

PART OF THE
TECHNICAL DOCUMENTATION

PRODUCT DESCRIPTION
MUTARS[®] RS SYSTEM

PRODUCT-GROUP: PRIMARY AND REVISION
ARTHROPLASTY

RISK-CLASS: III

LOCATION: HIP

DATE: 25.10.2021, REV.0

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1 MUTARS® RS System

The *MUTARS® RS System* is a modular femoral hip system for primary and revision hip arthroplasty in patients with severe femoral bone deficiencies whose bone stock is inadequate for other more conservative methods of treatment. The *MUTARS® RS System* includes the following components (cf. FIGURE 1):

- MUTARS® RS proximal component,
- MUTARS® RS metaphyseal component,
- MUTARS® RS extension piece,
- MUTARS® RS screws,
- MUTARS® RS stems (cf. “Product Description_MUTARS RS Stems”),
- MUTARS® RS coupling device,
- MUTARS® intramed. (intramedullary) connecting modules
 - for KRI
 - for GenuX® femur
 - for GenuX® MK femur

The individual components are connected by means of a cylindrical fit and serration connection and a Morse-type taper connection and connecting screws.

The cylindrical fit and serration connection is provided by a precise male ($\text{Ø } 15 \text{ g6 } \begin{pmatrix} -0,006 \\ -0,017 \end{pmatrix}$) / female ($\text{Ø } 15 \text{ H7 } \begin{pmatrix} +0,018 \\ 0 \end{pmatrix}$) cylindrical fit and a serration of interdigitating 72 teeth to provide rotational stability. A connecting screw is axially applied across the connection during component assembly to connect and secure the MUTARS® cylindrical fit connection.

The MUTARS® male taper features a taper angle of $5.72^\circ \pm 0.05^\circ$ and $\text{Ø } 14.8 \begin{pmatrix} +0,05 \\ 0 \end{pmatrix}$ mm and the MUTARS® female taper features a taper angle of $5.72^\circ \pm 0.05^\circ$ and $\text{Ø } 14.8 \begin{pmatrix} -0,05 \\ -0,10 \end{pmatrix}$ mm.

The individual components are further described in Sections 10 to 13.

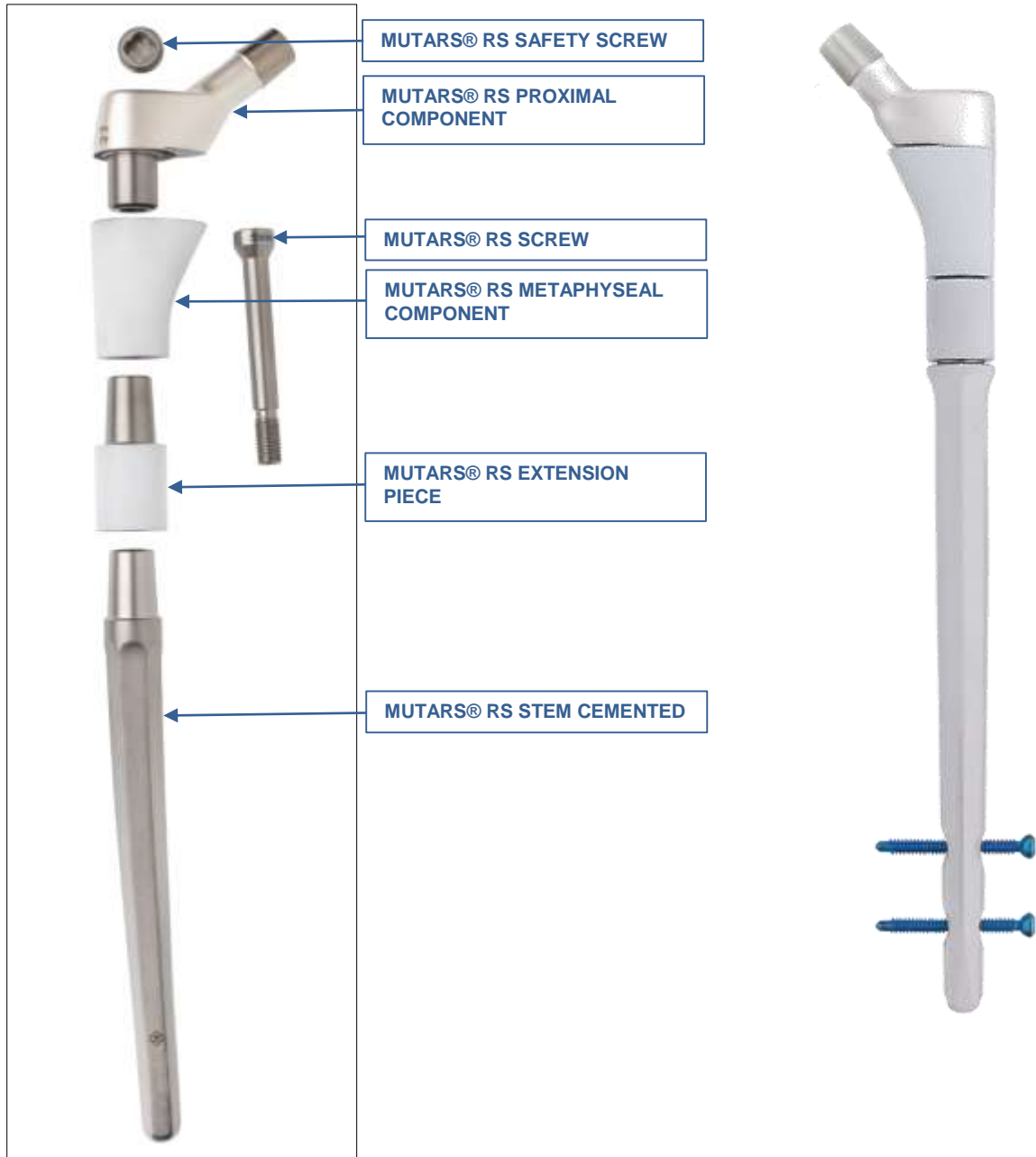


FIGURE 1. MUTARS® RS SYSTEM WITH MUTARS® RS STEM CEMENTED; WITH MUTARS® RS STEM CEMENTLESS HA (RIGHT PICTURE)

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 components of the MUTARS® RS 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 components of the MUTARS® RS 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 components of the MUTARS® RS 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 components of the MUTARS® RS 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® 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”

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”

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”

10 Design Description

10.1 MUTARS® RS proximal component

The *MUTARS® RS proximal component* is a femoral component that replaces the proximal part of the femur including the femoral neck.

The *MUTARS® RS proximal component* is an extraosseous component. The *MUTARS® RS proximal component* is available in two lengths and two CCD angles (127° and 135°).

The *MUTARS® RS proximal component* features a 12/14 Morse-type taper trunnion for connection to a femoral head. The taper has an angle of 5°42'30"-0°5'0", a length of 13.5 mm, a diameter of 12.7-0.06 mm, roundness of 0.008 mm, and straightness of 0.003 mm. The taper has a machine turned surface finish producing circular microgrooves to provide a roughness of Rz of 6 +14 µm.

The *MUTARS® RS proximal component* utilizes a male cylindrical fit ($\varnothing 15 \text{ g6} \begin{pmatrix} -0,006 \\ -0,017 \end{pmatrix}$) and serration connection at its distal end for attachment to the *MUTARS® RS metaphyseal component*. The serration

of interdigitating 72 teeth provides rotational stability and allows for an intraoperative adjustment of the antetorsion angle in 5° increments for avoiding and correction of malalignments.



FIGURE 2. MUTARS® RS PROXIMAL COMPONENT

10.2 MUTARS® RS metaphyseal component

The *MUTARS® RS metaphyseal component* is available in two variants to better match the patients' individual anatomy: "standard" which combines a conical shape (cone) and an extended triangle (spout) and "small" with a conical shape. The *MUTARS® RS metaphyseal component* utilizes a female cylindrical fit ($\text{Ø } 15 \text{ H7 } \left(\begin{smallmatrix} +0,018 \\ 0 \end{smallmatrix} \right)$) and serration connection for attachment to the *MUTARS® RS proximal component* at its proximal end and the *MUTARS®* female taper connection (the taper has an angle of $5.72^\circ \pm 0.05^\circ$ and $\text{Ø } 14.8 \left(\begin{smallmatrix} -0,05 \\ -0,10 \end{smallmatrix} \right)$ mm) at its distal end for attachment to the *MUTARS® RS Extension Piece* or *MUTARS® RS stems*.

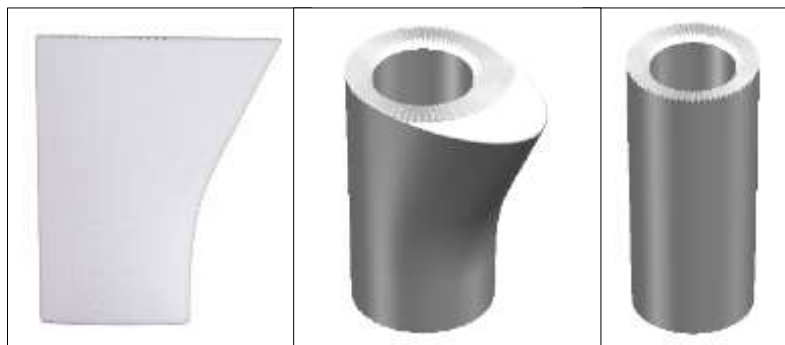


FIGURE 3. MUTARS® RS METAPHYSEAL COMPONENT; STANDARD (LEFT PICTURE) AND SMALL (RIGHT PICTURE) SIZE

10.3 MUTARS® RS Extension Piece

The *MUTARS® RS extension piece* is an optional component that serves as an intraosseous length adjustment. The extension piece has a cylindrical cross-section (cf. FIGURE 4).

The *MUTARS® extension piece* utilizes the *MUTARS®* male taper connection (taper angle of $5.72^\circ \pm 0.05^\circ$; $\text{Ø } 14.8 \left(\begin{smallmatrix} +0,05 \\ 0 \end{smallmatrix} \right)$ mm) at its proximal end for attachment to the *MUTARS® RS metaphyseal component* and the *MUTARS®* female taper connection (the taper has an angle of $5.72^\circ \pm 0.05^\circ$ and $\text{Ø } 14.8 \left(\begin{smallmatrix} -0,05 \\ -0,10 \end{smallmatrix} \right)$ mm) at its distal end for attachment to the *MUTARS® RS stems* or *MUTARS® intramedullary connecting modules*.



FIGURE 4. MUTARS® RS EXTENSION PIECE

10.4 MUTARS® RS Screw and MUTARS® RS Safety Screw

The *MUTARS® RS screw* (FIGURE 5) connects and secures the system components together (i.e. proximal component, metaphyseal component, extension piece, and stem). Due to the various length adjustments within the MUTARS® RS System, the screw is available in different sizes in order to connect the full prosthesis length.

The *MUTARS® RS safety screw* (FIGURE 5) is intended to hold the *MUTARS RS screw* in place and prevent the connection screw from backing out (lock screw).



FIGURE 5. MUTARS® RS SCREW (LEFT PICTURE) AND MUTARS® RS SAFETY SCREW (RIGHT PICTURE)

10.5 MUTARS® RS Coupling Device and MUTARS® Screw for RS Coupling Device

The *MUTARS® RS coupling device* (FIGURE 6) provides coupling of a component with the MUTARS® male taper connection to a component with the MUTARS® female cylindrical fit connection. For this purpose the coupling device has the MUTARS® female taper connection (the taper has an angle of $5.72^{\circ} \pm 0.05^{\circ}$ and $\varnothing 14.8 \begin{smallmatrix} -0,05 \\ -0,10 \end{smallmatrix}$ mm) at its one end and the MUTARS® male cylindrical fit and serration connection at its other end.

An 8 mm diameter screw (*MUTARS® screw for RS coupling device*; FIGURE 7) is axially applied across the connection during components assembly to secure the connection.



FIGURE 6. MUTARS® RS COUPLING DEVICE



FIGURE 7. MUTARS® SCREW FOR RS COUPLING DEVICE FOR RS COUPLING DEVICE

10.6 MUTARS® intramed. connecting module for KRI

The *MUTARS® intramed. (intramedullary) connecting module for KRI* is used in cases of intramedullary femur replacement in which the femoral diaphysis is preserved and the proximal femur and knee joint are replaced by endoprotheses, which are then connected using this intramedullary rod. The intramedullary connecting module is placed into the reamed medullary cavity and therefore allows for a bone preserving surgery. The rib profile provides rotational stability. It utilizes the MUTARS® male taper connection (taper angle of $5.72^{\circ} \pm 0.05^{\circ}$; $\varnothing 14.8 \left(\begin{smallmatrix} +0,05 \\ 0 \end{smallmatrix} \right)$ mm) for attachment to MUTARS® KRI (MOM / HD) ant to *MUTARS® RS coupling device* or *MUTARS® RS metaphyseal component*.

The *MUTARS® intramed. connecting module for KRI* is intended to be used without bone cement.

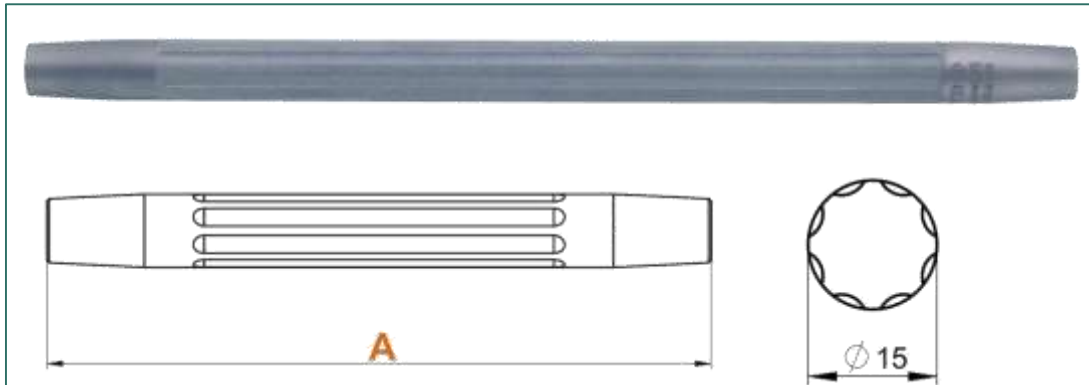


FIGURE 8. MUTARS® INTRAMED. (INTRAMEDULLARY) CONNECTING MODULE FOR KRI

10.7 MUTARS® intramed. connecting module for GenuX® MK femur and the MUTARS® intramed. connecting module for GenuX® femur

The *MUTARS® intramed. (intramedullary) connecting module for GenuX® MK femur* has the same design characteristics as the *MUTARS® intramedullary connecting module for KRI*. The only difference is that the *MUTARS® intramed. connecting module for GenuX® MK femur* is designed to be connected to the *MUTARS® GenuX® MK Femur* (cf. FIGURE 12) instead of the *MUTARS® KRI*. For this reason it provides the *MUTARS® male taper connection* (taper angle of $5.72^{\circ} \pm 0.05^{\circ}$; $\varnothing 14.8 \left(\begin{smallmatrix} +0.05 \\ 0 \end{smallmatrix} \right)$ mm) at its one end and a *female cylindrical fit* ($\varnothing 12 \text{ H7} \left(\begin{smallmatrix} +0.018 \\ 0 \end{smallmatrix} \right)$) and a *female taper connection* (taper angle of $3^{\circ}1'18'' \pm 0^{\circ}5'0''$ and $\varnothing 9.99 \pm 0.02$ mm) at its other end.

The *MUTARS® intramed. connecting module for GenuX® femur* has the same design characteristics as the *MUTARS® intramedullary connecting module for KRI*. The only difference is that the *MUTARS® intramed. connecting module for GenuX® femur* is designed to be connected to the *MUTARS® GenuX® Femur* instead of the *MUTARS® KRI*. For this reason it provides the *MUTARS® male taper connection* (taper angle of $5.72^{\circ} \pm 0.05^{\circ}$; $\varnothing 14.8 \left(\begin{smallmatrix} +0.05 \\ 0 \end{smallmatrix} \right)$ mm) at its one end and a *female cylindrical fit* ($\varnothing 14 \text{ H7} \left(\begin{smallmatrix} +0.018 \\ 0 \end{smallmatrix} \right)$) and a *female taper connection* (taper angle of $3^{\circ}1'18'' \pm 0^{\circ}5'0''$ and $\varnothing 12 \pm 0.02$ mm) at its other end.

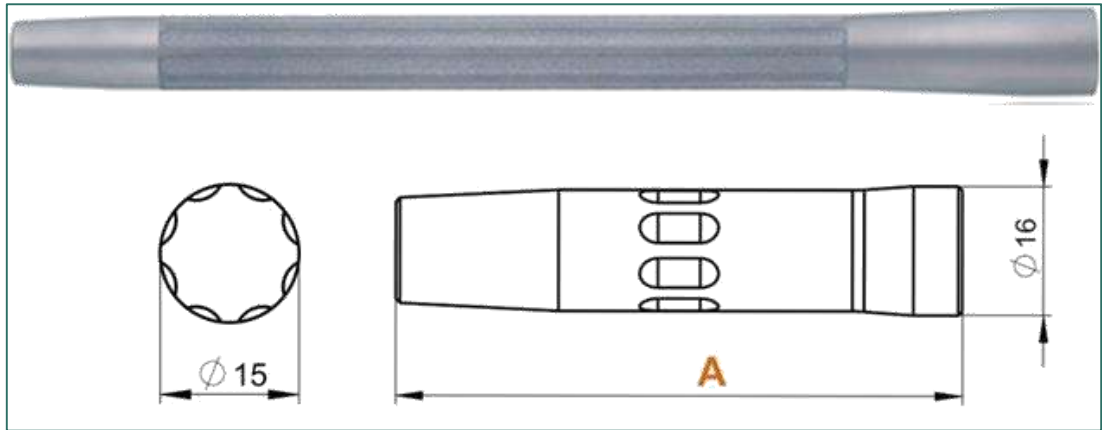


FIGURE 9. MUTARS® INTRAMED. CONNECTING MODULE FOR GENUX® MK FEMUR



FIGURE 10. MUTARS® INTRAMED. CONNECTING MODULE FOR GENUX® FEMUR

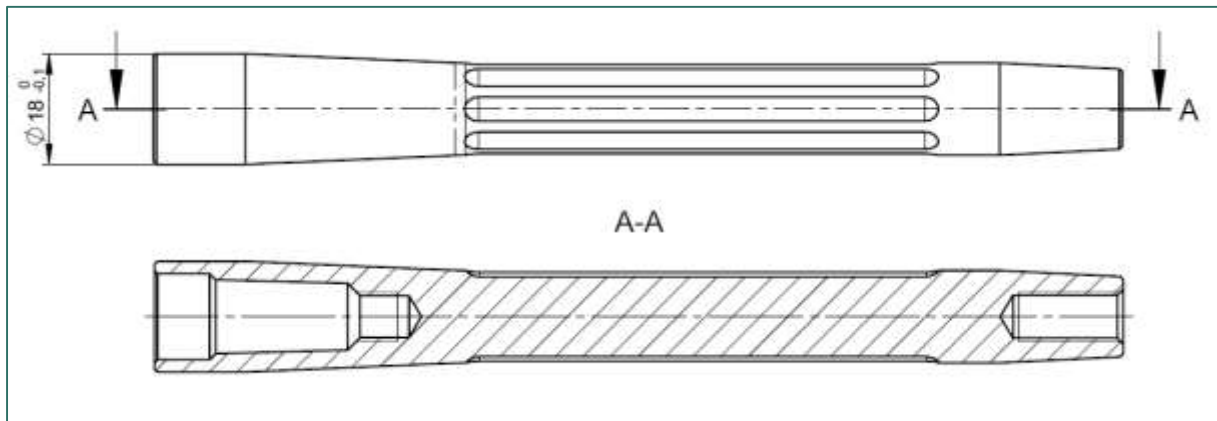


FIGURE 11. MUTARS® INTRAMED. CONNECTING MODULE FOR GENUX® FEMUR



FIGURE 12. MUTARS® RS PROXIMAL COMPONENT + MUTARS® RS METAPHYSEAL COMPONENT + MUTARS® RS EXTENSION PIECE WITH MUTARS® INTRAMED. CONNECTING MODULE FOR KRI AND MUTARS® KRI (LEFT PICTURE) / MUTARS® INTRAMED. CONNECTING MODULE FOR GENUX® FEMUR AND MUTARS® GENUX®

11 Materials

The MUTARS® RS proximal component, MUTARS® RS metaphyseal component, MUTARS® RS extension piece, MUTARS® RS screw, MUTARS® RS safety screw, MUTARS® RS coupling device, MUTARS® screw for RS coupling device, MUTARS® intramed. connecting module for KRI, MUTARS® intramed. connecting module for GenuX® femur, and MUTARS® intramed. connecting module for GenuX® MK femur are manufactured from TiAl₆V₄ wrought alloy acc. to ISO 5832-3.

12 Coatings / Surfaces

MUTARS® RS proximal component

The *MUTARS® RS proximal component* has a sand blasted surface finish. It is available uncoated and with silver coating that is applied circumferentially.

TABLE 1: COATING SPECIFICATIONS FOR SILVER

CHARACTERISTICS	VALUE	
	Gold (Surface Specification SUR_E1)	Silver (Surface Specification SUR_F1)
APPEARANCE	Sealed golden coating	Silver white, satin metal layer
COATING THICKNESS	> 0.2µm AuCo0,2 on adhesive layer	15 ± 5 µm
TENSILE STRENGTH	No delamination of coating on implant surface	According to thermal shock equipment DIN EN ISO 4521:2009-1 Annex C-C.6

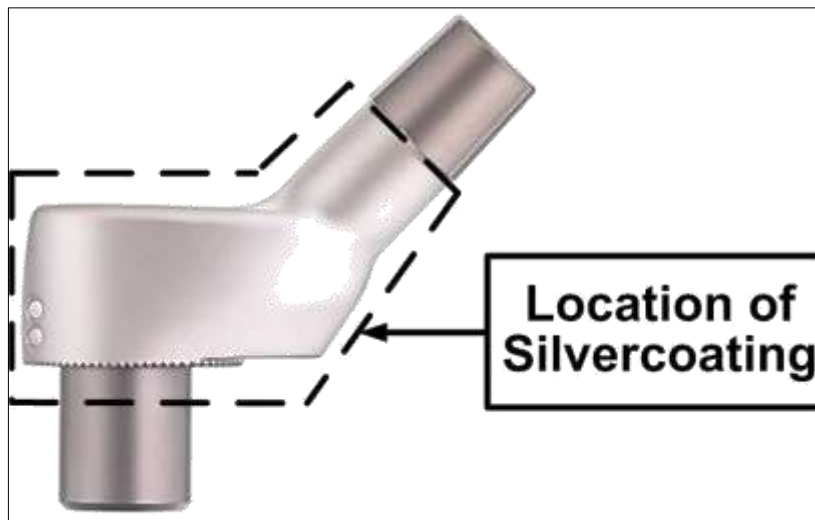


FIGURE 13. MUTARS® RS PROXIMAL COMPONENT – LOCATION OF SILVER COATING

TABLE 2. MUTARS® RS PROXIMAL COMPONENT – SURFACE AREA AND SILVER MASS

REF NUMBER	ITEM DESCRIPTION	SIZE	SURFACE AREA SILVER COATING (mm ²)	MASS SILVER [g]
67101527S	MUTARS® RS proximal component silver	127°/32 mm	2644	0.56
67101535S	MUTARS® RS proximal component silver	135°/32 mm	2488	0.52
67101627S	MUTARS® RS proximal component silver	127°/42 mm	3402	0.71
67101635S	MUTARS® RS proximal component silver	135°/42 mm	3253	0.68

MUTARS® RS metaphyseal component

The *MUTARS® RS metaphyseal component* has a rough corundum blasted surface. It is available uncoated and with HA (hydroxyapatite) coating (thickness: $90\pm 30\ \mu\text{m}$; Coating Specification B3) that is applied circumferentially.



FIGURE 14. MUTARS® RS METAPHYSEAL COMPONENT: WITH HA COATING (LEFT), WITHOUT COATING (RIGHT)

MUTARS® RS extension piece

The *MUTARS® RS extension piece* has a rough corundum blasted surface. It is available uncoated and with HA (hydroxyapatite) coating (thickness: $90\pm 30\ \mu\text{m}$; Coating Specification B3) that is applied circumferentially.



FIGURE 15. MUTARS® RS EXTENSION PIECE: WITHOUT COATING (LEFT PICTURE), WITH HA COATING (RIGHT PICTURE)

Screws

The *MUTARS® RS screw*, *MUTARS® RS safety screw*, and *MUTARS® screw for RS coupling device* have a sand blasted surface.

MUTARS® RS coupling device

The *MUTARS® RS coupling device* has a sand blasted surface finish. It is available uncoated and with silver coating that is applied circumferentially.



FIGURE 16. MUTARS® RS COUPLING DEVICE – LOCATION OF SILVER COATING

TABLE 3. MUTARS® RS COUPLING DEVICE – SURFACE AREA AND SILVER MASS

REF NUMBER	ITEM DESCRIPTION	SIZE	SURFACE AREA SILVER COATING (mm ²)	MASS SILVER [g]
57720030S	MUTARS® RS coupling device silver	30 mm	2507	0.53

MUTARS® intramed. connecting module for KRI

The *MUTARS® intramed. connecting module for KRI* has a rough corundum blasted surface. It is available uncoated and with silver coating that is applied circumferentially.

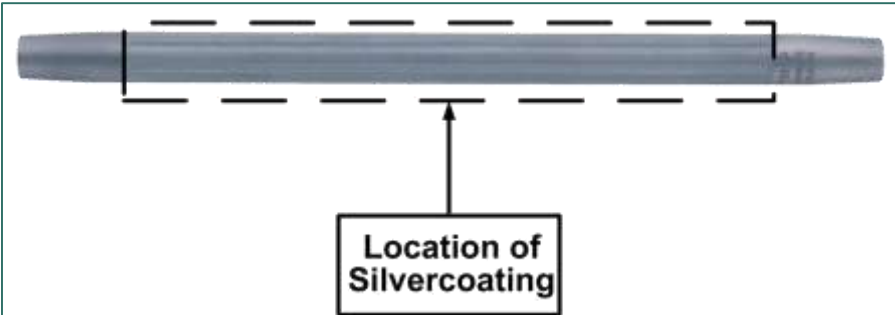


FIGURE 17. MUTARS® INTRAMED. CONNECTING MODULE FOR KRI – LOCATION OF SILVER COATING

TABLE 4. MUTARS® INTRAMED. CONNECTING MODULE FOR KRI – SURFACE AREA AND SILVER MASS

REF NUMBER	ITEM DESCRIPTION	SIZE	SURFACE AREA SILVER COATING (mm ²)	MASS SILVER [g]
57205100S	MUTARS® intramed. connecting module for KRI silver	15/100mm	4704	0.99
57205120S	MUTARS® intramed. connecting module for KRI silver	15/120mm	5712	1.20
57205140S	MUTARS® intramed. connecting module for KRI silver	15/140mm	6704	1.41
57205160S	MUTARS® intramed. connecting module for KRI silver	15/160mm	7697	1.62
57205180S	MUTARS® intramed. connecting module for KRI silver	15/180mm	8689	1.82
57205200S	MUTARS® intramed. connecting module for KRI silver	15/200mm	9681	2.03
57205220S	MUTARS® intramed. connecting module for KRI silver	15/220mm	10674	2.24
57205240S	MUTARS® intramed. connecting module for KRI silver	15/240mm	11666	2.45
57205260S	MUTARS® intramed. connecting module for KRI silver	15/260mm	12658	2.66
57205280S	MUTARS® intramed. connecting module for KRI silver	15/280mm	13650	2.87
57205300S	MUTARS® intramed. connecting module for KRI silver	15/300mm	14643	3.08
57205320S	MUTARS® intramed. connecting module for KRI silver	15/320mm	15635	3.28
57205340S	MUTARS® intramed. connecting module for KRI silver	15/340mm	16627	3.49
57205360S	MUTARS® intramed. connecting module for KRI silver	15/360mm	17620	3.70

MUTARS® intramed. connecting module for GenuX® MK femur

The MUTARS® intramed. connecting module for GenuX® femur and MUTARS® intramed. connecting module for GenuX® MK femur have a rough corundum blasted surface. They are available uncoated and with silver coating that is applied circumferentially.

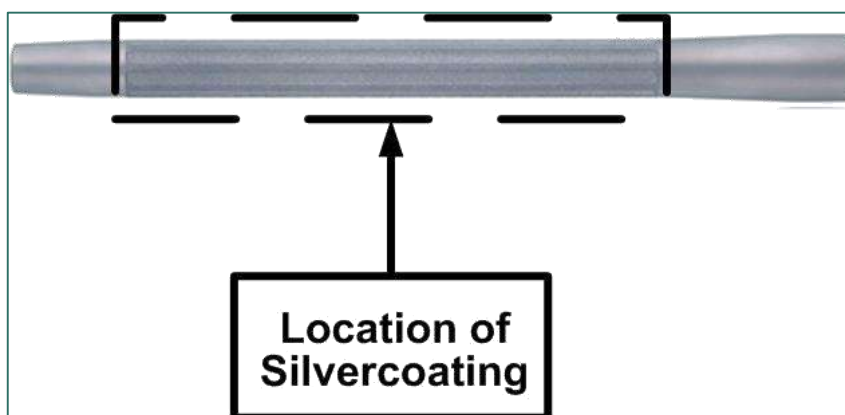


FIGURE 18. MUTARS® INTRAMED. CONNECTING MODULE FOR GENUX® MK FEMUR – LOCATION OF SILVER COATING

TABLE 5. MUTARS® INTRAMED. CONNECTING MODULE FOR GENUX® MK FEMUR – SURFACE AREA AND SILVER MASS

REF NUMBER	ITEM DESCRIPTION	SIZE	SURFACE AREA SILVER COATING (mm ²)	MASS SILVER [g]
57216100S	MUTARS® intramed. connecting module for GenuX® MK femur silver	Ø15/100 mm	-	-
57216120S	MUTARS® intramed. connecting module for GenuX® MK femur silver	Ø15/120 mm	2242	0.47
57216140S	MUTARS® intramed. connecting module for GenuX® MK femur silver	Ø15/140 mm	3234	0.68
57216160S	MUTARS® intramed. connecting module for GenuX® MK femur silver	Ø15/160 mm	4227	0.89
57216180S	MUTARS® intramed. connecting module for GenuX® MK femur silver	Ø15/180 mm	5219	1.10
57216200S	MUTARS® intramed. connecting module for GenuX® MK femur silver	Ø15/200 mm	6211	1.30
57216220S	MUTARS® intramed. connecting module for GenuX® MK femur silver	Ø15/220 mm	7204	1.51
57216240S	MUTARS® intramed. connecting module for GenuX® MK femur silver	Ø15/240 mm	8196	1.72
57216260S	MUTARS® intramed. connecting module for GenuX® MK femur silver	Ø15/260 mm	9188	1.93
57216280S	MUTARS® intramed. connecting module for GenuX® MK femur silver	Ø15/280 mm	10180	2.14
57216300S	MUTARS® intramed. connecting module for GenuX® MK femur silver	Ø15/300 mm	11173	2.35
57216320S	MUTARS® intramed. connecting module for GenuX® MK femur silver	Ø15/320 mm	12165	2.55
57216340S	MUTARS® intramed. connecting module for GenuX® MK femur silver	Ø15/340 mm	13157	2.76
57216360S	MUTARS® intramed. connecting module for GenuX® MK femur silver	Ø15/360 mm	14150	2.97
57216380S	MUTARS® intramed. connecting module for GenuX® MK femur silver	Ø15/380 mm	15142	3.18
57216400S	MUTARS® intramed. connecting module for GenuX® MK femur silver	Ø15/400 mm	16134	3.39
57216420S	MUTARS® intramed. connecting module for GenuX® MK femur silver	Ø15/420 mm	17126	3.60
57216440S	MUTARS® intramed. connecting module for GenuX® MK femur silver	Ø15/440 mm	18119	3.80

13 Sizes and Dimensions

13.1 MUTARS® RS proximal component

The *MUTARS® RS proximal component* is available with two (2) stem – neck angles (CCD angle) of 127° and 135° offering two offsets 46.8 mm and 41.8 mm, respectively, and in two (2) nominal heights of 32 mm and 42 mm. The sizes and their respective dimensions are given in TABLE 6.

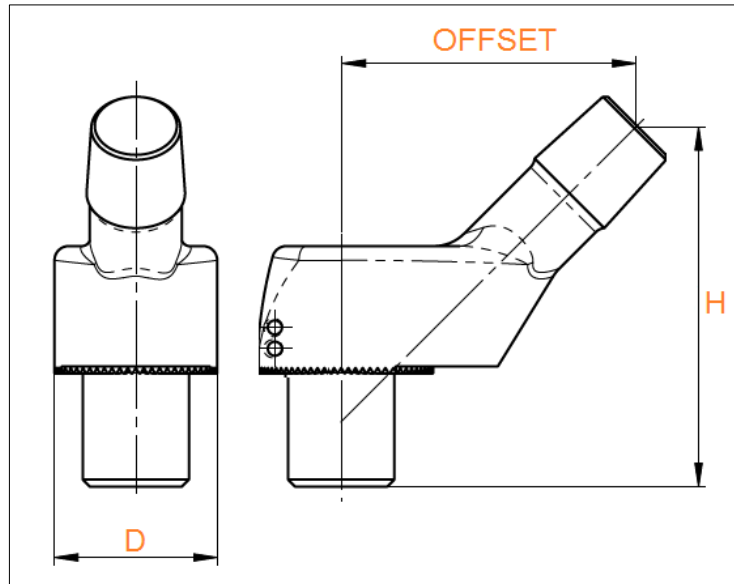


FIGURE 19. DIMENSIONS OF THE MUTARS® RS PROXIMAL COMPONENT

TABLE 6. SIZES AND DIMENSIONS OF THE MUTARS® RS PROXIMAL COMPONENT

SIZE	HEIGHT (H) [mm]	D [mm]	CCD	OFFSET [mm]
127°/32mm	32	23	127°	46.8
135°/32mm	32	23	135°	41.8
127°/42mm	42	23	127°	46.8
135°/42mm	42	23	135°	41.8

13.2 MUTARS® RS metaphyseal component

The *MUTARS® RS metaphyseal component* is available in two variants: standard and small, both in two lengths of 40 mm and 50 mm, to match the patients' individual anatomy. The sizes and their respective dimensions are given in TABLE 7.

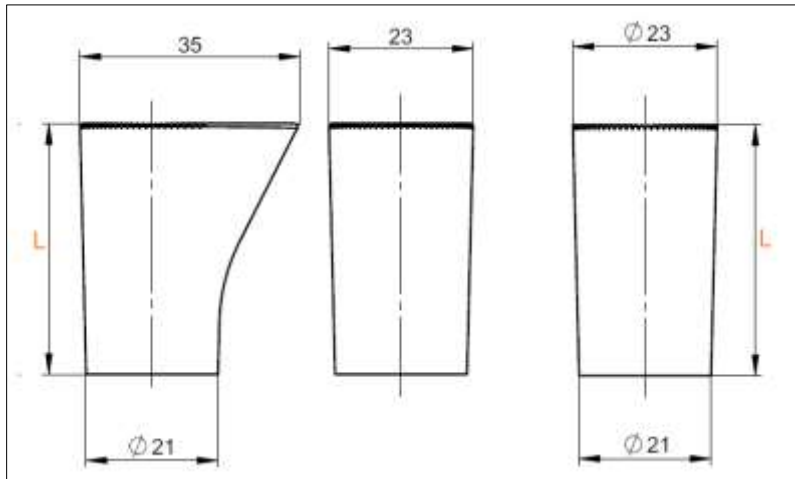


FIGURE 20. DIMENSIONS OF THE MUTARS® RS METAPHYSEAL COMPONENT: STANDARD (LEFT PICTURES), SMALL (RIGHT PICTURE)

TABLE 7. SIZES AND DIMENSIONS OF THE MUTARS® RS METAPHYSEAL COMPONENT

SIZE	LENGTH (L) [mm]
40mm	40
50mm	50
40mm small	40
50mm small	50

13.3 MUTARS® RS extension piece

The *MUTARS® RS extension piece* is available in only one size. It has a length of 25 mm and a diameter of 21 mm (FIGURE 21).

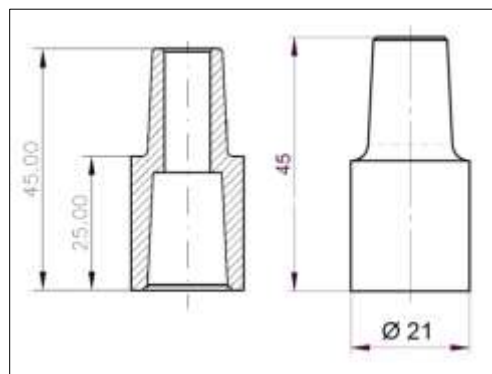


FIGURE 21. DIMENSIONS OF THE MUTARS® RS EXTENSION PIECE

13.4 MUTARS® RS screw and MUTARS® RS safety screw

Due to the various length adjustments within the MUTARS® RS System, the *MUTARS® RS screw* is available in different lengths ranging from 40 mm to 125 mm. The diameter of the thread is 8 mm and of the head 12.4 mm. The length of the head is 5 mm and the length of the thread itself is 13 mm in all sizes. The pitch of the thread is 1 mm (M8x1) (cf. Fehler! Verweisquelle konnte nicht gefunden werden.).

The sizes and their respective lengths are given in TABLE 8.

TABLE 8. SIZES AND LENGTHS OF THE MUTARS® RS SCREW

SIZE	LENGTH (L) [mm]
M8x40mm	40
M8x50mm	50
M8x65mm	65
M8x75mm	75
M8x90mm	90
M8x100mm	100
M8x115mm	115
M8x125mm	125

The *MUTARS® safety screw* (cf. Fehler! Verweisquelle konnte nicht gefunden werden.) has a diameter of 14 mm and an overall length of 5 mm. The pitch of the thread is 1mm (M16x1).

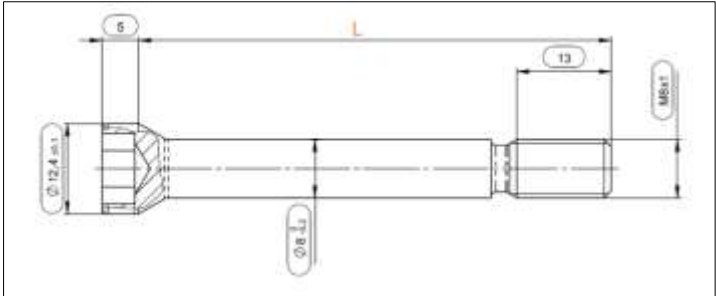


FIGURE 22. DIMENSIONS OF THE MUTARS® RS SCREW

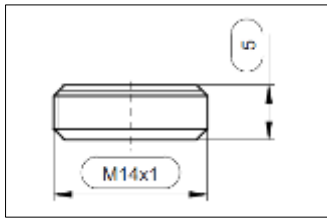


FIGURE 23. DIMENSIONS OF THE MUTARS® RS SAFETY SCREW

13.5 MUTARS® RS coupling device and MUTARS® screw for RS coupling device

The *MUTARS® RS coupling device* has a diameter of 28 mm and length of 30 mm. The dimensions are shown in FIGURE 24.

The *MUTARS® screw for RS coupling device* is available in different lengths ranging from 60 to 140 mm. The diameter of the thread is 8 mm and of the head 14 mm. The length of the head is 8.5 mm and the length of the thread itself is 15 mm in all sizes. The pitch of the thread is 1 mm (M8x1) (cf. FIGURE 25).

The screw sizes and their respective lengths are given in TABLE 9.

TABLE 9. SIZES AND LENGTHS OF THE MUTARS® SCREW FOR RS COUPLING DEVICE

SIZE	LENGTH (L) [mm]
M8x60mm	60
M8x80mm	80
M8x100mm	100
M8x120mm	120
M8x140mm	140

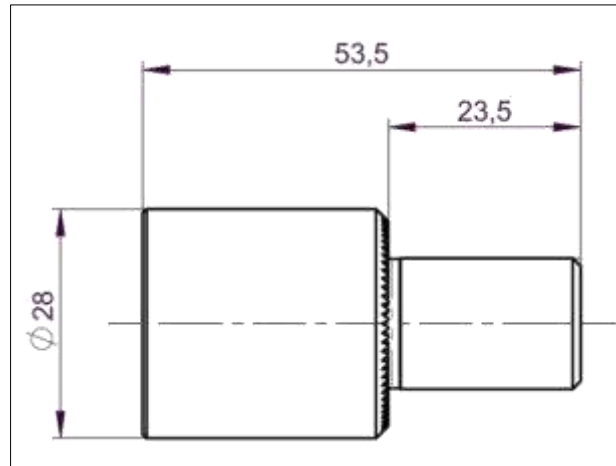


FIGURE 24. DIMENSIONS OF THE MUTARS® RS COUPLING DEVICE

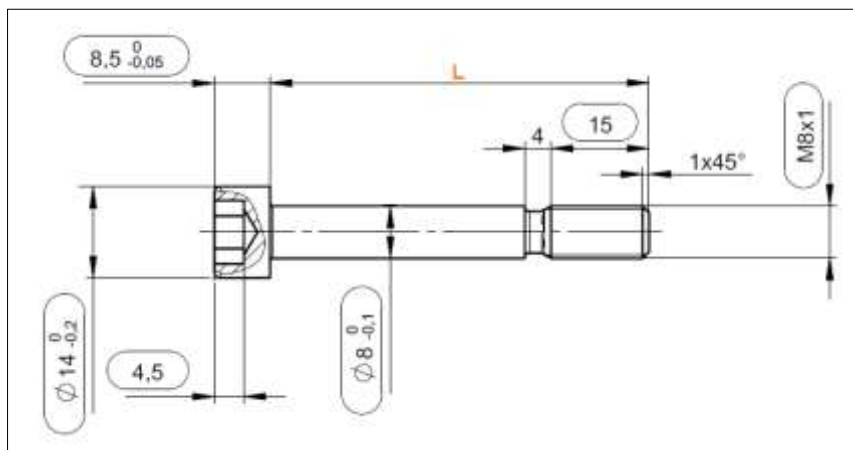


FIGURE 25. DIMENSIONS OF THE MUTARS® SCREW FOR RS COUPLING DEVICE

13.6 MUTARS® intramed. connecting module for KRI

The *MUTARS® intramed. connecting module for KRI* is available in length (**L**) from 100 mm to 360 mm in 20 mm increments to offer an individual reconstruction of the leg length as well as an adjustment in case of an existing leg length discrepancy. It is only available in one diameter of 15 mm (cf. FIGURE 26).

The sizes and their respective lengths are given in TABLE 10.

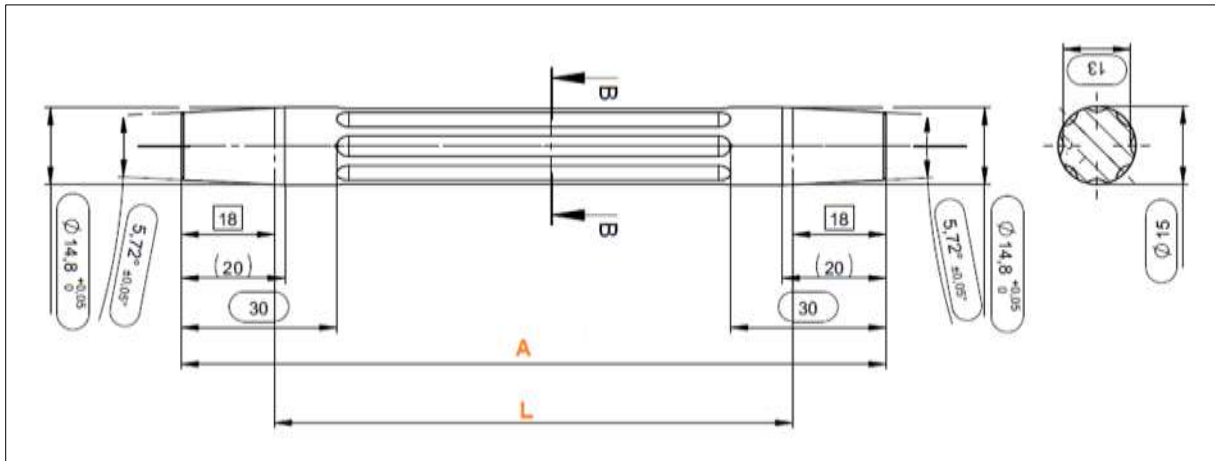


FIGURE 26. DIMENSIONS OF MUTARS® INTRAMED. CONNECTING MODULE FOR KRI

TABLE 10. SIZES AND LENGTHS OF THE MUTARS® INTRAMED. CONNECTING MODULE FOR KRI

SIZE	LENGTH (L) [mm]	LENGTH (A) [mm]	Ø at B-B [mm]
15/100mm	100	136	15
15/120mm	120	156	15
15/140mm	140	176	15
15/160mm	160	196	15
15/180mm	180	216	15
15/200mm	200	236	15
15/220mm	220	256	15
15/240mm	240	276	15
15/260mm	260	296	15
15/280mm	280	316	15
15/300mm	300	336	15
15/320mm	320	356	15
15/340mm	340	376	15
15/360mm	360	396	15

13.7 MUTARS® intramed. connecting module for GenuX® MK femur and the MUTARS® intramed. connecting module for GenuX® femur

The MUTARS® intramed. connecting module for GenuX® MK femur is available in length from 66.29 mm to 386.29 mm in 20 mm increments to offer an individual reconstruction of the leg length as well as

an adjustment in case of an existing leg length discrepancy. It is only available in one diameter of 15 mm (cf. FIGURE 27). The sizes and their respective lengths are given in TABLE 11.

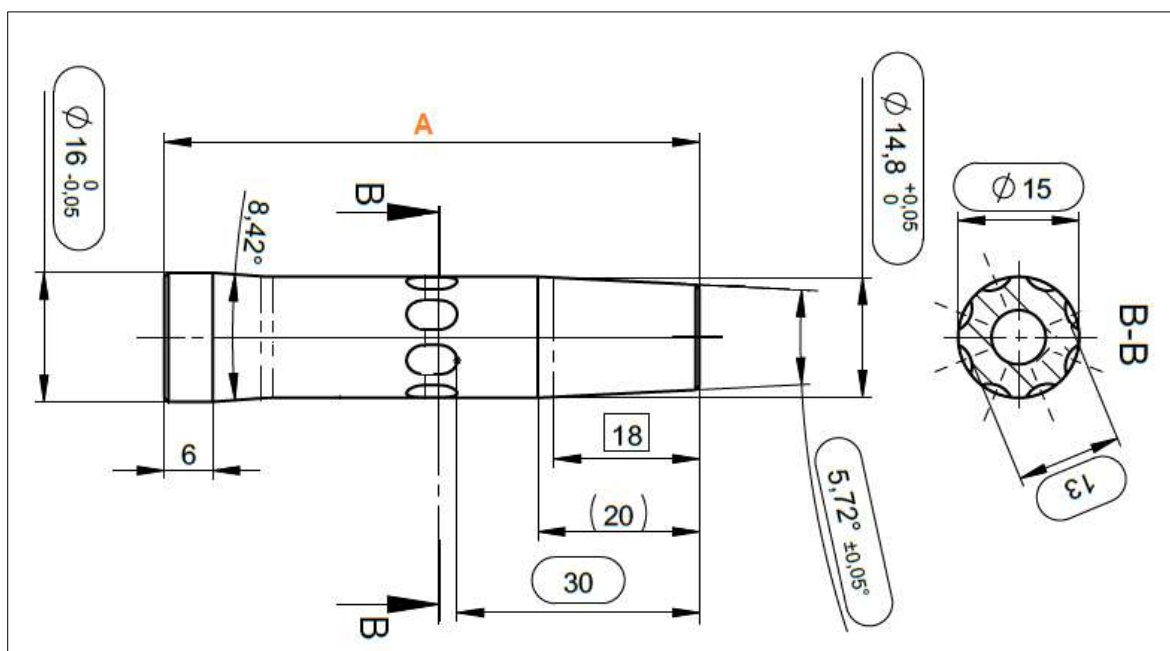


FIGURE 27. DIMENSIONS OF THE MUTARS® INTRAMED. CONNECTING MODULE FOR GENUX® MK FEMUR

TABLE 11. SIZES AND LENGTHS OF THE MUTARS® INTRAMED. CONNECTING MODULE FOR GENUX® MK FEMUR

SIZE	LENGTH (A) [mm]	Ø at B-B [mm]
15/120mm	66.29	15
15/140mm	86.29	15
15/160mm	106.29	15
15/180mm	126.29	15
15/200mm	146.29	15
15/220mm	166.29	15
15/240mm	186.29	15
15/260mm	206.29	15
15/280mm	226.29	15
15/300mm	246.29	15
15/320mm	266.29	15
15/340mm	286.29	15
15/360mm	306.29	15
15/380mm	326.29	15

SIZE	LENGTH (A) [mm]	Ø at B-B [mm]
15/400mm	346.29	15
15/420mm	366.29	15
15/440mm	386.29	15

The MUTARS® intramed. connecting module for GenuX® femur is available in length from 158 mm to 418 mm in 20 mm increments to offer an individual reconstruction of the leg length as well as an adjustment in case of an existing leg length discrepancy. It is only available in one diameter of 15 mm.

The sizes and their respective lengths are given in TABLE 12.

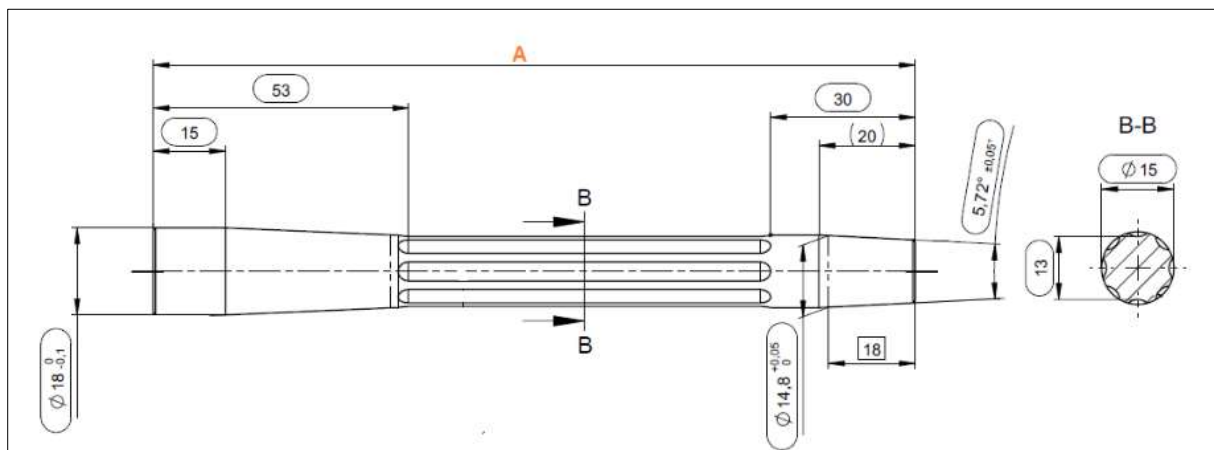


FIGURE 28. MUTARS® INTRAMED. CONNECTING MODULE FOR GENUX® FEMUR

TABLE 12. SIZES AND LENGTHS OF THE MUTARS® INTRAMED. CONNECTING MODULE FOR GENUX® FEMUR

SIZE	LENGTH (A) [mm]	Ø at B-B [mm]
15/180mm	158	15
15/200mm	178	15
15/220mm	198	15
15/240mm	218	15
15/260mm	238	15
15/280mm	258	15
15/300mm	278	15
15/320mm	298	15
15/340mm	318	15

SIZE	LENGTH (A) [mm]	Ø at B-B [mm]
15/360mm	338	15
15/380mm	358	15
15/400mm	378	15
15/420mm	398	15
15/440mm	418	15

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 for the MUTARS® RS System can be found in the Instruction for Use.

⇒ See Doc. Instruction for Use “09300015_MUTARS RS Revisionsystem” 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 Hip 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 13: LIST OF ABBREVIATIONS

ABBREVIATION	ABBREVIATED TERM
CCD	caput-collum-diaphyseal angle
Ha	Hydroxyapatite
MDR	Medical Device Regulation
L	Length
TiN	Titanium Nitride
∅	Diameter



21 DOCUMENT REVISION HISTORY

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