



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

0400-0104 REV W 2020-07

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 DJO Surgical® 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

DJO Surgical® hip stems can be used with any DJO Surgical® femoral heads for total joint replacement. DJO Surgical® 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.				
Femoral Heads	Cementless	CoCr	ASTM F799 / ASTM 1537	ISO 5832-4
BioloX® <i>delta</i> Ceramic Femoral Head	Cementless	BioloX® <i>delta</i> Ceramic		ISO 6474
BioloX® <i>delta</i> Option Ceramic Femoral Heads BioloX® <i>delta</i> Option Sleeve	Cementless	BioloX® <i>delta</i> Ceramic Ti6Al4V Alloy	ASTM F136 / ASTM F1472	ISO 6474 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 (atracoheral)	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)	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 (atracoheral)	ASTM F648 / ASTM F2565 ASTM F2695	ISO 5834-1 / ISO 5834-2
The Bipolar components are compatible with all hip stems and 22 & 28mm CoCr Femoral Heads listed above.				
Bipolar Liners (Head)	Cementless	CoCr Medical grade UltraHigh Molecular Weight Polyethylene	ASTM F799 / F-1537-07 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 / F-1537-07	ISO 5832-4
The Foundation Hip Offset Sleeve is compatible with the Unipolar Heads and 497-34, 36, 40, 44 Series CoCr Femoral Heads.				
Offset Sleeve	Cementless	Ti6Al4V Alloy	ASTM F136 / ASTM F1472	ISO 5832-3

¹Use only with Empowr Acetabular System

3. Indications (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 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

DJO Surgical® 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.

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 DJO Surgical® 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.

Precautions and Warnings Specific to the Constrained Acetabular Liner

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

United States:

DJO Surgical® hip systems listed in Section 2 of this document have not been evaluated for safety and compatibility in the Magnetic resonance environment. These devices have not been tested for heating, migration, or image artifact in the MR environment. The safety of these DJO Surgical® components in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

EU and ROW:

Non-clinical testing has demonstrated that DJO Surgical®'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, DJO Surgical®'s Total Hip Replacement System is expected to produce a maximum temperature rise of less than 1.5°C 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 DJO Surgical®'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: For the United States, the TaperFill® Hip Stem has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of this DJO Surgical® hip component in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Note: For the European Union, the TaperFill® Hip Stem and EMPOWR Acetabular™ System is considered as MRI unsafe.

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 DJO Surgical® 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, DJO Surgical® 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 DJO Surgical® Instrumentation Instructions for Use.

WARNING: DO NOT resterilize any hip prosthesis distributed by DJO Surgical® (Encore Medical, L.P.) as listed in the following warning if sterile packaging is opened or damaged. Return the implant with respective packaging to DJO Surgical® for inspection and disposition.

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















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








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

11. Trademarks and patents

FOUNDATION®, LINEAR®, Revelation®, TaperFill® and Exprt® are registered trademarks of Encore® Medical, L.P., Austin, TX 78758 USA or its affiliates.

Icon Key:

 ISO 15223-1 5.4.2	<i>Single use – do not reuse</i>
 ISO 15223-1 5.1.4	<i>Expiration Date</i>
 ISO 15223-1 5.3.4	<i>Keep Dry</i>
 ISO 15223-1 5.1.5	<i>Lot number/Batch Code</i>
 ISO 15223-1 5.2.1	<i>Sterile</i>
 ISO 15223-1 5.2.4	<i>Sterility symbol: R: Sterile Using Irradiation</i>
 	<i>Sterile symbol: H₂O₂: Sterilized Using Hydrogen Peroxide Gas Plasma</i>
 ISO 15223-1 5.2.7	<i>Non-sterile</i>
 ISO 15223-1 5.4.3	<i>See "Instructions for Use"</i>
 ISO 15223-1 5.1.1	<i>Manufacturer</i>
 	<i>Quantity of items in package</i>
 ISO 15223-1 5.1.2	<i>Authorized Representative in European Community</i>
 ISO 15223-1 5.1.6	<i>Catalog Number</i>
 ISO 15223-1 5.2.6	<i>Do not resterilize</i>

 ISO 15223-1 5.2.8	<i>Do not use if package is damaged</i>
 ASTM F2503:2013	<i>MR Safe</i>
 ASTM F2503:2013	<i>MR Conditional</i>
 ASTM F2503:2013	<i>MRI Unsafe</i>
Rx 21 CFR 801.109	<i>Federal Law (USA) restricts this device to sale by or on the order of a physician.</i>
	<i>Importer</i>
	<i>Medical Device</i>
	<i>Country Code of Manufacturer – US</i>

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

Document No. 0400-0299	Rev. A	Pg. 1 of 3	Approvals / Date
Title: INSTRUCTIONS FOR USE – IFU Addendum for EMPOWR DUAL MOBILITY™ for the following sterile implant part numbers: 951-01-38D/58K Metal Liner 952-28-38D/58K Poly Bearing			DC-19193

Revision	ECO Date	ECO	Summary of Changes
A	SEE AGILE	DC-19193	RELEASE TO REVISION "A".



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EMPOWR Dual Mobility™ is a modular bearing consisting of an acetabular liner and head intended for use in a Total Hip Arthroplasty (THA) that are compatible with previously cleared acetabular implants from the DJO EMPOWR Acetabular™ system, all DJO Surgical® 28mm femoral heads, and all DJO Surgical® femoral stems.

Product Description and Implant Materials

Component	Fixation Method	Material	Applicable ASTM Standard	Applicable ISO Standard
The EMPOWR Dual Mobility™ system is compatible with the EMPOWR Acetabular™ system listed in 0400-0104.				
The EMPOWR Dual Mobility™ system is compatible with the 28mm femoral heads and all hip stems listed in 0400-0104.				
EMPOWR Dual Mobility™ Metal Liner ¹	Cementless	CoCr Alloy	ASTM F799 / ASTM F1537	ISO 5832-4 / ISO 5834-1
EMPOWR Dual Mobility™ Poly Bearing 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

¹This system is not approved for sale in the European Union (EU).

Indications for Use

EMPOWR Dual Mobility™ Indications:

The EMPOWR Dual Mobility™ bearing is indicated as part of a total hip replacement for patients suffering from pain and dysfunction due to:

- Noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis
- Rheumatoid arthritis
- Correction of functional deformity
- Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable by other techniques
- Revision of previously failed total hip arthroplasty
- Dislocation risks
- To be used for uncemented applications

Contraindications

Joint replacement is contraindicated where there is:

- Infection, sepsis, and osteomyelitis;
- Distant foci of infections which may spread to the implant site;
- Rapid joint destruction, marked bone loss or bone resorption apparent on roentgenogram;
- Vascular insufficiency, muscular atrophy, or neuromuscular disease;
- 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;
- Uncooperative patient or a patient with neuralgic disorders and incapable of following instructions;
- Osteoporosis;
- Metabolic disorders which may impair bone formation;
- Osteomalacia;
- Alcoholism or other addictions;
- Materials sensitivity;
- Loss of ligamentous structures;

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.

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.

MRI Safety Information

The EMPOWR Dual Mobility™ System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the EMPOWR Dual Mobility™ System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Trademarks and Patents

EMPOWR Acetabular™ and EMPOWR Dual Mobility™ are trademarks of DJO Surgical.

See 0400-0104 for additional information (e.g., product handling, intended use, precautions and warnings, adverse effects).