

## Specificații Tehnice

		Numărul procedurii de achiziție:		ocds-b3wdp1-MD-1674818516778 din 04.02.2023				
		Obiectul achiziției:		Endoproteză oncologică (conform specificației atașate)				
Nr. Lot	Denumire Lot	Denumirea bunurilor și/sau a serviciilor	Modelul articolului	Țara de origine	Producătorul	Specificarea tehnică deplină solicitată de către autoritatea contractantă	Specificarea tehnică deplină propusă de către ofertant	Standarde de referință
1	2	3	4	5	6	7	8	9
1	Endoproteză individuală oncologică modulară cimentată / necimentată de cot cu substituția extremității distale a humerusului și/sau a extremității proximale a ulnei	Endoproteză individuală oncologică modulară cimentată / necimentată de cot cu substituția extremității distale a humerusului și/sau a extremității proximale a ulnei-	MUTARS® Distal humerus 50 mm incl. axle, safety screw and 2 lock screws humerus cap, Proximal ulna incl. safety screw, ulna stop, cancellous screw 4mm, attachment tube, humerus screw, humerus stem cemented, humerus tension piece, humerus connection piece	Germania	implantcast GmbH	Endoproteză oncologică de producție individuală pentru articulația cotului, cu înlocuirea humerusului distal, cu înlocuirea ulnei proximale (denumită în continuare Endoproteză). Produsul este realizat prin topirea cu laser a pulberii de aliaj de titan, folosind un software conceput pentru proiectarea unor astfel de produse. Produsul este fabricat individual conform datelor de tomografie computerizată (conform protocolului Antreprenorului) (denumite în continuare CT) și imaginilor cu raze X cu marcaje furnizate de Client. Proxim, produsul se fixează cu o tijă cilindrică lustruită de ciment cu șanțuri pentru ciment osos în canalul medular al humerusului, care are o lungime și un diametru estimate, conform datelor CT. Trecerea la piciorul cilindric este conică, conform datelor CT. La distal, produsul este atașat cu o tijă conică cimentată lustruită, cu șanțuri pentru ciment osos în canalul medular al ulnei, care are lungimea și diametrul estimate, conform datelor CT. Conectivitatea produsului este asigurată de un mecanism balama. Tip de atașament proximal: tijă cilindrică* Fixarea cu țesuturile biologice a părții proximale: Ciment* Diametrul țije, mm: 6-10 Lungimea țije, mm: minim 70 Diametrul corpului părții distale fără tijă, mm: 20** Lungimea corpului părții distale fără tijă, mm: 134** Tip de atașament distal: tijă conică* Fixare cu țesuturi biologice a părții distale: Cimentată* Diametrul minim al țije, mm: 4 Diametru maxim al țije, mm: 8,5 Lungimea țije, mm: minim 50** Dimensiunile corpului părții distale fără tijă, mm: 20x22** Lungimea corpului părții distale, excluzând tijă, mm: 36** Diametru balama cilindrică, mm: 5** Amplitudine de flexie, grade: 60° Amplitudinea extensiei, grade: 180° *Determinat de Aplicația Clientului ** Determinat de datele CT	Endoproteză oncologică de producție individuală pentru articulația cotului, cu înlocuirea humerusului distal, cu înlocuirea ulnei proximale (denumită în continuare Endoproteză). Produsul este realizat prin topirea cu laser a pulberii de aliaj de titan, folosind un software conceput pentru proiectarea unor astfel de produse. Produsul este fabricat individual conform datelor de tomografie computerizată (conform protocolului Antreprenorului) (denumite în continuare CT) și imaginilor cu raze X cu marcaje furnizate de Client. Proxim, produsul se fixează cu o tijă cilindrică lustruită de ciment cu șanțuri pentru ciment osos în canalul medular al humerusului, care are o lungime și un diametru estimate, conform datelor CT. Trecerea la piciorul cilindric este conică, conform datelor CT. La distal, produsul este atașat cu o tijă conică cimentată lustruită, cu șanțuri pentru ciment osos în canalul medular al ulnei, care are lungimea și diametrul estimate, conform datelor CT. Conectivitatea produsului este asigurată de un mecanism balama. Tip de atașament proximal: tijă cilindrică* Fixarea cu țesuturile biologice a părții proximale: Ciment* Diametrul țije, mm: 6-10 Lungimea țije, mm: minim 70 Diametrul corpului părții distale fără tijă, mm: 20** Lungimea corpului părții distale fără tijă, mm: 134** Tip de atașament distal: tijă conică* Fixare cu țesuturi biologice a părții distale: Cimentată* Diametrul minim al țije, mm: 4 Diametru maxim al țije, mm: 8,5 Lungimea țije, mm: minim 50** Dimensiunile corpului părții distale fără tijă, mm: 20x22** Lungimea corpului părții distale, excluzând tijă, mm: 36** Diametru balama cilindrică, mm: 5** Amplitudine de flexie, grade: 60° Amplitudinea extensiei, grade: 180° *Determinat de Aplicația Clientului ** Determinat de datele CT	ISO, CE
1	Endoproteză individuală oncologică modulară cimentată / necimentată de cot cu substituția extremității distale a humerusului și/sau a extremității proximale a ulnei	Set de instrumente gratuit în folosință	MUTARS® Instrumental Set	Germania	implantcast GmbH	Setul de instrumente oferit gratuit în folosință va corespunde următoarelor cerințe: 1. compatibil cu endoprotezele livrate 2. va fi oferit pe toată perioada derulării contractului până la implantarea ultimei proteze existente în stocul beneficiarului. 3. va fi în trusă de sterilizare specială cu indicarea codurilor de instrumente din catalog și desenelor pentru acestea. 4. va fi nou (neutilizat). În caz de defecțiune, furnizorul va fi obligat să repare sau să înlocuiască utilajul deteriorat în decurs de 72 ore de la solicitarea scrisă a beneficiarului.	Setul de instrumente oferit gratuit în folosință va corespunde următoarelor cerințe: 1. compatibil cu endoprotezele livrate 2. va fi oferit pe toată perioada derulării contractului până la implantarea ultimei proteze existente în stocul beneficiarului. 3. va fi în trusă de sterilizare specială cu indicarea codurilor de instrumente din catalog și desenelor pentru acestea. 4. va fi nou (neutilizat). În caz de defecțiune, furnizorul va fi obligat să repare sau să înlocuiască utilajul deteriorat în decurs de 72 ore de la solicitarea scrisă a beneficiarului.	ISO, CE

Semnat: \_\_\_\_\_ Numele, Prenumele: Dmitrii Kojevnikov În calitate de: Administrator

Ofertantul: S.C. OXIVIT-MED S.R.L Adresa: mun. Chişinău, str. Decebal 82-90

## Specificații de Preț

Numărul procedurii de achiziție:		ocds-b3wdp1-MD-1674818516778 din 04.02.2023										
Obiectul achiziției:		Endoproteză oncologică (conform specificației atașate)										
Nr. Lot	Denumire Lot	Denumirea bunurilor și/sau a serviciilor	Cantitatea	Unitatea de măsură	Preț unitar (fără TVA)	Preț unitar (cu TVA)	Suma fără TVA	Suma cu TVA	Termenul de livrare/ prestare	Cod CPV	Clasificație bugetară (IBAN)	Discount %
1	2	3	4	5	6	7	8	9	10	11	12	13
1	Endoproteză individuală oncologică modulară cimentată / necimentată de cot cu substituția extremității distale a humerusului și/sau a extremității proximale a ulnei	Endoproteză individuală oncologică modulară cimentată / necimentată de cot cu substituția extremității distale a humerusului și/sau a extremității proximale a ulnei-	1	set	178 200.00	178 200.00	178 200.00	178 200.00	în termen de 30 de zile de la solicitarea scrisă a beneficiarului	33100000-1	-	-
1	Endoproteză individuală oncologică modulară cimentată / necimentată de cot cu substituția extremității distale a humerusului și/sau a extremității proximale a ulnei	Set de instrumente gratuit în folosință	1	set	0.00	0.00	0.00	0.00	în termen de 30 de zile de la solicitarea scrisă a beneficiarului	33100000-1	-	-
<b>TOTAL Oferta</b>							<b>178 200.00</b>	<b>178 200.00</b>				

Semnat: \_\_\_\_\_ Numele, Prenumele: Dmitrii Kojevnikov În calitate de: Administrator

Ofertantul: S.C. OXIVIT-MED S.R.L Adresa: mun. Chişinău, str. Decebal 82-90

# Certificate

The Certification Body

**MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH  
Pilatuspool 2 – 20355 Hamburg – Germany**

herewith certifies that the company

**implantcast GmbH  
Lüneburger Schanze 26  
21614 Buxtehude  
Germany**

has introduced, applies and maintains a quality management system in the area of activities, products/services and locations listed in the appendix.

The conformity of this quality management system to the requirements of the following standard has been verified by an audit:

**EN ISO 13485:2016**

This certification is subject to surveillance by MEDCERT.

**Effective date: 2021-12-23**  
**Expiry date: 2024-01-02**

Report No.: 7092IA13F  
Procedure No.: QS – 7092  
Certificate No.: 7092GB445211223

Hamburg, 2021-12-23

  
\_\_\_\_\_  
MEDCERT Certification Body  
Lorenz Runge

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## Appendix of certificate

Procedure No.: QS – 7092  
Certificate No.: 7092GB445211223

### Activities and products/services in the scope of certification

Design and development, manufacturing, final inspection, and distribution of

- Primary endoprosthesis
- Tumor endoprosthesis
- Revision endoprosthesis
- Instruments (rasps, handles, reamer, drills, sawblades)
- Trial prostheses
- Metal augments

### Locations in the scope of certification

implantcast GmbH  
Lüneburger Schanze 26  
21614 Buxtehude  
Germany

implantcast GmbH  
Alter Postweg 10b  
21614 Buxtehude  
Germany

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MEDCERT is a management systems certification body  
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## EU Quality Management System Certificate

### The Notified Body

**MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH**  
**Pilatuspool 2 – 20355 Hamburg – Germany**

herewith certifies that the company

**implantcast GmbH**  
**Lüneburger Schanze 26**  
**21614 Buxtehude**  
**Germany**

**SRN: DE-MF-000010002**

with locations listed in the appendix

has introduced, applies and maintains a quality management system for the medical devices/groups of medical devices listed in the appendix.

The compliance of this quality management system to the requirements of the **Regulation (EU) 2017/745 on medical devices** was verified by assessment according to:

### Annex IX Chapter I

Any applicable limitations of this certification for certain medical devices are included in the appendix. This certification is subject to surveillance by MEDCERT.

**Effective date:** 2021-12-23  
**Expiry date:** 2026-01-02

Final assessment report No.: 7092IA13F  
Procedure No.: QS – 7092  
Certificate No.: 7092GB448211223

Preceding certificate No.: –  
Preceding certificate date: –  
Identification of changes: –

Hamburg, 2021-12-23

  
\_\_\_\_\_  
MEDCERT Certification Body  
Lorenz Runge

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MEDCERT Notified Body Identification Number: 0482



## Appendix of EU Quality Management System Certificate

Procedure No.: QS – 7092  
Certificate No.: 7092GB448211223

### Locations included in the scope of certificate

implantcast GmbH  
Lüneburger Schanze 26  
21614 Buxtehude  
Germany

implantcast GmbH  
Alter Postweg 10b  
21614 Buxtehude  
Germany

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BS-MDR-096

**Appendix of EU Quality Management System Certificate**

Procedure No.: QS – 7092  
Certificate No.: 7092GB448211223

**Class I medical devices**

For class I medical devices that are reusable surgical instruments (class Ir), the audit of the quality management system was limited to the aspects relating to the reuse of the device, in particular cleaning, disinfection, sterilisation, maintenance and functional testing, and the related instructions for use.

Category	Medical devices/groups of medical devices	Class
<b>MDN 1208</b>	Non-active non-implantable instruments	Ir

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## Appendix of EU Quality Management System Certificate

Procedure No.: QS – 7092  
Certificate No.: 7092GB448211223

### Class IIa medical devices

Category	EMDN code	Medical devices/groups of medical devices
<b>MDN 1208</b>	<b>L091199</b>	Orthopaedic prosthetics instruments, reusable - other
	<b>Z121305</b>	Motorised orthopaedic surgery system instruments
	<b>L091001</b>	Instruments for insertion and extraction of materials for osteosynthesis, reusable

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## Appendix of EU Quality Management System Certificate

Procedure No.: QS – 7092  
Certificate No.: 7092GB448211223

### Class III custom-made implantable medical devices

Category	Medical devices/groups of medical devices
<b>MDN 1102</b>	Non-active osteo- and orthopaedic implants

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# MUTARS®

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implantcast



**Total Elbow**  
Surgical Technique



# MUTARS®

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## Distal Humerus Surgical Technique

MUTARS® was developed in co-operation with Univ.-Prof. Dr. W. Winkelmann (ex-director) and Univ.-Prof. Dr. G. Gosheger (director) Department of General Orthopaedics and Orthopaedic Oncology at the University Hospital of Münster, Germany. MUTARS® is in successful clinical use since 1992.

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**Nota Bene:** The herein described surgical technique shows the treatment suggested by the author in uncomplicated surgical procedures. However, it is ultimately the operating surgeon's decision, which approach is the most reasonable and effective for the respective patient.

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## The Silver Coating

Infections represent the most severe complications of tumour arthroplastic treatments. Although local and systemic antibiotic treatments are considered, the scientific literature reports of infection rates from 5 to 35 percent [1]. Reasons for these high rates are, for example, the long surgery time, the large incisions and the immunosuppression due to chemo therapy and radio therapy as well as the increasing resistance of the bacteria against antibiotic drugs.

Silver, in particular free silver ions, is well known for its broad-spectrum antimicrobial activity. The silver coating has been shown to reduce bacterial colonization on the device surface.

Until now only non-articulating surfaces and surfaces without direct bony contact are coated with silver.

In the catalogue information of this surgical technique you can find the supplement \*S indicating which MUTARS® components are available in a silver coated version. The eight digit REF number receives an addition after the last digit (e.g. 5220-0020S).

## Important Intra-Operative Instructions for the Use of Silver-Coated Implants

It is not permitted to flush the wound with antiseptics that contain H<sub>2</sub>O<sub>2</sub>, Iodine or heavy metals (such as Betaisodona®) and acetic acid during surgery since this can lead to a subsequent loss of effectiveness of the silver coating due to their oxidative properties. Alternatively, solutions such as NaCl or Lavasept® and Prontosan® can be used. The additional use of antibiotic-containing bone cement can be an advantage particular in case of a septic revision.

## The TiN Coating for Allergy Prophylaxis

All metallic implant components release ions to their environment over time. In some patients such ions can elicit allergic reactions. Nickel, cobalt and chromium, which are elements of the base material CoCrMo of the articulating implant components, are considered the most frequently allergy eliciting metals [2] The TiN-coating is biocompatible and acts like a barrier; the potential release of allergy eliciting ions of the base material is reduced to a minimum [3]. Also in clinical practice there have never been any evidence of allergic reactions with implants that have been TiN-coated showing an intact surface [5]. Therefore the TiN-coating on implant components is especially suitable for patients with sensitivity to nickel, chromium or cobalt [4][5].

Since almost all components of the MUTARS® tumour system consist of titanium alloy, this only concerns those components, which are made of a cast CoCrMo alloy. The REF-numbers of the TiN-coated implants have the suffix N after the last digit (e.g. 5720-0005N). Items which are available with Silver and TiN coating have the suffix SN after the last digit (e.g. 5720-0005SN).

**\*S:** Implants are available with Silver coating!

**\*N:** Implants are available with TiN coating!

**\*SN:** Implants are available with Silver and TiN coating!

[1] Gosheger et al. 2004. Silver-coated megaendoprostheses in a rabbit model – an analysis of the infection rate and toxicological side effects. *Biomaterials* 25, 5547-5556.

[2] Eben R et al. (2009) Implantatallergieregister - ein erster Erfahrungsbericht. *Orthopäde* 38: 557-562

[3] Wisbey et al. (1987) Application of PVD TiN coating to Co-Cr-Mo based surgical implants. *Biomaterials*, 11

[4] Prof. Thomas LMU München Final Report Effect of a TiNbN or TiN surface coating on cobaltchromium- molybdenum and stainless steel test specimens regarding the release of nickel, chromium and cobalt: evaluation via eluate analysis and in-vitro cytokine release from peripheral human blood cells, Data on file

[5] Baumann A. (2001) Keramische Beschichtungen in der KTEP Standardlösung für Allergiker. *JATROS Orthopädie & Rheumatologie* 6: 16-17

# MUTARS® Total Elbow

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## Pre-Operative Planning

Pre-operative planning and precise surgical techniques are mandatory for optimal results. The instructions and the procedure given in the surgical technique to the system must be adhered to. Familiarity with the recommended surgical technique and its careful application is essential to achieve the best possible outcome.

Before surgery a surgical planning with regard to the dimensions of the prosthetic model and the positioning of the implant components in the bone has to be carried out by the surgeon.

For this purpose, x-ray templates are available:

**Digital templates:** Digital templates are included in the data base of the common planning systems. For missing templates, please contact the provider of the planning software and request for these templates.

**Radiographic templates:** Alternatively radiographic templates are available in various scale factors, which can be obtained from your local representative.



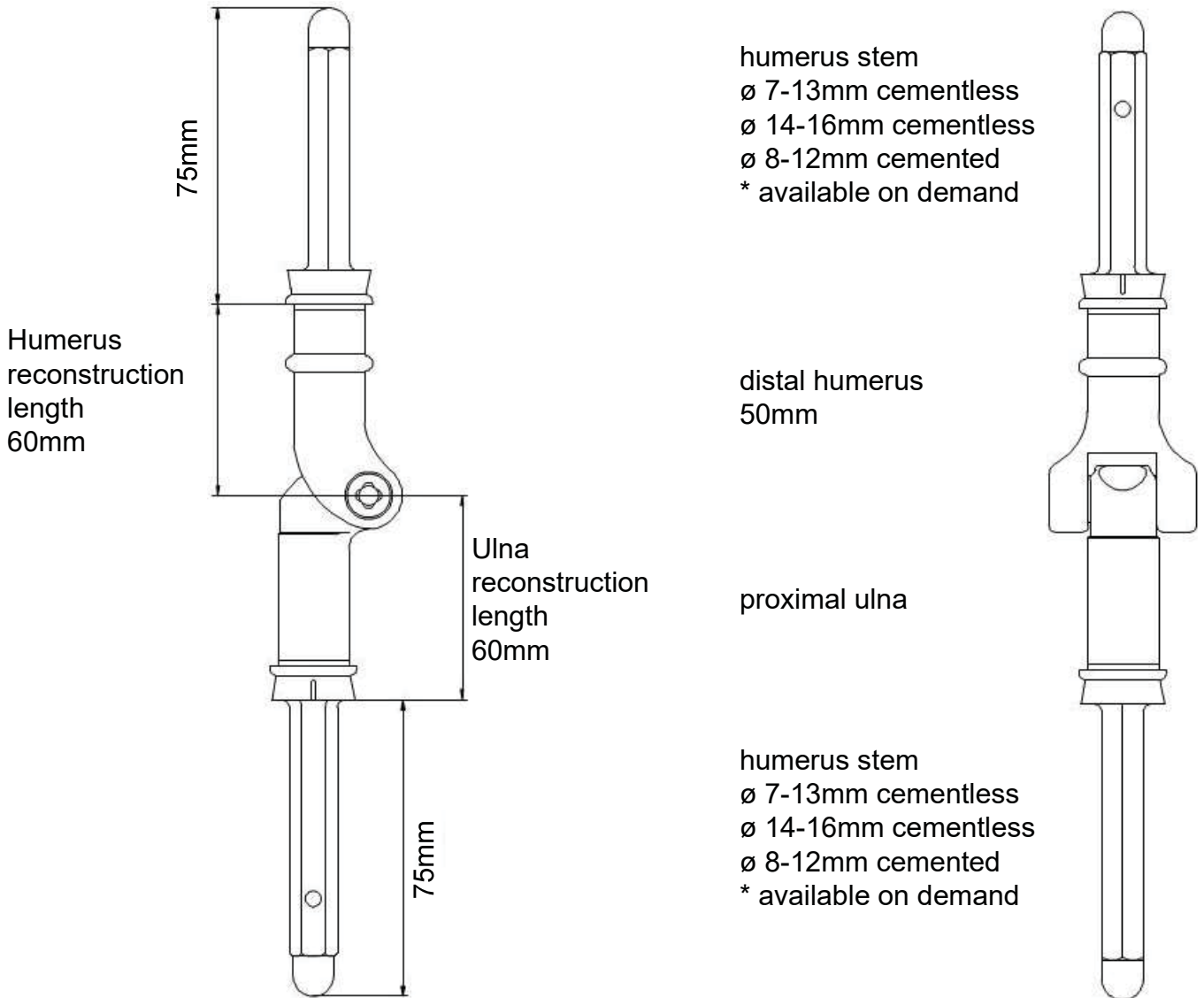
Picture shown: MUTARS® Total Elbow implant in A/P view



Picture shown: MUTARS® Total Elbow implant in M/L view



## System Overview



Reconstruction length  
60 mm



# MUTARS® Total Elbow

## Assembling Options

Humeral Components					
Reconstruction (mm)	Distal Humerus (mm)	Extension piece (mm)	Connection piece (mm)	Extension piece (mm)	Humerus screw
60	50				15
80	50	20			35
100	50	40			55
120	50	60			75
140	50		80		15 + 15
160	50	20	80		35 + 15
180	50	40	80		55 + 15
200	50	60	80		75 + 15
220	50	60	80	20	75 + 35
240	50	60	80	40	75 + 55
260	50	60	80	20 + 40	75 + 75

Ulnar Components					
Reconstruction (mm)	Distal Humerus (mm)	Extension piece (mm)	Connection piece (mm)	Extension piece (mm)	Humerus screw
60	50				15
80	50	20			35
100	50	40			55
120	50	60			75
140	50		80		15 + 15
160	50	20	80		35 + 15
180	50	40	80		55 + 15
200	50	60	80		75 + 15
220	50	60	80	20	75 + 35
240	50	60	80	40	75 + 55
260	50	60	80	20 + 40	75 + 75

**Note:** Please notice that the amount of implants and instruments send with an individual shipment may differ from the information in the catalogue information of this brochure. Please make sure, during the preoperatively planning, that all necessary implants and instruments are available for the surgery.



## Tumour Resection

Resect the tumour and determine the length of the explanted bone.

The minimal resection on the humeral bone is 60mm on the ulna bone is 60mm (Fig. 2).

**Remark:** In the case that the radius head is free of tumour it needn't be resected.



Fig. 1

## Preparation of the Proximal Ulna

### Cementless use

Drill the medullary cavity with a humerus drill 1mm smaller than the size of the preoperatively chosen humerus stem (Fig. 3).

Make sure that a minimum cortical bone contact of app. 4 cm is achieved.



Fig. 2

### Cemented Use

Drill the medullary cavity with a humerus drill 2mm larger than the size of the preoperatively chosen humerus stem (Fig. 3).

Make sure that a minimum cortical bone contact of app. 4 cm is achieved.



Fig. 3

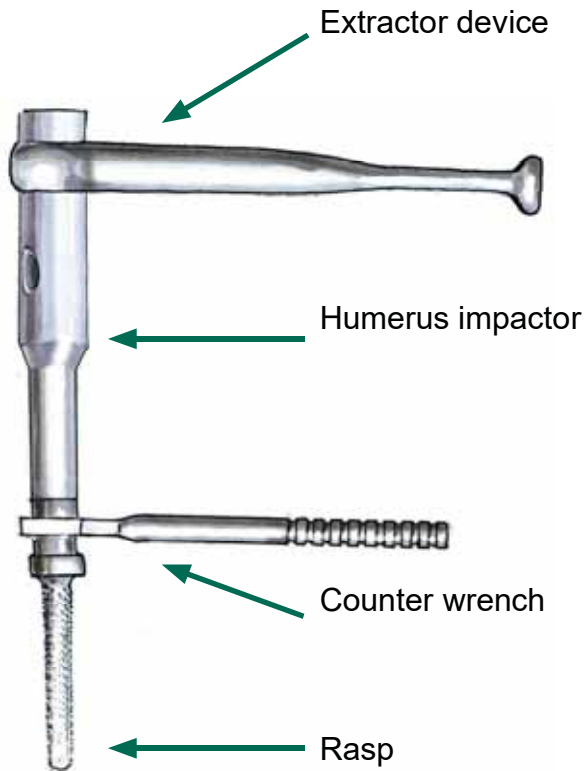
**Remark:** An even cortical contact must be obtained, since there is a danger

Prepare the medullary cavity with the medullary cavity reamer (Fig. 4).

**Remark:** There is a danger of Via falsa with a corticalis perforation. An X-Ray control in two planes is advised!



Fig. 4



**Fig. 5**

## Rasping of the Ulnar Cavity

Assemble the humeral rasp of the appropriated size (see tables below), the extractor device, the humerus impactor and the sleeve. Lock the rasp on the humerus impactor by using the counter wrench.

**Remark:** The use of a humeral rasp for a cemented stem is optional. Generally you can proceed with the trial assembly.

## Use of Cementless Stems

Use the humeral rasp (Fig. 5), of the same size as the preoperatively chosen humerus stem (table 1).

Stem size	Rasp size
7mm	7mm
8mm	8mm
9mm	9mm
10mm	10mm
11mm	11mm
12mm	12mm
13mm	13mm

**Table 1**

## Optional Technique for the Use of Cemented Stems

If you want to prepare for a cemented stem with the humeral rasp, please use the rasp which is 2 mm larger than the preoperatively chosen cemented humerus stem (Fig. 5).

That will provide a cement mantle of 1mm thickness (table 2).

Stem size	Rasp size
8 mm	10 mm
9 mm	11 mm
10 mm	12 mm
11 mm	13 mm
12 mm	14 mm

**Table 2**

Rasp the medullary cavity with the chosen humeral rasp (Fig. 6 and Fig. 7). A carefully use of the mallet is recommended.



Fig. 6

**Remark:** It is recommended to clean the rasp from bone chips during the rasping.  
To prevent fractures of the cortical bone, it is helpful to fix a bone forceps around the ulnar bone during rasping.

Leave the humeral rasp in the bone for the trialing.

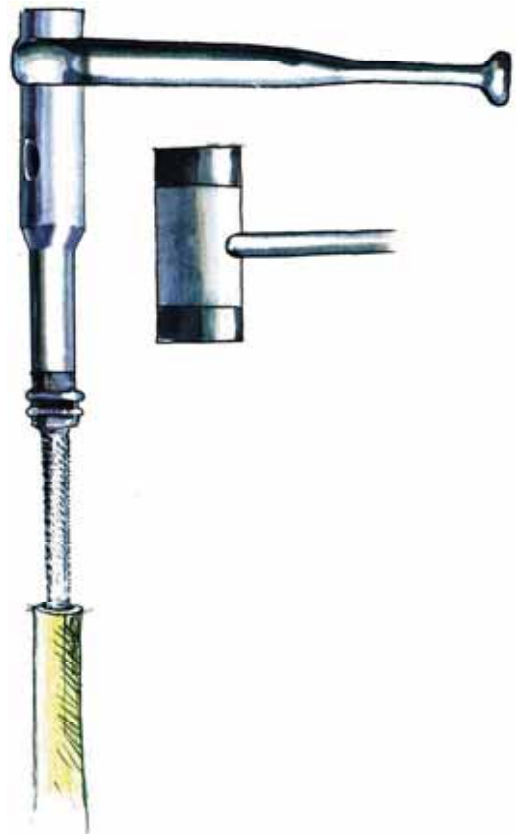


Fig. 7



**Fig. 8**

## Humeral Bone Preparation

### Cementless Use

Drill the medullary cavity with a humerus drill 1 mm smaller than the size of the preoperatively chosen humerus stem (Fig. 8).

### Cemented Use

Drill the medullary cavity with a humerus drill 2 mm larger than the size of the preoperatively chosen humerus stem (Fig. 8).

**Remark:** An even cortical contact must be obtained, since there is a danger of jamming.



**Fig. 9**

Prepare bone cavity with the MUTARS® medullary cavity reamer (Fig. 9).

## Rasping of the Humeral Cavity

Assemble the humeral rasp of the appropriated size (see tables below), the extractor device, the humerus impactor and the sleeve. Lock the rasp on the humerus impactor by using the counter wrench.

**Remark:** The use of a humeral rasp for a cemented stem is optional. Generally you can proceed with the trial assembly.

## Use of Cementless Stems

Use the humeral rasp (Fig. 10), of the same size as the preoperatively chosen humerus stem (table 3).

Stem size	Rasp size
9 mm	9 mm
10 mm	10 mm
11 mm	11 mm
12 mm	12 mm
13 mm	13 mm

**Table 3**

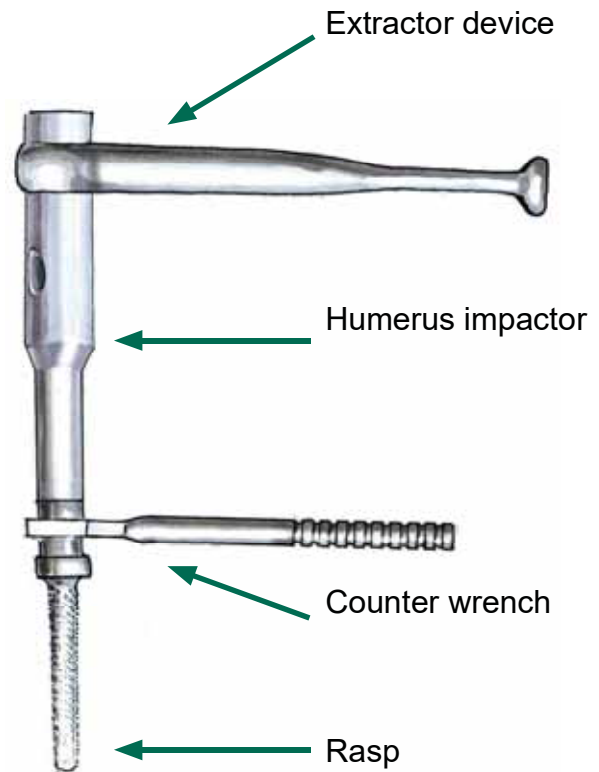
## Optional Technique for the Use of Cemented Stems

If you want to prepare for a cemented stem with the humeral rasp, please use the rasp which is 2 mm larger than the preoperatively chosen cemented humerus stem (Fig. 10).

That will provide a cement mantle of 1mm thickness (table 4).

Stem size	Rasp size
8 mm	10 mm
9 mm	11 mm
10 mm	12 mm
11 mm	13 mm
12 mm	14 mm

**Table 4**



**Fig. 10**

# MUTARS® Total Elbow



Fig. 11

Rasp the medullary cavity with the chosen humeral rasp (Fig. 11 and Fig. 12). A carefully use of the mallet is recommended.

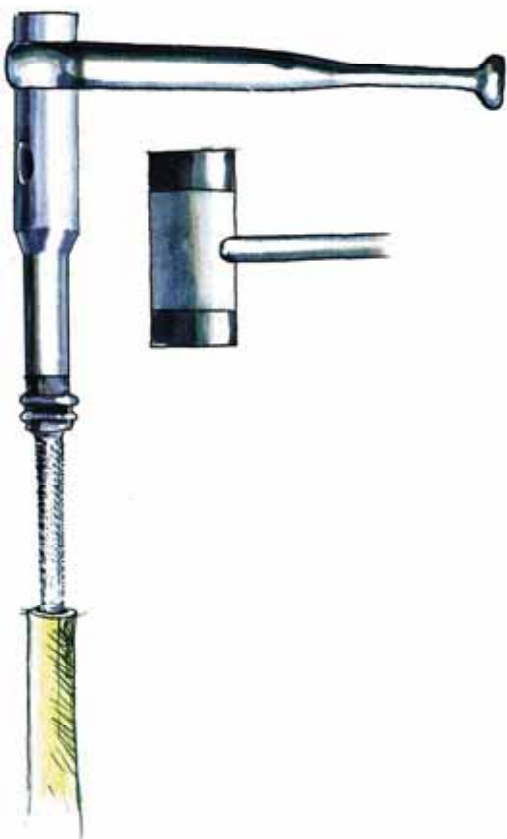


Fig. 12

**Remark:** It is recommended to clean the rasp from bone chips during the rasping.  
To prevent fractures of the cortical bone, it is helpful to fix a bone forceps around the humeral bone during rasping.

Leave the humeral rasp in the bone for the trialing.

## Trial Reduction

Mount the distal humerus and the possibly used extension pieces (possible enlargement from 20 to 200mm; see table page 5) onto the top of the rasp.

Assemble the articulating mechanism by inserting the trial axle (Fig. 13).

Also mount the Proximale Ulna onto the rasp which left in the ulna cavity (Fig. 14).

Assemble the articulating mechanism by inserting the trial axle (Fig. 15 and Fig. 16).

Perform a trial reduction, control the muscle tension and check the rotational alignment of the components.

**Remark:** At this stage the use of a bar screw is not mandatory, the teeth mechanism is stabilising the assembly. If you want to enhance the stability you may insert the bar screw of the correct length into the Proximal Ulna and lock it (see table on page 5).



Fig. 13



Fig. 14



Fig. 15



Fig. 16

## Implantation of the Humeral Stem

Mount the humerus stem of the proper size, the impact sleeve on the impactor.

Fasten the connection using the counter instrument. Impact the humerus stem (Fig. 17).

When using the cementless stem, insert the stem of the same size as the previously used rasp.

**Remark:** To prevent fractures of the cortical bone, it is helpful to fix a bone forceps around the humeral bone during impactation.

It is possible to protect the humerus stem against rotation using a 3.5mm cortical screw.

If a cemented implantation is planned, insert the cement and use the cemented stem which is 2 mm smaller than the previously used drill or rasp.

Remove all instruments, especially during the cement hardening to prevent bending moments.

## Implantation of the Ulna Stem

Repeat the stem impactation procedure and impact the ulna stem in the way as described above (Fig. 18).

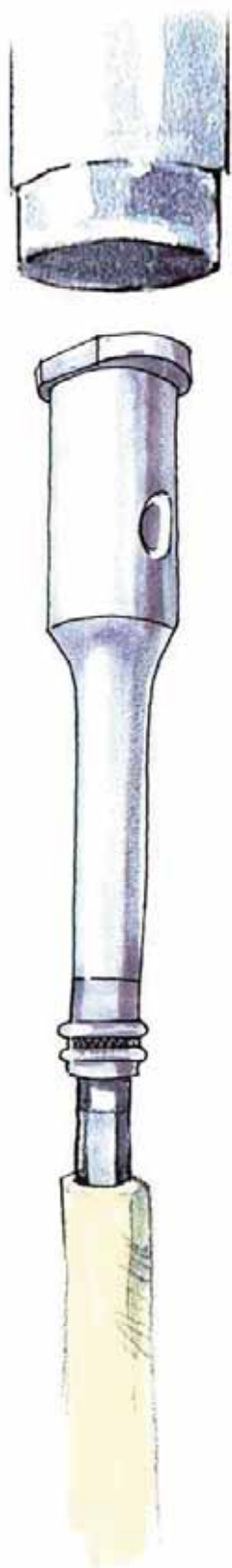


Fig. 17



Fig. 18



## Implantation of the Distal Components

Combine the distal humerus on the humerus stem (Fig. 19). If necessary extend with humerus extension pieces. Adjust the correct rotation position.

Lock the components with the corresponding humerus screw of the correct length (see table on page 5).

Secure the components with the MUTARS® socket wrench small (Fig. 21).

Secure the assembly by using the counter instrument (Fig. 20).

Lock the humerus safety screw in the same way (Fig. 22).



Fig. 19



Fig. 20



Fig. 21



Fig. 22

# MUTARS® Total Elbow



**Fig. 23**

Insert the ulna stop with the setting instrument for ulna anchorage (Fig. 23).

The ulna stop must entirely close the hole of the distal humerus to ensure a free run of the joint.



**Fig. 24**

Connect the Proximale Ulna with the stem (Fig. 24). If necessary use the extension pieces to reconstruct the previously resected amount of bone. Adjust the correct rotational alignment.

Lock the assembly by inserting the bar screw of the correct length (see table on page 5).



**Fig. 25**

Use the small MUTARS® socket wrench to tighten the screw (Fig. 25). Use the counter wrench to secure the assembly.

Insert the safety screw and lock it in the same way (Fig. 26).



**Fig. 26**

## Final Reduction

Connect the distal humerus 30mm to the Proximal Ulna by inserting the articulating axle (Fig. 27).

## Locking of the Hinge Mechanism

After coupling of the joint components (Fig. 28) please insert the locking screws on both sides in order to cover the articulating mechanism and to protect the axle. Therefore the small socket wrench is used (Fig. 29 and Fig. 30-).



Fig. 27



Fig. 29



Fig. 28



Fig. 30



# MUTARS® Total Elbow

## Implants

**\*S:** For anti-infective treatment, silver coated implants are available.

**\*N:** For anti-allergic treatment, TiN coated implants are available.



### MUTARS® Distal humerus 50 mm incl. axle, safety screw and 2 lock screws humerus cap \*S

mat.: *implatan®*;  $TiAl_6V_4$  according to ISO 5832-3

axle *CoCrMo* according to 5832-12

bushing *CoCrMo* according to 5832-12

REF 5250-0000



### MUTARS® Proximal ulna incl. safety screw \*S

Mat.: *implatan®*;  $TiAl_6V_4$  according to ISO 5832-3

bushing *CoCrMo* according to ISO 5832-12

REF 5250-0030



### MUTARS® ulna stop

mat.: *UHMWPE* according to ISO 5834-2

REF 5250-1100



### cancellous screw 4mm

mat.: *implatan®*;  $TiAl_6V_4$  according to ISO 5832-3

size

REF 5793-4026 26mm

REF 5793-4028 28mm

REF 5793-4030 30mm

REF 5793-4032 32mm

REF 5793-4034 34mm



### MUTARS® attachment tube

mat.: *polyethylene terephthalate (PET)*

size

REF 5900-0300 35 mm

REF 5900-0310 55 mm



## MUTARS® humerus screw

mat.: *implatan®*;  $TiAl_6V_4$  according to ISO 5832-3  
size

REF 5230-0015	M8x15 mm
REF 5230-0035	M8x35 mm
REF 5230-0055	M8x55 mm
REF 5230-0075	M8x75 mm



## MUTARS® humerus stem HA cementless

mat.: *implatan®*;  $TiAl_6V_4$  according to ISO 5832-3  
*implaFix®* HA; HA-coating acc. to ISO 13779-2  
size

REF 5240-0807	7 mm
REF 5240-0808	8 mm
REF 5240-0809	9 mm
REF 5240-0810	10 mm
REF 5240-0811	11 mm
REF 5240-0812	12 mm
REF 5240-0813	13 mm
REF 5240-0814	14 mm*
REF 5240-0815	15 mm*
REF 5240-0816	16 mm*

\*available on request.



## MUTARS® humerus stem cemented \*N

mat.: *implavit®*; CoCrMo according to ISO 5832-4  
size

REF 5240-0408	8 mm
REF 5240-0409	9 mm
REF 5240-0410	10 mm
REF 5240-0411	11 mm
REF 5240-0412	12 mm

Special stem sizes are available on request.



## MUTARS® humerus extension piece \*S

mat.: *implatan®*;  $TiAl_6V_4$  according to ISO 5832-3

REF	size
5220-0020	20 mm
5220-0040	40 mm
5220-0060	60 mm



## MUTARS® humerus connection piece \*S

mat.: *implatan®*;  $TiAl_6V_4$  according to DIN ISO 5832/3

REF 5221-0080	80 mm
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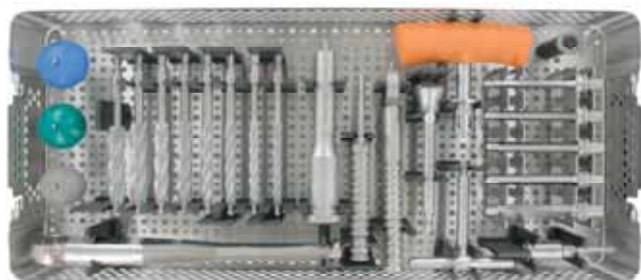




# MUTARS® Total Elbow

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## Instruments



**MUTARS® humerus container**  
7999-5200



**MUTARS® humerus trial container**  
7999-5202



**MUTARS® proximal ulna container**  
7999-5205



**MUTARS® humerus container**  
7999-5200

**MUTARS® extractor device**  
REF 7220-0000



**MUTARS® socket wrench small**  
REF 7608-1010



**MUTARS® humerus drill ic-connection**

- |               | size  |
|---------------|-------|
| REF 7630-0207 | 7 mm  |
| REF 7630-0208 | 8 mm  |
| REF 7630-0209 | 9 mm  |
| REF 7630-0210 | 10 mm |
| REF 7630-0211 | 11 mm |
| REF 7630-0212 | 12 mm |
| REF 7630-0213 | 13 mm |
| REF 7630-0214 | 14 mm |



**MUTARS® medullary cavity reamer**  
REF 4220-0000



**MUTARS® rasp for humerus stem**

- |               | size  |
|---------------|-------|
| REF 7770-0809 | 9 mm  |
| REF 7770-0810 | 10 mm |
| REF 7770-0811 | 11 mm |
| REF 7770-0812 | 12 mm |
| REF 7770-0813 | 13 mm |



**MUTARS® humerus impactor**  
REF 7710-0000



**MUTARS® humerus impact + extract sleeve**  
REF 7721-0000



**MUTARS® wrench for cap/ counter instrument**  
REF 7710-0001



**MUTARS® counter instrument Ø6mm**  
REF 7420-0001



**MUTARS® humerus trial cap**

- |               | size   |
|---------------|--------|
| REF 7710-1000 | small  |
| REF 7710-1005 | medium |
| REF 7710-1010 | large  |



**ic- T-handle Zimmer-Jakobs**  
REF 4223-0023



**ic-adapter**  
REF 4223-0022








# MUTARS® Total Elbow

## MUTARS® humerus trial container 7999-5202




### MUTARS® humerus trial cap with thread

	size	
REF 7710-1200	small	
REF 7710-1205	medium	
REF 7710-1210	large	


### MUTARS® humerus trial head REF 7710-1252



### MUTARS® humerus trial extension piece

	size	
REF 7710-0020	20 mm	
REF 7710-0040	40 mm	
REF 7710-0060	60 mm	





### MUTARS® humerus trial reducer

	size	
REF 7710-2100	10 mm	
REF 7710-2101	100 mm	

### MUTARS® humerus trial connecting part REF 7710-2180 80 mm



### MUTARS® humerus trial screw

	size	
REF 7710-2315	M8x15 mm	
REF 7710-2335	M8x35 mm	
REF 7710-2355	M8x55 mm	
REF 7710-2375	M8x75 mm	

### MUTARS® distal humerus 50mm trial REF 7710-1275



## MUTARS® proximal ulna container 7999-5205

### MUTARS® trial axle for distal humerus REF 7420-0015






### hexagon screw driver 2,5 mm REF 7608-1001



### MUTARS® humerus drill ic-connection 6mm REF 7630-0206



### MUTARS® humerus trial extension piece

REF 7710-0020	20mm	
REF 7710-0040	40mm	
REF 7710-0060	60mm	


### MUTARS® proximal trial ulna REF 7710-1280



### MUTARS® humerus trial screw

REF 7710-2315	M8x15mm	2x	
REF 7710-2335	M8x35mm		
REF 7710-2355	M8x55mm		
REF 7710-2375	M8x75mm	2x	

### MUTARS® rasp for humerus stem

REF 7770-0807	7mm	
REF 7770-0808	8mm	





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Your local distributor:

MUTD50PD-201017



PART OF THE  
TECHNICAL DOCUMENTATION

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PRODUCT DESCRIPTION  
**MUTARS<sup>®</sup> HUMERUS**

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**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.

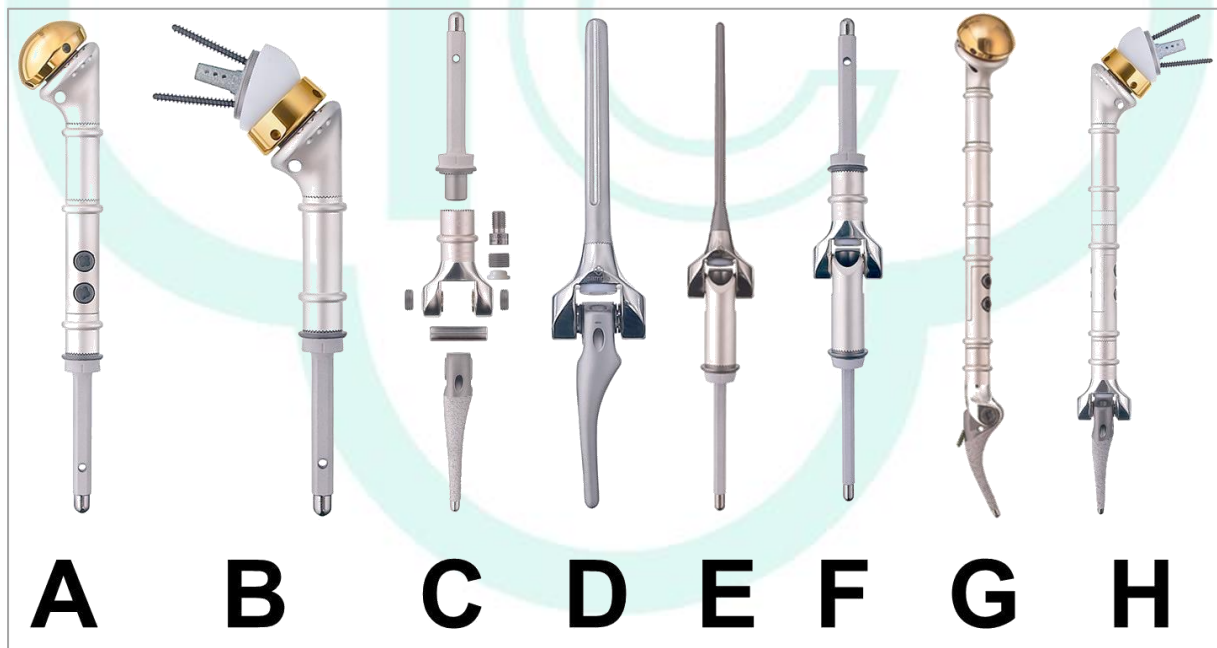


Figure 1: Overview MUTARS® Humerus System

### **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.

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## 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.

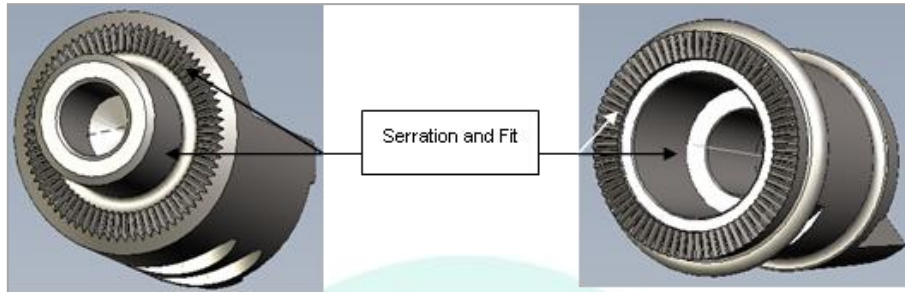


Figure 2: MUTARS® Cylindrical Fit Connection

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.

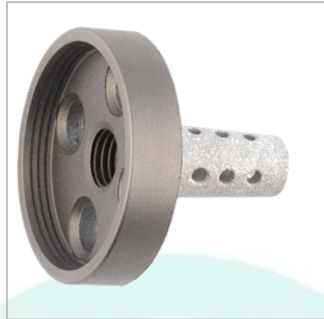


Figure 8: Glenoid Cementless Round

### **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.

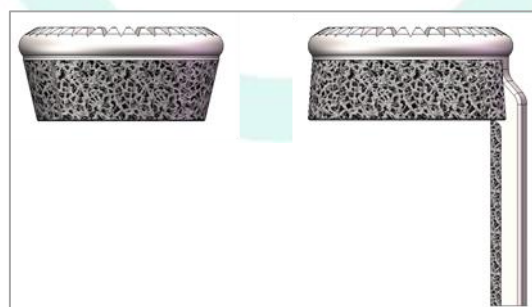


Figure 15: MUTARS® EPORE® HA Collar Humerus (left) and with flange (right)



### **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**

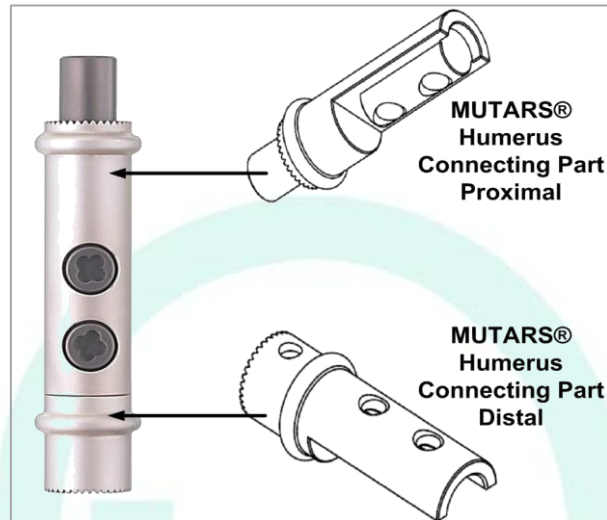


Figure 20: MUTARS® Humerus Connecting Part

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 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.

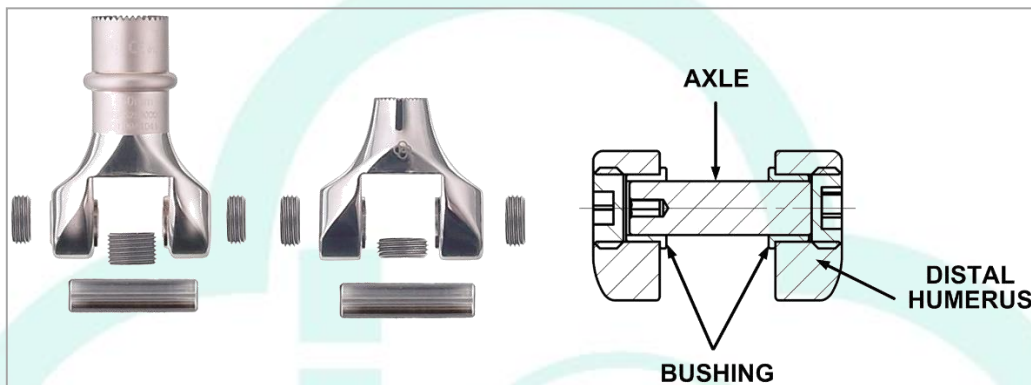


Figure 23: MUTARS® Distal Humerus 50mm (Left), 30mm (Center) and Assembling (Right)

### **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.

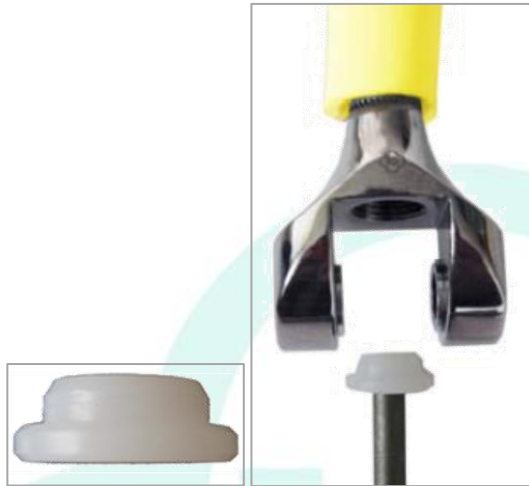


Figure 29: MUTARS® Ulna Stop

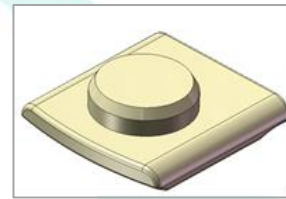


Figure 30: MUTARS® Ulna Stop HD

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.



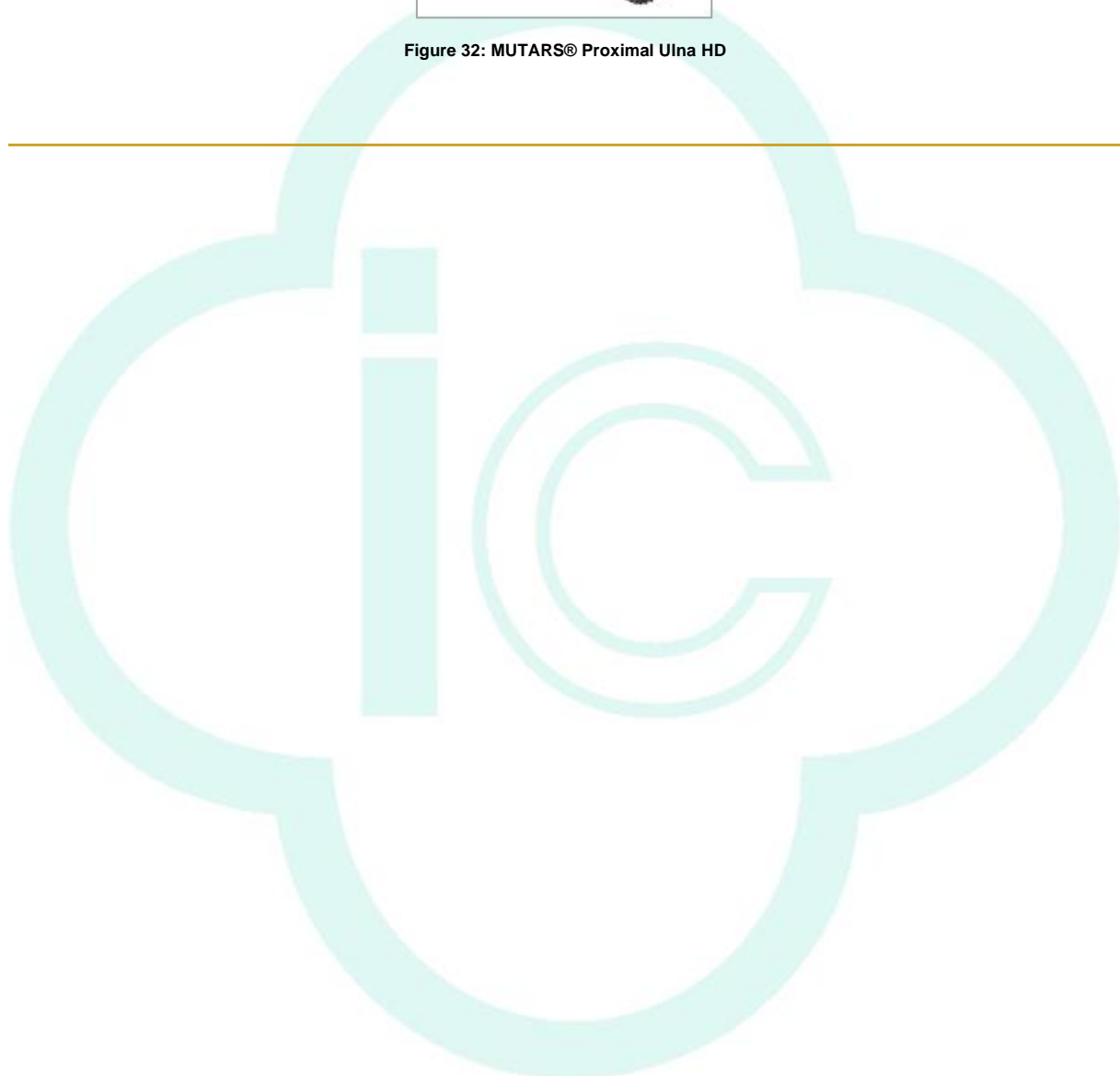
Figure 31: MUTARS® Proximal Ulna

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 TiAl<sub>6</sub>V<sub>4</sub> 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 TiAl<sub>6</sub>V<sub>4</sub> 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 TiAl<sub>6</sub>V<sub>4</sub> acc. to ISO 5832-3.

The MUTARS® Glenosphere and AGILON® PE-Glenoid Cemented provide x-ray wire made of TiAl<sub>6</sub>V<sub>4</sub> 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 TiAl<sub>6</sub>V<sub>4</sub> alloy.

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

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### 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 <sup>2</sup> ]	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

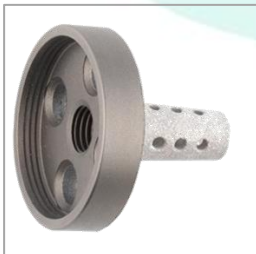
The wear surface of the cemented Glenoid component has a roughness Ra of 2 µm while the bone opposing back side is structured for better fixation with the cement.

#### 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.

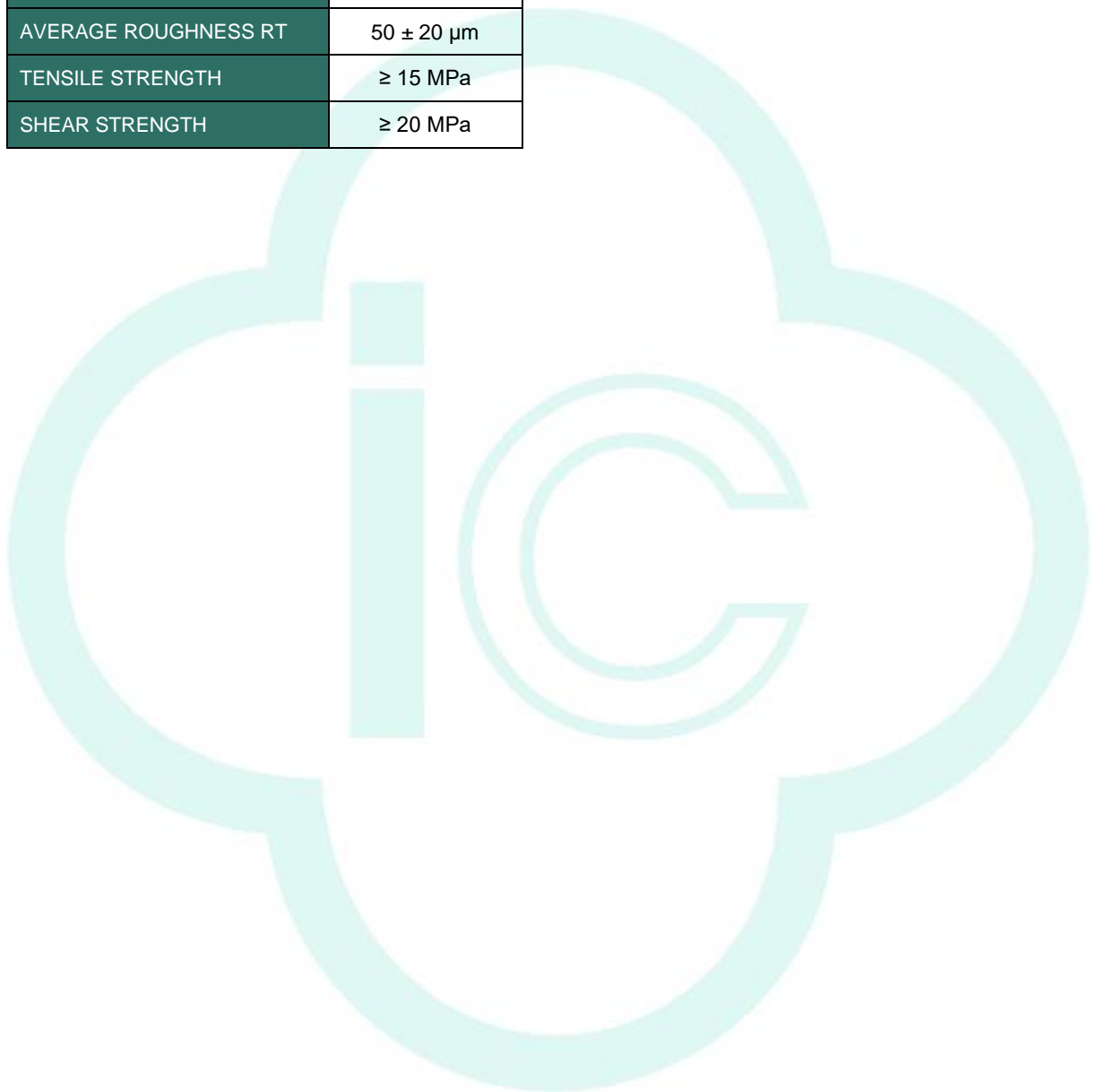


**Figure 36: Glenoid Cementless Round**

**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 <sup>2</sup> ]	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.

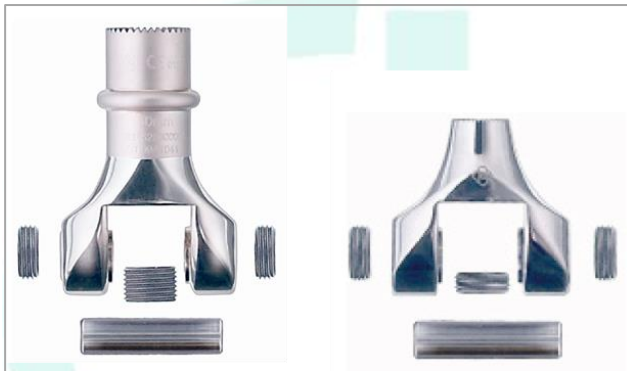


Figure 40: MUTARS® Distal Humerus 50mm (left) and Distal Humerus 30mm (right)

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 <sup>2</sup> ]	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 (Surface Specification SUR_C6)	HA (Surface Specification SUR_B3)
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.

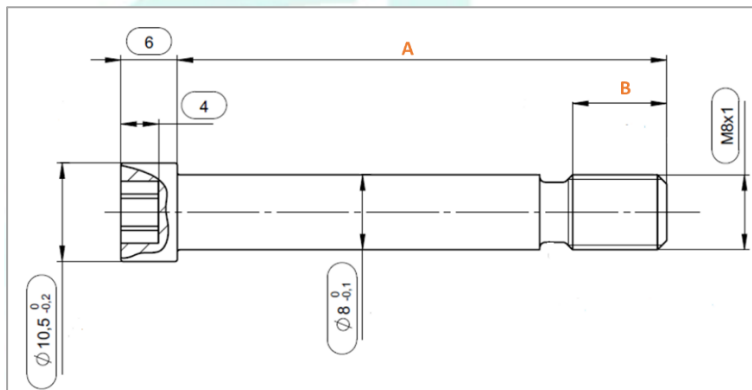


Figure 44: MUTARS® Humerus Screw - Dimensions

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.

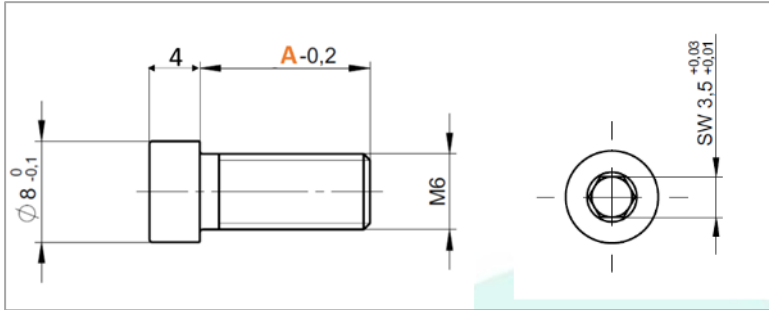


Figure 45: MUTARS® Screw for Distal Humerus 30mm (Standard) – Dimensions

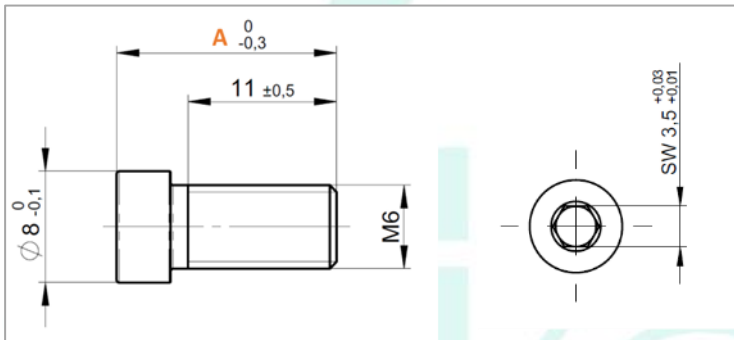


Figure 46: MUTARS® Screw for Distal Humerus 30mm (Extended) - Dimensions

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.

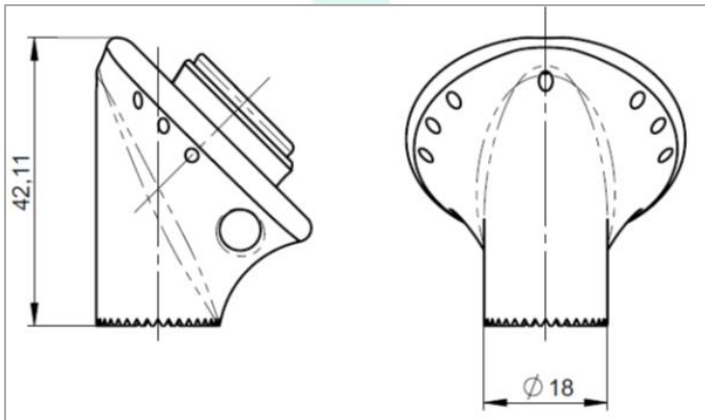


Figure 47: MUTARS® Humerus Head - Dimensions



## 13.4. MUTARS® Humerus Caps

### MUTARS® Humerus Cap

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

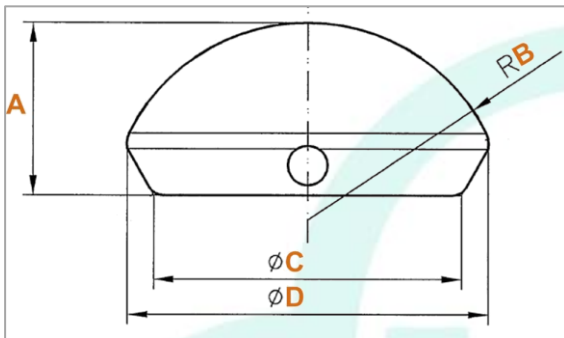


Figure 48: MUTARS® Humerus Cap – Dimensions

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.

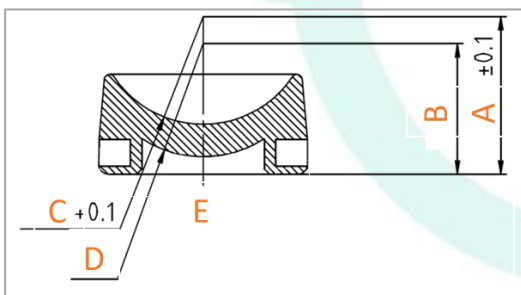


Figure 49: MUTARS® Humerus Cap Inverse - Dimensions

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.

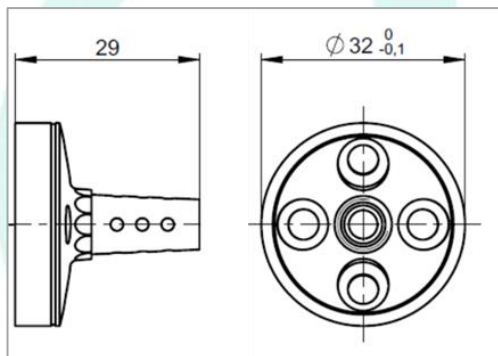


Figure 50: Glenoid Cementless Round - Dimensions

#### MUTARS® Glenosphere

The MUTARS® Glenosphere is only available in one size.

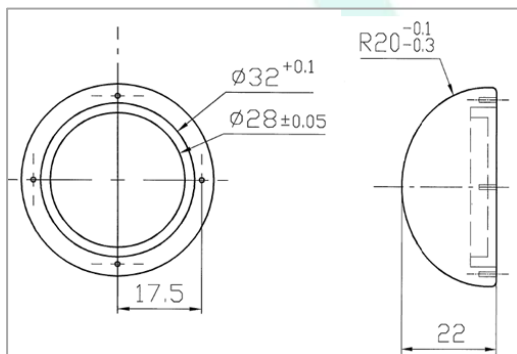


Figure 51: MUTARS® Glenosphere - Dimensions

## Glenoid Cemented

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

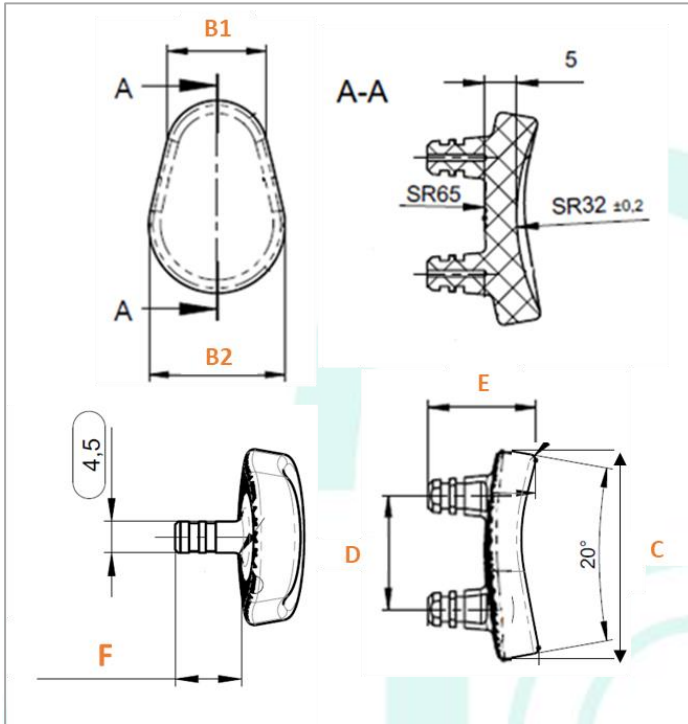


Figure 52: AGILON® PE-Glenoid Cemented - Dimensions

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									

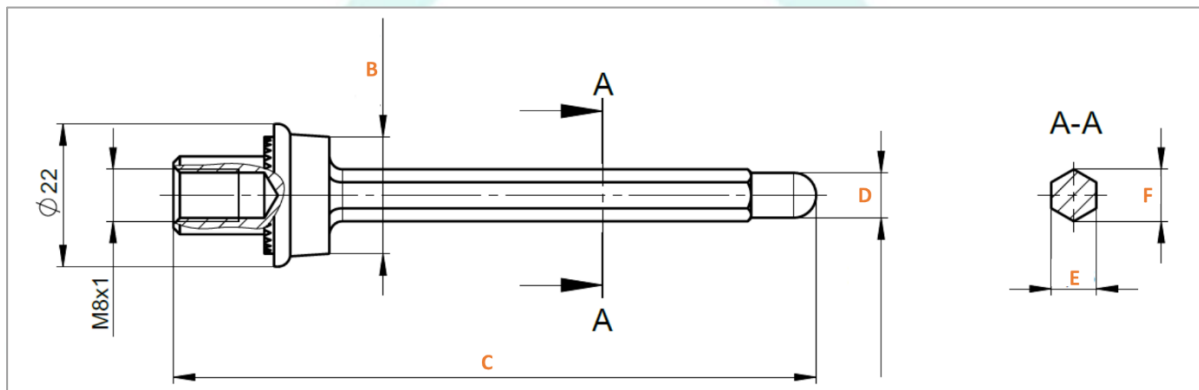


Figure 53: MUTARS® Humerus Stem Cemented - Dimensions

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**

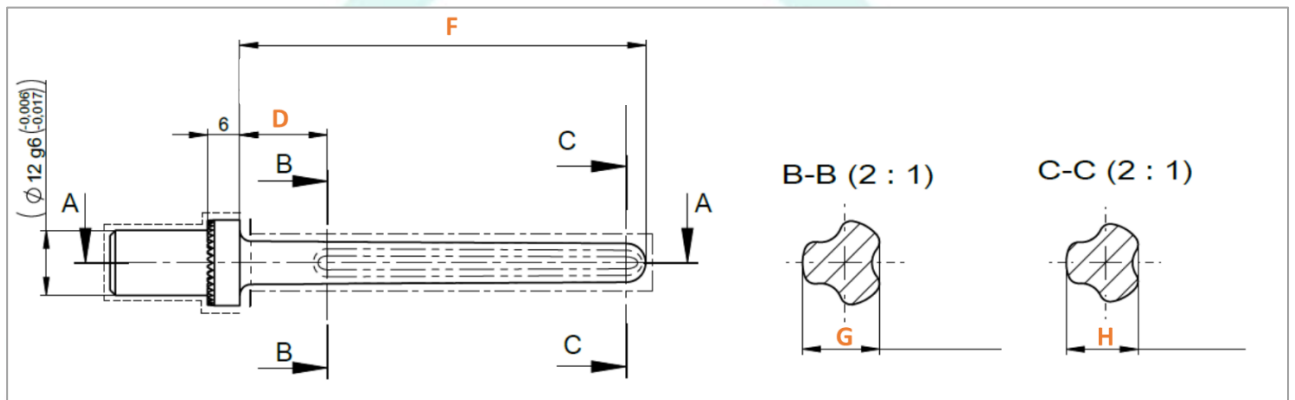
The MUTARS® Humerus Stem Type A Modular Cemented is available in the three length from 75 mm to 150 mm and nine diameters from 8 mm to 16 mm.



**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

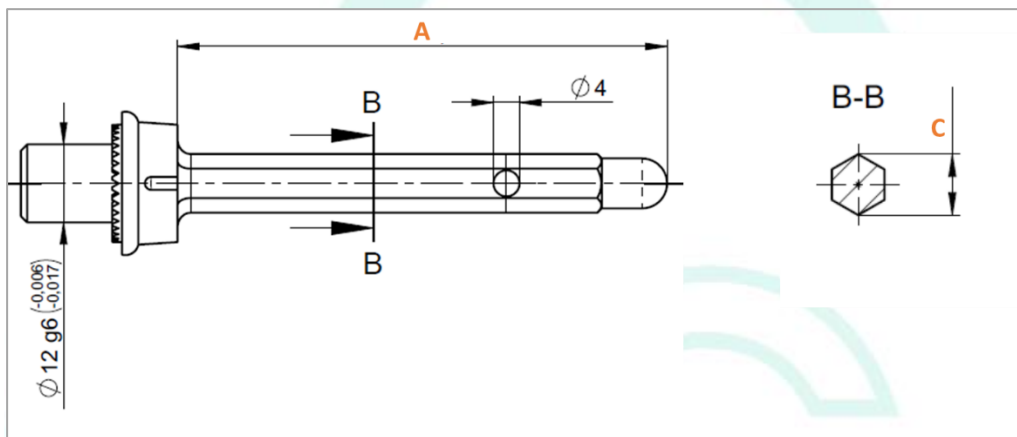


Figure 55: MUTARS® Humerus Stem Cementless - Dimensions

Table 28: MUTARS® Humerus Stem Cementless - Dimensions

SIZE	Ø7	Ø 8	Ø 9	Ø 10	Ø 11	Ø 12	Ø 13	Ø 14	Ø 15	Ø 16	Ø 17
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

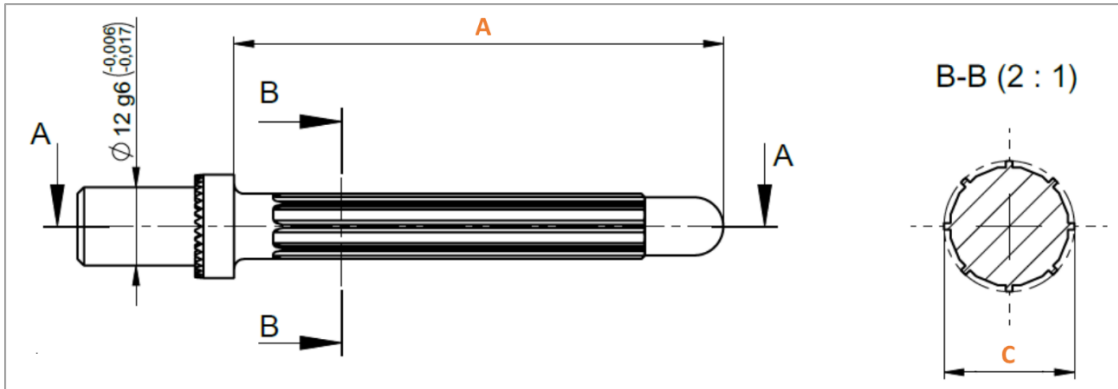


Figure 56: MUTARS® Humerus Stem Type A Modular Cementless - Dimensions

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).

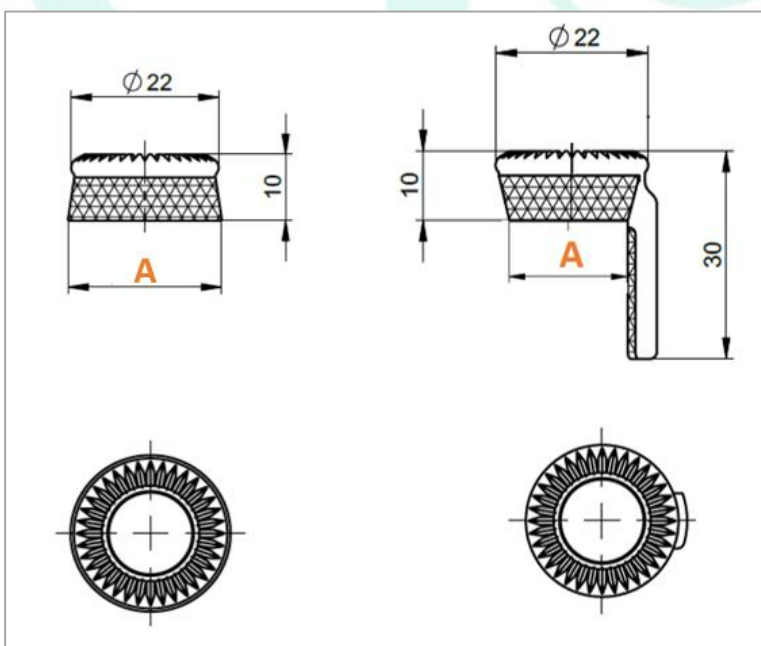


Figure 57: MUTARS® EPORE® HA Collar Humerus (left) and with flange (right) - Dimensions



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

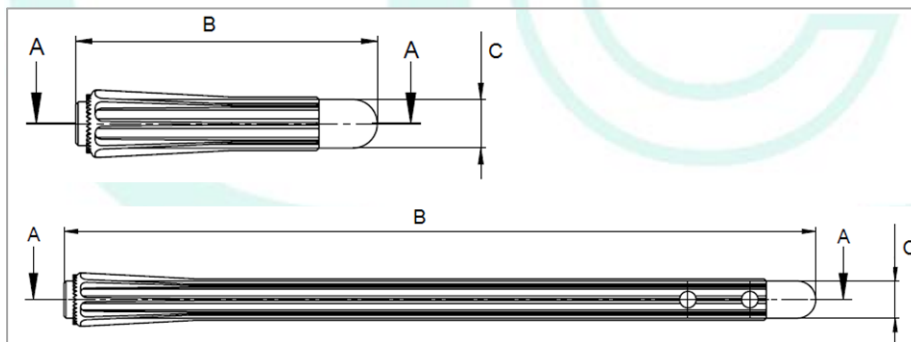


Figure 58: AGILON® Stem Cementless - Dimensions

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.

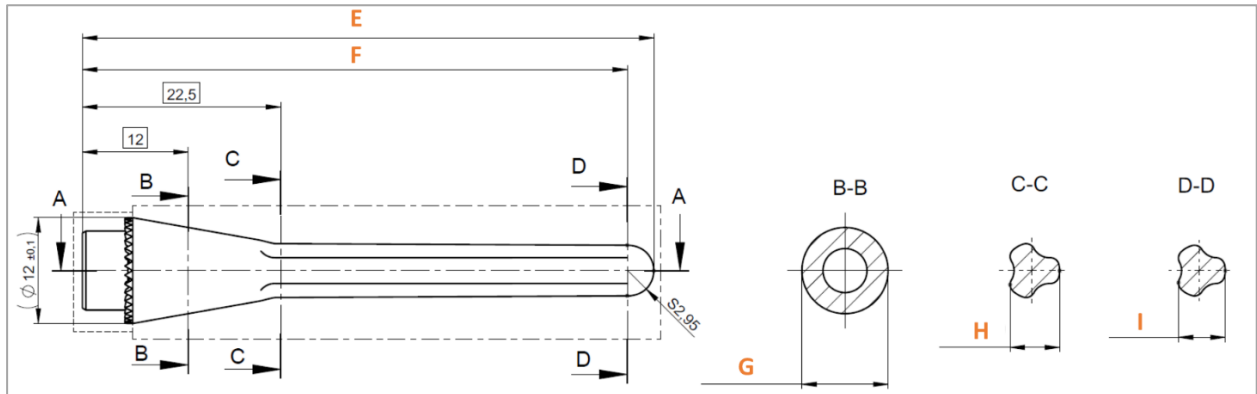


Figure 59: AGILON® Stem Cemented- Dimensions

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	∅ 9.78	5.6	5.3
8 x 60		61	∅ 9.78	7.5	7.2
10 x 60		59.9	∅ 10.42	9.7	9.3
12 x 60		59.1	∅ 11.92	11.2	10.8
6 x 90	94.8	92	∅ 9.78	5.6	5.1
8 x 90		91	∅ 9.78	7.5	6.9
10 x 90		90	∅ 10.42	9.7	9.1
12 x 90		89.3	∅ 11.92	11.2	10.5
6 x 120	124.8	122.3	∅ 9.78	5.6	4.8
8 x 120		121.3	∅ 9.78	7.5	6.7
10 x 120		120.3	∅ 10.42	9.7	8.8
12 x 120		120.3	∅ 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.

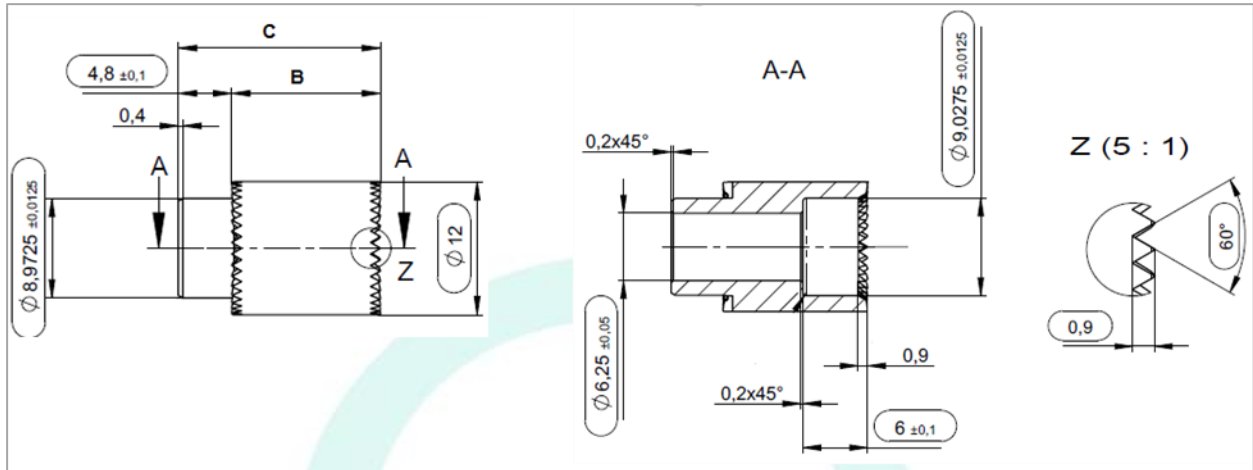


Figure 60: AGILON® Extension Piece - Dimensions

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.

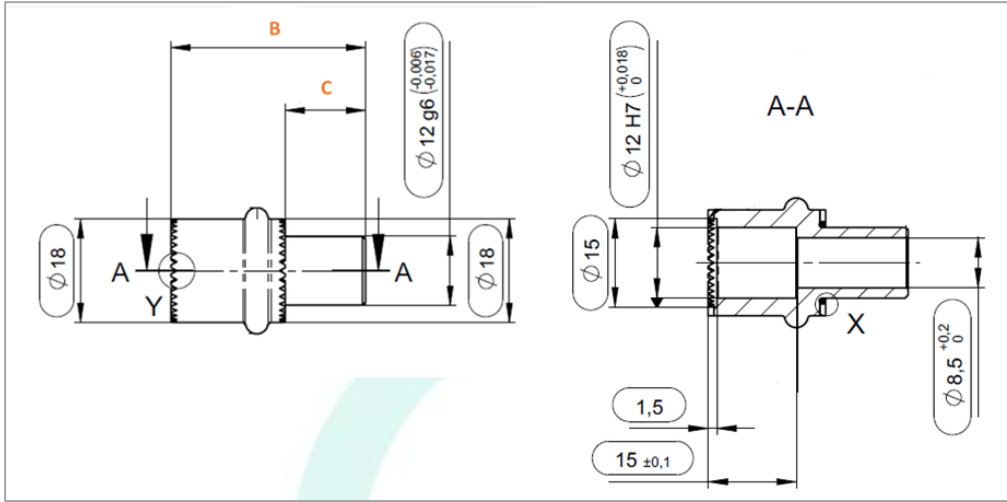


Figure 61: MUTARS® Humerus Extension Piece – Dimensions

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.

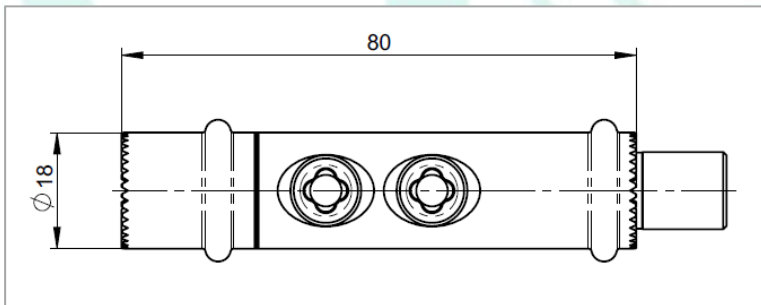


Figure 62: MUTARS® Humerus Connecting Part – Dimensions

### MUTARS® Humerus End Piece

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

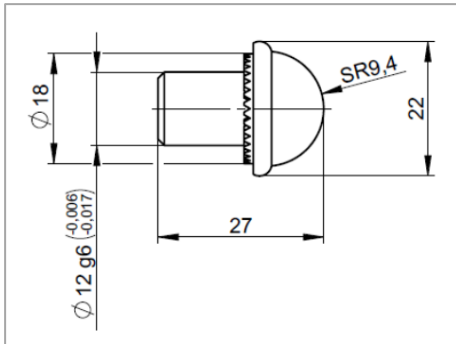


Figure 63: MUTARS® Humerus End Piece - Dimensions

### 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.

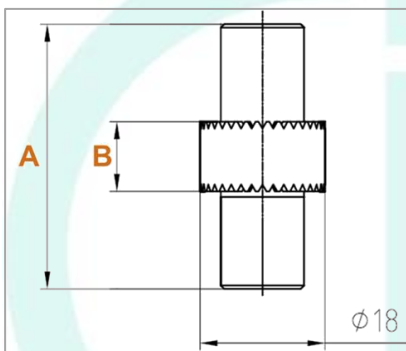


Figure 64: MUTARS® Humerus Reducer – Dimensions

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.

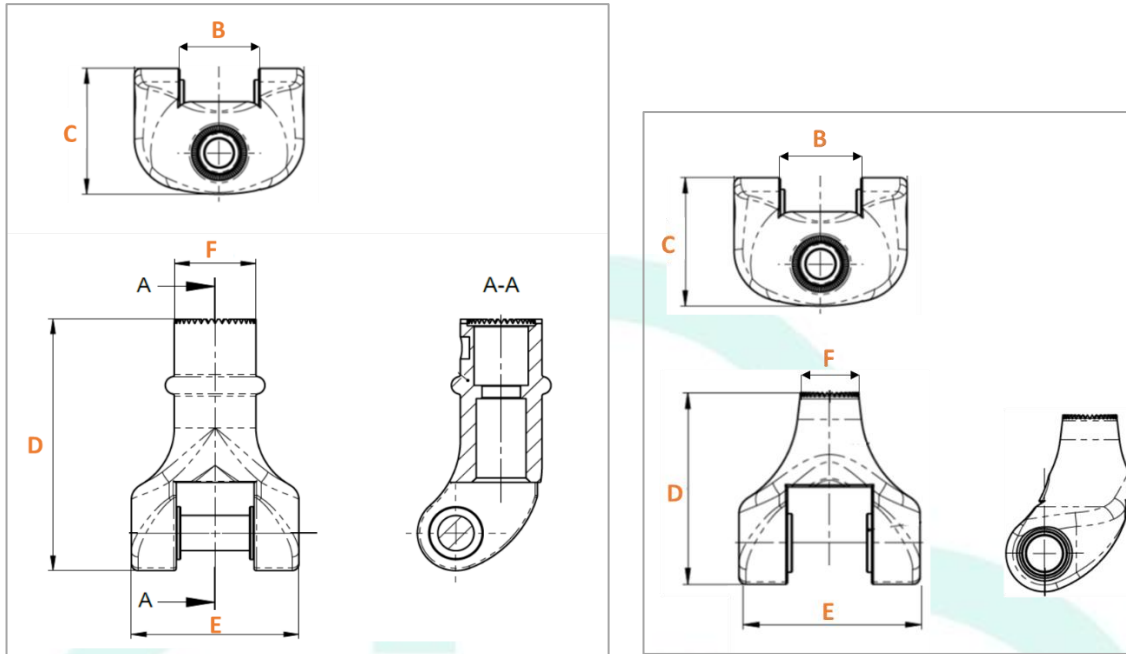


Figure 65: MUTARS® Distal Humerus 50mm (left) and 30mm (right) - Dimensions

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.

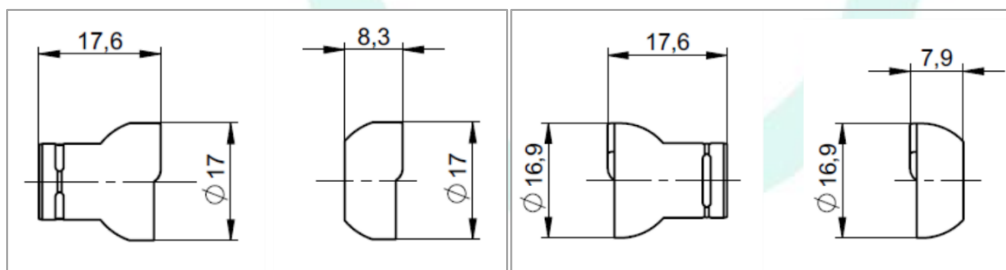


Figure 66: Part 1 and Part 2 of PE Bearing FC (left) and PE Bearing SC (right) - Dimensions

### 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).

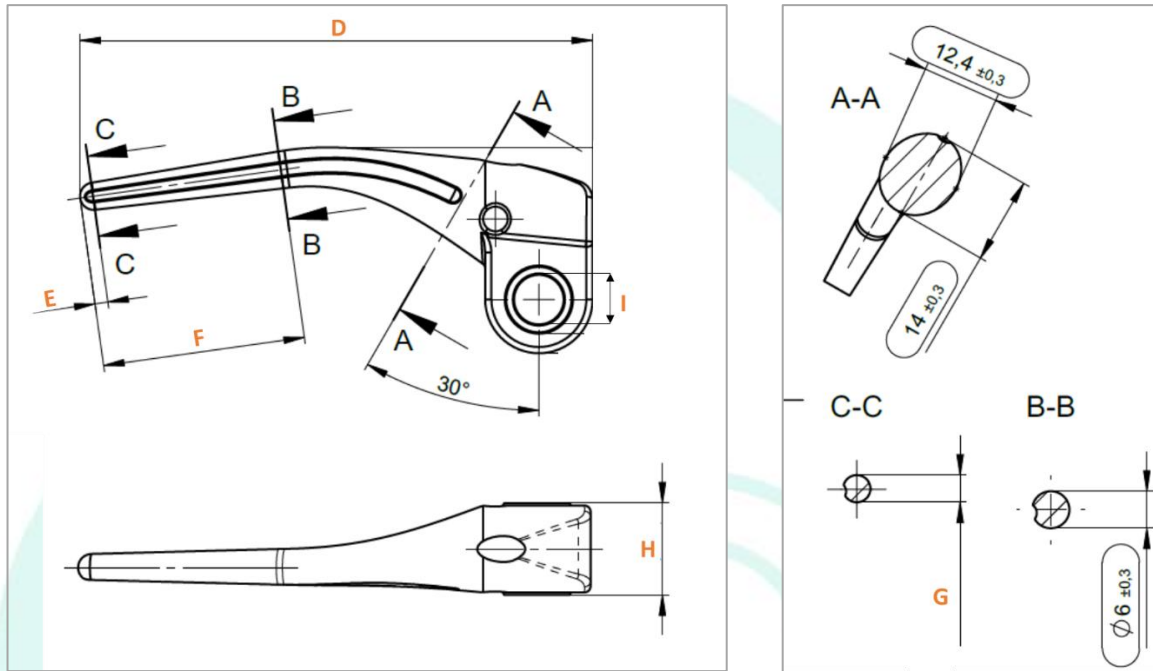


Figure 67: MUTARS® Ulnar Component Cemented - Dimensions

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.

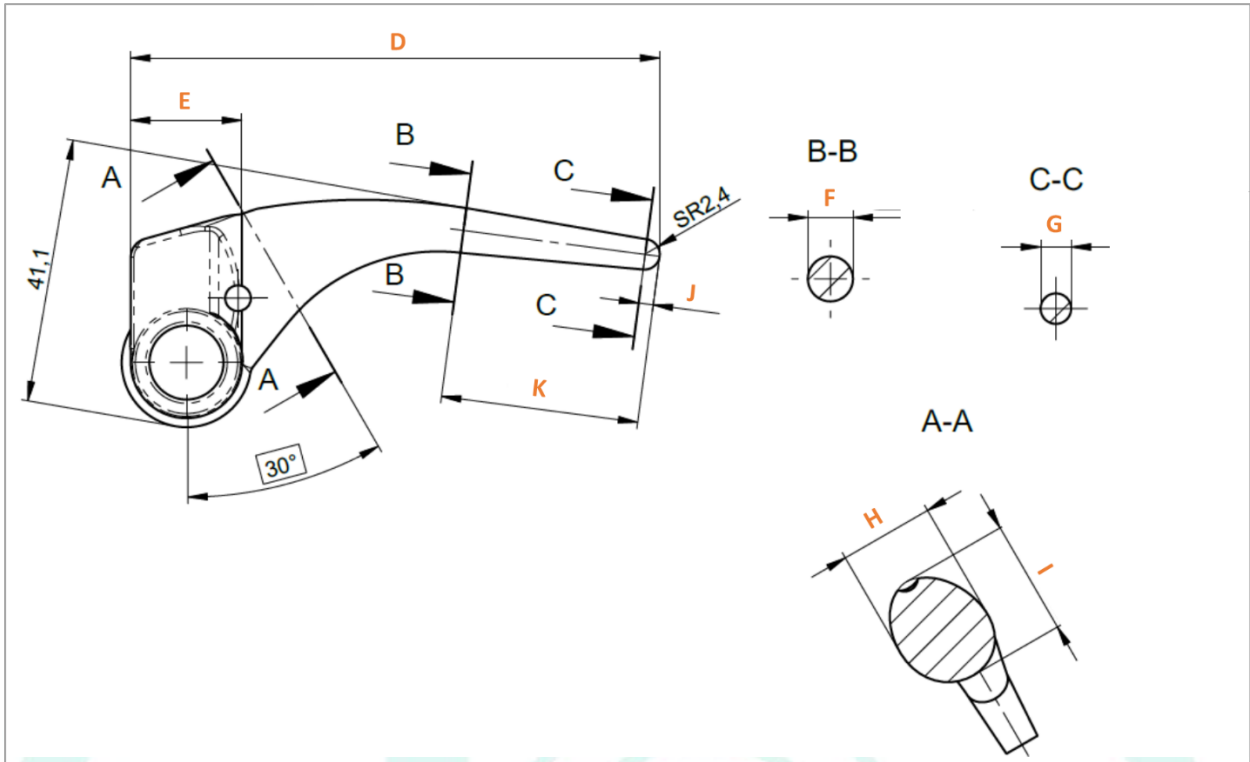


Figure 68: MUTARS® Ulna Anchorage Cementless – Dimensions

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.

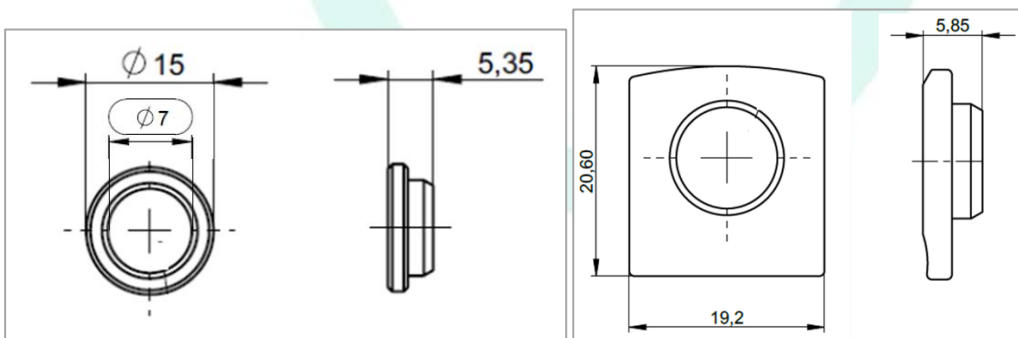


Figure 69: MUTARS® Ulna Stop (left) and MUTARS® Ulna Stop HD (right) - Dimensions



## MUTARS® Proximal Ulna

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

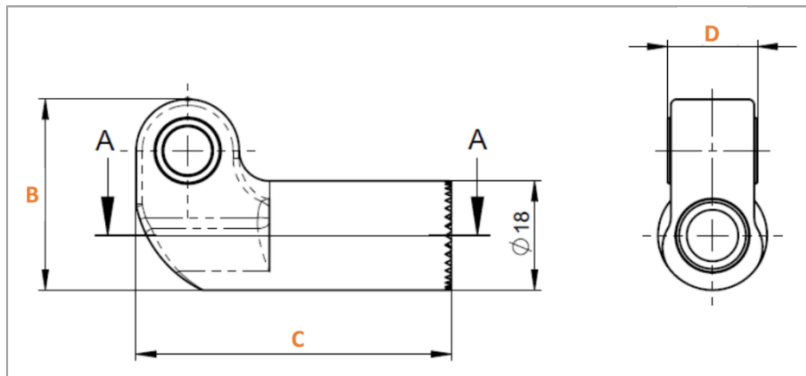


Figure 70: MUTARS® Proximal Ulna – Dimensions

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”

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### 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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TABLE 42 LIST OF ABBREVIATIONS

ABBREVIATION	ABBREVIATED TERM
CoCrMo	Cobalt Chrome Molybdenum
cpTi	Commercially Pure Titanium
HA	Hydroxylapatite
PE	Polyethylene
TCP	Tricalcium Phosphate
TiAl <sub>6</sub> V <sub>4</sub>	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
21.09.2017	0	Creation	S. Deutsch	---
03.09.2021	1	<ul style="list-style-type: none"> <li>• Conversion acc. to MDR</li> <li>• Complete update</li> </ul>	J. Müller	ÄA 21-740, ÄA 21-709
25.10.2021	2	<ul style="list-style-type: none"> <li>• Adjustment of the references</li> <li>• Products removed due to an update of the product list</li> </ul>	J. Müller	ÄA 21-869

