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Document Title HUMERAL RESURFACING PACKAGE INSERT			
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GENERAL INFORMATION:

The Biocore9 Humeral Resurfacing System, in providing the surgeon with maximum options for Shoulder resurfacing reconstruction, consists of the following components; A Humeral resurfacing component for a conservative approach on patients with adequate humeral head bone and ligamentous stability, available in a range of sizes for optimum fixation and fit.

DESCRIPTION:

The Biocore9 Humeral Resurfacing Head Component is manufactured from Ti-6Al-4V alloy with a Titanium Nitride (TiN) thin film ceramic coating (C-TiN-C). The component consists of a thin walled spherical shell with an integrally attached, tapered stem. The Humeral resurfacing Component is available in outside diameters from 40 mm to 56 mm in 4 mm increments. The Humeral Resurfacing component is axisymmetric with a truncated spherical shell and a tapered central stem. The exterior of the spherical surface is intended to articulate with the Glenoid, 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 Humeral resurfacing Component rim is anatomical with a rounded relief. The stem is not porous coated.

INDICATIONS:

The Biocore9 Humeral Head Resurfacing Shoulder Component is intended for the reconstruction of painful and/or severely disabled shoulder joints resulting from osteoarthritis and rheumatoid arthritis. For proper function of this device, the humeral head and neck must be of sufficient bone stock to support the loads on it. Also, the presence of an intact or reconstructable rotator cuff is important for proper functioning and dislocation resistance. Porous-coated components are intended for cemented use only. This device is indicated for hemiarthroplasty/replacement of the humeral head only.

CONTRAINDICATIONS:

The device is contraindicated for use with forms of post-traumatic arthritis, rotator cuff dysfunction, humeral head avascular necrosis, failed previous prosthesis, congenital dysplasia, or where there is loss

of, or insufficient head and neck bone stock to support the loads on the device.

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 procedures.

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 life 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.

The Biocore9 Humeral 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 Biocore9 Humeral Resurfacing Component in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

If the patient's anatomical glenoid erodes in the future, the resurfacing component may impede adequate visualization and/or access to the anatomical glenoid. This device is not cleared for use with a glenoid component and it may be necessary to remove the resurfacing component in future revisions.

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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