



M3 MED

Surgical technique

Silktœ®

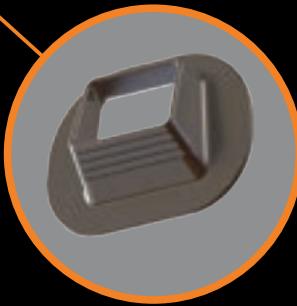
Anatomical design
5 right and 5 left sizes
2 pressfit grommets per implant



Right



Left



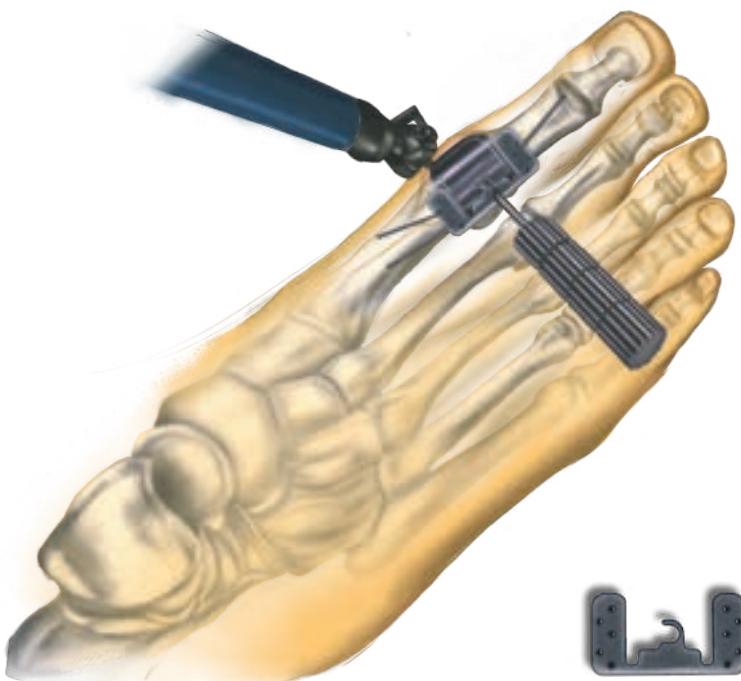
Hallux rigidus or limitus
Osteoarthritis
Rheumatoid arthritis
Destroyed articular surfaces
Ankylosed joint
Limited range of joint motion

 **BRM®**
Extremities

The following guidelines are indicative; it is responsibility of the surgeon to evaluate the adequacy and the use of this technique according to his experience and his medical skills.

1 Incision

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 Articular surfaces resection

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. Fix the guide to the bone by applying the proper mask and two Kirschner wires on each side. Then proceed with the resection of the metatarsal and phalangeal joint surfaces using a 0.8 mm thick blade and paying attention to the short flexor of the big toe. Remove the resected surfaces.



3 Medullary canals preparation

Manually identify the metatarsal and phalangeal medullary canals 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.

4 Size identification

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.



5 Grommets positioning

Once the definitive size has been identified, open the package of the chosen implant and remove the grommets, leaving the silicone spacer inside its envelope. Check grommets on the trial sizer in order to be sure to identify the correct portions and press-fit them in the medullary canals using impactor instrument: the impactor with rectangular section is used for positioning the metatarsal grommet, trapezoidal impactor for phalangeal grommet. Bring the grommets into contact with the resected bone surface. Use Volkmann spoon to remove possible bone residues that could interfere with spacer's stem.

6 Final implant

Insert the final spacer of the same size of the tested one (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 grommets and implant positioning.



7 Wound closure

Proceed with an accurate suture of the capsule, subcutaneous and skin planes and with the dressing and bandage of the wound.

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 forcep. 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.

IMPLANT

- **Spacer**
Silicone elastomer
- **Grommets**
Titanium alloy
- **Sterilization**
Ethylene Oxide (EO)

MAIN CONTRAINDICATIONS:

- Active sepsis
- Neurological and/or circulatory and/or skin and/or bone irreparable deficiency and/or non-functioning musculotendinous system
- Psychologically unsuitable patient
- Child patient

INSTRUMENTS

Product manufactured by



510K (191966) 0426

CODE	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
SET.SILKTOE	Silktoe Instruments Set (full box)
BRDNEWPTSBOX	Silktoe Sterilization Box (no instruments)
BRDNPTHANDLE	Multifunctional Silktoe Handle
BRDNPTHANDSU	Silktoe Handle Sliding Unit
BRDNPTCG2030	20-30 Silktoe Cutting Guide
BRDNPTCG3535	35 Silktoe Cutting Guide
BRDNPTCG4050	40-50 Silktoe Cutting Guide
BRDNPTCGMASK	Silktoe Cutting Guide Mask
BRDNPTR2030P	20-30 Silktoe Metatarsal Rasp
BRDNPTR3535P	35 Silktoe Metatarsal Rasp
BRDNPTR4050P	30-40 Silktoe Metatarsal Rasp
BRDNPTR2030D	20-30 Silktoe Phalangeal Rasp
BRDNPTR3535D	35 Silktoe Phalangeal Rasp
BRDNPTR4050D	40-50 Silktoe Phalangeal Rasp
BRDNPTRADAPT	Silktoe Rasp Adapter
BRDNPTEST20L	20 Left Silktoe Trial Sizer (Green)
BRDNPTEST30L	30 Left Silktoe Trial Sizer (Orange)
BRDNPTEST35L	35 Left Silktoe Trial Sizer (Yellow)
BRDNPTEST40L	40 Left Silktoe Trial Sizer (Blue)
BRDNPTEST50L	50 Left Silktoe Trial Sizer (Red)
BRDNPTEST20R	20 Right Silktoe Trial Sizer (Green)
BRDNPTEST30R	30 Right Silktoe Trial Sizer (Orange)
BRDNPTEST35R	35 Right Silktoe Trial Sizer (Yellow)
BRDNPTEST40R	40 Right Silktoe Trial Sizer (Blue)
BRDNPTEST50R	50 Right Silktoe Trial Sizer (Red)
BRDNPTI2030P	20-30 Silktoe Metatarsal Grommets Impactor
BRDNPTI3535P	35 Silktoe Metatarsal Grommets Impactor
BRDNPTI4050P	30-40 Silktoe Metatarsal Grommets Impactor
BRDNPTI2030D	20-30 Silktoe Phalangeal Grommets Impactor
BRDNPTI3535D	35 Silktoe Phalangeal Grommets Impactor
BRDNPTI4050D	40-50 Silktoe Phalangeal Grommets Impactor