

*Product*  
Catalog



## Vertebral Body Augmentation



**CONFIDENCE NEEDLELESS KIT 11cc**



**CONFIDENCE PLUS KIT 11cc**



**CONFIDENCE NEEDLELESS KIT 5cc**

<b>CODES</b>	<b>Code</b>	<b>Description</b>	
<b>CONFIDENCE</b> <b>Diamond Tip</b> <b>Introducer Needle</b>	2839-03-510	CONFIDENCE Introducer Needle, Diamond, 10G 5"	
	2839-03-411	CONFIDENCE Introducer Needle, Diamond, 11G 4"	
	2839-03-611	CONFIDENCE Introducer Needle, Diamond, 11G 6"	
	2839-03-413	CONFIDENCE Introducer Needle, Diamond, 13G 4"	
	2839-03-613	CONFIDENCE Introducer Needle, Diamond, 13G 6"	
	2839-03-415	CONFIDENCE Introducer Needle, Diamond, 15G 4"	
<b>CONFIDENCE</b> <b>Beveled Tip</b> <b>Introducer Needle</b>	2839-02-510	CONFIDENCE Introducer Needle, Beveled, 10G 5"	
	2839-02-411	CONFIDENCE Introducer Needle, Beveled, 11G 4"	
	2839-02-611	CONFIDENCE Introducer Needle, Beveled, 11G 6"	
	2839-02-413	CONFIDENCE Introducer Needle, Beveled, 13G 4"	
	2839-02-613	CONFIDENCE Introducer Needle, Beveled, 13G 6"	
<b>CONFIDENCE</b> <b>Side Hole</b> <b>Introducer Needle</b>	2839-04-411	CONFIDENCE Introducer Needle, Side Hole, 11G 4"	
	2839-04-611	CONFIDENCE Introducer Needle, Side Hole, 11G 6"	
	2839-04-413	CONFIDENCE Introducer Needle, Side Hole, 13G 4"	
	2839-04-613	CONFIDENCE Introducer Needle, Side Hole, 13G 6"	
<b>CONFIDENCE</b> <b>Biopsy Needle</b>	2839-01-913	CONFIDENCE Biopsy Needle, 13G 9"	
	2839-01-915	CONFIDENCE Biopsy Needle, 15G 9"	
<b>CONFIDENCE</b> <b>Luer Adaptor</b>	2839-99-001	ADAPTOR: Standard Luer to CONFIDENCE Needle	
	2839-99-002	ADAPTOR: CONFIDENCE Reservoir to Standard Luer	

## CONFIDENCE SPINAL CEMENT SYSTEM®: KIT CONFIGURATIONS

DESCRIPTION	Item Code	Cement Volume	High Viscosity Spinal Cement	Hydraulic Pump	Cement Reservoir & Mixer	Mini Mallet with Needle Holder	Introducer Needles (2), Diamond, 13G 4"	Biopsy Needle, 15G 9"
CONFIDENCE Plus Kit 11cc	2839-10-000	11cc	✓	✓	✓	✓	✓	✓
CONFIDENCE Needleless Kit 11cc	2839-13-000	11cc	✓	✓	✓	✓		
CONFIDENCE Needleless Kit 5cc	2839-05-000	5cc	✓	✓	✓			

## CONFIDENCE SPINAL CEMENT SYSTEM: COMPONENT DESCRIPTIONS



### CONFIDENCE HIGH VISCOSITY SPINAL CEMENT

Consists of an ampoule of liquid monomer and a packet of powder polymer. Mixing the 2 components for 40-60 seconds results in a high viscosity, radiopaque cement. This high viscosity texture allows for an 8-10 minute working time at 68F/20C, and enables a controlled introduction of cement.



### INTRODUCER NEEDLE

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.



### SIDE HOLE NEEDLE

Allows for directional cement introduction. Consists of a stylet and introducer needle with a diamond tip and side opening at the distal end for directional cement introduction.



### BIOPSY NEEDLE

The 15 gauge biopsy needle consists of a needle and stylet intended for use through an 11 gauge or 13 gauge introducer needle.



### LONG HANDLE 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 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 of the direct fluoroscopy field.



### LUER ADAPTOR

Radiolucent luer adaptors allow the CONFIDENCE System to attach to standard sized luer.

## Vertebral Body Augmentation

### INDICATIONS

The **CONFIDENCE SPINAL CEMENT SYSTEM®** is intended for 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 (hemangioma), and malignant lesions (metastatic cancer, myeloma).

### CONTRAINDICATIONS

The use of CONFIDENCE High Viscosity Spinal Cement is contraindicated in patients presenting with any of the following conditions:

- Use of CONFIDENCE High Viscosity Spinal Cement for prophylaxis (such as in metastatic or osteoporotic patients with no evidence of acute vertebral fracture).
- Coagulation disorders, or severe cardiopulmonary disease.
- Haemorrhagic diathesis.
- Non-pathological, acute, traumatic fractures of the vertebra.
- Patient clearly improving on medical therapy.
- Spinal stenosis (>20% by retropulsed fragments).
- Compromise of the vertebral body or walls of the pedicles.
- Compromise or instability of vertebral fractures due to posterior involvement.
- Anatomical damage of the vertebra that prevents safe access of the needle to the vertebral body.
- Vertebral body collapse to less than 1/3 (33%) original height.
- Vertebral plana (collapse >90%).
- Active or incompletely treated infection.
- Coagulopathy or inability to reverse anti-coagulant therapy (both during and approximately 24 hours post-procedure).
- Severe pulmonary insufficiency.
- Allergic reaction to any of the components of the CONFIDENCE High Viscosity Spinal Cement.

**Limited Warranty and Disclaimer:** DePuy Spine products are sold with a limited warranty to the original purchaser against defects in workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed.

**WARNING:** In the USA, this product has labeling limitations. See package insert for complete information.

**CAUTION:** USA Law restricts these devices to sale by or on the order of a physician.

Not all products are currently available in all markets.

[www.confidencespinalcement.com](http://www.confidencespinalcement.com)

**DePuy Spine Inc.**  
325 Paramount Drive  
Raynham, MA 02767  
USA  
Tel: +1 (800) 227-6633

[www.depuy.com](http://www.depuy.com)

©DePuy Spine, Inc., 2010. All rights reserved.

VB01-10-003 11/10 ADDB

*never stop moving®*

**DePuy**  
Spine Inc.  
a Johnson & Johnson company