StageOne™ cement spacer molds are designed to provide the surgeon with choices never before offered in two-stage revision knee surgery for an infected total joint.

StageOne™ cement spacer molds empower the surgeon with the potential to customize an antibiotic loaded articulating cement spacer specifically for the patient (Figure 1).

StageOne™ cement spacer molds are designed to help retain the patient’s natural range of motion (Figure 2), maintain soft tissue tension and assist in enabling patient ambulation. Available in multiple sizes, StageOne™ knee cement spacer molds are sterile disposables made of medical grade silicone.

Figure 1: Internal depth gauge allows surgeon to customize thickness of tibial spacer.

Figure 2: Articulating spacer retains patient’s natural range of motion.
Tibial Technique

Select tibial mold size by using available x-ray template. Inject cement into mold. Use the depth gauge to determine thickness of the tibial component.

After cement has cured, invert the tibial mold and flex gently to remove spacer.

...Custom Articulating Spacers...
Select femoral mold size by using available X-ray templates. To fill the femoral mold, place the cement delivery nozzle tightly against the fill port on the side of the mold and inject the cement. Fill mold completely without pressurizing the full mold.

Upon completion of filling, examine the side walls of the femoral mold for distortion. Over-filling the mold will result in a malformed spacer. If necessary, squeeze mold so that excess cement exits the fill port.

After cement has cured, remove femoral spacer from mold by peeling the mold away from the spacer.

Trim the spacer with a knife or burr to remove residual cement.

...Reduced O.R. Time
Tibial and femoral sizes are completely interchangeable.

Tibial Sizing

80mm
75mm
70mm
65mm

Femoral Sizing

75mm
70mm
65mm
60mm

*Sizes not to scale
**Disposal Cement Spacer Molds for Temporary Knee Prosthesis**

**Femoral and Tibial Components**

**Description**

The disposable cement spacer molds (femoral and tibial) are sterile disposables made of medical grade silicone. They are filled with polymethylmethacrylate/gentamicin bone cement, or equivalents, either by injecting with a dispenser/gun, or by pouring the prepared cement into the mold. After the cement cures, the temporary spacers are to be removed from the molds and placed into the joint space. The spacers remain in place (180 days or less) until the second stage of the two-stage procedure is performed to implant a conventional knee joint prosthesis.

**Material**

Cement Spacers: Medical Grade Silicon

**Indications**

Disposable cement spacer molds are indicated for use to mold a temporary total knee replacement (TKR) for skeletally mature patients undergoing a two-stage procedure due to a septic process. The molded temporary knee prosthesis is indicated for an implantation period of 180 days or less. Because of inherent mechanical limitations of the device material (gentamicin/polyethylmethacrylate), the molded temporary prosthesis is only indicated for patients who will consistently use traditional mobility assist devices (e.g., crutches, walkers) throughout the implant period.

**Contraindications**

The temporary knee prosthesis made with the disposable cement spacer molds is 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 general health and systemic conditions.
5. Poor bone quality (as in osteoporosis) could cause the prosthesis to migrate or to fracture host bone.
6. Infection of the TKR cannot be confirmed.
7. The infected TKR devices cannot be removed.
8. The infecting pathogens are resistant to gentamicin.
9. The patient is sensitive (allergic) to gentamicin, polymyxins, or Pseudomonas aeruginosa.
10. A systemic or secondary infection is expected or confirmed.
11. The patient does not have a TKR and the infection is secondary to trauma, septic arthritis or other surgical procedures.
12. The patient does not have a TKR but the infection is secondary to trauma, septic arthritis or other surgical procedures.
13. The patient has neurovascular 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.

**Warnings**

1. Voids, air pockets, or cracks in the cement significantly decrease the strength of the lines spacer.
2. The lines cement spaces made using the Biomet Knee Spacer Molds cannot be expected to replace the load bearing capability of normal healthy bone or knee joint replacement prostheses.
3. The patient is to be warned that there is a high-risk of cement spacer fracture upon full weight bearing or high activity.
4. DO NOT implant spacer molds.

**Precautions**

1. The temporary joint prosthesis has inherent mechanical limitations and is for patients who will consistently use traditional mobility assist devices (e.g., crutches, walkers) throughout the implant period.
2. The molded temporary knee prosthesis is intended for an implantation period of 180 days or less.
3. Do not reuse. The molds are disposable, single use only.

**Potential Adverse Effects**

1. Fracture of the molded temporary knee components.
2. Allergic reaction to bone cement or antibiotic.
3. Do not reuse. The molds are disposable, single use only.

**Instructions for Use — Single Use Device**

Cement Molds are intended for use with Cobalt™ G-HV Bone Cement and the disposable cement spacer molds before starting.

1. Read the complete instructions for use of the Cobalt™ G-HV Bone Cement.
2. Select mold sizes appropriate for producing the temporary cement lines spacers to fill the space vacated by the explanted prostheses and any other explanted material (X-ray templates are available).
3. Trim delivery nozzle short to minimize cement waste.
4. Prepare cement mixture (see table below) and transfer to a delivery syringe, or alternatively, prepare the cement mixture in the delivery syringe. Depending on the syringes design and spacer size being fabricated, it may be necessary to employ more than one syringe, or to fill the syringes during mold filling. (Use of a delivery syringe is optional when using the tibial mold.)
5. Assemble delivery gun, syringe and nozzle.
6. While the cement is still low in viscosity (flowing easily), begin filling the selected mold. Fill the femoral mold by butting the delivery nozzle against the delivery port and injecting cement. Fill the tibial mold by pouring or injecting cement into its open top. (Cement viscosity can be reduced and the application phase extended by chilling the cement components prior to mixing. Consult cement manufacturers instructions for use.)
7. For the femoral mold, as filling nears completion, tip the mold so that the two small vents nearest the filling port are directed upward so that all air can escape as filling is completed. Do not pressurize the full mold.
8. Examine the sidewalls of the femoral mold for distension. Convexity of the sidewalls will result in a malformed spacer and suggests that cement viscosity was too high during fill. It may be possible to correct this problem by squeezing the mold to that excess cement exits the filling port.
9. Two to three minutes after filling, observe the level of cement in the femoral mold at the filling port. If the level has dropped, inject additional cement to compensate for the pre-cure shrinkage.
10. After the cement has hardened, remove the spacer from the mold either by pressing thumbs between the tabs on the femoral mold and peeling the mold away from the spacer, or inserting tibial mold and flexing gently. (If it is difficult to initiate separation of the femoral mold halves, a scalpel may be used to cut along the joining line of the mold halves.)
11. Trim the spacers with a knife or burr as necessary.

**Stage-One Knee Cement Spacer Molds**

**Implantation Technique**

1. Clean and prepare infected area using pulse lavage and thoroughly remove all residual cement remaining form primary implant before implanting cement spacer.
2. Spacers should be fixed to bone using Cobalt™ G-HV Bone Cement. Apply cement to spacers while cement is still medium viscosity. Apply spacers to bone after cement reaches high viscosity. Cement should stabilize the spacers but deep cement penetration into bone should be avoided to facilitate spacer removal at the 2nd stage revision.
3. Thoroughly remove all excess bone cement around spacers.
4. Before cement has cured, run leg through flexion and extension allowing femoral component to properly center tibial component.
5. Clean area using pulse lavage taking care to remove any excess cement particles.

**Note Prior to Implantation of 2nd Stage Revision Prostheses**

The Disposable Cement Spacer Molds are sterilized by exposure to a minimum dose of 250 kGy of gamma radiation. Do not re-sterilize. Do not use after expiration date. Caution Federal law (USA) restricts this device to sale by or on the order of a physician.

The information contained in this package insert was current on the date this brochure was printed. However, the package insert may have been revised after that date. To obtain a current package insert, please contact Biomet at the contact information provided herein.

---

**Knee Cement Spacer Molds**

**Cruciate Sacrificing Universal AGC-Style Components**

<table>
<thead>
<tr>
<th>Catalog No.</th>
<th>Femoral Mold Size</th>
<th>Recommended Number Cement Single Mixes</th>
</tr>
</thead>
<tbody>
<tr>
<td>432160</td>
<td>60mm</td>
<td>2</td>
</tr>
<tr>
<td>432165</td>
<td>65mm</td>
<td>2</td>
</tr>
<tr>
<td>432170</td>
<td>70mm</td>
<td>2</td>
</tr>
<tr>
<td>432175</td>
<td>75mm</td>
<td>2</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Catalog No.</th>
<th>Tibial Mold Size</th>
<th>Recommended Number Cement Single Mixes</th>
</tr>
</thead>
<tbody>
<tr>
<td>433165</td>
<td>65mm</td>
<td>2</td>
</tr>
<tr>
<td>433170</td>
<td>70mm</td>
<td>2</td>
</tr>
<tr>
<td>433175</td>
<td>75mm</td>
<td>2</td>
</tr>
<tr>
<td>433180</td>
<td>80mm</td>
<td>2</td>
</tr>
</tbody>
</table>

---

**Biomet Orthopedics, Inc.**

PO Box 587, Warsaw, IN 46581-0587 • 800.348.9500 ext. 1501

copyright ©2005 Biomet Orthopedics, Inc. All Rights Reserved • www.biomet.com

**Form No. Y-BMT-936/093005/K**

---

**Biomet Orthopedics, Inc.**

PO Box 587, Warsaw, IN 46581-0587 • 800.348.9500 ext. 1501

copyright ©2005 Biomet Orthopedics, Inc. All Rights Reserved • www.biomet.com

**Form No. Y-BMT-936/093005/K**