

PART OF THE
TECHNICAL DOCUMENTATION

PRODUCT DESCRIPTION
METAL AUGMENTS HIP

(METAUG_IIB, EMDN: P09088003)

PRODUCT-GROUP: PRIMARY-, REVISION-, AND TUMOR-
ARTHROPLASTY,

RISK-CLASS: IIB

LOCATION: HIP

DATE: 04.06.2024, REV. 5

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1 Metal Augments Hip

Below, all variations and components of the “Metal Augments Hip” are shown:

- EPORE® acetabular spacer 8 mm
- EPORE® buttress augment straight
- EPORE® buttress augment
- EPORE® shim augment
- MUTARS® PRS incl. central hole cover
- ic restrictor acetabulum

FIGURE 1: EPORE® ACETABULAR SPACER 8 mm

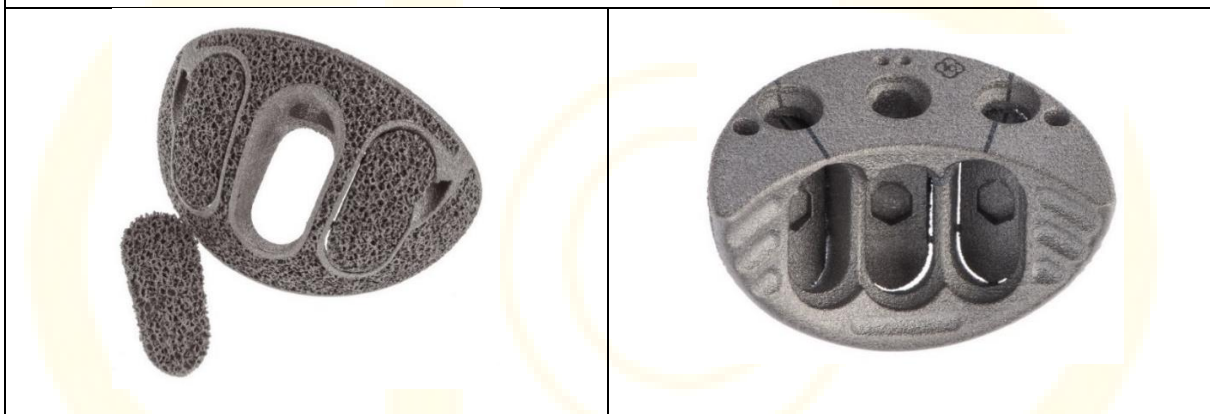


FIGURE 2: EPORE® BUTTRESS AUGMENT STRAIGHT
(on the right: with bone screws and EPORE® buttress augment)

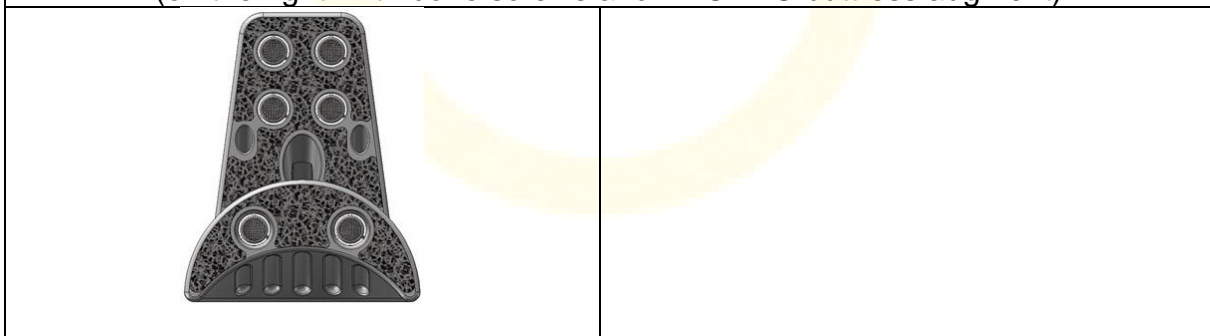


FIGURE 2: EPORE® BUTTRESS AUGMENT STRAIGHT
 (on the right: with bone screws and EPORE® buttress augment)

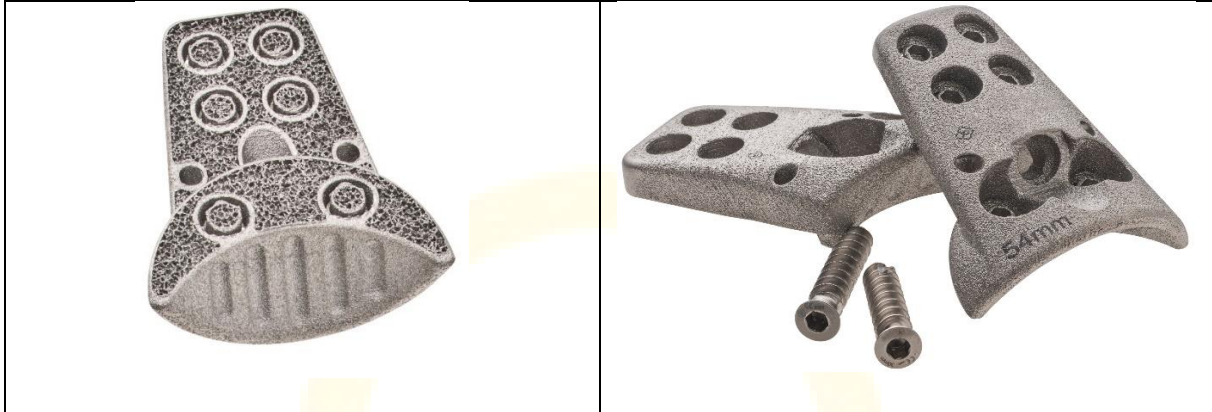


FIGURE 3: EPORE® BUTTRESS AUGMENT
 (on the right: with bone screws and EPORE® buttress augment straight)

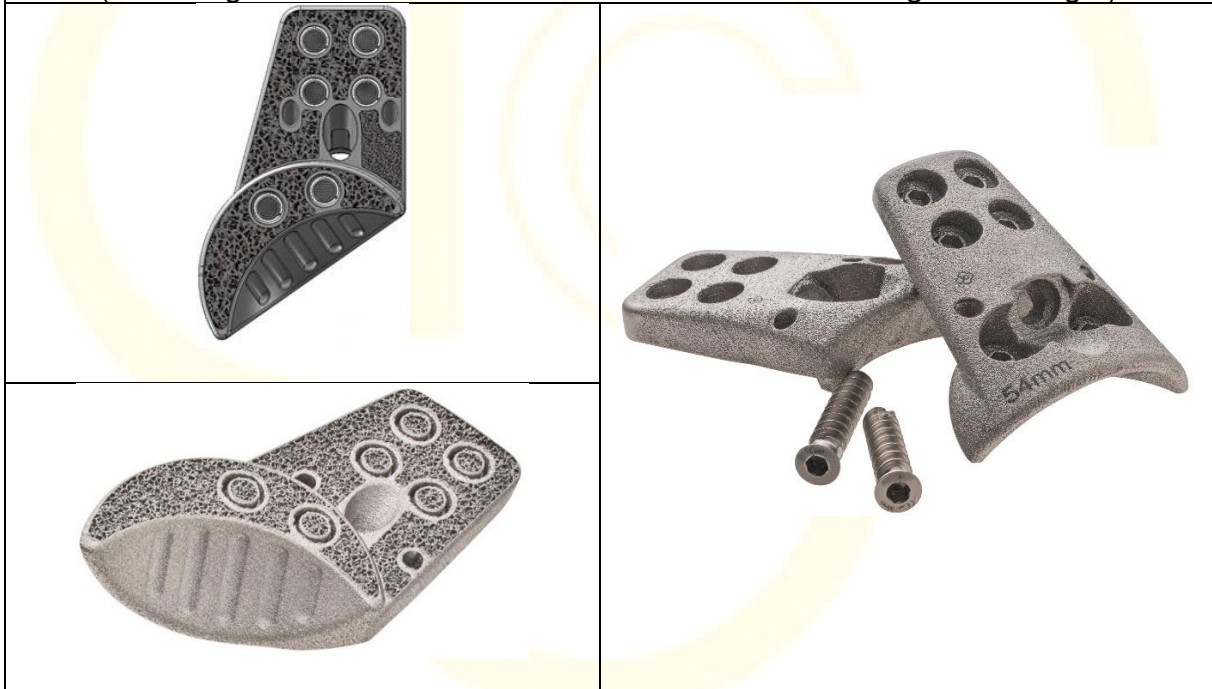


FIGURE 4: EPORE® SHIM AUGMENT

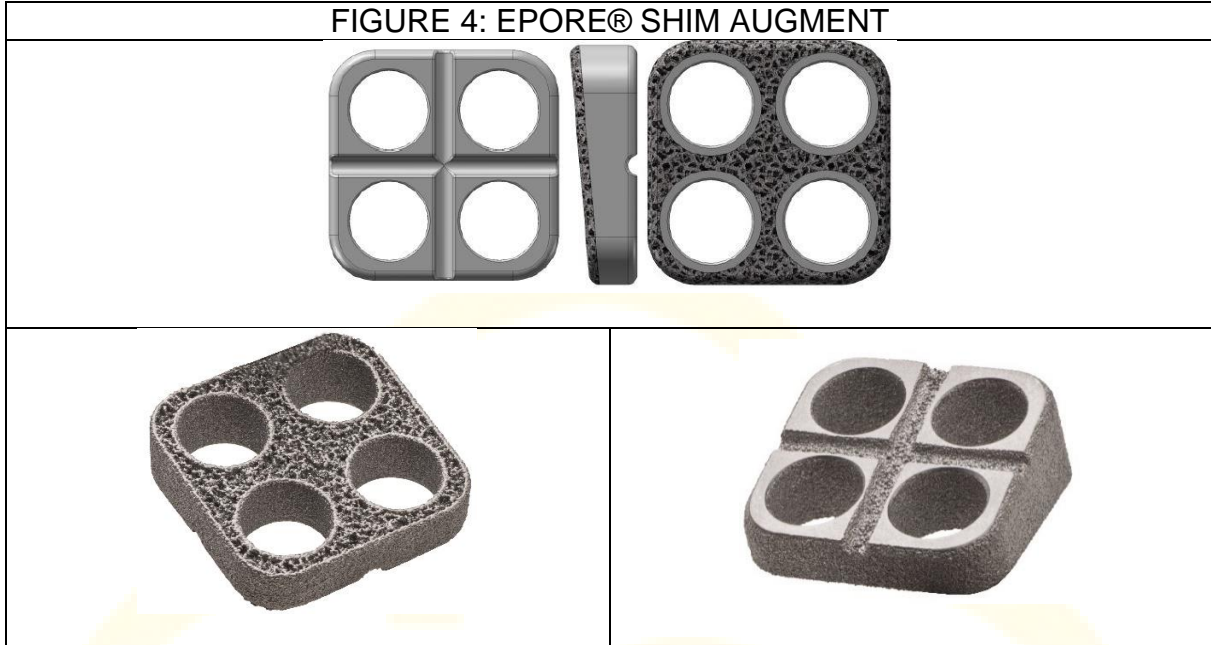
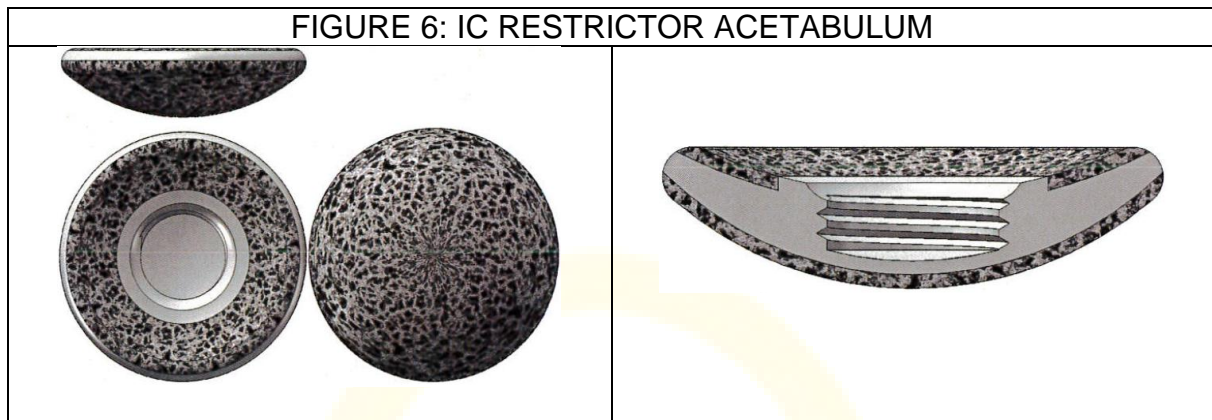


FIGURE 5: MUTARS® PRS incl. central hole cover
(on the right: with bone screws)





2 Intended Use

⇒ Please see the following documents each for the respective products in the folder “1_Device\1.1_Description_Specification\Description\IntendedUse“

Products	Intended use is mentioned in:
EPORE® acetabular spacer 8 mm	Zweckbestimmung_EPORE Acetabulumspacer8mm
EPORE® buttress augment straight	Zweckbestimmung_EPORE Buttress Augmente
EPORE® buttress augment	
EPORE® shim augment	Zweckbestimmung_EPOREShimAugmente
MUTARS® PRS incl. central hole cover	Zweckbestimmung_MUTARS PRS
ic restrictor acetabulum	Zweckbestimmung_ic-Restriktor Acetabulum

3 Qualification of the Product as a Medical Device

The products „metal augments hip,“ as listed in chapter 1 are medical devices in accordance with the Council Directive 93/42/EEC and the Definitions in Article 2 of the Medical Device Regulations MDR (EU) 2017/745 of 05. April 2017. The “metal augments hip” listed in chapter 1 are “medical devices” “for human beings for the specific medical purposes” as described in the Article 2 under (1) of the Medical Device Regulations MDR (EU) 2017/745 of 05. April 2017.

4 Risk-class: IIb implantable

The risk classification of the metal augments hip can be found in the following document:

⇒ See Doc. „RiskClassification_MDR_2017-745_METAUG_Ilb_P09088003_Rev.0” in the folder “1_Device\1_Description_Specification\1_Description\RiskClassification”

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

⇒ See Doc. (instruction for use) “09300087 Metal Augments ” in the folder “2_Information\2.3_IFU”

7 Indications

⇒ See Doc. (instruction for use) “09300087 Metal Augments ” in the folder “2_Information\2.3_IFU”

8 Contraindications

⇒ See Doc. (instruction for use) “09300087 Metal Augments ” in the folder “2_Information\2.3_IFU”

9 Risk factors

⇒ See Doc. (instruction for use) “09300087 Metal Augments ” in the folder “2_Information\2.3_IFU”

10 Design Description

A combination of the MUTARS® PRS, MUTARS® PRS reinforcement cages, EPORE® Acetabular spacer 8 mm and EPORE® buttress augments und EPORE® shim augments with the corresponding bone screws (Spongiosa screw flat head Ø 6.5 mm or cancellous screw Ø 8 mm) is mandatory. At least one bone screw must be placed to ensure secure primary stability and rotational stability. It is the responsibility of the user to check whether there is reliable primary stability and corresponding rotational stability with the selected number of screws.

10.1 Design Description of EPORE® acetabular spacer 8 mm

On the cementless contact side to the bone, the EPORE® acetabular spacer 8 mm has a porous three-dimensional surface structure, called EPORE®.

The interface between the EPORE® acetabular spacer 8 mm and the artificial acetabular implant is cemented.

The following bone screws may be used for the three segments/long holes:

- ⊕ Either cancellous screw Ø 8 mm or
- ⊕ Spongiosa screw flat head Ø 6.5 mm with a Shim for EPORE® acetabular spacer sz. 8 mm.

EPORE® acetabular spacer 8 mm feature screw holes plugged with “crunch plugs”, which can be removed with appropriate instrument. Only one screw can be fixed per segment (hole).

Into the side holes, the spongiosa screws flat head Ø 6.5 mm can be screwed.

10.2 Design Description of EPORE® buttress augment

On the cementless contact side to the bone, the EPORE® buttress augment has a porous three-dimensional surface structure, called EPORE®.

The EPORE® buttress augment must be cementless to the contact side to the bone and cemented to the contact side to the acetabular implant.

The EPORE® buttress augment has 6 screw holes for the spongiosa screw flat head Ø 6.5 mm. The screw holes are plugged with “crunch plugs”, which can be removed with appropriate instrument.

Following versions are available:

- ⊕ EPORE® buttress augment sz. 54 mm straight (see FIGURE 2 and FIGURE 7)
- ⊕ EPORE® buttress augment sz. 58 mm straight (see FIGURE 2 and FIGURE 7)
- ⊕ EPORE® buttress augment left posterior / right anterior (see FIGURE 3 and FIGURE 8)
- ⊕ EPORE® buttress augment right posterior / left anterior (see FIGURE 3 and FIGURE 8)

10.3 Design Description of EPORE® shim augments

The EPORE® shim augment has a square shape with beveled support surface. The EPORE® shim augment will be implanted under an EPORE® buttress augment to provide stable support.

On the cementless contact side to the bone, the EPORE® shim augment has a porous three-dimensional surface structure, called EPORE®.

The contact side of the EPORE® shim augment to the EPORE® buttress augment must be cemented to combine with the EPORE® buttress augment.

The EPORE® shim augment has 4 screw holes for spongiosa screw flat head Ø 6.5 mm.

The EPORE® shim augments must not be combined with the artificial acetabular cups.

10.4 Design Description of MUTARS® PRS incl. central hole cover

The MUTARS® PRS covers nearly the whole surface of the combined acetabular cup with its almost hemi-spherical form. In the medial area, it provides a flattening.

The cementless contact side to the bone, the MUTARS® PRS has a porous three-dimensional surface structure, called EPORE®. The interface with the artificial acetabular implant is cemented.

The MUTARS® PRS are compatible with the following bone screws:

- ⊕ There are 9 screw holes for the spongiosa screws flat head Ø 6.5 mm and
- ⊕ 3 screw holes for the cancellous screws Ø 8 mm. With a shim for spongiosa screw flat head Ø 6.5 mm, the spongiosa screws flat head Ø 6.5 mm can also be screwed in these 3 screw holes.

These 12 screw holes are plugged with “crunch plugs”, which can be removed with appropriate instrument.

The MUTARS® PRS incorporates a 10 mm diameter threaded apex hole, which serves as a holding fixture for the cup impactor. A central hole cover threaded M10x1 (REF02803100) is provided to cover the apex hole after insertion of the cup to protect the threads.

10.5 Design Description of ic restrictor acetabulum

The ic restrictor acetabulum has a porous three-dimensional surface structure, called EPORE®, on the front and back side.

The ic restrictor acetabulum is intended for bone-side cementless and implant-side cemented fixation. There is a thread (M10x1) in the pole. To protect the threads, the central hole cover threaded M10x1 (REF02803100) is used to close the thread (This cover is not included to the ic restrictor acetabulum).

11 Materials

Following products are manufactured using electron beam melting (EBM) process (additive manufacturing) with TiAl₆V₄ alloy powder:

- ⊕ EPORE® acetabular spacer 8 mm
- ⊕ EPORE® buttress augment straight

- ☞ EPORE® buttress augment
- ☞ EPORE® shim augment
- ☞ MUTARS® PRS
- ☞ ic restrictor acetabulum

The central hole cover threaded M10x1, which is used with the MUTARS® PRS is made from wrought TiAl₆V₄ alloy acc. to ISO 5832-3.

(Note: The central hole cover threaded M10x1 is part of the technical documentation "EcoFit Cups". Therefore, it will not be considered further in this product description.)

12 Coatings / Surfaces

All the "metal augments hip" as listed in chapter 1 are uncoated.

Following products have the EPORE® structure (surface specification SUR_G1):

- EPORE® acetabular spacer 8 mm
- EPORE® buttress augment straight
- EPORE® buttress augment
- EPORE® shim augment
- MUTARS® PRS
- ic restrictor acetabulum

The EPORE® structure has the following parameters:

TABLE 1: SPECIFICATION FOR EPORE®

CHARACTERISTICS	VALUE
	EPORE® <i>(Surface Specification SUR_G1)</i>
MANUFACTURING PROCESS	Additive Manufacturing
POROSITY	61% ± 8%
SPECIFIC E-MODULE	3.1 GPa ± 0.6 GPa
ROD DIAMETER	360 μm ± 50 μm

12.1 Coatings/Surfaces of EPORE® acetabular spacer 8 mm

On the cementless contact side to the bone, the surface has the EPORE® structure.

On the interface with the artificial acetabular cup implant and the frontside, the surface is sandblasted.

12.2 Coatings/Surfaces of EPORE® buttress augment

On the cementless contact side to the bone, the surface has the EPORE® structure.

The contact side to the soft tissues/muscles, the surface is sandblasted.

The contact side to the acetabular cup implant must be cemented which has a grooved blasted surface.

12.3 Coatings/Surfaces of EPORE® shim augments

On the cementless contact side to the bone, the surface has the EPORE® structure.

The contact side to the EPORE® buttress augment, the surface is blasted matte. The same surface is applied around the sides of the implant.

12.4 Coatings/Surfaces of MUTARS® PRS

The inner surface of the MUTARS® PRS is corundum blasted and has circumferential circular grooves and equally spaced radial grooves.

The outer side of the MUTARS® PRS has an EPORE® structure.

12.5 Coatings/Surfaces of ic restrictor acetabulum

On the front and back side of the ic restrictor acetabulum, the surface has the EPORE® structure, except the thread at the pole.

13 Sizes and Dimensions

The metal augments hip are available in following sizes:

METAL AUGMENT HIP	SIZE RANGE	
EPORE® acetabular spacer 8 mm	26 sizes	46 / 10 to 70 / 30
EPORE® buttress augment straight	2 sizes	54 mm, 58 mm
EPORE® buttress augment	2 sizes	left posterior / right anterior, right posterior / left anterior
EPORE® shim augment	3 sizes	5°, 10°, 15°
MUTARS® PRS incl. central hole cover	11 sizes	52 mm to 72 mm
ic restrictor acetabulum	3 sizes	26 mm, 32 mm, 38 mm

13.1 Sizes and Dimensions of EPORE® acetabular spacer 8 mm

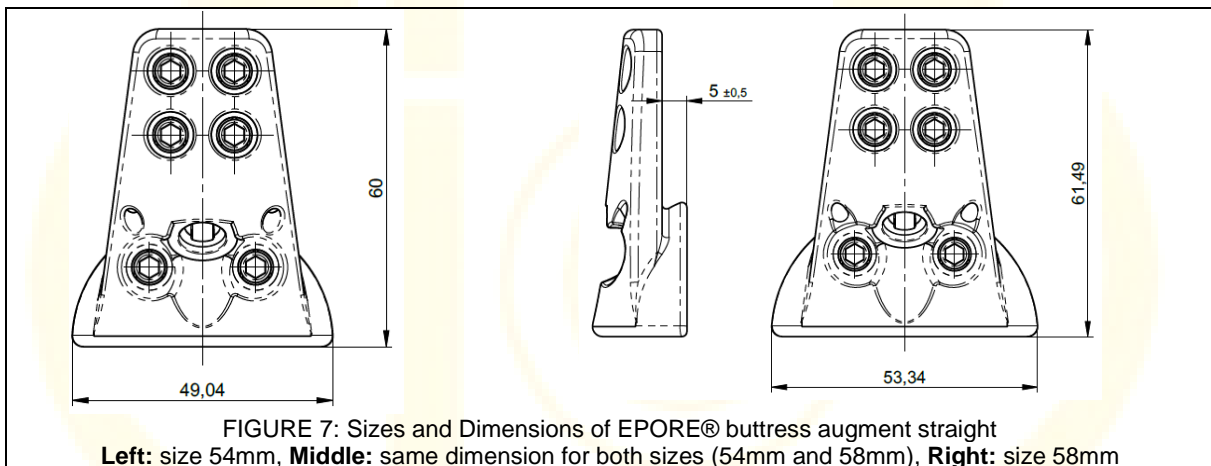
The sizes are given in the following table. The EPORE® acetabular spacer 8 mm is available in 7 inner diameters with 3 or 4 height options for respective inner diameters.

Table 2: SIZES AND DIMENSIONS OF EPORE® ACETABULAR SPACER 8 mm

EPORE® ACETABULAR SPACER 8 mm							
INNER DIAMETER [MM]	46	50	54	58	62	66	70
HEIGHT [MM]	10	10	10	10	10	10	10
	15	15	15	15	15	15	15
	20	20	20	20	20	20	20
	/	/	30	30	30	30	30

13.2 Sizes and Dimensions of EPORE® buttress augment straight

Sizes and dimensions are given below (in mm).

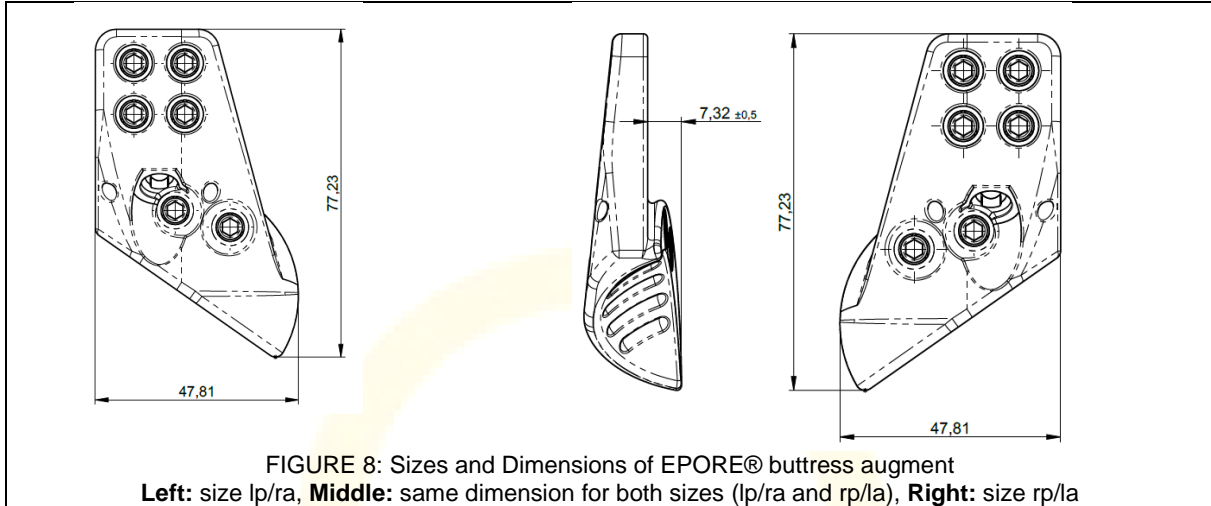


13.3 Sizes and Dimensions of EPORE® buttress augment

Sizes and dimensions are given below (in mm).

Following abbreviations are used:

- lp/ra: left posterior/right anterior
- rp/la: right posterior/ left anterior



13.4 Sizes and Dimensions of EPORE® shim augments

4 holes of the EPORE® shim augments have diameter of 8.6 mm.

The sizes are given in the following table.

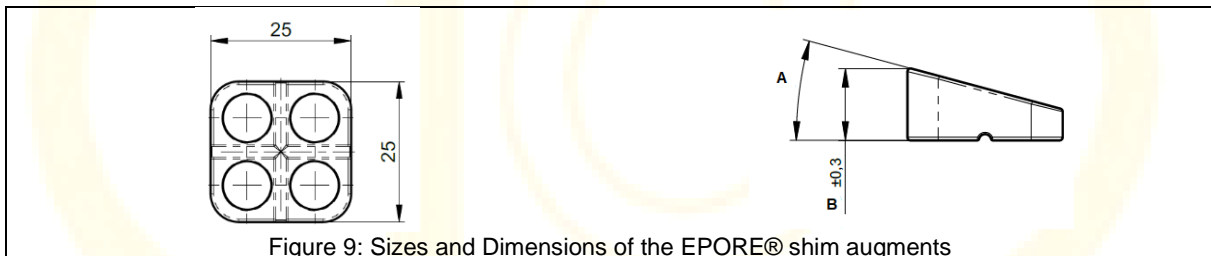


Table 3: Sizes and Dimensions of the EPORE® shim augments

Sizes and Dimensions of the EPORE® shim augments				
REF	Item description	Size	A [°]	B [mm]
02961005	EPORE® shim augment	5°	5	7.14
02961010	EPORE® shim augment	10°	10	9.31
02961015	EPORE® shim augment	15°	15	11.55

13.5 Sizes and Dimensions of MUTARS® PRS

The sizes are given in the following table.

Table 4: SIZES AND DIMENSIONS OF MUTARS® PRS

MUTARS® PRS											
SIZE [MM]	52	54	56	58	60	62	64	66	68	70	72

OUTER DIAMETER [MM]	53.6	55.67	57.7	59.78	61.8	63.88	65.9	67.98	70	70.02	74
HEIGHT [MM]	23,9	24,94	26	26,99	28	29	30	31	32	33	34

13.6 Sizes and Dimensions of ic restrictor acetabulum

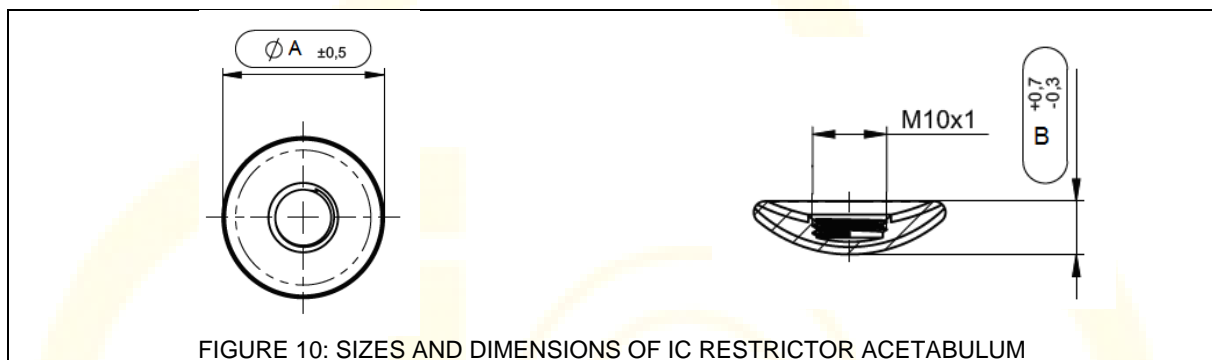


FIGURE 10: SIZES AND DIMENSIONS OF IC RESTRICTOR ACETABULUM

Table 5: Sizes and dimensions of the ic restrictor acetabulum

Sizes and Dimensions of the ic restrictor acetabulum				
REF	Item description	Size	A [mm]	B [mm]
02950026	ic restrictor acetabulum	26 mm	26	7.2
02950032	ic restrictor acetabulum	32 mm	32	7.2
02950038	ic restrictor acetabulum	38 mm	38	7.2

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 instruction for use “09300087 Metal Augments” and annex I of the instruction for use “09300098 Metal augments” in the folder “2_Information\2.3_IFU”
- ⇒ See “combinationtable_MUTARS PRS”
- ⇒ See “combinationtable MUTARS PRS_Cage”
- ⇒ See “combinationtable MUTARS PRS_Devices”
- ⇒ See “combinationtable_Restrictor_Buttruss_ic hip cups”

- ⇒ See “combinationtable_Spacer_Buttress_Shims_Restriktor”
 - ⇒ See “combinationtable_Spacer_ic hip cups”
in the folder “1_Device\1.1_Description_Specification\Description\Compatibility\Draft”
-

15 Warnings

- ⇒ See Doc. (instruction for use) “09300087 Metal Augments” in the folder “2_Information\2.3_IFU”
-

16 Product List (Identification of the products)

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

- ⇒ See Doc. “Productlist_METAUG_IIb_P09088003_Devices” and ” Productlist_METAUG_IIb_P09088003_Art22” in the folder “1_Device\1.1_Description_Specification\Description\ProductList”
-

17 Reference to previous generations and similar devices

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

- ⇒ See Doc. “Produktgeschichte Technische Dokumentation” in the folder “1_Device\1.2_History_SimilarDevice\History”

Similar device available on the markets is the Trabecular Metal reconstruction system from the company ZimmerBiomet.

- ⇒ See Doc. “SimilarDevice_Augments_METAUG_IIb_P09088003” in the folder “1_Device\1.2_History_SimilarDevice\SimilarDevice”
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LISTS

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ABBREVIATION	ABBREVIATED TERM
ID	Inner Diameter
lp/ra	left posterior/right anterior
OD	Outer Diameter
PRS	Pelvic Reconstruction System
rp/la	right posterior/ left anterior
TiAl ₆ V ₄	Titanium Aluminium Vanadium

DOCUMENT REVISION HISTORY

DATE	REVISION	CHANGES	AUTHOR	COMMENTS
---	0	Creation	I. Fateev	In German; in Excel-document
16.04.2018	1	<ul style="list-style-type: none"> - Creation: "MUTARS® PRS" (former "EPORE® RS acetabulum spacer full") and "Shim for cancellous bone screw sz. 6.5 mm" - Changes: <ul style="list-style-type: none"> - German to English - New layout 	S. Schlüter	in Word
17.01.2023	2	<p>Full revision, new layout Following implants are added:</p> <ul style="list-style-type: none"> • EPORE® acetabular spacer 8 mm <ul style="list-style-type: none"> • with shim for EPORE® acetabular spacer sz. 8 mm • EPORE® buttress augment straight • EPORE® buttress augment • EPORE® shim augment • ic restrictor acetabulum • MUTARS® PRS reinforcement cage 	S. Schlüter	Change notification No. 23-013
01.02.2023	3	The material of the central hole cover threaded M10x1 is added.	S. Schlüter	Change notification no. 23-052
21.05.2024	4	Change notification 24-250, 24-294	S. Schlüter	<p>MDR</p> <p>Following products are removed from this product description:</p> <ul style="list-style-type: none"> • shim for spongiosa screw flat head Ø 6,5mm • shim for EPORE® acetabular spacer 8 mm • MUTARS® PRS reinforcement cage <p>These products are described in separate product descriptions from the MDR onwards.</p> <p>EPORE® acetabular spacer is removed because of the product termination acc. to the change notification 23-578</p>
04.06.2024	5	<ul style="list-style-type: none"> • Change notification 24-346 • Updating design description • The document name of the intended use is adjusted as follows: 	S. Schlüter	/

PRODUCT DESCRIPTION METAL AUGMENTS HIP

		Old: "Zweckbestimmung_Rev.0_Product"		
		New: "Zweckbestimmung_Product"		

