Instructions for Use

Bodycad Unicompartmental Knee System

CEMENTED

REF: 010-003

English – US
Labeling Symbols

⚠️ Caution, see instructions for use

🚫 Single use

 cháSterile R chá Sterilized using irradiation

⏳ Use by date

📅 Date of manufacture

🛠️ Manufacturer

🔍 REF Catalog number

 Serialized Serial number

Rx ONLY Federal law (USA) restricts this device to sale by or on the order of a physician
General

This product must be handled and implanted by trained and qualified medical staff who have read these instructions for use.

The implantation of the **Bodycad** patient specific knee prosthesis system can only be made by a surgeon mastering the specific surgical techniques required for the knee system.

⚠️

- The surgeon is responsible for the possible complications which may arise as a result of improper use, poor surgical technique, and/or non-aseptic conditions. **Bodycad** is not responsible, under any circumstances, for these complications.
- The patient specific prostheses and instruments must be used per the surgical technique; placement of instruments and implants not described in the surgical technique protocol are contra indicated.
- The product must be implanted in a sterile environment in compliance with hospital and standard operating guidelines.
- **MAGNETIC RESONANCE IMAGING (MRI) INFORMATION:** **Bodycad** implants are manufactured of non-ferromagnetic material such as, titanium alloy (Ti-6Al-4V), cobalt-chromium-molybdenum alloy (Co-Cr-Mo), and ultra-high molecular weight polyethylene (UHMWPE).
- This device has not been evaluated for safety and compatibility in the MR environment. The devices have not been tested for heating or migration in the MR environment. The risks associated with a passive implant in a MR environment have been evaluated and are known to include heating, migration, and image artifacts at or near the implant site.
- **STERILITY:** Prosthetic components are sterilized by exposure to a minimum dose of 25 kGy of gamma radiation. Single Use Only. Do Not Reuse. Do not resterilize. Do not use any component from an opened or damaged package. Do not use implants after expiration date.
- **CAUTION:** This device is custom-made and restricted to sale by or on the order of a physician.
- **SHELF-LIFE:** The shelf life date for the system is based on the shortest time between those:
  1. 3 months from the date of sterilization
  2. 6 months from the date of the MRI
Description

The **Bodycad** unicompartmental knee system is designed from data imaging taken by MRI (magnetic resonance imaging), or CT scan, from a specific patient and from a specific knee (left or right). Every single prosthesis is unique; i.e. it is patient specific. The **Bodycad** system consists of single use and reusable instruments and femoral and tibial components. The purpose of implanting the Bodycad system is to restore the medial tibiofemoral compartment of the knee. The system components are the following:

**Femoral component:**

This component is designed to fit the bone after the cartilage has been removed. It is specific to one patient. The femoral component is meant to be used with bone cement and then secured to bone with a bone screw. Knee ligaments are conserved. Minimal femoral bone is resected using a patient-specific, single use cutting guide.

**Tibial component:**

This component is designed to fit a medial tibial cut made with a patient specific, single use cutting guide. The tibial component is meant to be used with bone cement and then secured to the bone with a bone screw. It is composed of:

1. A metallic baseplate that conforms to the medial bone anatomy,
2. A polyethylene articular insert that is assembled onto the tibial baseplate intra-operatively,
3. A locking pin to secure the polyethylene insert, and
4. A bone screw to secure the tibial baseplate to bone.

**Patient specific cutting guides:**

Each cutting guide is designed from data from the patient’s MRI. There is a cutting guide for the tibial cut and a second one for the femoral cut. These guides are not interchangeable. Knee ligaments are conserved. Mounting screws are included. The cutting guides are designed to guide the surgeon to perform the bone cutting and drilling. The cutting guides are single-use items.
Materials

ASTM F1537 Cobalt-chrome alloy (Co-28Cr-6Mo)
  Femoral component and femoral screw

ASTM F136 Titanium alloy (Ti-6Al-4V ELI)
  Tibial baseplate, locking pin for the polyethylene articular insert, tibial screw, and screws for temporary fixation of cutting guides

ASTM F648 Ultra High Molecular Weight Polyethylene (UHMWPE)
  Tibial articular inserts

Polyamide 12 (Nylon 12)
  Cutting guides

Indications for use

The patient-specific Bodycad Unicompartmental Knee System (Bodycad UKS) is indicated for unicompartmental knee arthroplasty (UKA) in patients with advanced knee osteoarthritis (OA) of the medial compartment with evidence of adequate healthy bone to support the implanted components. Candidates for unicompartmental knee replacement include those with:

- joint impairment due to osteoarthritis or traumatic arthritis of the knee,
- varus deformity of the knee, and
- as an alternative to tibial osteotomy in patients with unicompartmental OA.

The patient-specific Bodycad UKS components fit within an envelope of dimensions that are specific to each patient. The Bodycad UKS femoral component and tibial baseplate are intended for cemented fixation. The Bodycad screws must be used for fixation of the femoral and tibial components.
Contraindications

The implantation of the Bodycad UKS prosthesis as treatment for medial unicompartmental knee osteoarthritis is contraindicated for the following situations:

• Bone mass compromised by disease, infection, or not enough to provide adequate support or fixation to the prosthesis.

• Severe instability of the knee joint resulting from the loss of integrity and functions in ligaments.

• Skeletal immaturity.

• Mental or neuromuscular disorder which may provoke postoperative complications or prosthesis instability. Patient’s intellectual disability to understand indications.

• Any suspected, latent or active knee infection or near the zone.

• Sources of infection which may cause hematogenous spread to the implant site.

• Obesity or overweight which may provoke a failure in the prosthesis.

• In case of bone tumor, uncontrolled diabetes, alcohol, tobacco or drug abuse.

• A patient who may expose the prosthesis to overload by the practice of contact or high impact sports such as: baseball, hockey, basketball, football, soccer, karate, skiing etc.

• A patient with a known sensitivity to materials used in the manufacture of the prosthesis.

Utilization and implantation

• The technique, developed by Bodycad must be used to remove cartilage from the femur.

• To perform tibial and femoral bone cuts, it is mandatory to use the customized cutting guides so that prosthesis may be implanted and perfectly fit.

• Pay attention when removing bone chips or bone cement fragments (if necessary).
• Use only the screws included and specifically designed for **Bodycad** prosthesis.

• Prosthesis are custom made and fitted for a specific patient.

• Use the tibial cut validator to verify cutting accuracy for the future prosthesis.

• Verify cartilage removal.

• Surgical technique protocol provides more detailed information.

• The cutting guides and the prosthesis are single-use devices.

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**Information for patients**

• The surgeon must inform the patient about the limitations of the use of a prosthesis in a knee joint surgery. He must inform the patient about the possible risks of such surgery.

• The patient must provide his/her clear consent for the surgery.

• The patient must inform the surgeon about any event which may affect the adequate prosthesis integration and a successful surgery.

• The patient must undergo to postoperative check-ups to detect any signs announcing possible malfunctions.

• For any treatment or exploration (e.g. MRI), the patient must inform medical staff he/she wears a metallic prosthesis.

• The surgeon must inform the patient to strictly follow post-operative care instructions given to him/her.

• A bacteraemia case may occur in daily life. It could have been triggered by a medical examination, dental interventions and some other minor interventions. To reduce the infection risk in the implant site, it may be advisable to prescribe antibiotics before or after such intervention.

• Patients receiving knee joint replacements should be advised that the longevity of the implant may depend on their weight and level of activity.
Warning

• Never use a **Bodycad** patient specific component combined with a component from another manufacturer. In the case of such use, **Bodycad** is not responsible for the implant failure and the compromised system performance.

• Never interchange any components or cutting guides aimed for a bone section with another. Every component is designed to fit a specific zone on the bone. The pre-planned, patients specific locations must be respected.

• Never use a patient specific component in a different patient.

• Discard any damaged implant.

• The polished supporting surfaces must be clean and free of any debris before assembling and closing tissues.

• Never use a metallic tool on polished surfaces.

• Use the screws designed for the **Bodycad** system only. The use of different screws coming from a different manufacturer may compromise the prostheses stability and implant success.

• Never use a polyethylene insert different from the one specially designed for the **Bodycad** system and made for a specific patient. The use of any other polyethylene insert is likely to compromise the success of the implant.

• Any package with flaws in the sterile barrier must be returned to the manufacturer.

Packaging and handling

• Every single implant system is packaged in a large heat-sealed pouch (secondary packaging) placed in the product box. The large pouch contains implant components also packaged in heat sealed pouches (primary packaging).

• Verify labeling.

• In case of a damaged primary packaging, treat the product as non-sterile.

• Strictly observe surgical procedure.

• Avoid any contact with objects which may alter implant surface.

• Never modify the implants.
Sterilization

- Prosthetic components are sterilized by exposure to a minimum dose of 25 kGy of gamma radiation.

- Check the integrity of every sterile product packaging barrier before opening. In case a fault or damage is found on the primary components packaging, consider the product as non-sterile.

- Use the tibial cut validator and trial articular inserts before opening the prosthesis package or using the prosthesis as per **Bodycad** technique.

- Take all necessary precautions to avoid product contamination. In case of product contamination, discard the product.

- Re-sterilization + cleaning: This product is single-use only; do not re-sterilize patient specific implants or instruments.

- The product should not be used after the expiration date written in the label, since packaging integrity is not guaranteed after this date.
Adverse effect

- Any prosthesis has a limited lifetime. One or several components may eventually stop responding as expected to normally applied loads as those made by a healthy joint. Many factors (mechanical, biological or else) may affect the implant useful lifetime. The surgeon must inform the patient about those factors and the patient must have reasonable expectations concerning his/her prosthesis performance.

- There is a risk of loosening or moving for the components of the **Bodycad** customized system due to an incorrect implantation (very fast handling when drilling or implanting), a latent infection, biological complications, including osteolysis, or mechanical complications. Any of these may lead to an improper implant performance.

- Misuse may cause damage to one or several prosthesis components.

- Breakage of one or several prosthesis components is possible. To avoid implant breakage, the surgeon must be sure that every component fits perfectly to the bone without any space between the upper and lower bones, and that all cartilage has been removed.

- There is a risk of bone loss, peripheral neuropathies, neurologic sequelae, compromised blood stream and ectopic bone formation.

- It is possible to observe a wear on the polyethylene articular insert.

- Metal sensitivity reactions have been reported following joint replacements.

- Adverse effects may require re operation, necessity to re make surgery, arthrodesis of the involved joint or amputation of the limb.

- Soft tissue imbalance or laxity have been associated to component misalignment which may result in early wear or failure of the prosthesis or from its components.

- Very small metal or polyethylene particles (or debris) may separate from implant components and spread (migrate) into the human body. In general, those particles remain caught in the synovial membrane or in the surrounding scar tissue. However, it is possible that microscopic particles migrate to different parts of the body such as the lymph nodes. At the time this publication is released, information about freed particles released from prosthesis components is limited. Although any major medical complication resulting from particles migration (or accumulation) in the human body has been reported, the fact has been described in the literature. As a result, the lack of enough scientific data about the particles and their long term effects are still unknown. The long term effects
which have been theorized include the following:

- **Cancer:** There is no scientific evidence linking metallic or polyethylene debris and cancer.

- **Systemic disease:** There are hypotheses in which a possible link between debris migration and the systemic effects not yet identified. Nevertheless, there is scarce scientific evidence suggesting a link between debris migration and systemic disease.

- **Lymphadenopathy and accumulation in other tissues/organs:** Rare cases about debris accumulation in the lymph nodes have been reported. Although any medical complication nor any pathogenic process has been reported as being caused by such accumulations, their existence must be identified to facilitate the diagnosis and avoid confusion with suspicious lesions, cancerous or otherwise.

• Any total or partial knee joint replacement may lead to severe complications. Those complications include, without limiting to, vascular problems (including thrombus), gastrointestinal problems, genitourinary problems, broncopulmonary problems (embolism), myocardial infarction or death.