**DESCRIPTION**

StabiliT ER® Bone Cement is indicated for the intended use of the procedure of vertebroplasty or kyphoplasty. It is a bone cement system that consists of a single-use ceramic vial containing fine-grained powder and a vial of liquid. Once mixed, the cement provides support and consolidation for vertebral bodies that are susceptible to fracturing. During the polymerization reaction, bone cement releases heat that may cause temporary tissue damage.

**PRECAUTIONS**

- Bone cement is flammable. Handle with care and avoid any smoking or open flames to minimize the risk of fire.
- Never attempt to accelerate the setting time by pushing or manipulate against the bone cement.
- Care should be taken to avoid excessive exposure to the monomer vapor for extended periods. The operating room should be adequately ventilated.
- Only use the device as intended. Do not attempt to render the device suitable for further use.
- Do not re-sterilize any of the components. Reconditioning, refurbishing, repair, modification, or resterilization is prohibited as it may result in loss of function or infection.
- Sterility is assured only if the unit container is not damaged or opened.
- Cement leakage may cause tissue damage, nerve or circulatory problems, and other serious adverse events.
- Evidence of safety for use of this material in children or during pregnancy or lactation has not been established.

**INDICATIONS**

- StabiliT ER® Bone Cement is indicated for the treatment of bone lesions such as hemangiomas, myelomas, and vertebral fractures.

**CONTRAINDICATIONS**

- PMMA bone cement is contraindicated in the presence of active or incompletely treated infection, at the site of its intended application and damage to the surrounding tissues.
- Product use is contraindicated with patients with extended vertebral collapse superior to 2/3 of the standard vertebral body.
- Use of this device is contraindicated in the presence of active or incompletely treated infection at the site of the intended application and damage to the surrounding tissues. Evidence of safety for use of this material in children or during pregnancy or lactation has not been established.

**HOW SUPPLIED**

- StabiliT ER® Bone Cement is supplied as a single-use device that consists of a ceramic vial containing fine-grained powder and a vial of liquid. The powder and liquid are mixed per the USP 797 cleanroom environment or equivalent. StabiliT® ER Bone Cement is supplied for single-use only.

**REFERENCES**

- Additional references may be required with a PMMA cement intended for vertebral augmentation or kyphoplasty.

**CAUTIONS:**

- Never return an unused portion of the bone cement to the manufacturer's vials. Once the bone cement is mixed, it is no longer sterile.
- Do not use if package is damaged or opened.
- Do not use if there is evidence of signs of infection at the injection site or elsewhere.

**NOTICE:**

- The contents of this package are intended for single-use only. Proper care should be taken to ensure sterile technique and correct usage of the device.

**STORAGE**

- Store StabiliT ER® Bone Cement at room temperature.

**TABLES**

<table>
<thead>
<tr>
<th>Operation</th>
<th>Injection Temperature (°C)</th>
<th>Cement Setting Temperature (°C)</th>
<th>Cement Working Temperature (°C)</th>
</tr>
</thead>
<tbody>
<tr>
<td>VAS</td>
<td>25</td>
<td>50</td>
<td>40</td>
</tr>
<tr>
<td>Without VAS</td>
<td>30</td>
<td>52</td>
<td>45</td>
</tr>
</tbody>
</table>

**NOTES:**

- All mixing is to be conducted in a cleanroom environment to prevent contamination.
- Follow the IFU for ER² Saturate Mixing System and StabiliT Vertebral Augmentation.