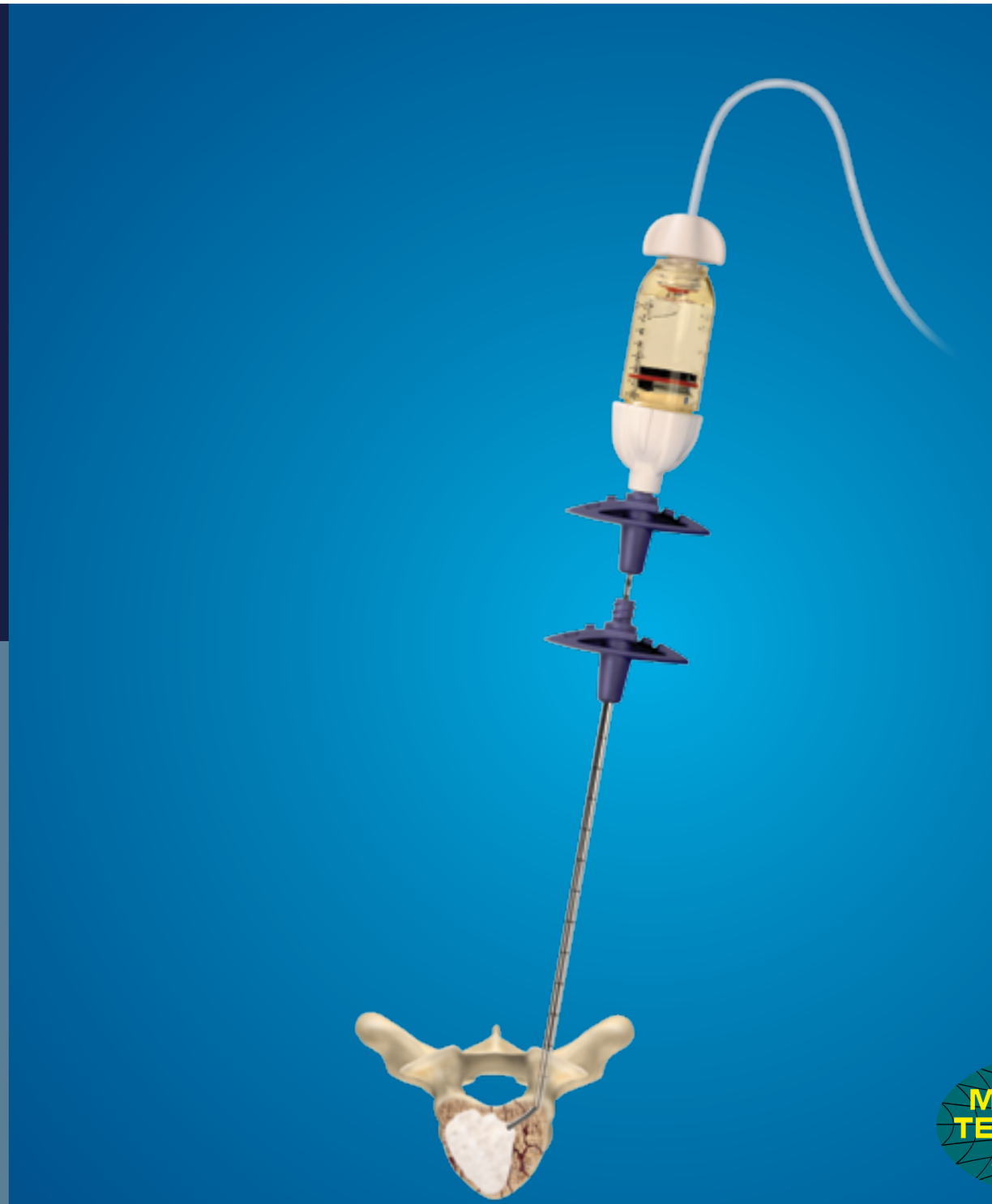
Medtronic

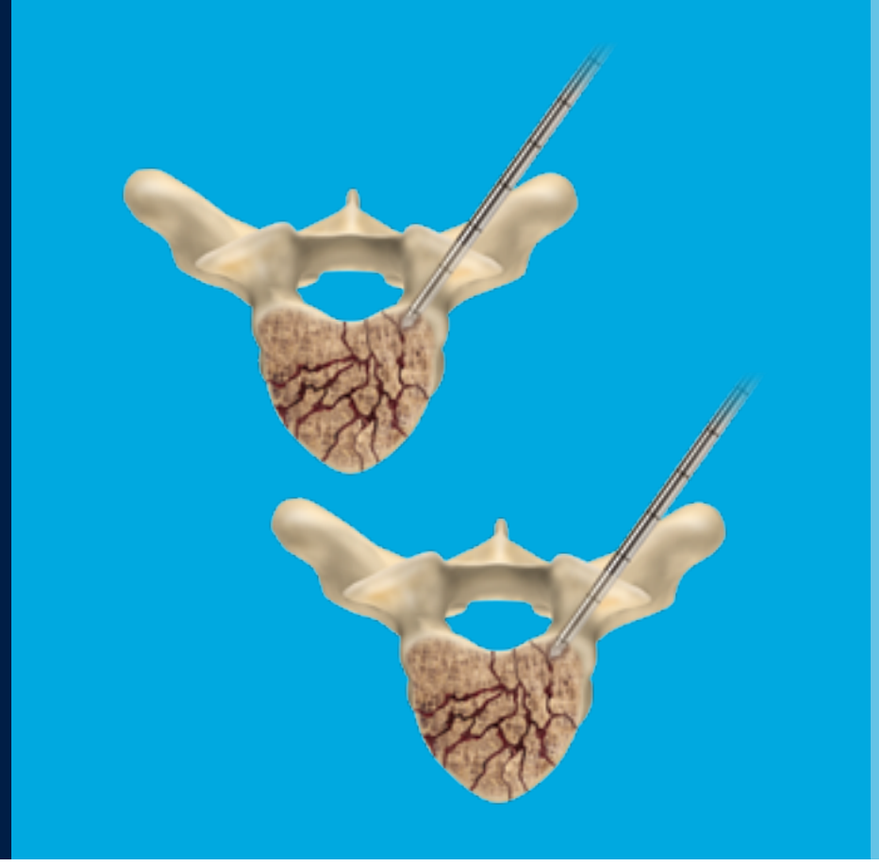
Kyphon Kurve™

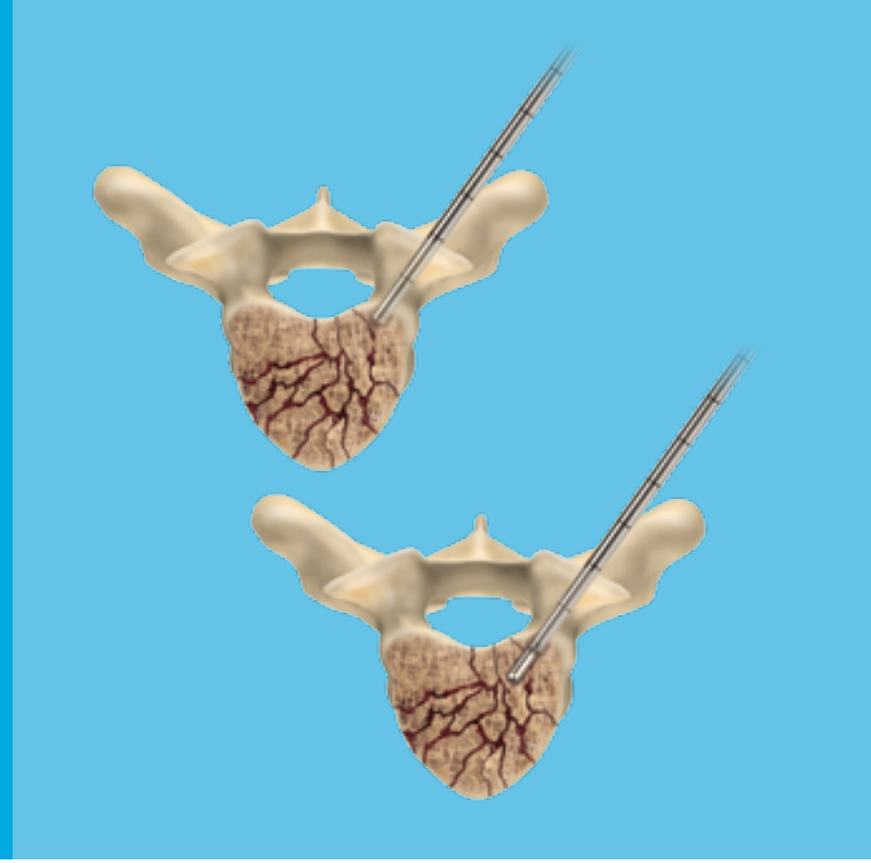
TECHNIQUE GUIDE



MICHELSON TECHNOLOGY AT WORK

STEP 1:
VERTEBRAL BODY ACCESS





Using manual control and image guidance, insert the 10ga Kyphon V™ Osteo Introducer® System (OIS) into bone to the desired depth.

While holding the Cannula, rotate the Stylet handle counter-clockwise to remove the Stylet. Pull the Stylet straight out from the Cannula. The Cannula is now in place and ready to accept other devices. Wait to remove the Stylet until ready to insert the next device.

BIOPSY

If a biopsy is desired, follow instructions for using Kyphon V Bone Biopsy Device (BBD). Remove the Plunger from the Nozzle of the Kyphon V BBD.

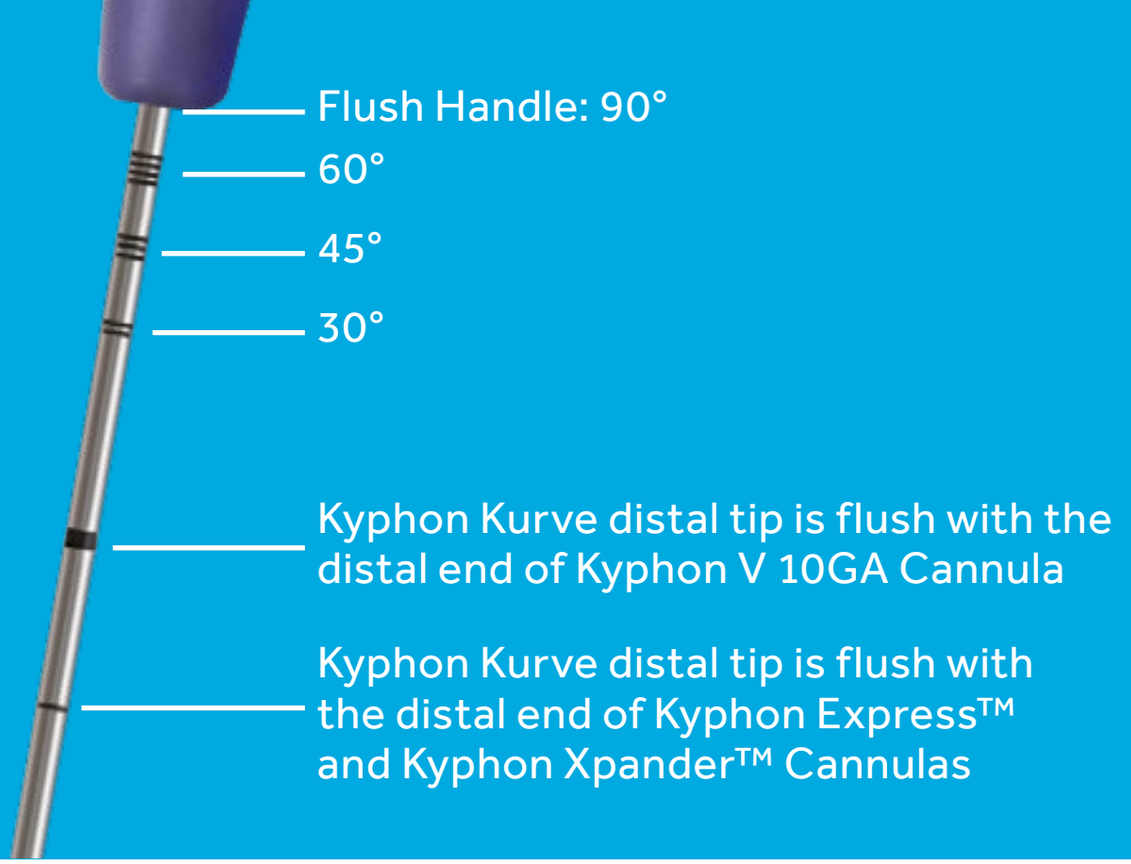
Using direct visualization or fluroscopic guidance:

- Advance the BBD Nozzle through the OIS Cannula and bring it into contact with the bone.
- Verify placement of the Nozzle tip at the intended location

Rotate the Nozzle handle 90° to 180° to free the core specimen from the surrounding tissue. Pull the Nozzle straight out of the Cannula.

Remove the specimen from the Nozzle by advancing the Plunger within the Nozzle.

KYPHON KURVE
NEEDLE MARKINGS

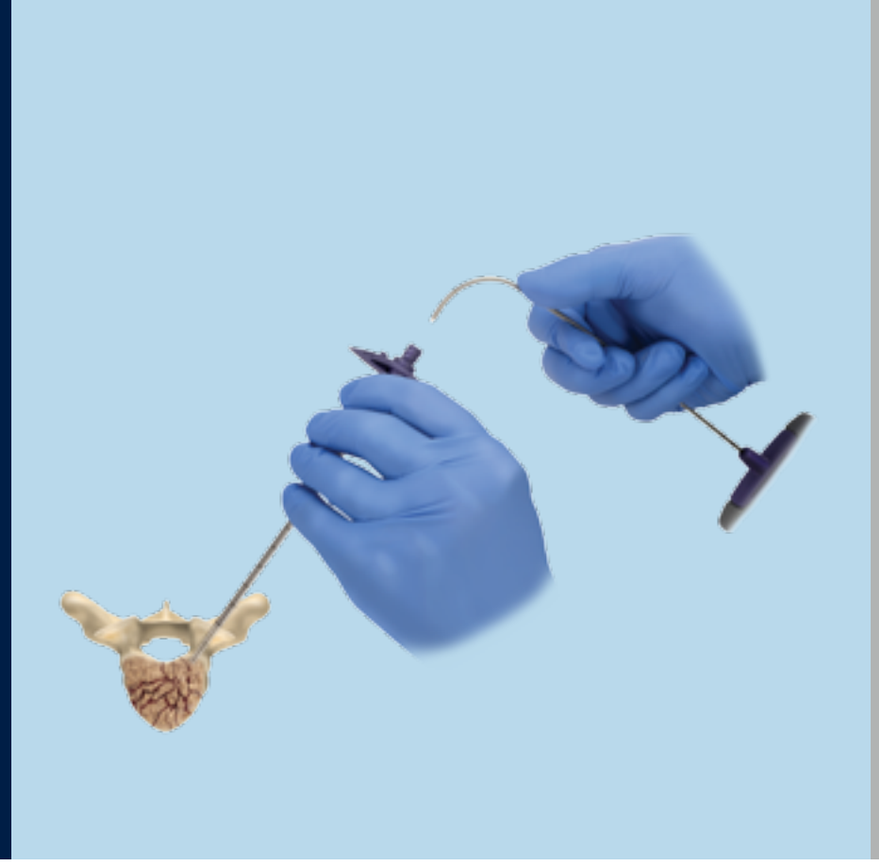


The position markers on the Kyphon Kurve Bone Filler Device (BFD) Nozzle are used during advancement within the Kyphon V Osteo Introducer Cannula to indicate the position of the distal tip of the Kyphon Kurve BFD with respect to the Kyphon V Osteo Introducer Cannula.

- The Exit Marker indicates when the Nozzle is resting against the end of the Cannula.
- The 1st Nozzle Position Marker indicates when the Nozzle is angled at approximately 30° beyond the end of the Cannula.
- The 2nd Nozzle Position Marker indicates when the Nozzle is angled at approximately 45° beyond the end of the Cannula.
- The 3rd Nozzle Position Marker indicates when the Nozzle is angled at approximately 60° beyond the end of the Cannula.
- When the Nozzle handle and the Cannula handle are resting against one another, the Nozzle is angled at approximately 90°.

The position marker on the BFD Plunger is used during cement delivery to indicate when the distal tip of the Kyphon Kurve BFD Plunger is at the beginning of the curve in the Kyphon Kurve Bone Filler Device.

STEP 2: OPTION 1
USE OF KYPHON KURVE BONE FILLER DEVICE (BFD)



Place the Kyphon Kurve BFD with stylet into the 10ga Kyphon V OIS Cannula while holding the Cannula to prevent movement within the vertebral body.

Note

Securely grasp the OIS Cannula while resting your hand on the patient. Advance the BFD gradually with several short incremental advancing movements as the curved needle straightens into the OIS Cannula.

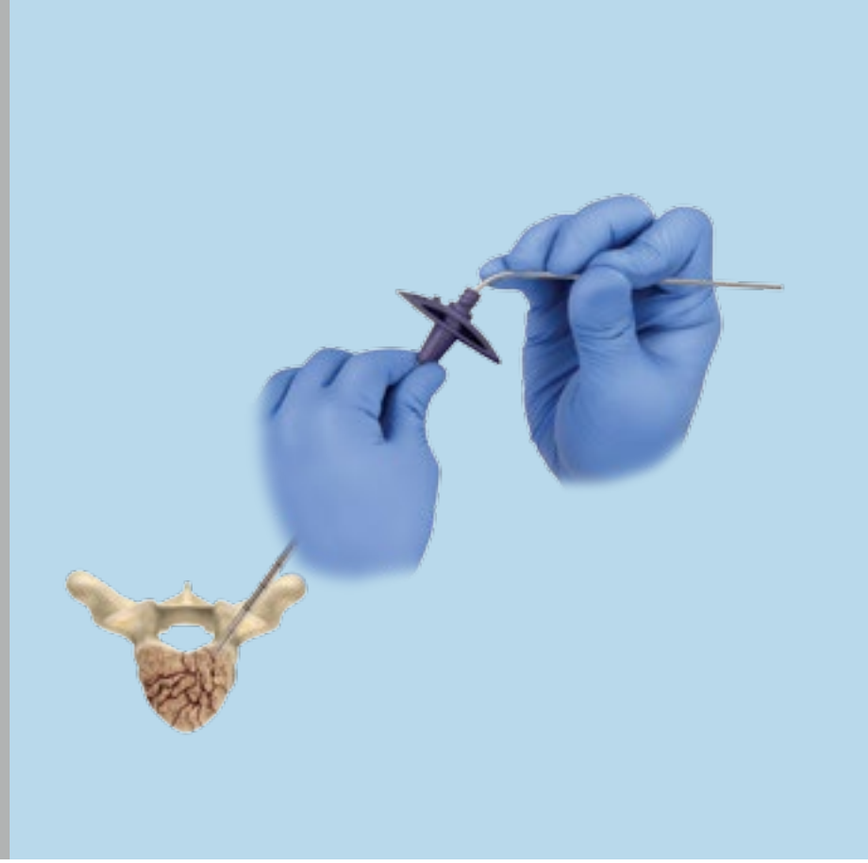
The distal tip of the Kyphon Kurve BFD has reached the distal end of the Cannula when the distal edge of the Exit Marker is at the top of the Cannula luer hub.

Note

Markings on the Nozzle may be used as reference marks only. They are not intended to replace the use of fluoroscopic observation.

Before advancing the BFD tip beyond the OIS Cannula tip, verify that the arrow is pointing to the desired target location. Advance the BFD tip to the target location using fluoroscopic image guidance. Verify the correct trajectory on images in both AP and lateral planes. Verify the tip has been placed at the intended location prior to delivering bone cement.

STEP 2: OPTION 2



This demonstrates a slightly different method for advancing the BFD into the OIS.

Note

Securely grasp the OIS Cannula while resting your hand on the patient. Advance the BFD gradually with several short incremental advancing movements as the curved needle straightens into the OIS Cannula.

The distal tip of the Kyphon Kurve BFD has reached the distal end of the Cannula when the distal edge of the Exit Marker is at the top of the Cannula luer hub.

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STEP 3

Remove the Stylet from the Nozzle when the BFD is at the intended position.

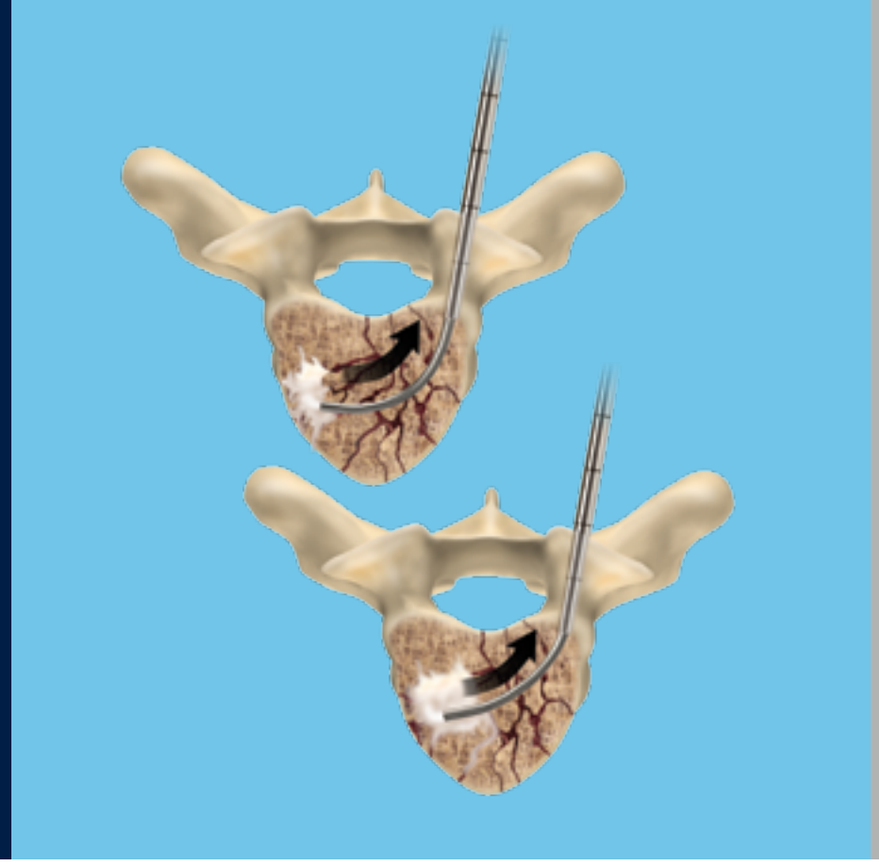
Attach the Cartridge Cap end of the Cement Cartridge to the Kyphon Kurve BFD.

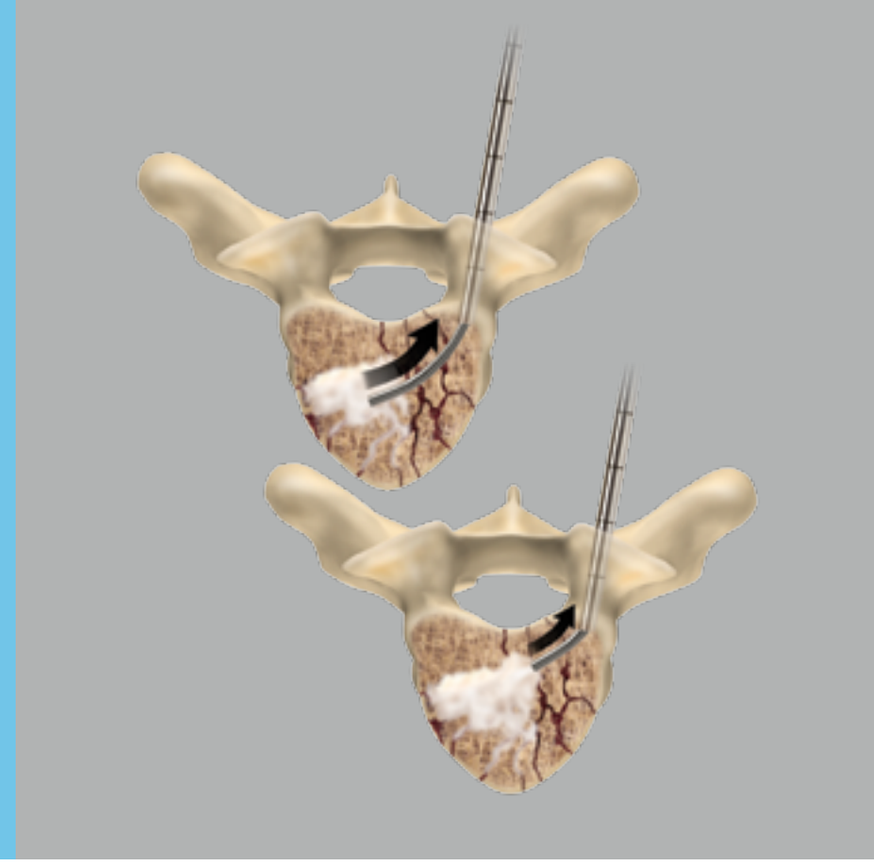
Note

Cement Delivery System Preparation (Back Table)

- Follow the Instructions For Use for mixing bone cement
- Fill both Cement Cartridges
- Prime the Gun by squeezing the Gun Lever slowly and repeatedly until a small amount of sterile water is expelled from the No-Bleed Connector.
- Attach the Back End of the Cement Cartridge to the Gun's No-Bleed Connector
- Test the partially assembled system by ejecting a small amount of cement from the Cement Cartridge

STEP 4: CEMENT DELIVERY





Step away from the radiation source (up to 4 feet away). Squeeze the Gun Lever until cement flow is initiated.

Each full squeeze of the Gun Lever ejects approximately 0.2cc of cement.

To stop the flow of cement at any time, press the Quick Release Button for a 1 second count and release. To restart the cement flow, squeeze the lever until cement resumes flowing.

Note
Deliver only enough PMMA cement to adequately fill the targeted region. The Kyphon Kurve BFD can be moved to any desired location within the bone by observing the arrow and repositioning the Kurve BFD under fluoroscopy.

Note
REPOSITIONING the Kyphon Kurve BFD as needed.
To redirect the placement of cement within the vertebral body, hold the 10ga Cannula to prevent movement and either: (1) withdraw the Kyphon Kurve BFD to the Exit Marker. Then rotate the Kyphon Kurve handle and re-insert the Kyphon Kurve BFD to your desired position; or, (2) withdraw to the 30deg mark, for example, and then re-advance. Continue cement fill. The Kyphon Kurve BFD **MUST** be fully retracted and straightened by withdrawing the BFD into the OIS (to the indicator mark on the BFD) prior to removing the OIS from the patient. It is recommended to completely remove the BFD prior to removing the OIS.

STEP 4: CEMENT DELIVERY

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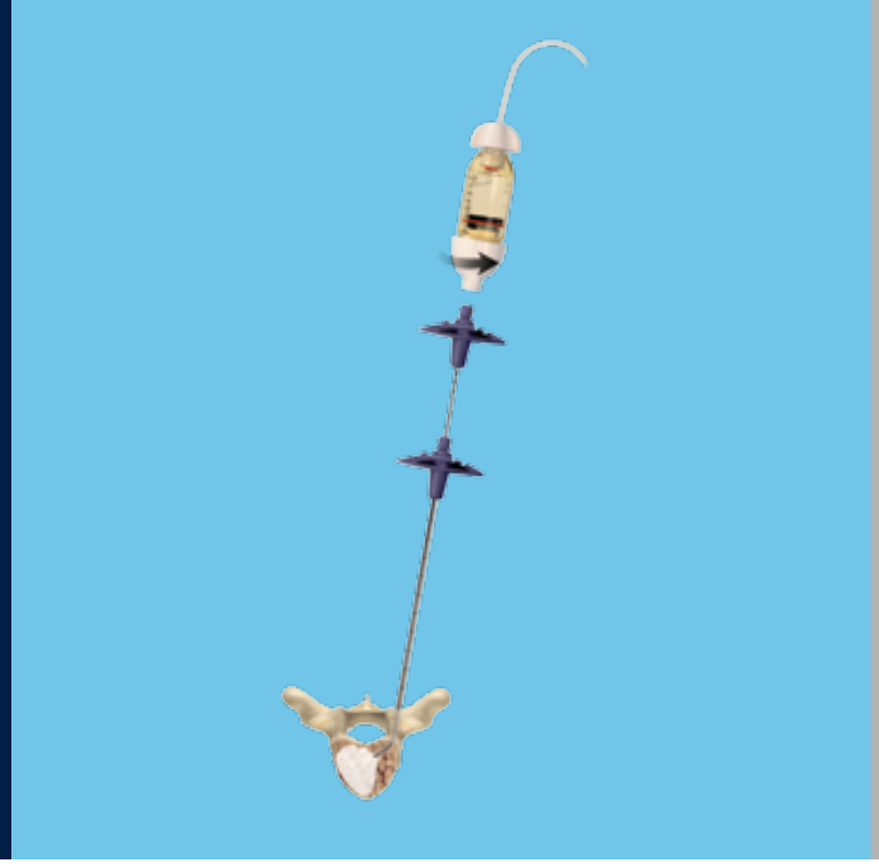


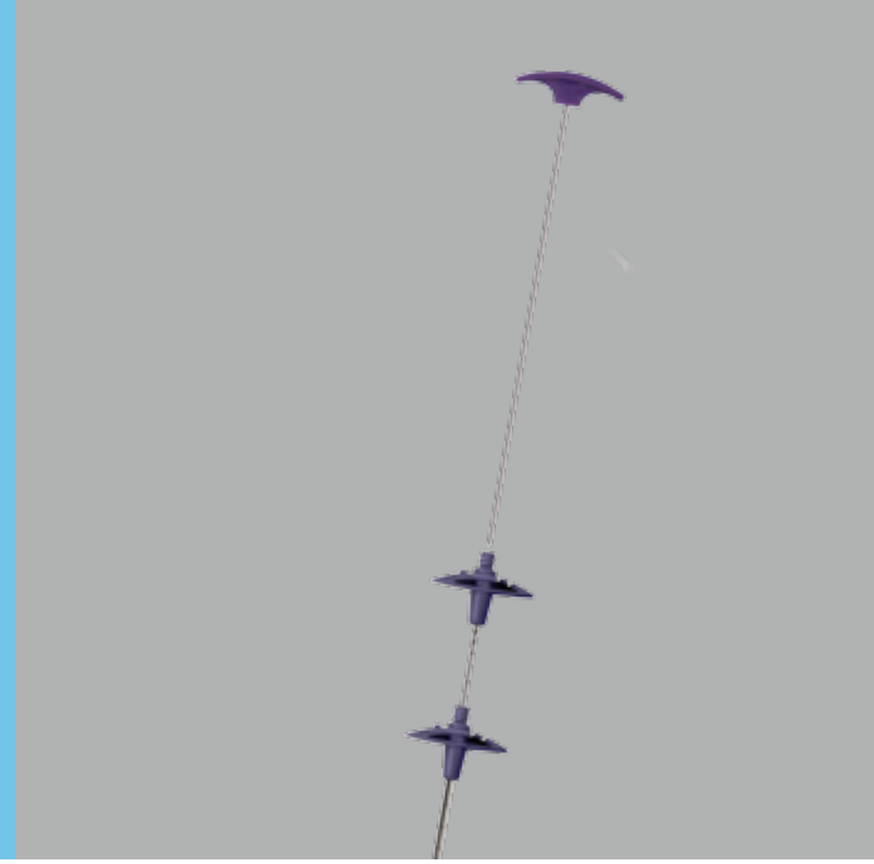
When completely finished with cement fill, remove the Cement Cartridge from the Kyphon Kurve BFD.

The Kyphon Kurve BFD **MUST** be fully retracted and straightened by withdrawing the BFD into the OIS (to the indicator mark on the BFD) prior to removing the OIS from the patient. It is recommended to completely remove the BFD prior to removing the OIS.

Tamp down with the BFD plunger, as needed, to expel cement from Kyphon Kurve BFD.

Note

Stop BFD Plunger advancement when the position marker on the Plunger enters the proximal end of the handle.



Upon completion of procedure, remove the OIS Cannula and Kyphon Kurve BFD from the patient.

IMPORTANT PRODUCT INFORMATION

The Kyphon V Osteo Introducer® System is intended for percutaneous access to bone and for the delivery of bone cement, including during a kyphoplasty or vertebroplasty procedure.

The Kyphon V Bone Biopsy Device is intended for obtaining a bone biopsy specimen, including use during a kyphoplasty or vertebroplasty procedure.

The Kyphon Kurve Bone Filler Device is intended for the delivery of bone cement.

The Kyphon® Cement Delivery System is intended for the delivery of bone cement, including use during a kyphoplasty or vertebroplasty procedure.

The Kyphon V Osteo Introducer System, Kyphon Kurve Bone Filler Device, and Kyphon Cement Delivery System are single use devices intended to contact body tissues. Do not reuse, reprocess, or resterilize. Reusing these devices carries the risk of contamination and may cause patient infection or cross-infection, regardless of the cleaning and resterilization methods. There is also an increased risk of the deterioration of the device performance due to the reprocessing steps, which may lead to patient injury or death.

Please see the package insert for the complete list of indications, warnings, precautions, and other important medical information.

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The surgical technique shown is for illustrative purposes only. The technique(s) actually employed in each case will always depend upon the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient.

Please see the package insert for the complete list of indications, warnings, precautions, and other important medical information.

Consult instructions for use at this website www.medtronic.com/manuals.

Note: Manuals can be viewed using a current version of any major internet browser. For best results, use Adobe Acrobat® Reader with the browser.