SHOULDER INNOVATIONS TOTAL SHOULDER SYSTEM WITH HUMERAL STEMLESS 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.

1. Description:
Shoulder Innovations' (S.I.) Total Shoulder System with Humeral Stemless is for implantation of a semi-constrained glenohumeral prosthesis intended for use as a total shoulder replacement. The total shoulder consists of a metal humeral stemless component, a metal humeral head and an ultrahigh molecular weight polyethylene glenoid. 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 defined as being compatible with one another. Glenoid components are labelled "for cemented use only" and are indicated only for use with bone cement. Humeral stemless components are indicated for press fit un-cemented use.

2. Materials:
The material used in the manufacture of the S.I. humeral stemless component is titanium alloy according to ASTM F136 which has a proximal porous coating of commercially pure titanium according to ASTM F67. The humeral head is manufactured from cobalt-chromium alloy (CoCr) according to ASTM standard F1537. The glenoid component is manufactured from ultrahigh molecular weight polyethylene (UHMWPE) according to ASTM F648. The instruments are manufactured from stainless steel, polyphenylsulfone and acetal copolymer.

3. Indications:
The Shoulder Innovations Total Shoulder System with Humeral Stemless is intended for use as an orthopedic implant for total shoulder arthroplasty to treat severely painful and/or disabled joint resulting from osteoarthritis or traumatic arthritis.

The S.I. Total Shoulder System with Humeral Stemless components are intended for single use only.

The Humeral Stemless components are indicated for press-fit, un-cemented use.

The glenoid component is intended for cemented fixation only.

4. Contraindications:
The S.I. Total Shoulder System with Humeral Stemless is contraindicated in the following situations:
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 or erosive arthritis,
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 bone resorption apparent on roentgenogram
7) lack of quality bone to seat and support the implant, including that resulting from skeletal immaturity
8) metal allergies or sensitivity
9) infection at or near the site of implantation
10) glenohumeral instability
11) rotator cuff insufficiency (subscapularis, supraspinatus, or infraspinatus).

5. Possible Adverse Events:
1) Material sensitivity reactions. Implantation of foreign material in tissues can result in histological reactions involving various sizes of 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. Particulate wear debris and discoloration from metallic and polyethylene components of joint implants may be present in adjacent tissue or fluid. It has been reported that wear debris may initiate a cellular response resulting in osteolysis or osteolysis may be a result of loosening of the implant.
2) Early or late postoperative, infection, and allergic reaction.
3) Intraoperative bone perforation or fracture may occur, particularly in the presence of poor bone stock caused by osteoporosis, bone defects from previous surgery, or while inserting the device.
4) Loosening or migration of the implant can occur due to loss of fixation, trauma, malalignment, bone resorption, excessive activity.
5) Periarticular calcification or ossification, with or without impediment of joint mobility.
6) Inadequate range of motion due to improper selection or positioning of components.
7) Undesirable shortening of limb.
8) Dislocation and subluxation due to inadequate fixation and improper positioning. Muscle and fibrous tissue laxity can also contribute to these conditions.
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 S.I. Total Shoulder System with Humeral Stemless 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 S.I. Total Shoulder 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 the S.I. Total Shoulder 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.

7. Precautions:
Specialized instruments are designed for S.I. 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. Surgical 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 implants 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 with Humeral Stemless Surgical Technique.

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

13. Instrumentation Sterilization:
The sterilization parameters identified in this section require the use of an FDA cleared wrap. The components are to be wrapped using an FDA cleared wrap prior to performing steam sterilization. Instruments are to be sterilized with steam sterilization at a temperature not to exceed 140^{o}C. Consult your sterilization equipment manufacturer's instructions for the specific sterilizer and load configuration to be used and your internal sterilization procedures. The following sterilization parameters are recommended for the S.I. instrumentation including the case and tray. After sterilization, the wrapped instrumentation shall be handled with care to the point of use to prevent any disruption of the sterile barrier.

Type of Sterilization	Temperature	Exposure Time	Dry Time
Pre-Vacuum Steam- Wrapped	270^{o}F (132^{o}C)	4 minutes	30 minutes vacuum

Flash sterilization of the instrumentation is not recommended.

14. Pre-Disinfection of Instrumentation:
Instrumentation should be reprocessed as soon as possible after use. If device is able to be disassembled, disassemble prior to cleaning. Devices with lumens/cannula should be manually processed prior to cleaning. Clear lumen/cannula of any debris by brushing thoroughly using an appropriately sized, tight fitting, soft-bristle brush with a twisting action. Using a brush that is too large or small for the diameter of the lumen/cannula may result in an inadequately cleaned surface. After brushing, blow clean, compressed air through lumen/cannula to clear debris. Use a firm bristle brush for cleaning bone-cutting features such as drill tips and reamer flutes and teeth. Soak soiled devices using a neutral pH enzymatic soak or detergent prior to cleaning to loosen debris. Follow the enzymatic cleaner or detergent manufacturers' instructions for correct exposure time, water quality, and concentration. Rinse with cold tap water for two minutes.

15. Cleaning of Instrumentation:
Manual cleaning is recommended for the cleaning of the S.I. instrument set. Automated washing systems are not recommended as the only cleaning method for the S.I. instruments.

1) Disassemble all instrumentation prior to cleaning.
2) Rinse soiled device under cold running tap water for a minimum of two minutes. Use soft bristled brush to assist in the removal of gross debris.
3) Soak the device for a minimum of fifteen minutes in a neutral pH enzymatic cleaner or detergent solution. Follow the enzymatic cleaner or detergent manufacturer's instructions for correct exposure time, water quality, and concentration.
4) Rinse device under cold running water for a minimum of two minutes using syringe, pipette, or water jet to clear lumens/cannulas and other hard to clean areas.
5) Manually clean device for a minimum of five minutes in a freshly prepared neutral pH enzymatic cleaner or detergent solution. Scrub interfaces several times using a twisting action. If device can be retracted or moved, retract or open the part in order to access and clean these areas. Scrub the inside of lumens/cannulas of any debris by brushing thoroughly using an appropriately sized, tight fitting soft-bristle brush with a twisting action. Using a brush that is too large or small for the diameter of the lumen/cannula may result in an inadequately cleaned surface. Use a firm bristle brush for cleaning bone-cutting features such as drill tips and reamer flutes and teeth.
6) Rinse device thoroughly with deionized (DI) or purified water for a minimum of two minutes. Make sure to irrigate the hard to access areas of the device. If the device can be retracted or moved, it is necessary to retract or open the part for thorough rinsing at these areas. Blind holes should be repeatedly filled and emptied.
7) Visually inspect the device under normal lighting for cleanliness. For hard to access areas of the device, apply a 3% hydrogen peroxide solution. Bubbling indicates the presence of blood and debris. If contamination is present, repeat steps 1 through 7 and reinspect.
8) Prepare an ultrasonic bath with a fresh cleaning solution using a neutral pH enzymatic cleaner or detergent solution at the concentration and temperature recommended by the detergent manufacturer.
9) Immerse device completely in the bath and ultrasonically clean for a minimum of 15 minutes using a minimum frequency of 40 kHz.
10) Perform a final rinse using DI or purified water for a minimum of two minutes. If device can be retracted or moved, retract or open the part in order to rinse thoroughly under running water.
11) Visually inspect the device under normal lighting for cleanliness. For hard to access areas of the device, apply a 3% hydrogen peroxide solution. Bubbling indicates the presence of blood and debris. If contamination is present, repeat steps 1 through 10 and reinspect.
12) Perform a final rinse using DI or purified water for a minimum of 2 minutes.
13) Dry the device using a clean, lint-free cloth or clean compressed air.
14) Return dry instrumentation to correct location in the case or tray, areas designated for specific devices shall contain only the devices intended for those areas.

16. **Storage, Handling and Transportation of Instrumentation:**
Instrumentation must be stored and handled with care. Storage must be in a dry, clean location protected from pests and extremes of temperature and humidity. The instruments must not be stored in contact with or near products which may have a corrosive effect. . It is the responsibility of the end-user to ensure devices, once sterilized, are stored in such a way as to maintain the sterility of the instrumentation until use. The instruments are supplied in designated cases and trays to ensure the instrumentation is kept in a way they do not receive any damage, and their functionality is preserved during transportation. To prevent mechanical damage during transport to the processing area after use, do not mix heavy devices with delicate ones. Transport reusable instrumentation to the processing area as soon as possible after use. When transporting instrumentation, it should be handled with care to ensure that it is not dropped, tossed about, thrown or experiences any impaction loading.

17. Product Complaints:
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. 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.

18. Symbols Glossary

Symbol	Title of Symbol	ISO 15223-1 Ref No.
	Catalog Number	5.1.6
	Batch Code	5.1.5
	Manufacturer	5.1.1
	Date of Manufacture	5.1.3
	Use By Date	5.1.4
	Sterilized using ethylene oxide	5.2.3
	Sterilized using irradiation	5.2.4
	Do not re-sterilize	5.2.6
	Do not use if package is damaged	5.2.8
	Do not re-use	5.4.2
	Consult instructions for use	5.4.3
	Caution	5.4.4
	Double sterile barrier system	5.2.1.2
	Keep dry	5.3.4
	Medical device	5.7.7
Rx only	Sale by or on the order of a physician	

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