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	Freigabeseite Produktinformationen		
Datum: **15.08.2016**	Revision: **3**	Seite: **1** von **1**	Fbl_423-5-1

Produkt:	MUTARS® femoral stems
Dokumenten-Nr.:	Stand: 21.10.2021

Dokumententyp			
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Flyer:	☐	**Patienteninformation:**	☐
Werbeanzeige:	☐	**Newsletter:**	☐
Information Website:	☐	**Gebrauchsinformation:**	☐
Produktbeschreibung:	☒	**Produktliste:**	☐
Äquivalenzvergleich	☐	**Sonstiges:**	

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Beschreibung der Änderungen zur Vorversion
Neuerstellung

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Location: Moldova

PART OF THE
TECHNICAL DOCUMENATION

PRODUCT DESCRIPTION

MUTARS® FEMORAL STEMS

PRODUCT-GROUP: REVISION AND TUMOR ARTHROPLASTY

RISK-CLASS: III

LOCATION: HIP

DATE: 21.10.2021, REV. 0

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1 TABLE OF CONTENTS

1 MUTARS® Femoral Stems

The MUTARS® femoral 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 products of the MUTARS® Hip 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® Hip 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® Hip 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® Hip 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 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 “09300013 MUTARS Tumor- und Revisionssystem” in the folder “05 Kennzeichnung” subfolder “Gebrauchsinformation”

8 Contraindications

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

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

9 Risk Factors

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

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

10 Design Description

10.1 MUTARS® femoral stem cemented

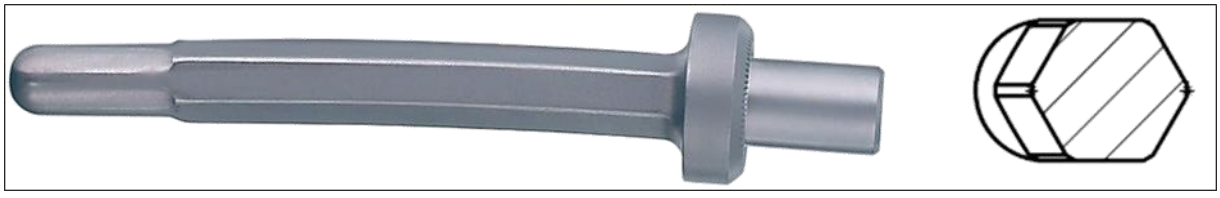


FIGURE 1. *MUTARS® FEMORAL STEM CEMENTED; CROSS SECTION (RIGHT)*

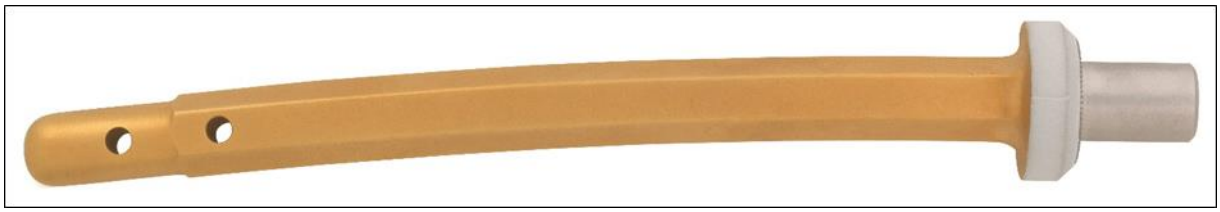


FIGURE 2. *MUTARS® FEMORAL STEM CEMENTED WITH HA COLLAR*

The MUTARS® femoral stem cemented is curved to match the physiological antecurvature of the femur. The stem has a hexagonal cross section (FIGURE 1, FIGURE 2) for rotation stability and a collar at its proximal end to prevent subsidence. While stems with diameter of 11mm have a round cross section below the collar (FIGURE 3), the stems with diameters of 13 - 17 mm have hexagonal cross section throughout the entire length (FIGURE 4). Stems of lengths 160 - 240 mm have two distal interlocking screw holes (5 mm in diameter) perpendicular to the long axis of the stem for placement of cortical screws for additional fixation if required (FIGURE 2, FIGURE 3 & FIGURE 4 (lower picture)).

The proximal end of the MUTARS® femoral stem cementless utilizes a male cylindrical fit and serration connection (FIGURE 3, FIGURE 4) for attachment to other MUTARS® Hip and Knee System components incorporating a matching female cylindrical fit connection. The MUTARS® cylindrical fit connection is provided by a precise male/female cylindrical fit along with a connection screw that is axially applied across the connection during component assembly to connect and secure the two components. In addition, a serration connection of interdigitating teeth provide rotational stability. The serrated teeth also allow for an adjustment of the antetorsion angle in 5° increments.

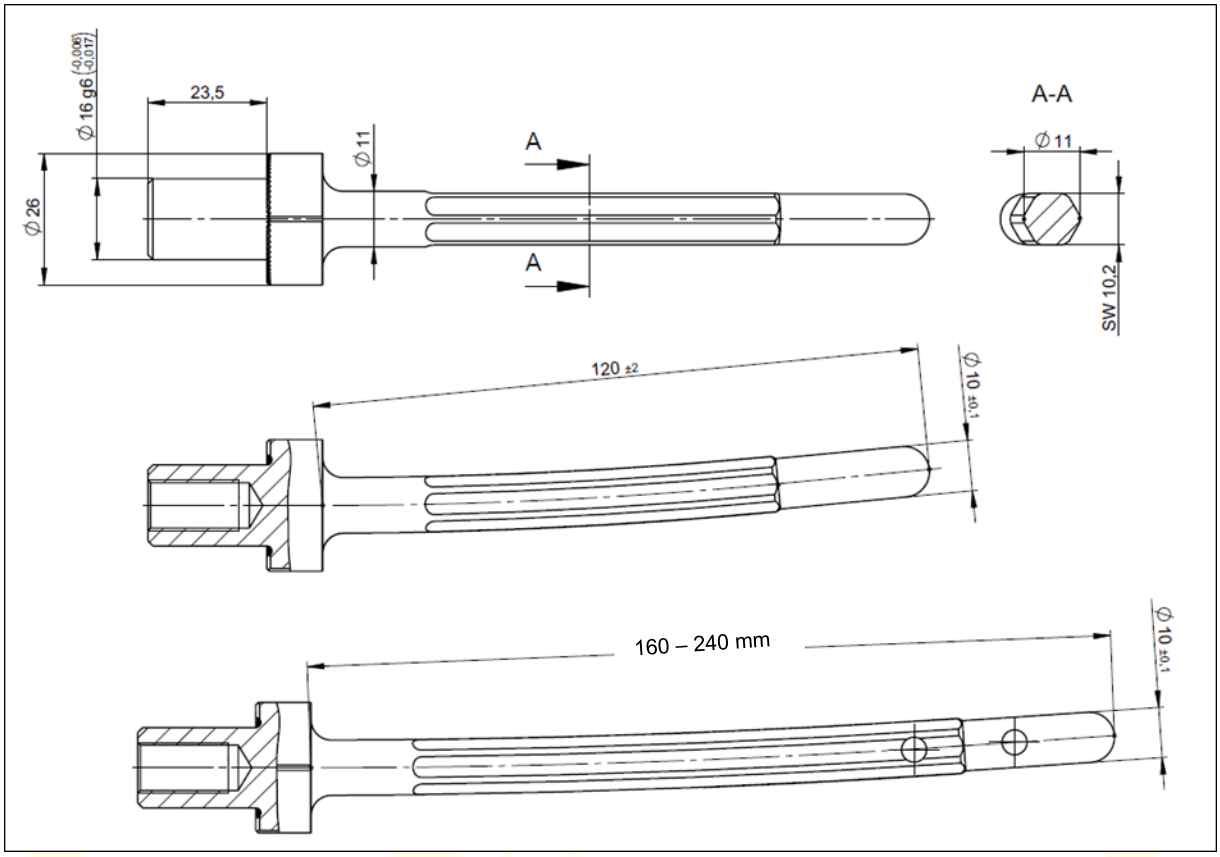


FIGURE 3. *Ø11MM STEMS; 120MM STEM (UPPER PICTURE); 160-240 MM STEMS (LOWER PICTURE)*

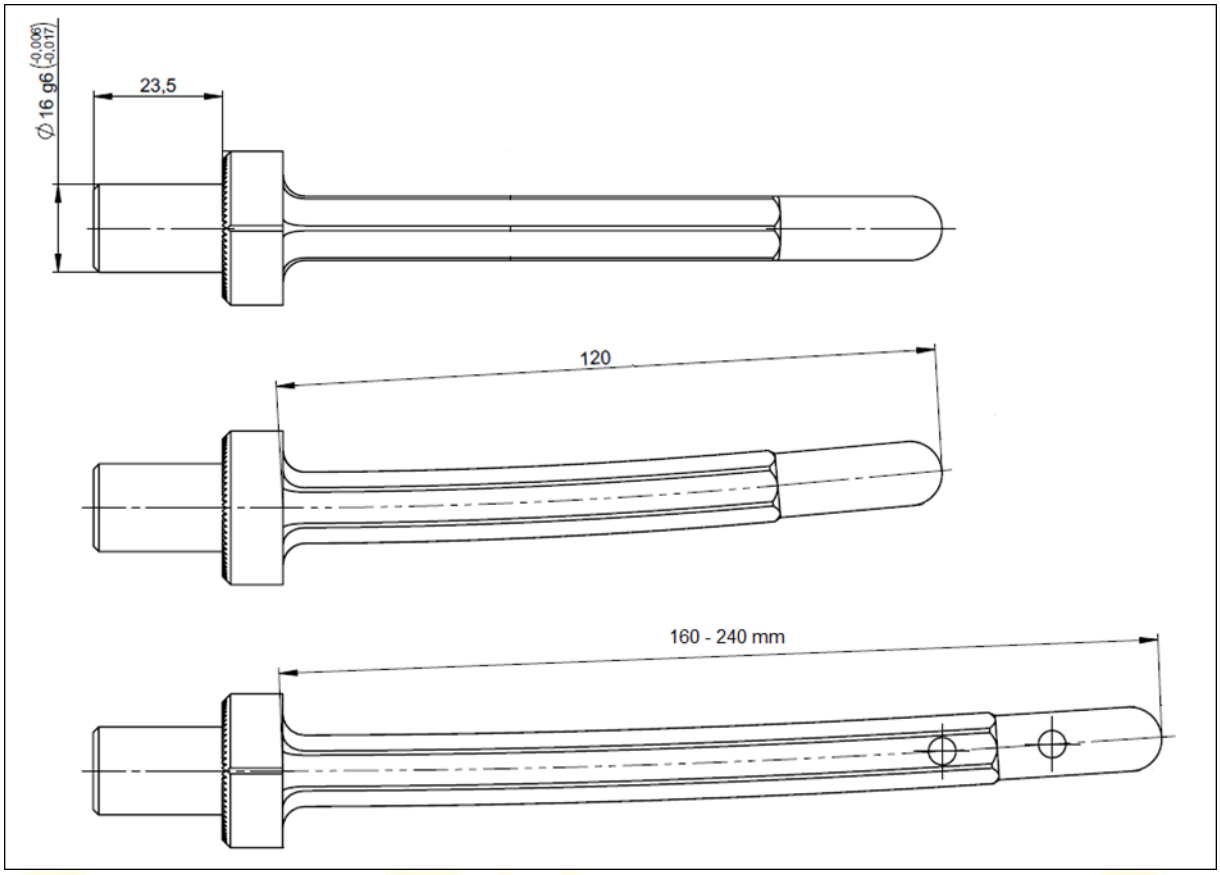


FIGURE 4. Ø13-17MM STEMS; 120MM STEMS (UPPER PICTURES); 160-240 MM STEMS (LOWER PICTURE)

10.2 MUTARS® femoral stem cementless

FIGURE 5. MUTARS® FEMORAL STEM CEMENTLESS (REPRESENTATIVE IMAGE, STEM WITH HA COATING)

The MUTARS® femoral stem cementless is curved to match the physiological antecurvature of the femur. The stem has a hexagonal cross section (FIGURE 6) for rotation stability and a collar at its proximal end to prevent subsidence. While the 12 - 20 mm stem sizes have edges (FIGURE 6, left), the 10 and 11 mm stems have rounded edges (FIGURE 6, right). The design is intended to provide increased fatigue resistance for the smaller stem sizes. The cross section of the 10 and 11 mm stems,

20 mm below the collar is round while the cross section of the 12 - 20 mm stems is hexagonal throughout the entire length (FIGURE 7).

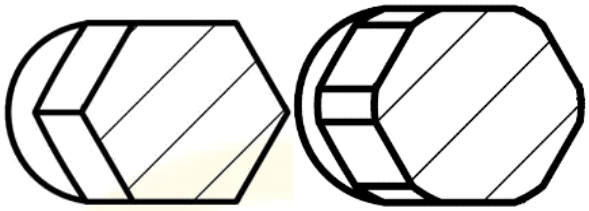


FIGURE 6. *CROSS SECTION: Ø12-20MM STEMS (LEFT); Ø10-11MM STEMS (RIGHT)*

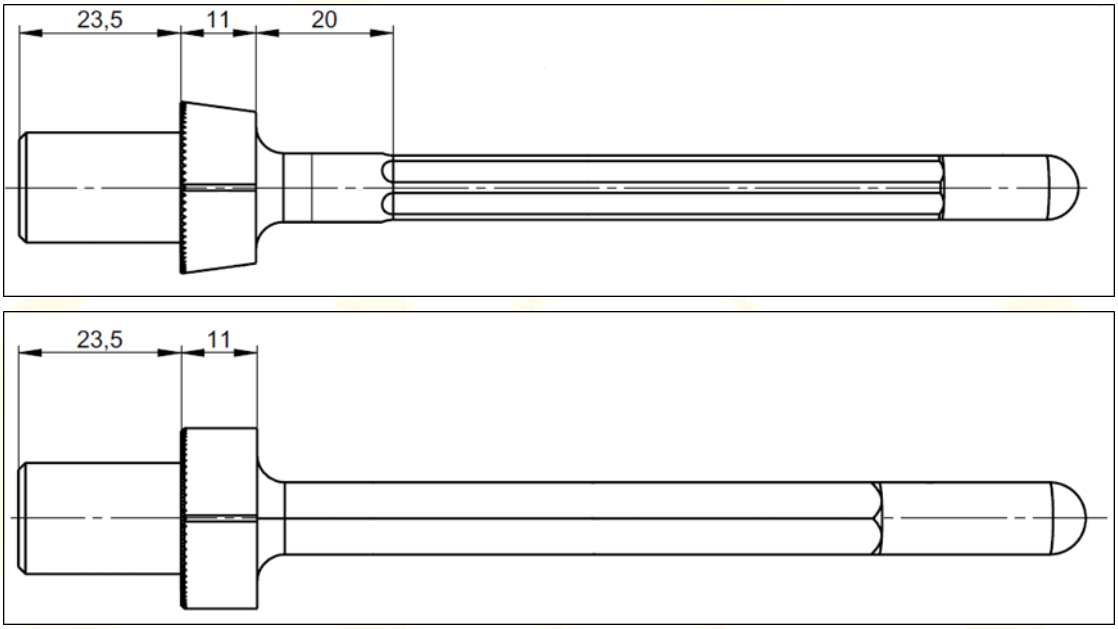


FIGURE 7. *Ø10-11MM STEMS (UPPER PICTURE); Ø12-20MM STEMS (LOWER PICTURE)*

The MUTARS® femoral stem cementless utilizes a male cylindrical fit and serration connection for attachment to other MUTARS® Hip and Knee System components incorporating a matching female cylindrical fit connection. The MUTARS® cylindrical fit connection is provided by a precise male/female cylindrical fit along with a connection screw that is axially applied across the connection during component assembly to connect and secure the two components. In addition, a serration connection of interdigitating teeth provide rotational stability. The serrated teeth also allow for an adjustment of the antetorsion angle in 5° increments.

The MUTARS® PT femoral stem cementless HA features a shorter length of the cylindrical fit (18 mm instead of 23.5mm).

10.3 MUTARS® stem modular cemented

The MUTARS® stem modular cemented is available in both 'curved' and 'straight' versions.

The MUTARS® stems modular cemented are always to be used in conjunction with MUTARS® EPORE® HA collar (FIGURE 10, FIGURE 11, FIGURE 15). The MUTARS® stems modular cemented have a hexagonal cross section for rotation stability and a collar at its proximal end to prevent subsidence. While the stems with diameter of 11mm have a round cross section below the collar (FIGURE 12), the stems with diameters of 12 - 17 mm have hexagonal cross section throughout the entire length (FIGURE 13). Stems of lengths 160 - 240 mm have two distal interlocking screw holes (5 mm in diameter) perpendicular to the long axis of the stem for placement of cortical screws for additional fixation if required (FIGURE 12 & FIGURE 13 (lower picture)).

The proximal end of the MUTARS® stems modular cemented utilize a male cylindrical fit connection and serration (FIGURE 8) for attachment to MUTARS® EPORE® HA collars and other MUTARS® Hip and Knee System components incorporating a matching female cylindrical fit connection. The MUTARS® cylindrical fit connection is provided by a precise male/female cylindrical fit along with a connection screw that is axially applied across the connection during component assembly to connect and secure the two components. In addition, a serration connection of interdigitating teeth provide rotational stability. The serrated teeth also allow for an adjustment of the antetorsion angle in 5° increments.

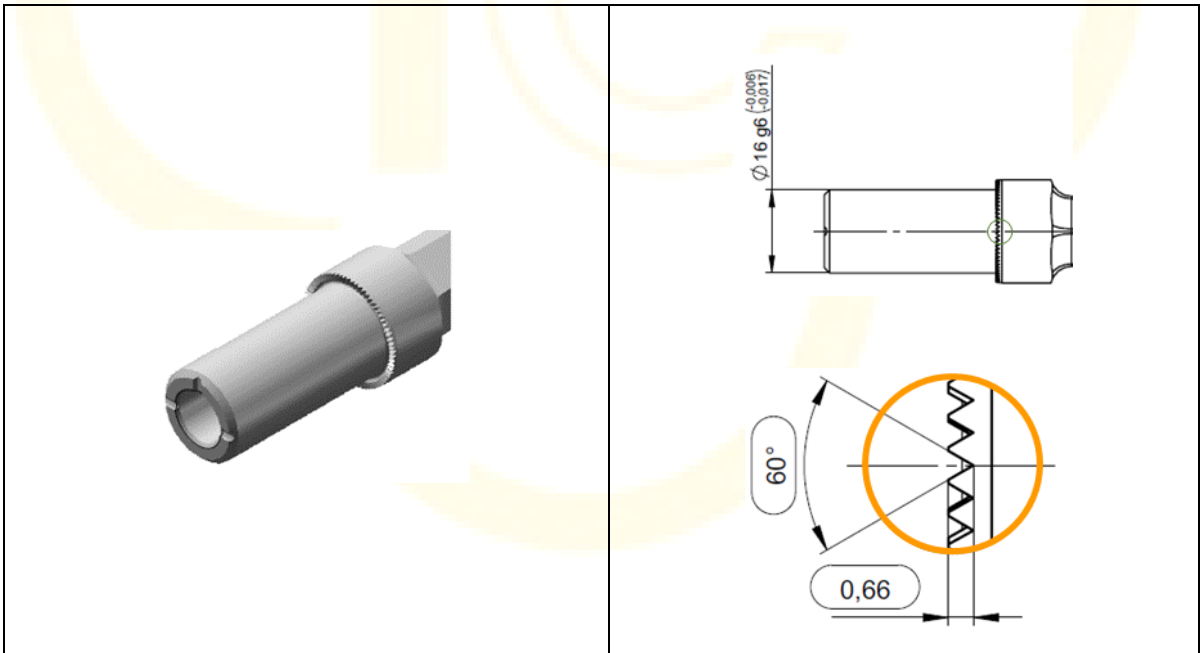


FIGURE 8. *MUTARS® CYLINDRICAL FIT CONNECTION AND SERRATION*

MUTARS® stem modular curved cemented

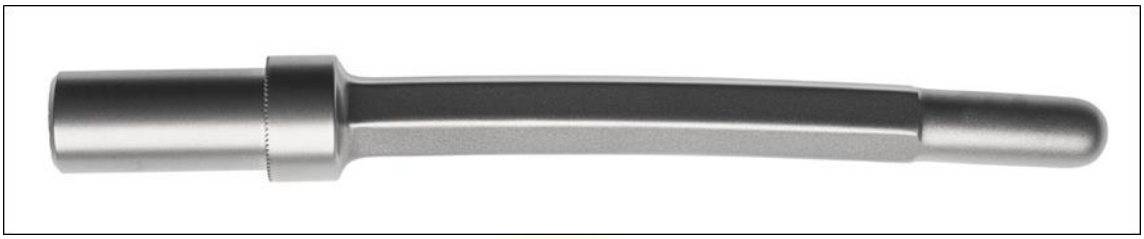


FIGURE 9. *MUTARS® STEM MODULAR CURVED CEMENTED*

FIGURE 10. *MUTARS® STEM MODULAR CURVED CEMENTED WITH MUTARS® EPORE® HA COLLAR 20MM ROUND*

FIGURE 11. *MUTARS® STEM MODULAR CURVED CEMENTED WITH MUTARS® EPORE® HA COLLAR 20MM OVAL*

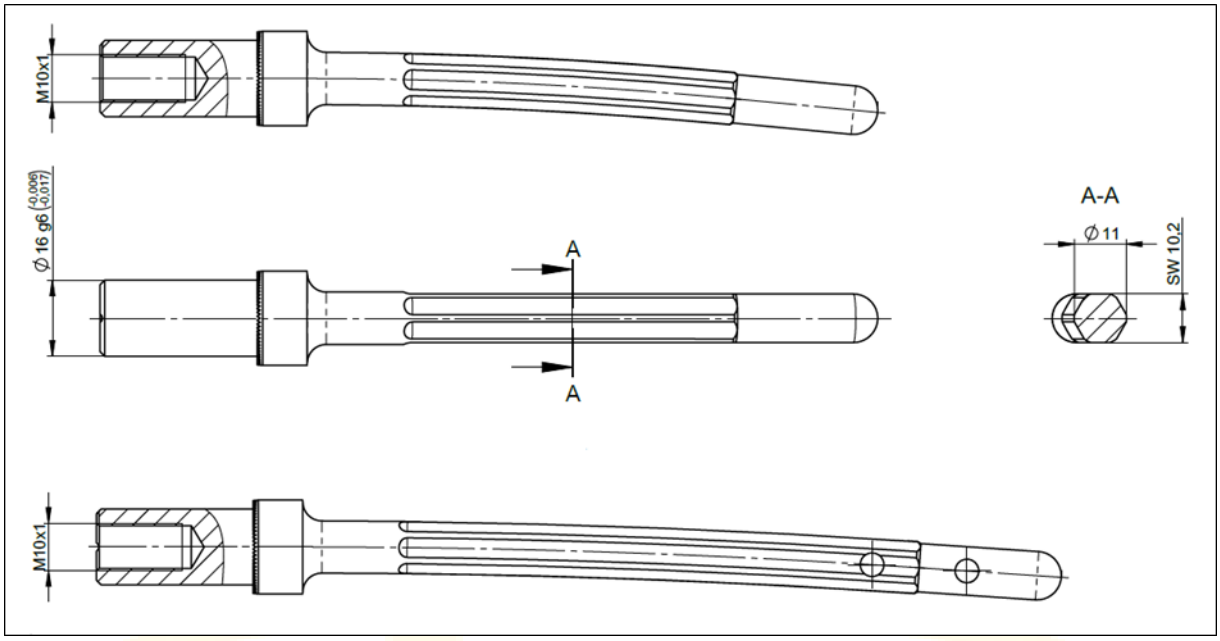


FIGURE 12. Ø11MM STEMS; STEM OF LENGTH OF 120MM (UPPER PICTURES); STEMS OF LENGTHS 160 - 240 MM (LOWER PICTURE); CROSS SECTION (RIGHT PICTURE)

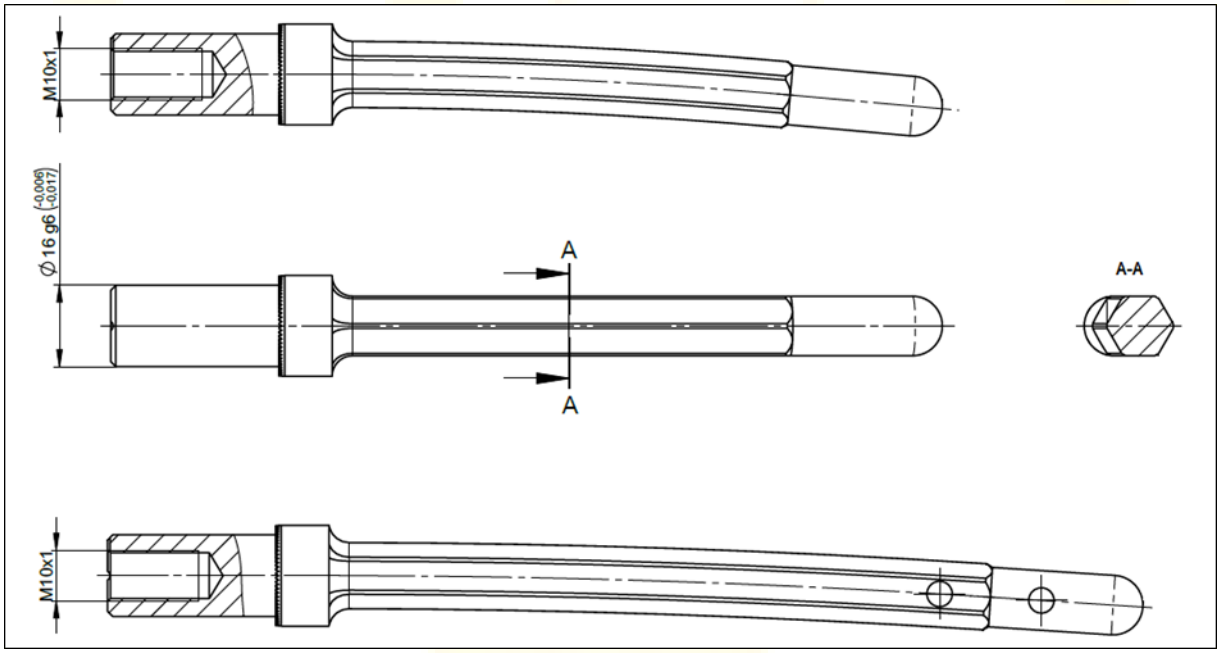


FIGURE 13. Ø12-17MM STEMS; STEMS OF LENGTH OF 120MM (UPPER PICTURES); STEMS OF LENGTHS 160 - 240 MM (LOWER PICTURE); CROSS SECTION (RIGHT PICTURE)

MUTARS® stem modular straight cemented

FIGURE 14. *MUTARS® STEM MODULAR STRAIGHT CEMENTED*

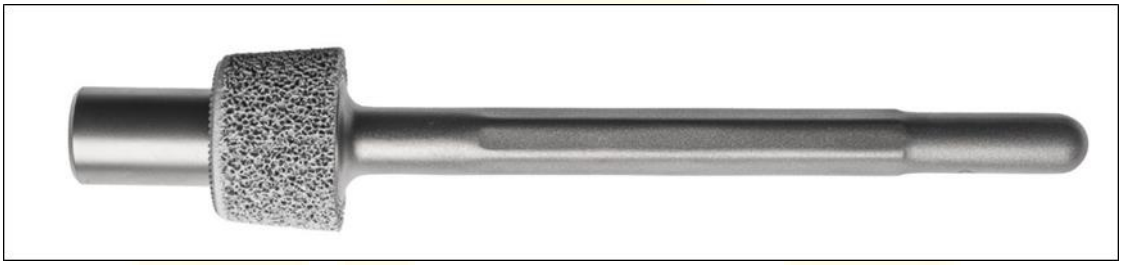


FIGURE 15. *MUTARS® STEM MODULAR STRAIGHT CEMENTED WITH MUTARS® EPORE® HA COLLAR 20MM OVAL*

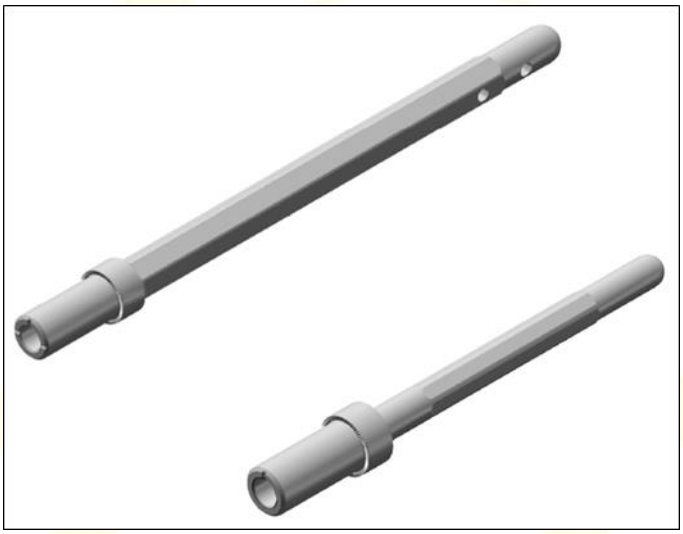


FIGURE 16. *STEMS OF LENGTHS 160 - 200 MM AND Ø12-15MM (UPPER PICTURE); STEM OF LENGTH OF 120MM AND Ø11MM (LOWER PICTURE)*

10.4 MUTARS® EPORE® HA collars

The MUTARS® EPORE® HA collars are modular collars to be used (for use) with the MUTARS® stems modular cemented curved and straight.

The collars consist of a solid core and an external EPORE® structure. The MUTARS® EPORE® HA collars round have a round outer shape and the MUTARS® EPORE® HA collars oval have an oval outer shape. The MUTARS® EPORE® HA collars tibial have a cylindrical outer shape with two surfaces at

80° angle to each other to mimic the tibial anatomy. The MUTARS® EPORE® HA collars incorporate a female MUTARS® cylindrical fit connection and serration for attachment to MUTARS® stems modular cemented.

The MUTARS® EPORE® HA collars, which are available in different cross-sectional shapes (round, oval, triangular) and diameters allow the user to better adapt to the individual anatomical conditions of the tibia and femur. The collars prevent subsidence and allow for additional bone ingrowth.

***FIGURE 17**. MUTARS® EPORE® HA COLLAR 20MM ROUND*

***FIGURE 18.** MUTARS® EPORE® HA COLLAR 20MM OVAL*

***FIGURE 19.** MUTARS® EPORE® HA COLLAR 20MM TIBIAL*

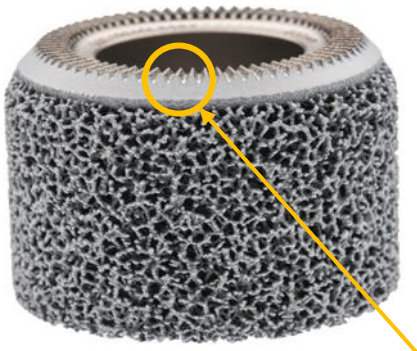


FIGURE 20. *MUTARS® EPORE® HA COLLAR 20MM ROUND (UPPER SIDE)*

FIGURE 21. *MUTARS® EPORE® HA COLLAR 20MM ROUND (UPPER SIDE)*

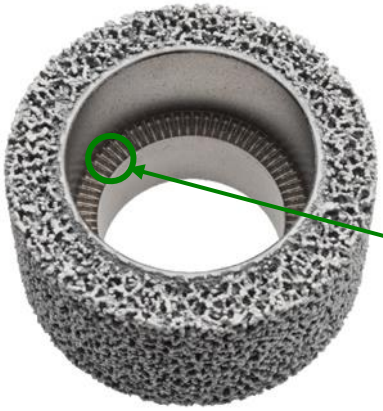
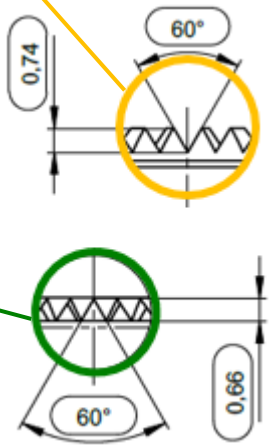


FIGURE 22. *MUTARS® EPORE® HA COLLAR 20MM ROUND (LOWER SIDE)*



MUTARS® SERRATION (UPPER PICTURE)
ADAPTED MUTARS® SERRATION (LOWER PICTURE)

FIGURE 23. *MUTARS® EPORE® HA COLLAR 20MM OVAL*

FIGURE 24. *MUTARS® EPORE® HA COLLAR 20MM OVAL (UPPER SIDE)*

FIGURE 25. *MUTARS® EPORE® HA COLLAR 20MM OVAL (LOWER SIDE)*

FIGURE 26. *MUTARS® EPORE® HA COLLAR 20MM OVAL (LOWER SIDE)*

FIGURE 27. *MUTARS® EPORE® HA COLLAR 20MM TIBIAL*

FIGURE 28. *MUTARS® EPORE® HA COLLAR 20MM TIBIAL (UPPER SIDE)*

FIGURE 29. *MUTARS® EPORE® HA COLLAR 20MM TIBIAL (LOWER SIDE)*

FIGURE 30. *MUTARS® EPORE® HA COLLAR 20MM TIBIAL (LOWER SIDE)*

11 Materials

11.1 MUTARS® femoral stem cemented

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

11.2 MUTARS® femoral stem cementless

MUTARS® femoral stem cementless is made of wrought $TiAl_6V_4$ alloy meeting the specifications of ISO 5832-3.

11.3 MUTARS® stem modular cemented

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

11.4 MUTARS® EPORE® HA collars

The *MUTARS® EPORE® HA collars* are manufactured using the Electron Beam Melting (EBM) process with $TiAl_6V_4$ alloy powder.

12 Coatings / Surfaces

12.1 MUTARS® femoral stem cemented

MUTARS® femoral stem cemented features a sandblasted surface. It is also available with:

- a Titanium Nitride (TiN) coating (thickness: 5.5±1.5µm; Surface Specification A1) that is applied circumferentially to the whole stem (stem and collar),
- a Titanium Nitride (TiN) coating (thickness: 5.5±1.5µm; Surface Specification A1) that is applied circumferentially to the stem and a hydroxyapatite (HA) coating (thickness: 155±30µm; Surface Specification B4) applied to the collar.

12.2 MUTARS® femoral stem cementless

MUTARS® femoral stem cementless has a rough-blasted surface for bone ongrowth. It is also available with plasma sprayed hydroxyapatite (HA) coating (thickness: 90±30 µm; Surface Specification B3) to support osseointegration. The tip of the stem is highly polished.

MUTARS® PT femoral stem cementless HA has a rough-blasted surface and is coated with plasma sprayed hydroxyapatite (HA) (thickness: 90±30 µm; Surface Specification B3).

12.3 MUTARS® stem modular cemented

MUTARS® stem modular curved cemented

MUTARS® stem modular curved cemented features a sandblasted surface. It is also available with a Titanium Nitride (TiN) coating (thickness: 5.5±1.5µm; Coating Specification A1) that is applied circumferentially to the stem.

MUTARS® stem modular straight cemented

MUTARS® stem modular straight cemented features a sandblasted surface. It is also available with a Titanium Nitride (TiN) coating (thickness: 5.5±1.5µm; Coating Specification A1) that is applied circumferentially to the stem.

12.4 MUTARS® EPORE® HA collars

The *MUTARS® EPORE® HA collars* incorporate a porous EPORE® structure on their bone-facing side. EPORE® is a porous three-dimensional structure based on $TiAl_6V_4$ alloy. High porosity and a low modulus of elasticity are supporting the biological in-growth. The structure is characterized by a rod thickness of 360 ± 50 µm and features a high affinity with trabecular bone tissue (cf. TABLE 1).

The cups are optionally available with a TCP (Tricalcium Phosphate) coating for enhanced osseointegration (cf. TABLE 2).

TABLE 1. EPORE® SPECIFICATIONS

PARAMETER	VALUE
MANUFACTURING PROCESS	ADDITIVE MANUFACTURING (ELECTRON BEAM MELTING (EBM))
POROSITY	61% ± 8%
SPECIFIC E-MODULE	3.1 GPa ± 0.6 GPa
ROD DIAMETER	360 µm ± 50 µm

TABLE 2. TRICALCIUM PHOSPHATE (TCP) COATING

PARAMETER	VALUE
COATING PROCESS	ELECTROCHEMICAL
LAYER THICKNESS	20 ± 10 µm
TENSIL STRENGTH (ACC. TO ISO 13779-2)	≥ 15 µm
COMPOSITION ACC. TO FTIR	≥ 70% Brushite ≤ 30% Hydroxyapatite

13 Sizes and Dimensions

13.1 MUTARS® femoral stem cemented

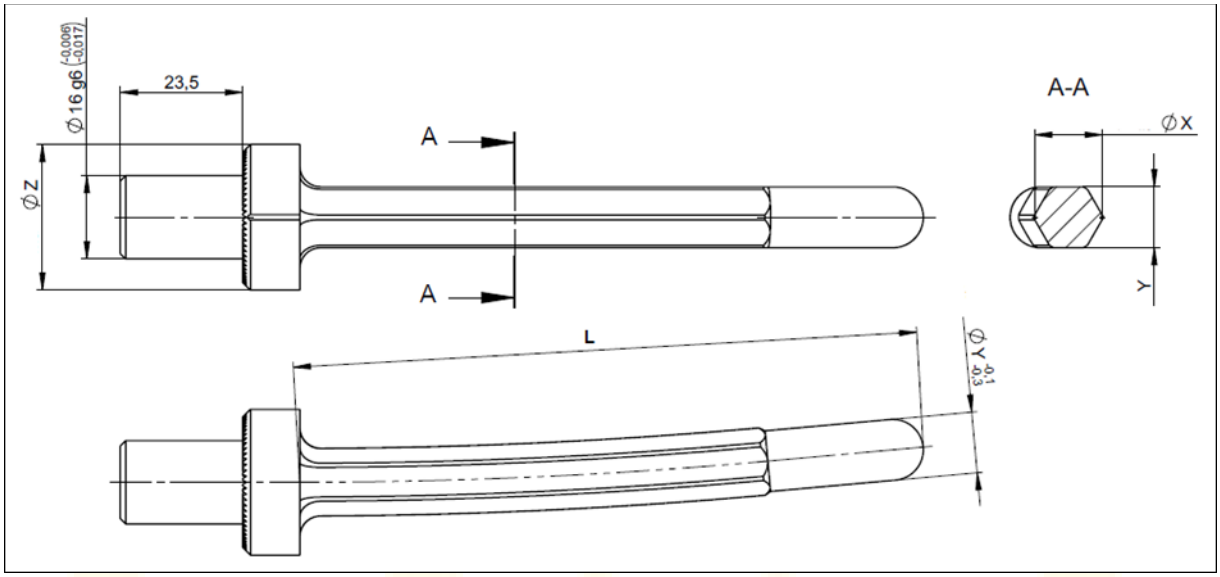


FIGURE 31. MEASUREMENTS OF THE MUTARS® FEMORAL STEMS CEMENTED

TABLE 3: MEASUREMENTS OF THE MUTARS® FEMORAL STEMS CEMENTED

Size	L [mm]	ØX [mm]	Y [mm]	ØZ [mm]
11/120mm	120	11	10,20	26
13/120mm	120	13	11,69	28
15/120mm	120	15	13,42	30
17/120mm	120	17	15,16	32
11/160mm	160	11	10,2	26
13/160mm	160	13	11,69	28
15/160mm	160	15	13,42	30
17/160mm	160	17	15,16	32
11/200mm	200	11	10,20	26
13/200mm	200	13	11,69	28
15/200mm	200	15	13,42	30
17/200mm	200	17	15,16	32
11/240mm	240	11	10,20	26
13/240mm	240	13	11,69	28
15/240mm	240	15	13,42	30
17/240mm	240	17	15,16	32

13.2 MUTARS® femoral stem cementless

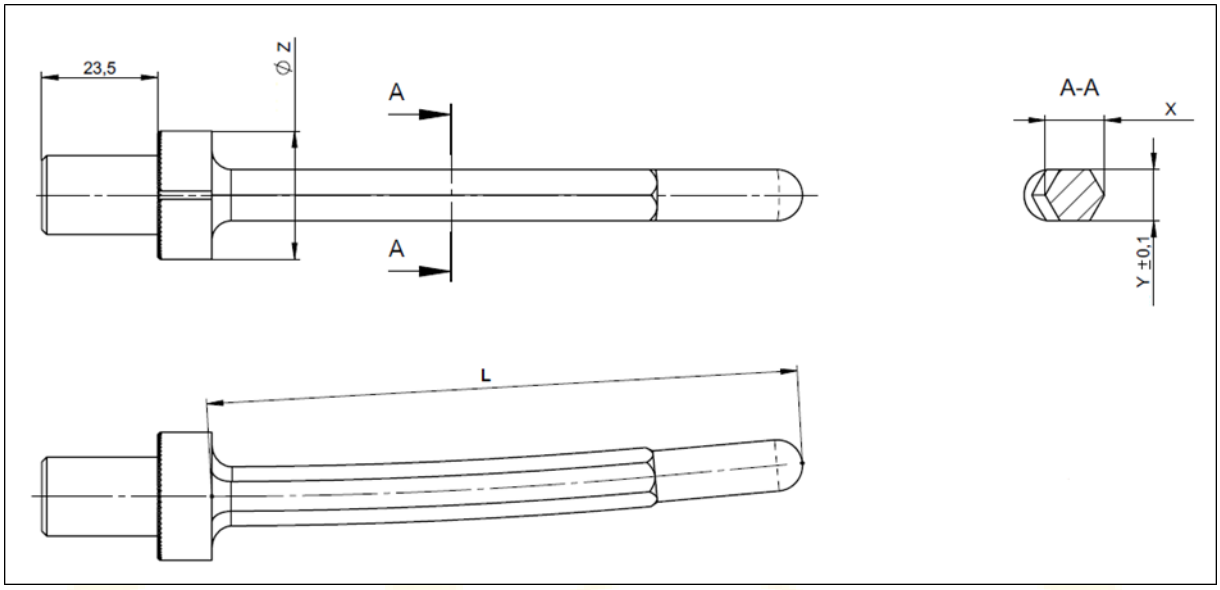


FIGURE 32. MEASUREMENTS OF THE MUTARS® FEMORAL STEMS CEMENTLESS

TABLE 4: MEASUREMENTS OF THE MUTARS® FEMORAL STEMS CEMENTLESS

Size	L [mm]	X [mm]	Y [mm]	ØZ [mm]
10/90mm(*)	90	10	9,34	22
11/90mm(*)	90	11	10,2	23
12/90mm(*)	90	12	10,39	26
13/90mm(*)	90	13	11,26	27
14/90mm(*)	90	14	12,12	28
15/90mm(*)	90	15	13,00	29
16/90mm(*)	90	16	13,85	30
10/120mm(**)	120	10	9,34	22
11/120mm	120	11	10,2	23
12/120mm	120	12	10,39	26
13/120mm	120	13	11,26	27
14/120mm	120	14	12,12	28
15/120mm	120	15	13,00	29
16/120mm	120	16	13,85	30
17/120mm(***)	120	17	14,72	31
18/120mm(***)	120	18	15,58	32
19/120mm(***)	120	19	16,45	33
20/120mm(***)	120	20	17,32	34

(*) only the MUTARS® PT femoral stem cementless HA is available in the length of 90 mm

(**) Only MUTARS® PT femoral stem cementless HA and MUTARS® femoral stem cementless uncoated are available in the diameter of 10 mm

(***) The MUTARS® PT femoral stem cementless HA is not available in the diameters 17 to 20 mm

The MUTARS® PT femoral stem cementless HA features a shorter length of the cylindrical fit (18 mm instead of 23.5mm).

13.3 MUTARS® stem modular cemented

MUTARS® stem modular curved cemented

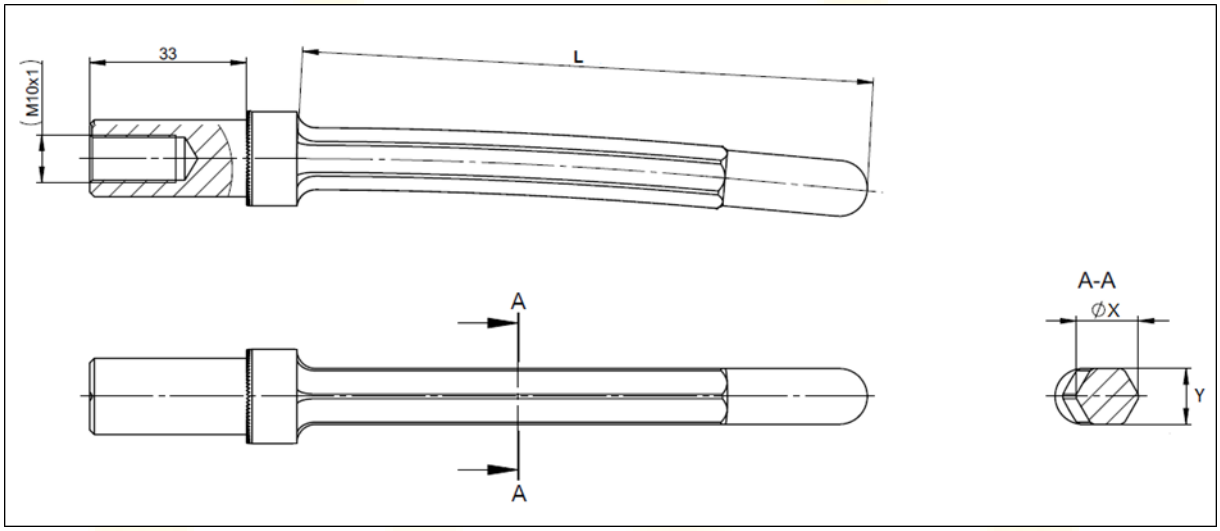


FIGURE 33. MEASUREMENTS OF THE MUTARS® STEMS MODULAR CURVED CEMENTED

TABLE 5: MEASUREMENTS OF THE MUTARS® STEMS MODULAR CURVED CEMENTED

Size	L [mm]	ØX [mm]	Y [mm]
11/120mm	120	11	10,20
12/120mm	120	12	10,83
13/120mm	120	13	11,69
14/120mm	120	14	12,56
15/120mm	120	15	13,42
16/120mm	120	16	14,28
17/120mm	120	17	15,16
11/160mm	160	11	10,2
13/160mm	160	13	11,69
15/160mm	160	15	13,42
17/160mm	160	17	15,16

Size	L [mm]	ØX [mm]	Y [mm]
11/200mm	200	11	10,20
13/200mm	200	13	11,69
15/200mm	200	15	13,42
17/200mm	200	17	15,16
11/240mm	240	11	10,20
13/240mm	240	13	11,69
15/240mm	240	15	13,42
17/240mm	240	17	15,16

MUTARS® stem modular straight cemented

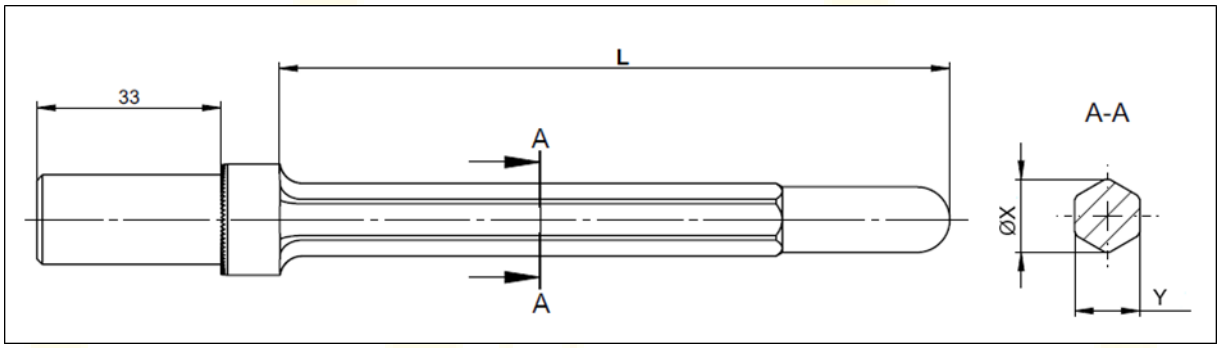


FIGURE 34. MEASUREMENTS OF THE MUTARS® STEMS MODULAR STRAIGHT CEMENTED

TABLE 6: MEASUREMENTS OF THE MUTARS® STEMS MODULAR STRAIGHT CEMENTED

Size	L [mm]	ØX [mm]	Y [mm]
11/120mm	120	11	10,20
12/120mm	120	12	10,83
13/120mm	120	13	11,69
14/120mm	120	14	12,56
15/120mm	120	15	13,42
11/160mm	160	11	10,2
13/160mm	160	13	11,69
15/160mm	160	15	13,42
11/200mm	200	11	10,20
13/200mm	200	13	11,69
15/200mm	200	15	13,42

13.4 MUTARS® EPORE® HA collars

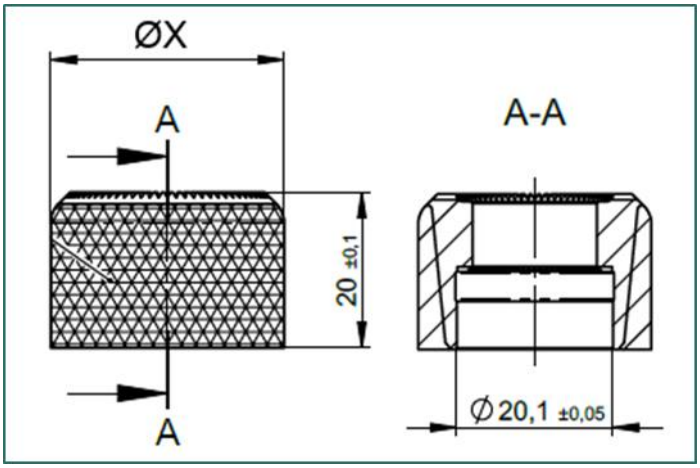


FIGURE 35. *MEASUREMENTS OF THE MUTARS® EPORE® HA KRAGEN 20MM RUND*

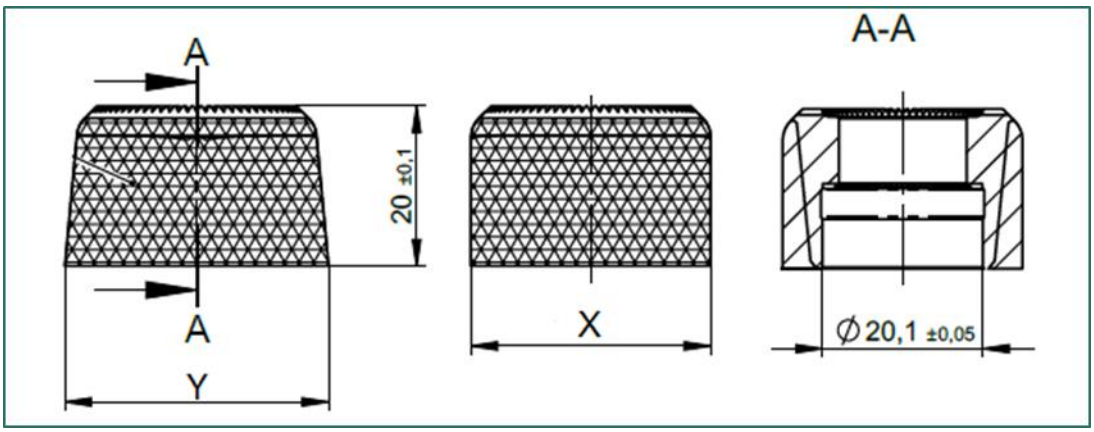


FIGURE 36. *MEASUREMENTS OF THE MUTARS® EPORE® HA KRAGEN 20MM OVAL*

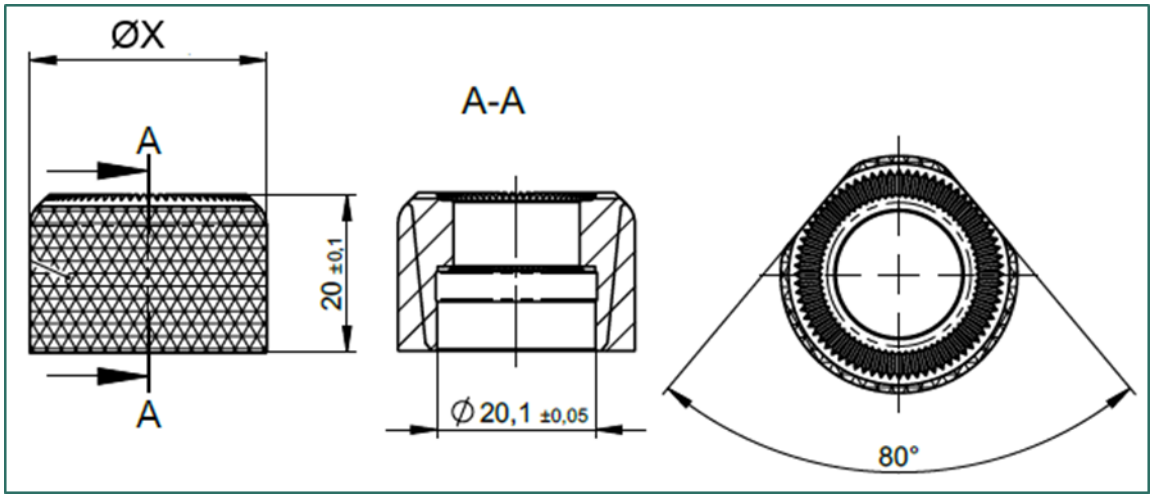


FIGURE 37. *MEASUREMENTS OF THE MUTARS® EPORE® HA KRAGEN 20MM TIBIAL*

TABLE 7: MEASUREMENTS OF THE THE MUTARS® EPORE® HA KRAGEN 20MM RUND

Size	ØX [mm]
Ø24 mm	24
Ø27 mm	27
Ø30 mm	30
Ø33 mm	33
Ø36 mm	36

TABLE 8: MEASUREMENTS OF THE THE MUTARS® EPORE® HA KRAGEN 20MM TIBIAL

Size	ØX [mm]
Ø27 mm	27
Ø30 mm	30
Ø33 mm	33

TABLE 9: MEASUREMENTS OF THE THE MUTARS® EPORE® HA KRAGEN 20MM OVAL

Size	X [mm]	Y [mm]
Ø24/27 mm	24	27
Ø27/30 mm	27	30
Ø30/33 mm	30	33
Ø33/36 mm	33	36
Ø36/39mm	36	39

14 Compatibility

The detailed component compatibility is given in the ANNEX I to the Instructions for Use for the MUTARS® Tumor and Revision System.

⇨ See „09300095 MUTARS Tumor- und Revisionssystem Kombinationsmöglichkeiten_Anhang I" (ANNEX I - IFU – MUTARS® COMBINABILITY) in the folder "05 Kennzeichnung" subfolder „Gebrauchsinformation"

15 Warnings

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

⇨ See Doc. Instruction for Use “09300013 MUTARS Tumor- und Revisionssystem” 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 Prox. Femur System” (product list for MUTARS® Proximal Femur System) 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.

LISTS

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20 LIST OF ABBREVIATIONS

TABLE 10: LIST OF ABBREVIATIONS

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

2 DOCUMENT REVISION HISTORY

DATE	REVISION	CHANGES	AUTHOR	COMMENTS
21.10.2021	0	Creation	A. Kerber	---