

PART OF THE
TECHNICAL DOCUMENTATION

PRODUCT DESCRIPTION
MUTARS® RS CUP SYSTEM

PRODUCT-GROUP: PRIMARY AND REVISION
ARTHROPLASTY

RISK-CLASS: III

LOCATION: HIP

DATE: 18.11.2021, REV.5

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1. MUTARS® RS Cup System

The MUTARS® RS Cup System consists of:

- ❖ MUTARS® RS cup, available in left and right versions
- ❖ Fastening bolt for MUTARS® RS cup.

The MUTARS® RS Cups are to be used in conjunction with the implacross® PE inserts (0° neutral 0mm, 15° neutral 0mm, and 15° offset 4mm) (cf. FIGURE 2) or with the 2M insert 15° for MUTARS® RS cup and LUMiC® TiN (cf. FIGURE 1).



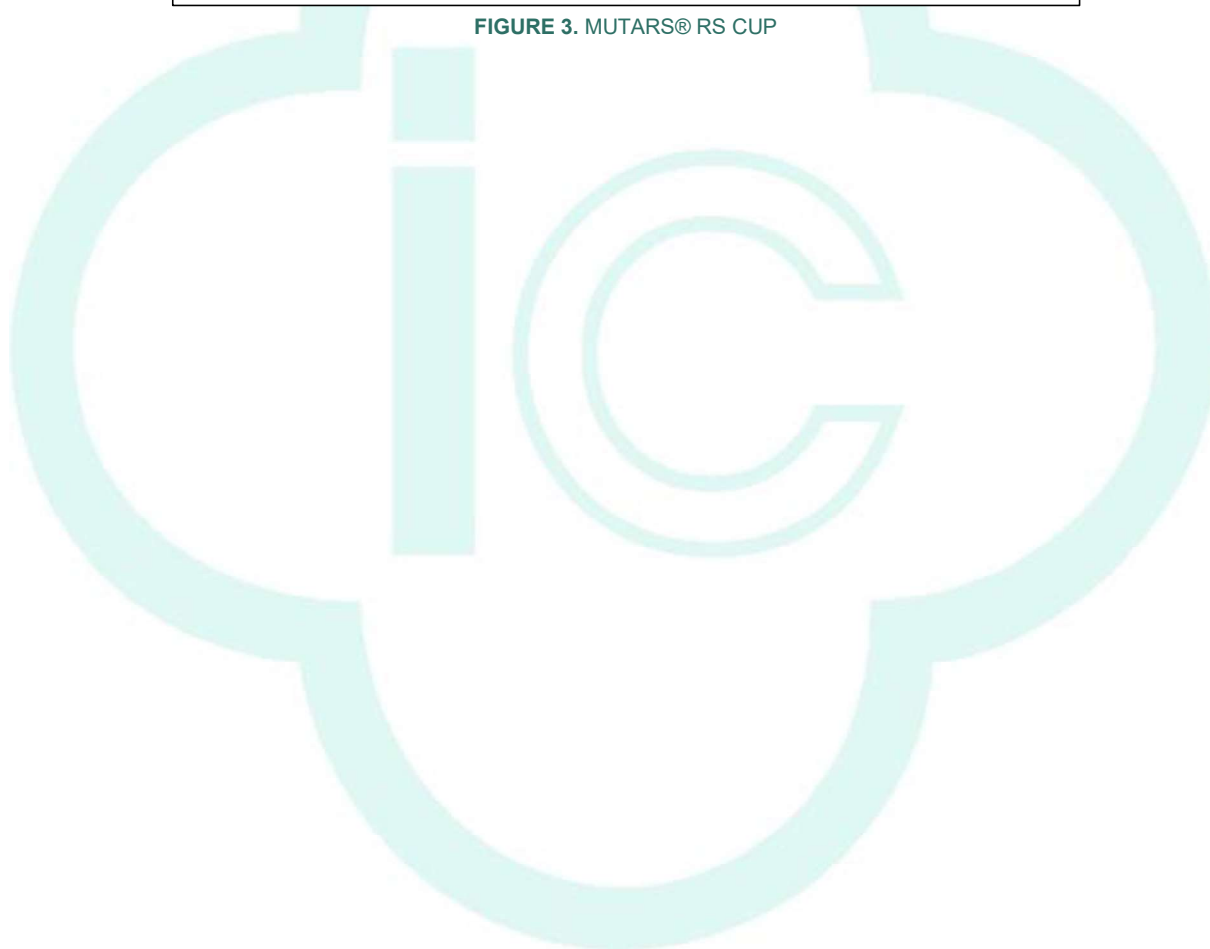
FIGURE 1. MUTARS® RS CUP WITH 2M INSERT 15° AND 2M IMPLACROSS® E HEAD



FIGURE 2. MUTARS® RS CUP WITH IMPLACROSS® PE INSERT



FIGURE 3. MUTARS® RS CUP



2. Intended Use

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

3. Qualification of the Product as a Medical Device

The components of the MUTARS® RS Cup System are medical devices in accordance with the definitions in Article 2 of the Medical Device Regulations MDR (EU) 2017/745 of 05. April 2017. The components of the MUTARS® RS Cup System are “medical devices” “for human beings for the specific medical purposes” as described in the Article 2 under (1) of the of the Medical Device Regulations MDR (EU) 2017/745 of 05. April 2017.

4. Risk-class: III

The components of the MUTARS® RS Cup System are classified in risk class III in accordance with the classification rules in Annex VIII of the Medical Device Regulations MDR (EU) 2017/745 of 05. April 2017. The risk class is justified as the components of the MUTARS® RS Cup System meet the Rule 8 in 5.4 of the Medical Device Regulations MDR (EU) 2017/745 that they are total or partial joint replacement.

5. Intended User

The use of these implants is restricted to persons who, based on their education, knowledge and practical experience, are capable of proper handling and use of the device. Familiarity with the recommended surgical technique and its careful application as well as a pre-operative planning are essential to achieve the best possible outcome. The implantcast GmbH offers special user trainings to ensure an optimal preparation.

6. Target Group

The target population corresponds to the population likely to benefit from the product in indication for joint replacement. Finally, the surgeon decides whether and which version of prosthesis for the individual patient is suitable. This decision depends on several factors, such as the age and the patient's weight,

bone quality, shape of the bone, patient's physical activity levels and deformation of the joint. The provision of prostheses is generally indicated only in patients whose skeleton is fully grown.

7. Indications

Cf. Technical Documentation folder "05 Kennzeichnung" subfolder "Gebrauchsinformation" and the respective document "09300090 MUTARS Hüftpfannensysteme" for Indications.

8. Contraindications

Cf. Technical Documentation folder "05 Kennzeichnung" subfolder "Gebrauchsinformation" and the respective document "09300090 MUTARS Hüftpfannensysteme" for Contraindications.

9. Risk factors

Cf. Technical Documentation folder "05 Kennzeichnung" subfolder "Gebrauchsinformation" and the respective document "09300090 MUTARS Hüftpfannensysteme" for Risk Factors.

10. Design Description

10.1 MUTARS® RS cup

The *MUTARS® RS cup* has a spherical single radius design and is flattened at the pole. The backside (bone facing side) of the *MUTARS® RS cup* incorporates the highly porous EPORE® structure to enhance biological in-growth.

The *MUTARS® RS cup* is intended for cementless application. Initial fixation is achieved by press-fit and screw fixation. Secondary fixation occurs by bone ingrowth into the porous surface.

The *MUTARS® RS cup* has two anatomically shaped flanges which allow for fixation of the cup in the vital portion of the os coxae. The cranial flange is attached to the os ilium by means of screws. Before impacting the cup the cranial flange can be bend (adjusted) to fit the patient's anatomy.

The caudal flange is anchored (inserted) in the ischium. For insertion of the caudal flange, a groove is prepared in the ischium. The caudal flange is wedge shaped, which facilitates the insertion of the flange into the bone.

Due to the anatomical shaped flanges the *MUTARS*® *RS cup* is available in a left and right configuration.

The *MUTARS*® *RS cup* has a central hole in the bottom of the cup, which serves as a holding fixture for the impactor (insert). A central plug (M16x1mm) is provided to cover the apex hole after insertion of the cup to avoid direct contact between polyethylene inserts and bone.

The *MUTARS*® *RS cup* incorporates a cluster of five (5) cranial screw holes for additional screw fixation if required to support the primary fixation. The optional 6.5 mm diameter cancellous screws (spongiosa screws flat head Ø 6.5mm) for additional fixation are provided in lengths from 15 mm to 50 mm in 5 mm increments (lengths till 80mm are provided on request).

The *MUTARS*® *RS cup* is designed to be coupled with polyethylene inserts (implacross® PE inserts) as well as with metal insert (2M insert 15° for *MUTARS*® *RS cup* and LUMiC® TiN). The *MUTARS*® *RS cup* features a taper inner geometry (Taper angle = 18°55'-0°5'). The cup incorporates an internal circumferential groove (cf. FIGURE 4) for connecting of polyethylene (implacross® PE inserts) and metal (2M insert 15° for *MUTARS*® *RS cup* and LUMiC® TiN) inserts and symmetrically spaced anti-rotation notches (grooves) placed at the rim of the shell for enhanced rotational stability of the insert within the shell.

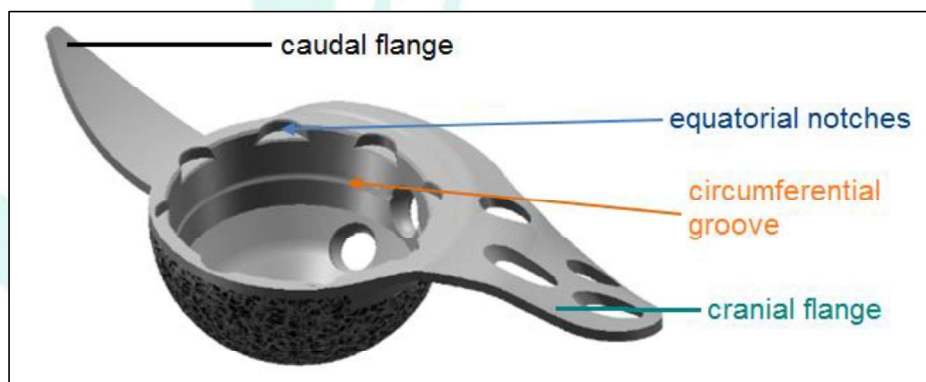


FIGURE 4. MUTARS® RS CUP: INNER GEOMETRY, FLANGES

10.2 implacross® PE inserts

The *implacross*® *PE inserts* are available in a 0° and 15° profile configuration. The 15° profile configuration is available with and without a 4mm offset while the 0° profile configuration is only available without offset. These three Versions allow for adjusting the cup version and offset.

The *implacross® PE inserts* exhibit a conical external shape (Taper angle = $18^{\circ}55' \pm 0^{\circ}25'$). The inserts incorporate a circumferential ring (lug) and equatorial symmetrically spaced anti-rotation tabs (lugs).

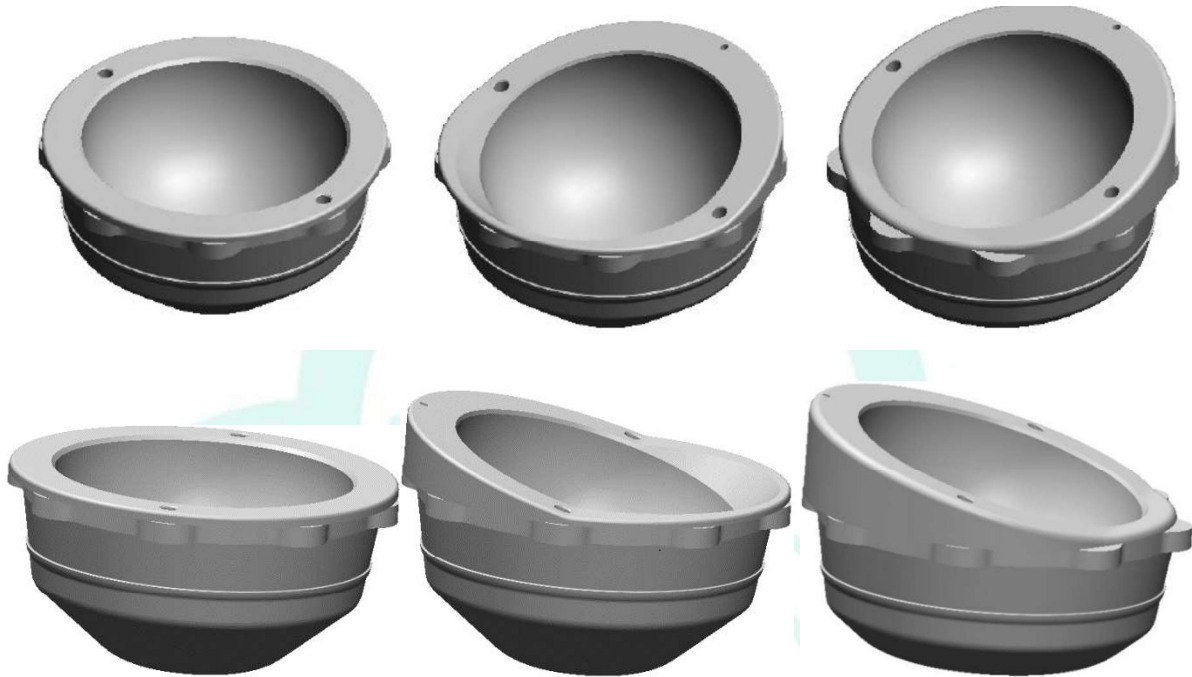


FIGURE 5. IMPLACROSS® PE INSERTS: 0° NEUTRAL 0MM (ON THE LEFT), 15° NEUTRAL 0MM (IN THE MIDDLE), 15° OFFSET 4MM (ON THE RIGHT)

Secure fixation of the *implacross® PE inserts* to shell by a “snap-lock mechanism”, conical coupling and anti-rotation tabs. The *implacross® PE inserts* are fixed to the shell by three mechanisms: 1) a taper fit between the insert and the shell provided by a conical taper shape of the exterior surface of the insert that matches the conical taper geometry and diameter of the interior of the shell, 2) a snap fit mechanism of the circumferential ring (lug) on the inferior aspect of the insert that snap into a circumferential groove of the shell, and 3) equatorial anti-rotation tabs (lugs) that engage the equatorial grooves of the shell.



FIGURE 6. SNAP FIT MECHANISM

10.3 2M insert 15° for MUTARS® RS cup and LUMiC® TiN

The *2M insert 15° for MUTARS® RS cup and LUMiC® TiN* exhibits a conical external shape ($18.917^\circ \pm 0.042^\circ$) and a 15° lip (cf. FIGURE 7). The *2M insert 15°* incorporates a pre-assembled snap ring and pre-assembled polyethylene antirotation tappets for enhanced (improved) rotational stability of the insert within the shell. The *2M insert 15°* is intended to articulate with the outer spherical surface of the 2M polyethylene head (EcoFit® 2M head, 2M implacross® E head) in Dual Mobility Total Hip Arthroplasty.



FIGURE 7. 2M INSERT 15° FOR MUTARS® RS CUP AND LUMiC® TiN

The *2M insert 15°* is coupled to the *MUTARS® RS cup* by three mechanisms: 1) a taper fit between the insert and the shell provided by a conical taper shape of the exterior surface of the insert that matches the conical taper geometry and diameter of the interior of the shell, 2) a snap-fit mechanism of a polyethylene snap ring (*snap ring for 2M insert 15° for MUTARS® RS cup and LUMiC® TiN*) on the inferior aspect of the insert that snaps into a circumferential groove of the shell, and 3) by anti-rotation tappets that engage the equatorial grooves of the shell. The taper angle of the insert is $18.917^\circ \pm 0.042^\circ$ and is slightly greater than that of the cup being $18.917^\circ - 0.083^\circ$ ($18^\circ 55' - 0^\circ 5'$).

11. Materials

The *MUTARS® RS cups* are manufactured using the Electron Beam Melting (EBM) process with TiAl₆V₄ alloy powder.

The central plug and the fastening bolt are manufactured from TiAl₆V₄ wrought alloy acc. to ISO 5832-3.

The implacross® PE inserts are made of cross-linked UHMW-PE (Gamma Radiation with 75kGy).

The *2M insert 15° for MUTARS® RS cup and LUMiC® TiN* is made of CoCrMo casting alloy acc. to ISO 5832-4. The *snap ring* and the *antirotation tappets* are made of UHMW-PE acc. to ISO 5834-2.

12. Coatings / Surfaces

The *MUTARS® RS cups* incorporate a porous EPORE® structure on their bone-facing side. EPORE® is a porous three-dimensional structure based on TiAl₆V₄ alloy. High porosity and a low modulus of elasticity are supporting the biological in-growth. The structure is characterized by a rod thickness of 360 ± 50 µm and features a high affinity with trabecular bone tissue (cf. TABLE 1).

For better osseointegration the cranial flange is rough blasted on the bone facing side and the caudal flange on both sides. The inner surface of the cup is sand blasted.

TABLE 1. EPORE® SPECIFICATIONS

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



FIGURE 8. EPORE® STRUCTURE ON THE BONE-FACING SIDE

The taper connection area of the *2M insert 15° for MUTARS® RS cup and LUMiC® TiN* is rough blasted while the articulating surface is highly polished and coated with Titanium Nitride (TiN) allowing for articulation against the outer convex surface of a matching dual mobility liner (*2M implacross® E head, EcoFit® 2M head*). The rim of the insert is polished and coated with Titanium Nitride (TiN). The specifications of the TiN coating are given in the table below.

TABLE 2. COATING SPECIFICATIONS FOR TiN

PARAMETER	VALUE
COATING TECHNIQUE	PVD-Arc
COATING THICKNESS	5.5 ± 1.5 µm
COATING HARDNESS	HV = 2400 ± 400
AVERAGE ROUGHNESS Ra	< 0.05 µm
TENSILE STRENGTH	≥ 22 MPa
VDI 3824 – ROCKWELL C	HF 1-4

13. Sizes and Dimensions

13.2 MUTARS® RS cups

The *MUTARS® RS cups* are available in five sizes with outer diameters (OD) from 46 to 62 mm in 4 mm increments and 5 inner diameters (ID) from 39 to 52 mm. The sizes of the *MUTARS® RS cup* are provided in the following table (TABLE 3). Each size is available in left and right configurations (cf. FIGURE 9).

TABLE 3. SIZES AND DIMENSIONS OF THE MUTARS® RS CUP

SIZE [mm]	Ø 46	Ø 50	Ø 54	Ø 58	Ø 62
Radius R [mm]	23	25	27	29	31
OD [mm]	46	50	54	58	62
ID [mm]	39	44	48	52	52
L [mm]	103.3	114.5	123.4	132.3	141.3
H [mm]	23.5	25.5	27.5	29.5	31.5

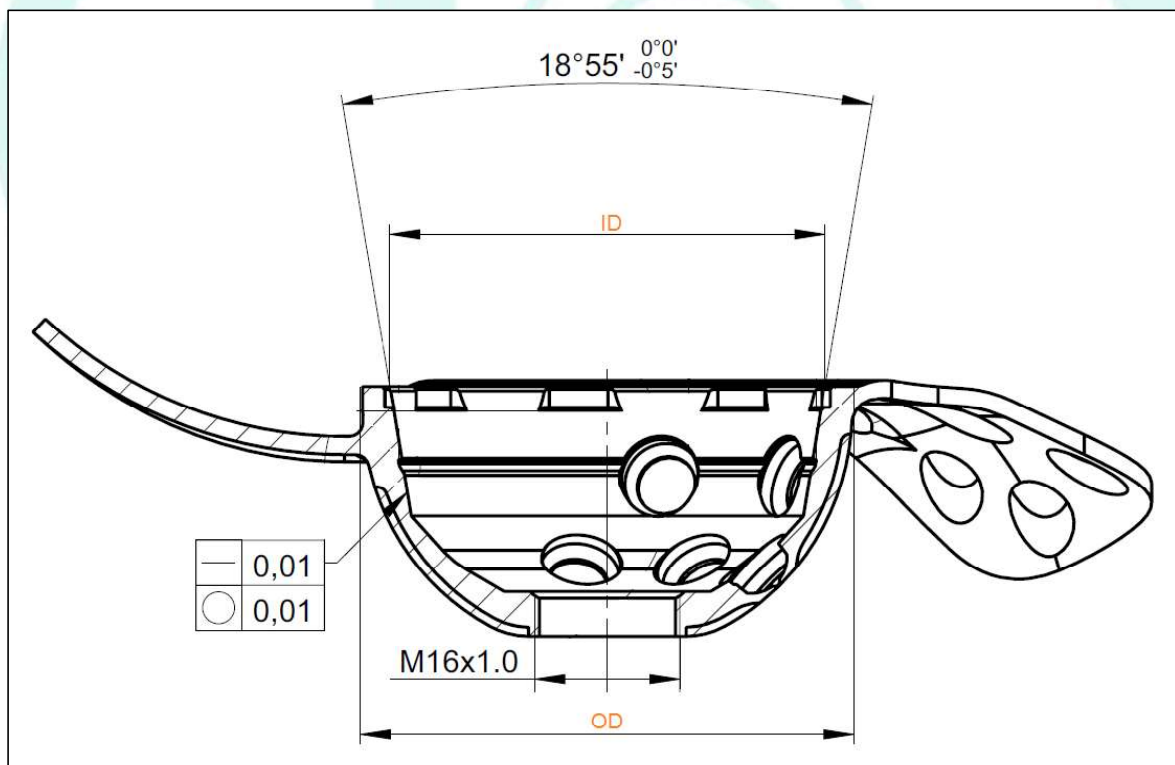


FIGURE 9. INNER (ID), OUTER (OD) DIAMETER, AND CONE ANGLE OF THE MUTARS® RS CUP

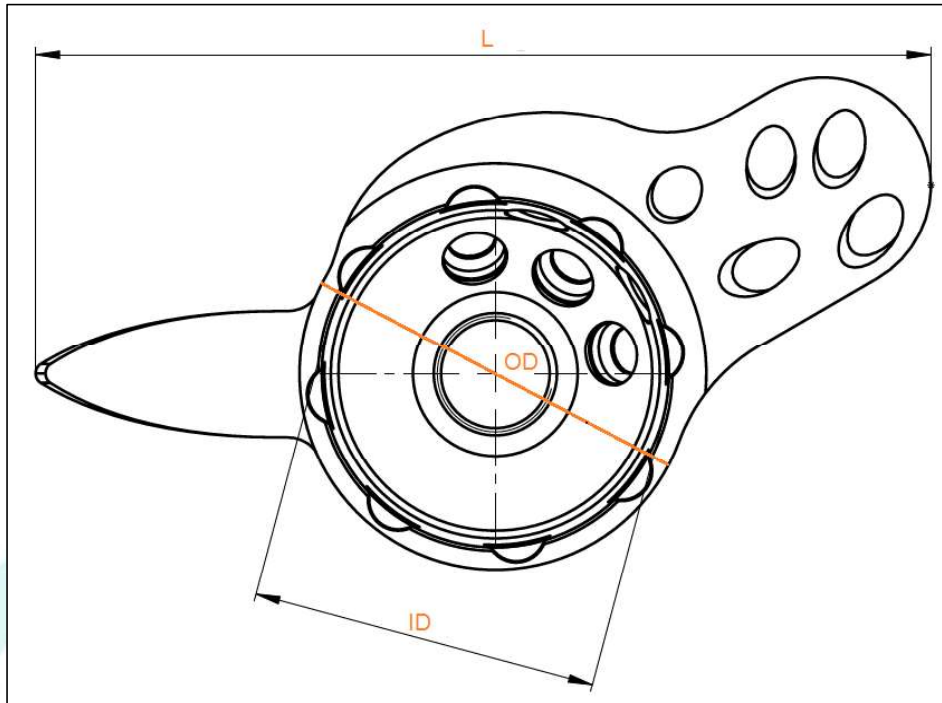


FIGURE 10. INNER (ID) AND OUTER (OD) DIAMETER OF THE MUTARS® RS CUP

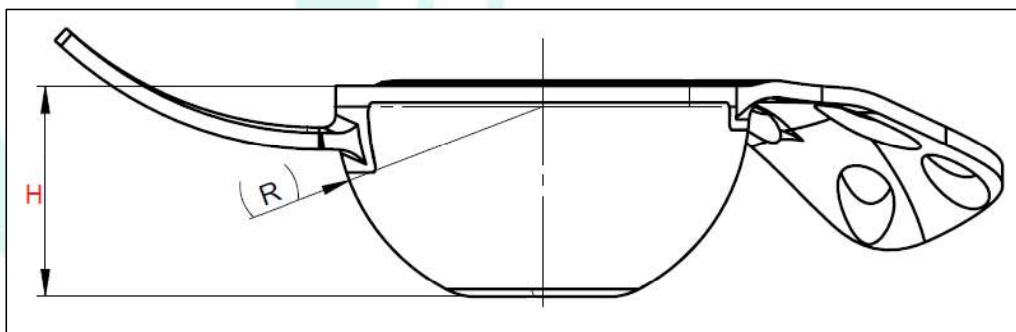


FIGURE 11. HEIGHT (H) OF THE MUTARS® RS CUP

13.3 implacross® PE inserts

The implacross® PE inserts are available in four outer diameters and two inner diameters. The sizes of the implacross® PE inserts are provided in the following table (TABLE 4).

TABLE 4. SIZES AND DIMENSIONS OF THE IMPLACROSS® PE INSERTS

SIZE [mm]	Ø 32/39mm	Ø 36/44mm	Ø 36/48mm	Ø 36/52mm
OD [mm]	39	44	48	52
Ø D1 [mm]	38.33	43.33	47.33	51.33

SIZE [mm]	Ø 32/39mm	Ø 36/44mm	Ø 36/48mm	Ø 36/52mm
Ø D2 [mm]	36.6	41.6	45.6	49.6
Ø D3 [mm]	42.95	47.95	51.95	55.95
Inner Radius R [mm]	16.1±0.05	18.1±0.05	18.1±0.05	18.1±0.05
H [mm] 0° neutral 0mm	21.6	23.6	23.6	23.6
H [mm] 15° neutral 0mm	20.8	23.3	23.6	23.6
H [mm] 15° offset 4mm	26.95	19.3	19.6	19.6
T [mm]	5	5	5	5

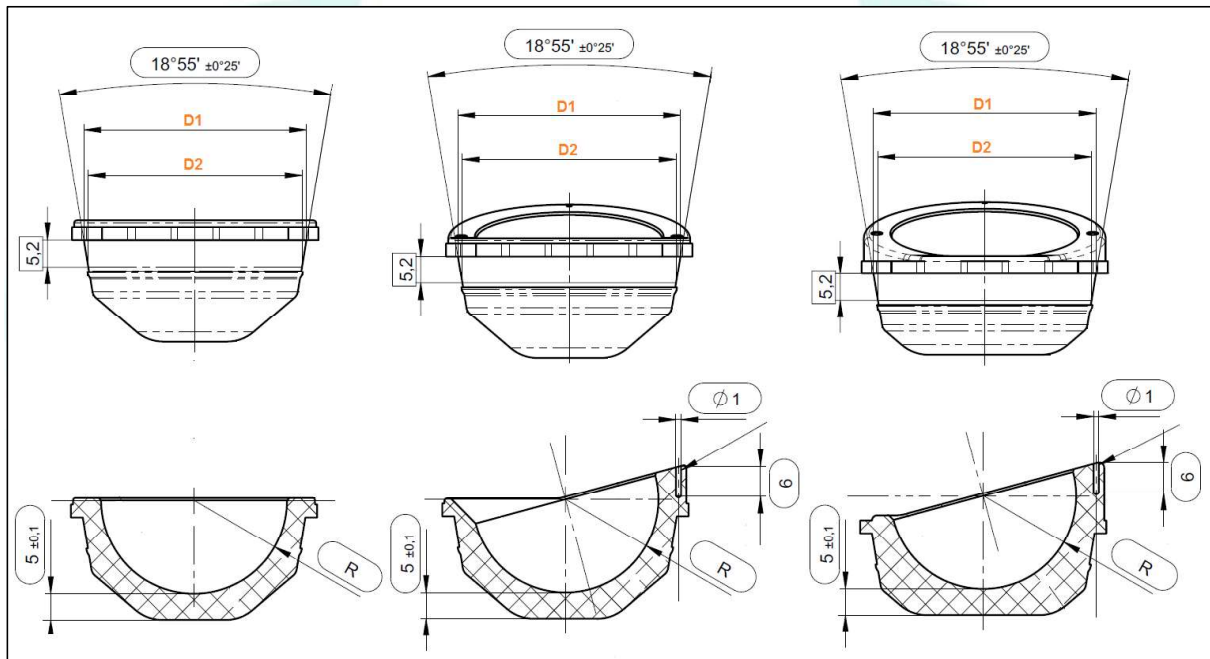


FIGURE 12. DIMENSIONS OF THE IMPLACROSS® PE INSERTS: 0° NEUTRAL 0MM (ON THE LEFT), 15° NEUTRAL 0MM (IN THE MIDDLE), 15° OFFSET 4MM (ON THE RIGHT)

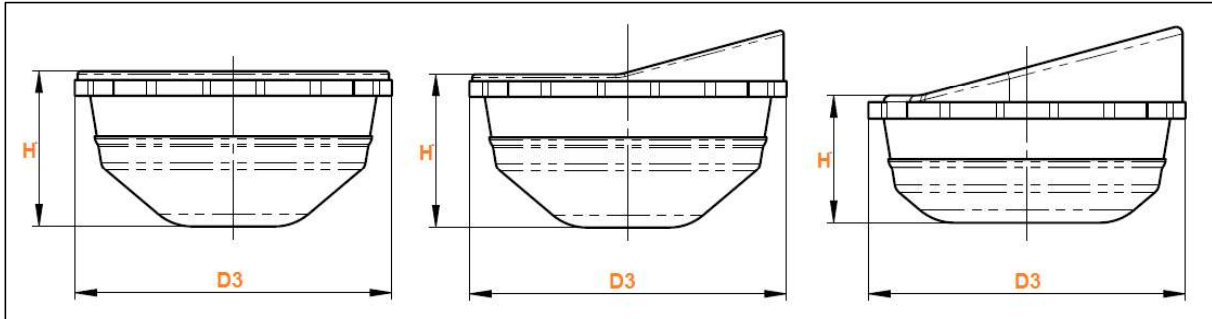


FIGURE 13. DIMENSIONS OF THE IMPLACROSS® PE INSERTS: 0° NEUTRAL 0MM (ON THE LEFT), 15° NEUTRAL 0MM (IN THE MIDDLE), 15° OFFSET 4MM (ON THE RIGHT)

13.4 2M insert 15° for MUTARS® RS cup and LUMiC® TiN

The *2M insert 15° for MUTARS® RS cup and LUMiC® TiN* is available in four sizes with outer diameters (OD) from 39 to 52 mm and four inner diameters (ID) from 38 to 46 mm.

The sizes of the insert are provided in the following table (TABLE 5).

TABLE 5. SIZES AND DIMENSIONS OF THE 2M INSERTS 15°

SIZE [mm]	Ø 38/39mm	Ø 42/44mm	Ø 44/48mm	Ø 46/52mm
ID [mm]	38	42	44	46
OD [mm]	39.07	44.07	48.07	52.07
H [mm]	15	16	17	19.2
T [mm]	1.4	2.47	1.5	1.5

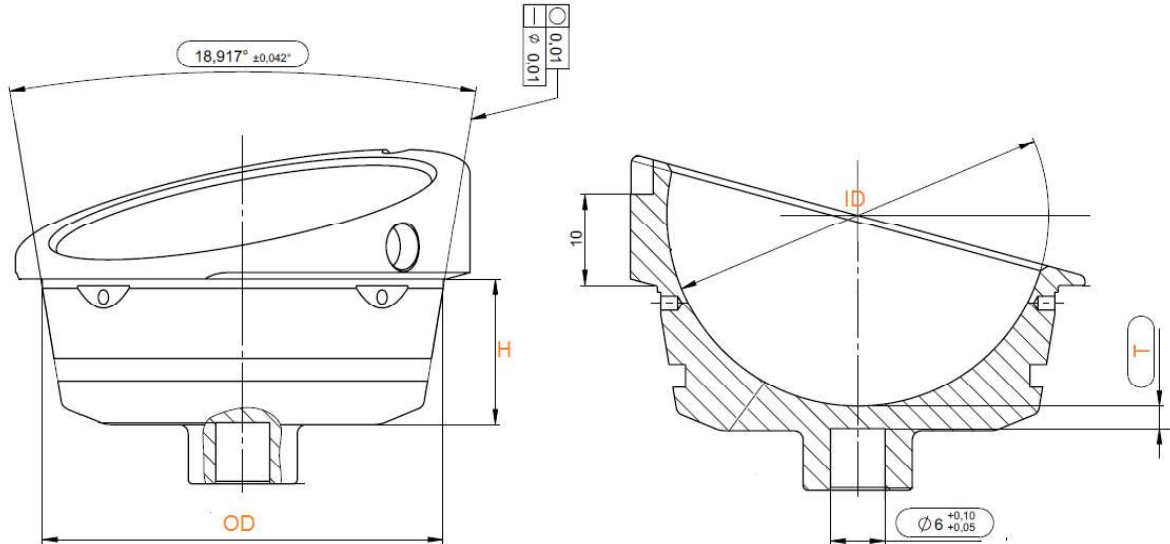


FIGURE 14. DIMENSIONS OF THE 2M INSERT 15° FOR MUTARS® RS CUP AND LUMIC® TIN

14. Compatibility

The *MUTARS® RS cups* are only allowed to be used in combination with cup inserts approved by the implantcast GmbH for use with them.

The compatible *MUTARS® RS cups* and inserts are listed in the following tables.

TABLE 6. MUTARS® RS CUP– IMPLACROSS® PE INSERTS – COMPATIBILITY

	MUTARS® RS CUPS					
	SIZE	Ø 46	Ø 50	Ø 54	Ø 58	Ø 62
IMPLACROSS® PE INSERT 0° NEUTRAL 0MM, IMPLACROSS® PE INSERT 15° NEUTRAL 0MM, IMPLACROSS® PE INSERT 15° OFFSET 4MM	Ø 32/39mm	✓				
	Ø 36/44mm		✓			
	Ø 36/48mm			✓		
	Ø 36/52mm				✓	✓

TABLE 7. MUTARS® RS CUP– 2M INSERT 15° – COMPATIBILITY

	MUTARS® RS CUPS					
	SIZE	Ø 46	Ø 50	Ø 54	Ø 58	Ø 62
2M INSERT 15°	Ø 38/39mm	✓				

MUTARS® RS CUPS						
	Ø 42/44mm		▼			
	Ø 44/48mm			▼		
	Ø 46/52mm				▼	▼

▼ indicates "Combination is allowed"

■ indicates "Combination is not allowed"

The 2M inserts 15° for MUTARS® RS cup and LUMiC® TiN are only allowed to be used in combination with acetabular cups and 2M polyethylene heads approved by the implantcast GmbH for use with them. The 2M insert 15° for MUTARS® RS cup and LUMiC® TiN mates with 2M polyethylene heads (2M implacross® E head, EcoFit® 2M head) having an outer diameter corresponding to the inner diameter of the insert (i.e., 2M insert 15° with an inner diameter of 42mm mates with any liner having an outer diameter of 42mm). The compatible 2M inserts 15 and 2M polyethylene heads are listed in the following table.

TABLE 8. 2M INSERT 15° – 2M POLYETHYLENE HEADS – COMPATIBILITY

	SIZE	2M IMPLACROSS® E HEAD ECO FIT® 2M HEAD			
		Ø 22/38mm	Ø 28/42mm	Ø 28/44mm	Ø 28/46mm
2M INSERT 15°	Ø 38/39mm	▼			
	Ø 42/44mm		▼		
	Ø 44/48mm			▼	
	Ø 46/52mm			▼	▼

▼ Indicates "Combination is allowed"

■ Indicates "Combination is not allowed"

The detailed component compatibility is given in the following documents:

- ⇒ Doc. "Kombinationstabelle_MUTARS® RS Cup" (compatibility table for MUTARS® RS cups) in the folder "11 Kombinationstabellen"

15. Warnings

Cf. Technical Documentation folder “05 Kennzeichnung” subfolder “Gebrauchsinformation” and the respective document “09300090 MUTARS Hüftpfannensysteme” for Warnings.

16. Product List (Identification of the Products)

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

⇒ See Doc. “Fbl_732-1-0-14_Produktliste_MUTARS RS Cup” in the folder “02 Produktliste”

17. Reference to Previous Generations and Similar Devices

Information about previous generations or variants of the products can be found in the product history.

⇒ See Doc. “Fbl_423-1-2-2_Produkthistorie Technische Dokumentation_MUTARS RS Cup” (Product history Technical Documentation_MUTARS RS Cup) in the folder “16 Produkthistorie”

Similar devices available on the market is the Delta Revision TT by Lima Corporate.

LISTS

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LIST OF ABBREVIATIONS

TABLE 9. LIST OF ABBREVIATIONS

ABBREVIATION	ABBREVIATED TERM
EBM	Electron Beam Melting
H	Height
ID	Inner Diameter
MDR	Medical Device Regulation
OD	Outer Diameter
PE	Polyethylene
R	Radius

PRODUCT DESCRIPTION MUTARS® RS Cup System

T	Thickness
TiN	Titanium Nitride



DOCUMENT REVISION HISTORY

DATE	REVISION	CHANGES	AUTHOR	COMMENTS
04.12.2012	0	Creation	J. Höppner	---
13.05.2014	1	Update	J. Höppner	Design and Content Update
31.03.2016	2	Update	J. Höppner	Inclusion of 2M Inlays
08.12.2016	3	Update	J. Höppner	Exclusion of Inlays (Separate Document)
26.09.2019	4	Update	Dr. S. Frey	New Images for the RS Cup®
18.11.2021	5	Complete update conforming to MDR Adding the Inserts	A. Kerber	ÄA 21-917