

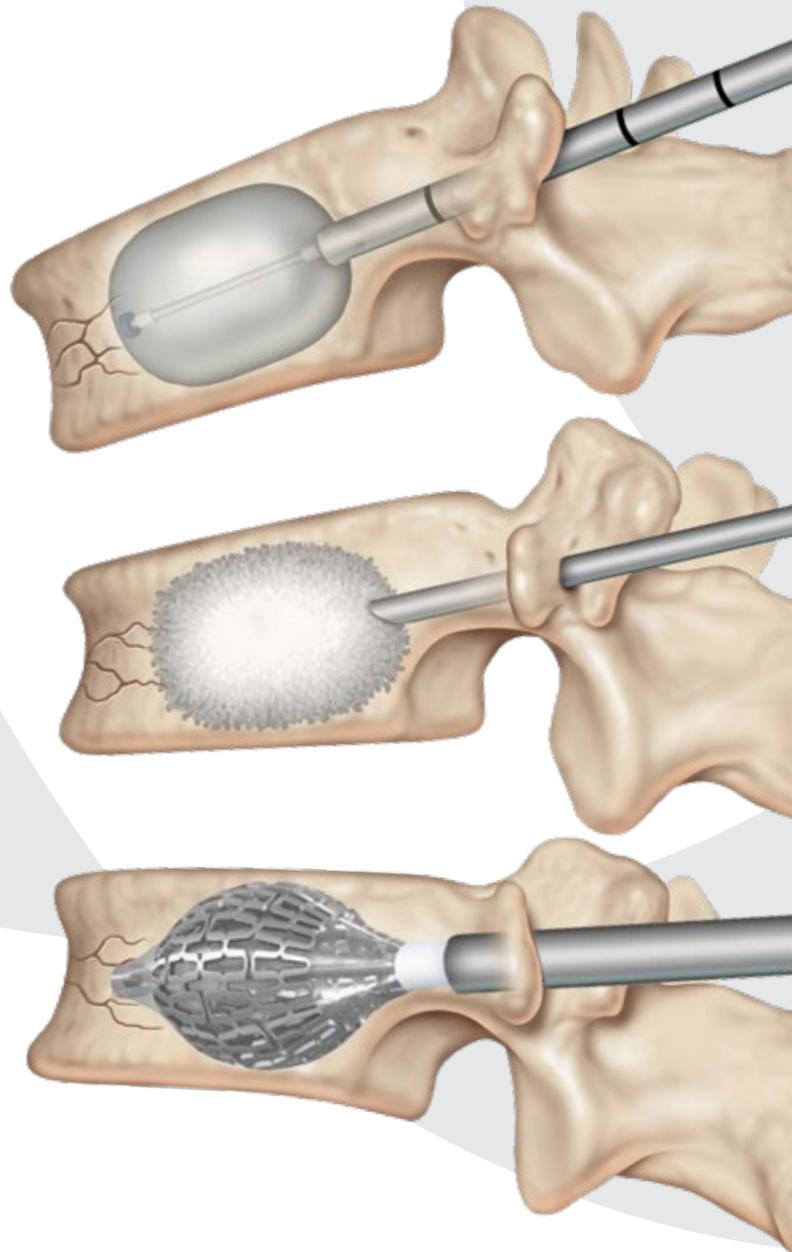
# Vertebral Body Augmentation

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



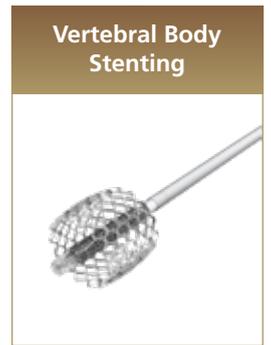
### Bone Access

Choose an access kit



### Cavity Creation

Choose an instrument



### Cement Delivery

Choose a cement and delivery system



# approach and your patient's individual needs

## VERTEBROPLASTY



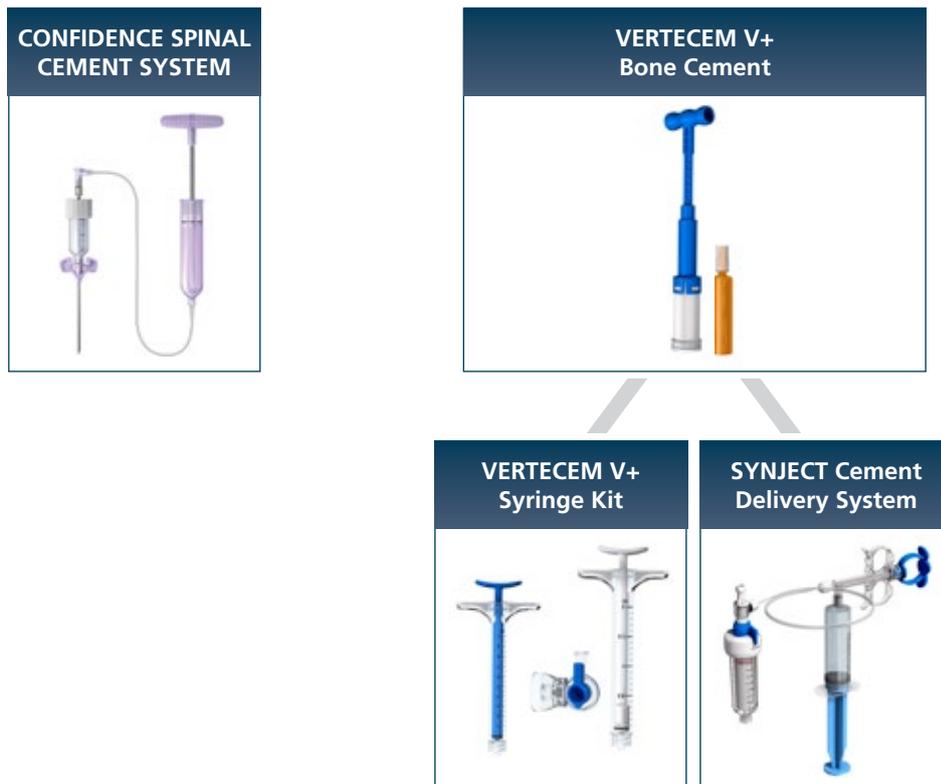
### Bone Access

Choose a needle



### Cement Delivery

Choose a cement and delivery system



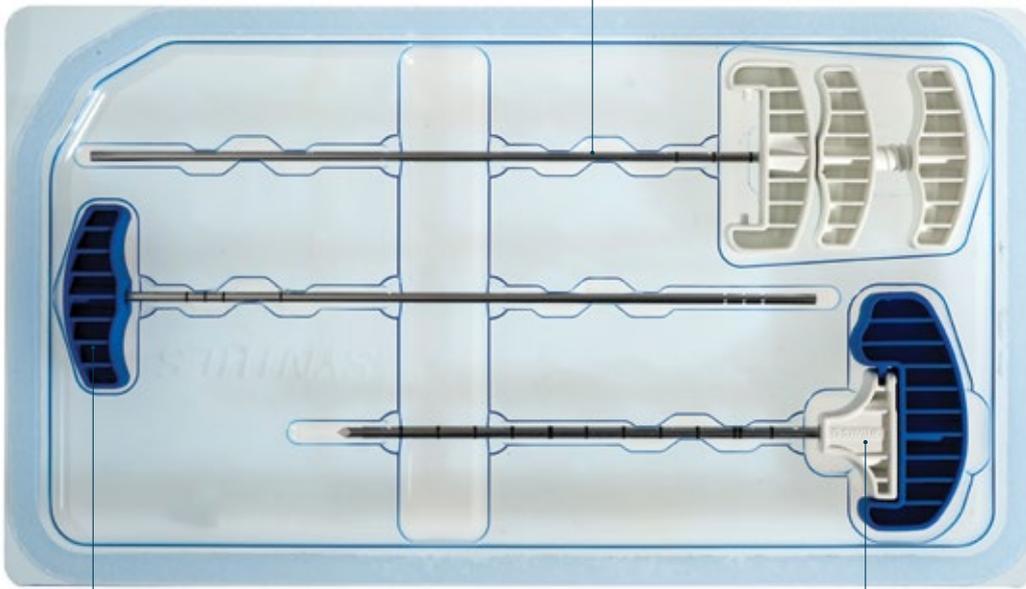


# SYNFLATE® Vertebral Balloon



## 10G Access Kit – Single Pack

VARIETY OF TIP AND INJECTION OPTIONS



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

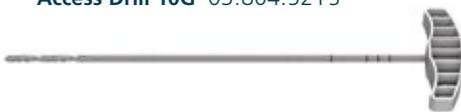
**SINGLE STEP ACCESS and locking mechanism**  
simplifies insertion

### 10G Access Kit Configurations

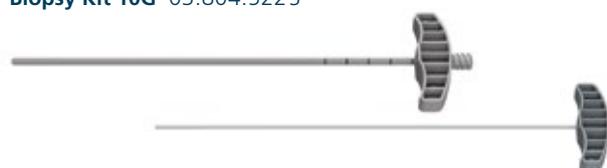
DESCRIPTION	CODE
Diamond Tip, Side Opening Needle	03.804.514S (double pack) 03.804.519S (single pack)
Beveled Tip, Side Opening Needle	03.804.515S (double pack) 03.804.520S (single pack)

### Accessories (optional)

**Access Drill 10G** 03.804.521S



**Biopsy Kit 10G** 03.804.522S





## 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

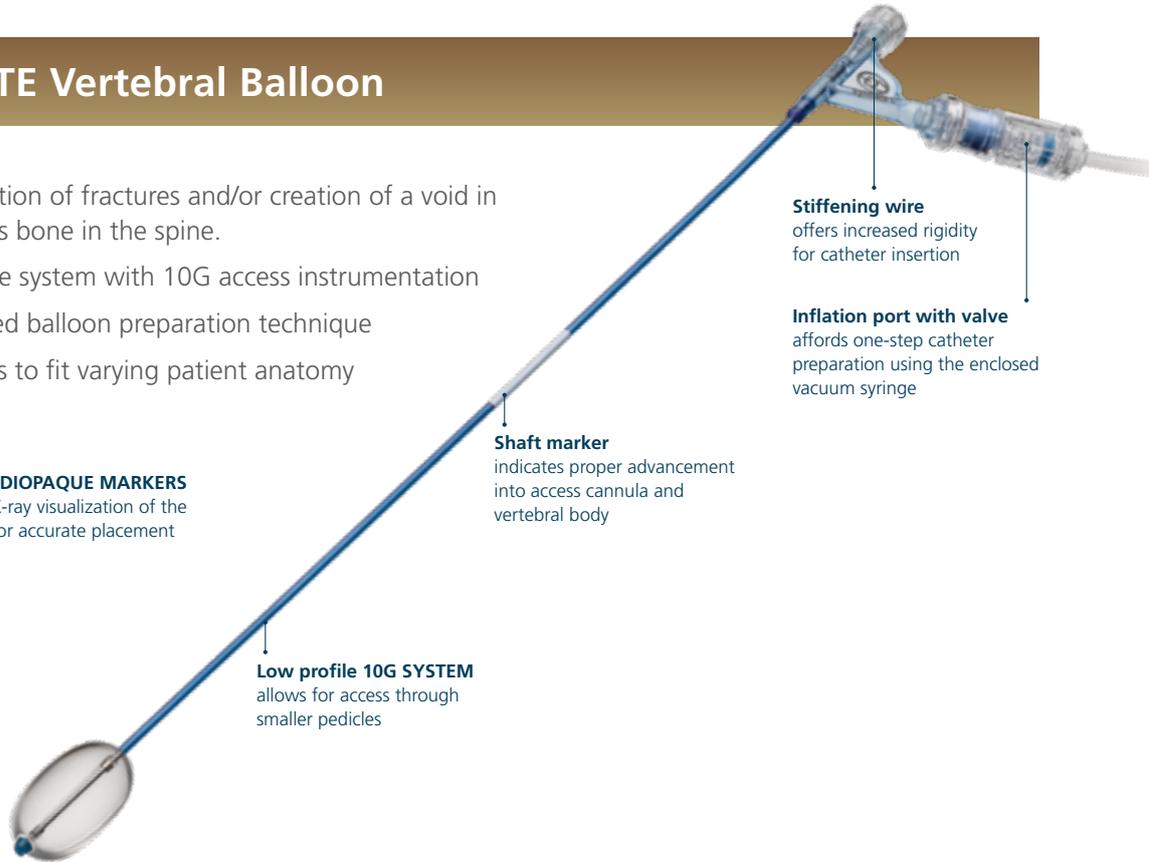
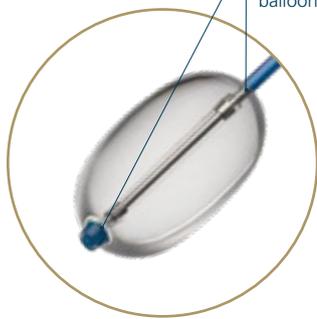
**Stiffening wire**  
offers increased rigidity for catheter insertion

**Inflation port with valve**  
affords one-step catheter preparation using the enclosed vacuum syringe

**TWO RADIOPAQUE MARKERS**  
provide X-ray visualization of the balloon for accurate placement

**Shaft marker**  
indicates proper advancement into access cannula and vertebral body

**Low profile 10G SYSTEM**  
allows for access through smaller pedicles



### SYNFLATE Vertebral Balloon Options

DESCRIPTION	PRE-INFLATED LENGTH	MAXIMUM VOLUME	INFLATED MAXIMUM PRESSURE		CODE
Small	10 mm	4.0 ml	30 bar / 440 PSI		03.804.700S
Medium	15 mm	5.0 ml	30 bar / 440 PSI		03.804.701S
Large	20 mm	6.0 ml	30 bar / 440 PSI		03.804.702S

### Inflation System

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

**Inflation System**  
03.804.413S



## Cement Delivery - Refer to pages 12–13



# VBS – Vertebral Body Stenting System

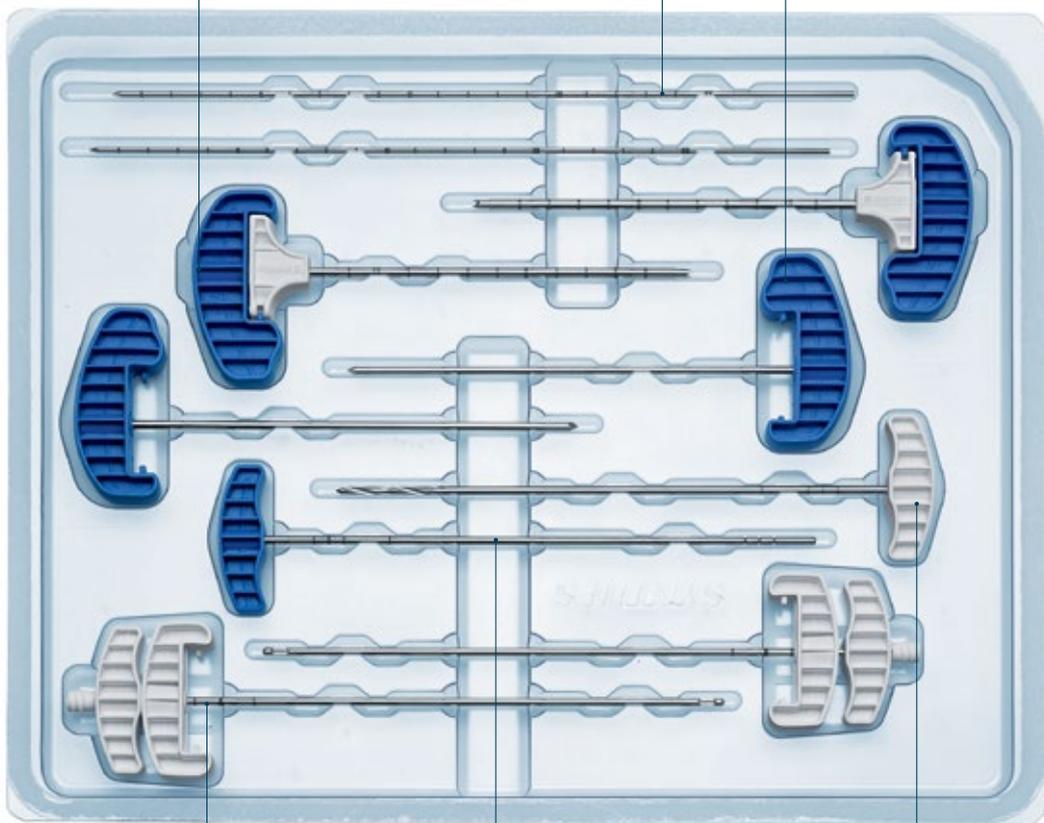
Minimally invasive, percutaneous, reconstructive treatment for vertebral body fractures.



## 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 03.804.6125

### Accessories (optional)

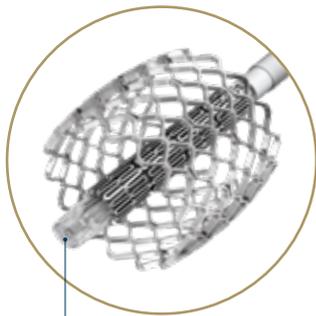
Biopsy Kit 03.804.6135





## 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.



### VERTEBRAL BODY BALLOON (VBB)

Instrument insertion through a stab incision allows performing the procedure under either local or general anaesthesia.



### CONTROLLED BALLOON DILATION 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.

## Inflation System

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



**Inflation System**  
03.804.413S

## Vertebral Body Stent Options

DESCRIPTION	PRE-INFLATED LENGTH	MAXIMUM VOLUME	INFLATED MAXIMUM PRESSURE		CODE
<b>VERTEBRAL BODY STENT</b>					
Small	22 mm	4.5 ml	30 ATM / 440 PSI		09.804.500S
Medium	27 mm	5.0 ml	30 ATM / 440 PSI		09.804.501S
Large	31 mm	5.5 ml	30 ATM / 440 PSI		09.804.502S
<b>VERTEBRAL BODY STENT WITH BALLOON</b>					
Small	22 mm	4.0 ml	30 ATM / 440 PSI		09.804.600S
Medium	27 mm	4.5 ml	30 ATM / 440 PSI		09.804.601S
Large	31 mm	5.0 ml	30 ATM / 440 PSI		09.804.602S



# VBS – Vertebral Body Stenting System

Minimally invasive, percutaneous, reconstructive treatment for vertebral body fractures.



## VBS – Vertebral Body Stenting System (continued)



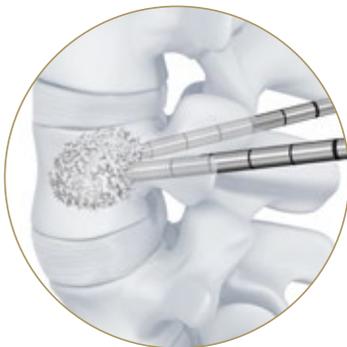
### **Optional Vertebral Body Balloon pre-cavity creation**

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**

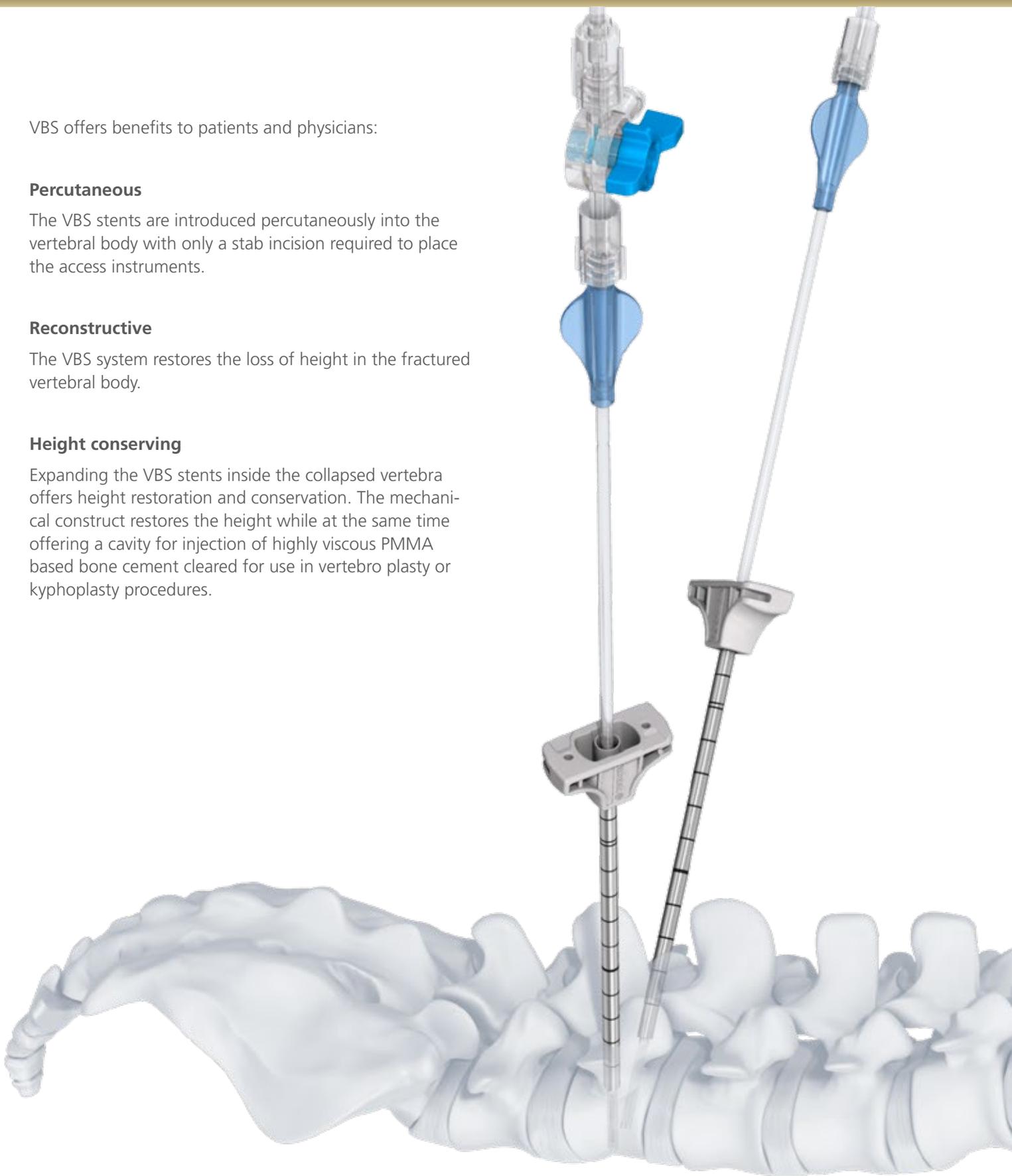
The VBS stents are introduced percutaneously into the vertebral body with only a stab incision required to place the access instruments.

### **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.



**Cement Delivery** - Refer to pages 12–13



# Cement Delivery



## 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** 07.702.0165



**VERTECEM V+ Syringe Kit** 03.702.215S



SYNJECT Cement Delivery System:

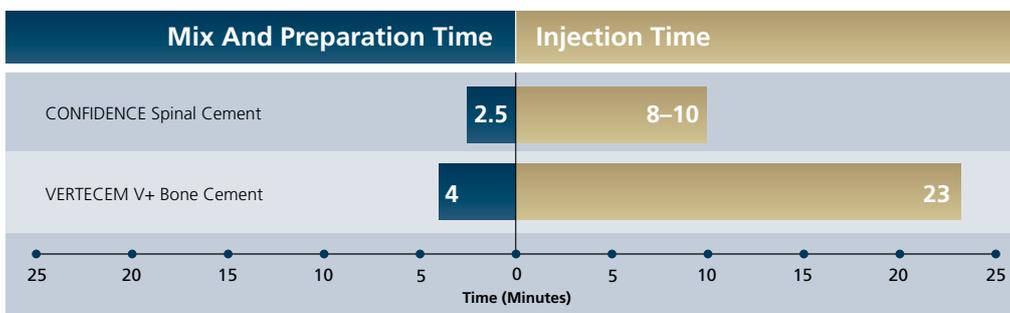
- Remote cement delivery to minimize physician exposure to radiation
- Hydraulic-based delivery system that allows for controlled and responsive cement flow with tactile feedback
- Dual line injection system for bi-lateral cement delivery
- Separately packaged single cartridge for additional cement delivery



**SYNJECT Single 1 x 9ML**  
03.702.5115



**SYNJECT Dual 2 x 9ML**  
03.702.5175



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

<b>1</b> <b>Bone Access</b>	CHOOSE ACCESS KIT	10G Access Kit, Diamond Tip, Double Pack	03.804.514S
		10G Access Kit, Beveled Tip, Double Pack	03.804.515S
		10G Access Kit, Diamond Tip, Single Pack	03.804.519S
		10G Access Kit, Beveled Tip, Single Pack	03.804.520S
	CHOOSE ACCESSORIES [OPTIONAL]	Access Drill 10G, [optional]	03.804.521S
	Biopsy Kit 10G, [optional]	03.804.522S	
<b>2</b> <b>Cavity Creation</b>	CHOOSE BALLOON(S)	SYNFLATE Balloon, Small	03.804.700S
		SYNFLATE Balloon, Medium	03.804.701S
		SYNFLATE Balloon, Large	03.804.702S
	ORDER INFLATION SYSTEM	Inflation System	03.804.413S
<b>3</b> <b>Cement Delivery</b>	ORDER CEMENT	CONFIDENCE Needleless Kit 11cc	283913000
		CONFIDENCE Needleless Kit 7cc	283907000
	ORDER ADAPTOR**	Luer Adaptor [Box of 10]	2839-99-002

\*\*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

### SYNFLATE Vertebral Balloon

<b>1</b> <b>Bone Access</b>	CHOOSE ACCESS KIT	10G Access Kit, Diamond Tip, Double Pack	03.804.514S
		10G Access Kit, Beveled Tip, Double Pack	03.804.515S
		10G Access Kit, Diamond Tip, Single Pack	03.804.519S
		10G Access Kit, Beveled Tip, Single Pack	03.804.520S
	CHOOSE ACCESSORIES [OPTIONAL]	Access Drill 10G, [optional]	03.804.521S
	Biopsy Kit 10G, [optional]	03.804.522S	
<b>2</b> <b>Cavity Creation</b>	CHOOSE BALLOON(S)	SYNFLATE Balloon, Small	03.804.700S
		SYNFLATE Balloon, Medium	03.804.701S
		SYNFLATE Balloon, Large	03.804.702S
ORDER INFLATION SYSTEM	Inflation System	03.804.413S	
<b>3</b> <b>Cement Delivery</b>	ORDER CEMENT <sup>†</sup>	VERTECEM V+, Cement Kit	07.702.016S
		VERTECEM V+, Syringe Kit	03.702.215S
		SYNJECT Single 1 x 9ML	03.702.511S
		SYNJECT Single 2 x 9ML	03.702.512S
		SYNJECT Dual 2 x 9ML	03.702.517S
		SYNJECT Cartridges, 1 x 9ML	03.702.520S

### Vertebral Body Stenting

<b>1</b> <b>Bone Access</b>	ORDER ACCESS KIT	Access Kit	03.804.612S
	CHOOSE ACCESSORIES [OPTIONAL]	Biopsy Kit	03.804.613S
<b>2</b> <b>Cavity Creation</b>	CHOOSE STENT(S)	Vertebral Body Stent, Small	09.804.500S
		Vertebral Body Stent, Medium	09.804.501S
		Vertebral Body Stent, Large	09.804.502S
	CHOOSE STENT WITH BALLOON(S)	Vertebral Body Balloon Stent with Balloon, Small	09.804.600S
		Vertebral Body Balloon Stent with Balloon, Medium	09.804.601S
	Vertebral Body Balloon Stent with Balloon, Large	09.804.602S	
ORDER INFLATION SYSTEM	Inflation System	03.804.413S	
<b>3</b> <b>Cement Delivery</b>	ORDER CEMENT <sup>†</sup>	VERTECEM V+, Cement Kit	07.702.016S
		VERTECEM V+, Syringe Kit	03.702.215S
		SYNJECT Single 1 x 9ML	03.702.511S
		SYNJECT Single 2 x 9ML	03.702.512S
		SYNJECT Dual 2 x 9ML	03.702.517S
		SYNJECT Cartridges, 1 x 9ML	03.702.520S

<sup>†</sup>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

	GAUGE	LENGTH	NEEDLES PER KIT	CODE	OPTIONAL BIOPSY	
<div style="display: flex; align-items: center; margin-bottom: 10px;"> <div style="background-color: #1a3d54; color: white; border-radius: 50%; width: 30px; height: 30px; display: flex; align-items: center; justify-content: center; margin-right: 10px; font-size: 24px; font-weight: bold;">1</div> <div> <p><b>Bone Access</b></p> <p>CHOOSE NEEDLE(S):</p> <p>-TIP</p> <p>-GAUGE</p> <p>-LENGTH</p> </div> </div>	CONFIDENCE Needles					
		DIAMOND 10G 11G 11G 13G 13G 15G	5" 4" 6" 4" 6" 4"	2 2 2 2 2 2	2839-03-510 2839-03-411 2839-03-611 2839-03-413 2839-03-613 2839-03-415	2839-01-913 2839-01-913 2839-01-915
		BEVELED 10G 11G 11G 13G 13G	5" 4" 6" 4" 6"	2 2 2 2 2	2839-02-510 <span style="background-color: #e0e0ff;">2839-02-411</span> 2839-02-611 <span style="background-color: #e0e0ff;">2839-02-413</span> 2839-02-613	2839-01-913 2839-01-913
	CONFIDENCE Introducer Needle					
		SIDE HOLE 11G 11G 13G 13G	4" 6" 4" 6"	2 2 2 2	2839-04-411 2839-04-611 2839-04-413 2839-04-613	
	Vertebroplasty Needle Kits					
		DIAMOND 8G 10G 12G	140 mm 120 mm 120 mm	2 2 2	03.702.216S 03.702.218S 03.702.220S	03.702.222S 03.702.223S
		BEVELED 10G 11G	120 mm 120 mm	2 2	03.702.219S 03.702.221S	03.702.223S
	Bone Access Needles					
		DIAMOND 8G 11G 11G 13G	140 mm 100 mm 150 mm 100 mm	1 1 1 1	03.702.240S 03.702.241S 03.702.244S 03.702.246S	03.702.250S 03.702.251S 03.702.252S
		BEVELED 11G 11G 13G	100 mm 150 mm 100 mm	1 1 1	03.702.243S 03.702.245S 03.702.247S	03.702.251S 03.702.252S

## VERTEBROPLASTY with CONFIDENCE or VERTECEM V+ Cement

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

### CONFIDENCE System Kit Configurations

DESCRIPTION	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"
Plus Kit 11cc	283910000	11cc	●	●	●	●	●	●
Needleless Kit 11cc	283913000	11cc	●	●	●	●		
Needleless Kit 7cc	283907000	7cc	●	●	●			

\*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 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

## 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

**Limited Warranty and Disclaimer:** DePuy Synthes 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.

Not all products are currently available in all markets.

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*Note: For recognized manufacturer, refer to product label.*



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