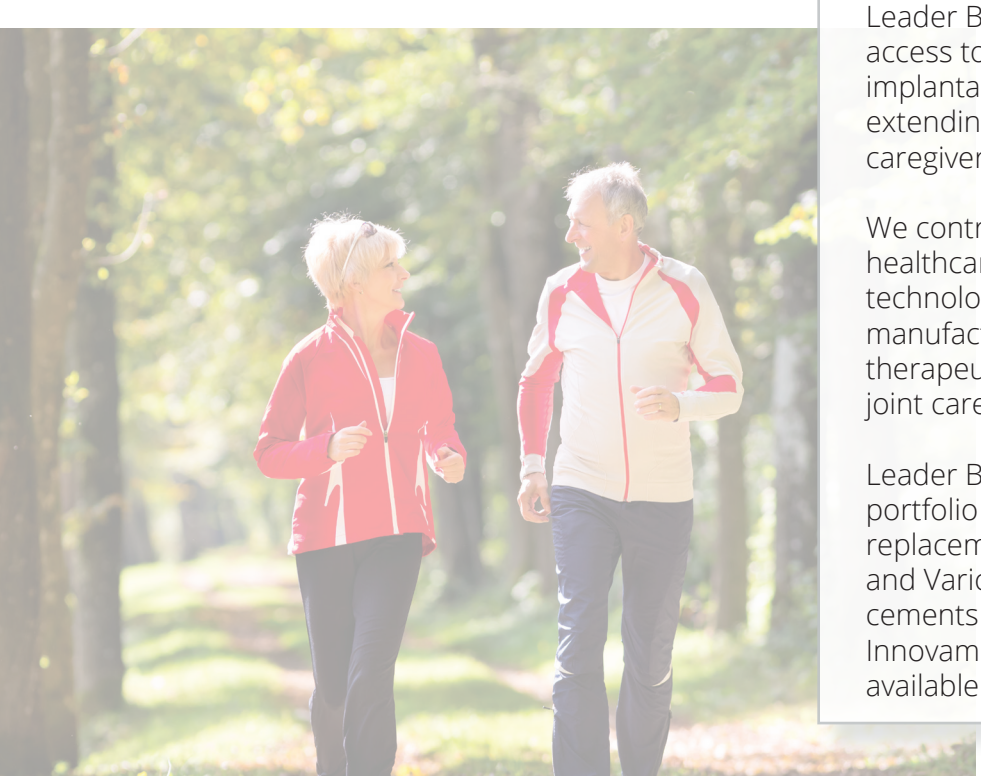
LEADER® BIOMEDICAL

> EXTENDING YOUR REACH >

Innovamix®

Bone cement mixing and dispensing system

Joint replacement
Joint revision



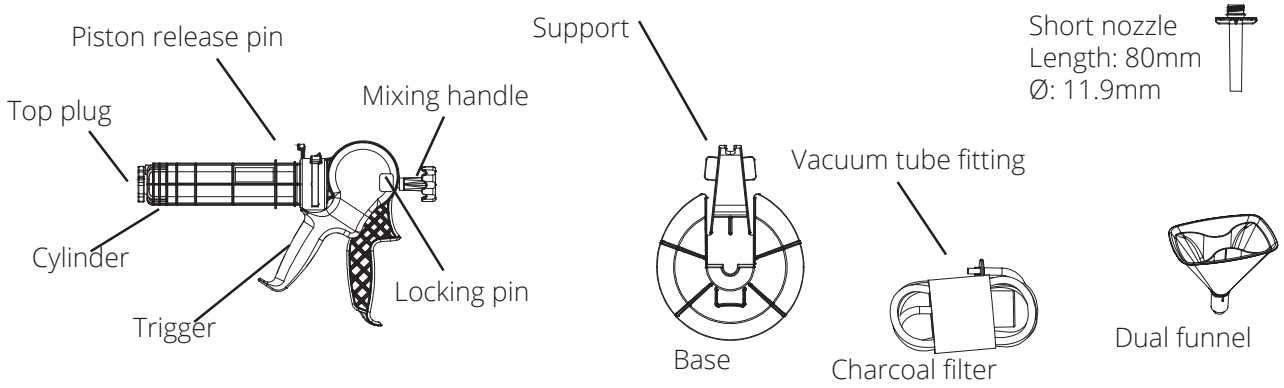
Leader Biomedical is committed to improving access to innovative biomaterials and implantable medical devices, thereby extending the reach of patients and caregivers worldwide.

We contribute to the betterment of the healthcare sector by developing new technologies, delivering world-class contract manufacturing, and providing targeted therapeutic solutions for dental, spine, joint care, and sports medicine indications.

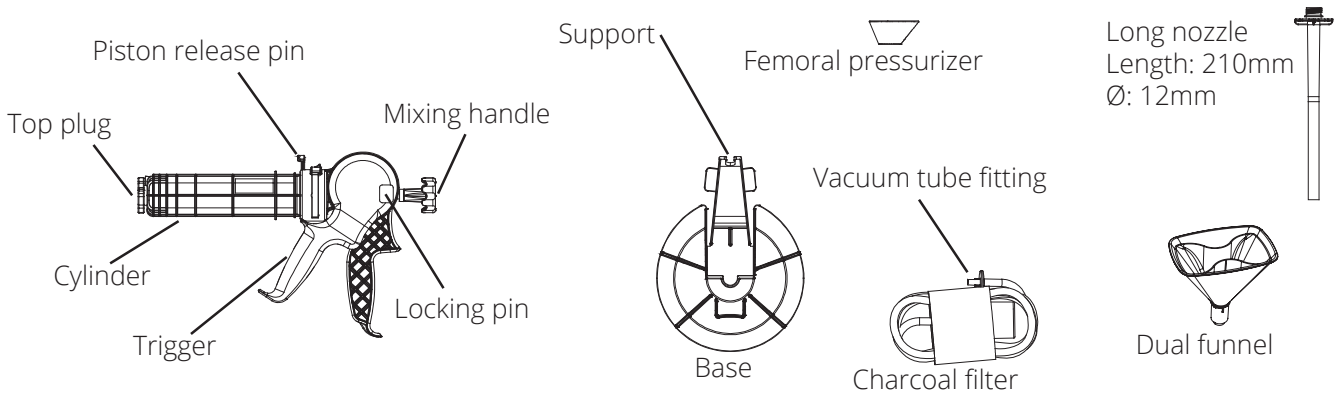
Leader Biomedical's Joint Care Reconstruction portfolio offers targeted solutions for replacement and revision with VarioNXT® and VarioClassic™ hip systems, PMMA bone cements with cement restrictor and also Innovamix™ Mixing and Dispensing System, available in two complete configurations.

Innovamix™ | Configurations

Innovamix™ V |System with short nozzle



Innovamix™ U | System with long nozzle and pressurizer



Innovamix™ Mixing and Dispensing System

Innovamix™ is a single use mixing and delivery system for use with both low and high viscosity cements. Combining mixing and delivery system in one device and under vacuum provides a few crucial advantages in the operating theatre, in terms of bone cement quality, safety and ease of use.

Quality of bone cement

Ever since the first implantation of a total hip replacement using a PMMA cement in the 1950's, using bone cement is considered a golden standard in joint arthroplasty. The mechanical properties of bone cement are essential as they influence the connection between the bone and bone cement, and bone cement has an important task of uniformly distributing the impacting forces as evenly as possible. This transfer of forces ensures long-term stability of the implanted cement and any prostheses.

Bone cement failure in a total joint replacement is most often the result of air bubbles and bone cement porosity following incorrect mixing of the bone cement and much research has been done into how mixing impacts the quality of bone cement. Vacuum mixing systems have been proven and recorded as highly effective systems to reduce bone cement porosity, improve stability of cement and prostheses, as well as increase the longevity of the cemented implant.

Safety for OR staff and patient

Vacuum mixing systems effectively eliminate the amount of methyl-methacrylate fumes released into the OR, providing a safer working environment for both OR staff and the patient undergoing surgery.

Innovamix™ mixes acrylic bone cements under vacuum. A 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.

Innovamix™ offers a two-in-one design, and combines the clinical benefits of vacuum mixing with the convenience of one single use, fully disposable product. Innovamix™ eliminates the time, cost, and risks associated with the handling, cleaning and sterilising process of reusable metal cement guns after each procedure.

Advantages of Innovamix™

Ease of use

- Mixing and delivering in one device
- Suitable for all cemented orthopaedic procedures
- Vacuum system and carbon filter reduce monomer fumes

Single use

- No risk of cross-contamination
- No re-sterilisation required
- No need to replace or repair

Fully disposable

- InnovamixTM bone cement mixing and delivering system is composed of injection moulded plastic components and single metal components.
- Plastic components are PP, PA, PE, POM and EPDM. These are easily destroyed via combustion by customary means.
- Metal components can return to new processes after combustion.

Innovamix™ System

single use mixing and delivery system

Innovamix™ | Design Rationale

Ease of use

- Mixing and dispensing in one unit
- Suction can be applied prior to introduction of both bone cement components (powder and liquid)

Dual funnel

- Eliminates loss of product
- Mitigates any glass residue from the ampoule to be transmitted into cement
- Inner funnel to pour liquid
- Outer funnel to add powder

Flexible

- Suitable for high, medium and low viscosity bone cement
- Cylinder holds 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

Adaptable

- Available in 2 configurations for hip and knee fractures
- Separate nozzles available in short, long and slim

Low environmental impact

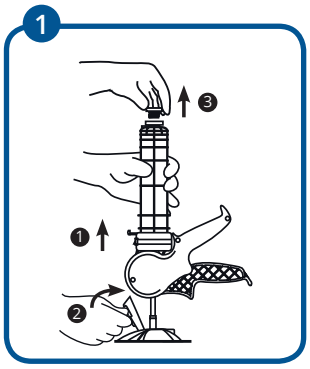
- Made of recyclable materials

Fully disposable

- No need for expensive, time-consuming logistical handling between surgeries
- No (heavy) chemicals required for sterilisation of unit between surgeries

Innovamix™ | Handling

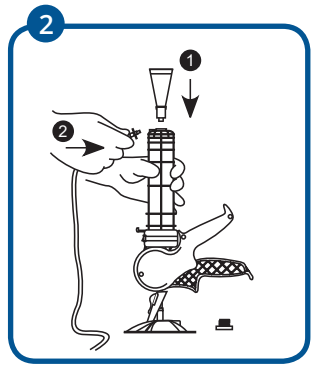
1



START POSITION
Pull out mixing rod 5–7cm.
Set mixing rod into base.
Lock into position.
Unscrew top plug and set aside for later use.

! Make sure base rests on flat and steady surface.

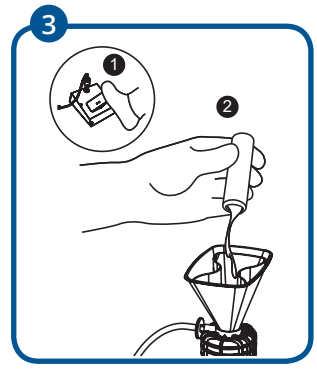
2



FUNNEL - VACUUM TUBE
Connect the vacuum tube fitting to the top of the cylinder.

! Ensure funnel is securely seated into cylinder top.

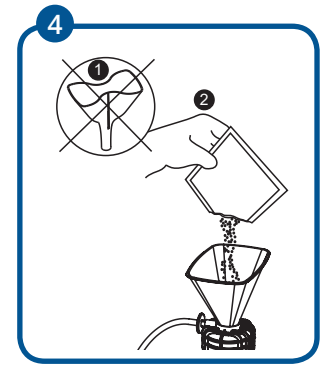
3



MONOMER FILLING
Start the vacuum pump.
Fill the monomer.

! Use vacuum during monomer filling to reduce exposure to monomer fumes.

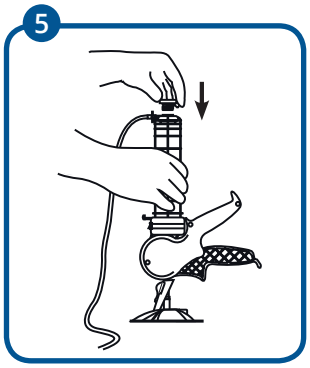
4



POWDER FILLING
Take out inner funnel.
Add bone cement powder.

! Remove inner funnel after monomer filling and before powder filling to prevent sticking.

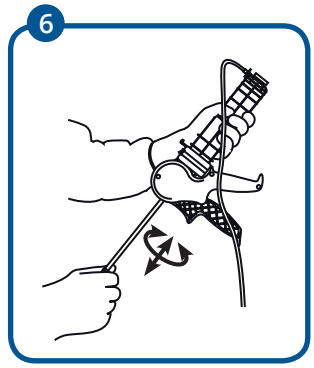
5



POWDER – FILLING
Detach and dispose funnel. Thread the plug into cylinder top until tight.

! Ensure the plug is tight.

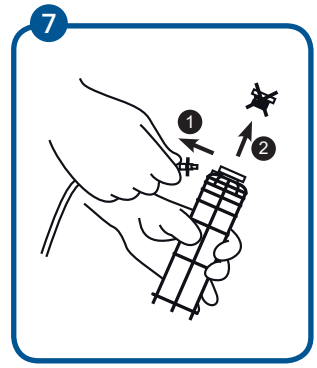
6



MIXING – START
Detach unit from the base.
Using mixing handle to move mixing rod back and forth with rotating action.

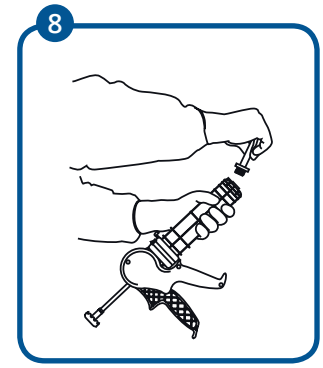
! Recommended mixing duration: 30–40 sec.

7



NOZZLE – SELECT
Turn off vacuum pump.
Remove vacuum tube.
Unscrew and dispose plug.

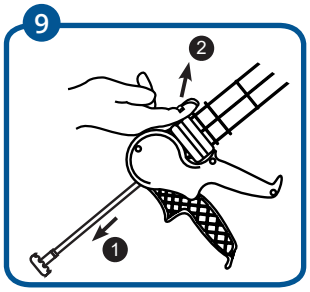
8



NOZZLE – SELECT
Select nozzle and screw firmly in place.

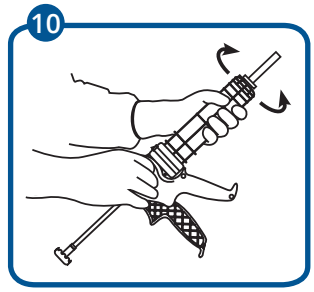
! Ensure pressurizer is secured in place on femoral canal before attaching long nozzle.

9



DISPENSING – ENGAGE
Pull mixing rod to its rearmost position.
Remove and dispose piston release pin.

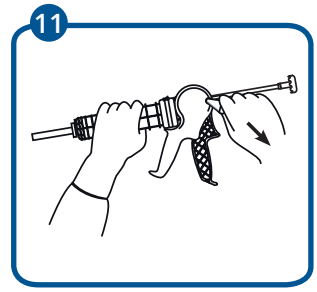
10



DISPENSING – ENGAGE
While holding the unit, rotate cylinder to a full stop.

! Turn cylinder (either left or right) to a full stop.

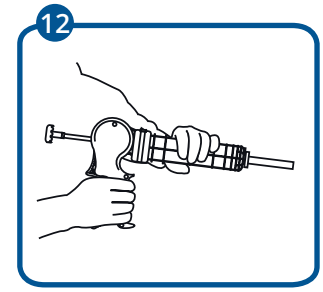
11



DISPENSING – READY
Remove and dispose the locking pin.

! Ensure mixing rod is parked at rearmost position before removing locking pin.

12



DISPENSING – READY
The gun is now ready for dispensing.

! Extrude bone cement within handling phase period to avoid cylinder to fracture.

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Innovamix®
bone cement mixing and dispensing system

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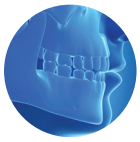
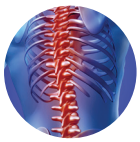
info@leaderbiomedical.com
www.leaderbiomedical.com

Targeted therapeutic solutions



Dental
Reconstruction
- Guided bone and tissue regeneration



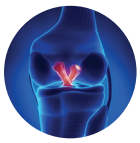
Spine
Intervention
- Spinal fusion
- Adhesion control and prevention
- Treating osteoarthritis

Stabilisation
- Vertebroplasty

Joint Care
Intervention
- Treating osteoarthritis
- Osteotomy

Reconstruction
- Replacement
- Revision

Stabilisation
- Replacement
- Guided bone regeneration



Sports Medicine
Intervention
- Treating osteoarthritis

Reconstruction
- ACL reconstruction

Product Configurations

Innovamix™ bone cement mixing and delivering system is available in 2 configurations:

Innovamix™ V	System with short nozzle	Product Code: LB-JV039	GTIN: 8719327432709
Innovamix™ U	System with long nozzle and pressurizer	Product Code: LB-JU039	GTIN: 8719327432716

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Disposal

Innovamix™ bone cement mixing and delivering system is composed of injection moulded plastic components and single metal components.
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Metal components can return to new processes after combustion.