

MDSS, Burckhardtstrasse 1
D-30163 Hannover, Germany
Telefon 49 511 6262 8630

0400-0145 Rev. B

E

1. Product Handling

Implants are provided sterile and should always be stored unopened in their respective protective containers. Prior to use, inspect package for damage which may compromise sterility. If packaging has been opened or damaged, contact manufacturer's representative. When unpacking the implant, verify the labeling for correct Ref. No. and size. When removing the implant from its packaging, the relevant aseptic instructions must be observed. Protect prosthesis from contact with objects, which may damage the surface finish. Inspect each implant prior to use for visual damage.

This implant is part of a system and should be used only in combination with other original ENCORE® products belonging to the same system.

2. Product Description and Implant Materials

The ENCORE Reverse® Shoulder Prosthesis System is a semi-constrained total shoulder replacement consisting of humeral stem for cemented application and glenoid components for cementless application. The humeral stem prosthesis is manufactured from titanium alloy (wrought Ti6Al4V per ASTM F136). The glenoid baseplate is manufactured from titanium alloy (wrought Ti6Al4V per ASTM F136) with commercially pure titanium beads (ASTM F67 Grade 2). The glenoid head components are available in CoCr (ASTM F799). All polyethylene humeral components are manufactured from UHMWPE (ASTM F648, ISO Standard 5834/1+2). The humeral socket assembly is manufactured from both titanium alloy (wrought Ti6Al4V per ASTM F136) and UHMWPE (ASTM F648, ISO Standard 5834/1+2).

3. Indications

The Reverse Shoulder Prosthesis is indicated for use in patients with:

- Grossly rotator cuff deficient shoulder joint with severe arthropathy;
- Failed joint replacement with a grossly rotator cuff deficient shoulder joint;
- Evidence of upward displacement of the humeral head with respect to the glenoid;
- Loss of glenohumeral joint space;

Patients must have a functional deltoid muscle.

While Reverse Prosthesis 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.

4. Contraindications

Total joint replacement 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).

5. 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 ENCORE Reverse Shoulder Prosthesis 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, 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.

This shoulder is a semi-constrained device designed to address irreparable rotator cuffs. 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.

The ranges of motion below are based on in-vitro testing. Clinical results may vary based on an individual patient's skeletal and soft tissue makeup. Total arcs of motion achieved may be greater or less than the degrees measured in-vitro since these motions are influenced by other body kinematics.

Range of Motion

Forward Flexion	Adduction	Abduction	External Rotation	Internal Rotation
No Impingement	-9° to 8°	71° to 98°	10° to 30°	26° to 53°

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

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.

6. 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 ENCORE Reverse Prosthesis Shoulder 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.

7. Adverse Effects

1. 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.
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. Implants can loosen or migrate due to trauma or loss of fixation.
7. Infection can lead to failure of the joint replacement.
8. While rare, fatigue fracture of the implant can occur as a result of strenuous activity, improper alignment, or duration of service.
9. Fracture of the humerus can occur while press-fitting (seating) the humeral stem into the prepared humeral canal.
10. Allergic reactions.

Intraoperative and early postoperative complications can include:

- 1) humeral perforation, or fracture;
- 2) humeral 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 shoulder 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) humeral 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.

8. Sterilization

Unless opened or damaged, Encore implants are supplied sterile in multiple pouches or barrier blister trays. Check all packaging for punctures or other damage. If packaging is opened or damaged, contact manufacturer or manufacturer's representative for instructions.

Sterilization of implants is 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. However, should the original sterile package be inadvertently opened or compromised before implantation, the metallic devices may be resterilized prior to use following the guidelines listed below.

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 the implant or component should be avoided. The manufacturer and distributor assume no responsibility for the cleaning and/or resterilization of implants, components, or reusable instruments performed by the individual or hospital.

Encore instruments and instrument cases are generally composed of titanium, stainless steel, aluminum, and/or polymeric materials. The cases may be multi-layered with various inserts to hold surgical instrumentation in place during handling and storage. The inserts may consist of trays, holders, and silicone mats. The instrument cases will allow sterilization of the contents to occur in a steam autoclave utilizing the cleaning, sterilization, and drying cycle that has been validated and listed below. Instrument cases do not provide a sterile barrier and must be used in conjunction with sterilization wrap to maintain sterility. Instruments are provided nonsterile and should be stored in their original packaging until cleaned and sterilized according to the recommended guidelines listed below.

User Resterilization Guidelines for Implants:

Porous coated or non-coated metallic implants or components, which have not been previously used or implanted, can be resterilized using the following steam sterilization cycle. All devices should be disassembled prior to resterilization and care should be taken to protect implant or component from mechanical damage.

WARNING: DO NOT resterilize UHMWPE (ultra-high molecular weight polyethylene) implants, PMMA (polymethylmethacrylate) spacers, HA (hydroxylapatite) coated implants, and ceramic implants.

<u>Steam Resterilization</u> for metallic implants and components ONLY!	Remove from supplied packaging and wrap in protective sterilization wrap according to AAMI / AORN guidelines or place into appropriate case configuration. Pre-Vacuum Autoclave (HI-VAC): 270-272° F (132-134° C), 6-minute exposure time, with 4 pulses and a 5-minute dry time shall achieve a SAL of 10 ⁻⁶ . Gravity Displacement Autoclave: 270-272° F (132-134° C), 30-minute exposure time, with a 30-minute dry time shall achieve a SAL of 10 ⁻⁶ .
---	--

Encore has validated the above steam sterilization cycles and has data on file. Other sterilization cycles may also be suitable, however individuals or hospitals not using the recommended method are advised to validate any alternate method using appropriate laboratory techniques. Proper validation of the autoclave is essential to ensure proper sterilization temperatures and cycle times. **NOTE: Encore does not recommend Flash or Chemical Sterilization.**

User Cleaning and Resterilization Guidelines for Reusable Surgical Instruments:

Keep instruments moist and do not allow blood and/or bodily fluids to dry on the instruments. The decontamination process should begin immediately after completion of the surgical procedure.

All instruments should be positioned to allow sterilant to come in contact with all surfaces. All jointed instruments should be in the open or unlocked position with ratchets not engaged. Instruments composed of more than one part, with sliding pieces, screws, or removable parts should be disassembled, if possible.

- Decontamination:** Saturate the surface completely with full strength disinfectant/cleaner* (e.g. Cavicide) and allow to remain in contact with devices for 5 minutes.
- Pre-Cleaning:** Remove gross contaminants by immersing the devices in room temperature neutral pH enzymatic cleaner* (e.g. Metrizyme) and disassemble instruments, if suitable. Scrub with the appropriate soft bristle brush until visibly clean.
- Washing:** Immerse devices in the ultrasonic washer/cleaner with room temperature neutral pH enzymatic cleaner* (e.g. Metrizyme) and sonicate for 10 minutes. For ultrasonic cleaning follow the manufacturer's specifications for suggested water level and concentration. When using mechanical washers, make sure the instruments are secured in place, and do not touch or overlap.
- Rinsing:** Thoroughly rinse the devices with deionized or distilled water. For example, a minimum of 2 minutes, three (3) times.
- Drying:** Allow devices to air dry a minimum of 20 minutes prior to inspection and sterilization preparation. Instruments must be thoroughly dried to remove residual moisture before they are stored.
- Preparation and Assembly:** After cleaning/disinfection, the disassembled instruments should be reassembled and visually inspected. Check for misalignment, burrs, bent, or fractured tips. Mechanically test the working parts to verify that each instrument functions correctly. Place instruments into appropriate configuration within instrument case and wrap with protective sterilization wrap according to AAMI / AORN guidelines.


* Do not use high acidic (pH <4) or high alkaline (pH >10) products for disinfection or cleaning, since these can corrode metal, cause discoloration or stress fractures. Encore has qualified the above cleaning method with the provided solution examples, for a 3 Spore Log Reduction (SLR). Other cleaning/disinfection methods may also be suitable, however individuals or hospitals not using the recommended method are advised to validate any alternate method using appropriate laboratory techniques.

- Sterilization with a Pre-Vacuum Autoclave (HI-VAC):**
270-272° F (132-134° C), 16-minute exposure time, with 4 pulses and a 30-minute dry time.
Sterilization with a Gravity Displacement Autoclave:
270-272° F (132-134° C), 30-minute exposure time, with a 30-minute dry time.

Encore has validated the above steam sterilization cycles achieve a SAL of 10⁻⁶ with components loosened and has data on file. Other sterilization cycles may also be suitable, however individuals or hospitals not using the recommended method are advised to validate any alternate method using appropriate laboratory techniques. Proper validation of the autoclave is essential to ensure proper sterilization temperatures and cycle times. **NOTE: Encore does not recommend Flash Sterilization within instrument cases or Chemical Sterilization.**

For further information regarding the use of the ENCORE Reverse Shoulder Prosthesis System contact your representative or distributor. ENCORE Reverse Shoulder Prosthesis System is manufactured by ENCORE MEDICAL, L.P. (Made in USA) 9800 Metric Blvd., Austin, TX 78758.

	Single use - do not reuse Nicht wiederverwenden Usage unique- No pas réutiliser No debe utilizarse Non riutilizzare
	Expiration Date Verwendbar bis Datum Date de péremption Fecha de caducidad Data di scadenza
LOT	Lot number Chargen-code Numéro de code du lot Código del lote Codice del lotto
STERILE R	Sterility symbol: R: gamma rad. min.25 kGy Steril-symbol R: Gammastrahlen, mind. 25kGy Symbole de stérilité R rayons gamma, au moins 25kGy Simbolo de esteridad R: rayos al menos 25kGy Simbolo di sterilità R: raggi almeno 25 kGy
non-sterile	Non-sterile symbol: nonsterile Non sterile-Symbol: unsteril Symbole de non stérilité Simbolo de "no esteril": no esterilizado Simbolo di non sterilità: non sterile

Qty.	Quantity of items in package Packungsinhalt in Stück Nombre de produits dans le conditionnement Número de artículos del envase Numero di oggetti contenuti nella confezione
	See "Instructions for Use" Siehe Gebrauchsanweisung Voir "mode d'emploi" Ver "Instrucciones de empleo" Vedi la voce "Istruzioni per l'uso"