

BIOLOGICALLY ORIENTED PROSTHESES

BIO PRO

SilkToe®

Surgical Technique



 **BRM**
Extremities®

Contents

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Indications & Contraindications

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

The BRM Extremities Silktoe device is intended for use in:

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

Silktoe is 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.

Implant Specifications

The BRM SilkToe® Implant is a new generation flexible silicone spacer for first metatarsophalangeal (1st MTP) joint arthroplasty.

The implant is available in five sizes in both left and right orientation to preserve valgus alignment. It features an anatomically contoured hinge to allow for improved range of motion.

The implant's design features an angled resection that preserves the flexor hallucis brevis tendon and titanium grommets to allow for ingrowth and improved stability.



Surgical Technique

The following surgical technique is recommended; however, it is the responsibility of the surgeon to evaluate the adequacy and the use of this technique according to their experience and medical training.

The BRM Silktoe Spacer has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration or image artifact in the MR environment. The safety of the BRM Silktoe Spacer in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.



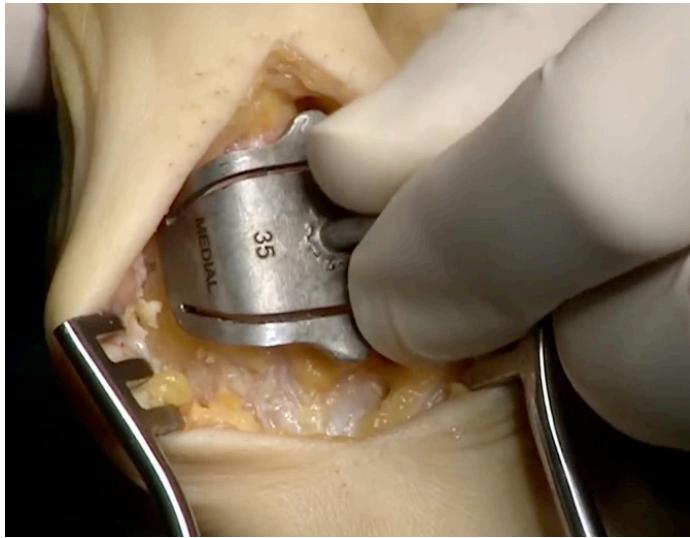
Step One:

Make a longitudinal dorsal incision along the long extensor tendon of the big toe and perform a full thickness capsulotomy. The deformed and hypertrophic bone portions should be completely exposed and can be removed.



Step Two

All hypertrophic bone is resected from the first metatarsal head and the base of the proximal phalanx to allow the cutting guide to sit flush on the joint surface.

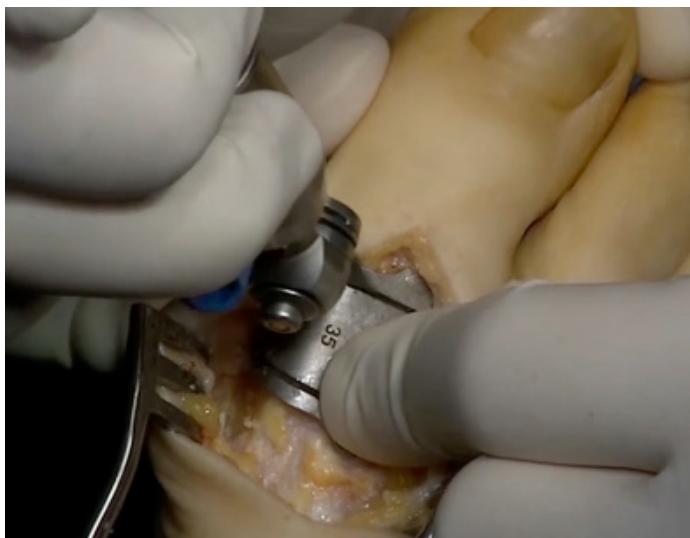


Step Three:

Evaluate the most appropriate cutting guide (20/30, 35 or 40/50): the cutting guide must adhere as closely as possible to the bone sections to make an accurate cut. The guide must be positioned along the dotted line drawn on the dorsal and medial sides of the guide itself. The tab of the inferior side of the guide shall be placed within the joint space.

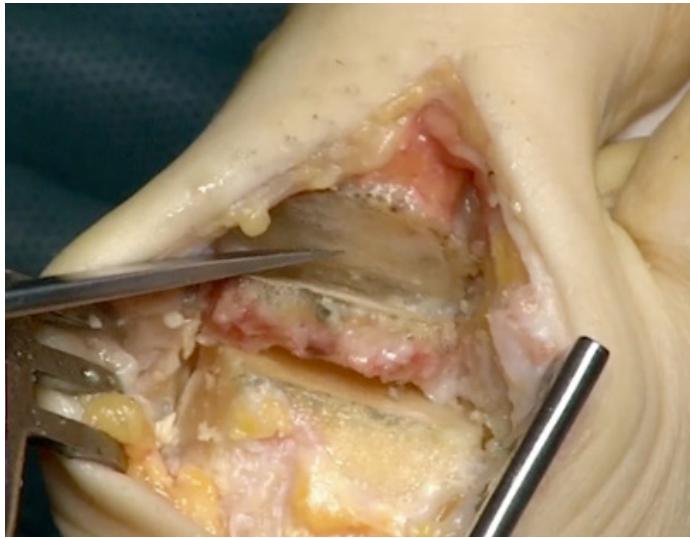
Note:

Before making any cuts, ensure the toe is positioned in the desired final valgus alignment.



Step Four:

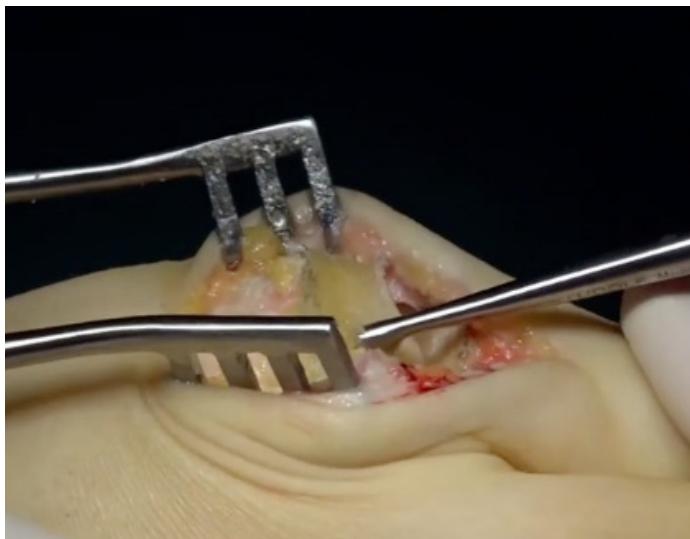
Using a sagittal or oscillating saw of 0.8mm, perform the bone resections on both metatarsal and phalangeal surfaces, paying attention to the short flexor of the hallux. The cuts should be angled to accommodate the dorsiflexion of the implant. Remove the resected surfaces.



Step Five:

Remove the resected bone fragments from both sides of the joint. If necessary, make the final cuts with the cutting guide removed. Use a scalpel to release any remaining soft tissue attachments to the resected bone.

Note: Take care to preserve the flexor hallucis brevis tendon.



Step Six:

Manually identify the metatarsal and phalangeal channels using a ferrule.

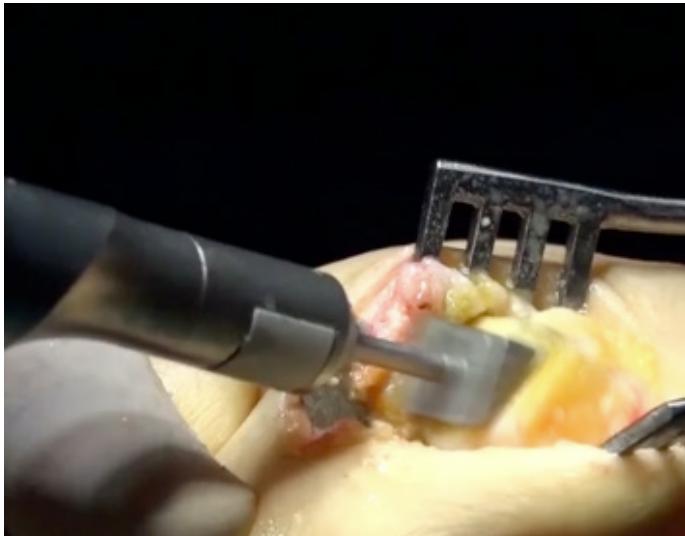


Step Seven:

Mount the rectangular rasp (using rasp size equivalent to the chosen implant size) on the appropriate rasp holder and use it to prepare the metatarsal canal. Similarly, use the trapezoidal rasp to prepare the phalangeal canal.

Note: The power adapters are designed for a reciprocating saw attachment.

Note: Before insertion, verify that the correct rasp is being used for each side of the joint: PM for the proximal side and DM for the distal side.



Step Eight:

Either the metatarsal channel or phalangeal channel may be prepared first. It is important to take care to keep upper, lateral and medial edges of the rasp parallel with the corresponding edges of metatarsal and phalangeal portions. Rasp until you reach full contact with bone surfaces.

**Step Nine:**

Insert the trial sizer (equivalent to the selected implant size) starting from proximal stem. Check that the spacer adheres perfectly to resected bone surfaces and control the mobility and stability of the implant.

Note: Insert the proximal stem first, followed by the distal component.

Note: Be sure to use the non-toothed pickups to avoid damaging the trials and final implants.

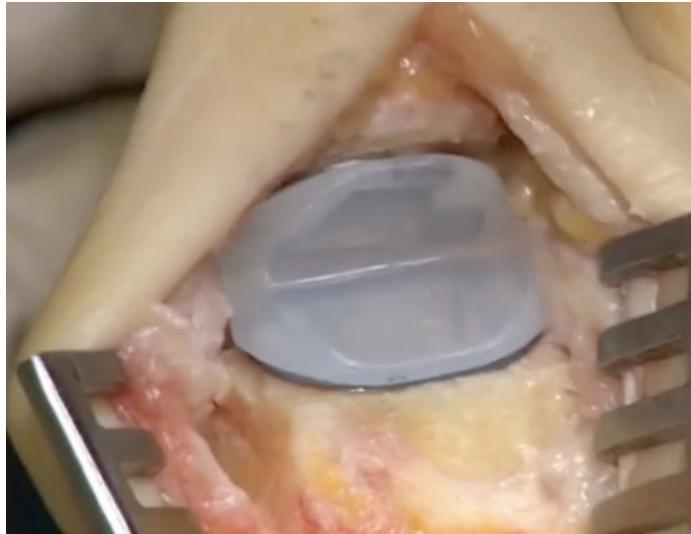
**Step 10**

Once the final implant has been identified, open the package and extract the grommets, but not the spacer. Check grommets on trial sizer 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 of the metatarsal grommet, trapezoidal impactor for phalangeal grommet.



Step Eleven:

Use Volkmann spoon to remove possible bone residues that could interfere with spacer's stem.



Step Twelve:

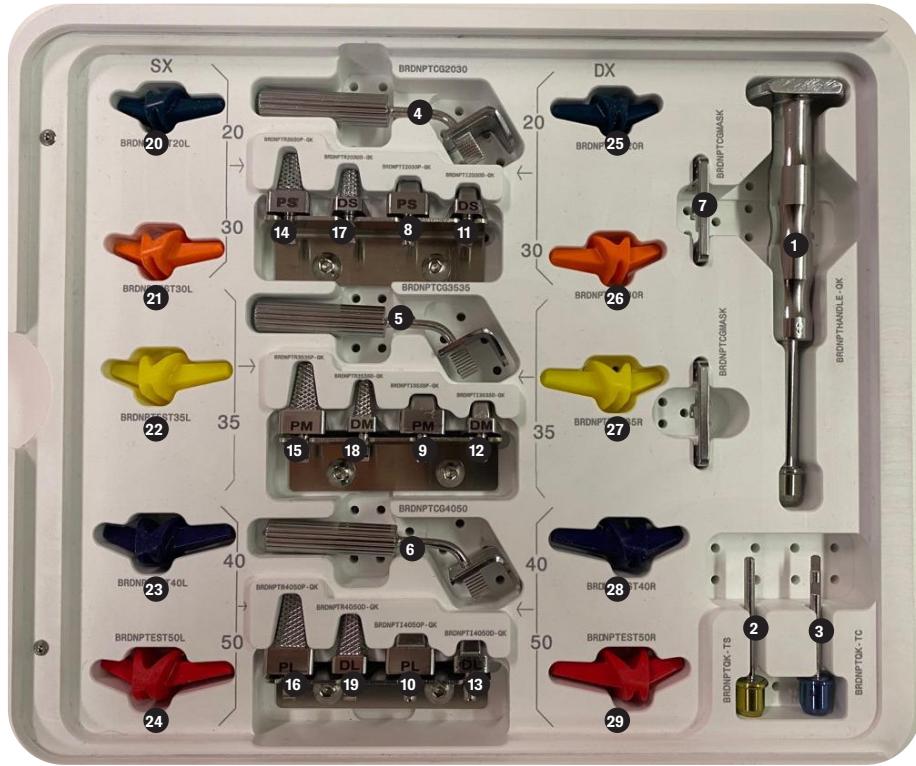
Insert the final implant starting from proximal stem and test the mobility and the stability of the joint through flexion movements of the big toe. Grommets and implant positioning may be evaluated through an X-ray.

Suture the joint capsule, subcutaneous and cutaneous planes paying attention to completely cover the implant; medicate and bandage the wound.

In the event of a revision surgery:

If it is necessary 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. Remove the silicone component first, using a needle holder, and then the grommets, using surgical forceps. If you find resistance in the extraction of the metal component, use a small chisel. Perform a revision of the implant or an arthrodesis intervention according to the most appropriate clinical indication for the case and re-suture the patient's capsule and skin.

Instrument Overview



SilkToe Instrument Kit - SET.SILKTOE-QK

#	Item #	Description	#	Item #	Description
1	BRDNPHANDLE-QK	SILKTOE QUICK HANDLE	14	BRDNPTR2030P-QK	20-30 SILKTOE METATARSAL RASP
2	BRDNPTQK-TS	QUICK CONNECTION TYPE-S	15	BRDNPTR3535P-QK	35 SILKTOE METATARSAL RASP
3	BRDNPTQK-TC	QUICK CONNECTION TYPE-C	16	BRDNPTR4050P-QK	40-50 SILKTOE METATARSAL RASP
4	BRDNPTCG2030	20-30 SILKTOE CUTTING GUIDE	17	BRDNPTR2030D-QK	20-30 SILKTOE PHALANGEAL RASP
5	BRDNPTCG3535	35 SILKTOE CUTTING GUIDE	18	BRDNPTR3535D-QK	35 SILKTOE PHALANGEAL RASP
6	BRDNPTCG4050	40-50 SILKTOE CUTTING GUIDE	19	BRDNPTR4050D-QK	40-50 SILKTOE PHALANGEAL RASP
7	BRDNPTCGMASK	SILKTOE CUTTING GUIDE MASK FOR FIXATION	20	BRDNPTEST20L	20 LEFT SILKTOE TRIAL SIZER (GREEN)
8	BRDNPTI2030P-QK	20-30 SILKTOE METATARSAL GROMMETS IMPACTOR	21	BRDNPTEST30L	30 LEFT SILKTOE TRIAL SIZER (ORANGE)
9	BRDNPTI3535P-QK	35 SILKTOE METATARSAL GROMMETS IMPACTOR	22	BRDNPTEST35L	35 LEFT SILKTOE TRIAL SIZER (YELLOW)
10	BRDNPTI4050P-QK	40-50 SILKTOE METATARSAL GROMMETS IMPACTOR	23	BRDNPTEST40L	40 LEFT SILKTOE TRIAL SIZER (BLUE)
11	BRDNPTI2030D-QK	20-30 SILKTOE PHALANGEAL GROMMETS IMPACTOR	24	BRDNPTEST50L	50 LEFT SILKTOE TRIAL SIZER (RED)
12	BRDNPTI3535D-QK	35 SILKTOE PHALANGEAL GROMMETS IMPACTOR	25	BRDNPTEST20R	20 RIGHT SILKTOE TRIAL SIZER (GREEN)
13	BRDNPTI4050D-QK	40-50 SILKTOE PHALANGEAL GROMMETS IMPACTOR	26	BRDNPTEST30R	30 RIGHT SILKTOE TRIAL SIZER (ORANGE)
			27	BRDNPTEST35R	35 RIGHT SILKTOE TRIAL SIZER (YELLOW)
			28	BRDNPTEST40R	40 RIGHT SILKTOE TRIAL SIZER (BLUE)
			29	BRDNPTEST50R	50 RIGHT SILKTOE TRIAL SIZER (RED)

Implant Ordering

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

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



BRM Extremities S.r.l.
Registered Office:
Via Mascheroni, 29
20145 Milano (MI) Italy

Headquarters:
Via Privata ai Campi, 7 23862
Civate LC Italy

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BioPro, Inc.
2929 Lapeer Road, Port Huron, MI 48060, USA
info@bioproimplants.com | 1-810-982-7777
www.bioproimplants.com

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