Instructions for Use

Meril
Orthopedics

OPULENT™ Knee System

Bionik Gold Surface for Enriched Performance

Meril
Orthopedics

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Carefully read all instructions and be familiar with the surgical techniques prior to use:

1. Description:

The Meril Healthcare Opulent™ Knee System - Primary knee components, Stemmed tibial Components (Primary / Revision) & Uni Knee components are available in many style and sizes and are manufactured from various types of metallic and non-metallic materials. The component style, size, compatibility and specific component material is provided on the outside carton label.

The different product categories include:

- **Primary knee components**
  - a. Opulent™ Femoral Knee Component PS & CR (Left & Right)
  - b. Opulent™ Tibial Base Plate
  - c. Tibial Liner PS & CR
  - d. All Poly Tibial liner
  - e. Patella

Note: Tibial Liner PS & CR, All Poly Tibial liner & Patella will either be used of DestiKnee™ / VitElon™ / Opulent™ Brand.

- **Stemmed Tibial components**
  - a. Opulent™ Revision Stemmed Tibial Base Plate
  - b. Opulent™ Revision Stem Extension

Note: Stemmed tibial components are intended to use for primary or revision option for a case in which the femoral component are to remain in situ.

- **Uni Knee components**

  It is designed to achieve partial reconstructive replacement of the deficient and damaged tibiofemoral joint surfaces with metal components and provide a low-friction articulation with a polyethylene bearing. This is to restore optimum function and have longevity of the knee replacement.
  - a. Opulent™ Femoral Uni Implant (RMLL & RLLM)
  - b. Opulent™ Tibial Uni Base Plate (RMLL & RLLM)
  - c. Tibial Uni Liner (RMLL & RLLM)

Note: Tibial Uni Liner will either be used of DestiKnee™ / Opulent™ Brand.

2. Product Selection Information:

- **Primary knee & Stemmed Tibial components**

  Appropriate matching of the components will occur when the articular component is matched to the femoral component (by letter size designation and constraint style) and to the tibial base (by numerical size designation). For example a size B1-2 PS (Posterior Stabilized) articular component is appropriately matched to a size B PS femoral component and either a size 1 or size 2 tibial base plate. Mismatching may result in poor surface contact and produce pain, decrease wear resistance, produce instability of the implant, or otherwise reduce implant life.

- **Uni Knee components**

  Appropriate matching of the components will occur when the articular component is matched to the tibial uni base plate (by numerical size designation and orientation designation - RM/LL* or RL/LM*) and to the femoral component (by numerical size designation and orientation designation - RM/LL* or RL/LM*). The orientation designation must match for the components.

  For example: Size 1 RM/LL Tibial Uni Base Plate component is appropriately matched to the size 1 articular component and matched to the any size with orientation designation RM/LL of the femoral component.

  (*RM/LL: Right Medial / Left Lateral, *RL/LM: Right Lateral / Left Medial)

- Use only instruments and trials specifically designed for use with these devices to help ensure accurate surgical implementation, soft tissue balancing, and evaluation of knee function.
- Selections between the various sizes and options are matters of physician discretion.

3. Indications:

- **Primary knee & Stemmed Tibial components**
- Severe knee joint pain, loss of mobility, and disability due to: rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis.
- Correction of functional deformities.
- Post-traumatic loss of knee joint contour, particularly when there is patellofemoral erosion, dysfunction, or prior patellectomy.
- Moderate valgus, varus, or flexion trauma.
- Knee fractures untreatable by other methods.
- Revision surgery where sufficient bone stock and soft tissue integrity are present.

- **Uni Knee components**
- Non-inflammatory degenerative joint disease including osteoarthritis, traumatic arthritis or avascular necrosis.
- Inflammatory degenerative joint disease, excluding rheumatoid arthritis.
- Functional deformity such as varus, valgus or flexion deformities.
- Fractures that are unmanageable using other techniques.
- Correction of functional deformities.

4. Contraindications:

- History of infection in the affected joint that may affect the function of the implanted prosthetic.
- Less than optimal bone stock on femoral or tibial surfaces resulting from a history of disease, infection, or prior surgical procedures which cannot provide adequate support for the implantation.
- Compromised skeletal bone quality.
- Neuropathic disease that adversely affects the prosthetic joint.
- Osteoporosis or deficiency of musculature that compromises the affected limb.
- Pain-free and stable arthrodesis in an adequate functional position.
- Instable knee joint secondary to negative collateral ligament integrity.

The conditions like obesity or overweight, active sports participation and high levels of patient activity tend to impose severe loading on the affected extremity, thereby placing the patient at higher risk for failure of the knee implant.

Note: WHO (World Health Organization) defines "overweight" as a BMI (Body mass index) greater than or equal to 25, and "obesity" as a BMI greater than or equal to 30.

5. Precautions:

- Before clinical use, the surgeon should thoroughly understand all aspects of the surgical procedure and the limitations of the product. Patients should also be instructed on the limitations of the product, including but not limited to, the impact of patient weight and activity, and be taught to govern their activity accordingly.
- The prosthesis will not restore functions to the level expected with normal healthy bone, and the patient should temper their expectations to a realistic level.
- As with all prosthetic implants, the durability of the components is affected by numerous biological, biomechanical, and other external factors which can limit their service life. Adherence to the indications, contraindications, precautions, and warnings for this product is essential for maximizing service life.

6. Possible Adverse Effects:

- Long term swelling or infection.
- No improvement in range of motion.
- Neuropathic disorders.
- Dislocations, bone fractures, and/or joint instability.
- Per literature, there is a chance that wear of polyethylene components may result in bone resorption, loosening, and related infection.
- Possibility for metal sensitivity reactions.
- Venous thrombosis.
- Prolonged and excessive joint pain and/or inflammation.
- Aseptic loosening of implant.

7. Warnings:

- This device is intended for cemented use only.
- This device is for single patient use only. Reuse can potentially compromise device performance and patient safety. If prosthesis is reused, there are chances of infection, loosening or revision surgery.
- Discard all damaged implants.
- Polished bearing areas must not come in contact with hard or abrasive surfaces.
- Bearing areas must be free of debris and clean prior to assembly.
- Contouring or bending of the implant may reduce its fatigue strength and cause premature failure under load.
- Return all packages with flaws in the sterile barrier to the supplier. Do not re-sterilize.
- All Poly Tibial liner should be limited to use in low demand (i.e. modest weight, activity level) patients with good bone quality.
- Stem extension are intended for screw attachment to the Stemmed Tibial Base plate.

8. Materials:

All of the material used in the Meril Healthcare's Opulent™ Knee System meets applicable ASTM / ISO standard as given in below table.

Component	Material Grade	ASTM / ISO	Sterile
Opulent™ Femoral	Cobalt Chromium molybdenum TiNbN - Coating Material	ASTM F75 / ISO 5832 - 4	Gamma Irradiation
Opulent™ Tibial Base Plate	Cobalt Chromium molybdenum TiNbN - Coating Material	ASTM F75 / ISO 5832 - 4	Gamma Irradiation
Tibial Liner PS & CR	Highly Crosslinked UHMWPE blended with Vitamin E - E-XLPE (E-CiMa)	ASTM F2695 -12	Ethylene Oxide
	UHMWPE blended with Vitamin E	ASTM F2695 -12	
	UHMWPE (GUR - 1020)	ASTM F648 / ISO 5834 - 2	
All Poly Tibial Liner	Highly Crosslinked UHMWPE blended with Vitamin E - E-XLPE (E-CiMa)	ASTM F2695 -12	Ethylene Oxide
	UHMWPE blended with Vitamin E	ASTM F2695 -12	
	UHMWPE - (GUR 1020)	ASTM F648 / ISO 5834 - 2	
Patella	Highly Crosslinked UHMWPE blended with Vitamin E - E-XLPE (E-CiMa)	ASTM F2695 -12	Ethylene Oxide
	UHMWPE blended with Vitamin E	ASTM F2695 -12	
	UHMWPE - (GUR 1020)	ASTM F648 / ISO 5834 - 2	
Opulent™ Revision Stemmed Tibial Base Plate	Cobalt Chromium molybdenum TiNbN - Coating Material	ASTM F75 / ISO 5832 - 4	Gamma Irradiation
Opulent™ Revision Stem Extension	Titanium alloy [Ti6Al4V-Extra Low Interstitials (ELI)] TiNbN - Coating Material	ASTM F136 / ISO 5832-3	Gamma Irradiation
Opulent™ Femoral Uni Implant	Cobalt Chromium molybdenum TiNbN - Coating Material	ASTM F75 / ISO 5832 - 4	Gamma Irradiation
Opulent™ Tibial Uni Base Plate	Titanium alloy [Ti6Al4V-Extra Low Interstitials (ELI)] TiNbN - Coating Material	ASTM F36 / ISO 5832-3	Gamma Irradiation
Tibial Uni Liner	Highly Crosslinked UHMWPE blended with Vitamin E - E-XLPE (E-CiMa)	ASTM F2695 -12	Ethylene Oxide
	UHMWPE - (GUR 1020)	ASTM F648 / ISO 5834 - 2	

9. MRI Safety Information:

The Opulent™ knee system has been evaluated for safety and compatibility and tested for heating or migration in the MR environment in accordance with ASTM F2503-20.

MRI Safety Information A patient with the Meril Healthcare Primary Knee Replacement System may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.	
Name/Identification of device	Meril Healthcare Primary Knee Replacement System
Nominal value(s) of Static Magnetic Field [T]	1.5 T or 3 T
Maximum Spatial Field Gradient [T/m and gauss/cm]	19 T/m (1900 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Whole body transmit coil, Head RF transmit-receive coil
Maximum Whole Body SAR [W/kg]	2.0 W/kg or 1.0 W/kg
Limits on Scan Duration (SAR 2.0 W/kg)	2.0 W/kg whole body average SAR for 15 minutes of continuous RF (a sequence or back to back series/scan without breaks)
MR Image Artifact	The presence of this implant may produce an image artifact of 88 mm.
If information about a specific parameter is not included, there are no conditions associated with that parameter.	

Note: The Opulent™ Stemmed Tibial components have not been evaluated for safety and compatibility and also not been tested for heating or migration in the MR environment.

MRI Safety Information A patient with the Meril Healthcare Uni Knee Replacement System may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.	
Name/Identification of device	Meril Healthcare Uni Knee Replacement System
Nominal value(s) of Static Magnetic Field [T]	1.5 T or 3 T
Maximum Spatial Field Gradient [T/m and gauss/cm]	19 T/m (1900 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Whole body transmit coil, Head RF transmit-receive coil
Maximum Whole Body SAR [W/kg]	2.0 W/kg or 1.0 W/kg
Limits on Scan Duration (SAR 2.0 W/kg)	2.0 W/kg whole body average SAR for 15 minutes of continuous RF (a sequence or back to back series/scan without breaks)
MR Image Artifact	The presence of this implant may produce an image artifact of 88 mm.
If information about a specific parameter is not included, there are no conditions associated with that parameter.	

10. Sterilization:

- All Implants are supplied sterile in protective packaging to a Sterility Assurance Level (SAL) of 10^{-6} using Ethylene oxide or Gamma irradiation.
- The method of sterilization is provided on the outside carton label.
- The packaging of all sterile products should be inspected for flaws in the sterile barrier before opening. In the event of such a flaw, the product must be returned non-sterile. Trial components should be used to avoid having to open any aspect of the sterile package prior to the component use.
- Care should be taken to prevent contamination of the component. In the event of contamination, this product should be discarded.
- If the package is opened, but the product is not used, the component should not be re-sterilized and should be discarded or returned to the supplier.

11. Patient Guidance:

- The probability of resulting complications and/or failure of knee prostheses is increased in cases where the patient's physical and medical presentation (e.g. weight, or other diseases) is a detriment, the patient's functional outcome goals are above what is reasonably attainable, the patient's expectations for knee joint function are unrealistic, and/or the patient's engages in a less than optimal level of rehabilitation post-surgery. Excessive physical activity and injury can result in loosening, wear, and/or fracture of the knee implant. The patient must be instructed about all postoperative restrictions, particularly those related to occupational and sports activities and about the possibility that the implant or its components may wear out, fail, or need to be replaced. The implant may not, and is not guaranteed to last the rest of the patient's life. Because prosthetic joints are not as strong, reliable, or durable as natural, healthy joints, all prosthetic knees may need to be replaced at some point.

WARNING: THIS DEVICE IS INTENDED FOR CEMENTED USE ONLY.

Symbols used in labeling

Contains one unit	Keep dry
Keep away from sunlight	Use by
Consult instruction for use	Caution
Sterilized using ethylene oxide	Lot number
Sterilized using Irradiation	Reference number
Do not use if box open or damaged	Manufacturer
℞ Only This device to sale by or on the order of a physician	Manufacturing date
For single use only do not reuse	Do not resterilize
MR Conditional	Temperature Limitation
Non-Pyrogenic	