STAGEONE™ SELECT DISPOSABLE CEMENT SPACER MOLDS
FOR MAKING TEMPORARY HEMI-HIP PROSTHESIS
WITH REINFORCEMENT STEM

FOR USE IN THE U.S.A. ONLY

DESCRIPTION

The single-use cement spacer molds are sterile disposables made of medical grade silicone with a 316L stainless steel reinforcement stem. They are designed to be filled with Cobalt™ G-HV polymethylmethacrylate/gentamicin bone cement by injecting with a dispenser/gun into the mold. After the cement cures, the hemi-hip prosthesis is to be removed from the molds with the reinforcement remaining as the core of the hemi-hip prosthesis, assembled using the neck length adapter and placed into the joint space. The hemi-hip prosthesis remains in place (180 days or less) until the second stage of the two-stage procedure is performed to implant a conventional hip joint prosthesis.

MATERIALS

Cement Spacer Molds: Medical Grade Silicone
Reinforcement Stem: 316L Stainless Steel
Adapter/Insert: 316LVM Stainless Steel
Threaded Fitment: Glass Filled Nylon
Port Plug: Polypropylene

INDICATIONS

Disposable cement spacer molds with stainless steel reinforcement stems, adapters and inserts are indicated for use to mold a temporary hemi-hip replacement for skeletally mature patients undergoing a two-stage revision procedure due to a septic process. The temporary prosthesis is molded using Cobalt™ G-HV polymethylmethacrylate/gentamicin bone cement, assembled and inserted into the femoral medullary canal and acetabular cavity following removal of the existing femoral and acetabular implants and debridement. The device is intended for use in conjunction with systemic antimicrobial antibiotic therapy (standard treatment approach to an infection).

The hemi-hip prosthesis made from the StageOne Select disposable cement molds is not intended for use more than 180 days, at which time it must be explanted and permanent devices implanted or another appropriate treatment performed (e.g. resection arthroplasty, fusion, etc.).

Due to the inherent mechanical limitations of the hemi-hip prosthesis material (polymethylmethacrylate/gentamicin), the temporary hemi-hip 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 hemi-hip prosthesis made with the StageOne Select 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. Lack of adequate bone structure precludes adequate support of the hemi-hip prosthesis in the proximal femur or acetabular region.
3. The procedure is unjustified due to deficiencies in the patient’s muscular, nervous vascular systems, or soft tissue stability.
4. Poor bone quality (as in osteoporosis) could cause the hemi-hip prosthesis to migrate or to fracture host bone.
5. Infection of the Total Hip Replacement (THR) cannot be confirmed.
6. The infected THR devices cannot be removed.
7. A systemic or secondary remote infection is expected or confirmed.
8. The patient is sensitive (allergic) to gentamicin, aminoglycosides or PMMA bone cement.
9. The patient is sensitive (allergic) to stainless steel.
10. The patient does not have a THR and the infection is secondary to trauma, septic arthritis or other surgical procedures.
11. The patient does not have sufficient bone stock to allow control of the hip joint.
12. The patient has neuromuscular disorders that do not allow control of the hip joint.
13. The patient’s age, weight, or activity level would cause the surgeon to expect early failure of the system.
14. The infecting pathogens are resistant to gentamicin.
15. Patients with mental or neurologic conditions who are unwilling or incapable of following postoperative care instructions.

WARNINGS

1. Imperfections can significantly decrease the strength of the temporary hemi-hip prosthesis. Do not implant temporary hemi-hip prosthesis with voids, air pockets, or cracks in the cement. The temporary prosthesis can be inspected for internal voids via X-ray imaging prior to implantation.
2. Thoroughly clean and dry tapers prior to attachment of the modular head, adapter and stem components to avoid improper seating and crevice corrosion. Firmly seat modular head, adapter and stem components to prevent dissociation.
3. The temporary hemi-hip prosthesis made using the StageOne Select disposable cement spacer molds cannot be expected to replace the load bearing capacity of normal healthy bone or hip joint replacement prosthesis.
4. The patient is to be warned that there is a risk of temporary hemi-hip prosthesis fracture upon full weight bearing or high activity.
5. DO NOT implant silicone spacer molds.
6. Failure to thoroughly clean joint space of all cement wear debris may result in loosening wear and failure of the 2nd stage revision arthroplasty.
7. Patient smoking may result in delayed healing, non-healing and/or compromised stability in or around the placement site.
8. Device is single use only. Do not attempt to clean or re-sterilize this product. After use this product may be a potential biohazard. Reuse of devices labeled for single-use may result in product contamination, patient infection, and/or failure of the device to perform as intended.

**PRECAUTIONS**
1. The temporary hemi-hip prosthesis made using the StageOne Select disposable cement spacer molds has inherent mechanical limitations and is for compliant patients who will consistently use traditional mobility assist devices (e.g. crutches, walkers) throughout the implant period.
2. The molded temporary hemi-hip prosthesis is intended for an implantation period of 180 days or less.
3. DO NOT REUSE. The silicone molds are disposable, single use ONLY.
4. All trial, packaging, and instrument components must be removed prior to closing the surgical site. Do not implant.

**POTENTIAL ADVERSE EFFECTS**
1. Fracture of the temporary hemi-hip prosthesis component, made using the StageOne Select disposable cement spacer molds.
2. Allergic reaction to bone cement or antibiotic.
3. Allergic reaction to exposed stainless steel.
4. Foreign materials can serve as a host for bacterial adhesion.
5. Dislocation has been reported with two-stage revisions.

**INSTRUCTIONS FOR USE - SINGLE USE DEVICE**
Temporary hemi-hip prosthesis are intended for use with Cobalt G-HV Bone Cement.

1. Read the complete instructions for use of Cobalt G-HV Bone Cement and the disposable cement spacer molds before starting.
2. Select head mold and stem mold sizes appropriate for producing the temporary hemi-hip prosthesis to fill the space vacated by the explanted prostheses and any other explanted material (Trials available).
3. Ensure the reinforcement stem is in proper position in the hip mold. (The reinforcement stem taper should be fully seated in the proximal neck of the silicone mold.)
4. Check to ensure that the insert is properly positioned in the head mold. (Insert should be securely fastened to silicone mold post.)
5. 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 syringe design and hemi-hip prosthesis size being fabricated, it may be necessary to employ more than one syringe, or to refill the syringe during mold filling. (Chilling the cement components prior to mixing is recommended to reduce the viscosity of the bone cement and extend the application phase. Consult bone cement instructions for use.)
6. Assemble delivery gun/syringe and if using a cartridge with a compatible thread, firmly attach the mold directly to the cartridge. Otherwise, attach a short nozzle to the cartridge and push the end of the nozzle into the mold fill port.
7. While the cement is still low in viscosity (flowing easily), fill the head mold by injecting cement. Avoid pressurizing or overfilling the mold. Ensure no air is trapped between the cement and mold. Trapped air can be removed by inserting a hypodermic needle through the silicone to vent the air bubble. Once completely filled, separate the head mold from the cartridge, allow any pressurized cement to escape through the fill port for approximately 30 seconds, attach the port plug to the mold and place it on a flat surface.
8. While the cement is still low in viscosity (flowing easily) fill the stem mold by injecting cement. During filling, keep the proximal part of the stem pointed down in order to encourage the bone cement to flow around the reinforcement. Avoid pressurizing or overfilling the mold. Ensure no air is trapped between the cement and mold. Trapped air can be removed by inserting a hypodermic needle through the silicone to vent the air bubble. Once completely filled, separate the stem mold from the cartridge, allow any pressurized cement to escape through the fill port for approximately 30 seconds, attach the port plug to the mold and place it on a flat surface.
9. After the cement has hardened, remove the temporary hemi-hip prosthesis from the mold by cutting the silicone mold away from the hemi-hip prostheses, removal of the stem may be facilitated by first cutting around the glue joint, then cutting longitudinally down the stem. Removal of head may be facilitated by first cutting around glue joint, then section head top like an orange. A #12 scalpel blade may facilitate removal of silicone.
10. Trim the temporary hemi-hip prosthesis with a knife or deburr as necessary to create smooth surfaces.
11. Assemble with desired size of neck length adapter.

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<th>Stems</th>
<th>Part Numbers</th>
<th>Estimated # of Cobalt G-HV Mixes (40g)</th>
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IMPLANTATION TECHNIQUE

1. Clean and prepare infected area using pulse lavage and thoroughly remove all residual cement remaining from primary implant before implanting temporary hemi-hip prosthesis.
2. If cement fixation is desired, the temporary hemi-hip prosthesis should be fixed to bone using Cobalt G-HV Bone Cement. Apply cement to the temporary hemi-hip prosthesis while cement is still medium viscosity. Apply spacer to bone after cement reaches high viscosity. Cement should stabilize the temporary hemi-hip prosthesis but deep cement penetration into bone should be avoided to facilitate the temporary hemi-hip prosthesis removal at the 2nd stage revision.
3. Thoroughly remove all excess bone cement around the temporary hemi-hip prosthesis.
4. Again, clean area using pulse lavage, taking care to remove any loose cement particles.

NOTE: PRIOR TO IMPLANTATION OF 2ND STAGE REVISION PROSTHESIS, THOROUGHLY CLEAN JOINT SPACE WITH PULSE LAVAGE, TAKING CARE TO REMOVE ALL CEMENT PARTICULATE RESULTING FROM WEAR OF TEMPORARY HEMI-HIP PROSTHESIS.

MRI INFORMATION
The StageOne Select Hemi-Hip Cement Spacer Molds and Cement Spacers have not been evaluated for safety and compatibility in the MR environment. The devices have not been tested for heating or migration in the MR environment. The risks associated with a passive implant in an MR environment have been evaluated and are known to include heating, migration, and image artifacts at or near the implant site.

STERILITY
The Disposable Cement Spacer Molds are sterilized by exposure to a minimum dose of 25kGy of gamma radiation. Single Use Only. Do Not Reuse. Do not re-sterilize. Do not use any component from an opened or damaged package. Do not use after expiration date.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.

Comments regarding this device can be directed to Attn: Regulatory Dept., Biomet, Inc., P.O. Box 587, Warsaw, IN 46581 USA, Fax 574-372-3968

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