SILKTOE

USE AND MAINTENANCE MANUAL

CE 0426

DISCLAIMER

BRM Extremities S.r.l. declines all responsibility for damage to persons or property due to improper use of this product and failure to follow the instructions, warnings, instructions and precautions described in this user manual.

This user manual is provided only in paper format and must always be provided together with Silktoe device.

Silktoe is manufactured by:

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SUMMARY

1 GENERAL INFORMATION

Silktoe is a medical device designed and manufactured to offer specialist orthopaedic surgeons with a good solution for patients affected by severe arthritic diseases for which arthroplasty of the metatarsophalangeal joint of the big toe (MTP1) is necessary. The device consists of an elastomeric medical grade silicone spacer (NuSilTM MED-4735) for joint replacement and two metallic rings (Titanium alloy Ti6Al4V) that interface between the spacer and the bone sites where the device is placed

The spacer has two specific shaped stems:

- the distal stem, with trapezoidal section, which guarantees an anatomical adaptation with respect to the intramedullary canal of the phalanx;
- the proximal stem, with rectangular section, which helps adaptation to the intramedullary metatarsal canal.

The metal rings in titanium alloy, placed above the taproots, act as a support for the silicone joint spacer in the area of interface of the spacer with the surgical sites excavated in the two bone stumps. Furthermore, they improve the stability of the spacer into the medullary canal, thanks to superficial reliefs designed over their geometry in the area of contact with the bone. The hinge joint between the taproots allows to restore the dorsiflexion movement of the toe and avoids the contact between the rings during the movement.

1.1 INTENDED USE

The intended use of the Silktoe device is arthroplasty of the first metatarsophalangeal joint (MTP1) of the foot. It represents a permanent implant, used in all severe forms of arthritis, such as:

- Hallux rigidus or hallux limitus;
- Painful rheumatoid arthritis;
- Hallux abducto valgus associated with arthritis;
- Unstable or painful joint from previous surgery

1.2 CLASSIFICATION

Classification according to the Directive 93/42/CEE Annex IX rule 8 class IIb.

BE CAREFUL!

THE DEVICE HAS TO BE USED ONLY BY SURGEONS PROPERLY TRAINED IN THE EXECUTION OF FOOT ARTHROPLASTIC SURGERY.

1.3 USEFUL LIFE

The device is provided sterile and disposable. The useful life of the device therefore corresponds to its use or to the expiration of the sterility guarantee, the date of which is clearly indicated on the packaging. Once implanted the device has a shelf life of 5 years. During this period, it is necessary to perform periodic checks according to what is contained in section 2.1 INFORMATION TO BE PROVIDED TO THE PATIENT.

1.4 CONTRAINDICATIONS AND KNOWN SIDE EFFECTS

Silktoe is generally contraindicated for use in the following cases:

- Inadequate muscle-tendon and cutaneous system;

- Insufficiency of the neuro-vascular system;
- Bone demineralization at a significant stage;
- Inadequate bone conformation and quantity;
- Active infection;
- Patients who are not in an adequate psychological state.
- Patients in childhood or who have not yet reached skeletal maturity.

Furthermore, the following side effects due to the characteristics of the device or potential implant errors may occur:

- Infection
- Device breakage
- Pain
- Displacement of the device or rings
- Hypersensitivity to silicone and/or metal
- Foreign body reaction
- Damage to surrounding soft tissues, nerves, blood vessels and tendons
- Loss or reduction of joint mobility.

1.5 SIMBOLOGY

	Below are shown the symbols used for the management of the main warnings for a proper and safe use of the device, in order to make more comfortable and easier the manual reading.

	**Requirement for a correct use** This symbol identifies the presence of information for correct use of the device.
	**Information requirement** This symbol identifies the presence of useful and general information whose reading guides the user to a conscious use of the device and / or to the execution of actions.
CE 0426	This symbol identifies that the device is design and manufactured according to the safe requirements (RES) of the Medical Devices Directive 93/42/CEE (Medical device class IIb, according to classification rule n.8 of the Annex IX).

1.6 PRELIMINARY WARNINGS

Failure to comply with the warnings listed below as well as with the standards and precautions described in this user manual entails the immediate termination of any warranty on the Silktoe device.

BRM Extremities S.r.l. is not responsible for any damage to people or things as a result of failure to comply with the rules or precautions listed below and reported in this user manual.

	LACKS OR NEGLIGENCE IN COMPLIANCE WITH THE FOLLOWING INDICATIONS MAY CAUSE DEVICE MALFUNCTION, DAMAGE AND INJURY TO THE USER OR PATIENT
	DO NOT USE THE DEVICE BEFORE READING AND UNDERSTANDING OF THIS USE MANUAL IN ALL ITS PARTS
	NO MODIFICATION OF THE DEVICE AND/OR OF ITS PARTS IS ALLOWED
	THE USE OF THE DEVICE FOR PURPOSES OTHER THAN THOSE INDICATED IN THIS USER MANUAL COULD EXPOSE THE PATIENT AND THE OPERATOR TO HAZARDS

1.7 PACKAGING CONTENT AND ACCESSORIES

Silktoe device is provided sterile (ethylene oxide sterilization) inside a cardboard package. Inside the box there is a first envelope which contains a second envelope. In this second envelope there are two smaller envelopes: one for the silicone spacer and one for the grommets. Inside the box there are also a copy of these instructions for use and the traceability labels intended for the medical record.

Silktoe is provided in 5 different sizes, left and right, listed below:

REF	Description
BRDNEWP2020L	Silktoe Spacer – Size 20 Left
BRDNEWP3030L	Silktoe Spacer – Size 30 Left
BRDNEWP3535L	Silktoe Spacer – Size 35 Left
BRDNEWP4040L	Silktoe Spacer – Size 40 Left
BRDNEWP5050L	Silktoe Spacer – Size 50 Left
BRDNEWP2020R	Silktoe Spacer – Size 20 Right
BRDNEWP3030R	Silktoe Spacer – Size 30 Right
BRDNEWP3535R	Silktoe Spacer – Size 35 Right
BRDNEWP4040R	Silktoe Spacer – Size 40 Right
BRDNEWP5050R	Silktoe Spacer – Size 50 Right

The Silktoe device also includes a dedicated surgical instrument (device accessory), sold separately and to be used for the execution of the surgical intervention and the correct implantation of the device.

	THE USE OF ELEMENTS NOT INCLUDED IN THE SYSTEM ABOVE DESCRIBED OR NOT SUPPLIED WITH THE DEVICE COULD AFFECT ITS SAFETY AND EFFECTIVENESS
	In the event that all the elements listed above are not included in the pack, contact the manufacturer immediately

2 METHOD OF USE

2.1 INFORMATION FOR THE PATIENT

Before receiving the implant, the patient has to be informed about the following issues:

Avoid to subject the operated anatomical district to excessive mechanical efforts.

The Silktoe device allows to relieve pain and to recover the functionality of the first metatarsophalangeal joint; however, it is not recommended to the patients who received the implant to perform sporting activities that can excessively stress the joint.

In the event of an evident stiffening or excessive elasticity of the joint, it is recommended to contact the facility where the implant was performed.

It is strongly discouraged to perform tests that require magnetic resonance imaging.

It is recommended the following sequence of checks: 1 month - 6 months - 12 months - 24 months - 36 months - 48 months - 60 months; or to follow the doctor's prescriptions.

2.2 REMOVAL FROM PACKAGING

CHECK THE INTEGRITY OF THE DEVICE AND OF THE PRIMARY PACKAGING BEFORE PROCEEDING WITH THE OTHER STEPS: IF THE DEVICE OR THE PRIMARY PACKAGING ARE DAMAGED DO NOT USE THE DEVICE AND DISPOSE OF IT ACCORDING TO THE INSTRUCTIONS OF THE "DISPOSAL" CHAPTER

CHECK THE EXPIRATION DATE OVER THE PACKAGING: IF THE DATE HAS BEEN EXCEEDED DO NOT USE THE DEVICE AND DISPOSE OF IT FOLLOWING THE INSTRUCTIONS OF THE “DISPOSAL” CHAPTER.

It is recommended to remove the device from its primary packaging only after selecting the appropriate size (using the trial sizers supplied 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 dustproof film has been removed and the box and the envelopes containing the grommets and the spacer have been opened, the spacer shall be positioned, waiting for the implant, in a sterile saline solution.

2.3 SURGICAL TECHNIQUE FOR IMPLANTATION AND REMOVAL OF THE DEVICE

1. Make a dorsal incision medially to the long extensor tendon of the big toe and perform a full thickness capsulotomy. Remove the deformed and hyperostotic portions, now exposed, by means of ossivora and saw.
2. Position the specific cutting guide using the dotted line on the back and medial sides of the guide as reference, so as to obtain the correct positioning of the cutting surfaces. The line has to coincide with the joint space. Evaluate the proper guide size (20/30; 35; 40/50), ensuring that the cutting mask adheres to the best with the bone portions.

3. Then proceed with the resection of the metatarsal and phalangeal joint surfaces using a 0.8mm thick blade and paying attention to the short flexor of the big toe.
4. Remove the resected surfaces.
5. Manually identify the metatarsal and phalangeal medullary canal using a tip. Once the canal has been identified, use the rasp (mounted on the appropriate rasp holder), of the size corresponding to the device chosen for the implant, to prepare the relative medullary canals (regardless of whether you rasp the metatarsal canal first and then the phalangeal one or vice-versa); pay attention to keep the upper, lateral and medial edges of the rasp parallel with the corresponding edges of the related metatarsal and phalangeal portions. Rasp up to the complete contact with the bone surfaces.
6. Insert the test spacer, corresponding to the size of the implant that is presumed to be definitive, introducing first the proximal stem and then the distal one. Verify the perfect adherence of the spacer to the surface of the resected bone planes, checking the mobility and stability of the implant.
7. Once the definitive size has been established, open the package of the chosen implant and remove the titanium rings (grommets); instead leave the silicone spacer inside its envelope.
8. Insert the "press fit" grommets using the appropriate impactor instruments, making sure to position the rectangular one in the metatarsal portion and the trapezoidal one in the phalangeal portion. It can be useful at this step to test the grommets on the trial spacer to be sure of positioning them in the correct bone portions. Bring the grommets into contact with the resected bone surface. If bone residue forms inside the canal, remove it with a spoon of Volkmann, to avoid it to interferes with the spacer stem.
9. Insert the final spacer of the size corresponding to the test one (also in this case introducing first the proximal stem and then the distal one) and test both its mobility and stability through bending movements of the big toe. It is useful at this phase to perform an X-ray for the evaluation of the positioning of the grommets and therefore of the implant.
10. Proceed with an accurate suture of the capsule and subcutaneous and skin planes and with the dressing and bandage of the wound.
11. In the case you need to remove the implant: make a dorsal incision of the big toe (proceeding medially to the long extensor tendon) and perform a full thickness capsulotomy. First remove the silicone component, using a needle holder, and then the grommets, using a surgical forceps. If resistance is encountered during the extraction of the metal component, use a small chisel. Perform an implant revision or an arthrodesis intervention according to the most appropriate clinical indication for the case and suture the patient's capsule and skin again.

THE DEVICE IS DISPOSABLE THEREFORE, ONCE REMOVED FROM THE IMPLANTATION SITE, IT HAS TO BE DISPOSED OF ACCORDING TO THE INSTRUCTIONS OF THE "DISPOSAL" CHAPTER.

INCORRECT REUSE CAN CAUSE THE TRANSMISSION OF SERIOUS INFECTIONS AND THE IMPOSSIBILITY OF GETTING THE RANGE OF YOUR DESTINATION FOR USE.

3 DISPOSAL

The devices have to be disposed according to the waste management regulation of the Local Management Authority (Special hospital waste). In any case do not disperse the product or its packaging in the environment.

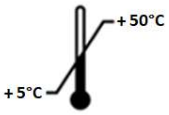
4 ENVIRONMENTAL CONDITIONS

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

Environmental Conditions	Temperature:	Use	+10 / +40°C
		Storage / transport	+5 / +50°C
	Humidity:	Use	20 / 80% Ur without condensation
		Storage / transport	5 / 95% Ur without condensation
	Atmospheric pressure:	Use	700 at 1020 hPa
		Storage / transport	500 at 1060 hPa

5 SYMBOLS USED ON THE LABEL

	Identification of the manufacturer
	Product reference
	Batch number
	Attention, refer to the user manual. Security information
	Warning, to be sale only on prescription from an authorized health care professional
	Sterilized by ethylene oxide
	Do not re-sterilize
	Do not use if the packaging is not intact
	Do not reuse

	Consult the instructions for use
	Use by the date indicated
	Keep away from light
	Keep dry
	Storage environment temperature
	The device and its packaging are manufactured without the use of natural rubber latex
	Compliant with Council Directive 93/42/EEC and subsequent amendments, DM Class IIb. The 4-digit code indicates the device certification Notified Body