reverse Total Shoulder Arthroplasty (rTSA) System

INSTRUCTIONS FOR USE

DEVICE DESCRIPTION

The restor3d reverse Total Shoulder Arthroplasty (rTSA) System is a reverse total shoulder prothesis designed for patients with glenoid and/or humeral bone defect and a deficient rotator cuff. The reverse design inverts the articulating surfaces compared to a traditional anatomic shoulder replacement by placing a sphere on the scapular side of a joint and a fixed cup on the humeral side.

The glenoid implant system consists of a baseplate, peripheral fixation screws, and glenosphere. Each baseplate features a porous printed bone-facing surface. The baseplate is additively manufactured from titanium alloy (Ti6AL4V). The baseplate is secured with a central post and peripheral screws (Ti6AL4V). The glenosphere is secured to the baseplate by a taper lock and additional security screw. The glenospheres (Co28Cr6Mo) include a captured security screw (Ti6AL4V).

The humeral implant system consists of a humeral stem and polymer bearing insert. Each humeral stem is a monoblock implant with fins and porous printed portions in the proximal body for stability. The humeral stems are additively manufactured (Ti6AL4V). The humeral polys (HXLPE Vit-E) have a snap-fit connection with the stem. The polys have a concave bearing geometry that radially matches the different sized glenospheres. The polys are offered in varying thicknesses and a spacer tray (Ti6AL4V) is available if needed to achieve stability of the glenohumeral joint.

INDICATIONS FOR USE

The restor3d rTSA System is indicated for use in patients whose shoulder joint has a grossly deficient rotator cuff with severe arthropathy and/or previously failed shoulder joint replacement with a grossly deficient rotator cuff. The patient must be anatomically and structurally suited to receive the implants and a functional deltoid muscle is necessary.

The restor3d rTSA System is indicated for primary, fracture, or revision total shoulder replacement for the relief of pain and significant disability due to gross rotator cuff deficiency.

Glenoid component with porous surface is indicated for uncemented fixation application only. The restor3d rTSA System glenoid baseplate components are intended for cementless application with the addition of screw fixation.

Humeral components with porous surface are indicated for either cemented or uncemented fixation applications.

CONTRAINDICATIONS

- Non-functional deltoid
- Presence of an active infection, sepsis, and/or osteomyelitis.
- Sensitivity or allergy to the metal implant. Where material sensitivity is suspected, appropriate tests should be performed, and sensitivity ruled out prior to implantation.
- In the presence of significant injury to the upper brachial plexus
- Paralysis of the axillary nerve
- Neuromuscular disease (e.g., joint neuropathy)
- Uncooperative patient or patient with neurologic disorders who is incapable or unwilling to follow directions
- Osteoporosis
- Metabolic disorders which may impair bone formation
- Osteomalacia

WARNINGS & PRECAUTIONS

- Enzymatic & cleaning agents with a neutral pH are recommended
- The surgeon must be fully knowledgeable about all aspects of the restor3d rTSA system surgical technique and use these implants in accordance with the indications and contraindications summarized in this IFU. The system is intended for use only with restor3d rTSA system instrumentation, unless generic instrumentation is specified (e.g., power saw) in the surgical technique.
- Only qualified surgeons knowledgeable in anatomy, biomechanics, and reconstructive surgery should utilize the restor3d rTSA system. Proper size selection, placement, positioning, alignment and/or cemented fixation are required to achieve the expected longevity of the implants. The implants must be dry and free of surgical debris to ensure proper connection of components and fixation.
- Implants are for single patient use only
- Avoid scratching, gouging, or notching the prosthesis. Do not use any component that is damaged during implantation.
- Shoulder replacement success is most threatened in patients with a high activity level, are likely to fall, abuse alcohol or drugs, are unable to follow surgeon recommendations and/or lack full skeletal maturity.
- The use of restor3d trials informs proper size selection of implants.
- Ensure all peripheral screws are seated flush with or below the face of the baseplate before implanting the glenosphere
- Do not tighten components with power operated drills
- Impact the glenosphere onto the taper prior to engaging the security screw
- The interference fit of the bearing implant may only be engaged one time. Do not attempt to reinsert a bearing implant that has already been inserted into a humeral implant.
- Improper component size selection, placement, or fixation may result in unusual loading conditions, reducing implant service life.

POSSIBLE ADVERSE EVENTS

The following adverse events have been reported after shoulder replacement surgery:

- Loosening or instability of the components
- Infection
- Osteolysis
- Reaction due to metal sensitivity
- Fracture of the components or the bone
- Wear and damage to articular surfaces
- Adverse events related to the use of bone cement
- Impingement
- Overstuffing of the joint if the incorrect size of prosthesis is used
- Stiffness
- Myositis ossificans
- Ankylosis

Some adverse events may require revision surgery.

In addition, the following adverse events are possible after any shoulder arthroplasty:

- Nerve injury
- Deep vein thrombosis
- Hematoma
- Pneumonia
- Cardiovascular disorders
- Systemic pain

MATERIALS

The restor3d rTSA System components are manufactured from the materials found in the table below, all of which conform to ASTM or ISO standards.

Component	Material	Label Specification
Implant	Titanium Alloy (ASTM F2924 or F136)	Ti6Al4V
Implant	Cobalt Chrome Molybdenum Alloy (ASTM F3213 or F1537)	Co28Cr6Mo
Implant	Ultra High Molecular Weight Polyethylene (with Vitamin E) (ASTM F2695)	HXLPE Vit-E
Instrument	Stainless Steel (ASTM F899 or F138)	SS
Instrument	Biocompatible Polymers	Radiopaque polymer or acrylic polymer

MR SAFETY INFORMATION

The restor3d rTSA System has not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of restor3d rTSA System in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.

CLEANING, HANDLING AND STERILIZATION

Point of Use Processing

To facilitate subsequent cleaning steps, remove excess fluids or tissue from the instruments with a sterile disposable, non-shedding wipe. Keep instruments moist and do not allow blood and/or bodily fluids to dry on the instruments. Instruments should be cleaned within 30 minutes of use to minimize the potential for drying prior to cleaning.

Reusable Instrument & Screws Cleaning- Manual

1. Disassemble relevant instruments per surgical technique guide.
2. Prepare a cleaning bath with an enzymatic detergent at the concentration and temperature specified by the detergent manufacturer.
3. Completely submerge instrument in the enzyme solution for 20 minutes.
4. Thoroughly clean the device. Scrub with soft bristle brush to remove all visible soil. Pay close attention to threads, crevices, seams, and any other hard-to-access areas. Actuate any moving mechanisms to free trapped blood and debris.
5. Remove instruments from the cleaning solution. Rinse with tap water for 3 minutes or until all traces of cleaning solution are removed, whichever is longer. Thoroughly and aggressively flush lumens, holes, and other hard-to-access areas.
6. Prepare an ultrasonic bath with an enzymatic detergent at the concentration and temperature specified by the detergent manufacturer.
7. Completely submerge instruments in ultrasonic cleaner with prepared enzymatic solution. Clean for 10 minutes.
8. Rinse instruments in purified water for 3 minutes or until rinse stream is clean of blood or soil, whichever is longer. Thoroughly and aggressively flush lumens, holes, and other hard-to-access areas.
9. Visually inspect each device for remaining soil. If soil remains, repeat the ultrasonic cleaning process (steps 5-8).
10. Dry instruments immediately after final rinse.

Instruments must be terminally sterilized prior to surgical use. See sterilization instructions.

Reusable Instrument & Screws Cleaning- Automated

Note: fully automated cleaning is not recommended without manual pre-cleaning (steps 1-4).

1. Prepare a cleaning solution with an enzymatic detergent at the concentration and temperature specified by the detergent manufacturer.
2. Completely submerge the instruments in an enzyme solution and allow to soak for 10 minutes.
3. Scrub with soft bristle brush to remove all visible soil. Pay close attention to threads, crevices, seams, and any other hard-to-access areas. Actuate any moving mechanisms to free trapped blood and debris.
4. Remove instruments from the cleaning solution and rinse in purified water for a minimum of 1 minute. Thoroughly and aggressively flush lumens, holes, and other hard-to-access areas.
5. Prior to loading into the automated washer, place instruments into their tray. Washer cycles will be performed with trays open. Remove individual levels from main tray.
6. Operate the washer-disinfector cycle following the minimum parameters described below:

Step	Description	Min Temp	Min Cycle Time
1	Pre-wash	Cold tap water (facility)	2 min
2	Enzyme wash (0.8% cleaning agent) Includes spray, soak & 2 rinses	Hot tap water (facility)	4 min
3	Detergent wash	66°C (150°F)	6 min
4	Hot water rinse	Hot tap water (facility)	15 sec
5	Thermal rinse	88°C (190°F)	6 min
6	Hot air dry	115°C (239°F)	15 min

7. Upon completion, unload the washer-disinfector.
8. Visually inspect each device for remaining soil and dryness. If soil remains, repeat the cleaning process.

Instruments must be terminally sterilized prior to surgical use. See sterilization instructions.

Reusable Instrument Maintenance

Instruments with moveable parts should be checked for proper function. Surgical-grade instrument lubricant suitable for steam sterilization may be applied as needed per the manufacturer's instructions.

Sterile Devices

restor3d implants, instruments, and accessories may be supplied and packaged sterile. The packaging of sterile components is labeled to indicate that the component has been sterilized prior to arrival at the surgical facility. Sterilized products should be stored in a clean, dry location at room temperature and out of direct sunlight. These components should not be used if the date of surgery is beyond the packaging expiration date. Open the sterile barrier using standard aseptic techniques.

DO NOT USE if the sterile barrier appears to be compromised or the package is damaged.

DO NOT re-sterilize components manufactured using HXLPE Vit-E or if the packaging is labeled with the following:

Sterilization:

Non-sterile products should be stored in a clean, dry location at room temperature and out of direct sunlight. Open the packaging using a clean, gloved hand.

DO NOT USE if the packaging appears to be compromised or the package is damaged

Steam Sterilization of Reusable Instruments & Single Use Implants

The minimum recommended steam sterilization conditions for reusable instruments and single use implants are as follows:

1. Double wrap the component in an FDA-cleared CSR wrap or similar non-woven medical grade wrapping material.
2. Autoclave according to the following parameters:

Steam Sterilization		
Cycle Time	Parameter	Minimum Set Point
Pre-vacuum 270°F (132°C)	Exposure Temperature	270°F (132°C)
	Exposure Time	4 minutes
	Dry Time	30 minutes

3. After sterilization, remove the component from its wrapping using accepted sterile technique with powder-free gloves. Ensure that implants are at room temperature prior to implantation. Avoid contact with hard objects that may cause damage. These recommendations are consistent with ANSI/AAMI ST 79 guidelines and have been developed and validated using specific equipment. Due to variations in environment and equipment, it must be demonstrated that these recommendations produce sterility in your environment. If processing conditions, wrapping materials, or equipment changes occur, the effectiveness of the sterilization process must be demonstrated.

TRAINING

Surgeons may obtain training from a qualified instructor prior to implantation of this device to ensure thorough understanding of instrumentation, implantation, and removal techniques. Please contact restor3d Customer Service toll-free in the U.S. at 984-888-0593 or email customerservice@restor3d.com to arrange training with a qualified instructor.

CAUTION

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U.S. law restricts this device to sale by or on the order of a physician.

For symbols glossary, please refer to:
https://www.restor3d.com/resources/instructions-for-use/

Manufacturer: restor3d, Inc.
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Phone: 984-888-0593
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