The cement and accessories portfolio

Smith & Nephew offers a full cement and accessories portfolio from bone cement to pulse lavage. To adequately promote and sell the cement and accessories portfolio, a thorough understanding of each product is required.

Characteristics of bone cement

Bone cement comes in two parts:
1. Powder, or the polymer
2. Liquid, or the monomer
Once the powder and the liquid are mixed together, polymerization occurs and an exothermic reaction creates the final, hardened bone cement.

The powder component typically consists of the following three materials:
- The polymer (in the form of one or a combination of the following)
  - PMMA – Polymethylmethacrylate
  - MMA/Styrene Copolymer – Methylmethacrylate/Styrene Copolymer
  - MMA/MA Copolymer – Methylmethacrylate/Methacrylate Copolymer
- Radiopacifier – Zirconium Oxide or Barium Sulfate
- Initiator – Benzoyl Peroxide

The liquid component typically consists of the following materials:
- MMA – Methylmethacrylate
- Initiator – N-Dimethyl-P-Toluidine
- Inhibitor/Stabilizer – Hydroquinone

Competitive compositions¹,²,³

<table>
<thead>
<tr>
<th>Company/Brand</th>
<th>Polymer</th>
<th>Radiopacifier</th>
</tr>
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<tbody>
<tr>
<td>S&amp;N RALLY*</td>
<td>PMMA</td>
<td>Barium Sulphate</td>
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<tr>
<td>S&amp;N VERSABOND*</td>
<td>PMMA + MMA/MA copolymer</td>
<td>Zirconium Dioxide</td>
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<tr>
<td>Biomet Cobaltᵀᴹ HV</td>
<td>MMA/MA copolymer</td>
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<td>Biomet Cobaltᵀᴹ MV</td>
<td>PMMA + MMA/Styrene copolymer</td>
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<td>DePuy SmartSetᵀᴹ HV</td>
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<td>Exactech Cemexᵀᴹ</td>
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<td>Stryker Simplexᵀᴹ P</td>
<td>PMMA + MMA/Styrene copolymer</td>
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<tr>
<td>Zimmer Palacosᵀᴹ R</td>
<td>MMA/MA copolymer</td>
<td>Zirconium Dioxide</td>
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</table>

Important terms
- **Polymer**: Many molecules combined together to form chains or structures
- **Monomer**: Single molecules that will combine with other molecules to form the polymer (the building blocks)
- **Polymerization**: A chemical reaction in which two or more molecules combine to form larger molecules or chains that contain repeating structural units
- **Exothermic reaction**: A reaction/process that gives off heat as a product of the reaction
- **Radiopacifier**: Component that allows the substance to show up on an X-ray
- **Initiator**: Component that starts a chemical reaction
- **Inhibitor/Stabilizer**: Prevents degradation or uncontrolled recombinations of the polymer
How does it work?

Polymerization

Polymerization is the reaction that occurs when mixing the powder and the liquid components. The reaction begins as soon as the liquid wets the powder. The liquid initiator (N-Dimethyl-p-Toluidine) reacts with the powder initiator (Benzoyl Peroxide) and the monomer and polymer begin to polymerize (join together to create longer chains) causing the mix to change into a doughy state. Polymerization continues unassisted via an exothermic reaction. Heat is released until the polymerization process is complete.

The setting process

There are three aspects to the bone cement setting process. The dough time, or wait time, is the time from when the cement is mixed until it no longer adheres to the moist surgical glove. The working phase, or handling time, is the amount of time the cement is workable or implantable. Finally, the overall setting time is from the moment the powder and liquid components are mixed until the hardening phase is complete.

The following are variables that can impact the amount of setting and handling time and must be considered in surgery:

- **OR Temperature** – the warmer the temperature, the faster the cement sets and the shorter the handling time.
- **Chilling the monomer and powder** – the colder the temperature, the slower the cement sets. Cooling the components slows the reaction. The reverse happens when the components are warmed.
- **Chemical composition of the cement** – the components of the cement and its inherent viscosity affect the setting process. Every cement is different, and therefore, every cement requires an understanding of its own temperature vs time curves.

Time vs temperature characteristics

Note: Lighter shades of blue, green and grey suggest +/- 1 min tolerances. Phase tolerances may overlap.

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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.

- Low Viscosity (Palacos™ LV) – Very runny for a longer period of time, like milk.
- Medium Viscosity (VERSABOND®, 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) – Reaches a dough state within the first few minutes of mixing, like PlayDoh™.

The features and benefits of RALLY

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. Smith & Nephew's goal for RALLY was to offer 2 different cement options – a cement that is doughy and sets quickly conducive to TKA and a cement that takes longer to set up conducive to injecting cement. This further enables Smith & Nephew to offer a solution for more surgical scenarios.

Bone cement is an integral part of the long-term survival of cemented TJA and the following features and benefits of RALLY cements should be noted:

- RALLY comes in two viscosities allowing for use in different total joint procedures.
- RALLY has a long-lasting spearmint green color for easy visualization during surgery and in the event of any revision procedures.
- 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 lower porosity than competitive cements due to its powder characteristics, even when hand-mixed. Bone cement porosity is caused by air bubble inclusions and is seen as the starting point for fatigue fractures.
- RALLY has shown excellent shear, tensile, and bending strengths compared to competitive cements based on independently published data. Shear, tensile, and bending stresses are believed to be the most common sources of cement failure.

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Important terms

- **Porosity:** The presence of air pockets in the mixed cements; lower porosity results in higher fatigue strength.
- **Shear strength:** Strength of a material against sliding forces parallel to the direction of force.
- **Tensile strength:** Strength of a material against stretching or pulling forces.
- **Bending strength:** Strength of a material against deforming or breaking under a force, also known as flexural strength.

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Cement accessories

Smith & Nephew is a total cement company. Everything your surgeons need for cemented knees, hips and shoulder cases, is included in the following accessories.

VORTEX™ Vacuum Mixer and Vacuum Bowl
The VORTEX Vacuum Mixer has many unique features. It has a gear driven mechanism, which provides three mixing revolutions with each handle turn. The VORTEX mixer is ergonomically angled to provide a consistent homogeneous mix. The VORTEX can successfully mix several types of cement and can handle from half units to three units at one time (1 unit = 40g). The VORTEX inner cylinder adapts to Smith & Nephew and Stryker cement guns.

PREP-IM™ Enhance Total Hip Kit
The PREP-IM Enhance Total Hip Kit sets the standard in total hip prep kits. It is a pre-cementing bone preparation kit for total joint surgery with tools and implants to clean the cut bone and intramedullary canal, plug the intramedullary canal prior to cementing and clean the cemented areas. The kit contains instruments designed to clear bone and tissue debris, and to remove excess blood, fluid and cement in order to improve interdigitation of the bone cement. The kit contains the following:
- 2 BUCK Cement Restrictors, 18.5mm and 25mm
- 1 BUCK Disposable Inserter
- 1 Femoral Canal Brush, 19mm
- 1 Femoral Canal Suction Absorber
- 1 Medium Femoral Pressurizer
- 2 CONCISE Cement Sculps

BUCK™ Cement Restrictors
The BUCK Cement Restrictor provides cement support of the femoral or tibial prosthesis stem by plugging the intramedullary canal. The BUCK restrictor can be inserted quickly and accurately. The distal ring centers the restrictor and the proximal ring conforms to the inside of the medullary canal to address a wide range of canal variations. The PREP-IM Enhance Total Hip Kit includes both the 18.5mm and 25mm sizes, but the BUCK Restrictor is also available in 13, 30 and 35mm sizes. The BUCK Restrictor can also be purchased in a combination of 18.5, 25 and 30mm sizes with disposable inserters.

POWERPULSE™ Lavage
The POWERPULSE Lavage System is a metal, precision-engineered surgical instrument which provides excellent bone and tissue cleansing in the O.R. Competitive systems are fully disposable resulting in extra weight in medical waste leading to an increased expense for hospitals. With POWERPULSE, only the nozzles are disposed of, significantly reducing the medical waste. POWERPULSE is powered by existing O.R. sources so there are no battery packs or special pumps to purchase. POWERPULSE also features a non-clogging suction design and a variable speed trigger for improved control of pulse strength and frequency.
Cement mixing techniques

The following technique is for informational and educational purposes only. It is not intended to serve as medical advice. It is the responsibility of the treating physician to determine and utilize the appropriate products and techniques according to their own clinical judgment for each of their patients. For detailed product information, including indications for use, contraindications, effects, precautions and warnings, please consult the product's Instructions for Use (IFU) prior to use.

Hand mixing technique – 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 the ampoule of monomer at the neck and pour into the sterile mixing bowl.
   **Note:** Take care to gently break away from the body as to prevent injury and small glass particles in the mixture.
2. Add all of the powder from the packet carefully into the bowl.
3. Stir with the spatula slowly and carefully for one minute taking care to avoid spilling contents.
4. Allow to stand for 30 seconds* for the escape of air and for cement to reach the dough phase.

Vacuum mixing technique – RALLY All-in-One System
The RALLY All-in-One System is a premier, unique product composed of 70g of antibiotic cement completely contained inside the 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 comes in both RALLY HVAB and RALLY MVAB 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, pop the monomer vial with a sharp hit to the button on the top of the system. When you see monomer flowing, pump the release button several times to transfer all of the monomer into the powder chamber.
   **Tip:** Before releasing the monomer, invert the system and lightly tap the powder chamber to loosen the powder.
3. Grab the base mixing handle and pull the mixing handle in and out for one 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.
4. Disconnect the vacuum source.
5. Fully extend the mixing handle until it is engaged and turn the handle counter clockwise to disengage it from the system.
6. Attach the breakaway nozzle by screwing onto the end of system where the mixing handle was disconnected.
7. Push the monomer end of the system into the powder chamber and load the whole system into the RALLY All-in-One Cement Gun for dispensing.
   **Tip:** Pushing the monomer chamber into the powder chamber to the point where cement reaches the dispensing point before loading into the gun, removes more air from the cement chamber.

*Adjust according to temperature/time data for RALLY HV and RALLY MV cements.
Vacuum mixing technique – VORTEX Mixing System

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 VORTEX Vacuum Mixer.

1. The VORTEX 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 powder into the bowl, then all the liquid monomer down the side chute.
   - **2 Doses** – Pour 1 packet of powder into the bowl, followed by 1 ampoule of monomer down the side chute. Repeat with second packet of powder and ampoule of monomer.
   - **3 Doses** – Follow the procedure for 2 doses, repeating with the third dose of the cement.
3. Affix the VORTEX lid with the stirring element firmly attached.
4. Activate the vacuum source to 25mmHg.
5. Turn the VORTEX handle at 2 cycles per second for 1 minute.
   **Tip:** Tap sharply on the side of the mixer occasionally during mixing to dislodge any unwetted powder in the bowl.
6. Shut off the vacuum and remove the vacuum from the mixer. Remove the lid.

   **To apply cement via syringe application:**
7. Extract the funnel and cartridge (inner components) from the mixer and unscrew the funnel.
8. Connect the desired nozzle.
9. Place the assembly in the VORTEX gun for dispensing.

   **To apply cement via bowl and spatula:**
7. Extract the funnel and cartridge and insert the push up rod into the base of the cartridge.
8. Push the rod upwards until all of the cement is inside the funnel.
9. Use as a bowl.

   **Note:** The VORTEX mixer can be reused if another batch of cement is needed, unlike other mixing systems. Simply remove the stirring element, funnel, and cartridge from the VORTEX mixer and install the new components from the VORTEX Re-Use Kit.

*Not recommended for RALLY HV.*
Step 1
The proximal flange of the BUCK™ cement restrictor should always be larger than the distal canal diameter to ensure a good canal fit. Accurate cement restrictor depth placement is then determined by placing the prosthesis selected for implantation next to the inserter (Figure 1) and adding 2cm to the length.

Step 2 (Optional)
Remove the vent-occluding membrane by inserting the vent-opening tool into the threaded end of the restrictor and pushing the pin through the venthole (Figure 2). Remove and discard the plastic membrane.

Step 3
Screw the cement restrictor onto the inserter with a clockwise motion. Insert the device to the level of the medullary canal you have already determined (Figure 3). Once this level has been reached, disengage the restrictor from the inserter with a counterclockwise twisting maneuver. Remove the inserter from the medullary canal. Should it be necessary to remove the restrictor prior to cement insertion, it can be re-attached to the inserter rod and pulled out of the canal. In this way, the surgeon may adjust the restrictor as many times as required. After placing the BUCK cement restrictor, prepare the femoral canal by pulse lavaging, clearing debris with the femoral canal brush, and repeat lavaging if necessary to remove remaining debris.
Step 4
After insertion of the BUCK restrictor, the femoral canal should be cleaned and dried. First use the POWERPULSE lavage system to clean the canal. Next, hook the femoral suction absorber to suction and place back inside the canal while mixing the cement (Figure 4).

Step 5
Fill the canal with bone cement in a retrograde manner (Figure 5). It is important that the proximal femur be filled with cement that is placed under pressure to assure adequate packing of the proximal femur.

Step 6
After the cement is injected into the canal, break off the long nozzle and place the femoral pressurizer over the short nozzle. Apply the disposable femoral pressurizer into the mouth of the canal (Figure 6). This will occlude the canal and compress the cement. Maintain firm pressure until the cement is in the doughy state and can withstand displacement and will allow for proper cement interdigitation into the trabecular bone. Withdraw the femoral pressurizer and remove any extruded cement around the periphery of the canal.

Step 7
Once the cement is securely packed in the confines of the medullary canal, insert the femoral component (Figure 7). Note that the restrictor level maintains a 2cm cement mantle at the distal end of the prosthesis.

Step 8
After the stem has been inserted into the canal, remove any excess cement around the prosthesis with the Concise Cement Sculps (Figure 8).
The sticking points

**RALLY™ Bone Cement**
- High and medium viscosity cements
- Long-lasting spearmint green color for easy visualization of the cement now or down the road for implant revisions
- Low porosity for increased fatigue life
- Unique 70g All-in-One system for completely isolated mixing and dispensing of the cement

**VORTEX™**
- Gear driven stirring mechanism provides consistent mix
- No cement transfer results in less cement waste
- Intuitive design minimizes learning curve

**PREP-IM™ Enhance**
- Contains everything needed for femoral or tibial preparation

**POWERPULSE™ Pulse Lavage System**
- Less biohazard / medical waste
- Uses existing OR power sources
- Has a non-clogging suction design

**BUCK™ Cement Restrictor**
- Can be inserted quickly and accurately

The absolute bottom line of cement & accessories – Smith & Nephew is a total cement company offering a comprehensive range of products to meet all cementing needs.
### Bone Cement

<table>
<thead>
<tr>
<th>Cat. Item</th>
<th>Description</th>
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<tbody>
<tr>
<td>7127-1560</td>
<td>RALLY™ HV Bone Cement, 40 grams</td>
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<tr>
<td>7127-1570</td>
<td>RALLY™ HV AB Bone Cement, 40 grams</td>
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<td>7127-1580</td>
<td>RALLY™ MV Bone Cement, 40 grams</td>
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<td>RALLY™ MV AB Bone Cement, 40 grams</td>
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<td>7127-1340</td>
<td>VERSABOND™ Bone Cement, 40 grams</td>
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<tr>
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<td>VERSABOND™ AB Bone Cement, 40 grams</td>
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### Mixer and Dispensing Components
#### Mixing Systems

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<th>Description</th>
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<tr>
<td>7127-1600</td>
<td>RALLY™ HV AB All-in-One System, 70 grams</td>
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<tr>
<td>7127-1680</td>
<td>RALLY™ MV AB All-in-One System, 70 grams</td>
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<td>7127-0070</td>
<td>VORTEX™ Vacuum Mixing System</td>
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<tr>
<td>7127-0071</td>
<td>VORTEX™ Re-use Kit</td>
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<tr>
<td>7127-0068</td>
<td>VORTEX™ Vacuum Mixing Bowl</td>
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<td>210098</td>
<td>Mixing Bowl with Spatula</td>
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<tr>
<td>7127-0020</td>
<td>MIXOR™ Vacuum Mixing System w/Syringe</td>
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<td>7127-0069</td>
<td>VORTEX™ Vacuum Mixing Sample</td>
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<tr>
<td>7127-0090</td>
<td>MIXOR™ System w/ Syringe Sample</td>
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#### Nozzles

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<tr>
<td>7127-0080</td>
<td>VORTEX™ Standard Breakaway Nozzle</td>
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<td>7127-0081</td>
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<td>VORTEX™ Angled Nozzle</td>
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<td>7127-0084</td>
<td>VORTEX™ Revision Nozzle</td>
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<td>7127-0085</td>
<td>VORTEX™ Umbrella Nozzle</td>
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<tr>
<td>7127-0072</td>
<td>VORTEX™ Nozzle Adaptor</td>
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#### Mixing and Dispensing Accessories

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<tr>
<td>7127-1610</td>
<td>RALLY™ All-in-One Cement Gun</td>
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<td>7127-2001</td>
<td>VORTEX™ Cement Gun</td>
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<td>7127-0042</td>
<td>MIXOR™ Foot Pump Only</td>
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<td>7127-0041</td>
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<td>MIXOR™ Foot Pump Connector, D.I.S.S</td>
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### Pulse Lavage
#### POWERPULSE Lavage System

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<td>Powerhose w/Zimmer Coupling</td>
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<td>7127-7004</td>
<td>Hip/Knee Disposable Unit w/ Suction</td>
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<td>7127-7005</td>
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Cement Accessories

BUCK Cement Restrictors

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<tr>
<td>91-4535</td>
<td>BUCK Cement Restrictor 13mm</td>
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<tr>
<td>12-9418</td>
<td>BUCK Cement Restrictor, 18.5mm</td>
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<td>12-9419</td>
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<td>7127-9421</td>
<td>BUCK Cement Restrictor, 35mm</td>
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<td>BUCK Cement Restrictor w/Disposable Inserter, 18.5mm</td>
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<td>BUCK Cement Restrictor w/Disposable Inserter, 30mm</td>
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<td>11-2428</td>
<td>BUCK Cement Restrictor Inserter</td>
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<tr>
<td>11-0028</td>
<td>Vent Opening Tool</td>
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PREP-IM Enhance Total Hip Kit

<table>
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<tr>
<td>12-1010</td>
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<td>Includes:</td>
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<td>12-9418</td>
<td>BUCK Cement Restrictor, 18.5mm</td>
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<tr>
<td>12-9419</td>
<td>BUCK Cement Restrictor, 25mm</td>
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<td>11-2428</td>
<td>BUCK Disposable Inserter</td>
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<td>11-0003</td>
<td>Femoral Canal Brush, 19mm</td>
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<td>11-0037</td>
<td>Femoral Canal Suction Absorber, Std</td>
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<td>7127-0027</td>
<td>Medium Femoral Pressurizer</td>
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<tr>
<td>11-1000</td>
<td>CONCISE Cement Sculps</td>
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</tbody>
</table>

References:
1. Ref. RALLY Bone Cement IFUs.
2. Biomet Cobalt IFU.
4. Data provided by the manufacturer.
7. Data provided by the manufacturer.
11. Ref. Smith & Nephew. CPCS Surgical Technique. 7138-0787. 05/07.

Please see the Instructions for Use for each product for a complete list of indications, warnings, precautions and other important medical information.
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