

Document No. 0400-0234	Rev. B	Pg. 1 of 2	Approvals / Date
Title: INSTRUCTIONS FOR USE – DJO ADDENDUM FOR REBEL 3DKNEE STERILE IMPLANTS			JOHN GREEN 29-MAY-2015
			JENNA VEGAHUSSEY 29-MAY-2015
			DESIREE HUBBY 01-JUN-2015
			MIKE COPPO 01-JUN-2015
			AMANDA MCNABB 01-JUN-2015

Revision	ECO Date	ECO	Summary of Changes
A	24-FEB-2015	DC-02074	RELEASE TO MANUFACTURING AT REVISION "A".
B	02-JUN-2015	DC-02770	ADDED CONTRAINDICATION FOR EMPOWR 3DKNEE AND CHANGE THE BRAND NAME FOR THE TIBIA BASEPLATE FROM EMPOWR 3DKNEE TO DJO EMPOWR KNEE.

ADDENDUM TO IFU 0400-0034

0400-0234 Rev. B 2015-06

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SECTION 2. Product Description and Implant Materials

Component	Fixation Method	Material	Applicable ASTM Standard	Applicable ISO Standard
EMPOWR 3DKNEE™ Femur	Cemented	CoCrMo	ASTM F75	ISO 5832-4
DJO EMPOWR KNEE™ Tibia	Cemented	CoCrMo	ASTM F75	ISO 5832-4
EMPOWR 3DKNEE™ Tibial Insert - e+	Cemented	Highly Cross-Linked Vitamin E UHMWPE	ASTM F2695 ASTM F2565	

Contraindications

- The EMPOWR 3DKNEE™ is also contraindicated for patients without sufficient soft tissue integrity to provide adequate stability.

Depending on the DJO Surgical Knee System, femoral prostheses may be available in left and right configurations. Femoral augmentation blocks are available in corresponding distal and posterior sizes and femoral extension stems and tibial extension stems are available in various lengths and diameters. Depending on the DJO Surgical Knee System, the stemmed baseplate is available in left and right configurations. Tibial augmentation blocks are available in corresponding medial and lateral sizes of tibial baseplates.

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