

restor3d

PATELLA IMPLANT

For use with restor3d[®] Total Knee Replacement Systems

Instructions for Use FOR CEMENTED USE ONLY

CAUTION: USA FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

THE restor3d[®] TOTAL KNEE REPLACEMENT SYSTEMS ARE INTENDED FOR USE ONLY BY MEDICALLY TRAINED PHYSICIANS.

IF THERE ARE ANY QUESTIONS CONTACT restor3d[®] AT +1.781.345.9001 OR YOUR LOCAL SALES REPRESENTATIVE OR DISTRIBUTOR.



Important Information: Please read before use.



Refer to <https://www.restor3d.com/resources/instructions-for-use/> for an electronic version of this IFU. For a printed copy or to have an electronic copy e-mailed to you call +1.781.345.9001



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restor3d[®] PATELLA IMPLANTS ARE FOR USE WITH ITOTAL[®] CR/PS, ITOTAL[®] IDENTITY[™] CR/PS, AND IDENTITY[™] IMPRINT[™] CR/PS KNEE REPLACEMENT SYSTEMS. CONSULT THE APPROPRIATE PRIMARY IMPLANT INSTRUCTIONS FOR USE DOCUMENT FOR SPECIFIC INDICATIONS FOR USE, CONTRAINDICATIONS, PRECAUTIONS, AND WARNINGS.

Device Description

The patella implant is intended to be used with restor3d® Total Knee Replacement Systems to repair or replace the natural patella. The patella implant is manufactured and offered in either ultra-high molecular weight polyethylene (iPoly®) or highly cross-linked ultra- high molecular weight Vitamin-E enriched polyethylene (iPoly® XE) and is indicated for implantation with bone cement.

The patella implant is compatible with the following Knee Replacement Systems:

iTotal® CR (Cruciate Retaining)

iTotal® Identity™ PS (Posterior Stabilized)

iTotal® PS (Posterior Stabilized)

Identity™ Imprint™ CR (Cruciate Retaining)

iTotal® Identity™ CR (Cruciate Retaining)

Identity™ Imprint™ PS (Posterior Stabilized)

This implant is intended for cemented use only.

Patella Implant Warnings and Precautions

- **The iTotal® patella implant is for single use only. Do not re-sterilize or reuse.**
- **Implants and components from different manufacturers should never be used together.**
- **The guides and trials are for use to fit the components and must never be left implanted.**
- **Do not alter or modify the implants in any way.**
- **Avoid notching, scratching or striking the device during preparation and insertion.**
- **Using bio-contamination controls can minimize the potential for deep sepsis**

How Supplied

The patella implant is supplied individually packaged and STERILE. The packaging is labeled with the description of the implant including size and material and the manufacturing lot number and this information should be checked prior to opening the components. Open the sterile barrier using standard aseptic techniques. **DO NOT USE IF THE STERILE BARRIER APPEARS TO BE COMPROMISED OR THE PACKAGE IS DAMAGED.**

Caution: Do not re-sterilize the patella implant. The patella implant is for single use only. The risk of reuse could compromise performance or sterility


















Magnetic Resonance (MR) Environment

For MR safety information on the iTotal® CR / PS Knee Replacement Systems, the iTotal® Identity™ CR / PS Knee Replacement Systems, and Identity™ Imprint™ CR / PS Knee Replacement Systems, consult the appropriate implant system Instructions For Use document.

Additional Information

If further information is desired, please contact restor3d® at +1.781.345.9001.

Labeling Symbol Definitions

	Caution: USA Federal Law restricts this device to sale by or on the order of a physician.
	Caution. Consult Accompanying Documents
	Reference Number
	Serial Number
	Do not use if package is open or damaged
	Double <i>sterile</i> barrier system
	Medical Device
	Unique Device Identifier
	Patient No.
	Lot Number
	Single Use Only. Do Not Reuse
	Expiration Date. (Use by)
	Sterilized Using Vaporized Hydrogen Peroxide
	Sterilized Using Ethylene Oxide
	MR Conditional
	Manufacturer
	Consult electronic Instructions For Use (eIFU)

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