**STABILI-T® BONE CEMENT AND SATEURATE MIXING SYSTEM**

**TABLE 2: EFFECT OF AMBIENT TEMPERATURE ON CEMENT.**

<table>
<thead>
<tr>
<th>Temperature (°C)</th>
<th>Minimum Setting Time (Minutes)</th>
</tr>
</thead>
<tbody>
<tr>
<td>18</td>
<td>12</td>
</tr>
<tr>
<td>22</td>
<td>6</td>
</tr>
<tr>
<td>26</td>
<td>3</td>
</tr>
</tbody>
</table>

**WARNINGS**

- Use only the components that were included in the package. Do not use if the package is not opened, is damaged, or is missing components.
- Do not be tempted to use expired components.
- All components are provided sterile. Do not re-sterilize and/or reuse any of the components. The Stabili-T Bone Cement and Saturate Mixing System is intended for mixing of Stabili-T Bone Cement.
- This device is intended for the treatment of painful vertebral compression fractures. The bone cement and associated techniques should be used only by qualified and trained professionals.

**CONTRAINDICATIONS**

- This device is contraindicated for patients with a history of latex allergy.
- This device is contraindicated for patients who have a history of sensitivity to bone cements.
- This device is contraindicated for patients who have a history of sensitivity to N,N-dimethyl-p-toluidine or methyl methacrylate.

**ADVERSE REACTIONS**

- The most frequent adverse reactions reported with acrylic bone cement intended for vertebroplasty, or kyphoplasty include myocardial infarction, cardiac arrest, cerebrovascular accident, pulmonary embolism, and vascular system resulting in embolism of the lung.

**CAUTION:**

- The released heat may damage bone or other tissues surrounding the implant. It is important to read the IFU for Stabili-T VP and the precautions prior to device operation.
- Hypotensive reactions have occurred between 10 and 165 seconds following application of bone cement; they result from osteoporosis, benign lesions (hemangioma), and malignant lesions (metastatic cancers, myeloma).
- Soft contact lenses should not be worn when handling bone cement.
- Because soft contact lenses are quite permeable, personnel wearing contact lenses should not be near the bone cement.
- Do not allow the liquid component to contact latex gloves.
- Diminish the possibility of hypersensitivity reactions. The liquid component is a powerful lipid solvent. Do not allow the liquid component to contact skin, eyes, or mucous membranes.

**STABILI-T® BONE CEMENT AND SATEURATE MIXING SYSTEM**

- The Stabili-T Bone Cement and Saturate Mixing System is packaged sterile. Components include a vial of a colorless, flammable liquid as a solvent (4.2g), a vial of a colorless, flammable liquid that is viscous at room temperature (10.5g), a syringe, and a Stopcock. The liquid (4.2g) is sterilized by filtration method and the outer surface of the vial is sterilized by ethylene oxide gas. The locking syringe and Stopcock are sterilized by ethylene oxide gas. This device is intended for use in vertebroplasty and kyphoplasty procedures

**INFORMATION**

- This device is intended for vertebroplasty and kyphoplasty procedures. The most frequent adverse reactions reported with acrylic bone cement intended for vertebroplasty, or kyphoplasty include myocardial infarction, cardiac arrest, cerebrovascular accident, pulmonary embolism, and vascular system resulting in embolism of the lung.

**REFERENCE**

- The information contained in this IFU is intended to provide the user with a safe and effective method of using the Stabili-T Bone Cement and Saturate Mixing System. The user is responsible for ensuring that all users of the device are properly trained and that the device is used in accordance with the instructions provided.

**Figure 1**

- The Stabili-T Bone Cement and Saturate Mixing System is provided sterile. The powder (10.5g) is sterilized by asceptic processing. The Saturate Mixing System is provided sterile. The liquid (4.2g) is sterilized by filtration method and the outer surface of the vial is sterilized by ethylene oxide gas. The locking syringe and Stopcock are sterilized by ethylene oxide gas.

**Figure 2**

- Deviating from the mixing instructions in this IFU will result in inadequate cement.

**Figure 3**

- Pointing the Cement Syringe luer down, tap the luer opening of the Cement Syringe to assure that little or no vacuum pressure exists. The cement will not be forced out of the syringe. To close off Stopcock, rotate the lever down. To close off Stopcock by rotating lever UPWARD, then separate the Syringe Filter from the Stopcock to relieve vacuum pressure. If not already, rotate the Stopcock off lever towards the Locking Syringe to temporarily close off flow and secure the Stopcock. To join Syringe Filter to the Stopcock, turn Stopcock 180° to allow the female filter luer to join with the male Stopcock adapter. To lock, rotate plunger to the Locking position. To remove the following components from the Stabili-T Bone Cement and Saturate Mixing System:

**Figure 4**

- It is important to read the IFU for Stabili-T VP and the precautions prior to device operation.

**Figure 5**

- Make sure that the Stabili-T Bone Cement and Saturate Mixing System is provided sterile. Components include a vial of a colorless, flammable liquid that is viscous at room temperature (10.5g), a syringe, and a Stopcock. The liquid (4.2g) is sterilized by filtration method and the outer surface of the vial is sterilized by ethylene oxide gas. The locking syringe and Stopcock are sterilized by ethylene oxide gas. This device is intended for use in vertebroplasty and kyphoplasty procedures.

**Figure 6**

- If not already, rotate the Stopcock off lever towards the Locking Syringe to temporarily close off flow and secure the Stopcock. To join Syringe Filter to the Stopcock, turn Stopcock 180° to allow the female filter luer to join with the male Stopcock adapter. To lock, rotate plunger to the Locking position. To remove the following components from the Stabili-T Bone Cement and Saturate Mixing System:

**Figure 7**

- Closely observe the progression of the monomer liquid as it saturates through the powder. When the powder is uniformly saturated, it is time to inject the cement. To begin the injection, press vacuum lever down on the Cement Injector. To discontinue the cement injection, press vacuum lever up to release vacuum pressure.