Vertebral Body Augmentation

Complete Procedural Solutions.
Flexibility to Choose.
Personalized Patient Care.

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

VERTEBRAL AUGMENTATION

**Bone Access**
Choose an access kit

**Cavity Creation**
Choose an instrument

**Cement Delivery**
Choose a cement and delivery system

---

**10G Access Kit**

**Access Kit 4.7 mm**

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**SYNFLATE® Vertebral Balloon**

**VERTECEM V+ Bone Cement**

**CONFIDENCE SPINAL CEMENT SYSTEM®**

**VERTECEM V+ Syringe Kit**

**SYNJECT Cement Delivery System**

**SYNFLATE® Vertebral Balloon**

**Vertebral Body Stenting**

**CONFIDENCE SPINAL CEMENT SYSTEM®**

**VERTECEM V+ Bone Cement**

**VERTECEM V+ Syringe Kit**

**SYNJECT Cement Delivery System**
Procedural Steps and Portfolio Map

proach and your patient’s individual needs

VERTEBROPLASTY

Bone Access
Choose a needle

Vertebroplasty Needsles

CONFIDENCE
Introducer Needles

Verteoplasty Needle Kit

Bone Access Needles

Verteoplasty Needles

CONFIDENCE SPINAL CEMENT SYSTEM

VERTECEM V+
Bone Cement

Cement Delivery
Choose a cement and delivery system

VERTECEM V+
Syringe Kit

SYNJECT Cement Delivery System

VERIFY and your patient’s individual needs
### 10G Access Kit – Single Pack

**SYNFLATE® Vertebral Balloon**

**10G Access Kit Configurations**

<table>
<thead>
<tr>
<th>DESCRIPTION</th>
<th>CODE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diamond Tip, Side Opening Needle</td>
<td>03.804.514S (double pack) 03.804.519S (single pack)</td>
</tr>
<tr>
<td>Beveled Tip, Side Opening Needle</td>
<td>03.804.515S (double pack) 03.804.520S (single pack)</td>
</tr>
</tbody>
</table>

**Accessories (optional)**

<table>
<thead>
<tr>
<th>Access Drill 10G</th>
<th>03.804.521S</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biopsy Kit 10G</td>
<td>03.804.522S</td>
</tr>
</tbody>
</table>
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>10 mm</td>
<td>4.0 ml</td>
<td>30 bar / 440 PSI</td>
<td>03.804.700S</td>
</tr>
<tr>
<td>Medium</td>
<td>15 mm</td>
<td>5.0 ml</td>
<td>30 bar / 440 PSI</td>
<td>03.804.701S</td>
</tr>
<tr>
<td>Large</td>
<td>20 mm</td>
<td>6.0 ml</td>
<td>30 bar / 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
VBS – Vertebral Body Stenting System
Minimally invasive, percutaneous, reconstructive treatment for vertebral body fractures.

Access Kit 4.7 mm

- 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

Access Kit

Access Kit 4.7 mm 03.804.612S

Accessories (optional)

Biopsy Kit 03.804.613S
VBS – Vertebral Body Stenting System

VBS is a treatment method for painful vertebral body fractures and lesions. It helps to prevent effects such as postural damage and pain caused by postural kyphosis.

**Expansion Ratio Up to 400%**
The Vertebral Body Stenting technology offers an expansion ratio up to 400% for the reconstruction of collapsed vertebrae.

**Controlled Balloon Dilatation with the VBS Inflation System**
The applied pressure and injected volume of the mixture of saline solution and contrast medium can constantly be monitored and controlled with the help of the phosphorescent display.

**Vertebral Body Stent Options**

<table>
<thead>
<tr>
<th>DESCRIPTION</th>
<th>PRE-INFLATED LENGTH</th>
<th>MAXIMUM VOLUME</th>
<th>INFLATED MAXIMUM PRESSURE</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>VERTEBRAL BODY STENT</strong></td>
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<td></td>
</tr>
<tr>
<td>Small</td>
<td>22 mm</td>
<td>4.5 ml</td>
<td>30 ATM / 440 PSI</td>
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<tr>
<td>Medium</td>
<td>27 mm</td>
<td>5.0 ml</td>
<td>30 ATM / 440 PSI</td>
</tr>
<tr>
<td>Large</td>
<td>31 mm</td>
<td>5.5 ml</td>
<td>30 ATM / 440 PSI</td>
</tr>
<tr>
<td><strong>VERTEBRAL BODY STENT WITH BALLOON</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Small</td>
<td>22 mm</td>
<td>4.0 ml</td>
<td>30 ATM / 440 PSI</td>
</tr>
<tr>
<td>Medium</td>
<td>27 mm</td>
<td>4.5 ml</td>
<td>30 ATM / 440 PSI</td>
</tr>
<tr>
<td>Large</td>
<td>31 mm</td>
<td>5.0 ml</td>
<td>30 ATM / 440 PSI</td>
</tr>
</tbody>
</table>

**Inflation System**

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

**Inflation System**

03.804.4135
VBS – Vertebral Body Stenting System
Minimally invasive, percutaneous, reconstructive treatment for vertebral body fractures.

Optional Vertebral Body Balloon
pre-cavity creation
Simulation of stent expansion via balloon trialing allows fracture/lesion mobility confirmation.

Restoration through balloon dilatation and stent expansion
Simultaneous dilatation of the bilaterally positioned VBS Stents offers an in situ controlled and continuous expansion.

Augmentation with VERTECEM V+
VERTECEM V+ is a radiopaque, injectable polymethyl methacrylate cement, indicated for use in spine pathologies being treated using vertebroplasty or kyphoplasty procedures.
VBS offers benefits to patients and physicians:

**Percutaneous**
The VBS stents are introduced percutaneously into the vertebral body with only a stab incision required to place the access instruments.

**Reconstructive**
The VBS system restores the loss of height in the fractured vertebral body.

**Height conserving**
Expanding the VBS stents inside the collapsed vertebra offers height restoration and conservation. The mechanical construct restores the height while at the same time offering a cavity for injection of highly viscous PMMA based bone cement cleared for use in vertebro plasty or kyphoplasty procedures.
CONFIDENCE SPINAL CEMENT SYSTEM

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

- Cement that achieves high viscosity immediately post-mixing
- Predictable and reliable cement viscosity for 8-10 minutes of working time (at a standard OR temperature of 68°F/20°C)
- 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 V+ Cement, Syringe Kit and SYNJECT CDS

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

- Ready-to-use viscosity
- The application time is approximately 27 minutes at room temperature
- Visibility under fluoroscopy
- VERTECEM V+ Syringes have wide integrated wings and reinforced syringe plungers to guarantee excellent force transfer, combined with tactile feedback.

VERTECEM V+ Cement Kit 07.702.016S

VERTECEM V+ Syringe Kit 03.702.215S
SYNJECT Cement Delivery System:

- Remote cement delivery to minimize physician exposure to radiation
- Hydraulic-based delivery system that allows for controlled and responsive cement flow with tactile feedback
- Dual line injection system for bi-lateral cement delivery
- Separately packaged single cartridge for additional cement delivery

<table>
<thead>
<tr>
<th>CONFIDENCE Spinal Cement</th>
<th>VERTECEM V+ Bone Cement</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.5</td>
<td>4</td>
</tr>
<tr>
<td>8–10</td>
<td>23</td>
</tr>
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</table>

All data at 20°C.
Source: CONFIDENCE SPINAL CEMENT SYSTEM Instructions for Use and VERTECEM V+ Bone Cement Instructions for Use.
# CONFIDENCE SPINAL CEMENT SYSTEM for Vertebral Augmentation

## SYNFLATE Vertebral Balloon

<table>
<thead>
<tr>
<th>Step</th>
<th>Accessory</th>
<th>Description</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1</strong> Bone Access</td>
<td>CHOOSE ACCESS KIT</td>
<td>10G Access Kit, Diamond Tip, Double Pack</td>
<td>03.804.514S</td>
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<tr>
<td></td>
<td></td>
<td>10G Access Kit, Beveled Tip, Double Pack</td>
<td>03.804.515S</td>
</tr>
<tr>
<td></td>
<td></td>
<td>10G Access Kit, Diamond Tip, Single Pack</td>
<td>03.804.519S</td>
</tr>
<tr>
<td></td>
<td></td>
<td>10G Access Kit, Beveled Tip, Single Pack</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><strong>2</strong> Cavity Creation</td>
<td>CHOOSE BALLOON(S)</td>
<td>SYNFLATE Balloon, Small</td>
<td>03.804.700S</td>
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<tr>
<td></td>
<td></td>
<td>SYNFLATE Balloon, Medium</td>
<td>03.804.701S</td>
</tr>
<tr>
<td></td>
<td></td>
<td>SYNFLATE Balloon, Large</td>
<td>03.804.702S</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><strong>3</strong> Cement Delivery</td>
<td>ORDER CEMENT</td>
<td>CONFIDENCE Needleless Kit 11cc</td>
<td>283913000</td>
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<tr>
<td></td>
<td></td>
<td>CONFIDENCE Needleless Kit 7cc</td>
<td>283907000</td>
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<tr>
<td></td>
<td>ORDER ADAPTOR**</td>
<td>Luer Adaptor [Box of 10]</td>
<td>2839-99-002</td>
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</tbody>
</table>

**In order to pair CONFIDENCE SPINAL CEMENT SYSTEM with needles that have a product code beginning with “03,” it is necessary to order the Luer Adaptor 2839-99-002.**
# VERTECEM V+ Bone Cement for Vertebral Augmentation

## CHOOSE ACCESS KIT
- 10G Access Kit, Diamond Tip, Double Pack
- 10G Access Kit, Beveled Tip, Double Pack
- 10G Access Kit, Diamond Tip, Single Pack
- 10G Access Kit, Beveled Tip, Single Pack

## CHOOSE ACCESSORIES [OPTIONAL]
- Access Drill 10G, [optional]
- Biopsy Kit 10G, [optional]

## CHOOSE BALLOON(S)
- SYNFLATE Balloon, Small
- SYNFLATE Balloon, Medium
- SYNFLATE Balloon, Large

## ORDER INFLATION SYSTEM
- Inflation System

## ORDER CEMENT†
- VERTECEM V+, Cement Kit
- VERTECEM V+, Syringe Kit
- SYNJECT Single 1 x 9ML
- SYNJECT Single 2 x 9ML
- SYNJECT Dual 2 x 9ML
- SYNJECT Cartridges, 1 x 9ML

### Vertebral Body Stenting

## ORDER ACCESS KIT
- Access Kit

## CHOOSE ACCESSORIES [OPTIONAL]
- Biopsy Kit

## CHOOSE STENT(S)
- Vertebral Body Stent, Small
- Vertebral Body Stent, Medium
- Vertebral Body Stent, Large

## CHOOSE STENT WITH BALLOON(S)
- Vertebral Body Balloon Stent with Balloon, Small
- Vertebral Body Balloon Stent with Balloon, Medium
- Vertebral Body Balloon Stent with Balloon, Large

## ORDER INFLATION SYSTEM
- Inflation System

## ORDER CEMENT†
- VERTECEM V+, Cement Kit
- VERTECEM V+, Syringe Kit
- SYNJECT Single 1 x 9ML
- SYNJECT Single 2 x 9ML
- SYNJECT Dual 2 x 9ML
- SYNJECT Cartridges, 1 x 9ML

---

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

<table>
<thead>
<tr>
<th>Bone Access</th>
<th>CONFIDENCE Needles</th>
<th>CONFIDENCE Introducer Needle</th>
<th>Verteplasty Needle Kits</th>
<th>Bone Access Needles</th>
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<tbody>
<tr>
<td>GAUGE</td>
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<td>NEEDLES PER KIT</td>
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<td>5&quot;</td>
<td>2</td>
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<tr>
<td></td>
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<td>2</td>
<td>2839-03-411</td>
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<td></td>
<td>11G</td>
<td>6&quot;</td>
<td>2</td>
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<td></td>
<td>13G</td>
<td>4&quot;</td>
<td>2</td>
<td>2839-03-413</td>
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<tr>
<td></td>
<td>13G</td>
<td>6&quot;</td>
<td>2</td>
<td>2839-03-613</td>
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<tr>
<td></td>
<td>15G</td>
<td>4&quot;</td>
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<td>13G</td>
<td>6&quot;</td>
<td>2</td>
<td>2839-02-613</td>
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<td>4&quot;</td>
<td>2</td>
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<td>DIAMOND</td>
<td>8G</td>
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<td></td>
<td>10G</td>
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<td>03.702.218S</td>
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<tr>
<td></td>
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<td>03.702.220S</td>
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<tr>
<td>BEVELED</td>
<td>10G</td>
<td>120 mm</td>
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<td>03.702.219S</td>
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<tr>
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<td>11G</td>
<td>120 mm</td>
<td>2</td>
<td>03.702.221S</td>
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<tr>
<td>DIAMOND</td>
<td>8G</td>
<td>140 mm</td>
<td>1</td>
<td>03.702.240S</td>
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<tr>
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<td>03.702.241S</td>
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<tr>
<td></td>
<td>11G</td>
<td>150 mm</td>
<td>1</td>
<td>03.702.244S</td>
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<td>13G</td>
<td>100 mm</td>
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<td>03.702.247S</td>
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</table>
# VERTEBROPLASTY with CONFIDENCE or VERTECEM V+ Cement

<table>
<thead>
<tr>
<th>DESCRIPTION</th>
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</tr>
</thead>
<tbody>
<tr>
<td>CHOOSE CEMENT</td>
<td></td>
</tr>
<tr>
<td>CONFIDENCE Plus Kit 11cc</td>
<td>283910000</td>
</tr>
<tr>
<td>CONFIDENCE Needleless Kit 11cc</td>
<td>283913000</td>
</tr>
<tr>
<td>CONFIDENCE Needleless Kit 7cc</td>
<td>283907000</td>
</tr>
<tr>
<td>Luer Adaptor: Standard Luer to CONFIDENCE Needle [Box of 10]§</td>
<td>2839-99-001</td>
</tr>
<tr>
<td>Luer Adaptor: CONFIDENCE Reservoir to Standard Luer [Box of 10]†</td>
<td>2839-99-002</td>
</tr>
<tr>
<td>VERTECEM V+, Cement Kit</td>
<td>07.702.016S</td>
</tr>
<tr>
<td>VERTECEM V+, Syringe Kit</td>
<td>03.702.215S</td>
</tr>
<tr>
<td>SYNJECT Single 1 x 9ML</td>
<td>03.702.511S</td>
</tr>
<tr>
<td>SYNJECT Single 2 x 9ML</td>
<td>03.702.512S</td>
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<tr>
<td>SYNJECT Dual 2 x 9ML</td>
<td>03.702.517S</td>
</tr>
<tr>
<td>SYNJECT Cartridges, 1 x 9ML</td>
<td>03.702.520S</td>
</tr>
</tbody>
</table>

## CONFIDENCE System Kit Configurations

<table>
<thead>
<tr>
<th>DESCRIPTION</th>
<th>CODE</th>
<th>CEMENT VOLUME</th>
<th>HIGH VISCOSITY 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, 15G 4&quot;</th>
<th>BIOPSY NEEDLE, 15G 9&quot;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plus Kit 11cc</td>
<td>283910000</td>
<td>11cc</td>
<td>●</td>
<td>●</td>
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<td>Needleless Kit 11cc</td>
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<td>●</td>
<td>●</td>
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<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 V+ 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 SPINAL CEMENT SYSTEM with needles that have a product code beginning with “03,” it is necessary to order the Luer Adaptor 2839-99-002.

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

SYNFLATE Vertebral Balloon

**Indications**
- Painful vertebral compression fractures
- Treatment of osteolytic lesions located within the vertebral body

**Contraindications**
- Stand-alone use with neurological deficits
- Stand-alone use with instability of posterior wall and/or pedicles
- Lesions requiring open anterior column reconstruction
- If vertebral dimensions or fracture pattern do not allow safe placement and inflation of the balloon
- Acute and chronic systemic or localized spinal infections
- Allergies to contrast media

VBS – Vertebral Body Stenting System

**Indications**
- Painful osteoporotic vertebral compression fractures without posterior wall involvement. Classified after Genant, Grade 2 and Grade 3.
- Painful vertebral compression fractures classified after the AO classification:
  - A1.1 Endplate impaction
  - A1.2 Wedge impaction fracture
  - A1.3 Vertebral body collapse
  - A3.1 Incomplete burst fracture; matter of discretion (depending on the degree of posterior wall involvement, internal fixation must be used in addition)

  In combination with internal fixation:
  - A3.1 Incomplete burst fracture
  - A3.2 Burst-split fracture; matter of discretion (the extent of the gap width should not be too wide)
  - B1.2 Posterior disruption predominantly ligamentous associated with type A fracture of the vertebral body
  - B2.3 Posterior disruption predominantly osseous with type A fracture of the vertebral body

- Palliative treatment of osteolytic lesions located within the vertebral body with intact cortical shell. Classified after Tomita Type 1.

**Contraindications**
- Lesions requiring open anterior column reconstruction
- Acute or chronic systemic or localized spinal infections
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 diasthesis
- 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

VERTECEM V+ Cement Kit

Indications

- Vertebral compression fractures (VCF)
- Progressive compression fractures of one or multiple vertebrae with subsequent development of increasing kyphosis
- Patients with persisting instability after a vertebral fracture
- Combined procedures with internal fixation in osteoporosis
- Osteolysis
- Metastatic lesions
- Aggressive type of haemangioma

Contraindications

- Infections
- Patients with clotting disorders
- Patients with severe cardiac and / or pulmonary insufficiency
- Patients with known hypersensitivity or allergy to any of the components of VERTECEM V+ bone cement
- Vertebra plana or circumstances where safe percutaneous access to the vertebra cannot be guaranteed
- Unstable vertebral fractures with involvement of the posterior wall in standalone vertebral augmentation procedures (e.g. vertebroplasty)
- Previous damage to the pedicle wall (transpedicular access)
- Lesions that feature narrowing of the spinal canal (more than 20%), including fracture or neoplasm, with or without myelopathy
- Retropulsing vertebral fragments with myelopathy
- A satisfactory response to conservative treatment
- Asymptomatic stable vertebral fractures
- VERTECEM V+ bone cement is contraindicated for use in arthroplasty procedures
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