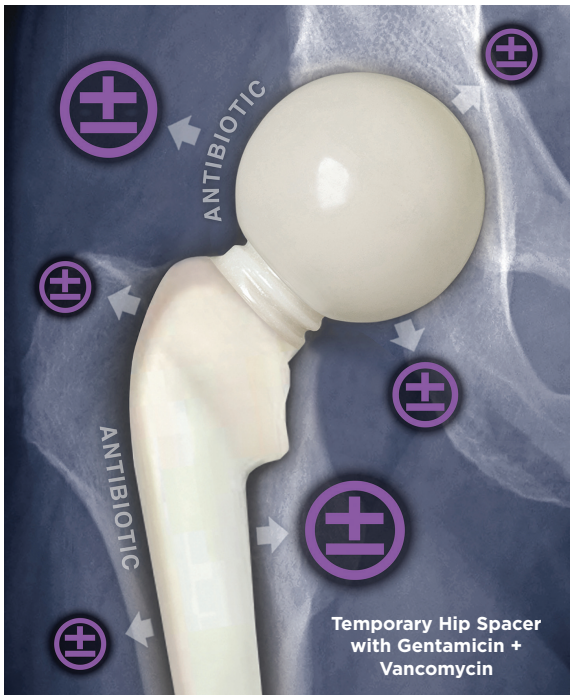
REMEDY SPECTRUM® GV HIP AND REMEDY® SPACER SYSTEMS

OSTEOREMEDIES®
ADVANCED MEDICAL TECHNOLOGIES

REMEDY SPECTRUM® GV HIP SPACER

THE FIRST **GENTAMICIN+ VANCOMYCIN** HIP SPACER*

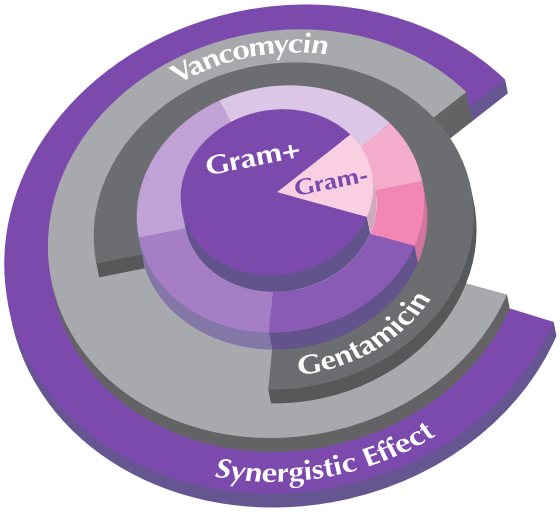
- Averages 4.5 grams Gent + Vanc per construct
- Long term elution compared to intra-operative molds
- Improved OR efficiency



BROAD SPECTRUM COVERAGE

- Increased spectrum of coverage to include MRSA/MRSE[1,2]
- The first Gentamicin + Vancomycin hip spacer and bone cement available in the U.S.

Synergistic antimicrobial effect against most common infecting pathogens[3,4]



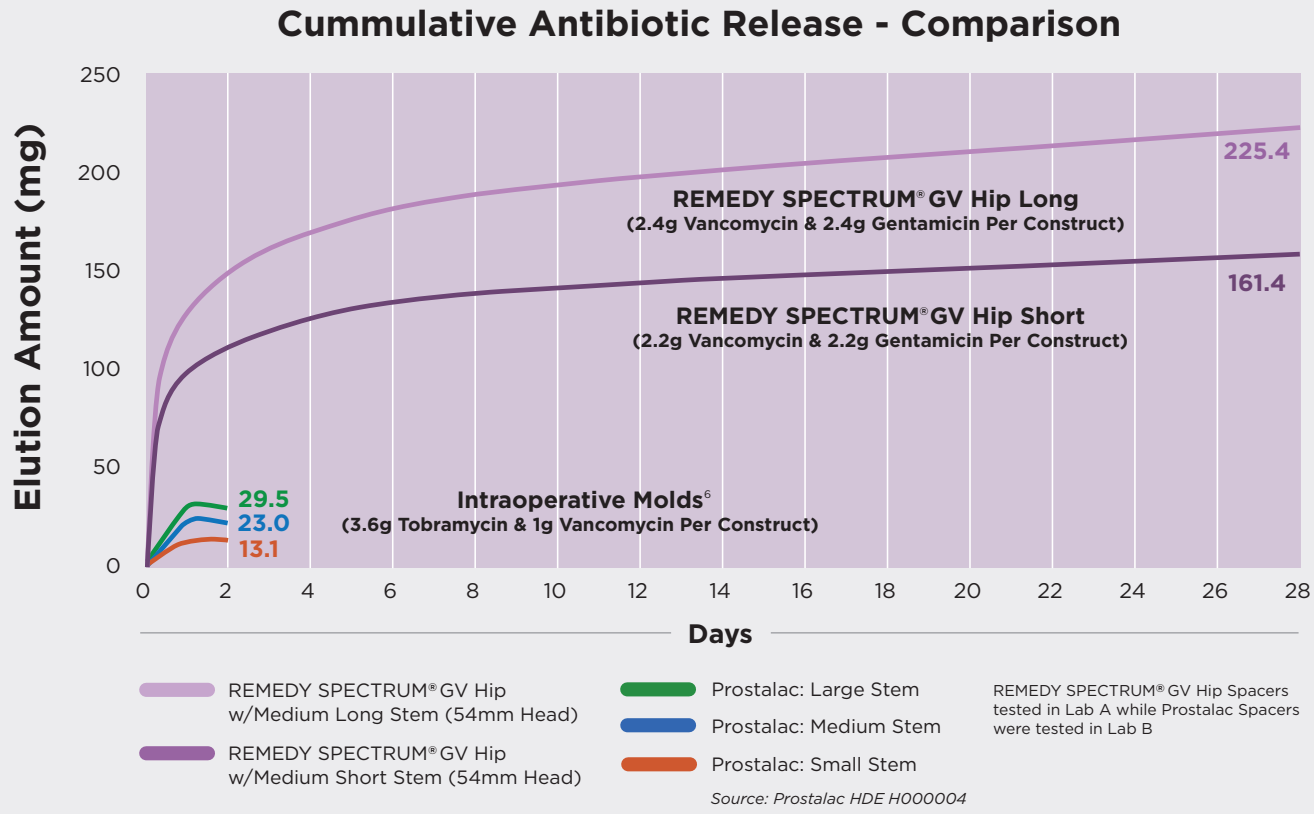
Spectrum Of Activity Of Vancomycin & Gentamicin[5]

- Pseudomonas spp.
- Enterobacteriaceae
- Streptococcus spp.
- Enterococcus spp.
- Staphylococcus spp. (Methicillin-resistant) MRSA/MRSE
- Staphylococcus spp. (Methicillin-sensitive)

**Statement applies to the US market only.*

Pre-formed Gentamicin + Vancomycin

Extended Antibiotic Release



REMEDY SPECTRUM® GV Hip elution extends beyond 28 days[5] while intra-operative mold elution was undetectable after 14 hours[6]

Proven Clinically Effective

HIP SUBJECTS	Success at Stage 2		
	N	n	%
REMEDY SPECTRUM® GV Spacer	22	21	95.5%

The REMEDY SPECTRUM® GV Hip is 95.5% Clinically Effective, defined as the absence of 2 or more positive cultures at the time of reimplantation.[5]

SYSTEMIC ANTIBIOTIC USAGE	Duration of Antibiotic Usage After Reimplantation (Days)					
	0 - <7	7 - <14	14 - <30	30 - <90	>365	Total
REMEDY SPECTRUM® GV Spacer*	93% (39)	0% (0)	2% (1)	2% (1)	2% (1)	42

93% of the GV subjects were finished with their antibiotic course within a week.[5]
*Data includes 22 hip and 20 knee GV subjects.

SPECTRUM® GV BONE CEMENT

SPECTRUM® GV Bone Cement is indicated for use only with REMEDY SPECTRUM® GV Hip Spacer

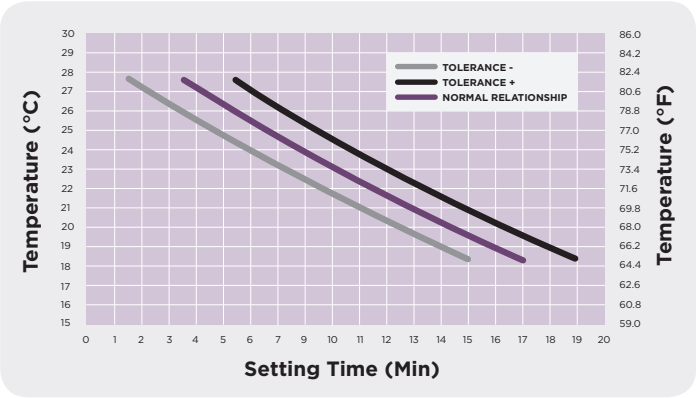
POWERFUL COMBINATION, RELIABLE PERFORMANCE

Powerful:

- 4X the antibiotic content compared to Palacos® R+G
- Dual Antibiotic Spectrum includes Gram (+) and Gram (-) Pathogens

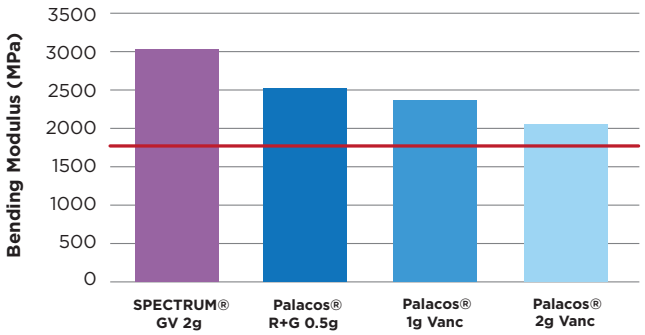
Reliable:

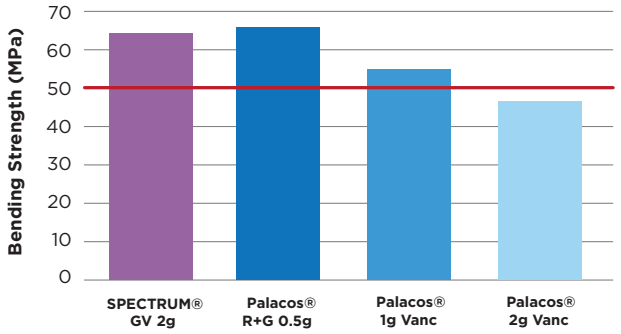
- Mechanical Performance comparable to Palacos® R+G
- Exceeded Required ISO Bone Cement Standards

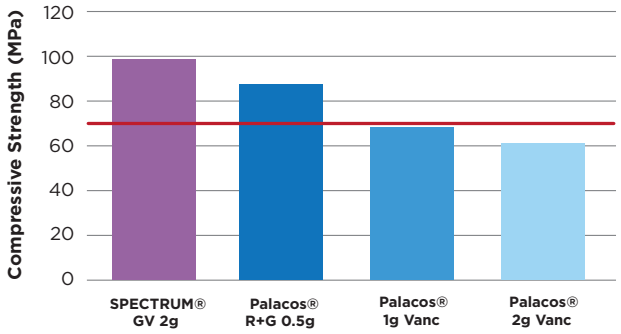


Antibiotic Bone Cement Mechanical Performance[5,7,8]

ISO Standard







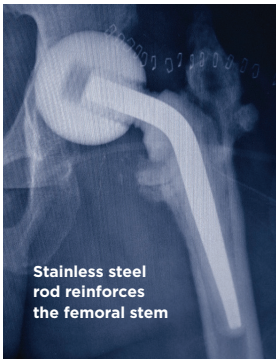
SPECTRUM® GV Bone Cement was tested in Lab A, Palacos R+G in Lab B, and Palacos 1g Vanc and Palacos 2g Vanc were tested in Lab C

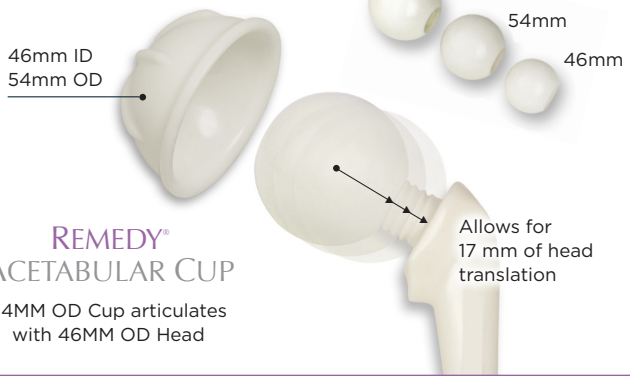
40g Bag Spectrum® GV Bone Cement	Catalog # SPECTRUM40	Gentamicin Base	Vancomycin Base	Total
		1g	1g	2g
		2.5%	2.5%	5%

REMEDY® MODULARITY

The REMEDY® Hip, Knee, & Shoulder Spacer System is part of the treatment foreseen in a two-stage procedure performed in the event of permanent prosthesis infection. The REMEDY® 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® Spacer and replace it with a permanent joint implant.

HIP SPACERS
TOTAL SYSTEM MODULARITY

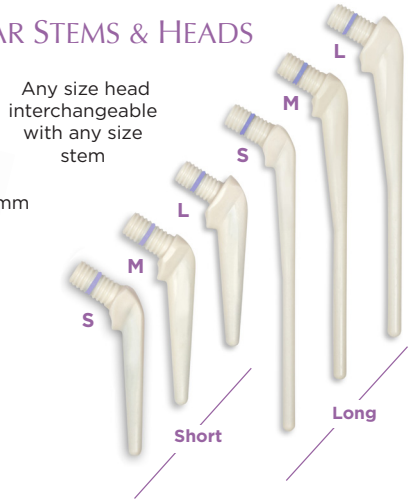




REMEDY® ACETABULAR CUP

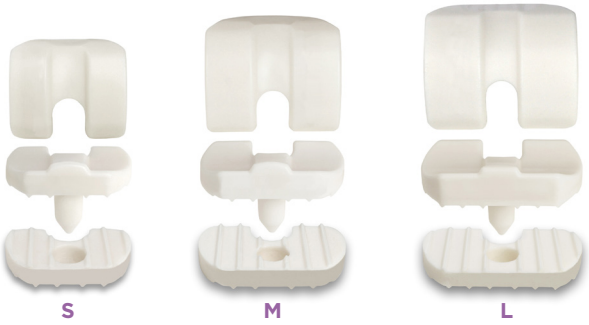
54MM OD Cup articulates with 46MM OD Head

REMEDY® MODULAR STEMS & HEADS

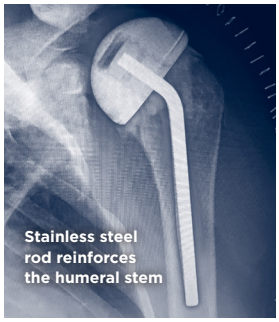


KNEE SPACER
TOTAL SYSTEM INTERCHANGEABILITY

- Any size femoral component with any size tibial component provides 9 possible combinations
- 65% of cases result in different size femur and tibia*
- 35% of cases use a tibial insert wedge*



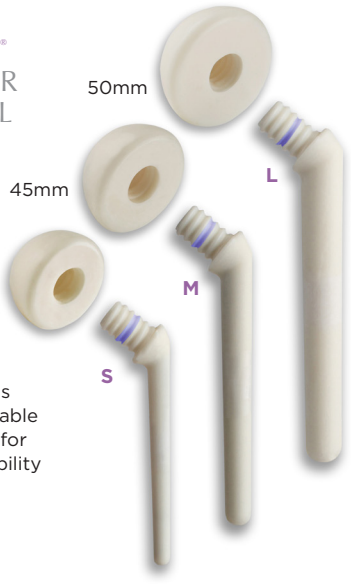
SHOULDER SPACER
TOTAL SYSTEM MODULARITY



Variable head and neck design allows desired placement and positioning up to 9mm

REMEDY® MODULAR HUMERAL HEADS

REMEDY® MODULAR HUMERAL STEMS



Head sizes interchangeable with stems for surgical flexibility

* Internal OsteoRemedies® Data

ANTIBIOTIC TREATMENT PLAN

1 **Antibiotics In Spacers:**

REMEDY® Spacers – 4.8% Gentamicin Sulfate

Molds – Various/Inconsistent

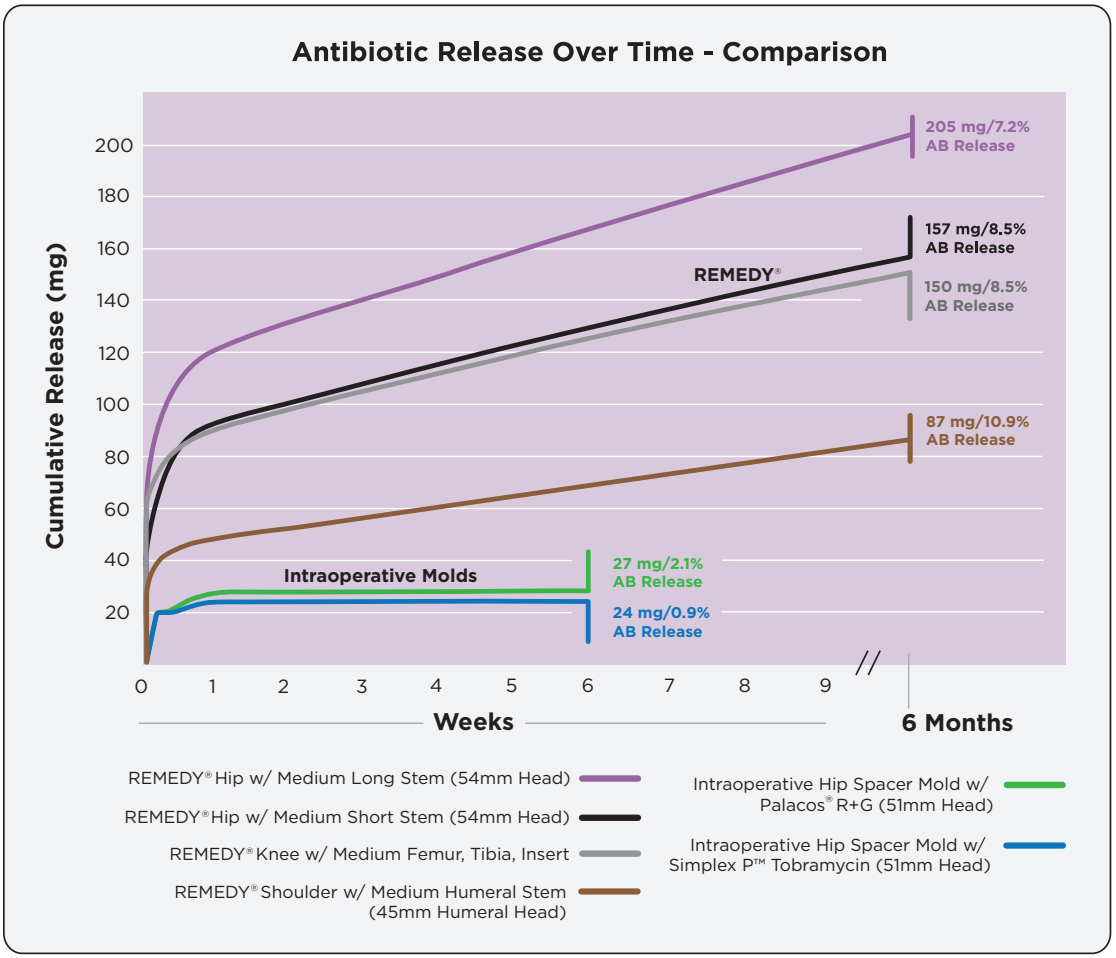
2 **Antibiotics In Cement For Fixation**

Same With Molds Or REMEDY® Spacer System

3 **Systemic Antibiotic Treatment Plan**

Same With Molds Or REMEDY® Spacer System

ELUTION OVERVIEW



REMEDY® data supported by third-party analysis and referenced in available testing report

Data of Palacos® R+G and Simplex P™ Tobramycin are taken from: Moojen et al., 2008 - *J. Arthroplasty*

Palacos is a registered trademark of Heraeus Medical GmbH

Simplex P Tobramycin is a trademark of Stryker®

REMEDY® & REMEDY SPECTRUM® GV HIP SPACER TECHNIQUE

STEP 1

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

STEP 2

Using the REMEDY® Spacer Trials,† select the appropriate size femoral stem, femoral head, and acetabular cup (if applicable).†† If using the acetabular cup, check the dimensions of the native acetabulum using the TRIAL end of the REMEDY® Acetabular Cup Trial/Handle.

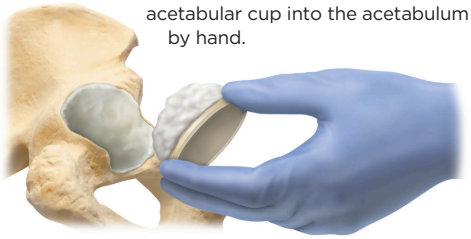
TRIALS

Note: Only the 46mm femoral head will fit the 46mm ID/54mm OD acetabular cup.

If implanting without an acetabular cup, proceed to Step 6.

STEP 3

Using UNITE® AB Bone Cement, or any FDA-cleared gentamicin-based PMMA, apply cement to the native acetabulum and the backside of the REMEDY® Acetabular Cup. Place the acetabular cup into the acetabulum by hand.



STEP 4

Using the IMPLANT end of the REMEDY® Acetabular Cup Trial/Handle, position the cup spacer into the desired orientation within the native acetabulum.

Note: When placing the components with cement, do not impact with a mallet. It is recommended to use the trial/handle with hand pressure only.

STEP 5

With the acetabular cup in place, a final trial reduction may be performed using the trial stem and head components to confirm or correct implant positioning, noting the chosen off-set with the head seated past the missing thread on the stem neck.

STEP 6

With the appropriate head size selected, open the packages and remove the monomer vial.

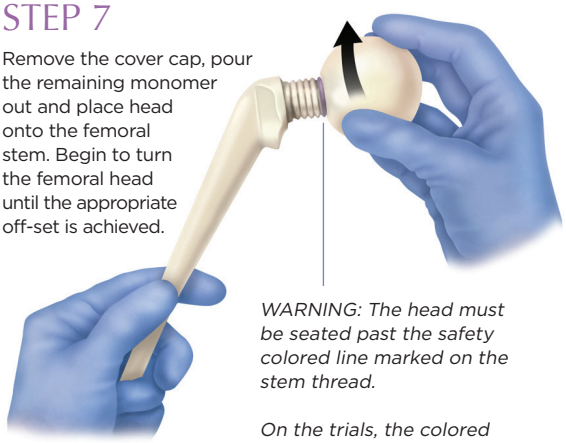
Break the vial open and pour all the monomer into the screw opening of the head.

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

COVER CAP

STEP 7

Remove the cover cap, pour the remaining monomer out and place head onto the femoral stem. Begin to turn the femoral head until the appropriate off-set is achieved.



WARNING: The head must be seated past the safety colored line marked on the stem thread.

On the trials, the colored line is designated with a missing thread on the stem neck.

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.

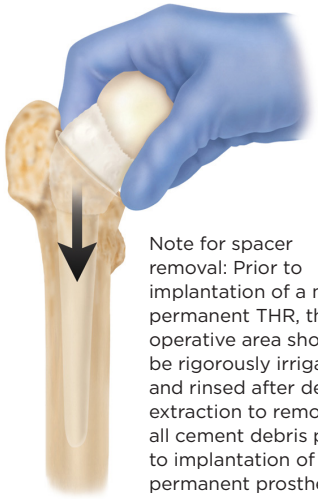
STEP 8

Using UNITE® AB Bone Cement, or SPECTRUM® GV Bone Cement, apply cement to the proximal aspect of the stem.†† The use of the cement is compulsory to avoid rotation and to limit the risk of dislocation.

Note: For additional fixation to the stem the remaining offset space and threads of the stem, up to the femoral head, can be filled with antibiotic-loaded bone cement. Cement may also be applied once seated within the femoral canal.

STEP 9

Insert the stem (with head properly affixed) into the canal. Perform a final reduction to assess joint stability and implant alignment.

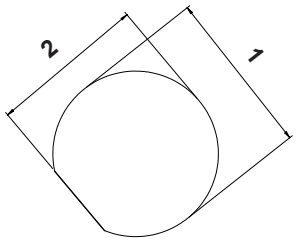


Note for spacer removal: Prior to implantation of a new permanent THR, the operative area should be rigorously irrigated and rinsed after device extraction to remove all cement debris prior to implantation of the permanent prosthesis or other surgical procedures (e.g., resection arthroplasty, etc.).

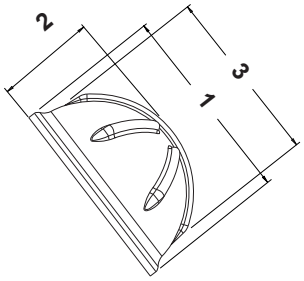
†The REMEDY® SPACER TRIALS can be used with the REMEDY® & REMEDY SPECTRUM® GV Hip Spacers.
††The SPECTRUM® GV Bone Cement is indicated for the fixation of a REMEDY SPECTRUM® GV Spacer to the host bone.

Hip Specifications

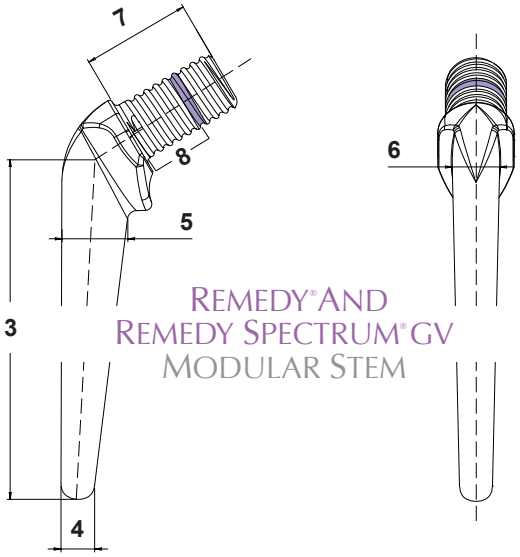
Remedy® and Remedy Spectrum® GV Modular Head



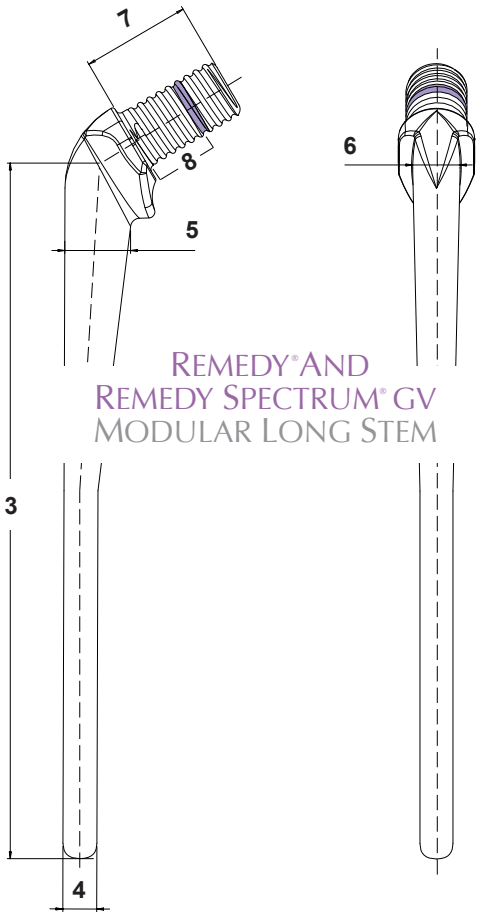
Remedy® Acetabular Cup



Remedy® and Remedy Spectrum® GV Modular Stem



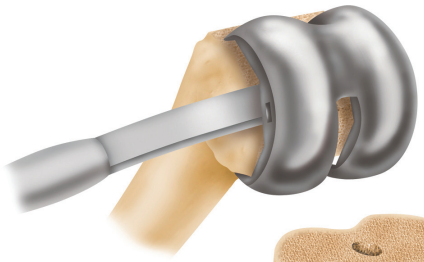
Remedy® and Remedy Spectrum® GV Modular Long Stem

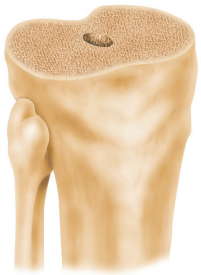


Remedy® and Remedy Spectrum® GV Hip Spacer

Hip Component Description	Remedy® Catalog #	Remedy Spectrum® GV Catalog #	(mm)								Remedy®	Remedy Spectrum® GV	
			1	2	3	4	5	6	7	8	Gentamicin Base (g)	Gentamicin Base (g)	Vancomycin Base (g)
Remedy® Acetabular Cup 46mm ID/54mm OD	RHACSM	–	58.5	31	54						0.3	–	–
Remedy® & Remedy Spectrum® GV Femoral Head – 46 mm	RHHDSM	GVHDSM	46	42.3							0.9	0.9	0.9
Remedy® & Remedy Spectrum® GV Femoral Head – 54 mm	RHHDMD	GVHDMD	54	50.9							1.6	1.6	1.6
Remedy® & Remedy Spectrum® GV Femoral Head – 60 mm	RHHDLG	GVHDLG	60	57.3							2.3	2.3	2.3
Remedy® & Remedy Spectrum® GV Femoral Stem - Small	RHSTSM	GVSTSM			111	10	16.5	11.3	35.6	17	0.5	0.5	0.5
Remedy® & Remedy Spectrum® GV Femoral Stem - Medium	RHSTMD	GVSTMD			112	11	21.7	15.5	35.6	17	0.6	0.6	0.6
Remedy® & Remedy Spectrum® GV Femoral Stem - Large	RHSTLG	GVSTLG			117	11.5	24	16.5	35.6	17	0.7	0.7	0.7
Remedy® & Remedy Spectrum® GV Femoral Long Stem - Small	RHLSSM	GVLSSM			227	10	16.5	11.3	35.6	17	0.6	0.6	0.6
Remedy® & Remedy Spectrum® GV Femoral Long Stem - Medium	RHLSMD	GVLSMD			227	11	21.7	15.5	35.6	17	0.8	0.8	0.8
Remedy® & Remedy Spectrum® GV Femoral Long Stem - Large	RHLSLG	GVLSLG			231	11.5	24	16.5	35.6	17	0.9	0.9	0.9

REMEDY® KNEE SPACER TECHNIQUE





STEP 1

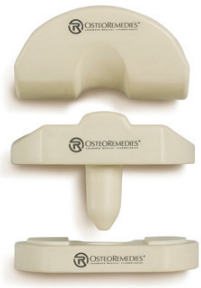
In accordance with the existing total joint manufacturer's technique, prepare the infected joint space by first removing the prosthesis and any PMMA cement, if present, and any hardware (which may be a reservoir of infection).

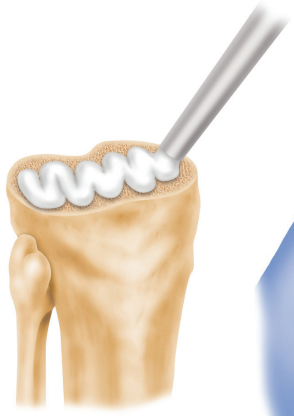
Continue to prepare the joint space with aggressive debridement and pulse lavage.

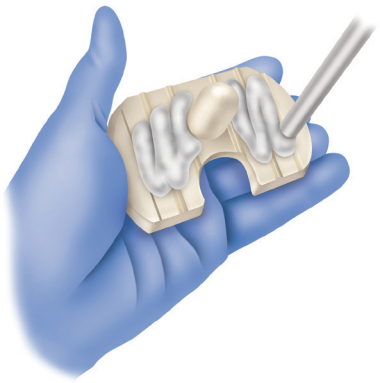
STEP 2

Using the REMEDY® Spacer Trials, select the appropriate size femoral and tibial components. It is important that the joint is neither loose nor tight, therefore the surgeon will have to consider the additional room occupied by the cement needed for the fixation.

TRIALS

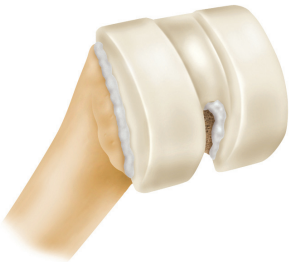






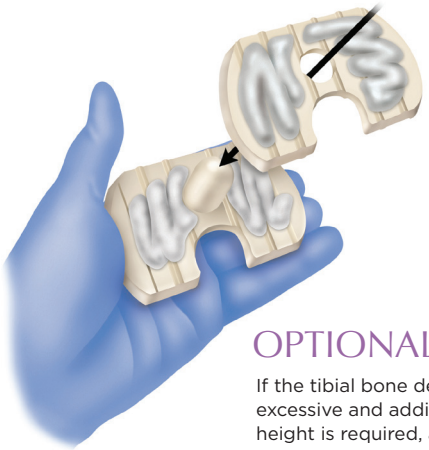
STEP 3

Using UNITE®AB Bone Cement, or FDA cleared gentamicin-based PMMA, apply cement over the entire surface of the component and tibial plateau and insert into the tibia.



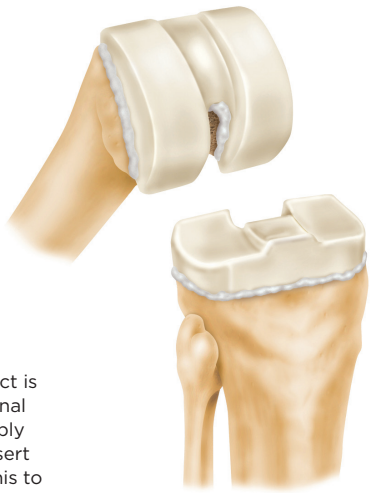
STEP 4

Apply PMMA bone cement (see Step 3) to the femoral component and femoral surface.



OPTIONAL

If the tibial bone defect is excessive and additional height is required, apply PMMA to the tibial insert wedge and cement this to the inferior aspect of the tibial component.



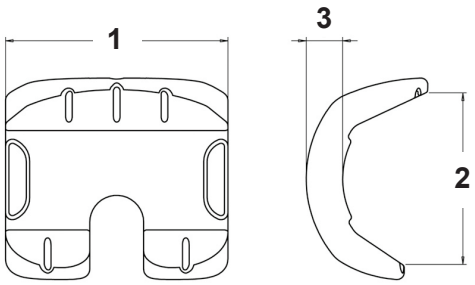
STEP 5

Reduce the joint, removing all the excess cement, avoiding the cement that may go on the articular surface. To assure correct alignment of the components, make flex/extension movements before the cement curing occurs. Then close and check flex/extension movements and lateral stability.

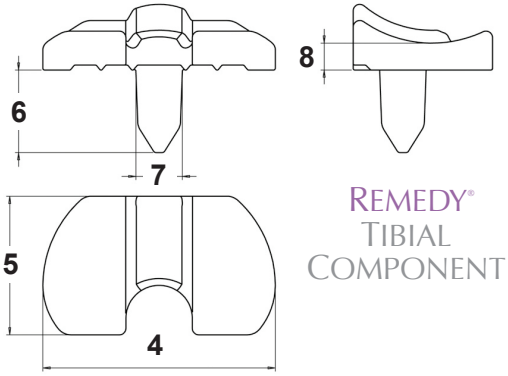
Depending on the stability of the knee, it may be necessary to apply a brace to avoid the risk of dislocation.

Note: When placing the components with cement, DO NOT impact the device with a mallet. It is recommended to use hand pressure only while placing the components.

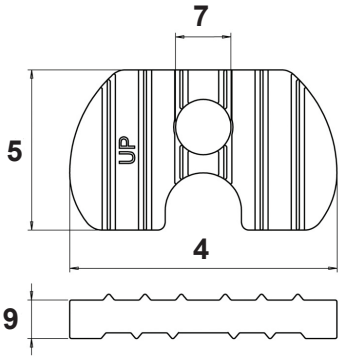
KNEE SPECIFICATIONS



REMEDY®
FEMORAL COMPONENT



REMEDY®
TIBIAL
COMPONENT



REMEDY®
TIBIAL INSERT
WEDGE

REMEDY® KNEE SPACER

		(MM)									
Description	**Catalog #**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**Gentamicin Base (g)**
REMEDY® Tibial Component 60mm	RKTBSM				60	36	25	14	7.8		0.4
REMEDY® Tibial Component 70mm	RKTBMD				70	42	25	14	8.2		0.6
REMEDY® Tibial Component 80mm	RKTBLG				80	48	25	14	8.8		0.9
REMEDY® Femoral Component 54mm	RKFMSM	54	41.6	9.5							0.5
REMEDY® Femoral Component 64mm	RKFMMD	64	49.3	10.5							0.8
REMEDY® Femoral Component 74mm	RKFMLG	74	56.3	11.5							1.2
REMEDY® Tibial Insert Wedge 60mm	RKINSM				60	36		14.5		10	0.3
REMEDY® Tibial Insert Wedge 70mm	RKINMD				7	42		14.5		10	0.5
REMEDY® Tibial Insert Wedge 80mm	RKINLG				80	48		14.5		10	0.7

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.

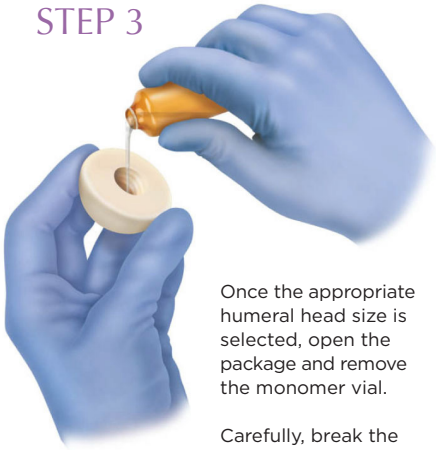
Continue to prepare the joint space with aggressive debridement, pulse lavage and other standard practices for preparing the infected joint space.

STEP 2

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

TRIAL

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.

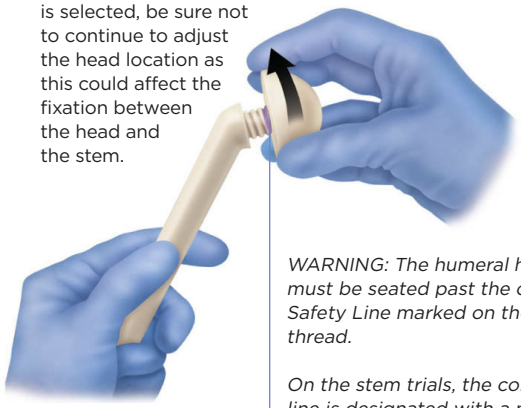
Insert and seal the hole with the plastic cover cap supplied with the humeral head. Shake the head for 60 seconds to ensure all of the threads within the head are wet with monomer.

COVER CAP

STEP 4

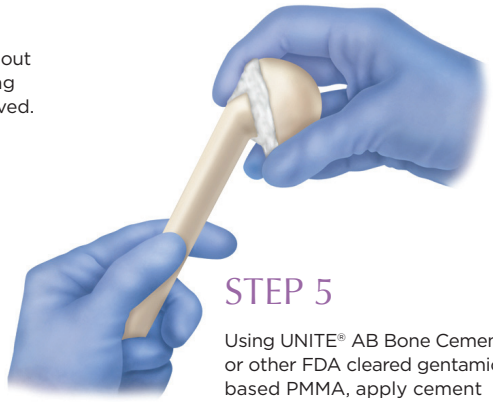
Remove the plastic cap, pour the remaining monomer out and place the head on the humeral stem. Begin turning the head until the desired offset and length are achieved.

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 colored Safety Line marked on the stem thread.

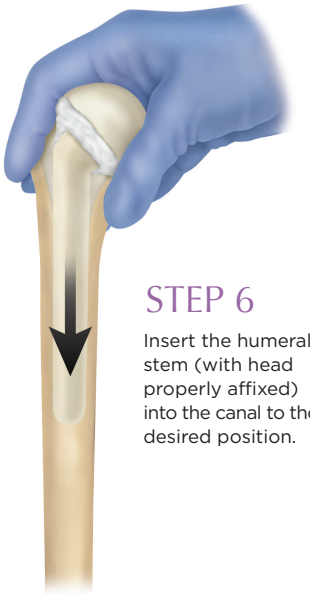
On the stem trials, the colored line is designated with a missing thread on the stem trunnion.



STEP 5

Using UNITE® AB Bone Cement, or other FDA cleared gentamicin-based 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.

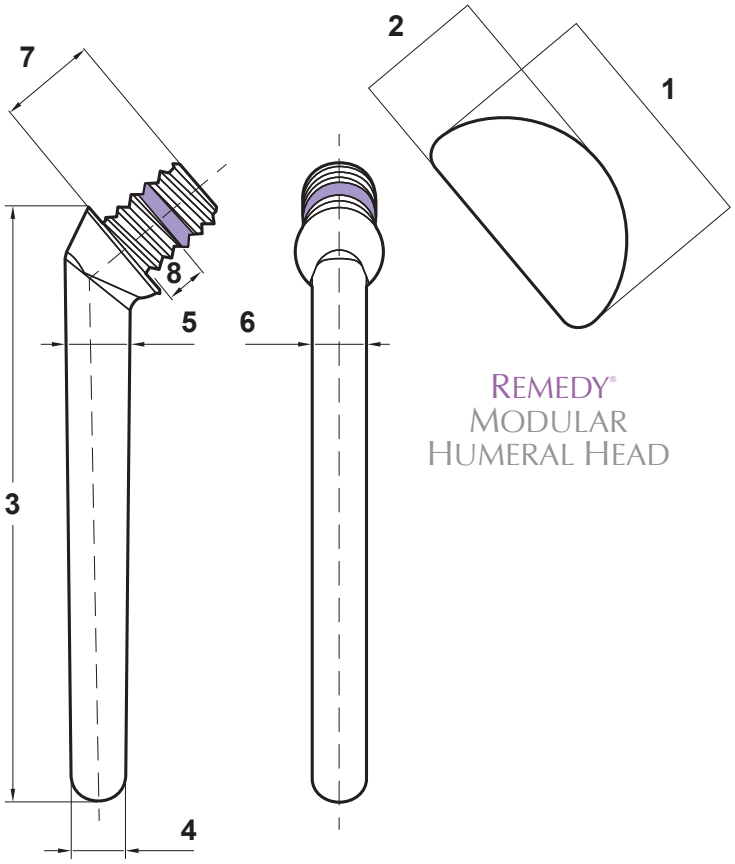
Note: For additional fixation to the stem the remaining offset space and threads of the stem, up to the humeral head, can be filled with gentamicin-loaded bone cement. Cement may also be applied once seated within the humeral canal.



STEP 6

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

SHOULDER SPECIFICATIONS



REMEDY®
MODULAR
HUMERAL STEM

REMEDY®
MODULAR
HUMERAL HEAD

REMEDY®
SHOULDER SPACER

Description	Catalog #	(MM) 1	2	3	4	5	6	7	8	Gentamicin Base (g)
REMEDY® Modular Humeral Head 40mm	RSHHSM	40	25							0.5
REMEDY® Modular Humeral Head 45mm	RSHHMD	45	25							0.5
REMEDY® Modular Humeral Head 50mm	RSHHLG	50	25							0.6
REMEDY® Modular Humeral Stem - Small	RSHSSM			101	7	9.4	7.8	19	9	0.1
REMEDY® Modular Humeral Stem - Medium	RSHSMD			116	10.5	12.6	10.5	19	9	0.3
REMEDY® Modular Humeral Stem - Large	RSHSLG			131	14	15.8	14	19	9	0.5

[1] Minelli, E. Bertazzoni, et al., 2011. Anaerobe 17(6), 380-383.
[2] Trampuz, A., et. al., 2005. Swiss Med Weekly. 135(17-18): 243-51. Review.
[3] Watanakunakom, et al., 1980 Journal of Antimicrobial Chemotherapy 6, 785-791.
[4] Watanakunakom, et al., 1982. Antimicrobial Agents and Chemotherapy, 903-905.
[5] For complete data and associated risks reference the REMEDY SPECTRUM® GV Hip IFU. In a review of 22 patients, clinical effectiveness was defined as the absence of 2 or more positive cultures at the time of reimplanation. Patients should be monitored for ototoxicity and nephrotoxicity while under-going treatment for PJI.
[6] Prostalac HDE H000004 Data.
[7] Bishop, A., et al., 2018. Data in Brief. 20. 14-19.
[8] Carann, R. et al., 2013. World Journal of Orthopaedics. 9327(36).

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