Document No. 0400-0264	Rev.	Pg. 1 of 2	Approvals / Date
Title: INSTRUCTIONS FOR USE – IFU, DJO ADDENDUM FOR EMPOWR CR IMPLANTS			Deann Rector 26APR2017 Elisha Hough 26APR2017 Aaron Zimmel 01MAY2017 Desiree HubbyWells 26APR2017 Luke Silverman 01MAY2017 Mike Coppo 26APR2017

Revision	ECO Date	ECO	Summary of Changes
A	1MAY2017	DC-08123	INITIAL RELEASE TO REVISION “A”.

ADDENDUM TO IFU 0400-0034

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EN

SECTION 2. Product Description and Implant Materials

Component	Fixation Method	Material	Applicable ASTM Standard	Applicable ISO Standard
EMPOWR CR KNEE™ Tibial Insert - e+	Cemented	Highly Cross-Linked Vitamin E UHMWPE	ASTM F2695 ASTM F2565	

Depending on the DJO Surgical Knee System, femoral prostheses may be available in left and right. Depending on the DJO Surgical Knee System, the stemmed baseplate is available in left and right configurations.

Note: Size interchangeability between the EMPOWR 3DKNEE™ femur and EMPOWR CR KNEE™ tibial inserts is compatible with the same size component, up to two sizes smaller femur on a larger insert, or up to two sizes larger femur on a smaller insert.

SECTION 5. Contraindications

The EMPOWR 3DKNEE™ and EMPOWR CR KNEE™ are also contraindicated for patients without sufficient soft tissue integrity to provide adequate stability.

MRI Safety

DJO Surgical Knee components have 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 DJO Surgical Knee components in the MR environment in unknown. Scanning a patient who has this device may result in patient injury.