

Reference:

1. Data on file at DePuy Spine™ 2008

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X-ray on front cover courtesy of David Mitchell M.D Spartanburg SC, USA.

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DePuy International Ltd

St Anthony's Road
Leeds LS11 8DT
England

Tel: +44 (0)113 387 7800
Fax: +44 (0)113 387 7890

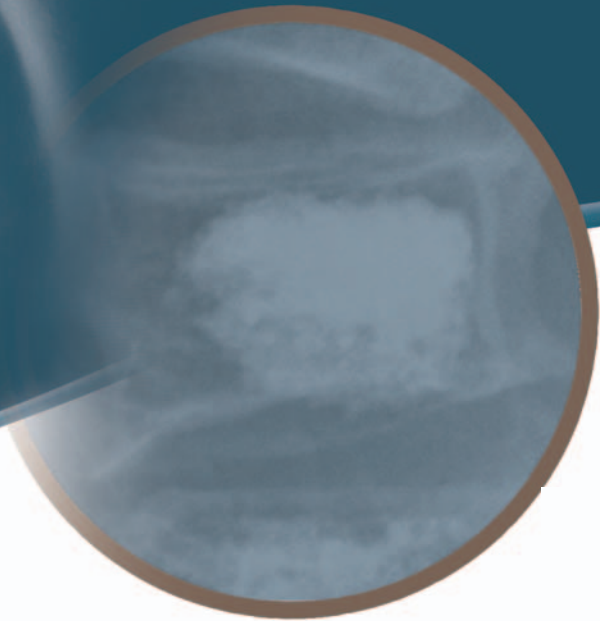


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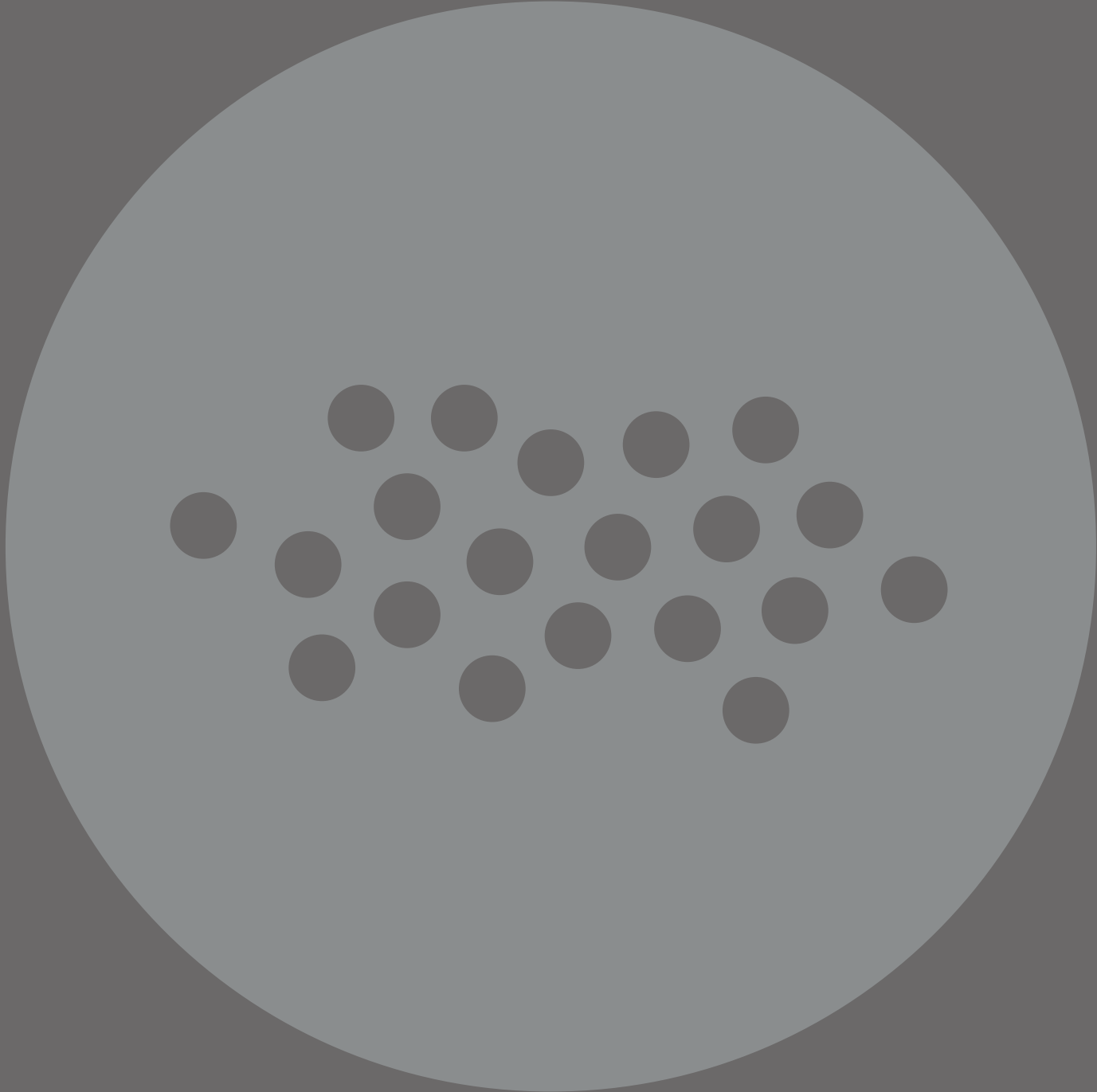
Product Information & Surgical Technique



 **DePuySpine™**
a *Johnson & Johnson* company



Confidence™
SPINAL CEMENT SYSTEM



Contents

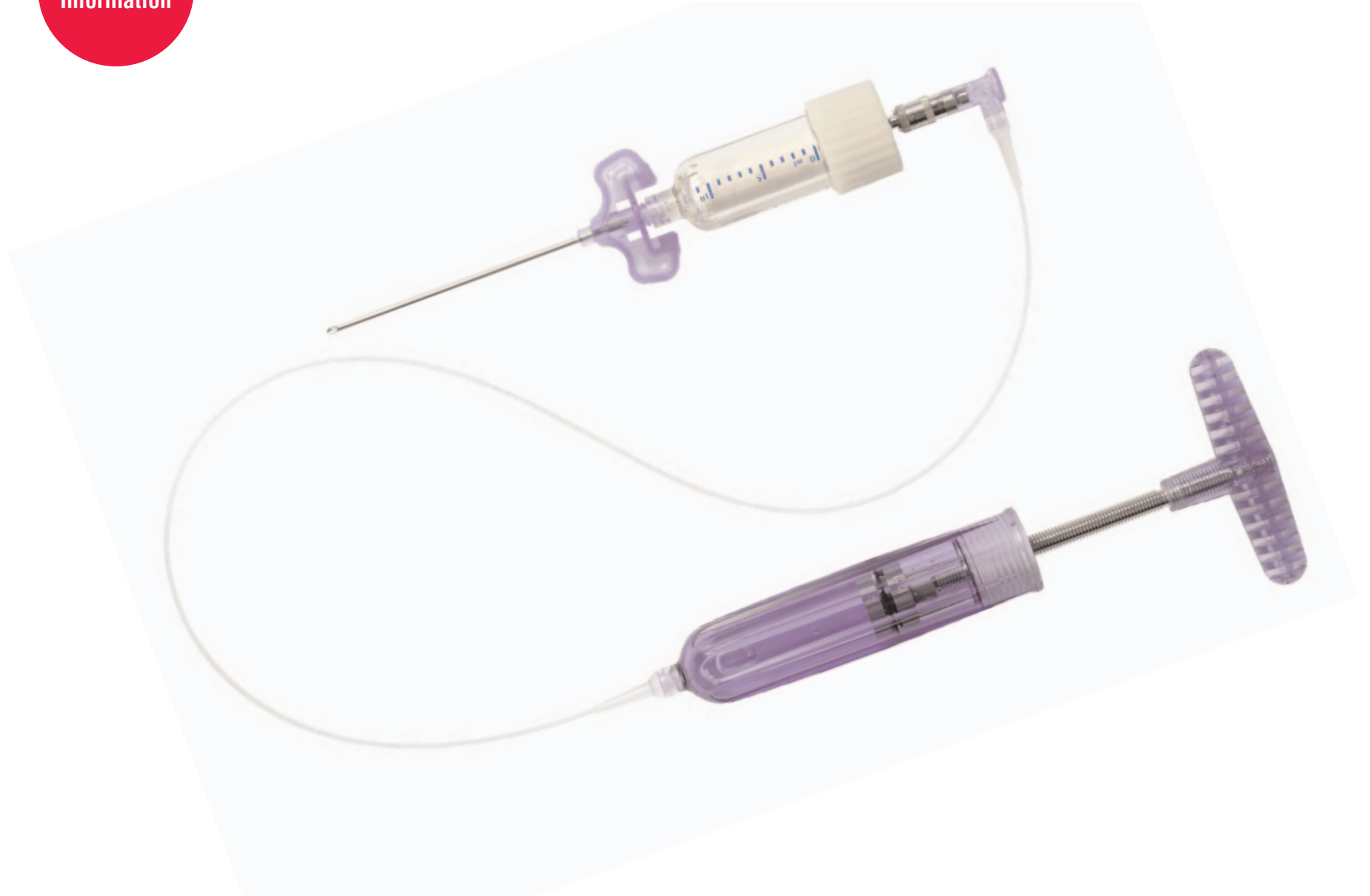
Product information	
Introduction	3
Surgical Technique	
Indications for use	11
Needle Placement	12
Biopsy Needle Placement	14
Cement Preparation	15
Cement Delivery	20
Ordering Information	
CONFIDENCE SPINAL CEMENT SYSTEM™	24
Supplementary Components	26



Percutaneous vertebroplasty, and more recently kyphoplasty, are Vertebral Body Augmentation (VBA) procedures used for the treatment of painful vertebral compression fractures caused by osteoporosis, tumours or trauma, that have failed conservative and medical treatment.

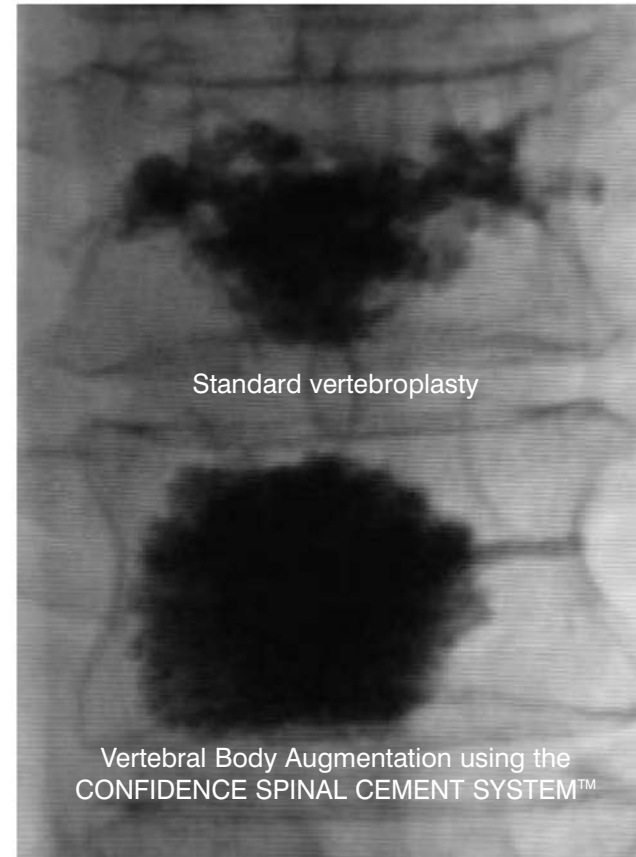
Providing a novel treatment for vertebral compression fractures, the revolutionary CONFIDENCE SPINAL CEMENT SYSTEM™ blends the best aspects of both vertebroplasty and kyphoplasty procedures, offering a unique capability to deliver high viscosity cement through a small introducer needle.

**Product
Information**



Osteoporotic or pathologic fractures are a common source of pain and disability in our aging population. The initial treatment is usually conservative with bed rest or bracing. The surgical treatment of compression fractures involves the introduction of cement into the fractured vertebral body. This frequently results in satisfactory resolution of the pain syndrome, with improvement in overall function and an improved sense of well-being. Common complications of the introduction of cement are related to the flow of the material outside the vertebral body such as veins, spinal canal, or lungs.

The CONFIDENCE SPINAL CEMENT SYSTEM™ combines highly viscous cement with a novel hydraulic delivery system. The radiopaque CONFIDENCE High Viscosity Cement reaches a dough-like phase immediately after the cement components have been mixed, without going through a liquid phase. In addition, the viscosity of the CONFIDENCE cement remains relatively constant throughout the entire working time of 8-10 minutes (at a standard OR temperature of 20°C)¹. The hydraulic delivery system enables a smooth introduction of this highly viscous cement through a specially designed 11G, 13G or 15G introducer needle.



*Image courtesy of Dr Giovanni Carlo Anselmetti,
Institute for Cancer Research & Treatment, Turin, Italy*

CONFIDENCE High Viscosity Cement is a PMMA (polymethylmethacrylate) cement, designed for use in the treatment of vertebral compression fractures caused by osteoporosis, tumours or trauma.

Novel Cement Formulation

No Waiting

- As soon as CONFIDENCE has been mixed, it is immediately in a high viscosity phase and ready to be injected.¹

Introduction Through a Narrow Cannula

- Despite the dough-like consistency of CONFIDENCE, it is still possible to inject it through a narrow cannula (11, 13 or 15G), in combination with the CONFIDENCE SPINAL CEMENT SYSTEM™.

Constant Highly Viscous State¹

- Once the cement has been mixed, CONFIDENCE has a working time of 8-10 minutes (at 20°C).¹



Cement Interdigitation

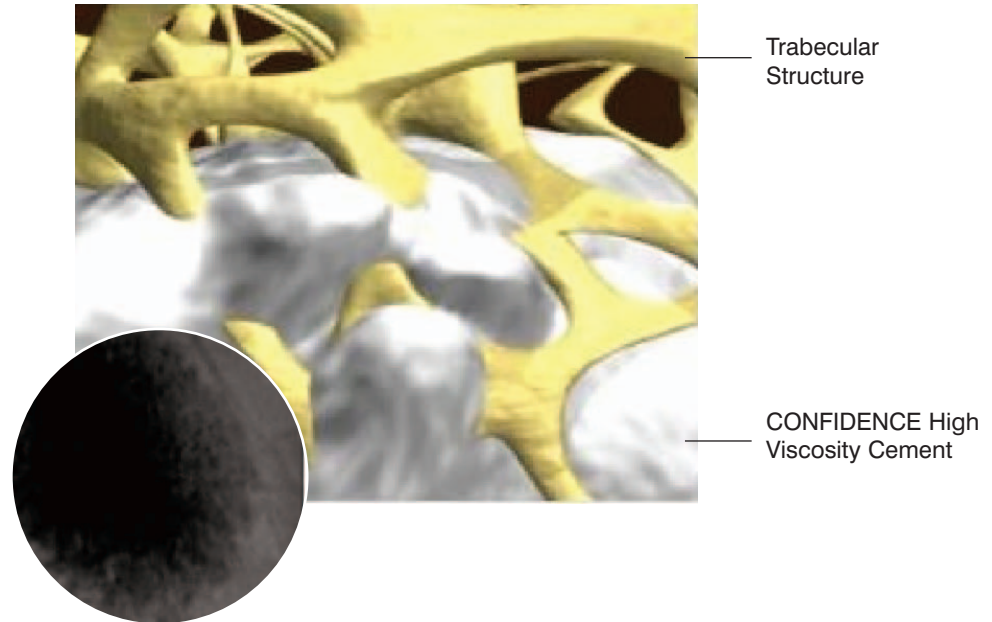
- The high viscosity properties of the CONFIDENCE cement allow for interdigitation, preserving the remaining trabecular structure of the vertebral body.

Fluoroscopic Evaluation

- The pre-mixed radiopaque agent (barium sulphate 30% w/w) allows accurate evaluation of cement distribution under fluoroscopy.

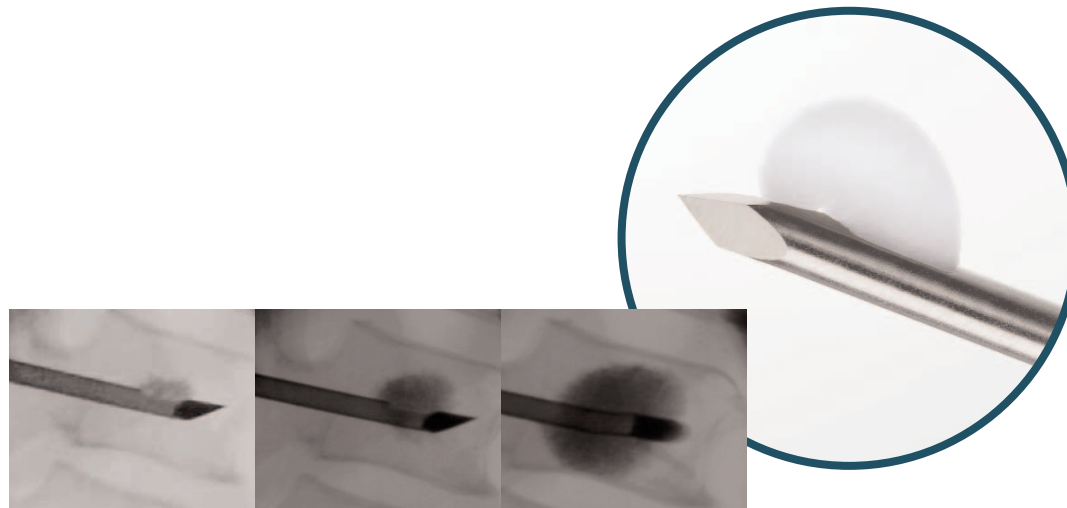
Easy Storage

- No pre-chilling required.



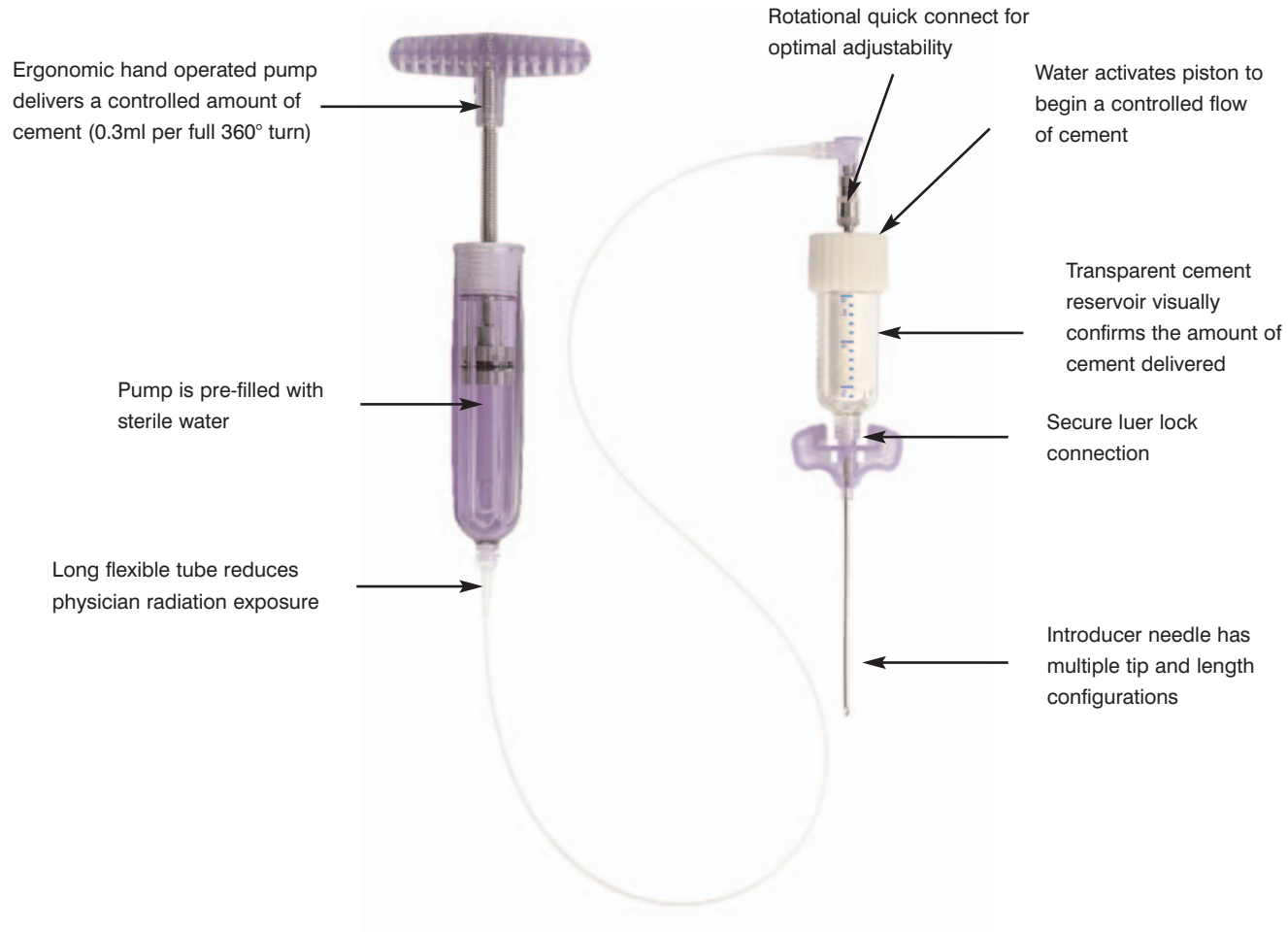
Proprietary Side-Hole Needle Allows Directional Placement of Cement

An optional side-hole needle incorporates a combination of a diamond tip with the unique side-hole feature, allowing the physician ease of placement and directional cement flow control.



Control Through Delivery...

Hydraulic-based delivery system allows for a controlled flow of highly viscous cement through a small gauge introducer needle.



Control Through Simplicity...

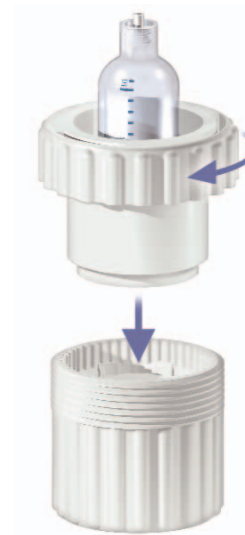
Novel mixing and transfer accessories allow for a simple and streamlined procedure.



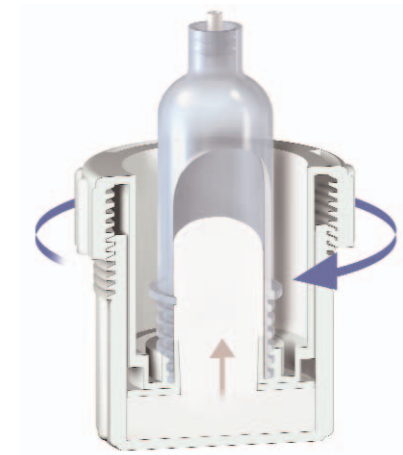
40-60 Seconds of mixing achieves optimal viscosity.



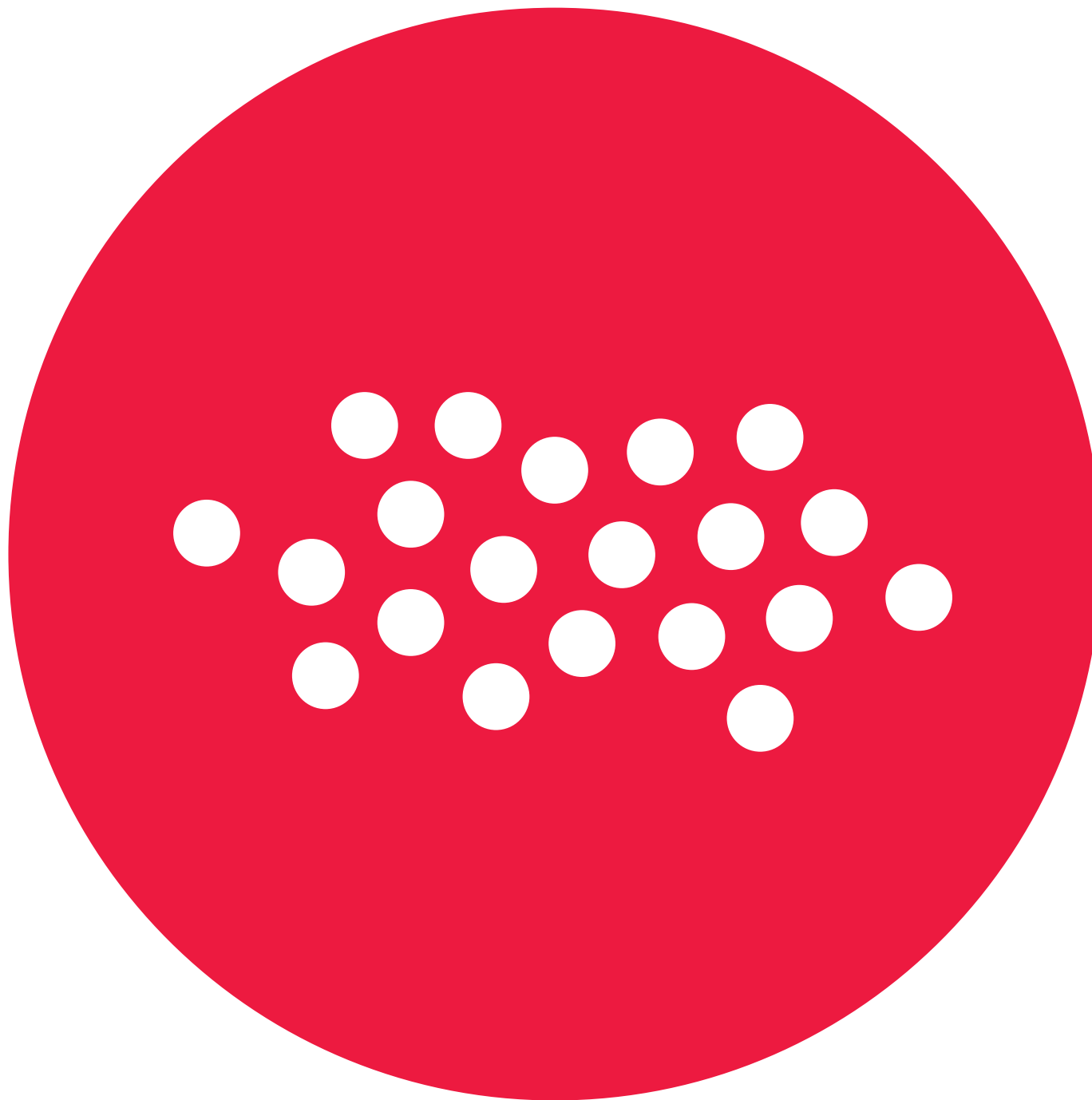
Wiper blade retains cement in the bottom of the mixing bowl.



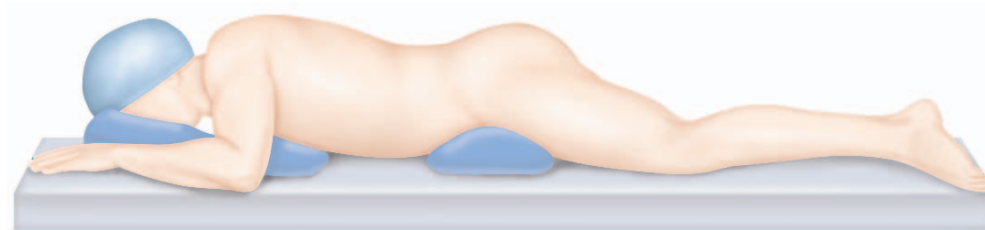
Simple one-step transfer of cement into reservoir.



Transfer mechanism auto-fills reservoir.

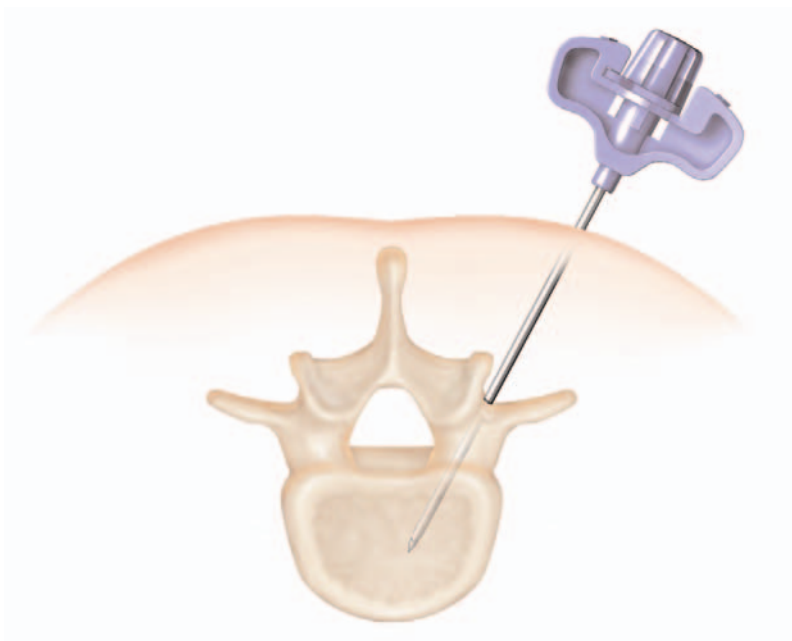


The CONFIDENCE SPINAL CEMENT SYSTEM™ is intended for the percutaneous delivery of CONFIDENCE spinal cements, which are indicated for fixation of pathological fractures of the vertebral body during vertebroplasty or kyphoplasty procedures. Painful vertebral compression fractures may result from osteoporosis, benign lesions (haemangioma), and malignant lesions (metastatic cancer, myeloma).

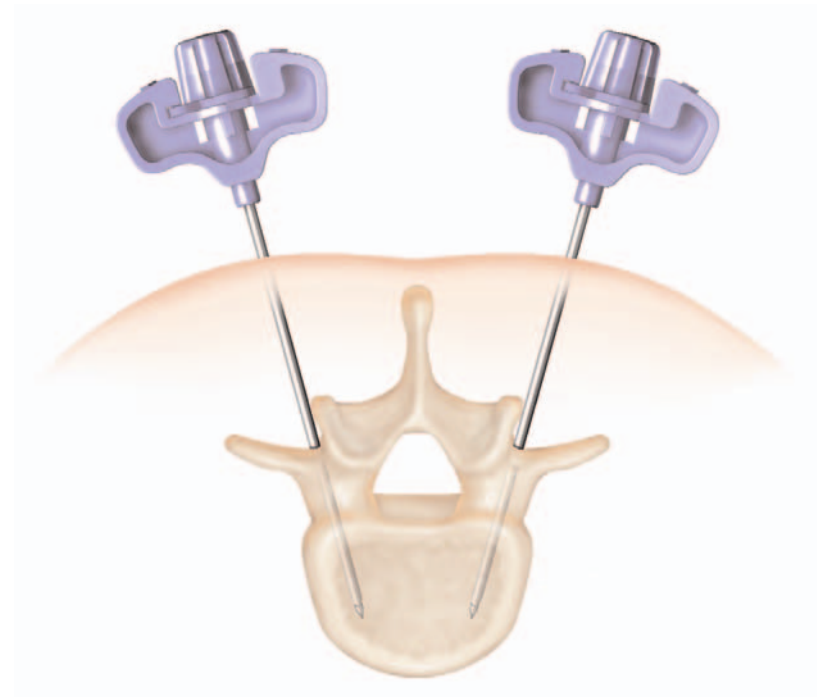


Patient Positioning and Preparation

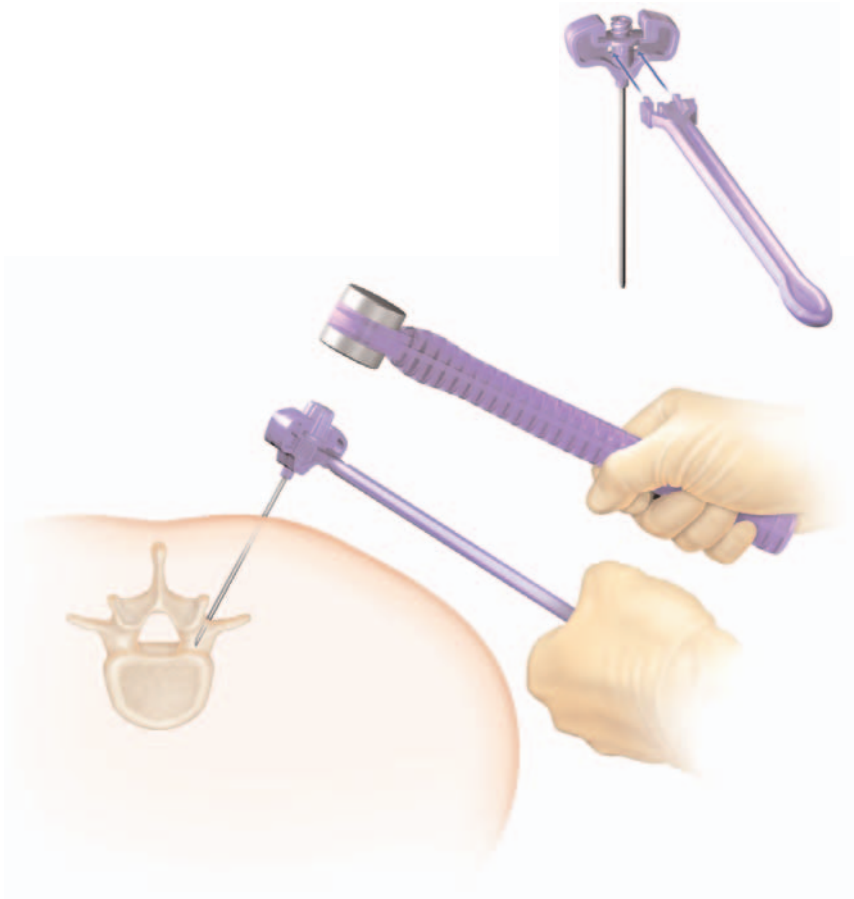
The patient should be in a prone position on a radiolucent table, permitting A/P and lateral imaging using uni or bi-planar x-ray and / or CT. Either local or general anaesthesia may be used.



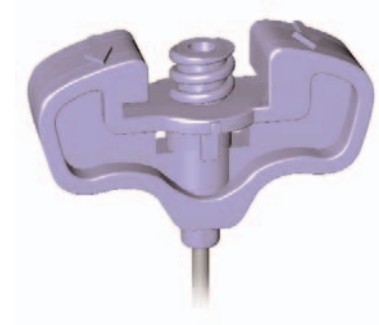
The trajectory by which the needle is inserted varies depending on the vertebra to be treated. Most commonly a transpedicular or extrapedicular approach is performed. A uni-pedicular or bi-pedicular approach may be used at the operator's discretion. Using alternating A/P and lateral fluoroscopy the needle can be guided into the vertebral body. The tip of the needle should commonly begin superior and lateral to the border



of the pedicle on an A/P image. The needle is advanced, under lateral fluoroscopy, into the vertebral body. During needle advancement, great care should be taken to avoid breaching the medial border of the pedicle. This is accomplished by checking that when the tip of the needle on lateral fluoroscopy is flush with the posterior border of the vertebral body, that it is not medial to the medial border of the pedicle on the A/P image.



The needle holder, in combination with the long armed mallet, may be used to position and advance the needle under fluoroscopy, while keeping the physician's hands outside the x-ray field.



Note: The CONFIDENCE introducer needles have a large inner lumen and a specifically designed luer lock fitting. Only these needles are compatible with the CONFIDENCE SPINAL CEMENT SYSTEM™. In the case of the side-hole and bevel tipped needles, the arrows on the handle of the needle point to the location of the side injection port or bevel respectively.



After passing the vertebral posterior wall using the CONFIDENCE introducer needle, remove the stylet from the cannula.



Under fluoroscopy and/or CT guidance, insert the CONFIDENCE biopsy needle through the introducer needle for biopsy collection.



Pour the entire contents of the cement powder into the mixing bowl.



Pour the entire contents of the liquid monomer vial over the cement powder in the mixing bowl.

Note: Powder should always be poured into the mixing bowl first. Care should be taken not to open the liquid monomer vial over the mixing bowl due to risk of glass splinters.

Surgical Technique



While holding the mixing bowl vertically on the table, push down on the outer ring of the mixer handle and screw this ring onto the mixing bowl in a clockwise direction.

Note: Prior to introducing the mixer handle into the mixing bowl, verify that the wiper blade is attached to the inside of the mixer handle. If it is not, attach the wiper blade to the mixer handle by snapping it into place. Keep in mind that the teeth should point upwards.



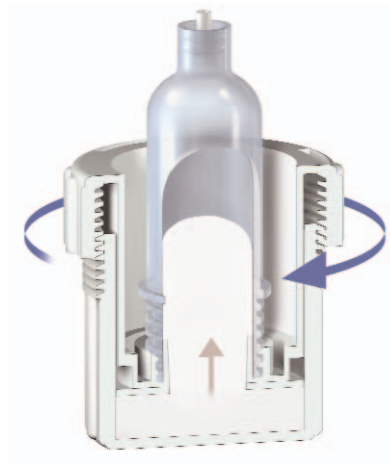
Mix the cement by turning the handle 3 turns in one direction, then 3 turns in the opposite direction. Repeat for a total of 40-60 seconds.



Unscrew the ring on the mixer handle in a counter-clockwise direction and remove the handle from the mixing bowl. The cement and wiper blade will remain in the mixing bowl.

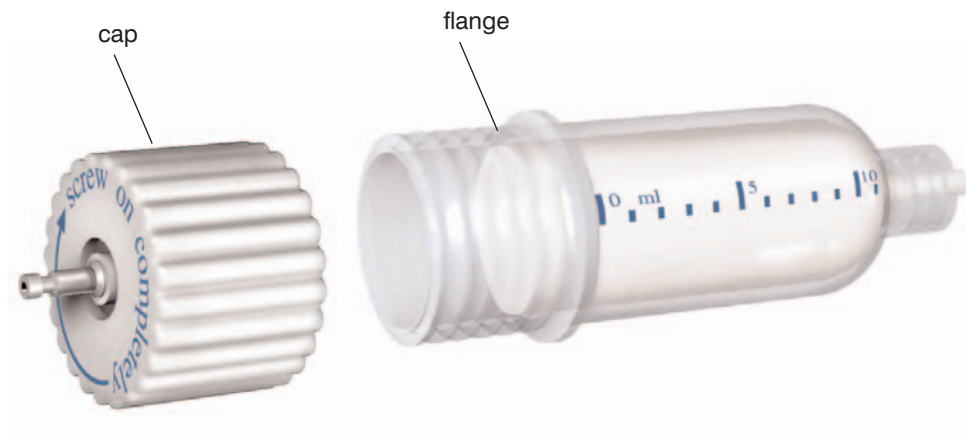


Surgical Technique



Push and screw the cement reservoir adaptor onto the mixing bowl with a clockwise rotation until firmly seated in the bottom of the bowl. This process will force the cement into the cement reservoir. Ensure that the cement is fully distributed to the distal tip of the reservoir.

Unscrew the cement reservoir from the cement reservoir adaptor with a counter-clockwise rotation.



Screw the cement reservoir cap securely onto the cement reservoir. Care should be taken to align the cap carefully with the threaded reservoir to ensure proper thread engagement. It is important that the cap is fully tightened before pressurising or delivering cement. A small amount of cement may extrude from the tip and should be removed before assembly to the needle.

Notes: *The reservoir cap must be fully seated against the flange on the cement reservoir. Ensure the piston inside the cap is properly attached to the cap before threading onto the reservoir.*



Connect the hydraulic pump flexible tube to the cement reservoir cap by pushing and snapping the quick-connect assembly onto the cement reservoir cap.

Note: If the quick connect will not attach to the reservoir cap, rotate the handle of the pump counter-clockwise to relieve some pressure. This will allow the connector to attach to the cap.



If not already removed for biopsy collection, turn the stylet counter-clockwise and remove from the cannula.



Screw the reservoir tip onto the luer fitting on the needle. Prepare the system for delivery by turning the pump handle a few turns. This should be done under fluoroscopic guidance. Once the cement approaches the tip of the needle, quickly turn the handle counter-clockwise 3-4 turns to stop the flow.

Surgical Technique

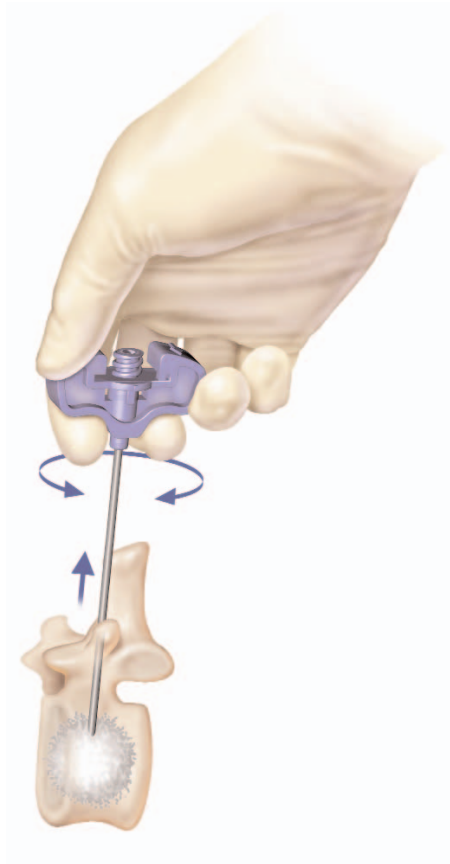


While monitoring the needle tip under fluoroscopy, slowly rotate the pump handle clockwise half a turn at a time, until cement begins to extrude from the needle tip. Each half turn (180 degrees) of the handle will inject approximately 0.15 ml of cement.

Notes: The hydraulic pump has a safety release valve that restricts the build-up of excess pressure in the reservoir. The scale on the cement reservoir is intended to approximate the amount of cement introduced. Fluoroscopy should be used to confirm the correct amount of cement introduced into the vertebral body. Note that the volume of cement in the introducer needle may be up to 1ml, depending on the gauge of the needle selected.



Upon completion, or at any point during the procedure, cement flow can be stopped by rapidly rotating the handle counter-clockwise 3-4 turns. When cement introduction is complete, disconnect the cement reservoir from the introducer needle.



Remove the introducer needle from the vertebral body by rotating and pulling the needle. The needle introduction site can be closed with a single suture, a steri-strip, or in any other manner preferred by the operator.

Catalogue No. 2839-10-000 CONFIDENCE PLUS kit

Components included in kit:

- CONFIDENCE High Viscosity Spinal Cement (11ml)
- Hydraulic Pump
- Cement Reservoir & Mixer
- Mallet & Needle Holder
- 2 Introducer Needles, Diamond Tip, 13G, 100mm
- Biopsy Needle, 15G, 230mm



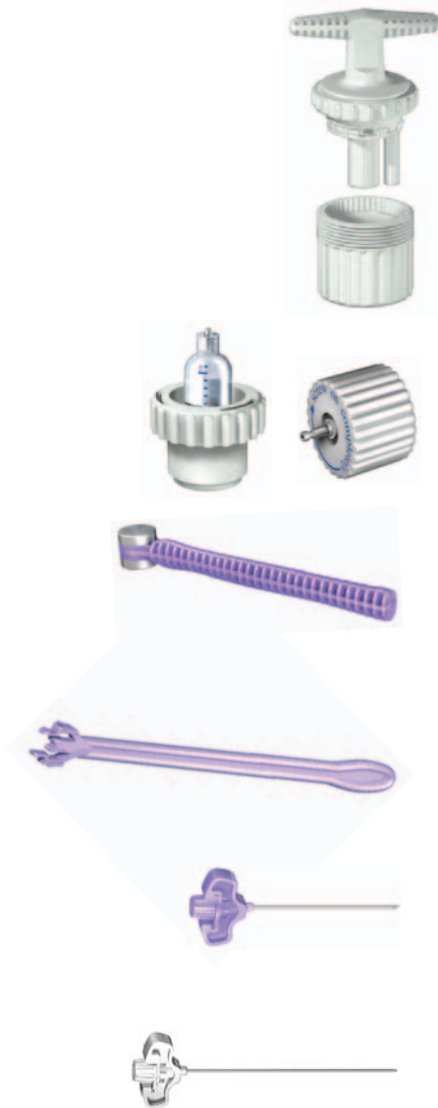
CONFIDENCE High Viscosity Spinal Cement (11ml)

Consists of an ampoule of liquid monomer and a packet of powder polymer. Mixing the two components for 40-60 seconds results in a high viscosity, radiopaque cement, with a working time of 8-10 minutes at 20°C.¹



Hydraulic Pump

The hydraulic pump enables a smooth and effortless introduction of highly viscous cement into the vertebra. It is provided pre-filled with sterile water. Its flexible extension tube enables the physician to keep his/her hands outside of the direct fluoroscopy exposure field.



Cement Mixer

Consisting of a mixing bowl and mixer handle, this unique, closed mixer enables easy mixing of the cement.

Cement Reservoir & Cement Reservoir Adaptor

The cement reservoir is an 11ml transparent barrel with volumetric reference markings. The cement reservoir adaptor enables the transfer of the cement into the cement reservoir following mixing.

Long Handled Radiolucent Mallet

A long handled, 150-gram disposable mallet to aid in needle introduction. The long radiolucent handle allows the physician to tap the needle during fluoroscopy, while keeping his/her hands outside of the direct fluoroscopy field.

Needle Holder

Radiolucent needle holder, allowing for manipulation of needle placement while keeping the hands of the physician outside the direct fluoroscopy field.

Introducer Needle, Diamond Tip, 13G, 100mm

Consists of a needle and a stylet for bone access. The needle also acts as a cannula through which the cement is introduced into the vertebra.

Biopsy Needle, 15G, 230mm

The biopsy needle consists of a needle and stylet intended for use through an 11 gauge or 13 gauge introducer needle.

Supplementary Components



<i>Catalogue No.</i>	<i>Description</i>
2839-03-411	Introducer Needle, Diamond Tip, 11G x 100mm
2839-03-611	Introducer Needle, Diamond Tip, 11G x 150mm
2839-03-413	Introducer Needle, Diamond Tip, 13G x 100mm
2839-03-613	Introducer Needle, Diamond Tip, 13G x 150mm
2839-03-415	Introducer Needle, Diamond Tip, 15G x 100mm



2839-02-411	Introducer Needle, Beveled Tip, 11G x 100mm
2839-02-611	Introducer Needle, Beveled Tip, 11G x 150mm
2839-02-413	Introducer Needle, Beveled Tip, 13G x 100mm
2839-02-613	Introducer Needle, Beveled Tip, 13G x 150mm



2839-04-413	Introducer Needle, Side-hole, 13G x 100mm
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2839-01-915	Biopsy Needle, 15G x 230mm
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Notes

