



Encore Medical, L.P.
9800 Metric Blvd.
Austin, TX 78758-5445

0400-0324 REV. B 2025-05

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.

EN**1. Product Handling**

Devices not returned to Enovis™ should be treated as biohazardous material and disposed of in accordance with local laws and regulations.

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 Enovis™ products belonging to the same shoulder system, unless otherwise specified.

2. Product Description and Implant Materials

Component	Fixation Method	Material	Applicable ASTM Standard	Applicable ISO Standard
Reverse® Shoulder Prosthesis (RSP®) Humeral Stems				
Reverse® Shoulder Prosthesis (RSP®) Modular Humeral Stem (Primary and Revision)	Cemented	Ti6Al4V alloy	ASTM F136 / ASTM F1472	ISO 5832-3
RSP® Humeral Socket Shell (<i>for use with Modular Stem</i>)	Cementless	Ti6Al4V alloy	ASTM F136 / F1472	ISO 5832-3
RSP® Monoblock Humeral Stem (Primary and Revision)	Cemented or Cementless ¹	Ti6Al4V alloy Ti Plasma Coating	ASTM F136 / ASTM F1472 ASTM F1580	ISO 5832-3
Altivate Reverse® Humeral Stem (Primary, Short Stem and Revision)	Cemented or Cementless	Ti6Al4V alloy CP Ti Porous Coating	ASTM F1472 ASTM F67	ISO 5832-3 ISO 5832-2
Reverse® Shoulder Prosthesis (RSP®) Humeral Inserts				
RSP® Humeral Socket Insert (Standard and Semi-Constrained)	Cementless	Medical Grade Ultra High Molecular Weight Polyethylene	ASTM F648	ISO 5834-1 / ISO 5834-2
RSP® Humeral Socket Insert e+™ (Standard and Semi-Constrained) ⁵	Cementless	Medical Grade Ultra High Molecular Weight Polyethylene (Highly Cross-Linked) Vitamin E UHMWPE (a-tocopheral)	ASTM F648 / ASTM F2565 ASTM F2695	ISO 5834-1 / ISO 5834-2
Reverse® Shoulder Prosthesis (RSP®) Humeral Adapters and Spacers				
RSP® Humeral Stem Adapter ¹	Cementless	Ti6Al4V alloy	ASTM F136 / ASTM F1472	ISO 5832-3
RSP® Monoblock Hemi-Adapter with Retaining Screw ²	Cementless	CoCrMo Ti6Al4V alloy	ASTM F799 ASTM F136 / ASTM F1472	ISO 5832-4 ISO 5832-3
RSP® Monoblock Hemi-Adapter Retaining Screw ³	Cementless	Ti6Al4V alloy	ASTM F136 / ASTM F1472	ISO 5832-3
RSP® Monoblock Spacer with Retaining Screw ²	Cementless	Ti6Al4V alloy	ASTM F136 / ASTM F1472	ISO 5832-3
RSP® Monoblock Spacer Retaining Screw ⁴	Cementless	Ti6Al4V alloy	ASTM F136 / ASTM F1472	ISO 5832-3
<ol style="list-style-type: none"> 1. The RSP® Humeral Stem Adapter is for use with Modular Stems and Foundation Heads to convert to a Hemi system. 2. RSP® Monoblock Hemi-Adapter and RSP® Monoblock Spacer are compatible with the RSP® Monoblock and Altivate Reverse® Stems above. The RSP® Monoblock Hemi-Adapter is compatible with Turon® Shoulder Heads and Altivate® Anatomic™ Heads. 3. RSP® Monoblock Hemi-Adapter Retaining Screw is also compatible with the Altivate Reverse® Small Hemi-Adapter. 4. RSP® Monoblock Spacer Retaining Screw is also compatible with the Altivate Reverse® Small Spacer. 5. The RSP® Humeral System above is compatible with the SMR Shoulder System and PRIMA Glenoid System only when a size 36 or 40 RSP® Humeral Socket Insert e+™ (Standard and Semi-Constrained) are used. Instructions for use of SMR Shoulder System and PRIMA Glenoid System should be consulted prior to use. 				

AltiVate Reverse® Small Shell Humeral System				
AltiVate Reverse® Small Shell Humeral Stem (Primary, Short Stem and Revision)	Cemented or Cementless	Ti6Al4V alloy CP Ti Porous Coating	ASTM F1472 ASTM F67	ISO 5832-3 ISO 5832-2
AltiVate Reverse® Small Humeral Socket Insert (Neutral and Semi-Constrained)	Cementless	Medical grade Ultra High Molecular Weight Polyethylene	ASTM F648	ISO 5834-1 / ISO 5834-2
AltiVate Reverse® Small Humeral Socket Insert e+™ (Neutral and Semi-Constrained) ⁴	Cementless	Medical grade Ultra High Molecular Weight Polyethylene (Highly Cross-Linked) Vitamin E UHMWPE (a-tocopheral)	ASTM F648 / ASTM F2565 ASTM F2695	ISO 5834-1 / ISO 5834-2
AltiVate Reverse® Small Hemi-Adapter ^{1,2} with Retaining Screw	Cementless	CoCrMo Ti6Al4V alloy	ASTM F1537 ASTM F1472	ISO 5832-3
AltiVate Reverse® Small Spacer—8mm & 12mm with Retaining Screw ³	Cementless	Ti6Al4V alloy	ASTM F1472	ISO 5832-3
1. The AltiVate Reverse® Small Hemi-Adapter is compatible with Turon® Shoulder Humeral Heads and AltiVate® Anatomic™ Heads. 2. RSP® Monoblock Hemi-Adapter Retaining Screw is also compatible with the AltiVate Reverse® Small Hemi-Adapter. 3. RSP® Monoblock Spacer Retaining Screw is also compatible with the AltiVate Reverse® Small Spacer. 4. The AltiVate Reverse® Small Shell Humeral System above is compatible with the SMR Shoulder System and PRIMA Glenoid System only when a size 36 or 40 AltiVate Reverse® Small Shell Socket Insert e+™ (Neutral and Semi-Constrained) are used. Instructions for use of SMR Shoulder System and PRIMA Glenoid System should be consulted prior to use.				
Reverse Shoulder Glenoid Systems				
RSP® Glenoid Head with Retaining Screw ²	Cementless	CoCrMo Ti6Al4V alloy	ASTM F1537 ASTM F136 / ASTM F1472	ISO 5832-4 ISO 5832-3
AltiVate Reverse® Glenosphere with Retaining Screw ²	Cementless	CoCrMo Ti6Al4V alloy	ASTM F1537 ASTM F136 / ASTM F1472	ISO 5832-4 ISO 5832-3
RSP® Glenoid Head Retaining Screw	Cementless	Ti6Al4V alloy	ASTM F136 / ASTM F1472	ISO 5832-3
RSP® Glenoid Baseplate with HA Coating	Cementless	Ti6Al4V alloy CP Ti Porous Coating Hydroxyapatite Coating	ASTM F136 / ASTM F1472 ASTM F67 ASTM F1185	ISO 5832-3 ISO 5832-2 ISO 13779-1
RSP® Glenoid Baseplate with P ² ™	Cementless	Ti6Al4V alloy CP Ti Porous Coating	ASTM F136 / ASTM F1472 ASTM F67	ISO 5832-3 ISO 5832-2
AltiVate Reverse® Modular Baseplate (Neutral and Wedge) with Taper	Cementless	Ti6Al4V alloy CP Ti Porous Coating	ASTM F1472 ASTM F67	ISO 5832-3 ISO 5832-2
AltiVate Reverse® Modular Central Screw	Cementless	Ti6Al4V alloy	ASTM F1472	ISO 5832-3
RSP® Glenoid Baseplate Screws (Locking and Non-Locking)	Cementless	Ti6Al4V alloy	ASTM F136 / ASTM F1472	ISO 5832-3
AltiVate Reverse® Torx Peripheral Screw	Cementless	Ti6Al4V alloy	ASTM F1472	ISO 5832-3
AltiVate Reverse® Porous Coated Peripheral Locking Peg	Cementless	Ti6Al4V alloy CP Ti Porous Coating	ASTM F1472 ASTM F67	ISO 5832-3 ISO 5832-2
1. The RSP® Glenoid system is compatible with all Reverse® Shoulder Humeral systems listed above 2. The Reverse Shoulder Glenoid Systems above are compatible with the SMR Shoulder System and PRIMA Humeral System only when a size 36 or 40 RSP® Glenoid Head or AltiVate Reverse® Glenosphere are used. Instructions for use of SMR Shoulder System and PRIMA Humeral System should be consulted prior to use.				

3. Indications for Use

Indications for RSP® Modular Stem:

The Reverse® Shoulder Prosthesis (RSP®) Humeral Stem and Socket Shell are indicated for use in patients with a grossly rotator cuff deficient shoulder joint with severe arthropathy or a previously failed joint replacement with a grossly rotator cuff deficient shoulder joint.

The patient's joint must be anatomically and structurally suited to receive the selected implant(s), and a functional deltoid muscle is necessary to use the device.

The glenoid baseplate is intended for cementless application with the addition of screws for fixation. The humeral stem is intended for cemented use only.

Indications for RSP® Monoblock Stem:

The Reverse® Shoulder Prosthesis Monoblock is indicated for patients with a functional deltoid muscle with a grossly deficient rotator cuff shoulder joint with severe arthropathy or a previously failed joint replacement with a grossly deficient rotator cuff shoulder joint.

- In cases of fracture of glenohumeral joint from trauma or pathologic conditions of the shoulder, including humeral head fracture or displaced 3- or 4-part fractures of proximal humerus.
- In cases of bone defect in proximal humerus.

The patient's joint must be anatomically and structurally suited to receive the selected implant(s).

The glenoid baseplate is intended for cementless application with the addition of screws for fixation. The humeral stem is intended for cemented or Cementless use (Cementless use not cleared in the EU).

Additional Indications for RSP® Humeral Stem Adapters used with RSP® Modular and RSP® Monoblock:

During primary surgery, after the humerus is prepared for the RSP® humeral stem, if the glenoid bone stock appears “insufficient” to bear the load of the glenoid baseplate, a RSP® humeral stem adapter can be used to convert the RSP® humeral stem to hemiarthroplasty prosthesis. During revision surgery of an RSP®, if the glenoid bone stock appears to be “insufficient” to bear the load of the glenoid baseplate, a RSP® humeral stem adapter is used to convert the RSP® device to hemiarthroplasty prosthesis.

Indications for AltıVate Reverse® Humeral Stem and Small Shell Humeral Stem (Primary, Short Stem and Revision)

Anatomic Total Shoulder Indications:

The AltıVate Reverse® Shoulder Prosthesis Stem is indicated as an Anatomic shoulder joint replacement for patients suffering from pain and dysfunction due to:

- Noninflammatory degenerative joint disease including osteoarthritis;
- Inflammatory arthritis of the glenohumeral joint including rheumatoid arthritis;
- Post-traumatic arthritis of the glenohumeral joint;
- Avascular necrosis of the humeral head with and without involvement of the glenoid;
- Correction of functional deformity

The all-poly glenoid is intended for cemented use. Reference 0400-0316, Enovis Anatomic Shoulder System IFU for complete Anatomic Head and Glenoid for more information.

Hemi Shoulder Indications:

The AltıVate Reverse® Shoulder Prosthesis Stem is indicated as a hemi shoulder joint replacement for patients suffering from pain and dysfunction due to:

- Noninflammatory degenerative joint disease including osteoarthritis;
- Inflammatory arthritis of the glenohumeral joint including rheumatoid arthritis;
- Post-traumatic arthritis of the glenohumeral joint;
- Avascular necrosis of the humeral head with and without involvement of the glenoid;
- Correction of functional deformity;
- Rotator cuff tear arthropathy;
- Humeral fracture;
- Failed previous shoulder surgery.

Reverse Total Shoulder Indications:

The AltıVate Reverse® Shoulder Prosthesis is indicated as a reverse shoulder replacement for patients with a functional deltoid muscle and a grossly deficient rotator cuff joint suffering from pain and dysfunction due to:

- Severe arthropathy with a grossly deficient rotator cuff;
- Previously failed joint replacement with a grossly deficient rotator cuff;
- Fracture of glenohumeral joint from trauma or pathologic conditions of the shoulder including humeral head fracture, displaced 3- or 4-part fractures of proximal humerus, or reconstruction after tumor resection;
- Bone defect in proximal humerus;
- Non-inflammatory degenerative disease including osteoarthritis and avascular necrosis of the natural humeral head and/or glenoid;
- Inflammatory arthritis including rheumatoid arthritis;
- Correction of functional deformity.

The glenoid baseplate is intended for cementless application with addition of screws for fixation. This device may also be indicated in the salvage of previously failed surgical attempts for anatomic and hemi procedures.

All RSP® Monoblock and AltıVate Reverse® humeral stems are intended for cemented or cementless use.

4. Intended Use

Enovis™ shoulder devices are intended for treatment of patients who are candidates for shoulder arthroplasty per the Indication for use. While total shoulder 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

Total 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;
- Alcoholism or other addictions;
- Materials (metals, etc.) sensitivity;
- Loss of ligamentous structures;
- High levels of physical activity (e.g. competitive sports, heavy physical labor);
- Non-functional deltoid muscle;
- Rotator cuff insufficiency for anatomic shoulder arthroplasty with the AltıVate Reverse® humeral stem;
- Intraoperative conversion from a reverse to an anatomic shoulder.

Contraindications for the RSP® Humeral Stem Adapters:

Hemi-arthroplasty is contraindicated where there is:

- Non-functional deltoid muscle;
- Active sepsis;
- Excessive glenoid bone loss;
- Pregnancy;
- Muscular, neurological or vascular deficiencies, which compromise the affected extremity;
- Conditions that place excessive demand on the implant (i.e. Charcot's joints, muscle deficiencies, refusal to modify postoperative physical activities, skeletal immaturity);
- Known metal allergy (i.e., jewelry).

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. Enovis™ Shoulder 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.

This shoulder is a semi-constrained device designed to address irreparable soft tissue, irreparable rotator cuffs, musculature and bony deficiencies. Due to the constraints built into the design, there may be limits to the patient's achievable range of motion. In addition, because of the limit to the range of motion, there may be the possibility of impingement and/or additional wear.

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

RSP® Humeral Socket Assembly (Shell/Insert):

- Replace both the polyethylene insert and metal shell if the insert is damaged or deformed during the implant procedure or postoperative timeframe.
- Do not reassemble a polyethylene insert and metal shell once they have been disassembled.
- Do not re-use implants. Although the implant may appear undamaged, previous stresses could create imperfections that may lead to mechanical failure.

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 Reverse® Prosthesis Shoulder 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/her activities accordingly as the risk of implant failure increases with weight and activity levels of the patient.

8. MRI Safety Information

The Enovis™ shoulder systems listed in Section 2 of this document have been evaluated for safety in the MR environment. These devices have been tested for heating or unwanted movement in the MR environment with MR Conditional labeling stated in the table below.

When used in conjunction with the SMR Shoulder System, PRIMA Humeral System, and PRIMA Glenoid System, the respective instructions for use should be consulted for MRI Safety Information.

AltıVate Reverse® Shoulder System

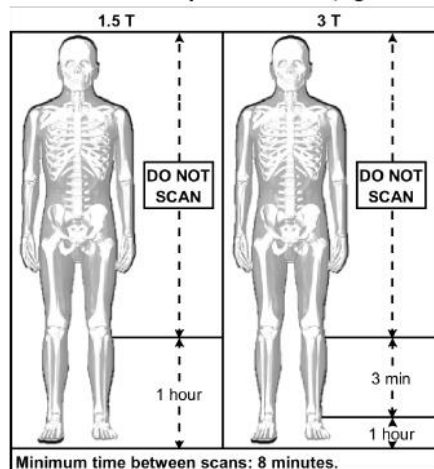


MRI Safety Information

A person with Enovis Total Shoulder Systems 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 Reverse Shoulder System
Static Magnetic Field Strength (B0)	1.5T and 3T
MR Scanner Type	Cylindrical
B0 Field Orientation	Horizontal
Maximum Spatial Field Gradient	25 T/m (2,500 G/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Integrated Whole Body Transmit Coil
Operating Mode	Normal Operating Mode
RF Conditions	Maximum Whole-body SAR: 2 W/kg if scan duration and landmark limitations listed below are applied (see MRI Restricted Zone Summary)
Scan Duration and Landmark Restrictions	<p>For 1.5 T MR Scanner:</p> <ul style="list-style-type: none"> • Landmark above the knee: Do not scan • Landmark at or below the knee: Scan for up to 1 hour of continuous scanning <p>For 3 T MR Scanner:</p> <ul style="list-style-type: none"> • Landmark above the knee: Do not scan

Whole-Body SAR Limit: 2 W/kg



	<ul style="list-style-type: none"> Landmark between the knee and ankle: Scan for up to 3 minutes followed by an 8-minute cooling period (may be repeated up to 5 times in one imaging session) Landmark at or below the ankle: Scan for up to 1 hour of continuous scanning
Image Artifact	The presence of the Enovis Reverse Shoulder System may produce an image artifact of 7.0 cm. Some manipulation of scan parameters may be needed to compensate for the artifact.

9. Adverse Effects

- Accelerated wear of the polyethylene articulating surfaces have been reported following total shoulder 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.
- Metallosis and osteolysis may be implicated from wear debris associated with the use of orthopedic implants.
- Peripheral neuropathies have been reported following total joint surgery. Subclinical nerve damage occurs more frequently, possibly the result of surgical trauma.
- 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.
- 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.
- Implants can loosen or migrate due to trauma or loss of fixation.
- Infection can lead to failure of the joint replacement.
- While rare, fatigue fracture of the implant can occur as a result of strenuous activity, improper alignment, or duration of service.
- Fracture of the humerus can occur while press-fitting (seating) the humeral stem into the prepared humeral canal.
- Allergic reactions.

Intraoperative and early postoperative complications can include:

- humeral perforation, or fracture;
- humeral fracture can occur while seating the device;
- damage to blood vessels;
- temporary or permanent nerve damage resulting in pain or numbness of the affected limb;
- undesirable shortening or lengthening of the limb;
- traumatic arthrosis of the shoulder from intraoperative positioning of the extremity;
- cardiovascular disorders including venous thrombosis, pulmonary embolism, or myocardial infarction;
- hematoma;
- delayed wound healing; and
- infection.

Late postoperative complications can include:

- avulsion as a result of excess muscular weakening;
- non-union due to inadequate reattachment and/or early weight bearing;
- aggravated problems of other joints of the affected limb or muscle deficiencies;
- humeral fracture by trauma or excessive loading, particularly in the presence of poor bone stock;
- fatigue fracture of the acromion or the scapular spine;
- periarticular calcification or ossification, with or without impediment to joint mobility; and
- 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 Humeral Socket Inserts manufactured from Highly Cross-Linked Polyethylene with Vitamin E (e+™), is by gamma radiation at the minimum dose of 25 kGy to achieve a Sterility Assurance Level (SAL) of 10⁻⁶.

Sterilization of Humeral Socket Inserts manufactured from Highly 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 shoulder 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, 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), Highly Cross-Linked Polyethylene Vitamin E (e+™), or HA (hydroxyapatite) coated 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™ Shoulder System, contact your Enovis™ representative or distributor.

Enovis™ Shoulder Systems are manufactured by ENCORE MEDICAL, L.P.

9800 Metric Blvd., Austin, TX 78758 USA (Made in the USA)

11. Trademarks and patents

FOUNDATION®, Turon®, Altivare®, CS EDGE®, RSP®, Reverse®, DJO Surgical® and e+™ are trademarks and registered trademarks of Encore Medical, L.P.

Enovis™ is a trademark of Enovis Corporation.

Patented: USPN 10,561,501

© 2022 Encore Medical, L.P. All Rights Reserved.

SMR Shoulder System, PRIMA Humeral System, and PRIMA Glenoid System are products owned and manufactured by Limacorporate, S.p.A.







12. Implant Card Instructions

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 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)







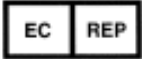






Place a patient implant card label for each implant component used (except for screws) in Sections D of the foldable patient implant card. Also place one patient guidance label on the patient implant card which directs them to the Enovis IFU website. Each foldable implant card contains five Sections D. 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 patient implant card used.







Foldable Patient Implant Card:

D	D	<div> Implant Card <div><div></div><div><u> </u></div><div>A</div></div><div><div></div><div><u> </u></div><div>B</div></div><div><div></div><div><u> </u></div><div>C</div></div><div><u> </u></div><div><u> </u></div><div> Encore Medical, L.P. 9800 Metric Blvd Austin, TX 78758  www.djosurgicalifu.com <small>0400-1117 Rev. C</small></div></div>	D	D	D
---	---	---	---	---	---

Symbol Glossary:

Symbol	Standard Reference	Symbol Title	Explanatory Text
	ISO 15223-1, 5.4.2	Single use - do not re-use	Indicates device is intended for single-use and cannot be re-used.
	ISO 15223-1, 5.1.4	Expiration Date	Followed by text indicating the expiration date.
	ISO 15223-1, 5.3.4	Keep Dry	Indicates that the device should be kept dry.
	ISO 15223-1, 5.1.5	Lot number/Batch Code	Followed by text indicating the Lot or Batch number. Can be used for traceability
	ISO 15223-1, 5.2.1	Sterile	Indicates the medical device is provided sterile.

	ISO 15223-1, 5.2.4	Sterility symbol: R: Sterile Using Irradiation	Indicates the device has been sterilized using an irradiation method, such as gamma.
	ISO 15223-1, 5.2.10	Sterile symbol: H ₂ O ₂ : Sterilized Using Hydro- gen Peroxide Gas Plasma	Indicates a medical device that has been sterilized using vaporized hydrogen peroxide
	ISO 15223-1 5.2.7	Non-sterile	Indicates the medical device is provided non-sterile.
	ISO 15223-1, 5.4.3	\See "Instructions for Use"	Indicates the need for the user to consult the instructions for use. For electronic IFU, the symbol is accompanied by a URL or QR code.
	ISO 15223-1, 5.1.1	Manufacturer	Followed by the name and address of the medical device manufacturer.
	N/A	Quantity of items in package	Indicates the quantity of items in package
	ISO 15223-1, 5.1.2	Authorized Representa- tive in European Com- munity	Indicates the Authorized Representative in EU.
	ISO 15223-1, 5.1.6	Catalog Number	Indicates the manufacturers catalog number so that the device can be identified.
	ISO 15223-1, 5.2.6	Do not resterilize	Indicates that the medical device is not to be resterilized.
	ISO 15223-1, 5.2.8	Do not use if package is damaged.	Indicates that a device should not be used if the package has been damaged or opened and that IFU should be consulted for additional information.
	ASTM F2503-13	MR Safe	Indicates the device poses no known hazards from exposure to any MR environment.
	ASTM F2503-13	MR Conditional	Indicates the device with demonstrated safety in an MR environment, within defined conditions.
	ASTM F2503-13	MRI Unsafe	Indicates the device poses unacceptable risks to patient or staff in an MR environment.

R Only	21 CFR 801.109	Federal Law restricts this device to sale by or on the order of a physician.	Indicates the device is professional use only or prescription.
	ISO 15223-1, 5.1.8	Importer	Indicates the entity importing the device into the locale.
MD	ISO 15223-1, 5.7.7	Medical Device	Indicates the item is a medical device.
	ISO 15223-1, 5.1.11	Country Code of Manufacture - US	Identifies the country of manufacture. "CC" is replaced by the ISO 3166-1 code.
	ISO 15223-1, 5.7.3	Patient Name or Patient ID	Indicates the identification data of the patient.
	ISO 15223-1, 5.7.4	Information Website for Patients	Indicates a website where a patient may obtain additional information on the device.
	ISO 15223-1, 5.7.5	Name and Address of the Implanting Healthcare Institution/Provider	Indicates the address of the health care center or doctor where medical information about the patient may be found.
	ISO 15223-1, 5.7.6	Date of Implantation	Identifies the date that information was entered or a medical procedure took place.

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