MIRROR™ Partial Knee System

Instructions for Use

DESCRIPTION

The Cayenne Medical, Inc. *MIRROR™* Partial Knee System has been designed to replace the articular surface of a single condyle and adjacent mating articular surface. Components include individually packaged femoral components made of cobalt-chromium alloy and tibial components of titanium alloy and ultra-high molecular weight polyethylene. Implants are intended for cemented use only. Components of this system are designed to be used as a system and do not allow for the substitution of components to or from other implant systems.

INDICATIONS

The *MIRROR* Partial Knee System is intended for arthroplasty of either condyle of a knee with the following indications:

1. Non-inflammatory degenerative joint disease including post-traumatic arthritis and osteoarthritis.
2. Failed previous implant.
3. Correctable deformity.
4. All *MIRROR* Partial Knee System implants are intended for cemented use only.
5. Implant components of this system are designed for single use and to be used as a system.

CONTRAINDICATIONS

The *MIRROR* Partial Knee System is contraindicated in:

1. Infection, sepsis, or infections with potential to spread to the implant site.
2. Patients incapable or unwilling to comply with surgeon instructions, including ability to maintain weight and limit activity.
3. Osteomalacia, insufficient bone stock, excessive bone loss or bone resorption apparent on roentgenogram.
4. Deficient or absent ACL, PCL or collateral ligament; incomplete or deficient soft tissue.
5. Neuropathic joint, vascular insufficiency or muscular atrophy.
6. Skeletal immaturity.
7. Severe varus or valgus deformity.
8. Severe extension or flexion contracture.

POSSIBLE ADVERSE EFFECTS

1. Wear of the polyethylene articulating surfaces.
2. Third-body (such as cement particulate) wear leading to reduced implant life.
3. Osteolysis leading to implant loosening as a consequent reaction to particulate and wear debris.
4. Inadequate range of motion due to improper implant selection, positioning or alignment.
5. Tibia, femur, or patella fractures.
6. Material sensitivity and histological reactions.
7. Loosening or migration of the implants due to loss of fixation.
8. Undesirable shortening or lengthening of limb.
9. Valgus-varus deformity.
10. Intraoperative or postoperative bone fracture and/or postoperative pain.
11. Hematoma, delayed wound healing.

PACKAGING, LABELING AND STERILIZATION

Products being received by hospitals or surgeons should be accepted only if the original packaging and labeling is intact. Tibial and femoral implant components are packaged individually and supplied sterile. All implant components are sterilized by Ethylene Oxide gas. Sterile packaging should only be opened intraoperatively once the proper size component has been selected. Implant components may not be re-sterilized; DO NOT USE IF STERILE PACKAGING HAS BEEN COMPROMISED. DO NOT RE-STERILIZE IMPLANTS.

WARNINGS AND PRECAUTIONS

PREOPERATIVE

1. Surgeon should be familiar with implants, instruments and the *MIRROR* Partial Knee System Surgical Technique prior to performing surgery.
2. Patients should be warned of all potential surgical risks and outcomes prior to surgery. Patients should be aware that this implant system does not fully replace or restore the function of a normal healthy knee; strenuous activity or trauma may lead to implant damage or breakage resulting in the need for early revision.
3. An adequate inventory of implant sizes and properly maintained instruments should be verified prior to beginning surgery.

INTRAOPERATIVE

1. Do not modify implants in any manner.
2. Do not re-use any implant component even if it appears undamaged.
3. Limit bone resections to accommodate smallest appropriate implant.
4. This procedure requires intact ACL, PCL and collateral ligaments. An intraoperative assessment of the quality of these structures should be made prior to resection of bone. Intraoperative knee flexion of at least 135° is required for implant placement.
5. Selecting implants to properly fit prepared bone surfaces is extremely important. Implants must allow for adequate bone support throughout the implant-bone interface. Failure to properly fit implants may result in implant loosening and/or damage implant and/or bone.
6. Improper alignment of implants can lead to excessive wear and/or early failure.
7. Thoroughly clean implant support surfaces prior to cementing implants to insure proper fixation.
8. Assure that all support surfaces of the implants are completely covered with bone cement to prevent stress concentrations which may lead to early failure.
9. Following the placement of implants, care should be taken not to move or load components until the cement has cured.
10. Use caution when handling implants to avoid scratching or denting. Always handle implants with clean dry gloves.
11. Remove all excess cement from around the implants; complete pre-closure cleaning and removal of cement debris at the implant site to minimize chance of third-body wear on articular surface.

POSTOPERATIVE

1. Strict adherence by patients to the surgeon's instructions is extremely important; follow accepted practices for postoperative care. Patient should be advised of limitations and the need to protect the implanted joint until adequate fixation and healing have occurred.
2. Patient activity should be limited to a level that protects the joint from unnecessary stress.
3. Periodic follow-up including x-ray comparison to post-op is recommended to monitor long term changes in implant performance, position and fixation.
4. The *MIRROR* Partial Knee System has not been evaluated for safety, compatibility, heating or migration in the MRI environment.

Manufactured By
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Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

US Pat. No. 6,482,209; and patents pending

KEY TO SYMBOLS ON LABELING

Symbol	Used for
	**Use by**
	**Lot Number**
	**Reference Number**
	**Sterilized using ethylene oxide**
	**Date of Manufacture**
	**Do not reuse**
	**Consult instructions for use**
	**CAUTION: Federal law (USA) restricts this device to sale only by or on the order of a physician**