PART OF THE
TECHNICAL DOCUMENTATION

PRODUCT DESCRIPTION

MUTARS® MK/HD KNEE TIBIAL COMPONENT

PRODUCT-GROUP: REVISION AND TUMOR ARTHROPLASTY

RISK-CLASS: III

LOCATION: KNEE

DATE: 20.09.2022, REV.4

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1. MUTARS® MK/HD Knee System - Tibial Components

The MUTARS® MK/HD Knee System includes following tibial components

…to resurface the tibial condyles:

- MUTARS® GenuX® MK Tibia
- MUTARS® GenuX® MK Tibia Monoblock
- MUTARS® MK BioXpand Tibial Plateau

…to replace the entire proximal tibia:

- MUTARS® MK Proximal Tibia

The following tibial spacers are available:

- MK Tibial Spacer

The following tibial bearings are available:

- MUTARS® GenuX® MK MB PE-Insert
- MUTARS® GenuX® MK FB PE-Insert

2. Intended Use

⇨ See Doc. „Fbl_423-1-2-4_Zweckbestimmung_EPORE® met. Komponente" and "Fbl_423-1-2-4_Zweckbestimmung_MUTARS® Knie" in the folder "043 Produktbeschreibung"

3. Qualification of the Product as a Medical Device

The products of the MUTARS® MK/HD Knee System are medical devices in accordance with the Definitions in Article 2 of the Medical Device Regulations MDR (EU) 2017/745 of 05. April 2017. The products of the MUTARS® MK/HD Knee System are "medical devices" "for human beings for the specific medical purposes" as described in the Article 2 under (1) of the of the Medical Device Regulations MDR (EU) 2017/745 of 05. April 2017.

4. Risk-class: III

The products of the MUTARS® MK/HD Knee System are classified in risk class III in accordance with the classification rules in Annex VIII of the Medical Device Regulations MDR (EU) 2017/745 of 05. April 2017. The risk class is justified as the products of the MUTARS® MK/HD Knee System meet the Rule 8 in 5.4 of the Medical Device Regulations MDR (EU) 2017/745 that they are total or partial joint replacement.

5. Intended User

The use of this implant is restricted to persons who, based on their education, knowledge and practical experience, are capable of proper handling and use of the device. Familiarity with the recommended surgical technique and its careful application as well as a pre-operative planning are essential to achieve the best possible outcome. The implantcast GmbH offers special user trainings to ensure an optimal preparation.

6. Target Group

The target population corresponds to the population likely to benefit from the product in indication for joint replacement. Finally, the surgeon decides whether and which version of prosthesis for the individual patient is suitable. This decision depends on several factors, such as the age and the patient's weight, bone quality, shape of the bone, patient's physical activity levels and deformation of the joint. The provision of prostheses is generally indicated only in patients whose skeleton is fully grown.

7. Indications

Information about indications of the MUTARS® MK/HD Knee System can be found in the Instruction for Use.

⇨ See Doc. Instruction for Use “09300013 MUTARS Tumor- und Revisionssystem” in the folder “05 Kennzeichnung\Gebrauchsinformation”

8. Contraindications

Information about contraindications of the MUTARS® MK/HD Knee System can be found in the Instruction for Use.

⇨ See Doc. Instruction for Use “09300013 MUTARS Tumor- und Revisionssystem” in the folder “05 Kennzeichnung\Gebrauchsinformation”

9. Risk Factors

Information about risk factors of the MUTARS® MK/HD Knee System can be found in the Instruction for Use.

⇨ See Doc. Instruction for Use “09300013 MUTARS Tumor- und Revisionssystem” in the folder “05 Kennzeichnung\Gebrauchsinformation”

10. Design Description

10.1. MUTARS® GenuX® MK Tibia

The MUTARS® GenuX® MK Tibia is a modular resurfacing tibial plateau component. It is available in cemented and cementless version.

The tray portion of the component has a symmetrical kidney shape. The tray utilizes a posterior bevel to reduce soft tissue irritation. Two curved oblong recesses in the superior surface of the tray provide the attachment mechanism for tibial bearing PE-inserts.

FIGURE 1 MUTARS® GenuX® MK Tibia (Upper Line: Cemented Version, Bottom Line: Cementless Version)

Distal, the component has a central finned and ribbed cylindrical post. The distal end of the post provides a female morse taper / MUTARS® fit connection for attachment of the MUTARS® GenuX® MK offset adapter which in turn is used to attach a tibial stem. Extending medial and lateral from the post, fins are positioned 150° apart for tray support and rotational stability (see Figure 2).

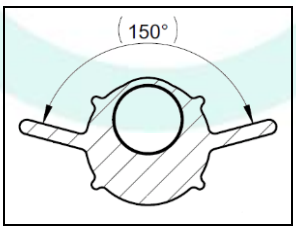

FIGURE 2: MUTARS® GenuX® MK Tibia - Fins

Posterior-medial and posterior-lateral threaded holes on the underside of the cemented component (fixation surface) provide attachment points for spacer. There is a 0.7 mm deep cement pocket on the underside of the tray.

The MUTARS® GenuX® MK Tibia is coupled to the femoral component via the MUTARS® Coupling or MUTARS® HD Coupling. This component is secured to the MUTARS® GenuX® MK Tibia by a fixation screw that is inserted anterior to posterior into a threaded central hole in the tibial component (see Figure 3).

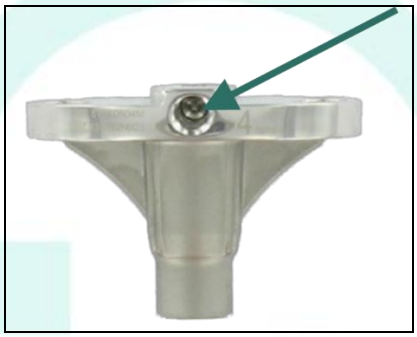

FIGURE 3: MUTARS® GenuX® MK Tibia - Coupling Attachment

10.2. MUTARS® Peg for GenuX® MK Tibia

The MUTARS® Peg for GenuX® MK Tibia is intended to connect the MUTARS® GenuX® MK Tibia with the MUTARS® Dist. Femur and MUTARS® KRI via the MUTARS® PEEK-OPTIMA® Lock. A hole is used for placement of a screw to securely attach the peg to the tibia.

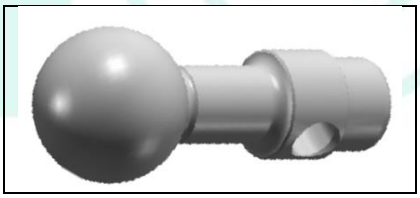

FIGURE 4: MUTARS® Peg for GenuX® MK Tibia

10.3. MUTARS® GenuX® MK Tibia Monoblock

The MUTARS® GenuX® MK Tibia Monoblock is a monoblock version of the MUTARS® GenuX MK Tibia and is also intended for use with bone cement. It has similar design features and dimensions as the MUTARS® GenuX® MK Tibia.

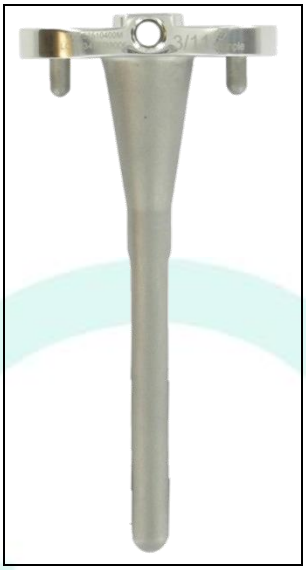

FIGURE 5: MUTARS® GenuX® MK Tibia Monoblock

The MUTARS® GenuX® MK Tibia Monoblock has a kidney shaped symmetrical tray and a posterior bevel for reduction of soft tissue irritation. The MUTARS® GenuX® MK Tibia Monoblock uses the same tibial bearing PE-inserts that are used for the modular MUTARS® GenuX® MK Tibia.

In contrast to the MUTARS® GenuX® MK Tibia, the MUTARS® GenuX® MK Tibia Monoblock has an integrated stem with round profile and longitudinal cement grooves. Instead of fins, the monoblock version utilizes two pegs for rotational stability.

The coupling between the MUTARS® GenuX® MK Tibia Monoblock and the MUTARS® GenuX® MK Femoral Monoblock is formed using the MUTARS® Coupling. Like the other MUTARS® tibial components, the MUTARS® GenuX® MK Tibia Monoblock has a central anterior to posterior threaded hole for securing the coupling to the tibial component with a fixation screw.

10.4. MUTARS® MK Proximal Tibia

The MUTARS® MK Proximal Tibia is a tibial component used to replace the entire proximal portion of the tibia. The MUTARS® MK Proximal Tibia must be used with the MUTARS® Connecting Part for Mod. Prox. Tibia. The MUTARS® MK Proximal Tibial attaches to the connecting part by two screws that are placed through holes in the distal body of the MUTARS® MK Proximal Tibia into corresponding threaded holes in the connecting part.

FIGURE 6: MUTARS® MK Proximal Tibia

The MUTARS® MK Proximal Tibia attaches to the femoral component used the MUTARS® Coupling or MUTARS® HD Coupling.

10.5. MUTARS® MK BioXpand Tibial Plateau

The MUTARS® MK BioXpand Tibial Plateau is intended for cementless use to resurface the tibial condyles.

FIGURE 7: MUTARS® MK BioXpand Tibial Plateau

The MUTARS® MK BioXpand Tibial Plateau has a kidney shaped symmetrical. Two curved oblong recesses in the superior surface of the tray provide the attachment mechanism for the MUTARS® GenuX® MK PE-Insert.

The MUTARS® MK BioXpand Tibial Plateau has an integrated stem with round profile. The hinge joint between the MUTARS® MK BioXpand Tibial Plateau and the femoral component is formed using the MUTARS® Coupling or MUTARS® HD Coupling. Like the other MUTARS® tibial components, the MUTARS® MK BioXpand Tibial Plateau has a central anterior to posterior threaded hole for securing the coupling to the tibial component with a fixation screw.

10.6. MK Tibial Spacer

The MK Tibial Spacer is used for bridging bone defects in the proximal tibia. The MK Tibial Spacers are bilateral and connected to a cemented MUTARS® GenuX® MK Tibia by screws. The tibial spacers are symmetrical, have slots included for the fins of the tibial component and are intended to be used with

bone cement. A flattening at the front of the spacer is provided for preserving the tibial tuberosity as well as holes for the fixation of soft tissue. The spacers have the bore holes for attachment to the tibial component by means of screws.

FIGURE 8: MUTARS® Tibial Spacer

10.7. MK Tibial Spacer LL/RM / RL/LM

The MK Tibial Spacers LL/RM / RL/LM are unilateral spacers used for bridging bone defects in the area of the proximal tibia. The MK Tibial Spacers LL/RM / RL/LM are available for the left lateral / right medial side and right lateral / left medial side. They have slots included for the fins of the tibial component and are intended to be used with bone cement. Flattening at the front of the spacer is provided for preserving the tibial tuberosity as well as holes for fixation of soft tissue. The spacers have the bore holes for screw attachment to the distal aspect of the cemented MUTARS® GenuX® MK Tibia.

FIGURE 9: MUTARS® Tibial Spacer LL/RM / RL/LM

10.8. MUTARS® GenuX® MK FB PE-Insert

The MUTARS® GenuX® MK FB PE-Inserts have a symmetric “flat-on-flat” articular geometry design. A ventral deepening reduces soft tissue irritation and a circular beveling avoids overhang at the edge during rotation. Flexion is facilitated by dorsal flattening and chamfering. The PE-inserts have curved oblong attachment “feet” that match the geometry and dimensions of the curved oblong insert attachment recesses in the surface of the tibial components.

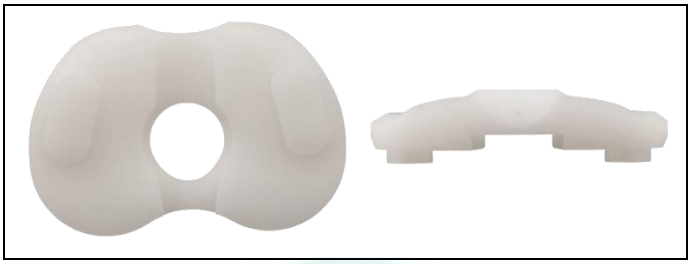

FIGURE 10: MUTARS® GenuX® MK FB PE-Insert

10.9. MUTARS® GenuX® MK MB PE-Insert

The MUTARS® GenuX® MK MB PE-Inserts are identical to the MUTARS® GenuX® MK FB PE-Inserts described above with the exception of the geometry of the attachment feet and a posterior opening between the medial and lateral condyles. The PE-inserts have a symmetric flat-on-flat articular surface design. A ventral deepening reduces soft tissue irritation and a circular beveling avoids overhang at the edge during rotation. More flexion is provided by the dorsal flattening and chamfering.

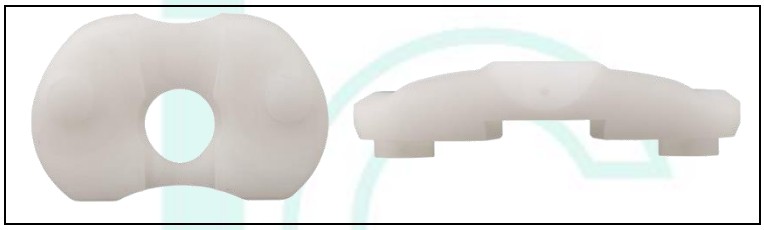

FIGURE 11: MUTARS® GenuX® MK MB PE-Insert

In contrast to the MUTARS® GenuX® MK FB PE-Inserts, the MUTARS® GenuX® MK MB PE-Inserts have round feet instead of oblong feet that snap into the curved oblong recesses in the proximal surface of the tibial component. The round feet allow the bearing to move hereby providing a 10° internal / external rotation of the hinge joint.

FIGURE 12: MUTARS® GenuX® MK MB PE-Insert - Internal / External Rotation

11. Materials

11.1. Tibial Components

The MUTARS® MK Proximal Tibia is made of $TiAl_6V_4$ acc. to ISO 5832-3. The MUTARS® Peg for GenuX® MK Tibia is made of CoCrMo acc. to ISO 5832-12.

All other MUTARS® tibial components are made of CoCrMo acc. to ISO 5832-4.

11.2. Spacer

All tibial spacers are made of $TiAl_6V_4$ acc. to ISO 5832-3.

11.3. PE-Inserts

The MUTARS® GenuX® MK FB/MB PE-Inserts are available made of UHMWPE acc. to ISO 5834-2 and crosslinked UHMWPE enriched with 1000 ppm Vitamin E that has been crosslinked by gamma radiation with a dose of 50 kGy. The MUTARS® GenuX® MK FB/MB PE-Inserts include an X-ray marker wire made of $TiAl_6V_4$ acc. to ISO 5832-3.

12. Coatings / Surfaces

TABLE 1: Coating Specifications

CHARACTERISTICS	VALUE	
	TiN	silver
COATING THICKNESS	5.5 ± 1.5 µm	15 ± 5 µm
AVERAGE ROUGHNESS RA	< 0.05 µm	/
TENSILE STRENGTH	≥ 22 MPa	/

12.1. MUTARS® GenuX® MK Tibia

The MUTARS® GenuX® MK Tibia is available non-coated or with a TiN coating (see Table 1 for specifications) that is applied circumferentially. In case of TiN coating version, only the inner cone and the fit retains non-coated.

The superior surface of the tray is highly polished. All inferior surfaces of the cemented component, including the fins and the cement pocket, have a sandblasted surface. The underside of the cementless version has a porous structure of casted balls. The diameter of the casted balls is 0.8 mm. The porosity is about 33%.

12.2. MUTARS® Peg for GenuX® MK Tibia

The MUTARS® Peg for GenuX® MK Tibia is available non-coated or with a TiN coating (see Table 1 for specifications) that is applied circumferentially.

The MUTARS® Peg for GenuX® MK Tibia is highly polished.

12.3. MUTARS® GenuX® MK Tibia Monoblock

The MUTARS® GenuX® MK Tibia Monoblock is available non-coated only.

The superior surface of the tray is highly polished. The underside of the tray has a sandblasted surface finish and a recessed cement pocket. The surface of the stem is sandblasted, too.

12.4. MUTARS® MK Proximal Tibia

The MUTARS® MK Proximal Tibia is available with a TiN coating or with a TiN/silver coating (see Table 1 for specifications). In case of the TiN coated version the hole component is coated except the fits for the coupling attachment screw and the PE-insert. For location of the TiN/silver coating see Figure 13. In case of the TiN/silver coated version, the fits also remain non-coated.

The superior surface of the component is highly polished.

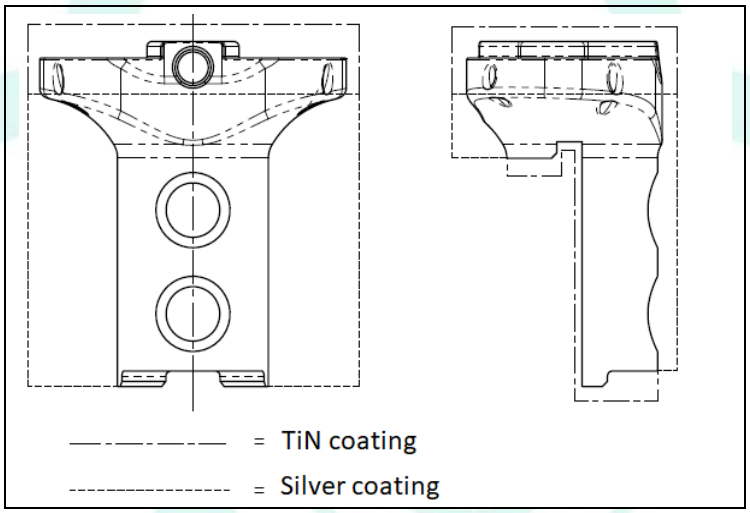

FIGURE 13: MUTARS® MK Proximal Tibia – Location of the TiN/Silber Coating

TABLE 2: MUTARS® MK Proximal Tibia - Surface Area and Mass of the Silver Coating

ITEM DESCRIPTION	SIZE	SURFACE AREA SILVER COATING [mm²]	MASS SILVER [g]
MUTARS® MK proximal tibia silver	/	5495	1.15

12.5. MUTARS® MK BioXpand Tibial Plateau

The MUTARS® MK BioXpand Tibial Plateau is available non-coated only. The superior surface and the stem are highly polished. The underside has a porous structure of casted balls. The diameter of the casted balls is 0.8 mm and the porosity is about 33%. The pegs on the underside are sandblasted.

12.6. MK Tibial Spacer

The MK Tibial Spacer are available non-coated or with a silver coating (see Table 1 for specifications). For the location of the silver coating see Figure 14.

The surfaces of the MK Tibial Spacer have a sandblasted finish.

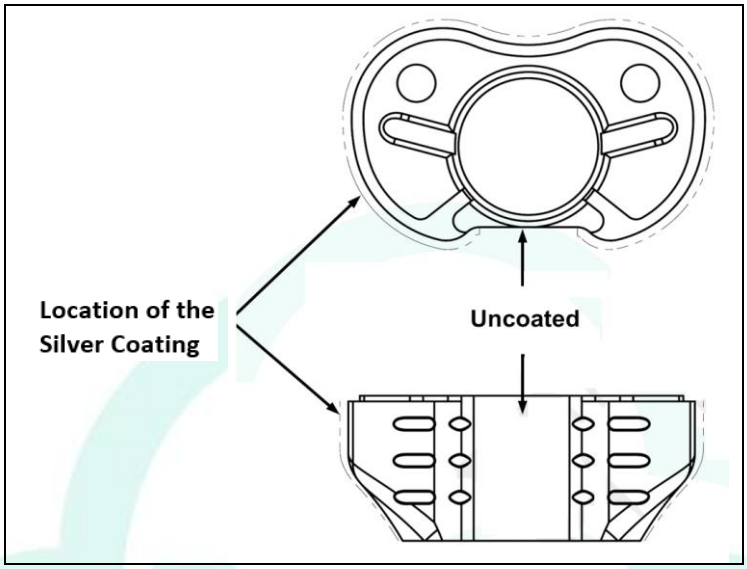

FIGURE 14: MK Tibial Spacer – Location of the Coating

TABLE 3: MK Tibial Spacer - Surface Area and Mass of the Silver Coating

ITEM DESCRIPTION	SIZE	SURFACE AREA SILVER COATING [mm²]	MASS SILVER [g]
MK tibial spacer silver	2/25 mm	3305	0.69
	3/25 mm	3665	0.77
	4/25 mm	4082	0.86
	5/25 mm	4490	0.94
	6/25 mm	4847	1.02
	2/35 mm	5000	1.05
	3/35 mm	4722	0.99
	4/35 mm	5176	1.09
	5/35 mm	5650	1.19
	6/35 mm	6085	1.28
	2/45 mm	5290	1.11
	3/45 mm	5546	1.16
	4/45 mm	6087	1.28
	5/45 mm	6557	1.38
	6/45 mm	6845	1.44

12.7. MK Tibial Spacer LL/RM / RL/LM

The MK Tibial Spacer LL/RM / RL/LM are available non-coated or with a silver coating (see Table 1 for specifications). For the location of the silver coating see Figure 15.

The surfaces of the MK Tibial Spacer have a sandblasted finish.

FIGURE 15: MK Tibial Spacer LL/RM / RL/LM – Location of the Coating

TABLE 4: MK Tibial Spacer LL/RM / RL/LM - Surface Area and Mass of the Silver Coating

ITEM DESCRIPTION	SIZE	SURFACE AREA SILVER COATING [mm²]	MASS SILVER [g]
MK tibial spacer rl/lm silver	2/5 mm	384	0.08
	3/5 mm	422	0.09
	4/5 mm	460	0.10
	5/5 mm	498	0.10
	6/5 mm	537	0.11
	2/10 mm	792	0.17
	3/10 mm	877	0.18
	4/10 mm	961	0.20
	5/10 mm	1054	0.22
	6/10 mm	1161	0.24
	2/15 mm	1217	0.26
	3/15 mm	1356	0.28
	4/15 mm	1482	0.31
	5/15 mm	1612	0.34
	6/15 mm	1752	0.37
	2/20 mm	1584	0.33
	3/20 mm	1764	0.37
	4/20 mm	1942	0.41
	5/20 mm	2109	0.44
	6/20 mm	2270	0.48
MK tibial spacer ll/rm silver	2/5 mm	384	0.08
	3/5 mm	422	0.09
	4/5 mm	460	0.10
	5/5 mm	498	0.10
	6/5 mm	537	0.11
	2/10 mm	792	0.17
	3/10 mm	877	0.18

TABLE 4: MK Tibial Spacer LL/RM / RL/LM - Surface Area and Mass of the Silver Coating

ITEM DESCRIPTION	SIZE	SURFACE AREA SILVER COATING [mm²]	MASS SILVER [g]
	4/10 mm	961	0.20
	5/10 mm	1054	0.22
	6/10 mm	1161	0.24
	2/15 mm	1217	0.26
	3/15 mm	1356	0.28
	4/15 mm	1482	0.31
	5/15 mm	1612	0.34
	6/15 mm	1752	0.37
	2/20 mm	1584	0.33
	3/20 mm	1764	0.37
	4/20 mm	1942	0.41
	5/20 mm	2109	0.44
	6/20 mm	2270	0.48

12.8. MUTARS® GenuX® MK FB/MB PE-Inserts

The MUTARS® GenuX® MK FB/MB PE-Inserts have a surface roughness of Ra = 1.6 µm.

13. Sizes and Dimensions

13.1. MUTARS® GenuX® MK Tibia

The MUTARS® GenuX® MK Tibia is available in sizes 2 to 6.

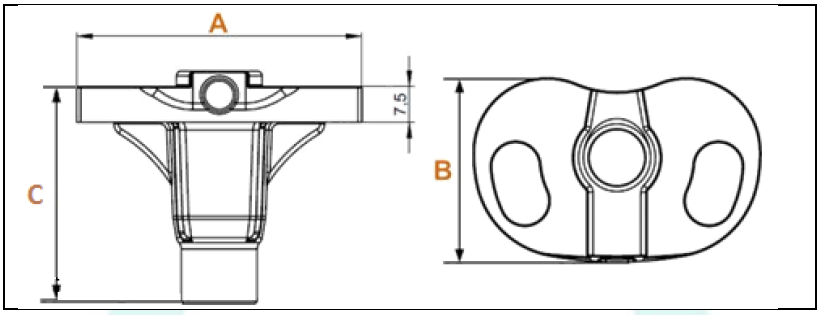

FIGURE 16: MUTARS® GenuX® MK Tibia - Dimensions

TABLE 5: MUTARS® GenuX® MK Tibia - Dimensions

SIZE	DIMENSION [MM]		
	A	B	C
2	60	38	49
3	65	42	
4	70	45	
5	75	48	
6	81	52	

13.2. MUTARS® Peg for GenuX® MK Tibia

The MUTARS® Peg for GenuX® MK Tibia is available in one size.

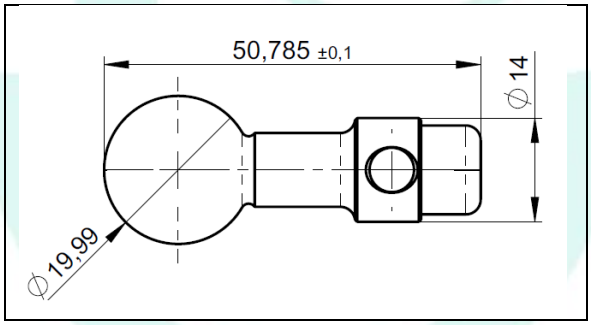

FIGURE 17: MUTARS® Peg For GenuX® MK Tibia

13.3. MUTARS® GenuX® MK Tibia Monoblock

The MUTARS® GenuX® MK Tibia is available in following sizes: 2/10 mm, 3/11 mm, 4/12 mm, 5/13 mm.

The tray is 7.5 mm thick.

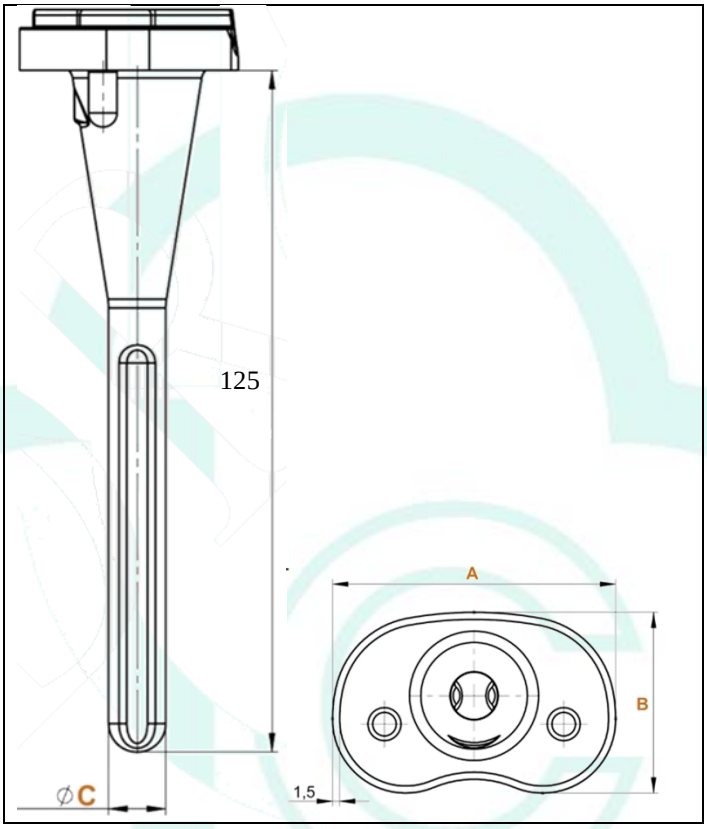

FIGURE 18: MUTARS® GenuX® MK Tibia Monoblock - Dimensions

TABLE 6: MUTARS® GenuX® MK Tibia Monoblock - Dimensions

SIZE	DIMENSION [MM]	
	A	B
2/10mm	60	38
3/11mm	65	42
4/12mm	70	45
5/13mm	75	48

13.4. MUTARS® MK Proximal Tibia

The MUTARS® MK Proximal Tibia is available in one size only.

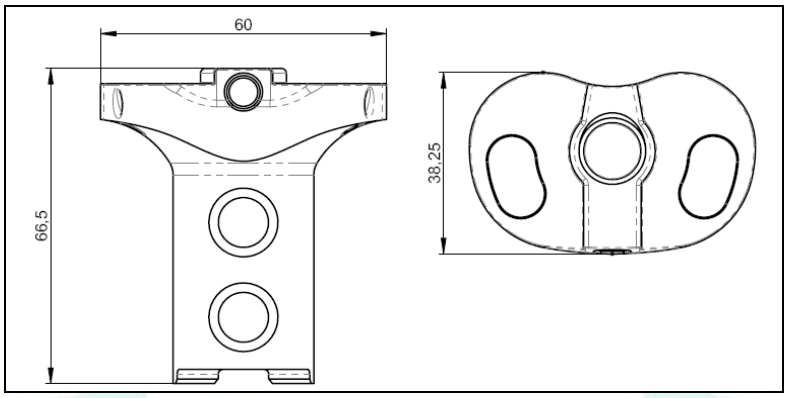

FIGURE 19: MUTARS® MK Proximal Tibia - Dimensions

13.5. MUTARS® MK BioXpand Tibial Plateau

The MUTARS® MK BioXpand Tibia Plateau is available in one size only.

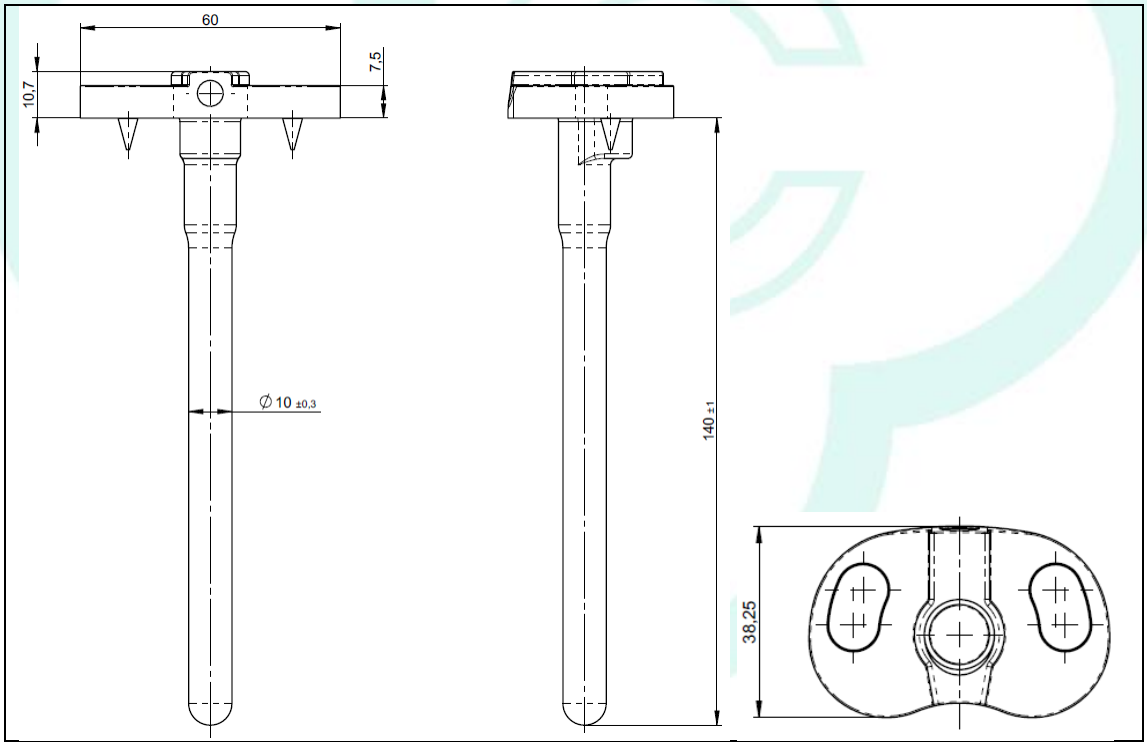

FIGURE 20: MUTARS® MK BioXpand Tibial Plateau - Dimensions

13.6. MK Tibial Spacer

The MK Tibial Spacers are available in five sizes (2 - 6) in heights of 25 mm to 45 mm in 10 mm increments.

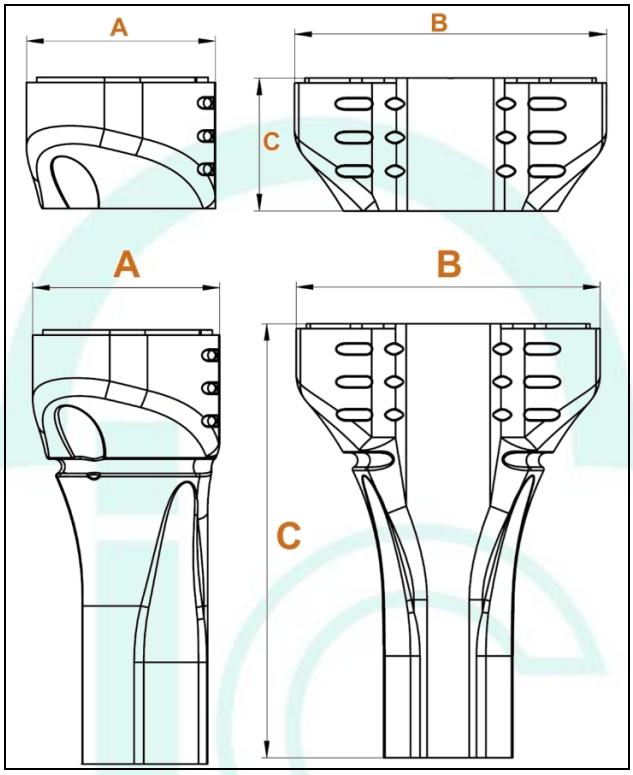

FIGURE 21: MK Tibial Spacer - Dimensions

TABLE 7: MK Tibial Spacer - Dimensions

SIZE	DIMENSION [mm]		
	A	B	C
2/25 mm	36.9	60	25.7
3/25 mm	40.6	65	
4/25 mm	44.1	70	
5/25 mm	47.2	75	
6/25 mm	51.2	81	
2/35 mm	36.9	60	35.7
3/35 mm	40.6	65	
4/35 mm	44.1	70	
5/35 mm	47.3	75	
6/35 mm	51.2	81	
2/45 mm	36.9	60	45.7
3/45 mm	40.6	65	
4/45 mm	44.1	70	
5/45 mm	47.3	75	
6/45 mm	51.2	81	

13.7. MK Tibial Spacer LL/RM / RL/LM

The MK Tibial Spacer LL/RM / RL/LM are available in five sizes (2 - 6) in heights of 5 mm to 20 mm in 5 mm increments.

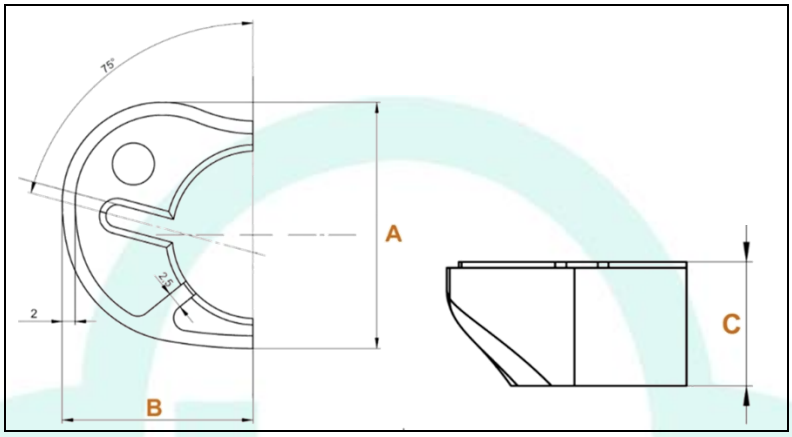

FIGURE 22: MK Tibial Spacer LL/RM / RL/LM - Dimensions

TABLE 8: MK Tibial Spacer LL/RM / RL/LM - Dimensions

SIZE	DIMENSION [mm]		
	A	B	C
2/5 mm	38.3	29.5	5.7
3/5 mm	41.7	32.0	
4/5 mm	45.2	34.5	
5/5 mm	48.3	37.0	
6/5 mm	52.2	40.0	
2/10 mm	38.3	29.5	10.7
3/10 mm	41.7	32.0	
4/10 mm	45.2	34.5	
5/10 mm	48.3	37.0	
6/10 mm	52.2	40.0	
2/15 mm	38.3	29.5	15.7
3/15 mm	41.7	32.0	
4/15 mm	45.2	34.5	
5/15 mm	48.3	37.0	
6/15 mm	52.2	40.0	
2/20 mm	38.3	29.5	20.7
3/20 mm	41.7	32.0	
4/20 mm	45.2	34.5	
5/20 mm	48.3	37.0	
6/20 mm	52.2	40.0	

13.8. MUTARS® GenuX® MK FB/MB PE-Insert

The MUTARS® GenuX® MK FB/MB PE-Inserts are available in five sizes (2, 3, 4, 5 and 6) and three heights (12.5 mm, 15 mm and 17.5 mm).

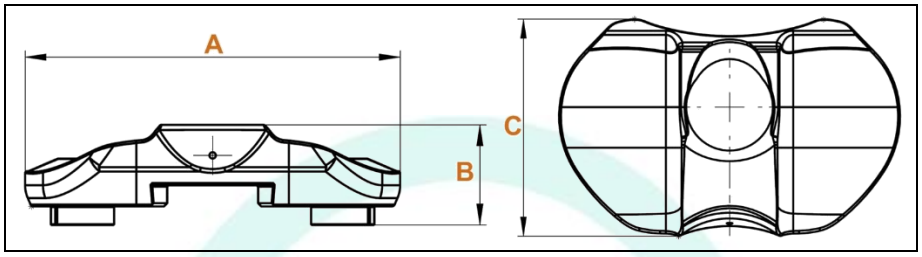

FIGURE 23: MUTARS® GenuX® MK FB PE-Insert - Dimensions

TABLE 9: MUTARS® GenuX® MK FB PE-Insert - Dimensions

SIZE	DIMENSION [mm]		
	A	B	C
2/12,5mm	59.4	15.7	38.5
3/12,5mm	64.3		42.4
4/12,5mm	69.3		45.3
5/12,5mm	74.0		46.1
6/12,5mm	80.0		47.4
2/15mm	59.4	18.9	38.6
3/15mm	64.3		42.4
4/15mm	69.3		46.5
5/15mm	74.0		49.2
6/15mm	80.0		47.5
2/17,5mm	59.4	20.7	38.6
3/17,5mm	64.3		42.4
4/17,5mm	69.3		46.6
5/17,5mm	74.0		49.2
6/17,5mm	80.0		47.5

TABLE 10: MUTARS® GenuX® MK MB PE-Insert - Dimensions

SIZE	DIMENSION [mm]		
	A	B	C
2/12,5mm	59.0	15.7	37.4
3/12,5mm	64.0		40.1
4/12,5mm	69.0		43.1
5/12,5mm	74.0		45.0
6/12,5mm	80.0		46.8
2/15mm	59.0	18.9	37.7
3/15mm	64.0		40.6

TABLE 10: MUTARS® GenuX® MK MB PE-Insert - Dimensions

SIZE	DIMENSION [mm]		
	A	B	C
4/15mm	69.0		43.7
5/15mm	74.0		45.7
6/15mm	80.0		46.9
2/17,5mm	59.0		37.8
3/17,5mm	64.0		40.8
4/17,5mm	69.0	20.7	44.0
5/17,5mm	74.0		46.0
6/17,5mm	80.0		47.0

14. Compatibility

The detailed component compatibility is given in the table of combinations. The summary can be found in the attachment of the instructions for use.

- ⇨ See folder “11 Kombinationstabellen”
- ⇨ See Doc. “09300095 MUTARS Tumor- und Revisionssystem Kombinationsmöglichkeiten_Anhang I“ in the folder „05 Kennzeichnung\Gebrauchsinformation“

15. Warnings

Information about warnings of the MUTARS® MK/HD Knee System can be found in the Instruction for Use.

- ⇨ See Doc. Instruction for Use “09300013 MUTARS Tumor- und Revisionssystem” in the folder “05 Kennzeichnung\Gebrauchsinformation”

16. Product List (Identification of the Products)

For identification of the products by their respective number (Basic UDI-DI, reference number), please refer to the product list.

- ⇨ See Doc. “Produktliste_MUTARS® MK/HD Kniesystem” (product list for MUTARS® MK/HD Knee System) in the folder “02 Produktliste”

17. Reference to Previous Generations and Similar Devices

Information about previous generations of the products can be found in the product history.

⇨ See Doc. “Fbl_423-1-2-2_Produkthistorie Technische Dokumentation” (Product history Technical Documentation) in the folder “16 Produkthistorie”

Similar device available on the markets is the GMRS™ from the company Stryker/Howmedica.

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TABLE 11: List of Abbreviations

ABBREVIATION	ABBREVIATED TERM
AP	anterior-posterior
CoCrMo	cobalt chrome molybdenum
C-O-M	carbon-on-metal
DP	distal-proximal
HD	high demand
KRI	knee reconstruction implant
MDR	medical device regulations
MK	modular knee
ML	medial-lateral
M-O-M	metal-on-metal
MUTARS	modular universal tumor and revision system
PD	proximal-distal
PE	polyethylene
PEEK	polyether ether ketone
PET	polyethylene terephthalate
TiAl6V4	titanium 6 aluminium 4 vanadium
TiN	titanium nitride
TiNbN	titanium niobium nitride
UDI-DI	unique device identification – device identifier
UHMWPE	ultra-high molecular weight polyethylene
TiN	titanium nitride
UHMWPE	ultra-high molecular weight polyethylene

DOCUMENT REVISION HISTORY

DATE	REVISION	CHANGES	AUTHOR	COMMENTS
08.12.2016	0	Creation	N. Kapitonov	Separation of the product description “MUTARS® Knee System” into three separate documents corresponding to the three MUTARS® Knee Systems (PEEK, M-O-M, HD)
20.09.2022	1	Deletion of discontinued products	A. Meier	ÄA 22-352