taken to confirm the correct articulation of the implants.

FIGURE 6.14.1

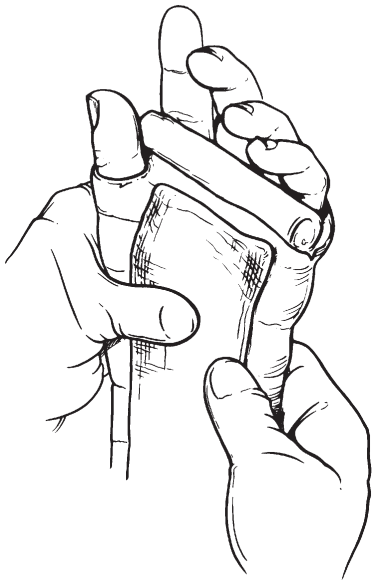
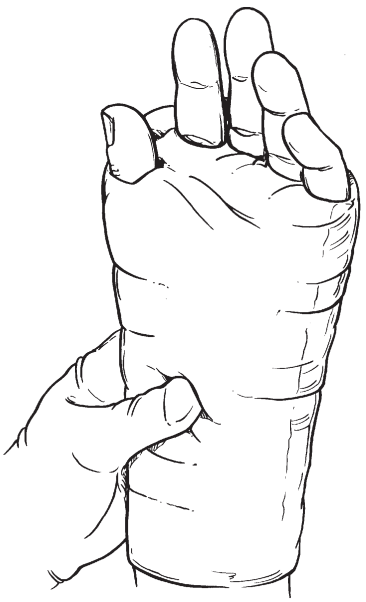


FIGURE 6.14.2



6.14 Post-Operative Dressing

Post-operatively, the hand is placed in a bulky dressing. The dressing should maintain the wrist at 10-15° of dorsiflexion and slight ulnar deviation if possible. The MCPs should be held in full extension and the PIPs in slight flexion (5-10°). If Swan-neck deformities were present pre-operatively, the PIPs should be placed in the maximum flexion possible. A palmar plaster splint should be used to maintain this position (**FIGURE 6.14.1**), with the final wrap over the entire hand leaving the distal tips of the digits exposed (**FIGURE 6.14.2**) during the first two days to help with edema control. Active range of motion (AROM) of the shoulder and elbow should be encouraged.

6.15 Implant Removal

In the event that it becomes necessary to remove an Ascension® MCP component or implant, the following should be considered.

First, it is recommended that extracted components not be reused due to potential damage to the component created during the removal process. Second, use of instruments not manufactured by Ascension Orthopedics to extract the Ascension® MCP is not recommended. Metallic instruments normally used for grasping objects, such as rongeurs or hemostats, or instruments with serrations, teeth or sharp edges can fracture the implant, making it more difficult to remove any remaining implant stem, and should not be used.

To aid in component removal, a blunt plastic osteotome, called the Implant Extractor, is provided in the Instrument Tray. To remove a component, the wedged end of the osteotome should be placed against the subarticular collar of the prosthesis and gently tapped with a small mallet. If this is not successful, the surgeon should try to extract the device with other blunt ended osteotomes or periosteal elevators.

If this approach is not successful, the surgeon should consider making a small axial cut dorsally in the metacarpal or proximal phalanx cortex adjacent to the subarticular collar of the implant. This will allow the surgeon to open the cortex like a "book" to access the implant after which gentle impaction on the stem of the implant may be used to remove the component from the medullary canal. If another implant is to be inserted, a circumferential suture may be placed around the medullary cortex to close the gap that was created.

If the component head fractures from the stem during the removal attempt, and the stem cannot be easily extracted with a grasping instrument, a burr may be used to remove a portion of or all of the remaining stem. The use of a burr in this manner will result in debris in the wound, and irrigation and debridement are recommended to eliminate the foreign particles.

7.0 Appendix – MCP Instrument Set and Part Numbers

Catalog Number	Description	Quantity
INS-100-00	MCP Instrument Set	1
CSA-100-01	MCP Lid (Case)	1
CSA-100-02	MCP Base (Case)	1
CSA-100-03	MCP Insert (Case)	1
IMP-100-00P	MCP Proximal Impactor	1
IMP-100-00D	MCP Distal Impactor	1
EXT-100-00	MCP Trial Extractor	1
EXT-100-01	MCP Implant Extractor	1
ALG-100-00	Alignment Guide	1
OSG-100-00P	MCP Proximal Osteotomy Guide	1
OSG-100-00D	MCP Distal Osteotomy Guide	1
AWL-100-00	Alignment Awl	1
AWL-100-01	Starter Awl	1
TRL-100-10P	MCP Proximal Trial Size 10	1
TRL-100-20P	MCP Proximal Trial Size 20	1
TRL-100-30P	MCP Proximal Trial Size 30	1
TRL-100-40P	MCP Proximal Trial Size 40	1
TRL-100-50P	MCP Proximal Trial Size 50	1
TRL-100-10D	MCP Distal Trial Size 10	1
TRL-100-20D	MCP Distal Trial Size 20	1
TRL-100-30D	MCP Distal Trial Size 30	1
TRL-100-40D	MCP Distal Trial Size 40	1
TRL-100-50D	MCP Distal Trial Size 50	1
BRH-100-10P	MCP Proximal Broach Size 10	1
BRH-100-20P	MCP Proximal Broach Size 20	1
BRH-100-30P	MCP Proximal Broach Size 30	1
BRH-100-40P	MCP Proximal Broach Size 40	1
BRH-100-50P	MCP Proximal Broach Size 50	1
BRH-100-10D	MCP Distal Broach Size 10	1
BRH-100-20D	MCP Distal Broach Size 20	1
BRH-100-30D	MCP Distal Broach Size 30	1
BRH-100-40D	MCP Distal Broach Size 40	1
BRH-100-50D	MCP Distal Broach Size 50	1

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