Document No. 0400-0247	Rev. B	Pg. 1 of 2	Approvals / Date	
Title: INSTRUCTIONS FOR USE – DJO ADDENDUM FOR EMPOWR PS KNEE STERILE IMPLANTS			John Greeen	05MAY2016
			Brian Kinson	04MAY2016
			Greg Klein	04MAY2016
			Jennifer VegaHussy	05MAY2016
			Desiree Wells	05MAY2016

Revision	ECO Date	ECO	Summary of Changes
A	23-FEB-2016	DC-04762	RELEASE TO MANUFACTURING AT REVISION “A”.
B	052016	DC-05324	UPDATE TO ADD SECTION ON MRI SAFETY.

ADDENDUM TO IFU 0400-0034

0400-0247 Rev. B 2016-05

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SECTION 2. Product Description and Implant Materials

Component	Fixation Method	Material	Applicable ASTM Standard	Applicable ISO Standard
EMPOWR™ PS KNEE™ Femur	Cemented	CoCrMo	ASTM F75	ISO 5832-4
EMPOWR™ PS 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 PS KNEE™ femur and EMPOWR PS KNEE™ tibial inserts is compatible with the same size component, one size smaller femur on a larger insert, or one size larger femur on a smaller insert.

1. MRI Safety

DJO Surgical Knee components have not been reviewed for safety and compatibility in the MR environment. The devices have not been tested for heating or migration in the MR environment. The risks associated with a passive implant in the MR environment have been evaluated and are known to include heating, migration, and image artifacts at or near the implant site.