

smith&nephew

RALLY®

Bone Cement

Surgical Technique



RALLY[◇] Bone Cement portfolio

RALLY is manufactured by Tecres, S.p.A in Verona, Italy. Tecres has 30+ years of experience developing, manufacturing, and selling bone cement and accessory products. The RALLY Bone Cement portfolio comprises an extensive range of high-quality bone cements for total joint arthroplasty. RALLY Bone Cement is available in both high and medium viscosities for different orthopedic procedures and is available with and without antibiotic (1g Gentamicin).

The RALLY Bone Cement long-lasting spearmint green color contrasts optically with the surrounding tissue to facilitate easier handling during surgery and easy visibility in the event of any revision procedure.

RALLY can be hand-mixed (HV and MV), vacuum-mixed (MV), or mixed and dispensed in a unique All-in-One system (HV and MV). The All-in-One system contains both the monomer and powder in one device, removes risk of contamination or broken glass, and is vacuum-compatible for decreased porosity. RALLY has long fatigue life and low porosity, even when hand-mixed.¹ Bone cement porosity is caused by air bubble inclusions and is seen as a starting point for fatigue fractures.²

The mechanical properties of bone cement are tested for compressive strength, bending strength and bending modulus according to ISO 5833. RALLY Bone Cement has shown excellent shear, tensile, and bending strengths compared to competitive cements.³⁻⁶



Viscosity

Viscosity is the relative flow resistance of a material. The viscosity of bone cement affects its handling characteristics, handling time, and penetration of the cement into the cancellous bone. There are three levels of viscosity in bone cement.^{4,7}

- Low Viscosity (PALACOS™ LV) – Very runny for a longer period of time, like milk.
- Medium Viscosity (RALLY° MV, Simplex™ P) – Initially more liquid, but sets up 5 – 8 minutes faster than low viscosity, like pudding.
- High Viscosity (RALLY HV, PALACOS™ R, Refobacin™ R) – Reaches a dough state within the first few minutes of mixing, like PlayDoh™.

Application and preparation instructions

- Bone cement is a temperature sensitive device.
- The handling properties will vary depending on the temperature of the cement and the operating room: higher temperatures and more humidity will result in a shorter working phase and faster setting time. If longer handling and setting time is needed, the bone cement can be pre-chilled. It is recommended the bone cement is stored at 23°C for at least 24 hours before surgery to allow for the bone cement to acclimate to the environment.
 - The product can be stored and used at different temperatures bearing in mind that bone cements are temperature-sensitive. Temperatures of more than 23°C for the product, the preparation accessories and the environment accelerate the various stages in the preparation procedure. Lower temperatures slow the preparation stages.
- Cement should only be removed from the foil packing approximately 10 minutes prior to mixing to avoid the polymer from absorbing moisture.
- Remove debris and irrigate the bone site carefully with saline solution.
 - It is important to avoid the presence of liquid between the bone tissue and the cement. The bone surface must be dried with gauze and/or suction catheters before and during the cementation process.
 - The surface of the implant that is intended to be cemented should be covered by a uniform coating of bone cement. It is important to apply an optimal thickness of bone cement.
- The surgeon will determine the amount of cement needed based on the clinical application and needs.

Hand mixing technique with open bowl and spatula

The RALLY[®] HV bone cement is recommended to be mixed by bowl and spatula as it is a high viscosity cement and more easily and uniformly mixed by hand. The RALLY MV cement can also be mixed by hand if desired.

1. Break open the vial and pour the liquid monomer into a sterile mixing bowl.

Note Take care to gently break vial to ensure small glass particles don't get into the mixture. Also break away from the body to prevent injury.

2. Open powder and pour over liquid.

Note Never change the ratio between liquid and solid components.

3. Mix the cement with a spatula slowly for one minute taking care to avoid spilling contents.
4. Allow bone cement to rest for 30 seconds for the escape of air and for cement to reach the dough phase.



Vacuum mixing techniques

RALLY® All-In-One system

The RALLY All-in-One System is a premier, unique product composed of 70g of RALLY Bone Cement completely contained mixing and dispensing system. The cement components are isolated from outside contamination or influences and has a filter screen to prevent glass from entering the final cement mixture. This system is available with RALLY HV, MV, with and without antibiotic formulations.

1. The RALLY All-in-One system can be connected to a vacuum source such as a wall suction or dedicated vacuum pump, or it can be used without vacuum.
2. With the system standing upright on the base, strike the top button. When you see liquid monomer flowing, pump the release button several times to transfer all the liquid monomer into the powder chamber.

Tip Before releasing the monomer, invert the system and lightly tap the powder chamber to loosen the powder.

3. Attach the vacuum tube to the device and vacuum pump for 10-30 seconds. It is optional to use vacuum.
4. Rotate the mixing rod counter-clockwise to unlock the rod and begin mixing by pulling and pushing the mixing rod for 1 minute.
Tip After a few seconds of mixing upright, turn the device upside down and tap the mixing chamber several times to loosen any powder not yet mixed in.
5. Remove the mixing rod by pulling the mixing rod to full extension and rotating the rod counter-clockwise until it is removed.
6. Attach the breakaway nozzle by screwing onto the end of system where the mixing rod was removed.
7. Remove air from the mixing chamber by holding the system vertically with the nozzle upright and pushing the ampoule chamber in to the mixing chamber until air has been expelled and cement moves in the nozzle.
8. Load the whole system into the RALLY All-in-One Cement Gun for dispensing.



RALLY® Vacuum mixing bowl

Today, most operating rooms mix cement under a partial vacuum, which helps to decrease porosity and fumes created during mixing. The following is a brief description of the mixing technique using RALLY MV (40g = 1 dose) and the RALLY Vacuum Mixing Bowl.

Note RALLY Vacuum Mixing Bowl was designed to fit 3 doses of RALLY Bone Cement (40G).

1. The RALLY Vacuum Mixing Bowl should be connected to a vacuum source such as a wall suction or dedicated vacuum pump.
2. Pour powder and monomer into the bowl as follows:
 - 1 Dose** – Pour all liquid monomer into the bowl followed by the powder.
 - 2 Doses** – Pour 2 vials of liquid monomer into the bowl followed by the 2 packets of powder.
 - 3 Doses** – Pour 3 vials of liquid monomer into the bowl followed by the 3 packets of powder.
3. Lock on the the RALLY Vacuum Mixing Bowl lid by twisting it onto the bowl.
4. Activate the vacuum source to 25mmHg.
5. Turn the RALLY Mixing Bowl handle at 2 cycles per second for one minute.
6. Shut off the vacuum and remove the vacuum from the mixer. Remove the lid.
7. Apply the cement with the spatula provided.



Catalog information

Bone Cement

Cat. Item	Description
71271560	RALLY® HV Bone Cement, 40 grams
71271570	RALLY HV AB Bone Cement, 40 grams
71271580	RALLY MV Bone Cement, 40 grams
71271590	RALLY MV AB Bone Cement, 40 grams
71271600	RALLY HV AB All in One, 70 grams
71271605	RALLY HV All in One System, 70 grams
71271680	RALLY MV AB All in One, 70 grams
71271685	RALLY MV All in One System, 70 grams



Mixer Devices

Cat. Item	Description
71271801	RALLY Vacuum Bowl
S727	Summit Medical Mix In Syringe
SMMM1	Summit Medical Minimix - Mixer
SMDS1C	Summit Medical Minimix Delivery Syringe
B710	Summit Medical Open Bowl With Spatula



Cement Guns

Cat. Item	Description
71271610	RALLY All In One Cement Gun
H719	Summit Medical Syringe Cement Gun

Pulse Lavage and Cement Accessories

Cat. Item	Description
110028	Vent Opening Tool
111000	CONCISE Cement Sculps Kit
110032	Acetabular Brush
890095	RICHARDS Cement Hook
110003	Femoral Canal Brush, Standard, 19mm
110033	Femoral Canal Brush, Narrow, 12.5mm
110037	Femoral Canal Suc Absorb, Standard
110038	Femoral Canal Suc Absorb, Large
WZWDS01	Summit Medical Pulse Lavage
WZPT-03	Summit Medical Pulse Lavage Femoral Brush
H550	Summit Medical Vacuum Foot Pump
SC01	Summit Medical Spatula With Curette



BUCK Cement Restrictors

Cat. Item	Description
112428	BUCK Cement Restrictor Inserter
129418	BUCK Cement Restrictor, 18.5mm
129419	BUCK Femoral Cement Restrictor, 25mm
71279420	BUCK Cement Restrictor, 30mm
71279421	BUCK Cement Rest, 35mm
71279422	BUCK with Disp Insert, 18.5mm
71279423	BUCK with Disp Inserter, 25mm
71279424	BUCK with Disp Inserter, 30mm
914535	BUCK Cement Restrictor, 13mm
11-0028	Vent Opening Tool

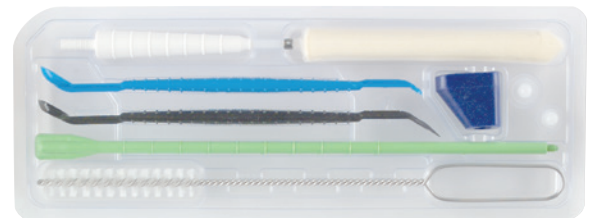


Cement Femoral Pressurizer

Cat. Item	Description
111430	Acetabular Cement Compressor
111431	Acetabular Compressor with Shd, Small, 54mm
111432	Acetabular Compressor with Shd, Medium, 62mm
111433	Acetabular Compressor with Shd, Large, 70mm
P721	Summit Medical Femoral Pressuriser
111434	Femoral Cement Compressor
111435	Femoral Cement Compressor Cap
120709	Acet Cement Restrictor Pe, Large

PREP-IM Enhance Total Hip Kit

Cat. Item	Description
121010	PREP-IM Enhance Total Hip Kit
Includes:	
129418	BUCK Cement Restrictor, 18.5mm
129419	BUCK Cement Restrictor, 25mm
112428	BUCK Disposable Inserter
110003	Femoral Canal Brush, 19mm
110037	Femoral Canal Suction Absorber, Standard
71270027	Medium Femoral Pressurizer
111000	CONCISE Cement Sculps



Bone Cement Samples

Cat. Item	Description
71271700	RALLY® HV Bone Cement Sample
71271710	RALLY MV Bone Cement Sample
71271720	RALLY HV All In One System Sample
71271730	RALLY MV All In One System Sample

References

1. Tecres Data on file.
2. Hoey D, Taylor D. Quantitative analysis of the effect of porosity on the fatigue strength of bone cement. *Acta Biomaterialia*. 2009;5(2):719-26.
3. Smith+Nephew 2015. OR-15-135.
4. PALACOS® R Instructions for Use.
5. Lewis G. Properties of Acrylic Bone Cement: State of the Art Review. *J Biomed Mater Res*. 1997. 38:155-182.
6. ISO 5833, Implants for Surgery – Acrylic Resin Cements. 2002.
7. PALACOS® LV+G Instructions for Use.

Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your Smith+Nephew representative or distributor if you have questions about the availability of Smith+Nephew products in your area.

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