



NOTICE BELGELENDİRME MUAYENE ve DENETİM HİZMETLERİ A.Ş.

Hereby certifies that

aap Joints GmbH

With the address(es) below:

Address : Wilhelm-von-Siemens-Strasse 23, Aufgang F, 12277 Berlin

has implemented a quality management system according to

EN ISO 13485:2016

The scope of this Quality Management System includes:

Design, development, manufacturing and distribution of knee prosthesis, hip prosthesis and hip accessories and distribution and sales of surgical instruments

Certificate Number : ISO.MED.0058.09.2019.RC
First Issue Date : 2019.09.30
Reissue Date : 2022.09.30
Validity Date : 2025.09.29
Revision : --
Revision Date : --

Approved by
Özlem VİCDAN AKDAĞ
Chairman of the Board

Signature

According to ISO/IEC 17021 rules, the company is subject to surveillance audits. This certificate is valid as long as the company complies with NOTICE certification rules. You can check the validity of this certificate through contacting the phone number and email address given below. The validity can also be verified via Certificate Query part in our website: www.notice.com.tr

EC CERTIFICATE

Annex II excluding section 4 of the Directive 93/42/EEC on Medical Devices

Full Quality Assurance System

Certificate Number

CE-MDD-0058/09/2019/02

Manufacturer : aap Joints GmbH

Address : Wilhelm-von-Siemens-Strasse 23, Ausgang F, 12277 Berlin

Product(s) : 1. The hip accessories
- Acetabular screw
- Screw plug
- Dome plug
2. Cement Restrictor and Centralizer
- Cement Restrictor, UHMWPE
- Centralizer, UHMWPE
- Centralizer, PMMA

Model(s) : Please see 2nd page for details of products

Report Number : CE/ISO-MED-0065-09, CE-MED-0108-09

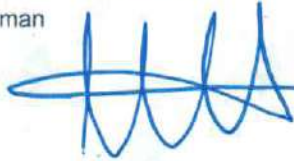
First Issue Date and Place : 2020.03.04 & Istanbul

Revision Number and Date : 01 / 2020.04.30

Validity Date : 2024.05.26

NOTICE, Notified Body 2764, declares that the aforementioned manufacturer has implemented a quality assurance system according to Annex II (excluding section 4), Section 3 of the directive 93/42/EEC on medical devices. This quality assurance system covers those aspects of manufacturing concerned with securing and maintaining safe conditions of the respective product(s) and conforms to the provisions of this Directive. The approved quality system is subject to surveillance pursuant to Annex II, Section 5 of Directive 93/42/EEC and unannounced audits. NOTICE must be informed of any significant changes in the design and/or construction of the product(s).

Özlem Vicdan Akdağ
Chairman




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Product Name	Model Name	Size (mm)
The hip accessories -Acetabular screw -Screw plug -Dome plug	Acetabular screw	6,5mm-15mm
		6,5mm-20mm
		6,5mm-25mm
		6,5mm-30mm
		6,5mm-35mm
		6,5mm-40mm
		6,5mm-45mm
		6,5mm-50mm
		6,5mm-55mm
		6,5mm-60mm
		6,5mm-65mm
		6,5mm-70mm
	Screw plug	7,4mmX2,6mm
	Dome plug	7,7mmX3,5mm

Product Name	Model Description	Size(mm)
Cement Restrictor and Centralizer - Cement Restrictor, UHMWPE - Centralizer, UHMWPE - Centralizer, PMMA	Cement Restrictor, UHMWPE	10mm
		12mm
		14mm
		16mm
		18mm
		20mm
	Centralizer, UHMWPE	10mm
		12mm
		14mm
		16mm
		18mm
		20mm
	Centralizer, PMMA	10mm
		12mm
		14mm
		16mm
		18mm
		20mm



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EC CERTIFICATE

According to Annex II (excluding article 4) of the Directive 93/42/EEC on Medical Devices

Full Quality Assurance System

Certificate Number

CE-MDD-0058/09/2019/01

Manufacturer : aap Joints GmbH

Address : Wilhelm-von-Siemens-Strasse 23, Aufgang F, 12277 Berlin

Product(s) : Hip-Joint Replacement Implants

- | | |
|-------------------------------------|--------------------------------------|
| 1. VarioLoc Hip System | 8. VarioLoc Modular Hip Prosthesis |
| 2. Bipolar Hip Prosthesis | 9. Dual Mobility 4X Hip Prosthesis |
| 3. Ceramic Hip Prosthesis | 10. VarioLoc Pressfit Hip Prosthesis |
| 4. VarioLoc Hip Prosthesis | 11. VarioCup Plus Acetabular System |
| 5. VarioLoc Cemented Hip Prosthesis | 12. VarioLoc Short Stem |
| 6. Dual Mobility Hip (DMH) System | 13. Bipolar Insert (UHMWPE) |
| 7. OSSEOMATRIX Acetabular Cup | |

Knee-joint Replacement Implants

- | | |
|----------------------------|---------------------------------------|
| 14. Mebio Knee | 16. PreciTotal Cementless Knee System |
| 15. PreciTotal Knee System | 17. PreciTotal Revision Knee System |

Model(s) : Please see 2nd to 32nd pages for details of product

Report Number :

CE/ISO-MED-0058	CE/ISO-MED-0065-01-Rev.01	CE/ISO-MED-0065-02
CE/ISO-MED-0065-03	CE/ISO-MED-0065-04	CE/ISO-MED-0065-05
CE/ISO-MED-0065-06	CE/ISO-MED-0065-07	CE/ISO-MED-0065-08
CE-MED-0108-01	CE-MED-0108-02	CE-MED-0108-03
CE-MED-0108-04	CE-MED-0108-05-Rev.01	CE-MED-0108-06
CE-MED-0108-07	CE-MED-0108-08	---

First Issue Date and Place : 2019.09.30 & Istanbul

Revision Number and Date : 03 / 2021.04.20

Validity Date : 2024.05.26

NOTICE, Notified Body 2764, declares that the aforementioned manufacturer has implemented a quality assurance system according to Annex II, Section 3 of the directive 93/42/EEC on medical devices. This quality assurance system covers those aspects of manufacturing concerned with securing and maintaining safe conditions of the respective product(s) and conforms to the provisions of this Directive. The approved quality system is subject to surveillance pursuant to Annex II, Section 5 of Directive 93/42/EEC and unannounced audits. NOTICE must be informed of any significant changes in the design and/or construction of the product(s). This certificate is valid together with Design Certificate issued according to 93/42/EEC Annex II (Section 4) for products defined below.

Özlem Vicdan Akdağ
Chairman

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Product Name	Components	Related Model list	Size
Hip-Joint Replacement Implants 1. VarioLoc Hip System	1.1 VarioLoc Hip Stem	VarioLoc Stem, TPS Coating STD	5 mm 6 mm 7.5 mm 9.0 mm 10.0 mm 11.0 mm 12.5 mm 13.5 mm 15.0 mm 16.0 mm 17.5 mm 20.0 mm
		VarioLoc Stem, TPS Coating LAT	7.5 mm 9.0 mm 10.0 mm 11.0 mm 12.5 mm 13.5 mm 15.0 mm 16.0 mm 17.5 mm 20.0 mm
	1.2 Femoral Head	Femoral Head, CoCrMo	22/-3.0 mm 22/+0.0 mm 28/-3.5 mm 28/+0.0 mm 28/+3.5 mm 28/+7.0 mm 28/+10.5 mm 32/-4.0 mm 32/+0.0 mm 32/+4.0 mm 32/+7.0 mm 32/+10.5 mm 36/-4.0 mm 36/+0.0 mm 36/+4.0 mm 36/+8.0 mm 36/+10.5 mm
	1.3 Acetabular Cup	VarioCup, TPS Coating No-hole	42 mm BB 44 mm MM 46 mm NN 48 mm OO 50 mm PP 52 mm PP 54 mm QQ 56 mm QQ 58 mm RR 60 mm RR 62 mm SS 64 mm SS 66 mm TT 68 mm TT



Product Name	Components	Related Model list	Size
Hip-Joint Replacement Implants 1. VarioLoc Hip System	1.3 Acetabular Cup	VarioCup, TPS Coating Three-hole	42 mm BB 44 mm MM 46 mm NN 48 mm OO 50 mm PP 52 mm PP 54 mm QQ 56 mm QQ 58 mm RR 60 mm RR 62 mm SS 64 mm SS 66 mm TT 68 mm TT
	1.4 Acetabular Insert	VarioCup Insert, Highly cross-linked UHMWPE- Neutral	22 mm ID BB 22 mm ID MM 28 mm ID BB 28 mm ID MM 28 mm ID NN 28 mm ID OO 28 mm ID PP 28 mm ID QQ 28 mm ID RR 28 mm ID SS 32 mm ID OO 32 mm ID PP 32 mm ID QQ 32 mm ID RR 32 mm ID SS 36 mm ID QQ 36 mm ID RR 36 mm ID SS 36 mm ID TT
		VarioCup Insert, Highly cross-linked UHMWPE- 15° hooded	22 mm ID BB 22 mm ID MM 28 mm ID BB 28 mm ID MM 28 mm ID NN 28 mm ID OO 28 mm ID PP 28 mm ID QQ 28 mm ID RR 28 mm ID SS 32 mm ID OO 32 mm ID PP 32 mm ID QQ 32 mm ID RR 32 mm ID SS 36 mm ID QQ 36 mm ID RR 36 mm ID SS 36 mm ID TT



Product Name	Components	Sizes
Hip-Joint Replacement Implants 2. Bipolar Hip Prosthesis	2.1 Bipolar Head	39 mm 40 mm 41 mm 42 mm 43 mm 44 mm 45 mm 46 mm 47 mm 48 mm 49 mm 50 mm 51 mm 52 mm 53 mm 54 mm 55 mm 56 mm 57 mm 58 mm 59 mm
	2.2 Bipolar Insert, Highly crosslinked UHMWPE	28 mm ID 42-44 mm 28 mm ID 45-47 mm 28 mm ID 48-50 mm 28 mm ID 51-53 mm 28 mm ID 54-56 mm 28 mm ID 57-59 mm 22 mm ID 39-41 mm 22 mm ID 42-44 mm

Product Name	Components	Sizes
Hip-Joint Replacement Implants 3. Ceramic Hip Prosthesis	Ceramic Head	28/-3.5 mm 28/+0.0 mm 28/+3.5 mm 32/-4.0 mm 32/+0.0 mm 32/+4.0 mm 32/+7.0 mm 36/-4.0 mm 36/+0.0 mm 36/+4.0 mm 36/+8.0 mm 40/-4.0 mm 40/+0.0 mm 40/+4.0 mm 40/+8.0 mm
	Ceramic Insert	28mm ID MM 28mm ID NN 32mm ID OO 32mm ID PP 36mm ID QQ 36mm ID RR 36mm ID SS 40mm ID RR 40mm ID SS 28mm ID OO 28mm ID PP 28mm ID QQ 28mm ID RR 28mm ID SS 32mm ID QQ 32mm ID RR 32mm ID SS

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Product Name	Components	Model	Size
Hip-Joint Replacement Implants 4. VarioLoc Hip Prosthesis	4.1 VarioLoc HA Hip Stem	VarioLoc Stem, HA Coating, STD	7.5 mm 9.0 mm 10.0 mm 11.0 mm 12.5 mm 13.5 mm 15.0 mm 16.0 mm 17.5 mm 20.0 mm
		VarioLoc Stem, HA Coating, LAT	7.5 mm 9.0 mm 10.0 mm 11.0 mm 12.5 mm 13.5 mm 15.0 mm 16.0 mm 17.5 mm 20.0 mm
	4.2 VE Acetabular insert	VE Acetabular insert, VE Highly cross-linked UHMWPE, Neutral	22 mm ID BB 22 mm ID MM 28 mm ID BB 28 mm ID MM 28 mm ID NN 28 mm ID OO 28 mm ID PP 28 mm ID QQ 28 mm ID RR 28 mm ID SS 32 mm ID OO 32 mm ID PP 32 mm ID QQ 32 mm ID RR 32 mm ID SS 36 mm ID QQ 36 mm ID RR 36 mm ID SS 36 mm ID TT
		VE Acetabular insert, VE Highly cross-linked UHMWPE, 15° hooded	22 mm ID BB 22 mm ID MM 28 mm ID BB 28 mm ID MM 28 mm ID NN 28 mm ID OO 28 mm ID PP 28 mm ID QQ 28 mm ID RR 28 mm ID SS 32 mm ID OO 32 mm ID PP 32 mm ID QQ 32 mm ID RR 32 mm ID SS 36 mm ID QQ 36 mm ID RR 36 mm ID SS 36 mm ID TT



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Product Name	Components	Models	Sizes
Hip-Joint Replacement Implants 5. VarioLoc Cemented Hip Prosthesis	5.1 VarioLoc cemented stem	VarioLoc stem, cemented, STD	7.5 mm
			9.0 mm
			10.0 mm
			11.0 mm
			12.5 mm
			13.5 mm
			15.0 mm
	5.2 VarioCup cemented cup	VarioCup, Cemented Highly Crosslinked UHMWPE, Neutral	7.5 mm
			9.0 mm
			10.0 mm
			11.0 mm
			12.5 mm
			13.5 mm
			15.0 mm
	5.2 VarioCup cemented cup	VarioCup, Cemented Highly Crosslinked UHMWPE, Hooded	28 mm ID 47 mm
			28 mm ID 49 mm
			28 mm ID 51 mm
			28 mm ID 53 mm
			28 mm ID 55 mm
			28 mm ID 57 mm
			28 mm ID 59 mm
			32 mm ID 51 mm
			32 mm ID 53 mm
			32 mm ID 55 mm
			32 mm ID 57 mm
			32 mm ID 59 mm

Product Name	Components	Sizes
Hip-Joint Replacement Implants 6. Dual Mobility Hip (DMH) System	6.1 DMH CoCr Cup	46 x 40 mm
		48 x 42 mm
		50 x 44 mm
		52 x 46 mm
		54 x 48 mm
		56 x 50 mm
		58 x 52 mm
		60 x 54 mm
		62 x 56 mm
		64 x 58 mm
		66 x 60 mm
	6.2 DMH VE Highly cross-linked UHMWPE bearing	40 x 28 mm
		42 x 28 mm
		44 x 28 mm
		46 x 28 mm
		48 x 28 mm
		50 x 28 mm
		52 x 28 mm
		54 x 28 mm
		56 x 28 mm
		58 x 28 mm
		60 x 28 mm

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Product Name	Components	Models	Sizes
Hip-Joint Replacement Implants 7. OSSEOMATRIX Acetabular Cup	7.1 OSSEOMATRIX Acetabular Cup	Osseomatrix, Acetabular Cup, No-hole	44 mm MM 46 mm NN 48 mm OO 50 mm PP 52 mm PP 54 mm QQ 56 mm QQ 58 mm RR 60 mm RR 62 mm SS 64 mm SS 66 mm TT
		Osseomatrix, Acetabular Cup, Three-hole	44 mm MM 46 mm NN 48 mm OO 50 mm PP 52 mm PP 54 mm QQ 56 mm QQ 58 mm RR 60 mm RR 62 mm SS 64 mm SS 66 mm TT



Product Name	Description	Size
Hip-Joint Replacement Implants 8. VarioLoc Modular Hip Prosthesis a. Proximal Body	Proximal Body, TPS Coating, VarioLoc Modular, STD	60mm, AA
	Proximal Body, TPS Coating, VarioLoc Modular, STD	60mm, BB
	Proximal Body, TPS Coating, VarioLoc Modular, STD	60mm, CC
	Proximal Body, TPS Coating, VarioLoc Modular, STD	60mm, DD
	Proximal Body, TPS Coating, VarioLoc Modular, STD	60mm, EE
	Proximal Body, TPS Coating, VarioLoc Modular, STD	60mm, FF
	Proximal Body, TPS Coating, VarioLoc Modular, LAT	60mm, AA
	Proximal Body, TPS Coating, VarioLoc Modular, LAT	60mm, BB
	Proximal Body, TPS Coating, VarioLoc Modular, LAT	60mm, CC
	Proximal Body, TPS Coating, VarioLoc Modular, LAT	60mm, DD
	Proximal Body, TPS Coating, VarioLoc Modular, LAT	60mm, EE
	Proximal Body, TPS Coating, VarioLoc Modular, LAT	60mm, FF
	Proximal Body, TPS Coating, VarioLoc Modular, STD	70mm, AA
	Proximal Body, TPS Coating, VarioLoc Modular, STD	70mm, BB
	Proximal Body, TPS Coating, VarioLoc Modular, STD	70mm, CC
	Proximal Body, TPS Coating, VarioLoc Modular, STD	70mm, DD
	Proximal Body, TPS Coating, VarioLoc Modular, STD	70mm, EE
	Proximal Body, TPS Coating, VarioLoc Modular, STD	70mm, FF
	Proximal Body, TPS Coating, VarioLoc Modular, LAT	70mm, AA
	Proximal Body, TPS Coating, VarioLoc Modular, LAT	70mm, BB
	Proximal Body, TPS Coating, VarioLoc Modular, LAT	70mm, CC
	Proximal Body, TPS Coating, VarioLoc Modular, LAT	70mm, DD
	Proximal Body, TPS Coating, VarioLoc Modular, LAT	70mm, EE
	Proximal Body, TPS Coating, VarioLoc Modular, LAT	70mm, FF
	Proximal Body, TPS Coating, VarioLoc Modular, STD	80mm, AA
	Proximal Body, TPS Coating, VarioLoc Modular, STD	80mm, BB
	Proximal Body, TPS Coating, VarioLoc Modular, STD	80mm, CC
	Proximal Body, TPS Coating, VarioLoc Modular, STD	80mm, DD
	Proximal Body, TPS Coating, VarioLoc Modular, STD	80mm, EE
	Proximal Body, TPS Coating, VarioLoc Modular, STD	80mm, FF
	Proximal Body, TPS Coating, VarioLoc Modular, LAT	80mm, AA
	Proximal Body, TPS Coating, VarioLoc Modular, LAT	80mm, BB
	Proximal Body, TPS Coating, VarioLoc Modular, LAT	80mm, CC
	Proximal Body, TPS Coating, VarioLoc Modular, LAT	80mm, DD
	Proximal Body, TPS Coating, VarioLoc Modular, LAT	80mm, EE
	Proximal Body, TPS Coating, VarioLoc Modular, LAT	80mm, FF



Product Name	Description	Size
Hip-Joint Replacement Implants 8. VarioLoc Modular Hip Prosthesis a. Proximal Body- continue	Proximal Body, Pressfit, VarioLoc Modular, STD	60mm, AA
	Proximal Body, Pressfit, VarioLoc Modular, STD	60mm, BB
	Proximal Body, Pressfit, VarioLoc Modular, STD	60mm, CC
	Proximal Body, Pressfit, VarioLoc Modular, STD	60mm, DD
	Proximal Body, Pressfit, VarioLoc Modular, STD	60mm, EE
	Proximal Body, Pressfit, VarioLoc Modular, STD	60mm, FF
	Proximal Body, Pressfit, VarioLoc Modular, LAT	60mm, AA
	Proximal Body, Pressfit, VarioLoc Modular, LAT	60mm, BB
	Proximal Body, Pressfit, VarioLoc Modular, LAT	60mm, CC
	Proximal Body, Pressfit, VarioLoc Modular, LAT	60mm, DD
	Proximal Body, Pressfit, VarioLoc Modular, LAT	60mm, EE
	Proximal Body, Pressfit, VarioLoc Modular, LAT	60mm, FF
	Proximal Body, Pressfit, VarioLoc Modular, STD	70mm, AA
	Proximal Body, Pressfit, VarioLoc Modular, STD	70mm, BB
	Proximal Body, Pressfit, VarioLoc Modular, STD	70mm, CC
	Proximal Body, Pressfit, VarioLoc Modular, STD	70mm, DD
	Proximal Body, Pressfit, VarioLoc Modular, STD	70mm, EE
	Proximal Body, Pressfit, VarioLoc Modular, STD	70mm, FF
	Proximal Body, Pressfit, VarioLoc Modular, LAT	70mm, AA
	Proximal Body, Pressfit, VarioLoc Modular, LAT	70mm, BB
	Proximal Body, Pressfit, VarioLoc Modular, LAT	70mm, CC
	Proximal Body, Pressfit, VarioLoc Modular, LAT	70mm, DD
	Proximal Body, Pressfit, VarioLoc Modular, LAT	70mm, EE
	Proximal Body, Pressfit, VarioLoc Modular, LAT	70mm, FF
	Proximal Body, Pressfit, VarioLoc Modular, STD	80mm, AA
	Proximal Body, Pressfit, VarioLoc Modular, STD	80mm, BB
	Proximal Body, Pressfit, VarioLoc Modular, STD	80mm, CC
	Proximal Body, Pressfit, VarioLoc Modular, STD	80mm, DD
	Proximal Body, Pressfit, VarioLoc Modular, STD	80mm, EE
	Proximal Body, Pressfit, VarioLoc Modular, STD	80mm, FF
	Proximal Body, Pressfit, VarioLoc Modular, LAT	80mm, AA
	Proximal Body, Pressfit, VarioLoc Modular, LAT	80mm, BB
	Proximal Body, Pressfit, VarioLoc Modular, LAT	80mm, CC
	Proximal Body, Pressfit, VarioLoc Modular, LAT	80mm, DD
	Proximal Body, Pressfit, VarioLoc Modular, LAT	80mm, EE
	Proximal Body, Pressfit, VarioLoc Modular, LAT	80mm, FF



Product Name	Description	Size
Hip-Joint Replacement Implants 8. VarioLoc Modular Hip Prosthesis b. Distal Stem	Distal Stem, Straight, VarioLoc Modular	12mm, 150mm
	Distal Stem, Straight, VarioLoc Modular	13mm, 150mm
	Distal Stem, Straight, VarioLoc Modular	14mm, 150mm
	Distal Stem, Straight, VarioLoc Modular	15mm, 150mm
	Distal Stem, Straight, VarioLoc Modular	16mm, 150mm
	Distal Stem, Straight, VarioLoc Modular	17mm, 150mm
	Distal Stem, Straight, VarioLoc Modular	18mm, 150mm
	Distal Stem, Straight, VarioLoc Modular	19mm, 150mm
	Distal Stem, Straight, VarioLoc Modular	20mm, 150mm
	Distal Stem, Straight, VarioLoc Modular	21mm, 150mm
	Distal Stem, Straight, VarioLoc Modular	22mm, 150mm
	Distal Stem, Straight, VarioLoc Modular	12mm, 190mm
	Distal Stem, Straight, VarioLoc Modular	13mm, 190mm
	Distal Stem, Straight, VarioLoc Modular	14mm, 190mm
	Distal Stem, Straight, VarioLoc Modular	15mm, 190mm
	Distal Stem, Straight, VarioLoc Modular	16mm, 190mm
	Distal Stem, Straight, VarioLoc Modular	17mm, 190mm
	Distal Stem, Straight, VarioLoc Modular	18mm, 190mm
	Distal Stem, Straight, VarioLoc Modular	19mm, 190mm
	Distal Stem, Straight, VarioLoc Modular	20mm, 190mm
	Distal Stem, Straight, VarioLoc Modular	21mm, 190mm
	Distal Stem, Straight, VarioLoc Modular	22mm, 190mm
	Distal Stem, Angled, VarioLoc Modular	16mm, 250mm
	Distal Stem, Angled, VarioLoc Modular	17mm, 250mm
	Distal Stem, Angled, VarioLoc Modular	18mm, 250mm
	Distal Stem, Angled, VarioLoc Modular	19mm, 250mm
	Distal Stem, Angled, VarioLoc Modular	20mm, 250mm
	Distal Stem, Angled, VarioLoc Modular	21mm, 250mm
	Distal Stem, Angled, VarioLoc Modular	22mm, 250mm
	Distal Stem, Angled, VarioLoc Modular	23mm, 250mm
	Distal Stem, Angled, VarioLoc Modular	24mm, 250mm
	Distal Stem, Angled, VarioLoc Modular	25mm, 250mm
	Distal Stem, Angled, VarioLoc Modular	26mm, 250mm

Product Name	Description	Size
Hip-Joint Replacement Implants 8. VarioLoc Modular Hip Prosthesis c. Connecting Screw	Connecting Screw	/



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Hip-Joint Replacement Implants 9. Dual Mobility 4X Hip Prosthesis	DMH CoCr Liner	Description	Size
		DMH CoCr Liner	34mm, NN
		DMH CoCr Liner	36mm, OO
		DMH CoCr Liner	38mm, PP
		DMH CoCr Liner	40mm, QQ
		DMH CoCr Liner	44mm, RR
		DMH CoCr Liner	48mm, SS
		DMH CoCr Liner	52mm, TT
		DMH CoCr Liner	56mm, UU
	DMH Bearing	Description	Size
		DMH VE Highly cross-linked UHMWPE bearing	34mm x 22mm
		DMH VE Highly cross-linked UHMWPE bearing	36mm x 22mm
		DMH VE Highly cross-linked UHMWPE bearing	38mm x 22mm
		DMH Highly cross-linked UHMWPE bearing	34mm x 22mm
		DMH Highly cross-linked UHMWPE bearing	36mm x 22mm
		DMH Highly cross-linked UHMWPE bearing	38mm x 22mm
		DMH Highly cross-linked UHMWPE bearing	40mm x 28mm
		DMH Highly cross-linked UHMWPE bearing	42mm x 28mm
		DMH Highly cross-linked UHMWPE bearing	44mm x 28mm
		DMH Highly cross-linked UHMWPE bearing	46mm x 28mm
		DMH Highly cross-linked UHMWPE bearing	48mm x 28mm
		DMH Highly cross-linked UHMWPE bearing	50mm x 28mm
		DMH Highly cross-linked UHMWPE bearing	52mm x 28mm
		DMH Highly cross-linked UHMWPE bearing	54mm x 28mm
		DMH Highly cross-linked UHMWPE bearing	56mm x 28mm
		DMH Highly cross-linked UHMWPE bearing	58mm x 28mm
		DMH Highly cross-linked UHMWPE bearing	60mm x 28mm



Hip-Joint Replacement Implants 10. VarioLoc Pressfit Hip Prosthesis a.VarioLoc Stem, Pressfit	Description	Size (mm)
	VarioLoc Stem, Pressfit, STD	7.5
	VarioLoc Stem, Pressfit, STD	9
	VarioLoc Stem, Pressfit, STD	10
	VarioLoc Stem, Pressfit, STD	11
	VarioLoc Stem, Pressfit, STD	12.5
	VarioLoc Stem, Pressfit, STD	13.5
	VarioLoc Stem, Pressfit, STD	15
	VarioLoc Stem, Pressfit, STD	16
	VarioLoc Stem, Pressfit, STD	17.5
	VarioLoc Stem, Pressfit, LAT	7.5
	VarioLoc Stem, Pressfit, LAT	9
	VarioLoc Stem, Pressfit, LAT	10
	VarioLoc Stem, Pressfit, LAT	11
	VarioLoc Stem, Pressfit, LAT	12.5
	VarioLoc Stem, Pressfit, LAT	13.5
	VarioLoc Stem, Pressfit, LAT	15
	VarioLoc Stem, Pressfit, LAT	16
	VarioLoc Stem, Pressfit, LAT	17.5



	Description	Size
Hip-Joint Replacement Implants 10. VarioLoc PressFit Hip Prosthesis a. Acetabular Cup (VarioCup, Pressfit)	VarioCup, Pressfit, No-hole	42mm, BB
	VarioCup, Pressfit, No-hole	44mm, MM
	VarioCup, Pressfit, No-hole	46mm, NN
	VarioCup, Pressfit, No-hole	48mm, OO
	VarioCup, Pressfit, No-hole	50mm, PP
	VarioCup, Pressfit, No-hole	52mm, PP
	VarioCup, Pressfit, No-hole	54mm, QQ
	VarioCup, Pressfit, No-hole	56mm, QQ
	VarioCup, Pressfit, No-hole	58mm, RR
	VarioCup, Pressfit, No-hole	60mm, RR
	VarioCup, Pressfit, No-hole	62mm, SS
	VarioCup, Pressfit, No-hole	64mm, SS
	VarioCup, Pressfit, No-hole	66mm, TT
	VarioCup, Pressfit, No-hole	68mm, TT
	VarioCup, Pressfit, Three-hole	42mm, BB
	VarioCup, Pressfit, Three-hole	44mm, MM
	VarioCup, Pressfit, Three-hole	46mm, NN
	VarioCup, Pressfit, Three-hole	48mm, OO
	VarioCup, Pressfit, Three-hole	50mm, PP
	VarioCup, Pressfit, Three-hole	52mm, PP
	VarioCup, Pressfit, Three-hole	54mm, QQ
	VarioCup, Pressfit, Three-hole	56mm, QQ
	VarioCup, Pressfit, Three-hole	58mm, RR
	VarioCup, Pressfit, Three-hole	60mm, RR
	VarioCup, Pressfit, Three-hole	62mm, SS
	VarioCup, Pressfit, Three-hole	64mm, SS
	VarioCup, Pressfit, Three-hole	66mm, TT
	VarioCup, Pressfit, Three-hole	68mm, TT
	VarioCup, Pressfit, Multi-hole	42mm, BB
	VarioCup, Pressfit, Multi-hole	44mm, MM
	VarioCup, Pressfit, Multi-hole	46mm, NN
	VarioCup, Pressfit, Multi-hole	48mm, OO
	VarioCup, Pressfit, Multi-hole	50mm, PP
	VarioCup, Pressfit, Multi-hole	52mm, PP
	VarioCup, Pressfit, Multi-hole	54mm, QQ
	VarioCup, Pressfit, Multi-hole	56mm, QQ
	VarioCup, Pressfit, Multi-hole	58mm, RR
	VarioCup, Pressfit, Multi-hole	60mm, RR
	VarioCup, Pressfit, Multi-hole	62mm, SS
	VarioCup, Pressfit, Multi-hole	64mm, SS
	VarioCup, Pressfit, Multi-hole	66mm, TT
	VarioCup, Pressfit, Multi-hole	68mm, TT
	VarioCup, Pressfit, Multi-hole	70mm, UU
	VarioCup, Pressfit, Multi-hole	72mm, UU
	VarioCup, Pressfit, Multi-hole	74mm, UU



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	Description	Size
Hip-Joint Replacement Implants 11. VarioCup Plus Acetabular System a. VarioCup Plus	VarioCup, TPS Coating, Multi-hole	42mm, BB
	VarioCup, TPS Coating, Multi-hole	44mm, MM
	VarioCup, TPS Coating, Multi-hole	46mm, NN
	VarioCup, TPS Coating, Multi-hole	48mm, OO
	VarioCup, TPS Coating, Multi-hole	50mm, PP
	VarioCup, TPS Coating, Multi-hole	52mm, PP
	VarioCup, TPS Coating, Multi-hole	54mm, QQ
	VarioCup, TPS Coating, Multi-hole	56mm, QQ
	VarioCup, TPS Coating, Multi-hole	58mm, RR
	VarioCup, TPS Coating, Multi-hole	60mm, RR
	VarioCup, TPS Coating, Multi-hole	62mm, SS
	VarioCup, TPS Coating, Multi-hole	64mm, SS
	VarioCup, TPS Coating, Multi-hole	66mm, TT
	VarioCup, TPS Coating, Multi-hole	68mm, TT
	VarioCup, TPS Coating, Multi-hole	70mm, UU
	VarioCup, TPS Coating, Multi-hole	72mm, UU
	VarioCup, TPS Coating, Peripheral-hole	54mm, OO
	VarioCup, TPS Coating, Peripheral-hole	56mm, PP
	VarioCup, TPS Coating, Peripheral-hole	58mm, PP
	VarioCup, TPS Coating, Peripheral-hole	60mm, QQ
	VarioCup, TPS Coating, Peripheral-hole	62mm, QQ
	VarioCup, TPS Coating, Peripheral-hole	64mm, RR
	VarioCup, TPS Coating, Peripheral-hole	66mm, RR
	VarioCup, TPS Coating, Peripheral-hole	68mm, SS
	VarioCup, TPS Coating, Peripheral-hole	70mm, SS
	VarioCup, TPS Coating, Peripheral-hole	72mm, TT
	VarioCup, TPS Coating, Peripheral-hole	74mm, TT
	VarioCup, TPS Coating, Peripheral-hole	76mm, TT
	VarioCup, TPS Coating, Peripheral-hole	78mm, UU
	VarioCup, TPS Coating, Peripheral-hole	80mm, UU



	Description	Size
Hip-Joint Replacement Implants 11. VarioCup Plus Acetabular System b. VarioCup Insert	VarioCup Insert, High hooded, Highly cross-linked UHMWPE	28mm ID, BB
	VarioCup Insert, High hooded, Highly cross-linked UHMWPE	28mm ID, MM
	VarioCup Insert, High hooded, Highly cross-linked UHMWPE	28mm ID, NN
	VarioCup Insert, High hooded, Highly cross-linked UHMWPE	28mm ID, OO
	VarioCup Insert, High hooded, Highly cross-linked UHMWPE	28mm ID, PP
	VarioCup Insert, High hooded, Highly cross-linked UHMWPE	28mm ID, QQ
	VarioCup Insert, High hooded, Highly cross-linked UHMWPE	28mm ID, RR
	VarioCup Insert, High hooded, Highly cross-linked UHMWPE	28mm ID, SS
	VarioCup Insert, High hooded, Highly cross-linked UHMWPE	32mm ID, OO
	VarioCup Insert, High hooded, Highly cross-linked UHMWPE	32mm ID, PP
	VarioCup Insert, High hooded, Highly cross-linked UHMWPE	32mm ID, QQ
	VarioCup Insert, High hooded, Highly cross-linked UHMWPE	32mm ID, RR
	VarioCup Insert, High hooded, Highly cross-linked UHMWPE	32mm ID, SS
	VarioCup Insert, High hooded, Highly cross-linked UHMWPE	36mm ID, QQ
	VarioCup Insert, High hooded, Highly cross-linked UHMWPE	36mm ID, RR
	VarioCup Insert, High hooded, Highly cross-linked UHMWPE	36mm ID, SS
	VarioCup Insert, High hooded, Highly cross-linked UHMWPE	36mm ID, TT
	VarioCup Insert, High hooded, Highly cross-linked UHMWPE	36mm ID, UU
	VarioCup Insert, High hooded, UHMWPE	28mm ID, MM
	VarioCup Insert, High hooded, UHMWPE	28mm ID, NN
	VarioCup Insert, High hooded, UHMWPE	28mm ID, OO
	VarioCup Insert, High hooded, UHMWPE	28mm ID, PP
	VarioCup Insert, High hooded, UHMWPE	28mm ID, QQ
	VarioCup Insert, High hooded, UHMWPE	28mm ID, RR
	VarioCup Insert, High hooded, UHMWPE	28mm ID, SS
	VarioCup Insert, High hooded, UHMWPE	32mm ID, OO
	VarioCup Insert, High hooded, UHMWPE	32mm ID, PP
	VarioCup Insert, High hooded, UHMWPE	32mm ID, QQ
	VarioCup Insert, High hooded, UHMWPE	32mm ID, RR
	VarioCup Insert, High hooded, UHMWPE	32mm ID, SS



Hip-Joint Replacement Implants 11. VarioCup Plus Acetabular System b. VarioCup Insert- continue	Description	Size
	VarioCup Insert, Neutral, UHMWPE	22mm ID, BB
	VarioCup Insert, Neutral, UHMWPE	22mm ID, MM
	VarioCup Insert, Neutral, UHMWPE	28mm ID, MM
	VarioCup Insert, Neutral, UHMWPE	28mm ID, NN
	VarioCup Insert, Neutral, UHMWPE	28mm ID, OO
	VarioCup Insert, Neutral, UHMWPE	28mm ID, PP
	VarioCup Insert, Neutral, UHMWPE	28mm ID, QQ
	VarioCup Insert, Neutral, UHMWPE	28mm ID, RR
	VarioCup Insert, Neutral, UHMWPE	28mm ID, SS
	VarioCup Insert, Neutral, UHMWPE	32mm ID, OO
	VarioCup Insert, Neutral, UHMWPE	32mm ID, PP
	VarioCup Insert, Neutral, UHMWPE	32mm ID, QQ
	VarioCup Insert, Neutral, UHMWPE	32mm ID, RR
	VarioCup Insert, Neutral, UHMWPE	32mm ID, SS
	VarioCup Insert, 15° hooded, UHMWPE	22mm ID, BB
	VarioCup Insert, 15° hooded, UHMWPE	22mm ID, MM
	VarioCup Insert, 15° hooded, UHMWPE	28mm ID, MM
	VarioCup Insert, 15° hooded, UHMWPE	28mm ID, NN
	VarioCup Insert, 15° hooded, UHMWPE	28mm ID, OO
	VarioCup Insert, 15° hooded, UHMWPE	28mm ID, PP
	VarioCup Insert, 15° hooded, UHMWPE	28mm ID, QQ
	VarioCup Insert, 15° hooded, UHMWPE	28mm ID, RR
	VarioCup Insert, 15° hooded, UHMWPE	28mm ID, SS
	VarioCup Insert, 15° hooded, UHMWPE	32mm ID, OO
	VarioCup Insert, 15° hooded, UHMWPE	32mm ID, PP
	VarioCup Insert, 15° hooded, UHMWPE	32mm ID, QQ
	VarioCup Insert, 15° hooded, UHMWPE	32mm ID, RR
	VarioCup Insert, 15° hooded, UHMWPE	32mm ID, SS

Hip-Joint Replacement Implants 11. VarioCup Plus Acetabular System c. Peripheral Screw	Description	Size
	Peripheral Screw	5.0mm, 25mm
	Peripheral Screw	5.0mm, 30mm
	Peripheral Screw	5.0mm, 35mm
	Peripheral Screw	5.0mm, 40mm
	Peripheral Screw	5.0mm, 45mm
	Peripheral Screw	5.0mm, 50mm
	Peripheral Screw	5.0mm, 55mm
	Peripheral Screw	5.0mm, 60mm
	Peripheral Screw	5.0mm, 65mm



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Hip-Joint Replacement Implants 12. VarioLoc Short Stem	Description	Size
	VarioLoc Stem, TPS Coating, Short, STD	5 mm
	VarioLoc Stem, TPS Coating, Short, STD	6 mm
	VarioLoc Stem, TPS Coating, Short, STD	7.5 mm
	VarioLoc Stem, TPS Coating, Short, STD	9 mm
	VarioLoc Stem, TPS Coating, Short, STD	10 mm
	VarioLoc Stem, TPS Coating, Short, STD	11 mm
	VarioLoc Stem, TPS Coating, Short, STD	12.5 mm
	VarioLoc Stem, TPS Coating, Short, STD	13.5 mm
	VarioLoc Stem, TPS Coating, Short, STD	15 mm
	VarioLoc Stem, TPS Coating, Short, STD	16 mm
	VarioLoc Stem, TPS Coating, Short, STD	17.5 mm
	VarioLoc Stem, TPS Coating, Short, STD	20 mm
	VarioLoc Stem, TPS Coating, Short, LAT	7.5 mm
	VarioLoc Stem, TPS Coating, Short, LAT	9 mm
	VarioLoc Stem, TPS Coating, Short, LAT	10 mm
	VarioLoc Stem, TPS Coating, Short, LAT	11 mm
	VarioLoc Stem, TPS Coating, Short, LAT	12.5 mm
	VarioLoc Stem, TPS Coating, Short, LAT	13.5 mm
	VarioLoc Stem, TPS Coating, Short, LAT	15 mm
	VarioLoc Stem, TPS Coating, Short, LAT	16 mm
	VarioLoc Stem, TPS Coating, Short, LAT	17.5 mm
	VarioLoc Stem, TPS Coating, Short, LAT	20 mm

Hip-Joint Replacement Implants 13. Bipolar Insert (UHMWPE)	Description	Size
	Bipolar Insert, 28mm ID, UHMWPE	45-47mm
	Bipolar Insert, 28mm ID, UHMWPE	48-50mm
	Bipolar Insert, 28mm ID, UHMWPE	51-53mm
	Bipolar Insert, 28mm ID, UHMWPE	54-56mm
	Bipolar Insert, 28mm ID, UHMWPE	57-59mm
	Bipolar Insert, 22mm ID, UHMWPE	39-41mm
	Bipolar Insert, 22mm ID, UHMWPE	42-44mm



Product Name	Components	Models	Size	
Knee-joint replacement implants 14. Mebio Knee	14.1.Mebio CR	Femoral Component, CR	Left	S, M, L, XL
			Right	S, M, L, XL
		Tibial Insert, CR	S	7.5 mm 9.0 mm 10.5 mm 12.0 mm 13.5 mm 15.0 mm 18.0 mm 21.0 mm
				7.5 mm 9.0 mm 10.5 mm 12.0 mm 13.5 mm 15.0 mm 18.0 mm 21.0 mm
				7.5 mm 9.0 mm 10.5 mm 12.0 mm 13.5 mm 15.0 mm 18.0 mm 21.0 mm
				7.5 mm 9.0 mm 10.5 mm 12.0 mm 13.5 mm 15.0 mm 18.0 mm 21.0 mm
		Tibial Component, CR	S, M, L, XL	
		Patellar Component, CR, One Peg	S, M, L, XL	
	14.2 Mebio PS	Femoral Component, PS	Left	1 2 3 4 5
				1 2 3 4 5
				1 2 3 4 5
				1 2 3 4 5
				1 2 3 4 5
		Tibial Insert, PS	1/2	8 mm 10 mm 12 mm 14 mm
			3/4	8 mm 10 mm 12 mm 14 mm
			5	8 mm 10 mm 12 mm 14 mm
		Tibial Component, PS	1 2 3 4 5	
			7.5 mm	0 1 2
		Patellar Component, PS, Three-Peg	10 mm	1 2 3



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Product Name	Component	Models	Sizes	
Knee-joint replacement implants 15. PreciTotal Knee System	15.1 Femoral Component, Hi-Flex	PS	L	1 2 3 4 5 6 7 8 9
			R	1 2 3 4 5 6 7 8 9
		CR	L	1 2 3 4 5 6 7 8 9
			R	1 2 3 4 5 6 7 8 9
	15.2 Tibial Insert, VE Highly cross-linked UHMWPE	PS	1	6 mm 8 mm 10 mm 12 mm 14 mm 16 mm
			2	6 mm 8 mm 10 mm 12 mm 14 mm 16 mm
			3	6 mm 8 mm 10 mm 12 mm 14 mm 16 mm
			4	6 mm 8 mm 10 mm 12 mm 14 mm 16 mm



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Product Name	Component	Models	Sizes	
Knee-joint replacement implants 15. PreciTotal Knee System	15.2 Tibial Insert, VE Highly cross-linked UHMWPE	PS	5	6 mm 8 mm 10 mm 12 mm 14 mm 16 mm
				6 mm 8 mm 10 mm 12 mm 14 mm 16 mm
				6 mm 8 mm 10 mm 12 mm 14 mm 16 mm
				6 mm 8 mm 10 mm 12 mm 14 mm 16 mm
				6 mm 8 mm 10 mm 12 mm 14 mm 16 mm
		CR	1	6 mm 8 mm 10 mm 12 mm 14 mm 16 mm
				6 mm 8 mm 10 mm 12 mm 14 mm 16 mm
				6 mm 8 mm 10 mm 12 mm 14 mm 16 mm
				6 mm 8 mm 10 mm 12 mm 14 mm 16 mm
				6 mm 8 mm 10 mm 12 mm 14 mm 16 mm



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Product Name	Component	Models	Sizes	
Knee-joint replacement implants 15. PreciTotal Knee System	15.2 Tibial Insert, VE Highly cross-linked UHMWPE	CR	6	6 mm 8 mm 10 mm 12 mm 14 mm 16 mm
			7	6 mm 8 mm 10 mm 12 mm 14 mm 16 mm
			8	6 mm 8 mm 10 mm 12 mm 14 mm 16 mm
			9	6 mm 8 mm 10 mm 12 mm 14 mm 16 mm
	15.3 Stemmed Tray, Polished	-	1 2 3 4 5 6 7 8 9	
	15.4 Patellar Component, VE Highly cross-linked UHMWPE	-	7.5 mm	1 2 3 4 5
			10 mm	1 2 3 4 5



Knee-joint replacement implants 16. PreciTotal Cementless Knee System a. Femoral Component	Description	Size
	PreciTotal, Femoral Component, PS, Hi-Flex, TPS Coating	1, L
	PreciTotal, Femoral Component, PS, Hi-Flex, TPS Coating	2, L
	PreciTotal, Femoral Component, PS, Hi-Flex, TPS Coating	3, L
	PreciTotal, Femoral Component, PS, Hi-Flex, TPS Coating	4, L
	PreciTotal, Femoral Component, PS, Hi-Flex, TPS Coating	5, L
	PreciTotal, Femoral Component, PS, Hi-Flex, TPS Coating	6, L
	PreciTotal, Femoral Component, PS, Hi-Flex, TPS Coating	7, L
	PreciTotal, Femoral Component, PS, Hi-Flex, TPS Coating	8, L
	PreciTotal, Femoral Component, PS, Hi-Flex, TPS Coating	9, L
	PreciTotal, Femoral Component, PS, Hi-Flex, TPS Coating	1, R
	PreciTotal, Femoral Component, PS, Hi-Flex, TPS Coating	2, R
	PreciTotal, Femoral Component, PS, Hi-Flex, TPS Coating	3, R
	PreciTotal, Femoral Component, PS, Hi-Flex, TPS Coating	4, R
	PreciTotal, Femoral Component, PS, Hi-Flex, TPS Coating	5, R
	PreciTotal, Femoral Component, PS, Hi-Flex, TPS Coating	6, R
	PreciTotal, Femoral Component, PS, Hi-Flex, TPS Coating	7, R
	PreciTotal, Femoral Component, PS, Hi-Flex, TPS Coating	8, R
	PreciTotal, Femoral Component, PS, Hi-Flex, TPS Coating	9, R
	PreciTotal, Femoral Component, CR, Hi-Flex, TPS Coating	1, L
	PreciTotal, Femoral Component, CR, Hi-Flex, TPS Coating	2, L
	PreciTotal, Femoral Component, CR, Hi-Flex, TPS Coating	3, L
	PreciTotal, Femoral Component, CR, Hi-Flex, TPS Coating	4, L
	PreciTotal, Femoral Component, CR, Hi-Flex, TPS Coating	5, L
	PreciTotal, Femoral Component, CR, Hi-Flex, TPS Coating	6, L
	PreciTotal, Femoral Component, CR, Hi-Flex, TPS Coating	7, L
	PreciTotal, Femoral Component, CR, Hi-Flex, TPS Coating	8, L
	PreciTotal, Femoral Component, CR, Hi-Flex, TPS Coating	9, L
	PreciTotal, Femoral Component, CR, Hi-Flex, TPS Coating	1, R
	PreciTotal, Femoral Component, CR, Hi-Flex, TPS Coating	2, R
	PreciTotal, Femoral Component, CR, Hi-Flex, TPS Coating	3, R
	PreciTotal, Femoral Component, CR, Hi-Flex, TPS Coating	4, R
	PreciTotal, Femoral Component, CR, Hi-Flex, TPS Coating	5, R
	PreciTotal, Femoral Component, CR, Hi-Flex, TPS Coating	6, R
	PreciTotal, Femoral Component, CR, Hi-Flex, TPS Coating	7, R
	PreciTotal, Femoral Component, CR, Hi-Flex, TPS Coating	8, R
	PreciTotal, Femoral Component, CR, Hi-Flex, TPS Coating	9, R



	Description	Size	Thickness
			(mm)
Knee-joint replacement implants 16. PreciTotal Cementless Knee System b. Tibial Insert PS	PreciTotal, PS Tibial Insert, UHMWPE	1	6
	PreciTotal, PS Tibial Insert, UHMWPE		8
	PreciTotal, PS Tibial Insert, UHMWPE		10
	PreciTotal, PS Tibial Insert, UHMWPE		12
	PreciTotal, PS Tibial Insert, UHMWPE		14
	PreciTotal, PS Tibial Insert, UHMWPE		16
	PreciTotal, PS Tibial Insert, UHMWPE	2	6
	PreciTotal, PS Tibial Insert, UHMWPE		8
	PreciTotal, PS Tibial Insert, UHMWPE		10
	PreciTotal, PS Tibial Insert, UHMWPE		12
	PreciTotal, PS Tibial Insert, UHMWPE		14
	PreciTotal, PS Tibial Insert, UHMWPE		16
	PreciTotal, PS Tibial Insert, UHMWPE	3	6
	PreciTotal, PS Tibial Insert, UHMWPE		8
	PreciTotal, PS Tibial Insert, UHMWPE		10
	PreciTotal, PS Tibial Insert, UHMWPE		12
	PreciTotal, PS Tibial Insert, UHMWPE		14
	PreciTotal, PS Tibial Insert, UHMWPE		16
	PreciTotal, PS Tibial Insert, UHMWPE	4	6
	PreciTotal, PS Tibial Insert, UHMWPE		8
	PreciTotal, PS Tibial Insert, UHMWPE		10
	PreciTotal, PS Tibial Insert, UHMWPE		12
	PreciTotal, PS Tibial Insert, UHMWPE		14
	PreciTotal, PS Tibial Insert, UHMWPE		16
	PreciTotal, PS Tibial Insert, UHMWPE	5	6
	PreciTotal, PS Tibial Insert, UHMWPE		8
	PreciTotal, PS Tibial Insert, UHMWPE		10
	PreciTotal, PS Tibial Insert, UHMWPE		12
	PreciTotal, PS Tibial Insert, UHMWPE		14
	PreciTotal, PS Tibial Insert, UHMWPE		16
	PreciTotal, PS Tibial Insert, UHMWPE	6	6
	PreciTotal, PS Tibial Insert, UHMWPE		8
	PreciTotal, PS Tibial Insert, UHMWPE		10
	PreciTotal, PS Tibial Insert, UHMWPE		12
	PreciTotal, PS Tibial Insert, UHMWPE		14
	PreciTotal, PS Tibial Insert, UHMWPE		16
	PreciTotal, PS Tibial Insert, UHMWPE	7	6
	PreciTotal, PS Tibial Insert, UHMWPE		8
	PreciTotal, PS Tibial Insert, UHMWPE		10
	PreciTotal, PS Tibial Insert, UHMWPE		12
	PreciTotal, PS Tibial Insert, UHMWPE		14
	PreciTotal, PS Tibial Insert, UHMWPE		16
	PreciTotal, PS Tibial Insert, UHMWPE	8	6
	PreciTotal, PS Tibial Insert, UHMWPE		8
	PreciTotal, PS Tibial Insert, UHMWPE		10
	PreciTotal, PS Tibial Insert, UHMWPE		12
	PreciTotal, PS Tibial Insert, UHMWPE		14
	PreciTotal, PS Tibial Insert, UHMWPE		16
	PreciTotal, PS Tibial Insert, UHMWPE	9	6
	PreciTotal, PS Tibial Insert, UHMWPE		8
	PreciTotal, PS Tibial Insert, UHMWPE		10
	PreciTotal, PS Tibial Insert, UHMWPE		12
	PreciTotal, PS Tibial Insert, UHMWPE		14
	PreciTotal, PS Tibial Insert, UHMWPE		16



	Description	Size	Thickness (mm)
Knee-joint replacement implants 16. PreciTotal Cementless Knee System b. Tibial Insert CR	PreciTotal, CR Tibial Insert, UHMWPE	1	6
	PreciTotal, CR Tibial Insert, UHMWPE		8
	PreciTotal, CR Tibial Insert, UHMWPE		10
	PreciTotal, CR Tibial Insert, UHMWPE		12
	PreciTotal, CR Tibial Insert, UHMWPE		14
	PreciTotal, CR Tibial Insert, UHMWPE		16
	PreciTotal, CR Tibial Insert, UHMWPE	2	6
	PreciTotal, CR Tibial Insert, UHMWPE		8
	PreciTotal, CR Tibial Insert, UHMWPE		10
	PreciTotal, CR Tibial Insert, UHMWPE		12
	PreciTotal, CR Tibial Insert, UHMWPE		14
	PreciTotal, CR Tibial Insert, UHMWPE		16
	PreciTotal, CR Tibial Insert, UHMWPE	3	6
	PreciTotal, CR Tibial Insert, UHMWPE		8
	PreciTotal, CR Tibial Insert, UHMWPE		10
	PreciTotal, CR Tibial Insert, UHMWPE		12
	PreciTotal, CR Tibial Insert, UHMWPE		14
	PreciTotal, CR Tibial Insert, UHMWPE		16
	PreciTotal, CR Tibial Insert, UHMWPE	4	6
	PreciTotal, CR Tibial Insert, UHMWPE		8
	PreciTotal, CR Tibial Insert, UHMWPE		10
	PreciTotal, CR Tibial Insert, UHMWPE		12
	PreciTotal, CR Tibial Insert, UHMWPE		14
	PreciTotal, CR Tibial Insert, UHMWPE		16
	PreciTotal, CR Tibial Insert, UHMWPE	5	6
	PreciTotal, CR Tibial Insert, UHMWPE		8
	PreciTotal, CR Tibial Insert, UHMWPE		10
	PreciTotal, CR Tibial Insert, UHMWPE		12
	PreciTotal, CR Tibial Insert, UHMWPE		14
	PreciTotal, CR Tibial Insert, UHMWPE		16
	PreciTotal, CR Tibial Insert, UHMWPE	6	6
	PreciTotal, CR Tibial Insert, UHMWPE		8
	PreciTotal, CR Tibial Insert, UHMWPE		10
	PreciTotal, CR Tibial Insert, UHMWPE		12
	PreciTotal, CR Tibial Insert, UHMWPE		14
	PreciTotal, CR Tibial Insert, UHMWPE		16
	PreciTotal, CR Tibial Insert, UHMWPE	7	6
	PreciTotal, CR Tibial Insert, UHMWPE		8
	PreciTotal, CR Tibial Insert, UHMWPE		10
	PreciTotal, CR Tibial Insert, UHMWPE		12
	PreciTotal, CR Tibial Insert, UHMWPE		14
	PreciTotal, CR Tibial Insert, UHMWPE		16
	PreciTotal, CR Tibial Insert, UHMWPE	8	6
	PreciTotal, CR Tibial Insert, UHMWPE		8
	PreciTotal, CR Tibial Insert, UHMWPE		10
	PreciTotal, CR Tibial Insert, UHMWPE		12
	PreciTotal, CR Tibial Insert, UHMWPE		14
	PreciTotal, CR Tibial Insert, UHMWPE		16
	PreciTotal, CR Tibial Insert, UHMWPE	9	6
	PreciTotal, CR Tibial Insert, UHMWPE		8
	PreciTotal, CR Tibial Insert, UHMWPE		10
	PreciTotal, CR Tibial Insert, UHMWPE		12
	PreciTotal, CR Tibial Insert, UHMWPE		14
	PreciTotal, CR Tibial Insert, UHMWPE		16



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Knee-joint replacement implants 16. PreciTotal Cementless Knee System c. OSSEOMATRIX Tibial Tray	Description	Size
	OSSEOMATRIX Tibial Tray	1
	OSSEOMATRIX Tibial Tray	2
	OSSEOMATRIX Tibial Tray	3
	OSSEOMATRIX Tibial Tray	4
	OSSEOMATRIX Tibial Tray	5
	OSSEOMATRIX Tibial Tray	6
	OSSEOMATRIX Tibial Tray	7
	OSSEOMATRIX Tibial Tray	8

Knee-joint replacement implants 16. PreciTotal Cementless Knee System d. Patellar Component	Description	Size	Thickness (mm)
	PreciTotal, Patellar Component, UHMWPE	1	7.5
	PreciTotal, Patellar Component, UHMWPE	2	7.5
	PreciTotal, Patellar Component, UHMWPE	3	7.5
	PreciTotal, Patellar Component, UHMWPE	4	7.5
	PreciTotal, Patellar Component, UHMWPE	5	7.5
	PreciTotal, Patellar Component, UHMWPE	1	10.00
	PreciTotal, Patellar Component, UHMWPE	2	10.00
	PreciTotal, Patellar Component, UHMWPE	3	10.00
	PreciTotal, Patellar Component, UHMWPE	4	10.00
	PreciTotal, Patellar Component, UHMWPE	5	10.00



Knee-joint replacement implants 17. PreciTotal Revision Knee System a. Femoral Component	Description	Size
	PreciTotal, Femoral Component, Revision	1, L
	PreciTotal, Femoral Component, Revision	2, L
	PreciTotal, Femoral Component, Revision	3, L
	PreciTotal, Femoral Component, Revision	4, L
	PreciTotal, Femoral Component, Revision	5, L
	PreciTotal, Femoral Component, Revision	6, L
	PreciTotal, Femoral Component, Revision	7, L
	PreciTotal, Femoral Component, Revision	8, L
	PreciTotal, Femoral Component, Revision	9, L
	PreciTotal, Femoral Component, Revision	1, R
	PreciTotal, Femoral Component, Revision	2, R
	PreciTotal, Femoral Component, Revision	3, R
	PreciTotal, Femoral Component, Revision	4, R
	PreciTotal, Femoral Component, Revision	5, R
	PreciTotal, Femoral Component, Revision	6, R
	PreciTotal, Femoral Component, Revision	7, R
	PreciTotal, Femoral Component, Revision	8, R
	PreciTotal, Femoral Component, Revision	9, R

Knee-joint replacement implants 17. PreciTotal Revision Knee System b. Tibial Component	Description	Size
	PreciTotal, Tibial Component, Revision	1
	PreciTotal, Tibial Component, Revision	2
	PreciTotal, Tibial Component, Revision	3
	PreciTotal, Tibial Component, Revision	4
	PreciTotal, Tibial Component, Revision	5
	PreciTotal, Tibial Component, Revision	6
	PreciTotal, Tibial Component, Revision	7
	PreciTotal, Tibial Component, Revision	8
	PreciTotal, Tibial Component, Revision	9



	Description	Size	Thickness (mm)
Knee-joint replacement implants 17. PreciTotal Revision Knee System c. Tibial Insert	PreciTotal, PS Tibial Insert, Revision, UHMWPE	1	6
	PreciTotal, PS Tibial Insert, Revision, UHMWPE		8
	PreciTotal, PS Tibial Insert, Revision, UHMWPE		10
	PreciTotal, PS Tibial Insert, Revision, UHMWPE		12
	PreciTotal, PS Tibial Insert, Revision, UHMWPE		14
	PreciTotal, PS Tibial Insert, Revision, UHMWPE		16
	PreciTotal, PS Tibial Insert, Revision, UHMWPE		18
	PreciTotal, PS Tibial Insert, Revision, UHMWPE	2	6
	PreciTotal, PS Tibial Insert, Revision, UHMWPE		8
	PreciTotal, PS Tibial Insert, Revision, UHMWPE		10
	PreciTotal, PS Tibial Insert, Revision, UHMWPE		12
	PreciTotal, PS Tibial Insert, Revision, UHMWPE		14
	PreciTotal, PS Tibial Insert, Revision, UHMWPE		16
	PreciTotal, PS Tibial Insert, Revision, UHMWPE		18
	PreciTotal, PS Tibial Insert, Revision, UHMWPE	3	6
	PreciTotal, PS Tibial Insert, Revision, UHMWPE		8
	PreciTotal, PS Tibial Insert, Revision, UHMWPE		10
	PreciTotal, PS Tibial Insert, Revision, UHMWPE		12
	PreciTotal, PS Tibial Insert, Revision, UHMWPE		14
	PreciTotal, PS Tibial Insert, Revision, UHMWPE		16
	PreciTotal, PS Tibial Insert, Revision, UHMWPE		18
	PreciTotal, PS Tibial Insert, Revision, UHMWPE	4	6
	PreciTotal, PS Tibial Insert, Revision, UHMWPE		8
	PreciTotal, PS Tibial Insert, Revision, UHMWPE		10
	PreciTotal, PS Tibial Insert, Revision, UHMWPE		12
	PreciTotal, PS Tibial Insert, Revision, UHMWPE		14
	PreciTotal, PS Tibial Insert, Revision, UHMWPE		16
	PreciTotal, PS Tibial Insert, Revision, UHMWPE		18
	PreciTotal, PS Tibial Insert, Revision, UHMWPE	5	6
	PreciTotal, PS Tibial Insert, Revision, UHMWPE		8
	PreciTotal, PS Tibial Insert, Revision, UHMWPE		10
	PreciTotal, PS Tibial Insert, Revision, UHMWPE		12
	PreciTotal, PS Tibial Insert, Revision, UHMWPE		14
	PreciTotal, PS Tibial Insert, Revision, UHMWPE		16
	PreciTotal, PS Tibial Insert, Revision, UHMWPE		18
	PreciTotal, PS Tibial Insert, Revision, UHMWPE	6	6
	PreciTotal, PS Tibial Insert, Revision, UHMWPE		8
	PreciTotal, PS Tibial Insert, Revision, UHMWPE		10
	PreciTotal, PS Tibial Insert, Revision, UHMWPE		12
	PreciTotal, PS Tibial Insert, Revision, UHMWPE		14
	PreciTotal, PS Tibial Insert, Revision, UHMWPE		16
	PreciTotal, PS Tibial Insert, Revision, UHMWPE		18



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	Description	Size	Thickness (mm)
Knee-joint replacement implants 17. PreciTotal Revision Knee System c. Tibial Insert - continue	PreciTotal, PS Tibial Insert, Revision, UHMWPE	7	6
	PreciTotal, PS Tibial Insert, Revision, UHMWPE		8
	PreciTotal, PS Tibial Insert, Revision, UHMWPE		10
	PreciTotal, PS Tibial Insert, Revision, UHMWPE		12
	PreciTotal, PS Tibial Insert, Revision, UHMWPE		14
	PreciTotal, PS Tibial Insert, Revision, UHMWPE		16
	PreciTotal, PS Tibial Insert, Revision, UHMWPE		18
	PreciTotal, PS Tibial Insert, Revision, UHMWPE	8	6
	PreciTotal, PS Tibial Insert, Revision, UHMWPE		8
	PreciTotal, PS Tibial Insert, Revision, UHMWPE		10
	PreciTotal, PS Tibial Insert, Revision, UHMWPE		12
	PreciTotal, PS Tibial Insert, Revision, UHMWPE		14
	PreciTotal, PS Tibial Insert, Revision, UHMWPE		16
	PreciTotal, PS Tibial Insert, Revision, UHMWPE		18
	PreciTotal, PS Tibial Insert, Revision, UHMWPE	9	6
	PreciTotal, PS Tibial Insert, Revision, UHMWPE		8
	PreciTotal, PS Tibial Insert, Revision, UHMWPE		10
	PreciTotal, PS Tibial Insert, Revision, UHMWPE		12
	PreciTotal, PS Tibial Insert, Revision, UHMWPE		14
	PreciTotal, PS Tibial Insert, Revision, UHMWPE		16
	PreciTotal, PS Tibial Insert, Revision, UHMWPE		18



	Description	Size
Knee-joint replacement implants 17. PreciTotal Revision Knee System d. Augment Femoral Distal	PreciTotal, Augment Femoral Distal	5 mm Sz 1 RL/LM
	PreciTotal, Augment Femoral Distal	10 mm Sz 1 RL/LM
	PreciTotal, Augment Femoral Distal	15 mm Sz 1 RL/LM
	PreciTotal, Augment Femoral Distal	5 mm Sz 1 LL/RM
	PreciTotal, Augment Femoral Distal	10 mm Sz 1 LL/RM
	PreciTotal, Augment Femoral Distal	15 mm Sz 1 LL/RM
	PreciTotal, Augment Femoral Distal	5 mm Sz 2 RL/LM
	PreciTotal, Augment Femoral Distal	10 mm Sz 2 RL/LM
	PreciTotal, Augment Femoral Distal	15 mm Sz 2 RL/LM
	PreciTotal, Augment Femoral Distal	5 mm Sz 2 LL/RM
	PreciTotal, Augment Femoral Distal	10 mm Sz 2 LL/RM
	PreciTotal, Augment Femoral Distal	15 mm Sz 2 LL/RM
	PreciTotal, Augment Femoral Distal	5 mm Sz 3 RL/LM
	PreciTotal, Augment Femoral Distal	10 mm Sz 3 RL/LM
	PreciTotal, Augment Femoral Distal	15 mm Sz 3 RL/LM
	PreciTotal, Augment Femoral Distal	5 mm Sz 3 LL/RM
	PreciTotal, Augment Femoral Distal	10 mm Sz 3 LL/RM
	PreciTotal, Augment Femoral Distal	15 mm Sz 3 LL/RM
	PreciTotal, Augment Femoral Distal	5 mm Sz 4 RL/LM
	PreciTotal, Augment Femoral Distal	10 mm Sz 4 RL/LM
	PreciTotal, Augment Femoral Distal	15 mm Sz 4 RL/LM
	PreciTotal, Augment Femoral Distal	5 mm Sz 4 LL/RM
	PreciTotal, Augment Femoral Distal	10 mm Sz 4 LL/RM
	PreciTotal, Augment Femoral Distal	15 mm Sz 4 LL/RM
	PreciTotal, Augment Femoral Distal	5 mm Sz 5 RL/LM
	PreciTotal, Augment Femoral Distal	10 mm Sz 5 RL/LM
	PreciTotal, Augment Femoral Distal	15 mm Sz 5 RL/LM
	PreciTotal, Augment Femoral Distal	5 mm Sz 5 LL/RM
	PreciTotal, Augment Femoral Distal	10 mm Sz 5 LL/RM
	PreciTotal, Augment Femoral Distal	15 mm Sz 5 LL/RM
	PreciTotal, Augment Femoral Distal	5 mm Sz 6 RL/LM
	PreciTotal, Augment Femoral Distal	10 mm Sz 6 RL/LM
	PreciTotal, Augment Femoral Distal	15 mm Sz 6 RL/LM
	PreciTotal, Augment Femoral Distal	5 mm Sz 6 LL/RM
	PreciTotal, Augment Femoral Distal	10 mm Sz 6 LL/RM
	PreciTotal, Augment Femoral Distal	15 mm Sz 6 LL/RM
	PreciTotal, Augment Femoral Distal	5 mm Sz 7 RL/LM
	PreciTotal, Augment Femoral Distal	10 mm Sz 7 RL/LM
	PreciTotal, Augment Femoral Distal	15 mm Sz 7 RL/LM
	PreciTotal, Augment Femoral Distal	5 mm Sz 7 LL/RM
	PreciTotal, Augment Femoral Distal	10 mm Sz 7 LL/RM
	PreciTotal, Augment Femoral Distal	15 mm Sz 7 LL/RM



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Knee-joint replacement implants 17. PreciTotal Revision Knee System d. Augment Femoral Distal - continue	Description	Size
	PreciTotal, Augment Femoral Distal	5 mm Sz 8 RL/LM
	PreciTotal, Augment Femoral Distal	10 mm Sz 8 RL/LM
	PreciTotal, Augment Femoral Distal	15 mm Sz 8 RL/LM
	PreciTotal, Augment Femoral Distal	5 mm Sz 8 LL/RM
	PreciTotal, Augment Femoral Distal	10 mm Sz 8 LL/RM
	PreciTotal, Augment Femoral Distal	15 mm Sz 8 LL/RM
	PreciTotal, Augment Femoral Distal	5 mm Sz 9 RL/LM
	PreciTotal, Augment Femoral Distal	10 mm Sz 9 RL/LM
	PreciTotal, Augment Femoral Distal	15 mm Sz 9 RL/LM
	PreciTotal, Augment Femoral Distal	5 mm Sz 9 LL/RM
	PreciTotal, Augment Femoral Distal	10 mm Sz 9 LL/RM
	PreciTotal, Augment Femoral Distal	15 mm Sz 9 LL/RM

Knee-joint replacement implants 17. PreciTotal Revision Knee System e. Augment Femoral Posterior	Description	Size
	PreciTotal, Augment Femoral Posterior	5 mm Sz 1
	PreciTotal, Augment Femoral Posterior	10 mm Sz 1
	PreciTotal, Augment Femoral Posterior	5 mm Sz 2
	PreciTotal, Augment Femoral Posterior	10 mm Sz 2
	PreciTotal, Augment Femoral Posterior	5 mm Sz 3
	PreciTotal, Augment Femoral Posterior	10 mm Sz 3
	PreciTotal, Augment Femoral Posterior	5 mm Sz 4
	PreciTotal, Augment Femoral Posterior	10 mm Sz 4
	PreciTotal, Augment Femoral Posterior	5 mm Sz 5
	PreciTotal, Augment Femoral Posterior	10 mm Sz 5
	PreciTotal, Augment Femoral Posterior	5 mm Sz 6
	PreciTotal, Augment Femoral Posterior	10 mm Sz 6
	PreciTotal, Augment Femoral Posterior	5 mm Sz 7
	PreciTotal, Augment Femoral Posterior	10 mm Sz 7
	PreciTotal, Augment Femoral Posterior	5 mm Sz 8
	PreciTotal, Augment Femoral Posterior	10 mm Sz 8
	PreciTotal, Augment Femoral Posterior	5 mm Sz 9
	PreciTotal, Augment Femoral Posterior	10 mm Sz 9



Description	Size
PreciTotal, Augment Tibial	5 mm Sz 1
PreciTotal, Augment Tibial	10 mm Sz 1 RL/LM
PreciTotal, Augment Tibial	15 mm Sz 1 RL/LM
PreciTotal, Augment Tibial	10 mm Sz 1 LL/RM
PreciTotal, Augment Tibial	15 mm Sz 1 LL/RM
PreciTotal, Augment Tibial	5 mm Sz 2
PreciTotal, Augment Tibial	10 mm Sz 2 RL/LM
PreciTotal, Augment Tibial	15 mm Sz 2 RL/LM
PreciTotal, Augment Tibial	10 mm Sz 2 LL/RM
PreciTotal, Augment Tibial	15 mm Sz 2 LL/RM
PreciTotal, Augment Tibial	5 mm Sz 3
PreciTotal, Augment Tibial	10 mm Sz 3 RL/LM
PreciTotal, Augment Tibial	15 mm Sz 3 RL/LM
PreciTotal, Augment Tibial	10 mm Sz 3 LL/RM
PreciTotal, Augment Tibial	15 mm Sz 3 LL/RM
PreciTotal, Augment Tibial	5 mm Sz 4
PreciTotal, Augment Tibial	10 mm Sz 4 RL/LM
PreciTotal, Augment Tibial	15 mm Sz 4 RL/LM
PreciTotal, Augment Tibial	10 mm Sz 4 LL/RM
PreciTotal, Augment Tibial	15 mm Sz 4 LL/RM
PreciTotal, Augment Tibial	5 mm Sz 5
PreciTotal, Augment Tibial	10 mm Sz 5 RL/LM
PreciTotal, Augment Tibial	15 mm Sz 5 RL/LM
PreciTotal, Augment Tibial	10 mm Sz 5 LL/RM
PreciTotal, Augment Tibial	15 mm Sz 5 LL/RM
PreciTotal, Augment Tibial	5 mm Sz 6
PreciTotal, Augment Tibial	10 mm Sz 6 RL/LM
PreciTotal, Augment Tibial	15 mm Sz 6 RL/LM
PreciTotal, Augment Tibial	10 mm Sz 6 LL/RM
PreciTotal, Augment Tibial	15 mm Sz 6 LL/RM
PreciTotal, Augment Tibial	5 mm Sz 7
PreciTotal, Augment Tibial	10 mm Sz 7 RL/LM
PreciTotal, Augment Tibial	15 mm Sz 7 RL/LM
PreciTotal, Augment Tibial	10 mm Sz 7 LL/RM
PreciTotal, Augment Tibial	15 mm Sz 7 LL/RM
PreciTotal, Augment Tibial	5 mm Sz 8
PreciTotal, Augment Tibial	10 mm Sz 8 RL/LM
PreciTotal, Augment Tibial	15 mm Sz 8 RL/LM
PreciTotal, Augment Tibial	10 mm Sz 8 LL/RM
PreciTotal, Augment Tibial	15 mm Sz 8 LL/RM
PreciTotal, Augment Tibial	5 mm Sz 9
PreciTotal, Augment Tibial	10 mm Sz 9 RL/LM
PreciTotal, Augment Tibial	15 mm Sz 9 RL/LM
PreciTotal, Augment Tibial	10 mm Sz 9 LL/RM
PreciTotal, Augment Tibial	15 mm Sz 9 LL/RM

Knee-joint replacement implants

17. PreciTotal Revision Knee System

f. Augment Tibial



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Knee-joint replacement implants 17. PreciTotal Revision Knee System g. Extension Stem	Description	Size
	Extension Stem	10 X 40 mm
	Extension Stem	12 X 40 mm
	Extension Stem	14 X 40 mm
	Extension Stem	16 X 40 mm
	Extension Stem	18 X 40 mm
	Extension Stem	20 X 40 mm
	Extension Stem	10 X 80 mm
	Extension Stem	12 X 80 mm
	Extension Stem	14 X 80 mm
	Extension Stem	16 X 80 mm
	Extension Stem	18 X 80 mm
	Extension Stem	20 X 80 mm
	Extension Stem	22 X 80 mm
	Extension Stem	10 X 120 mm
	Extension Stem	12 X 120 mm
	Extension Stem	14 X 120 mm
	Extension Stem	16 X 120 mm
	Extension Stem	18 X 120 mm
	Extension Stem	20 X 120 mm
	Extension Stem	22 X 120 mm
	Extension Stem	10 X 160 mm
	Extension Stem	12 X 160 mm
	Extension Stem	14 X 160 mm
	Extension Stem	16 X 160 mm
	Extension Stem	18 X 160 mm
	Extension Stem	20 X 160 mm
	Extension Stem	22 X 160 mm

Knee-joint replacement implants 17. PreciTotal Revision Knee System h. Screws	Description	Size
	Knee augment screw	M 8x1.25
	Adaptor connecting screw	M 4x0.7

Knee-joint replacement implants 17. PreciTotal Revision Knee System i. Offset Adaptor	Description	Size
	Offset adaptor	2.5mm
	Offset adaptor	5.0mm
	Offset adaptor	0mm



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	EC Declaration of Conformity Council Directive 93/42/EEC Annex II, incl. section 4	Doc. No.: DCE-AH01-A21.04
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We, the manufacturer

aap Joints GmbH,
Wilhelm-von-Siemens-Strasse 23, Aufgang F,
12277 Berlin, Germany

hereby declare under our sole responsibility, that the medical devices specified below fulfil the obligations of Council Directive 93/42/EEC and meet the relevant Essential Requirements of Annex I of aforementioned directive.

Product Group:	Hip Joint Replacement Implants
Product:	VarioLoc Hip System
Catalog Numbers:	see Annex 1 – Product list
Classification:	Class III (according to Rule 8, 93/42/EEC and Article 1, 2005/50/EC on the reclassification of hip, knee and shoulder joint replacement)
Conformity assessment route:	Annex II, EC Declaration of Conformity (Full quality assurance system) including section 4, 93/42/EEC
Certifications:	EC Certificate: CE-MDD-0058/09/2019/01 Design Examination Certificate: CE-MD-0058/09/2019/01/DD.02 ISO 13485:2016 Certificate: ISO.Med.0058.09.2019
Applied standards:	ISO 13485:2016; EN ISO 14971:2019; EN 556-1:2001; EN 62366-1:2015/A1:2020; ISO 10993-1:2018; EN ISO 10993-3:2014; EN ISO 10993-5:2009; ISO 10993-6:2016; ISO 10993-7:2008/A1:2019; ISO 10993-10:2010; ISO 10993-11:2017; EN 1041:2008/A1:2013; EN 15223-1:2016; ISO 11135:2014/A1:2018; ISO 11137-1:2006/A2:2018; ISO 11137-2:2015; ISO 11607-1:2019; ISO 11607-2:2019; ISO 14630:2012; EN ISO 21534:2009; EN ISO 21535:2009

All supporting documentation is retained under the premises of the manufacturer. The compliance with the requirements is controlled by:

Notified Body: Notice Belgelendirme, Muayene ve Denetim Hizmetleri A.Ş.
Esentepe Mahallesi Milangaz Caddesi No:75 A/92
Kartal/İstanbul, Istanbul

NB identification number: 2764

This declaration of conformity is valid until 26.May 2024.

Berlin, 24. May 2021

Signature:



Name: Feipeng Huang

Position: Managing Director

	EC Declaration of Conformity Council Directive 93/42/EEC Annex II, incl. section 4	Doc. No.: DCE-AH01-A21.04
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Annex 1 - Product List

VarioLoc Stem TPS Coating		GMDN Code: 60516
Catalog #	Description	Size
A1101-0-1050	VarioLoc Stem, TPS Coating, STD	5mm
A1101-0-1060	VarioLoc Stem, TPS Coating, STD	6mm
A1101-0-1075	VarioLoc Stem, TPS Coating, STD	7.5mm
A1101-0-1090	VarioLoc Stem, TPS Coating, STD	9mm
A1101-0-1100	VarioLoc Stem, TPS Coating, STD	10mm
A1101-0-1110	VarioLoc Stem, TPS Coating, STD	11mm
A1101-0-1125	VarioLoc Stem, TPS Coating, STD	12.5mm
A1101-0-1135	VarioLoc Stem, TPS Coating, STD	13.5mm
A1101-0-1150	VarioLoc Stem, TPS Coating, STD	15mm
A1101-0-1160	VarioLoc Stem, TPS Coating, STD	16mm
A1101-0-1175	VarioLoc Stem, TPS Coating, STD	17.5mm
A1101-0-1200	VarioLoc Stem, TPS Coating, STD	20mm
A1101-0-2075	VarioLoc Stem, TPS Coating, LAT	7.5mm
A1101-0-2090	VarioLoc Stem, TPS Coating, LAT	9mm
A1101-0-2100	VarioLoc Stem, TPS Coating, LAT	10mm
A1101-0-2110	VarioLoc Stem, TPS Coating, LAT	11mm
A1101-0-2125	VarioLoc Stem, TPS Coating, LAT	12.5mm
A1101-0-2135	VarioLoc Stem, TPS Coating, LAT	13.5mm
A1101-0-2150	VarioLoc Stem, TPS Coating, LAT	15mm
A1101-0-2160	VarioLoc Stem, TPS Coating, LAT	16mm
A1101-0-2175	VarioLoc Stem, TPS Coating, LAT	17.5mm
A1101-0-2200	VarioLoc Stem, TPS Coating, LAT	20mm

Femoral Head		GMDN Code: 33175
Catalog #	Description	Size
A1100-9-2201	Femoral Head, CoCrMo	22mm,-3mm
A1100-9-2202	Femoral Head, CoCrMo	22mm,+0mm
A1100-9-2801	Femoral Head, CoCrMo	28mm,-3.5mm
A1100-9-2802	Femoral Head, CoCrMo	28mm,+0mm
A1100-9-2803	Femoral Head, CoCrMo	28mm,+3.5mm
A1100-9-2804	Femoral Head, CoCrMo	28mm,+7mm
A1100-9-2805	Femoral Head, CoCrMo	28mm,+10.5mm
A1100-9-3201	Femoral Head, CoCrMo	32mm,-4mm
A1100-9-3202	Femoral Head, CoCrMo	32mm,+0mm
A1100-9-3203	Femoral Head, CoCrMo	32mm,+4mm
A1100-9-3204	Femoral Head, CoCrMo	32mm,+7mm
A1100-9-3205	Femoral Head, CoCrMo	32mm,+10.5mm

	EC Declaration of Conformity Council Directive 93/42/EEC Annex II, incl. section 4	Doc. No.: DCE-AH01-A21.04
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Femoral Head		GMDN Code: 33175
Catalog #	Description	Size
A1100-9-3601	Femoral Head, CoCrMo	36mm,-4mm
A1100-9-3602	Femoral Head, CoCrMo	36mm,+0mm
A1100-9-3603	Femoral Head, CoCrMo	36mm,+4mm
A1100-9-3604	Femoral Head, CoCrMo	36mm,+8mm
A1100-9-3605	Femoral Head, CoCrMo	36mm,+10.5mm

VarioCup, TPS Coating		GMDN Code: 60516
Catalog #	Description	Size
A1402-0-1042	VarioCup, TPS Coating, No-hole	42mm, BB
A1402-0-1044	VarioCup, TPS Coating, No-hole	44mm, MM
A1402-0-1046	VarioCup, TPS Coating, No-hole	46mm, NN
A1402-0-1048	VarioCup, TPS Coating, No-hole	48mm, OO
A1402-0-1050	VarioCup, TPS Coating, No-hole	50mm, PP
A1402-0-1052	VarioCup, TPS Coating, No-hole	52mm, PP
A1402-0-1054	VarioCup, TPS Coating, No-hole	54mm, QQ
A1402-0-1056	VarioCup, TPS Coating, No-hole	56mm, QQ
A1402-0-1058	VarioCup, TPS Coating, No-hole	58mm, RR
A1402-0-1060	VarioCup, TPS Coating, No-hole	60mm, RR
A1402-0-1062	VarioCup, TPS Coating, No-hole	62mm, SS
A1402-0-1064	VarioCup, TPS Coating, No-hole	64mm, SS
A1402-0-1066	VarioCup, TPS Coating, No-hole	66mm, TT
A1402-0-1068	VarioCup, TPS Coating, No-hole	68mm, TT
A1402-0-2042	VarioCup, TPS Coating, Three-hole	42mm, BB
A1402-0-2044	VarioCup, TPS Coating, Three-hole	44mm, MM
A1402-0-2046	VarioCup, TPS Coating, Three-hole	46mm, NN
A1402-0-2048	VarioCup, TPS Coating, Three-hole	48mm, OO
A1402-0-2050	VarioCup, TPS Coating, Three-hole	50mm, PP
A1402-0-2052	VarioCup, TPS Coating, Three-hole	52mm, PP
A1402-0-2054	VarioCup, TPS Coating, Three-hole	54mm, QQ
A1402-0-2056	VarioCup, TPS Coating, Three-hole	56mm, QQ
A1402-0-2058	VarioCup, TPS Coating, Three-hole	58mm, RR
A1402-0-2060	VarioCup, TPS Coating, Three-hole	60mm, RR
A1402-0-2062	VarioCup, TPS Coating, Three-hole	62mm, SS
A1402-0-2064	VarioCup, TPS Coating, Three-hole	64mm, SS
A1402-0-2066	VarioCup, TPS Coating, Three-hole	66mm, TT
A1402-0-2068	VarioCup, TPS Coating, Three-hole	68mm, TT

	EC Declaration of Conformity Council Directive 93/42/EEC Annex II, incl. section 4	Doc. No.: DCE-AH01-A21.04
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VarioCup, insert, Highly cross-linked UHMWPE		GMDN Code: 43168
Catalog #	Description	Size
A1403-2-2242	VarioCup insert, Neutral, Highly cross-linked UHMWPE	22mm ID, BB
A1403-2-2244	VarioCup insert, Neutral, Highly cross-linked UHMWPE	22mm ID, MM
A1403-2-2842	VarioCup insert, Neutral, Highly cross-linked UHMWPE	28mm ID, BB
A1403-2-2844	VarioCup insert, Neutral, Highly cross-linked UHMWPE	28mm ID, MM
A1403-2-2846	VarioCup insert, Neutral, Highly cross-linked UHMWPE	28mm ID, NN
A1403-2-2848	VarioCup insert, Neutral, Highly cross-linked UHMWPE	28mm ID, OO
A1403-2-2850	VarioCup insert, Neutral, Highly cross-linked UHMWPE	28mm ID, PP
A1403-2-2854	VarioCup insert, Neutral, Highly cross-linked UHMWPE	28mm ID, QQ
A1403-2-2858	VarioCup insert, Neutral, Highly cross-linked UHMWPE	28mm ID, RR
A1403-2-2862	VarioCup insert, Neutral, Highly cross-linked UHMWPE	28mm ID, SS
A1403-2-3248	VarioCup insert, Neutral, Highly cross-linked UHMWPE	32mm ID, OO
A1403-2-3250	VarioCup insert, Neutral, Highly cross-linked UHMWPE	32mm ID, PP
A1403-2-3254	VarioCup insert, Neutral, Highly cross-linked UHMWPE	32mm ID, QQ
A1403-2-3258	VarioCup insert, Neutral, Highly cross-linked UHMWPE	32mm ID, RR
A1403-2-3262	VarioCup insert, Neutral, Highly cross-linked UHMWPE	32mm ID, SS
A1403-2-3654	VarioCup insert, Neutral, Highly cross-linked UHMWPE	36mm ID, QQ
A1403-2-3658	VarioCup insert, Neutral, Highly cross-linked UHMWPE	36mm ID, RR
A1403-2-3662	VarioCup insert, Neutral, Highly cross-linked UHMWPE	36mm ID, SS
A1403-2-3666	VarioCup insert, Neutral, Highly cross-linked UHMWPE	36mm ID, TT
A1403-3-2242	VarioCup insert, 15° hooded, Highly cross-linked UHMWPE	22mm ID, BB
A1403-3-2244	VarioCup insert, 15° hooded, Highly cross-linked UHMWPE	22mm ID, MM
A1403-3-2842	VarioCup insert, 15° hooded, Highly cross-linked UHMWPE	28mm ID, BB
A1403-3-2844	VarioCup insert, 15° hooded, Highly cross-linked UHMWPE	28mm ID, MM
A1403-3-2846	VarioCup insert, 15° hooded, Highly cross-linked UHMWPE	28mm ID, NN
A1403-3-2848	VarioCup insert, 15° hooded, Highly cross-linked UHMWPE	28mm ID, OO
A1403-3-2850	VarioCup insert, 15° hooded, Highly cross-linked UHMWPE	28mm ID, PP
A1403-3-2854	VarioCup insert, 15° hooded, Highly cross-linked UHMWPE	28mm ID, QQ
A1403-3-2858	VarioCup insert, 15° hooded, Highly cross-linked UHMWPE	28mm ID, RR
A1403-3-2862	VarioCup insert, 15° hooded, Highly cross-linked UHMWPE	28mm ID, SS
A1403-3-3248	VarioCup insert, 15° hooded, Highly cross-linked UHMWPE	32mm ID, OO
A1403-3-3250	VarioCup insert, 15° hooded, Highly cross-linked UHMWPE	32mm ID, PP
A1403-3-3254	VarioCup insert, 15° hooded, Highly cross-linked UHMWPE	32mm ID, QQ
A1403-3-3258	VarioCup insert, 15° hooded, Highly cross-linked UHMWPE	32mm ID, RR
A1403-3-3262	VarioCup insert, 15° hooded, Highly cross-linked UHMWPE	32mm ID, SS
A1403-3-3654	VarioCup insert, 15° hooded, Highly cross-linked UHMWPE	36mm ID, QQ
A1403-3-3658	VarioCup insert, 15° hooded, Highly cross-linked UHMWPE	36mm ID, RR

	EC Declaration of Conformity Council Directive 93/42/EEC Annex II, incl. section 4	Doc. No.: DCE-AH01-A21.04
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VarioCup, insert, Highly cross-linked UHMWPE		GMDN Code: 43168
Catalog #	Description	Size
A1403-3-3662	VarioCup insert, 15° hooded, Highly cross-linked UHMWPE	36mm ID, SS
A1403-3-3666	VarioCup insert, 15° hooded, Highly cross-linked UHMWPE	36mm ID, TT

	EC Declaration of Conformity Council Directive 93/42/EEC Annex II, excl. section 4	Doc. No.: DCE-AH21-A21.04
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We, the manufacturer

aap Joints GmbH,
Wilhelm-von-Siemens-Strasse 23, Aufgang F,
12277 Berlin, Germany

hereby declare under our sole responsibility, that the medical devices specified below fulfil the obligations of Council Directive 93/42/EEC and meet the relevant Essential Requirements of Annex I of aforementioned directive.

Product Group:	Hip Accessories
Product:	Acetabular Screw, Screw plug, Dome plug
Catalog Numbers:	see Annex 1 – product list
Classification:	Class IIb (according to Rule 8, 93/42/EEC)
Conformity assessment route:	Annex II, EC Declaration of Conformity (Full quality assurance system) excluding section 4, 93/42/EEC
Certifications:	EC Certificate: CE-MD-0058/09/2019/02 ISO 13485:2016 Certificate: ISO.Med.0058.09.2019
Applied standards:	ISO 13485:2016; EN ISO 14971:2019; EN 556-1:2001; EN ISO 10993-1:2018, EN 62366-2008; ISO 10993-5:2009; EN 1041:2008/A1:2013; EN 15223-1:2016; ISO 11135:2014; ISO 11137-1:2006/A2:2018; ISO 11137-2:2015; ISO 11607-1:2019; ISO 11607-2:2006/A1:2014; ISO 14630:2012; EN ISO 21534:2009; EN ISO 21535:2009

All supporting documentation is retained under the premises of the manufacturer. The compliance with the requirements is controlled by:

Notified Body Notice Belgelendirme, Muayene ve Denetim Hizmetleri A.Ş
Esentepe Mahallesi Milangaz Caddesi No:75 A/92
Kartal/Istanbul, Istanbul

NB identification number: 2764

This declaration of conformity is valid until 26.May 2024.

Berlin, 24. May 2021

Signature:



Name:

Feipeng Huang

Position:

Managing Director

	EC Declaration of Conformity Council Directive 93/42/EEC Annex II, incl. section 4	Doc. No.: DCE-AH21-A21.04
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Annex 1 - Product List

Cancellous Bone Screw		GMDN Code: 46646
Catalog #	Description	Size
A1103-9-6515	Cancellous Bone Screw	6.5mm, 15mm
A1103-9-6520	Cancellous Bone Screw	6.5mm, 20mm
A1103-9-6525	Cancellous Bone Screw	6.5mm, 25mm
A1103-9-6530	Cancellous Bone Screw	6.5mm, 30mm
A1103-9-6535	Cancellous Bone Screw	6.5mm, 35mm
A1103-9-6540	Cancellous Bone Screw	6.5mm, 40mm
A1103-9-6545	Cancellous Bone Screw	6.5mm, 45mm
A1103-9-6550	Cancellous Bone Screw	6.5mm, 50mm
A1103-9-6555	Cancellous Bone Screw	6.5mm, 55mm
A1103-9-6560	Cancellous Bone Screw	6.5mm, 60mm
A1103-9-6565	Cancellous Bone Screw	6.5mm, 65mm
A1103-9-6570	Cancellous Bone Screw	6.5mm, 70mm

Screw Plug		GMDN Code: 56710
Catalog #	Description	Size
A1103-9-0003	Screw Plug Long	Ø7.4×2.6mm

Dome Plug		GMDN Code: 56710
Catalog #	Description	Size
A1103-9-0001	Dome Plug	Ø7.7×3.5mm

EC CERTIFICATE

Annex II excluding section 4 of the Directive 93/42/EEC on Medical Devices

Full Quality Assurance System

Certificate Number

CE-MDD-0058/09/2019/02

Manufacturer : aap Joints GmbH

Address : Wilhelm-von-Siemens-Strasse 23, Aufgang F, 12277 Berlin

Product(s) :
 1. The hip accessories
 - Acetabular screw
 - Screw plug
 - Dome plug
 2. Cement Restrictor and Centralizer
 - Cement Restrictor, UHMWPE
 - Centralizer, UHMWPE
 - Centralizer, PMMA

Model(s) : Please see 2nd page for details of products

Report Number : CE/ISO-MED-0065-09, CE-MED-0108-09

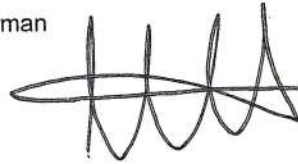
First Issue Date and Place : 2020.03.04 & Istanbul

Revision Number and Date : 01 / 2020.04.30

Validity Date : 2024.05.26

NOTICE, Notified Body 2764, declares that the aforementioned manufacturer has implemented a quality assurance system according to Annex II (excluding section 4), Section 3 of the directive 93/42/EEC on medical devices. This quality assurance system covers those aspects of manufacturing concerned with securing and maintaining safe conditions of the respective product(s) and conforms to the provisions of this Directive. The approved quality system is subject to surveillance pursuant to Annex II, Section 5 of Directive 93/42/EEC and unannounced audits. NOTICE must be informed of any significant changes in the design and/or construction of the product(s).

Özlem Vicdan Akdağ
Chairman




**NOTİCE BELGELENDİRME
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Esentepe Mahallesi Milangaz Caddesi
No:75/A/92 Kartal / İstanbul / TÜRKİYE
www.notice.com.tr



Product Name	Model Name	Size (mm)
The hip accessories -Acetabular screw -Screw plug -Dome plug	Acetabular screw	6,5mm-15mm
		6,5mm-20mm
		6,5mm-25mm
		6,5mm-30mm
		6,5mm-35mm
		6,5mm-40mm
		6,5mm-45mm
		6,5mm-50mm
		6,5mm-55mm
		6,5mm-60mm
		6,5mm-65mm
		6,5mm-70mm
	Screw plug	7,4mmX2,6mm
	Dome plug	7,7mmX3,5mm

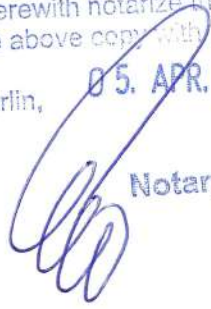
Product Name	Model Description	Size(mm)
Cement Restrictor and Centralizer - Cement Restrictor, UHMWPE - Centralizer, UHMWPE - Centralizer, PMMA	Cement Restrictor, UHMWPE	10mm
		12mm
		14mm
		16mm
		18mm
		20mm
	Centralizer, UHMWPE	10mm
		12mm
		14mm
		16mm
		18mm
		20mm
	Centralizer, PMMA	10mm
		12mm
		14mm
		16mm
		18mm
		20mm



I herewith notarize the literal accordance of
the above copy with the original at hand.

Berlin, 05. APR. 2022

Notary



EC DESIGN EXAMINATION CERTIFICATE

According to Annex II, Section 4 of the Directive 93/42/EEC on Medical Devices

Certificate Number

CE-MDD-0058/09/2019/01/DD.13

Manufacturer : aap Joints GmbH

Address : Wilhelm-von-Siemens-Strasse 23, Ausgang F, 12277 Berlin

Product(s) : Hip-Joint Replacement Implants
VarioCup Plus Acetabular System

Model(s) : Please see 2nd – 4th pages for details of products

Report Number : CE-MED-0108-04-DD

First Issue Date and Place : 2020.04.30 & Istanbul

Revision Number and Date : 00 / --

Validity Date : 2024.05.26

Issued by NOTICE, Notified Body 2764, this document approves that the design documentation of the mentioned product complies with Annex II, Section 4 of the 93/42/EEC Medical Devices Directive. The manufacturer is subject to EC surveillance in accordance with Annex II, Section 5 of 93/42/EEC Medical Devices Directive and unannounced audits.

Özlem Vicdan Akdağ
Chairman



**NOTICE BELGELENDİRME
MUAYENE VE DENETİM
HİZMETLERİ A.Ş.**

Esentepe Mahallesi Milangaz Caddesi
No:75/A/92 Kartal / İstanbul / TÜRKİYE
www.notice.com.tr

Hip-Joint Replacement Implants
 § VarioCup Plus Acetabular System
 a. VarioCup Plus

Description	Size
VarioCup, TPS Coating, Multi-hole	42mm, BB
VarioCup, TPS Coating, Multi-hole	44mm, MM
VarioCup, TPS Coating, Multi-hole	46mm, NN
VarioCup, TPS Coating, Multi-hole	48mm, OO
VarioCup, TPS Coating, Multi-hole	50mm, PP
VarioCup, TPS Coating, Multi-hole	52mm, PP
VarioCup, TPS Coating, Multi-hole	54mm, QQ
VarioCup, TPS Coating, Multi-hole	56mm, QQ
VarioCup, TPS Coating, Multi-hole	58mm, RR
VarioCup, TPS Coating, Multi-hole	60mm, RR
VarioCup, TPS Coating, Multi-hole	62mm, SS
VarioCup, TPS Coating, Multi-hole	64mm, SS
VarioCup, TPS Coating, Multi-hole	66mm, TT
VarioCup, TPS Coating, Multi-hole	68mm, TT
VarioCup, TPS Coating, Multi-hole	70mm, UU
VarioCup, TPS Coating, Multi-hole	72mm, UU
VarioCup, TPS Coating, Peripheral-hole	54mm, OO
VarioCup, TPS Coating, Peripheral-hole	56mm, PP
VarioCup, TPS Coating, Peripheral-hole	58mm, PP
VarioCup, TPS Coating, Peripheral-hole	60mm, QQ
VarioCup, TPS Coating, Peripheral-hole	62mm, QQ
VarioCup, TPS Coating, Peripheral-hole	64mm, RR
VarioCup, TPS Coating, Peripheral-hole	66mm, RR
VarioCup, TPS Coating, Peripheral-hole	68mm, SS
VarioCup, TPS Coating, Peripheral-hole	70mm, SS
VarioCup, TPS Coating, Peripheral-hole	72mm, TT
VarioCup, TPS Coating, Peripheral-hole	74mm, TT
VarioCup, TPS Coating, Peripheral-hole	76mm, TT
VarioCup, TPS Coating, Peripheral-hole	78mm, UU
VarioCup, TPS Coating, Peripheral-hole	80mm, UU



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Hip-Joint Replacement Implants
VarioCup Plus Acetabular System
b. VarioCup Insert

Description	Size
VarioCup Insert, High hooded, Highly cross-linked UHMWPE	28mm ID, BB
VarioCup Insert, High hooded, Highly cross-linked UHMWPE	28mm ID, MM
VarioCup Insert, High hooded, Highly cross-linked UHMWPE	28mm ID, NN
VarioCup Insert, High hooded, Highly cross-linked UHMWPE	28mm ID, OO
VarioCup Insert, High hooded, Highly cross-linked UHMWPE	28mm ID, PP
VarioCup Insert, High hooded, Highly cross-linked UHMWPE	28mm ID, QQ
VarioCup Insert, High hooded, Highly cross-linked UHMWPE	28mm ID, RR
VarioCup Insert, High hooded, Highly cross-linked UHMWPE	28mm ID, SS
VarioCup Insert, High hooded, Highly cross-linked UHMWPE	32mm ID, OO
VarioCup Insert, High hooded, Highly cross-linked UHMWPE	32mm ID, PP
VarioCup Insert, High hooded, Highly cross-linked UHMWPE	32mm ID, QQ
VarioCup Insert, High hooded, Highly cross-linked UHMWPE	32mm ID, RR
VarioCup Insert, High hooded, Highly cross-linked UHMWPE	32mm ID, SS
VarioCup Insert, High hooded, Highly cross-linked UHMWPE	36mm ID, QQ
VarioCup Insert, High hooded, Highly cross-linked UHMWPE	36mm ID, RR
VarioCup Insert, High hooded, Highly cross-linked UHMWPE	36mm ID, SS
VarioCup Insert, High hooded, Highly cross-linked UHMWPE	36mm ID, TT
VarioCup Insert, High hooded, Highly cross-linked UHMWPE	36mm ID, UU
VarioCup Insert, High hooded, UHMWPE	28mm ID, MM
VarioCup Insert, High hooded, UHMWPE	28mm ID, NN
VarioCup Insert, High hooded, UHMWPE	28mm ID, OO
VarioCup Insert, High hooded, UHMWPE	28mm ID, PP
VarioCup Insert, High hooded, UHMWPE	28mm ID, QQ
VarioCup Insert, High hooded, UHMWPE	28mm ID, RR
VarioCup Insert, High hooded, UHMWPE	28mm ID, SS
VarioCup Insert, High hooded, UHMWPE	32mm ID, OO
VarioCup Insert, High hooded, UHMWPE	32mm ID, PP
VarioCup Insert, High hooded, UHMWPE	32mm ID, QQ
VarioCup Insert, High hooded, UHMWPE	32mm ID, RR
VarioCup Insert, High hooded, UHMWPE	32mm ID, SS



	Description	Size
Hip-Joint Replacement Implants VarioCup Plus Acetabular System b. VarioCup Insert- continue	VarioCup Insert, Neutral, UHMWPE	22mm ID, BB
	VarioCup Insert, Neutral, UHMWPE	22mm ID, MM
	VarioCup Insert, Neutral, UHMWPE	28mm ID, MM
	VarioCup Insert, Neutral, UHMWPE	28mm ID, NN
	VarioCup Insert, Neutral, UHMWPE	28mm ID, OO
	VarioCup Insert, Neutral, UHMWPE	28mm ID, PP
	VarioCup Insert, Neutral, UHMWPE	28mm ID, QQ
	VarioCup Insert, Neutral, UHMWPE	28mm ID, RR
	VarioCup Insert, Neutral, UHMWPE	28mm ID, SS
	VarioCup Insert, Neutral, UHMWPE	32mm ID, OO
	VarioCup Insert, Neutral, UHMWPE	32mm ID, PP
	VarioCup Insert, Neutral, UHMWPE	32mm ID, QQ
	VarioCup Insert, Neutral, UHMWPE	32mm ID, RR
	VarioCup Insert, Neutral, UHMWPE	32mm ID, SS
	VarioCup Insert, 15° hooded, UHMWPE	22mm ID, BB
	VarioCup Insert, 15° hooded, UHMWPE	22mm ID, MM
	VarioCup Insert, 15° hooded, UHMWPE	28mm ID, MM
	VarioCup Insert, 15° hooded, UHMWPE	28mm ID, NN
	VarioCup Insert, 15° hooded, UHMWPE	28mm ID, OO
	VarioCup Insert, 15° hooded, UHMWPE	28mm ID, PP
	VarioCup Insert, 15° hooded, UHMWPE	28mm ID, QQ
	VarioCup Insert, 15° hooded, UHMWPE	28mm ID, RR
	VarioCup Insert, 15° hooded, UHMWPE	28mm ID, SS
	VarioCup Insert, 15° hooded, UHMWPE	32mm ID, OO
	VarioCup Insert, 15° hooded, UHMWPE	32mm ID, PP
	VarioCup Insert, 15° hooded, UHMWPE	32mm ID, QQ
	VarioCup Insert, 15° hooded, UHMWPE	32mm ID, RR
	VarioCup Insert, 15° hooded, UHMWPE	32mm ID, SS

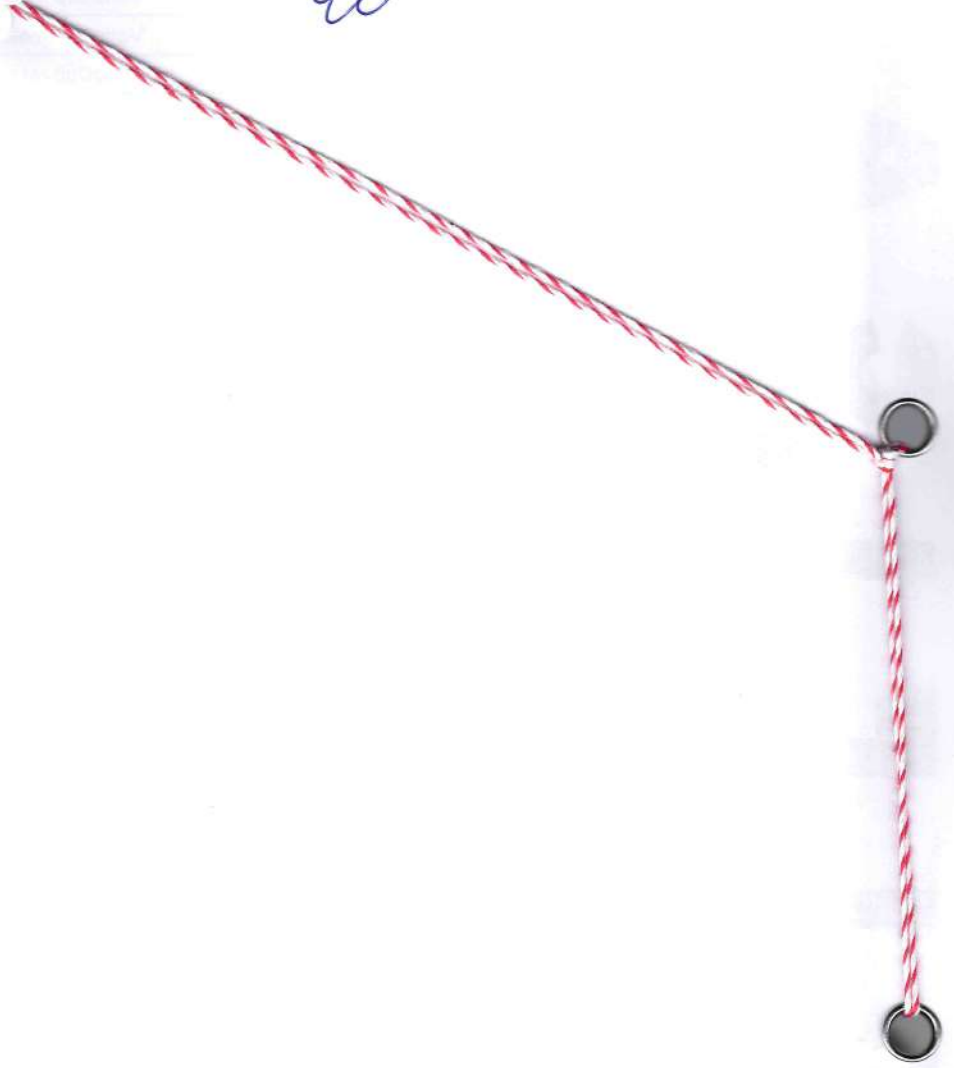
	Description	Size
Hip-Joint Replacement Implants VarioCup Plus Acetabular System c. Peripheral Screw	Peripheral Screw	5.0mm, 25mm
	Peripheral Screw	5.0mm, 30mm
	Peripheral Screw	5.0mm, 35mm
	Peripheral Screw	5.0mm, 40mm
	Peripheral Screw	5.0mm, 45mm
	Peripheral Screw	5.0mm, 50mm
	Peripheral Screw	5.0mm, 55mm
	Peripheral Screw	5.0mm, 60mm
	Peripheral Screw	5.0mm, 65mm



I herewith notarize the literal accordance of
the above copy with the original at hand.

Berlin, 05. APR. 2022

Notary



EC DESIGN EXAMINATION CERTIFICATE

According to Annex II, Section 4 of the Directive 93/42/EEC on Medical Devices

Certificate Number**CE-MDD-0058/09/2019/01/DD.06**

Manufacturer : aap Joints GmbH
Address : Wilhelm-von-Siemens-Strasse 23, Aufgang F, 12277 Berlin
Product(s) : VarioLoc Cemented Hip Prosthesis
Model(s) : Please see 2nd page for details of product
Report Number : CE/ISO-MED-0065-05-DD
First Issue Date and Place : 2020.03.04 & Istanbul
Revision Number and Date : 00 / --
Validity Date : 2024.05.26

Issued by NOTICE, Notified Body 2764, this document approves that the design documentation of the mentioned product complies with Annex II, Section 4 of the 93/42/EEC Medical Devices Directive. The manufacturer is subject to EC surveillance in accordance with Annex II, Section 5 of 93/42/EEC Medical Devices Directive and unannounced audits.

Özlem Vicdan Akdağ
Chairman



**NOTİCE BELGELENDİRME
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Product Name	Components	Models	Sizes
Hip-Joint Replacement Implants VarioLoc Cemented Hip Prosthesis	VarioLoc cemented stem	VarioLoc stem, cemented, STD	7.5 mm
			9.0 mm
			10.0 mm
			11.0 mm
	VarioLoc cemented stem	VarioLoc stem, cemented, LAT	12.5 mm
			13.5 mm
			15.0 mm
			7.5 mm
	VarioCup cemented cup	VarioCup, Cemented Highly Crosslinked UHMWPE, Neutral	9.0 mm
			10.0 mm
			11.0 mm
			12.5 mm
			13.5 mm
			15.0 mm
			28 mm ID 47 mm
			28 mm ID 49 mm
			28 mm ID 51 mm
			28 mm ID 53 mm
			28 mm ID 55 mm
			28 mm ID 57 mm
			28 mm ID 59 mm
			32 mm ID 51 mm
			32 mm ID 53 mm
			32 mm ID 55 mm
			32 mm ID 57 mm
			32 mm ID 59 mm
		VarioCup, Cemented Highly Crosslinked UHMWPE, Hooded	28 mm ID 47 mm
			28 mm ID 49 mm
			28 mm ID 51 mm
			28 mm ID 53 mm
			28 mm ID 55 mm
			28 mm ID 57 mm
			28 mm ID 59 mm
			32 mm ID 51 mm
			32 mm ID 53 mm
			32 mm ID 55 mm
			32 mm ID 57 mm
			32 mm ID 59 mm



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the above copy with the original at hand.

Berlin,

05. APR. 2021

Notary



Jan	0.00
Feb	0.00
Mär	0.00
Apr	0.00
Mai	0.00
Juni	0.00
Juli	0.00
Aug	0.00
Sept	0.00
Oktober	0.00
Nov	0.00
Dz	0.00
Jahr	0.00

EC DESIGN EXAMINATION CERTIFICATE

According to Annex II, Section 4 of the Directive 93/42/EEC on Medical Devices

Certificate Number

CE-MDD-0058/09/2019/01/DD.02

Manufacturer : aap Joints GmbH
Address : Wilhelm-von-Siemens-Strasse 23, Ausgang F, 12277 Berlin
Product(s) : Hip-Joint Replacement Implants
- VarioLoc Hip System
Model(s) : Please see 2nd – 3rd pages for details of products
Report Number : CE/ISO-MED-0065-01-DD - Rev.01
First Issue Date and Place : 2020.03.04 & Istanbul
Revision Number and Date : 01 / 2021.04.20
Validity Date : 2024.05.26

Issued by NOTICE, Notified Body 2764, this document approves that the design documentation of the mentioned product complies with Annex II, Section 4 of the 93/42/EEC Medical Devices Directive. The manufacturer is subject to EC surveillance in accordance with Annex II, Section 5 of 93/42/EEC Medical Devices Directive and unannounced audits.

Özlem Vicdan Akdağ
Chairman



**NOTİCE BELGELENDİRME
MUAYENE VE DENETİM
HİZMETLERİ A.Ş.**

Esentepe Mahallesi Milangaz Caddesi
No:75/A/92 Kartal / İstanbul / TÜRKİYE
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Product Name	Components	Related Model list	Size
Hip-Joint Replacement Implants 1. VarioLoc Hip System	1.1 VarioLoc Hip Stem	VarioLoc Stem, TPS Coating STD	5 mm
			6 mm
	1.1 VarioLoc Hip Stem	VarioLoc Stem, TPS Coating LAT	7.5 mm
			9.0 mm
Hip-Joint Replacement Implants 1. VarioLoc Hip System	1.1 VarioLoc Hip Stem	VarioLoc Stem, TPS Coating LAT	10.0 mm
			11.0 mm
	1.1 VarioLoc Hip Stem	VarioLoc Stem, TPS Coating LAT	12.5 mm
			13.5 mm
Hip-Joint Replacement Implants 1. VarioLoc Hip System	1.1 VarioLoc Hip Stem	VarioLoc Stem, TPS Coating LAT	15.0 mm
			16.0 mm
	1.1 VarioLoc Hip Stem	VarioLoc Stem, TPS Coating LAT	17.5 mm
			20.0 mm
Hip-Joint Replacement Implants 1. VarioLoc Hip System	1.2 Femoral Head	Femoral Head, CoCrMo	22/-3.0 mm
			22/+0.0 mm
	1.2 Femoral Head	Femoral Head, CoCrMo	28/-3.5 mm
			28/+0.0 mm
Hip-Joint Replacement Implants 1. VarioLoc Hip System	1.2 Femoral Head	Femoral Head, CoCrMo	28/+3.5 mm
			28/+7.0 mm
	1.2 Femoral Head	Femoral Head, CoCrMo	28/+10.5 mm
			32/-4.0 mm
Hip-Joint Replacement Implants 1. VarioLoc Hip System	1.2 Femoral Head	Femoral Head, CoCrMo	32/+0.0 mm
			32/+4.0 mm
	1.2 Femoral Head	Femoral Head, CoCrMo	32/+7.0 mm
			32/+10.5 mm
Hip-Joint Replacement Implants 1. VarioLoc Hip System	1.3 Acetabular Cup	VarioCup, TPS Coating No-hole	36/-4.0 mm
			36/+0.0 mm
	1.3 Acetabular Cup	VarioCup, TPS Coating No-hole	36/+4.0 mm
			36/+8.0 mm
Hip-Joint Replacement Implants 1. VarioLoc Hip System	1.3 Acetabular Cup	VarioCup, TPS Coating No-hole	36/+10.5 mm
			42 mm BB
	1.3 Acetabular Cup	VarioCup, TPS Coating No-hole	44 mm MM
			46 mm NN
Hip-Joint Replacement Implants 1. VarioLoc Hip System	1.3 Acetabular Cup	VarioCup, TPS Coating No-hole	48 mm OO
			50 mm PP
	1.3 Acetabular Cup	VarioCup, TPS Coating No-hole	52 mm PP
			54 mm QQ
Hip-Joint Replacement Implants 1. VarioLoc Hip System	1.3 Acetabular Cup	VarioCup, TPS Coating No-hole	56 mm QQ
			58 mm RR
	1.3 Acetabular Cup	VarioCup, TPS Coating No-hole	60 mm RR
			62 mm SS
Hip-Joint Replacement Implants 1. VarioLoc Hip System	1.3 Acetabular Cup	VarioCup, TPS Coating No-hole	64 mm SS
			66 mm TT
	1.3 Acetabular Cup	VarioCup, TPS Coating No-hole	68 mm TT





Product Name	Components	Related Model list	Size
Hip-Joint Replacement Implants 1. VarioLoc Hip System	1.3 Acetabular Cup	VarioCup, TPS Coating Three-hole	42 mm BB 44 mm MM 46 mm NN 48 mm OO 50 mm PP 52 mm PP 54 mm QQ 56 mm QQ 58 mm RR 60 mm RR 62 mm SS 64 mm SS 66 mm TT 68 mm TT
	1.4 Acetabular Insert	VarioCup Insert, Highly cross-linked UHMWPE- Neutral	22 mm ID BB 22 mm ID MM 28 mm ID BB 28 mm ID MM 28 mm ID NN 28 mm ID OO 28 mm ID PP 28 mm ID QQ 28 mm ID RR 28 mm ID SS 32 mm ID OO 32 mm ID PP 32 mm ID QQ 32 mm ID RR 32 mm ID SS 36 mm ID QQ 36 mm ID RR 36 mm ID SS 36 mm ID TT
		VarioCup Insert, Highly cross-linked UHMWPE- 15° hooded	22 mm ID BB 22 mm ID MM 28 mm ID BB 28 mm ID MM 28 mm ID NN 28 mm ID OO 28 mm ID PP 28 mm ID QQ 28 mm ID RR 28 mm ID SS 32 mm ID OO 32 mm ID PP 32 mm ID QQ 32 mm ID RR 32 mm ID SS 36 mm ID QQ 36 mm ID RR 36 mm ID SS 36 mm ID TT



Berlin, ~~05. APR. 2022~~

Berlin, ~~05. APR. 2022~~

Notary

Certified Copy



EC DESIGN EXAMINATION CERTIFICATE

According to Annex II, Section 4 of the Directive 93/42/EEC on Medical Devices

Certificate Number

CE-MDD-0058/09/2019/01/DD.05

Manufacturer : aap Joints GmbH
Address : Wilhelm-von-Siemens-Strasse 23, Ausgang F, 12277 Berlin
Product(s) : VarioLoc Hip Prosthesis
Model(s) : Please see 2nd page for details of product
Report Number : CE/ISO-MED-0065-04-DD
First Issue Date and Place : 2020.03.04 & Istanbul
Revision Number and Date : 00 / --
Validity Date : 2024.05.26

Issued by NOTICE, Notified Body 2764, this document approves that the design documentation of the mentioned product complies with Annex II, Section 4 of the 93/42/EEC Medical Devices Directive. The manufacturer is subject to EC surveillance in accordance with Annex II, Section 5 of 93/42/EEC Medical Devices Directive and unannounced audits.

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CERTIFICATE



Product Name	Components	Model	Size
Hip-Joint Replacement Implants VarioLoc Hip Prosthesis	VarioLoc HA Hip Stem	VarioLoc Stem, HA Coating, STD	7.5 mm
			9.0 mm
			10.0 mm
			11.0 mm
			12.5 mm
			13.5 mm
			15.0 mm
			16.0 mm
			17.5 mm
			20.0 mm
		VarioLoc Stem, HA Coating, LAT	7.5 mm
			9.0 mm
			10.0 mm
			11.0 mm
			12.5 mm
			13.5 mm
			15.0 mm
			16.0 mm
			17.5 mm
			20.0 mm
	VE Acetabular insert	VE Acetabular insert, VE Highly cross- linked UHMWPE, Neutral	22 mm ID BB
			22 mm ID MM
			28 mm ID BB
			28 mm ID MM
			28 mm ID NN
			28 mm ID OO
			28 mm ID PP
			28 mm ID QQ
			28 mm ID RR
			28 mm ID SS
			32 mm ID OO
			32 mm ID PP
			32 mm ID QQ
			32 mm ID RR
			32 mm ID SS
			36 mm ID QQ
			36 mm ID RR
			36 mm ID SS
		VE Acetabular insert, VE Highly cross- linked UHMWPE, 15° hooded	36 mm ID TT
			22 mm ID BB
			22 mm ID MM
			28 mm ID BB
			28 mm ID MM
			28 mm ID NN
			28 mm ID OO
			28 mm ID PP
			28 mm ID QQ
			28 mm ID RR
			28 mm ID SS
			32 mm ID OO
			32 mm ID PP
			32 mm ID QQ
			32 mm ID RR
			32 mm ID SS
			36 mm ID QQ
			36 mm ID RR
			36 mm ID SS
			36 mm ID TT



I herewith notarize the literal accordance of
the above copy with the original at hand.

05. APR. 2022

Berlin,

Notary



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