

StageOne™ Shoulder Cement Spacer Molds

Surgical Technique



DESCRIPTION/INDICATIONS

The StageOne Shoulder Spacer Molds are single use silicone spacer molds intended to be filled with PALACOS® R+G or Refobacin™ Bone Cement R*. Upon curing of the antibiotic loaded cement, the StageOne Shoulder Spacer Mold creates a temporary cement spacer for patients undergoing the first stage of a two-stage revision due to infection. The device is intended for use in conjunction with systemic antimicrobial antibiotic therapy (standard treatment approach to an infection).

ⓘ **Note:** The StageOne Shoulder Spacer is not intended for use for more than 180 days, at which time it must be explanted and replaced with a permanently implanted device or another appropriate treatment performed (e.g. resection arthroplasty, fusion, etc.)

Due to the inherent mechanical limitations of the spacer material, the StageOne Shoulder Spacer is only indicated for patients who will consistently follow surgeons' activity limitations throughout the implant period.

INSTRUCTIONS FOR USE

After removal of the infected implants and all associated cement that is present, it is recommended to debride and copiously lavage all bone surfaces of any remaining tissue that appears to be infected.

Expose the glenohumeral joint to allow for proper access. Carefully debride and ream the bone surface to assist with sizing of the temporary spacer.

Utilize Biomet's Comprehensive® shoulder standard length reamers to assist with debridement and bone preparation of the humerus. Once stability has been attained, the surgeon can then trial. Broach the proximal humerus sequentially using the Comprehensive mini length broaches until the broach size is equal to the size of the humeral reamer.

Using the explanted humeral head for comparison, select an appropriately sized head trial and assemble to a standard trial taper adapter. The trial assembly should be set to the offset marked "A." Move the shoulder through its range of motion to check arm length, soft tissue tension and overall stability.

ⓘ **Note:** The StageOne Shoulder Spacers do not contain a porous coating on the humeral stem as the Comprehensive implants do; therefore the final spacer implant fit will be equivalent to the broach fit.

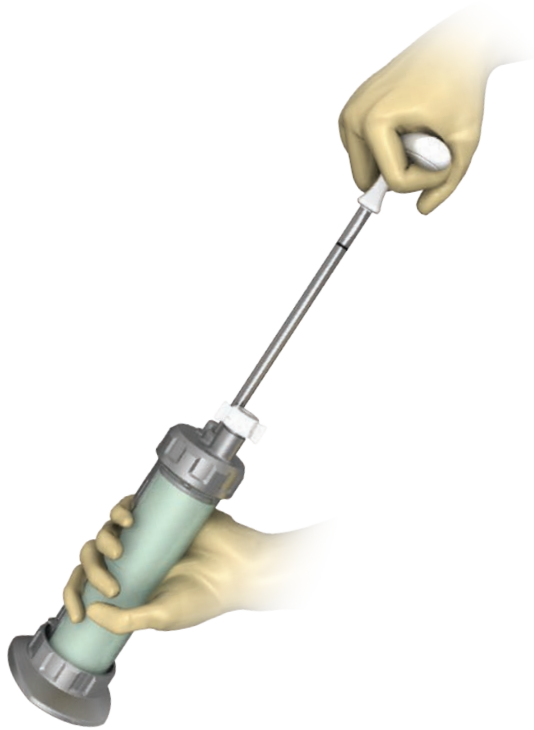


Figure 1

Spacer Mold Preparation

The StageOne Shoulder Spacer System is intended for use with PALACOS R+G Bone Cement or Refobacin Bone Cement R* in combination with a compatible threaded cartridge mixing system.

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.

To begin with spacer mold preparation, use the reference chart on page 8 as an aid to determine the estimated number of 40 g batches of cement needed to fill the one piece stem and head mold.

Prepare cement mixture using a cartridge mixing system. (Figure 1).

ⓘ **Note:** Surgeon should read the complete instructions for use for use of bone cement and the disposable cement spacer molds before starting.



Figure 2

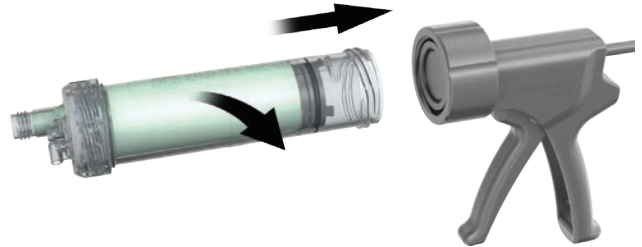


Figure 3

Spacer Mold Preparation (cont.)

Snap off the mixing rod and remove the white port plug. (Figure 2).

ⓘ **Note:** When using a compatible threaded cartridge do not attach the mixing system's nozzle. The delivery port of the cartridge will be screwed directly to the distal end of the mold.

Assemble the cartridge into the delivery gun (Figure 3).



Figure 4

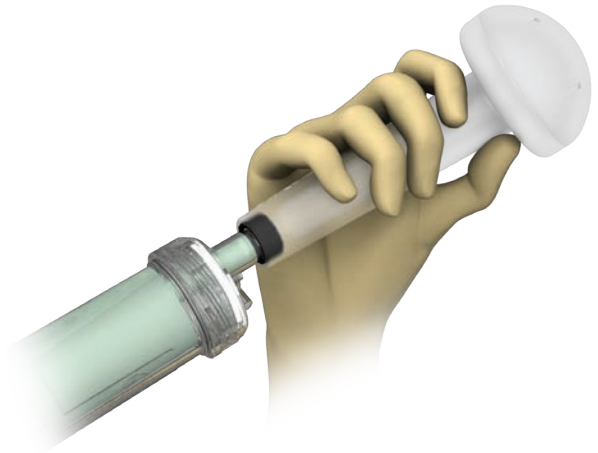


Figure 5

Filling the Mold

Select appropriate mold size for making a shoulder cement spacer needed to fill the space vacated by the explanted prosthesis and other explanted material (Figure 4).

Note: Broaches and humeral head trials are available for trialing before choosing the shoulder spacer mold. Select a spacer size that most closely matches the final broach/trials used.

If using a cartridge with a compatible thread, screw the cartridge delivery port directly to the distal threaded opening on the mold (Figure 5).

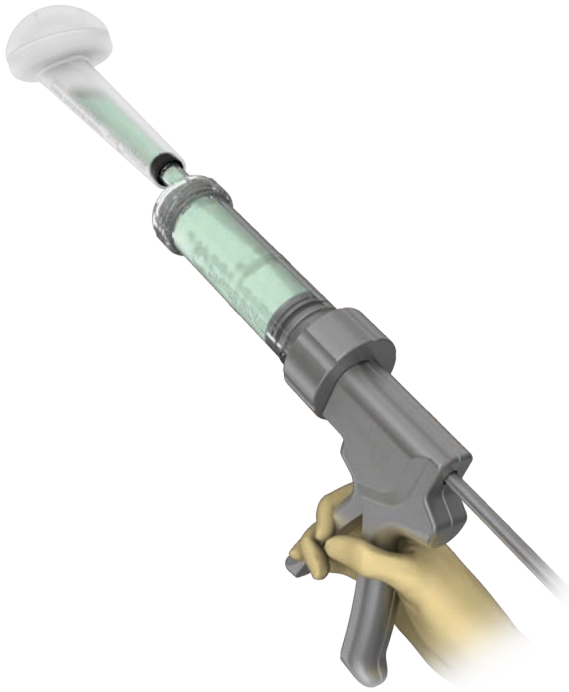


Figure 6



Figure 7

Filling the Mold (cont.)

Fill the mold (Figure 6).

Note: Begin filling the mold at any speed, but finish slowly as cement exits the vent holes or the mold is filled.

Take care not to overfill the mold. Ensure no air is trapped between the cement and the mold. Trapped air can be removed by inserting a hypodermic needle through the silicone to vent the air bubble.

Remove the cartridge from the threaded port. Allow the mold to relax and excess cement to extrude from the threaded port. Clean off any excess cement from the port or vent holes. Screw the port plug clockwise into the threaded port until tight (Figure 7).

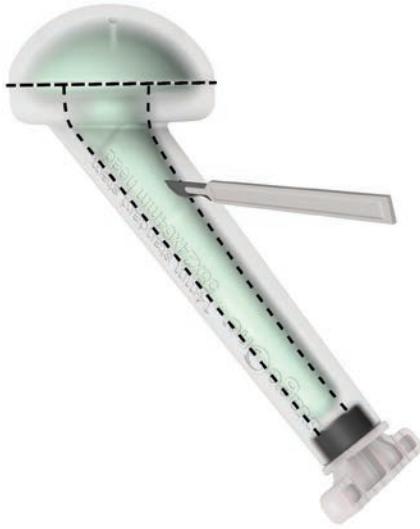


Figure 8

Filling the Mold (cont.)

After the bone cement has cured, leave the port plug in place and use a scalpel to cut open the silicone mold.

Removal of the spacer may be facilitated by first cutting around the glue joint, then cutting longitudinally down the stem (Figure 8).

Note: A hooked #12 blade is recommended to facilitate the opening of the mold.

Remove the spacer from the mold. Discard the mold.



Figure 9

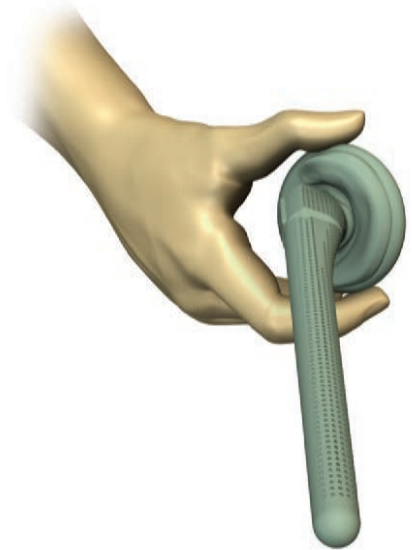


Figure 10

Instructions for Implantation

Before inserting the shoulder cement spacer, thoroughly clean the joint with high-pressure pulse lavage to remove any loose debris (Figure 9).

The shoulder spacer can either be press fit or lightly cemented depending on implant stability and bone quality. If cement fixation is desired, fix the shoulder spacer to bone using the identical bone cement used to form the spacer (i.e. PALACOS R+G Bone Cement or Refobacin Bone Cement R*). Apply cement to shoulder spacer when cement is nearing the end of the working phase.

Note: Apply cement to the underside of the head to stabilize the spacer but avoid deep cement penetration into bone in order to facilitate removal of the spacer before the second-stage revision (Figure 10).

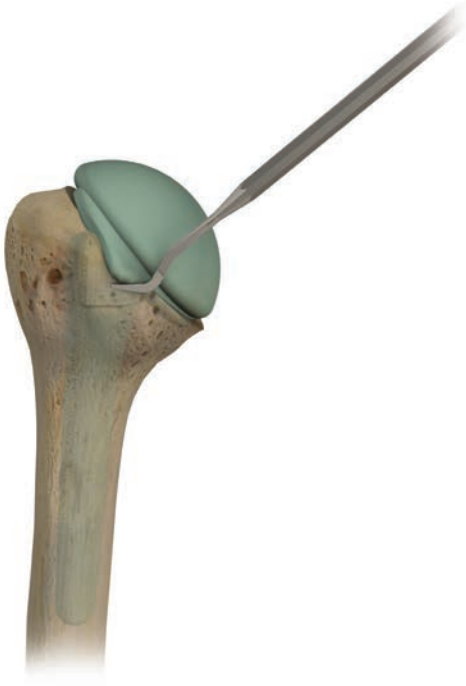


Figure 11

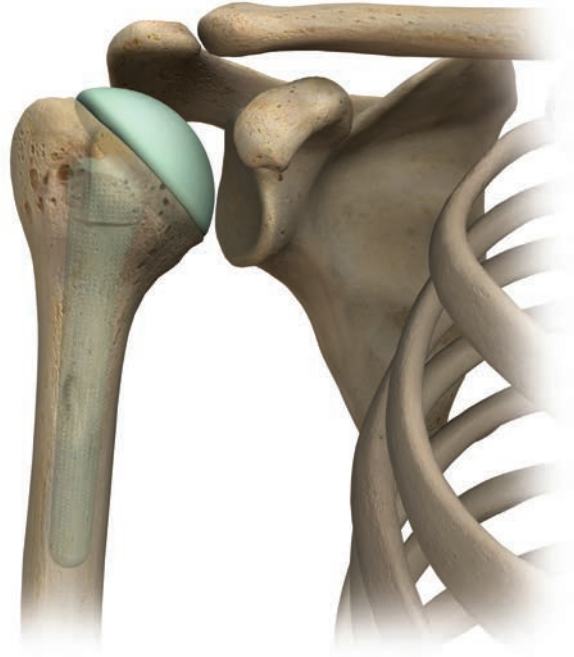


Figure 12

Instructions for Implantation (cont.)

Manually insert the shoulder spacer into the humeral canal while approximating anatomical version. When further seating is desired, use a head-pusher for leverage. DO NOT impact the spacer with a mallet directly as this can result in fracture of the device.

Thoroughly remove all excess bone cement around the shoulder spacer (Figure 11).


Clean area again using pulse lavage, taking proper care to completely remove any loose cement particles (Figure 12).

Close wound.




ⓘ **Note:** Prior to implantation of second stage prosthesis, thoroughly clean the joint space with pulse lavage, taking care to remove all cement particulate resulting from wear of temporary and hemi-shoulder prosthesis.

Implants and Accessories

StageOne Shoulder Spacer Molds

Product	Description	Size	Estimated Number of 40g Cement Mixes	Part Number
	StageOne Shoulder Spacer Molds	6mm stem w/ 42x18x46 mm head	1	431406
		8mm stem w/ 46x18x53 mm head	2	431408
		10mm stem w/ 50x21x57 mm head	2	431410
		12mm stem w/ 54x21x64 mm head	2	431412
		14mm stem w/ 58x24x64 mm head	2	431414

Bone Cement and Cementing Systems

Product	Description	Part Number
	Refobacin Bone Cement R 1x40	5003940001
	Refobacin Bone Cement R 2x40	5003940002
	PALACOS R+G with Gentamicin 40G	00111314001
	Vacuum Mixing Cartridge 80g Double	414702
	Cartridge Delivery Gun	414700

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