PART OF THE
TECHNICAL DOCUMENTATION

PRODUCT DESCRIPTION

MUTARS® MK/HD KNEE FEMORAL COMPONENT

PRODUCT-GROUP: REVISION AND TUMOR ARTHROPLASTY

RISK-CLASS: III

LOCATION: KNEE

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

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

…to resurface the femoral condyles:

- MUTARS® GenuX® MK Femur
- MUTARS® GenuX® MK Femur HD
- MUTARS® GenuX® MK Femur Monoblock
- MUTARS® GenuX® MK Femur Monoblock HD

…to replace the femoral condyles or a part of the distal femur:

- MUTARS® KRI HD

…to replace the entire distal femur:

- MUTARS® Dist. Femur HD

The following femoral spacer are available:

- MK Femoral Spacer Posterior
- MK Femoral Spacer Distal

The femoral components are connected to the tibial components via the following components:

- MUTARS® HD Coupling M-O-M
- MUTARS® HD Coupling C-O-M

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 "04 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 Femur / MUTARS® GenuX® MK Femur HD

The MUTARS® GenuX® MK Femur and MUTARS® GenuX® MK Femur HD are revision total knee femoral components used to re-surface the femoral condyles and trochlear groove. Both components are available in a cemented version and a cementless version. The articular surface design is a “flat-on-flat” geometry in the frontal and sagittal planes.

The fixation surfaces of the cemented version provide 0.7 mm deep cement pockets for cement fixation and threaded holes for attachment of defect spacers.

FIGURE 1: MUTARS® GenuX® MK Femur Cemented (Left: A/P View; Right: M/L View)

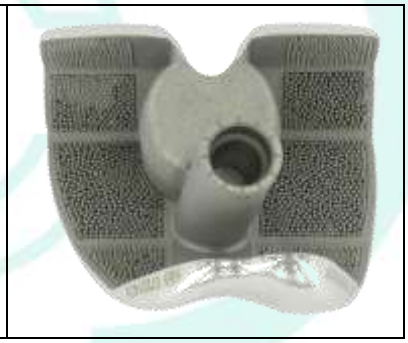

FIGURE 2: MUTARS® GenuX® MK Femur Cemented (P/D View)

The femoral stem attachment is tilted 6° medially and the patellar groove 5° medially to match anatomical and biomechanical knee characteristics. The MUTARS® GenuX® MK Femur and MUTARS® GenuX® MK Femur HD have a female MUTARS® morse taper / MUTARS® cylindrical fit connection for attachment to the MUTARS® GenuX® MK Offset Adapter which in turn attaches to MUTARS® GenuX® MK Stems.

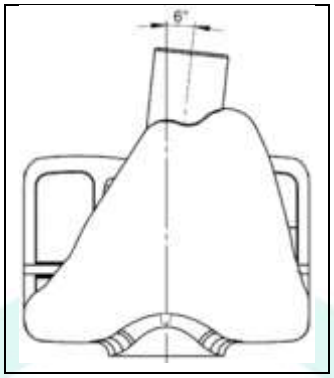

FIGURE 3: MUTARS® GenuX® MK Femur [HD] – Stem Attachment

The MUTARS® GenuX® MK Femur and MUTARS® GenuX® MK Femur HD articulate with a tibial bearing PE-insert that is attached to the tibial component.

10.2. MUTARS® GenuX® MK Femur Monoblock / MUTARS® GenuX® MK Femur Monoblock HD

MUTARS® GenuX® MK Femur Monoblock and MUTARS® GenuX® MK Femur Monoblock HD are monoblock versions of the cemented MUTARS® GenuX® MK Femur and MUTARS® GenuX® MK Femur HD described above, respectively. These monoblock components include an integral round profile stem with cement grooves for anchorage in the femur. The stem is tilted 6° medially to match knee anatomical and biomechanical characteristics. The MUTARS® GenuX® MK Femur Monoblock and MUTARS® GenuX® MK Femur Monoblock HD are intended for use with bone cement. Unlike the MUTARS® GenuX® MK Femur and MUTARS® GenuX® MK Femur HD cemented, the monoblock components will not accept spacers for bridging or augmenting bone defects. The MUTARS® GenuX® MK Femur Monoblock is coupled to the MUTARS® GenuX® MK Tibia Monoblock via the MUTARS® Coupling. The MUTARS® GenuX® MK Femur Monoblock HD is coupled to the MUTARS® GenuX® MK Tibia Monoblock via the MUTARS® HD Coupling M-O-M / C-O-M.

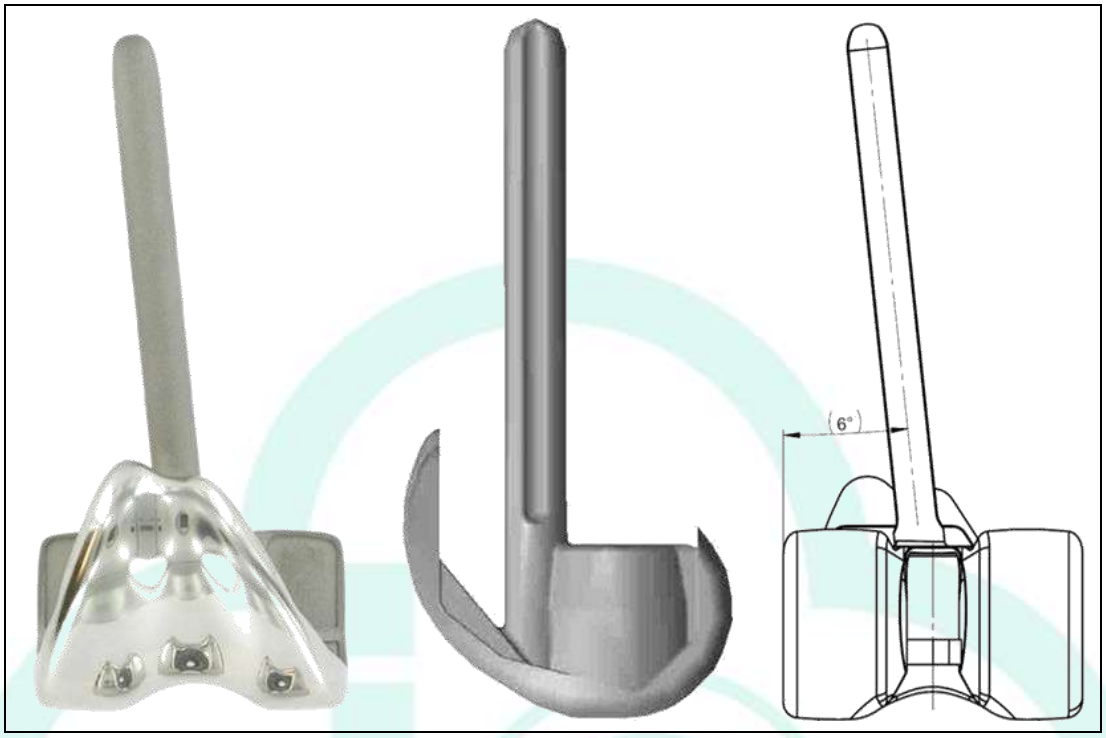

FIGURE 4: MUTARS® GenuX® MK Femur Monoblock (Left: A/P View; Center: L/M View; Right: P/A View)

10.3. MUTARS® KRI HD

The MUTARS® KRI HD replaces the condyles or a part of the distal femur.

FIGURE 5: MUTARS® KRI HD

FIGURE 6: MUTARS® KRI HD – TiN Coated

In accordance to the MUTARS® GenuX® MK Femur, the MUTARS® KRI HD have a frontal and sagittal plane “flat-on-flat” articular design, a 5° medial axis tilt of the stem attachment to match the anatomical characteristics of the distal femur.

10.4. MUTARS® Dist. Femur HD

The MUTARS® Dist. Femur HD components replace the entire distal femur.

FIGURE 7: MUTARS® Dist. Femur HD – TiN Coated

In accordance to the MUTARS® GenuX® MK Femur, the condyles of the MUTARS® Dist. Femur HD have a “flat-on-flat” design in the frontal and sagittal planes and articulate with a tibial bearing PE-insert.

The components include an “extra-osseous portion” that replaces the bone of the distal femoral shaft superior to the condyles. The MUTARS® Dist. Femur HD are designed with medial and lateral voids that are filled with metal plugs.

There is a 5° tilt between rotational and femoral axis to match the anatomical characteristics of the distal femur. The component utilizes the MUTARS® cylindrical fit connection for the attachment of a femoral stem and is designed with a retention ring for fixation of an attachment tube.

The MUTARS® KRI HD is similar to the MUTARS® Dist. Femur HD except that the MUTARS® KRI HD do not have the extra-osseous portion provided by the MUTARS® Dist. Femur HD.

10.5. MK Femoral Spacer Posterior

The MK Femoral Spacer Posterior is used for the bridging of bone defects in the posterior area of the distal femur. The MK Femoral Spacer Posterior are connected in the posterior part of the condyles of the MUTARS® GenuX® MK Femur [HD] cemented by the means of screws. The 0.7 mm deep cement pockets on the bottom surface are provided to augment the cement fixation. For the connection to the femoral component by screws, 6.5 mm bore holes are provided.

FIGURE 8: MK Femoral Spacer Posterior

10.6. MK Femoral Spacer Distal

The MK Femoral Spacers Distal are for used for bridging bone defects on the medial and lateral aspects of the distal femur. The MK Femoral Spacers Distal are connected to the distal part of the condyles of the MUTARS® GenuX® MK Femur [HD] cemented by the means of the MK spacer screws. They are available for the left lateral / right medial and right lateral / left medial applications. The 0.7 mm deep cement pockets on the bottom surface are provided to augment the cement fixation. For the connection to the femoral component by screws, 6.5 mm bore holes are provided.

FIGURE 9: MK Femoral Spacer Distal

10.7. MUTARS® HD Coupling M-O-M

The MUTARS® HD coupling M-O-M is used to connect a femoral component to a tibial component to create a hinge joint which replaces the missing ligaments and restrains the movement of the knee joint. When used with a MUTARS® GenuX® MK MB PE-Insert a 10° internal / external rotation is allowed.

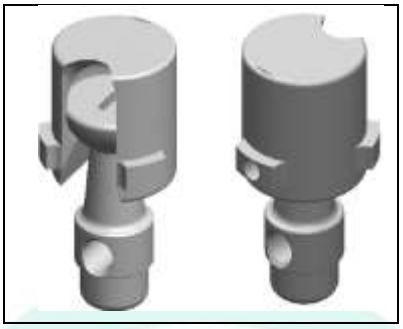

FIGURE 10: MUTARS® HD Coupling M-O-M

The MUTARS® HD Coupling M-O-M consists of two components: 1) a locking bolt that serves as the "socket" portion of the hinge joint (2-piece design in combination with the cap) and 2) a connecting pin that serves as the "ball" portion of the joint. The locking bolt serves as the "outer" portion of the rotating hinge mechanism and is attached to the femoral component while the connecting pin serves as the "inner" portion of the mechanism and is secured to the tibial component of the knee prosthesis.

The locking bolt has a distal internal conical geometry to capture and articulate with the terminal "ball" portion of the connecting pin (Ø 19 mm) and a posterior slot opening with a 20° angle for the body of the connecting pin, which allows a hinging motion of the joint created by the two components. The locking bolt is a 2-piece design to allow assembly of the connecting pin component with the bolt component during the manufacturing process. Following assembly of the connecting pin into the bolt, a cap piece is welded to the top of the bolt to produce the final MUTARS® HD coupling M-O-M component.

The locking bolt has a polyethylene pin fixed in the surface of the barrel of the locking bolt; the pin protrudes slightly above the surface of the locking bolt and provides a "snap-fit" mechanism for retention of the locking bolt body when it is secured to the femoral component. The locking bolt portion of the MUTARS® HD coupling M-O-M is secured to the femoral components by inserting the barrel of the locking bolt into a matching cylindrical receiver in the femoral component. Once fully inserted, the locking bolt is twisted until the PE pin engages and "snaps" into a recess within of the femoral component locking bolt cylindrical receiver wall.

The connecting pin has a hemispherical proximal terminal end that articulates within the internal conical geometry of the locking bolt. The shaft is tapered with an angle of 9° and the distal portion has two cylindrical portions that mate with matching cylinders in the tibial component. A diameter hole for placement of a screw is used to secure the attachment of the coupling to the tibial component.

10.8. MUTARS® HD Coupling C-O-M

The MUTARS® HD Coupling C-O-M is identical to the MUTARS® HD Coupling M-O-M in its design characteristics. The differences are the assembly of the bolt and the materials of the bolt and cap. The cap is made of PEEK C (carbon fiber enforced polyether ether ketone). The bolt consists of two parts.

The proximal part is made of PEEK C, too. The material of the distal part is CoCrMo alloy acc. to ISO 5832-12 that increase the mechanical safety of the coupling.

The pin is made of CoCrMo alloy acc. to ISO 5832-12 like the MUTARS® HD Coupling M-O-M.

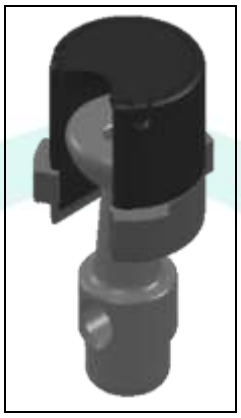

FIGURE 11:
MUTARS® HD
Coupling C-O-M

The PEEK C serves as an alternative wear pairing to the metal-on-metal coupling to reduce metal ion release. The carbon fiber enforcement serves to enhance mechanical stability of the joint coupling.

11. Materials

11.1. Femoral Component

All MUTARS® Femoral Components are manufactured from CoCrMo acc. to ISO 5832-4.

The MUTARS® PE-Spacers for Dist. Femur M-O-M and KRI M-O-M are manufactured from UHMWPE acc. to ISO 5834-2.

11.2. Spacer

The MK Femoral Spacer is manufactured from $TiAl_6V4$ acc. to ISO 5832-3.

11.3. Coupling

The MUTARS® HD Coupling M-O-M (locking bolt, connecting pin) is manufactured from CoCrMo acc. to ISO 5832-12. The MUTARS® PE-Safety Peg of the locking bolt is manufactured from standard UHMWPE acc. to ISO 5834-2.

The cap piece and the proximal part of the locking bolt of the MUTARS® HD Coupling C-O-M is manufactured from PEEK C. PEEK C is a strong and abrasion resistant polymer with high impact strength and a low coefficient of friction which can absorb the forces occurring in the femoral-tibial coupling. The material of the distal part of the locking bolt is CoCrMo acc. to ISO 5832-12. The

MUTARS® PE-Safety Peg of the locking bolt is manufactured from standard UHMWPE acc. to ISO 5834-2.

12. Coatings / Surfaces

TABLE 1: Coating Specifications

CHARACTERISTICS	VALUE		
	TiN	TiNbN	silver
COATING THICKNESS	5.5 ± 1.5 µm	4.5 ± 1.5 µm	15 ± 5 µm
POROSITY	/	/	/
AVERAGE ROUGHNESS RA	< 0.05 µm	< 0.05 µm	/
AVERAGE ROUGHNESS RT	/	/	/
TENSILE STRENGTH	≥ 22 MPa	≥ 22 MPa	/
SHEAR STRENGTH	/	/	/
CAP - RATIO	/	/	/

12.1. MUTARS® GenuX® MK Femur / MUTARS® GenuX® MK Femur HD

The articulating surface of the MUTARS® GenuX® MK Femur / MUTARS® GenuX® MK Femur HD is highly polished. The fixation surfaces of the cemented version have a sand blasted surface finish. The fixation surface of the cementless version provides a porous structure of casted balls. The diameter of the casted balls is 1.2 mm and the porosity is about 35%.

The MUTARS® GenuX® MK Femur / MUTARS® GenuX® MK Femur HD are available non-coated and with a TiN coating (see Table 1 for specifications) which is applied on all articulating and non-articulating surface of the component.

12.2. MUTARS® GenuX® MK Femur Monoblock / MUTARS® GenuX® MK Femur Monoblock HD

The articulating surface of the MUTARS® GenuX® MK Femur Monoblock / MUTARS® GenuX® MK Femur Monoblock HD is highly polished. The other surfaces have a sand blasted surface finish.

The MUTARS® GenuX® MK Femur Monoblock / MUTARS® GenuX® MK Femur Monoblock HD are available in a non-coated version.

12.3. MUTARS® KRI HD

All outer surfaces of the MUTARS® KRI HD are highly polished. Only the cone fit and the medial/lateral voids for the PE-spacer have a sand blasted surface finish.

The MUTARS® KRI HD are available non-coated and with a TiN coating (see Table 1 for specifications). The TiN coating is applied on the articulating and non-articulating surface of the component.

12.4. MUTARS® Dist. Femur HD

The MUTARS® Dist. Femur HD is available non-coated and with a TiN coating (see Table 1 for specifications). The TiN coating is applied on the articulating and non-articulating surface of the component (except the cone fit).

The articulating surface is highly polished while the extra-osseous portion has a sandblasted finish (coated versions: with an additional TiN coating which is applied circumferentially).

12.5. MK Femoral Spacer Posterior

The MK Femoral Spacers Posterior are available without coating and with silver coating. The upper and bottom surfaces of the uncoated MK Femoral Spacers Posterior are sandblasted. The outer contour of the MK Femoral Spacers Posterior Silver is sand blasted as well and provides a silver coating (see Figure 12 and Table 2).

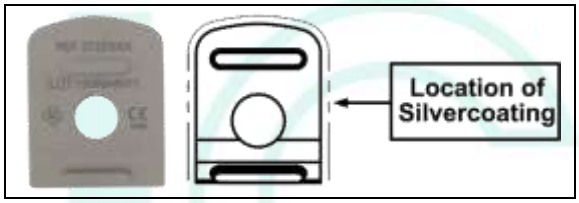

FIGURE 12: MK Femoral Spacer Posterior Silver - Location Of The Silver Coating

TABLE 2: MK Femoral Spacer Posterior Silver – Surface Area and Mass of the Silver Coating

	SIZE	SURFACE AREA SILVER COATING [mm²]	MASS SILVER [g]
MK Femoral Spacer Posterior Silver	1/5mm	235	0.05
	2/5mm	230	0.05
	2,5/5mm	270	0.06
	3/5mm	284	0.06
	4/5mm	280	0.06
	5/5mm	302	0.06
	6/5mm	313	0.07
	1/10mm	454	0.10
	2/10mm	510	0.11
	2,5/10mm	542	0.11
	3/10mm	648	0.14
	4/10mm	670	0.14
	5/10mm	715	0.15

TABLE 2: MK Femoral Spacer Posterior Silver – Surface Area and Mass of the Silver Coating

	SIZE	SURFACE AREA SILVER COATING [mm²]	MASS SILVER [g]
	6/10mm	678	0.14

12.6. MK Femoral Spacer Distal

The MK Femoral Spacers Distal are available without coating and with silver coating. The upper and bottom surfaces of the uncoated MK Femoral Spacers Distal are sandblasted. The outer contour of the MK Femoral Spacers Distal Silver is sand blasted as well and provides a silver coating (see Figure 13 and Table 3).

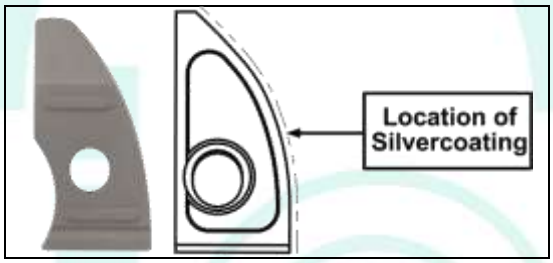

FIGURE 13: MK Femoral Spacer Distal Silver -
Location Of The Silver Coating

TABLE 3: MK Femoral Spacer Distal Silver – Surface Area and Mass of the Silver Coating

	SIZE	SURFACE AREA SILVER COATING [mm²]	MASS SILVER [g]
MK Femoral Spacer Distal Silver	1/5mm	148	0.03
	2/5mm	155	0.03
	2,5/5mm	165	0.03
	3/5mm	171	0.04
	4/5mm	175	0.04
	5/5mm	184	0.04
	6/5mm	188	0.04
	1/10mm	314	0.07
	2/10mm	338	0.07
	2,5/10mm	362	0.08
	3/10mm	390	0.08
	4/10mm	397	0.08
	5/10mm	420	0.09
	6/10mm	436	0.09

12.7. MUTARS® HD Coupling M-O-M

The MUTARS® HD coupling M-O-M is available non-coated and with a TiNbN coating (see Table 1 for specifications) that is applied circumferentially. The MUTARS® HD coupling M-O-M is also available with the TiNbN coated connecting pin only.

The components have highly polished surfaces.

12.8. MUTARS® HD Coupling C-O-M

The MUTARS® HD coupling C-O-M is available non-coated and with a TiN coating (metal surfaces, see Table 1 for specifications) that is applied circumferentially.

The metal components have highly polished surfaces.

The PEEK C components have a roughness RA of 0.8 µm.

13. Sizes and Dimensions

13.1. MUTARS® GenuX® MK Femur / MUTARS® GenuX® MK Femur HD

The MUTARS® GenuX® MK Femur / MUTARS® GenuX® MK Femur HD are provided in left and right versions in five sizes: 2, 3, 4, 5 and 6.

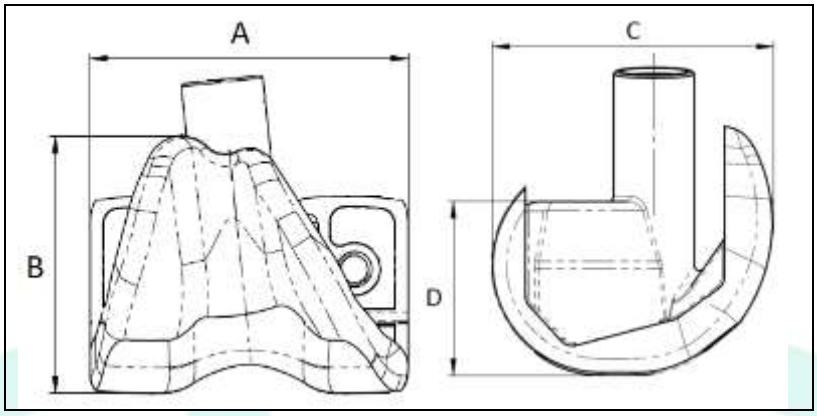

FIGURE 14: MUTARS® GenuX® MK Femur - Dimensions

TABLE 4: MUTARS® GenuX® MK Femur / MUTARS® GenuX® MK Femur HD - Dimensions

SIZE	A [mm]	B [mm]	C [mm]	D [mm]
2	62.0	49.7	56.0	34.7
3	67.0	50.0	61.5	
4	72.0	53.6	64.6	
5	77.0	58.8	66.8	
6	82.0	68.1	71.7	34.8

13.2. MUTARS® GenuX® MK Femur Monoblock / MUTARS® GenuX® MK Femur Monoblock HD

The MUTARS® GenuX® MK Femur Monoblock and MUTARS® GenuX® MK Femur Monoblock HD are available in left and right versions in four sizes: 2/10mm, 3/11mm, 4/12mm and 5/13mm.

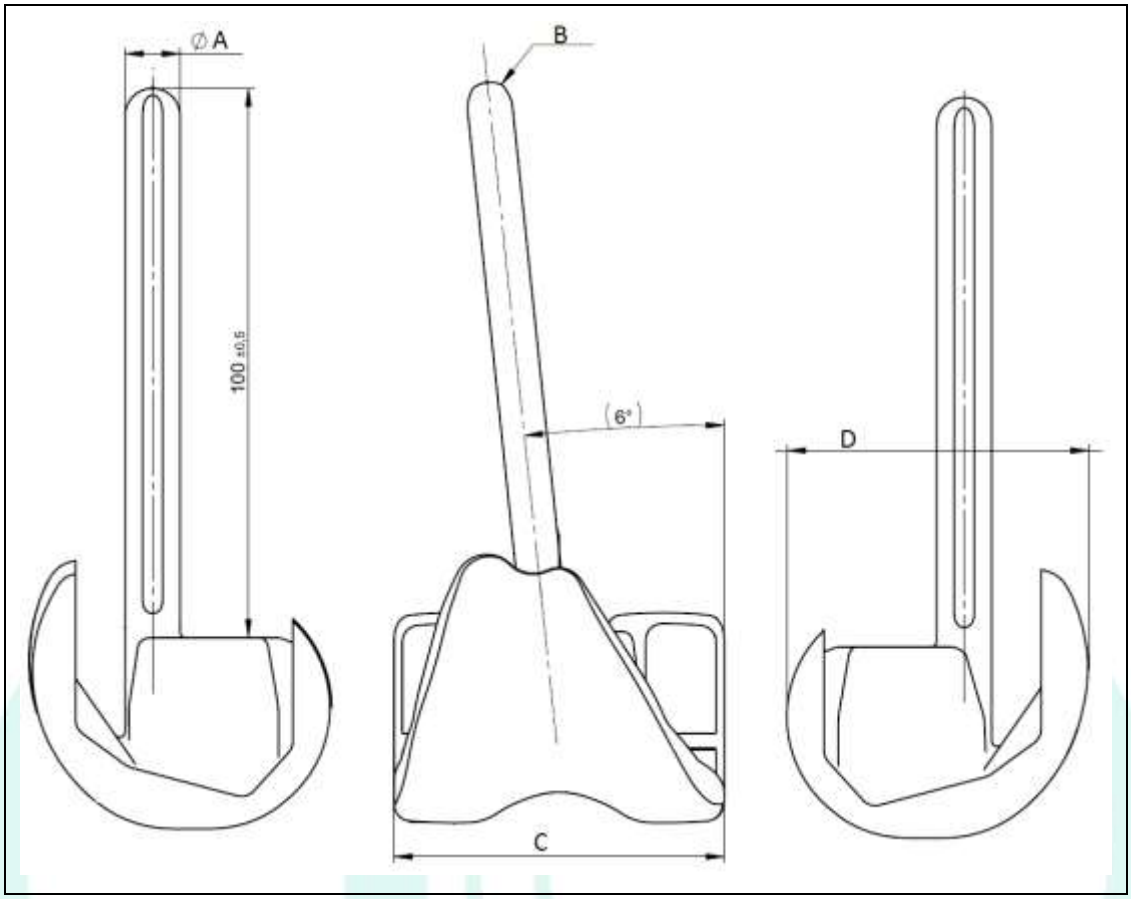

FIGURE 15: MUTARS® GENUX® MK Femur Monoblock - Dimensions

TABLE 5: MUTARS® GenuX® MK Femur Monoblock / MUTARS® GenuX® MK Femur Monoblock HD - Dimensions

SIZE	A [mm]	B [mm]	C [mm]	D [mm]
2/10mm	10	5	60	55
3/11mm	11	5.5	65	60.5
4/12mm	12	6	70	63.6
5/13mm	13	6.5	75	65.8

13.3. MUTARS® KRI HD

The MUTARS® KRI HD is available in one size and in a left and a right version.

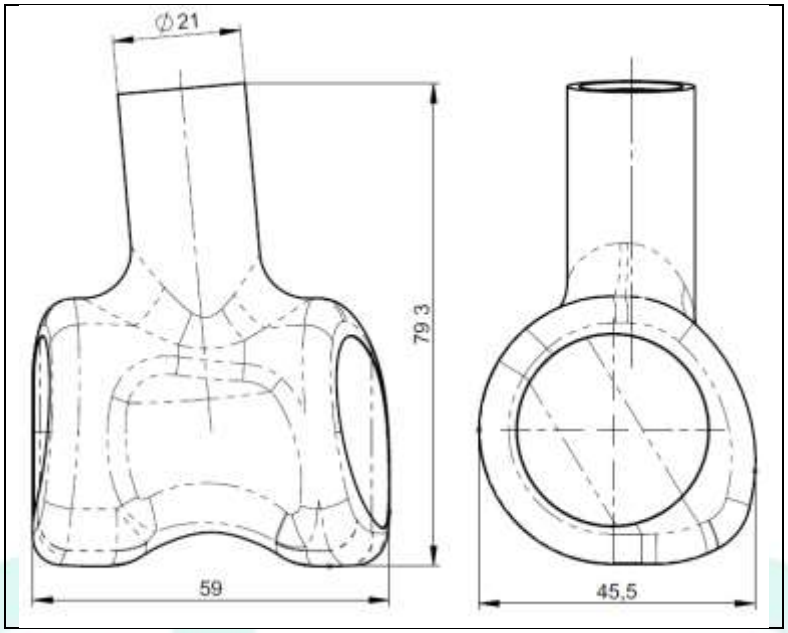

FIGURE 16: MUTARS® KRI HD - Dimensions (in mm)

13.4. MUTARS® Dist. Femur HD

The MUTARS® Dist. Femur HD is available in a left and a right version and in following sizes: 90mm, 90mm/XXS, 90mm/extra small, 90mm/large, 110mm, 110mm/XXS, 110mm/extra small and 110mm/large.

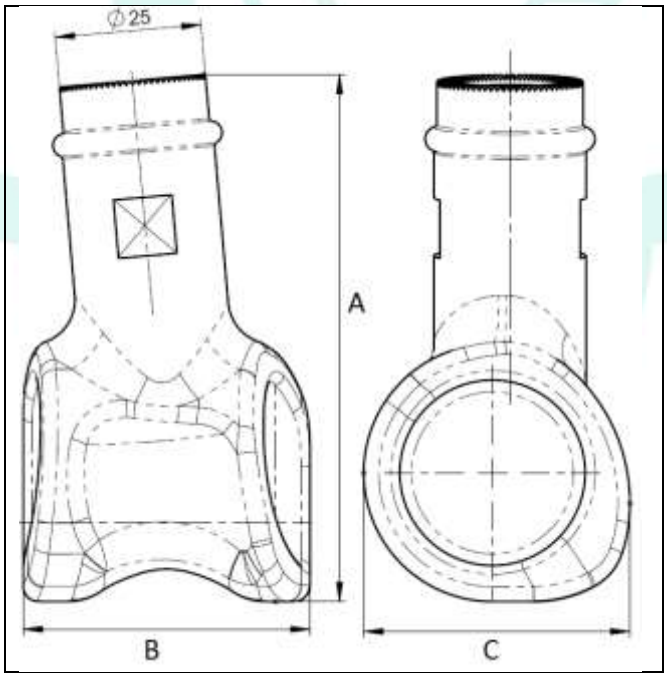

FIGURE 17: MUTARS® Dist. Femur HD - Dimensions

TABLE 6: MUTARS® Dist. Femur HD - Dimensions

SIZE	A [mm]	B [mm]	C [mm]
90mm	90.0	59.0	45.5
90mm/XXS		49.0	
90mm/extra small		56.0	
90mm/large		70.0	50.0
110mm	110.0	59.0	45.5
110mm/XXS		49.0	
110mm/extra small		56.0	
110mm/large		70.0	50.0

13.5. MK Femoral Spacer Posterior

The MK Femoral Spacers Posterior are available in two heights 5 mm and 10 mm and in the following sizes: 1, 2, 2.5, 3, 4, 5 and 6. A summary of the dimensions of each size is provided in the table below.

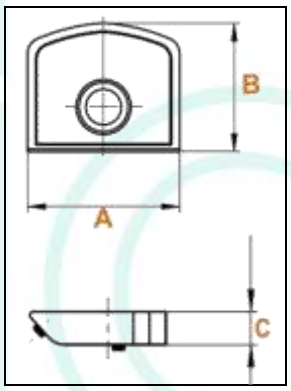

FIGURE 18: MK Femoral Spacer Posterior - Dimensions

TABLE 7: MK Femoral Spacer Posterior - Dimensions

SIZE	DIMENSION		
	A [mm]	B [mm]	C [mm]
1/5mm	15.40	19.60	4.90
2/5mm	17.90	20.56	
2,5/5mm	19.15	22.54	
3/5mm	20.40	25.52	
4/5mm	22.90	23.94	
5/5mm	25.40	24.73	
6/5mm	27.90	23.48	
1/10mm	15.40	19.67	9.90
2/10mm	17.90	20.71	
2,5/10mm	19.15	23.02	
3/10mm	20.40	26.30	

TABLE 7: MK Femoral Spacer Posterior - Dimensions

SIZE	DIMENSION		
	A [mm]	B [mm]	C [mm]
4/10mm	22.90	27.08	
5/10mm	25.40	27.60	
6/10mm	27.90	27.68	

13.6. MK Femoral Spacer Distal

The MK Femoral Spacers Distal are available in 5 mm and 10 mm thicknesses in the following sizes: 1, 2, 2.5, 3, 4, 5 and 6 in two geometries, one that can be used on the right lateral aspect or left medial aspect (rl/lm) and another for application on the left lateral or right medial (ll/rm) aspect. The MK Femoral Spacers Distal are secured to the femoral component with 6.5 mm spacer attachment screws. The dimensions of each size and thickness of the MK Femoral Spacers Distal is provided in the table below.

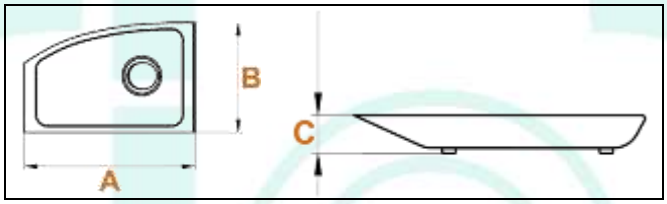

FIGURE 19: MK Femoral Spacer Distal - Dimensions

TABLE 8: MK Femoral Spacer Distal - Dimensions

SIZE	DIMENSION		
	A [mm]	B [mm]	C [mm]
1/5mm	32.20	15.40	
2/5mm	35.31	17.90	
2,5/5mm	37.87	19.15	
3/5mm	40.31	20.40	5.70
4/5mm	39.51	22.90	
5/5mm	42.12	25.40	
6/5mm	43.66	27.90	
1/10mm	33.86	15.40	
2/10mm	36.82	17.90	
2,5/10mm	39.60	19.15	
3/10mm	42.39	20.40	10.70
4/10mm	43.97	22.90	
5/10mm	46.33	25.40	
6/10mm	50.06	27.90	

13.7. MUTARS® HD Coupling M-O-M

The MUTARS® HD Coupling M-O-M is available in following sizes: 12.5 mm, 15 mm and 17.5 mm. The cap piece and the locking bolt have the same dimensions in all sizes.

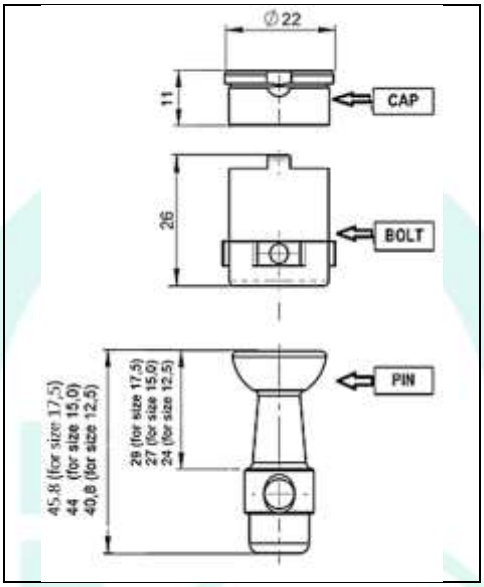

FIGURE 20: MUTARS® HD Coupling M-O-M - Dimensions (in mm)

13.8. MUTARS® HD Coupling C-O-M

The MUTARS® HD Coupling C-O-M is available in following sizes: 12.5mm, 15mm and 17.5mm. The cap piece and the locking bolt have the same dimensions in all sizes.

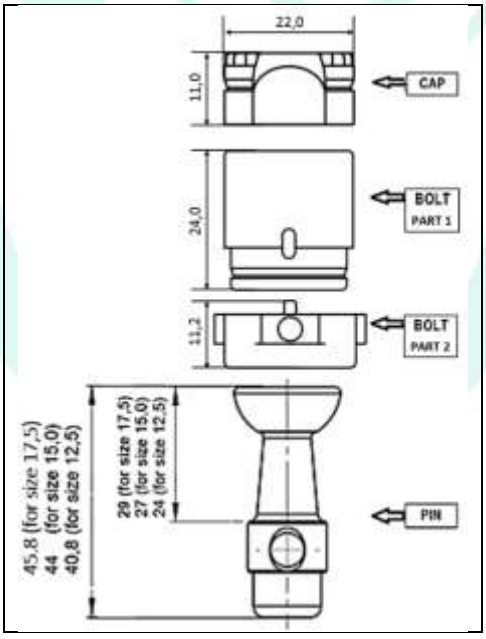

FIGURE 21: MUTARS® HD Coupling C-O-M - Dimensions (in mm)

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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LIST OF ABBREVIATIONS

TABLE 9: 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

DOCUMENT REVISION HISTORY

DATE	REVISION	CHANGES	AUTHOR	COMMENTS
01.10.2021	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, MK/HD)