

Document number PI 010100XX	Rev. A	Date 12/11/2024	
BIOCORE9 ACETABULAR CUP SYSTEM PACKAGE INSERT			
Originator Stan Matlak	Page Page 1 of 2		

GENERAL INFORMATION

The Biocore9 Acetabular Cup System provides the surgeon with maximum options for Acetabular cup reconstruction. The components include acetabular shells and liners and bone screws. Components are intended to replace the articular surface of the acetabular socket in the patient's hip joint. It is intended for the reconstruction of painful and or severely disabled hip joints resulting from osteoarthritis or rheumatoid arthritis for patients who would be candidates for total hip procedure, whose acetabular socket has not been excessively damaged by disease or trauma and where damage is primarily associated with the articular surface damage

BIOCORE9 ACETABULAR SHELL COMPONENT

The Biocore9 acetabular shell components are manufactured from Ti-6Al-4V alloy (ASTM F136) with a single radius spherical outer geometry coated with three layers of Commercially Pure (CP)-Ti (ASTM F67) spherical bead porous coating allowing for cemented or cementless fixation and an anatomical shaped rim to limit impingement with the femoral side of the joint or the psoas muscle. A crescent peripheral groove provides for assembly interlock and three rim tabs provide anti rotational interlock with the bearing liner. The acetabular shells are available in two configurations: one with No screw holes and a second with five screw holes for supplemental bone screw fixation. All surfaces are coated with Titanium Nitride (TiN) thin film ceramic coating. Porous structured acetabular shells are intended for cementless or cemented fixation.

Acetabular components are available in nine sizes with available outside diameters from 50 mm to 66 mm in 2 mm increments.

BEARING

The acetabular cup bearing liner components are manufactured from highly cross linked UHMWPe (ASTM F648) which locks into the acetabular cup shell with ten flexible lip tabs and has three rotation resisting tabs. The components are available in fourteen sizes with corresponding to the inner diameter range of 39 mm to 52 mm in 1 mm increments.

BONE SCREW

Biocore9Cancellous Bone screws are manufactured from Ti-6Al-4V alloy with low profile screw heads designed to fit the Acetabular shells with nominal diameter of 6.5 mm. Screw components are available in 6.5 mm diameter in five sizes from 15 mm to 50 mm lengths.

INDICATIONS

1. Painful hip arthritis refractory to medical management resulting from post-traumatic arthritis, osteoarthritis, or rheumatoid arthritis.
2. Painful femoral head. cup arthroplasty, or bi-polar or universal type femoral head replacement.
3. Cases where more conventional arthroplasty techniques or arthrodesis are contraindicated because of a difficult clinical management problem, age, sex, occupation, or height of the patient

The Biocore9 Acetabular Cup System components are intended for use in total hip arthroplasty in primary or revision surgery of skeletally mature patients. Biocore9 Acetabular Cup System Shells and Liners are single use implants intended for cemented or cementless arthroplasty.

CONTRAINDICATIONS

1. Any active or suspected latent infection in or about the hip joint.

2. Mental or neuromuscular disorders which would create an unacceptable risk of prostheses instability, prostheses fixation failure, or complications in postoperative care. Other contraindications for use as a total hip replacement include pathological conditions of the acetabulum which would prevent achieving proper range of motion, and/or a well-seated and supported articulation of the femoral head within the acetabulum.
3. Inadequate, viable bone stock to adequately support a component fixation.

STERILIZATION

The **Biocore9** Acetabular Cup System components are provided sterilized by exposure to Ethylene Oxide. If package is damaged, contents should not be used and Biocore9 should be contacted. The associated instrumentation is provided non-sterile. The sterilization parameters for the associated instrumentation are listed in the table below. Further details are available upon request.

Method	Moist heat sterilization
Cycle	Pre-Vacuum (Pre-Vac)
Temperature	270°F (132°C)
Exposure Time	4 minutes
Pressure	2-15 PSIA
Drying Time ²	30 minutes (minimum, in chamber)
Cool Time	60 minutes (minimum, at room temperature)

PRECAUTIONS

Before clinical use, the surgeon should be familiar with all aspects of the surgical procedure. Surgical procedure is available on www.biocore9.com. Patients should be instructed in the limitations of the prosthesis and should be taught to govern their activities accordingly. Sizing between components should only be performed as indicated in the surgical procedure.

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WARNINGS

Where there is loss of, or insufficient bone stock, bone grafting or other adjunctive reinforcement procedures are at the discretion of the surgeon at the time of surgery. A stemmed implant and alternate acetabular shell should be made available at the time of surgery in case the surgeon decides that existing components or there is insufficient bone stock to support a Biocore9 Implant Components. Improper selection, placement, positioning, and fixation of the implant components may result in unusual stress conditions and subsequent reduction in the service of the prosthetic implants. Accepted practices should be followed meticulously in postoperative care and the patient should be made aware of the limitations of total joint reconstruction. If the acetabular liner erodes in the future, it may be exchanged. Existing components may impede adequate visualization and/or access to the acetabulum for revision. In this case it may be necessary to completely remove the existing components in future revisions.

The Biocore9 Acetabular Cup System Components have not been evaluated for safety and compatibility in the MR environment. They have not been tested for heating, migration, or image artifact in the MR environment. The safety of Biocore9 Components in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

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**BIOCORE9 ACETABULAR CUP
SYSTEM COMPONENTS FOR
SINGLE-USE ONLY**

Rx ONLY

Symbol	Symbol Title	Standard References
	Date of Manufacture	ISO 15223-1 Reference #5.1.3 FDA Recognition #5-117 ISO 7000 Reference #2497 FDA Recognition #5-103
	Batch Number	ISO 15223-1 Reference #5.1.5 FDA Recognition #5-117 ISO 7000 Reference #2492 FDA Recognition #5-103
	Sterilized using ethylene oxide	ISO 15223-1 Reference #5.2.3 FDA Recognition #5-117 ISO 7000 Reference #2501 FDA Recognition #5-103
	Sterilized using irradiation	ISO 15223-1 Reference #5.2.4 FDA Recognition #5-117 ISO 7000 Reference #2502 FDA Recognition #5-103
	Manufacturer	ISO 15223-1 Reference #5.1.1 FDA Recognition #5-117 ISO 7000 Reference #3082 FDA Recognition #5-103
	Consult instructions for use	ISO 15223-1 Reference #5.4.3 FDA Recognition #5-117 ISO 7000 Reference #1641 FDA Recognition #5-103
	Do not re-use	ISO 15223-1 Reference #5.4.2 FDA Recognition #5-117 ISO 7000 Reference #1051 FDA Recognition #5-103
	Caution	ISO 15223-1 Reference #5.4.4 FDA Recognition #5-117 ISO 7000 Reference #0434A FDA Recognition #5-103
	Keep Away from Sunlight	ISO 15223-1 Reference #5.3.2 FDA Recognition #5-117 ISO 7000 Reference #0624 FDA Recognition #5-103
	Temperature Limit	ISO 15223-1 Reference #5.3.7 FDA Recognition #5-117 ISO 7000 Reference #0632 FDA Recognition #5-103
	Keep Dry	ISO 15223-1 Reference #5.3.4 FDA Recognition #5-117 ISO 7000 Reference #0626 FDA Recognition #5-103
	Use-by date	ISO 15223-1 Reference #5.1.4 FDA Recognition #5-117 ISO 7000 Reference #2607 FDA Recognition #5-103

SYMBOLS GLOSSARY

COMPONENT COMPATIBILITY

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The Biocore9 Acetabular Cup System is intended to be used with the BioPro PSL Hip System femoral heads. The table list the catalogue numbers of the compatible Biocore9 acetabular cup components with the corresponding catalogue numbers of the BioPro Femoral Heads.

Cup OD (mm)	Bearing ID (mm)	BC9 Catalogue Number	BioPro PSL Hip system Femoral Heads Catalogue Number					
			Size (mm)	BIPOLAR*	UNIPOLAR ENDO MD**	UNIPOLAR ENDO SH**	ENDO MODULAR CERAMIC SH***	ENDO MODULAR CERAMIC MD***
50	39	01-12-3950	39	18131				
52	40	01-12-4052	40	18132				
	41	01-12-4152	41	18133	10180	10189	13007	13014
54	42	01-12-4254	42	18134				
56	43	01-12-4356	43	18135	10181	10190	13008	13015
	44	01-12-4456	44	18136				
58	45	01-12-4558	45	18137	10182	10191	13009	13016
60	46	01-12-4660	46	18138				
	47	01-12-4760	47	18139	10183	10192	13010	13017
62	48	01-12-4862	48	18140				
	49	01-12-4962	49	18141	10184	10193	13011	13018
64	50	01-12-5064	50	18142				
	51	01-12-5164	51	18143	10185	10194	13012	13019
66	52	01-12-5266	52	18144				

*Materials –UHMWPE liner, CoCr outer shell, UHMWPE retention ring, Ti-6Al-4v spring

**Material - CoCr

***Material - Ceramic