

# SerenoCem™ Otologic Cement

## Instructions for Use

**IMPORTANT:** Upon receiving the Invotec Serenocem™ Mixer, Cat # BC-280), and prior to OPERATION, the **TWO (2) RED COLORED SHIPPING BOLTS** found on the bottom of the unit, **MUST BE REMOVED**. FAILURE TO DO SO, COULD DAMAGE THE MIXER.

SerenoCem™ Cement is a reaction-bonded polymer composite formed by the neutralization gelletation of a basic inorganic ionomer and an organic polyelectrolyte (Polyacrylic) acid. It is recommended for use in hard tissue replacement in Middle Ear Surgery, and anchoring of Cochlear Implants.

### Properties

- Non-exothermic snap set
- SerenoCem glass has an apatite stoichiometry
- Chemical adhesion to bone and metals
- Hydrophilic—promotes physical bone bonding
- High compressive strength (84MPa at 1 week)
- Bioactive/Osteoconductive ion release
- Moldable on placement
- Easy to trim when set using surgical burs or scalpel
- Minimal shrinkage on setting
- Bactericidal prior to set

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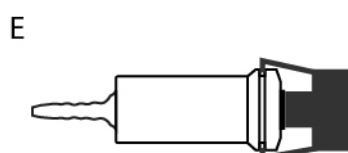
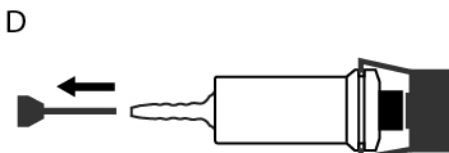
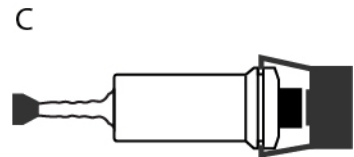
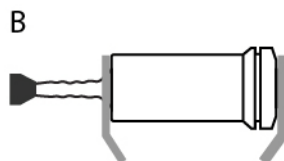
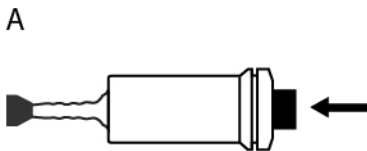
### How Supplied

SerenoCem Cement is supplied sterile and double wrapped. Cement is prepared by the unsterile circulating nurse and instilled onto the back table by the circulator. Do not place the capsules onto the sterile field. Do not use if the outer wrapper is damaged.

Catalog #	Description	UOM
BC-010	SerenoCem Cement two each, capsules (1Gm), sterile, double wrapped.	2 capsules
BC-010S	SerenoCem Cement one each, capsule (1Gm), sterile, double wrapped.	1 capsule

### Activation

1. *Circulating nurse* removes inner foil pack from outer wrapper.
2. Tear open foil package and expose capsule.
3. When the surgeon is ready to use the cement, the *circulating nurse* grasps the capsule and drives the black pin into the body. (Diagram A)
4. Immediately, place in the tines of the mixer, top is closed and shaken/mixed for ten (10) seconds. (Diagram B)
5. The *circulating nurse* removes the mixed capsule from the mixer and loads the capsule into the unsterile cement applicator. (Diagram C)
6. When ready to express into the sterile field, the *circulating nurse* will pull out the tip from mixed capsule. (Diagram D)
7. Aim- point the open capsule tip at a flat nonporous surface on the back table. By squeezing the applicator handles together, the cement will be expressed on the working surface, ready for the surgeon. (Diagram E)
8. Remove and dispose of capsule appropriately.



### Distributed By

Invotec International, Inc.

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**Attention:** The setting time of the cement will vary depending on the ambient temperature of the operating room. The times indicated for setting are based on a temperature of 73.4°F (23°C).

To obtain the maximum working time, it is recommended to refrigerate the cement between 35° to 46°F (2 to 8°C), for 30 minutes prior to use.

**Storage:** Maintain in a dry environment, between 59 to 73°F (15 to 23°C).

### Placement

- Cement should be placed in a dry field within 1 to 3 ½ minutes of being mixed.
- Place directly onto bone avoiding contact with blood, fluid, or soft tissue until set (~ 10 minutes)
- Maintain a dry operating field during application and setting of the cement.
- Ideally, place the wet cement just prior to the snap set (3 ½ to 4 minutes)
- Use a minimal amount of cement. Less is best.
- Upon setting (~ 10 minutes), the cement may be fashioned into a specific shape with diamond bur under irrigation. The cement does not reach its full strength for several hours, thus, care must be taken in trimming and fashioning.

### Contraindications

These contraindications do not apply to set material.

SerenoCem related materials, while in a nonsolid state, must not be placed directly in contact with peripheral nerves, cranial nerves, neural tissue or the brain, dura or any part of the Central Nervous System. A blockage of nerve conduction, which may not be reversible, may occur. Wet cement should not come in direct contact with the inner ear.

This product must not be used in acoustic neuroma or skull base surgery.

Invotec International or the manufacturer cannot be held responsible for any incorrect usage of this product that is contrary to the specific instructions given.

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