PART OF THE
TECHNICAL DOCUMENTATION

PRODUCT DESCRIPTION

MUTARS® KNEE SYSTEM STEMS

PRODUCT-GROUP: REVISION AND TUMOR ARTHROPLASTY

RISK-CLASS: III

LOCATION: KNEE

DATE: 28.05.2021, REV. 1

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1. MUTARS® Knee System - Stems

The MUTARS® Knee System includes following stems:

- MUTARS® Stem for Tibial Plateau Modular
- MUTARS® Tibial Stem
- MUTARS® PT Tibial Stem
- MUTARS® GenuX® Stem
- MUTARS® GenuX® Offset Stem
- MUTARS® GenuX® MK Stem
- MUTARS® GenuX® MK Extension Stem

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 "03 Produktbeschreibung"

3. Qualification of the Product as a Medical Device

The products of the MUTARS® 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® 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® 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® 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® Knee System can be found in the Instruction for Use.

⇨ See Doc. Instruction for Use “09300013 MUTARS Tumor- und Revisionssystem” in the folder “04 Gebrauchsinformation”

8. Contraindications

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

⇨ See Doc. Instruction for Use “09300013 MUTARS Tumor- und Revisionssystem” in the folder “04 Gebrauchsinformation”

9. Risk Factors

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

⇨ See Doc. Instruction for Use “09300013 MUTARS Tumor- und Revisionssystem” in the folder “04 Gebrauchsinformation”

10. Design Description

10.1. MUTARS® Stem for Tibial Plateau Modular

The MUTARS® Stem for Tibial Plateau Modular allows for a diaphyseal anchorage of the knee joint replacement in the tibia. This stem is available in cemented and cementless versions.

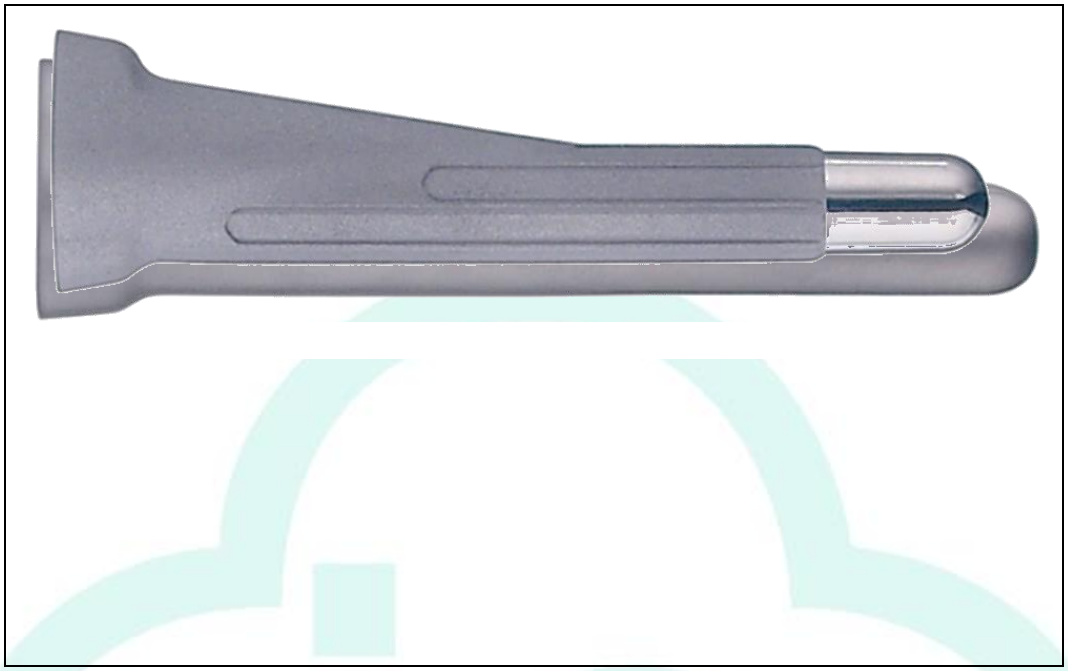

FIGURE 1: MUTARS® Stem for Tibial Plateau Modular (Upper Line: Cementless, Bottom Line: Cemented)

The MUTARS® Stem for Tibial Plateau Modular Cemented has a straight cylindrical stem design with a round profile and two cement grooves for rotational stability. The stem has an eccentric position (offset of 5 mm) for a physiological load transfer.

The MUTARS® Stem for Tibial Plateau Modular Cementless is a straight cylindrical stem design with a hexagonal profile with fins for rotation stability. The stem has an eccentric position (offset of 5 mm) for a physiological load transfer.

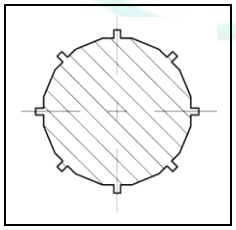

FIGURE 2:
MUTARS® Stem for
Tibial Plateau
Modular Cementless
– Cross Section

10.2. MUTARS® Tibial Stem

The MUTARS® Tibial Stem allows for a diaphyseal anchorage of the knee joint replacement in the tibia. This stem is available in cemented and cementless versions.

The MUTARS® Tibial Stem has a straight shaft design with a hexagonal cross section for rotation stability and a collar at the proximal end to prevent subsidence. The stems utilize the MUTARS®

cylindrical fit connection mechanism with serrated teeth on its proximal end which allows an adjustment of the antetorsion angle in 5° steps.

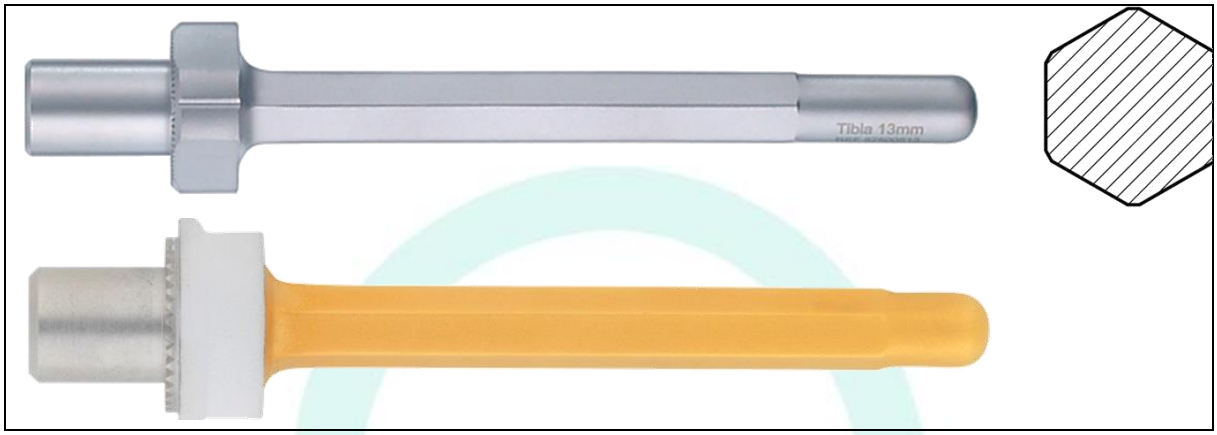

FIGURE 3: MUTARS® Tibial Stem Cemented (Upper Line: Uncoated, Bottom Line: With HA Collar, Right: Cross Section)

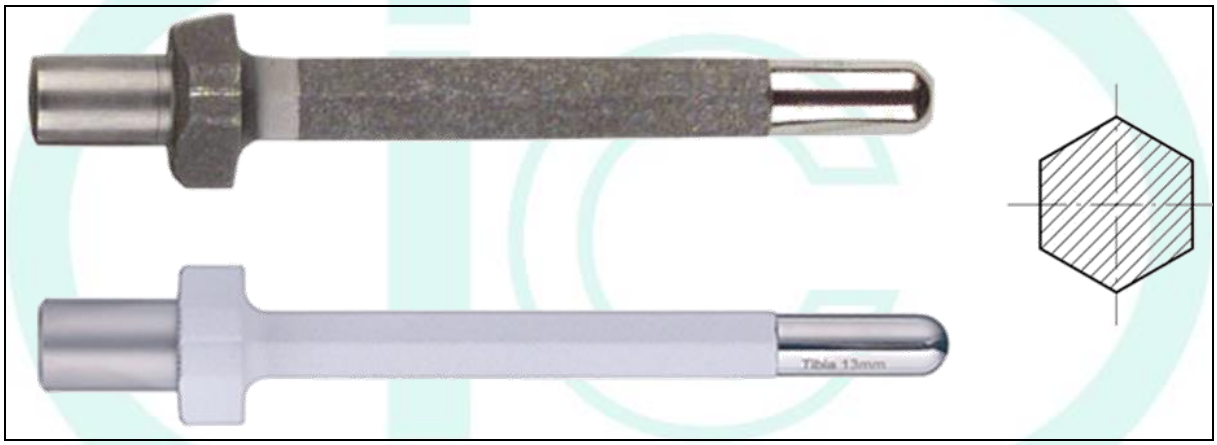

FIGURE 4: MUTARS® Tibial Stem Cementless (Upper Line: Uncoated, Bottom Line: HA Coated, Right: Cross Section)

10.3. MUTARS® PT Tibial Stem

The MUTARS® PT Tibial Stem allows for a diaphyseal anchorage of the knee joint replacement in the tibia. This stem is available cementless version only.

The design of the MUTARS® PT Tibial Stem is mostly the same as the MUTARS® Tibial Stem.

FIGURE 5: MUTARS® PT Tibial Stem (Left: Stem, Right: Cross Section)

10.4. MUTARS® GenuX® Stem

The MUTARS® GenuX® Stem allows for a diaphyseal anchorage of the knee joint replacement in the femur. The stem provides a female morse taper and MUTARS® cylindrical fit connection for attachment to the MUTARS® Offset Adapter and MUTARS® GenuX® Femoral Component. This stem is available in cemented and cementless versions.

For length of 200 mm and greater, the MUTARS® GenuX® Stems have interlocking screw holes for the connection of cortical screws (Ø 4,5 mm).

The MUTARS® GenuX® Stem Cemented has a straight cylindrical stem design with a round profile and two cement grooves for rotational stability.

FIGURE 6: MUTARS® GenuX® Stem Cemented (Upper Line), MUTARS® GenuX® Offset Stem Cemented (Bottom Line) and Cross Section (Right)

The MUTARS® GenuX® Stem Cementless has a straight cylindrical stem design with a hexagonal profile with fins for rotation stability.

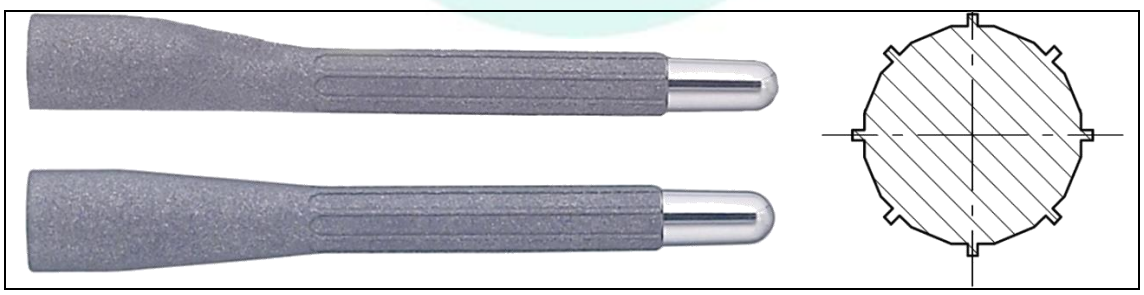

FIGURE 7: MUTARS® GenuX® Stem Cementless (Upper Line), MUTARS® GenuX® Offset Stem Cementless (Bottom Line) and Cross Section (Right)

MUTARS® GenuX® Offset Stem

The MUTARS® GenuX® Stem is also available as MUTARS® GenuX® Offset Stem with an offset of 2.5 mm (see Figure 6 and Figure 7).

10.5. MUTARS® GenuX® MK Stem

The MUTARS® GenuX® MK Stem allows for diaphyseal anchorage of the knee joint replacement in the femur and tibia. This stem is available in cemented and cementless versions.

For length of 200 mm and greater, the MUTARS® GenuX® MK Stems have interlocking screw holes for the connection of cortical screws (Ø 4,5 mm).

The MUTARS® GenuX® MK Stem Cemented has a straight cylindrical stem design with a round profile and a cement groove for rotational stability.

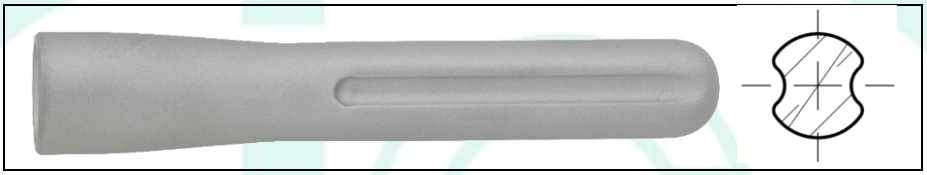

FIGURE 8: MUTARS® GenuX® MK Stem Cemented (Left) and Cross Section (Right)

The MUTARS® GenuX® MK Stem Cementless has a straight cylindrical stem design with a hexagonal profile with fins for rotational stability.

FIGURE 9: MUTARS® GenuX® MK Stem Cementless (Left) and Cross Section (Right)

10.6. MUTARS® GenuX® MK Extension Stem

The MUTARS® GenuX® MK Extension Stem allows to achieve the minimal drilling depth (125mm of the distal cut) of a MUTARS® GenuX® MK component in combination with an EPORE® Metaphyseal Component Femoral for GenuX® MK. It is intended for cementless use and has a straight cylindrical stem design with a round profile.

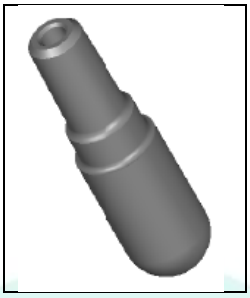

FIGURE 10:
MUTARS® GenuX®
MK Extension Stem

11. Materials

All cemented stems are made of CoCrMo acc. to ISO 5832-4.

All cementless stems inkl. MUTARS® GenuX® MK Extension Stem are made of $TiAl_6V_4$ acc. to ISO 5832-3.

12. Coatings / Surfaces

TABLE 1: Coating Specifications

CHARACTERISTICS	VALUE			
	TiN	cpTi	TCP	HA
COATING THICKNESS	5.5 ± 1.5 µm	250 ± 50 µm	20 ± 10 µm	90 ± 30 µm
POROSITY	/	10…30%	≤ 30%	/
AVERAGE ROUGHNESS RA	< 0.05 µm	5…55 µm	/	8 ± 3 µm
AVERAGE ROUGHNESS RT	/	125…225 µm	/	50 ± 20 µm
TENSILE STRENGTH	≥ 22 MPa	> 22 MPa	≥ 15 MPa	≥ 15 MPa
SHEAR STRENGTH	/	> 20 MPa	/	≥ 20 MPa
CAP - RATIO	/	/	1.1 ± 0.1	1.67…1.76

12.1. MUTARS® Stem for Tibial Plateau Modular

The MUTARS® Stem for Tibial Plateau Modular Cemented is available uncoated and with TiN coating that is applied circumferentially (for specifications see Table 1). The stems have a sand blasted surface finish.

The MUTARS® Stem for Tibial Plateau Modular Cementless is available uncoated and with TCP coating that is applied circumferentially (for specifications see Table 1). The stem tip is uncoated and highly polished. The stem has a corundum blasted rough surface.

12.2. MUTARS® Tibial Stem

The MUTARS® Tibial Stem Cemented is available uncoated, with TiN, with cpTi/HA double coating that that is applied on the collar only or with TiN/HA (for specifications see Table 1). In the version with TiN/HA coating, the stem is coated with TiN up to the collar and the HA coating is applied on the collar only. The stem has a sandblasted surface.

The MUTARS® Tibial Stem Cementless is available uncoated and with HA coating (for specifications see Table 1). The stem has a corundum blasted rough surface. The tip of the stem is highly polished and uncoated.

12.3. MUTARS® PT Tibial Stem

The MUTARS® PT Tibial Stem is available with a HA coating. The stem has a sandblasted surface. The tip of the stem is highly polished and uncoated.

12.4. MUTARS® GenuX® Stem

The MUTARS® GenuX® Stem Cemented is available uncoated and with TiN coating that is applied circumferentially (for specifications see Table 1). The stems have a sand blasted surface finish.

The MUTARS® GenuX® Stem Cementless is available uncoated and with TCP coating that is applied circumferentially (for specifications see Table 1). The stem tip is uncoated and highly polished. The stem has a corundum blasted rough surface.

12.5. MUTARS® GenuX® MK Stem

The MUTARS® GenuX® MK Stem Cemented is available uncoated and with TiN coating that is applied circumferentially (for specifications see Table 1). The stems have a sand blasted surface finish.

The MUTARS® GenuX® MK Stem Cementless is available uncoated and with HA coating (for specifications see Table 1). The stem tip is uncoated and highly polished. The stem has a corundum blasted rough surface.

12.6. MUTARS® GenuX® MK Extension Stem

The MUTARS® GenuX® MK Extension Stem is available without coating and has a corundum blasted rough surface.

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13. Sizes and Dimensions

13.1. MUTARS® Stem for Tibial Plateau Modular

The MUTARS® Stem for Tibial Plateau Modular Cemented is available in three lengths (120 mm, 160 mm, 200 mm) and three diameters (11 mm, 13 mm, 15 mm).

The MUTARS® Stem for Tibial Plateau Modular Cementless is available in three lengths (120 mm, 160 mm, 200 mm) and four diameters (12 mm, 14 mm, 16 mm, 18 mm).

13.2. MUTARS® Tibial Stem

The MUTARS® Tibial Stem Cemented is available in a length of 120 mm in three diameters (11 mm, 13 mm, 15 mm).

The uncoated version of the MUTARS® Tibial Stem Cementless is available in a length of 120 mm and in following diameters: 10 mm, 11 mm, 12 mm, 13 mm, 14 mm, 15 mm, 16 mm, 18 mm.

The HA coated version of the MUTARS® Tibial Stem Cementless is available in the length of 120 mm in following diameters: 10 mm, 11 mm, 12 mm, 13 mm, 14 mm, 15 mm, 16 mm, 18 mm; and in the length of 200 mm in following diameters: 12 mm, 13 mm, 14 mm,15 mm, 16 mm.

13.3. MUTARS® PT Tibial Stem

The MUTARS® PT Tibial Stem is available in two lengths (120 mm, 90 mm) and seven diameters (10 mm, 11 mm, 12 mm, 13 mm, 14 mm, 15 mm, 16 mm).

13.4. MUTARS® GenuX® Stem

The MUTARS® GenuX® Stem Cemented is available in four lengths (130 mm, 160 mm, 200 mm, 240 mm) and four diameters (11 mm, 13 mm, 15 mm, 17 mm).

The uncoated version of the MUTARS® GenuX® Stem Cementless is available in four lengths (130 mm, 160 mm, 200 mm, 240 mm) and four diameters (12 mm, 14 mm, 16 mm, 18 mm).

The TCP coated version is available in three lengths (160 mm, 200 mm, 240 mm) and four diameters (12 mm, 14 mm, 16 mm, 18 mm)

13.5. MUTARS® GenuX® Offset Stem

The MUTARS® GenuX® Offset Stem Cemented is available in three lengths (160 mm, 200 mm, 240 mm) and four diameters (11 mm, 13 mm, 15 mm, 17 mm).

The MUTARS® GenuX® Offset Stem Cementless is available in three lengths (160 mm, 200 mm, 240 mm) and four diameters (12 mm, 14 mm, 16 mm, 18 mm).

13.6. MUTARS® GenuX® MK Stem

The MUTARS® GenuX® MK Stem Cemented is available in four length (125 mm, 150 mm, 200 mm, 250 mm) and five diameters (11 mm, 13 mm, 15 mm, 17 mm, 19 mm).

The MUTARS® GenuX® MK Stem Cementless is available in the length of 125 mm with following diameters: 12 mm, 14 mm, 16 mm, 18 mm, 20 mm, 22 mm, 24 mm, 26 mm, 28 mm; and in the lengths 150 mm, 200 mm and 250 mm in the following diameters: 12 mm, 14 mm, 16 mm, 18 mm, 20 mm, 22 mm.

13.7. MUTARS® GenuX® MK Extension Stem

The MUTARS® GenuX® MK Extension Stem is available in one size with a diameter of 14 mm.

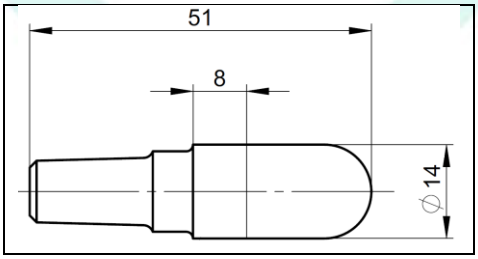

FIGURE 11: MUTARS® GenuX® MK Extension Stem - Dimensions

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 “12 Kombinationstabellen”
- ⇨ See Doc. “09300095 MUTARS Tumor- und Revisionssystem Kombinationsmöglichkeiten_Anhang I“ in the folder „04 Gebrauchsinformation“

15. Warnings

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

- ⇨ See Doc. Instruction for Use “09300013 MUTARS Tumor- und Revisionssystem” in the folder “04 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® Kniesystem” (product list for MUTARS® Knee System) in the folder “01 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 “17 Produkthistorie”

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

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LIST OF ABBREVIATIONS

TABLE 2: 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
PT	pediatric treatment
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
16.01.2017	0	Creation	Dr. F. Teuscher A. Kerber	---
28.05.2021	1	• Conversation acc. to MDR • Complete update	N. Kapitonov	ÄA 21-671