Warning
This description alone does not provide sufficient background for direct use of the instrument set. Instruction by a surgeon experienced in handling these instruments and the attendance of a VBS training in order to know the VBS instrumentation and technique is highly recommended.

Reprocessing, Care and Maintenance of Synthes Instruments
For general guidelines, function control and dismantling of multi-part instruments, please refer to: www.synthes.com/reprocessing
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VBS is a safe treatment method for painful osteoporotic vertebral body fractures. It helps to prevent effects such as postural damage and pain caused by postural kyphosis.

VBS offers unique 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 bone cement for vertebroplasty or kyphoplasty.

Minimally invasive, percutaneous insertion of the Vertebral Body Stenting System
Instrument insertion through a stab incision allows performing the procedure under either local or general anaesthesia.
Restoration through dilatation and stent expansion
Simultaneous dilation of the bilaterally positioned VBS Stents offers an in situ controlled and continuous expansion.

Vertecem is a vertebroplasty PMMA bone cement for the treatment of osteoporotic vertebral body compression fractures.

- **Side-opening application cannulae** Controlled direction of cement injection
- **Viscosafe Viscometer** Simplifies bone cement preparation

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

**Controlled 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.
In 1958, the AO formulated four basic principles, which have become the guidelines for internal fixation\(^1\). They are:

- Anatomic reduction
- Stable fixation
- Preservation of blood supply
- Early, active mobilization

The fundamental aims of fracture treatment in the limbs and fusion of the spine are the same. But a specific goal of spine treatment is to restore as much function as possible to the injured neural elements.\(^1\)

**AO Principles as applied to the spine\(^2\)**

**Anatomical reduction**

Restoration of normal spine alignment improves the biomechanics of the spine and reduces pain by reestablishing and maintaining the natural curvature and the protective function of the spine.

**Stable internal fixation**

In the spine, the goal of internal fixation is to maintain not only the integrity of a mobile segment, but also to maintain the balance and the physiologic three-dimensional form of the spine. A stable spinal segment allows bony fusion at the junction of the lamina and pedicle.

**Preservation of blood supply**

The proper atraumatic technique enables minimal retraction or disturbance of the nerve roots and dura, and maintains the stability of the facet joints. The ideal surgical technique and implant design minimize damage to anatomical structures, i.e. facet capsules and soft tissue attachment remain intact, and create a physiological environment that facilitates healing.

**Early, active mobilization**

The ability to restore normal spinal anatomy may permit the immediate reduction of pain, resulting in a more active, functional patient. The reduction in pain and improved function can result when a stable spine is achieved.

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Indications and Contraindications

The VBS system is designed to treat painful vertebral body compression fractures and is an alternative to conventional therapies.

**Intended use**
The VBS System is intended for the reduction of osteoporotic vertebral compression fractures and/or creation of a void in cancellous bone in the spine for the treatment of levels ranging from Th10-L5. It is intended to be used in combination with a legally-marketed PMMA bone cement indicated for use in vertebroplasty or kyphoplasty procedures.

**Indications**
Osteoporotic vertebral compression fractures from Th10-L5 without involvement of the posterior vertebral edge classified after Genant, Grade 2 and Grade 3 with a kyphotic angulation of more than 15°.

– Fractures without the involvement of the posterior vertebral edge, 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

**Contraindications**
– Fractures that need internal fixation:
  A2 Split fractures
  A3.3 Complete burst fracture
  B1.1 Posterior disruption predominantly ligamentous with transverse disruption of the disc
  B2.1 Transverse bicolumn fracture
  B2.2 Posterior disruption predominantly osseous with disruption of the disc
  B3 Anterior disruption through the disc
  All C types
Preoperative Planning

**Patient assessment**
Requirements for assessing the indication:
- Current X-ray images, if possible in standing position, of the thoracic and lumbar spine in two planes to assess the fracture and spinal alignment
- A spiral CT or MRI scan (ideally with STIR frequency) of the painful region of the spine
- If an MRI scan is contraindicated a bone scan may identify an acute fracture
- Ruling out another cause of pain
- Feasibility of surgery and use of anaesthesia
- Ruling out impaired clotting

**Warning:** The patient should be checked for allergy to the contrast medium.

**Planning of stent placement**
The placement of the stents should be planned based on the AP image which gives hints for the route of insertion.

**Intraoperative X-ray imaging**
The Vertebral Body Stent must be implanted using X-ray on both planes, two C-arms, or with one freely mobile C-arm.
Preparation

Instrument preparation

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<th>03.804.412S Vertebral Augmentation Access Kit</th>
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<td>Instruments and implants</td>
<td>03.804.413S VBS Inflation System</td>
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</table>

The VBS inflation system has an angled manometer that shows the pressure in the balloon in pounds/inch\(^2\) (psi) and atmospheres (atm). The volume scale on the fluid chamber measures milliliters (ml).

It is necessary to prepare two VBS inflation systems.

1. **Connect VBS inflation system to connector**
   Attach the tube of the VBS inflation system with the Luer connector to the supplied 3-way connector as shown. Rotate the knob on the 3-way connector to position the “off” indicator towards the lateral outlet (1).

2. **Fill VBS inflation system**
   Fill the VBS inflation system with saline solution and a liquid contrast medium.

   **Note:** It is essential to fill the VBS inflation system with saline/contrast agent mixture to ensure better visibility of the VBS balloon catheter during inflation. The ratio of contrast medium to saline solution should be at least 1:2, and preferably 1:1.

   Prepare the contrast medium mixture in a cup and place the 3-way connector under the solution. Push forward on the white wings on the VBS inflation system and pull back on the handle until the plunger bottoms out. With the handle pointing upwards, tap the unit to clear the gauge portion of the inflation system of air (2).
Then hold the VBS inflation system with the handle facing downward, and rotate the handle clockwise to expel all the air in the barrel until solution starts to emerge. Keep turning the handle clockwise until the leading edge of the red mark on the plunger reaches to approximately 2 to 3 ml under the zero marking (3).

3. Close VBS inflation system
Rotate the knob on the 3-way connector to place the “off” indicator towards the inflation system (4).

The VBS inflation system has now been prepared accordingly and can be set aside. Repeat for the second VBS inflation system.

**Tip:** The white wings may be pushed to unlock the plunger when large changes to the handle position are desired. The handle must be moved carefully to avoid overshooting the desired target.
**Preparation**

**Anatomical landmarks**

For vertebral body augmentation with VBS, the stents should be placed in a symmetrical, paramedian position within the affected vertebra to achieve optimum reduction of the spinal fracture without damaging the lateral vertebral body edges. Ideally, the distance from the compressed endplate to the stents should be about 5 mm (1).

The position of the stents needs to be planned based in pre-operative imaging. Take care to achieve the planned position by determining the landmarks accordingly.

The following landmarks have to be defined on the spine:
- Both pedicles
- Spinous process
- Endplates
- Posterior wall of vertebral body
Patient Positioning

Place the patient in the prone position on a lumbar support. The table must be radiolucent in both planes.

The OR table should allow free manipulation of the C-arm over the operative site in both planes.
Access Options

There are two access options to the fractured vertebral body, depending on its anatomy:

1. **Transpedicular access**
   As a general rule, the bilateral skin incisions for the transpedicular approach are 1–2 cm lateral and up to 1 cm cranial to the centre of the pedicle (1).

2. **Extra-/Parapedicular access**
   The bilateral skin incisions for the extra-/parapedicular technique are planned according to the anatomical situation (2).

The instruments for inserting the VBS system can be placed using either a guide wire or a trocar. In the chapter "Instrument Positioning" each procedure is explained for a transpedicular and an extra-/parapedicular access.

For positioning instruments with guide wires see page 13.
For positioning instruments with trocar see page 20.
Instrument Positioning
A With Guide Wires

Set

03.804.412S Vertebral Augmentation Access Kit

First the guide wires are positioned. The other instrumentation follows the path created by the guide wires.

Once the anatomical landmarks are detected, the guide wires can be percutaneously introduced through skin incisions using X-ray control (AP and lateral).

Either a transpedicular or extra-/parapedicular access may be selected depending on the anatomy of the vertebral body to be treated.

Note: With either access technique it is important to plan to place the two stents symmetrically towards the midline and the anterior wall of the vertebral body at a medial location. In this position the stents have room to expand without pressing against either the lateral wall, or the other stent (1).
1

**Position guide wires**

Make the skin incisions.

Under AP and lateral X-ray control insert the guide wires to the superior outer pedicle quadrant using slight manual pressure.

Once the guide wires touch bone the outlines of the lateral pedicle are reached. Drive both guide wires with controlled blows from a hammer through the cortex. Cautiously advance the guide wires into the center of the vertebral body.

The tips of the guide wires should be about and not closer than 5 mm to the anterior wall of the vertebral body. They should be positioned symmetrically and aligned in both AP and lateral views. Confirm this placement for the positioning of the stents.

**Warning:** The tips of the guide wires must not pass the mid-line wall in AP view until they have passed the posterior wall in the lateral view. When advancing the guide wires, ensure that they are not inserted too far medially, to avoid penetration into the spinal canal. It is also essential to avoid overdri-ving the guide wires into vascular structures beyond the an-terior cortical wall.
2
**Position working sleeves over guide wires**

Place a working sleeve over a side-opening cannula (1). Push the instrument assembly with a twisting motion over the first guide wire (2).

**Warning:** Do not insert the working sleeve into the bone without the side-opening cannula. This could damage the working sleeve and obstruct stent insertion. Do not hammer on the side-opening cannula.

There is clearance between the diameter of the guide wire and the side-opening cannula to allow for minor correction in the trajectory when positioning the working sleeve. This can lead to a slight resistance when penetrating the bony vertebral body surface (3).
Monitor working sleeve placement under lateral X-ray control. Ensure that the tip of the working sleeve has passed the pedicle and is positioned inside the vertebral body.

Note: When inserting the working sleeve, carefully monitor the position of the guide wire to confirm that it is not advancing forward.

Repeat on the contra-lateral side (4).

Once both working sleeves are in place, remove the side-opening cannulae and the guide wires (5).

The working sleeves remain in the vertebral body.

Warning: It is important to advance the instrument assembly carefully in order to avoid any injury to the physician’s hand. The guide wire is longer than the combined length of the working sleeve and the side-opening cannula and will protrude through the handle of the side-opening cannula (6).
**A2 Extra-/Parapedicular Access**

1 **Position guide wires**

Make the skin incisions.

- Under AP and lateral X-ray control, insert the guide wires using slight manual pressure.

Insert both guide wires up to the vertebral body and drive them with controlled blows from a hammer through the cortex. Should you touch bone before reaching the vertebral body you have reached the outline of the lateral pedicle.

Cautiously advance the guide wires and, if necessary, redirect in order to reach the center of the vertebral body. The tips of the guide wires should be about and not closer than 5 mm to the anterior wall of the vertebral body.

- **Warning:** The tips of the guide wires must not pass the midline in AP view until they have passed the posterior wall in the lateral view. When advancing the guide wires, ensure that they are not inserted too far medially, to avoid penetration into the spinal canal. It is also essential to avoid overdriving the guide wires into vascular structures beyond the anterior cortical wall.
2

Positioning working sleeves over guide wires

Place a working sleeve over a side-opening cannula (1). Push the instrument assembly with a twisting motion over the first guide wire (2).

**Warning:** Do not insert the working sleeve into the bone without the side-opening cannula. This could damage the working sleeve and obstruct stent insertion. Do not hammer on the side-opening cannula.

There is clearance between the diameter of the guide wire and the side-opening cannula to allow for minor correction in the trajectory when positioning the working sleeve. This can lead to a slight resistance when penetrating the bony vertebral body surface (3).
Monitor working sleeve placement under lateral X-ray control. Advance the tip of the working sleeve until it has penetrated the cortex and is tightly seated into the bone.

Note: When inserting the working sleeve, carefully monitor the position of the guide wire to confirm that it is not advancing forward.

Repeat on the contra-lateral side (4).

Once both working sleeves are in place, remove the side-opening cannulae and the guide wires (5).

The working sleeves remain in the vertebral body.

Warning: It is important to advance the instrument assembly carefully in order to avoid any injury to the physician’s hand. The guide wire is longer than the combined length of the working sleeve and the side-opening cannula and will protrude through the handle of the side-opening cannula (6).
Instrument Positioning
B With Trocars

Set

03.804.412S  Vertebral Augmentation Access Kit

When using trocars for instrument positioning, creating the pathway and positioning of the instrumentation is achieved in one step.

Either a transpedicular or extra-/parapedicular access may be selected depending on the anatomy of the vertebral body to be treated.

**Note:** With either access technique it is important to plan to place the two stents symmetrically towards the midline.
Make skin incisions.

Place a working sleeve over a side-opening cannula. Place the trocar through the side-opening cannula and lock it into place with a clockwise rotation (1).

Under AP and lateral X-ray control insert the instrument assembly through the skin incision to the superior outer pedicle quadrant using slight manual pressure and a twisting motion. If necessary the instrument assembly can be inserted through the cortex with light impaction on the metal end of the trocar using a hammer (2).

**Tip:** Pull back the side-opening cannula to verify the positioning of the working sleeve.

**Warning:** When advancing the instrument assembly, ensure that the trocar tip is not inserted too far medially, to avoid penetration into the spinal canal. It is also essential to avoid overdriving the trocar tip into vascular structures beyond the anterior cortical wall.

Hold the working sleeve in place and carefully rotate and remove the trocar and the side-opening cannula. The working sleeve remains in the vertebral body.

**Repeat for the contra-lateral side (3).**

**Warning:** Do not insert the working sleeve into the bone without the side-opening cannula and trocar. This could damage the working sleeve and obstruct stent insertion.

Do not redirect the instrument assembly without removing it and re-accessing the pedicle.
Make skin incisions.

Place a working sleeve over a side-opening cannula. Place the trocar through the side-opening cannula and lock it into place with a clockwise rotation (1).

Under AP and lateral X-ray control insert the instrument assembly through the skin incision into the vertebral body using slight manual pressure and a twisting motion. If necessary the instrument assembly can be inserted through the cortex with light impaction on the metal end of the trocar using a hammer (2).

Advance the instrument assembly so that the opening of the working sleeve is anterior to the posterior wall of the vertebral body.

**Warning:** When advancing the instrument assembly, ensure that the trocar tip is not inserted too far medially, to avoid penetration into the spinal canal. It is also essential to avoid overdriving the trocar tip into vascular structures beyond the anterior cortical wall.

Hold the working sleeve in place and carefully rotate and remove the trocar and the side-opening cannula. The working sleeve remains in the vertebral body (2).

**Repeat for the contra-lateral side (3).**

**Warning:** Do not insert the working sleeve into the bone without the side-opening cannula and trocar. This could damage the working sleeve and obstruct stent insertion.

Do not redirect the instrument assembly without removing it and re-accessing the bone.
Create access channel for stents

Set

03.804.412S  Vertebral Augmentation Access Kit

Guide the drill (1) or alternatively the blunt plunger (2) through the working sleeves to create an access channel for the stents.

**Warning:** Use lateral image intensification to avoid penetrating the anterior cortex of the vertebral body. It is essential to avoid overdriving these instruments into vascular structures beyond the anterior cortical wall.

The plunger can be driven forward with light hammer blows. Ensure that the hammer blows hit the protruding metal pin and not the handle (2).

**Warning:** Do not use a hammer to drive the drill forward. The drill may aggressively advance with rotation.

**Warning:** When manipulating drill and/or plunger, it is important to ensure that the working sleeves do not move.

Repeat on the contra-lateral side.
2

**Determine length of stents**

The Vertebral Body Stents are available in two sizes:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>09.804.401S</td>
<td>Vertebral Body Stent, Ø 17 mm × 15 mm</td>
</tr>
<tr>
<td>09.804.402S</td>
<td>Vertebral Body Stent, Ø 17 mm × 20 mm</td>
</tr>
</tbody>
</table>

Both the drill and the plunger have two grooves towards their distal tips that correspond to the two stent lengths (1).

Use lateral imaging to select the length of the stent on the basis of these grooves.

- One groove visible: 15 mm stent
- Two grooves visible: 20 mm stent

Establish the stent size on both sides, they may differ.

Remove the stents from the sterile packaging. Carefully remove the packaging wire and dispose of it (2).

There is a marking ring on the balloon catheter shaft indicating the stent position when inserted into the working sleeve (2).
Connecting balloon catheters to inflation systems

Instrument
03.804.413S  VBS Inflation System

Connect the prepared VBS inflation systems with the selected stents using the Luer connector. Rotate the knob on the 3-way connector to place the “off” indicator towards the lateral side opening (1).

Note: It is important to ensure that all Luer connectors are securely attached. Loose connections may result in inaccurate filling volumes and pressures.

Push the white wings on the VBS inflation system forward to unlock the handle. Pull the handle all the way back, and release the wings to lock the handle in position. This pulls air out of the catheter, creating a vacuum inside it. The vacuum can be monitored on the display “vac” (2).
Close the balloon catheter with the 3-way connector by positioning the “off” indicator towards the catheter. This retains the vacuum inside the catheter (3).

Turn the handle clockwise in order to set the volume scale to zero. This is done by turning the handle until the red ring on the plunger is precisely at “0”(4).
Rotate the knob on the 3-way connector to position the “off” indicator towards the lateral side opening. This allows flow from the VBS inflation system into the VBS balloon catheter (6).

**Tip:** Suspend the 3-way connector over a receptacle for all steps that involve expelling excess solution.
4 Insert and display stents

Insert the balloon catheter with the attached stent under lateral X-ray control. Stop insertion when the white indicator on the catheter shaft is aligned with the top of the working sleeve. Check the position under X-ray control and confirm the desired position under AP view (1).

Repeat for the contra-lateral side.

**Note:** Simultaneous dilation of bilateral devices is essential for optimal device performance.

**Warning:** It is essential to use AP and lateral X-rays to track stent expansion.

Slowly increase pressure and volume by rotating the handles of the bilaterally connected inflation systems in a clockwise direction.
Proceed slowly after the stents begin expanding at 12 atm (2). Match the expansion bilaterally by tracking the fluid volume on the scales. When the pressure reaches 26 atm, continue dilation gradually. Wait a few seconds then slowly continue until the desired stent diameter is reached (3). The maximum stent diameter is 17 mm.

Stop increasing pressure when any of the following happens:
1. Desired vertebral body height or angle is reached
2. Pressure reaches 30 atm
3. Volume reaches maximum
   – 5 ml for 15 mm stent
   – 5.5 ml for 20 mm stent

**Warning:** Do not fill the balloons over their maximum volume or pressure. If this is done, they may leak.

Once the expansion is stopped, record the volume of solution used indicated on the inflation system.
5
Retrieve balloon catheters

To maintain maximum stent expansion, gradually decrease the pressure simultaneously on both sides. Slowly turn the handles of the inflation systems counter-clockwise to draw the liquid out of the balloon catheter (1). Once the pressure has reached 10 atm, push the white wings forward, slowly pull the handle back all the way, and release the white wings (2). This draws and holds a vacuum in the catheter and collapses the balloon for its smooth removal.

Hold the working sleeves in place and pull firmly on the catheters to retrieve the balloons. Rotate the catheters if needed to ease balloon removal. The stents remain in the vertebral body.

Verify the position of the bilaterally positioned stents under AP and lateral X-ray control.

**Tip:** If the expansion is inadvertently asymmetric, the balloon catheter can be repositioned in the stent and used for further expansion.

**Note:** If the contrast medium/saline solution mixture leaks when the stents are expanded, it may be more difficult to remove the balloon catheters through the working sleeves. If necessary remove the balloon catheters together with the working sleeves.
Inject PMMA bone cement

Additional stent augmentation with a legally marketed PMMA bone cement is mandatory.

After implantation of the stents, inject PMMA cement bilaterally.

Insert the side-opening cannulae into the working sleeves. Connect the syringes. The volume of cement required can be estimated from the volume of inflation medium needed for stent expansion (1).

It is mandatory to monitor cement flow under real-time x-ray control.

Cement should be injected until it infiltrates the surrounding bone around the stent. For safer cement application a high viscosity cement should be used (2).

It is recommended to use Vertecem PMMA bone cement.

Vertecem is a PMMA bone cement to treat osteoporotic vertebral body compression fractures:
- **Side-opening application cannulae**
  The direction of the cement injection can be controlled by manipulating the side-opening Vertecem cannulae.
- **Viscosafe Viscometer**
  The Viscosafe Viscometer provides visual and acoustic signals for viscosity.
2

Remove side-opening needles and working cannulae

Wait until the cement has fully hardened. Observe the bone cement manufacturer’s instructions as the hardening times for PMMA cements can greatly vary.

Usually instruments used for the cement injection can be removed approximately 2–3 minutes after the last injection of PMMA bone cement by twisting the instrument assembly several times to sever the cement bridge.

Suture the wound with tight stitches for hemostasis.

Postoperative procedure

To compress the wound the patient should be placed in a supine position for an hour after surgery. Bruising may occur at the puncture sites. The patient can then be mobilized at discretion.
Implants

09.804.401S  VBS Vertebral Body Stent,
Ø 17 mm × 15 mm

The stent reaches a length of 15 mm when fully extended up to its maximum diameter of 17 mm. The stent expansion starts at a diameter of 4.2 mm.

The recommended minimum expansion diameter is 11 mm. The VBS inflation system dilates the VBS balloon catheter, gradually expanding it.

The maximum capacity for the VBS balloon catheter is 5 ml.

09.804.402S  VBS Vertebral Body Stent,
Ø 17 mm × 20 mm

The stent reaches a length of 20 mm when fully expanded up to a maximum diameter of 17 mm. The stent expansion starts at a diameter of 4.2 mm.

The recommended minimum expansion diameter is 11 mm. The VBS inflation system dilates the VBS balloon catheter, gradually expanding it.

The maximum capacity for the VBS balloon catheter is: 5.5 ml
Instruments

03.804.412S  Vertebral Augmentation Access Kit

Contents:
2 × Cannulae with Side Opening, with Luer lock (length 134 mm)
2 × Internal Sleeves with Side Opening, with Luer lock (8 gauge)

2 × Guide Wires, with Depth Markings
2 × Trocar
2 × Vertebral Augmentation Access Working Sleeve

1 × Vertebral Augmentation Access Drill
1 × Vertebral Augmentation Access Plunger

03.804.413S  VBS Inflation System
Optional Instruments

399.410 Hammer, 300 g

Vertecem System

07.702.010 Vertecem Mixing Kit

07.702.210 Viscosafe Injection Kit

03.702.010 Viscosafe Viscosimeter*

* Optional


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