



Encore Medical, L.P.
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Austin, TX 78758

0400-0145 REV. M 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 shoulder system, unless otherwise specified.

2. Product Description and Implant Materials

| Component | Fixation Method | Material | Applicable ASTM Standard | Applicable ISO Standard |
|--|-------------------------------------|--|--------------------------------------|--------------------------|
| Reverse® Shoulder Prosthesis (RSP®) Humeral Stems | | | | |
| Reverse® Shoulder Prosthesis (RSP®) Modular Humeral Stem (Primary and Revision) | Cemented | Ti6Al4V alloy | ASTM F136 / ASTM F1472 | ISO 5832-3 |
| RSP® Humeral Socket Shell (for use with Modular Stem) | Cementless | Ti6Al4V alloy | ASTM F136 / F1472 | ISO 5832-3 |
| RSP® Monoblock Humeral Stem (Primary and Revision) | Cemented or Cementless ¹ | Ti6Al4V alloy Ti Plasma Coating | ASTM F136 / ASTM F1472 ASTM F1580 | ISO 5832-3 |
| Altivate Reverse® Humeral Stem (Primary, Short Stem and Revision) | Cemented or Cementless | Ti6Al4V alloy CP Ti Porous Coating | ASTM F1472 ASTM F67 | ISO 5832-3 ISO 5832-2 |
| 1. Cementless use not cleared in the European Union (EU). | | | | |
| Reverse® Shoulder Prosthesis (RSP®) Humeral Inserts | | | | |
| RSP® Humeral Socket Insert (Standard and Semi-Constrained) | Cementless | Medical Grade UltraHigh Molecular Weight Polyethylene | ASTM F648 | ISO 5834-1 / ISO 5834-2 |
| RSP® Humeral Socket Insert e+™ (Standard and Semi-Constrained) | Cementless | Medical Grade UltraHigh Molecular Weight Polyethylene (Highly Cross-Linked) Vitamin E UHMWPE (α-tocopheral) | ASTM F648 / ASTM F2565 ASTM F2695 | ISO 5834-1 / ISO 5834-2 |
| Reverse® Shoulder Prosthesis (RSP®) Humeral Adapters and Spacers | | | | |
| RSP® Humeral Stem Adapter ¹ | Cementless | Ti6Al4V alloy | ASTM F136 / ASTM F1472 | ISO 5832-3 |
| RSP® Monoblock Hemi-Adapter with Retaining Screw ² | Cementless | CoCrMo | ASTM F799 | ISO 5832-4 |
| | | Ti6Al4V alloy | ASTM F136 / ASTM F1472 | ISO 5832-3 |
| RSP® Monoblock Hemi-Adapter Retaining Screw ³ | Cementless | Ti6Al4V alloy | ASTM F136 / ASTM F1472 | ISO 5832-3 |
| RSP® Monoblock Spacer with Retaining Screw ² | Cementless | Ti6Al4V alloy | ASTM F136 / ASTM F1472 | ISO 5832-3 |
| RSP® Monoblock Spacer Retaining Screw ⁴ | Cementless | Ti6Al4V alloy | ASTM F136 / ASTM F1472 | ISO 5832-3 |
| 1. The RSP® Humeral Stem Adapter is for use with Modular Stems and Foundation Heads to convert to a Hemi system. 2. RSP® Monoblock Hemi-Adapter and RSP® Monoblock Spacer are compatible with the RSP® Monoblock and Altivate Reverse® Stems above. The RSP® Monoblock Hemi-Adapter is compatible with Turon® Shoulder Heads and Altivate® Anatomic™ Heads. 3. RSP® Monoblock Hemi-Adapter Retaining Screw is also compatible with the Altivate Reverse® Small Hemi-Adapter. 4. RSP® Monoblock Spacer Retaining Screw is also compatible with the Altivate Reverse® Small Spacer. | | | | |
| Altivate Reverse® Small Shell Humeral System | | | | |
| Altivate Reverse® Small Shell Humeral Stem (Primary, Short Stem and Revision) | Cemented or Cementless | Ti6Al4V alloy | ASTM F1472 | ISO 5832-3 |
| | | CP Ti Porous Coating | ASTM F67 | ISO 5832-2 |
| Altivate Reverse® Small Humeral Socket Insert (Neutral and Semi-Constrained) | Cementless | Medical grade UltraHigh Molecular Weight Polyethylene | ASTM F648 | ISO 5834-1 / ISO 5834-2 |
| Altivate Reverse® Small Humeral Socket Insert e+™ (Neutral | Cementless | Medical grade UltraHigh Molecular Weight | ASTM F648 / ASTM F2565 | ISO 5834-1 / ISO 5834-2 |

| | | | | |
|---|------------|---|--|---|
| and Semi-Constrained) | | Polyethylene (Highly Cross-Linked) Vitamin E UHMWPE (a-tocopheral) | ASTM F2695 | |
| AltiVate Reverse® Small Hemi-Adapter ^{1,2} with Retaining Screw | Cementless | CoCrMo Ti6Al4V alloy | ASTM F1537 ASTM F1472 | ISO 5832-3 |
| AltiVate Reverse® Small Spacer—8mm & 12mm with Retaining Screw ³ | Cementless | Ti6Al4V alloy | ASTM F1472 | ISO 5832-3 |
| 1. The AltiVate Reverse® Small Hemi-Adapter is compatible with Turon® Shoulder Humeral Heads and Allivate® Anatomic™ Heads. 2. RSP® Monoblock Hemi-Adapter Retaining Screw is also compatible with the AltiVate Reverse® Small Hemi-Adapter. 3. RSP® Monoblock Spacer Retaining Screw is also compatible with the AltiVate Reverse® Small Spacer. | | | | |
| Reverse® Shoulder Prosthesis (RSP®) Glenoid System | | | | |
| RSP® Glenoid Head with Retaining Screw | Cementless | CoCrMo Ti6Al4V alloy | ASTM F799 ASTM F136 / ASTM F1472 | ISO 5832-4 ISO 5832-3 |
| RSP® Glenoid Head Retaining Screw | Cementless | Ti6Al4V alloy | ASTM F136 / ASTM F1472 | ISO 5832-3 |
| RSP® Glenoid Baseplate with HA Coating | Cementless | Ti6Al4V alloy CP Ti Porous Coating Hydroxyapatite Coating | ASTM F136 / ASTM F1472 ASTM F67 ASTM F1185 | ISO 5832-3 ISO 5832-2 ISO 13779-1 |
| RSP® Glenoid Baseplate with P ² ™ | Cementless | Ti6Al4V alloy CP Ti Porous Coating | ASTM F136 / ASTM F1472 ASTM F67 | ISO 5832-3 ISO 5832-2 |
| RSP® Glenoid Baseplate Screws (Locking and Non-Locking) | Cementless | Ti6Al4V alloy | ASTM F136 / ASTM F1472 | ISO 5832-3 |
| The RSP® Glenoid system is compatible with all Reverse® Shoulder Humeral systems listed above | | | | |

3. Indications

Indications for RSP® Modular Stem:

The Reverse® Shoulder Prosthesis (RSP®) Humeral Stem and Socket Shell are indicated for use 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 glenoid baseplate is intended for cementless application with the addition of screws for fixation. The humeral stem is intended for cemented use only.

Indications for RSP® Monoblock Stem:

The Reverse® Shoulder Prosthesis Monoblock is indicated for patients with a functional deltoid muscle with a grossly deficient rotator cuff shoulder joint with severe arthropathy or a previously failed joint replacement with a grossly deficient rotator cuff shoulder joint:

In cases of fracture of glenohumeral joint from trauma or pathologic conditions of the shoulder, including humeral head fracture or displaced 3- or 4-part fractures of proximal humerus.

In cases of bone defect in proximal humerus.

The patient's joint must be anatomically and structurally suited to receive the selected implant(s).

The glenoid baseplate is intended for cementless application with the addition of screws for fixation. The humeral stem is intended for cemented or Cementless use (Cementless use not cleared in the EU).

Additional Indications for RSP® Humeral Stem Adapters used with RSP® Modular and RSP® Monoblock:

During primary surgery, after the humerus is prepared for the RSP® humeral stem, if the glenoid bone stock appears "insufficient" to bear the load of the glenoid baseplate, a RSP® humeral stem adapter can be used to convert the RSP® humeral stem to hemiarthroplasty prosthesis. During revision surgery of an RSP®, if the glenoid bone stock appears to be "insufficient" to bear the load of the glenoid baseplate, a RSP® humeral stem adapter is used to convert the RSP® device to hemiarthroplasty prosthesis.

Indications for AltiVate Reverse® Humeral Stem and Small Shell Humeral Stem (Primary, Short Stem and Revision)

Anatomic Total Shoulder Indications:

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

- Noninflammatory degenerative joint disease including osteoarthritis;
- Inflammatory arthritis of the glenohumeral joint including rheumatoid arthritis;
- Post-traumatic arthritis of the glenohumeral joint;
- Avascular necrosis of the humeral head with and without involvement of the glenoid;
- Correction of functional deformity

The all-poly glenoid is intended for cemented use. Reference 0400-0061, IFU Shoulder Systems DJO Surgical for complete Anatomic Head and Glenoid for more information

Hemi Shoulder Indications:

The AltiVate Reverse® Shoulder Prosthesis Stem is indicated as a hemi shoulder joint replacement for patients suffering from pain and dysfunction due to:

- Noninflammatory degenerative joint disease including osteoarthritis;
- Inflammatory arthritis of the glenohumeral joint including rheumatoid arthritis;
- Post-traumatic arthritis of the glenohumeral joint;
- Avascular necrosis of the humeral head with and without involvement of the glenoid;
- Correction of functional deformity;
- Rotator cuff tear arthropathy;
- Humeral fracture.
- Failed previous shoulder surgery

Reverse Total Shoulder Indications:

The AltiVate Reverse® Shoulder Prosthesis Stem is as a reverse shoulder replacement for patients with a functional deltoid muscle and a grossly deficient rotator cuff joint suffering from pain and dysfunction due to:

- Severe arthropathy with a grossly deficient rotator cuff;
- Previously failed joint replacement with a grossly deficient rotator cuff;

- Fracture of glenohumeral joint from trauma or pathologic conditions of the shoulder including humeral head fracture, displaced 3- or 4-part fractures of proximal humerus, or reconstruction after tumor resection;
- Bone defect in proximal humerus;
- Non-inflammatory degenerative disease including osteoarthritis and avascular necrosis of the natural humeral head and/or glenoid;
- Inflammatory arthritis including rheumatoid arthritis;
- Correction of functional deformity.

The glenoid baseplate is intended for cementless application with addition of screws for fixation. This device may also be indicated in the salvage of previously failed surgical attempts for anatomic and hemi procedures

All RSP® Monoblock and Altivate Reverse® humeral stems are intended for cemented or cementless use. (Cementless use of RSP® Monoblock not cleared in the EU).

4. Intended Use

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

Total 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 (metals, etc.) sensitivity;
- Loss of ligamentous structures;
- High levels of physical activity (e.g. competitive sports, heavy physical labor);
- Non-functional deltoid muscle.
- Rotator cuff insufficiency for anatomic shoulder arthroplasty with the Altivate Reverse® humeral stem;
- Intraoperative conversion from a reverse to an anatomic shoulder

Contraindications for the RSP® Humeral Stem Adapters:

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).

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. 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.

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

The ranges of motion below are based on in-vitro testing of the RSP® standard design. 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 for RSP® Standard Design – Stem with attached socket and insert with glenoid head and baseplate:

| 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.

RSP® 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.

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 Reverse® Prosthesis Shoulder 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:
 - o 3,730 G/cm (37.3 T/m) for 1.5T systems.
 - o 1,860 G/cm (18.6 T/m) for 3.0T systems.
- Maximum whole body averaged specific absorption rate (SAR) of:
 - o 0.6 W/kg for 15 minutes of scanning in Normal Operating Mode at 1.5T.
 - o 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 3.0°C 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 5.0°C 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

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.
2. Accelerated wear shortens the useful life of the prosthesis and leads to early revision surgery to replace the worn prosthetic components.
3. Metallosis and osteolysis may be implicated from wear debris associated with the use of orthopedic implants.
4. Peripheral neuropathies have been reported following total joint surgery. Subclinical nerve damage occurs more frequently, possibly the result of surgical trauma.
5. 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.
6. 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.
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 humerus can occur while press-fitting (seating) the humeral stem into the prepared humeral canal.
11. 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) fatigue fracture of the acromion or the scapular spine;
- 6) periarticular calcification or ossification, with or without impediment to joint mobility; and
- 7) 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 Humeral Socket Inserts manufactured from Highly 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 Humeral Socket Inserts manufactured from Highly 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 inserts 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, 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), Highly Cross-Linked Polyethylene Vitamin E (e+™), or HA (hydroxylapatite) 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® Reverse® Shoulder System, contact your DJO Surgical® representative or distributor.

DJO Surgical® Shoulder Systems are manufactured by ENCORE MEDICAL, L.P.







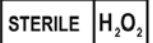
9800 Metric Blvd., Austin, TX 78758 USA (Made in the USA)












11. Trademarks and patents



Reverse®, RSP®, Turon®, Allivate®, e+™, P2™ and AlliVate Reverse® are trademarks of DJO Surgical®.

U.S. patents: 6,679,916; 6,790,234

Icon Key:

| | |
|--|---|
|  ISO 15223-1 5.4.2 | <p style="text-align: center;"><i>Single use – do not reuse</i></p> |
|  ISO 15223-1 5.1.4 | <p style="text-align: center;"><i>Expiration Date</i></p> |
|  ISO 15223-1 5.3.4 | <p style="text-align: center;"><i>Keep Dry</i></p> |
|  ISO 15223-1 5.1.5 | <p style="text-align: center;"><i>Lot number/Batch Code</i></p> |
|  ISO 15223-1 5.2.1 | <p style="text-align: center;"><i>Sterile</i></p> |
|  ISO 15223-1 5.2.4 | <p style="text-align: center;"><i>Sterility symbol: R: Sterile Using Irradiation</i></p> |
|  | <p style="text-align: center;"><i>Sterile symbol: H2O2: Sterilized Using Hydrogen Peroxide Gas Plasma</i></p> |

| | |
|--|--|
|  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> |

| | |
|---|--|
| <p>Rx</p> <p>21 CFR 801.109</p> | <p><i>Federal Law (USA) restricts this device to sale by or on the order of a physician.</i></p> |
|  | <p><i>Importer</i></p> |
| <p>MD</p> | <p><i>Medical Device</i></p> |
|  | <p><i>Country Code of Manufacturer - US</i></p> |

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 |