SHOULDER INNOVATIONS TOTAL SHOULDER SYSTEM INSTRUCTIONS FOR USE

IMPORTANT: The implantation of a joint prosthesis requires knowledge of anatomy, biomechanics, and reconstructive surgery of the musculoskeletal system and may be performed only by a qualified surgeon. The surgeon must operate in accordance with current information on the state of scientific progress and the art of surgery. Patients should be aware of the possible complications that can occur by disregarding the precautions listed below.

Caution: Federal (United States) law restricts this device to sale by or on the order of a physician.

1. Description:
Shoulder Innovation’s (S.I.) Shoulder System is for implantation of a non-constrained glenohumeral prosthesis intended for use as a total or hemi-shoulder replacement. The total shoulder consists of a metal humeral stem, a metal humeral head and an ultrahigh molecular weight polyethylene glenoid. The hemi-shoulder consists of a metal humeral stem and a metal humeral head. It is essential to implant the S.I. Shoulder System prosthesis with the S.I. instrumentation specifically designed for this purpose. S.I. implants must be assembled using S.I. components designed as being compatible with one another. Glenoid components are labelled “for cemented use only” and are indicated only for use with bone cement. Humeral stems are indicated for press-fit un-cemented use or for use with bone cement.

2. Materials:
The material used in the manufacture of the S.I. stem and humeral head is cobalt-chromium alloy (CoCr) according to ASTM standard F1537. The glenoid component is manufactured from ultrahigh molecular weight polyethylene (UHMWPE) according to ASTM standard F648. The instruments are manufactured from stainless steel and polypropylene.

3. Indications:
The Shoulder Innovations Total Shoulder System is intended for use as an orthopedic implant for partial or total shoulder arthroplasty to treat the following:
1. Significant disability in degenerative, rheumatoid, or traumatic disease of the glenohumeral joint;
2. United humeral head fractures of long duration;
3. Irreducible 3- and 4-part proximal humeral fractures;
4. Avascular necrosis of the humeral head.
The assembled humeral component may be used alone for hemiarthroplasty or combined with the glenoid component for total shoulder arthroplasty. The Total Shoulder System components are intended for single use only. The glenoid component is intended for cemented fixation only; the humeral stem may be implanted by press-fit or cement fixation.

4. Contraindications:
Absolute contraindications include infection, sepsis, and osteomyelitis. Relative contraindications include: 1) uncooperative patient or patient with neurologic disorders who are incapable of following directions, 2) osteoporosis, 3) metabolic disorders which may impair bone formation, 4) osteomalacia, 5) distant foci of infections which may spread to the implant site, 6) rapid joint destruction, marked bone loss or disorders which may impair bone formation, 4) osteomalacia, 5) dislocation and subluxation due to inadequate fixation and improper positioning, 9) fatigue fracture of component can occur as a result of loss of fixation, strenuous activity, malalignment, trauma, non-union, or excessive weight. 10) Fretting and crevice corrosion can occur at interfaces between components. 11) Wear and/or deformation of articulating surfaces. 12) Accelerated wear of glenoid articular cartilage. 13) Intraoperative or postoperative bone fracture and/or postoperative pain.

6. Warnings:
The functional life expectancy has not been determined for this device.

CAUTION: FEDERAL LAW (USA) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

Improper selection, placement, positioning, alignment and fixation of the implant components may result in unusual stress conditions which may lead to subsequent reduction of the service life of the implants. Mis-alignment of the component or inaccurate implantation can lead to excessive wear and/or failure of the implants or procedure. Inadequate preclosure cleaning (removal of surgical debris) can lead to excessive wear. Use clean gloves when handling implants. Improper preoperative or intraoperative implant handling or damage (scratches, dents, etc.) can lead to crevice corrosion, fretting, fatigue fracture and/or excessive wear. Do not modify implants. The surgeon is to be thoroughly familiar with the implants and instruments, prior to performing surgery.

The Shoulder Innovations Total Shoulder System provides the surgeon with a means of reducing pain and restoring function for many patients. While these devices are generally successful in attaining these goals, they cannot be expected to withstand the activity levels and loads of normal healthy bone and joint tissue.

Accepted practices in postoperative care are important. Failure of the patient to follow postoperative care instructions involving rehabilitation can compromise the success of the procedure. The patient is to be advised of the limitations of the reconstruction and the need for protection of the implants from full load bearing until adequate fixation and healing have occurred. Excessive activity, trauma and excessive weight and excessive weight bearing have been implicated with premature failure of the implant by loosening, fracture, and/or wear. Loosening of the implants can result in increased production of wear particles, as well as accelerate damage to bone making successful revision surgery more difficult. The patient is to be made aware and warned of general surgical risks, possible adverse effects as listed, and to follow the instructions of the treating physician including follow-up visits.

The Shoulder Innovations’ Total Shoulder System Implants have not been evaluated for safety and compatibility in the MR environment. The Shoulder Innovations’ Total Shoulder System Implants have not been tested for heating or migration in the MR environment.

7) Precautions:
Specialized instruments are designed for Shoulder Innovations Total Shoulder System to aid in the accurate implantation of the implants. The use of instruments from other systems can result in inaccurate fit, sizing, excessive wear and device failure. Intraoperative fracture or breaking of instruments have been reported. Shoulder Innovations’ instruments are subject to wear with normal usage. Instruments, which have experienced extensive use or excessive force, are susceptible to fracture. Surgical instruments should only be used for their intended purpose. Shoulder Innovations recommends that all instruments be regularly inspected for wear and disfigurement.

Do not reuse implants. Implants are single use only. While an implant may appear undamaged, previous stress may have created imperfections that would reduce the service life of the implant. Do not treat patients with implants that have been, even momentarily, placed in a different patient.

Do not implant trials.
Do not modify the implant.
Do not use any implant from a previously opened or damaged package.
Do not use implants after expiration date or use by date.

8. Surgical process:

- Pre-operatively:
  - The surgeon must be fully conversant with all the aspects of the surgical technique and know the indications and contraindications of this type of implant. The surgeon must have acquainted himself before the operation with the specific operative technique of the product which is available from the manufacturer. As part of the pre-operative examination, the surgeon must check that no biological, biomechanical or other factors are present that will affect the correct conduct of the operation and the postoperative period. An appropriate range of sizes must be available at the time of the operation. Check that the implant package has not suffered from any deterioration.
  - Per-operatively:
    - The correct selection of the type and size of the implant appropriate to the patient and the position of the implant are extremely important. Handle the implant using proper aseptic technique including the use of sterile surgical gloves. The functional...
surfaces of the implant must not suffer any damage, abrasion or other deterioration. Before closing the incision, clean out all ectopic bone, extraneous cement and bone chips as debris left in the site may cause dislocation, pain, restricted movement or pre-mature wear.

- Post-operatively:
  - Patients should be informed about the precautions they must take in everyday life to help maximize the service life of the implant. It is recommended that a regular postoperative follow-up be undertaken to detect early signs of wear, loosening of the prosthesis, etc., and to consider the action to be taken. Normal wear of the implant according to the state of knowledge at the time of its design cannot in any way be considered to constitute a dysfunction or deterioration in the characteristics of the implant. A suitable rehabilitation program must be designed and implemented.

9. Storage and handling:
The prosthetic components must be handled and stored in accordance with the provisions of the ISO standard 8828. The implant must be stored in their sealed packaging of origin.

10. Implant Packaging and Sterilization:
The implants are individually packaged and supplied sterile. All metal implants have been sterilized by gamma irradiation. All polyethylene implants have been sterilized using Ethylene Oxide sterilization. The expiration date for sterilization must be checked. Only those products implanted before the end of the expiration date may be considered sterile. The packaging and labelling must be checked for integrity. Reject any implant if the packaging is damaged. Every precaution must be taken to ensure sterility when opening the packaging of the implant and when inserting it. Never re-sterilize an implant.

11) Instrumentation Description
The S.I. Total Shoulder System instrumentation is made up of the manual instruments and the case and tray. The instrumentation has been specifically designed to facilitate the implantation of the S.I. shoulder system implants. For a more detailed description, please refer to the S.I. Total Shoulder System Surgical Technique.

12) Instrumentation Delivered Non-Sterile
Instruments are provided non-sterile and must be sterilized prior to use.

13) Instrumentation Sterilization
Instruments are to be sterilized with steam sterilization at a temperature not to exceed 140°C. Consult your sterilization equipment manufacturer’s instructions for the specific sterilizer and load configuration to be used and your internal sterilization procedures. Flash sterilization of the instrumentation is not recommended.

<table>
<thead>
<tr>
<th>Type of Sterilization</th>
<th>Temperature</th>
<th>Exposure Time</th>
<th>Dry Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-Vacuum Steam-Wrapped</td>
<td>270°F-275°F (132°C-135°C)</td>
<td>4 minutes</td>
<td>30 minutes vacuum</td>
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- Pre-Vacuum Steam-Wrapped:...

- Perform a final rinse using DI or purified water for a minimum of 15 sec...

- Use by or on the order of a physician

- Sale by or on the order of a physician

- Consult Instructions For Use

- Sterilized Using Ethylene Oxide

- Sterilized by Irradiation

- Single Use Only

- Do Not Use If Package Damaged

- Do not resterilize

- Catalog Number

- Manufacturer:
  - Shoulder Innovations LLC
  - 13827 Port Sheldon St.
  - Holland, MI 49426
  - Phone: 616-294-1026
  - Fax: 877-989-7335
  - IFU #: 2016-01 Rev. A

- Rx only

- Manufactured by

- Sterilized immediately by telephone, fax, or written correspondence. When filing a complaint, please include the component(s) name and reference number, lot number, your name and address, and the nature of the complaint.

- Any dissatisfaction with the product quality, labeling, or performance should be reported to Shoulder Innovations immediately. Further, if any of the implants or instruments “malfunction” (i.e. does not perform as intended), or is suspected of doing so and may have caused or contributed to the death or serious injury of a patient, Shoulder Innovations should be notified immediately by telephone, fax, or written correspondence.

- Patient, Shoulder Innovations should be not...