StageOne™ hip cement spacer molds are designed to mold a temporary hip spacer for patients undergoing a two-stage revision due to an infected total joint.

- Spacer helps retain the patient’s natural range of motion (Figure 1)
- Spacer preserves the soft tissue envelope for second stage reimplantation
- Reinforced core allows for partial weight bearing applications (Figure 2)*
- Spacer design based on clinically proven Biomet® hip geometry

*See indications and warnings in package insert herein.
Hip Technique

Select proper size hip mold by using available X-ray template. Start by filling the mold at the proximal fill port. Upon filling the head and proximal portion of stem, proceed to step 2.

Complete filling of the mold by placing the cement delivery nozzle tightly against the distal fill port and fill the distal portion of the stem.

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

Custom Articulating Spacers

*Sizes not to scale
Hip Cement Spacer Molds:

The disposable cement spacer mold is indicated for compliant patients who will consistently use traditional mobility assist devices (e.g. crutches, walkers) throughout the implant period.

INDICATIONS

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 unfeasible due to deficiencies in the patient’s musculature, nervous or vascular systems.
4. Poor bone quality (e.g. osteoporosis) could cause the prosthesis to migrate or to fracture host bone.
5. Infection of the THR cannot be confirmed.
6. The infected THR device cannot be removed.
7. A systemic or secondary remote infection is expected or confirmed.

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 spacer mold cannot be expected to replace the load bearing capacity 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 hip 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.

PRODUCT AND PATIENT INSTRUCTIONS

1. Fracture of the molded temporary hip component.
2. Allergic reaction to bone cement or antibiotic.

INSTRUCTIONS FOR USE - SINGLE USE DEVICE

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 hip spacer to fill the space vacated by the explanted prosthesis and any other explanted material (X-ray templates are available).
3. Check to ensure that the reinforcement stem is properly seated within the hip mold. (This step 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 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 ribs 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 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.
12. Trim the spacer with a knife or burr as necessary to create a smooth surface.

PRODUCT AND PATIENT INSTRUCTIONS - STAGEONE™ CEMENT SPACER MOLDS HIP WITH REINFORCEMENT STEM IMPLANTATION TECHNIQUE

1. Clean and prepare infected area using pulse lavage and thoroughly remove all residual cement remaining from primary implant before implanting cement spacer.
2. 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.
3. Thoroughly remove all excess bone cement around spacers.
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 SPACER.

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: Regulatory Dept., Biomet, Inc., P.O. Box 587, Warsaw, IN 46581 USA, Fax 574-372-1683

The information contained in the 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.

Products

Hip Cement Spacer Molds:
Collarless Bi-Metric Style Stem with an Endo Style Head.

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Reference