

**Title: INSTRUCTIONS FOR USE – DJO SURGICAL™
MODULAR REVISION HIP SYSTEM AND ACETABULAR
CAGE**

DC-13467

Revision	ECO Date	ECO	Summary of Changes
A	07/02/10	13419	RELEASE TO REVISION "A".
B	8/12/10	13822	CHANGE THE TITLE, ADD INFORMATION ABOUT THE REVISION NECK AND ACETABULAR CAGE TO SECTION 1. (PRODUCT HANDLING), SECTION 2. (PRODUCT DESCRIPTION AND IMPLANT MATERIALS) SECTION 3. (INDICATIONS), SECTION 4. (INTENDED USE), SECTION 6. (PRECAUTIONS AND WARNINGS) AND SECTION 9. (STERILIZATION).
C	05-MAR-2019	DC-13467	UPDATE THE DJO SURGICAL LOGO, UPDATE SECTION 6. TO ADD MAGNETIC RESONANCE ENVIRONMENT STATEMENT, UPDATE SECTION 9. STERILIZATION TO MAKE THE VERIBIAGE CONSISTENT WITH OTHER IFU'S.



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Austin, TX 78758

0400-0205 Rev. C 2019-03

1. Product Handling

Implants are provided sterile and should always be stored unopened in their respective protective containers. Prior to use, inspect package for damage which may compromise sterility. If packaging has been opened or damaged upon receipt, please contact the manufacturer's representative. Also inspect the labeling to verify that the expiration date has not passed. If the product is expired, contact Customer Service and do not use the implant. When unpacking the implant, verify the labeling for correct Ref. No. and size. When removing the implant from its packaging, the relevant aseptic instructions must be observed. Protect prosthesis from contact with objects which may damage the surface finish. Inspect each implant prior to use for visual damage. This implant should be used only in combination with other original DJO Surgical™ products.

2. Product Description and Implant Materials

Device	Fixation Method	Material	Applicable Standard
Modular Revision Hip Stem	Cementless	Ti6Al4V Titanium alloy	ASTM F1472, ISO 5832/3
Modular Revision Neck	Cementless	Ti6Al4V Titanium alloy	ASTM F1472, ISO 5832/3
Acetabular Cage	Screw	CP Ti6Al4V	ASTM F67

DJO Surgical™ Modular Revision Hip System can be used with either DJO Surgical™ CoCr or Ceramic femoral heads.

DJO Surgical™ Acetabular Cages can be used with any DJO Surgical™ UHMWPE acetabular liner

3. Indications

The Modular Revision Hip System is indicated for patients whose bone stock is of poor quality or inadequate for other reconstruction techniques as indicated by deficiencies of the femoral head, neck or portions of the proximal femur. It is intended for cementless revision hip arthroplasty on both un-cemented and cemented femoral implants.

The Acetabular Cage is indicated for use of the Acetabular Plates in reconstruction of the hip joint due to disease, deformity or trauma. The devices are indicated for use in skeletally mature individuals undergoing primary and/or secondary revision surgery.

4. Intended Use

For treatment of patients who are candidates for total hip arthroplasty per the indications for use. While hip replacements are not intended to withstand activity levels and loads of normal healthy bone, they are a means of restoring mobility and reducing pain for many patients.

5. Contraindications

Joint replacement is contraindicated where there is:

- infection or sepsis;
- insufficient bone quality which may affect the stability of the implant;
- muscular, neurological or vascular deficiencies, which compromise the affected extremity;
- skeletally immature patients and cases where there is a loss of abductor musculature, poor bone stock, poor skin coverage around hip joint which would make the procedure unjustifiable;
- osteomyelitis;
- rapid joint destruction or bone absorption apparent on roentgenogram;
- pathological conditions of the acetabulum, which would prevent achieving proper range of motion, appropriate head stability, and/or a well-seated and supported smooth articulation of the head within the acetabulum;
- alcoholism or other addictions;
- materials sensitivity;
- loss of ligamentous structures;
- high levels of physical activity (e.g. competitive sports, heavy physical labor);
- pregnancy (contraindicated for Metal on Metal applications only)

6. Precautions and Warnings

- 1) An implant should never be reused. Although the implant may appear undamaged, previous stresses could create imperfections that may lead to mechanical failure. It is advised to utilize new prostheses of current design.
- 2) Familiarity with, and attention to the surgical technique recommended for this device is imperative for best results. The correct selection as well as the correct seating/placement of the prosthetic implant is extremely important. Use of the largest stem possible is recommended. Only DJO Surgical™ Hip System implants, instruments, and trial prostheses should be used.
- 3) Care must be taken to protect mating surfaces (i.e. tapers) and polished bearing surfaces from nicks and scratches which could become the focal point for failure. Contouring or bending of the implant may reduce its service life and may cause immediate or eventual failure under load. An implant must not be tampered with, as tampering will adversely affect the performance of the implant.
- 4) Do not implant HA (Hydroxyapatite) coated implants with bone cement.
- 5) To determine the use of the hip stem with the correct femoral head (CoCr or Ceramic), please refer to Section 2.
- 6) The Modular Revision Stem has not been evaluated for safety and compatibility in the Magnetic resonance environment. The Modular Revision Stem has not been tested for heating or migration in the Magnetic resonance environment.

DJO Surgical™ (Hip, Knee, and Shoulder) systems have not been evaluated for safety and compatibility in the magnetic resonance environment. The (Hip, Knee, Shoulder) systems have not been tested for heating or migration in the magnetic resonance environment.

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician.

7. Preoperative Planning and Postoperative Care

Preoperative planning provides essential information regarding the appropriate prosthesis and likely combinations of components. Use instrument trial components for fit verification (where applicable) and extra implant components for backup. X-ray templates for all sizes of the DJO Surgical™ Hip system are available upon request.

Accepted surgical practices should be followed for postoperative care. The patient should be made aware of the limitation of total joint reconstruction. Excessive physical activity and trauma affecting the replaced joint have been implicated in premature failure by loosening, fracture, and/or wear of the prosthetic implants. The patient should be cautioned to govern his/her activities accordingly as the risk of implant failure increases with weight and activity levels of the patient.

8. Adverse Effects

- 1) Accelerated wear of the polyethylene articulating surfaces have been reported following total hip replacement. Such wear may be initiated by particles of cement, metal, or other debris which can cause abrasion of the articulating surfaces. Accelerated wear shortens the useful life of the prosthesis, and leads to early revision surgery to replace the worn prosthetic components.
- 2) Metallosis and osteolysis may be implicated from wear debris associated with the use of orthopedic implants.
- 3) Peripheral neuropathies have been reported following total joint surgery. Subclinical nerve damage occurs more frequently, possibly the result of surgical trauma.
- 4) Metal sensitivity reactions in patients following joint replacement have been rarely reported. Implantation of foreign material in tissues can result in histological reactions involving macrophages and fibroblasts. The clinical significance of this effect is uncertain, as similar changes may occur as a precursor to, or during the healing process. In some cases, wear debris can initiate the process of histiocytic granuloma formation and consequent osteolysis and loosening of the implant.
- 5) Dislocation and subluxation of implant components can result from improper positioning of the components. Muscle and fibrous tissue laxity can also contribute to these conditions.
- 6) Ring fracture could lead to increased risk of dislocation.
- 7) Implants can loosen or migrate due to trauma or loss of fixation.
- 8) Infection can lead to failure of the joint replacement.
- 9) While rare, fatigue fracture of the implant can occur as a result of strenuous activity, improper alignment, or duration of service.
- 10) Fracture of the femur can occur while press-fitting (seating) the femoral stem into the prepared femoral canal.
- 11) Allergic reactions.

Intraoperative and early postoperative complications can include:

- 1) acetabular perforation, or fracture;
- 2) femoral fracture can occur while seating the device;
- 3) damage to blood vessels;
- 4) temporary or permanent nerve damage resulting in pain or numbness of the affected limb;
- 5) undesirable shortening or lengthening of the limb;
- 6) traumatic arthrosis of the hip from intraoperative positioning of the extremity;
- 7) cardiovascular disorders including venous thrombosis, pulmonary embolism, or myocardial infarction;

- 8) hematoma;
 9) delayed wound healing; and,
 10) infection.

Late postoperative complications can include:

- 1) avulsion as a result of excess muscular weakening;
 2) non-union due to inadequate reattachment and/or early weight bearing;
 3) aggravated problems of other joints of the affected limb or muscle deficiencies;
 4) femoral fracture by trauma or excessive loading, particularly in the presence of poor bone stock;
 5) periparticular calcification or ossification, with or without impediment to joint mobility;
 6) inadequate range of motion due to improper selection or positioning of components, by impingement, and calcification.

9. Sterilization

Unless opened or damaged, DJO Surgical™ implants are supplied sterile in multiple pouches or barrier blister trays. Upon receipt, check all packaging for punctures or other damage. If packaging is opened or damaged, contact the manufacturer or manufacturer's representative for instructions.

Sterilization is performed by gamma radiation at the minimum dose of 25 kGy to achieve a Sterility Assurance Level (SAL) of 10⁻⁶. Implants are single-use devices. Trials and other instruments are used to determine sizing before the sterile package needs to be opened. Should the original sterile package be inadvertently opened or compromised before implantation, the device cannot be implanted. Contact manufacturer or manufacturer's representative for instructions. Do not resterilize an implant or component that has been in contact with or contaminated by blood or other substances. Do not try to clean an implant since standard procedures cannot be relied upon to remove contamination from porous coating and storage of any opened implant or component should be avoided.

Instruments are provided nonsterile and should be stored in their original packaging until cleaned and sterilized according to the recommended guidelines found in the DJO Surgical™ Instrumentation Instructions for Use.

WARNING: DO NOT resterilize the Modular Revision Hip System or Acetabular Cage distributed by DJO Surgical™ (Encore Medical, L.P.) if sterile packaging is opened or damaged upon receipt return the implant with respective packaging to DJO Surgical™ for inspection and disposition.

WARNING: Protect all porous coated and polished surfaces. Standard cleaning procedures cannot be relied upon to remove contamination from porous coating.







DJO Surgical™ has validated sterilization cycle data on file.










NOTE: DJO Surgical™ does not recommend Flash or Chemical Sterilization.

For further information regarding the use of the DJO Surgical™ Hip Systems contact your DJO Surgical™ representative or distributor.

DJO Surgical™ Hip Systems are manufactured by ENCORE MEDICAL, L.P.
 9800 Metric Blvd., Austin, TX 78758 USA (Made in the USA)

An electronic version of the IFU can be located at:
<http://www.djosurgical.com/IFU>

	<p>Single use – do not reuse Zum einmaligen Gebrauch - Nicht zur Wiederverwendung Usage unique - Ne pas réutiliser Para un solo uso, no reutilizar Monouso - Non riutilizzare Για μία χρήση – μην επαναχρησιμοποιείτε Tek kullanimlidir – tekrar kullanmayın</p>
	<p>Expiration Date Verwendbar bis Date de péremption Fecha de caducidad Data di scadenza Ημερομηνία λήξης Son Kullanma Tarihi</p>
	<p>Keep Dry Trocken aufbewahren Protéger de l'humidité Mantener seco Tenere all'asciutto Να διατηρείται στεγνό Kuru Muhafaza Edin</p>
	<p>Store in a cool place: Do not store in environments with the potential for extreme heat or direct sunlight Kühl lagern: Nicht in Umgebungen lagern, in denen starke Hitze oder direkte Sonneneinstrahlung möglich ist Conserver dans un endroit frais : Ne pas conserver dans un environnement potentiellement exposé à une chaleur extrême ou à la lumière solaire directe Almacenar en un lugar fresco: No almacenar en entornos en los que pueda haber calor extremo o exposición directa a la luz solar Conservare in un luogo fresco. Non conservare in ambienti soggetti a calore estremo o esposti alla luce solare diretta Να φυλάσσεται σε δροσερό χώρο: Να μη φυλάσσεται σε περιβάλλοντα με ενδεχόμενο παρουσίας υπερβολικής θερμότητας ή άμεσου ηλιακού φωτός Serin bir yerde saklayın: Aşırı sıcaklık veya doğrudan güneş ışığı alma olasılığı bulunan ortamlarda saklamayın</p>
	<p>Lot number/Batch Code Chargennummer/Chargenbezeichnung Numéro de lot/Code de lot Número de lote/Código de lote Numero di lotto/Codice di partita Αριθμός/κωδικός παρτίδας Lot sayısı/Parti Kodu</p>
	<p>Sterile Steril Stérile Estéril Sterile Στείρο Steril</p>

	<p>Sterility symbol: R: Sterile Using Irradiation Sterilitätssymbol: R: strahlensterilisiert Symbole de stérilité : R : Stérilisé par rayonnement Símbolo de esterilidad: R: Estéril utilizando irradiación Simbolo di sterilità: R: Sterilizzato mediante irradiazione Σύμβολο στειρότητας: R: Στείρο με χρήση ακτινοβολίας Sterilite işareti: R: Radyasyonla Sterilize Edilmiştir</p>
	<p>Sterile symbol: H₂O₂: Sterilized Using Hydrogen Peroxide Gas Plasma Sterilitätssymbol: H₂O₂: Sterilisiert mit Wasserstoffperoxid-Gasplasma Symbole de stérilité : H₂O₂ : Stérilisé par plasma gazeux de peroxyde d'oxygène Símbolo de esterilidad: H₂O₂: Esterilizado con plasma de gas de peróxido de hidrógeno Simbolo di sterilità: H₂O₂: Sterilizzato al gas plasma di perossido di idrogeno Σύμβολο αποστείρωσης: H₂O₂: Έχει αποστειρωθεί με χρήση αερίου πλάσματος υπεροξειδίου του υδρογόνου Steril sembolü: H₂O₂: Hidrojen Peroksit Gaz Plasma Kullanılarak Sterilize Edilmiştir</p>
	<p>Non-sterile Nicht steril Non stérile No estéril Non sterile Μη στείρο Steril değildir</p>
	<p>See "Instructions for Use" Siehe „Gebrauchsanleitung“ Consulter le mode d'emploi Consultar las instrucciones de uso Vedere le istruzioni per l'uso Δείτε τις «Οδηγίες χρήσης» Bkz. "Kullanma Talimatları"</p>
	<p>Manufacturer Hersteller Fabricant Fabricante Fabbicante Κατασκευαστής Üretici</p>
	<p>Quantity of items in package Anzahl Artikel pro Packung Quantité d'articles dans l'emballage Cantidad de artículos en el envase Quantità di prodotti nella confezione Αριθμός τεμαχίων στη συσκευασία Paket içindeki ürün sayısı</p>
	<p>Authorized Representative in European Community Bevollmächtigter in der EU Mandataire dans la Communauté européenne Representante autorizado en la Unión Europea Rappresentante Autorizzato nella Comunità Europea Εξουσιοδοτημένος αντιπρόσωπος στην Ευρωπαϊκή Κοινότητα Avrupa Topluluğu Yetkili Temsilcisi</p>
	<p>Catalog Number Bestellnummer Numéro de référence Número de catálogo Numero di catalogo Αριθμός καταλόγου Katalog Numarası</p>
	<p>Federal Law (USA) restricts this device to sale by or on the order of a physician. Laut US-Gesetzgebung darf dieses Produkt nur von einem Arzt oder im Auftrag eines Arztes gekauft werden. Selon la loi fédérale (États-Unis), ce dispositif ne peut être vendu que par un médecin ou sur sa prescription. Las leyes federales estadounidenses restringen la venta de este dispositivo a médicos o por prescripción facultativa. Le leggi federali degli Stati Uniti d'America vietano la vendita del presente dispositivo a personale non autorizzato e/o senza prescrizione. Η ομοσπονδιακή νομοθεσία (των Η.Π.Α.) περιορίζει την πώληση της διάταξης αυτής σε ιατρούς ή κατόπιν εντολής ιατρού. ABD yasalarına göre bu cihaz sadece bir doktor tarafından veya emriyle satılabilir.</p>

Bone Cement Usage – The following legends are displayed on the product labeling to indicate bone cement usage:

Usage	Legend
Implants intended to be used with bone cement	CEMENTED
Implants intended to be used without bone cement	CEMENTLESS
Implants intended to be used optionally	NO LEGEND