Bone Cement is a polymethylmethacrylate (PMMA) radiopaque bone cement. StabiliT ER® Bone Cement is indicated for treating painful osteoporotic vertebral compression fractures in adults by the kyphoplasty procedure. Painful vertebral compression fractures may result from osteoporosis, Paget's disease, metastatic bone disease, and other medical conditions.

Injections of cement into vertebral bodies (VBs) are performed to:• Treat painful vertebral compression fractures
• Diminish pain associated with vertebroplasty
• Minimize bleeding
• Prevent leakage of bone cement

**Injections of cement into VBs**

- **10.5 g of Sterile Powder**
  - Store below 25°C
  - Do not use if package is opened or damaged

- **4.2 g of Sterile Liquid**
  - See IFU (StabiliT Vertebral Augmentation System)

**Activity**

**Injection Procedure**

1. **Asceptic Processing**
   - Steriliy is assured only if the unit container is not damaged or opened.
   - For proper mixing and use, follow this IFU and StabiliT Vertebral Augmentation System (VAS) IFU.

2. **System Preparation**
   - Wear safety glasses or a face shield when delivering the material. Follow handling and mixing instructions to avoid releasing heat which may damage bone or other tissues surrounding the implant.
   - Inadequate joining of the Syringe Filter to the Stopcock

3. **Cement Preparation**
   - **Pointing the Cement Syringe luer down, tap the luer opening of the Cement Syringe to assure that little or no excess cement is left in the luer-opening.**

4. **Drying**
   - **For dried powder to come out of the Cement Syringe.**

5. **Setting**
   - **Time lost is irreversible.**

6. **Use**
   - Do not re-sterilize and/or reuse any of the components. The StabiliT ER² Bone Cement and Saturate Mixing System is intended for single use only.

7. **Evidence of Safety**
   - Evidence of safety for use of this material in children or during pregnancy or lactation has not been established.
   - The liquid is highly volatile and flammable. The operating room should be adequately ventilated to eliminate as much ethylene oxide gas. The liquid (4.2g) is sterilized by filtration method and the outer surface of the vial is sterilized by introduction into the vascular system.
   - When the powder and liquid components are mixed, an exothermic reaction occurs resulting in a liquid that progressively hardens as a cement-like complex.
   - Therapeutic bone cement. To the powder component, barium sulphate is added to assist in visualization of bone cement.
   - The liquid is highly volatile and flammable. The operating room should be adequately ventilated to eliminate as much ethylene oxide gas. The liquid (4.2g) is sterilized by filtration method and the outer surface of the vial is sterilized by introduction into the vascular system.
   - When the powder and liquid components are mixed, an exothermic reaction occurs resulting in a liquid that progressively hardens as a cement-like complex.

8. **Sterility**
   - Sterility is assured only if the unit container is not damaged or opened.
   - Evidence of safety for use of this material in children or during pregnancy or lactation has not been established.

9. **Transitory**
   - Transitory worsening of pain due to introduction into the vascular system

10. **Potential Adverse Events**
    - Transitory worsening of pain due to introduction into the vascular system
    - Evidence of safety for use of this material in children or during pregnancy or lactation has not been established.
    - Transitory worsening of pain due to introduction into the vascular system

11. **Dosage**
    - Do not apply more than 250 µl of the liquid component to the cement

12. **PMMA Bone Cement**
    - PMMA bone cement is contraindicated in the presence of active or incompletely treated infection, at the site where bone cement is to be applied.

13. **Other**
    - Aqueous polymer solutions of PMMA offer the desired physical properties and effectiveness of bone cement.
    - Diffusion of the resin outside the vertebral body: in

14. **Precautions**
    - Pneumothorax
    - Diffusion of the resin outside the vertebral body: in

15. **Limitations**
    - Diffusion of the resin outside the vertebral body: in

16. **CAUTION:**
    - Diffusion of the resin outside the vertebral body: in

17. **Manufacturing Information**
    - Diffusion of the resin outside the vertebral body: in

18. **Disposal**
    - Diffusion of the resin outside the vertebral body: in

19. **Summary**
    - Diffusion of the resin outside the vertebral body: in

20. **Storage**
    - Diffusion of the resin outside the vertebral body: in

21. **Reporting**
    - Diffusion of the resin outside the vertebral body: in

22. **Declaration**
    - Diffusion of the resin outside the vertebral body: in

23. **Contact Information**
    - Contact Information

24. **Packaging Information**
    - Packaging Information

25. **Quality Control**
    - Quality Control

26. **EC Customer Service**
    - EC Customer Service

27. **Authorized Representative**
    - Authorized Representative

    - U.S.A Customer Service

29. **Address**
    - Address

30. **Website**
    - Website

31. **Name**
    - Name

32. **Abbreviations**
    - Abbreviations

33. **Definition**
    - Definition

34. **DIRECTIONS**
    - DIRECTIONS

35. **Table**
    - Table

36. **Notes**
    - Notes

37. **References**
    - References

38. **Figure**
    - Figure

39. **Legend**
    - Legend

40. **Glossary**
    - Glossary