Document No. 0400-0317	Rev. A	Pg. 1 of 8	Approvals / Date
Title: INSTRUCTIONS FOR USE – IFU for EMPOWR™ blade stem for the following sterile implant part numbers: 425-91/93-004/021 And the compatible components			DC-25671

Revision	ECO Date	ECO	Summary of Changes
A	SEE AGILE	DC-25671	RELEASE TO REVISION “A”.

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EMPOWR™ blade stem Implant eIFU

0400-0317 Rev. A 2023-04

A printable copy of the eIFU for this device can be located at: www.djosurgicalifus.com. A paper copy can be requested via phone at +1-800-520-8973.

1. Product Handling
Implants are provided sterile and should always be stored unopened in their 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 Number and size. When removing the implant from its packaging, aseptic technique must be observed. Protect implant 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™ products belonging to the same hip system, unless otherwise specified.

2. Product Description and Implant Materials

Fixation Method	Material	Applicable ASTM Standard	Applicable ISO Standard
Cementless	Ti-6Al-4V	ASTM F1472	ISO 5832-3
	CP Ti Porous Coating	ASTM F67	ISO 5832-2

This system is not approved for sale in the European Union (EU).

3. Compatibility Information
The EMPOWR™ blade stem is compatible with all heads and offsets unless specified below:

Stem Size(s) and Offset(s)	Head Offset(s) Restrictions
EMPOWR™ blade stem Size 4 (all offsets)	Cannot be used with heads > +4mm, the safety and performance of these stem and head combinations have not been established.
EMPOWR™ blade stem Coxa Vara offset (all sizes)	Cannot be used with heads > +10.5mm, the safety and performance of these stem and head combinations have not been established.

4. Indications for Use
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; and
- revision procedures where other treatments or devices have failed.

This stem is to be press-fit. This stem is intended for cementless use.

5. Intended Use
The hip joint metal uncemented prosthesis is intended to replace a hip joint. The device is intended 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 intraoperative instability and for whom all other options to constrained acetabular components have been considered.

6. 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;
- 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;
- severe osteoporosis (consider cemented option); and
- deformity or anatomic abnormality of the proximal femur that prevents proper insertion and seating of the femoral stem.

7. Precautions and Warnings
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.

To correctly position the metallic locking ring, surgeons should consult the manufacturer's instructions for appropriate device assembly.

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.

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

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

8. MRI Safety Information
The EMPOWR™ blade stem system has not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of the EMPOWR™ blade stem system in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.

9. 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 EMPOWR™ blade stem 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.

10. 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.

11. 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 EMPOWR™ blade stem implants 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.

Do not resterilize an implant or component. Do not try to clean an implant since standard procedures cannot be relied upon to remove contamination from the implant or component.

Refer to Enovis™ Instrumentation Instructions for Use for instrument information.

12. Trademarks and Patents

EMPOWR™ blade stem is a trademark of Encore® Medical, L.P., Austin, TX 78758 USA or its affiliates.

Symbol Glossary:

Symbol	Standard Reference	Symbol Title
	ISO 15223-1, 5.4.2	Do not re-use
	ISO 15223-1, 5.1.4	Use-by Date
	ISO 15223-1, 5.3.4	Keep Dry
	ISO 15223-1, 5.1.5	Batch Code
	ISO 15223-1, 5.2.1	Sterile
	ISO 15223-1, 5.2.4	Sterilized Using Irradiation
	ISO 15223-1, 5.2.10	Sterilized using vaporized hydrogen peroxide

	ISO 15223-1, 5.2.7	Non-sterile
	ISO 15223-1, 5.4.3	Consult Instructions for Use or Consult Electronic Instructions for Use
	ISO 15223-1, 5.1.1	Manufacturer
QTY	NA	Quantity
EC REP	ISO 15223-1, 5.1.2	Authorized Representative in European Community/European Union
REF	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.
MR	ASTM F2503-13	MR Safe
	ASTM F2503-13	MR Conditional
	ASTM F2503-13	MR Unsafe
℞ Only	21 CFR 801.109	Caution: Federal Law restricts this device to sale by or on the order of a physician.
	ISO 15223-1, 5.1.8	Importer
MD	ISO 15223-1, 5.7.7	Medical Device
	ISO 15223-1, 5.1.11	Country Code of Manufacture

For further information regarding the use of the Enovis™ EMPOWR™ blade stem system, 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)