



ASCENSION⁺ MCP

PyroCarbon Joint Replacement

Surgical Technique



Table of contents

Introduction

Warnings and precautions	1
System overview	2
Preoperative assessment	2

Surgical technique

Step 1 • Initial Incision and Joint Exposure	3
Step 2 • Opening the Metacarpal Medullary Canal	3
Step 3 • Establishing Metacarpal Medullary Canal Alignment	4
Step 4 • Metacarpal Osteotomy	4
Step 5 • Opening the Phalangeal Medullary Canal	5
Step 6 • Establishing Phalangeal Medullary Canal Alignment	5
Step 7 • Phalangeal Osteotomy	6
Step 8 • Distal Component Broaching	7
Step 9 • Proximal Component Broaching	8
Step 10 • Trial Insertion and Reduction	9
Step 11 • Removal of Trial Components	11
Step 12 • Implantation of Components	11
Step 13 • Final Reduction and Soft Tissue Closure	12
Step 14 • Closure	12
S+N ASCENSION MCP Removal	13
Postoperative Therapy Protocol – Osteoarthritis and Trauma Patients	16
Postoperative Therapy Protocol – Rheumatoid Patients	17
Instrumentation	18
Ordering information	19
Implant dimensions	20
Surgical technique	21

Note Bena

The following technique is for informational and educational purposes only. It is not intended to serve as medical advice. It is the responsibility of treating physicians to determine and utilize the appropriate products and techniques according to their own clinical judgment for each of their patients. For more information on the product, including its indications for use, contraindications, and product safety information, please refer to the product's label and the Instructions for Use packaged with the product.

Prior to performing this technique, please consult the Instructions for Use documentation provided with each device for additional health and safety information, including indications, contraindications, warnings and precautions.

Introduction

Warnings

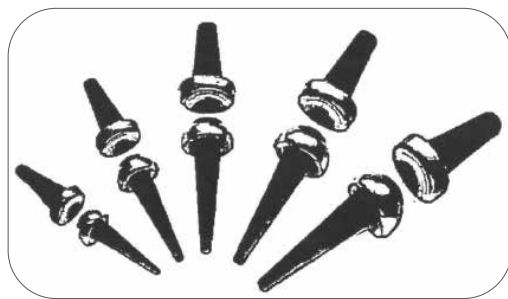
- Do not modify the ASCENSION[®] MCP Joint Replacement implant in any manner. Reshaping the implant using cutters, grinders, burrs, or other means will damage the structural integrity of the device and could result in implant fracture and/or particulate debris.
- Do not mismatch proximal and distal component 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 Joint Replacement implant with metal instruments, or instruments with teeth, serrations, or sharp edges. Implants should be handled only with instrumentation provided by ASCENSION MCP Joint Replacement 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 the ASCENSION MCP Joint Replacement components in combination with proximal and distal components from other products. The wear behavior of ASCENSION MCP Joint Replacement components against proximal and distal component 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.

Precautions

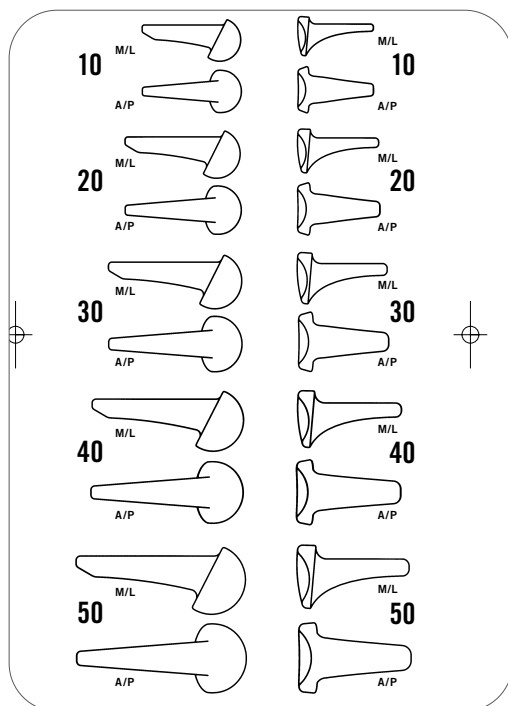
- Do not use the ASCENSION MCP Joint Replacement in a joint where soft tissue reconstruction cannot provide adequate stabilization. Similar to the natural joint, the ASCENSION MCP Joint Replacement attains stabilization from the surrounding capsuloligamentous structures. Because soft tissue reconstruction may be unable to maintain joint stability, the ASCENSION MCP Joint Replacement is not recommended for use in joints:
 - Where it is not possible to reconstruct the radial-collateral ligament, or
 - In joints that exhibit extension lag greater than 45 degrees,
 - Ulnar deviation greater than 30 degrees, or
 - Severe subluxation and/or shortening greater than 1 centimeter.
 - Special attention should be given to soft tissue reconstruction and joint stability in the ring and small fingers.
- Corrective wrist surgery may be required prior to use of the ASCENSION MCP Joint Replacement. In patients with severe intercarpal supination and radial deviation of the wrist, ulnar deviation of the digits may not be correctable with soft tissue reconstruction at the MCP alone. In these instances, it is recommended that corrective wrist surgery be performed first at a separate setting.
- Obtain proper training prior to use. Surgeons should obtain training from a qualified instructor prior to implanting the ASCENSION MCP Joint Replacement to ensure thorough understanding of the indications, implantation and removal techniques, instrumentation, and postoperative rehabilitation protocol.
- Inspect the articulating surfaces of the ASCENSION MCP Joint Replacement to insure they are clean and free of all debris prior to use. Foreign debris could result in excessive wear.
- Do not resterilize this device. Resterilization could lead to mishandling and surface damage that could result in implant fracture.

* Essential product use information: For additional important information pertaining to the use of this product, please see product package insert.

This information was current at the time of printing, but may have been revised after that date.



Phalangeal Components (Distal)



Metacarpal Components (Proximal)

- Do not reuse this device. Any implant that has been damaged, mishandled, or removed from the sterile field may have surface damage that could result in implant fracture and should be discarded.

System overview

The ASCENSION MCP Joint Replacement 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. Implants are available in 6 sizes and use the same color-coded instrumentation, providing an intraoperative choice. Components are press-fit, eliminating the need for cement. Successful use of these implants depends on proper patient selection, surgical technique, and postoperative therapy.

Preoperative 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 the 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. The templates are 3% magnified approximating the standard magnification of most routine x-ray techniques. Note that digital 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. The smallest implant (size 05) 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, radial deviation of the wrist, and ulnar deviation of the digits may not be correctable with soft tissue surgery. In these instances it is recommended that corrective wrist surgery be performed first at a separate setting.



Surgical technique

Step 1 • Initial Incision and Joint Exposure

1-1 Make a longitudinal incision over the dorsum of the metacarpophalangeal (MCP) joint.

For multiple joint involvement:

A curving transverse incision across the dorsum of the MCPs is recommended when multiple joints are involved. 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.

Split the capsule longitudinally and dissect to expose the joint, preserving the capsule as much as possible for later repair. Continue the dissection so that the dorsal base of the proximal phalanx and the metacarpal head with the collateral ligaments are visualized. The metacarpal is removed to gain access to phalangeal head which is cut, broached and sized prior to the metacarpal.

The implant is sized by the phalangeal end with the exception of the ring finger, where the metacarpal side is broached first.

Step 2 • Opening the Metacarpal Medullary Canal

2-1 Flex finger to expose the head of the metacarpal. Use a K-wire to make the initial entry point in the metacarpal head confirming alignment on X-ray.

Entry point is made in the dorsal 1/3 of the metacarpal head and centered across the width of the head. Remove K-wire and open with starter awl rotating 360° with the cutting edge until the laser mark is reached. The opening should be aligned with the long axis of the metacarpal's medullary canal.

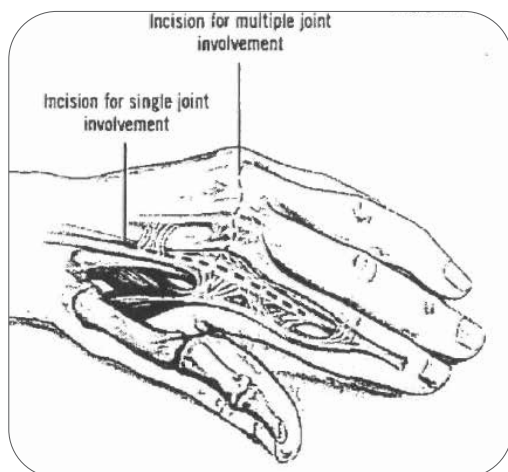


Figure 1-1

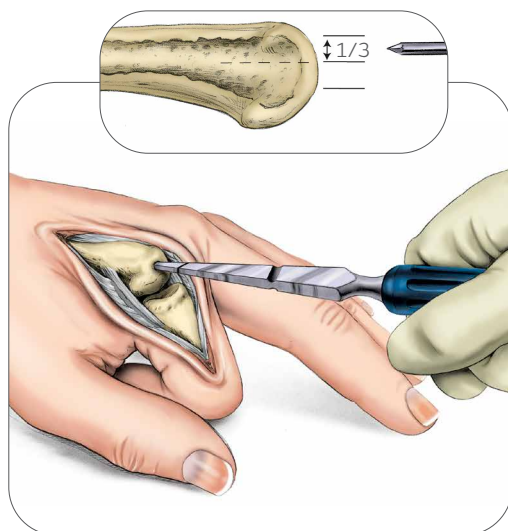


Figure 2-1

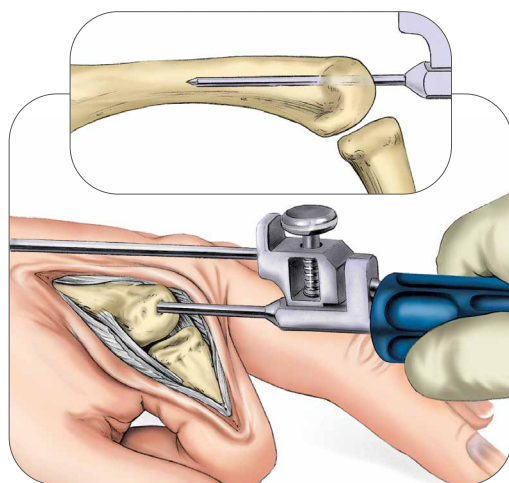


Figure 3-1

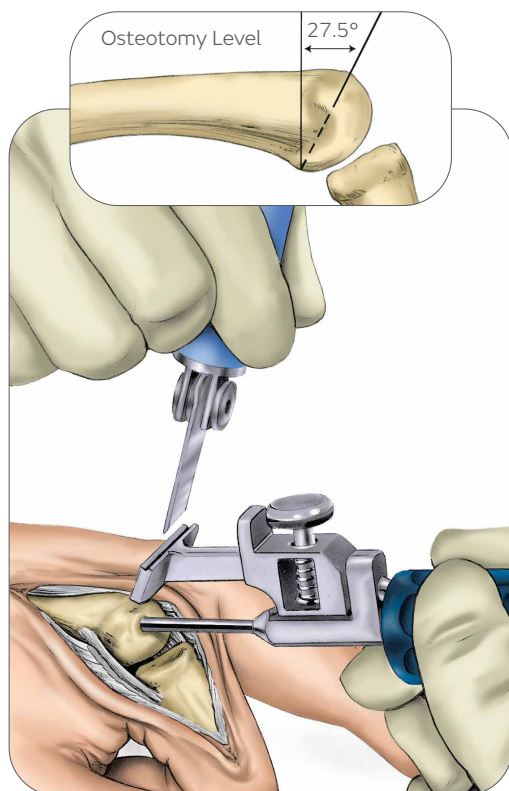


Figure 4-1

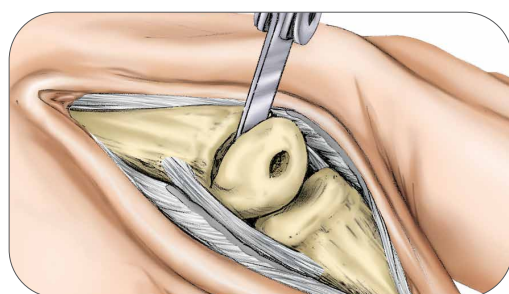


Figure 4-2

Step 3 • Establishing Metacarpal Medullary Canal Alignment

3-1 Attach the Alignment Guide to the Alignment Awl. Insert the Alignment Awl into the initial entry point.

Advance into the medullary canal 1/2 to 2/3 the length of the metacarpal. With the alignment awl 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. Confirm proper alignment with X-ray.

Step 4 • Metacarpal Osteotomy

4-1 Remove Alignment Guide and place the Proximal Osteotomy Guide on the Awl. The Osteotomy Guide provides a 27.5° distal back cut. Advance the Osteotomy Guide 1.0-2.0mm distal to the dorsal attachments of the collateral ligaments near the cortical-chondral junction. Withdraw or advance Awl into position, holding steady to avoid toggling. The Osteotomy Guide should be parallel to the surface of the metacarpal bone. Position saw blade in the Osteotomy Guide slot and create the initial cut until the rod of the Alignment Awl is reached. 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.

Special Thin Blade Requirements

- Use of a small oscillating saw blade (7mm x 29.5mm x 0.4mm) is strongly recommended, such as that in the MCP disposable pack provided.

Surgical Pearls

- Test correct positioning by sliding blade through the cutting guide slot before initiating the saw. The proximal cut should be 1.0-2.0mm distal to the collateral ligaments. The collateral ligaments' integrity should be retained as far as possible. Articular cartilage left behind does not need to be removed from the articular head.
- An initial conservative osteotomy allows for alterations and joint space adjustments during trial insertion.

4-2 Remove the Alignment Awl and complete the osteotomy freehand by following the previously established plane.

Step 5 • Opening the Phalangeal Medullary Canal

Caution: Flex the joint to avoid damage, by impingement of the K-wire or Starter Awl, to the dorsal edge of the metacarpal osteotomy.

5-1 Place a K-Wire in the center of the proximal phalanx in the AP and lateral views. Remove K-Wire and use the Starter Awl to enlarge initial entry point.

Step 6 • Establishing Phalangeal Medullary Canal Alignment

6-1 Mount the Alignment Guide on the Alignment Awl and flex the joint. Insert and advance the Alignment Awl into the proximal phalangeal medullary canal approximately 1/2 to 2/3 the length of the phalanx. With the alignment awl 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.

6-2 Caution: The joint must be flexed to avoid damage (by impingement) to the dorsal edge of the metacarpal osteotomy.

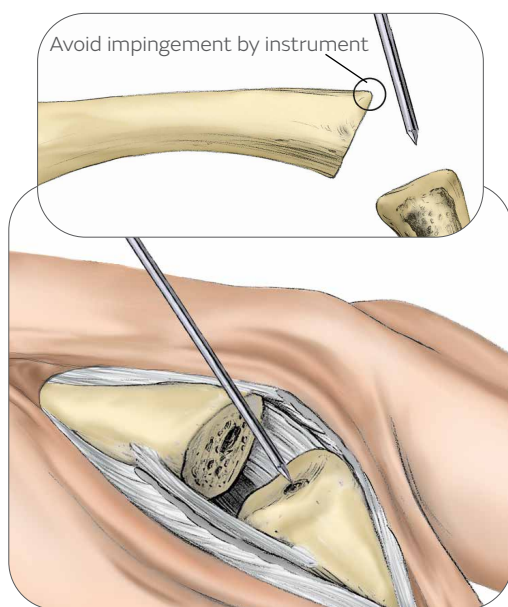


Figure 5-1

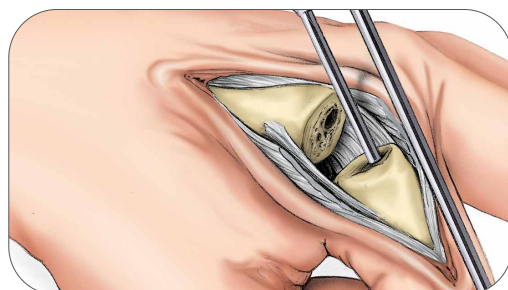


Figure 6-1

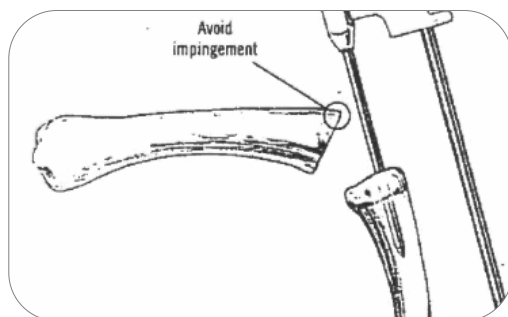


Figure 6-2

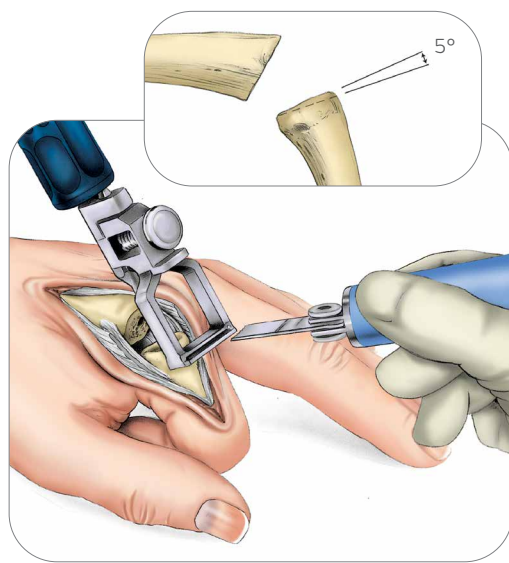


Figure 7-1

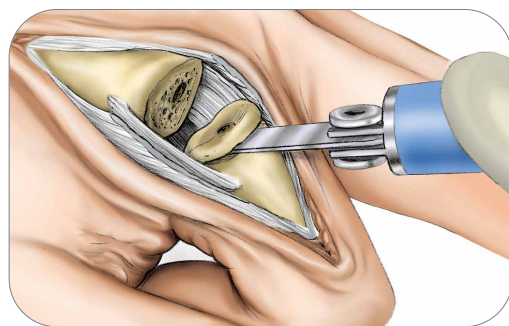


Figure 7-2

Step 7 • Phalangeal Osteotomy

7-1 Remove Alignment Guide and place the Distal Osteotomy Guide on to the awl. The Osteotomy Guide provides a 5° distal back cut. Advance the Osteotomy Guide 0.5-1.0mm proximal to the collateral ligament attachments. Advance the awl into position. The Osteotomy Guide should be parallel to the surface of the phalanx. Position saw blade in the Osteotomy Guide slot and create the initial cut until the rod of the Alignment Awl is reached. 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. The collateral ligaments' integrity should be retained as far as possible.

Caution: The joint must be flexed to avoid damage (by impingement) to the dorsal edge of the metacarpal osteotomy.

Surgical Pearls

- Test correct positioning by sliding blade through cutting guide slot before initiating the saw. The distal cut should remove only the articular surface.
- If the proximal phalanx is badly deformed or deficient dorsally, the cut may need to be done free hand.

7-2 Remove the Alignment Awl and complete the osteotomy freehand by following the previously established plane.

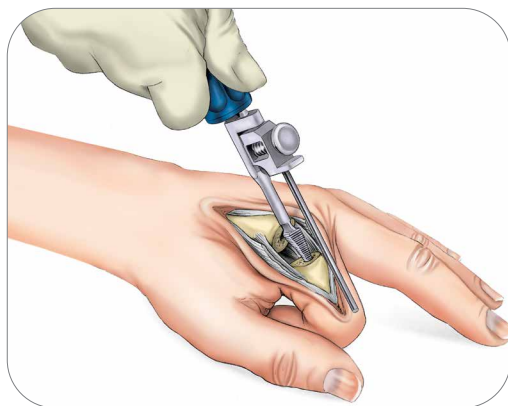


Figure 8-1



Figure 8-2

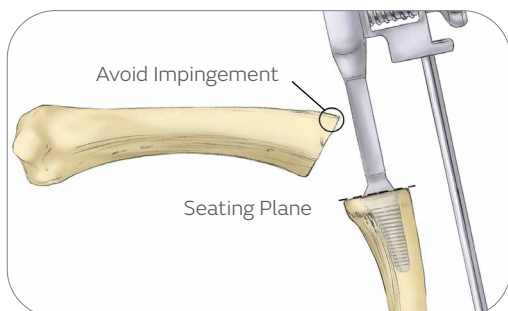


Figure 8-3

Step 8 • Distal Component Broaching

8-1 Broaches are provided in six color-coded sizes that correspond to color-coded trial and final implant sizes. After an entry way is made to allow insertion of the Size 10 Distal Broach, the canal is broached. The goal is to insert the largest implant possible while maintaining a centralized alignment within the canal.

Caution:

- The size of the phalangeal medullary canal is generally the limiting factor in implant size determination. Use clinical judgement and the x-ray templates to assess implant sizing.
- Do not mismatch proximal and distal component sizes. Example: 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.
- Matched Component Sizes



8-2 A burr can be used to remove remaining cortical bone at the opening of the canal. Sculpt opening in the shape of the broach. Do not use burr within the intramedullary canal. It is important to minimize burring within the canal as this will disrupt the press fit of the implant and may damage the endosteal bone. Overheating the bone is to be avoided at all costs. It is strongly suggested to use irrigation while utilizing powered burrs. If burring within the canal is necessary, impaction grafting is highly recommended.

8-3 Begin with the smallest size Distal Broach with the Alignment Guide attached and insert it halfway into the medullary canal. Proper positioning is confirmed with lateral and AP X-rays. If you notice any malalignment, remove the Broach and correct positioning with a side-cutting bur. Re-insert the Broach and confirm position with X-ray. Once proper position is confirmed, the canal may be sequentially enlarged with the broaches until the final broach rests flush to 1mm below the osteotomy level. Incomplete or partial insertion of the Broach should be corrected before the Trial is inserted.

Caution: The joint must be flexed to avoid damage (by impingement) to the dorsal edge of the metacarpal osteotomy.

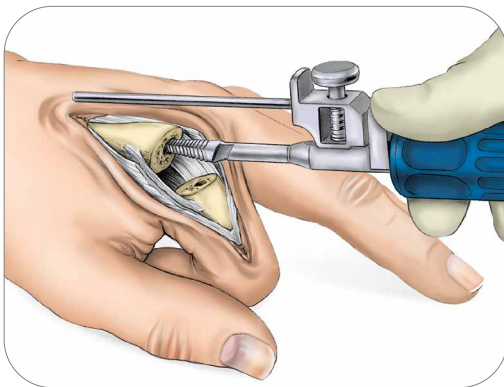


Figure 9-1

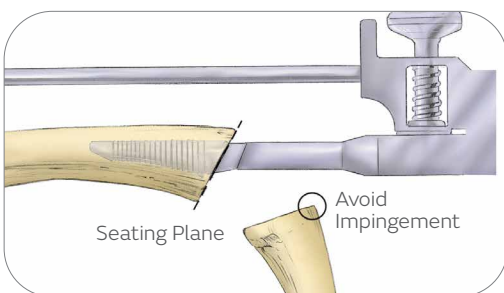


Figure 9-2

Step 9 • Proximal Component Broaching

9-1 The goal is to fill the medullary canal with the same size broach that was used on the proximal phalanx while maintaining centralized alignment within the canal. Be sure to evaluate both the AP and Lateral views on the X-ray before proceeding to the next Broach to ensure proper positioning.

Caution:

- The size of the phalangeal medullary canal is generally the limiting factor in implant size determination. Use clinical judgement 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 only with a size 10 distal component. The wear behavior of mismatched proximal and distal component size combinations has not been evaluated and is unknown.

With the Alignment Guide attached, begin with the smallest size Broach and insert it halfway into the medullary canal. Proper positioning is confirmed with lateral and AP X-rays. If you notice any malalignment, remove the broach and correct positioning. Re-insert the Broach and confirm position with X-ray.

9-2 Continue upsizing the Broach size until you have matched the broach size used in the proximal phalanx. The final Broach should be seated flush to 1mm below the edge of the osteotomy. Incomplete or partial insertion of the Broach should be corrected prior to Trial insertion.

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

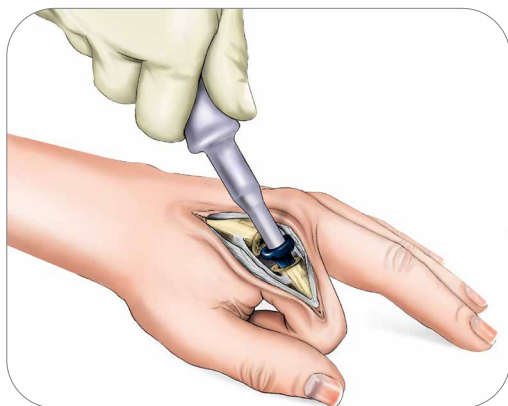


Figure 10-1

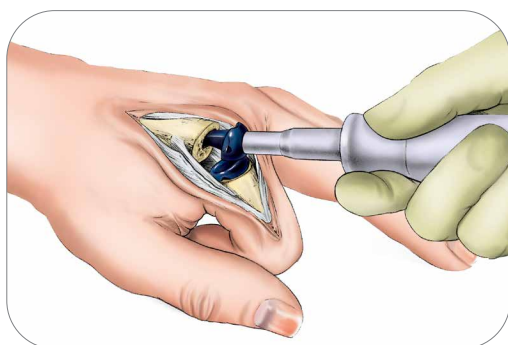


Figure 10-2

Step 10 • Trial Insertion and Reduction

10-1 Broaching is complete when both sides have been broached to equal sizes in the distal and proximal ends. Flex the joint. Insert the Distal Trial. Gently impact with the Distal Impactor until the collar of the trial is flush with the phalangeal osteotomy.

10-2 After seating Distal Trial, insert the Proximal Trial. Gently impact the Proximal Trial with the Proximal Impactor until the collar of the trial seats against the metacarpal osteotomy. Reduce the joint and assess stability, joint laxity, and range of motion. Hyperextension of 5-10° of the joint should be possible.

Surgical Pearls

If you have over-broached or utilized burs in the intramedullary canal:

This may occur inadvertently during attempts at placing larger implants or in patients with very sclerotic bone. In such cases, cancellous allograft may be impaction grafted into the intramedullary canal using the Trial. Grafting is performed using morcellized graft from the proximal phalanx osteotomies. Grafting may be continued until the final Broach or Trial size fits snugly against the osteotomy edge. Many surgeons frequently use impaction grafting.

If a lax joint is encountered: Ensure you have selected the largest size implant that can fit into the medullary canals. Occasionally, a larger implant may be placed, either proximally or distally, by enlarging the intramedullary canal with a burr. If stability is not obtained with a larger implant, closely examine the collateral ligament insertion site. These ligaments may have been inadvertently damaged during the osteotomy process. If collateral ligament stability has been compromised, a collateral ligament stitch will be required to re-establish lateral stability. Collateral ligament stabilizing sutures may be useful at the MCP joint where there is joint laxity. It is recommended to use this suture for every patient with RA. (See page 9.)

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.

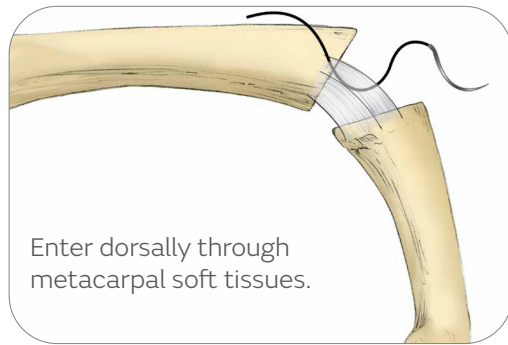


Figure A

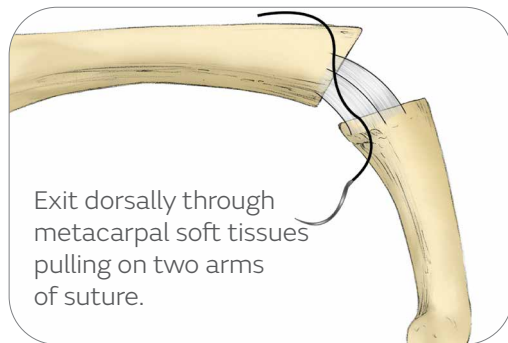


Figure B

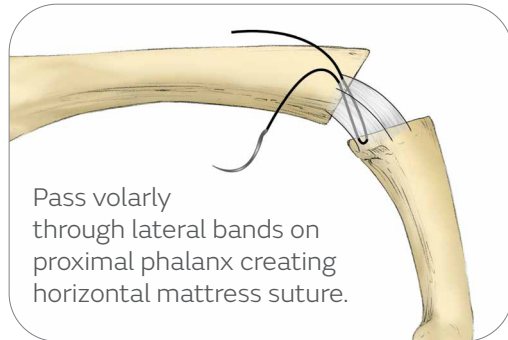


Figure C

Collateral Ligament Suture

Adequate soft tissue is usually found at the dorsal portion of the metacarpal bone in the vicinity of the accessory collateral ligament. Distally, the insertion areas of the collateral ligament are usually sufficient to support a strong suture. If adequate soft tissue purchase is not possible with a standard suture, a drill hole prepared with a .045" K-wire can be utilized to pass suture through bone for fixation. The drill holes may be created at the lateral margins of the metacarpal and proximal phalanx.

The suture should be placed before the implant is inserted. A strong "0" absorbable suture (such as Dexon or Vicryl) with a large non-cutting needle should be used. The suture is passed in a horizontal mattress fashion dorsally through metacarpal soft tissues **(A)** and then through the proximal phalanx volarly exiting external to the lateral bands **(B)**.

The two arms of the suture are individually pulled dorsally and proximally **(C)**. If properly placed, the sutures will pull the proximal phalanx to either the respective radial or ulnar direction, and the proximal phalanx will be pulled up to the metacarpal. If the proximal phalanx is not angulated with closure of the joint space by the individual radial and ulnar sutures, the sutures need to be replaced.

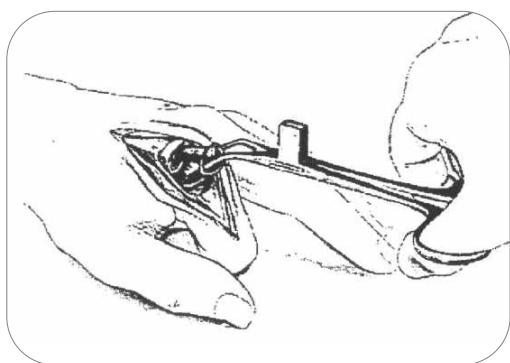


Figure 11-1

Step 11 • Removal of Trial Components

11-1 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.

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 components 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. 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.

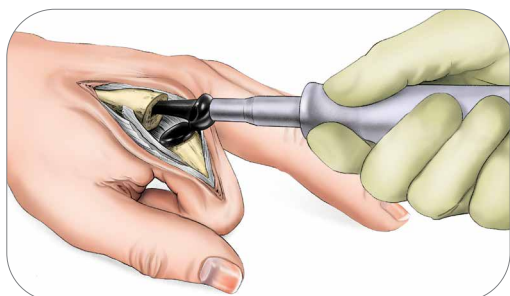


Figure 12-1

Step 12 • Implantation of Components

12-1 Flex the joint. Ensure 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. Insert the ASCENSION MCP Distal Component manually guiding implant into place using thumb pressure to seat into place. Gently use impactor for final positioning. Insert the equally sized ASCENSION MCP Proximal Component and gently impact with the Proximal Impactor until the collar of the component is flush with the metacarpal osteotomy.

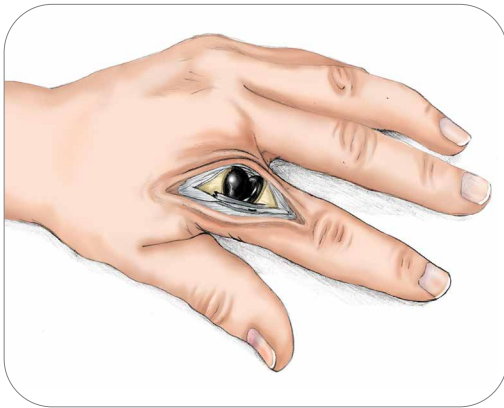


Figure 13-1

Step 13 • Final Reduction and Soft Tissue Closure

13-1 Reduce the joint. Recheck stability, joint axial alignment and range of motion of the components, which should mimic the performance of the trial components. Full digit extension should be possible. If collateral ligament suture has been placed, the radial collateral ligament suture is tied tightly with the MCP fully extended and slight radial deviation.

The ulnar suture is then tied into position with the finger held in the same radial deviated position. Tighten the soft tissue envelope with a capsular repair to provide support and prevent volar subluxation/dislocation of the implant.

Step 14 • Closure

The extensor tendon is centralized and snug, which can be accomplished by imbrication of the radial hood under the ulnar side of the central tendon then repairing the radial side central tendon to the radial hood. 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. Confirm the correct position of the implants with X-ray.

Postoperative Dressing – Osteoarthritis and Trauma Patients

Apply a bulky dressing with palmar and dorsal plaster splint maintaining wrist at 10-15° of dorsiflexion and slight ulnar deviation. The MCPs should be held in full extension and the PIPs in slight flexion at 5-10°. X-ray to confirm correct implant position after splints are applied in the OR.

Postoperative Dressing – Rheumatoid Patients and Patients with Systemic Lupus Erythematosus

- Apply a bulky dressing with a palmar and dorsal plaster splint maintaining the wrist at 10-15° of dorsiflexion and slight ulnar deviation. The MCPs should be held in full extension and the PIPs in slight flexion at 5-10°. Position must be checked in the OR with postoperative X-ray.
- If SWAN-neck deformities are present preoperatively, the PIPs should be placed in maximum flexion.

ASCENSION[®] MCP Removal

In the event that it becomes necessary to remove a 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 S+N LifeSciences 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.



Postoperative Therapy Protocol – Osteoarthritis and Trauma Patients*

Postoperative Dressing

Apply a bulky dressing with palmar and dorsal plaster splint maintaining wrist at 10-15° of dorsiflexion and slight ulnar deviation. The MCPs should be held in full extension and the PIPs in slight flexion at 5-10°. X-ray to confirm correct implant position after splints are applied in the OR.

One Week Postoperative Care

- Remove plaster splint and lightly dress the wound.
- First therapy appointment. Take care not to rotate, compress, or distract the joint during routine therapy.

Splint

Dynamic Extension Assist

- Positions the wrist at 0-10° extension with slight ulnar deviation; MCPs at 0° extension and slight radial deviation; with PIPs and thumb free. Alternatively, the splint may be based volarly or radially as a gutter splint.
- A volar wrist block added to the dynamic splint can focus flexion through the joints themselves and not the wrist. Oval 8's could also be used for this.
- Use as necessary: derotational slings to correct digit supination or pronation, and distal radial pull outriggers may be added to the dynamic splint to correct ulnar drift.

Initiate active MCP motion in dynamic splint with controlled flexion of 0-60°. Maintain PIP motion. If the surgeon reports good stability, dynamic splinting may not be necessary for the central digits. Buddy taping to the adjacent finger may be satisfactory.

If stable, the surgeon may choose not to use dynamic splinting.

Static MCP Flexion Block

An MCP flexion block splint should be made to maintain full MCP extension yet allow PIP flexion for day exercises and rest periods. It is also worn as a night resting splint. Individual or all fingers may be included. X-ray to confirm correct implant position after fabrication of splints. Once this is done, patients may begin the following exercises.

*Postoperative care is individualized and is determined by the physician based on the patient's injury pattern, unique patient anatomy, and pathologic kinematics. Not all patients will have the same surgical procedure or timelines for rehabilitation. The views and opinions expressed for postoperative care are for informational and educational purposes only. Smith & Nephew, Inc. does not provide medical advice. In no event shall Smith & Nephew, Inc., be liable for any damages whatsoever (including, without limitation, damages for loss of business profits, business interruption, loss of business information, or other pecuniary loss) arising out of the use of or inability to use the expressed views

Exercises

It is important that the MCPs extend fully. In osteoarthritis and trauma patients, the soft tissue envelope may be very stable and flexion to 90° may be achievable. However, flexion should be limited to 60° during the first two weeks postoperatively to protect the extensor repair. Care must be taken to assure that there is no rotation or ulnar deviation occurring through this flexion arc. The patient should not begin any resistive use of the hand, even for ADLs. Basic joint protection principals to prevent recurrent subluxation should be discussed. All exercises should be done in a slow, pain-free manner while wearing the dynamic splint.

Exercise Frequency and Repetition

It is recommended that exercise sessions be performed hourly throughout the day. The patient should do 10-15 repetitions of each exercise during each session.

Exercise #1: MCP Flexion to 45-60°, according to surgeon's instructions

Exercise #2: Touch Each Finger Tip to Thumb Tip

Exercise #3: Full PIP/DIP Flexion and Extension

Four Weeks Postoperative Care

- Continue wearing splints or use buddy taping and do exercises as previously prescribed.
- Resume light ADL outside of the splint.
- Increase MCP flexion to 90° actively. If 60° of flexion has not been achieved, active assistive ROM exercises and a dynamic MCP flexion assist splint may be required.
- X-ray to confirm correct implant position.

Six+ Weeks Postoperative Care – progress to full activities as tolerated.



Postoperative Therapy Protocol – Rheumatoid Patients and Patients with Systemic Lupus Erythematosus*

Postoperative Dressing

- Apply a bulky dressing with a palmar and dorsal plaster splint maintaining the wrist at 10-15° of dorsiflexion and slight ulnar deviation. The MCPs should be held in full extension and the PIPs in slight flexion at 5-10°. Position must be checked in the OR with postoperative X-ray.
- If SWAN-neck deformities are present preoperatively, the PIPs should be placed in maximum flexion.

Approximately Two Days Postoperative Care

- Remove the bulky dressing and apply a short arm cast that maintains wrist in ulnar deviation at 0-10° and MCP joints in full extension with slight radial deviation (apply moleskin-tape straps to hold digits in radial deviation and extension), and allows full PIP/DIP extension/flexion.
- X-ray to confirm correct implant position after cast is applied.

Approximately Two Days–Three Weeks Postoperative Care

- If necessary, minimize edema by elevation, massage, or compression.
- Take care not to rotate, compress, or distract the joints.
- Gentle, active and passive motion of individual PIPs/DIPs can be performed to maintain IP flexibility.

Three Weeks Postoperative Care

- Patient's first formal therapy appointment.
- Remove sutures, and lightly dress wound.
- Take care not to rotate, compress, or distract the joint during routine therapy.

Splint

Dynamic Extension Assist:

- Wrist at 0-10° with slight ulnar deviation
- MCPs at 0° extension and slight radial deviation
- IPs and thumb free
- Alternatively, the splint may be based volarly or radially as a gutter splint
- A volar wrist block added to the dynamic splint can focus flexion through the joints themselves and not the wrist. Oval 8's could also be used for this.
- Use as necessary: derotational slings to correct digit supination or pronation, and distal radial pull outriggers may be added (as shown) to the dynamic splint to correct ulnar drift.
- If MCPs tend to hyperextend, decrease sling tension, or add MCP hypertension blocks to splint.

*Postoperative care is individualized and is determined by the physician based on the patient's injury pattern, unique patient anatomy, and pathologic kinematics. Not all patients will have the same surgical procedure or timelines for rehabilitation. The views and opinions expressed for postoperative care are for informational and educational purposes only. Smith & Nephew, Inc. does not provide medical advice. In no event shall Smith & Nephew, Inc., be liable for any damages whatsoever (including, without limitation, damages for loss of business profits, business interruption, loss of business information, or other pecuniary loss) arising out of the use of or inability to use the expressed views

Static MCP Flexion Block:

This is an exercise splint for intrinsic tightness and/or to maintain IP joint mobility.

- Supports the MCPs volarly and allows IP flexion.
- Forearm-based with wrist neutral and slight ulnar deviation.
- MCPs at 0° of extension, and IPs and thumb are free.

Static Resting Splint:

- Positions the wrist at 0-10 degrees of extension and slight ulnar deviation.
- The MCPs at 0 degrees with finger dividers or otoform to promote slight radial deviation.
- The PIPs are held in comfortable flexion, and
- The thumb should be in a position of rest. Confirm proper implant position in splints with x-ray. Once the splints are made and have been checked with x-ray, patients may begin the exercises as described in the next section.

Exercises

It is imperative for the success of this surgery in RA that the MCPs are not allowed to flex past 45° for the first six weeks. More aggressive motion can result in recurrent ulnar deviation or an extension lag of the MCPs. The patient should not begin any resistive use of the hand, even for ADL until week 6, as this can result in subluxation. Basic joint protection principals to prevent recurrent ulnar drift and subluxation should be discussed. A review of appropriate ADL techniques, and adaptive equipment may be necessary to maintain patient's overall independence. All exercises should be done in a slow and pain-free manner.

Exercise Frequency and Repetition

It is recommended that exercise sessions be performed hourly throughout the day, with 10-15 repetitions of each exercise during each session. Frequency and number of repetitions depends on soft tissue stability and rate of healing.

Exercise #1: Controlled MCP flexion 0-30° using the dynamic splint (regulated by lead sinkers on outrigger fish line)

Exercise #2: Touch each finger tip to thumb tip (careful not to flex more than 30°)

Exercise #3: Radial Finger Walking

Exercise #4: PIP/DIP Flexion and Extension

Four Weeks Postoperative Care

- Continue wearing splints and do exercises as previously described.
- If the MCPs cannot actively flex to 45° after the first four weeks, finger slats can be taped either dorsally or volarly to block flexion at the IPs and focus motion at the MCP joints (reverse oval 8's also work). Dynamic flexion assist splints may be used.
- Continue MCP flexion to 45° and begin light functional activities in dynamic splint.
- Monitor to ensure there is no hypertension, ulnar drift, or rotation when using the hand.

Six Weeks Postoperative Care

- Continue wearing splints and do exercises as previously prescribed.
- Begin gentle motion outside of splint but continue dynamic splinting to ensure proper alignment.
- Increase MCP flexion to 60° in dynamic splint.
- Resume light ADL only while wearing dynamic splint.
- Increase to light activity outside of dynamic splinting ONLY under supervision of the therapist.

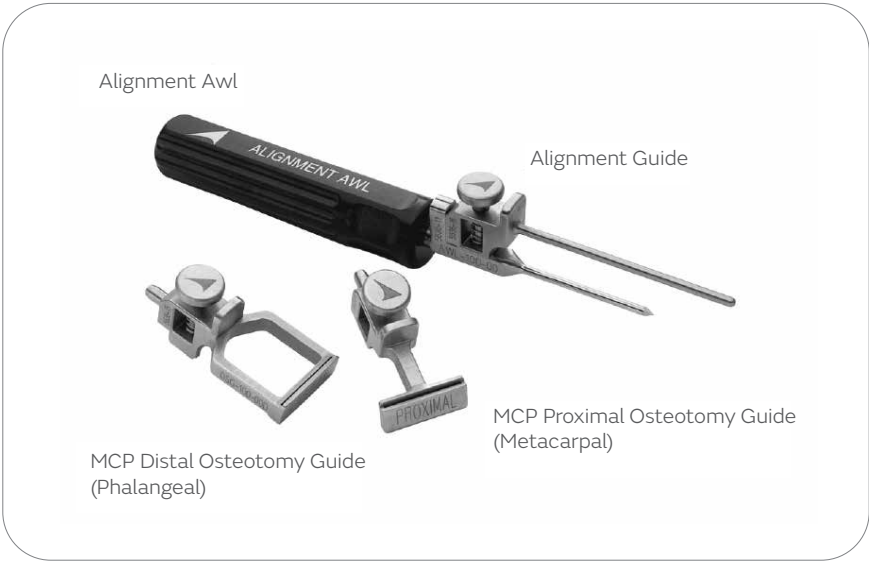
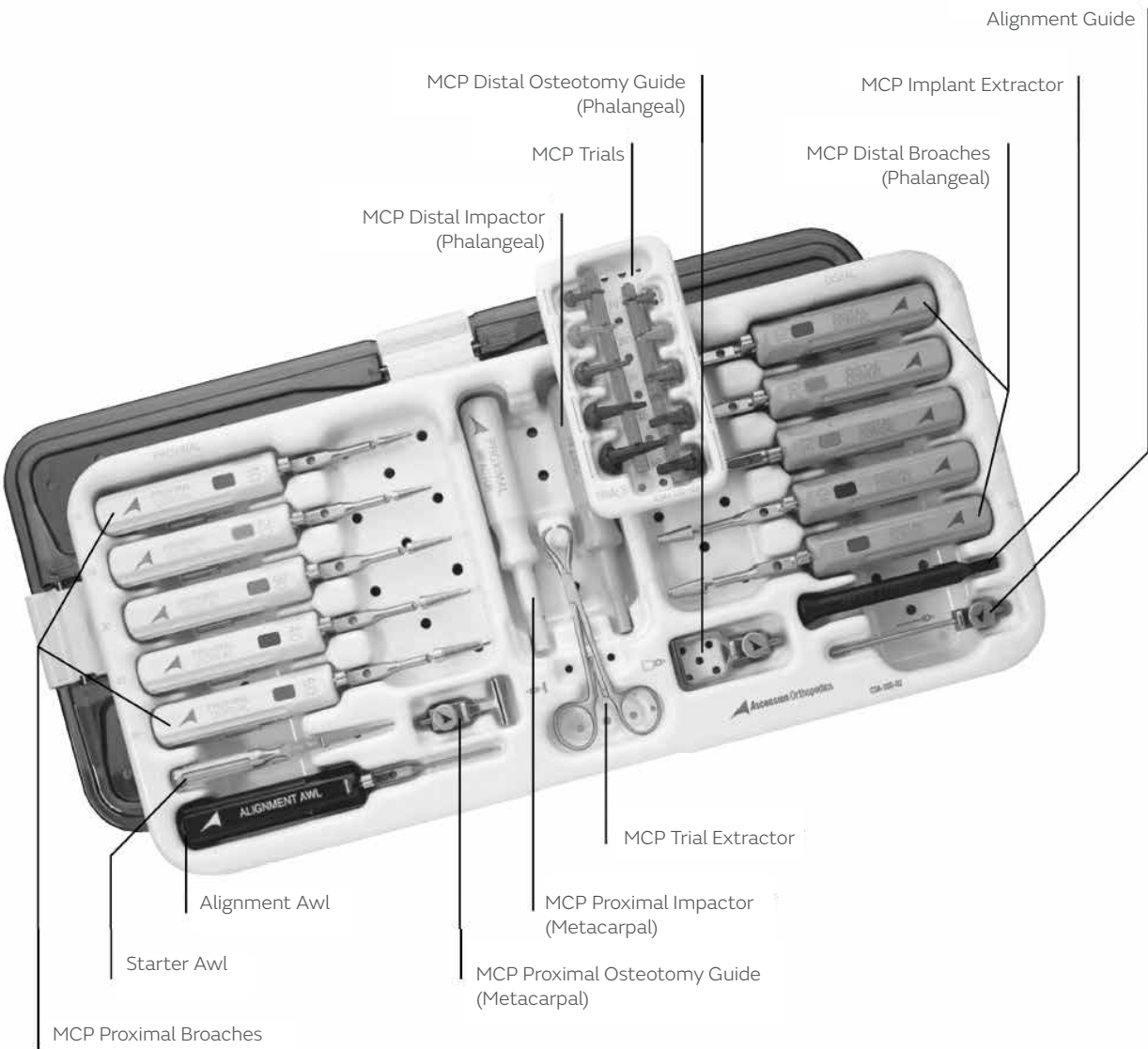
6-12 Weeks Postoperative Care

Gradual weaning from the dynamic splint if alignment maintained; resume light ADLs.

12+ Weeks Postoperative Care

- Continue therapy as needed.
- Night resting splint worn for life.

Instrumentation



Ordering information

Implants

Catalog Number	Description
MCP-110-05P	ASCENSION MCP Proximal Component, Size 05
MCP-110-05D	ASCENSION MCP Distal Component, Size 05
MCP-100-10P	ASCENSION MCP Proximal Component, Size 10
MCP-100-10D	ASCENSION MCP Distal Component, Size 10
MCP-100-20P	ASCENSION Ascension MCP Proximal Component, Size 20
MCP-100-20D	ASCENSION MCP Distal Component, Size 20
MCP-100-30P	ASCENSION MCP Proximal Component, Size 30
MCP-100-30D	ASCENSION MCP Distal Component, Size 30
MCP-100-40P	ASCENSION MCP Proximal Component, Size 40
MCP-100-40D	ASCENSION MCP Distal Component, Size 40
MCP-100-50P*	ASCENSION MCP Proximal Component, Size 50
MCP-100-50D*	MCP Distal Component, Size 50

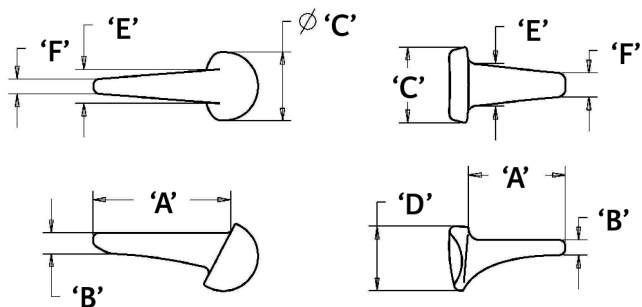
* Size 50 implants are not available in all markets.

Instruments

Catalog Number	Description
CSA-000-01	Lid (Case)
CSA-100-05	MCP Base 05-40 (Case)
CSA-100-06	MCP Trial Caddy 05-40 (Case)
IMP-100-00P	MCP Proximal Impactor
IMP-100-00D	Distal Impactor
EXT-200-00	Trial Extractor
EXT-100-01	MCP Implant Extractor
ALG-100-00	E/M Alignment Guide
OSG-100-00P	MCP Proximal Osteotomy Guide
OSG-100-00D	MCP Distal Osteotomy Guide
AWL-200-00	Alignment Awl
AWL-100-01	Starter Awl
TRL-101-10P	MCP Proximal Trial Sz. 10 (Metal)
TRL-101-20P	MCP Proximal Trial Sz. 20 (Metal)
TRL-101-30P	MCP Proximal Trial Sz. 30 (Metal)
TRL-101-40P	MCP Proximal Trial Sz. 40 (Metal)
TRL-101-05P	MCP Proximal Trial Sz. 05 (Metal)
TRL-101-10D	MCP Proximal Trial Sz. 10 (Metal)
TRL-101-20D	MCP Distal Trial Sz. 20 (Metal)
TRL-101-30D	MCP Distal Trial Sz. 30 (Metal)
TRL-101-40D	MCP Distal Trial Sz. 40 (Metal)
TRL-101-05D	MCP Proximal Trial Sz. 05 (Metal)
BRH-100-10P	MCP Proximal Broach Sz. 10
BRH-100-20P	MCP Proximal Broach Sz. 20
BRH-100-30P	MCP Proximal Broach Sz. 30
BRH-100-40P	MCP Proximal Broach Sz. 40
BRH-101-05P	MCP Proximal Broach Sz. 05 (Cutting)
BRH-100-10D	MCP Distal Broach Sz. 10
BRH-100-20D	MCP Distal Broach Sz. 20
BRH-100-30D	MCP Distal Broach Sz. 30
BRH-100-40D	MCP Distal Broach Sz. 40
BRH-101-05D	MCP Distal Broach Sz. 05 (Cutting)

Implant dimensions

Implant Dimensions (mm)



Size	A) STEM Length	(B) STEM Height	(C) Hinge Diameter	(D) Height	E) Stem Width	(F) Stem Width
05P	16.5	3.2	9.9	N/A	5.0	2.1
05D	14.1	1.5	11.0	9.2	6.5	3.1
10P	19.3	3.4	9.8	N/A	5.0	2.0
10D	15.6	1.7	11.2	8.8	6.2	2.7
20P	23.0	3.6	11.3	N/A	5.7	2.4
20D	16.7	2.2	12.5	10.3	6.9	3.6
30P	26.6	4.0	12.9	N/A	6.4	2.7
30D	18.3	2.8	14.4	12.0	7.6	4.4
40P	30.2	4.5	14.6	N/A	7.3	3.1
40D	21.2	3.3	15.6	13.4	8.4	5.3
50P*	33.7	5.0	16.4	N/A	8.1	3.4
50D*	22.8	4.0	16.8	15.0	9.4	5.9

* Size 50 implants are not available in all market

Surgical technique



Smith+Nephew does not practice medicine and does not recommend this or any other surgical technique for use on a specific patient. The surgeon who performs any procedure is responsible for determining and using the appropriate technique in each patient.

Caution: Federal law restricts this device to sale by or on the order of a physician or practitioner.

Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your Smith+Nephew representative or distributor if you have questions about the availability of Smith+Nephew products in your area.

Smith & Nephew, Inc.
1450 Brooks Road
Memphis, TN 38116
USA

www.smith-nephew.com
T: 1-901-396-2121
Orders and Inquiries: 1-800-238-7538

®Trademark of Smith+Nephew.
All trademarks acknowledged.
©2022 Smith+Nephew. All rights reserved.
31779 V2 LC-04-107-022 REVI 09/22

Manufacturer:



Ascension Orthopedics, Inc
11101 Metric Blvd
Austin, TX 78758 • USA