

implantpartners

TOTAL KNEE SYSTEM

150809-0

The following languages are included in this packet:

English (en) only

For additional information please contact the manufacturer or local distributor.



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Rx ONLY
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Attention Operating Surgeon
IMPORTANT MEDICAL INFORMATION
TOTAL KNEE SYSTEM
(150809-0)

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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
	Batch code
	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
	Authorized EC Representative in the European Community
	Sterilized using ethylene oxide
	Sterilized using radiation
	Sterilized using gas plasma
	Sterilized using aseptic processing techniques
	Caution: U.S. federal law restricts this device to sale by or on the order of a physician
	Do not use if package is damaged
Abbreviation	Material
Ti	Titanium
Ti6Al4V	Titanium Alloy
CoCr	Cobalt Chrome Alloy
SS	Stainless Steel
UHMWPE	Ultra High Molecular Weight Polyethylene

DESCRIPTION

Implant Partners has a variety of knee joint replacement prostheses. The components for these systems include femoral, tibial and patellar components, and accessories. Only components from Implant Partners should be used to prevent mismatch or misalignment of components.

The femoral, tibial and patellar components are manufactured from a variety of materials that include cobalt-chromium-molybdenum alloy, titanium alloy, unalloyed titanium, and ultra high molecular weight polyethylene (UHMWPE), all of which conform to ASTM or ISO standards. The component material is provided on the outside carton label. Device size compatibility is indicated in the relevant surgical technique.

The implants are single-use only devices.

A. INDICATIONS

Total Knee Systems

Implant Partners Total Knee Systems are indicated for use in knee arthroplasty in skeletally mature patients with the following conditions:

- 1) noninflammatory degenerative joint disease including osteoarthritis, traumatic arthritis, or avascular necrosis;
- 2) inflammatory degenerative joint disease including rheumatoid arthritis;
- 3) correction of functional deformity;
- 4) revision procedures where other treatments or devices have failed; and treatment of fractures that are unmanageable using other techniques.

Implant Partners Knee Systems are for cemented use only.

B. CONTRAINDICATIONS

Patients should be warned of these contraindications. 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;
- 5) cases where there is inadequate neuromuscular status (e.g., prior paralysis, fusion and/or inadequate abductor strength), poor bone stock, or poor skin coverage around the joint that would make the procedure unjustifiable.

C. WARNINGS

The potential long-term biological effects of metal wear debris and metal ion production are not known. Questions regarding carcinogenicity have been raised in literature; no studies have conclusive evidence that metal wear debris or metal ions are carcinogenic.

NEVER combine components made by different manufacturers.

D. PRECAUTIONS

Preoperative Precautions

The surgeon must evaluate each situation individually based on the patient's clinical presentation in making any decisions regarding implant selection. The surgeon must be thoroughly familiar with the implant, instruments and surgical procedure prior to performing surgery. The surgeon should contact Implant Partners for product-specific surgical techniques.

Patient selection should consider the following factors which could lead to increased risk of failure and can be critical to the eventual success of the procedure: the patient's weight, activity level, and occupation. Additional 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;
- 5) poor prognosis for good wound healing (e.g., decubitus ulcer, end-stage diabetes, severe protein deficiency, and/or malnutrition).

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.

Intraoperative Precautions

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.

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.

Correct selection of the prosthesis is important. The potential for success in knee joint replacement is increased by selection of the proper size, shape, and design of the prosthesis. Knee 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.

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.

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 device or cement mantle. 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.

Modular Components. Modular components must be assembled securely to prevent disassociation. Avoid repeated assembly and disassembly of the modular components that 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 that may lead to early failure of the procedure.

Alignment of Components. Care should be taken to restore the proper joint alignment and to balance ligamentous tension. Malalignment 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.

Postoperative Precautions

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.

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.

Periodic postoperative 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.

There are inherent risks associated with the use of metallic implants in the MR environment; including component migration, heat induction, and signal interference or distortion near the component(s). Implant Partners knee implants are manufactured from non-magnetic materials; therefore, the risk for migration is low. Heat induction of metallic implants is a risk related to component geometry and material, as well as the MR power, duration, and pulse sequence. Since MR equipment is not standardized, the severity and likelihood of occurrence are unknown for these implants. As with any electrically conductive material, signal interference or distortion of the MR image are likely to occur in proximity to these implants, and therefore caution should be taken when performing measurements around these devices with an MR image.

Implant Partners Knee Systems have not been evaluated for safety and compatibility in the MR environment. Implant Partners Knee Systems have not been tested for heating or migration in the MR environment. Since these devices have not been tested, Implant Partners cannot make a recommendation for the use of MRIs with these implants.

These components are passive metallic devices, and as with all passive devices, there is potential for reciprocal interference with certain imaging modalities; including image distortion for MR and X-ray scatter in CT.

Recommendations Regarding Device Fragments

1. Inspect devices **immediately upon removal from the patient** for any signs of breakage or fragmentation.
2. If the device is damaged, retain it to assist with the manufacturer's analysis of the event.
3. Carefully consider and discuss with the patient (if possible) the risks and benefits of retrieving vs. leaving the fragment in the patient.
4. Advise the patient of the nature and safety of unretrieved device fragments including the following information:
 - a. The material composition, size, and location of the fragment (if known);
 - b. The potential mechanisms for injury, e.g., migration, infection;
 - c. 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.

E. ADVERSE EFFECTS can include:

- 1) osteolysis (progressive bone resorption). Osteolysis can be asymptomatic, and therefore, routine periodic radiographic examination is vital to prevent any serious future complication;
- 2) particulate generation leading to increased wear rates necessitating early revision. Soft tissue imbalance leading to excessive wear;
- 3) allergic reactions to materials; metal sensitivity that may lead to histological reactions;
- 4) delayed wound healing; 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;
- 5) a sudden drop in blood pressure intra-operatively due to the use of bone cement;
- 6) damage to blood vessels or hematoma;
- 7) temporary or permanent nerve damage, peripheral neuropathies and subclinical nerve damage as possible result of surgical trauma resulting in pain or numbness of the affected limb;
- 8) cardiovascular disorders including venous thrombosis, pulmonary embolism, or myocardial infarction;
- 9) dislocation, migration and/or subluxation of prosthetic components from improper positioning, trauma, loss of fixation and/or muscle and fibrous tissue laxity;
- 10) periarticular calcification or ossification, with or without impediment to joint mobility;
- 11) varus-valgus deformity;
- 12) traumatic arthrosis of the knee from intraoperative positioning of the extremity;
- 13) inadequate range of motion due to improper selection or positioning of components, periarticular calcification, flexion contracture;
- 14) femoral, tibial or patellar bone or component fracture intraoperatively or postoperatively; fracture by trauma or excessive loading, particularly in the presence of poor bone stock;
- 15) undesirable shortening or lengthening of the limb;
- 16) aggravated problems of the affected limb or contralateral extremity by leg length discrepancy, excess femoral medialization, or muscle deficiency;
- 17) pain.

F. HANDLING AND STERILIZATION

Implants

Implants are sterilized by gamma radiation or ethylene oxide. The immediate package label should be consulted for specific method of sterilization. Irradiated implants have been exposed to a minimum 25 and a maximum 40 kiloGrays of gamma radiation.

Unless supplied non-sterile, this product has been sterilized and should be considered sterile unless the inner package has been opened or damaged. If the inner package integrity has been compromised, contact the manufacturer for instructions. Remove from package, using aseptic OR technique, only after the correct size has been determined and the operative site has been prepared for final implantation. Always handle the product with powder-free gloves, and avoid contact with hard objects that may damage the product.

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.

A prosthesis should never be resterilized or reused after contact with body tissues or fluids, but rather should be discarded. Implant Partners does not take any responsibility for the use of implants resterilized after contact with body tissues or fluids.

WARNINGS:

- All packaging materials **MUST** be removed from the implant prior to implantation.
- You must **NEVER** steam sterilize/resterilize, plastic, and/or metal/plastic implants. If sterilization/resterilization of the metal component(s) is required, proceed as described below.

Instruments

Cleaning

1. **Disassemble** all components as per manufacturer instructions (if appropriate).
2. **Rinse** with cold tap water to remove any 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 reverse osmosis/deionized (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 Implant Partners reusable instruments 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 ANSI/AAMI ST79: 2006 Table 5 guidelines¹ 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.

For additional information regarding instruments, see Implant Partners's Cleaning and Handling of Implant Partners Instruments.

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 sale by or on the order of a physician.

¹ *Comprehensive guide to steam sterilization and sterility assurance in health care facilities* (ANSI/AAMI ST79:2006).