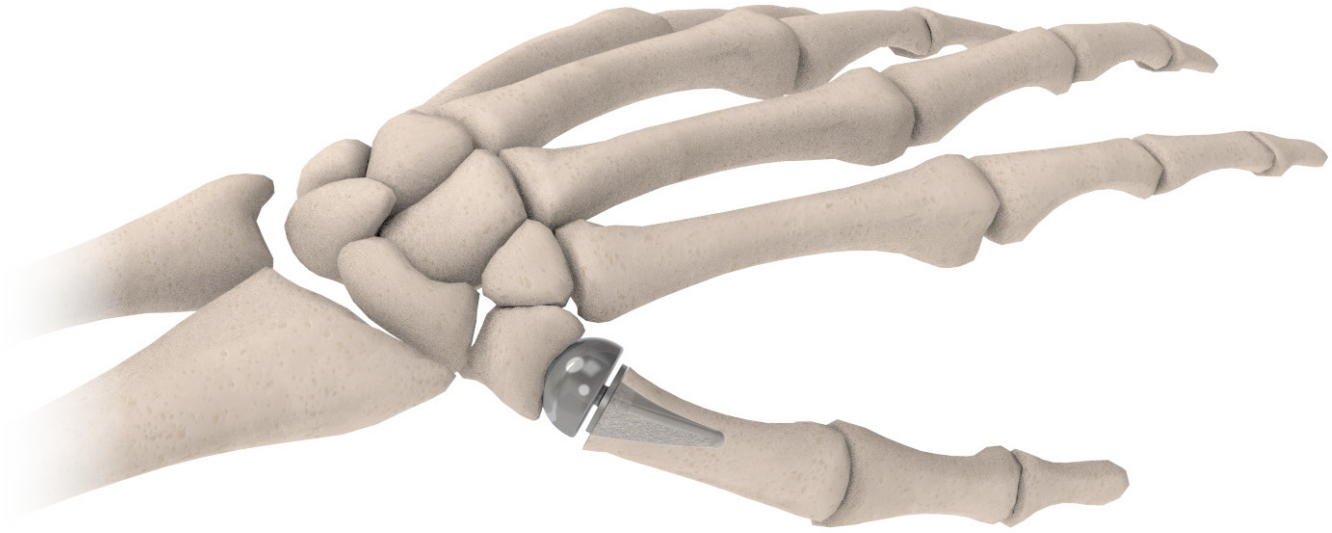
BIOLOGICALLY ORIENTED PROSTHESES

BIOPRO

Value Analysis Resource Guide
Modular Thumb Implant



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About Us

Founded as a research and development company for world-renowned surgeon, Charles Townley, MD, BioPro has been designing, developing, and manufacturing medical devices dating back to 1987.

BioPro's mission is to improve the quality of life for patients needing orthopedic surgery through the design, development, manufacturing and distribution of quality orthopedic products and services

As an FDA registered and ISO certified manufacturer, BioPro designs, develops, manufactures, and distributes products for companies across the globe.

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Product Overview

The Problem: Patients dissatisfied with traditional surgical procedures for thumb carpometacarpal arthritis.

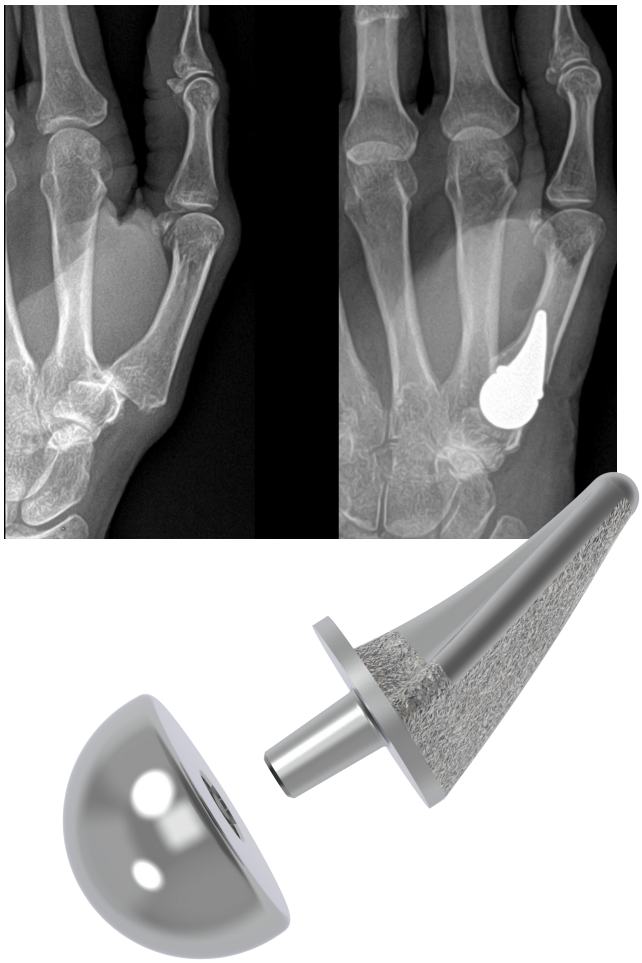
The thumb joint is one of the most common sites of arthritis in the body, affecting up to 15% of the population over age 30 and up to 33% of postmenopausal women.[1] The most common surgical treatment and the treatment often presented to patients involves the complete removal of the trapezium bone at the base of the thumb (trapeziectomy). Studies show that trapeziectomies with or without ligament reconstruction have a number of disadvantages leading to an unacceptably high number of dissatisfied patients.[6] These disadvantages include:

- Decrease in trapezium space, resulting in shortening of the thumb.[1,2,3]
- Initial decrease in pinch and grip strength, resulting in a long rehabilitation and recovery process.[2]
- If a trapeziectomy procedure fails, revision surgery results in significantly worse outcomes compared to primary surgery[4]

The Solution: The BioPro® Modular Thumb Implant

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 10 year outcomes.[5] The patented modular design allows the head to be sized independently of the stem to match the patient's anatomy.

- Maintains the length of the thumb
- Fast recovery with patients recovering on average 10 weeks faster than trapeziectomy with ligament reconstruction[5]
- Return of pinch and grip strength comparable to contra-lateral hand[5]
- 94% survivorship[5]
- 97% patient satisfaction[5]
- Multiple revision options available including revision to trapeziectomy with or without ligament reconstruction



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.

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.

Competitive Advantage

The BioPro Modular Thumb Implant is the only two piece thumb implant on the market today. Our patented design has addressed concerns with past implants and provides numerous advantages over traditional procedures.

Advantage 1: Maintains Thumb Length

Traditional Procedures
Trapeziectomy procedures allow for the metacarpal to subside into the trapezium space, resulting in shortening of the thumb.[1,2] Suspension techniques designed to suspend the first metacarpal to the second with suture or ligaments still may result in a significant decrease in trapezial space with possible degradation over time.[3]

The BioPro Modular Thumb
The procedure leaves the anatomy intact, only creating a shallow socket within the trapezium for the head to articulate. Follow up at an average of 6-years shows the procedure preserved metacarpal length and cosmetics in all patients.[5]

Advantage 2: Fast Recovery

Traditional Procedures
Trapeziectomy procedures typically require four weeks immobilization with initial decrease in strength noticed. Full recovery of strength is shown to take 12 months.[2]

The BioPro Modular Thumb
The procedure may allow patients to begin strengthening exercises at four to six weeks with full recovery by 12 weeks.[5]

Advantage 3: High Patient Satisfaction

Traditional Procedures
Due to the lengthy recovery process, thumb shortening and initial decrease in strength many patients express dissatisfaction after traditional procedures such as a trapeziectomy or trapeziectomy with ligament reconstruction.[6]

The BioPro Modular Thumb
Quick recovery, pain reduction and return of strength has led to a patient satisfaction rate of 97%. All patients surveyed that received both the BioPro Modular Thumb Implant and a trapeziectomy with ligament reconstruction, preferred the BioPro Modular Thumb Implant.[5]

Advantage 4: Doesn't Burn Bridges

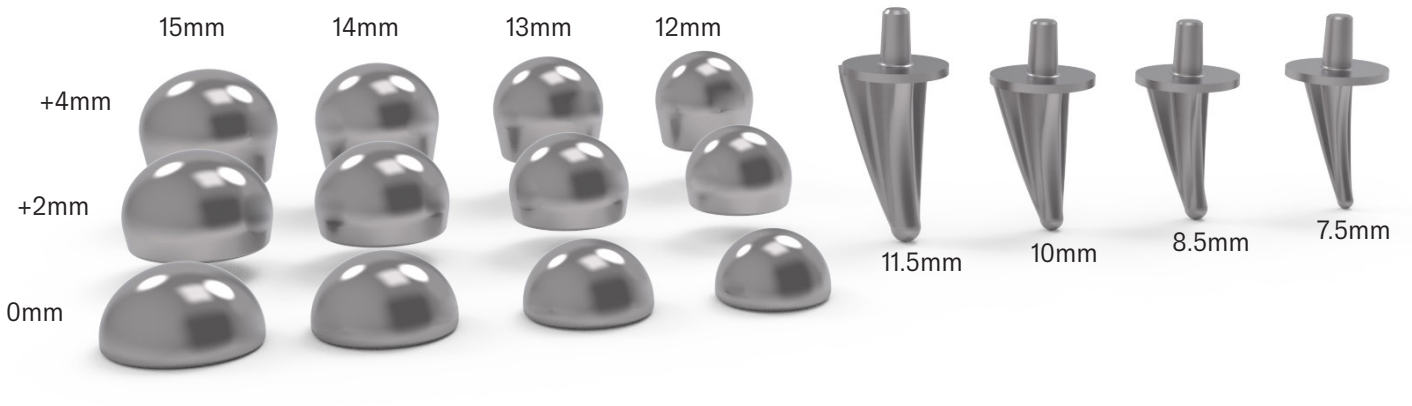
Traditional Procedures
If pain persists after a trapeziectomy procedure, the only option is a suspension technique. Data shows that revision surgery results in significantly worse outcomes compared to primary surgery.[4]

The BioPro Modular Thumb
Since the trapezium is preserved, multiple revision options are available including implant arthroplasty and a trapeziectomy with or without suspension.

Implant Options

Sizing

The system features 48 total combinations including four stem sizes for the metacarpal, four head diameters, and three head heights (offsets/neck lengths) for the trapezium.



Materials

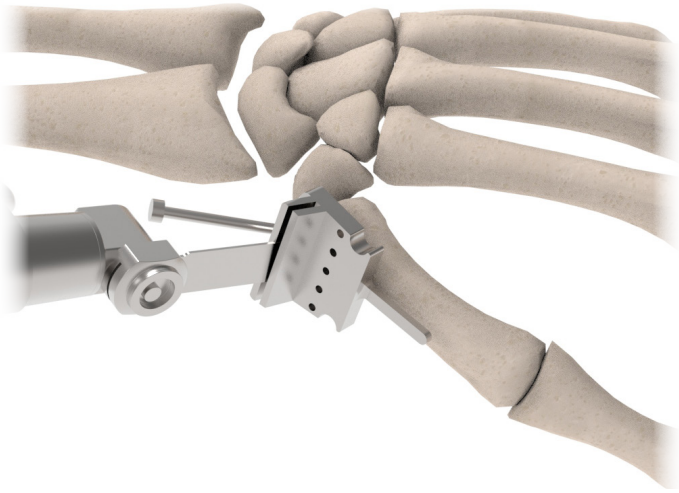
The standard implant is manufactured from cobalt chrome, a highly biocompatible and durable material. A titanium version is available for use in patients susceptible to nickel chromium allergies. The MELISA blood test may be performed to confirm a patient's potential metal sensitivities.

Revision Stems

If a revision is necessary, BioPro offers +4mm Revision stems for every stem size.

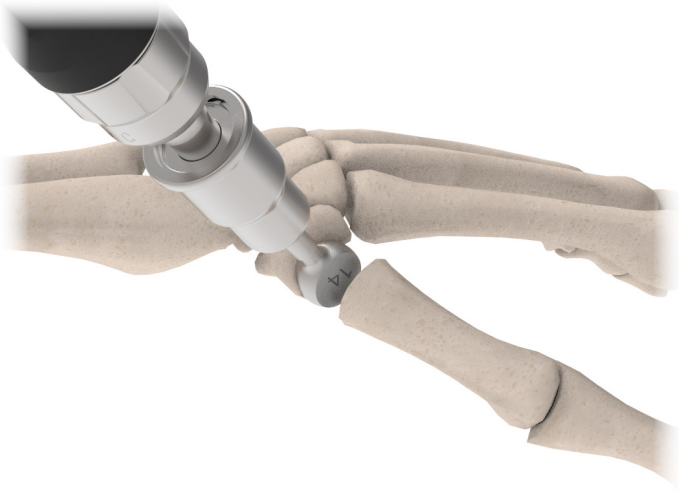
Surgical Technique

The following is an abbreviated technique. Please refer to surgical technique for complete details.

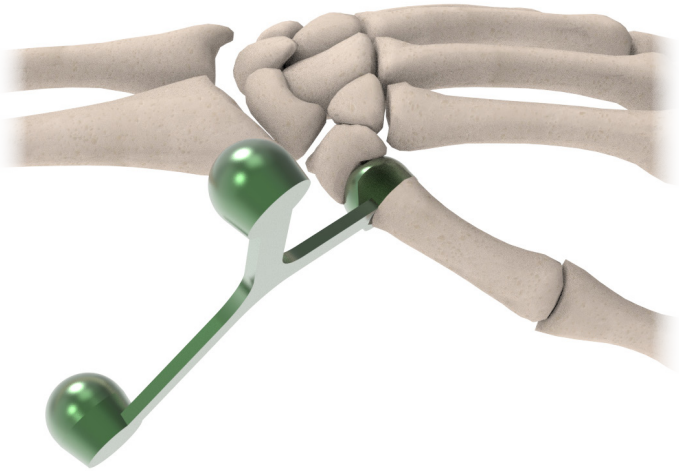


Step One
Utilizing the provided cutting guide, 5-6mm of bone is resected off the base of the metacarpal.

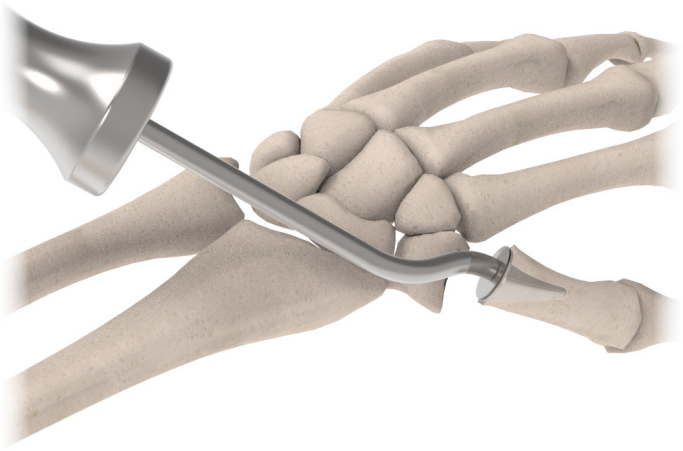
Step Two
After confirming the metacarpal resection, a medium size rotary burr (5-7mm) is used to create a medialized concentric concavity into the articulating surface of the trapezium.



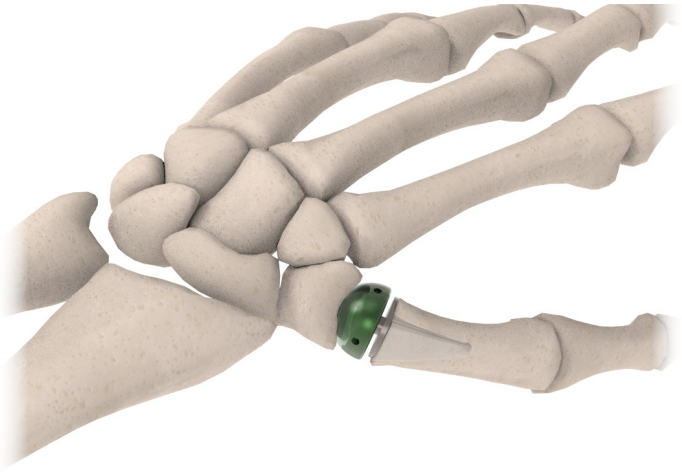
Step Three
Next, gradually enlarge the socket with the provided hemispherical burrs. There are four diameters (12, 13, 14, 15mm) available to choose from. Burr for the largest head possible, as this will allow the head to ride on the maximum surface area within the trapezium.



Step Four
The provided combination sizer and joint tensioning instrument is used to determine head diameter and height. Begin with the sizer matching the largest hemispherical burr used. The instrument allows the surgeon to assess stability and freedom of motion as well as examining the angle of the metacarpal resection.

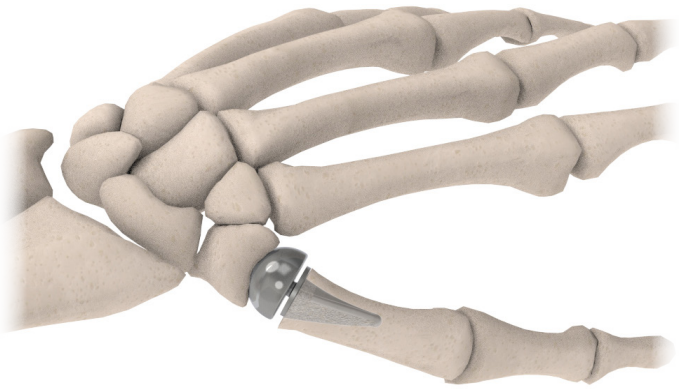


Step Five
After the desired head size is determined, insert the smallest (7.5mm) stem broach into the medullary canal of the metacarpal. The size of the stem broach is increased progressively until the periprosthetic cancellous bone has been fully compressed to provide an optimally tight medullary interference fit.



Step Six
Now a trial implant is used to confirm proper sizing prior to final implantation. Once the fully assembled trial component has been inserted into the joint, assess range of motion and joint stability.

Step Seven
After confirming proper sizing with the trial implant, the final implant is removed from the sterile packaging. The head is impacted onto the stem with the provided assembly block.



Step Eight
Insert the final implant into the metacarpal and impact until the collar of the implant is flush with the resected surface of the metacarpal. Again, stability and range of motion should be observed before wound closure.

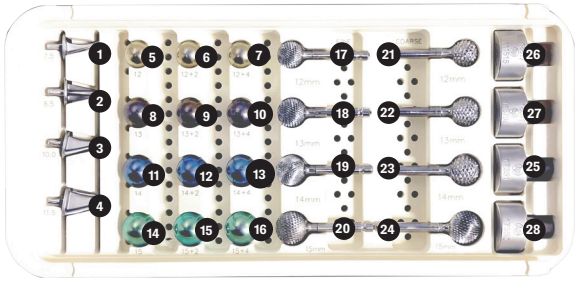
Ordering

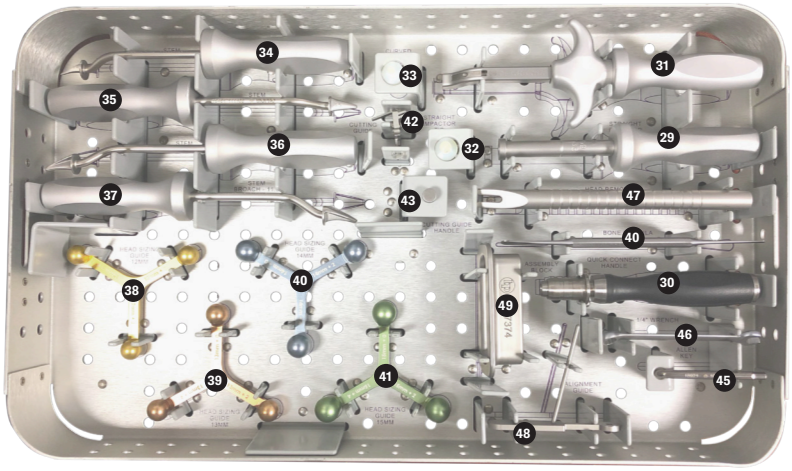
IMPLANTS	
ITEM #	**DESCRIPTION**
17596	Stem Cobalt Chrome TPS 7.5mm
17597	Stem Cobalt Chrome TPS 8.5mm
17598	Stem Cobalt Chrome TPS 10.0mm
17599	Stem Cobalt Chrome TPS 11.5mm
20050	Stem Cobalt Chrome 7.5mm Long +4mm
20048	Stem Cobalt Chrome 8.5mm Long +4mm
19294	Stem Cobalt Chrome 10.0mm Long +4mm
19295	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
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

ACCESSORIES	
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/J-Notch

Instrument Overview

The Modular Thumb Instrument Kit (ref 20066) is loaned to the facility at no cost. Please refer to the IFU for reprocessing parameters.





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

Reimbursement

Outpatient Reimbursement		National Medicare Average†				
CPT Code	Description	SI	APC	Hospital Outpatient	PI	Ambulatory Surgical Center
25445	Arthroplasty with prosthetic replacement, trapezium	J1	5114	$6,816	J8	$4,665

Physician Reimbursement		National Medicare Average	
CPT Code	Description	RVU	Payment (Facility)
25445	Arthroplasty with prosthetic replacement, trapezium	21.39	$718

†Payment may vary by location. Prices shown are national averages, based on Medicare's 2024 payments and copayments. Treatments may include one or more procedures.

The CPT codes provided in this reimbursement guide are for informational purposes only. The information provided is based upon AMA guidelines and CPT coding guidelines. CPT coding and billing is the sole responsibility of the billing party to ensure that all coding requirements, medical necessity standards and documentation requirements are met. BioPro assumes no responsibility for billing errors or billing decisions due to reliance on the CPT codes provided in this reimbursement guide, and, further, BioPro makes no claims, promises, or guarantees as to the availability of reimbursement for any of the CPT codes referenced herein. This reimbursement guide is not intended to constitute reimbursement or legal advice, nor is it intended to increase or maximize reimbursement by any payors. BioPro vigorously recommends consultation with payor organizations for insight as to their reimbursement policies prior to executing any billing decisions. Please contact your Medicare Contractor, other payors, and/or reimbursement specialists for interpretation of coding, coverage and payment policies.

FDA Information

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 15 2005

David Mrak
Director of Product Development
BioPro, Inc.
17 17th Street
Port Huron, Michigan 48060

Re: K052596
Trade/Device Name: BioPro Modular Thumb Implant
Regulation Number: 21 CFR 888.3770
Regulation Name: Wrist joint carpal trapezium polymer prosthesis
Regulatory Class: II
Product Code: KYI
Dated: August 2, 2005
Received: September 21, 2005

Dear Mr. Mrak:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

References

1. Higgenbotham C, Boyd A, Busch M, Heaton D, Trumble T. Optimal management of thumb basal joint arthritis: challenges and solutions. Orthop Res Rev. 2017 Nov 23;9:93-99. doi: 10.2147/ORR.S138809. PMID: 30774481; PMCID: PMC6209361.
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