INDICATIONS FOR USE

ZMI-90™ Cement Mixing and Injection System

Warnings (Safety Directives)

Before using this equipment, or any component compatible with this equipment, read and understand the instructions for use. Pay particular attention to safety information. Become familiar with the equipment before use.

- Only healthcare professionals trained and experienced in the use of this medical device should operate this equipment.
- Upon initial receipt and before use, inspect each component for damage. DO NOT use any equipment if damage is apparent.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. This device is intended to be used on a sterile, level surface.
- Before using this cement gun in a clinical environment, practice mixing bone cement and using the cement gun.
- The device will not withstand the excessive pressure that is created when doughy/hardened cement is extruded. DO NOT attempt to extrude the cement if excessive force is necessary. In this situation, utilize a new device.

Excessive force may cause the device to break. Pieces of the broken device may cause patient and/or operating room staff injury.

- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the ZMI-90, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

CAUTION: DO NOT repair this cement gun. In case of operating difficulties, please return to Zavation for inspection.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

Indication(s) for Use

This device is designed to mix and inject bone cements into osseous voids during kyphoplasty and vertebroplasty procedures, for the following indications: verbetral compression fractures, which may be caused by osteoporosis, osteomyelitis, cancer/tumor, or trauma.

INDICATIONS FOR USE (Continued)

Intended Use

This is a sterile, single-use cement mixer and injector that is designed to mix and inject low, medium or high viscosity bone cements.

The use of this device has been tested as small as a 14-Gauge Cannula.

Contraindication(s), Risks or other Precautions

This device is intended to use with only tested cements. Use of untested cements may lead to device failure.

This device is packaged and sterilized for single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or lead to device failure that in turn may result in patient injury, illness or death. Also, reprocessing or resterilization of single use devices may create a risk of contamination and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another.

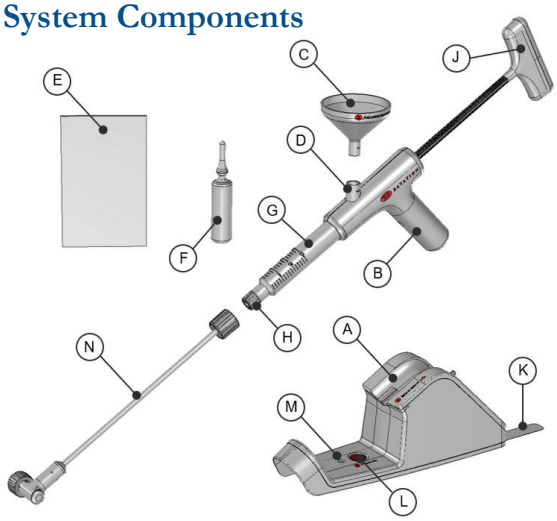
Contamination of the device may lead to injury, illness, or death of the patient.

NOTE: The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Product Complaints

Any Healthcare Professional (e.g., customer or user of this system of products), who has any complaints or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify Zavation Medical Products LLC, 3670 Flowood Dr., Flowood, MS 39232, USA, Telephone: 601-919-1119.

System Components



Component Names

(A) Mixing Base
(B) Delivery Device
(C) Funnel
(D) Fill Port
(E) Packet of Polymer Powder
(F) Ampoule of Liquid Monomer
(G) Barrel
(H) Barrel Cap
(J) Control Knob
(K) Battery Pull Tab
(L) Mix Button
(M) Status Indicator
(N) Delivery Tubing

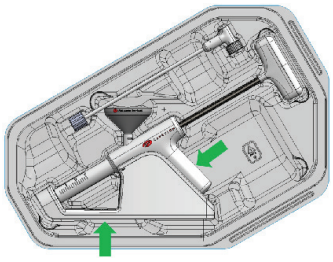
System Setup

CAUTION

Check that the package and system components are undamaged.

CAUTION

Lift and carry the device assembly by the Mixing Base when removing it from the sterile packaging.

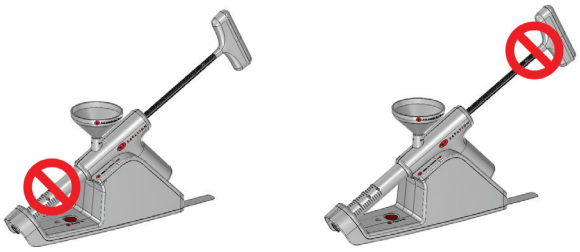


INDICATIONS FOR USE (Continued)

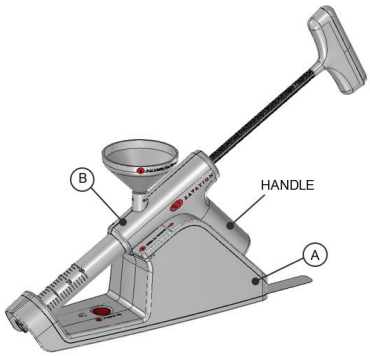
CAUTION

Do NOT lift or carry the device assembly by the Barrel.

Do NOT lift or carry the device assembly by the Control Knob.



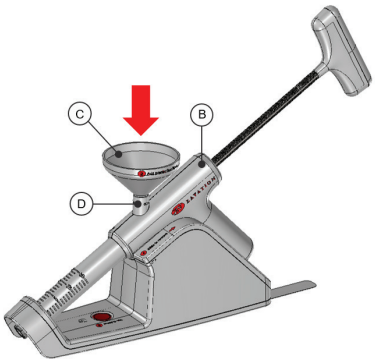
1. Remove all system components from the packaging and place on a sterile table surface.
2. Check that the **HANDLE** of the **DELIVERY DEVICE (B)** is resting on the back of the **MIXING BASE (A).**



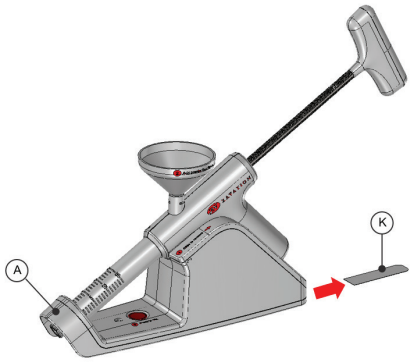
CAUTION

If the Delivery Device is not properly resting on the Mixing Base, the bone cement will not mix correctly

3. Check that the **FUNNEL (C)** is securely attached to the **FILL PORT (D)** of the **DELIVERY DEVICE (B)**.
4. If loose, push down on the **FUNNEL (C)** within the **FILL PORT (D)** until it feels secure.



5. Grasp and pull on the **BATTERY PULL TAB (K)** to remove it from the **MIXING BASE (A).**



Patient Setup

CAUTION

Place the trocar in the patient before proceeding. To ensure the maximum working time with the bone cement before it hardens, complete all patient prep before mixing the bone cement.

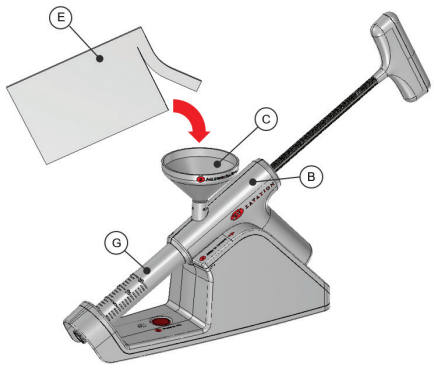
Bone Cement Mixing

CAUTION

Add bone cement components in the correct order to ensure proper mixing.

1. Tear open the **PACKET OF POLYMER POWDER (E)**.
2. Pour the entire contents of the **PACKET OF POLYMER POWDER (E)** packet into the **FUNNEL (C)**.
3. If necessary, gently tap the side of the **FUNNEL (C)** to ensure all **POLYMER POWDER** enters the **BARREL (G)**.

The **POLYMER POWDER** should be visible within the **BARREL (G)** of the **DELIVERY DEVICE (B)**.



INDICATIONS FOR USE (Continued)

CAUTION

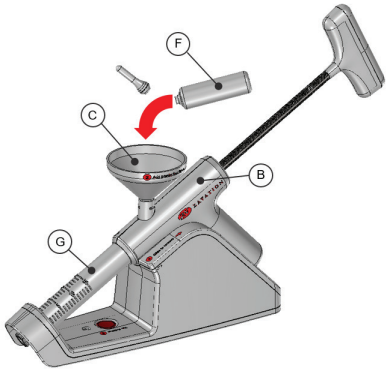
Confirm that all of the Powdered Polymer is in the Barrel of the Delivery Device. Incorrect amounts of Powdered Polymer could result in poor bone cement viscosity. Do not tilt device after pouring Polymer Powder into Barrel.

WARNING

Do not start mixing yet. Mixing too early could result in poor bone cement consistency.

4. Break the top off of the **AMPOULE OF LIQUID MONOMER (F).**
5. Pour the entire contents of the **AMPOULE OF LIQUID MONOMER (F)** into the **FUNNEL (C).**

The **LIQUID MONOMER** should be visible within the **BARREL (G)** of the **DELIVERY DEVICE (B)**.



WARNING

Handle the broken ampoule pieces with care. Sharp edges could cut gloves or fingers. Dispose of ampoule pieces safely when empty.

CAUTION

Confirm that all of the Liquid Monomer is in the Barrel of the Delivery Device. Incorrect amounts of Liquid Monomer could result in poor bone cement viscosity.

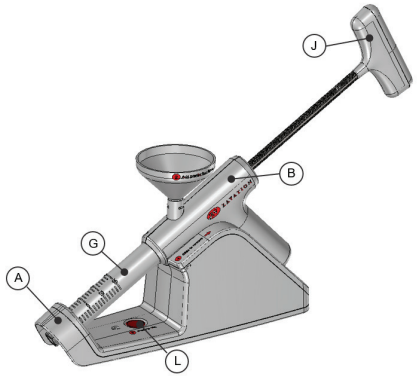
CAUTION

Clear the area around the Mixing Base and Delivery Handle so that nothing is touching the Control Knob and nothing is between the Control Knob and the Mixing Base.

6. To begin mixing the bone cement, press the **MIX BUTTON (L)** on the **MIXING BASE (A)**.
7. The **CONTROL KNOB (J)** will begin to spin towards the **DELIVERY DEVICE (B)**, and then spin back to its original position.

This cycle will repeat several times to mix the powdered and liquid bone cement components in the **BARREL (G)**.

Mixing will take approximately 90 seconds.

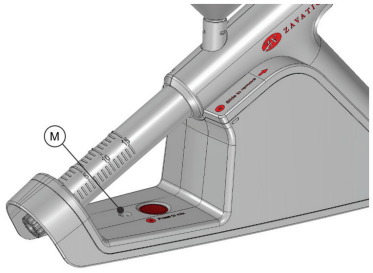


WARNING

Do not touch the spinning Control Knob, Delivery Device, or Mixing Base during the mixing cycle.

When the **STATUS INDICATOR (M)** lights **GREEN (●)**, the bone cement mixing is done and the **DELIVERY DEVICE (B)** is ready to use.

If the **STATUS INDICATOR (M)** lights **RED (●)**, an error has occurred. Do not proceed. Start over with a new system.



WARNING

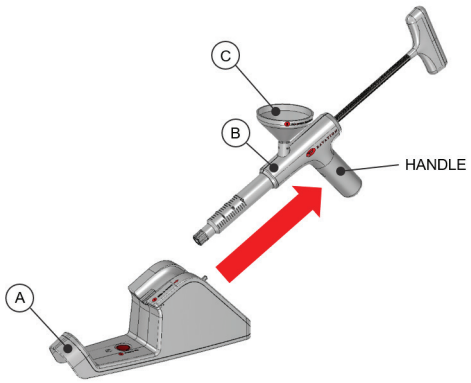
Do not proceed if the Status Indicator is red. A red indicator means the system encountered an error during mixing and the bone cement may not be mixed correctly.

INDICATIONS FOR USE (Continued)

Prepare for Delivery

1. Grasp the **HANDLE** of and pull to slide the **DELIVERY DEVICE (B)** out of the **MIXING BASE (A)**.

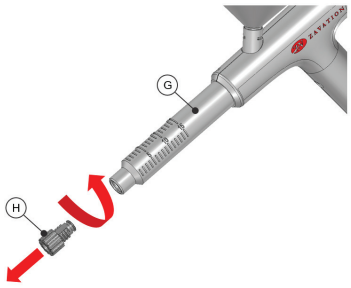
Note that the **FUNNEL (C)** may be removed from the **DELIVERY DEVICE (B)** for the remainder of the procedure.



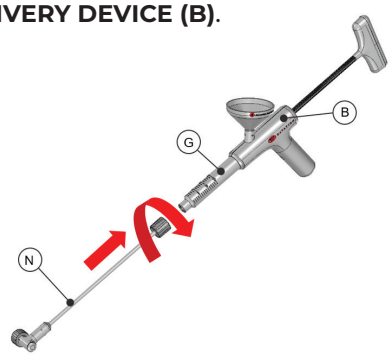
CAUTION

Only pull the Delivery Device by the handle. Do not grab the Delivery Device by the Funnel or the Control Knob while removing.

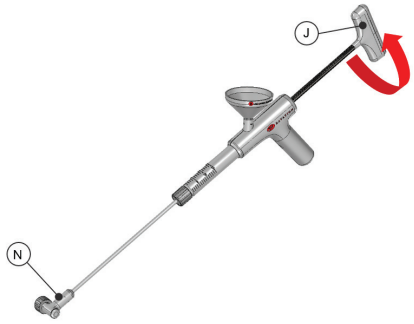
2. Twist the **BARREL CAP (H)** counter-clockwise to remove it from the **BARREL (G)**.



3. Attach the **DELIVERY TUBE (N)** to the **BARREL (G)** of the **DELIVERY DEVICE (B)**.



4. Manually prime the **DELIVERY TUBING (N)** by turning the **CONTROL KNOB (J)** clockwise until the bone cement can be seen exiting the distal end of the **DELIVERY TUBING (N)**.
5. Confirm that the viscosity of the bone cement is appropriate for the procedure to be performed.



CAUTION

The physician should, by specific training and experience, be thoroughly familiar with the properties, handling characteristics, application of bone cements, and amount of bone cement required per procedure. Because the handling and curing characteristics of this bone cement vary with temperature, humidity, and mixing technique, they are best determined by the physician's actual experience.

INDICATIONS FOR USE (Continued)

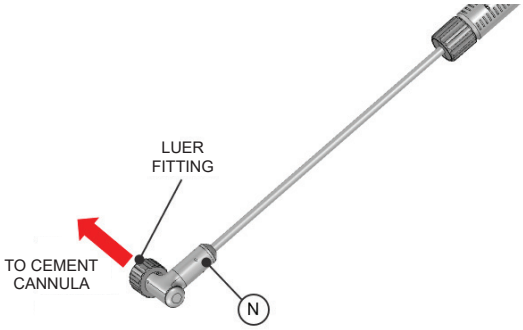
Deliver Bone Cement

CAUTION

Select the appropriate method to apply the bone cement to the bone. If applicable, follow the device manufacturer's instructions for application method.

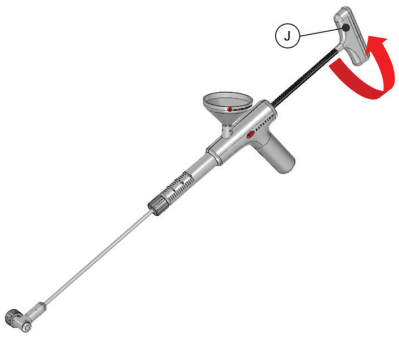
1. Attach the distal end of the **DELIVERY TUBING (N)** to the access cement cannula placed in patient.

The distal end of the **DELIVERY TUBING (N)** features a standard **LUER FITTING** that can be secured with a clockwise rotation.



2. Deliver the bone cement by turning the **Control Knob (J)** clockwise.

Note that 1 complete turn of the **Control Knob (J)** delivers 0.50 cc of bone cement.



CAUTION

Removal from the patient will depend on the application method used. If applicable, follow the device manufacturer's instructions for removal.

Disposal

Comply with local regulations relating to medical waste handling and disposal of the bone cement.

CAUTION

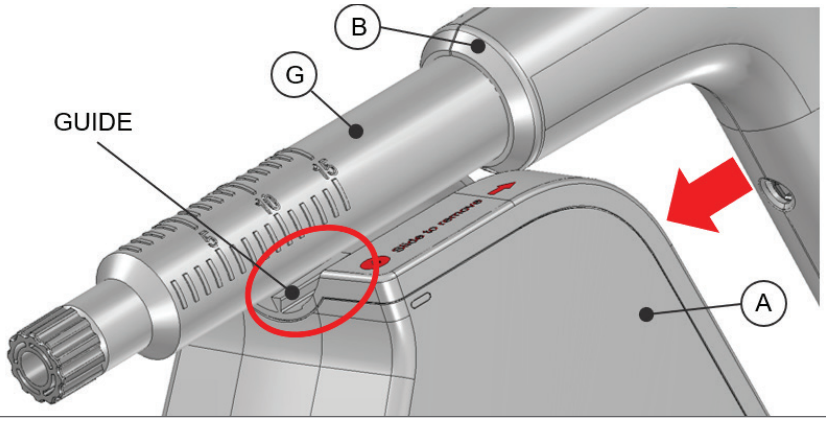
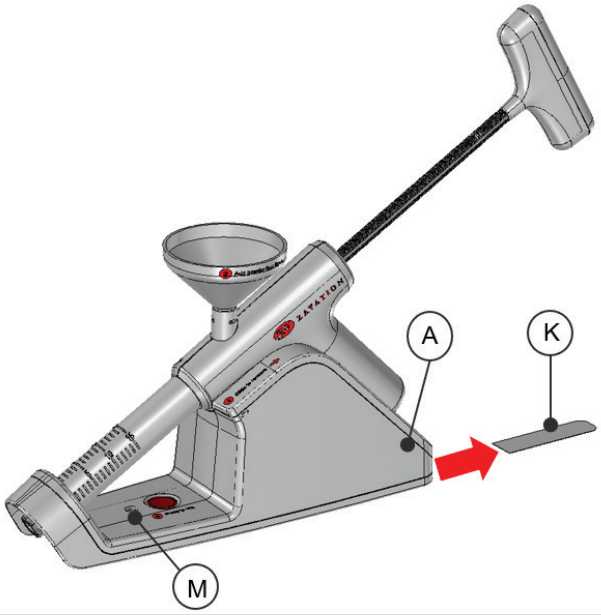
Dispose of the Delivery Device and Mixing Base according to conventional practices for your facility, to prevent contamination and environmental impact.

WARNING

This device is for single use only. Do not reuse, reprocess, or resterilize.

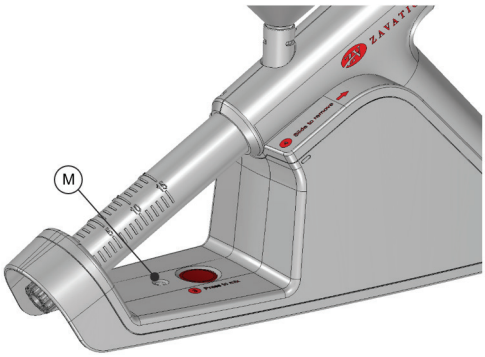
INDICATIONS FOR USE (Continued)

Troubleshooting

Problem	Potential Steps
DELIVERY DEVICE (B) came off the **MIXING BASE (A)** and does not fit.	Slide the **DELIVERY DEVICE (B)** into the **MIXING BASE (A)** at a downward angle. A **GUIDE** feature on the **MIXING BASE (A)** will mate with a slot on the bottom edge of the **DELIVERY DEVICE (B)** at the proximal end of the **BARREL (G)**. 
MIXING BASE (A) will not mix.	Ensure the **BATTERY PULL TAB (K)** has been removed from the **MIXING BASE (A)**. **NOTE:** The **MIXING BASE (A)** can only be used once, if the **STATUS INDICATOR (M)** is on, see the next entry. 

INDICATIONS FOR USE (Continued)

Troubleshooting

Problem	Potential Steps
STATUS INDICATOR (M) is on.	When the **STATUS INDICATOR (M)** lights **GREEN (●)**, the bone cement mixing is done and the **DELIVERY DEVICE (B)** is ready to use. If the **STATUS INDICATOR (M)** lights **RED (●)**, an error has occurred. Do not proceed. Start over with a new system. **Warning**: Do not proceed if the Status Indicator is red. A red indicator means the system encountered an error during mixing and the bone cement may not be mixed correctly. 
The **Control Knob (J)** no longer turns clockwise after removal from the **MIXING BASE (A).**	Check for kinks or clogs in the system. If there are none, the curing time of the bone cement may have been exceeded. Do not proceed. Follow the instructions to dispose the current system and open a new system if bone cement delivery is not complete. **Caution**: Because the handling and curing characteristics of this bone cement vary with temperature, humidity, and mixing technique, the curing time of the bone cement will vary and are best determined by the physician's actual experience.

Zavation Medical Products
3670 Flowood Drive
Flowood, MS 39232
USA

Explanation of Warning Symbols

Do not re-use.

Keep dry.

℞ Only — CAUTION: Federal law (US) restricts these to sale by or on the order of a physician.

STERILE EO — Sterilized using Ethylene Oxide.

Do not use if package is open or damaged.

INDICATIONS FOR USE (Continued)

Guidance and Manufacturer's Declaration – Emissions

The ZMI-90 is intended for use in the electromagnetic environment specified below. The customer or user of the ZMI-90 should ensure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF Emissions CISPR 11	Group 1	The ZMI-90 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class A	The ZMI-90 is suitable for use in all establishments other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Guidance and Manufacturer's Declaration – Immunity

The ZMI-90 is intended for use in the electromagnetic environment specified below. The customer or user of the ZMI-90 should ensure that it is used in such an environment.

Immunity Test	Compliance Level	Electromagnetic Environment - Guidance
ESD IEC 61000-4-2	+8kV Contact +15kV Air	Floors should be wood, concrete or ceramic tile. If floors are synthetic, the r/h should be at least 30%
Power Frequency 50/60Hz Magnetic Field IEC 61000-4-8	30 A/m	Power frequency magnetic fields should be that of a typical commercial or hospital environment.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz – 2.7 GHz 80% AM at 1kHz	PROFESSIONAL HEALTHCARE FACILITY ENVIRONMENT

Immunity Test	Test Frequency (MHz)	Band (MHz)	Maximum Power (W)	Distance (m)	Immunity Test Level (V/m)
Immunity to proximity fields from RF wireless communications equipment IEC 61000-4-3	385	380 – 390	1.8	0.3	27
	450	430 – 470	2	0.3	28
	710 745 780	704 – 787	0.2	0.3	9
	810 870 930	800 – 960	2	0.3	28
	1720 1845 1970	1700 – 1900	2	0.3	28
	2450	2400 – 2570	2	0.3	28
	5240 5500 5785	5100 – 5800	0.2	0.3	9