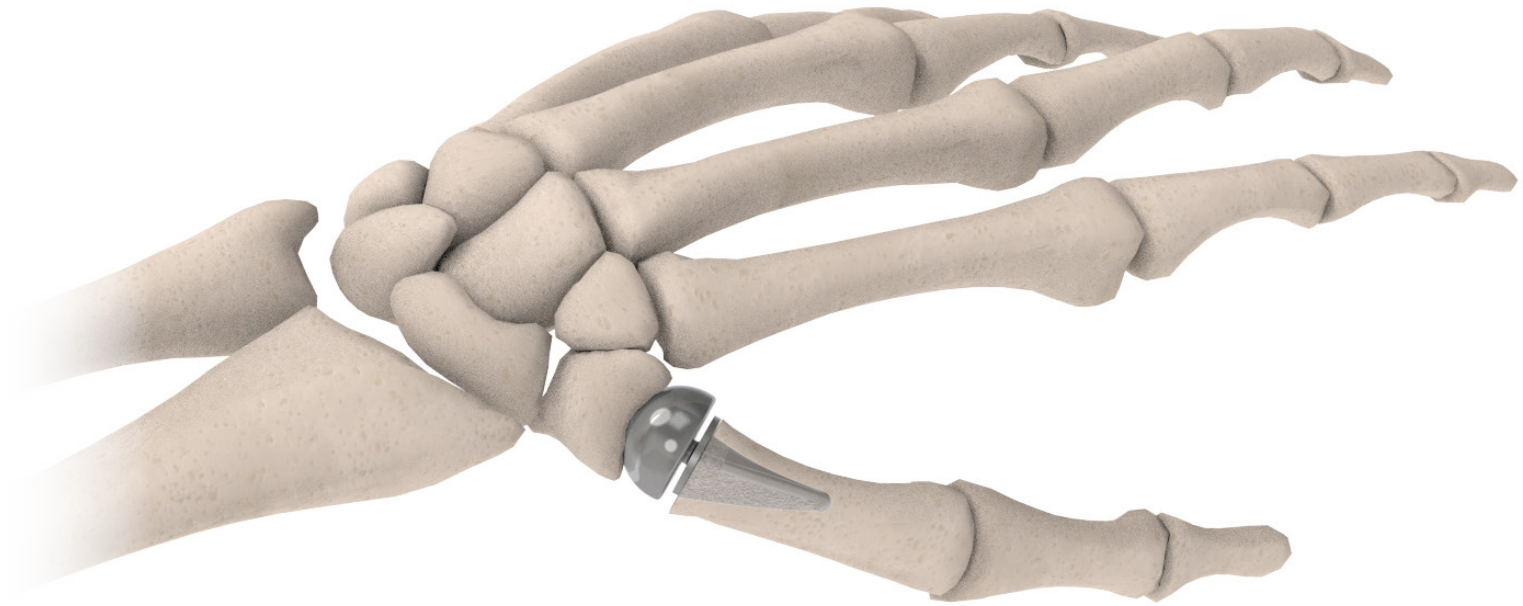
Biologically Oriented Prostheses

BIOPRO

Modular Thumb Implant

Surgical Technique



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Indications & Contraindications

Indications for use:
A painful, unstable thumb, one with limited range of motion, or subluxation of the trapeziometacarpal joint with the following indications:
1. Rheumatoid arthritis
2. Traumatic arthritis
3. Osteoarthritis
4. Post fracture deformation or bone loss

CANADA ONLY: Osteoarthritis

Contra-indications:
The age of the patient must be balanced against the severity of the disability and the need for surgery.
1. A debilitating general health problem that might pose a significant threat to the life of the patient if subjected to a major surgical procedure.
2. A previously infected thumb that has not been quiescent for at least six months.
3. A local or systemic infection (i.e. osteomyelitis).
4. Insufficient bone stock to support the prosthesis.
5. Scapho-Trapezium joint arthritis.
6. Foreign body sensitivity to metals including cobalt chrome or titanium. Where material sensitivity is suspected, appropriate tests should be made prior to implantation.

Precautions and Handling
- Inspect the sterile blisters used for the implants prior to use. Sterilization cannot be assured, and implants should not be used if blister or seal is damaged.
- Implants are single use devices.
- Do not autoclave implants.
- Exercise caution while threading the impactor tip into the handle to avoid cross-threading, as this can result in damage or the failure of the impactor tip.

Potential Complications and Adverse Effects
- Allergic reactions to metal
- Delayed Healing
- Loosening or migration of the implant components
- Subluxation or dislocation of implant resulting in reduced range of motion
- Bone fracture by trauma or improper surgical technique
- Pain due to bone remodeling or reaction to implant components

Contact surgeon if a change in performance or pain level is noticed.

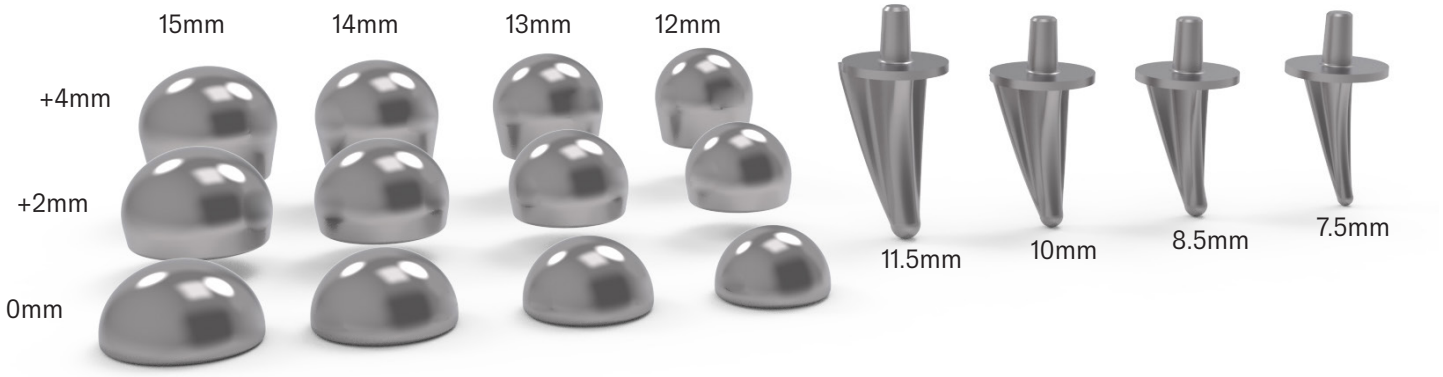
MR Safety Information
Warning: The Modular Thumb Implant has not been evaluated for safety and compatibility in the MR environment and has not been tested for heating or migration in the MR environment. The safety of the device in the MR environment is unknown. Scanning patients who have these devices may result in patient injury.

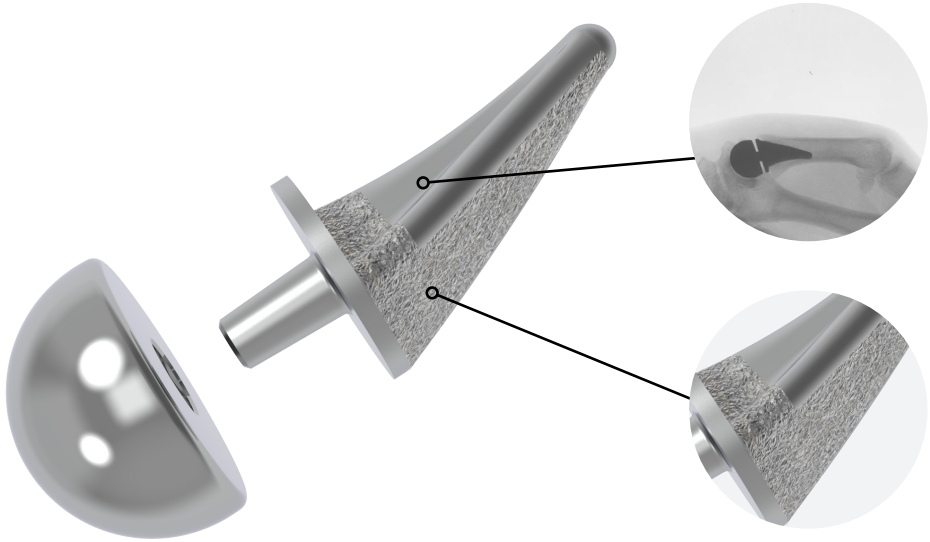
Implant Specifications

Description
The BioPro® Modular Thumb Implant is a two-piece implant consisting of a head and a press-fit plasma-sprayed stem. The implant is designed to address carpometacarpal (CMC) joint arthritis and the challenges with past implants including: dislocation, implant loosening and subluxation. The implant is supported by two decades of combined clinical experience and research with published results of 94% survivorship at 6 years[1]. The patented modular design allows the head to be sized independently of the stem to match the patient's anatomy. The modularity, along with the stems ulnar alignment has attributed to the promising advancement of cmc implant arthroplasty.

Material
The standard implant is manufactured from cobalt chrome, a highly biocompatible and durable material. A titanium version is available for use in patients susceptible to nickel chromium allergies. The MELISA blood test may be performed to confirm a patient's potential metal sensitivities.

Sizing
The head is available in Ø 12, 13, 14, 15mm and each diameter is available with a 0, +2 or +4mm height offset/neck length. The stem is available in 7.5, 8.5, 10, and 11.5mm with +4mm long stems available upon special request. There are 48 total configurations available with standard implants.

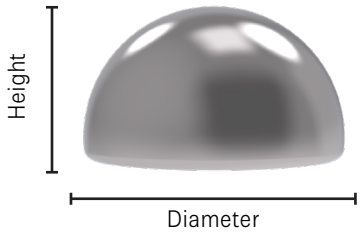


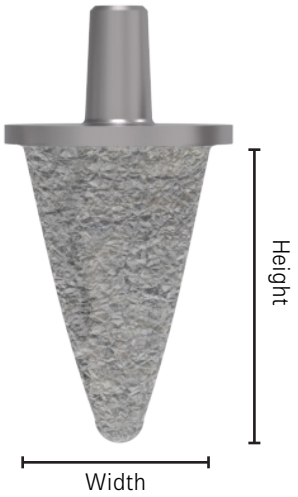


Ulnar Alignment
The stem features a 15 degree angle and medial offset head creating an ulnar alignment of the implant. Unlike implants of the past, this alignment allows the head to maintain contact with the socket during flexion and opposition.

Biological fixation
The backside of the stem is coated with titanium plasma spray. This allows biological fixation inside the metacarpal while also allowing stem removal if necessary.

Implant Specifications





Description	Diameter	Height
12mm	12mm	7mm
12mm+2	12mm	9mm
12mm+4	12mm	11mm
13mm	13mm	7.5mm
13mm+2	13mm	9.5mm
13mm+4	13mm	11.5mm
14mm	14mm	8mm
14mm+2	14mm	10mm
14mm+4	14mm	12mm
15mm	15mm	8.5mm
15mm+2	15mm	10.5mm
15mm+4	15mm	12.5mm

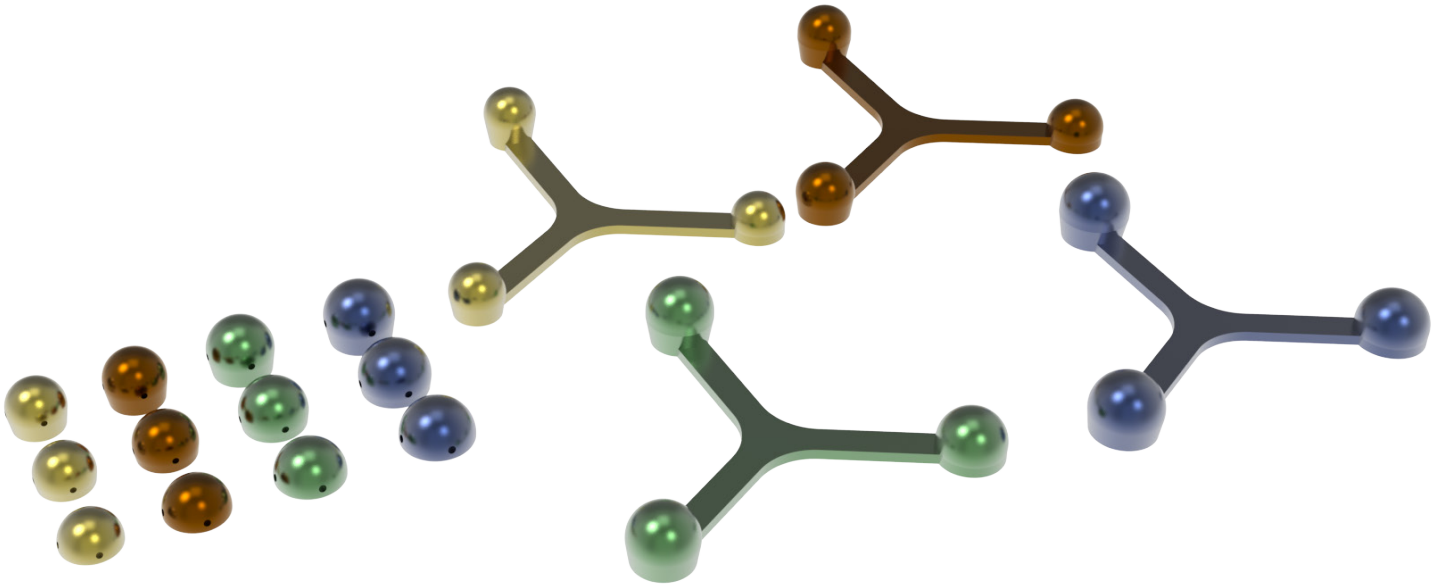
Description	Width	Height
7.5mm	7.5mm	15mm
8.5mm	8.5mm	15mm
10mm	10mm	16mm
11.5mm	11.5mm	18mm
7.5mm+4mm	7.5mm	19mm
8.5mm+4mm	8.5mm	19mm
10mm+4mm	10mm	20mm
11.5mm+4mm	11.5mm	22mm

Instrument Specifications

Color Coding

The head sizing guides, trial head implants and packaging all feature a color coding system to coordinate implant size. After determining the appropriate implant head size, always ensure you are using the same color code throughout the procedure.

Size	Color
12mm	Gold
13mm	Brown
14mm	Blue
15mm	Green



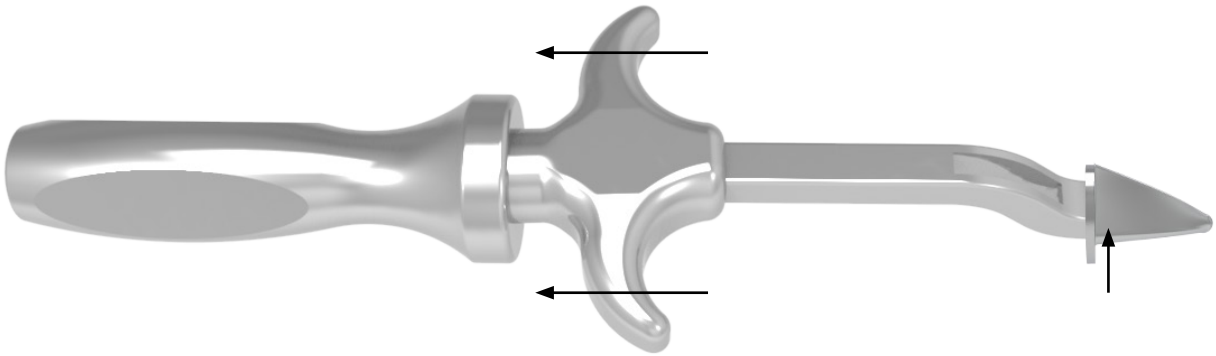
Instrument Specifications

Trial stems

The trial stems replicate the final implant sizes minus the plasma spray and are used to determine proper stem sizing. Trial stems include a notch on the neck to lock into the curved impactor. This can be used to either insert or remove the trial stems.

Caution

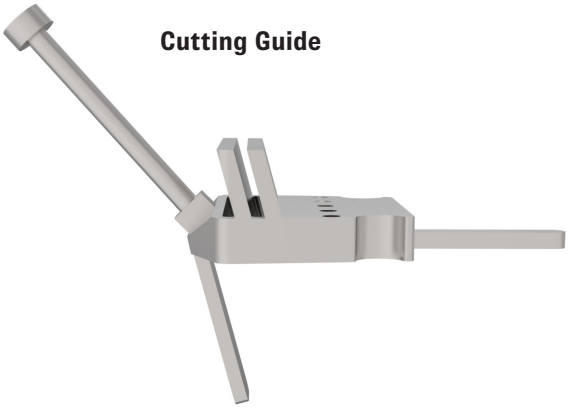
Plasma spray adds approximately 0.5mm of thickness to the implant stem over the trial. Take this into consideration when sizing the implant stem.



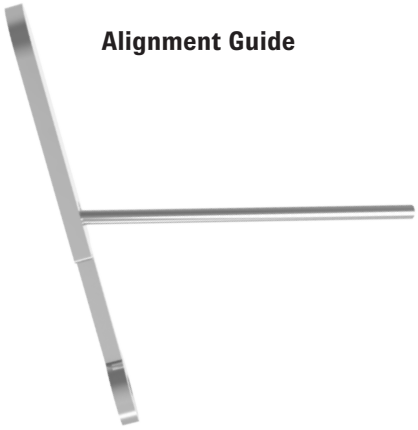
Instrument Specifications

Metacarpal Resection
Both a Cutting Guide and Alignment Guide are included in the instrument kit to aid in proper metacarpal resection. The Cutting Guide features cutting slots at both 3mm and 5mm. Once the metacarpal resection has been performed, the angle of the cut can be verified via the provided alignment guide.

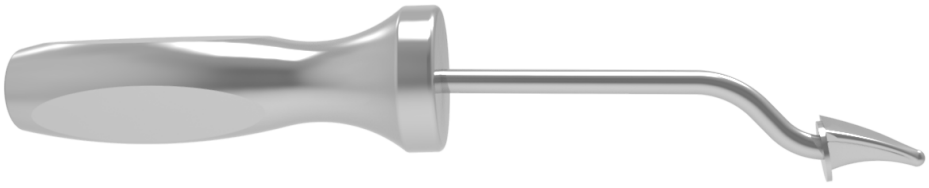
Cutting Guide



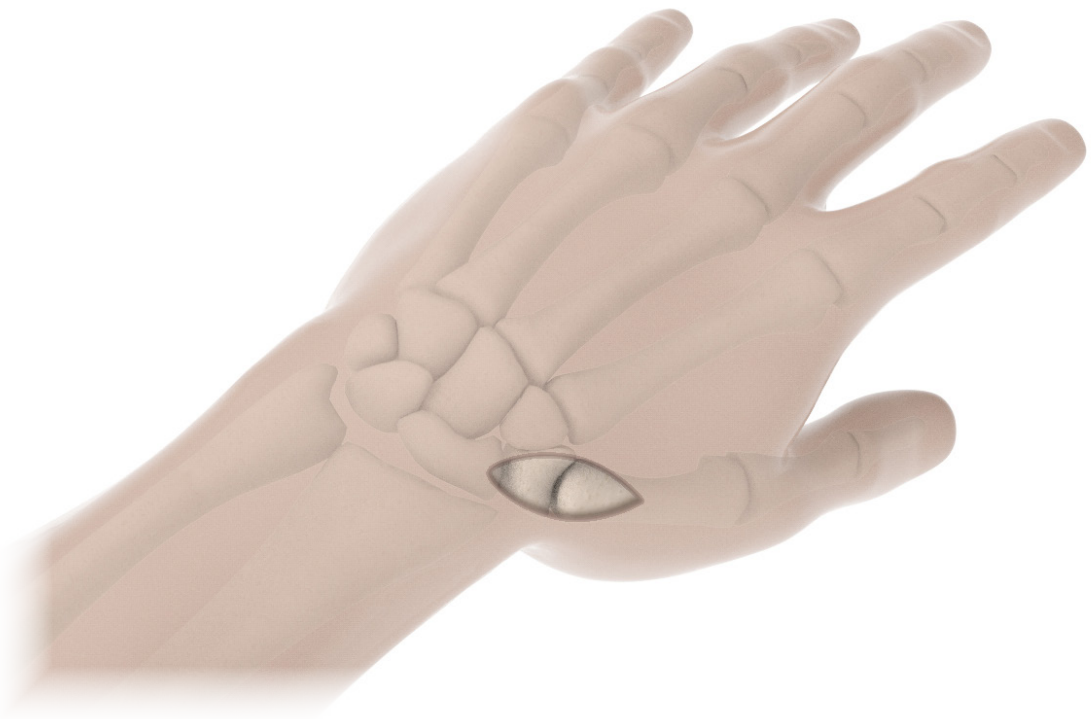
Alignment Guide



Stem Broaches
Four broaches are included. The broach sizes coordinate with the available stem sizes. It is recommended to start with the smallest broach size and work up to a larger size.



Surgical Technique

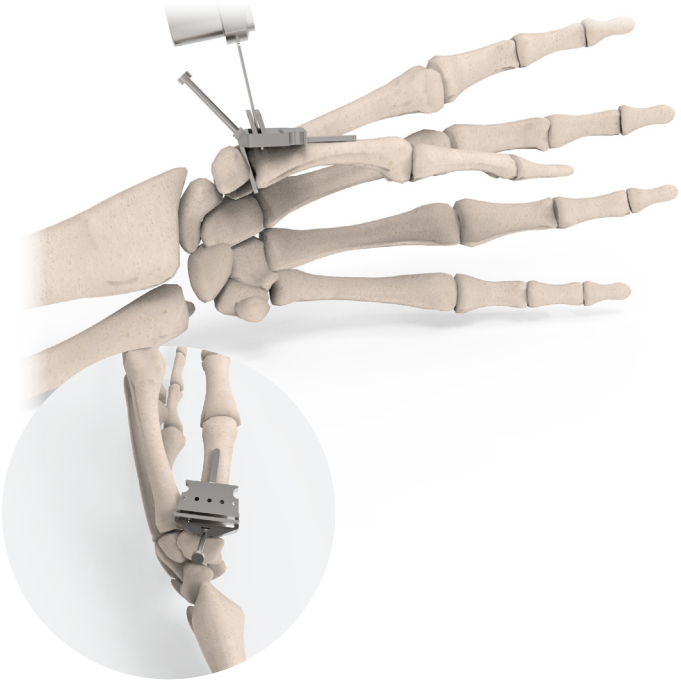


Step One
The first carpal-metacarpal joint is exposed through a 3cm longitudinal incision begun at the base of the first metacarpal extending proximally toward the first dorsal compartment.

The incision is equidistant to either side of the joint line. The superficial sensory branches of the radial nerve are identified and protected from surgical trauma.

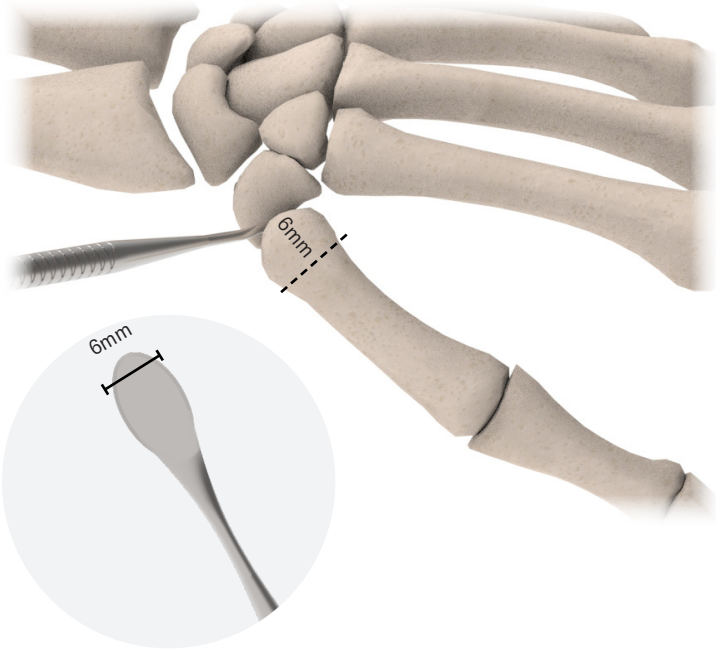
Step Two
The thumb is moved to identify the CMC joint. The interval between the abductor pollicis longus (APL) and extensor pollicis brevis (EPB) is developed to expose the dorsal radial capsule of the CMC joint.

The capsule is incised longitudinally and the dissection is carried both medial and lateral on the first metacarpal in a subperiosteal fashion to gain good visualization of the proximal metacarpal and CMC joint. The capsule is preserved for future closure and implant stability. A horseshoe shaped capsular incision can be used to offer better exposure as well as better closure options.



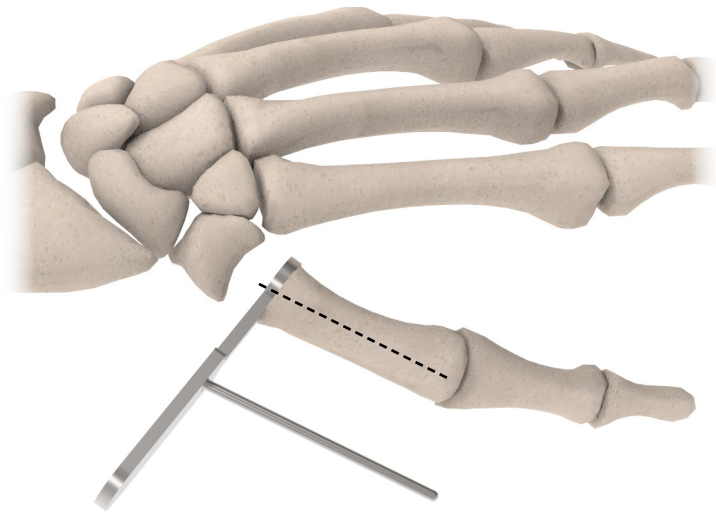
Step Three
The subperiosteally exposed base of the metacarpal is then resected by 5-6mm parallel to the varus positioned articular surface (approximately 15 degrees) in the sagittal plane.

A cutting guide is available to perform the resection. When using the cutting guide, the tail should sit subcutaneous, parallel to the metacarpal with the angled tongue inserted into the joint space. The guide can be clamped down using a towel clamp or simply held in place. The cutting slots are spaced 3mm and 5mm respectively.

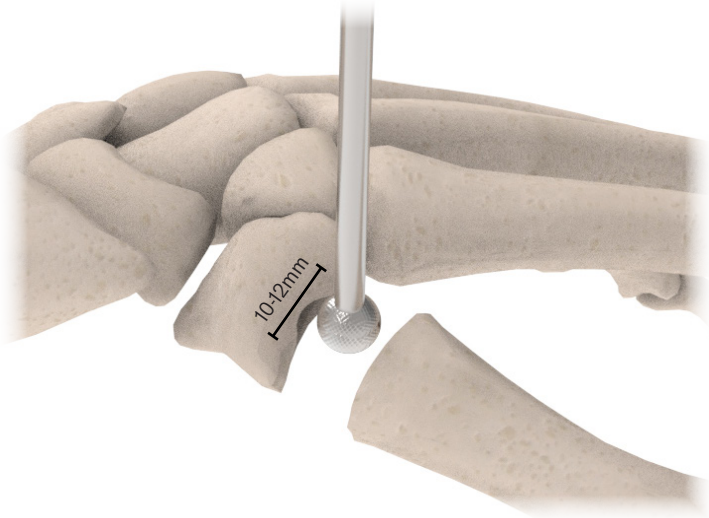


If you choose not to utilize the cutting guide, the bone spatula can be placed into the joint to assist in visualizing the angle before making the 5-6mm resection. The larger side of the bone spatula is 6mm in width and can be used to mark the resection.

If this resection is carried out correctly, equal portions of both condyles are seen in the resected segment of bone.



Step Four
The angle of metacarpal resection should now be verified with the alignment guide. Place the base of this guide flush on the resected surface of the metacarpal, with the pin distal. The pin should be parallel to the metacarpal. If it is not, adjust the angle of the cut.

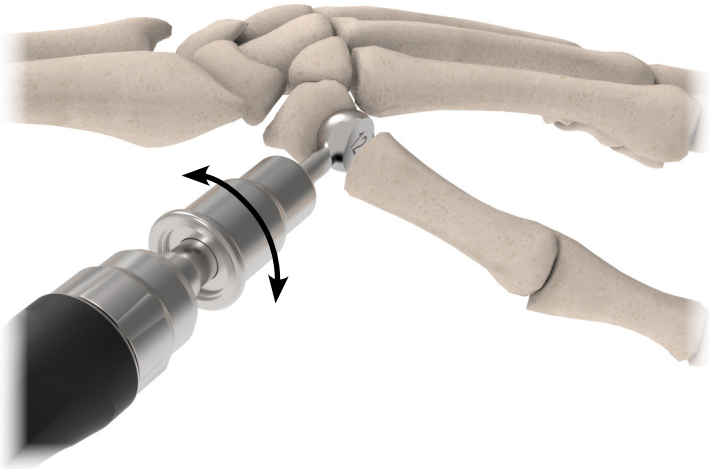


Step Five
The degenerated CMC joint is often radially and laterally subluxed with impinging osteophytes developed on the ulnar and medial aspect. If this has occurred, capsular dissection must be carried out on the ulnar aspect and any impinging osteophytes must be removed adjacent to the second metacarpal to allow relocation of the CMC joint.

Utilizing a medium size rotary burr (5-7mm) a medialized concentric concavity is fashioned into the articulating surface of the trapezium. Care is taken to preserve the radial border of the trapezium. Enlarge the recess in the trapezium to approximately 10-12mm in diameter with the rotary burr. This can be done in a circular fashion, beginning in the center of the trapezium, or by establishing the center point and burring on each side of it to create a 4-leaf clover pattern. When using a 6mm burr, this clover shape will help approximate a 12mm diameter socket.

Trapezial socket depth should be approximately 4mm to 5mm. Care should be taken to avoid burring deeper than 5mm.

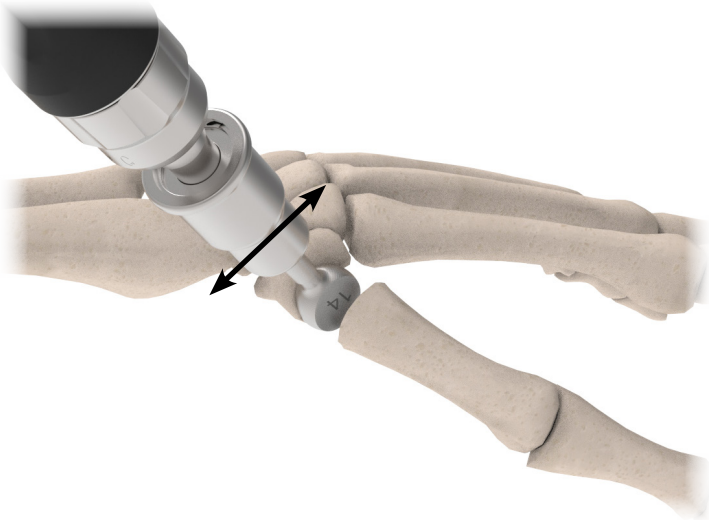
Important Note
Rotary burrs are not included in the Modular Thumb Implant instrument kit. Sterile burrs are provided with implant inventory, or the hospital may utilize their own stock of burrs.



Step Six
Gradually enlarge the socket with the hemispherical burrs, either in the manual hand-piece or using the provided power burr adapters in an oscillating saw. Begin with a twisting motion then, a rotating motion.

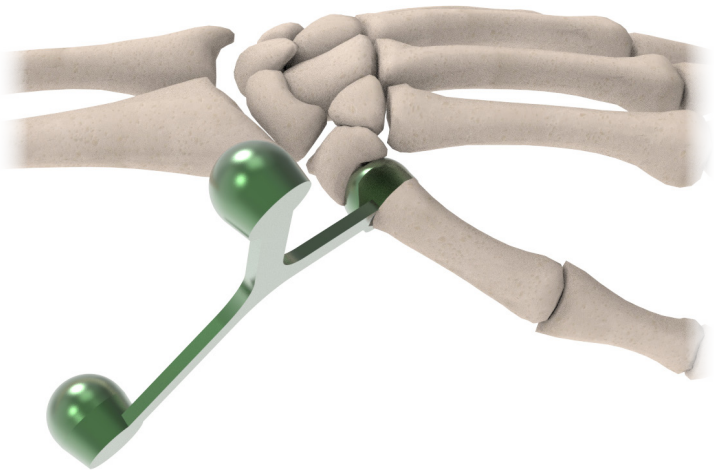
Progressively increase the size of the socket with larger burrs until the largest socket possible has been created, while again taking care to preserve the radial rim of the trapezium.

Important Note
Both coarse and fine burrs are provided in the instrument set. The fine burrs can be used to polish the socket, creating a smoother articulating surface.



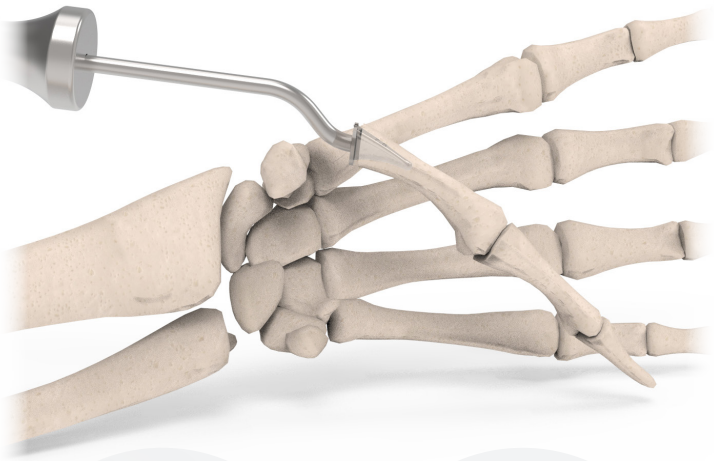
Important Note
Care must be taken to avoid damaging the proximal metacarpal bone. The depth of the socket need only be sufficient to provide a stable, non-dislocating articulation when evaluated with the trial head component in position, even when positioning the thumb in severe adduction.

Important Note
Burr for the largest head possible, as this will allow the head to ride on the maximum surface area within the trapezium, distributing forces over a greater area. For example, a 12mm head has a surface area of 226mm^2 compared to a 14mm's surface area of 307mm^2, a 36% increase in surface area. Please note, larger head sizes are strongly encouraged.



Step Seven
The head sizing guides allow 0, +2mm, and +4mm neck length trial heads to be applied and compared. This combination sizer and joint tensioning instrument allows the surgeon to assess stability and freedom of motion as well as examining the angle of the metacarpal resection. If the thumb cannot be brought to full range of abduction without undue force, the joint has been under spaced and must be corrected by resecting an additional appropriate amount of bone from the metacarpal or by deepening the socket if it was initially made too shallow. If the joint is too lax a +2mm or +4mm neck length is used for trial.

Important Note
Often times a head diameter 1mm larger than what was burred for can be utilized.



Step Eight
Access to the longitudinal axis of the metacarpal is facilitated by concurrently adducting and flexing the thumb. If necessary, additional axial exposure to the medullary canal is obtained by retracting the proximal end of the metacarpal outwardly with a Homan retractor placed on the ulnar aspect of the metacarpal. Avoid damage to the trapezium by lifting rather than levering against the bone.

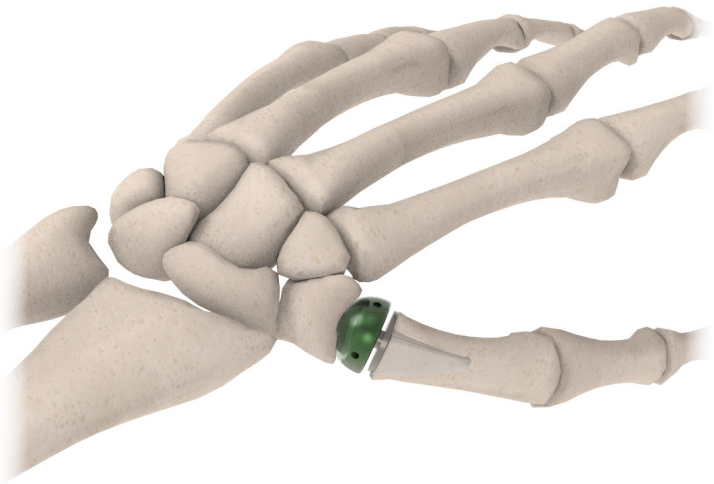
Begin insertion of the one piece broach 2mm inside the dorsal cortical bone with the flat, engraved surface of the broach in line with the flat dorsal radial aspect of the metacarpal. Continue progressing the broach until the flare of the broach is at or close to the cortical bone.

The size of the stem broach is increased progressively (7.5mm> 8.5mm>10.5mm>11.5mm) until the periprosthetic cancellous bone has been fully compressed to provide an optimally tight medullary interference fit.

Important Note
A mallet can be used to aid in impacting the broaches, but care should be taken to not damage the metacarpal by forcing in an oversized broach. Four stem sizes are available. With the appropriately sized broach fully seated, the resected surface of the metacarpal should parallel the surface of the stem collar. If the stem collar does not sit flush on the resected surface of the metacarpal adjust the insertion angle of the stem broach or the resection angle of the metacarpal.

Important Note
The plasma spray on the final implant adds approximately 0.5mm to the stem size. Take this into consideration prior to increasing broach sizes.

Important Note
X-ray can aid in determining optimal stem fit during stem broaching.

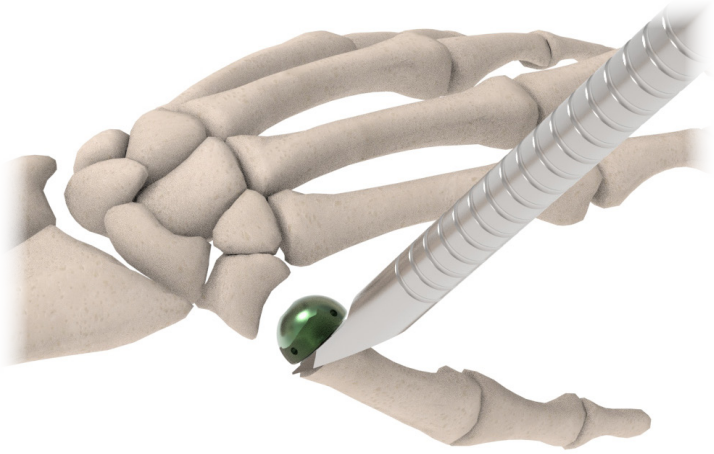


Step Nine
Once the desired stem broach size is achieved, the one piece broach should be exchanged for the corresponding size trial implant.

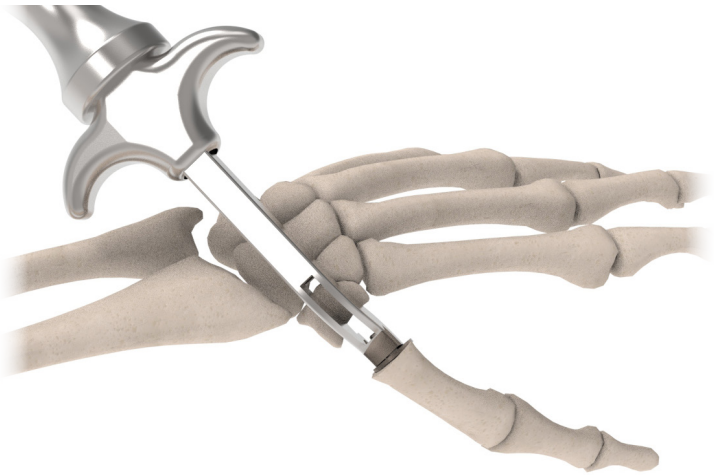
The trial head matching the head sizing guide is assembled onto the trial stem and seated into the bone. Be sure to utilize the trial head matching both the diameter and offset (0, +2, or +4) that provided the best combination of stability and motion in step seven.

Once the fully assembled trial component has been inserted into the joint, assess range of motion and joint stability.

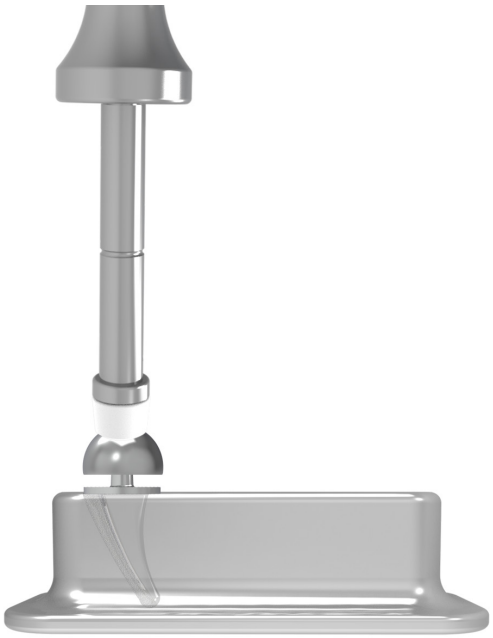
After the desired status of articulation has been assured (i.e., relative to stability, range of motion, etc.) the trial component is removed to be exchanged for the implantable prosthesis.



Using the Head Remover, the trial head is removed from the trial stem.

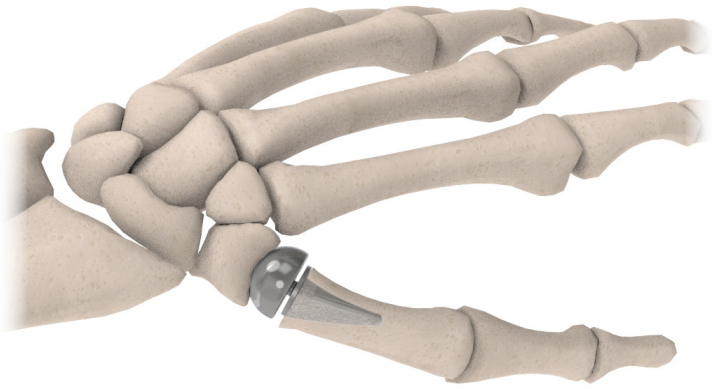


Using the Quick Connect Impactor, the trial stem is removed from the metacarpal.



Step Ten

Assemble the head and stem and place in the impaction block. Impact the head onto the stem using the impactor handle fitted with the impactor tip.



Step Eleven

Insert the assembly into the metacarpal and impact into the metacarpal until the collar of the prosthesis is flush with the resected surface of the metacarpal.

Again, stability and range of motion should be observed before wound closure.

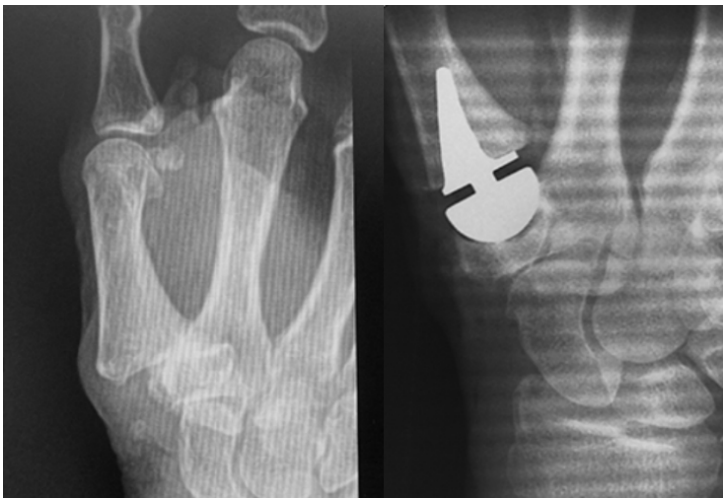
Step Twelve

The longitudinal contiguous capsule is closed tightly with 4-0 braided suture. Following the completion of the skin closure the thumb is immobilized in a position of abduction at the carpal-metacarpal joint and slight flexion at the metacarpalphalangeal joint for 4-6 weeks. A removable thumb spica is then worn for three to four weeks. Hand therapy may be required to regain motion and strength. Unrestricted activity is allowed 8-12 weeks post-op.

Important Note

If patient compliance is a potential concern, a non-removable cast is recommended for 4-6 weeks post-operatively.

Postoperative X-rays



Postoperative Protocol

The following protocol was developed as a guide to assist the hand therapist in treating patients who have undergone surgery for joint arthroplasty using the BioPro trapeziometacarpal implant. Patients undergoing this procedure have primarily been afflicted with CMC osteoarthritis at Eaton stages two and three. Post-operative care involves close communication between the hand therapist and surgeon in the planning of staged therapy and rehabilitation. Most importantly, the surgeon must decide how long the patient will remain in the immobilization stage for adequate biological fixation to occur. This will vary dependent upon the quality of the patient's bone. Other factors which may influence the progression rate of this protocol (delaying the advancement of therapy) include revision surgery, surgical complications such as fracture, diabetes or smoking.

In most instances, six weeks of immobilization in a thumb spica cast is recommended, with therapy initiated at Stage 2. In patients with excellent bone quality and a very stable implant confirmed by the surgeon, therapy is begun at Stage 1.

Stage 1: Immobilization (first 3 weeks post-operative)

Day 3-5 post-operative: Remove dressings and fabricate a forearm based, static palmer (volar) thumb spica splint, with the wrist in neutral radial/ ulnar deviation and in 10-15 degrees of extension. The thumb is positioned midway between palmer and radial abduction with the metacarpophalangeal (MP) joint in 30 degrees of flexion and the interphalangeal (IP) joint free. The splint is worn full time during the day and at night, removed only for therapist assisted range of motion in the clinic.

Day 7-21: Perform supervised, gentle, therapist assisted mobilization to the uninvolved joints in the therapy clinic only, consisting of wrist active assisted range of motion (AAROM) into extension/flexion and radial/ulnar deviation. AAROM is also performed by the therapist to the thumb MP and IP joints while fully supporting the carpometacarpal (CMC) joint of the thumb in abduction. The static splint is worn full time during the day and at night outside of the therapy clinic sessions. The splint is monitored closely to provide proper positioning, alignment, protection and immobilization at the CMC joint. Scar mobilization is initiated to minimize adhesions. Desensitization techniques are recommended to reduce hypersensitivity along the surgical site. Home instructions include arm and hand elevation to prevent/reduce swelling. Home exercises are permitted within the splint, to include active range of motion (AROM) of the fingers and thumb (IP joint only), 10-15 repetitions, 4-6 times per day. Passive range of motion (PROM), key/lateral pinching, thumb adduction and shearing pressures to the CMC joint of the thumb are avoided at all times.

Stage 2: Mobilization (weeks 4 through 7 post-operative)

Weeks 4-5: Consult with surgeon to determine if patient exhibits adequate stability or biological fixation of the implant for mobilization stage. If additional immobilization is warranted, continue stage one for an additional 1-2 weeks, for up to 6 weeks if indicated. If patient is cleared to begin mobilization, perform supervised, gentle, therapist assisted mobilization out of the splint, consisting of active assisted thumb palmar abduction from the relaxed position, 10-15 repetitions. In this exercise, the thumb is actively abducted perpendicular to the palm using the abductor pollicis brevis muscle. Next, perform active assisted thumb radial abduction, 10-15 repetitions. In this exercise, the thumb is actively abducted radially using the abductor pollicis longus. The patient is permitted to move the thumb in an arc from resting palmer abduction to a position of radial extension. Gentle active and active assisted wrist range of motion exercises are performed, 10-15 repetitions each. The lateral pinch position with flexion and adduction of the thumb metacarpal is avoided.

Continue to monitor splint for proper fit, alignment and positioning. With a reliable and responsible patient who demonstrates accuracy with these exercises in the therapy clinic, the therapist may initiate the exercises described above, to be performed outside of the therapy clinic, four to six times per day, 10-15 repetitions each. The splint is removed only for these exercises and bathing. Splinting is continued between exercise periods and at night.

Weeks 6-7: Modify forearm based splint into a hand based splint with surgeon approval, to be worn at all times except bathing and exercise. Opposition to each fingertip is begun out of the splint. Complete flexion across the palm to the fifth metacarpal crease should not be attempted until the thumb can oppose each fingertip with ease, and can be gradually mobilized down to the base of the small finger. Light grasp and prehension activities are permitted at home within the splint. Resistive gripping and pinching are avoided.

Stage 3: Strengthening (weeks 8 through 12 post-operative)

Weeks 8-9: Light strengthening exercises to the wrist and forearm are initiated. Light strengthening exercises to the thumb are begun, emphasizing palmar abduction, radial abduction and extension using rubberband resistance to the abductor pollicis brevis, abductor pollicis longus and extensor pollicis longus. Light resistance therapy putty exercises for grasp and opposition strengthening are begun. Light resistive 3-point pinching and opposition activities are begun out of the splint in the therapy clinic. Light functional self-care activities are initiated out of the splint at home. The patient is cautioned to avoid activities that require strong grasp and pinch.

Weeks 10-12: Grasp and pinch strengthening are progressed using therapy putty within pain free tolerance. As the strength of the thenar area increases, splint wear is gradually reduced until it is worn only for protection during heavy activities. By the end of the third month, the splint is eventually discontinued, at which time the patient is allowed more aggressive functional use for daily activities. Progressive, unrestricted use of the thumb usually occurs four to six months post surgery. Strength continues to improve for two years from the date of surgery.

Protocol provided by:
Joyce K. Stephens, MA, OTR, CHT.
Certified Hand Therapist

Implant Ordering

Cobalt Chrome

ITEM #	DESCRIPTION
17596	Stem Cobalt Chrome TPS 7.5mm
17597	Stem Cobalt Chrome TPS 8.5mm
17598	Stem Cobalt Chrome TPS 10.0mm
17599	Stem Cobalt Chrome TPS 11.5mm
20050	Stem Cobalt Chrome 7.5mm Long +4mm
20048	Stem Cobalt Chrome 8.5mm Long +4mm
19294	Stem Cobalt Chrome 10.0mm Long +4mm
19295	Stem Cobalt Chrome 11.5mm Long +4mm
17199	Head Cobalt Chrome 12mm
17238	Head Cobalt Chrome 12mm+2
17500	Head Cobalt Chrome 12mm+4
17005	Head Cobalt Chrome 13mm
17239	Head Cobalt Chrome 13mm+2
17501	Head Cobalt Chrome 13mm+4
17006	Head Cobalt Chrome 14mm
17240	Head Cobalt Chrome 14mm+2
17507	Head Cobalt Chrome 14mm+4
17007	Head Cobalt Chrome 15mm
17241	Head Cobalt Chrome 15mm+2
17508	Head Cobalt Chrome 15mm+4

*Highlighted implants are available upon special request

Implant Ordering

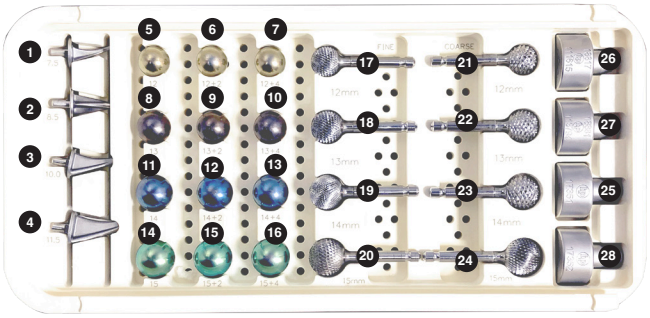
Titanium

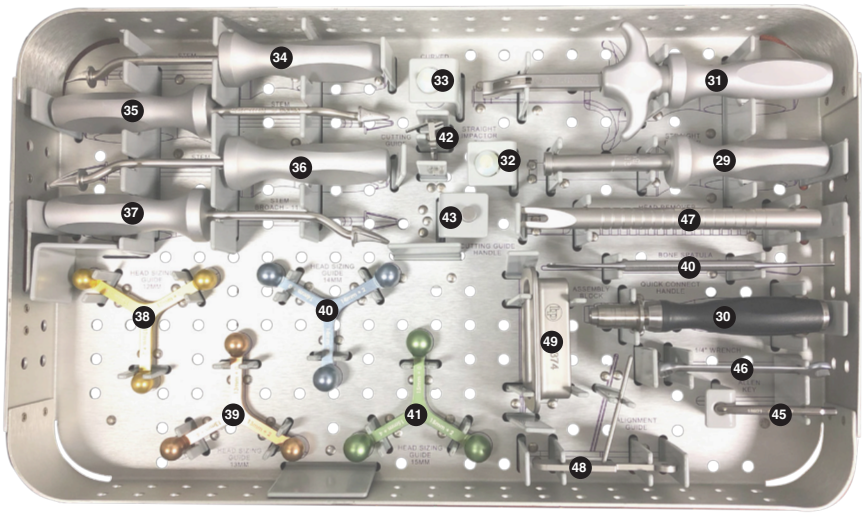
ITEM #	DESCRIPTION
17600	Stem Titanium TPS 7.5mm
17601	Stem Titanium TPS 8.5mm
17602	Stem Titanium TPS 10.0mm
17603	Stem Titanium TPS 11.5mm
17800	Head Titanium 12mm
17801	Head Titanium 12mm+2
20234	Head Titanium 12mm+4
17798	Head Titanium 13mm
17799	Head Titanium 13mm+2
20235	Head Titanium 13mm+4
17806	Head Titanium 14mm
17807	Head Titanium 14mm+2
20236	Head Titanium 14mm+4
17808	Head Titanium 15mm
17809	Head Titanium 15mm+2
20237	Head Titanium 15mm+4

Instrument Ordering

Item #	Description
18276	Round Carbide Burr 4.0mm
18277	Round Carbide Burr 5.0mm
18278	Round Carbide Burr 6.5mm
21691	Round Carbide Burr 6.0mm W/Notch

Instrument Overview





Modular Thumb Instrument Kit - 20066

Location	Item #	Description
1	17345	Stem Trial 7.5mm
2	17346	Stem Trial 8.5mm
3	17347	Stem Trial 10.0mm
4	17348	Stem Trial 11.5mm
5	17260	Head Trial 12mm
6	17264	Head Trial 12mm+2
7	17613	Head Trial 12mm+4
8	17261	Head Trial 13mm
9	17265	Head Trial 13mm+2
10	17614	Head Trial 13mm+4
11	17262	Head Trial 14mm
12	17266	Head Trial 14mm+2
13	17615	Head Trial 14mm+4
14	17263	Head Trial 15mm
15	17267	Head Trial 15mm+2
16	17616	Head Trial 15mm+4
17	19758	Burr Fine 12mm
18	19759	Burr Fine 13mm
19	19760	Burr Fine 14mm
20	19761	Burr Fine 15mm
21	19532	Burr Coarse 12mm
22	19533	Burr Coarse 13mm
23	19534	Burr Coarse 14mm
24	19535	Burr Coarse 15mm
25	17351	Burr Adaptor-Microaire
26	18817	Burr Adaptor Microchoice
27	18881	Burr Adaptor Mini Microaire
28	20284	Burr Adaptor Stryker TPS

Location	Item #	Description
29	15259	Impactor Handle
30	19125	Quick Connect Handle
31	19820	Quick Connect Trial Handle
32	17387	Impactor Tip (Straight)
33	17340	Impactor Tip (Curved)
34	19460	Stem Broach 7.5mm
35	19461	Stem Broach 8.5mm
36	19462	Stem Broach 10.0mm
37	19463	Stem Broach 11.5mm
38	19806	Sizing Guide 12mm
39	19807	Sizing Guide 13mm
40	19808	Sizing Guide 14mm
41	19809	Sizing Guide 15mm
42	20063	Cutting Guide
43	19399	Cutting Guide Handle
44	17383	Bone Spatula
45	18921	Allen Key
46	18929	Wrench
47	19832	Head Remover
48	19802	Alignment Guide W/Pin
49	17374	Assembly Block

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