

Introducing the Surgical Technique

MASTERING
Vertebral
Augmentation
Excellence

Masterflow™

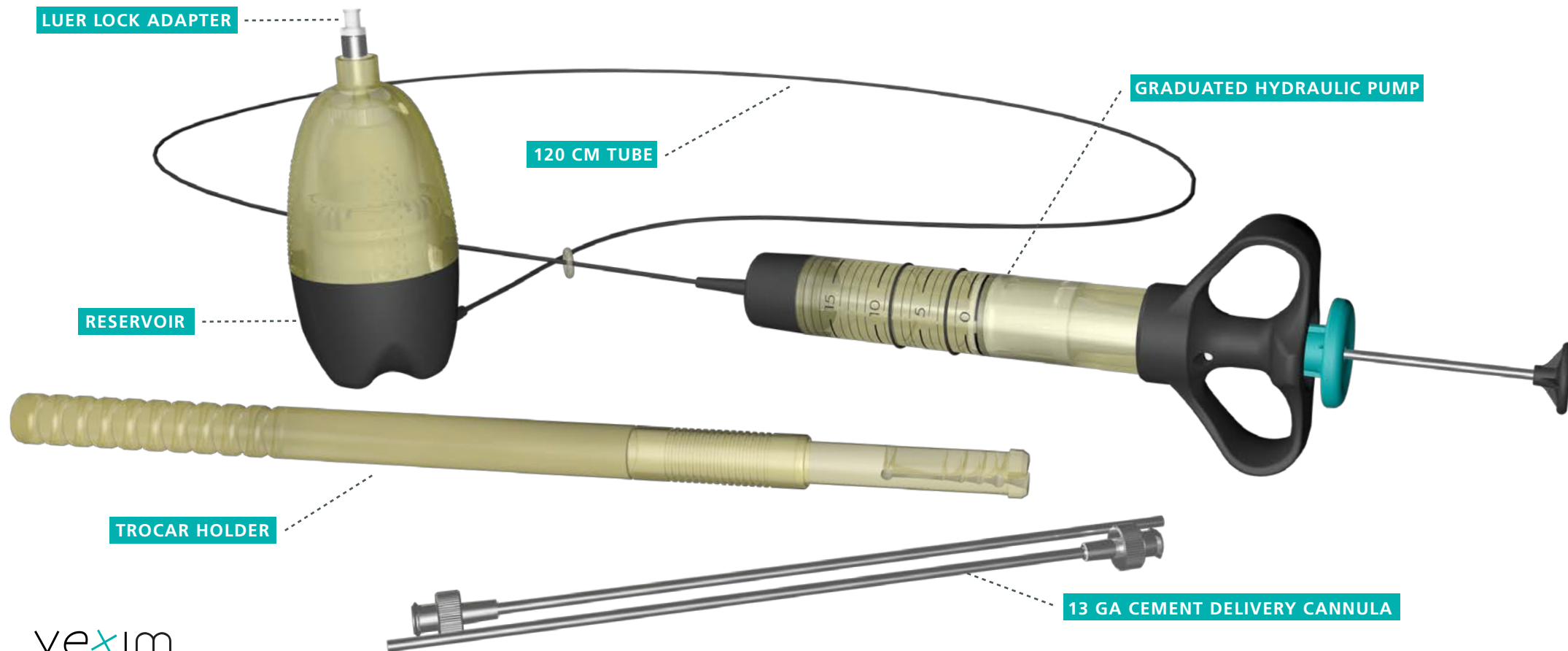
Controlled Injection System



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Controlled Injection System



Vexim's solutions master the vertebral augmentation experience.

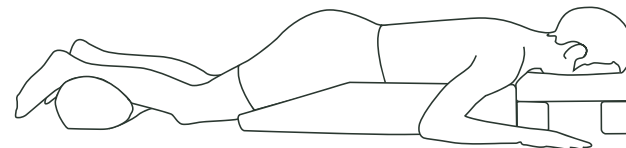
The **Masterflow™** is a cutting edge device designed for precise control of high viscosity biomaterial delivery. Please refer to the Instructions For Use for the indications.

The **Masterflow™** is composed of a hydraulic pump and a 18 cc reservoir connected to 120 cm flexible tube.

The **Masterflow™** is equipped with a Quick-Stop Button which immediately stops the biomaterial flow without any inertia, providing the user full control of the delivery.

The **Masterflow™** kit contains two 13 GA Cement Delivery Cannulas and a Trocar Holder.

This delivery system allows the operator to treat multiple vertebrae during a single procedure. Additionally, it provides the operator full control of the injection, thus minimizing the risk of cement leakage. Finally, it provides the operator maximum protection against radiation exposure due to the distance allowed between the operator and the patient during the injection phase.



Patient Positioning

The patient must be placed in prone position to minimise pressure on the fractured vertebra.

A hyper-lordotic position is recommended for lumbar fractures.

Anesthesia

General, local or regional anesthesia can be used depending on clinician preference and the patient's condition.

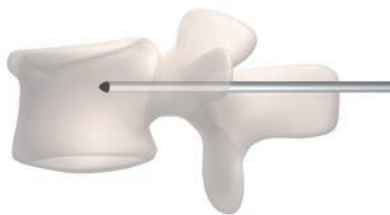
+According to clinician preference, a bipedicular or unipedicular trajectory could be performed through a transpedicular or extrapedicular approach.

+Fluoroscopic imaging is critical for both guiding the access trocar through the pedicle into the center of the vertebral body and during the cement delivery process.

+The pedicle access procedure requires accurate imaging of the two pedicles, especially the medial border which must be clearly visualized since its violation can result in neural injury.

+On AP view, the access trocar is carefully advanced through the pedicle towards its medial border and should never cross it until a lateral view can confirm the junction between

the base of the pedicle and the vertebral body has also been reached with the appropriately convergent trajectory.



Note: To decrease radiation exposure, a Trocar Holder is provided inside the **Masterflow™** packaging. The Trocar Holder is compatible with 13, 11, 10 and 8 GA trocars.

TIPS

If a unipedicular trajectory is chosen, we recommend a more medial approach into the vertebral body in order to have the appropriate positioning and distribution of the biomaterial.



If a biopsy is required, use the Vexim Bone Biopsy Needle.

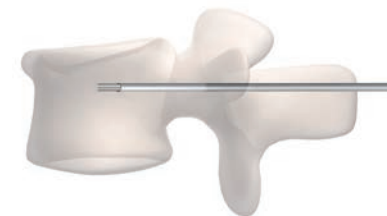
1. Position the trocar in accordance with the procedure.

2. Insert the biopsy needle through the trocar to sample the tissue.

3. Optionally, a syringe can be used to assist with collecting the specimen.

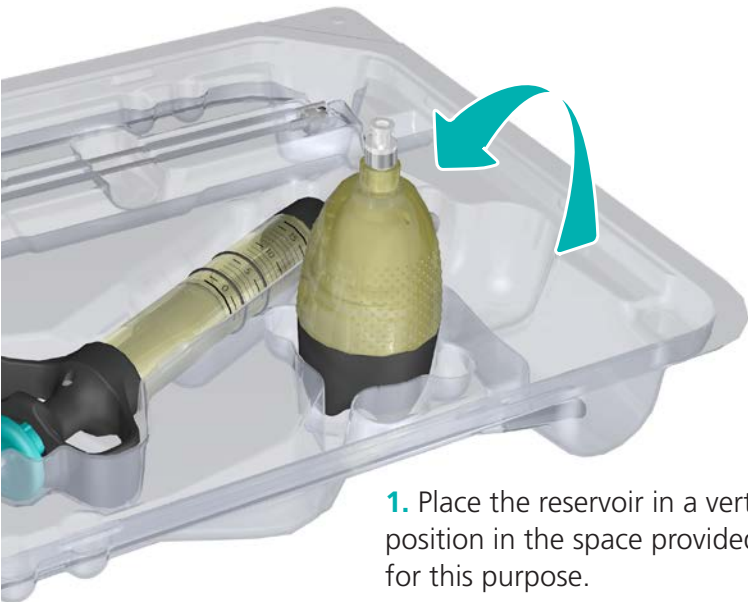
4. Withdraw the biopsy needle.

5. Insert the stylet provided into the biopsy needle to eject the specimen.

**TIPS**

If a multi-level procedure is being performed, insert all trocars before starting the cement delivery.

While following the sterility instructions, place the sterile inner blister pack on the work table to begin the preparation of the Masterflow™ system.



1. Place the reservoir in a vertical position in the space provided for this purpose.

Remove the elements of the Vexim Cement Mixing System and position them on the work table while following sterility instructions.

2. Mix the Vexim Biomaterials with the mixer.



2.1 Screw the reservoir onto its support base.

2.2 Place the reservoir and its holder upright then set up the funnel.

2.3 Pour the powder and the liquid into the reservoir and remove the funnel.

2.4 Screw the cover onto the reservoir.

2.5 Hold the upper handle and move up and down and rotate for at least 30 seconds in order to mix the Vexim Biomaterials homogeneously.

2.6 Remove the upper handle by bending until it breaks off and discard.

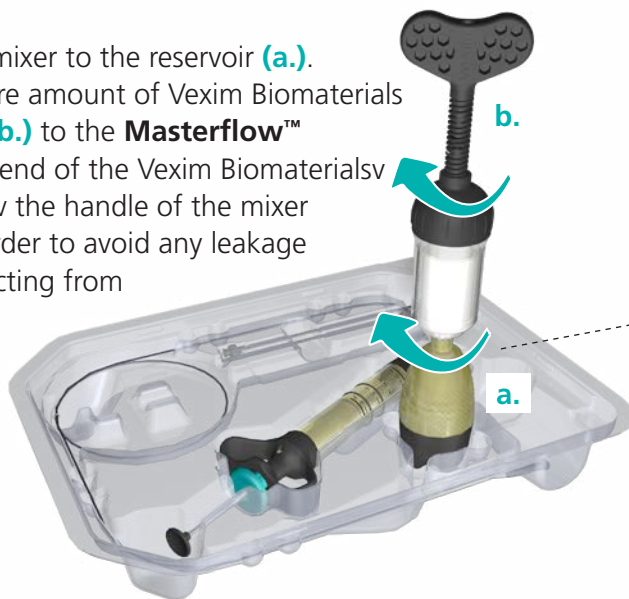


2.7 Turn the reservoir 180°, remove the support base and screw the wing grip until all the air contained in the reservoir is evacuated.

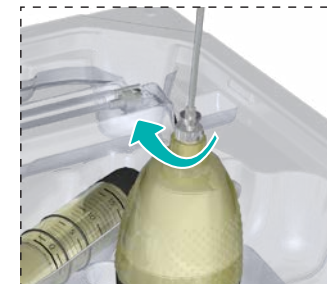


3. Connect the mixer to the reservoir (a.).

Transfer the entire amount of Vexim Biomaterials from the mixer (b.) to the **Masterflow™** reservoir. At the end of the Vexim Biomaterials transfer, unscrew the handle of the mixer a few turns in order to avoid any leakage before disconnecting from the reservoir.

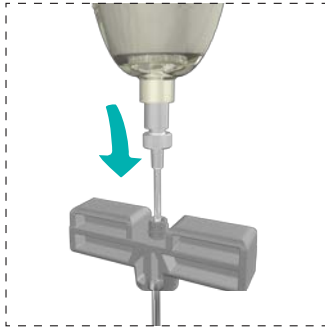
**4. Disconnect the mixer from the reservoir.**

5. If the white luer lock adapter is still on the reservoir, remove it manually.

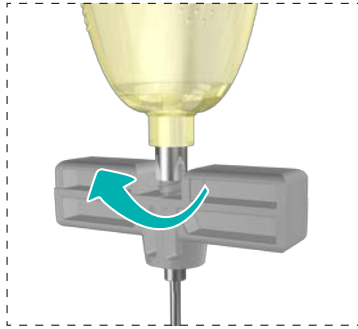
6. Connect the 13 GA Cement Delivery Cannula onto the reservoir.**7. Remove all items from the plastic tray.****ADVICE**

We recommend using the 13 GA Cement Delivery Cannula with 11GA trocar. The Cement Delivery Cannula allows you to perform multi-level biomaterial delivery in a controlled manner through an 11 GA trocar. If desired, direct connection of the reservoir to any trocar having a standard female luer lock connector is possible.

8. Insert the Cement Delivery Cannula through an 11GA trocar.

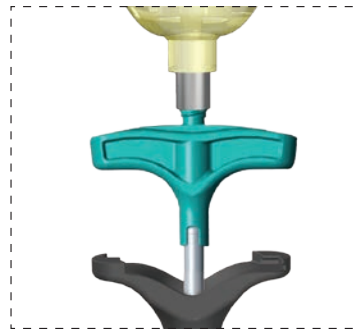


Alternative step : Connect the reservoir directly to the trocar.



Compatibility with SpineJack®

Connect the reservoir to the Injector Transfer Tube (TC05004/TC04004).

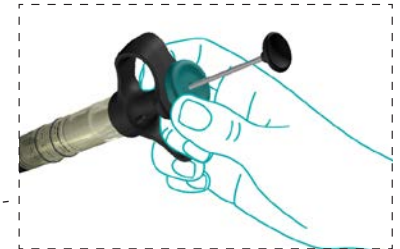


9. Priming

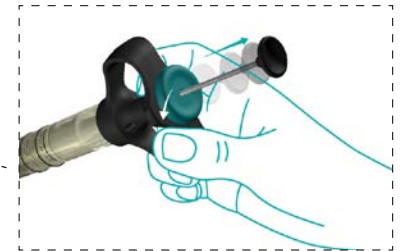


It is mandatory to prime the Masterflow™ by following these two steps :

9.1 Push the Quick-Stop Button.



9.2 Press down the Injection-Control Plunger. Immediately upon completely compressing the plunger, promptly release by shifting your thumb to one side allowing the plunger to quickly return to its original position.



9.3 At this point, the system is primed and ready for use.

10. Press the Injection-Control Plunger to start injection.

(one push = approx. 0.5 cc)



ADVICE

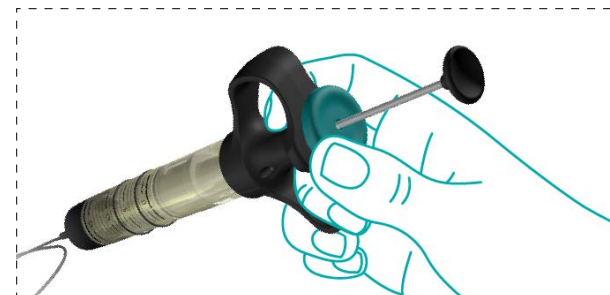
At this step, you will have 90 cm of flexible tube. If more distance from the radiation is needed, you may disconnect the gold clip on the flexible tube to reach 120 cm. If the tube is disconnected, we recommend holding the gold clip, to adjust the flexible tube, to prevent any sterility issue.



ADVICE

IMPORTANT: Should the system fail to advance cement after multiple presses of the Injection-Control Plunger, press the Quick-Stop Button and repeat the priming process as outlined in Step 9.

11. To immediately stop the flow of Vexim Biomaterials without any inertia, press the Quick-Stop Button. We recommend using the Quick-Stop Button at each step to control the injection of the Vexim Biomaterials.



TIPS

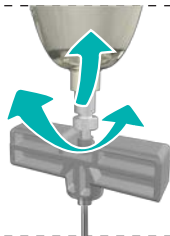
The estimated volume of cement injected is indicated by the graduated hydraulic pump. Two markers can be used to monitor multi-level cement injection.



12. When the appropriate amount of Vexim Biomaterials has been injected into the vertebral body, press the Quick-Stop Button and withdraw the Cement Delivery Cannula from the trocar. If multi-levels are performed, insert the Cement Delivery Cannula into another trocar.

If the reservoir is directly connected to the trocar, remove the reservoir and re-insert the stylet prior to removing the trocar. Caution should be used when removing the trocar from the patient to ensure the cement does not follow the trocar and exit the vertebral body.

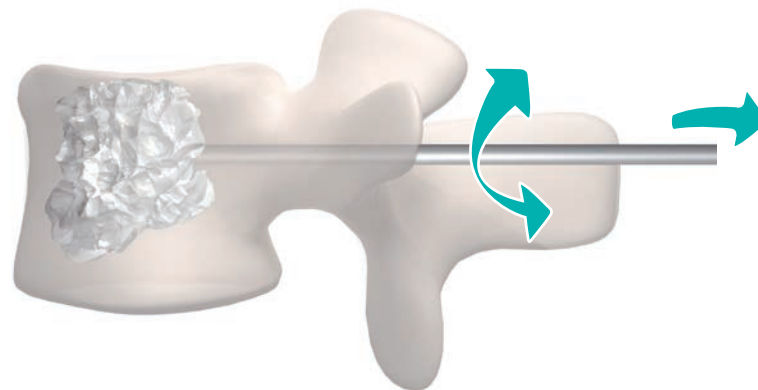
If the **Masterflow™** is used with SpineJack®, disconnect the reservoir from Injector Transfer Tube.

TIPS AND TRICKS

The 13 GA Cement Delivery Cannula should be rotated a few times before removal from the 11GA trocar in order to prevent the presence of cement inside the trocar.

13. In order to prevent presence of cement in the pedicle, simultaneously rotate and remove the trocar.

Then close the surgical access to end the surgery.



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