VBS – VERTEBRAL BODY STENTING SYSTEM

Minimally invasive, percutaneous, reconstructive treatment for vertebral body fractures

This publication is not intended for distribution in the USA.
This description alone does not provide sufficient background for direct use of DePuy Synthes products. Instruction by a surgeon experienced in handling these products is highly recommended.

**Processing, Reprocessing, Care and Maintenance**

For general guidelines, function control and dismantling of multi-part instruments, as well as processing guidelines for implants, please contact your local sales representative or refer to:

http://emea.depuysynthes.com/hcp/reprocessing-care-maintenance

For general information about reprocessing, care and maintenance of Synthes reusable devices, instrument trays and cases, as well as processing of Synthes non-sterile implants, please consult the Important Information leaflet (SE_023827) or refer to:

http://emea.depuysynthes.com/hcp/reprocessing-care-maintenance
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VBS – VERTEBRAL BODY STENTING SYSTEM.
MINIMALLY INVASIVE, PERCUTANEOUS,
RECONSTRUCTIVE TREATMENT FOR VERTEBRAL
BODY FRACTURES.

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.

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 based bone cement cleared for use in vertebroplasty or kyphoplasty procedures.

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.

Vertebral Body Balloon (VBB)
Simulate stent expansion in the vertebral body prior to VBS insertion.
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.

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 PMMA based bone cement for the treatment of vertebral compression fractures:
- About 27 minutes of working time
- Excellent X-ray visibility
The four principles to be considered as the foundation for proper spine patient management underpin the design and delivery of the Curriculum: Stability – Alignment – Biology – Function.

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**INDICATIONS AND CONTRAINDICATIONS**

**Intended use**
The VBS System is intended for the reduction of painful vertebral compression fractures and/or creation of a void in cancellous bone in the spine for the treatment of levels ranging from Th5-L5. It is intended to be used in combination with a legally-marketed PMMA\(^1\) based bone cement adequately indicated for use in vertebroplasty or kyphoplasty procedures.

*Note:* Refer to the manufacturer’s directions accompanying the bone cement for specific information on its use, precautions and warnings.

**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

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\(^1\) Note: Due to limited long-term efficacy data, the treating physician should weigh the benefits of the application of the PMMA based bone cement in younger patients against the potential risks.
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 and 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

Note: It is important, to treat only patients with non-consolidated fractures.

Warning: The patient should be checked for allergy to the contrast medium and stent material (CoCrWNi alloy).

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.

Pre-planning of stent size
The stent size for the procedure can roughly be planned preoperatively via CT scan.

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.

The VBS System may only be used with an X-ray control with a device that offers a high image quality.
Instrument preparation

Instrument Set

03.804.612S  Access Kit 4.7 mm

Instrument

03.804.413S  Inflation System

The inflation system has an angled manometer that shows the pressure in the balloon in pounds/inch² (psi) and atmospheres (atm). The volume scale on the fluid chamber measures milliliters (ml).

It is necessary to prepare two inflation systems.

1. Connect inflation system to connector
Attach the tube of the 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 inflation system
Fill the inflation system with saline solution and a liquid contrast medium.

Note: It is essential to fill the 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 about 1:2.

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 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 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 3 to 4 ml under the zero marking or until the red marker on the plunger is aligned with the black line above the ml sign, underneath the zero marking (3).

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

Warning: If the buttons (white wings) do not return to the locked position, do not force them as this could damage the plunger. Turn the handle gently, and the buttons (white wings) will return automatically to the locked position.
Anatomical landmarks
For vertebral body augmentation with VBS, the two stents per vertebra should be placed in a symmetrical, paramedian position within the affected vertebral body 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 preoperative 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.
Instrument options

| 03.804.612S | Access Kit, 4.7 mm |

The access instruments (guide wire or trocar) can be inserted through either a transpedicular or extrapedicular approach.

**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.
Option A. Transpedicular

Under fluoroscopy, determine the location of the incision. The incision should facilitate insertion directly through the pedicle. As a general rule, the location of the skin incision for the transpedicular approach is 1–2 cm lateral and up to 1 cm cranial to the centre of the pedicle.

Make a skin incision.

Under fluoroscopy, insert the tip of the access instrumentation through the incision until it contacts the base of the transverse process. Confirm the proper trajectory, then advance the instrumentation through the pedicle and into the vertebral body.

Precaution: Landmarks for placing the access instrumentation must be respected. The tips of the access instrumentation must not pass the midline wall in AP view until they have passed the posterior wall in the lateral view. When advancing the access instrumentation, ensure that they are not inserted too far medially, to avoid penetration into the spinal canal. Also, it is essential to avoid overdriving the access instrumentation tip into vascular structures beyond the anterior cortical wall. The tip of the access instrumentation should not be closer than 5 mm to the anterior cortical wall of the vertebral body.

Note: If considering a transpedicular approach, ensure that the diameter of the pedicle is large enough to be punctured by the 4.7 mm access instrumentation.
Option B. Extrapedicular

Under fluoroscopy, determine the location of the skin incision according to the anatomical situation. The access instrumentation assembly should enter the vertebral body lateral to the pedicle.

Make a skin incision.

Under fluoroscopy, insert the tip of the access instrumentation through the incision until it contacts the posterolateral border of the vertebral body. Confirm the proper trajectory, and then advance the instrumentation into the vertebral body in order to reach the center of the vertebral body.

Precaution: It is essential to avoid overdriving the access instrumentation tip into vascular structures beyond the anterior cortical wall. The tip of the access instrumentation should not be closer than 5 mm to the anterior cortical wall of the vertebral body.
Access options include trocar or guide wire access. The trocar allows access in a single step while the guide wire is first used to create a path for the access instruments.

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.

Option A. Trocar

Either a transpedicular or extrapedicular access may be selected depending on the anatomy of the vertebral body to be treated.

To position the working sleeve, insert the access construct into the vertebral body in a single step.

The trocar instrumentation (trocar in working sleeve) can be assembled by removing the pre-assembled cannulated trocar followed by inserting the trocar into the working sleeve. Once inserted, lock the assembly by turning the blue handle clockwise (1).

Under fluoroscopy, insert the trocar instrumentation until the end of the working sleeve is tightly seated approximately 3 mm into the vertebral body (2). The end of the working sleeve can be identified by locating the step in diameter between trocar and the working sleeve.
The sleeves are marked with equidistant depth markers to allow monitoring of the insertion process. If necessary, carefully hammer on the blue handle of the trocar to gently advance the trocar instrumentation.

**Precautions:**
- Ensure that the trocar instrumentation does not breach the anterior wall of the vertebral body.
- Only hammer on the blue plastic handles of the access instrumentation.

Confirm proper positioning of the access instrumentation under fluoroscopy in both AP and lateral view.

**Warning:** Do not redirect the instrument assembly without removing it and re-accessing the vertebral body.

Repeat on the contralateral side (3).

**Note:** Hold the working sleeve(s) in place and carefully remove the trocar(s) leaving the working sleeve(s) in the vertebral body (4).
Option B. Guide Wire

Insert the guide wire to create the access path, and position appropriately (1). Insert the working sleeve and cannulated trocar assembly over the guide wire and into the vertebral body (2).

Under fluoroscopy, position the tip of the guide wire approximately 5 mm from the anterior wall of the vertebral body in the lateral view. The guide wires are marked with equidistant depth markers to allow monitoring of the insertion process. Monitor the guide wire position with fluoroscopy while inserting the working sleeve and cannulated trocar assembly over the guide wire, until the end of the working sleeve is tightly seated approximately 3 mm into the vertebral body. The end of the working sleeve can be identified by locating the step in diameter between trocar and the working sleeve.

The sleeves are marked with equidistant depth markers to allow monitoring of the insertion process. If necessary, carefully hammer on the blue handle of the cannulated trocar to gently advance the instrumentation.

Precautions:
- Under fluoroscopy, while advancing the cannulated trocar, ensure that neither the guide wire nor the cannulated trocar breaches the anterior wall of the vertebral body at any time.
- Make sure that the opening on the plastic handle of the cannulated trocar is cleared at all times while advancing the cannulated trocar in order to avoid obstruction of the guide wire passage.
- Only hammer on the blue plastic handles of the access instrumentation.
- The guide wire will extend out the back of the handle. Advance the instruments carefully to avoid injury to the physician’s hand.
Confirm proper positioning of the access instrumentation under both AP and lateral fluoroscopy.

Repeat on the contralateral side (3).

**Note:** Hold the working sleeve(s) in place and carefully remove the guide wire and cannulated trocar leaving the working sleeve(s) in the vertebral body (4).

**Warnings:**
- Do not redirect the instrument assembly without removing it and re-accessing the vertebral body.
- Do not use excessive force on the guide wire to avoid potentially deforming the guide wire.
After placement of the working sleeve (see chapters Approach and Access before), an optional biopsy can be taken using the biopsy kit.

**Instrument**

| 03.804.613S | Biopsy Kit 4.7 mm |

Remove plunger from the biopsy needle.

- **Under fluoroscopy, insert the biopsy needle.** The tip of the biopsy needle leaves the working sleeve when the first marking on the shaft of the needle disappears into the working sleeve (1).

- **Under fluoroscopy, advance the biopsy needle further and rotate it at least one full turn (360°).** This will help to remove the biopsy.

**Warning:** Do not insert the biopsy needle beyond the anterior cortical wall of the vertebral body, as this could damage vascular structures.

If desired attach a syringe to the biopsy needle to create a vacuum to retain the bone biopsy in the needle. Remove the biopsy needle with, or without the attached syringe from the working sleeve.

**Note:** Hold the working sleeve in place and carefully remove the biopsy needle leaving the working sleeve in the vertebral body.
Use the biopsy plunger to push the collected bone tissue out of the biopsy needle (2).
CREATE ACCESS CHANNEL

**Instrument Set**

03.804.612S Access Kit 4.7 mm

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

**Warning:** Use lateral X-ray 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.

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

The plunger can be driven forward with light hammer blows.

**Warning:** While using drill or plunger, it is important to ensure that the working sleeves do not move. Do not use the drill or plunger to manipulate or correct the direction of the working sleeve.

**Repeat on the contralateral side.**
**DETERMINE LENGTH OF STENT**

The Vertebral Body Stents and Balloons are available in three sizes:

<table>
<thead>
<tr>
<th>Vertebral Body Stent/Balloon</th>
<th>Article No.</th>
<th>Max Stent Ø</th>
<th>Stent length expanded</th>
<th>Release length (VBB/VBS)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>09.804.500S</td>
<td>15 mm</td>
<td>13 mm</td>
<td>22 mm</td>
</tr>
<tr>
<td></td>
<td>09.804.600S</td>
<td>17 mm</td>
<td>15 mm</td>
<td>27 mm</td>
</tr>
<tr>
<td></td>
<td>09.804.501S</td>
<td>17 mm</td>
<td>20 mm</td>
<td>31 mm</td>
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The plunger has three grooves towards the distal tip that correspond to the three stent lengths (1).

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

From distal tip the first groove visible:
Vertebral Body Stent Small
From distal tip the second groove visible:
Vertebral Body Stent Medium
From distal tip the third groove visible:
Vertebral Body Stent Large

Establish the stent size on both sides, they may differ.
OPTIONAL: USE OF VBB

If you do not intend to use the VBB please continue to page 31 chapter “Using the VBS catheter”.

The VBS System can optionally be used with a Vertebral Body Balloon (VBB). The VBB allows simulating the stent expansion when bone quality, age of the fracture or the fracture/lesion mobility of the vertebral body is unknown.

1 Unpacking the VBB Catheter

Remove the VBB catheter from the sterile packaging (1).

Note: Slide back the white cover sleeve towards the Luer connector and attach it properly to the luer (2). This cover sleeve can be used later for stretching and folding back the VBB after catheter removal for reuse.

Do not remove the stiffening wire from the VBB catheter. The stiffening wire will be removed and the creation of the vacuum will be performed after the insertion of the VBB catheter on the patient. This is different compared to the VBS catheter insertion.

There is a white marking range on the balloon catheter shaft indicating release length, i.e. the overall length and both proximal and distal balloon shoulders segments when the white marking range is completely inserted into the working sleeve.

The VBB can be reused once within one surgery.

Warning: Only use the VBB of same size together with the corresponding VBS.

Note: The shaft marker indicates when balloon is fully inserted, use X-ray while inflating with contrast media.
**Insertion of the VBB catheter**

Insert the VBB catheter under lateral X-ray control.

**Note:** The full release (initial) length of the VBB is outside when the proximal end of the white marking of the catheter shaft disappears into the working sleeve.

Check the position under X-ray control and confirm the desired position under AP view (1). It is important, that the whole balloon portion is positioned completely inside the vertebra and that these inflatable segments have completely passed through the working sleeve. Make sure to position the VBB according to the anticipated VBS position.

**Repeat for the contralateral side.**

**Note:** Simultaneous dilatation of bilateral inserted VBBs is recommended for optimal performance.

**Note:** Make sure to position the VBB according to the anticipated VBS position.
### 3 Connecting VBB catheter to inflation system and create vacuum

**Instrument**

| 03.804.413S | Inflation System |

Remove stiffening wire prior to connecting the VBB to the inflation system and keep it.

**Note:** Stiffening wire will be used for balloon refolding (in conjunction with the cover sleeve) and reinsertion.

Connect the prepared inflation systems with the selected VBB catheters using the Luer connector (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 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).

**Warning:** If the buttons (white wings) do not return to the locked position, do not force them as this could damage the plunger. Turn the handle gently, and the buttons (white wings) will return automatically to the locked position.
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).

Hold the inflation system with the handle facing downward and 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).
INFLATION OF VBB

This flushes out the excess saline solution/contrast medium mixture and air through the lateral opening of the three-way connector (5).

**Tip:** Suspend the 3-way connector over a receptacle for all steps that involve expelling excess solution. If vacuuming on the patient, use absorbent cotton to soak up any expelled excess solution.

Rotate the knob on the 3-way connector to position the “off” indicator towards the lateral side opening. This allows flow from the Inflation system into the VBB balloon catheter (6).
1

Inflation of VBB

*Note:* Simultaneous dilatation of bilateral devices is recommended for optimal performance.

*Warning:* It is essential to use AP and lateral X-rays to track VBB expansion via the balloon contrast media solution inflation fluid.

Slowly increase pressure and volume by rotating the handles of the connected inflation systems in a clockwise direction on both sides.

Proceed slowly after each VBB balloon unfolds and starts expanding (1). Match the expansion bilaterally by tracking the fluid volume on the syringe body with the black volume markers positioned in ml increments. When the pressure reaches and increases beyond 26 atm, continue dilatation gradually. Wait a few seconds then slowly continue until the desired VBB diameter is reached (2). The maximum stent diameter is 15 mm for VBB Small and 17 mm for both VBB Medium and VBB Large.

Stop balloon expansion when any of the following happens:

1. Desired vertebral body height or angle is reached
2. Pressure reaches 30 atm (400 PSI)
3. VBB volume reaches maximum
   - 4.0 ml for VBB Small
   - 4.5 ml for VBB Medium
   - 5.0 ml for VBB Large

*Note:* The VBB expansion pressure and volume on the inflation system have to be monitored carefully on the inflation system’s phosphorescent manometer (units: bar/atm, PSI) and syringe body with black volume markers (units: ml/cc), respectively.
Warning: Do not fill the balloons over their maximum volume or pressure. If this is done, they may leak.

Warning: VBB maximum volumes differ from VBS maximum volumes!

Note: In case of contrast medium leakage, pull vacuum, insert stiffening wire and remove balloon, don’t reuse balloon.

2 Retrieve balloon catheters

Slowly turn the handles of the inflation systems counterclockwise 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.
Aerate the VBB catheter by first positioning the “off” indicator towards the catheter (1) and second turn back towards the lateral side opening (1 inset).

Disconnect the inflation system from the VBB catheter.

**Note:** Carefully insert the stiffening wire into the VBB catheter under X-ray control.

Apply a gentle force in order to stretch the deflated balloon prior to removal of the catheter (2). Make sure not to damage the VBB catheter by pushing too hard.

Hold the working sleeves in place and pull carefully on the catheters to retrieve the balloons. Rotate the catheters if needed to ease balloon removal.

**Note:** The VBB catheter can be re-used once within one surgery. Make sure by visual inspection that the VBB catheter has not been damaged.

**Warning:** do not use a VBB catheter when a visual damage is observed, or when a leak is evident.

**Warning:** If balloon-catheter material is remaining in vertebral body after removal of the VBB do not leave it implanted. The balloon-catheter material is not implant grade material.
Note: If the VBB catheter is planned to be reused within the same surgery, cover the re-folded balloon of the VBB catheter with the white cover sleeve (3) and reinsert stiffening wire to gently straighten the balloon.
Note: The fracture must be mobile in order for height restoration to be possible. In order to simulate stent expansion use optional VBB (s. page 22).

1 Unpacking the VBS Catheters

Remove the VBS catheter from the sterile packaging. Carefully remove the stiffening wire and put it aside for possible further use.

If preferred, the stiffening wire can also be removed after the insertion of the balloon catheter. If this method is chosen, the creation of the vacuum has to be performed after the insertion of the balloon catheter on the patient.

There is a white marking range on the balloon catheter shaft indicating the release length, i.e. the overall length including the stent and both proximal and distal balloon shoulders segments, when the white marking range is completely inserted into the working sleeve.
2
Connecting VBS catheter to inflation system and create vacuum

Instrument

03.804.413S Inflation System

Connect the prepared inflation system with the selected VBS balloon-catheters using the Luer connector (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 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).

Warning: If the buttons (white wings) do not return to the locked position, do not force them as this could damage the plunger. Turn the handle gently, and the buttons (white wings) will return automatically to the locked position.
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).

Hold the inflation system with the handle facing downward and 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).
Using the VBS Catheter

Thisflushes out the excess saline solution/contrast mediummixture and air through the lateral opening of the three-way connector (5).

**Tip:** Suspend the 3-way connector over a receptacle for all steps that involve expelling excess solution. If vacuuming on the patient, use absorbent cotton to soak up any expelled excess solution.

Rotate the knob on the 3-way connector to position the “off” indicator towards the lateral side opening. This allows flow from the inflation system into the VBS balloon catheter (6).
1

Insert and deploy stents
Insert the balloon catheter with the attached stent under lateral X-ray control. The full release (initial) length of the balloon with stent is outside the working sleeve when the proximal end of the white marking of the catheter shaft disappears into the working sleeve. Check the position under X-ray control and confirm the desired position under AP view (1). It is important, that the whole balloon portion including the stent is positioned completely inside the vertebra and that these parts have completely passed through the working sleeve.

Repeat on the contralateral side.

Note: Simultaneous dilatation of bilateral devices is essential for optimal device performance. Once stent expansion has begun the stent cannot be undeployed or repositioned. The system has been validated by simultaneously implanting two stents to ensure optimal intraoperative load capacities.

Warning: It is essential to use AP and lateral X-rays to track stent expansion and balloon shoulder inflation via the radiopacity due to the stent and the balloon contrast media solution inflation fluid, respectively.

Slowly increase pressure and volume by rotating the handles of the connected inflation system in a clockwise direction on both sides.
Proceed slowly after the stents begin expanding at approx. 12 atm (2). Match the expansion bilaterally by tracking the fluid volume on the scales. When the pressure reaches 26 atm, continue dilatation gradually. Wait a few seconds then slowly continue until the desired stent diameter is reached (3). The maximum stent diameter is 15 mm for VBS Small and 17 mm for both VBS Medium and VBS Large.

Stop balloon inflation when any of the following happens:
1. Desired vertebral body height or angle is reached
2. Pressure reaches 30 atm
3. VBS volume reaches maximum
   – 4.5 ml for VBS Small
   – 5.0 ml for VBS Medium
   – 5.5 ml for VBS Large

Note: The VBS expansion pressure and volume on the inflation system have to be monitored carefully on the inflation system’s phosphorescent manometer (units: bar/atm, PSI) and syringe body with black volume markers (units: ml/cc), respectively.

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

Warning: VBS maximum volumes differ from VBB maximum volumes.

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

To maintain maximum stent expansion, gradually decrease the pressure simultaneously on both sides. Slowly turn the handles of the inflation system 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 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 on 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 stent expansion is inadvertently asymmetric or if a balloon leaks, the intact balloon catheter from the contralateral side can be reinserted in the vertebral body on the ipsilateral side and be repositioned in the stent and can be reused for further expansion. In that case, disconnect the inflation system from the balloon catheter, carefully insert the stiffening wire and replace the balloon catheter through the working sleeve in the vertebral body. Carefully monitor the insertion under lateral X-ray control. Stop insertion when the top end of the white range 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. Ensure that the stent does not move while switching the balloon-catheter. Remove the stiffening wire and reconnect the inflation system, repeat the steps of creating a vacuum and re-inflate the balloon as described in this section.
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 or insert the stiffening wire for removal.

Warning: If balloon material is remaining in vertebral body after removal of the VBS balloon do not leave it implanted. The balloon material is not implant grade material.
1. Preparation of injection needle

Remove the injection needle assembled with the clip from package (1a).

**Precaution:** Move the clip to the starting marker position identified in image (1b). In this position, the distal tip of the injection needle is in line with the distal end of the working sleeve after insertion.

2. Insertion of injection needle

Under fluoroscopy, insert the injection needle with clip into the working sleeve (2) and fix the clip to the working sleeve.

**Notes:**
- Do not use the grey colored biopsy kit for cement application.
- Check the compatibility of the PMMA based bone cement with the injection needle prior to PMMA based bone cement application.

The filling volume of the injection needle is 1.8 ml.
3 Inject PMMA based bone cement

Additional cement augmentation with a legally marketed PMMA based bone cement adequately indicated for use in vertebroplasty or kyphoplasty procedures is mandatory.

Connect a cement delivery system via the luer lock (3). The volume of cement required can be estimated from the volume of balloon inflation fluid medium needed for VBB or VBS expansion.

Repeat on the contralateral side.

Under lateral fluoroscopy, inject the PMMA based bone cement bilaterally. The direction of the PMMA based bone cement flow can be changed by orienting the handle of the injection needle with the side-opening. Make sure to apply the appropriate amount of PMMA based bone cement according to the surgical situation.

**Warning:** Cement should be injected until it infiltrates the surrounding cancellous bone around the cavity created by the balloon or the stent. For safer cement application, high viscosity cement should be used (4).

**Tip:** The side-opening cement outflow window can be closed by turning the cannula.

**Notes:**
- Check the position of the side-opening while injecting the PMMA based bone cement. The arrow on the handle of the injection needle indicates the position of the side opening.
- Alternately fill both sides in increments. It is important to see the filling behavior of both needles. Once the filling of one side is accomplished, the lateral view of the opposite side may be hidden by the cement, which makes monitoring the flow more difficult.
**Warning:** Closely monitor the PMMA based bone cement injection under fluoroscopy to reduce the risk of PMMA based bone cement leakage. Severe leakage can cause death or paralysis. If PMMA based bone cement leakage is observed during the procedure, STOP injecting and consider the following: wait for the injected PMMA based bone cement to harden, reposition the needle, adjust the needle direction, or stop the procedure. If desired, continue PMMA based bone cement injection slowly, and carefully evaluate for further leakage. If further leakage is observed, cease PMMA based bone cement injection.

4. **Remove injection needles and working sleeves**

Refer to the system’s instructions for proper use and waiting times required prior the removal of injection needle and working sleeves.

**Warning:** The timing of the release of the PMMA based bone cement is dependent on the PMMA based bone cement selection. Its preparation, injection and setting times vary by product, refer to the system's instructions prior to surgery and plan accordingly. If the injection needle with the working sleeve is removed too early, there may be a risk of pulling cement fibers into the muscle tissue. If the injection needle is removed too late the injection needle may not or only hardly be removed.

**Precaution:** Leave both injection needles inserted while applying the PMMA based bone cement to avoid backflow into the working sleeve.

Close the wound.
## Vertebral Body Stent

<table>
<thead>
<tr>
<th></th>
<th>09.804.500S VBS Small</th>
<th>09.804.501S VBS Medium</th>
<th>09.804.502S VBS Large</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Release (initial) length</strong></td>
<td>22 mm</td>
<td>27 mm</td>
<td>31 mm</td>
</tr>
<tr>
<td><strong>Stent length expanded</strong></td>
<td>13 mm</td>
<td>15 mm</td>
<td>20 mm</td>
</tr>
<tr>
<td><strong>Max Ø expanded</strong></td>
<td>15 mm</td>
<td>17 mm</td>
<td>17 mm</td>
</tr>
<tr>
<td><strong>Max volume</strong></td>
<td>4.5 ml</td>
<td>5.0 ml</td>
<td>5.5 ml</td>
</tr>
<tr>
<td><strong>Max pressure</strong></td>
<td>30 bar/atm</td>
<td>30 bar/atm</td>
<td>30 bar/atm</td>
</tr>
</tbody>
</table>
**Vertebral Body Stent with Balloon**

The Vertebral Body Stent with Balloon consists out of a double pack containing one VBS and one corresponding VBB catheter.

The respective sizes are Small, Medium and Large:

<table>
<thead>
<tr>
<th>VBS</th>
<th>VBB</th>
</tr>
</thead>
<tbody>
<tr>
<td>Small</td>
<td>with Balloon</td>
</tr>
<tr>
<td>Medium</td>
<td>with Balloon</td>
</tr>
<tr>
<td>Large</td>
<td>with Balloon</td>
</tr>
</tbody>
</table>

09.804.600S  09.804.601S  09.804.602S

The dimensions of the VBS are as described on page 42 and the respective VBB are:

<table>
<thead>
<tr>
<th></th>
<th>Small Balloon</th>
<th>Medium Balloon</th>
<th>Large Balloon</th>
</tr>
</thead>
<tbody>
<tr>
<td>Release (initial)</td>
<td>22 mm</td>
<td>27 mm</td>
<td>31 mm</td>
</tr>
<tr>
<td>Max ø expanded</td>
<td>15 mm</td>
<td>17 mm</td>
<td>17 mm</td>
</tr>
<tr>
<td>Max volume</td>
<td>4.0 ml</td>
<td>4.5 ml</td>
<td>5.0 ml</td>
</tr>
<tr>
<td>Max pressure</td>
<td>30 bar/atm</td>
<td>30 bar/atm</td>
<td>30 bar/atm</td>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
<td></td>
<td></td>
</tr>
<tr>
<td>--------------</td>
<td>-------------------------------------------------------</td>
<td></td>
<td></td>
</tr>
<tr>
<td>03.804.612S</td>
<td>Access Kit 4.7 mm</td>
<td></td>
<td></td>
</tr>
<tr>
<td>03.804.613S</td>
<td>Biopsy Kit 4.7 mm, (optional)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>03.804.413S</td>
<td>VBS Inflation System</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- 2× Cement needle with Clip
- 2× Guide Wires, with Depth Markings
- 2× Trocar
- 2× Cannulated trocar
- 2× Vertebral Body Stent Access Working Sleeve
- 1× Vertebral Body Stent Access Drill
- 1× Vertebral Body Stent Access Plunger
Optional Instruments

399.410  Hammer, 300 g

292.210S  Kirschner Wire Ø 2.0 mm
with trocar tip, length 280 mm,
Stainless Steel, sterile
PMMA BASED BONE CEMENTS

VERTECEM™ V+ System –
Stabilize with extra time

07.702.016S  Vertecem V+ Cement Kit
Containing:
1× Vertecem V+ Mixer pre-filled with cement powder
1× Monomer glass ampoule

03.702.215S  Vertecem V+ Syringe Kit
Containing:
8× Blue 1 ml syringes
5× White 2 ml syringes
1× one-way stop cock


