

REMEDY® SHOULDER SYSTEM

SHOULDER MODULARITY

The REMEDY® Shoulder Spacer is part of the treatment foreseen in a two-stage procedure performed in the event of permanent prosthesis infection. The REMEDY® Shoulder Spacer implant is intended for temporary use only (180 days or less). It allows basic joint mobility and releases antibiotics into the joint area to protect the implant from bacterial colonization. A second surgery will be required at a later date to remove the REMEDY® Shoulder Spacer and replace it with a permanent shoulder joint implant.

REMEDY® Shoulder Spacers:

- Single-use medical devices/ethylene oxide sterile
- Formed with bone cement (PMMA) and gentamicin

REMEDY® MODULAR HEADS

Head sizes interchangeable with stems for surgical flexibility

REMEDY® MODULAR STEMS



REMEDY® SHOULDER SPACER TECHNIQUE



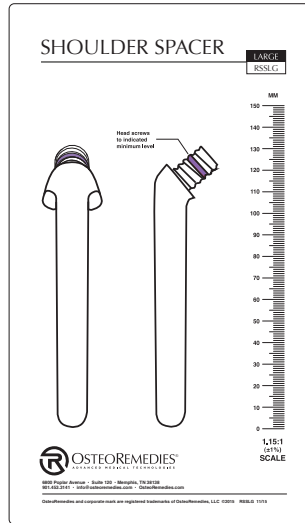
STEP 1

In accordance with the existing shoulder manufacturer's technique, prepare the infected joint space by first removing the shoulder prosthesis and any PMMA cement, if present, and any hardware that may be a reservoir of infection.

Continue to prepare the joint space with aggressive debridement, pulse lavage and other standard practices for preparing the infected joint space.

STEP 2

Using the Shoulder Spacer Trials and Templates, select the appropriate size humeral stem and humeral head components.



TEMPLATE

STEP 3



Once the appropriate humeral head size is selected, open the package and remove the monomer vial.

Carefully, break the vial open and pour all the monomer into the screw opening of the humeral head.

Insert and seal the hole with the plastic cover cap supplied with the humeral head. Shake the head for 60 seconds to ensure all of the threads within the head are wet with monomer.

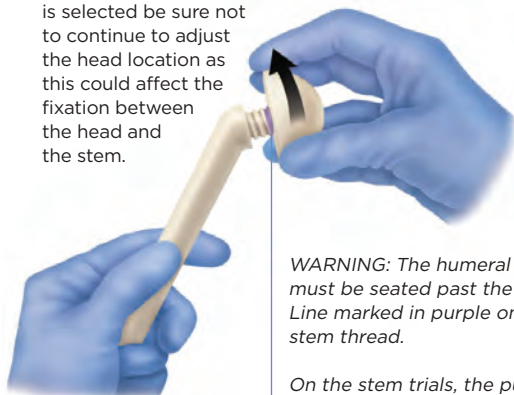


COVER CAP

STEP 4

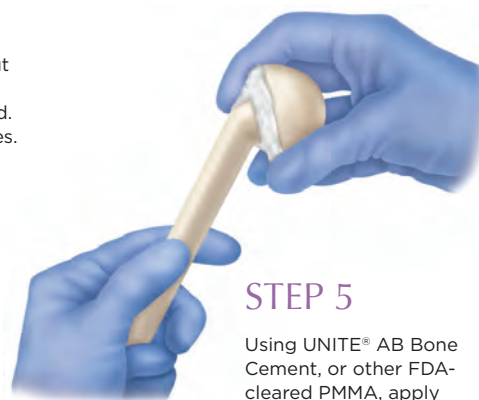
Remove the plastic cap, pour the remaining monomer out and place the head on the humeral stem. Begin turning the head until the desired offset and length are achieved. Approximate working time for the head is 10 to 15 minutes.

Important Note: Once the head location is selected be sure not to continue to adjust the head location as this could affect the fixation between the head and the stem.



WARNING: The humeral head must be seated past the Safety Line marked in purple on the stem thread.

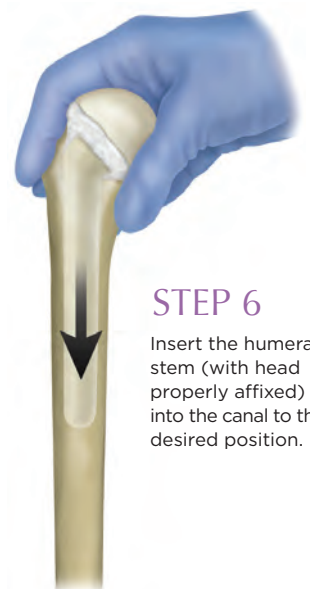
On the stem trials, the purple line is designated with a missing thread on the stem trunion.



STEP 5

Using UNITE® AB Bone Cement, or other FDA-cleared PMMA, apply cement to the proximal aspect of the stem. The use of bone cement is compulsory to avoid rotation and to limit the risk of dislocation or spacer loosening.

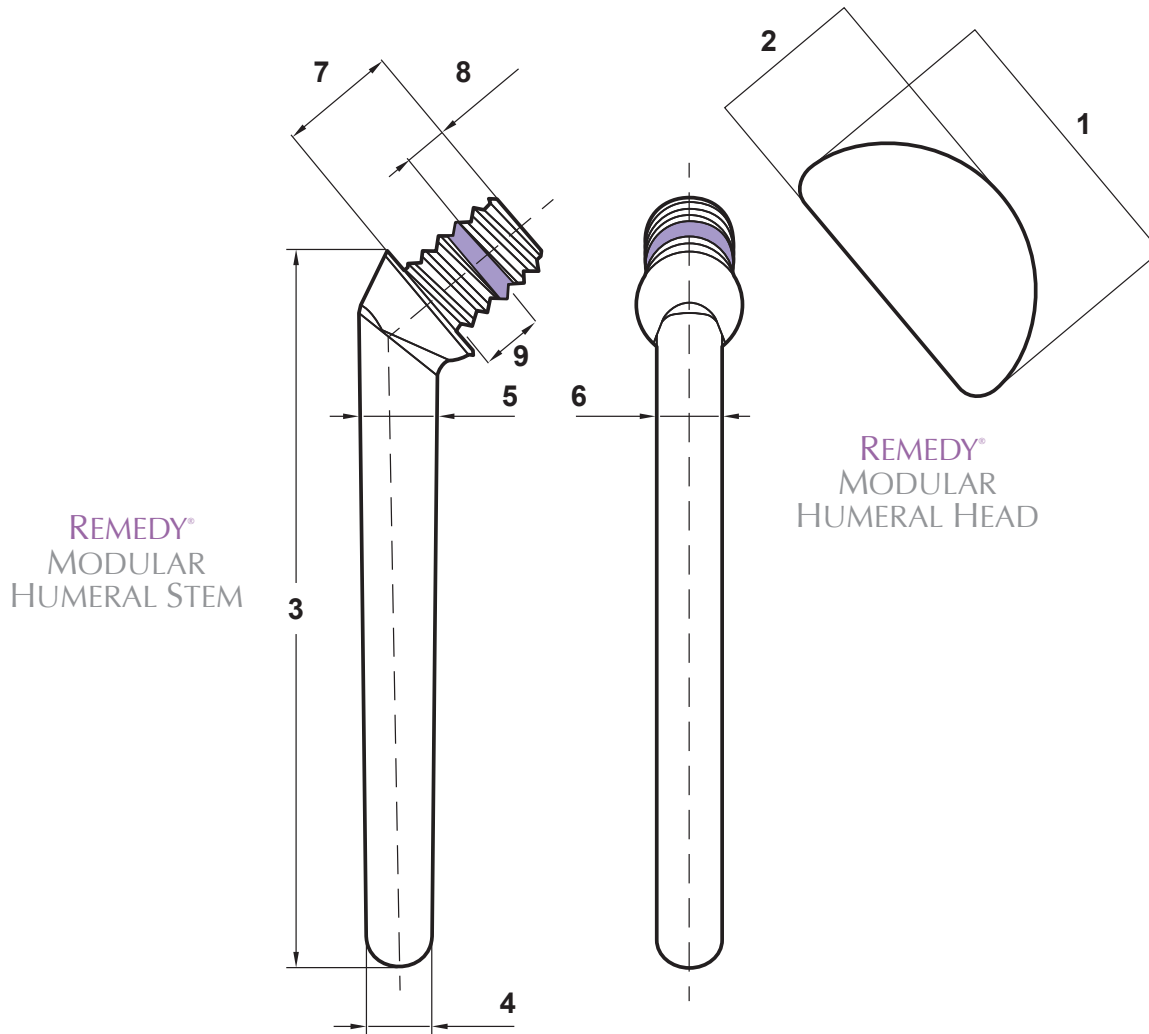
Note: Bone cement may also be applied once the stem is seated within the humeral canal.



STEP 6

Insert the humeral stem (with head properly affixed) into the canal to the desired position.

SHOULDER SPECIFICATIONS



REMEDY® SHOULDER SPACER

Description	Catalog #	(MM)									Gentamicin Base (g)
		1	2	3	4	5	6	7	8	9	
REMEDY® Modular Humeral Head 40mm	RSHHSM	40	25								0.5
REMEDY® Modular Humeral Head 45mm	RSHHMD	45	25								0.5
REMEDY® Modular Humeral Head 50 mm	RSHHLG	50	25								0.6
REMEDY® Modular Humeral Stem - Small	RSHSSM			101	7	9.4	7	19	7	12	0.1
REMEDY® Modular Humeral Stem - Medium	RSHSMD			116	10.5	12.6	10.5	19	7	12	0.3
REMEDY® Modular Humeral Stem - Large	RSHSLG			131	14	15.8	14	19	7	12	0.5