



Precautionary Statement (01-50-0936)

Biomet Orthopedics, Inc. 01-50-0936

P.O. Box 587

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56 East Bell Drive

Warsaw, Indiana 46581 USA

STAGEONE™ DISPOSABLE CEMENT SPACER MOLD FOR TEMPORARY 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 polymethylmethacrylate/gentamicin bone cement, or equivalent, by injecting with a dispenser/gun into the mold. After the cement cures, the temporary spacers are to be removed from the molds with the reinforcement remaining as the core of the spacer, 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 hip joint prosthesis.

MATERIALS:

Cement Spacer Molds Medical Grade Silicone

Reinforcement Stem CF3M 316L Stainless Steel

INDICATIONS

Disposable cement spacer molds with stainless steel reinforcement stems 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 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 femoral prosthesis is not intended for use more than 180 days, at which time it must be explanted and a permanent device implanted or another appropriate treatment performed (e.g. resection arthroplasty, fusion, etc.)

Because of inherent mechanical limitations of the device material (polymethylmethacrylate/gentamicin), the molded temporary prosthesis is only indicated for compliant patients who will consistently use traditional mobility assist devices (e.g. crutches, walkers) throughout the implant period.

CONTRAINDICATIONS

The temporary hip prosthesis made with the disposable cement spacer mold 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 prosthesis in the proximal femur or acetabular region.
3. The procedure is unjustified due to deficiencies in the patient's muscular, nervous or vascular systems.
4. Poor bone quality (as in osteoporosis) could cause the prosthesis to migrate or to fracture host bone.
5. Infection of the 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 does not have a THR and the infection is secondary to trauma, septic arthritis or other surgical procedures.
10. The patient does not have sufficient bone stock to allow insertion and fixation of the prosthesis.
11. The patient has neuromuscular disorders that do not allow control of the hip joint.
12. The patient's age, weight, or activity level would cause the surgeon to expect early failure of the system.
13. The infecting pathogens are resistant to gentamicin.
14. Patients with mental or neurologic conditions who are unwilling or incapable of following postoperative care instructions.

WARNINGS

1. DO NOT IMPLANT hip spacers with voids, air pockets, or cracks in the cement. These imperfections can significantly decrease the strength of the hip spacer.
2. The hip cement spacers made using the Biomet® StageOne™ hip spacer molds cannot be expected to replace the load bearing capability of normal healthy bone or hip joint replacement prostheses.
3. The patient is to be warned that there is a 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 compliant patients who will consistently use traditional mobility assist devices (e.g. crutches, walkers) throughout the implant period.
2. The molded temporary hip 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 hip component.
2. Allergic reaction to bone cement or antibiotic.

INSTRUCTIONS FOR USE - SINGLE USE DEVICE

Hip cement molds 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 mold before starting.
2. Select a mold size appropriate for producing the temporary cement hip spacer to fill the space vacated by the explanted prostheses and any other explanted material (X-ray templates are available).



3. Check to ensure that the reinforcement stem is properly situated within the hip mold. (The tip of the reinforcement should be just within the mold.)
4. Trim delivery nozzle to ease delivery and minimize waste.
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 spacer size being fabricated, it may be necessary to employ more than one syringe, or to refill the syringe during mold filling.
6. Assemble delivery gun, syringe and nozzle.
7. While the cement is still low in viscosity (flowing easily), begin filling the mold by butting the delivery nozzle against the mold filling port near the head and inject cement. (Chilling the cement components prior to mixing is highly recommended to reduce the viscosity of the cement and extend the application phase. Consult bone cement instructions for use.) At the start of filling, keep the femoral head pointed down to keep the reinforcement stem in place. Alternatively, squeezing the A/P nibs will also keep the reinforcement stem in place during filling. If an air void forms during filling, pierce the mold with a scalpel to release the air.



8. As filling of the femoral head nears completion, position the mold so that one of the small vents on the head portion of the mold is directed upward so that all air can escape. Continue filling through the proximal port until the head of the mold has filled completely.
9. Once the femoral head is filled, finish filling the stem of the mold through the distal port.



10. Once completely filled, the mold is to be placed on a flat surface so that it stands on its foot and distal tip. Two to three minutes after filling, observe the level of cement at the filling ports. If the level has dropped, inject additional cement to compensate for the pre-cure shrinkage.



11. After the cement has hardened, remove the spacer from the mold by using a scalpel to initiate separation of the

two halves of the mold. Once the mold has started to separate, press thumbs between the tabs on the hip mold and peel the mold away from the spacer.



- Trim the spacer with a knife or burr as necessary to create a smooth surface.



Nominal Stem Diameter	Stem Length	Endo-Style Head Diameter	Recommended #of Cement Mixes
9mm	125mm	43mm	2 X 40 grams
9mm	125mm	51mm	3 X 40 grams
13mm	145mm	57mm	3 X 40 grams
17mm	165mm	64mm	4 X 40 grams

STAGEONE™ CEMENT SPACER MOLDS HIP WITH REINFORCEMENT STEM IMPLANTATION TECHNIQUE

- Clean and prepare infected area using pulse lavage and thoroughly remove all residual cement remaining from primary implant before implanting cement spacer.
- If cement fixation is desired, spacer should be fixed to bone using Cobalt™ G-HV Bone Cement. Apply cement to spacer while cement is still medium viscosity. Apply spacer to bone after cement reaches high viscosity. Cement should stabilize the spacer but deep cement penetration into bone should be avoided to facilitate spacer removal at the 2nd stage revision.
- Thoroughly remove all excess bone cement around spacers.
- 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 SPACER.

WARNING: FAILURE TO THOROUGHLY CLEAN JOINT SPACE OF ALL CEMENT WEAR DEBRIS MAY RESULT IN LOOSENING AND FAILURE OF THE 2ND STAGE REVISION ARTHROPLASTY.

STERILIZATION

The Disposable Cement Spacer Molds are sterilized by exposure to a minimum dose of 25kGy 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.

Comments regarding this device can be directed to Attn: Regulatory Dept., Biomet, Inc., P.O. Box 587, Warsaw, IN 46581 USA, Fax 574-372-1683