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

Stainless steel rod reinforces the humeral stem

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

Stainless steel rods within stems provide added mechanical strength
The REMEDY® Hip Spacer is part of the treatment foreseen in a two-stage procedure performed in the event of permanent prosthesis infection. The REMEDY® Hip 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® Hip Spacer and replace it with a permanent hip joint implant.

**REMEDY® Hip Spacers:**
- Single-use medical devices/ethylene oxide sterile
- Formed with bone cement (PMMA) and gentamicin

Stainless steel rods within stems provide added mechanical strength.
Knee Interchangeability

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

**REMEDY® Knee Spacers:**

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

**Total System Interchangeability**

- 65% of cases result in different size femur and tibia*
- 35% of cases use a tibial wedge*

* Internal OsteoRemedies data
**Remedy® Elution Profile Of Antibiotics**

## Antibiotic Treatment Plan

1. **Antibiotics In Spacers:**
   - **Remedy® Spacers** – 4.8% Gentamicin In 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

![Antibiotic Release Over Time - Comparison](image)

- **Remedy® Hip w/ Long Stem (54mm Head)**
- **Remedy® Hip With Short Stem (54mm Head)**
- **Intra-Op Molds**
- **24 mg/0.9% AB Release**
- **27 mg/2.1% AB Release**
- **205 mg/7.2% AB Release**
- **157 mg/8.5% AB Release**
- **150 mg/8.5% AB Release**

**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® 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.

**STEP 2**
Using the Shoulder Spacer Trials and templates, select the appropriate size humeral stem and humeral head components.

**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.

**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.

**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.

**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 trunnion.
## Shoulder Specifications

### Remedy® Modular Humeral Head

<table>
<thead>
<tr>
<th>Description</th>
<th>Catalog #</th>
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<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
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<th>7</th>
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<th>Gentamicin Base (g)</th>
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<tr>
<td>Remedy® Modular Humeral Head 40mm</td>
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**Remedy® 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 and templates, select the appropriate size femoral stem and femoral head components.

**STEP 3**  
Once the appropriate head size is selected, open the package and remove the monomer vial. Break the vial open and pour all the monomer into the screw opening of the head.

**STEP 4**  
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.

**STEP 5**  
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.

**STEP 6**  
Using Unite®AB Bone Cement, or any FDA-cleared AB PMMA, 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.

**STEP 7**  
Insert the stem (with head properly affixed) into the canal.

**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 head must be seated past the Safety Line marked in blue or purple on the stem thread.

On the Trials, the blue or purple line is designated with a missing thread on the trunnion.

(Appearance working time for head position is 10 to 15 minutes.)
### Remedy Modular Head

**Catalog #:** RHHDSD

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<th>Description</th>
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### Remedy Modular Stem

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### Remedy Modular Long Stem

**Catalog #:** RHLSMD

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</table>
**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 and templates, 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.

**STEP 3**
Using UNITE®AB Bone Cement, or any FDA-cleared AB 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 wedge/insert 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 Knee Spacer

<table>
<thead>
<tr>
<th>Description</th>
<th>Catalog #</th>
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<th>2</th>
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</table>
UNITE® AB Bone Cement

is a high-viscosity, radiopaque bone cement containing and releasing gentamicin sulphate for manual application.

UNITE® AB Bone Cement is a single-use, sterile medical device provided in doses of 40g. UNITE® AB Bone Cement contains 1 gram of gentamicin per 40 gram dose versus 0.5 grams in Palacos R+G.

With a lower ratio of monomer to powder as compared to market leading bone cement mixtures, UNITE® provides benefits such as:

- Lower maximum temperature from the chemical reaction may reduce the risk to surrounding tissues.
- Reduced toxicity for those handling the cement.
- Reduced cement shrinkage may improve implant fixation.

<table>
<thead>
<tr>
<th>Component</th>
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<th>Palacos® R+G Gentamicin</th>
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<tbody>
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<td>Gentamicin in Resin</td>
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Specifically designed formulation to work effectively with REMEDY® Spacers

<table>
<thead>
<tr>
<th>Product</th>
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<th>Waiting</th>
<th>Working</th>
<th>Setting</th>
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Approximate set time as tested at 74° F.