StageOne™ Knee Cement Spacer Molds

Surgical Technique

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Indications

StageOne™ Knee Cement Spacer Molds are indicated for use to mold a temporary total knee replacement (TKR) for skeletally mature patients undergoing a two-stage revision procedure due to a septic process. The temporary prosthesis is molded using Refobacin Bone Cement R and inserted into the joint space following removal of the existing total knee replacement implants and debridement. The device is intended for use in conjunction with systemic antimicrobial antibiotic therapy (standard treatment approach to an infection).

The knee prosthesis made from the StageOne™ Knee Cement Spacer 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 knee prosthesis material (Refobacin Bone Cement R), the temporary knee prosthesis is only indicated for patients who will consistently use traditional mobility devices (e.g. crutches, walkers) throughout the implant period.

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

Figure 2: Articulating spacer supports patient range of motion.

Contraindications

StageOne™ Knee Cement Spacer Molds are contraindicated for the following situations:

- 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.
- Bone loss precluding adequate support of the prosthesis.
- Lack of adequate competence (anatomical and functional) of peripheral ligamentous apparatus and extensor mechanism.
- The procedure is unjustified due to deficiencies in the patient's muscular, nervous or vascular systems.
- Poor bone quality (as in osteoporosis) could cause the prosthesis to migrate or to fracture host bone.
- Infection of the TKR cannot be confirmed.
- The infected TKR devices cannot be removed.
- The infecting pathogens are resistant to gentamicin.
- The patient is sensitive (allergic) to gentamicin, aminoglycosides or PMMA bone cement.
- A systemic or secondary remote infection is expected or confirmed.
- The patient does not have a TKR and the infection is secondary to trauma, septic arthritis or other surgical procedures.
- The patient does not have sufficient bone stock to allow insertion and fixation of the prosthesis.
- The patient has neuromuscular disorders that do not allow control of the knee joint.
- The patient's age, weight, or activity level would cause the surgeon to expect early failure of the system.

Figure 3

Figure 4

Tibial Technique

Select tibial mold size by using available X-ray template. Inject or lap cement into mold (Figure 3). 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 (Figure 4).

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

Figure 5

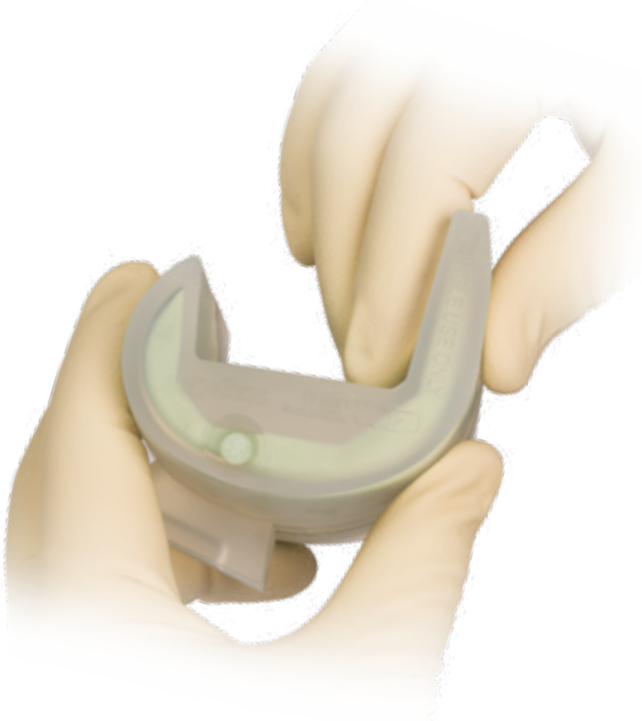


Figure 6

Femoral Technique

Select femoral mold size by using available X-Ray templates. Before filling the mold, trim cement nozzle short to minimize waste and to ensure proper mold filling. 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 (Figure 5). Fill mold completely without pressurizing the full mold.

As filling nears completion, tip the mold so that the two small vents nearest the filling port are directed upward so that air can escape as filling is completed.

Upon completion of filling, examine the side walls of the femoral mold for distortion (Figure 6). Over-filling the mold will result in a malformed spacer. If necessary, squeeze mold so that excess cement exits the fill port.

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.

Figure 7

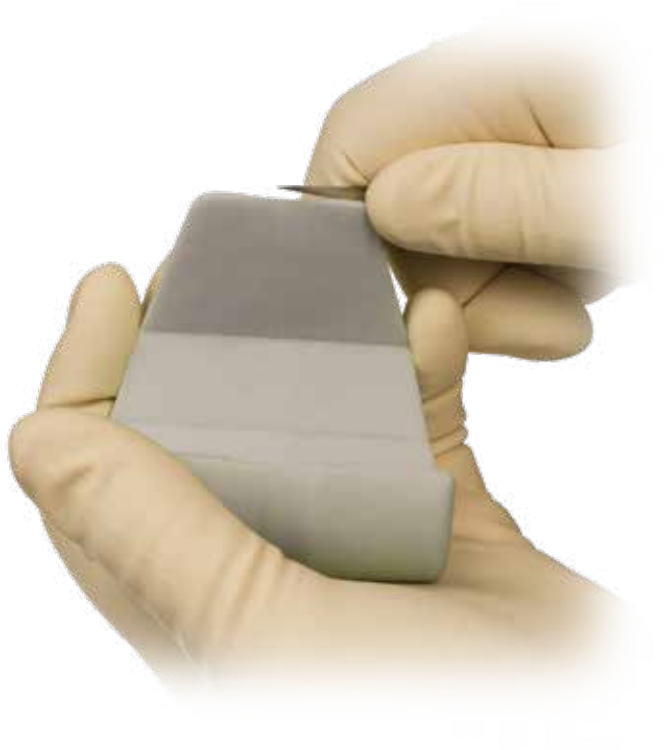


Figure 8

Femoral Technique (cont.)

After cement has cured, remove femoral spacer from mold by peeling the mold away from the spacer (Figure 7).

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.

Trim the spacer with a knife or burr to remove residual cement (Figure 8).

Implantation Instructions

Clean infected area using pulse lavage and thoroughly remove all residual cement remaining from primary implant before implanting cement spacers.

Spacers should be fixed to bone using the identical bone cement used to form the spacers (i.e. Refobacin® Bone Cement R). Cement should stabilize the spacers 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. Before cement has cured, run leg through flexion and extension allowing femoral component to properly center tibial component.

Finally, clean area using pulse lavage taking care to remove any loose cement particles.

Removal Instructions

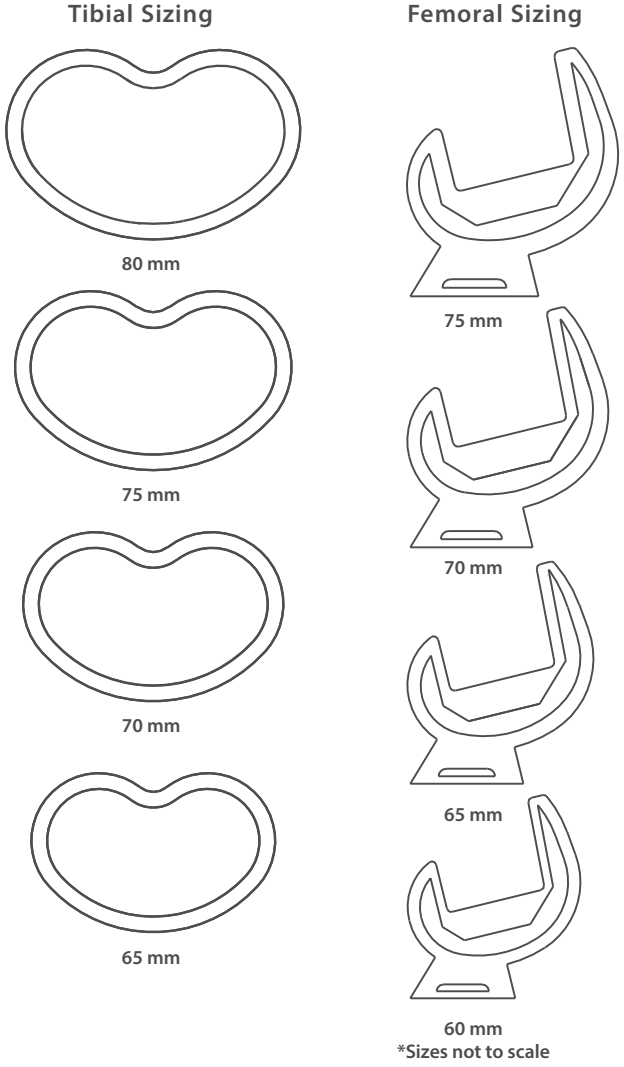
Remove the temporary spacers from the tibiofemoral joint space. Spacers must be removed within 180 days from implantation date.

Prior to implantation of second stage revision prosthesis, thoroughly clean joint space with pulse lavage, taking care to remove all cement particulate resulting from wear of the temporary knee prosthesis.

Warning: Failure to thoroughly clean joint space of all cement wear debris may result in loosening and failure of the 2nd stage revision arthroplasty.

Knee Cement Spacer Molds

Tibial and femoral sizes are completely interchangeable.



Cruciate Sacrificing Universal AGC®-Style Components

Catalog No.	Femoral Mold Size	Recommended Number Cement Single Mixes (40G)
432160	60 mm	2
432165	65 mm	2
432170	70 mm	2
432175	75 mm	2

Catalog No.	Tibial Mold Size	Recommended Number Cement Single Mixes (40G)
433165	65 mm	2
433170	70 mm	2
433175	75 mm	2
433180	80 mm	2

Catalog No.	Description
XR431100	StageOne Hip and Knee X-Ray Templates

Bone Cement

Product	Description	Part Number	Units/Case
	**Refobacin® Bone Cement R 1X40 (With Gentamicin)**	110034355	1

Vacuum Mixing Cartridges and Injection Systems

ClearMix® Vacuum Mixing Systems

Product	Description	Part Number	Units/Case
	**ClearMix Single/Double Vacuum Mixing System**	414701	1
	ClearMix Single/Double Vacuum Mixing System	414702	10
	**ClearMix Triple Vacuum Mixing System**	414703	1

Accessories

Product	Description	Part Number	Units/Case
	**ClearMix Delivery Gun**	414700	1

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As with all surgical procedures, the technique used in each case will depend on the surgeon's medical judgment as the best treatment for each patient. Results will vary based on health, weight, activity and other variables. Not all patients are candidates for this product and/or procedure.

Caution: Federal (USA) law restricts this device to sale by or on the order of a surgeon. Rx only.

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