Choices to accommodate your surgical approach and your patient’s individual needs — because no two fractures are alike.
DePuy Synthes Spine offers you complete procedural solutions for the personalized treatment of vertebral compression fractures, giving you the flexibility to choose the most appropriate solution.
Contents

Procedural Steps and Portfolio Map

Choices to accommodate your surgical approach ........................................ 4-5

Bone Access and Cavity Creation

SYNFLATE™ Vertebral Balloon .................................................................. 6-7
Cavity Creation Instrument ....................................................................... 8-9
Vertebral Body Balloon .......................................................................... 10-11

Cement Delivery

CONFIDENCE SPINAL CEMENT SYSTEM® .............................................. 12-13
VERTECEM® II Bone Cement ................................................................ 12-13

Product Ordering Guide

Vertebral Augmentation Procedural Options .......................................... 14-15
Vertebroplasty Procedural Options ......................................................... 16
Indications and Contraindications ......................................................... 17
Choices to accommodate your surgical approach and needs

VERTEBRAL AUGMENTATION

Bone Access
Choose an access kit

Cavity Creation
Choose an instrument

Cement Delivery
Choose a cement

10G Access Kit

SYNFLATE Vertebral Balloon

Cavity Creation Instrument

CONFIDENCE Cement

VERTEC EM II Bone Cement

CONFIDENCE Cement

VERTEC EM II Bone Cement
your patient’s individual needs

VERTEBROPLASTY

Access Kit
- Vertebral Body Balloon
- Vertebral Body Balloon
- Vertebral Body Balloon

Vertebroplasty Needles
- Bone Access
- Choose a needle

Confidence Cement
- Confide
- Bone Cement
- Bone Cement

Vertece II Bone Cement
- Bone Cement
- Bone Cement
- Bone Cement

Confidence Cement
- Bone Cement
- Bone Cement
- Bone Cement

Vertece II Bone Cement
- Bone Cement
- Bone Cement
- Bone Cement

Cement Delivery
- Choose a cement
SYNFLATE Vertebral Balloon

10G Access Kit

VARIETY OF TIP AND INJECTION OPTIONS

PLUNGER for creating access channels and intraoperative sizing of balloon

SINGLE STEP ACCESS AND LOCKING MECHANISM simplifies insertion

10G Access Kit Configurations

<table>
<thead>
<tr>
<th>DESCRIPTION</th>
<th>CODE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diamond Tip, End Opening Needle</td>
<td>03.804.517 S</td>
</tr>
<tr>
<td>Beveled Tip, End Opening Needle</td>
<td>03.804.518 S</td>
</tr>
<tr>
<td>Diamond Tip, Side Opening Needle</td>
<td>03.804.519 S</td>
</tr>
<tr>
<td>Beveled Tip, Side Opening Needle</td>
<td>03.804.520 S</td>
</tr>
</tbody>
</table>

Accessories (optional)

Access Drill 10G 03.804.521 S

Biopsy Kit 10G 03.804.522 S
SYNFLATE Vertebral Balloon

For the reduction of fractures and/or creation of a void in the cancellous bone in the spine.

- Low profile system with 10G access instrumentation
- Streamlined balloon preparation technique
- Three sizes to fit varying patient anatomy

SYNFLATE Vertebral Balloon Options

<table>
<thead>
<tr>
<th>DESCRIPTION</th>
<th>PRE-INFLATED LENGTH</th>
<th>MAXIMUM VOLUME</th>
<th>INFLATED MAXIMUM PRESSURE</th>
<th>CODE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Small</td>
<td>10mm</td>
<td>4.0ml</td>
<td>30 ATM / 440 PSI</td>
<td>03.804.700S</td>
</tr>
<tr>
<td>Medium</td>
<td>15mm</td>
<td>5.0ml</td>
<td>30 ATM / 440 PSI</td>
<td>03.804.701S</td>
</tr>
<tr>
<td>Large</td>
<td>20mm</td>
<td>6.0ml</td>
<td>30 ATM / 440 PSI</td>
<td>03.804.702S</td>
</tr>
</tbody>
</table>

Inflation System

- Simple, easy-to-use inflation device
- Clear indication of volume and pressure during inflation

Cement Delivery - Refer to pages 12–13
Cavity Creation Instrument

10G Access Kit

VARIETY OF TIP AND INJECTION OPTIONS

SINGLE STEP ACCESS AND LOCKING MECHANISM
simplifies insertion

10G Access Kit Configurations

<table>
<thead>
<tr>
<th>DESCRIPTION</th>
<th>CODE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diamond Tip, End Opening Needle</td>
<td>03.804.517S</td>
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<tr>
<td>Beveled Tip, End Opening Needle</td>
<td>03.804.518S</td>
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<tr>
<td>Diamond Tip, Side Opening Needle</td>
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</tr>
<tr>
<td>Beveled Tip, Side Opening Needle</td>
<td>03.804.520S</td>
</tr>
</tbody>
</table>

Accessories (optional)

Access Drill 10G 03.804.521S

Biopsy Kit 10G 03.804.522S
Cavity Creation Instrument

For the creation of a void in the cancellous bone of a vertebral body
• Simplified technique for directed cavity creation
• Full 360° rotation inside the vertebral body
• Two sizes to fit varying patient anatomy

Cavity Creation Instrument Options

<table>
<thead>
<tr>
<th>DESCRIPTION</th>
<th>DIAMETER</th>
<th>CODE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cavity Creation Instrument, 10 mm</td>
<td>10 mm</td>
<td>03.702.750S</td>
</tr>
<tr>
<td>Cavity Creation Instrument, 15 mm</td>
<td>15 mm</td>
<td>03.702.751S</td>
</tr>
</tbody>
</table>

NITINOL WIRE provides durability and stiffness for reliable cavity creation
ARROWS ON THE HANDLE show direction of the curved tip
DEPTH GRADUATIONS indicate level of advancement into the vertebral body
ADJUSTABLE STOP allows control of insertion depth

Cement Delivery - Refer to pages 12–13
Vertebral Body Balloon

Access Kit

- **TWO ACCESS INSTRUMENTS**
  - allow for flexibility in surgeon approach

- **GUIDEWIRES AND DIRECT TROCARS INCLUDED**

- **TWO SIDE OPENING INJECTION NEEDLES**

- **PLUNGER**
  - for creating access channels and intraoperative sizing of balloon

- **DRILL**
  - for optional use

Accessories (optional)

**Biopsy Kit** 03.804.613S
Bone Access and Cavity Creation

Vertebral Body Balloon

For the reduction of fractures and/or creation of a void in the cancellous bone in the spine.

- Predictable inflation with low compliant balloon technology
- High lifting forces in the craniocaudal direction
- Three sizes to fit varying patient anatomy

<table>
<thead>
<tr>
<th>DESCRIPTION</th>
<th>PRE-INFLATED LENGTH</th>
<th>MAXIMUM VOLUME</th>
<th>INFLATED MAXIMUM PRESSURE</th>
<th>CODE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Small</td>
<td>22mm</td>
<td>4.0ml</td>
<td>30 ATM / 440 PSI</td>
<td>03.804.500S</td>
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<tr>
<td>Medium</td>
<td>27mm</td>
<td>4.5ml</td>
<td>30 ATM / 440 PSI</td>
<td>03.804.501S</td>
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<tr>
<td>Large</td>
<td>31mm</td>
<td>5.0ml</td>
<td>30 ATM / 440 PSI</td>
<td>03.804.502S</td>
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</table>

Inflation System

- Simple, easy-to-use inflation device
- Clear indication of volume and pressure during inflation

Cement Delivery - Refer to pages 12–13
CONFIDENCE SPINAL CEMENT SYSTEM

A unique, proprietary, easy-to-use system that is characterized by:

- Cement that achieves high viscosity immediately post-mixing
- Predictable and reliable cement viscosity for 8-12 minutes of working time
- A hydraulic-based delivery system that allows for a controlled flow of cement
- Remote cement delivery to minimize physician exposure to radiation
- Streamlined setup with simple mixing and transfer tools

CONFIDENCE System Kit Components

Please refer to page 16 for CONFIDENCE System Kit Configurations.

VERTECEM II Bone Cement

A closed, clean, and easy-to-use system that is characterized by:

- Up to 17 minutes of working time
- 18cc of cement to allow for multi-level approach
- Wide, integrated wings and reinforced pistons on the injection syringes provide excellent leverage, rigidity, and tactile feedback
- Good visibility under fluoroscopy
- Ready to inject immediately after mixing
Mix And Preparation Time

<table>
<thead>
<tr>
<th>Cement Type</th>
<th>Mix And Preparation Time</th>
<th>Injection Time</th>
</tr>
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<tbody>
<tr>
<td>CONFIDENCE Spinal Cement</td>
<td>1</td>
<td>8–12</td>
</tr>
<tr>
<td>VERTECEM II Bone Cement</td>
<td>4</td>
<td>17</td>
</tr>
</tbody>
</table>

All data at 20°C.
Source: CONFIDENCE SPINAL CEMENT SYSTEM Instructions for Use and VERTECEM II Bone Cement Instructions for Use.

Viscosity Curves

Graphic for illustrative purposes only. Refer to product Instructions for Use for detailed information.
## CONFIDENCE System Bone Cement for Vertebral Augmentation

### SYNFLATE Vertebral Balloon

<table>
<thead>
<tr>
<th>Step</th>
<th>Procedure</th>
<th>Access Kit</th>
<th>Balloon Kit</th>
<th>Adaptor</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Bone Access</td>
<td>10G Access Kit, Diamond/End</td>
<td>SYNFLATE Balloon, Small</td>
<td>Needleless Kit 11cc</td>
</tr>
<tr>
<td></td>
<td></td>
<td>10G Access Kit, Beveled/End</td>
<td>SYNFLATE Balloon, Medium</td>
<td>Luer Adaptor [Box of 10]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>10G Access Kit, Diamond/Side</td>
<td>SYNFLATE Balloon, Large</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>10G Access Kit, Beveled/Side</td>
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<td></td>
</tr>
</tbody>
</table>

**CHOOSE ACCESSORIES [OPTIONAL]**

- Access Drill 10G, [optional]
- Biopsy Kit 10G, [optional]

**ORDER ADAPTOR**

- Needleless Kit 11cc
- Luer Adaptor [Box of 10]

### Cavity Creation Instrument

<table>
<thead>
<tr>
<th>Step</th>
<th>Procedure</th>
<th>Access Kit</th>
<th>Instrument</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Bone Access</td>
<td>10G Access Kit, Diamond/End</td>
<td>Cavity Creation Instrument, 10mm</td>
</tr>
<tr>
<td></td>
<td></td>
<td>10G Access Kit, Beveled/End</td>
<td>Cavity Creation Instrument, 15mm</td>
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<tr>
<td></td>
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<td>10G Access Kit, Diamond/Side</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>10G Access Kit, Beveled/Side</td>
<td></td>
</tr>
</tbody>
</table>

**CHOOSE ACCESSORIES [OPTIONAL]**

- Access Drill 10G, [optional]
- Biopsy Kit 10G, [optional]

**ORDER INFLATION SYSTEM**

- Inflation System

**ORDER CEMENT**

- Needleless Kit 11cc
- Luer Adaptor [Box of 10]

### Vertebral Body Balloon

<table>
<thead>
<tr>
<th>Step</th>
<th>Procedure</th>
<th>Access Kit</th>
<th>Balloon Kit</th>
<th>Adaptor</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Bone Access</td>
<td>Access Kit</td>
<td>Vertebral Body Balloon, Small</td>
<td>Needleless Kit 11cc</td>
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<tr>
<td></td>
<td></td>
<td>Biopsy Kit</td>
<td>Vertebral Body Balloon, Medium</td>
<td>Luer Adaptor [Box of 10]</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Vertebral Body Balloon, Large</td>
<td></td>
</tr>
</tbody>
</table>

**CHOOSE INSTRUMENT**

- Cavity Creation Instrument, 10mm
- Cavity Creation Instrument, 15mm

**ORDER INFLATION SYSTEM**

- Inflation System

**ORDER CEMENT**

- Needleless Kit 11cc
- Luer Adaptor [Box of 10]

**In order to pair CONFIDENCE System Bone Cement with needles that have a product code beginning with “03,” it is necessary to order the Luer Adaptor 2839.99.002.**
# VERTECEM II Bone Cement for Vertebral Augmentation

## SYNFLATE Vertebral Balloon

<table>
<thead>
<tr>
<th>Step</th>
<th>Action</th>
<th>Item</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Bone Access</td>
<td>10G Access Kit, Diamond/End</td>
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</tr>
<tr>
<td></td>
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<td>10G Access Kit, Beveled/End</td>
<td>03.804.518S</td>
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<tr>
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<td></td>
<td>10G Access Kit, Diamond/Side</td>
<td>03.804.519S</td>
</tr>
<tr>
<td></td>
<td></td>
<td>10G Access Kit, Beveled/Side</td>
<td>03.804.520S</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Biopsy Kit 10G, [optional]</td>
<td>03.804.522S</td>
</tr>
<tr>
<td>2</td>
<td>Cavity Creation</td>
<td>SYNFLATE Balloon, Small</td>
<td>03.804.700S</td>
</tr>
<tr>
<td></td>
<td></td>
<td>SYNFLATE Balloon, Medium</td>
<td>03.804.701S</td>
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<tr>
<td></td>
<td></td>
<td>SYNFLATE Balloon, Large</td>
<td>03.804.702S</td>
</tr>
<tr>
<td></td>
<td>ORDER INFLATION SYSTEM</td>
<td>Inflation System</td>
<td>03.804.413S</td>
</tr>
<tr>
<td>3</td>
<td>Cement Delivery</td>
<td>ORDER CEMENT†</td>
<td>VERTECEM II, Mixing Kit</td>
</tr>
<tr>
<td></td>
<td></td>
<td>VERTECEM V+, Syringe Kit</td>
<td>03.702.215S</td>
</tr>
</tbody>
</table>

## Cavity Creation Instrument

<table>
<thead>
<tr>
<th>Step</th>
<th>Action</th>
<th>Item</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Bone Access</td>
<td>10G Access Kit, Diamond/End</td>
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<tr>
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<td>10G Access Kit, Beveled/Side</td>
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</tr>
<tr>
<td></td>
<td></td>
<td>Biopsy Kit 10G, [optional]</td>
<td>03.804.522S</td>
</tr>
<tr>
<td>2</td>
<td>Cavity Creation</td>
<td>Cavity Creation Instrument, 10mm</td>
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</tr>
<tr>
<td></td>
<td></td>
<td>Cavity Creation Instrument, 15mm</td>
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</tr>
<tr>
<td>3</td>
<td>Cement Delivery</td>
<td>ORDER CEMENT†</td>
<td>VERTECEM II, Mixing Kit</td>
</tr>
<tr>
<td></td>
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<td>VERTECEM V+, Syringe Kit</td>
<td>03.702.215S</td>
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</table>

## Vertebral Body Balloon

<table>
<thead>
<tr>
<th>Step</th>
<th>Action</th>
<th>Item</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
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<tr>
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<td>CHOOSE ACCESSORIES [OPTIONAL]</td>
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<tr>
<td>2</td>
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<tr>
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<td>Vertebral Body Balloon, Large</td>
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<tr>
<td></td>
<td>ORDER INFLATION SYSTEM</td>
<td>Inflation System</td>
<td>03.804.413S</td>
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<tr>
<td>3</td>
<td>Cement Delivery</td>
<td>ORDER CEMENT†</td>
<td>VERTECEM II, Mixing Kit</td>
</tr>
<tr>
<td></td>
<td></td>
<td>VERTECEM V+, Syringe Kit</td>
<td>03.702.215S</td>
</tr>
</tbody>
</table>

†To deliver VERTECEM II Bone Cement, it is necessary to order both the mixing kit and syringe kit.
# VERTEBROPLASTY with CONFIDENCE or VERTECEM II Cement

## Product Ordering Guide

<table>
<thead>
<tr>
<th>GAUGE</th>
<th>LENGTH</th>
<th>NEEDLES PER KIT</th>
<th>CODE</th>
<th>OPTIONAL BIOPSY</th>
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<tr>
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<tr>
<td>8G*</td>
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<td>03.702.222S</td>
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<tr>
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<td>03.702.218S</td>
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<tr>
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<tr>
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<td>1</td>
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<td>03.702.211S</td>
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<tr>
<td>11G</td>
<td>6”</td>
<td>1</td>
<td>2839.03.611</td>
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</tr>
<tr>
<td>12G</td>
<td>4.7”</td>
<td>2</td>
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</tr>
<tr>
<td>13G</td>
<td>4”</td>
<td>1</td>
<td>2839.03.413</td>
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<tr>
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<td>6”</td>
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<td></td>
</tr>
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<td>2839.02.510</td>
<td>03.702.219S</td>
</tr>
<tr>
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<td>13G</td>
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<td>6”</td>
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</tbody>
</table>

## Cement Delivery

| | | | | |
|**CONFIDENCE System Kit Configurations** | | | | |

<table>
<thead>
<tr>
<th>DESCRIPTION</th>
<th>CODE</th>
<th>CEMENT VOLUME</th>
<th>HIGH VISCOITY SPINAL CEMENT</th>
<th>HYDRAULIC PUMP</th>
<th>CEMENT RESERVOIR &amp; MIXER</th>
<th>MINI MALLET WITH NEEDLE HOLDER</th>
<th>INTRODUCER NEEDLES (2), DIAMOND, 13G 4”</th>
<th>BIOPSY NEEDLE, 15G 9”</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plus Kit 11cc</td>
<td>2839.10.000</td>
<td>11cc</td>
<td>●</td>
<td>●</td>
<td>●</td>
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<tr>
<td>Needleless Kit 11cc</td>
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<td>●</td>
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<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Includes both trocar and guide wire access options. All other needles are trocar access only.

§In order to pair VERTECEM II Bone Cement with needles that have a product code beginning with “2839,”

it is necessary to order the Luer Adaptor 2839.99.001.

†In order to pair CONFIDENCE System Bone Cement with needles that have a product code beginning with “03,”

it is necessary to order the Luer Adaptor 2839.99.002.

‡To deliver VERTECEM II Bone Cement, it is necessary to order both the mixing kit and syringe kit.
Indications and Contraindications

SYNFLATE Vertebral Balloon System

Indications
The SYNFLATE Vertebral Balloon System is intended to be used for the reduction of fractures and/or creation of a void in cancellous bone in the spine. This includes use during percutaneous vertebral augmentation. The system is to be used with cleared spinal polymethylmethacrylate (PMMA) bone cements indicated for use during percutaneous vertebral augmentation procedures, such as kyphoplasty.

Contraindications
- Instability of posterior wall and/or pedicles
- Infection
- Severe bleeding
- Known allergies to bone cement
- Pregnancy
- Fractures in which more than 75% of vertebral height is lost
- Any known severe allergy to contrast material
- When safe placement and inflation of the balloon is not possible due to vertebral dimensions or fracture pattern

Refer to the SYNFLATE System package insert for complete system information including descriptions, indications, contraindications, and warnings.

Refer to specific Instructions for Use of the cement being used for complete system specific information including indications, contraindications, warnings, precautions, and adverse reactions related to bone cement.

Vertebral Body Balloon

Indications
The Vertebral Body Balloon System is intended to be used for the reduction of fractures and/or creation of a void in cancellous bone in the spine. This includes use during percutaneous vertebral augmentation. The system is to be used with cleared spinal polymethyl methacrylate (PMMA) bone cements indicated for use during percutaneous vertebral augmentation procedures, such as kyphoplasty.

Contraindications
- Instability of posterior wall and/or pedicles
- Infection
- Severe bleeding
- Known allergies to bone cement
- Pregnancy
- Fractures in which more than 75% of vertebral height is lost
- Any known severe allergy to contrast material
- Should not be used if vertebral dimensions or fracture pattern do not allow safe placement and inflation of the balloon

Refer to the Vertebral Body Balloon package insert for complete system descriptions, indications, and warnings.

Refer to specific Instructions for Use of the cement being used for complete system specific information including indications, contraindications, warnings, precautions, and adverse reactions related to bone cement.
CONFIDENCE SPINAL CEMENT SYSTEM

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 anticoagulant 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

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.

VERTECEM II Bone Cement

Indications
The VERTECEM II Bone Cement is used for the fixation of pathological fractures of the vertebral body using vertebroplasty or kyphoplasty procedures. Painful vertebral compression fractures of the vertebral body may result from osteoporosis, benign lesions (hemangioma), or malignant lesions (metastatic cancers, myeloma).

Contraindications
The use of VERTECEM II Mixing Kit is contraindicated in the event of:
- Acute or not completely healed local infections and active systemic infections
- Treatment-refractory coagulopathy or during anticoagulation
- Pulmonary insufficiency or severe heart and lung disorders
- Vertebra plana or if safe percutaneous access to the vertebra is not guaranteed
- Unstable vertebral fractures with involvement of the posterior margin
- Previous damage to the pedicle wall
- Fractures or neoplasia with narrowing of the spinal canal (>20%) and myelopathy
- Retropulsing vertebral fragments with myelopathy
- Acute traumatic fractures of non-osteoporotic vertebrae
- A satisfactory response to conservative treatment
- Asymptomatic stable vertebral fractures
- Known hypersensitivity or allergy to one of the components of VERTECEM II Mixing Kit
- Pregnancy or lactation

Refer to the package inserts for complete system descriptions, indications, contraindications and warnings.
Intended Use

Cavity Creation Instrument

Intended Use
The Cavity Creation Instrument is intended for the creation of a void in the cancellous bone of a vertebral body.

Warnings
DO NOT USE the Cavity Creation Instrument System when there is:
• Instability of posterior wall and/or pedicles
• Infection
• Severe bleeding

When using bone cement, refer to the specific Instructions for Use for contraindications, warnings, precautions, and adverse events related to bone cement.

Discard and DO NOT USE previously opened or damaged devices. Use only devices that are packaged in unopened and undamaged packages.

DO NOT USE if there is a loss of sterility of the device.

The Cavity Creation Instrument System components are for single use only. DO NOT recondition, reprocess, repair, modify or resterilize any component for further use in any way.

DO NOT USE the device after the expiration date printed on the package label.

Store in a cool, dry place.

Precautions
It is the responsibility of the physician performing this procedure to determine the appropriateness of the device and specific techniques.

The creation of voids in cancellous bone should be performed only by experienced physicians familiar with vertebral augmentation procedures (including access) and cavity creation devices.

Read the surgical technique guide prior to device operation.

Before using the Cavity Creation Instrument ensure that the size is suitable for the specific procedure.

The components of this system should only be used while under appropriate high quality imaging guidance.

The instrument or any part of the instrument should not be left implanted.

When implanting bone cement, refer to the specific Instructions for Use for contraindications, warnings, precautions, and adverse events related to bone cement.

Possible Adverse Events
In addition to the risks associated with any surgical procedure (i.e. death), adverse events when using this instrumentation system can include:
• Embolism of fat or other materials, or thrombus resulting in symptomatic pulmonary embolism or other clinical sequelae, including death
• Deep or superficial wound infection*
• Retropulsed vertebral body bone fragments which may cause injury to the spinal cord or nerve roots resulting in radiculopathy, paresis, paralysis, or death
• Incorrect placement of the instruments, possibly resulting in rupture of the aorta and/or nerve damage
• Fracture of the end plate and/or sidewall of the vertebral body
• Bleeding or hematoma*
• Pneumothorax*
• Pedicle fracture
• Breakage of the metal tip, possibly resulting in prolonged surgery to remove any fragments
*These risks can also be associated with general risks of surgery

For a transpedicular approach, if the pedicle is not large enough or stable enough to withstand the procedure, pedicle fracture may occur.

Complications that may occur during an extrapedicular approach include pneumothorax and bleeding.

When using bone cement, refer to the specific Instructions for Use for contraindications, warnings, precautions, and adverse events related to bone cement.
Limited Warranty and Disclaimer: DePuy Spine Inc. 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.