


Document number PI 010300XX	Rev. C	Date 12/11/2024	
Document Title FEMORAL RESURFACING PACKAGE INSERT			
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DESCRIPTION:

The Biocore9 Femoral Resurfacing Head Component is manufactured from Ti-6Al-4V alloy with a Titanium Nitride (TiN) thin film ceramic coating. The titanium nitride coating is an inert, highly adherent, near diamond hard surface coating. The component consists of a thin walled spherical shell with an integrally attached, tapered stem. The Femoral Resurfacing Head Component is available in outside diameters from 39.5 mm to 52.5 mm.

The Femoral Resurfacing Head Component is axisymmetric with a truncated spherical shell and a tapered central stem. Also, it is coated with TiN ceramic coating that is highly polished to a Ra of less than 50 nanometer surface finish. The internal surface of the spherical shell and the tapered stem are also coated with TiN.

The internal surface of the spherical shell is covered with a porous coating consisting of pure titanium beads. The stem is not porous coated.

INDICATIONS:

The Biocore9 Femoral Resurfacing Head Component, used with cement, is indicated for the treatment of painful hip arthritis due to post-traumatic arthritis, osteoarthritis, or rheumatoid arthritis, as well as painful hip arthroplasty when sufficient femoral head and neck stock exist to stabilize a resurfacing femoral head. The Biocore9 Femoral Resurfacing Head Component is intended for cemented use only. This device is intended for hemi-arthroplasty only.

CONTRAINDICATIONS:

The device is contraindicated for: Active or suspected infection of the hip, Inadequate femoral bone stock to support the femoral component, Loss of musculature or vascular deficiencies in the affected leg sufficient to inhibit success of the procedure, Charcot's Disease, Other contraindications include pathological conditions of the acetabulum which would prevent achieving proper range of motion, appropriate resurfacing head stability, and or a well seated and supported, smooth articulation of the head within the acetabulum. Patients with bone stock inadequate to support the device including:

- Patients with severe osteopenia should not receive a BC9 Femoral Resurfacing Component procedure.

- Patients with a family history of severe osteoporosis or severe osteopenia.
- Patients with osteonecrosis or avascular necrosis (AVN) with >50% involvement of the femoral head (regardless of FICAT Grade) should not receive a BC9 Femoral Resurfacing Component.
- Patients with multiple cysts of the femoral head (>1 cm) should not receive a BC9 Femoral Resurfacing Component.

Note: In cases of questionable bone stock, a dual-energy x-ray absorptiometry (DEXA) scan may be necessary to assess inadequate bone stock

STERILIZATION:

All titanium implant components are provided pre-sterilized by exposure to gamma irradiation.

PRECAUTIONS

Before clinical use, the surgeon should be familiar with all aspects of the surgical procedure. 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.

POROUS COATED COMPONENTS ARE INTENDED FOR CEMENTED USE ONLY.

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 should be made available at the time of surgery in case the surgeon decides that there is insufficient bone stock to support a resurfacing component. 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. 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 patient's acetabulum erodes in the future, the resurfacing component may impede adequate visualization and/or access to the acetabulum for revision. In this case it may be necessary to remove the resurfacing component in future revisions. The Biocore9

Femoral Resurfacing Component is not approved for use with an acetabular component.

MRI SAFETY INFORMATION

The Biocore9 Femoral Resurfacing Component has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of Femoral Resurfacing Component in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

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Rx ONLY**

SYMBOL	SYMBOL TITLE	STANDARD REFERENCES
	Date of Manufacturer	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 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