



TOTAL SHOULDER SYSTEM

150813-0

The following languages are included in this packet:

English (en)	Deutsch (de)	Nederlands (nl)	Français (fr)
Español (es)	Italiano (it)	Português (pt)	中文- Chinese (sch)
Türkçe (tk)			

For additional languages, visit our website www.wmt.com

Then click on the **Prescribing Information** option.

For additional information and translations please contact the manufacturer or local distributor.



0086

Wright Medical Technology, Inc.
1023 Cherry Road
Memphis, TN 38117
U.S.A.

EC REP

Wright Medical UK Ltd.
3rd Avenue
Letchworth
Hertfordshire, SG6 2JF
UK



R ONLY

October 2013
Printed in U.S.A

Attention Operating Surgeon
IMPORTANT MEDICAL INFORMATION
TOTAL SHOULDER SYSTEM
(150813-0)

OUTLINE:**GENERAL PRODUCT INFORMATION**

- A. INDICATIONS
- B. CONTRAINDICATIONS
- C. POTENTIAL COMPLICATIONS & ADVERSE REACTIONS
- D. PRECAUTIONS
- E. HANDLING & STERILIZATION
- F. STORAGE CONDITIONS

GENERAL PRODUCT INFORMATION

Through the advancement of partial and total joint replacement, the surgeon has been provided with a means of restoring mobility, correcting deformity, and reducing pain for many patients. While the prostheses used are largely successful in attaining these goals, it must be recognized that they are manufactured from a variety of materials and that any joint replacement system, therefore, cannot be expected to withstand activity levels and loads as would normal healthy bone. In addition, the system, including the implant/bone interface, will not be as strong, reliable, or durable as a natural human joint.

In using total joint prostheses, the surgeon should be aware of the following:

- **The correct selection of the prosthesis is extremely important.** The potential for success in total joint replacement is increased by selection of the proper size, shape, and design of the prosthesis. Total joint prostheses require careful seating and adequate bone support. Smaller sized implants are intended for patients with small bone and normally slight weight. Such components could be inappropriate for other patients. Surgeons are encouraged to use their best medical judgment when choosing the proper implant size regardless of the endosteal area of the bone.
- **Improper selection, placement, positioning, and fixation** of the prosthetic components may result in unusual stress conditions and a subsequent reduction in service life of the prosthetic component. The surgeon is to be thoroughly familiar with the implant, instruments, and surgical procedure prior to performing surgery. Periodic, long-term follow-up is recommended to monitor the position and state of the prosthetic components, as well as the condition of the adjoining bone.
- **In selecting patients for total joint replacements, the following factors can be critical to the eventual success of the procedure:**
 1. **Patient's occupation or activity.** If the patient is involved in an occupation or activity, which includes substantial walking, running, lifting, or muscle strain, the resultant forces can cause failure of the fixation or the device, or both. The prosthesis will not restore function to the level expected with normal healthy bone, and the patient should not have unrealistic functional expectations.
 2. **Condition of senility, mental illness, or alcoholism.** These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the prosthesis, leading to failure or other complications.

3. **Foreign body sensitivity.** Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.

A. INDICATIONS

Total shoulder system is indicated for use in shoulder arthroplasty for reduction or relief of pain and / or improved shoulder function in skeletally mature patients with sufficient and satisfactory bone stock to support the prosthesis with the following conditions:

- 1) Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
- 2) Rheumatoid arthritis or post-traumatic arthritis;
- 3) Revision where other devices or treatments have failed;
- 4) Correction of functional deformity;
- 5) Treatment of acute fracture of the humeral head unmanageable using other treatment methods; and
- 6) Cuff tear arthroplasty.

Hemi-shoulder replacement is also indicated for:

- 1) Displaced humeral head fractures; and
- 2) Avascular necrosis of the humeral head.

B. CONTRAINDICATIONS

Absolute contraindications include:

- 1) overt infection;
- 2) distant foci of infections (which may cause hematogenous spread to the implant site);
- 3) rapid disease progression as manifested by joint destruction or bone absorption apparent on roentgenogram;
- 4) skeletally immature patients; and
- 5) cases where there is inadequate neuromuscular status (e.g., prior paralysis, fusion and/ or inadequate abductor strength), poor bone stock, poor skin coverage around the joint which would make the procedure unjustifiable.

Conditions presenting increased risk of failure include:

- 1) uncooperative patient or patient with neurologic disorders, incapable of following instructions;
- 2) marked bone loss, severe osteoporosis, or revision procedures for which an adequate fit of the prosthesis cannot be achieved;
- 3) metabolic disorders that may impair bone formation;
- 4) osteomalacia; and
- 5) poor prognosis for good wound healing (e.g., decubitus ulcer, end-stage diabetes, severe protein deficiency and/or malnutrition).

C. POTENTIAL COMPLICATIONS & ADVERSE REACTIONS

In any surgical procedure, the potential for complications exists. The risks and complications with implants include:

1. Infection or painful, swollen or inflamed implant site

2. Fracture of the implant
3. Loosening or dislocation of the prosthesis requiring revision surgery
4. Bone restoration or over-production
5. Allergic reaction(s) to prosthesis material(s)
6. Untoward histological responses possibly involving macrophages and/or fibroblasts
7. Migration of particle wear debris possibly resulting in a bodily response
8. Embolism

Proper surgical procedures and techniques are the responsibility of the medical professional. Each surgeon must evaluate the appropriateness of the procedure based on personal medical training and experience. Although Wright Medical cannot recommend a particular surgical technique suitable for all patients, a detailed surgical technique is available for surgeon reference. Medical procedures for optimal utilization of the prosthesis should be determined by the physician. However, the physician is advised that there is recent evidence that the potential for deep sepsis following total joint arthroplasty may be reduced by:

1. Consistent use of prophylactic antibiotics.
2. Utilizing a laminar flow clean air system.
3. Having all operating room personnel, including observers, properly attired.
4. Protecting instruments from airborne contamination.
5. Impermeable draping.

Materials: Shoulder system components are manufactured from a variety of materials, which include titanium alloy, cobalt-chromium-molybdenum alloy, and ultra high molecular weight polyethylene (UHMWPE), all of which conform to ASTM or ISO standards and internal standards.

Warning: The following combinations of materials in ARTICULATING surfaces are inappropriate:

- Stainless steel /titanium alloy
- Stainless steel /stainless steel
- Stainless steel/ unalloyed titanium
- Stainless steel (ISO 5832-1) /cobalt chrome alloy
- Unalloyed titanium/unalloyed titanium
- Unalloyed titanium/titanium alloy
- Unalloyed titanium/cobalt chrome alloy
- Unalloyed titanium/ultra high molecular weight polyethylene
- Titanium alloy/cobalt chrome alloy
- Titanium alloy/ultra high molecular weight polyethylene
- Zirconia ceramics / Alumina ceramics

Warning: The following combinations of metals in NON-ARTICULATING contact surfaces are inappropriate:

- Stainless steel (excluding the stainless steel described in ISO 5832-9) /cobalt chrome alloy
- Stainless steel (excluding the stainless steel described ISO 5832-9) / unalloyed titanium.

Modular Head and Stem: The modular head component must be firmly seated on to the taper of the stem to prevent disassociation. Modular heads and stem components must be from the same manufacturer to prevent mismatch of tapers. Scratching of modular heads and

tapers should be avoided. Repeated assembly and disassembly of the head component to the stem could compromise the locking action of the taper. The head/stem component should be changed only when clinically necessary. The neck taper of the stem as well as the taper of the head **must** be clean and dry before assembly. Do not resterilize the modular head while it is seated on the stem.

Glenoid: Glenoids and modular heads must be from the same implant system and manufacturer to assure compatible component articulation.

Cemented Application. Care is to be taken to ensure complete support of all components of the prosthesis embedded in bone cement to prevent stress concentrations that may lead to failure of the procedure. Complete cleaning including complete removal of bone chips, bone cement fragments, and metallic debris, prior to closure of the prosthetic site is critical to prevent accelerated wear of the articular surfaces of the prosthesis.

Non-Cemented Application. Adequate fixation at the time of surgery is critical to the success of the procedure. The intramedullary stem component must press fit into the prepared canal, which necessitates precise operative technique and the use of specified instruments. Intraoperative fracture of the canal can occur during seating of the prosthesis. Bone stock must be adequate to support the device.

D. PRECAUTIONS

Following the instructions for use provided in product literature can minimize the potential for complications or adverse reactions with any implant.

It is the responsibility of each surgeon using implants to consider the clinical and medical status of each patient and to be knowledgeable about all aspects of implant procedure and the potential complications that may occur. The benefits derived from implant surgery may not meet the patient's expectations or may deteriorate with time, necessitating revision surgery to replace the implant or to carry out alternative procedures. Revision surgeries with implants are common. The patient's mental status must also be considered. Willingness and/or ability to follow post-operative instructions may also impact the surgical outcome. Surgeons must balance many considerations to achieve the best result in individual patients.

IF EXCESSIVE LOADING CANNOT BE PREVENTED, AN IMPLANT SHOULD NOT BE USED.

One of the goals of implant surgery is to minimize production of wear particles. Wear particles can never be eliminated because of all the moving parts, e.g., implants that articulate against bone will wear to some degree. In an implant arthroplasty, clinically significant wear can result from normal biomechanical forces. Abnormal or excessive force will further increase clinically significant wear.

Abnormal force loading and subsequent wear may be caused by:

1. Uncorrected instability
2. Improperly sized implant
3. Inadequate soft tissue support
4. Implant malposition
5. Excessive motion
6. Uncorrected or recurrent deformity
7. Patient misuse or overactivity
8. Intra-operative fixation

Some preventative measures to consider to minimize the potential for complications:

1. Follow guidelines for indications and contraindications provided above
2. Identify prior pathology

3. Stabilize collapse deformities
4. Bone graft pre-existing cysts
5. Use a properly sized implant

If complications develop, possible corrective procedures include:

1. Implant removal
2. Synovectomy
3. Bone grafting of cysts
4. Replacement of the implant
5. Removal of the implant with fusion of the joint

Clinical results depend on surgeon and technique, pre-operative and post-operative care, the implant, patient pathology and daily activity. It is important that surgeons obtain appropriate informed consent and discuss the potential for complications with each patient prior to surgery. This may include a review of alternative, non-implant procedures such as soft tissue reconstruction or arthrodesis.

Recommendations Regarding Device Fragments

1. Use medical devices in accordance with their labeled indications and the manufacturer's instructions for use, especially during insertion and removal.
2. Inspect devices **prior to use** for damage during shipment or storage or any out-of-box defects that might increase the likelihood of fragmentation during a procedure.
3. Inspect devices **immediately upon removal from the patient** for any signs of breakage or fragmentation.
4. If the device is damaged, retain it to assist with the manufacturer's analysis of the event.
5. Carefully consider and discuss with the patient (if possible) the risks and benefits of retrieving vs. leaving the fragment in the patient.
6. Advise the patient of the nature and safety of unretrieved device fragments including the following information:
 - a. The material composition of the fragment (if known);
 - b. The size of the fragment (if known);
 - c. The location of the fragment;
 - d. The potential mechanisms for injury, e.g., migration, infection;
 - e. Procedures or treatments that should be avoided such as MRI exams in the case of metallic fragments. This may help to reduce the possibility of a serious injury from the fragment.

Concerning Magnetic Resonance Environments

The devices described in this package insert have not been evaluated for safety and compatibility in the MR environment. The devices described in this package insert have not been tested for heating or migration in the MR environment.

E. HANDLING & STERILIZATION

IMPLANTS

The implants described in this package insert are either provided sterile or non-sterile as indicated on the individual product's label. Implants that are presented in instrument trays are provided non-sterile.

Implants in sterile packaging should be inspected to ensure that the packaging has not been damaged or previously opened. If the inner package integrity has been compromised, contact the manufacturer for further instructions. The implants should be opened using aseptic OR technique; they should only be opened after the correct size has been determined.

This product is for single use only. An implant should never be re-sterilized after contact with body tissues or fluids.

Devices labeled for single-use only should never be reused. Reuse of these devices may potentially result in serious patient harm. Examples of hazards related to the reuse of these devices include, but are not limited to: significant degradation in device performance, cross-infection, and contamination.

Implants provided non-sterile should be processed according to the recommended parameters for instruments (below).

WARNING: DO NOT steam sterilize/ resterilize ceramic, plastic, and / or metal/ plastic implants.

INSTRUMENTS

Surgical instruments (and non-sterile implants) should be cleaned and sterilized according to the following parameters:

Cleaning & Disinfection

Clean to remove gross contamination and disinfect to reduce the number of viable microorganisms.

1. Disassemble all components if appropriate (use surgical technique for clarification on which components can be separated).
2. **Rinse** in cold water to remove any gross contamination.
3. **Wash** with a detergent with a pH of 7.0 to 10.0.
 - If the contamination contains a heavy organic soil, an enzyme detergent may be used.
4. **Bathe** in an enzymatic solution prepared per manufacturer directions for 5 minutes.
5. **Scrub** components with a soft brush.
6. **Rinse** thoroughly with cold deionized or reverse osmosis water.
7. **Bathe** in a detergent solution prepared per manufacturer directions for 5 minutes.
8. **Scrub** with a soft brush.
9. **Rinse** in deionized water.
10. **Dry** with a clean, disposable, absorbent cloth.
11. **Visually inspect** for cleanliness. All visible surfaces, internal and external, should be visually inspected. If necessary re-clean/disinfect until it is visibly clean.

Sterilization

The minimum recommended steam sterilization conditions for Wright reusable instruments (and non-sterile implants) are as follows:

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

Steam Sterilization		
Cycle Type	Parameter	Minimum Set Point
Prevacuum 270 °F (132 °C)	Exposure Temperature	270 °F (132 °C)
	Exposure Time	4 minutes
	Dry Time	20 minutes

- 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 AAMI ST79 Table 5 guidelines and have been developed and tested 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.

For additional information see Wright's "Cleaning and Handling of Wright Medical Instruments".

These recommendations have been developed and tested 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.

F. STORAGE CONDITIONS

All implants must be stored in a clean, dry environment and be protected from sunlight and extremes in temperature.

CAUTION: Federal Law (U.S.) restricts this device to the sale, distribution, and use by or on the order of a physician.

Trademarks™ and Registered Trademarks® are owned or licensed by Wright Medical Technology, Inc.