

PART OF THE
TECHNICAL DOCUMENTATION

PRODUCT DESCRIPTION
MUTARS[®] RS STEMS

PRODUCT-GROUP: REVISION AND TUMOR
ARTHROPLASTY

RISK-CLASS: III

LOCATION: HIP

DATE: 25.10.2021, REV. 0

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1 MUTARS® RS Stems

The MUTARS® RS stems are available in cemented and cementless versions, with and without coating.

2 Intended Use

⇒ See Doc. “Fbl_423-1-2-4_Zweckbestimmung_MUTARS® Hip” in the folder “04 Produktbeschreibung”

3 Qualification of the Product as a Medical Device

The MUTARS® RS stems 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 MUTARS® RS stems 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 MUTARS® RS stems 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 MUTARS® RS stems 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 these implants 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® Hip System can be found in the Instruction for Use.

- ⇒ See Doc. Instruction for Use “09300015_MUTARS RS Revisionsssystem” in the folder “05 Kennzeichnung” subfolder “Gebrauchsinformation”
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8 Contraindications

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

- ⇒ See Doc. Instruction for Use “09300015_MUTARS RS Revisionsssystem” in the folder “05 Kennzeichnung” subfolder “Gebrauchsinformation”
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9 Risk Factors

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

- ⇒ See Doc. Instruction for Use “09300015_MUTARS RS Revisionsssystem” in the folder “05 Kennzeichnung” subfolder “Gebrauchsinformation”
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10 Design Description

10.1 MUTARS® RS stem cemented

The MUTARS® RS stem cemented has a collarless, curved and tapered stem design. The stem has a hexagonal cross section for rotational stability. The RS stem cemented incorporates the male MUTARS® taper connection for attachment to the MUTARS® RS metaphyseal component, optionally MUTARS® RS extension piece or MUTARS® RS coupling device.



FIGURE 1. MUTARS® RS STEM CEMENTED

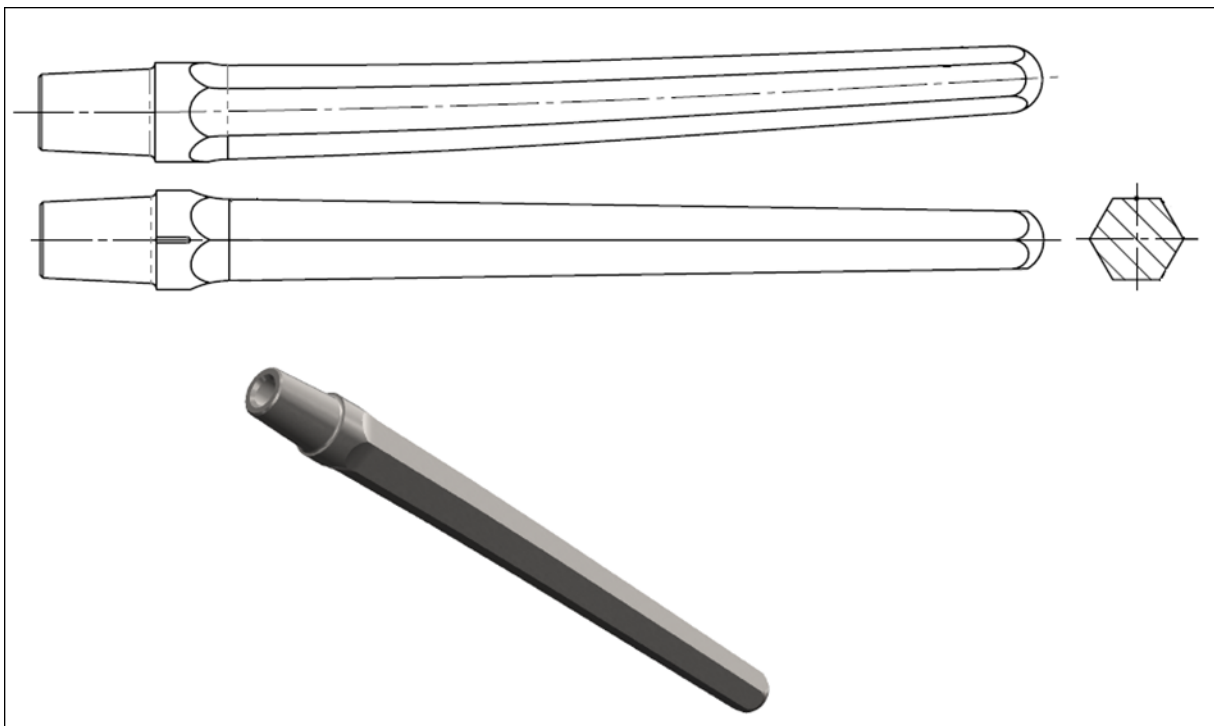


FIGURE 2. MUTARS® RS STEM CEMENTED; CROSS SECTION (RIGHT PICTURE)

10.2 MUTARS® RS stem cementless

The MUTARS® RS stem cementless has a collarless, curved and tapered stem design. The proximal area of the cementless RS stem has a hexagonal cross section while the distal area has longitudinal ribs, which provide a star-shaped cross section for additional rotational stability. The RS stem cementless incorporates the male MUTARS® taper connection (FIGURE 4) for attachment to the MUTARS® RS metaphyseal component, optionally MUTARS® RS extension piece or MUTARS® RS coupling device.

Stems of lengths 200 and 250 mm and with diameters of 15 - 22 mm and 17 - 22 mm, respectively, have two distal interlocking screw holes (5 mm in diameter) for placement of cortical screws for additional fixation if required.

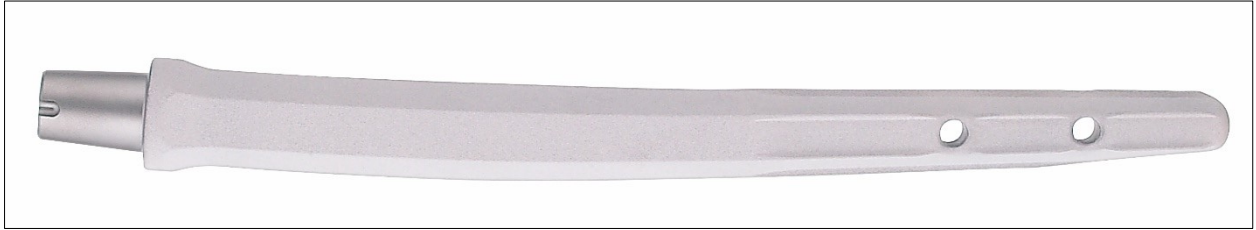


FIGURE 3. MUTARS® RS STEM CEMENTLESS HA WITH LOCKING SCREW HOLES

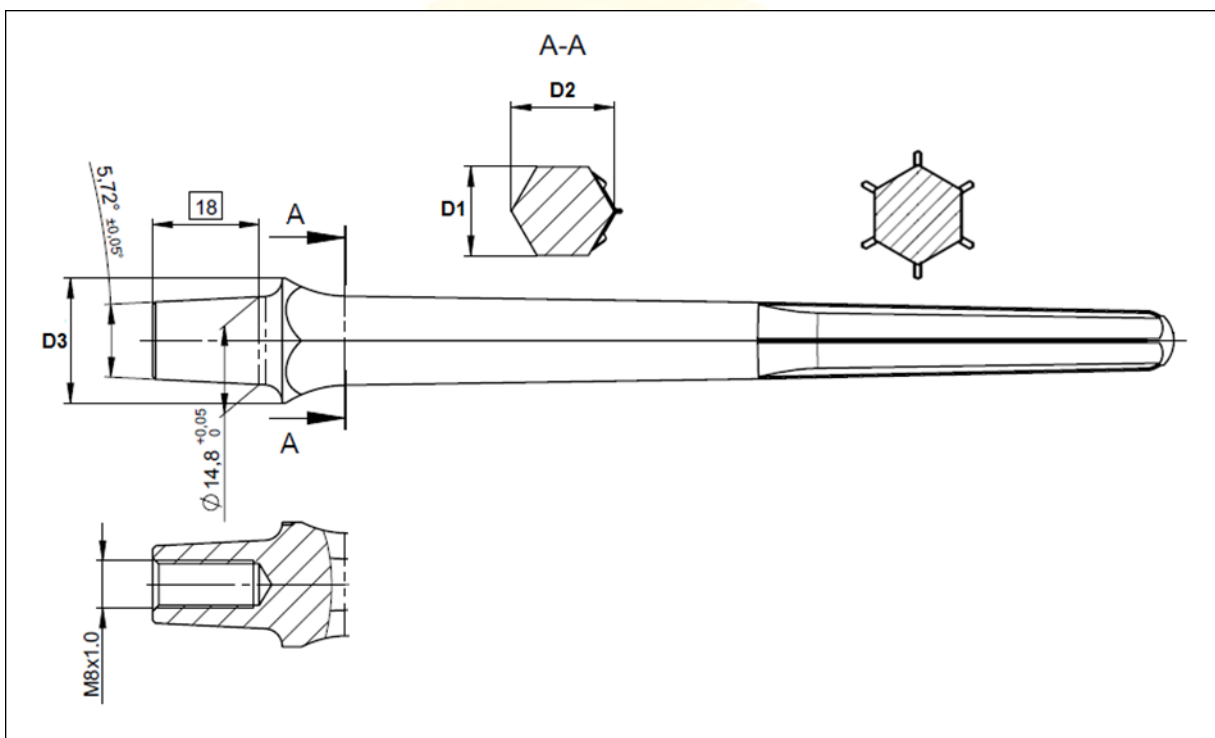


FIGURE 4. MUTARS® RS STEM CEMENTLESS WITH THE MALE MUTARS® TAPER; CROSS SECTION (UPPER PICTURES)

10.3 MUTARS® RS stem extra small cementless

The MUTARS® RS stem extra small cementless is curved to suit the femur's physiological antecurvature. The proximal area of the stem has a hexagonal cross section while the distal area has longitudinal ribs, which provide a star-shaped cross section for additional rotational stability.

For the attachment to the MUTARS® RS proximal component, the MUTARS® RS stem extra small cementless utilizes the MUTARS® cylindrical fit and serration connection design.

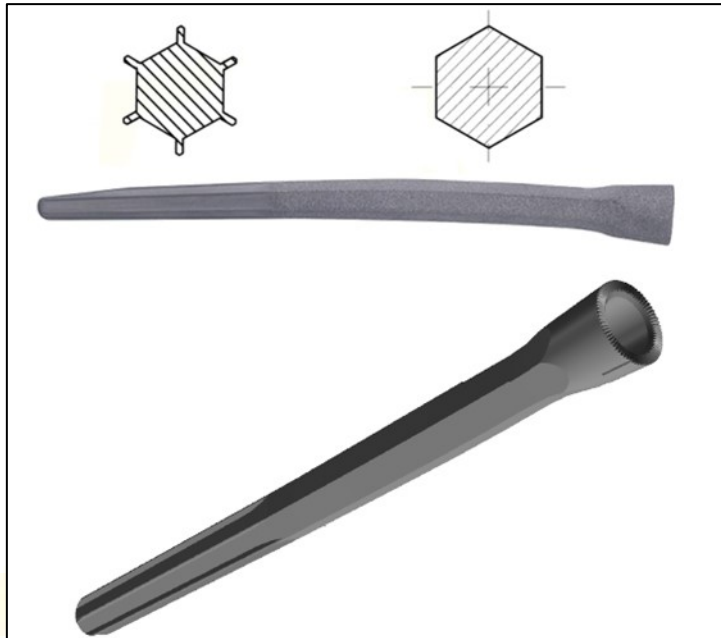


FIGURE 5. MUTARS® RS STEM EXTRA SMALL CEMENTLESS

11 Materials

11.1 MUTARS® RS stem cemented

MUTARS® RS stem cemented is made of CoCrMo casting alloy meeting the specifications of ISO 5832-4.

11.2 MUTARS® RS stem cementless

MUTARS® RS stem cementless is made of wrought TiAl₆V₄ alloy meeting the specifications of ISO 5832-3.

11.3 MUTARS® RS stem extra small cementless

MUTARS® RS stem extra small cementless is made of wrought TiAl₆V₄ alloy meeting the specifications of ISO 5832-3.

12 Coatings / Surfaces

12.1 MUTARS® RS stem cemented

MUTARS® RS stem cemented features a sandblasted surface. It is also available with a Titanium Nitride (TiN) coating (thickness: $5.5 \pm 1.5 \mu\text{m}$; Coating Specification A1) that is applied circumferentially to the stem.

12.2 MUTARS® RS stem cementless

MUTARS® RS stem cementless has a rough-blasted surface for bone ongrowth. It is also available with plasma sprayed hydroxyapatite (HA) coating (thickness: $90 \pm 30 \mu\text{m}$; Coating Specification B3) to support osseointegration.

12.3 MUTARS® RS stem extra small cementless

MUTARS® RS stem extra small cementless has a rough-blasted surface for bone ongrowth. It is also available with plasma sprayed hydroxyapatite (HA) coating (thickness: $90 \pm 30 \mu\text{m}$; Coating Specification B3) to support osseointegration.

13 Sizes and Dimensions

13.1 MUTARS® RS stem cemented

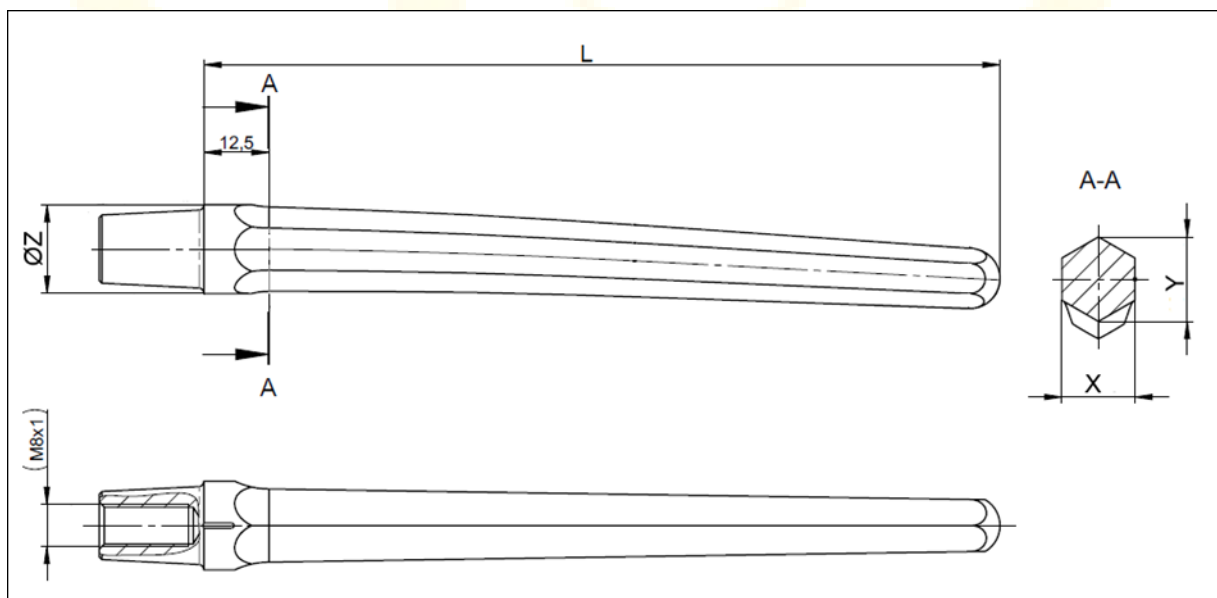


FIGURE 6. MEASUREMENTS OF THE MUTARS® RS STEM CEMENTED

TABLE 1: MEASUREMENTS OF THE MUTARS® RS STEM CEMENTED

Size	L [mm]	X [mm]	Y [mm]	ØZ [mm]
12/120mm	120	12	13,9	17
14/120mm	120	14	16,2	17
16/120mm	120	16	18,3	21
18/120mm	120	18	20,8	21
12/150mm	160	12	13,9	17
14/150mm	160	14	16,2	17
16/150mm	160	16	18,3	21
18/150mm	160	18	20,8	21
12/200mm	200	12	13,9	17
14/200mm	200	14	16,2	17
16/200mm	200	16	18,3	21
18/200mm	200	18	20,8	21

13.2 MUTARS® RS stem cementless

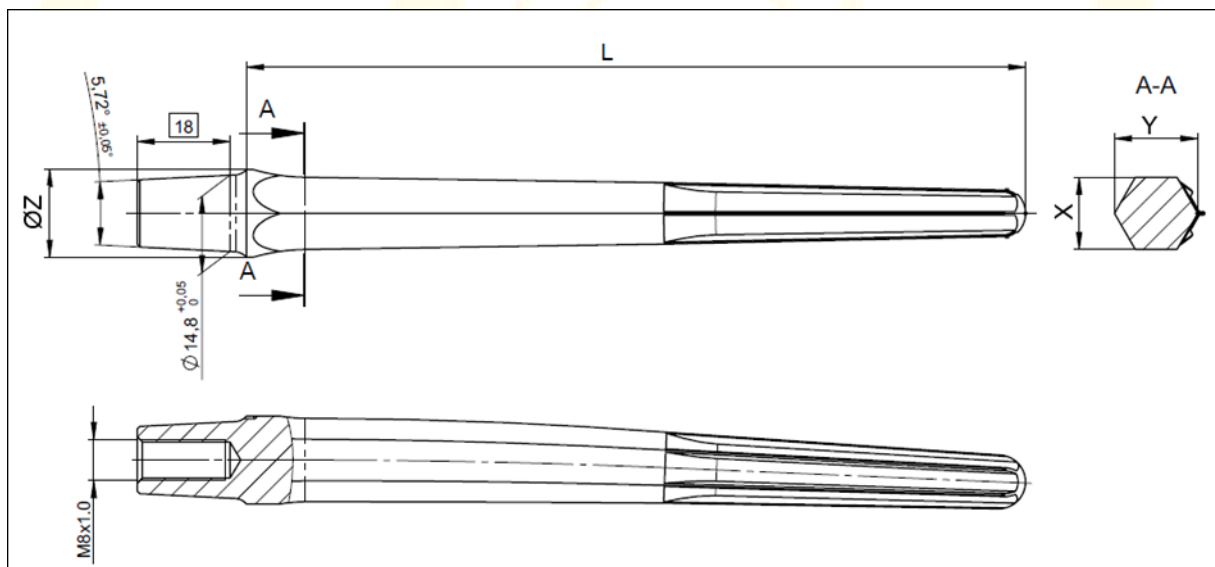


FIGURE 7. MEASUREMENTS OF THE MUTARS® RS STEM CEMENTLESS

TABLE 2: MEASUREMENTS OF THE MUTARS® RS STEM CEMENTLESS

Size	L [mm]	X [mm]	Y [mm]	ØZ [mm]
12/150mm	150	12	13,9	17
13/150mm	150	13	15,0	17
14/150mm	150	14	16,2	17

Size	L [mm]	X [mm]	Y [mm]	ØZ [mm]
15/150mm	150	15	17,3	21
16/150mm	150	16	18,5	21
17/150mm	150	17	19,6	21
18/150mm	150	18	20,8	21
19/150mm	150	19	21,9	21
20/150mm	150	20	23,1	21
21/150mm	150	21	24,3	21
22/150mm	150	22	25,4	21
12/200mm	200	12	13,9	17
13/200mm	200	13	15,0	17
14/200mm	200	14	16,2	17
15/200mm	200	15	17,3	21
16/200mm	200	16	18,5	21
17/200mm	200	17	19,6	21
18/200mm	200	18	20,8	21
19/200mm	200	19	21,9	21
20/200mm	200	20	23,1	21
21/200mm	200	21	24,3	21
22/200mm	200	22	25,4	21
14/250mm	250	14	16,2	17
15/250mm	250	15	17,3	21
16/250mm	250	16	18,5	21
17/250mm	250	17	19,6	21
18/250mm	250	18	20,8	21
19/250mm	250	19	21,9	21
20/250mm	250	20	23,1	21
21/250mm	250	21	24,3	21
22/250mm	250	22	25,4	21

13.3 MUTARS® RS stem extra small cementless

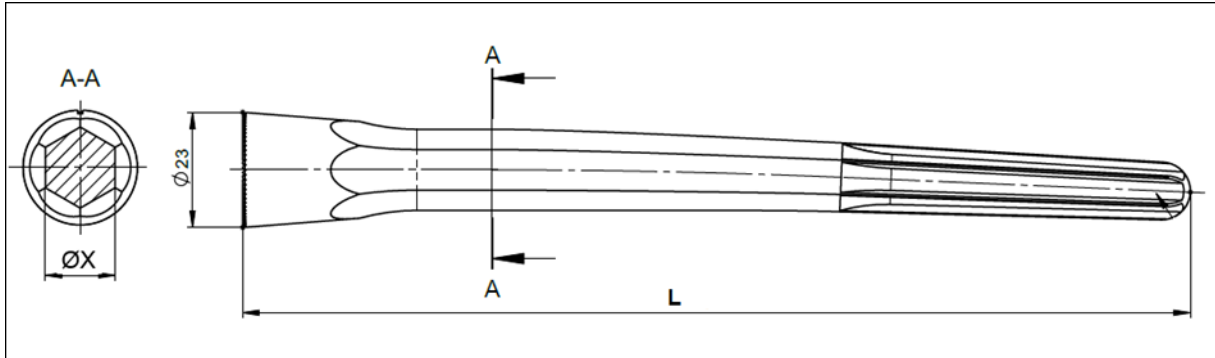


FIGURE 8. MEASUREMENTS OF THE MUTARS® RS STEM EXTRA SMALL CEMENTLESS

TABLE 3: MEASUREMENTS OF THE MUTARS® RS STEM EXTRA SMALL CEMENTLESS

Size	L [mm]	ØX [mm]	ØZ [mm]
14/190mm	190	14	23
14/240mm	240	14	23

14 Compatibility

The detailed component compatibility is given in the “Kompatibilitätsübersicht_MUTARS RS System”.

⇒ See “Kompatibilitätsübersicht_MUTARS RS System” in folder “11 Kombinationstabellen”

15 Warnings

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

⇒ See Doc. Instruction for Use “09300015_MUTARS RS Revisionsssystem” in the folder “05 Kennzeichnung” subfolder “Gebrauchsinformation”

16 Product List (Identification of the Products)

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

⇒ See Doc. “Fbl_732-1-0-14_Produktliste_MUTARS RS System” (product list for MUTARS® RS 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 Hip Revision System MRP-TITAN® from the company PETER BREHM GmbH.

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20 LIST OF ABBREVIATIONS

TABLE 4: LIST OF ABBREVIATIONS

ABBREVIATION	ABBREVIATED TERM
Ha	Hydroxyapatite
MDR	Medical Device Regulation
L	Length
TiN	Titanium Nitride
∅	Diameter

2 DOCUMENT REVISION HISTORY

DATE	REVISION	CHANGES	AUTHOR	COMMENTS
25.10.2021	0	Creation	A. Kerber	---

