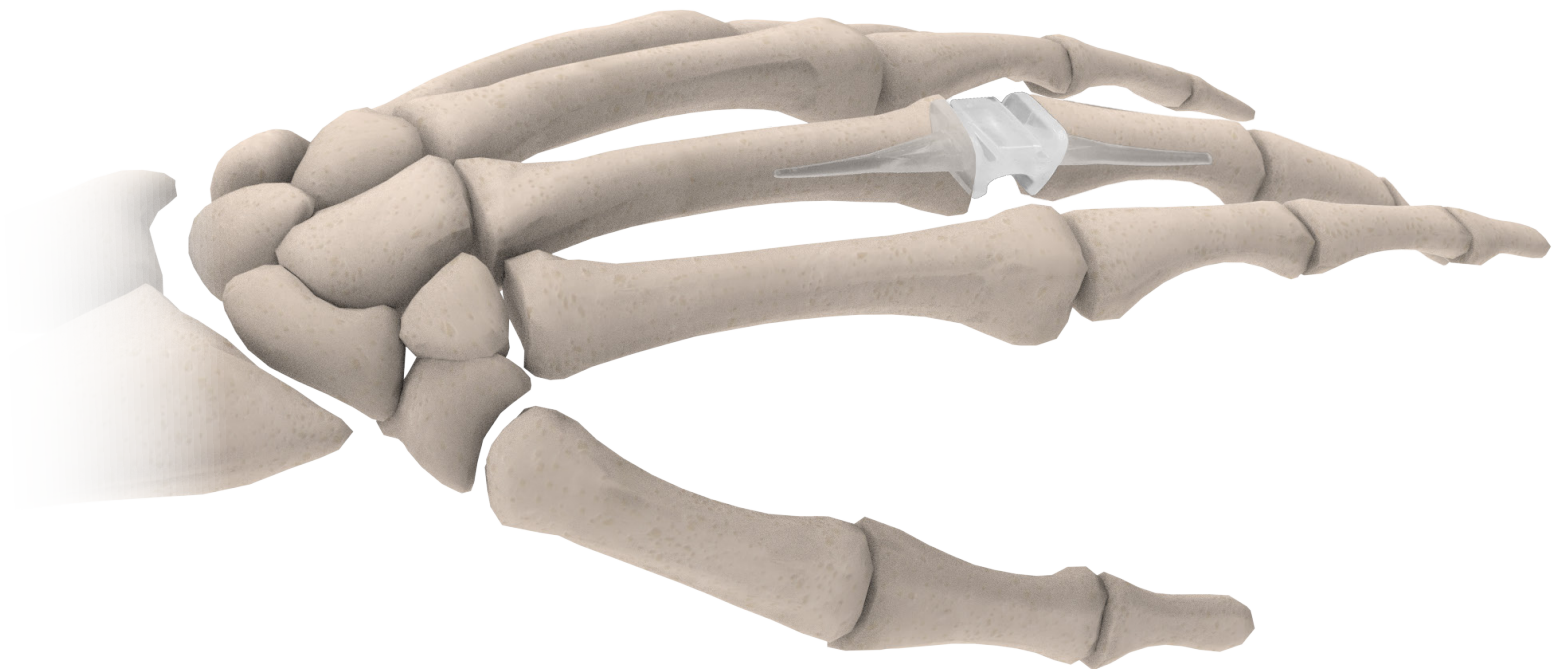


BIOLOGICALLY ORIENTED PROSTHESES

BIOPRO

Value Analysis Resource Guide
Digitalis Silicone Spacer



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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

Silicone implants, the current gold standard for metacarpophalangeal (MCP) and proximal interphalangeal (PIP) joint replacement, have unacceptably high fracture rates.

Studies have demonstrated that popular silicone implants exhibit fracture rates exceeding 50% at 72 months post-implantation. While these implants provide effective pain relief and restore function, the fracture potential presents a significant challenge in long-term clinical outcomes.

The Solution: Digitalis is a next-generation silicone spacer engineered to address the limitations of current implant designs.

By enhancing hinge strength and optimizing the implant's structural configuration, Digitalis minimizes the risk of fracture. Digitalis is designed to prevent hyperextension while preserving normal flexion, thereby replicating the natural kinematics of the finger joint. Furthermore, the implantation procedure for Digitalis has been streamlined to minimize the instrumentation required, reducing the complexity of the surgery.

5 Sizes MCP



4 Sizes PIP



Indications & Contraindications

Indications

The Digitalis Spacer MCP implants are intended for replacement of the metacarpophalangeal joint of the hand which has been damaged by:

- Osteoarthritis
- Rheumatoid arthritis
- Post traumatic arthritis

The Digitalis Spacer PIP implants are intended for replacement of the proximal interphalangeal joint of the hand which has been damaged by:

- Rheumatoid arthritis
- Osteoarthritis
- Ankylosed joints or those with limited range of motion which have not responded to conservative treatment
- Non-functional joint due to inadequate bony alignment and joint space which cannot be restored by soft tissue reconstruction alone
- Destroyed articular surface(s)

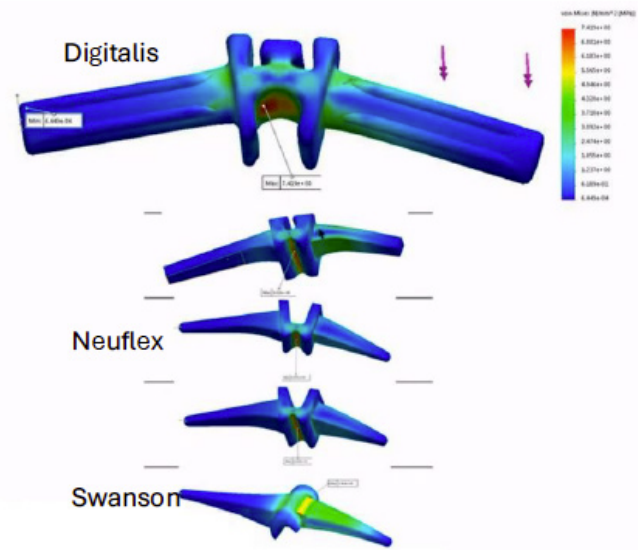
Contraindications

- Inadequate musculo-tendon and skin system
- Inadequate neuro-vascular system
- Bone demineralization at a significant stage
- Inadequate bone stock
- Child patient
- Infection in progress and active sepsis

Competitive Advantage

Advantage 1: Improved Strength

- Dorsal T design to avoid hyper-extension and strengthen the hinge.
- Spacers made of NuSil MED 4735: last generation silicone.
- Passed 10,000,000 load cycles and there was no failure or degradation of the implants.



Advantage 2: Improved Stability

- Thin stems to maintain intramedullary canal with triangular proximal section to improve stability.
- Stems with anti-rotational design: the proximal and distal parts of the stems are cylindrical with the same diameter. This part has a slightly contoured surface, which minimizes gliding out of the bony canal during bending.



Advantage 3: Natural Flexion

- Unlike traditional straight designs, the Digitalis offers 15°(PIP) and 30°(MCP) pre-flexed hinge to respect the normal finger position.



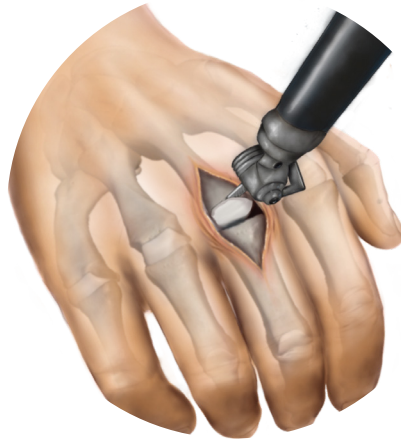
Surgical Technique

The following is an abbreviated technique. Please review the Instructions for Use prior to surgery.



Step One

Make a longitudinal incision along the MCP joint and expose the articulation, carefully preserving the capsule and the ligaments.



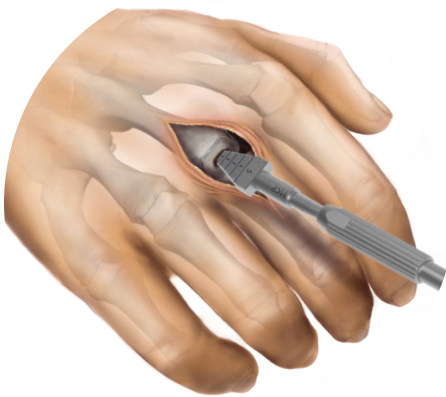
Step Two

Use a micro-oscillating saw for resecting the metacarpal head at the cartilage line. Remove any osteophytes or sharp spurs from the joint.



Step Three

Starting from the smallest size, use the test spacer to check and choose the one that best fits anatomically within the joint.



Step Four

Use the reamer to identify the metacarpal and proximal phalangeal canals. Then use the rasp to prepare the relative medullary canals: advance until reaching the depth corresponding to the chosen size, indicated by the laser lines on the instruments.



Step Five

Check again the correct sizing and the mobility of the joint using the trial spacer and insert the final implant.



Step Six

Correctly replace and suture the extensor tendon and wrap the radial cap and sagittal fascia. Move the joint again to ensure there is no extensor tendon subluxation from 0 to 90 degrees of flexion.

Ordering

ITEM #	DESCRIPTION
DDG3T01001	DIGITALIS MCP SPACER – SIZE 1
DDG3T01002	DIGITALIS MCP SPACER – SIZE 2
DDG3T01003	DIGITALIS MCP SPACER – SIZE 3
DDG3T01004	DIGITALIS MCP SPACER – SIZE 4
DDG3T01005	DIGITALIS MCP SPACER – SIZE 5
DDG3T02001	DIGITALIS PIP SPACER – SIZE 1
DDG3T02002	DIGITALIS PIP SPACER – SIZE 2
DDG3T02003	DIGITALIS PIP SPACER – SIZE 3
DDG3T02004	DIGITALIS PIP SPACER – SIZE 4

Instrument Overview

The Digitalis Instrument Kit is loaned to the facility at no cost. Please refer to the IFU for reprocessing parameters.



ITEM #	DESCRIPTION
DDGI203000	DIGITALIS HANDLE
DDGI201003	MULTISIZE TRIAL MCP
DDGI201004	MULTISIZE TRIAL PIP
DDGI201001	DIGITALIS MCP REAMER
DDGI202001	DIGITALIS MCP RASP
DDGI201002	DIGITALIS PIP REAMER
DDGI202002	DIGITALIS PIP RASP
DDGI201013	SILICONE MCP TRIAL SIZE 1
DDGI201023	SILICONE MCP TRIAL SIZE 2
DDGI201033	SILICONE MCP TRIAL SIZE 3
DDGI201043	SILICONE MCP TRIAL SIZE 4
DDGI201053	SILICONE MCP TRIAL SIZE 5
DDGI201014	SILICONE PIP TRIAL SIZE 1
DDGI201024	SILICONE PIP TRIAL SIZE 2
DDGI201034	SILICONE PIP TRIAL SIZE 3
DDGI201044	SILICONE PIP TRIAL SIZE 4

Reimbursement

Outpatient Reimbursement		National Medicare Average	
CPT Code	Description	Hospital Outpatient	Ambulatory Surgical Center
26531	Arthroplasty, metacarpophalangeal joint; with prosthetic implant, single, each	\$7,413	\$5,002
26536	Arthroplasty, interphalangeal joint; with prosthetic implant, single, each	\$7,413	\$4,782

†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

BRM Extremities Srl
% Margeaux Rogers
Director, Regulatory Affairs
Mera, LLC
803 7th Street NW
Washington, District of Columbia 20001

April 4, 2023

Re: K220142

Trade/Device Name: BRM Digitalis Spacer
Regulation Number: 21 CFR 888.3230
Regulation Name: Finger joint polymer constrained prosthesis
Regulatory Class: Class II
Product Code: KYJ
Dated: March 9, 2023
Received: March 9, 2023

Dear Margeaux Rogers:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Farzana Sharmin -S
Digitally signed by
Farzana Sharmin -S
Date: 2023.04.04
12:51:22 -04'00'

Farzana Sharmin, PhD
Acting Assistant Director
DHT6A: Division of Joint Arthroplasty Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure



Call us at 1-810-982-7777 to schedule a case today.

The Digitalis is a product manufactured by BRM Extremities. For more information visit www.brm-extremities.com

This content is provided as an educational tool only and is not meant as medical advice in the usage of specific BioPro products. A healthcare professional must use their professional judgment in making any final determinations in product usage and technique. The product's Instructions for Use, should always be reviewed prior to surgery. Postoperative management is patient-specific and dependent on the treating professional's assessment. Individual results will vary and not all patients will experience the same postoperative activity level or outcomes. This information does not constitute medical, legal, or any other type of professional advice and should not be relied upon as such. It is not to be redistributed, duplicated, or disclosed without the express written consent of BioPro, Inc.



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