DIGITALIS

USE AND MAINTENANCE MANUAL

CE 0426

LEGAL NOTICE

BRM Extremities S.r.l. disclaims any liability for damage to persons or objects, due to improper use of this product and failure to comply with the instructions, failure to observe the instructions, warnings, instructions and precautions contained in this user manual.

This user manual is provided printed only and must always accompany the Digitalis device.

Digitalis is manufactured by:

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SUMMARY

1 GENERAL INFORMATION

Digitalis is a medical device designed and manufactured to offer the surgeon specialized in hand surgery a solution for patients suffering from severe rheumatic diseases [arthritic diseases], for whom arthroplasty surgery of the metacarpophalangeal (MCP) or proximal interphalangeal joints (IFP) of the fingers is required. The device consists of a medical grade silicone elastomer spacer (NuSilTM MED-4735), which replaces the joint and consists of two stems:

- the distal stem that guarantees anatomical adaptation in relation to the intramedullary canal of the phalanx;
- the proximal stem that helps in adapting to the metacarpal (in case of MCP joint) or phalangeal (in case of IFP joint) intramedullary canal.

Stems allow stability of the spacer and keep it in the joint, and have anti-rotation design. The hinge is manufactured with a dorsal T-shaped design to prevent hyperextension. Stems also have an inclination in relation to the hinge of 15° (IFP) and 30° (MCP), pre-bending angle, to respect the normal position of the fingers and avoid an overload of the silicone material.
The presence of an articulated hinge, between the pivots, allows to restore the finger dorsiflexion movement.

1.1 INTENDED USE

The intended use of the device covered by this FT [fascicolo tecnico [technical file]] is the arthroplasty of MCP and IFP joints of the hand. Implants are intended to the treatment of degenerative or inflammatory diseases, dislocations or subluxations for which MCP or IFP 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 devices represent a permanent implant and are designed to be used as spacers between the bones, to relieve pain and promote greater range of motion in the extremities.

1.2 CLASSIFICATION

Classification according to Directive 93/42/EEC, Annex IX, rule 8, class IIb.

ATTENTION!

THE DEVICE IS INTENDED FOR USE BY SPECIALIZED ORTHOPEDIC SURGEONS, PROPERLY TRAINED IN PERFORMING HAND ARTHROPLASTY

1.3 USEFUL LIFE OF DEVICE

The device is provided sterile and is intended for single use only. The useful life of the device, therefore, corresponds to its use or to the end of the sterility guarantee, whose date is clearly indicated on the packaging.
Once implanted, the device has a useful life of 05 years.
During this period, it is necessary to carry out periodic checks, regarding the content of section 2.1 INFORMATION TO BE PROVIDED TO THE PATIENT.

1.4 KNOWN CONTRAINDICATIONS AND SIDE EFFECTS

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

- Inadequate muscle-tendon system and skin;
- Inadequacy of the 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.

The possibility of developing the following side effects due to the characteristics of the device or possible implant errors should be considered:

- Infection
- Device break
- Pain
- Device displacement
- Hypersensitivity to silicone
- Reaction to foreign body
- Damage to soft tissues, nerves, blood vessels and surrounding tendons
- Loss or reduction of joint mobility
- Synovitis
- Complications of bone cysts.

1.5 SYMBOLOGY

To make the reading of the manual pleasant and clear, the symbols used to manage important warnings for proper and safe use of the device are shown below.

	**Requirement for proper use** This symbol identifies the presence of information for proper use of the device.
	**Requirement of information** This symbol identifies the presence of useful and general information, whose reading guides the user towards the conscious use of the device and/or the performance of actions.

CE 0426	Identifies that the product is manufactured, designed and produced in compliance with the safety requirements (RES) of the Medical Devices Directive 93/42/EEC (Class IIb medical device, compliant with classification rule 8, according to in Annex IX).

1.6 PRELIMINARY NOTICES

Failure to follow the warnings below, as well as the rules and precautions described in this user manual, will result in the immediate loss of any warranty on the Digitalis device.
BRM Extremities S.r.l. is not responsible for any damage to people or property as a result of non-compliance with the rules or precautions listed below and generally reported in this user manual.

⚠	FAILURE OR NEGLIGENCE IN COMPLYING WITH THE FOLLOWING INSTRUCTIONS MAY CAUSE MALFUNCTION, DAMAGE AND INJURY TO THE USER OR PATIENT
⚠	DO NOT USE THE DEVICE UNTIL YOU HAVE FULLY READ AND UNDERSTOOD THIS USER MANUAL
⚠	NO DEVICE MODIFICATION IS ALLOWED
⚠	USE OF THE DEVICE FOR PURPOSES OTHER THAN THOSE INDICATED IN THIS USER'S MANUAL MAY EXPOSE THE PATIENT AND THE USER TO HAZARDS
⚠	THE DEVICE IS DISPOSABLE; RE-USE AND ANY REPROCESSING ACTIVITY IS STRICTLY PROHIBITED; REUSE MAY RESULT IN THE TRANSMISSION OF BIOCONTAMINATING AGENTS.

1.7 PACKAGE CONTENTS AND ACCESSORIES

Digitalis device is supplied sterile (ethylene oxide sterilization) in a cardboard package. Inside the box there is a double envelope containing the silicone device. The box also contains these instructions for use and traceability labels for medical records.
Digitalis device is sold in 09 different sizes, 04 for the IFP joint and 05 for the MCP joint, as listed below.

REF	Description
DDG3T01001	MCP SPACER DIGITALIS - SIZE 1
DDG3T01002	MCP SPACER DIGITALIS - SIZE 2
DDG3T01003	MCP SPACER DIGITALIS - SIZE 3
DDG3T01004	MCP SPACER DIGITALIS - SIZE 4
DDG3T01005	MCP SPACER DIGITALIS - SIZE 5
DDG3T02001	IFP SPACER DIGITALIS - SIZE 1
DDG3T02002	IFP SPACER DIGITALIS - SIZE 2

DDG3T02003	IFP SPACER DIGITALIS - SIZE 3
DDG3T02004	IFP SPACER DIGITALIS - SIZE 4

Digitalis device is also equipped with a dedicated surgical instrument (accessory of the device), sold separately and to be used during the performance of the surgery and in the correct implantation of the device.

THE USE OF ELEMENTS THAT DO NOT MAKE UP THE SYSTEM DESCRIBED ABOVE OR NOT PROVIDED WITH THE DEVICE MAY AFFECT SAFETY AND EFFECTIVENESS.

If all of the elements listed above have not been received, contact the manufacturer immediately

2 HOW TO USE

2.1 INFORMATION TO BE PROVIDED TO THE PATIENT

The patient must be warned and informed about the following aspects before being submitted to the implantation of this device:

Avoid subjecting the anatomical area operated to excessive mechanical stress

Digitalis device allows pain relief and recovery of the functionality of the affected metacarpophalangeal or interphalangeal joint; however, it is not recommended that patients who have been implanted with the device perform sports activities that may cause excessive stress on the joint

In case of evident stiffness perceived or excessive elasticity of the joint, it is advisable to contact the location where the implant was performed

It is highly inadvisable to perform tests that require magnetic resonance imaging

It is advisable to follow the following sequence of checks:

01 month - 06 months - 12 months - 24 months - 36 months - 48 months - 60 months.

Or follow your doctor's prescriptions.

2.2 UNPACKING

CHECK THE INTEGRITY OF THE DEVICE AND PRIMARY PACKAGING BEFORE PROCEEDING WITH THE NEXT STEPS: IF THE DEVICE OR THE PACKAGE IS DAMAGED, DO NOT USE THE DEVICE AND DISCARD IT, FOLLOWING THE INSTRUCTIONS IN THE CHAPTER “DISPOSAL”.

CHECK THE EXPIRY DATE ON THE PACKAGE: IF SUCH DATE IS EXPIRED, DO NOT USE THE DEVICE AND DISCARD IT BY FOLLOWING THE INSTRUCTIONS IN THE CHAPTER “DISPOSAL”.

It is recommended to remove the device from its primary packaging only after choosing the appropriate size (using the test devices provided with the instruments) and after the correct sizing and preparation of the implant site, in order to reduce the risk of contamination of the device.

Once the anti-dust film is removed and the box and packages containing the spacer are open, the latter must be placed, waiting for the implant, in sterile saline.

2.3 SURGICAL TECHNIQUE FOR IMPLANTATION AND REMOVAL OF THE DEVICE

DIGITALIS IFP SURGICAL TECHNIQUE

Stage 1 - Joint exposure

Make a gradual curved dorsal incision over the IFP 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 IFP joint. Some recession of the dorsal portion of the collateral ligaments may be necessary to allow adequate exposure of the proximal interphalangeal joint.

Step 2 - Osteotomy of the joint surfaces

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.

Step 3 - Choice of size

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 4 - Preparation of medullary canals

Manually locate the medullary canals of the proximal and medial phalanx using a tip. Once the canal has been identified, insert the scraper (mounted on the appropriate scraper holder) and scrape the relative medullary canals (regardless of whether you start first with the proximal or medial phalangeal canal), taking care to keep the upper, lateral and medial edges of the rasp parallel to the corresponding edges of the related bone portions. In the case of very sclerotic bone, first use a reamer to facilitate the posterior entry of the file. To avoid rotation when using a drill bit, use a retractable feed scraping method. Proceed until reaching the depth corresponding to the chosen size, clearly indicated in the file provided in the instruments provided.

Step 5 - Final implant

Insert the final implant after assessing the size. Use one or two tension sutures to position the extensor tendon directly over the midline of the dorsal portion of the proximal interphalangeal joint. 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-absorbable monofilament sutures No. 4-0. If necessary, repair the capsule and the extensor mechanism with non-absorbable monofilament sutures No. 4-0. Place a drain and close the skin with a compatible dressing, keeping the IFP 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 IFP 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.

DIGITALIS MCP SURGICAL TECHNIQUE

Stage 1 - Joint exposure

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 2 - Osteotomy of the joint surfaces

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.

Step 3 - Choice of size

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 4 - Preparation of medullary canals

Manually identify the metacarpal and proximal canals of the phalanx, using a tip. Once the channel has been identified, insert the scraper (mounted on the appropriate scraper holder) and scrape the relative medullary canals (regardless of whether you start first with the metacarpal or the phalangeal canal), taking care to keep the upper, side and medial edges to rasp parallel to the corresponding edges of the related bone portions. In the case of very sclerotic bone, first use a reamer to facilitate the posterior entry of the file. To avoid rotation when using a drill bit, use a retractable feed scraping method. Proceed until reaching the depth corresponding to the chosen size, clearly indicated in the file provided in the instruments provided.

Step 5 - Final implant

Insert the final implant after assessing the size. 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.

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.

THE DEVICE IS DISPOSABLE; THEREFORE, ONCE REMOVED FROM THE IMPLANT LOCATION, IT MUST BE DISCARDED FOLLOWING THE INSTRUCTIONS IN THE CHAPTER “DISPOSAL”.

3 DISPOSAL

The device that has expired or in any case to be disposed of must be managed in accordance with the waste management regulations of the Local Management Body (Special hospital

waste). Do not, under any circumstances, discard the product or its packaging in the environment.

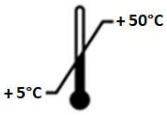
4 ENVIRONMENTAL CONDITIONS

Store the device in its original packaging, away from moisture and direct sources of light and heat, respecting the following environmental conditions.

Environmental conditions	Temperature:	Use	+10 / +40°C
		Storage / transportation	+5 / +50°C
	Humidity:	Use	20 / 80% RH without condensation
		Storage / transportation	5 / 95% RH without condensation
	Atmospheric pressure:	Use	700 to 1020 hPa
		Storage / transportation	500 to 1060 hPa

5 SYMBOLOGY USED ON LABEL

	Manufacturer identification
	Product identification code
	Lot number
	Attention, refer to the user manual. Safety information
	Attention, sales only with the prescription of an authorized health professional
	Sterilization with ethylene oxide
	Do not sterilize again
	Do not use if packaging is not intact
	Do not reuse
	See instructions for use

 MM/YYYY	Use until the indicated date
	Keep protected from light
	Store in a dry place
	Ambient storage temperature
	The device and its packaging are manufactured without the use of natural rubber latex
CE 0426	In accordance with Council Directive 93/42/EEC and subsequent additions and amendments, MD Class IIb. The 04 digit code indicates the certification body of the device.