Vacuum Mixing of Bone Cement

Since the introduction of bone cement to orthopedics, many advancements have been made in terms of improving the quality of the cement mantle surrounding the implant.

Improved Cement Quality
Studies\textsuperscript{1,2,3} have shown that bone cement failure in a total joint replacement most often results from cracks propagating from pores in the cement mantle. Therefore, major efforts have been dedicated to the reduction of bone cement porosity.

Through their documented ability to reduce bone cement porosity, vacuum mixing systems are today recognized as a means to increase the longevity of the cement mantle.\textsuperscript{4,5}

Improved Working Environment
By eliminating the amount of methyl-methacrylate fumes that are released into the OR,\textsuperscript{5} the use of vacuum mixing systems provides a safer working environment for OR staff.

The Combination of Mixing and Delivery
While traditional vacuum mixing systems rely on the re-processing of metal cement guns, the MIXIGUN Bone Cement Mixing and Dispensing System introduces a unique two-in-one design. MIXIGUN Bone Cement Mixing and Dispensing System combines the clinical benefits of vacuum mixing with the convenience of one single use, fully disposable product.

This new mixing/injecting design concept helps reduce both time and cost. With MIXIGUN Bone Cement Mixing and Dispensing System, there is no time and cost associated with the handling, cleaning and sterile re-processing of a reusable metal cement gun after the procedure. Furthermore, the logistical organization prior to surgery to ensure the availability of the reusable gun as well as cement gun maintenance are eliminated.

The MIXIGUN Bone Cement Mixing and Dispensing System is designed to mix acrylic bone cements under vacuum. The vacuum hose is connected and vacuum pump activated prior to the insertion of the cement components into the system. The suction created draws the methyl-methacrylate fumes into the active carbon filter rather than released into the operating theatre.
Design Rationale
At a Glance

Vacuum Mixing System
• Suction applied prior to introduction of both bone cement components (powder and liquid)

Provides flexibility in choice of bone cement
• Mixes high, medium and low viscosity bone cement
• Up to 80g of bone cement

Ergonomic
• Lightweight design
• Metal mixing handle provides a high stability during mixing
• High cement injection pressure achieved with low effort

Fully Disposable
• Unique Mixing/Injection Design
• No logistical handling of separate metal gun
• No sterile processing required (reduced costs)
• Validated industrial sterilization

Adaptable to various application areas
• Available in 3 configurations
  Hip, Knee and Hybrid
• Separate nozzles available
  Short, Long and Slim

Limited environmental impact
• Made entirely of recyclable materials
• No detergents needed for cleaning of a metal reusable gun
Instructions for Use

Step 1: Start - Position:
Pull out the mixing rod 5cm-7cm. Set the mixing rod into the base and lock into position using the support. Unscrew the top plug and set aside for later use.
Caution: Make sure that the base rests on a flat and steady surface.

Step 2: Funnel - Vacuum Tubing:
Put the dual funnel into place. Connect the vacuum tube fitting to the top of the cylinder.
Caution: Use vacuum during filling monomer. This significantly reduces exposure to monomer fumes.

Step 3: Monomer - Filling:
Start the vacuum pump. Fill the monomer.
Caution: Ensure the plug is tight.

Step 4: Powder - Filling:
Detach the inner funnel. Fill the cylinder with bone cement powder.

Step 5: Powder - Filling:
Detach and dispose the funnel. Thread the plug into cylinder top until tight.
Caution: Ensure the plug is tight.

Step 6: Mixing - Start:
Detach MIXIGUN System from the base. Using the mixing handle, move the mixing rod back and forth with rotating action.

Step 7: Nozzle - Select:
Stop the vacuum pump and remove the vacuum tube fitting. Unscrew and dispose the plug.

Step 8: Nozzle - Select:
Select nozzle and screw firmly in place.

Step 9: Dispense Mode - Engage
Pull the mixing rod to its rearmost position. Remove and dispose piston release pin.

Step 10: Dispense Mode - Engage
While holding the Mixigun, rotate the cylinder (either direction) to a full stop.

Step 11: Dispensing - Ready
Remove and dispose the locking pin.
Caution: Make sure that the mixing rod is parked at its rearmost position before removing the locking pin.

Step 12: Dispensing - Ready
The gun is now ready for dispensing.
Caution: The bone cement must be extruded well within the working phase period. Injection of bone cement at or near set time may cause cartridge to fracture.
Product Family
Mixigun Sets

Hip

Contents
- 2 mixing/dispensing systems
- 2 dual funnels
- 1 short nozzle
- 1 long nozzle
- 1 femoral pressurizer
- 1 obturator
- 1 base
- 1 vacuum tubing set with charcoal filter

Knee

Contents
- 1 mixing/dispensing system
- 1 dual funnel
- 1 short nozzle
- 1 obturator
- 1 base
- 1 vacuum tubing set with charcoal filter

Hybrid

Contents
- 1 mixing/dispensing system
- 1 dual funnel
- 1 long nozzle
- 1 femoral pressurizer
- 1 obturator
- 1 base
- 1 vacuum tubing set with charcoal filter

Separate Nozzles

MIXIGUN Nozzles are packaged sterile individually and sold in boxes of 5 nozzles. Available in Short, Long, Slim

Short
Length: 80 mm
D: 11.9 mm

Long
Length: 210 mm
D: 12 mm

Slim
Length: 130 mm
D: 8.5 mm

Vacuum Pumps

MIXIGUN Bone Cement Mixing and Dispensing System is designed to be used with the Promixa Vacuum Foot Pump.
### Ordering Information

#### MIXIGUN® Sets

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<tr>
<th>REF. NO</th>
<th>Description</th>
<th>Unit of Quantity</th>
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<td>50350</td>
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<td>MIXIGUN® System Knee</td>
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<td>MIXIGUN® System Hybrid</td>
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#### MIXIGUN® Nozzles

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<td>MIXIGUN® Nozzle - Short</td>
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<td>MIXIGUN® Nozzle - Slim</td>
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#### MIXIGUN® Vaccum Pumps

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<td>Promixa Pump with Schrader wall coupling</td>
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### References


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Please refer to the package inserts for important product information, including, but not limited to, contraindications, warnings, precautions, and adverse effects.

Contact or Visit us at [www.promixa.eu](http://www.promixa.eu)