Encore Medical, L.P.
9800 Metric Blvd.
Austin, TX 78758

0400-0314 Rev. F 2024-05

A printable copy of the IFU for this device can be located at: www.djosurgicalifus.com. A paper copy can be requested via phone at +1-800-520-8976.

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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 Surgical division of Enovis™ 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
EMPOWR KNEE System®				
EMPOWR 3D™ Femur[1,4] EMPOWR PS™ Femur[2,3] EMPOWR™ Revision Femur[7,8]	Cemented	CoCrMo	ASTM F75	ISO 5832-4
EMPOWR Porous® Femur[1,4]	Cementless	CoCrMo	ASTM F75	ISO 5832-4
		CoCrMo Porous Coating	ASTM F75	
EMPOWR Porous® Tibial Baseplate	Cementless	Ti6Al4V alloy	ASTM F620 / ASTM F1472	ISO 5832-3
		CP Ti Porous Coating	ASTM F67	ISO 5832-2
EMPOWR™ Tibial Baseplate	Cemented	CoCrMo	ASTM F75	ISO 5832-4
EMPOWR™ Universal Tibial Baseplate with Stem Plug	Cemented	CoCrMo	ASTM F75 ASTM F1537	ISO 5832-4
EMPOWR™ Universal Cemented Stem Extension and Stem Extender	Cemented	CoCrMo	ASTM F1537	ISO 5832-4
EMPOWR™ Universal Tibial Augment[5] - Half Block, 5mm (with 5mm screw) EMPOWR™ Revision Femur Augment[9] - Distal, 5mm (with 5mm screw) - Posterior, 5mm (with 5mm screw) EMPOWR™ Augment Screw, (5mm, 10mm, 15mm)[5]	Cemented	Ti6Al4V alloy	ASTM F136 / ASTM F1472	ISO 5832-3
EMPOWR™ Tibial Insert: - EMPOWR 3D™ Tibial Insert - e+™, [1] - EMPOWR PS™ Tibial Insert - e+™, [2] - EMPOWR CR® Tibial Insert - e+™, [4] - EMPOWR VVC® Tibial Insert - e+™, [3] - EMPOWR™ Revision VVC+, e+™ Tibial Insert [10]	Cementless	Medical grade UltraHigh Molecular Weight Polyethylene (Moderately Cross-Linked)	ASTM F648 / ASTM F2565	ISO 5834-1 / ISO 5834-2
		Vitamin E UHMWPE (a-tocopheral)	ASTM F2695	
EMPOWR™ Reinforcement Pin	Cementless	CoCrMo	ASTM F1537	ISO 5832-4
EMPOWR Revision Knee™ Symmetric Cones[11] - Tibial, Femoral, & Diaphyseal	Cementless Cemented	Ti6Al4V alloy	ASTM F1472	ISO 5832-3
		CP Ti Porous Coating	ASTM F67	ISO 5832-2

1. Size interchangeability between the EMPOWR 3D™ femur and EMPOWR Porous® Femur to EMPOWR 3D™ tibial inserts are compatible with the same size component, or one size smaller femur on a larger insert.
2. Size interchangeability between the EMPOWR PS™ femur and EMPOWR PS™ tibial inserts are compatible with the same size component, one size smaller femur on a larger insert, or one size larger femur on a smaller insert.
3. Size interchangeability between the EMPOWR PS™ femur and EMPOWR VVC® tibial inserts are compatible with the same size component, one size smaller femur on a larger insert, or one size larger femur on a smaller insert.
4. Size interchangeability between the EMPOWR 3D™ femur and EMPOWR Porous® Femur to EMPOWR CR® 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.
5. Tibial augmentation blocks for the EMPOWR KNEE SYSTEM® are available in 5mm thickness, configured to the lateral compartment for a given size. Additionally, these tibial augments can be stacked up to 15mm using the appropriate length assembly screw.
6. EMPOWR VVC® Insert, 22 & 25mm with corresponding reinforcement pin and EMPOWR™ Revision VVC+ Tibial Insert, all thicknesses with corresponding reinforcement pin to be used only with Universal Tibial Baseplate

7. Size interchangeability between the EMPOWR Revision™ femur and EMPOWR PS™ tibial inserts are compatible with the same size component, two size smaller femur on a larger insert, or two size larger femur on a smaller insert.
8. Size interchangeability between the EMPOWR Revision™ femur and EMPOWR VVC™ tibial inserts are compatible with the same size component, two size smaller femur on a larger insert, or two size larger femur on a smaller insert.
9. Femoral augment blocks for the EMPOWR KNEE SYSTEM® are available in 5mm thickness, configured to the distal or posterior bone interface for a smaller size, which can be grouped to attached for one size larger femur. Additionally, these tibial augments can be flipped and stacked to create a 10mm augment construct using the appropriate length assembly screw.
10. Size interchangeability between the EMPOWR™ Revision femur and EMPOWR™ Revision VVC+ Tibial Inserts are compatible with the same size component, two size smaller femur on a larger insert, or two size larger femur on a smaller insert.
11. Tibial Cones are compatible with the EMPOWR™ Universal Tibial Baseplate when used with EMPOWR™ Universal Cemented Stem Extension and Stem Extender. Femoral Cones are compatible with the EMPOWR™ Revision Femur when used with EMPOWR™ Universal Cemented Stem Extension and Stem Extender. Diaphyseal Cones are compatible with the EMPOWR™ Universal Tibial Baseplate and the EMPOWR™ Revision Femur when used with EMPOWR™ Universal Cemented Stem Extension and Stem Extender. Size interchangeability is indicated on the product label and surgical technique.

EMPOWR Partial KNEE™ System				
EMPOWR Partial KNEE™ Femur	Cemented	CoCrMo	ASTM F75	ISO 5832-4
EMPOWR Partial KNEE™ Tibial Baseplate	Cemented	Ti6Al4V alloy	AMS4965™	
EMPOWR Partial KNEE™ Tibial Insert e+™	Cementless	Medical grade UltraHigh Molecular Weight Polyethylene (Moderately Cross-Linked)	ASTM F648 / ASTM F2565	ISO 5834-1 / ISO 5834-2
		Vitamin E UHMWPE (a-tocopheral)	ASTM F2695	
Patella				
Patella – All Poly e+™, Domed	Cemented	Medical grade UltraHigh Molecular Weight Polyethylene (Moderately Cross-Linked)	ASTM F648 / ASTM F2565	ISO 5834-1 / ISO 5834-2
		Vitamin E UHMWPE (a-tocopheral)	ASTM F2695	
Porous Patella e+™	Cementless Cemented	Medical grade UltraHigh Molecular Weight Polyethylene (Moderately Cross-Linked)	ASTM F648 / ASTM F2565	ISO 5834-1 / ISO 5834-2
		Vitamin E UHMWPE (a-tocopheral)	ASTM F2695	
		Additive Ti6Al4V alloy	ASTM F2924	ISO 5832-3

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

3. Indications For Use

Indications for EMPOWR Knee™

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 patellofemoral 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. All devices are intended for cemented applications except for the EMPOWR Porous® Knee Femur, EMPOWR Porous® Knee Tibia, and Porous Patella which are intended for cementless applications.

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.

The EMPOWR™ Revision VVC+, e+™ Tibial Insert should be considered for use in total knee arthroplasty for patients under the following indications:

- Absence or loss of both cruciate ligaments
- Moderate varus-valgus or flexion instability that requires a bearing surface with increased constraint in the clinical judgment of the surgeon
- Bone loss that requires supplemental fixation in the clinical judgment of the surgeon

Indications for EMPOWR Partial Knee™

- Painful and/or disabling knee joints due to osteoarthritis or traumatic arthritis.
- Previous tibial condyle or plateau fractures with loss of anatomy or function.
- Varus or valgus deformities.
- Revision procedures where other treatments or devices have failed.
- These devices are indicated for cemented use only.

Indications for EMPOWR Revision Knee™ Symmetric Cones

- EMPOWR Revision Knee™ Symmetric Cones are intended for use in skeletally mature patients with bone defect or poor bone quality (osteoporotic bone) or in case of sclerotic bone that requires supplemental fixation in the clinical judgment of the surgeon.
- EMPOWR Revision Knee™ Symmetric Cones are intended for uncemented fixation to the bone and are fixed to the femoral and tibial implants using bone cement.

4. Intended Use

Enovis™ knee devices are intended for treatment of patients who are candidates for knee arthroplasty per the Indication for use. While total 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).
- The EMPOWR 3D KNEE® and EMPOWR CR® KNEE® are also contraindicated for patients without sufficient soft tissue integrity to provide adequate stability.

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. Malposition may predispose the device to excess wear and early failure. Only Enovis™ Knee System implants, 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.

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 Enovis™ 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. MRI Safety Information

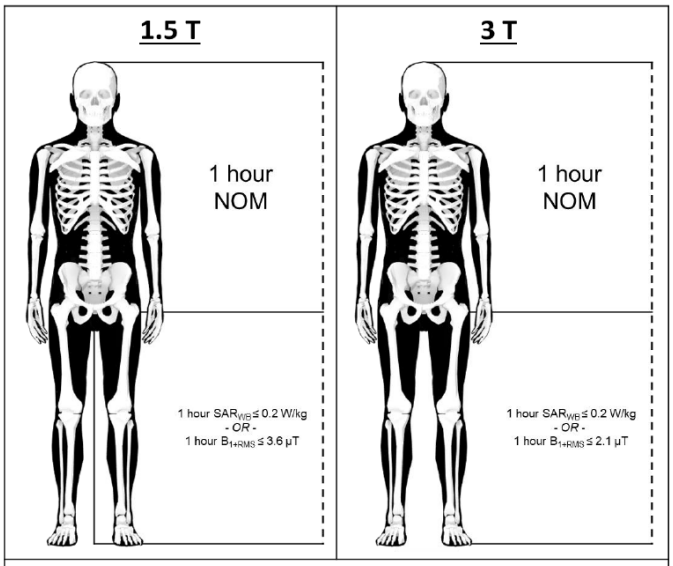
Enovis' EMPOWR knee implants are labeled MR Conditional. Please refer to the conditions and restricted zone summary listed below.

MRI Safety Information

A person with Enovis' EMPOWR Knee Implants may be safely scanned at 1.5T or 3.0T under the following conditions. Failure to follow these conditions may result in injury.

Parameter	Condition
Device Name	Enovis' EMPOWR Knee Implants
Static Magnetic Field Strength (B0)	1.5T and 3T
MR Scanner Type	Cylindrical
B0 Field Orientation	Horizontal
Maximum Spatial Field Gradient	40 T/m (4,000 G/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Integrated Whole Body Transmit Coil
Operating Mode	Operating mode and/or allowable whole-body SAR varies by landmark position as detailed in the MRI Restricted Zone Summary.
Scan Duration and Regions	Scan durations vary by landmark positions as detailed in the MRI Restricted Zone Summary. If successive scans are required, allow a minimum of 2 minutes between scans to allow for cooling.
Image Artifact	The presence of Enovis' EMPOWR Knee Implants may produce an image artifact of 7.5 cm. Some manipulation of scan parameters may be needed to compensate for the artifact.

MRI Restricted Zone Summary



Allow a minimum of two (2) minutes between successive scans to allow for tissue cooling.
Limitations above reflection conditions when the respective region is landmarked at the center of the coil.
NOM: Normal Operating Mode
SAR_{WB}: Whole-body averaged specific absorption rate.
B_{1+RMS}: Root mean squared magnetic field (B_1+)

9. 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;
- lengthening of limbs if severe deformity is present;
- metal sensitivity reactions.

10. Sterilization

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

Sterilization of implants other than Tibial Inserts and Patellae manufactured from Moderately Cross-Linked Polyethylene with Vitamin E (e+™) is performed by gamma radiation at the minimum dose of 25 kGy to achieve a Sterility Assurance Level (SAL) of 10^{-6}.

Sterilization of the Tibial Inserts and Patellae manufactured from Moderately Cross-Linked Polyethylene with Vitamin E (e+™) is performed by hydrogen peroxide gas plasma 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 integrity of the original sterile package be lost by being opened, punctured, or torn before implantation in the surgical field, contact manufacturer or manufacturer's representative for instructions. These inserts are single-use devices and CANNOT be resterilized by a healthcare facility. Contact manufacturer or manufacturer's representative for instructions.

Do not resterilize an implant or component that has been opened outside of the surgical field or 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 the implant or component and storage of the 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 Enovis™ Instrumentation Instructions for Use.

WARNING: DO NOT resterilize any knee prosthesis distributed by Enovis™ (Encore Medical, L.P.) if sterile packaging is opened or damaged upon receipt. Return the implant with respective packaging to Enovis™ 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 Moderately Cross-Linked Polyethylene Vitamin E (e+™) implants.

Enovis™ has validated sterilization cycle data on file.

NOTE: Enovis™ does not recommend Flash or Chemical Sterilization.

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

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

11. Trademarks and patents

EMPOWR Knee System™, EMPOWR 3D™, EMPOWR 3D KNEE®, EMPOWR Porous®, EMPOWR PS™, EMPOWR PS KNEE®, EMPOWR CR®, EMPOWR VVC®, EMPOWR Partial Knee™, and e+™ are trademarks of Enovis™.

U.S. patents: 5,413,604

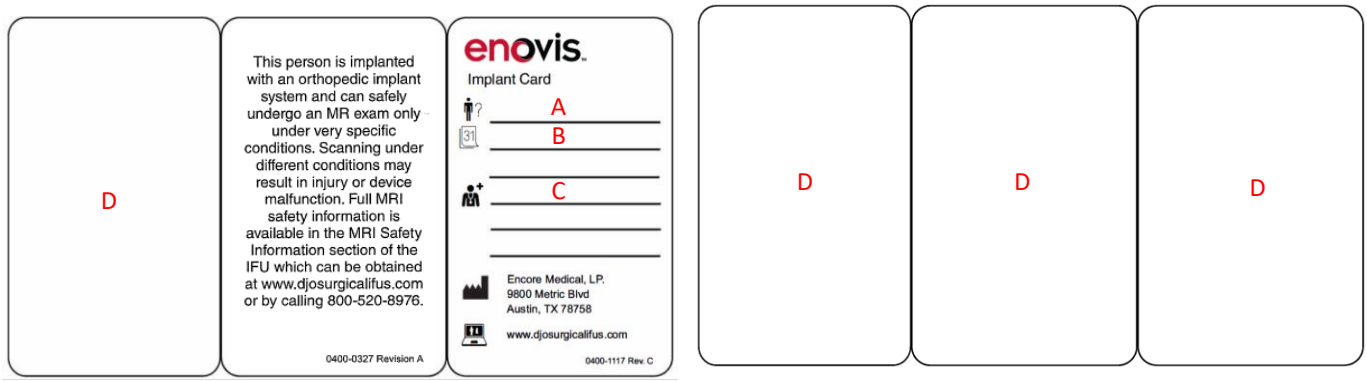
12. Implant Card Instructions

Implant cards are supplied as one foldable implant card and one sticker for each implant component. Each foldable implant card contains one fillable side and four blank sides. Reference the image below for each fillable field of the fillable side of the implant card. Text written in fillable fields of the implant card must be legible and at least 2mm high.

A. Patient Name or Patient ID (to be filled by healthcare institution/provider)
B. Date of Implantation (to be filled by healthcare institution/provider)
C. Name and Address of Healthcare Institution (to be filled by healthcare institution/provider)

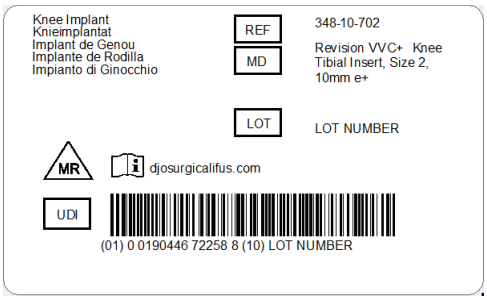
Place an implant card component sticker for each implant component used in Sections D of the foldable implant card. Each foldable implant card contains four Sections D.

Foldable Implant Card example:



Implant Card Component Sticker:

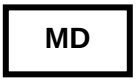
P/N 348-10-702 Implant Component Sticker Shown, A sticker will be provided for each Implant.



If more than five components are used, another implant card must be completed for the remaining component. The fillable fields A-C must be completed for each foldable implant card used.

Symbol Glossary:

 ISO 15223-1 5.4.2	***Single use – do not reuse***
 ISO 15223-1 5.1.4	***Expiration Date***
 ISO 15223-1 5.3.4	***Keep Dry***
 ISO 15223-1 5.1.5	***Lot number/Batch Code***
 ISO 15223-1 5.2.1	***Sterile***
 ISO 15223-1 5.2.4	***R: Sterile Using Irradiation***
	***H2O2: Sterilized Using Hydrogen Peroxide Gas Plasma***
 ISO 15223-1 5.2.7	***Non-sterile***
 ISO 15223-1 5.4.3	***See "Instructions for Use"***
 ISO 15223-1 5.1.1	***Manufacturer***
	***Quantity of items in package***

 ISO 15223-1 5.1.2	***Authorized Representative in European Community***
 ISO 15223-1 5.1.6	***Catalog Number***
 ISO 15223-1 5.2.6	***Do not resterilize***
 ISO 15223-1 5.2.8	***Do not use if package is damaged***
 ASTM F2503:2013	***MR Safe***
 ASTM F2503:2013	***MR Conditional***
 ASTM F2503:2013	***MRI Unsafe***
Rx only	***Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.***
 ISO 15223-1 5.1.8	***Importer***
 ISO 15223-1 5.7.7	***Medical Device***
 ISO 15223-1 5.1.11	***Country of Manufacture – US***
 ISO 7000-3704	***Double Sterile Barrier***

 ISO 15223-1 5.7.3	*Patient Name or Patient ID*
 ISO 15223-1 5.7.6	*Date of Implantation*
 ISO 15223-1 5.7.5	*Name and Address of the Implanting Healthcare Institution/Provider*
 ISO 15223-1 5.7.4	*Information Website for Patients*

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