

# Bone Cement Mixer Syringe

## T Syringe Type Instruction Manual

REF 5000-12

MODEL NO. SMX-5000-12

### General Description

The Syringe 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 Syringe 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 Syringe 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 Syringe 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.

#### 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.



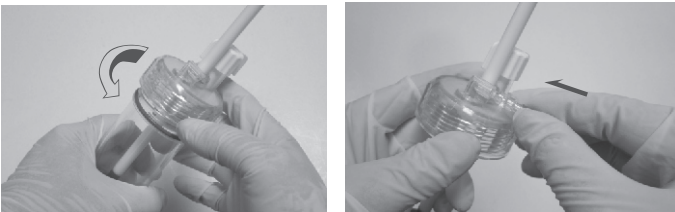
Syringe mixer kit

Standard package includes:

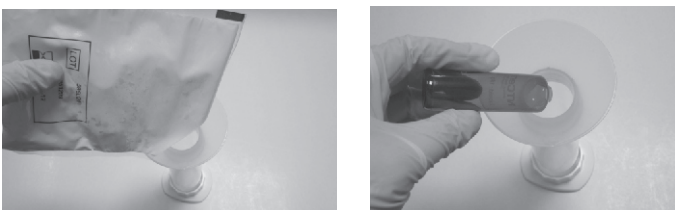
- 1 Syringe cap
- 2 Suction tube with filter
- 3 Mixing stand
- 4 Funnel
- 5 Syringe body
- 6 Mixing Rod
- 7 Stopper
- 8 Long nozzle
- 9 Push rod for nozzle
- 10 Ampoule breaker

### Instructions for Use

1. Peel open the pack and remove all of the items.
2. Open the mixing cap **1**, install the filter and attach the tube **2** to the vacuum pump at the other end.



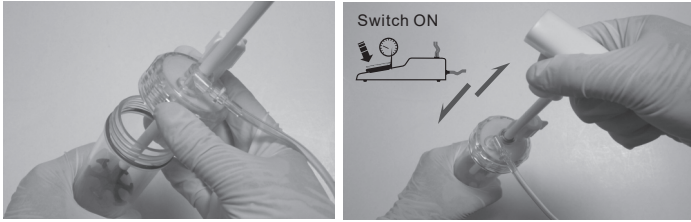
3. Place the stand **3** and funnel **4** on the bottom and mouth of the mixing body **5**.
4. Pour bone cement (powder and liquid) into the mixing body **5** and remove the funnel **4**.



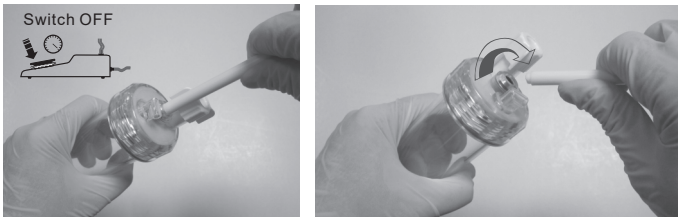
5. Close the mixing cap **1** tightly and switch on the vacuum pump **A**, ensuring that the vacuum source is working. Start mixing upwards and downwards and rotate the rod **6** gently until the mixture starts to homogenize.

**NOTE:**

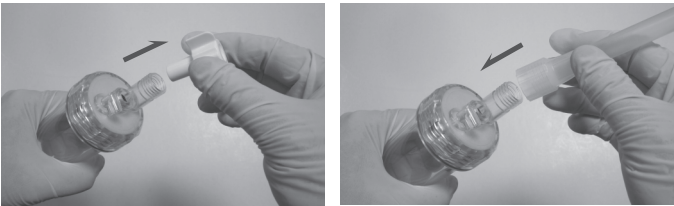
This mixer can work with any pump with the working pressure 20-22 inHg.



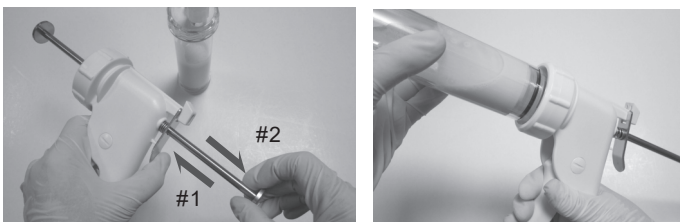
6. Stop the vacuum pump **A** and disconnect tubing **2** from the cap of the mixing device. Pull the mixing rod **6** until it reaches the top. Bend the rod until it breaks.



7. Remove the white stopper **7**. Install syringe nozzle **8**.



8. Mount the mixing body on the injection gun **B** or **C**. Activate the pistol trigger until it meets the plunger of the mixing body, and activate the trigger with the cannula upwards until it fills the application cannula. Position the cannula and activate the trigger to dispense bone cement.



**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 ~ 40°C
- Relative Humidity: 15%~75%RH

**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
- Catalog number
- Batch code
- Date of manufacture
- Complies with EU directives
- Manufacturer
- Authorized representative in the European Community
- Medical Device
- Humidity limitation
- Authorized representative in the European Community
- UK Responsible Person

**Option & Accessories**

