djosurgical®

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

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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 shoulder system, unless otherwise specified.

2. Product Description and Implant Materials

Component	Fixation Method	Material	Applicable ASTM Standard	Applicable ISO Standard
Foundation® Shoulder System				
FOUNDATION® Humeral Stem	Cemented	Ti6Al4V alloy or Cast Titanium Ti6Al4V Titanium Plasma Spray	ASTM F136 / ASTM F1472 ASTM 1580	ISO 5832-3 ISO 5832-3
FOUNDATION® Humeral Head (Neutral and Offset)	Cementless	CoCrMo	ASTM F799	ISO 5832-4
FOUNDATION® Glenoid (Keeled and Pegged)	Cemented	Medical grade UltraHigh Molecular Weight Polyethylene	ASTM F648	ISO 5834-1 / ISO 5834-2
Turon® Shoulder System				
Turon® Shoulder Humeral Stem	Cemented or Cementless	Ti6Al4V alloy Ti6Al4V Titanium Plasma Spray	ASTM F136 / ASTM F1472 ASTM 1580	ISO 5832-3 ISO 5832-3
Turon® Shoulder Humeral Head (Neutral and Offset)	Cementless	CoCrMo	ASTM F799	ISO 5832-4
Turon® Shoulder Humeral Neck	Cementless	CoCrMo	ASTM F799	ISO 5832-4
Turon® Shoulder Glenoid (Keeled and Pegged)	Cemented	Medical grade UltraHigh Molecular Weight Polyethylene	ASTM F648	ISO 5834-1 / ISO 5834-2
Turon® Shoulder Glenoid e+™ (Keeled and Pegged)	Cemented	Medical grade UltraHigh Molecular Weight Polyethylene (Moderately Cross-Linked) Vitamin E UHMWPE (a-tocopheral)	ASTM F648 / ASTM F2565 ASTM F2695	ISO 5834-1 / ISO 5834-2
AltiVate® Anatomic Shoulder System				
AltiVate® Anatomic Shoulder Humeral Stem	Cementless	Ti6Al4V alloy CP Ti Porous Coating	ASTM F1472 ASTM F67	ISO 5832-3 ISO 5832-2
AltiVate® Anatomic Shoulder Humeral Head (Neutral and Offset)	Cementless	CoCrMo	ASTM F1537	ISO 5832-4
AltiVate® Anatomic Shoulder, Humeral Neck	Cementless	CoCrMo	ASTM F1537	ISO 5832-4
AltiVate® Anatomic Shoulder Glenoid	Cemented	Medical grade UltraHigh Molecular Weight Polyethylene	ASTM F648	ISO 5834-1 / ISO 5834-2
AltiVate® Anatomic Shoulder Glenoid e+™	Cemented	Medical grade UltraHigh Molecular Weight Polyethylene (Moderately Cross-Linked) Vitamin E UHMWPE (a-tocopheral)	ASTM F648 / ASTM F2565 ASTM F2695	ISO 5834-1 / ISO 5834-2
AltiVate® Anatomic CS EDGE™ Shoulder System				
AltiVate® Anatomic CS EDGE™ Shoulder Humeral Stem	Cementless	Ti6Al4V alloy CP Ti Porous Coating	ASTM F1472 ASTM F67	ISO 5832-3 ISO 5832-2
AltiVate® Anatomic CS EDGE™ Shoulder Humeral Neck	Cementless	CoCrMo	ASTM F1537	ISO 5832-4
The AltiVate® Anatomic CS EDGE™ Humeral Stem and Neck is compatible with the Turon® Shoulder Neutral Humeral Head and Glenoid and the AltiVate® Anatomic Neutral Humeral Head and Glenoid.				

Component	Fixation Method	Material	Applicable ASTM Standard	Applicable ISO Standard
Humeral Adapters, Conversion Shells and Modules				
RSP® Humeral Stem Adapter[1]	Cementless	Ti6Al4V alloy	ASTM F136 / ASTM F1472	ISO 5832-3
RSP® Monoblock Hemi-Adapter[2] with Retaining Screw	Cementless	CoCrMo Ti6Al4V alloy	ASTM F799 ASTM F136 / ASTM F1472	ISO 5832-4 ISO 5832-3
AltiVate Reverse® Small Hemi-Adapter[3] with Retaining Screw	Cementless	CoCrMo Ti6Al4V alloy	ASTM F1537 ASTM F1472	 ISO 5832-3
Turon® to Reverse® Conversion Shell[4]	Cementless	Ti6Al4V alloy	ASTM F136 / ASTM F1472	ISO 5832-3
AltiVate® Anatomic to Reverse® Conversion Module[5]	Cementless	Ti6Al4V alloy	ASTM F1472	ISO 5832-3

1. The RSP® Humeral Stem Adapter is compatible with Modular RSP® Stems and Foundation Heads.
2. The RSP® Monoblock Hemi-Adapter is compatible with RSP® Monoblock Stems or AltiVate Reverse® Stems and Turon® Shoulder Humeral Heads or AltiVate® Anatomic Humeral Heads.
3. The AltiVate Reverse® Small Hemi-Adapter is compatible with AltiVate Reverse® Small Shell Humeral Stems, Turon® Shoulder Humeral Heads and AltiVate® Anatomic Humeral Heads.
4. The Turon® to Reverse® Conversion Shell is compatible with Turon® Shoulder Humeral Stems and RSP® Socket Inserts and Glenoid System
5. The AltiVate® Anatomic to Reverse® Conversion Module is compatible with AltiVate® Anatomic Shoulder Humeral Stem and RSP® Socket Inserts and Glenoid System

3. Indications

Indications for Foundation® and Turon® Shoulder Systems:

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

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

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

Indications for the AltiVate® Anatomic Shoulder Stem:

AltiVate® Anatomic Total Shoulder Indications:

The AltiVate® Anatomic Shoulder System is indicated as an anatomic shoulder joint replacement for patients suffering from pain and dysfunction due to:

- Non-inflammatory degenerative joint disease including osteoarthritis, avascular necrosis of the natural humeral head and/or glenoid, and post traumatic arthritis
- Rheumatoid and other inflammatory arthritis
- Correction of functional deformity, including fracture malunion
- Humeral head fracture
- Revision of other devices if sufficient bone stock remains

AltiVate® Anatomic Hemi Shoulder Indications:

The AltiVate® Anatomic Shoulder System is a hemiarthroplasty shoulder replacement for patients with a functional deltoid muscle suffering from pain and dysfunction due to:

- Non-inflammatory degenerative joint disease including osteoarthritis, avascular necrosis of the natural humeral head and/or glenoid, and post traumatic arthritis
- Rheumatoid and other inflammatory arthritis
- Correction of functional deformity, including fracture malunion
- Humeral head fracture
- Rotator cuff tear arthropathy
- Revision of other devices if sufficient bone stock remains

The AltiVate® Anatomic to Reverse Conversion Module is indicated for revision surgeries 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 assembled humeral component may be used alone for hemiarthroplasty or combined with the glenoid component for a total shoulder arthroplasty.

Humeral components with a porous coated surface are indicated for either cemented or uncemented applications. Glenoid components are indicated for cemented use only.

Indications for AltiVate® Anatomic CS EDGE™ Shoulder:

The AltiVate® Anatomic CS EDGE™ Shoulder is indicated for severely painful and/or disabled shoulder joint resulting from osteoarthritis or traumatic arthritis.

The humeral components with a porous coated surface are indicated for uncemented (press-fit) applications. Glenoid components are indicated for cemented use only.

Indications for RSP® Humeral Stem Adapters:

The Reverse® Shoulder Prosthesis (RSP®) is indicated for treatment of 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.

During primary surgery, after the humerus is prepared for the RSP® humeral stem (modular and monoblock), if purchase to the glenoid bone is insufficient to bear the load of the glenoid baseplate and alternative glenoid bone reconstruction and/or repair is inadequate, the corresponding RSP® humeral stem adapter can be used to convert the RSP® humeral stem to hemiarthroplasty prosthesis as a salvage procedure. During revision surgery of an RSP® (modular or monoblock), if the glenoid bone stock appears to be insufficient to bear the load of the glenoid baseplate and alternative glenoid bone reconstruction and/or repair is inadequate, the corresponding RSP® humeral stem adapter can be used to convert the RSP® device to hemiarthroplasty prosthesis as a salvage procedure. For modular RSP® stems, the Foundation Shoulder humeral head should be used. For the monoblock stem, the Turon® humeral head should be used.

This stem/adapter construct is not approved for use as a surrogate for traditional hemiarthroplasty or anatomic replacement indications.

Humeral components with a porous coated surface are indicated for uncemented applications. Glenoid components are indicated for cemented use only.

Indications for Turon® to Reverse® Conversion Shell

The Turon® to Reverse® Conversion Shell is indicated for revision surgeries 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 socket shell is only indicated for use with a well fixed Turon Humeral Stem.

4. Intended Use

DJO Surgical® shoulder devices are intended for treatment of patients who are candidates for shoulder arthroplasty per the indications for use. While 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

Foundation® and Turon® Shoulder Systems 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;
- Alcoholism or other addictions;
- Materials sensitivity;
- Loss of ligamentous structures;
- High levels of physical activity (e.g. competitive sports, heavy physical labor).

AltiVate® Anatomic Shoulder Contraindications:

The AltiVate® Anatomic Shoulder is contraindicated where there is:

- Active local or systemic infection;
- 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 sensitivity;
- Loss of ligamentous structures;
- High levels of physical activity (e.g. competitive sports, heavy physical labor)

AltiVate® Anatomic CS EDGE™ Shoulder Contraindications:

The AltiVate® Anatomic CS EDGE™ Shoulder is contraindicated where there is:

- Active local or systemic infection
- Insufficient bone quality which may affect the stability of the implant, including that resulting from skeletal immaturity, osteoporosis, or erosive arthritis
- Muscular, neurological, or vascular deficiencies, which compromise the affected extremity
- Materials allergy and sensitivity

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. Only DJO Surgical® 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.

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

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 FOUNDATION®, Turon® Shoulder, AltiVate® Anatomic, and AltiVate® Anatomic CS EDGE™ 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 Compatibility

United States:

DJO Surgical® shoulder 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 the devices contained in the shoulder systems listed as listed above are MR Conditional. Patients can be scanned safely under the following conditions:

- Static magnetic field of 1.5-Tesla (1.5T) or 3.0-Tesla (3.0T).
- Spatial gradient field of up to:
  - 3,730 G/cm (37.3 T/m) for 1.5T systems.
  - 1,860 G/cm (18.6 T/m) for 3.0T systems.
- Maximum whole body averaged specific absorption rate (SAR) of:
  - 0.6 W/kg for 15 minutes of scanning in Normal Operating Mode at 1.5T.
  - 1.0 W/kg for 15 minutes of scanning in Normal Operating Mode at 3.0T.

3.0T RF heating

In non-clinical testing with body coil excitation, representative devices produced a temperature rise of less than 3.0ºC at a maximum whole body averaged specific absorption rate (SAR) of 1.0 W/kg, as assessed by calorimetry for 15 minutes of scanning in a 3.0T Siemens Trio (MRC20587) MR scanner with SYNGO MR A30 4VA30A software.

1.5T RF heating

In non-clinical testing with body coil excitation, representative devices produced a temperature rise of less than 5.0ºC at a maximum whole body averaged specific absorption rate (SAR) of 0.6 W/kg, as assessed by calorimetry for 15 minutes of scanning in a 1.5T Siemens Espree (MRC30732) MR scanner with SYNGO MR B17 software.

Caution: The RF heating behavior does not scale with static field strength. Devices which do not exhibit detectable heating at one field strength may exhibit high values of localized heating at another field strength.

MR Artifact

In testing using a 3.0T system with spin-echo sequencing, the shape of the image artifact follows the approximate contour of the device and extends radially up to 7.4 cm from the implant.

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."

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;
- periarticular calcification or ossification, with or without impediment to joint mobility;
- 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 packaging is opened or damaged, contact the manufacturer or manufacturer's representative for instructions.

Sterilization of implants, other than the Glenoids manufactured from Moderately 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 Glenoids manufactured from Moderately 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 implants 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 DJO Surgical® Instrumentation Instructions for Use.

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

WARNING: Protect all porous coated and 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), Moderately Cross-Linked Polyethylene Vitamin E (e+™), or HA (hydroxyapatite) coated implants.

DJO Surgical® has validated sterilization cycle data on file.

NOTE: DJO Surgical® does not recommend Flash or Chemical Sterilization.

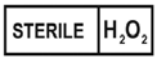
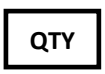
For further information regarding the use of the DJO Surgical® Shoulder Systems, contact your DJO Surgical® representative or distributor.

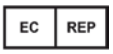
DJO Surgical® Shoulder Systems are manufactured by ENCORE MEDICAL, L.P.
9800 Metric Blvd., Austin, TX 78758 USA (Made in the USA)

11. Trademarks and patents

FOUNDATION®, Turon®, AltiVate®, CS EDGE™, RSP®, Reverse®, and e+™ are trademarks of DJO Surgical®.

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: H2O2: Sterilized Using Hydrogen Peroxide Gas Plasma***
 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.***
	***Importer***
MD	***Medical Device***
	***Country Code of Manufacturer - US***

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