Enovis Hip Systems

Encore Medical, L.P.
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Austin, TX 78758-5445 USA

0400-0104 REV YB 2025-10

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.

EN

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 Enovis product belonging to the same hip system, unless otherwise specified.

2. Product Description and Implant Materials

Hip Stem	Fixation Method	Material	Applicable ASTM Standard	Applicable ISO Standard
CLP™ Standard and Offset	Cementless	Ti6Al7Nb Niobium Alloy	ASTM F1295	ISO 5832-11
CLP-R™ Revision	Cemented or Cementless	Ti6Al7Nb Niobium Alloy	ASTM F1295	ISO 5832-11
Exprt® Precision System: Revision Hip	Cementless	Ti6Al4V Alloy	ASTM F136 / ASTM F1472	ISO 5832-3
Exprt® Precision System: Revision Hip Capture Bolt	Cementless	Ti6Al4V Alloy Medical Grade Ultra-High Molecular Weight Polyethylene	ASTM F136 / ASTM F1472 ASTM F648	ISO 5832-3 ISO 5834-1 / ISO 5834-2
Foundation® Fracture (Series 440) Collared or collarless	Cementless	Ti6Al4V Alloy	ASTM F136 / ASTM F1472	ISO 5832-3
Foundation® Porous (Series 470, 480)	Cementless	Ti-6Al-4V Alloy CP Ti Porous Coating	ASTM F136 / ASTM F1472 ASTM F67	ISO 5832-3 ISO 5832-2
Foundation® Porous w/HA (Series 470 HA)	Cementless	Ti-6Al-4V Alloy CP Ti Porous Coating Hydroxyapatite Coating	ASTM F136 / ASTM F1472 ASTM F67 ASTM F1185	ISO 5832-3 ISO 5832-2 ISO 13779-1
Foundation® Non-Porous (Series 450)	Cemented	CoCr	ASTM F799	ISO 5832-4
Foundation® Non-Porous (Series 460)	Cemented	CoCr PMMA	ASTM F799 ASTM F451	ISO 5832-4 ISO 8257-1
Linear®	Cementless	Ti-6Al-4V Alloy CP Ti Porous Coating	ASTM F136 / ASTM F1472 ASTM F67	ISO 5832-3 ISO 5832-2
Revelation® Revelation® MicroMax	Cementless	Ti6Al4V Alloy CP Ti Porous Coating	ASTM F136 / ASTM F1472 ASTM F67	ISO 5832-3 ISO 5832-2
TaperFill®	Cementless	Ti-6Al-4V Alloy CP Ti Porous Coating	ASTM F136 / ASTM F1472 ASTM F67	ISO 5832-3 ISO 5832-2

Enovis hip stems can be used with any Enovis femoral heads for total joint replacement. Enovis Hip Systems are for total hip replacement except for Bipolar and Unipolar which are for hemi arthroplasty applications. The CLP Offset, and CLP-R hip systems are for either total or hemi applications.

Component	Fixation Method	Material	Applicable ASTM Standard	Applicable ISO Standard
The following femoral heads and titanium sleeves are compatible with all hip stems listed in the previous table and with all acetabular liners below.				
CoCr Femoral Heads	Cementless	CoCr	ASTM F799 / ASTM 1537	ISO 5832-4
Ceramic Femoral Heads	Cementless	Ceramic (Alumina and Zirconia)		ISO 6474-2
The following sleeves are compatible with and required for 400-04 and 402-04 Series Ceramic Heads				
Offset Sleeves for Ceramic Femoral Heads	Cementless	Ti6Al4V Alloy	ASTM F136 / ASTM F1472	ISO 5832-3
The FMP system is compatible with the femoral heads and hip stems listed above.				
FMP Hemispherical Acetabular Shells (with or without holes, 3D Matrix or P2 coating) FMP Flared Acetabular Shells (with or without holes, 3D Matrix or P2 coating) FMP Hemispherical Spiked Acetabular Shells	Cementless	Ti6Al4V Alloy CP Ti porous coating	ASTM F136 / ASTM F1472 ASTM F67	ISO 5832-3 ISO 5832-2
Cancellous Bone Screws are compatible with all FMP holed acetabular shells listed above				
Cancellous Bone Screws	N/A	Ti6Al4V Alloy	ASTM F136 / ASTM F1472	ISO 5832-3
The following FMP acetabular liners are compatible with the femoral heads, hip stems and FMP acetabular shells listed above.				
FMP Acetabular Liners (Neutral, Hooded, Offset)	Cementless	Medical grade UltraHigh Molecular Weight Polyethylene	ASTM F648	ISO 5834-1 / ISO 5834-2
FMP Constrained Acetabular Liners FMP Constrained Acetabular Liner Locking Rings	Cementless	Medical grade UltraHigh Molecular Weight Polyethylene Ti6Al4V Alloy	ASTM F648 ASTM F136 / ASTM F1472	ISO 5834-1 / ISO 5834-2 ISO 5832-3
X-alt™ Acetabular Liner (Neutral, Hooded, Offset)	Cementless	Medical grade UltraHigh Molecular Weight Polyethylene (Highly Cross-Linked)	ASTM F648 / ASTM F2565	ISO 5834-1 / ISO 5834-2
HXe+ Acetabular Liner (Neutral, Hooded, Offset)	Cementless	Medical grade UltraHigh Molecular Weight Polyethylene (Highly Cross-Linked) Vitamin E UHMWPE (a-tocopheral)	ASTM F648 / ASTM F2565 ASTM F2695	ISO 5834-1 / ISO 5834-2
The EMPOWR Acetabular® system is compatible with the femoral heads and hip stems listed above.				
EMPOWR Acetabular® Cups (Solid Back, Cluster Hole, Multi Hole)[2]	Cementless	Ti-6Al-4V Alloy CP Ti porous coating	ASTM F1472 ASTM F67	ISO 5832-3 ISO 5832-2
EMPOWR Acetabular® Bone Screws[1]	N/A	Ti-6Al-4V Alloy	AMS4965™	
The following EMPOWR Acetabular® liners are compatible with all femoral heads, hip stems and EMPOWR Acetabular® shells listed above.				
EMPOWR Acetabular® Liner Hxe+ (Neutral, Hooded, Offset) [1]	Cementless	Medical grade UltraHigh Molecular Weight Polyethylene (Highly Cross-Linked) Vitamin E UHMWPE (a-tocopheral)	ASTM F648 / ASTM F2565 ASTM F2695	ISO 5834-1 / ISO 5834-2
The EMPOWR Dual Mobility™ system is compatible with the EMPOWR Acetabular® system, 28mm femoral heads and all hip stems listed above.				
EMPOWR Dual Mobility™ Metal Liner	Cementless	CoCr Alloy	ASTM F799 / ASTM F1537	ISO 5832-4
EMPOWR Dual Mobility™ Poly Bearing	Cementless	Medical grade UltraHigh Molecular Weight Polyethylene (Highly Cross-Linked) Vitamin E UHMWPE (a-tocopheral)	ASTM F648 / ASTM F2565 ASTM F2695	ISO 5834-1 / ISO 5834-2
The Bipolar components are compatible with all hip stems and 22mm CoCr & all 28mm Femoral Heads listed above.				
Bipolar Liners (Head)	Cementless	CoCr Medical grade UltraHigh Molecular Weight Polyethylene	ASTM F799 / ASTM F-1537 ASTM F648	ISO 5832-4 ISO 5834-1 / ISO 5834-2
The Unipolar components are compatible with all hip stems listed above and Offset Sleeves listed below.				
Unipolar Heads	Cementless	CoCr	ASTM F799 / ASTM F-1537	ISO 5832-4
The Foundation Hip Offset Sleeves are compatible with and required for Unipolar Heads and 497-34, 36, 40, 44 Series CoCr Femoral Heads.				
Offset Sleeves for Unipolar and CoCr Heads	Cementless	Ti6Al4V Alloy	ASTM F136 / ASTM F1472	ISO 5832-3

[1]Use only with Empowr Acetabular System

[2]The EMPOWR Acetabular® Cups are compatible with the ArTT Augments and Buttresses and Bone Screws manufacturered by Lima Corporate S.P.A. Instructions for use of the ArTT Augments and Buttresses and Bone Screws should be consulted prior to use.

3. Indications for Use (all hip systems in Section 2 above – unless noted below)

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

- noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis of the natural femoral head;
- rheumatoid arthritis;
- correction of functional deformity;
- femoral fracture.

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

The EMPOWR Dual Mobility™ system has the additional indication of joint replacement due to dislocation risks.

The constrained acetabular component is indicated for primary or revision patients at high risk of hip dislocation due to a history of prior dislocation, bone loss, soft tissue laxity, neuromuscular disease, or intra-operative instability and for who all other options to constrained acetabular components have been considered.

4. Intended Use

Enovis hip devices are intended 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;
- uncooperative patient or a patient with neuralgic disorders and Incapable of following instructions;
- distant foci of infections.

Joint replacement with the EMPOWER Dual Mobility™ system 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;
- alcoholism or other addictions;
- materials sensitivity;
- loss of ligamentous structures;
- uncooperative patient or a patient with neuralgic disorders and Incapable of following instructions;
- distant foci of infections.

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. Use of the largest stem possible is recommended. Only Enovis Hip 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. Do not implant HA (Hydroxyapatite) coated implants with bone cement.

1. Ceramic femoral heads are only indicated for use with stems during total hip replacement.

<u>Precautions and Warnings Specific to the Constrained Acetabular Liner</u>

Precautions:

1. In order to minimize the risks of dislocation and loosening of the shell-acetabular bone or shell-bone cement interface that may occur when using a metallic shell intended for biological fixation or cemented use only, surgeons should consider providing immediate resistance to tensile forces between the metallic shell and the acetabular bone or bone cement interface through the use of orthopedic bone fixation devices such as bone screws, spikes, screw threads, fins, or other bone fixation devices.
2. To correctly position the metallic locking ring, surgeons should consult the manufacturer's instructions for appropriate device assembly.
3. Physicians should consider component malposition, component placement, and the effect on range of motion when using modular heads (with sleeves or skirts) and extended liners.
4. Regarding component malposition above, recommendation is to caution physician regarding the malpositioned acetabular components cup and the potential for impingement, premature dislocation and revision.

Warnings

1. Closed reduction of this device is not possible. Patients should be made aware that treatment of device dislocation will require additional surgery.
2. There may be a failure of the retaining ring.
3. A retaining ring that is placed incorrectly may have a reduced life.
4. Retaining ring failure, which may be due to impingement, fatigue, and/or wear, increases the probability of dislocation.
5. Failure or migration of the retaining ring may require additional surgery.

Precautions Specific to the Revelation Short Stem:

1. Fracture in smaller sized stems is most likely to occur in patients who are young, physically active and/or obese.

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

7. MRI Safety Information

United States:

Enovis hip systems listed in Section 2 of this document are MR Conditional. Please refer to the conditions and restricted zone summary listed below.

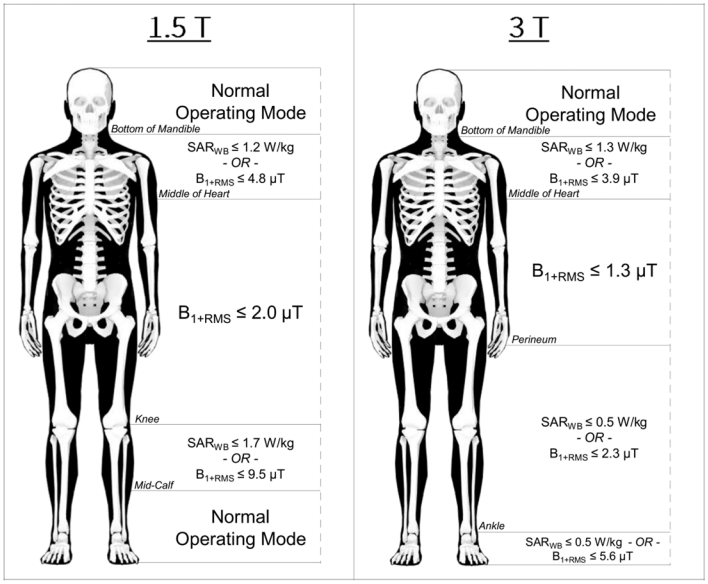
When used in conjunction with the ArTT Augments and Buttresses and Bone Screws, the respective instructions for use should be consulted for MRI Safety Information.

MRI Safety Information

Non-clinical testing has demonstrated that Enovis' hip arthroplasty systems are MR Conditional. A person with an Enovis hip arthroplasty system 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' Hip Arthroplasty Systems
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, allowable whole-body SAR (SAR_{wb}), and/or allowable B_{1+RMS} varies by landmark position as detailed in the MRI Restricted Zone Summary and below: 1.5 T Normal Operating Mode from top of head to bottom of mandible. $SAR_{wb} \leq 1.2$ W/kg or $B_{1+RMS} \leq 4.8$ µT from bottom of mandible to middle of heart. $B_{1+RMS} \leq 2.0$ µT from middle of heart to knee $SAR_{wb} \leq 1.7$ W/kg or $B_{1+RMS} \leq 9.5$ µT from knee to mid-calf Normal operating mode from from mid-calf to bottom of foot. 3.0 T Normal Operating Mode from top of head to bottom of mandible. $SAR_{wb} \leq 1.3$ W/kg or $B_{1+RMS} \leq 3.9$ µT from bottom of mandible to middle of heart. $B_{1+RMS} \leq 1.3$ µT from middle of heart to perineum. $SAR_{wb} \leq 0.5$ W/kg or $B_{1+RMS} \leq 2.3$ µT from perineum to ankle. $SAR_{wb} \leq 0.5$ W/kg or $B_{1+RMS} \leq 5.6$ µT from ankle to bottom of foot.
Scan Duration	Under the exposure conditions outlined in the MRI Restricted Zone Summary and in Operating Mode section above, up to 1 hour of continuous scanning is permissible without a cooling period.
Scan Regions	Under the exposure conditions outlined in the MRI Restricted Zone Summary and in Operating Mode section above, any landmark is acceptable.
Image Artifact	The presence of Enovis' Hip Arthoplasty Systems may produce an image artifact of 7.9 cm. Some manipulation of scan parameters may be needed to compensate for the artifact.

MRI Restricted Zone Summary



Under these conditions, continuous scanning for up to one hour is permitted. Limitations above reflect conditions when the respective region is landmarked at the center of the coil. If a SAR limit is not provided for a given landmark, then the B1+RMS restriction should be considered the limiting scanning parameter.
SAR_{wb}: Whole-body averaged specific absorption rate
B_{1+RMS}: RMS RF magnetic field (B_{1+})

EU and ROW:

Non-clinical testing has demonstrated that Enovis's Total Hip Replacement is MR Conditional in a 3 T MR environment. A patient with this device can be safely scanned in an MR system meeting the following conditions:
• Static magnetic field of 3-Tesla (3 T).
• Maximum spatial field gradient of 3,860 G/cm (38.6 T/m) for 3 T systems.
• Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2.0 W/kg (Normal Operating Mode) at 3 T.

3 T RF heating
Under the scan conditions defined above, Enovis's Total Hip Replacement System is expected to produce a maximum temperature rise of less than 1.5ºC after 15 minutes of continuous scanning.
Caution: The RF heating behavior does not scale with static field strength. Devices that do not exhibit detectable heating at one field strength may exhibit high values of localized heating at field strength.

3 T MR Artifact
In non-clinical testing, the image artifact caused by the Enovis's Total Hip Implant System may extend approximately 6.4 cm from the device when imaged with a gradient-echo pulse sequence in a 3 T MRI system.

Note: No other MR field strength is recommended.

Note: Patients receiving MRI should be made aware of risks associated with this procedure. This could include the following:

- "The strong, static magnetic field of the MRI scanner will pull on magnetic materials and may cause unwanted movement of the medical device."
- "The radiofrequency energy and magnetic fields that change with time may cause heating of the implanted medical device and the surrounding tissue, which could lead to burns."
- "The presence of the medical device will degrade the quality of the MR image, which may make the MRI scan uninformative or may lead to an inaccurate clinical diagnosis, potentially resulting in inappropriate medical treatment."

8. 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 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.

Patient Counseling Information Specific to the Constrained Acetabular Liner

1. The prosthesis will not restore function to the level expected with a normal healthy joint, and the patient should be instructed as to the limitations of the device.
2. The range of motion achievable with a constrained liner is less than the range of motion of a normal joint, and less than with a semi-constrained prosthesis.
3. The patient should be told that, although the constrained hip liner provides resistance to dislocation, it can dislocate if subjected to excessive loading.
4. Once dislocated, additional surgery will be required to reduce the joint.
5. Patients should be instructed that significant reduction in the range of motion is inherent to the design characteristic of a constrained acetabular liner, and activities that may force the joint to exceed those range of motion limits should be avoided.

9. 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. periarticular 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.

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 the Highly Cross-Linked Polyethylene Acetabular Liner and Highly Cross-Linked Polyethylene Acetabular Liner with Vitamin E has been 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 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.

Sterilization of the Highly Cross-Linked Polyethylene Acetabular Liner and Highly Cross-Linked Polyethylene Vitamin E Acetabular Liner has been 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. Liner trials and other instruments are used to determine sizing before the sterile package needs to be opened.

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 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 hip prosthesis distributed by Enovis (Encore Medical, L.P.) as listed in the following warning if sterile packaging is opened or damaged. Return the implant with respective packaging to Enovis for inspection and disposition.

WARNING: DO NOT resterilize UHMWPE (ultra-high molecular weight polyethylene) implants, Highly Cross-Linked Polyethelene, Highly Cross-Linked Polyethylene Vitamin E, PMMA (polymethylmethacrylate) spacers, HA (Hydroxyapatite) coated implants, and ceramic implants.

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

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

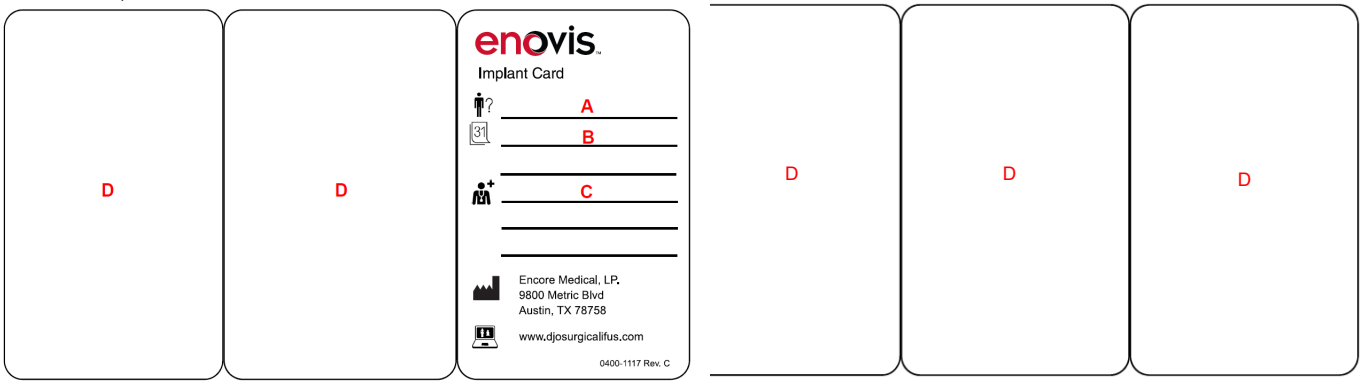
11. Trademarks and patents

12. Implant Card Instructions (Applicable where Implant Card is available)
Patient implant cards are supplied as a foldable implant card and one label for each implant component. Each foldable patient implant card contains one fillable side and five or more 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.

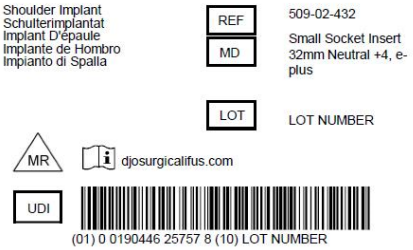
A. Patient Name or Patient ID (to be filled by healthcare institution/provider)
B. Date of Implantation (to be filled by healthcare institution/provider)
C. Name and Address of Healthcare Institution (to be filled by healthcare institution/provider)

Place a patient implant card label for each implant component used in Sections D of the foldable patient implant card. Another implant card must be completed as necessary to accommodate all components. The fillable fields A-C must be completed for each foldable patient implant card used.

Foldable Patient Implant Card:



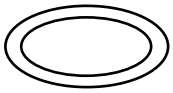
13. Implant Card Component Sticker
A sticker will be provided for each Implant. P/N 509-02-432 Implant Component Sticker Shown. (For reference only)

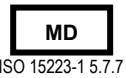


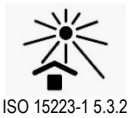
If more than five components are used, another implant card must be completed for the remaining components. The fillable fields A-C must be completed for each foldable implant card used.

Icon Key:

 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	***Sterility symbol: R: Sterile Using Irradiation***
	***Sterile symbol: H_2O_2: Sterilized Using Hydrogen Peroxide Gas Plasma***
	***Double Sterile Barrier***
 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 21 CFR 801.109	*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 5.4.10	*Contains substance (cobalt) that can be carcinogenic, mutagenic or reprotoxic*
 ISO 15223-1 5.1.11	*Country Code of Manufacturer – US*
 ISO 15223-1 5.3.2	*Keep away from sunlight*
 ISO 7000-0434-A	*Caution*
 ISO 15223-1 5.1.3	*Date of manufacture*
 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