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Title: INSTRUCTIONS FOR USE – DJO SURGICAL ADDENDUM FOR ALTIVATE ANATOMIC™ SHOULDER SYSTEM, STERILE IMPLANTS			Deann Rector	12DEC2016
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Revision	ECO Date	ECO	Summary of Changes
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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
AltiVate Anatomic™ Shoulder Humeral Stem	Cemented or Cementless[1]	Ti6Al4V alloy	ASTM F1472	ISO 5832-3
		CP Ti Porous Coating	ASTM F67	ISO 5832-2
AltiVate Anatomic™ Shoulder Humeral Head	Cemented or Cementless[1]	CoCrMo	ASTM F1537	ISO 5832-4
AltiVate Anatomic™ Shoulder, Humeral Neck	Cementless[1]	CoCrMo	ASTM F1537	ISO 5832-4
AltiVate Anatomic™ Shoulder Glenoid	Cemented	Medical grade UltraHigh Molecular Weight Polyethylene	ASTM F648	ISO 5834-1 & 2
		Highly Cross-Linked Vitamin E UHMWPE	ASTM F2695	

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

3. Indications

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

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 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.

4. Intended Use

Encore Medical 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

Joint replacement 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)

4. 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.

5. 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 AltiVate Anatomic™ 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.

6. 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.

7. MRI Safety

The Altivate Anatomic™ Shoulder 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 Altivate Anatomic™ Shoulder in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

8. Sterilization

Unless opened or damaged, DJO Surgical implants are supplied sterile in multiple pouches. 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 and Highly Cross-Linked Polyethylene with Vitamin E is 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 and Highly Cross-Linked Polyethylene with Vitamin E is 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 by a healthcare facility. 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 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, 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), HA (hydroxylapatite) coated and ceramic implants.

WARNING: Highly Cross-Linked Polyethylene CANNOT be resterilized by a healthcare facility.

WARNING: For revision surgery with a short stem, ensure that subject device has an intact metaphyseal bone for fixation.

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

For further information regarding the use of the DJO Surgical AltiVate Anatomic™ System, 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)

9. Trademarks and patents

AltiVate Anatomic™ is a trademark of DJO Surgical.