

## Competitor Overview: Vertebral Body Stenting System.

### Introduction

VBS System from Depuy Synthes Company is a treatment method for painful osteoporotic vertebral body fractures. In 2012, Johnson & Johnson completed the acquisition of Synthes, which was integrated with the Depuy franchise to establish the Depuy Synthes Companies of Johnson & Johnson. This new company has kept a portfolio of VCF products with inconsistent concepts.

Vertecem V+ Mid-Viscosity Cement*	≠	Confidence® High Viscosity Cement**
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Vertebroplasty  
≠  
Cavity creation

Synflate No implant	≠	VBS System Stent
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\*Deusser et al. Rheological and Curing Behavior of a Newly Developed, Medium Viscous Acrylic Bone Cement.  
ISRN Materials Science Volume 2011 (2011), Article ID 571728, 8 pages  
\*\*http://www.confidencespinalcement.com/default.aspx?tabid=275



## THE DEVICE

The objective is to deploy a stent (Cobalt Chromium Alloy stent) in the collapsed vertebral body using a balloon. Balloon and implant are simultaneously dilatated, expanding in all directions in the vertebral body, and by this creating a void.

### Vertebral Body Stent size

Vertebral Body Stent/Balloon	Max Stent expanded	Stent length expanded	Release length (VBB/VBS)
Small	15 mm	13 mm	22 mm
Medium	17 mm	15 mm	27 mm
Large	17 mm	20 mm	31 mm

- Stent deployment begins at a diameter of 4.2 mm.
- The minimum diameter deployment recommended is 11 mm.
- Need to consider Balloon size for Stent positioning. When fully deployed, the balloon will surpass approx. 5 mm at each side of the stent.

### Intended use

The VBS System is intended for the reduction of osteoporotic vertebral compression fractures only.

### Contraindications

A2 Split fractures and A.3.3 complete burst fractures.

### Indication

A1 and A3.1

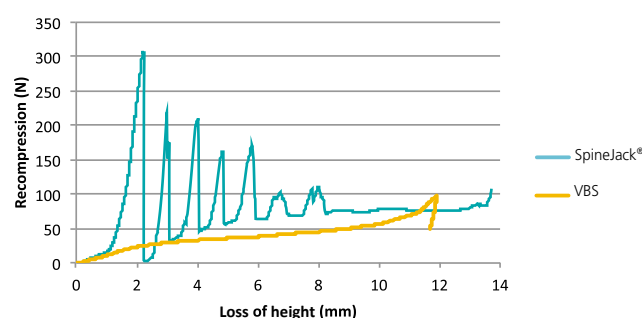
A.3.1 → A matter of the surgeon's own discretion depending on the degree of posterior wall involvement, additional posterior fixation must be used. In combination with posterior fixation: A.3.1 and A.3.2 burst-split fractures.

VBS System, without additional posterior fixation, is only intended to be used in osteoporotic A1 fractures.

## PRODUCT FEATURES

Anatomical restoration	VBS System	
Controlled Cranio-Caudal expansion	No	<ul style="list-style-type: none"> <li>No control during multidirectional balloon expansion</li> <li>Hydraulic system defines the pressure, but not the height of the implant</li> </ul>
Maintain the restoration	No	<ul style="list-style-type: none"> <li>Maximum of 100N of recompression forces (vs 300N for SpineJack®)*</li> </ul>
Preserve the trabecular bone	No	<ul style="list-style-type: none"> <li>Creation of a void into vertebral body</li> </ul>

\*Vexim internal R&D Tests



# STUDIES

## ■ Study Objective

The purpose of this prospective randomized clinical trial was to clarify whether there are differences between balloon kyphoplasty and vertebral body stenting with regard to relevant perioperative and postoperative findings

## PATIENT MATERIAL

		VBS	BKP
Number of patients	65		
Levels treated	100	50	50
Bone quality	Osteoporotic bone		
Type of Fractures	A.1.1, A.1.2, A.1.3 and A.3.1 cases		
Follow up Time	Post Op data		

## RESULTS

### Kyphosis Reduction\*

### Leakage Rate\*\*

### Radiation Time

### Mean Pressure (men/women)

### Total Complications

\* local vertebral angle used

\*\* in Rx and completed with CTscan in some cases

	VBS	BKP
Kyphosis Reduction*	4.7°	4.5°
Leakage Rate**	30%	20%
Radiation Time	116 sec	96 sec
Mean Pressure (men/women)	26/22 bar	18/15 bar
Total Complications	48%	22%

## CONCLUSIONS

- **No beneficial effect** of vertebral body stenting over BKP was found among patients with regard to kyphotic correction, cement leakage, radiation exposure time or neurologic sequelae.
- Vertebral body stenting was associated with **significantly higher pressures during balloon inflation and more material-related complications (18%)**.
- In two cases, the vertebral body stents did not open at all.

### Review article

#### Stentoplasty effectiveness and safety for the treatment of osteoporotic vertebral fractures: A systematic review

J.E. Martín-López<sup>a,\*</sup>, M.J. Pavón-Gómez<sup>b</sup>, A. Romero-Tabares<sup>a</sup>, T. Molina-López<sup>a</sup>

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Orthopaedics & Traumatology: Surgery & Research 101 (2015) 627–632.

## ■ Study Objective

A review of studies that included adults with osteoporotic VCFs treated with Vertebral Body Stenting (VBS) and the comparators were the intervention himself, balloon kyphoplasty (BKP) or vertebroplasty (VP). Five studies including 213 patients were finally evaluated.

## CONCLUSIONS

- **VBS is comparable to kyphoplasty** in terms of correction of kyphosis, and time of exposure to radiation.
- VBS has been associated with an **increase in the number of complications** related to the materials used during the procedure compared to BKP.
- Compared to VP, VBS has shown improvements in terms of vertebral height restoration, of kyphosis, and a lower cement leakage rate.
- The **technique of VBS is more demanding** compared to BKP and VP.

## ■ Study Objective

A review of the characteristics and methods of operation of three of the most common percutaneous vertebral augmentation systems for the treatment of osteoporotic VCF: Vertebral Body Stenting® (VBS), OsseoFix® and SpineJack®.

## CONCLUSIONS

The authors conclude that **SpineJack® is the only device suitable** for the treatment of VCFs due to osteoporosis, trauma and bone tumors considering the fact that:

- SpineJack® device includes a mechanical working system which allows a progressive and **controlled reduction** of the vertebral fracture.
- The SpineJack® system has a direct lift mechanism with the ability to produce a large force of elevation.
- It has been shown that the post-operative **increase in vertebral body height was greater in the SpineJack® group** compared to the kyphoplasty group (P<0.05).

### Review Article

#### Third-generation percutaneous vertebral augmentation systems

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# TAKE AWAY MESSAGE

- The device does not fulfill any of the 3 key design feature required for a successful anatomical restoration!
- Published results in JBJS shows that VBS had NO beneficial effect over BKP and,
- VBS was associated with material related complications as high as 18% (!).