

# StageOne™ Knee Cement Spacer Molds

Surgical Technique





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



Figure 2: Articulating spacer supports patient range of motion.

## Description/Indications

The disposable cement spacer molds (femoral and tibial) are sterile disposables made of medical grade silicone. They are intended to be filled with PALACOS® R+G Bone Cement\* or Refobacin® Bone Cement R\*, 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.

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 (PALACOS R+G Bone Cement and Refobacin Bone Cement R\*), 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.



Figure 3



Figure 4

### Tibial Technique

Select tibial mold size by using available x-ray template. Inject 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).



Figure 5

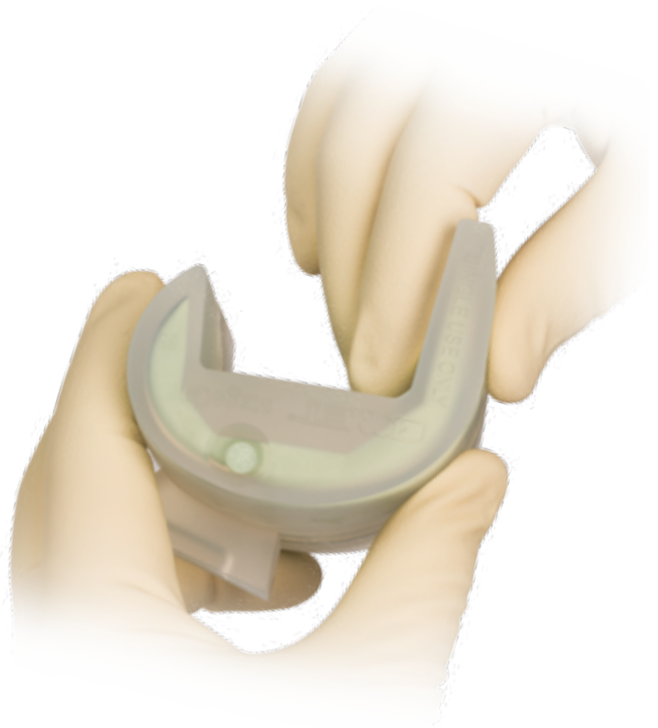


Figure 6

## Femoral Technique

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 (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 all 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.

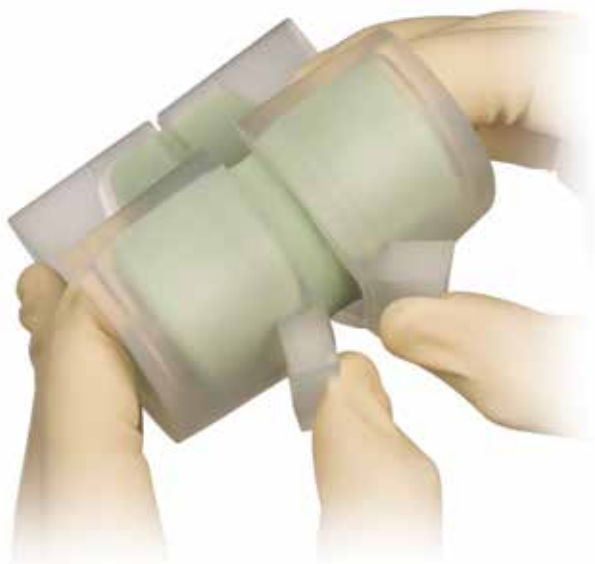


Figure 7



Figure 8

### Femoral Technique (cont.)

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

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 spacer.

Spacers should be fixed to bone using the identical bone cement used to form the spacers (i.e. PALACOS R+G Bone Cement or 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.

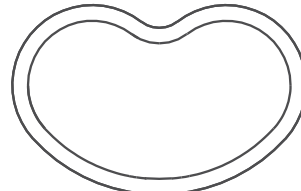
ⓘ **Note:** Failure to thoroughly clean joint space of all cement wear debris may result in loosening and failure of the 2nd stage revision arthroplasty.

## Knee Cement Spacer Molds

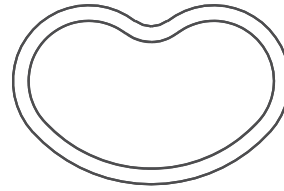
Tibial and femoral sizes are completely interchangeable.



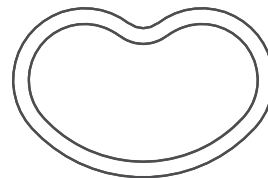
### Tibial Sizing



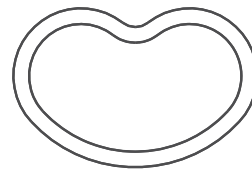
80 mm



75 mm

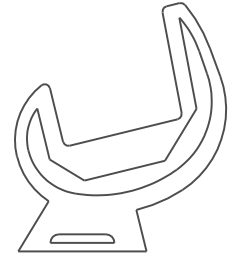


70 mm

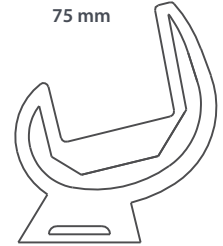


65 mm

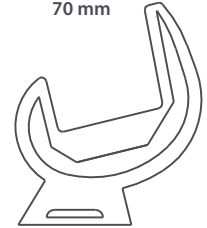
### Femoral Sizing



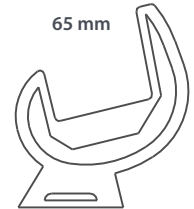
75 mm



70 mm



65 mm



60 mm

\*Sizes not to scale

## 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

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