Instructions For Use

Before any surgery, the surgeon must be familiar with the sales product literature and operative technique and must carefully read these instructions for use. Patient selection is as important as implant placement or positioning. Overweight patients, or unsuitable functional requirements may generate exceptional stresses and reduce the implant life. The warnings must be heeded, and the instructions for use must be strictly followed.

Device Description

The Engage Partial Knee System is intended for cemented or uncemented replacement of the medial compartment. The implant system consists of tibial trays, tibial inserts, tibial anchors, and femoral components. The tibial tray and tibial anchor are composed of Ti6Al4V ELI, the tibial insert is composed of UHMWPE, and the femoral component is composed of CoCr. The tibial tray includes an engineered porous surface, while femoral component includes a porous coating; both of which are intended to promote osseointegration when used without bone cement. The tibial anchors are intended to provide supplemental fixation for the tibial tray when implanted without bone cement. The tibial anchor should not be used when the tibial tray is used with bone cement.

How Supplied

The implants are provided sterile and should not be re-sterilized as they are intended for single-use only. The surgical instruments are provided separately, non-sterile and should be cleaned and sterilized via steam sterilization instrument tray prior to use. The instruments must be sterilized prior to use following the Instrument Hospital Cleaning and Sterilization Instructions USA.

Storage and Handling

- Store all packaged implants and instruments at room temperature.
- Handle all implants and instruments with care to prevent damage.

Intended Use

The Engage Partial Knee System is intended for medial unicompartmental knee arthroplasty to treat one or more of the following conditions:

- Moderately disabling joint disease of the knee resulting from painful osteo or post traumatic arthritis.
- Revision of previous unsuccessful surgical procedures, including prior unicompartmental knee arthroplasty.
- As an alternative to tibial osteotomy in patients with Unicompartmental osteoarthritis.
- The femoral component and tibial tray are intended for cementless or cemented fixation. The porous surfaces of both the femoral and tibial tray components provide biological fixation when used in a cementless application. When the tibial tray is implanted without the use of bone cement, the tibial anchor should be used. When the tibial tray is implanted with bone cement, the tibial anchor should not be used.

Contraindiciations

Partial knee replacement is contraindicated in the following cases:

- Progressive local or systemic infection.
- Patients with known metal sensitivity
- Muscular loss, neuromuscular disease or vascular deficiency of the affected limb, making the operation unjustifiable.
- Osteoporosis, osteopenia, or osteomalacia.
- Metabolic disorders which may impair bone formation.
- Rapid joint destruction, marked bone loss or bone resorption apparent on roentgenogram.
- Incomplete or deficient soft tissue surrounding the knee.
- Severe instability secondary to advanced destruction of condylar structures.
- Unicompartmental replacement is contraindicated in patients who have a permanent valgus or varus deformity that requires correction for the knee to function satisfactorily post-op.

Mental or neuromuscular disorders may create an unacceptable risk to the patient and can be a source of postoperative complications. It is the surgeon's responsibility to ensure that the patient has no known allergy to the materials used.

Warnings and Precautions

- The success of the operation depends on compliance with the operative technique supplied, and the proper use of the instrumentation supplied and specially designed for that range of implants.
- The trial instrumentation must be used to confirm the choice of sizes and verify the functionality of the joint.
- The surgeon should implant this system only in patients with sufficient intact soft tissue and intact collateral and cruciate ligaments.
- Do not use any implants after the expiration date.
- Do not use any components from opened or damaged packaging.
- Implant component are single use only
- Under no circumstances should an Engage Partial Knee component be used in combination with a component from another manufacturer unless otherwise specified by Engage Surgical.
- The packaging configuration for the tibial insert includes an oxygen absorbing pouch inside the packaging to maintain a low-oxygen environment. This packet should be discarded with the rest of the packaging materials.

Caution: Federal law restricts this device to sale by or on the order of a physician.

Risk Factors

The following conditions, individually or together, may cause excessive loading of the affected prosthesis, exposing the patient to greater risk of a partial knee arthroplasty failure:

- Obesity or overweight of the patient
- Hard physical labor
- Intense sporting activity
- High level of activity
- Probability of falling
- Alcoholism or drug addiction
- Smoking
- Other handicaps which could compromise the outcome of the operation

The following conditions, individually or together, will make fixation of the knee prosthesis challenging:

- Advanced osteoporosis or insufficient bone stock
- Metabolic disorders or systemic medications leading to gradual loss of bone support for the prosthesis (e.g. diabetes mellitus, treatment by steroids, immunosuppressives)
- History of disseminated systemic or local infection
- Significant deformations preventing correct fixation or placement of the prosthesis
- Tumors of the supporting bone structures
- Allergic reactions to the prosthesis materials or cement
- Tissue reaction to implant corrosion or wear debris
- Functional incapacity of the other joints.

MRI Safety Information

It is important to note that Engage Partial Knee System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the Engage Partial Knee System implant components in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Directions For Use

Preoperative Steps

The surgeon should verify possible patient physical limitations and mental deficiencies and should also discuss with the patient all the details of the procedure and prosthesis. The discussion should consider the limitations of the procedure and the constraints imposed by the selected implant. The factors which could limit the performance and stability of the implant, e.g. level of activity, patient's weight, should be set out to improve the patient's chances to avoid complications. The necessity to follow the postoperative instructions given by the surgeon should be fully understood by the patient. A stock of sterile implants of suitable sizes should be available and checked before surgery.

The prerequisites for partial knee replacement include:

- Osteoarthritic damage to only one femorotibial or femoropatellar compartment of the knee joint
- Unicompartmental disease with a correctable deformity with minimal to no ligament releases
- Stability of collateral and cruciate ligaments
- Integrity of the quadriceps and popliteal tendon

Surgical Technique

The surgeon should be fully familiar with the surgical technique. Supplementary information about the surgical techniques and products are available on request. Careful preoperative planning, documented by X-rays, is essential.

> Note: Surgeon should avoid excessive impaction of femoral component, tibial component, tibial insert, and tibial anchor during insertion. Excessive impaction forces may result in bone fracture.

Postoperative Care

The surgeon should caution the patients to control their level of activity and avoid excessive loads on the replaced joint, and make them aware of the precautions to be taken with regards to exercise, treatments and limitations on activities, as well as avoiding exposure to magnetic fields. Periodic follow-up and X-rays are recommended to make comparisons with the immediate postoperative condition and identify implant displacement, loosening, etc. Excessive physical activity, and operated limb traumas may cause early failure of the arthroplasty through implant displacement, fracture and/or wear. If the case occurs, it is necessary to place the patient under supervision, evaluate the possible progression of the deterioration, and weigh the benefit of early revision.

Adverse Effects and Complications

General

- Prosthesis dislocation, often related to the above-mentioned risk factors.
- Early or late loosening, tibial subsidence, bending, fissure fracture, fracture, deformation or wear of one or more of the prosthetic components, often related to the above-mentioned risk factors. Loosening can also occur as a result of an incorrect fixation or positioning of the components.
- Early or late infection which may require removal of the implant followed by arthrodesis or 2-stage reimplantation.
- Pain, dislocation, subluxation, flexion contracture, mobility reduction, leg shortening or lengthening, resulting from improper positioning, loosening or wear of the components.
- Excessive wear of the polyethylene component due to damage to the femoral component, loose cement or bone fragments and/or high levels of activity or weight.
- Fracture of the tibia or femur. Intra-operative fractures are usually associated with severe deformations and /or osteoporosis. Postoperative fractures are generally traumatic or fatigue fractures. They may result from cortex defects, multiple pin holes, former screw holes, misdirected reaming and/or uneven distribution of bone cement.
- Cardiovascular disorders and thromboembolic diseases, including thrombosis, embolism, and myocardial infarction.
- Tissue reactions, osteolysis and/or implant loosening caused by metal corrosion, allergy, wear debris, or loose cement particles.
- Myositis ossificans, especially in osteoarthritic males having a limited range of motion before the operation and/or a previous myositis. The incidence of myositis ossificans increases with past surgical history and in case of infection.

Intra-operative

Under no circumstances should the components meet hard objects. Before use, each component must be visually inspected for imperfections. Special surgical instruments are required for knee surgery. It is important to review the use and handling of these instruments based on the surgical technique. The alignment and cutting templates must be inspected visually before operation. Distorted or damaged instruments may result in improper positioning of the prosthesis and arthroplasty failure. Careful cleaning and correct preparation of the bone surfaces are essential for the fixation of the prosthesis. Bone resection must be kept minimal. Excessive bone resection or excessive use of pins to secure the instruments may induce mechanical problems and bone resorption resulting in failure of the surgery. When preparing the bone surfaces and placing the components, it is necessary to check the components for correct alignment. Before closing the wound, the surgical site must be cleaned free of bone particles, residual cement and any foreign particles that may cause excessive wear. The range of motion and the level of constraint must be carefully checked and corrected, if necessary, to avoid incorrect seating, instability or encroachment.

Immediately Postoperative

- Cardiovascular disorders, including vein thrombosis, embolism, and myocardial infarction.
- Hematoma and/or delayed healing.
- Pneumonia and/or atelectasis.
- Subluxation or dislocation.
- Uncontrolled varus or valgus.

Postoperative

- Poor range of motion due to incorrect selection or positioning
- Aggravation of the problems with the knee and ankle of the ipsilateral or contralateral limb caused by difference in leg length, femur displacement and/or muscular deficiency.
- Fracture of the patella resulting from excessive stress or intraoperative weakening.
- Bone resorption which may damage the fixation or result in implant loosening.
- Periarticular calcification or ossification which may reduce mobility and the articular range of motion, and or encroachment.
- Subluxation or dislocation.

Key To Symbols Used On Labeling

	See instructions for use
	Sterilized using gamma radiation
	Use by date
	Lot number
	Reference number
	Single use only
	Do not use if package is damaged
	Manufactured By
	Federal Law (USA) restricts this device to sale only by or on the order of a physician

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