# Instructions for Use

Meril
Orthopedics

# OPUL ENT™
## Knee System

**Bionik Gold Surface for Enriched Performance**

**EN (CR & PS)**


Meril
Orthopedics

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

**1. *Description:***

The Meril Healthcares' Opulent™ Total Knee System is a system of components intended to replace the femoral, tibial and patella articular surfaces of the knee joint. Components are available in many styles and sizes and are manufactured from various types of metals and non-metallic materials. The different product categories include.

1. Femoral Knee Component PS & CR (Left & Right),
2. Tibial Base Plate,
3. Tibial Liner PS & CR / All Poly (Tibial base plate + Tibial liner),
4. Patellar component.

The component style, size, compatibility, and specific component material is provided on the outside carton label. All implantable components are designed for single use only.

**2. *Product Selection Information:***

- 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.
- 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:***

- 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.

**4. *Contraindications:***

- History of infection in the affected joint that may affect the function of the implanted prosthetic.
- Possibility for metal sensitivity reactions.
- 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 biologic, 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. *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.
- All-polyethylene tibial base plates should be limited to use in low demand (i.e. modest weight, activity level) patients with good bone quality.
- Return all packages with flaws in the sterile barrier to the supplier. Do not re-sterilize.

**8. *Materials:***

All of the materials used in the Meril Healthcares' Opulent™ Total Knee System meet applicable ASTM / ISO standards as given in below table The Opulent™ Total Knee System has not been evaluated for safety and compatibility in the MR environment. The Opulent™ Total Knee System has not been tested for heating or migration in the MR environment.

| *Component* | *Material Grade* | *ASTM / ISO* |
|---|---|---|
| Femoral | Cobalt Chromium molybdenum - Base Material<br>TiNbN - Coating Material | ASTM F75 - 12 / ISO 5832 - 4:2014 |
| Tibial Base Plate | Cobalt Chromium molybdenum - Base Material<br>TiNbN - Coating Material | ASTM F75 - 12 / ISO 5832 - 4:2014 |
| Tibial Liner (Metal Back) | Highly Crosslinked UHMWPE blended with Vitamin E (E-CIMA) | ASTM F2695 -12 |
| | UHMW - PE (GUR - 1020) | F 648 / ISO 5834 - 4 |
| Tibial Liner All Poly | Highly Crosslinked UHMWPE blended with Vitamin E (E-CIMA) | ASTM F2695 -12 |
| | UHMW - PE (GUR - 1020) | F 648 / ISO 5834 - 4 |
| Patella | Highly Crosslinked UHMWPE blended with Vitamin E (E-CIMA) | ASTM F2695 -12 |
| | UHMW - PE (GUR - 1020) | F 648 / ISO 5834 - 4 |

**9. *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.

**10 *Patient Guidance:***

The probability of resulting complications and/or failure of total 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.**

**CONTROLLED COPY**
Sign.....

**Symbols used in labeling**

| | |
|---|---|
| Contains one unit | Keep dry |
| Keep away from sunlight | Use by |
| Consult instruction for use | Caution |
| STERILE EO<br>Sterilized using ethylene oxide | LOT<br>Lot number |
| STERILE R<br>Sterilized using Irradiation | REF<br>Reference number |
| Do not use if box open or damaged | Manufacturer |
| ℞ Only<br>This device to sale by or on the order of a physician | Manufacturing date |
| For single use only do not reuse | Do not resterilize |
| EC REP<br>Authorized representative in the European community | Temperature Limitation |