

PART OF THE
TECHNICAL DOCUMENTATION

PRODUCT DESCRIPTION
MUTARS[®] HUMERUS

PRODUCT-GROUP: REVISION AND TUMOR
ARTHROPLASTY

RISK-CLASS: III

LOCATION: SHOULDER, ELBOW

DATE: 25.10.2021, REV. 2

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1. MUTARS® Humerus System

The MUTARS® (Modular Universal Tumour and Revision System) is a universal system of tumor and revision prostheses developed in co-operation with Univ.-Prof. Dr. W. Winkelmann and Univ.-Prof. Dr. G. Gosheger, Department of General Orthopaedics and Orthopaedic Oncology at the University Hospital of Münster, Germany. The MUTARS® System has been in clinical use in Europe since 1992 for the treatment of extensive bone defects of the lower and upper limbs (shoulder, elbow, hip, and knee). The system offers the opportunity for a functional replacement in cases of major osseous defects, from tumour excisions, fractures, infections, or revisions of failed total joint replacement prostheses. The full MUTARS® system includes components to treat defects and failed joint replacement prostheses for the humerus, shoulder, hip joint, femur, knee joint and proximal tibia.

For the treatment of one of the major complication in tumor and revision arthroplasty the MUTARS® system offers the possibility of a silver coating which provides long-term prophylaxis against the colonisation of pathogenic bacteria and, therefore, effectively counteracts infection.

Patients who receive tumour prostheses generally have a weakened immune system due to bone marrow depression caused by chemotherapy, radiotherapy and an overall poor immune system. Additionally, compared to primary arthroplasty, in tumor and revision arthroplasty is a larger surgical area, greater blood loss as well as a larger surface of the implant, which significantly promotes the development of infections.

When all non-surgical measures, such as the administration of broad-spectrum antibiotics, no longer help to prevent a bacterial infection and there is the risk of an amputation or fatal sepsis, implanting a silver-coated tumour prosthesis is an option. The most important goal of the surgery with a silver-coated tumour prosthesis is to prevent the risk of an infection due to the patient's poor physical condition.

Presently all MUTARS® extraosseous components that do not have bony contact are coated with silver. The coating is located on the outer parts. No taper or other connection is coated.

The MUTARS® Humerus System is the shoulder and elbow portion of the overall MUTARS® System. It is a modular humerus replacement system offering various components that can be combined to replace the shoulder and elbow joint and address major bone defects with various options depending upon the size and location of the defects of each patient. The MUTARS® Humerus System consists of:

- ⊕ Humerus Head Components
- ⊕ Humerus Cap / Cap Inverse Components
- ⊕ Glenoid / Glenosphere Components
- ⊕ Distal Humerus Components
- ⊕ Proximal Ulna Components
- ⊕ Humeral Stems
- ⊕ Stem Extension Pieces
- ⊕ Connecting Parts
- ⊕ Component Connection Fixation Screws
- ⊕ A Soft Tissue Attachment PET Surgical Mesh Tube

The MUTARS® Humerus System provides modular proximal and distal humerus components as well as proximal ulna components for creating proximal and distal humerus replacements or proximal Ulna replacements respectively. By using the reducer piece total humeral replacements can be achieved. Caps and Glenoid components are used to form hemi shoulder replacement, reverse shoulder replacement or total (anatomical) shoulder replacement as needed.

Modular humeral stems, stem extension pieces, connecting parts, and end piece components are provided for use as needed in individual cases.

A knit polyethylene terephthalate (PET) mesh soft tissue attachment tube is provided for re-attaching soft tissues to the prosthetic reconstruction.

MUTARS® components are connected to one another through one of two (2) different coupling designs depending upon the components being joined together. The MUTARS® connections are designed to allow intraoperative component rotational adjustment when assembling the components.

The coupling designs are:

- 1) a precise male / female cylindrical connection, called the MUTARS® cylindrical fit connection;
- 2) a precise male / female cylindrical connection, called the AGILON® cylindrical fit connection.

The cylindrical fit connection includes serrated teeth to provide rotational stability and a fixation screw for connection security.

Examples of several possible MUTARS® humerus replacement configurations using these components are shown in the following overview.

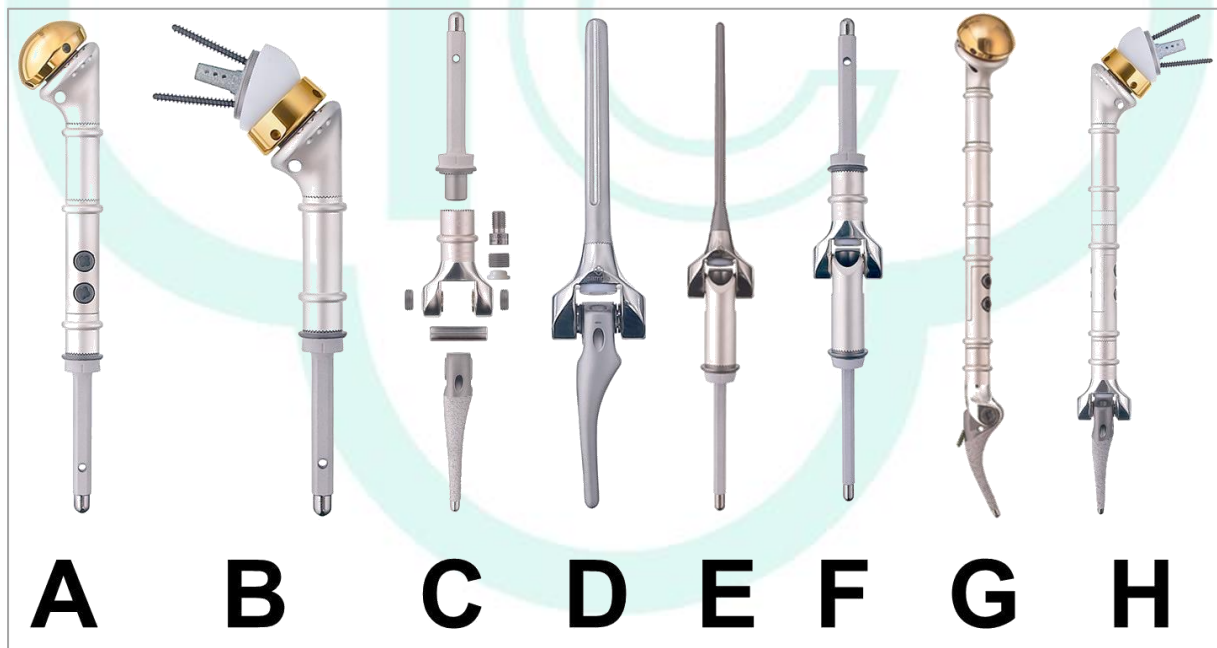


Figure 1: Overview MUTARS® Humerus System

A – *MUTARS® Proximal Humerus Replacement*

w/ MUTARS® Humerus Cap, MUTARS® Humerus Head, MUTARS® Humerus Extension Piece, MUTARS® Humerus Connecting Part, MUTARS® Humerus Stem

B – *MUTARS® Proximal Humerus Inverse Replacement*

w/ Glenoid Cementless, MUTARS® Glenosphere, MUTARS® Humerus Cap Invers, MUTARS® Humerus Head, MUTARS® Humerus Extension Piece, MUTARS® Humerus Stem

C – *MUTARS® Distal Humerus Replacement*

w/ MUTARS® Humerus Stem, MUTARS® Distal Humerus / MUTARS® Distal Humerus HD, MUTARS® Ulna Anchorage / MUTARS® Ulnar Component / MUTARS® Ulnar Component HD

D – *MUTARS® Distal Humerus Short Replacement*

w/ AGILON® Stem, MUTARS® Distal Humerus 30 mm / MUTARS® Distal Humerus HD 30 mm, MUTARS® Ulna Anchorage / MUTARS® Ulnar Component / MUTARS® Ulnar Component HD

E – *MUTARS® Proximal Ulna Replacement*

w/ AGILON® Stem, MUTARS® Distal Humerus 30 mm / MUTARS® Distal Humerus HD 30 mm, MUTARS® Proximal Ulna / MUTARS® Proximal Ulna HD, MUTARS® Humerus Stem

F – *MUTARS® Total Elbow Replacement*

w/ MUTARS® Humerus Stem, MUTARS® Distal Humerus / MUTARS® Distal Humerus HD, MUTARS® Proximal Ulna / MUTARS® Proximal Ulna HD, MUTARS® Humerus Stem

G – *MUTARS® Total Humerus Replacement*

w/ MUTARS® Humerus Cap, MUTARS® Humerus Head, MUTARS® Humerus Extension Piece, MUTARS® Humerus Reducer, MUTARS® Humerus Connecting Part, MUTARS® Distal Humerus / MUTARS® Distal Humerus HD, MUTARS® Ulna Anchorage / MUTARS® Ulnar Component / MUTARS® Ulnar Component HD

H – *MUTARS® Total Humerus Inverse Replacement*

w/ Glenoid Cementless, MUTARS® Glenosphere, MUTARS® Humerus Cap Invers, MUTARS® Humerus Head, MUTARS® Humerus Extension Piece, MUTARS® Humerus Reducer, MUTARS® Humerus Connecting Part, MUTARS® Distal Humerus / MUTARS® Distal Humerus HD, MUTARS® Ulna Anchorage / MUTARS® Ulnar Component / MUTARS® Ulnar Component HD

2. Intended Use

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

3. Qualification of the Product as a Medical Device

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

- ⇒ See Doc. Instruction for Use “09300013 MUTARS Tumor- and Revision System” in the folder “05 Kennzeichnung\Gebrauchsinformation”

8. Contraindications

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

- ⇒ See Doc. Instruction for Use “09300013 MUTARS Tumor- and Revision System” in the folder “05 Kennzeichnung\Gebrauchsinformation”

9. Risk Factors

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

- ⇒ See Doc. Instruction for Use “09300013 MUTARS Tumor- and Revision System” in the folder “05 Kennzeichnung\Gebrauchsinformation”

10. Design Description

10.1. MUTARS® Component Connections

MUTARS® Components are connected to one another through one of two (2) different coupling designs depending upon the components being joined together. The coupling designs are described first and the type of coupling mechanism utilized for each component of the system is identified in the descriptions of the individual components that follow.

The two (2) coupling designs utilized to connect MUTARS® Humerus Components are:

- 1) a precise male / female cylindrical connection, called the MUTARS® Cylindrical Fit Connection;
- 2) a precise male / female cylindrical connection, called the AGILON® Cylindrical Fit Connection;

The connections are designed to allow intraoperative component rotational adjustment when assembling the components.

MUTARS® Cylindrical Fit Connection

The MUTARS® Cylindrical Fit Connection is provided by a precise male / female cylindrical fit and a serration connection of interdigitating 36 teeth to provide rotational stability.

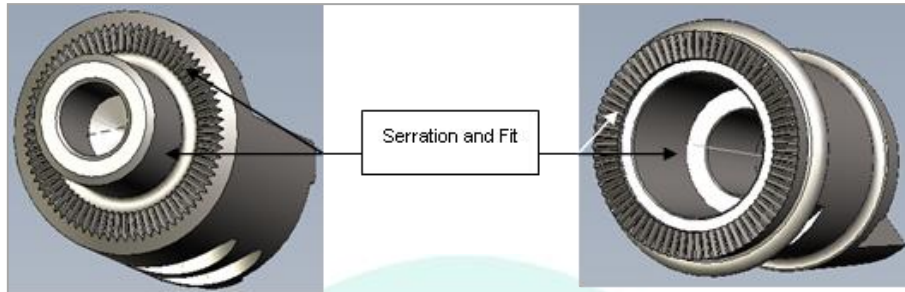


Figure 2: MUTARS® Cylindrical Fit Connection

A MUTARS® Cylindrical Fit Connection Screw (MUTARS® Humerus Screw) is axially applied across the connection during component assembly to connect and secure the MUTARS® Cylindrical Fit Connection.



Figure 3: MUTARS® Humerus Screw

AGILON® Cylindrical Fit Connection

The AGILON® Cylindrical Fit Connection is provided by a precise male / female cylindrical fit and a serration connection of interdigitating 36 teeth to provide rotational stability.

The AGILON® Cylindrical Fit is only used in the Short Distal Humerus Components and AGILON® Stems. There are two (2) versions of the AGILON® Cylindrical Fit Connection (standard and extended).



Figure 4: AGILON® Cylindrical Fit Connection

A MUTARS® Cylindrical Fit Connection Screw (MUTARS® Screw for Distal Humerus) is axially applied across the connection during component assembly to connect and secure the AGILON® Cylindrical Fit Connection.

10.2. MUTARS® Humerus Head

The MUTARS® Humerus Head is a shoulder joint component that replaces the proximal part of the shoulder. Coated and uncoated versions are available.

The MUTARS® Humerus Head utilizes the MUTARS® Cylindrical Fit and Serration Connection design for attachment to the Connecting Part, Extension Piece, Reducer Piece or a Humeral Stem.

Six bore holes at the proximal part of the head are used for securing a PET mesh soft tissue attachment tube component.

The slender design and slight medial geometry offer improved coverage of soft tissue. The thread at the proximal part serves for connecting with the MUTARS® Humerus Cap and MUTARS® Humerus Cap Inverse respectively.

The cross hole at the neck of the headpiece serves as a socket for the straight pivot of the humerus when assembling the implant components during implantation.



Figure 5: MUTARS® Humerus Head

10.3. MUTARS® Humerus Caps

MUTARS® Humerus Cap

The MUTARS® Humerus Cap replaces combined with the MUTARS® Humerus Head the humeral head. The MUTARS® Humerus Cap is screwed onto the MUTARS® Humerus Head and articulated either with the Glenoid Cemented or the natural glenoid cavity.

In addition, it is also possible to articulate with the Glenoid PE-inlay anatomical in combination with the Glenoid Cementless Anatomical after change from a reverse humerus replacement to a total humerus replacement and vice versa.

The four lateral bore holes at the rim of the cap serve as a holding fixture for the wrench.



Figure 6: MUTARS® Humerus Cap

MUTARS® Humerus Cap Inverse

The MUTARS® Humerus Cap Inverse replaces combined with the MUTARS® Humerus Head the humeral head in case of a reverse shoulder prosthesis. Its wearing partner is the MUTARS® Glenosphere.

The four lateral bore holes at the rim of the cap serve as a holding fixture for the wrench.



Figure 7: MUTARS® Humerus Cap Invers

10.4. MUTARS® Glenoid / Glenosphere

Glenoid Cementless

The Cementless Glenoid Component is to be connected to the MUTARS® Glenosphere in case of a reverse MUTARS® Humerus Replacement. The glenoid piece provides fixation in the glenoid cavity via press-fit. The Glenoid Component is intended to be used without bone cement (cementless). It is recommended to use at least two angle stable cancellous screws, which can be pivoted freely.

The convex posterior of the glenoid prosthesis only requires minimal removal of bone when preparing the glenoid prosthesis site. The central stem of the glenoid is conical and serves for stability in the glenoid. The six cross hole provide better bone ingrowth. The central bore hole is for the attachment of the impactor instrument while implanting.

MUTARS® Glenoid Cementless utilizes a thread for attachment to the MUTARS® Glenosphere Component and the Anatomical PE-Inlay respectively.

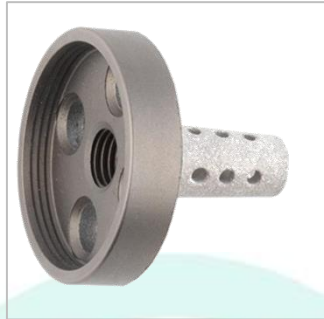


Figure 8: Glenoid Cementless Round

MUTARS® Glenosphere

The MUTARS® Glenosphere forms the wear partner for the MUTARS® Humerus Cap Inverse in case of a reverse shoulder replacement. The Glenosphere is fixed to the Glenoid Component Cementless via a snap mechanism realized by an inner serration at the rim which snaps into the circular groove of the plane area of the Glenosphere.



Figure 9: MUTARS® Glenosphere

AGILON® PE-Glenoid Cemented

The AGILON® PE-Glenoid Cemented replaces the natural glenoid and is intended to be used with cement only. The Glenoid is to be combined with MUTARS® Humerus Cap.



Figure 10: AGILON® PE-Glenoid Cemented

10.5. MUTARS® Humerus Stems, Stem Extensions, and End Piece

The MUTARS® Stems provide diaphyseal anchorage of the joint replacement in the humerus and ulna respectively. The MUTARS® System includes straight stems for cemented and cementless applications. The MUTARS® Humerus Extension Piece serves as an extraosseous length adjustment in the area of the humerus for the bridging of bone defects. The MUTARS® Humerus End Piece is used in rare cases of bone tumors and bone metastasis in which no full extremity preserving surgery can be carried out in which case the End Piece can be used as the terminal end of the MUTARS® Proximal Humeral Replacement to prosthetically preserve a stump.

MUTARS® Humerus Stem Cemented

The MUTARS® Humerus Stem Cemented is used for a diaphyseal anchorage of the shoulder or elbow joint replacement in the humerus and ulna respectively. It has a hexagonal cross section for rotation stability, a collar at the proximal end to prevent subsidence.

The MUTARS® Humerus Stem Type A Modular Cemented is used for a diaphyseal anchorage by combination with the MUTARS® EPORE® HA Collar Humerus of the shoulder or elbow joint replacement in the humerus and ulna respectively. It has a straight cylindrical stem design with a round profile and three cement grooves for rotational stability, as the AGILON® stem cemented. The stems also provide a cross hole (Ø 4 mm) from a length of 100 mm and diameter of 10mm for optional applicable cancellous screw (Ø 3.5 mm) for additional rotational stability.

The stems utilize the MUTARS® Cylindrical Fit Connection mechanism with serrated teeth for attaching to the MUTARS® Humerus Head, Connecting Part, Extension Piece, Distal Humerus and Proximal Ulna component, allowing an adjustment of antetorsion angle in 10° steps.



Figure 11: MUTARS® Humerus Stem Cemented



Figure 12: MUTARS® Humerus Stem Type A Modular Cemented

MUTARS® Humerus Stem Cementless

The MUTARS® Humerus Stem Cementless is used for a diaphyseal anchorage of the shoulder or elbow joint replacement in the humerus and ulna respectively. It has a hexagonal cross section for rotation stability and a collar at the proximal end to prevent subsidence.

The MUTARS® Humerus Stem Type A Modular Cementless is used for a diaphyseal anchorage by combination with the MUTARS® EPORE® HA Collar Humerus of the shoulder or elbow joint replacement in the humerus and ulna respectively. It has a straight stem design with a round profile and provide 8 longitudinal fins for press-fit and rotational stability, as the AGILON® stem cementless.

The stems utilize the MUTARS® Cylindrical Fit Connection mechanism with serrated teeth for attaching to the MUTARS® Humerus Head, Connecting Part, Extension Piece, Distal Humerus and Proximal Ulna component, allowing an adjustment of antetorsion angle in 10° steps. Both stems also provide a cross hole (Ø 4 mm) from a diameter of 9 mm for optional applicable cancellous screw (Ø 3.5 mm) for additional rotation stability.



Figure 13: MUTARS® Humerus Stem Cementless



Figure 14: MUTARS® Humerus Stem Type A Modular Cementless

MUTARS® EPORE® HA Collar Humerus

The MUTARS® EPORE® HA Collar Humerus is a modular stem collar for the MUTARS® Humerus Stem Type A Modular intended to enable bone ingrowth. It has a solid core with exterior EPORE® structure. The Collar is also available with flange, which additionally has the EPORE® structure on the inside of the flange.



Figure 15: MUTARS® EPORE® HA Collar Humerus (left) and with flange (right)

AGILON® Stem Cementless

The AGILON® Stem Cementless allows for a diaphyseal anchorage of the distal humerus replacement in the humerus intended for use without bone cement. The stem has a conical shape at the proximal end to enhance press fit. The stems also provide a cross hole (Ø 4 mm) from a length of 180 mm for optional applicable cancellous screw (Ø 3.5 mm) for additional rotation stability.

The stems utilize the AGILON® Cylindrical Fit Connection mechanism with serrated teeth for attaching to the MUTARS® Distal Humerus 30mm and AGILON® Extension Piece, allowing an adjustment of antetorsion angle in 10° steps.



Figure 16: AGILON® Stem Cementless

AGILON® Stem Cemented

The AGILON® Stem Cemented allows for a diaphyseal anchorage of the distal humerus replacement in the humerus intended for use with bone cement. It is a straight cylindrical stem design with a round profile and three cement grooves for rotational stability.

The stems utilize the AGILON® Cylindrical Fit Connection mechanism with serrated teeth for attaching to the MUTARS® Distal Humerus 30mm and AGILON® Extension Piece, allowing an adjustment of antetorsion angle in 10° steps.



Figure 17: AGILON® Stem Cemented

AGILON® Extension Piece

The AGILON® Extension Piece is for intra-osseous length adjustment in case of a MUTARS® Distal Humerus Replacement. It is intended to be used without bone cement.

The AGILON® Extension Piece utilize the AGILON® Cylindrical Fit Connection mechanism with serrated teeth on both ends for attaching to the MUTARS® Distal Humerus, AGILON® Stems and additional AGILON® Extension Piece, allowing an adjustment of antetorsion angle in 10° steps.



Figure 18: AGILON® Extension Piece

MUTARS® Humerus Extension Piece

The MUTARS® Humerus Extension Piece serves as an extraosseous length adjustment in the area of the proximal and distal humerus for the bridging of bone defects in cases where a proximal or distal humerus replacement component is used. The Extension Piece may also be used when a total humerus replacement component is required. Short extension segments are used if there is sufficient preserved metaphyseal bone while long segments are used if the bone defects are substantial or if correction of length is required. The Humerus Extension Piece utilizes the MUTARS® Cylindrical Fit and Serration Connection design for attachment to the MUTARS® Humerus Head, Humerus Reducer Piece, Humerus Connecting Part, Humerus End Piece, Humerus Stem, Distal Humerus and Proximal Ulna component. The Extension Piece has one retention ring for securing a PET mesh soft tissue attachment tube component.



Figure 19: MUTARS® Humerus Extension Piece

MUTARS® Humerus Connecting Part

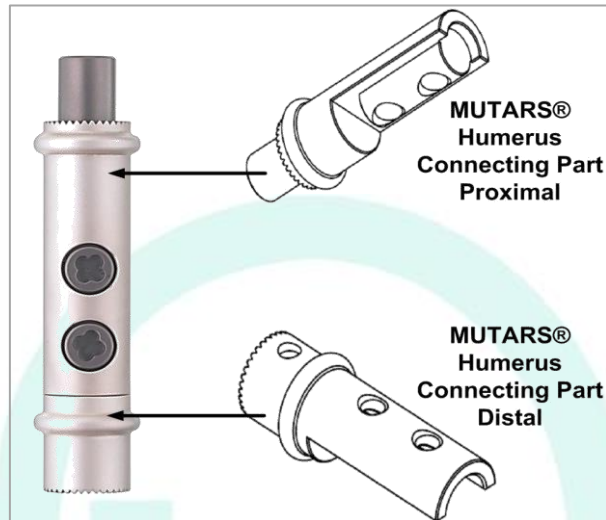


Figure 20: MUTARS® Humerus Connecting Part

Like the MUTARS® Humerus Extension Piece the MUTARS® Humerus Connecting Part serves as an extraosseous length adjustment in the area of the humerus for the bridging of bone defects. The connection piece consists of two parts: the MUTARS® Connecting Part Distal and MUTARS® Connecting Part Proximal, see figure above. The two parts are connected to each other with the MUTARS® Screw for Connecting Part. The Connecting Part utilizes the MUTARS® Cylindrical Fit and Serration Connection design for attachment to the MUTARS® Humerus Head, Humerus Extension Piece, Humerus Reducer Piece, Humerus End Piece, Humerus Stem, Distal Humerus and Proximal Ulna Component. The Connecting Part has retention rings for securing a PET mesh soft tissue attachment tube component.

MUTARS® Humerus End Piece

The MUTARS® Humerus End Piece is used in rare cases of bone tumors and bone metastases in which no full extremity preserving surgery can be carried out. In combination with the MUTARS® Humerus Head Replacement Component, the End Piece can be serve to prosthetically preserve a terminal humeral stump. The End Piece is designed with the MUTARS® Cylindrical Fit and Serration (36 teeth) Connection for attachment to the MUTARS® Humerus Extension Piece or Humerus Connecting Part to achieve a functional length adjustment to the stump terminus.



Figure 21: MUTARS® Humerus End Piece

MUTARS® Humerus Reducer

The MUTARS® Humerus Reducer is for the extraosseous length adjustment cases of a total humerus replacement to enable a connection between the MUTARS® Humerus Head and the Distal Humerus. Beside the MUTARS® Humerus Head and Distal Humerus it can be combined with the MUTARS® Humerus Connection Part as well as the MUTARS® Humerus Extension Piece to achieve the required length. The Reducer utilizes the MUTARS® Cylindrical Fit and Serration Connection design for attachment to the MUTARS® Humerus Head, Humerus Extension Piece, Humerus Connecting Part and Distal Humerus.



Figure 22: MUTARS® Humerus Reducer

10.6. MUTARS® Distal Humerus and Proximal Ulna

MUTARS® Distal Humerus

The MUTARS® Distal Humerus is a hinged elbow joint component that replaces the distal part of the humerus.

The hinged joint mechanism of the MUTARS® Distal Humerus consists of three parts: the MUTARS® Distal Humerus Component itself, the MUTARS® Distal Humerus Bushing and the MUTARS® Axle for Distal Humerus. The bushings are laterally pressed into the distal humerus and the bushings serve as the articulating component for the hinge mechanism (axle), see figure below.

The hinged joint mechanism of the MUTARS® Distal Humerus HD consists of three parts: the MUTARS® Distal Humerus HD Component itself, the PE Bearing and the MUTARS® Axle for Distal

Humerus HD. The PE bearings serve as the articulating component for the hinge mechanism (axle), see figure below.

The Distal Humerus is an all extraosseous part. The MUTARS® Distal Humerus 50mm utilizes the MUTARS® Cylindrical Fit and Serration Connection design while the MUTARS® Distal Humerus 30mm utilizes the AGILON® Cylindrical Fit and Serration Connection design.

The MUTARS® Distal Humerus 50 mm has a retention ring for securing a PET mesh soft tissue attachment tube component.

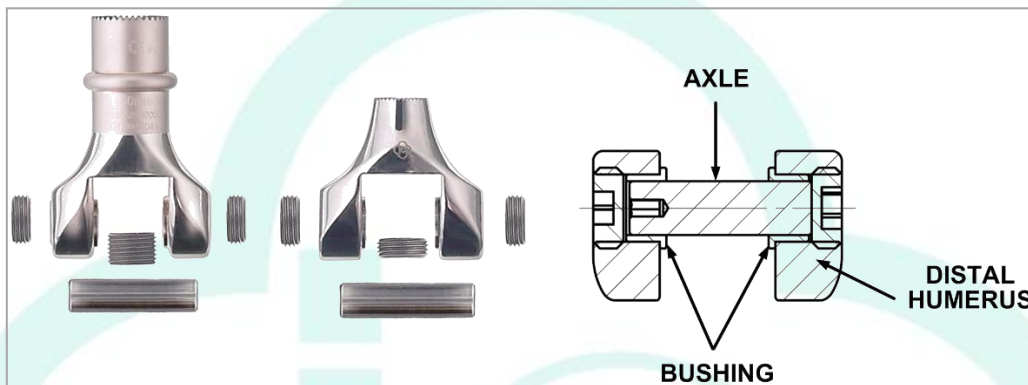


Figure 23: MUTARS® Distal Humerus 50mm (Left), 30mm (Center) and Assembling (Right)

PE Bearing

The PE Bearings serves as coupling for the MUTARS® Distal Humerus HD and MUTARS® Ulnar Components HD via the MUTARS® Axle for Distal Humerus HD. The PE Bearing FC provides backlash-free movement and the PE Bearing SC provides an overall laxity of 7°. Both PE Bearings consists of two parts: the PE Bearing Part 1 and Part 2, that are inserted into each other.



Figure 24: PE Bearing FC (left) and SC (right)

MUTARS® Ulnar Component Cemented

The MUTARS® Ulnar Component Cemented serves as the osseous anchorage in the ulna in case of a distal or total humerus replacement. It contains the corresponding wear pairing of the hinged MUTARS® Distal Humerus Joint Replacement. Therefore, bushings are also pressed into the Ulnar Component for coupling with the Distal Humerus via the axle.

The Ulnar Component is intended for cemented use and is available in left and right configurations.



Figure 25: MUTARS® Ulnar Component Cemented

The MUTARS® Ulnar Component HD Cemented serves as the osseous anchorage in the ulna in case of a distal or total humerus replacement. The stem design is identical to that of the MUTARS® Ulnar Component Cemented but is connected to the MUTARS® Distal Humerus HD via PE Bearing.

The Ulnar Component HD is intended for cemented use and is available in left and right configurations.



Figure 26: MUTARS® Ulnar Component HD Cemented

MUTARS® Ulna Anchorage Cementless

The MUTARS® Ulna Anchorage Cementless serves as the osseous anchorage in the ulna in case of a distal or total humerus replacement. It contains the corresponding wear pairing of the hinged MUTARS® Distal Humerus Joint Replacement. Therefore, bushings are also pressed into the ulna component for coupling with the distal humerus via the axle.

The Ulna Anchorage is intended for use without bone cement and is available in left and right configurations.



Figure 27: MUTARS® Ulna Anchorage Cementless

MUTARS® Ulnar Component HD Cementless

The MUTARS® Ulnar Component HD Cementless serves as the osseous anchorage in the ulna in case of a distal or total humerus replacement. The stem design is identical to that of the MUTARS® Ulnar Component Cementless but is connected to the MUTARS® Distal Humerus HD via PE Bearing.

The Ulnar Component HD is intended for use without bone cement and is available in left and right configurations.



Figure 28: MUTARS® Ulnar Component HD Cementless

MUTARS® Ulna Stop

The MUTARS® Ulna Stop serves to prevent hyperextension of the elbow replacement. It is used in the Distal Humerus after it has been screwed to the corresponding stems (see the figure below). The

MUTARS® Ulna Stop HD is used in the Distal Humerus HD after it has been screwed to the corresponding stems.

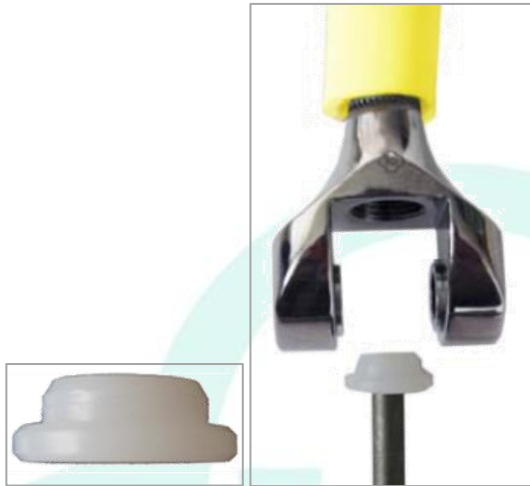


Figure 29: MUTARS® Ulna Stop

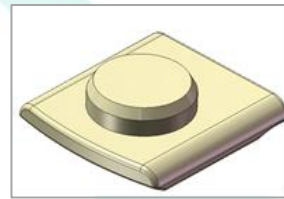


Figure 30: MUTARS® Ulna Stop HD

The distal border is located above the bore hole such that the ulna stops here when the elbow joint is extended. This prevents overextension of the elbow joint.

MUTARS® Proximal Ulna

The MUTARS® Proximal Ulna replaces the proximal ulna as part of a hinged elbow system. It contains the corresponding wear pairing of the hinged MUTARS® Distal Humerus Joint Replacement. Therefore, bushings are also pressed into the ulna component for coupling with the Distal Humerus via the axle.

The Proximal Ulna is an all extraosseous part and utilizes the MUTARS® cylindrical fit and Serration Connection design for attachment.

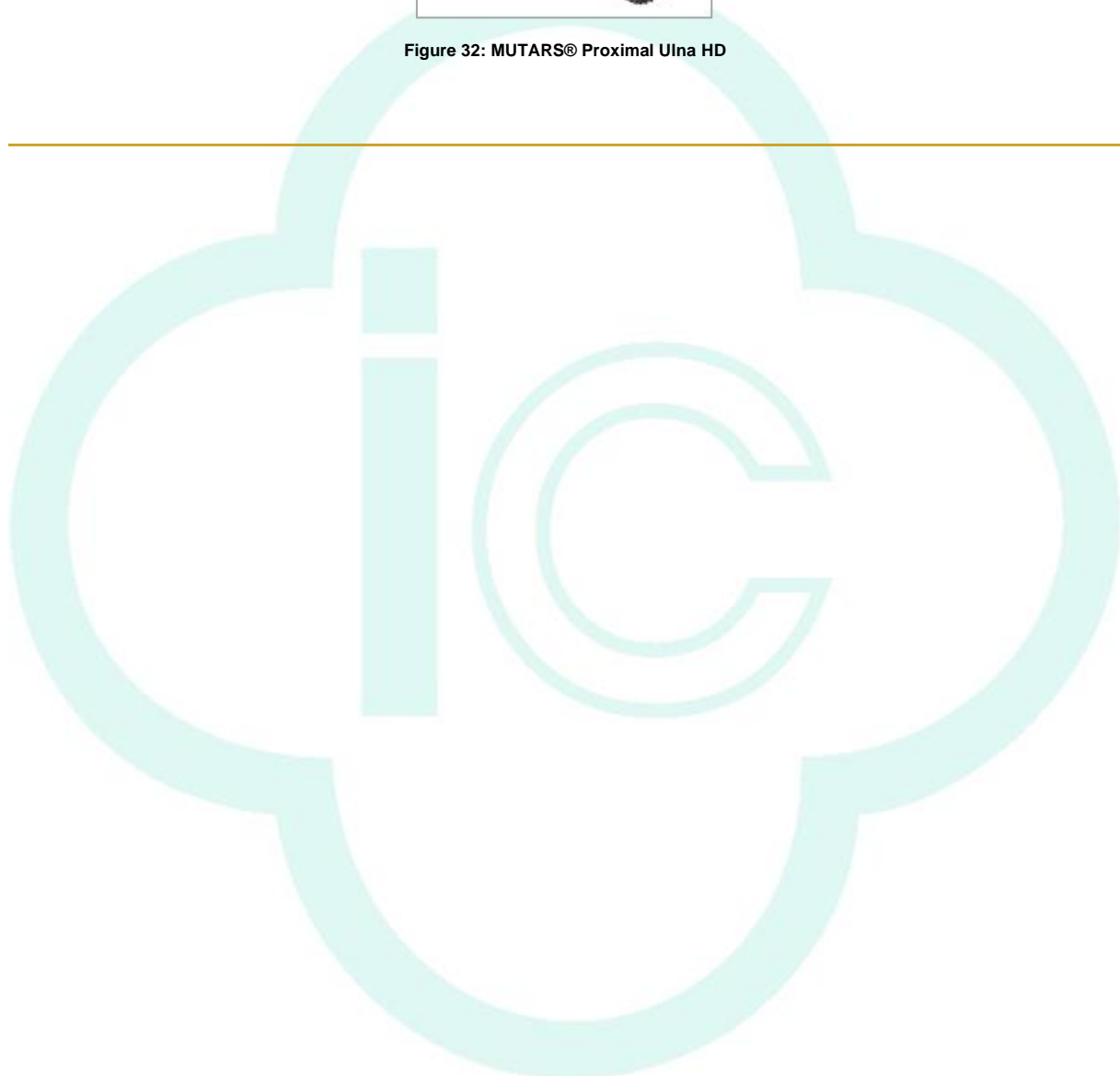


Figure 31: MUTARS® Proximal Ulna

The MUTARS® Proximal Ulna HD replaces the proximal ulna as part of a hinged elbow system. The design is identical to that of the MUTARS® Proximal Ulna but is connected to the MUTARS® Distal Humerus HD via PE Bearing.



Figure 32: MUTARS® Proximal Ulna HD



11. Materials

MUTARS® Axle for Distal Humerus, MUTARS® Axle for Distal Humerus HD, Bushing of MUTARS® Proximal Ulna, Bushing of MUTARS® Ulna Anchorage and Bushing of MUTARS® Ulnar Component, MUTARS® Proximal Ulna HD are manufactured from CoCrMo acc. to ISO 5832-12.

The MUTARS® Humerus Stem Cemented, MUTARS® Humerus Stem Type A Modular Cemented, MUTARS® Ulnar Component Cemented, MUTARS® Ulnar Component HD are manufactured from CoCrMo acc. to ISO 5832-4.

The MUTARS® Glenosphere, AGILON® PE-Glenoid Cemented, MUTARS® Ulna Stop are manufactured from UHMW-PE acc. to ISO 5834-2.

The MUTARS® Humerus Head incl. Safety Screw, MUTARS® Humerus Cap, MUTARS® Humerus Cap Inverse are manufactured from TiAl₆V₄ acc. to ISO 5832-3.

The MUTARS® Humerus Extension Piece, MUTARS® Humerus Connection Part, MUTARS® Humerus Screw for Connection Part, MUTARS® Humerus Stem Cementless, MUTARS® Humerus Stem Type A Modular Cementless, MUTARS® Humerus Screw, MUTARS® Humerus Safety Screw, MUTARS® Humerus End Piece, MUTARS® Humerus Reducer Piece are manufactured from TiAl₆V₄ acc. to ISO 5832-3.

The MUTARS® Distal Humerus incl. Safety Screw and Locking Screws, MUTARS® Distal Humerus HD incl. Safety Screw and Locking Screws, MUTARS® Screw for Distal Humerus 30mm, MUTARS® Proximal Ulna incl. Safety Screw, MUTARS® Ulna Anchorage Cementless are manufactured from TiAl₆V₄ acc. to ISO 5832-3.

The MUTARS® Glenosphere and AGILON® PE-Glenoid Cemented provide x-ray wire made of TiAl₆V₄ acc. to ISO 5832-3.

The PE Bearing SC, PE Bearing FC, MUTARS® Ulna Stop HD are manufactured from crosslinked UHMWPE with vitamin E.

The MUTARS® EPORE® HA Collars Humerus are manufactured from TiAl₆V₄ alloy.

The MUTARS® Attachment Tube is manufactured from polyethylene terephthalate (PET).

12. Coatings / Surfaces

12.1. MUTARS® Humerus Head

The MUTARS® Humerus Head is an all extraosseous part that has a sand blasted surface and provides a silver coating which is applied circumferentially with the serration, thread and internal fit not coated. An uncoated version is also available.



Figure 33: MUTARS® Humerus Head

Table 1: MUTARS® Humerus Head - 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

Table 2: MUTARS® Humerus Head – Surface Area and Silver Mass

REF NUMBER	ITEM DESCRIPTION	SIZE	SURFACE AREA SILVER COATING [mm ²]	MASS SILVER [g]
52000000S	MUTARS® humerus head silver incl. safety screw	50 mm	2730	0.57

12.2. MUTARS® Humerus Caps

MUTARS® Humerus Cap and MUTARS® Humerus Cap Inverse

The MUTARS® Humerus Cap and MUTARS® Humerus Cap Inverse have a polished surface finish of Ra of 0.05 µm. The Cap has and a roundness (sphericity) of 0.1 µm and the Cap Inverse of 0.01µm. Both provide a Titanium Nitride (TiN) coating.



Figure 34: MUTARS® Humerus Cap



Figure 35: MUTARS® Humerus Cap Invers

Table 3: MUTARS® Humerus Cap and Cap Invers- Coating Specifications for TiN

CHARACTERISTICS	VALUE
	TiN (Surface Specification SUR_A1)
COATING PROCESS	PVD-Arc
COATING THICKNESS	5.5 ± 1.5 µm
COATING HARDNESS	2400 ± 400 HV
AVERAGE ROUGHNESS RA	< 0.05 µm
TENSILE STRENGTH	≥ 22 MPa
ADHESIVE STRENGTH ROCKWELL C	0 - 1
ADHESIVE STRENGTH MANDREL BENDING TEST	No layer delamination

12.3. MUTARS® Glenoid

Glenoid Cemented

The wear surface of the cemented Glenoid component has a roughness Ra of 2 µm while the bone opposing back side is structured for better fixation with the cement.

MUTARS® Glensphere

The MUTARS® Glensphere has a sphericity of 0.1 µm and a roughness Ra of 2 µm.

Glenoid Cementless

The Glenoid Cementless round has a porous, corundum blasted surface on the posterior bone opposing side and both are available with Hydroxyapatite (HA) coating that complies with ISO 13779 requirements.

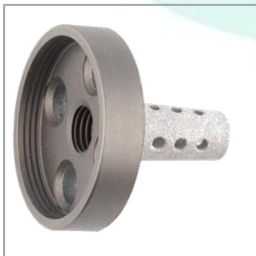
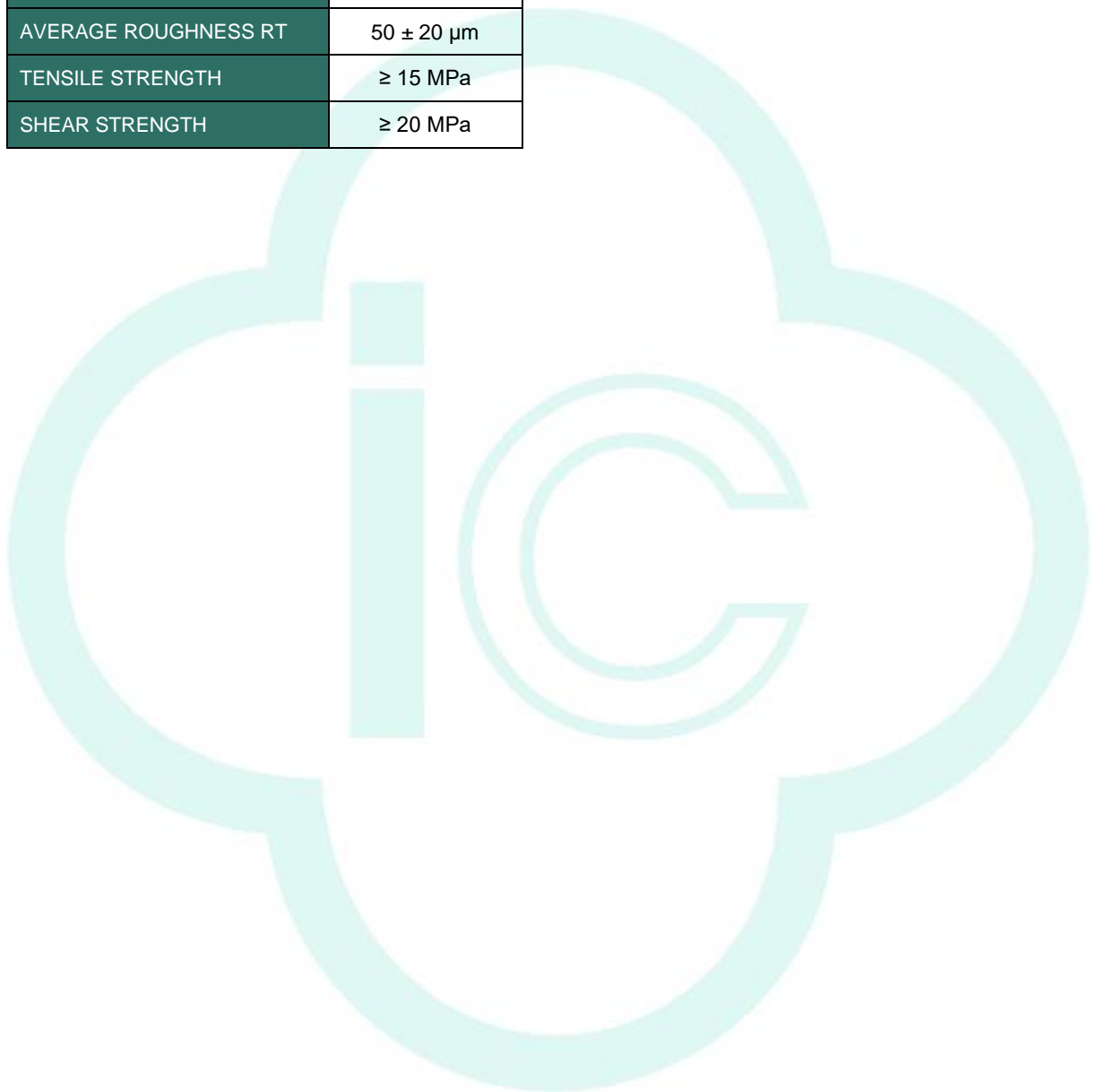


Figure 36: Glenoid Cementless Round

Table 4: Glenoid Cementless Round - Coating Specifications for HA

CHARACTERISTICS	VALUE
	HA (Surface Specification SUR_B3)
COATING THICKNESS	90 ± 30 µm

CHARACTERISTICS	VALUE
	HA (Surface Specification SUR_B3)
POROSITY	≤ 30%
AVERAGE ROUGHNESS RA	8 ± 3 μm
AVERAGE ROUGHNESS RT	50 ± 20 μm
TENSILE STRENGTH	≥ 15 MPa
SHEAR STRENGTH	≥ 20 MPa



12.4. MUTARS® Humerus Stems, Stem Extensions, and End Piece

MUTARS® Humerus Stem Cemented

The MUTARS® Humerus Stem Cemented and MUTARS® Humerus Stem Type A Modular Cemented have a sandblasted surface to enhance cement fixation. These stems are available uncoated and with a Titanium Nitride (TiN) coating that is applied circumferentially on the stem.



Figure 37: MUTARS® Humerus Stem Cemented with TiN

Table 5: MUTARS® Humerus Stem Cemented - Coating Specifications for TiN

CHARACTERISTICS	VALUE
	TiN (Surface Specification SUR_A1)
COATING TECHNOLOGY	PVD-Arc
COATING THICKNESS	5.5 ± 1.5 µm
COATING HARDNESS	2400 ± 400 HV
POROSITY	/
AVERAGE ROUGHNESS RA	< 0.05 µm
AVERAGE ROUGHNESS RT	/
TENSILE STRENGTH	≥ 22 MPa
SHEAR STRENGTH	/
ADHESIVE STRENGTH ROCKWELL C	0 - 1
ADHESIVE STRENGTH MANDREL BENDING TEST	No layer delamination

MUTARS® Humerus Stem Cementless

The MUTARS® Humerus Stem Cementless has a porous corundum blasted surface for better bone ingrowth and has a Hydroxyapatite (HA) coating that provides bone fixation, complies with ISO 13779 requirements and is applied circumferentially on the stem. It is also available uncoated. The tip of the stem is highly polished.



Figure 38: MUTARS® Humerus Stem Cementless HA

Table 6: MUTARS® Humerus Stem Cementless - Coating Specifications for HA

CHARACTERISTICS	VALUE
	HA (Surface Specification SUR_B3)
COATING THICKNESS	90 ± 30 µm
POROSITY	≤ 30%
AVERAGE ROUGHNESS RA	8 ± 3 µm
AVERAGE ROUGHNESS RT	50 ± 20 µm
TENSILE STRENGTH	≥ 15 MPa
SHEAR STRENGTH	≥ 20 MPa

MUTARS® Humerus Stem Type A Modular Cementless

The MUTARS® Humerus Stem Type A Modular Cementless has a corundum blasted surface and the tip of the stem is highly polished.

MUTARS® EPORE® HA Collar Humerus

The MUTARS® EPORE® HA Collar Humerus incorporate the highly porous EPORE® structure and has a Tricalcium Phosphate (TCP) coating. The EPORE® structure has a high porosity and a low modulus of elasticity so it can enhance biological ingrowth. The structure is characterized by rods of 330-390 µm thickness, which are arrayed in a way that resembles cancellous bone structures.

Table 7: MUTARS® EPORE® HA Collar Humerus – EPORE® Specification and Coating Specification for TCP

CHARACTERISTICS	VALUE	
	EPORE® (Surface Specification G1)	TCP (Surface Specification B1)
MANUFACTURING PROCESS	Additive Manufacturing	/
POROSITY	61% ± 8%	/
SPECIFIC E-MODULE	3.1 GPa ± 0.6 GPa	/
ROD DIAMETER	360 µm ± 50 µm	/
COATING THICKNESS	/	20 ± 10 µm

CHARACTERISTICS	VALUE	
	EPORE® (Surface Specification G1)	TCP (Surface Specification B1)
TENSILE STRENGTH	/	≥ 15 MPa
PHASE COMPOSITION ACC. TO FTIR	/	≥ 70% brushite ≤ 30% HA

AGILON® Stem Cementless

The AGILON® Stem Cementless has a porous corundum blasted surface for better bone ingrowth. The stem tip is highly polished (Ra = 0.1 µm).

AGILON® Stem Cemented

The AGILON® Stem Cemented has a sand blasted surface finish for use with bone cement. These stems are available uncoated and with a Titanium Nitride (TiN) coating that is applied circumferentially.

Table 8: AGILON® Stem Cemented - Coating Specifications for TiN

CHARACTERISTICS	VALUE
	TiN (Surface Specification SUR_A1)
COATING PROCESS	PVD-Arc
COATING THICKNESS	5.5 ± 1.5 µm
COATING HARDNESS	2400 ± 400 HV
AVERAGE ROUGHNESS RA	< 0.05 µm
TENSILE STRENGTH	≥ 22 MPa
ADHESIVE STRENGTH ROCKWELL C	0 - 1
ADHESIVE STRENGTH MANDREL BENDING TEST	No layer delamination

MUTARS® Humerus Extension Piece, MUTARS® Humerus Connecting Part, MUTARS® Humerus

End Piece, MUTARS® Humerus Reducer

The MUTARS® Humerus Extension Piece, MUTARS® Humerus Connecting Part, MUTARS® Humerus Reducer have a sand blasted surface finish. They are available uncoated and with silver coating that is applied circumferentially. The MUTARS® Humerus End Piece has a sand blasted surface finish. It is available uncoated and with silver coating applied to the cap.



Figure 39: MUTARS® Humerus Extension Piece, Connecting Part, Reducer and End Piece

Table 9: MUTARS® Humerus Extension Piece, Connecting Part, Reducer and End Piece - 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

Table 10: MUTARS® Humerus Extension Piece, Connecting Part, Reducer and End Piece – Surface Area and Silver Mass

REF NUMBER	ITEM DESCRIPTION	SIZE	SURFACE AREA SILVER COATING [mm ²]	MASS[MM] SILVER [g]
52200020S	MUTARS® humerus extension piece silver	20 mm	1250	0.26
52200040S	MUTARS® humerus extension piece silver	40 mm	2381	0.50
52200060S	MUTARS® humerus extension piece silver	60 mm	3673	0.77
52210080S	MUTARS® humerus connecting part silver	80 mm	4590	0.96
52200001S	MUTARS® humerus End piece silver	/	755	0.16
52210000S	MUTARS® humerus reducer piece silver	10 mm	524	0.11
52210100S	MUTARS® humerus reducer piece silver	100 mm	5935	1.25
52500000S	MUTARS® distal humerus silver incl. axle, safety screw and 2 locking screws	50 mm	4590	0.96

12.5. MUTARS® Distal Humerus and Proximal Ulna

MUTARS® Distal Humerus

The MUTARS® Distal Humerus 50mm is available uncoated, with a Titanium Niobium Nitride (TiNbN) coating and with a silver coating. The MUTARS® Distal Humerus Bushing and the MUTARS® Axle for Distal Humerus have a highly polished surface.

The MUTARS® Distal Humerus HD 50mm is available uncoated and with a silver coating. The MUTARS® Axle for Distal Humerus HD has a highly polished surface.

The MUTARS® Distal Humerus 30mm and Distal Humerus HD 30mm are uncoated.

The MUTARS® Distal Humerus with a length of 30 mm is overall high polished while the Distal Humerus with a length of 50 mm is proximally sandblasted and distally high polished. The sand blasted part provides a silver coating which is applied circumferentially.

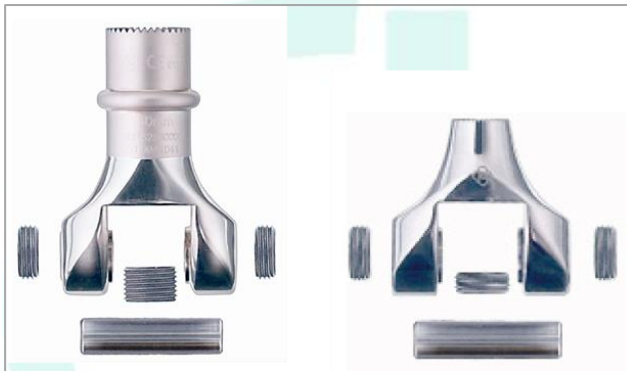


Figure 40: MUTARS® Distal Humerus 50mm (left) and Distal Humerus 30mm (right)

Table 11: MUTARS® Distal Humerus - Coating Specifications for TiNbN and Silver

CHARACTERISTICS	VALUE		
	TiNbN (Surface Specification SUR_A2)	Gold (Surface Specification SUR_E1)	Silver (Surface Specification SUR_F1)
COATING PROCESS	PVD-Arc	/	/
COATING THICKNESS	4.5 ± 1.5 µm	>0.2µm AuCo0,2 on adhesive layer	15 ± 5 µm
COATING HARDNESS	2400 ± 400 HV	/	/
AVERAGE ROUGHNESS RA	< 0.05 µm	/	/
TENSILE STRENGTH	≥ 22 MPa	No delamination of coating on implant surface	According to thermal shock equipment DIN EN ISO 4521:2009-1 Annex C-C.6
ADHESIVE STRENGTH ROCKWELL C	1 - 4	/	/
APPEARANCE	/	Sealed golden coating	Silver white, satin metal layer

Table 12: MUTARS® Distal Humerus - Surface Area and Silver Mass

REF NUMBER	ITEM DESCRIPTION	SIZE	SURFACE AREA SILVER COATING [mm ²]	MASS[MM] SILVER [g]
5250000S	MUTARS® distal humerus silver incl. axle, safety screw and 2 lock screws	50 mm	4590	0.96
5251000S	MUTARS® dist. humerus HD silver incl. axle, safety screw and 2 locking screws	50 mm	4766	0.75

PE Bearing

The surfaces of the PE Bearings FC and SC are machined without post-treatment.

MUTARS® Ulnar Component Cemented

The MUTARS® Ulnar Component Cemented has a sandblasted surface. It is available uncoated and with a Titanium Niobium Nitride (TiNbN) coating. The bushings have a highly polished surface.



Figure 41: MUTARS® Ulnar Component Cemented

Table 13: MUTARS® Ulnar Component Cemented - Coating Specifications for TiNbN

CHARACTERISTICS	VALUE
	TiNbN (Surface Specification SUR_A2)
COATING PROCESS	PVD-Arc
COATING THICKNESS	4.5 ± 1.5 µm
COATING HARDNESS	2400 ± 400 HV
AVERAGE ROUGHNESS RA	< 0.05 µm
TENSILE STRENGTH	≥ 22 MPa

CHARACTERISTICS	VALUE
	TiNbN (Surface Specification SUR_A2)
ADHESIVE STRENGTH ROCKWELL C	1 - 4
ADHESIVE STRENGTH MANDREL BENDING TEST	PVD-Arc

The MUTARS® Ulnar Component HD Cemented has a sandblasted surface. It is available uncoated and with a Titanium Niobium Nitride (TiN) coating. The bushings have a highly polished surface.

Table 14: MUTARS® Ulnar Component HD Cemented - Coating Specifications for TiN

CHARACTERISTICS	VALUE
	TiN (Surface Specification SUR_A1)
COATING PROCESS	PVD-Arc
COATING THICKNESS	5.5 ± 1.5 µm
COATING HARDNESS	2400 ± 400 HV
AVERAGE ROUGHNESS RA	< 0.05 µm
TENSILE STRENGTH	≥ 22 MPa
ADHESIVE STRENGTH ROCKWELL C	0 - 1
ADHESIVE STRENGTH MANDREL BENDING TEST	No layer delamination

MUTARS® Ulna Anchorage Cementless and MUTARS® Ulnar Component HD Cementless

The MUTARS® Ulna Anchorage Cementless and MUTARS® Ulnar Component HD Cementless have a double layer commercially pure Titanium (cpTi) and a Hydroxyapatite (HA) coating to provide bone fixation. The distal end is highly polished. The bushings also have a highly polished surface. The MUTARS® Ulna Anchorage Cementless is also available with a Titanium Niobium Nitride (TiNbN) coating.



Figure 42: MUTARS® Ulna Anchorage Cementless

Table 15: MUTARS® Ulna Anchorage Cementless and MUTARS® Ulnar Component HD Cementless - Coating Specifications for cpTi and HA

CHARACTERISTICS	VALUE	
	cpTi <i>(Surface Specification SUR_C6)</i>	HA <i>(Surface Specification SUR_B3)</i>
COATING PROCESS	APS	/
COATING THICKNESS	250 ± 50 µm	90 ± 30 µm
POROSITY	10 – 30%	≤ 30%
AVERAGE ROUGHNESS RA	5 -55 µm	8 ± 3 µm
AVERAGE ROUGHNESS RT	125 – 225 µm	50 ± 20 µm
TENSILE STRENGTH	≥ 22 MPa	≥ 15 MPa
SHEAR STRENGTH	≥ 20 MPa	≥ 20 MPa

MUTARS® Proximal Ulna

The MUTARS® Proximal Ulna and MUTARS® Proximal Ulna HD are proximally sandblasted and distally high polished. The sandblasted part provides a silver coating which is applied circumferentially. They are also available as uncoated version. The MUTARS® Proximal Ulna HD is also available with TiN-coating.



Figure 43: MUTARS® Proximal Ulna

Table 16: MUTARS® Proximal Ulna - 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

Table 17: MUTARS® Proximal Ulna HD - Coating Specifications for TiN

CHARACTERISTICS	VALUE
	TiN (Surface Specification SUR_A1)
COATING PROCESS	PVD-Arc
COATING THICKNESS	5.5 ± 1.5 µm
COATING HARDNESS	2400 ± 400 HV
AVERAGE ROUGHNESS RA	< 0.05 µm
TENSILE STRENGTH	≥ 22 MPa
ADHESIVE STRENGTH ROCKWELL C	0 - 1
ADHESIVE STRENGTH MANDREL BENDING TEST	No layer delamination

Table 18: MUTARS® Proximal Ulna – Surface Area and Silver Mass

REF NUMBER	ITEM DESCRIPTION	SIZE	SURFACE AREA SILVER COATING (mm²)	MASS SILVER [g]
52500030S	MUTARS® proximal ulna incl. safety screw silver	/	1858	0.39
52510030S	MUTARS® prox. ulna HD silver incl. safety screw	/	1667	0.26

13. Sizes and Dimensions

13.1. MUTARS® Component Connections

MUTARS® and AGILON® Cylindrical Fit Connection

Both the MUTARS® and AGILON® Cylindrical Fit Connection are provided by a precise male / female cylindrical fit and a serration connection of interdigitating 36 teeth to provide rotational stability. The AGILON® Cylindrical Fit Connection differs from the MUTARS® cylindrical fit in its diameter (9 mm opposed to 12 mm).

13.2. MUTARS® Humerus Screws

MUTARS® Humerus Screw

The MUTARS® Humerus Screw is available in four different lengths from 15 mm to 75 mm.

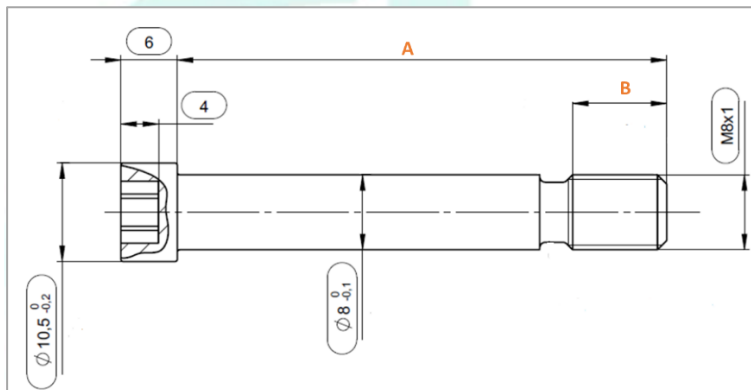


Figure 44: MUTARS® Humerus Screw - Dimensions

Table 19: MUTARS® Humerus Screw - Dimensions

DIMENSION	SIZE [mm]			
	M8 x 15	M8 x 35	M8 x 55	M8 x 75
A [mm]	12	32	52	72
B [mm]	8.5	10	10	10

MUTARS® Screw for Distal Humerus

The MUTARS® Screw for Distal Humerus is available in different lengths as standard and extended version.

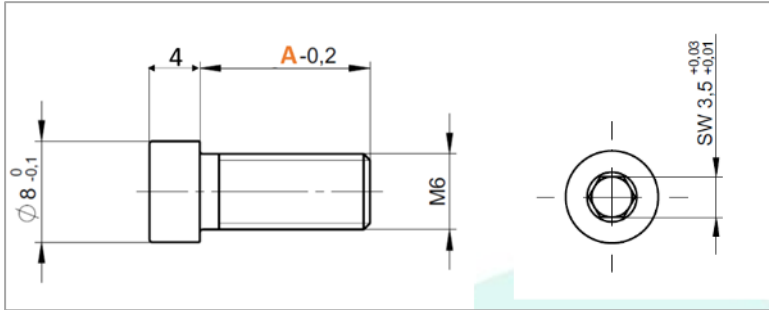


Figure 45: MUTARS® Screw for Distal Humerus 30mm (Standard) – Dimensions

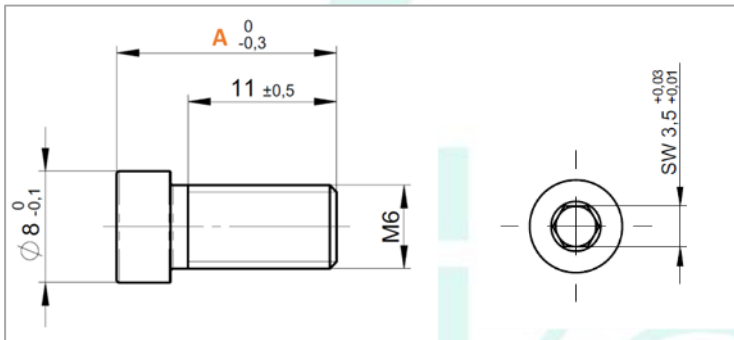


Figure 46: MUTARS® Screw for Distal Humerus 30mm (Extended) - Dimensions

Table 20: MUTARS® Screw for Distal Humerus Sizes (Standard and Extended) - Dimensions

DIMENSION	SIZE [mm]									
	Standard				Extended					
	M6 x 15	M6 x 20	M6 x 25	M6 x 30	M6 x 12.5	M6 x 20	M6 x 22.5	M6 x 25	M6 x 27.5	M6 x 30
A [mm]	13.5	18.5	23.5	28.5	16.3	23.8	26.3	28.8	31.3	33.8

13.3. MUTARS® Humerus Head

The MUTARS® Humerus Head 50mm is only available in one size.

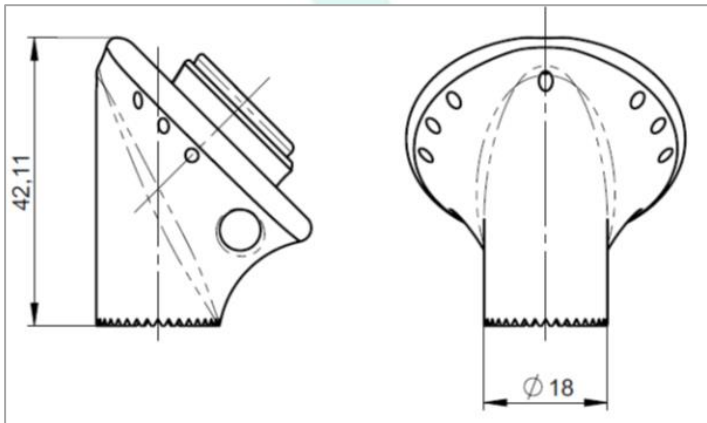


Figure 47: MUTARS® Humerus Head - Dimensions

13.4. MUTARS® Humerus Caps

MUTARS® Humerus Cap

The MUTARS® Humerus Cap is available in three sizes: small, medium, large.

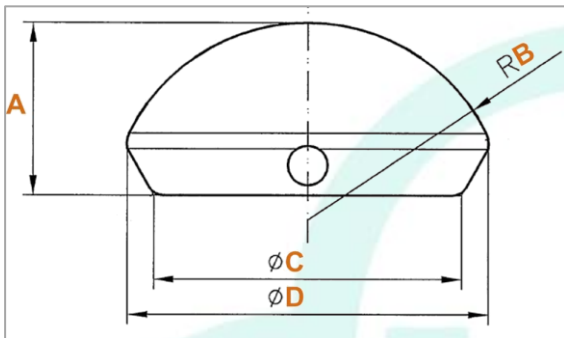


Figure 48: MUTARS® Humerus Cap – Dimensions

Table 21: MUTARS® Humerus Cap – Dimensions

DIMENSION	SIZE		
	SMALL	MEDIUM	LARGE
A [mm]	21.9		
B [mm]	21	23	25
C [mm]	38.7		
D [mm]	40.4	43	45.5

MUTARS® Humerus Cap Inverse

The MUTARS® Humerus Cap Inverse is available in three different sizes creating three different offsets: 0 mm, + 5 mm and +10 mm.

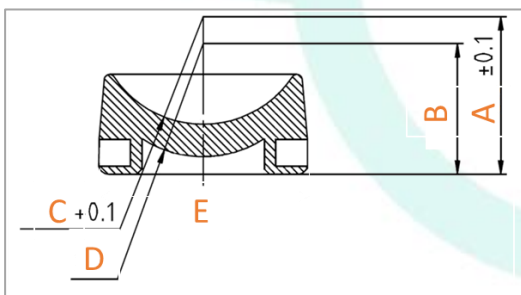


Figure 49: MUTARS® Humerus Cap Inverse - Dimensions

Table 22: MUTARS® Humerus Cap Inverse – Dimensions

DIMENSION	SIZE		
	0 mm	+5 mm	+10 mm
A [mm]	24.25	29.25	34.25
B [mm]	24.25		
C [mm]	R20		
D [mm]	R21		
E [mm]	39		

13.5. MUTARS® Glenoid / Glenosphere

Glenoid Cementless

The Cementless Glenoid Component is available in one version (round) to match the patients' individual anatomy.

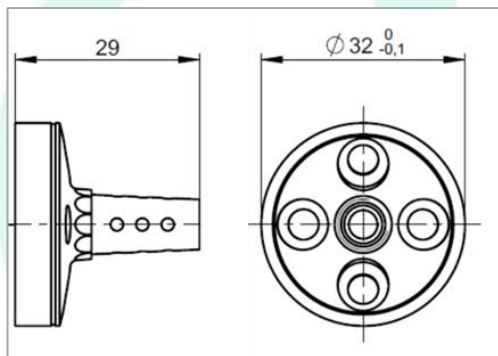


Figure 50: Glenoid Cementless Round - Dimensions

MUTARS® Glenosphere

The MUTARS® Glenosphere is only available in one size.

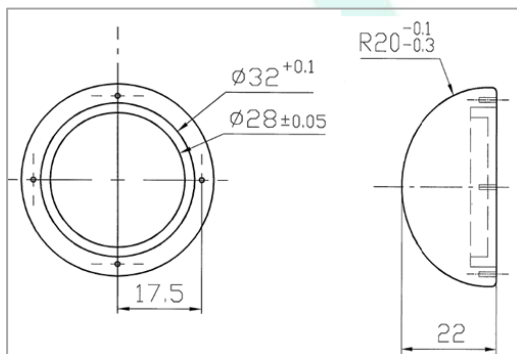


Figure 51: MUTARS® Glenosphere - Dimensions

Glenoid Cemented

The AGILON® PE-Glenoid Cemented is available in three sizes (2, 3, 4).

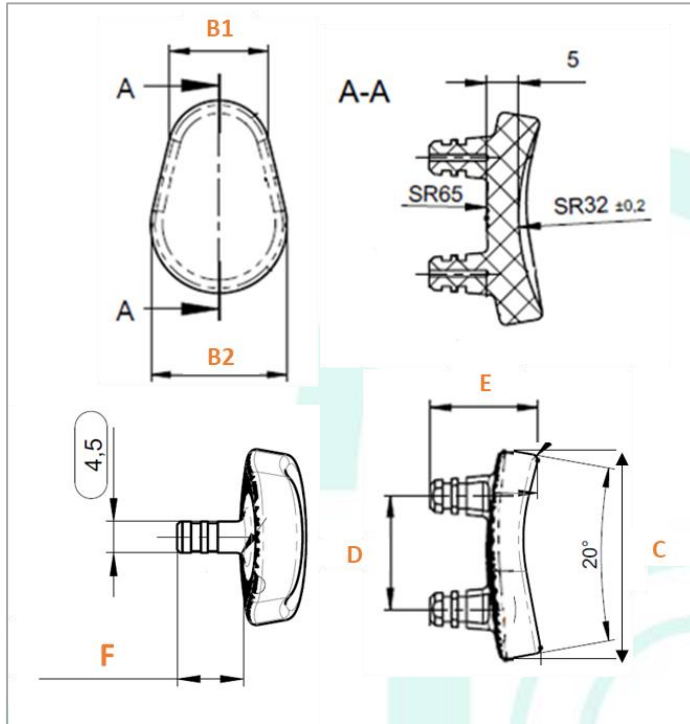


Figure 52: AGILON® PE-Glenoid Cemented - Dimensions

Table 23: AGILON® PE-Glenoid Cemented – Dimensions

DIMENSION	SIZE		
	2	3	4
B1 [mm]	16.8	18.7	22.5
B2 [mm]	23.2	25.2	29.1
C [mm]	33	35.8	39
D [mm]	18	21	26
E[mm]	17.23	17.9	19.06
F [mm]	9.35	9.5	9.85

13.6. MUTARS® Humerus Stems, Stem Extensions, and End Piece

MUTARS® Humerus Stem Cemented

The MUTARS® Humerus Stem Cemented is available in three lengths from 75 mm to 150 mm and nine diameters from 8 mm to 16 mm.

Table 24: MUTARS® Humerus Stem Cemented - Dimensions

LENGTH [mm]	DIAMETER [mm]								
	8	9	10	11	12	13	14	15	16
75									
100									
150									

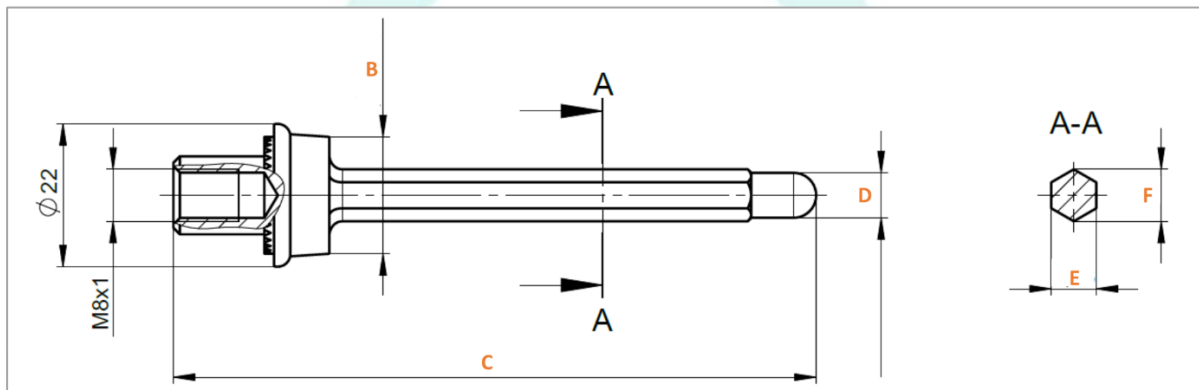


Figure 53: MUTARS® Humerus Stem Cemented - Dimensions

SIZE	75 mm	100 mm	150 mm
LENGTH C[mm]	99	124	174

Table 25: MUTARS® Humerus Stem Cemented – Dimensions

DIAMETER [mm]	DIMENSION			
	B [mm]	D [mm]	E [mm]	F [mm]
Ø8	Ø18	Ø6.93	6.93	8
Ø9	Ø19	Ø7.79	7.79	9
Ø10	Ø20	Ø8.66	8.66	10
Ø11	Ø21	Ø9.53	9.53	11
Ø12	Ø22	Ø10.39	10.39	12
Ø13	Ø23	Ø11.26	11.26	13
Ø14	Ø24	Ø12.12	12.12	14
Ø15	Ø25	Ø12.99	12.99	15
Ø16	Ø26	Ø13.86	13.86	16

MUTARS® Humerus Stem Type A Modular Cemented

The MUTARS® Humerus Stem Type A Modular Cemented is available in the three length from 75 mm to 150 mm and nine diameters from 8 mm to 16 mm.



Table 26: MUTARS® Humerus Stem Type A Modular Cemented – Dimensions

LENGTH [mm]	DIAMETER [mm]								
	8	9	10	11	12	13	14	15	16
75									
100			*	*	*	*	*	*	*
150			*	*	*	*	*	*	*

* provide two cross holes (Ø4mm) for optional cancellous screw (Ø3.5mm) for additional rotation stability

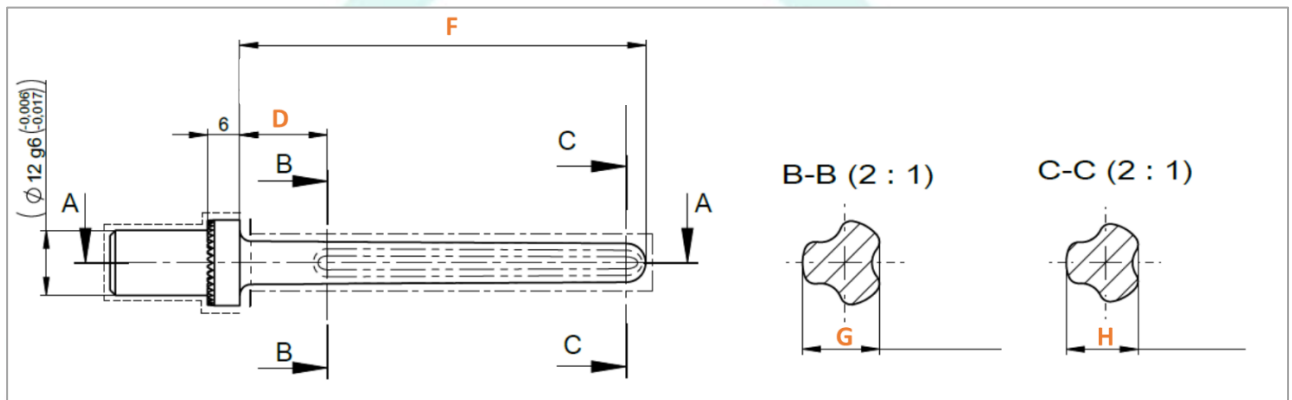


Figure 54: MUTARS® Humerus Stem Type A Modular Cemented - Dimensions

SIZE	75 mm	100 mm	150 mm
LENGTH D [mm]	16.2	16.2	16.2
LENGTH F [mm]	75	100	150

Table 27: MUTARS® Humerus Stem Type A Modular Cemented – Dimensions

DIAMETER [mm]	DIMENSION	
	G [mm]	H [mm]
Ø8	7.11	6.64
Ø9	8.18	7.71
Ø10	9.14	8.66
Ø11	10.12	9.62
Ø12	11.18	10.68
Ø13	12.23	11.73
Ø14	13.27	12.77
Ø15	14.31	13.81
Ø16	15.34	14.85

MUTARS® Humerus Stem Cementless

The MUTARS® Humerus Stem Cementless is available in the length of 75 mm and eleven (11) diameters from 7 mm to 17 mm.

LENGTH [mm]	DIAMETER [mm]										
	7	8	9	10	11	12	13	14	15	16	17
75			*	*	*	*	*	*	*	*	*

* provide a cross hole (Ø4mm) for optional cancellous screw (Ø3.5mm) for additional rotation stability

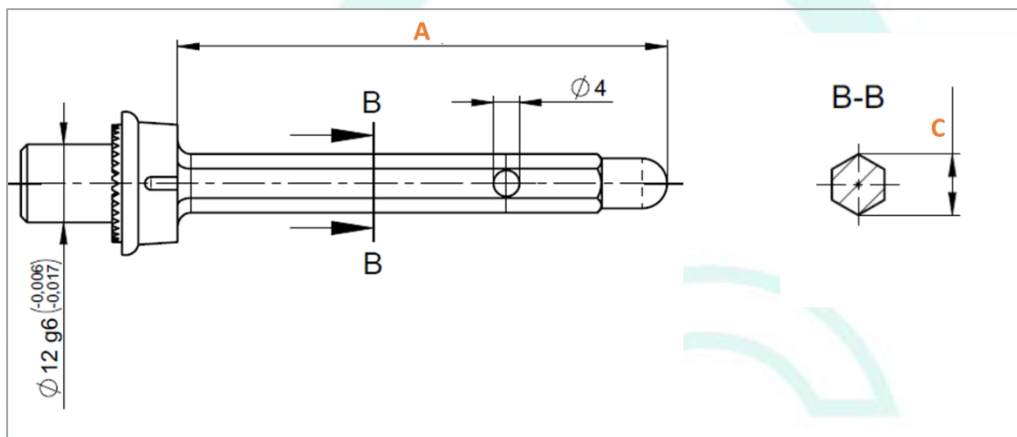


Figure 55: MUTARS® Humerus Stem Cementless - Dimensions

Table 28: MUTARS® Humerus Stem Cementless - Dimensions

SIZE	Ø7	Ø8	Ø9	Ø10	Ø11	Ø12	Ø13	Ø14	Ø15	Ø16	Ø17
A [mm]	75										
C [mm]	7	8	9	10	11	12	13	14	15	16	17

MUTARS® Humerus Stem Type A Modular Cementless

The MUTARS® Humerus Stem Type A Modular Cementless is available in three length ranging from 75 mm to 150 mm and in up to 10 different diameters (7 mm to 16 mm).

Table 29: MUTARS® Humerus Stem Type A Modular Cementless - Dimensions

LENGTH [mm]	DIAMETER [mm]									
	7	8	9	10	11	12	13	14	15	16
75										
100			*	*	*	*	*	*	*	*
150			*	*	*	*	*	*	*	*

* provide two cross holes (Ø4mm) for optional cancellous screw (Ø3.5mm) for additional rotation stability

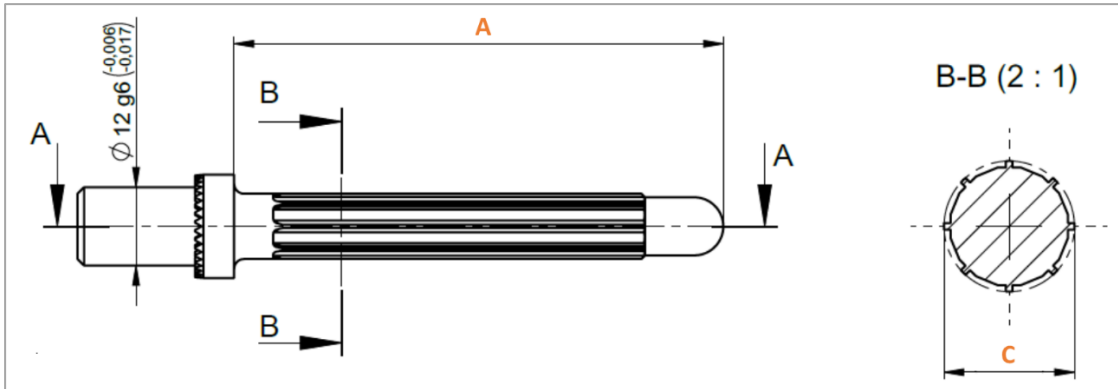


Figure 56: MUTARS® Humerus Stem Type A Modular Cementless - Dimensions

Table 30: MUTARS® Humerus Stem Type A Modular Cementless - Dimensions

SIZE	75 mm	100 mm	150 mm
LENGTH A[mm]	75	100	150

SIZE	Ø 7	Ø 8	Ø 9	Ø 10	Ø 11	Ø 12	Ø 13	Ø 14	Ø 15	Ø 16
DIAMETER C [MM]	7	8	9	10	11	12	13	14	15	16

MUTARS® EPORE® HA Collar Humerus

The MUTARS® EPORE® HA Collar Humerus and MUTARS® EPORE® HA Collar Humerus with flange are available in different diameters (Ø18 to Ø24 mm).

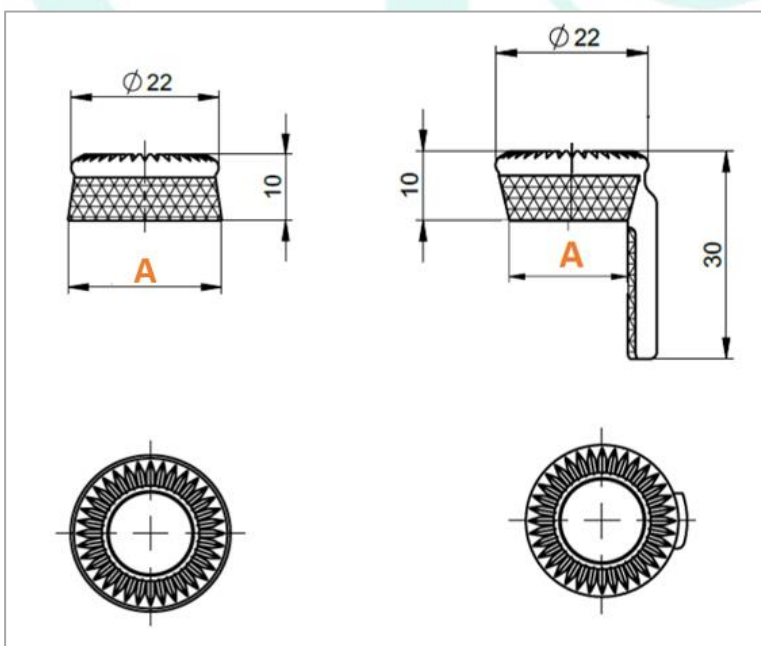


Figure 57: MUTARS® EPORE® HA Collar Humerus (left) and with flange (right) - Dimensions

SIZE	Ø 18	Ø 19	Ø 20	Ø 21	Ø 22	Ø 23	Ø 24
DIAMETER A [MM]	18.08	19.06	20.03	21	21.97	22.94	23.9

AGILON® Stem Cementless

The AGILON® Stem Cementless is available in length ranging from 30 to 240 mm (30 mm, 60 mm, 120 mm, 180 mm, and 240 mm) and in up to 9 different diameters (9 to 18 mm).

Table 31: AGILON® Stem Cementless - Dimensions

LENGTH [mm]	DIAMETER [mm]									
	9	10	11	12	13	14	15	16	17	18
30										
60	+									
120	+									
180	*	*	*	*	*	*	*	*		
240	*	*	*	*	*	*	*	*		

+ only AGILON® Stems Cementless with extended fit

* provide two cross holes (Ø4mm) for optional cancellous screw (Ø3.5mm) for additional rotation stability

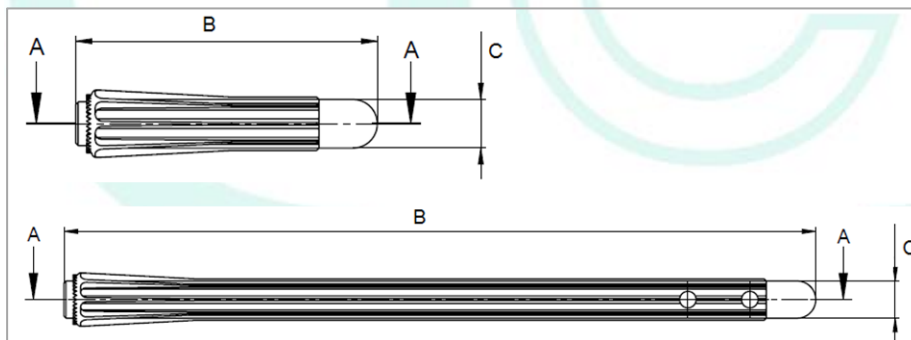


Figure 58: AGILON® Stem Cementless - Dimensions

Table 32: AGILON® Stem Cementless - Dimensions

SIZE	30 mm	60 mm	120 mm	180 mm	240 mm
LENGTH B [mm]	32.2	62.2	122.2	182.2	242.2

SIZE	Ø 9	Ø 10	Ø 11	Ø 12	Ø 13	Ø 14	Ø 15	Ø 16	Ø 17	Ø 18
DIAMETER C [MM]	9	10	11	12	13	14	15	16	17	18

AGILON® Stem Cemented

The AGILON® Stem Cemented is available in length ranging from 60 to 120mm (60 mm, 90 mm and 120 mm) and in up to 4 different diameters.

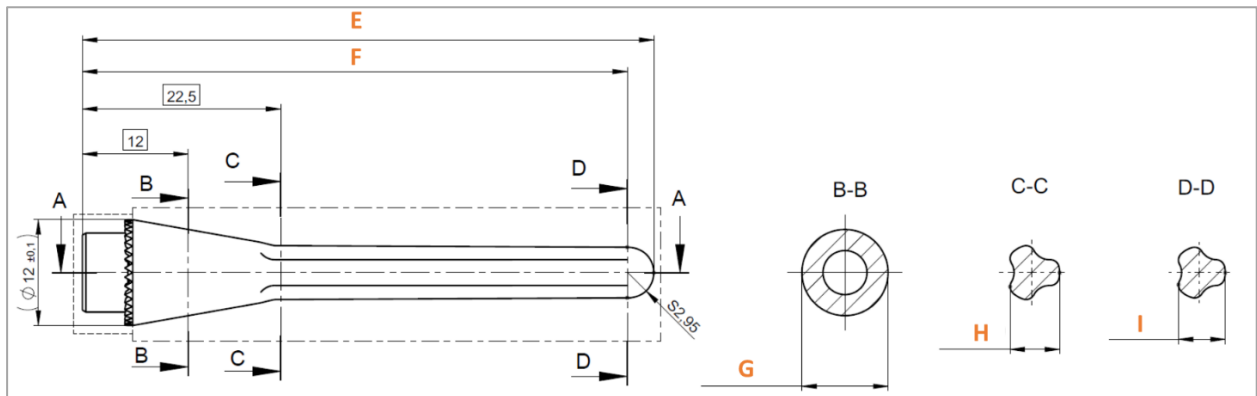


Figure 59: AGILON® Stem Cemented- Dimensions

Table 33: AGILON® Stem Cemented - Dimensions

SIZE [mm]	DIMENSION				
	E [mm]	F [mm]	G [mm]	H [mm]	I [mm]
6 x 60	64.8	61.8	$\varnothing 9.78$	5.6	5.3
8 x 60		61	$\varnothing 9.78$	7.5	7.2
10 x 60		59.9	$\varnothing 10.42$	9.7	9.3
12 x 60		59.1	$\varnothing 11.92$	11.2	10.8
6 x 90	94.8	92	$\varnothing 9.78$	5.6	5.1
8 x 90		91	$\varnothing 9.78$	7.5	6.9
10 x 90		90	$\varnothing 10.42$	9.7	9.1
12 x 90		89.3	$\varnothing 11.92$	11.2	10.5
6 x 120	124.8	122.3	$\varnothing 9.78$	5.6	4.8
8 x 120		121.3	$\varnothing 9.78$	7.5	6.7
10 x 120		120.3	$\varnothing 10.42$	9.7	8.8
12 x 120		120.3	$\varnothing 11.92$	11.2	10.3

AGILON® Extension Piece

The AGILON® Extension Piece is available in different lengths to create an individual length up to 17.5mm in steps of 2.5mm as needed.

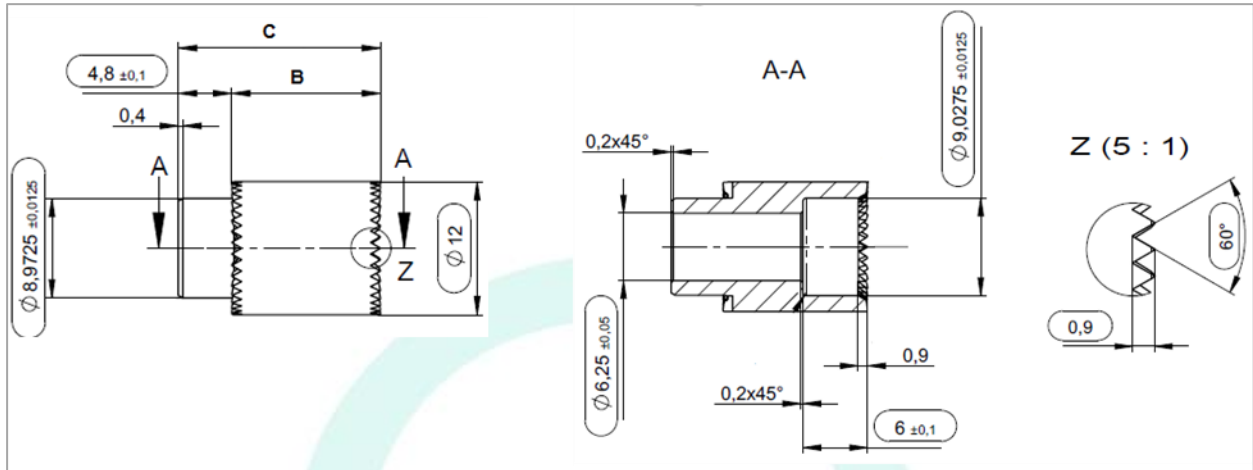


Figure 60: AGILON® Extension Piece - Dimensions

Table 34: AGILON® Extension Piece Standard Fit – Dimensions

DIMENSION	SIZE [mm]		
	5	7.5	10
A [MM]	2.2		
B [MM]	5	7.5	10
C [MM]	7.2	9.7	10.2

Table 35: AGILON® Extension Piece Extended Fit – Dimensions

DIMENSION	SIZE [mm]				
	7.5	10	12.5	15	17.5
A [MM]	4.8				
B [MM]	8.4	10.9	13.4	15.9	18.4
C [MM]	13.2	15.7	18.2	20.7	23.2
D [MM]	6				

MUTARS® Humerus Extension Piece

The MUTARS® Humerus Extension piece is available in lengths of 20, 40 and 60 mm.

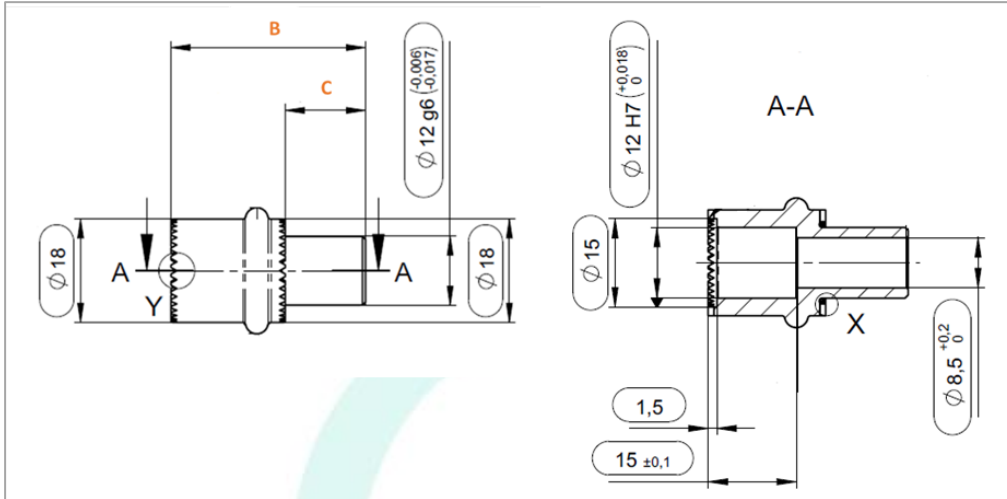


Figure 61: MUTARS® Humerus Extension Piece – Dimensions

Table 36: MUTARS® Humerus Extension Piece – Dimensions

DIMENSION	SIZE [mm]		
	20	40	60
B [MM]	34	54	74
C [MM]	14		

MUTARS® Humerus Connecting Part

The MUTARS® Humerus Connecting Part is available in 80 mm length.

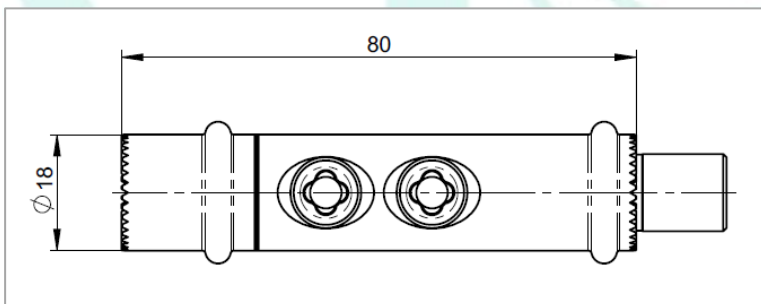


Figure 62: MUTARS® Humerus Connecting Part – Dimensions

MUTARS® Humerus End Piece

The MUTARS® Humerus End Piece is only available in one size.

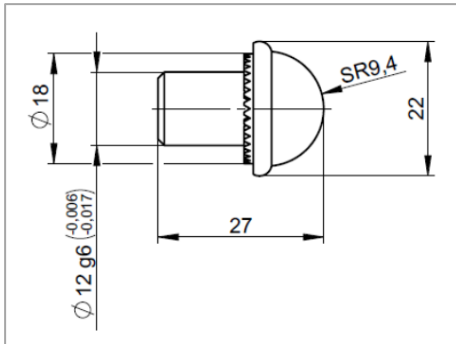


Figure 63: MUTARS® Humerus End Piece - Dimensions

MUTARS® Humerus Reducer

The MUTARS® Humerus Reducer is available in the length of 10 mm and 100 mm to match the patients' individual anatomy and adjust to the individual length.

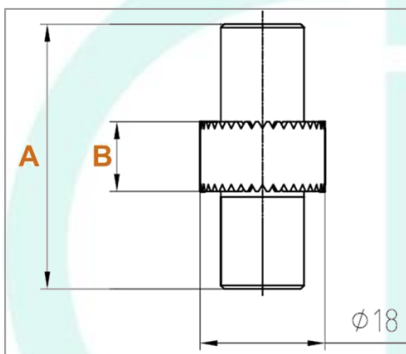


Figure 64: MUTARS® Humerus Reducer – Dimensions

Table 37: MUTARS® Humerus Reducer – Dimensions

SIZE	DIMENSION [mm]	
	A	B
10 mm	38	10
100 mm	128	100

13.7. MUTARS® Distal Humerus and Proximal Ulna

MUTARS® Distal Humerus

The MUTARS® Distal Humerus and MUTARS® Distal Humerus HD are available in a length of 30 mm and 50 mm.

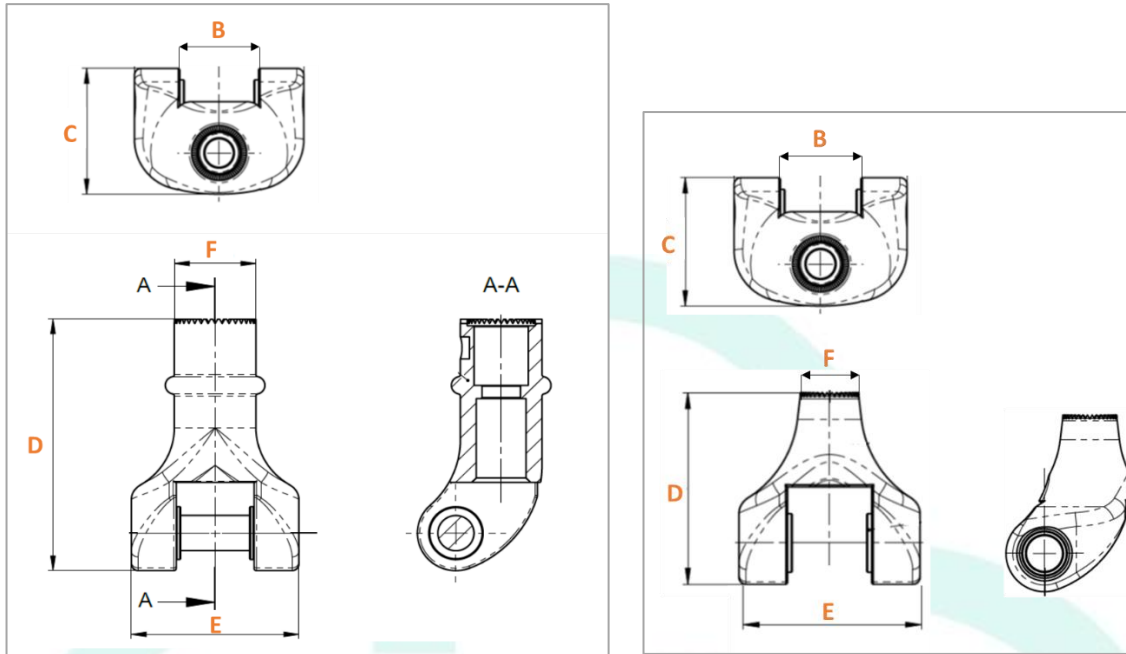


Figure 65: MUTARS® Distal Humerus 50mm (left) and 30mm (right) - Dimensions

Table 38: MUTARS® Distal Humerus – Dimensions

	DIMENSION [mm]				
	B	C	D	E	F
DISTAL HUMERUS 30mm	17.2	27.5	39.76	37	Ø12
DISTAL HUMERUS HD 30mm	19.4	27.5	39.36	32	Ø12
DISTAL HUMERUS 50mm	17.2	29.5	57	37	Ø18
DISTAL HUMERUS HD 50mm	19.4	27.5	57	32	Ø18

PE Bearing

The PE Bearing FC and SC are only available in one size respectively.

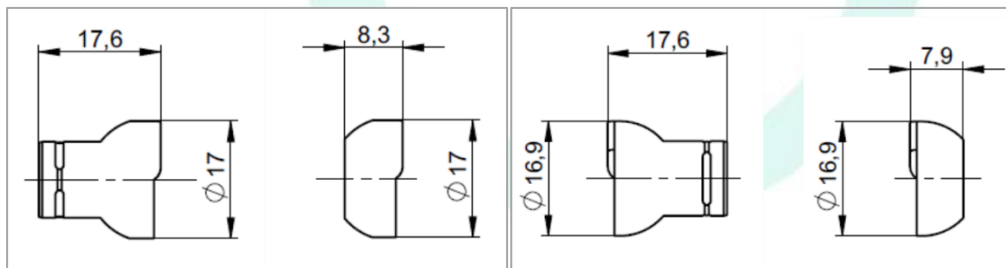


Figure 66: Part 1 and Part 2 of PE Bearing FC (left) and PE Bearing SC (right) - Dimensions

MUTARS® Ulnar Component Cemented

The MUTARS® Ulnar Component Cemented is available in left and right configurations in two lengths (70 mm and 100 mm) and the MUTARS® Ulnar Component HD Cemented is available in left and right configurations in three lengths (70 mm, 100 mm and 130 mm).

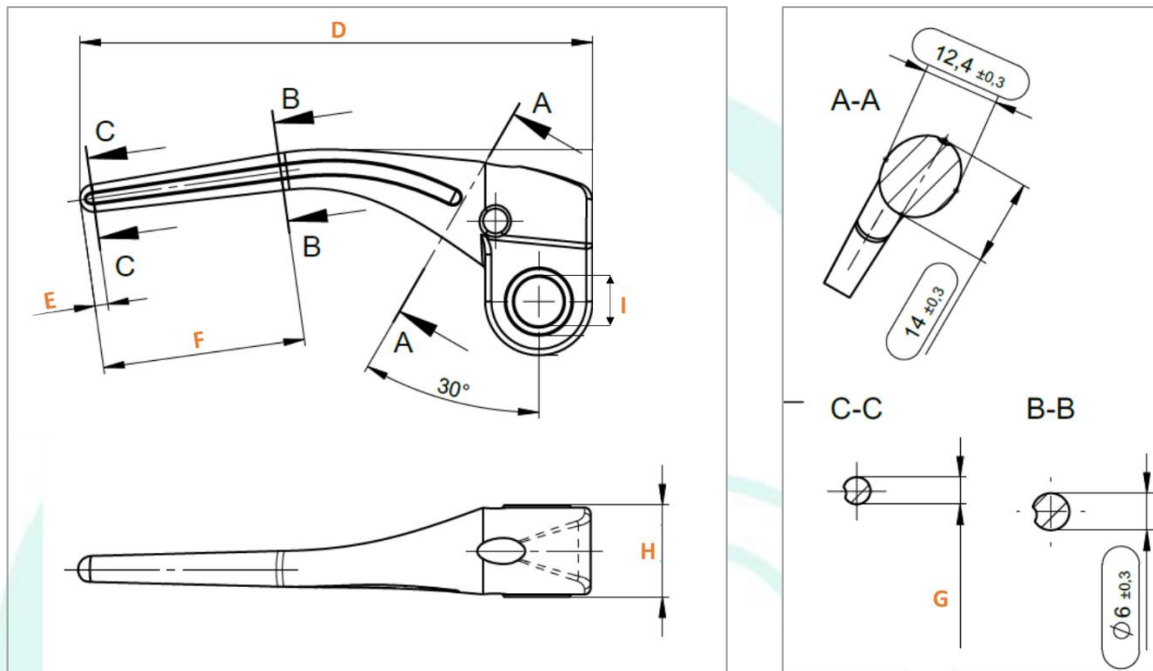


Figure 67: MUTARS® Ulnar Component Cemented - Dimensions

Table 39: MUTARS® Ulnar Component Cemented – Dimensions

		DIMENSION [mm]					
		D	E	F	G	H	I
MUTARS® ULNAR COMPONENT CEMENTED	70 mm	82.6	2.1	32.7	Ø4.4	14.8	Ø8 H7
	100 mm	108.7	1.4	59	Ø3	14.8	Ø8 H7
MUTARS® ULNAR COMPONENT HD CEMENTED	70 mm	78.71	1.95	28.69	Ø4.6	14	Ø11.5
	100 mm	108.66	1.42	58.98	Ø2.99	14	Ø11.5
	130 mm	138.67	1.4	89.26	Ø3.05	14	Ø11.5

MUTARS® Ulna Anchorage Cementless and MUTARS® Ulnar Component HD Cementless

The MUTARS® Ulna Anchorage Cementless and MUTARS® Ulnar Component HD Cementless are available in left and right configurations.

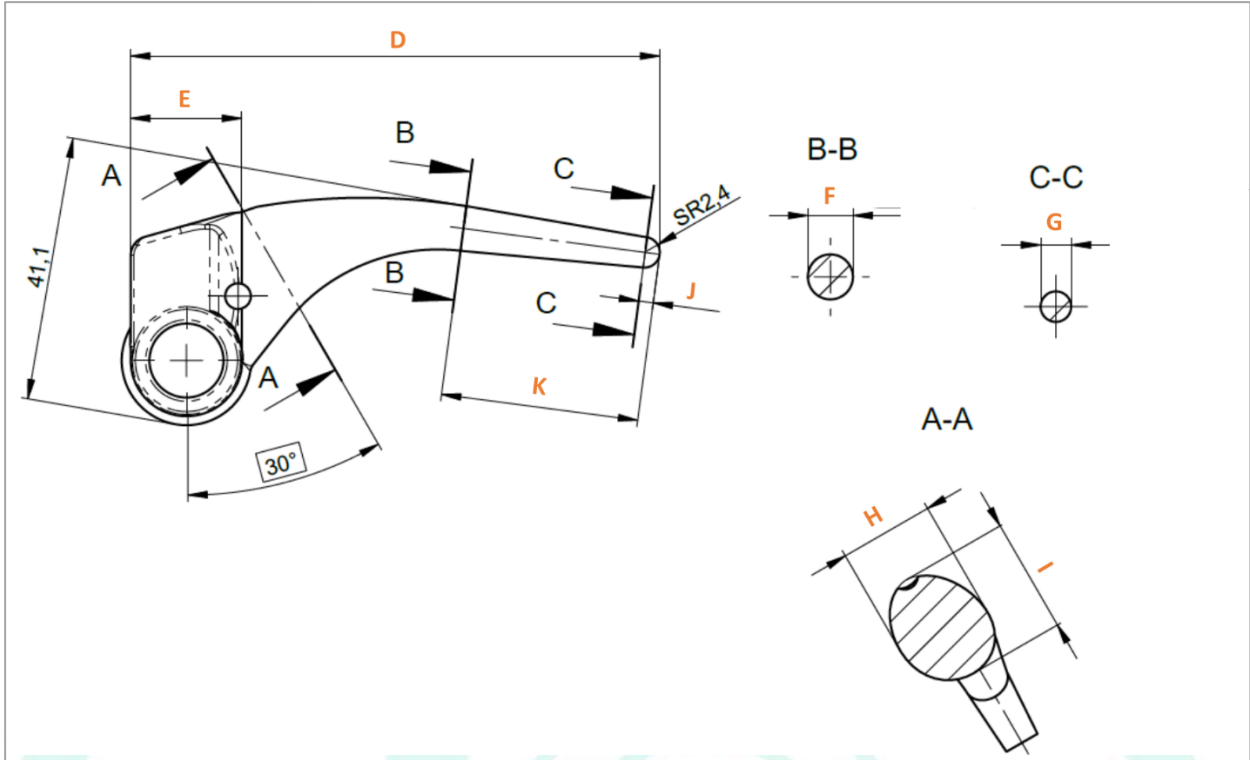


Figure 68: MUTARS® Ulna Anchorage Cementless – Dimensions

Table 40: MUTARS® Ulnar Component Cemented – Dimensions

	DIMENSION [mm]							
	D	E	F	G	H	I	J	K
MUTARS® ULNA ANCHORAGE CEMENTLESS	81.85	17.2	Ø7	Ø4.7	14.6	18	2.3	30.7
MUTARS® ULNAR COMPONENT HD CEMENTLESS	82.05	17.2	Ø7	Ø4.73	14.8	17.8	2.3	30.69

MUTARS® Ulna Stop

The MUTARS® Ulna Stop and MUTARS® Ulna Stop HD are only available in one size respectively.

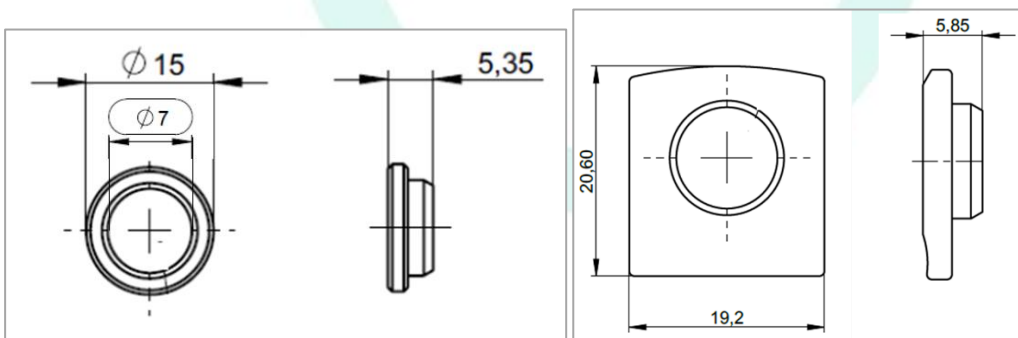


Figure 69: MUTARS® Ulna Stop (left) and MUTARS® Ulna Stop HD (right) - Dimensions

MUTARS® Proximal Ulna

The MUTARS® Proximal Ulna and MUTARS® Proximal Ulna HD are only available in one size.

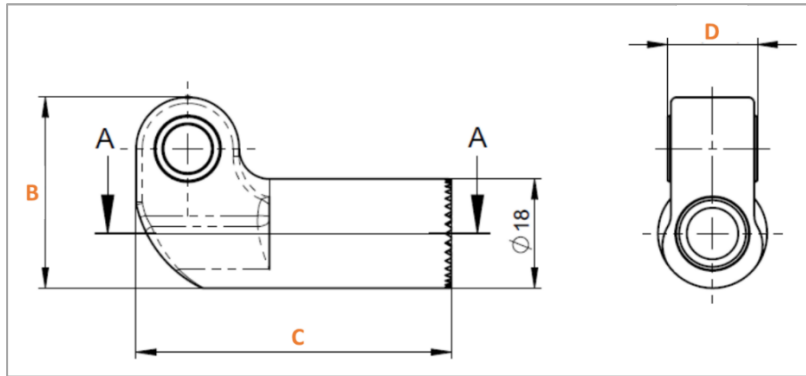


Figure 70: MUTARS® Proximal Ulna – Dimensions

Table 41: MUTARS® Proximal Ulna – Dimensions

	DIMENSION [mm]		
	B	C	D
PROXIMAL ULNA	31.5	52	14.8
PROXIAML ULNA HD	33.05	53.55	10

14. Compatibility

The detailed component compatibility is given in the tables of combination. The summary can be found in the attachment of the instructions for use.

- ⇒ See Doc. “Compatibility MUTARS® Humerus” in the folder “11 Kombinationstabellen”
- ⇒ See Doc. “09300095 MUTARS Tumor- und Revisionssystem Kombinationsmöglichkeiten_Anhang I” in the folder “05 Kennzeichnung\Gebrauchsinformation”

The components of the MUTARS® Humerus System are fully compatible and may only be used or combined with each other. Combinations with components from other manufacturers is not permitted.

15. Warnings

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

- ⇒ See Doc. Instruction for Use “09300013 MUTARS Tumor- and Revision System” in the folder “05 Kennzeichnung\Gebrauchsinformation”

16. Product List (Identification of the products)

For identification of the products by their respective number, please refer to the product list.

⇒ See Doc. “Fbl_732-1-14_Produktliste_MUTARS® Humerus System” (Productlist MUTARS® Humerus 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 Howmedica MRS from Stryker.

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ABBREVIATION	ABBREVIATED TERM
CoCrMo	Cobalt Chrome Molybdenum
cpTi	Commercially Pure Titanium
HA	Hydroxylapatite
PE	Polyethylene
TCP	Tricalcium Phosphate
TiAl ₆ V ₄	Titanium 6 Aluminium 4 Vanadium
TiN	Titanium Nitride
TiNbN	Titanium Niobium Nitride
UHMW-PE	Ultra-High-Molecular-Weight Polyethylene

DOCUMENT REVISION HISTORY

DATE	REVISION	CHANGES	AUTHOR	COMMENTS
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03.09.2021	1	<ul style="list-style-type: none"> • Conversion acc. to MDR • Complete update 	J. Müller	ÄA 21-740, ÄA 21-709
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