

General Description

The Bowl Mixer enables bone cement to be mixed in a sealed manner without human contact or exposure to the outer environment. This is vital for two main purposes:

Decreased Cement Porosity


Pores in bone cement can lead to implant insertion failure or loosened implants. The Vacuum Sealed Bowl reduces cement porosity, increasing mechanical strength and resistance to cement fatigue and deformation. As a result, aseptic loosening of implants and the rate of arthroplasty revision is reduced.

Prevents Exposure to Harmful Fumes

The enclosed chamber of the Vacuum Sealed Bowl reduces exposure to harmful fumes that are released during the cement mixing process.

The liquid methylmethacrylate (MMA) monomer is emitted during the preparation of PMMA bone cement, and may cause irritation of the respiratory tract and eyes. Side effects also include allergic reactions and neurological disorders. Using a Vacuum Bowl Mixer can reduce this risk.



 Read the operating instructions carefully before use. Failure to follow may cause injuries or damages.

Indications

Orthopaedic bone cement mixing for arthroplasty.

Warnings

Failure to follow may cause injuries to person.

- Always check the package before use.
- Sterile only if package is unopened and undamaged.
- Single use only! DO NOT Re-sterilize!
- DO NOT operate damaged or malfunctioning instrument
- Do not use this product in any other manner other than the purpose or the operation method described in this instruction manual.

Standard package includes:

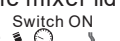
- ① Mixing Bowl
- ② Lid
- ③ Suction Tube with Filter
- ④ Spatula
- ⑤ Curette
- ⑥ Ampoule breaker

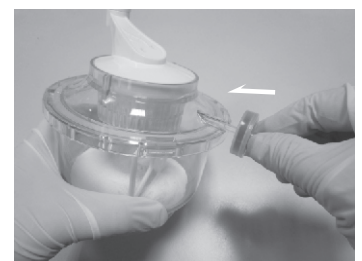
Caution

Failure to follow may cause damage to product.

- DO NOT drop or hit the instrument.
- Store in a cool dry place.
- Modification of this equipment is not allowed
- The user/patient should report any serious incident relating to the device to the manufacturer and competent authority of its Member State.

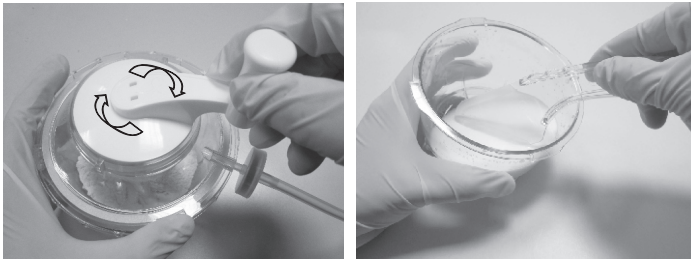
Instructions for Use

1. Remove all items in a standard sterile pack opening procedure.
2. Pour bone cement (powder and liquid) into the mixing bowl ①.
3. Close tightly the mixing lid ②.
4. Install suction tube with filter ③ on the mixer lid and attach the other end to vacuum source.
5. Ensure vacuum source is working  .



5. Start mixing according to bone cement product mixing time.
6. Stop vacuum pump and disconnect suction tube from the mixer. **A**
7. Open the mixer lid **2**.
8. Use the spatula **4** to smear uniformly the bone cement.

Switch OFF



NOTE:

This mixer can work with any pump with the working pressure 20-22 inHg.

Disposal

- Dispose of all single use components, as appropriate, immediately after use.
- Ensure that the device is disposed of safely and in accordance with all current national and international waste disposal directives.
- For the correct method of disposal, please contact your local municipality, waste disposal services.

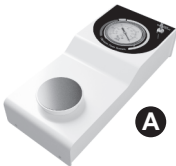
Shelf Life

Please check package label

Transportation and Storage

- Temperature: -10°C ~ +40°C
- Relative Humidity: 15%~75%RH

Option & Accessories



#5000-6
Vacuum foot pump

Labeling Symbols

- Refer to instruction manual/booklet
- General warning sign / Caution
- Do not use if package is damaged
- Do not re-use
- Keep dry
- Temperature limit
- Sterilized using ethylene oxide
- Complies with EU directives
- Manufacturer
- Authorized Representative in the European Community
- Not made with latex
- Medical Device
- Use by date
- Catalog number
- Date of manufacture
- Batch code
- Consult instructions for use
- Humidity limitation
- UK Responsible Person

