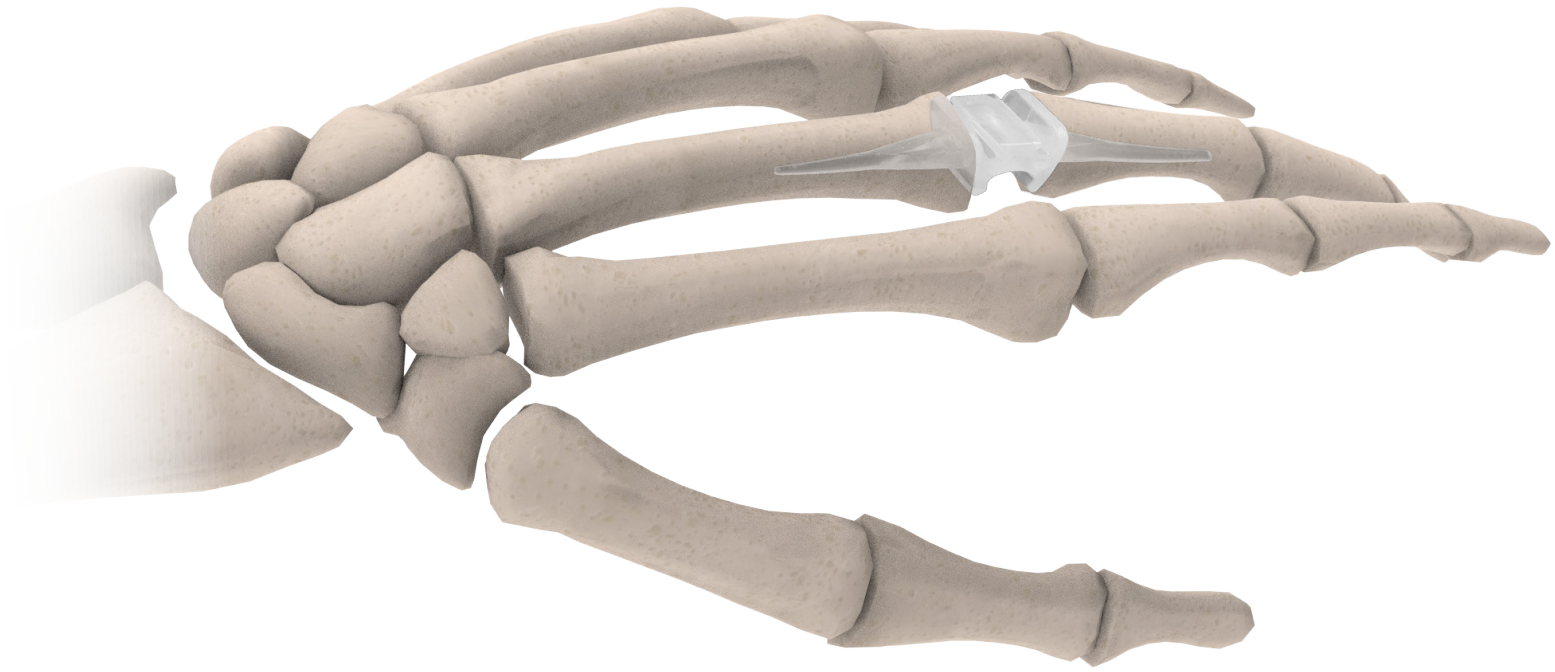
Biologically Oriented Prostheses

BIOPRO

# Digitalis®

## Surgical Technique



BRM® Extremities

# Contents

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# Indications & Contraindications

**The Digitalis is a product manufactured by BRM Extremities. For more information and indications for use visit www.brm-extremities.com**

**Implants are intended for the treatment of degenerative or inflammatory diseases, dislocations or subluxations for which MCP or PIP joint arthroplasty is necessary, such as:**

- Rheumatoid arthritis
- Arthrosis
- Ankylosing joints or joints with limited range of motion that did not respond to conservative treatment
- Non-functional joints due to inadequate bone alignment and joint space that cannot be restored by soft tissue reconstruction only
- Joint surfaces destroyed.

**The use of Digitalis device is generally not recommended in the following cases:**

- Inadequate muscle-tendon system and skin;
- Inadequacy of the neuro neuro-vascular system;
- Bone demineralization at a significant stage;
- Inadequate bone formation and quantity;
- Ongoing infection;
- Active sepsis;
- The psychological state of the patient is such that the implant is discouraged;
- Patients in childhood or who have not reached skeletal maturity yet.

# Implant Specifications

The Digitalis Silicone Spacer features a pre-flexed dual hinge design allowing for improved motion and longevity. The spacer is available in 5 sizes for the metacarpophalangeal (MCP) joints and 4 sizes for the proximal interphalangeal (PIP) joints.

| | |
|---|---|
| ✓ | 15°(PIP) and 30°(MCP) pre-flexed hinge to respect the normal finger position |
| ✓ | T-hinge prevents hyper-extension and improves strength |
| ✓ | Thin stems to maintain intramedullary canal with triangular proximal section to improve stability |
| ✓ | Proven durability: successfully tested to 10 million load cycles in accordance with ASTM F1781-2021. |
| ✓ | Modern instrumentation |

MCP
(30° Flexion)

PIP
(15° Flexion)

# Implant Specifications

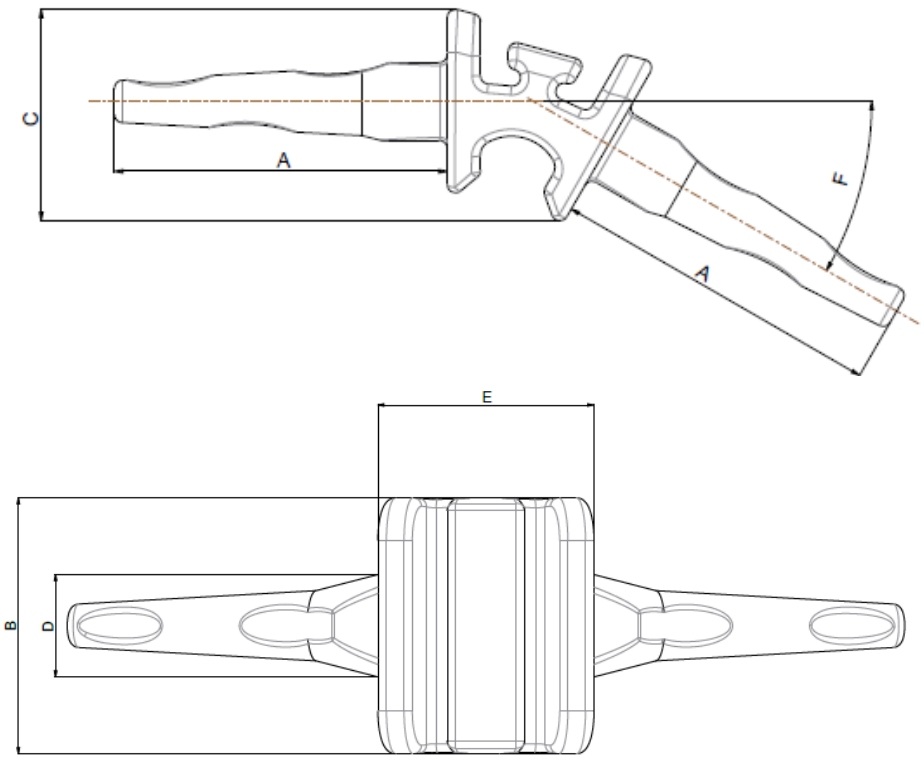



*Figure 1 – Identification of the main dimensions of the devices*

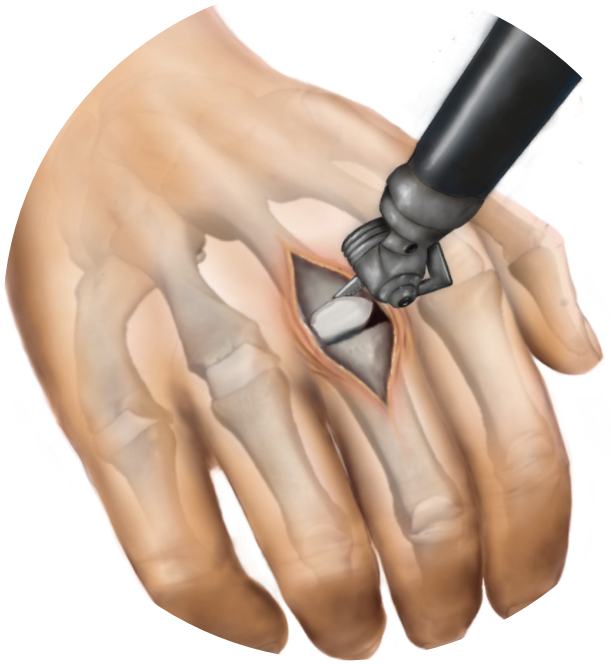
| Device | A (mm) | B (mm) | C (mm) | D (mm) | E (mm) | F (°) |
|---|---|---|---|---|---|---|
| DDG3T01001 | 12 | 9 | 7.6 | 3.6 | 7.6 | 30 |
| DDG3T01002 | 15 | 10.5 | 9.0 | 4.5 | 9 | 30 |
| DDG3T01003 | 18 | 12 | 10.6 | 5.4 | 10.7 | 30 |
| DDG3T01004 | 21 | 14 | 12.2 | 6.3 | 12.3 | 30 |
| DDG3T01005 | 24 | 16 | 14.7 | 7.2 | 15.2 | 30 |
| DDG3T02001 | 10 | 7 | 5.4 | 2.9 | 5 | 15 |
| DDG3T02002 | 12 | 8.5 | 6.4 | 3.9 | 6 | 15 |
| DDG3T02003 | 14 | 10 | 7.5 | 4.8 | 6.9 | 15 |
| DDG3T02004 | 16 | 11 | 8.5 | 5 | 7.9 | 15 |

*Table 1 – Main dimensions*

# Surgical Technique (MCP)

**Step One**

Make a 5 cm longitudinal incision along the back of the metacarpophalangeal joint (MCP). Divide the capsule lengthwise and dissect it to expose the joint, preserving as much of the capsule as possible for later repair. Continue the dissection so that the dorsal base of the proximal phalanx and the metacarpal head with the collateral ligament are visible.



**Step Two**

Resect the metacarpal head at the distal end and at the base of the proximal phalanx, using an oscillating micro saw in a plane perpendicular to the long axis of the metacarpal shaft. Remove any osteophytes or sharp spurs from the joint.

Note: Resection at the joint at the cartilage line is recommended.

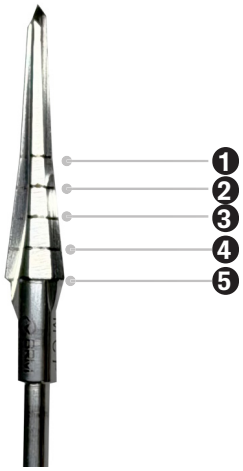

**Step Three:**

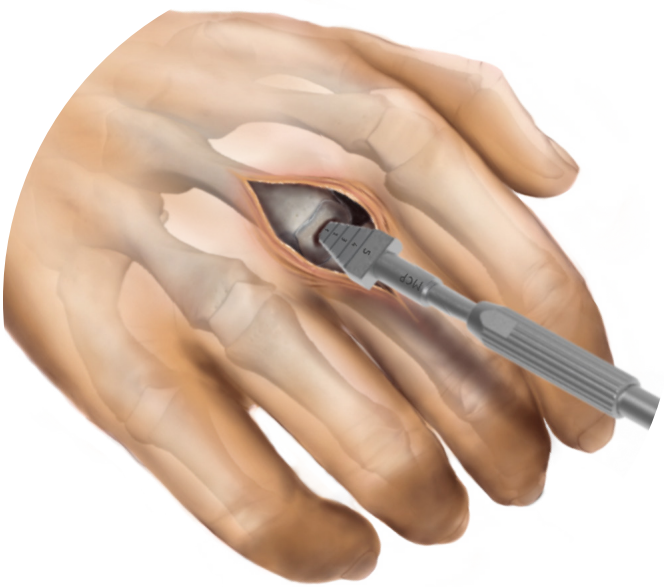
From the smallest size, insert the test spacer located inside the instrumentation supplied with the device, test it and choose the one that best anatomically fits to the joint. Check the perfect adherence of the spacer to the surface of the resected bone planes, checking the mobility, alignment and stability of the implant.

**Step Four:**

Manually identify the metacarpal and proximal canals of the phalanx, using a tip. Once the canal has been identified, introduce the reamer mounted on the handle. Proceed into the medullary canal until the depth corresponding to the chosen size, clearly indicated on the reamer, is reached.

Note: Each laser line coordinates with the implant size chosen with the test spacer in step three.

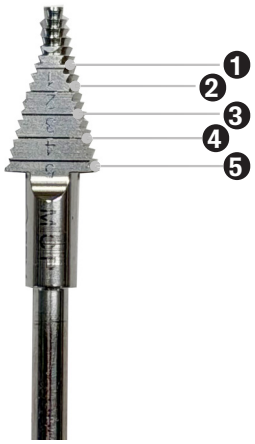




**Step Five:**

Then use the rasp to complete the preparation of the medullary canals (regardless of whether you start with the metacarpal or the phalangeal canal first), taking care to keep the upper, lateral and medial edges of the rasp parallel with the corresponding edges of the relevant bone portions. To avoid rotation during broaching, use an advance advance-retraction scraping method. Advance until the depth corresponding to the chosen size, clearly indicated on the rasp, is reached.

Note: Each laser line coordinates with the implant size chosen.




**Step Six:**

Insert the trial spacer corresponding to the chosen size and verify the perfect adherence of the spacer to the surface of the resected bone planes, checking the mobility, alignment and stability of the implant.

Note: Flex the joint at 90 ° insert the proximal stem and while holding the hinge in place, use non-toothed pickups to insert the distal stem. Continue holding the hinge of the implant while distracting and extending the joint.

**Step Seven:**

Insert the final implant. Use one or two tension sutures to position the extensor tendon directly over the midline of the dorsal portion of the metacarpophalangeal joint. Wrap the radial cap and sagittal fascia. Move the joint again to ensure that there is no subluxation of the extensor tendon from 0 to 90 degrees of flexion. Irrigate the wound.

**Step Eight:**

Suture capsule and cutaneous and subcutaneous tissues.

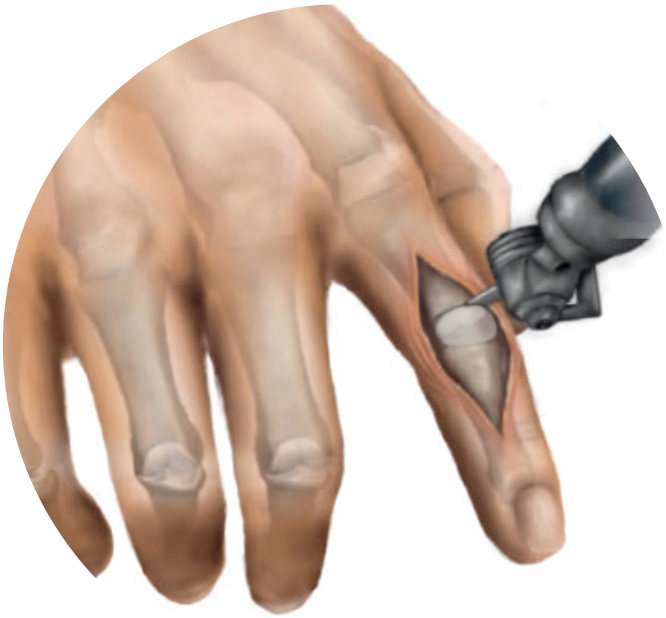
**Postoperative care**
Put on a thick splint bandage, keeping your finger fully extended. Leave the splint in place for 5 to 8 days before starting rehabilitation treatment.

**Removal**
If the implant needs to be removed: make a dorsal incision along the affected joint (proceeding medially to the extensor tendon) and perform a full thickness capsulotomy.
Remove the silicone component with the aid of a needle holder and perform an implant review or an arthrodesis operation depending on the most appropriate clinical indication for the case. Suture the capsule and the patient's skin again.

# Surgical Technique (PIP)

**Step One**

Make a gradual curved dorsal incision over the PIP joint. Dissect to the bundle of the extensor tendon. Gently lift the skin layers by means of careful dissection to expose an appropriate portion of the extensor tendon bundle. Make an incision between the central tendon of the extensor tendon bundle and the lateral fascia on one side of the finger using a No. 15 blade. Occasionally, it may be necessary to make an incision between the central tendon and the lateral fascia on the opposite side of the finger. Make an incision in the dorsal capsule longitudinally to expose the dorsal PIP joint. Some recession of the dorsal portion of the collateral ligaments may be necessary to allow adequate exposure of the proximal interphalangeal joint.



**Step Two**

Protecting the central tendon with retractors, use an oscillating micro-saw to resect the head of the proximal phalanx and medial base. Remove any osteophytes or sharp spurs from the joint.

Note: Resection at the joint at the cartilage line is recommended.

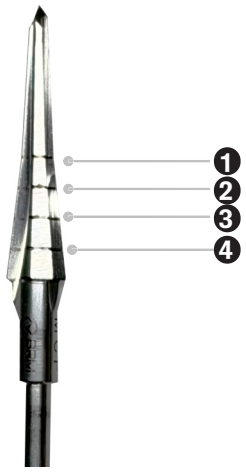

**Step Three:**

From the smallest size, insert the test spacer located inside the instrumentation supplied with the device, test it and choose the one that best anatomically fits to the joint. Check the perfect adherence of the spacer to the surface of the resected bone planes, checking the mobility, alignment and stability of the implant.

**Step Four:**

Manually locate the medullary canals of the proximal and medial phalanx using a tip. Once the canal is located, introduce the reamer mounted on the handle. Use the key on the Multisize Trial to tighten the reamer on the handle. Proceed into the medullary canal until the depth corresponding to the chosen size, clearly indicated on the reamer, is reached. Remove the reamer from the handle using the key on the Multisize Trial.

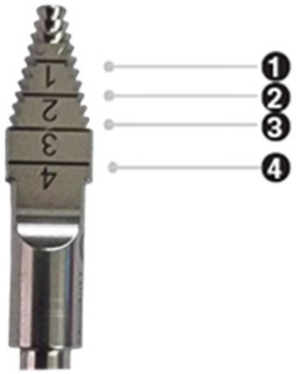
Note: Each laser line coordinates with the implant size chosen with the test spacer in step three.



**Step Five:**

Then use the rasp to complete the preparation of the medullary canals (regardless of whether you start with the proximal or medial phalangeal canal first), taking care to keep the upper and lateral and medial edges of the rasp parallel with the corresponding edges of the relevant bone portions. Use the key on the Multisize Trial for clamping the rasp on the handle. To avoid rotation during broaching, use an advance advance-retraction scraping method.
Advance until you reach the depth corresponding to the chosen size, clearly indicated on the rasp.

Note: Each laser line coordinates with the implant size chosen.




**Step Six:**

Insert the trial spacer corresponding to the chosen size and verify the perfect adherence of the spacer to the surface of the resected bone planes, checking the mobility, alignment and stability of the implant.

Note: Flex the joint at 90 ° insert the proximal stem and while holding the hinge in place, use non-toothed pickups to insert the distal stem. Continue holding the hinge of the implant while distracting and extending the joint.

**Step Seven:**

Insert the final implant. Use one or two tension sutures to position the extensor tendon directly over the midline of the dorsal portion of the proximal interphalangeal joint.

**Step Eight:**

Suture capsule and cutaneous and subcutaneous tissues.

**Observation**
To obtain sufficient exposure of the joint in difficult cases, it may be necessary for the collateral ligament to be sectioned on one side by the proximal phalanx to allow exposure. In this case, repair the collateral ligament using non non-absorbable monofilament sutures No. 4-0. If necessary, repair the capsule and the extensor mechnism with non non-absorbable monofilament sutures No. 4-0. Place a drain and close the skin with a compatible dressing, keeping the PIP joint in a very slight 10-20 degree flexion.

**Postoperative care**
Bandage your finger and keep it in a resting position for 03 to 04 weeks before starting rehabilitation treatment.

**Removal**
If the implant needs to be removed: make a gradual curved dorsal incision over the affected PIP joint (proceeding medially to the extensor tendon) and perform a full thickness capsulotomy. Remove the silicone component with the aid of a needle holder and perform an implant review or an arthrodesis operation depending on the most appropriate clinical indication for the case. Suture the capsule and the patient's skin again.

# Instrument Overview


**Digitalis Instrument Kit - KIT.DIGITALS**

| Location | Item # | Description |
|---|---|---|
| 1 | DDGI203000 | DIGITALIS HANDLE |
| 2 | DDGI201003 | MULTISIZE TRIAL MCP |
| 3 | DDGI201004 | MULTISIZE TRIAL PIP |
| 4 | DDGI201001 | DIGITALIS MCP REAMER |
| 5 | DDGI202001 | DIGITALIS MCP RASP |
| 6 | DDGI201002 | DIGITALIS PIP REAMER |
| 7 | DDGI202002 | DIGITALIS PIP RASP |
| 8 | DDGI201013 | SILICON MCP TRIAL SIZE 1 |
| 9 | DDGI201023 | SILICON MCP TRIAL SIZE 2 |
| 10 | DDGI201033 | SILICON MCP TRIAL SIZE 3 |
| 11 | DDGI201043 | SILICON MCP TRIAL SIZE 4 |
| 12 | DDGI201053 | SILICON MCP TRIAL SIZE 5 |
| 13 | DDGI201014 | SILICON PIP TRIAL SIZE 1 |
| 14 | DDGI201024 | SILICON PIP TRIAL SIZE 2 |
| 15 | DDGI201034 | SILICON PIP TRIAL SIZE 3 |
| 16 | DDGI201044 | SILICON PIP TRIAL SIZE 4 |

# Implant 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 |

BIOLOGICALLY ORIENTED PROSTHESES

BIOPRO

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

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intertek