TOTAL ELBOW SYSTEM

115298-5

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*** The CE-Marking of Conformity is applied per catalog number and appears on the outer label, if applicable.**

℞ ONLY

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EN

Attention Operating Surgeon

IMPORTANT MEDICAL INFORMATION

TOTAL ELBOW SYSTEM
(115298-5)

DEFINITIONS

Symbols and abbreviations may be used on the package label. The following table provides the definition of these symbols and abbreviations.

Table 1. Definitions of Symbols and Abbreviations

Symbol	Definition
LOT	Batch code
REF	Catalog number
	Do not re-use
	Caution, consult accompanying documents
	Consult operating instructions
	Use by
	Temperature limitation
	Keep dry
	Keep away from sunlight
	Date of manufacture
	Manufacturer
EC REP	Authorized EC Representative in the European Community
STERILE EO	Sterilized using ethylene oxide
STERILE R	Sterilized using radiation

STERILE GAS	Sterilized using gas plasma
STERILE A	Sterilized using aseptic processing techniques
℞ ONLY	For prescription use only
Abbreviation	**Material**
Ti	Titanium
Ti6Al4V	Titanium Alloy
CoCr	Cobalt Chrome Alloy
SS	Stainless Steel
UHMWPE	Ultra High Molecular Weight Polyethylene

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:

- **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.
- **In selecting patients for total joint replacements, the following factors can be critical to the eventual success of the procedure.**
  1. **Patient's weight.** An overweight or obese patient can produce high loads on the prosthesis, which can lead to failure of the prosthesis. This becomes a major consideration when the patient is small boned and a small size prosthesis must be used.
  2. **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.
  3. **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.
  4. **Foreign body sensitivity.** Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.

A. INDICATIONS

This device is indicated for use in total elbow arthroplasty for reduction or relief of pain and/or improved elbow function in skeletally mature patients with the following conditions:

1) noninflammatory degenerative joint disease including osteoarthritis or traumatic arthritis;

2) inflammatory degenerative joint disease including rheumatoid arthritis;
3) correction of functional deformity;
4) revision procedures where other treatments or devices have failed; and
5) treatment of fractures that are unmanageable using other techniques.

THIS PRODUCT IS FOR USE ONLY WITH BONE CEMENT.

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

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 must 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.

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 arthoplasty 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.

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.

Prosthetic Components. Do not mix humeral, ulnar, and radial head components of different prosthetic systems, or from different manufacturers. Be aware that mixing certain sizes of the same prosthetic system may be inadvisable. Modular components must be assembled securely to prevent disassociation. Avoid repeated assembly and disassembly of the modular components which could compromise the locking action of the components. Surgical debris must be cleaned from components before assembly since debris may inhibit the proper fit and interfere with the locking mechanisms of modular components which may lead to early failure of the procedure.

Materials. The humeral, ulnar, and radial head components are manufactured from a variety of materials that include cobalt-chromium-molybdenum alloy and ultra high molecular weight polyethylene (UHMWPE), all of which conform to ASTM 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 in ISO 5832-9) / unalloyed titanium.

Metal Components. Some of the alloys used to produce orthopedic prostheses may contain some elements that may be carcinogenic in tissue cultures or intact organisms. Questions have been raised in the scientific literature as to whether or not these alloys may be carcinogenic to actual prosthetic recipients. Studies conducted to date to evaluate these questions have not produced convincing evidence of such phenomenon.

Alignment of Components. Care should be taken to restore the proper joint alignment and to balance ligamentous tension. Misalignment of the joint can cause excessive wear, loosening of the prosthesis, and pain leading to premature revision of one or more of the prosthetic components.

D. PRECAUTIONS

1. The patient must be advised of the limitations of the reconstruction and the need for protection of the prosthesis from full weight bearing until adequate fixation and healing have occurred. Excessive activity and trauma affecting the joint replacement have been implicated with

failure of the reconstruction by loosening, fracture and/or wear of the prosthetic components. Loosening of the components can result in increased production of wear particles, as well as damage to the bone, making successful revision surgery more difficult.

2. The patient should be cautioned to limit activities and protect the replaced joint from unreasonable stresses, and follow the instructions of the physician with respect to follow-up care and treatment. The patient should be closely monitored if a change at the operative site has been detected. The possibility of deterioration of the joint should be evaluated and possible revision surgery considered.
3. The patient should be warned of surgical risks, and made aware of possible adverse effects. The patient should be warned that the prosthesis does not replace normal healthy bone, that the prosthesis can break or become damaged as a result of certain activity or trauma, has a finite expected service life, and may need to be replaced at some time in the future. The patient should also be advised of other risks that the surgeon believes should be disclosed.
4. Specialized instruments are available and must be used to assure the accurate implantation of prosthetic components. Do not mix instruments from different manufacturers. While rare, breakage of instruments may occur especially with extensive use or excessive force. For this reason, instruments should be examined for wear or damage prior to surgery.
5. A good fit between bone and prosthesis helps to achieve a secure mechanical interlock. Should any component demonstrate motion, consideration should be given to implanting another size component.
6. Preoperative templates and trial prostheses should also be used to assure proper sizing of prostheses. Use only with mating prosthetic components of appropriate size. Mismatching of components could impede component articulation, leading to wear and possible failure of the component and also contribute to joint laxity.
7. Periodic post-operative x-rays are recommended for close comparison with early post-op conditions to detect long term evidence of changes in position, loosening, bending, or cracking of components.

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. ADVERSE REACTIONS

1. Wear of the polyethylene articulating surfaces of acetabular components has been reported following total hip replacement. Higher rates of wear may be initiated by particles of cement, metal, or other debris that can cause abrasion of the articulating surfaces. Higher rates of wear may shorten the useful life of the prosthesis, and lead to early revision surgery to replace the worn prosthetic components.
2. With all joint replacements, asymptomatic, localized, progressive bone resorption (osteolysis) may occur around the prosthetic components as a consequence of foreign-body reaction to particulate matter. Particulate is generated by interaction between components, as well as between the components and bone, primarily through wear mechanisms of adhesion, abrasion, and fatigue including third-body wear. Osteolysis can lead to future complications necessitating the removal and replacement of prosthetic components. See **Important Physician Information** section for more information.
3. Although rare, metal sensitivity reactions in patients following joint replacement have been reported. Implantation of foreign material in tissues can result in histological reactions involving production of macrophages and fibroblasts.
4. Peripheral neuropathies have been reported following total joint surgery. Subclinical nerve damage has been reported, and may occur as the result of surgical trauma.
5. Dislocation and subluxation of prosthetic components can result from improper positioning and/or migration of the components. Muscle and fibrous tissue laxity can also contribute to these conditions.
6. Prosthetic components can loosen or migrate due to trauma or loss of fixation.
7. Infection can lead to failure of the joint replacement.
8. While rare, fatigue fracture of the prosthetic component can occur as a result of trauma, strenuous activity, improper alignment, or duration of service.
9. Intraoperative fracture(s) of the humerus, ulna, or radius can occur while preparing the bone sites and/or seating the components.
10. Soft tissue imbalance can cause excessive wear and/or failure of the implant.

Intraoperative and early postoperative complications can include:

1) humeral, ulnar, radial head, or component fracture;
2) damage to blood vessels;
3) temporary or permanent nerve damage resulting in pain or numbness of the affected limb;
4) a sudden drop in blood pressure intra-operatively due to the use of bone cement;
5) cardiovascular disorders including venous thrombosis, pulmonary embolism, or myocardial infarction;
6) hematoma;
7) delayed wound healing; and
8) deep wound infection (early or late) which may necessitate removal of the prosthesis. On rare occasions, arthrodesis of the involved joint or amputation of the limb may be required.

Late postoperative complications can include:

1) bone fracture as a result of excess tension, or inadvertent intraoperative weakening;

2) periarticular calcification or ossification, with or without impediment to joint mobility;

3) inadequate range of motion due to improper selection or positioning of components, impingement, and periarticular calcification;

4) late or early loosening, change in position of the components, wear, and bending or cracking of one or more prosthetic components represent potential adverse effects. Clinical experience suggests that particular attention to the items contained in the **Warnings and Precautions** sections of this package insert may help minimize the risk of their occurrence; and

5) bone fractures, dislocation, subluxation, flexion contracture, decreased range of motion, or lengthening or shortening of the arm have all been reported in association with total elbow replacement.

Important Physician Information

Bone resorption is a natural consequence of total joint arthroplasty due to changes in bone remodeling patterns. Bone remodeling is mediated by the changes in stress distribution caused by implantation. Extensive resorption around the prosthesis may lead to implant loosening and failure. It is generally agreed that osteolysis is the result of localized foreign-body reaction to particulate debris generated by cement, metal, ultra-high molecular-weight polyethylene (UHMWPE), and ceramic. Regarding the etiology, it has been hypothesized that particulate debris generated by the components of a prosthesis migrate into the synovial cavity and the bone-implant interface, where they recruit macrophages and stimulate phagocytic action. The degree of recruitment is determined by the size, distribution, and amount of particulate debris (rate of debris generation). The phagocytic action results in the release of cytokines and intercellular mediators (IL-1, 2, PE2) which encourage osteoclastic bone resorption. Clinical and basic research is continuing in order to provide scientific basis for the causes of this phenomenon and potential ways to reduce its occurrence.

Osteolysis can be asymptomatic and therefore routine periodic radiographic examination is vital to prevent any serious future complication. Presence of focal lesions that are progressive may necessitate replacement of the prosthetic component(s).

F. HANDLING AND 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).

INSTRUMENTS

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

Cleaning

1. **Disassemble** all components as per manufacturer instructions (if appropriate). Clean to remove gross contamination and disinfect to reduce the number of viable microorganisms.
2. **Rinse** with cold tap water to remove gross contamination.
3. **Bathe** in an enzymatic detergent solution prepared per manufacturer directions for 5 minutes.
4. **Scrub** thoroughly with a soft brush and/or pipe cleaner; repeatedly flush any very narrow lumens with enzymatic detergent solution using a syringe.
5. **Rinse** with cold tap water for a minimum of one minute; use a syringe to repeatedly flush any very narrow lumens.
6. **Bathe** in a detergent solution prepared per manufacturer directions for 5 minutes
7. **Scrub** thoroughly with a soft brush and/or pipe cleaner; repeatedly flush any very narrow lumens with detergent solution using a syringe.
8. **Rinse** thoroughly /flush with deionized / reverse osmosis (RO/DI) water.
9. **Sonicate** for a minimum of 10 minutes in an enzymatic detergent solution prepared per manufacturer directions
10. **Rinse** thoroughly /flush with RO/DI water.
11. **Dry** with a clean, soft, absorbent, disposable cloth.
12. **Visually inspect** for cleanliness. All visible surfaces, internal and external, should be visually inspected. If necessary re-clean until it is visibly clean.

Note: Brushes (i.e. pipe cleaners) could be used for cleaning most lumens**,** however, the use of a syringe to flush narrow lumens with diameters less than or equal to 0.041 inches is recommended.

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

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 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.

G. 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.