Instructions for Use
KASM® Knee Articulating Spacer Mold
Manufacturer
Ortho Development® Corporation
12187 South Business Park Drive
Draper, UT 84020
Phone 801-553-9991
Fax 801-553-9993
www.odev.com

For temporary knee prosthesis

DESCRIPTION

KASM® is a sterile, disposable cement spacer mold (femoral and tibial) made of USP class VI medical-grade thermoplastic urethane. The molds are filled with polymethylmethacrylate (PMMA)/gentamicin bone cement. After the cement cures, the KASM molds are removed from the temporary cement spacers. The spacers remain in vivo (180 days or less) until the second stage of the two-stage revision procedure is performed to implant a conventional knee joint prosthesis.

INDICATIONS

KASM is intended for use in temporary total knee arthroplasty procedures with the following indications:
1. Active sepsis which requires a two-stage revision arthroplasty procedure.
2. Skeletally mature patients who will consistently use limited mobility assistive devices such as a walker, canes, crutches, etc., for the entire implantation period.
3. Implantation period of 180 days or less.

Use only with polymethylmethacrylate/gentamicin bone cement.

The articulating cement spacer prosthesis fashioned using the KASM mold is intended for cemented fixation only.

CONTRAINDICATIONS

The temporary knee prostheses made with the KASM disposable cement spacer molds are contraindicated for the following situations:

1. The patient's condition is such that a two-stage arthroplasty procedure is contraindicated due to decreased immune response or other relevant systemic clinical conditions.
2. Bone loss precluding adequate support of the prosthesis.
3. Lack of adequate competence (anatomical and functional) of peripheral ligamentous apparatus and extensor mechanism.
4. The procedure is unjustified due to deficiencies in the patient's muscular, nervous or vascular systems.
5. Poor bone quality (i.e. osteoporosis) could cause the prosthesis to migrate or to fracture host bone.
6. Infection of the total knee replacement cannot be confirmed.
7. The infected total knee replacement devices cannot be removed.
8. The infecting pathogens are resistant to gentamicin.
9. The patient is sensitive (allergic) to gentamicin, aminoglycosides, or PMMA bone cement.
10. A systemic or secondary remote infection is expected or confirmed.
11. The patient does not have a total knee replacement and the infection is secondary to trauma, septic arthritis or other surgical procedures.
12. The patient does not have sufficient bone stock to allow insertion and fixation of the temporary prosthesis.
13. The patient has neuromuscular disorders that do not allow control of the knee joint.
14. The patient's age, weight, or activity level would cause the surgeon to expect early failure of the system.
15. The patient is unwilling to comply with post-operative instructions prior to second stage revision knee surgery regarding limited mobility, limited activity level, and the use of mobility assistive devices.

INTENDED USE
KASM is a single-use device intended for use with polymethylmethacrylate/gentamicin bone cement.

PRECAUTIONS
Before using KASM, the surgeon should be familiar with the fundamentals of knee arthroplasty as well as the limitations of the device. Instructions should be given to the patient on the limitations of the device and how to modify his/her lifestyle accordingly. KASM and the cement spacers should not be used with other cement spacer systems and vice versa. Different dimensional incompatibilities among the various systems may cause premature failure.

WARNINGS
1. The patient is to be warned that there is a high risk of cement spacer fracture upon full weight-bearing or high activity.
2. Voids, air pockets, or cracks in the cement significantly decrease the strength of the cement spacers.
3. The molded temporary cement spacer knee prosthesis is intended for an implantation period of 180 days or less.
4. The knee cement spacers made using KASM cannot be expected to replace the load-bearing capability of normal healthy bone or knee joint replacement prostheses.
5. The temporary joint prosthesis has inherent mechanical limitations and is for patients who will consistently use traditional mobility assistive devices (i.e. crutches, walkers) throughout the implantation period.
6. Do not implant spacer molds.
7. Do not reuse the molds. The molds are disposable and designed for single-use only.

ADVERSE EFFECTS
Temporary cement spacers created by KASM have the potential for adverse effects including but not limited to:
1. Allergic reaction to bone cement or antibiotic.
2. Fracture of the molded temporary knee cement spacers.

MAGNETIC RESONANCE (MR)
KASM has not been evaluated for safety and compatibility in the MR environment. KASM has not been tested for heating or migration in the MR environment.

PACKAGING AND STERILITY
KASM is sterilized by ethylene oxide at a sterility assurance level of 10^{-6}. Sterile product packaging should be inspected for flaws before and after opening. In the presence of a flaw, assume the product is non-sterile and do not use. Do not re-sterilize the spacer molds. Do not use after the expiration date.

PRODUCT HANDLING
Always store the product unopened in its respective protective package. Store in a COOL, DRY place away from sources of heat and direct sunlight. Prior to use, inspect the packaging for damage, which may compromise sterility. When removing the product from its packaging, observe relevant aseptic techniques. Protect the product from contact with objects that may damage the surface finish. Inspect prior to use for visual damage. Slight variations in color and gloss are normal.

PRODUCT COMPLAINTS
Any complaint or dissatisfaction with product quality, performance, labeling, and/or safety should be reported to Ortho Development Corporation. If any of the implants or instruments “malfunction” (i.e., do not meet any of their performance specifications or does not perform as intended), and/or are suspected to have caused or contributed to the death or serious injury of the patient, Ortho Development Corporation should be notified immediately by phone, fax or written correspondence.

When filing a complaint, please provide the product description, product number, lot number, complainant’s name and address, and the nature of the complaint.

CAUTION
Federal Law (USA) restricts this device to sale, distribution and use by or on the order of a physician.
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