djosurgical

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EC REP
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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 that may compromise sterility. If packaging has been opened or damaged upon receipt, 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 Reference No. and size. When removing the implant from its packaging, the relevant aseptic instructions must be observed. Protect prosthesis from contact with objects that may damage the surface finish. Inspect each implant prior to use for visual damage. This implant is part of a system and should be used only in combination with other original DJO Surgical™ product belonging to the same knee system, unless otherwise specified.

2. Product Description and Implant Materials

Component	Fixation Method	Material	Applicable ASTM Standard	Applicable ISO Standard
Femur	Cemented	CoCrMo	ASTM F75, ASTM E1742, ASTM E1417	ISO 5832-4
Tibial Baseplate	Cemented	CoCrMo	ASTM F75, ASTM E1742, ASTM E1417	ISO 5832-4
Stem Extensions	Cemented	Ti6Al4V alloy	ASTM F1472	ISO 5832-3
Tibial Insert	Cemented	Medical Grade UltraHigh Molecular Weight Polyethylene Highly Cross-Linked Vitamin E UHMWPE	ASTM F648 ASTM F2695 ASTM F2565	ISO 5834-1 & 2
Patellae	Cemented	Medical Grade UltraHigh Molecular Weight Polyethylene Highly Cross-Linked Vitamin E UHMWPE	ASTM F648 ASTM F2695 ASTM F2565	ISO 5834-1 & 2
Screws	Cementless	Ti6Al4V alloy	ASTM F136 / ASTM F1472	ISO 5832-3

Note: Size interchangeability between the Femur and the Baseplate is limited to size matching or up to two sizes smaller.

3. Indications

Joint replacement is indicated for patients suffering from disability due to:

- degenerative, post-traumatic or rheumatoid arthritis;
- avascular necrosis of the femoral condyle;
- post-traumatic loss of joint configuration, particularly when there is patella femoral erosion, dysfunction or prior patellectomy;
- moderate valgus, varus or flexion deformities;
- treatment of fractures that are unmanageable using other techniques.

This device may also be indicated in the salvage of previously failed surgical attempts.

The Movation Knee System is intended for cemented applications.

4. Intended Use

The DJO Surgical™ Movation Knee System is a posterior stabilized knee for cemented applications. The system is intended to treat patients who are candidates for primary total knee arthroplasty or revision arthroplasty where bone loss is minimal, and the collateral ligaments are intact. The design of the knee system is a total condylar design, increasing sagittal conformity and stability. The Femoral Component is available in right and left configurations, and fourteen proportional sizes to accommodate differences in patient anatomy. The tibial baseplate is available with a finned or trapezoid shaped keel in 10 sizes. The post and cam of the posterior stabilized design are crucial to inducing femoral rollback and providing resistance to tibial subluxation, substituting the function of the absent PCL. The tibial post, in combination with the femoral cam, provides for greater patient flexion by forcing the femur posteriorly on the tibia. The open box of the femoral component provides the surgical option of repairing a femoral fracture with a femoral nail without removing the implant. While knee 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 a history of infection), acute or chronic, local or systemic;
- insufficient bone quality which may affect the stability of the implant;
- muscular, neurological or vascular deficiencies, which compromise the affected extremity;
- obesity;
- alcoholism or other addictions;
- materials sensitivity;
- loss of ligamentous structures;
- high levels of physical activity (e.g. competitive sports, heavy physical labor).

6. Precautions and Warnings

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.

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. Only DJO Surgical™ Knee System instruments and trial prostheses should be used.

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.

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™ Knee systems 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 activities accordingly as the risk of implant failure increases with weight and activity levels of the patient.

8. Adverse Effects

Some of the adverse effects that could occur related to total knee arthroplasty are:

- fracture of the tibia or femur;
- transient peroneal palsy secondary to surgical manipulation;
- patellar subluxation or dislocation;
- patella femoral impingement;
- instability, changes in position, or loosening of components;
- ligamentous laxity;
- dissociation of components;
- infection;
- poor range of motion;
- shortening of limbs;
- metal sensitivity reactions.

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 of implants other than e+ Tibial Inserts and e+ Patella's are 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.

Sterilization of e+ Tibial Inserts and e+ Patella's are performed by hydrogen peroxide gas plasma to achieve a Sterility Assurance Level (SAL) of 10^{-6}. These liners are single-use devices and CANNOT be resterilized by a healthcare facility. 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.

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 any knee prosthesis 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.

WARNING: DO NOT resterilize UHMWPE (ultra-high molecular weight polyethylene).

WARNING: DO NOT resterilize Highly Cross-Linked Vitamin E UHMWPE (ultra-high molecular weight polyethylene).

DJO Surgical™ has validated sterilization cycle data on file.

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

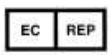
For further information regarding the use of the DJO Surgical™ Knee Systems, contact your DJO Surgical™ representative or distributor.

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

10. Trademarks and patents

U.S. patents: 5,413,604

	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 kullanımlıktır – tekrar kullanmayın
	Expiration Date Verwendbar bis Date de péremption Fecha de caducidad Data di scadenza Ημερομηνία λήξης Son Kullanma Tarihi
	Keep Dry Trocken aufbewahren Protéger de l'humidité Mantener seco Tenere all'asciutto Να διατηρείται στεγνό Kuru Muhafaza Edin
	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
	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
	Sterile Steril Stérile Estéril Sterile Στείρο Steril
	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 irrradiazione Σύμβολο στειρότητας: R: Στείρο με χρήση ακτινοβολίας Sterilite işareti: R: Radyasyonla Sterilize Edilmiştir
	Sterile symbol: H_2O_2: Sterilized Using Hydrogen Peroxide Gas Plasma Sterilitätssymbol: H_2O_2: Sterilisiert mit Wasserstoffperoxid-Gasplasma Symbole de stérilité : H_2O_2 : Stérilisé par plasma gazeux de peroxyde d'oxygène Símbolo de esterilidad: H_2O_2: Esterilizado con plasma de gas de peróxido de hidrógeno Simbolo di sterilità: H_2O_2: Sterilizzato al gas plasma di perossido di idrogeno Σύμβολο αποστείρωσης: H_2O_2: Έχει αποστειρωθεί με χρήση αερίου πλάσματος υπεροξειδίου του υδρογόνου Steril sembolü: H_2O_2: Hidrojen Peroksit Gaz Plasma Kullanılarak Sterilize Edilmiştir
	Non-sterile Nicht steril Non stérile No estéril Non sterile Μη στείρο Steril değildir
	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"
	Manufacturer Hersteller Fabricant Fabricante Fabbricante Κατασκευαστής Üretici
	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
	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
	Catalog Number Bestellnummer Numéro de référence Número de catálogo Numero di catalogo Αριθμός καταλόγου

	Katalog Numarası
℞	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.

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