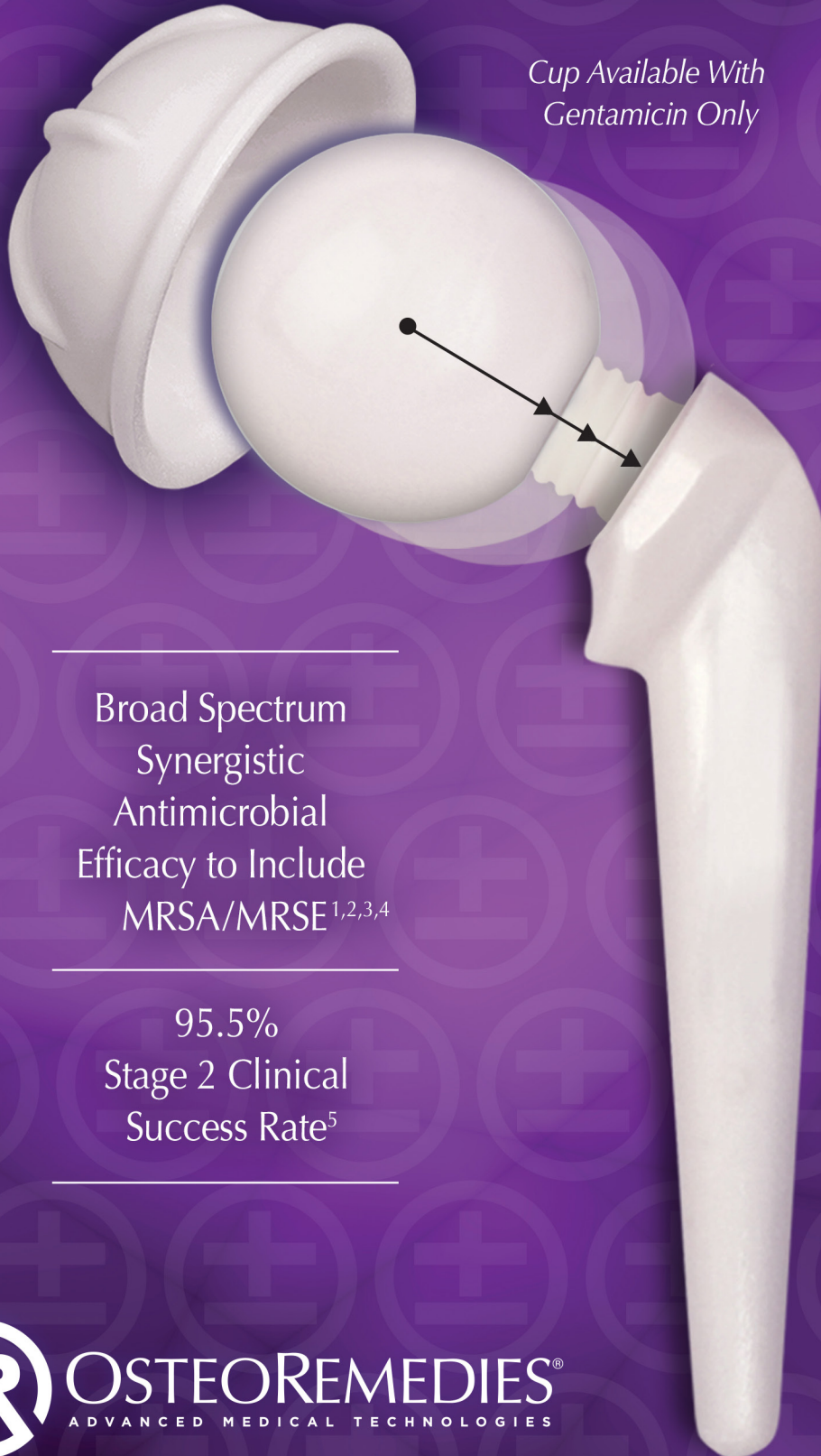


REMEDY SPECTRUM® GV HIP SPACER SYSTEM

GENTAMICIN

VANCOMYCIN



*Cup Available With
Gentamicin Only*

Broad Spectrum
Synergistic
Antimicrobial
Efficacy to Include
MRSA/MRSE^{1,2,3,4}

95.5%
Stage 2 Clinical
Success Rate⁵

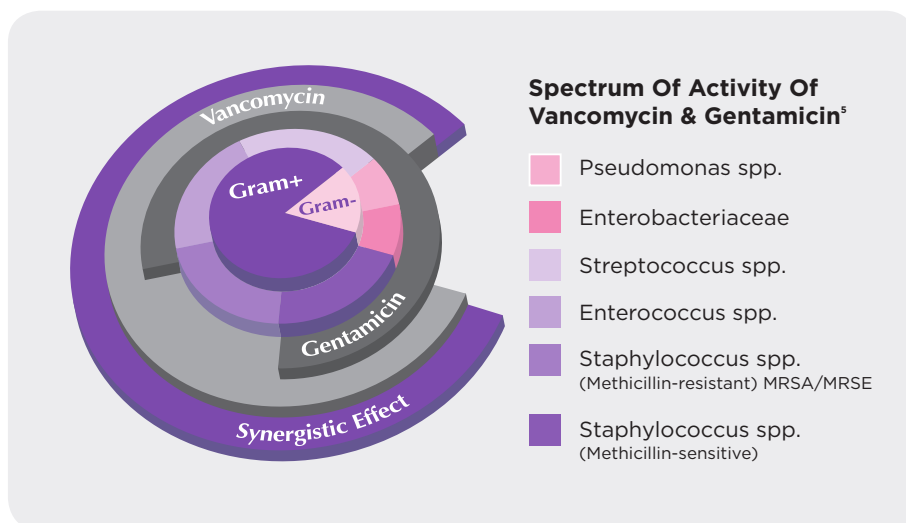


OSTEOREMEDIES®
ADVANCED MEDICAL TECHNOLOGIES

SPECTRUM® GV HIP SPACER

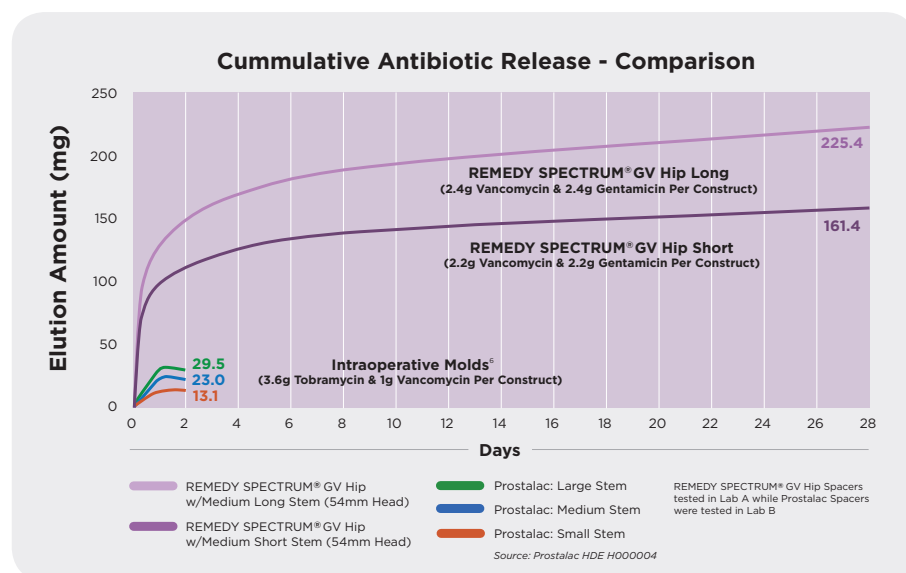
BROAD SPECTRUM COVERAGE

- The first Gentamicin + Vancomycin hip spacer and bone cement available in the U.S.
- Increased spectrum of coverage to include MRSA/MRSE^{1,2}
- Synergistic antimicrobial efficacy against gram (+) pathogens^{3,4}



EXTENDED ANTIBIOTIC RELEASE

- REMEDY SPECTRUM® GV Hip elution extends beyond 28 days⁵ while intra-operative mold elution was undetectable after 14 hours⁶



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

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.



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

TRIALS

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.

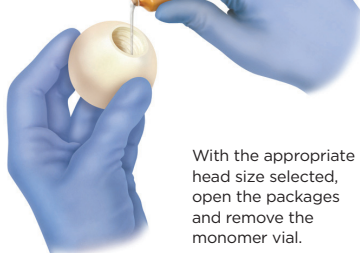


Note: When placing the components with cement, do not impact with a mallet. It is recommended to use the trial/handle with hand pressure only.

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.

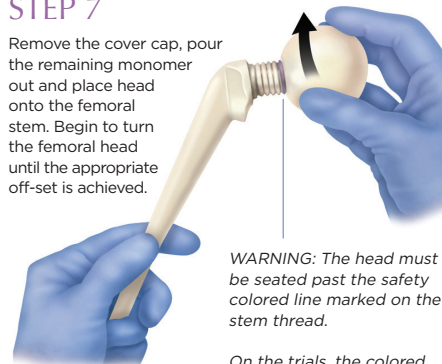
Break the vial open and pour all the monomer into the screw opening of the head.

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.).

GV HIP SPECIFICATIONS

HIP COMPONENT DESCRIPTION	Catalog #	Gentamicin Base (g)	Vancomycin Base (g)	Total GV (g)
REMEDY SPECTRUM® GV Modular Femoral Head - 40 mm	GVHDXS	.46	.46	.92
REMEDY SPECTRUM® GV Modular Femoral Head - 46 mm	GVHDSM	0.9	0.9	1.8
REMEDY SPECTRUM® GV Modular Femoral Head - 54 mm	GVHDMMD	1.6	1.6	3.2
REMEDY SPECTRUM® GV Modular Femoral Head - 60 mm	GVHDLG	2.3	2.3	4.6
REMEDY SPECTRUM® GV Modular Femoral Stem - Small	GVSTSM	0.5	0.5	1.0
REMEDY SPECTRUM® GV Modular Femoral Stem - Medium	GVSTMD	0.6	0.6	1.2
REMEDY SPECTRUM® GV Modular Femoral Stem - Large	GVSTLG	0.7	0.7	1.4
REMEDY SPECTRUM® GV Modular Femoral Long Stem - Small	GVLSM	0.6	0.6	1.2
REMEDY SPECTRUM® GV Modular Femoral Long Stem - Medium	GVLSMD	0.8	0.8	1.6
REMEDY SPECTRUM® GV Modular Femoral Long Stem - Large	GVLSLG	0.9	0.9	1.8

[†] 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 Hip Spacer to the host bone.

SPECTRUM® GV BONE CEMENT

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

POWERFUL COMBINATION, RELIABLE PERFORMANCE

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

Powerful:

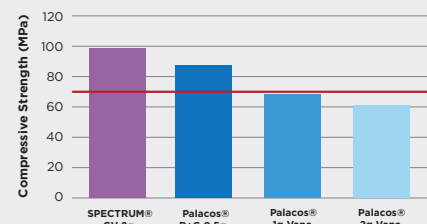
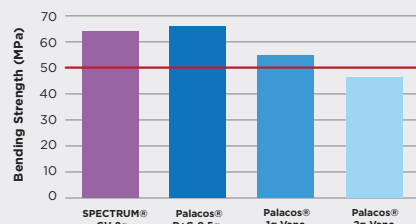
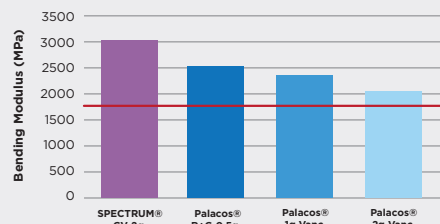
- 4X the antibiotic content compared to Palacos® R+G
- Dual Antibiotic Spectrum includes Gram (+) and Gram (-) Pathogens

Reliable:

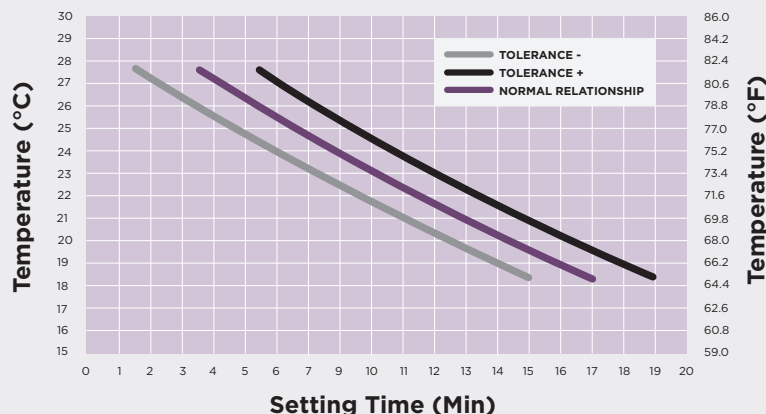
- Mechanical Performance comparable to Palacos® R+G
- Exceeded Required ISO Bone Cement Standards



Antibiotic Bone Cement Mechanical Performance^{5,7,8}



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



The REMEDY® and REMEDY SPECTRUM® GV Hip Spacer System Allows For Modularity Without The Waiting



The REMEDY® Hip Trials can be used with the REMEDY® Hip Spacer and REMEDY SPECTRUM® GV Hip Spacer.

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 reimplantation. Patients should be monitored for ototoxicity and nephrotoxicity while undergoing treatment for PJ.

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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