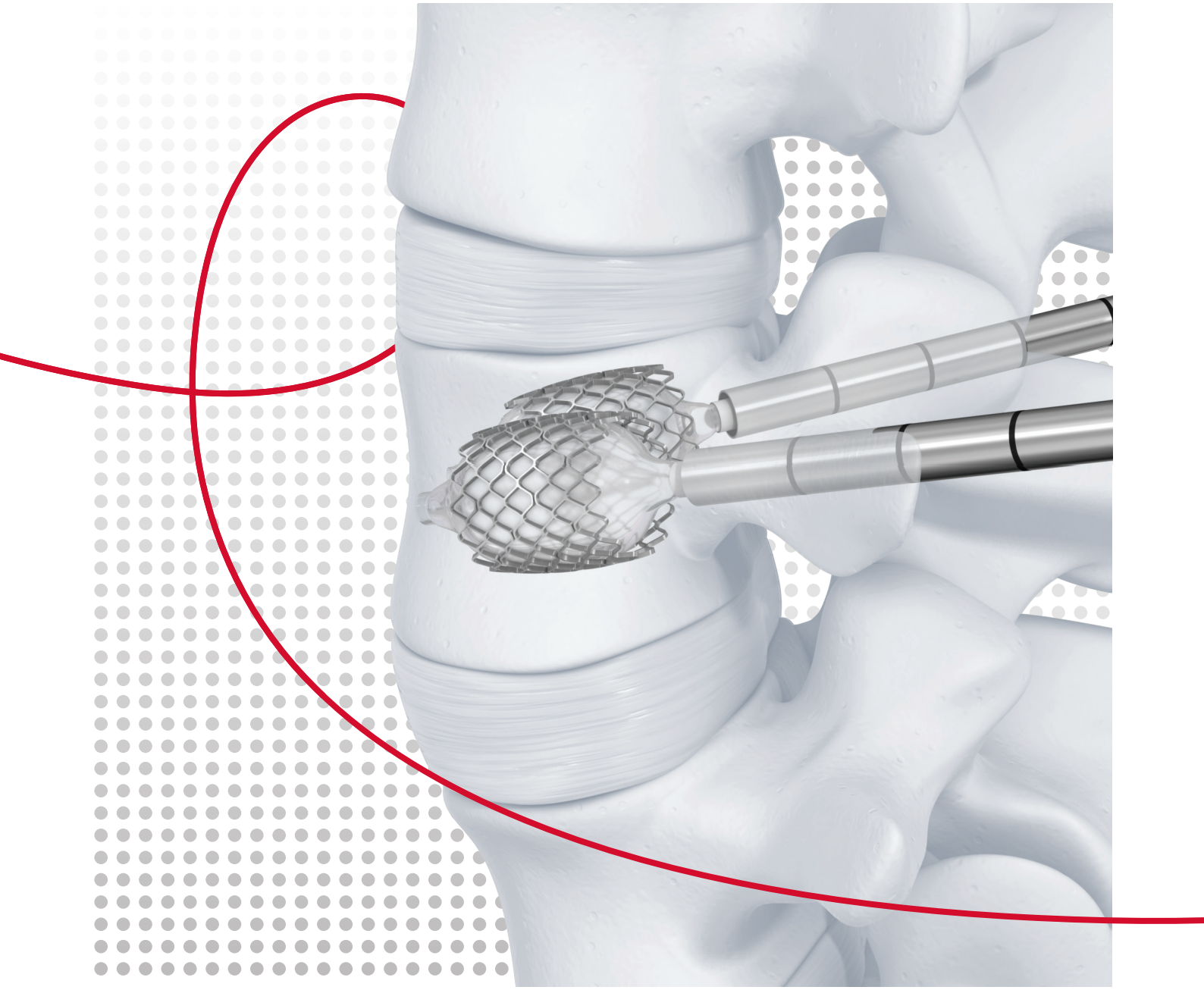
VBS

VERTEBRAL BODY STENTING SYSTEM

Surgical Technique Guide

Percutaneous treatment for vertebral body fractures



DePuy Synthes

THE ORTHOPAEDICS COMPANY OF Johnson & Johnson

Image Intensifier Control

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

Table of Contents

AO Spine Principles

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.[1,2]

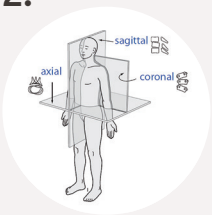
AO Principles

1.

Stability

Stabilization to achieve a specific therapeutic outcome.

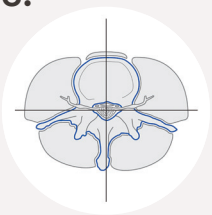
2.



Alignment

Balancing the spine in three dimensions.

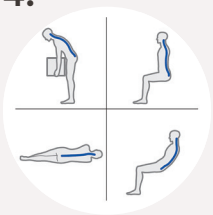
3.



Biology

Etiology, pathogenesis, neural protection, and tissue healing.

4.



Function

Preservations and restoration of function to prevent disability.

Preoperative Planning

Planning of stent placement

The placement of the stents should be planned based on the AP and lateral image which helps identify the proper insertion path.

Pre-planning of stent size

The stent size for the procedure can be approximated by using MRI or radiographs during preoperative planning.

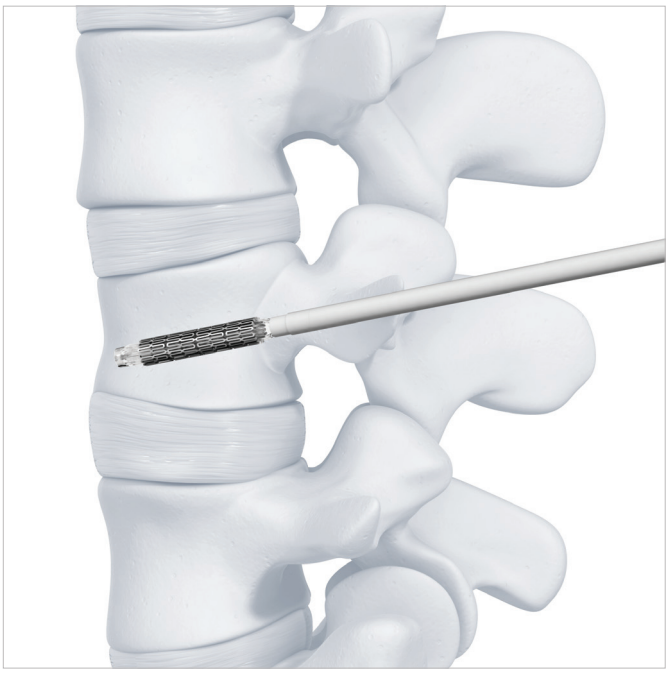
▲ Precaution:

Before using the VBS System ensure that the size is suitable for the specific procedure. See page 18 for details on sizes available.

Intraoperative X-ray imaging

The Vertebral Body Stent must be applied under fluoroscopic control in both planes with two C-arms, or one freely mobile C-arm.

The VBS System may only be used with high quality fluoroscopic imaging.



▲ Precaution:

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

▲ Warning:

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

Preparation

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.

▲ Precaution:

It is essential to fill the inflation system with saline/ contrast medium mixture to ensure visibility of the VBS balloon catheter during inflation.

▲ Precaution:

It is essential to observe the manufacturer’s instructions on the indications, use, and safety measures for the contrast medium.

▲ Precaution:

Only inflate the balloon with liquid, water-soluble, ionic or non-ionic contrast medium. VBS/VBB has been tested with a maximum iodine concentration of 320 mg/ml. Contrast media may have different viscosity and precipitation levels that may influence inflation and deflation times; therefore, a mixture ratio of contrast medium to saline solution of 1:2 is recommended.

1

Prepare the saline/contrast 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 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.

2

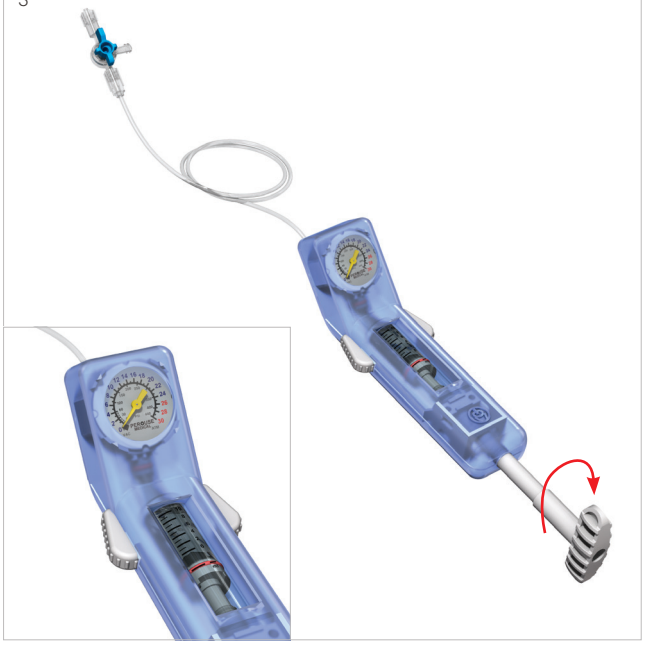
▲ Precaution:

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.

3

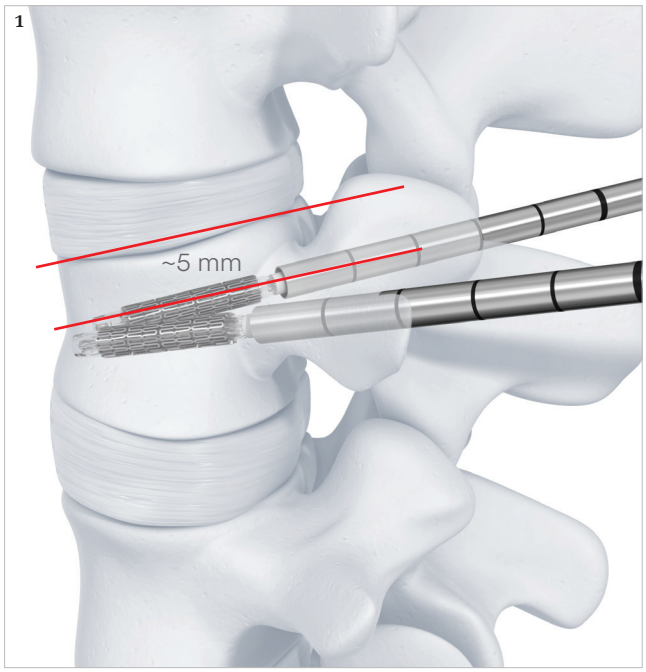


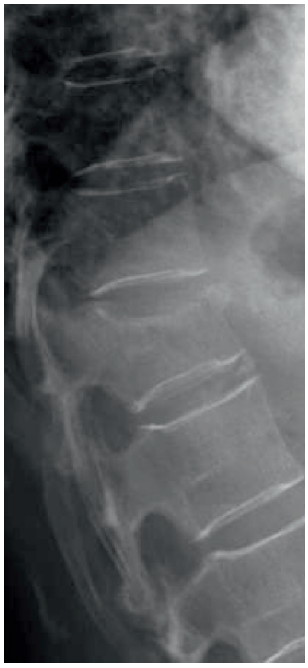
Anatomical landmarks

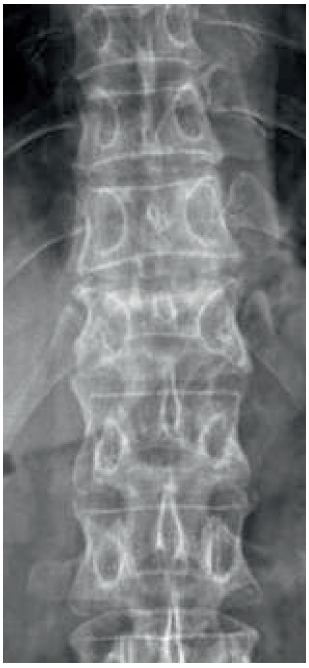
For vertebral body augmentation with VBS, the two stents per vertebra should be placed in a symmetrical, paramedian position within the affected vertebral body to achieve optimum reduction of the spinal fracture without damaging the lateral vertebral body edges. Ideally, the distance from the compressed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

The position of the stents needs to be planned based on preoperative imaging. Take care to achieve the planned position by determining the landmarks accordingly.

The following landmarks have to be identified on the biplanar fluoroscopic images:
- Both pedicles;
- Spinous process;
- Endplates;
- Posterior wall of vertebral body.



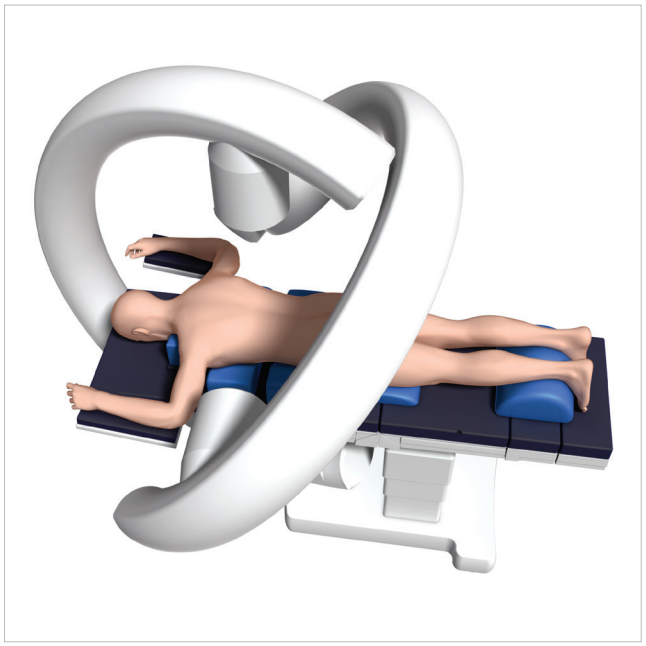




Patient Positioning

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.



Approach

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.

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.

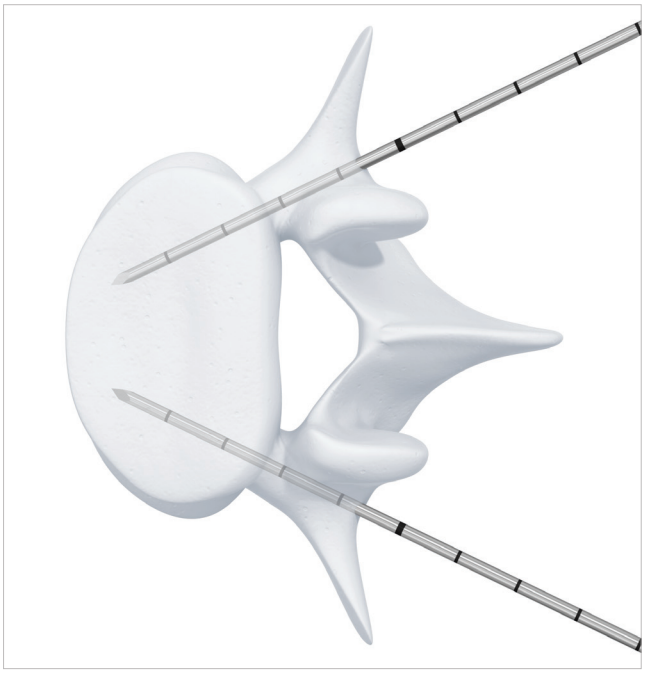
Make a skin incision.

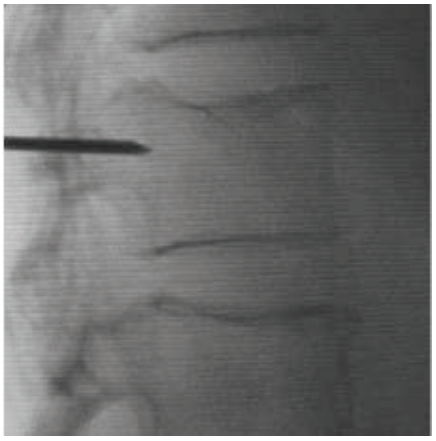
Under fluoroscopy, insert the tip of the access instrumentation through the incision until it contacts the base of the transverse process. Confirm the proper trajectory, then advance the instrumentation through the pedicle and into the vertebral body.

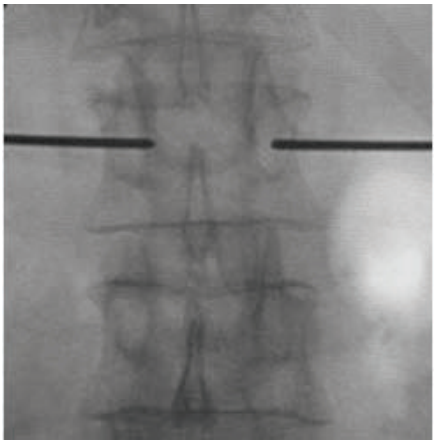
▲ Warnings:

- Landmarks for placing the access instrumentation must be respected. The tips of the access instrumentation must not pass the medial wall of the pedicle 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.
- True AP and lateral images are required to ensure accurate assessments.

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.

▲ Warnings:

- 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.
- True AP and lateral images are required to ensure accurate assessments.

Access

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.

▲ Precaution:

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

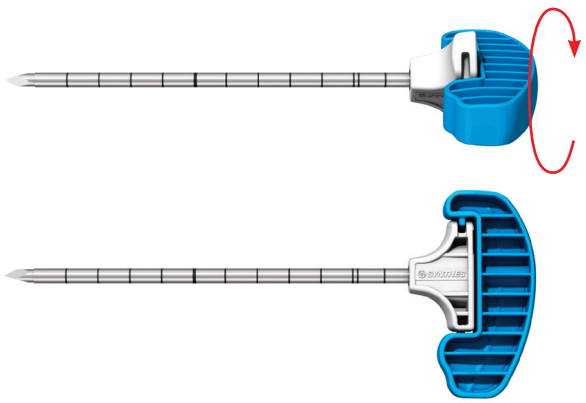
Either a transpedicular or extrapedicular access may be selected depending on the anatomy of the vertebral body to be treated.

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.

1



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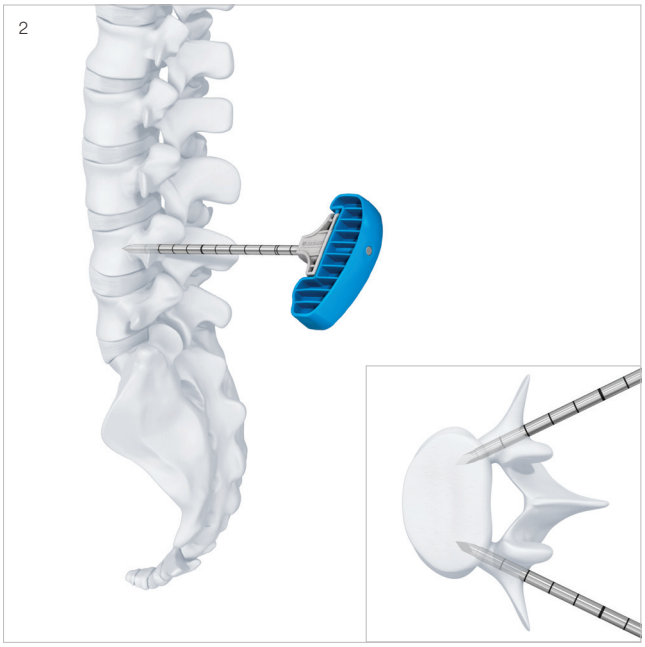


The sleeves are marked with equidistant depth markers to allow monitoring of the insertion process. If necessary, carefully hammer on the blue handle of the trocar to gently advance the trocar instrumentation.

▲ Warnings:

- **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.

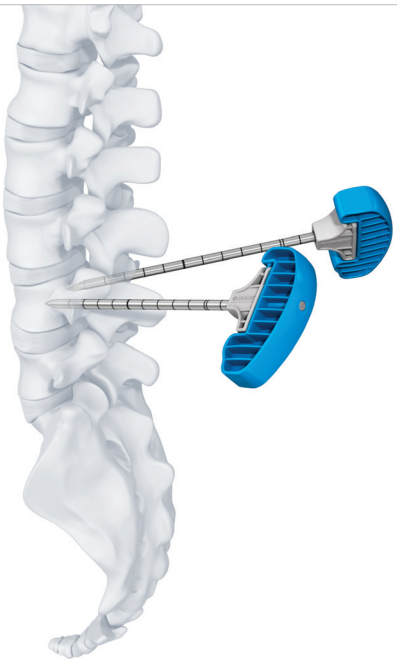
▲ Warning:

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

Repeat on the contralateral side (3).

Hold the working sleeve(s) in place and carefully remove the trocar(s) leaving the working sleeve(s) in the vertebral body (4).

3



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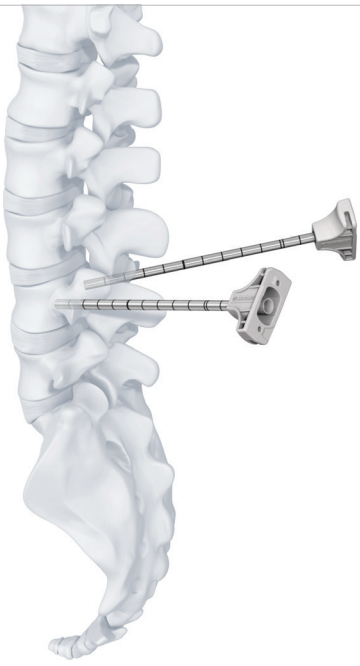


Option B. Guide Wire

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).

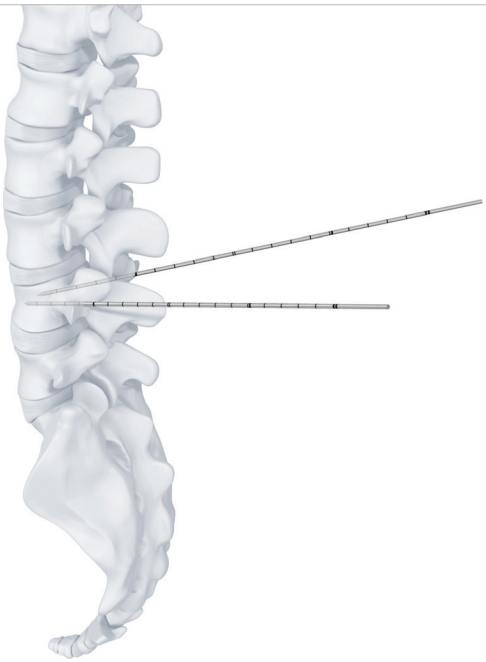
Under fluoroscopy, position the tip of the guide wire approximately 5 mm from the anterior wall of the vertebral body in the lateral view. The guide wires are marked with equidistant depth markers to allow monitoring of the insertion process. Monitor the guide wire position with fluoroscopy while inserting 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.

▲ Warnings:

- Use lateral fluoroscopy 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.
- True AP and lateral images are required to ensure accurate assessments.
- 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.
- Be sure to maintain the position of the guide wire to prevent it from advancing or backing out inadvertently.

1



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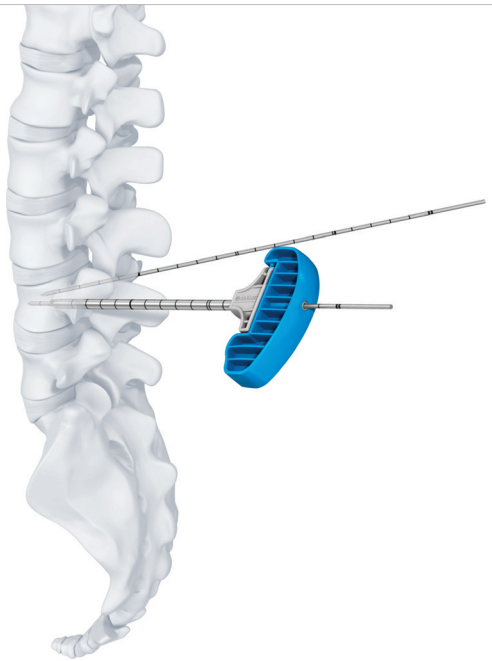


Confirm proper positioning of the access instrumentation under both AP and lateral fluoroscopy.

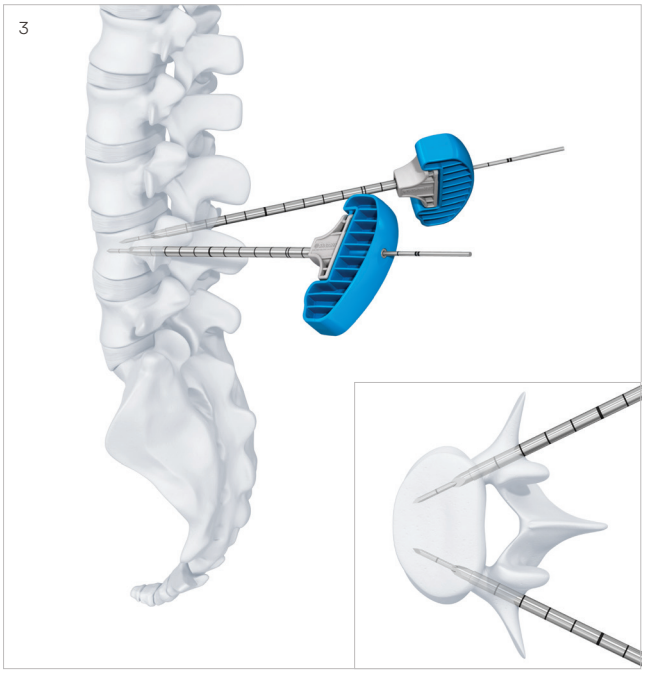
Repeat on the contralateral side (3).

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.**

3



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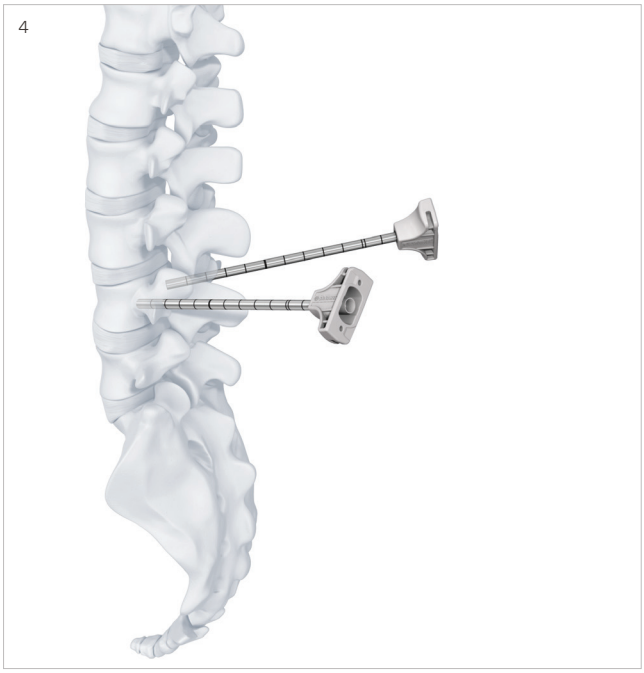


Biopsy

After placement of the working sleeve (see chapters Approach and Access), 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.

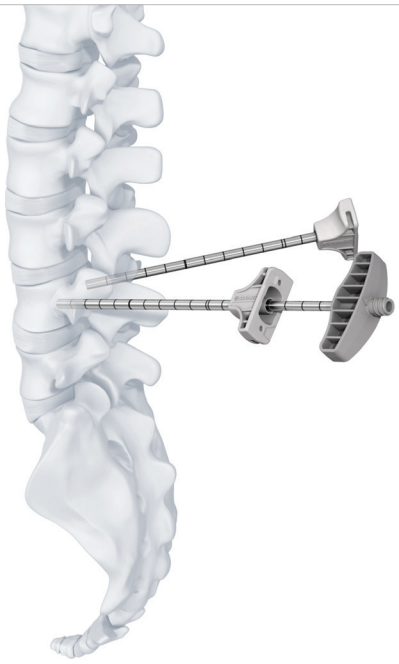
- **▲ Warning:**

  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.

  Hold the working sleeve in place and carefully remove the biopsy needle leaving the working sleeve in the vertebral body.

1



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 fluoroscopy 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.
- True AP and lateral images are required to ensure accurate assessments.

▲ Warning:

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

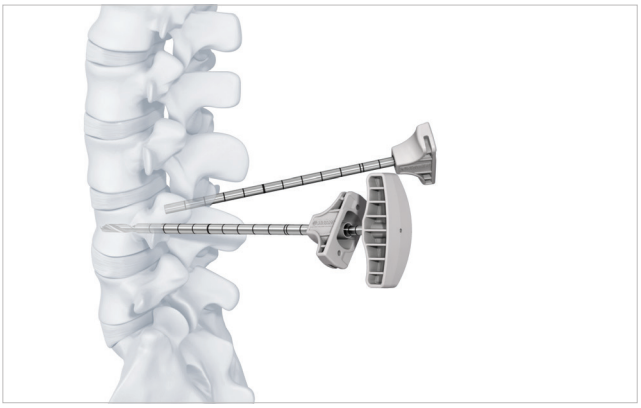
The plunger can be driven forward with light hammer blows.

▲ 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.

1



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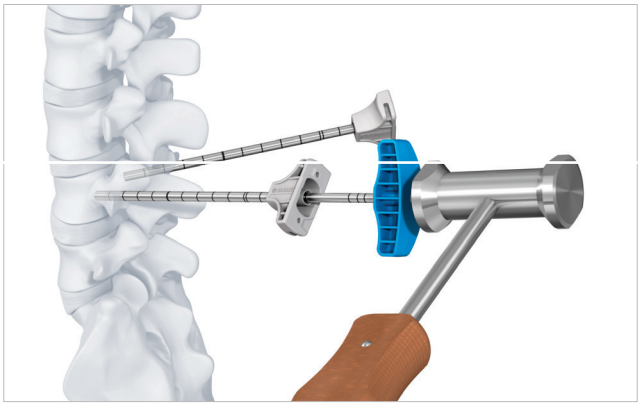


Determine Length of Stent

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

Vertebral Body Stent/Balloon

Article No.	Max Stent ∅ expanded	Stent length expanded	Release length (VBB/VBS)
09.804.500S 09.804.600S Small	15 mm	13 mm	22 mm
09.804.501S 09.804.601S Medium	17 mm	15 mm	27 mm
09.804.502S 09.804.602S Large	17 mm	20 mm	31 mm

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.

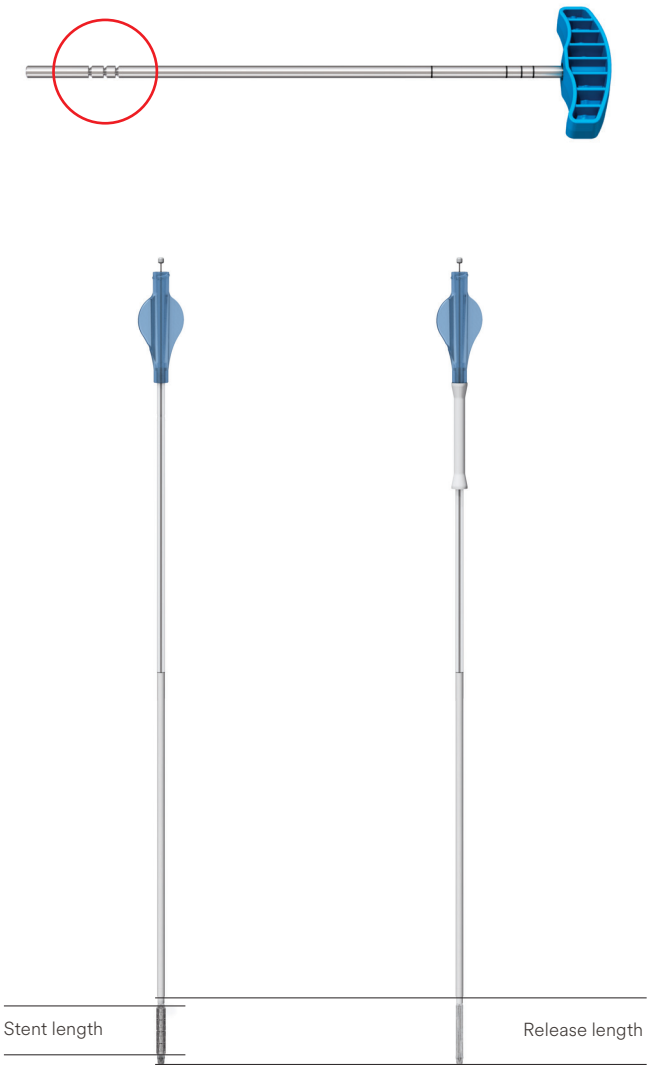
From distal tip the first groove visible:
- Vertebral Body Stent Small

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.

1



Optional: Use of VBB

If you do not intend to use the VBB please continue to page 28 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 the fracture/lesion mobility of the vertebral body is unknown.

1. Unpacking the VBB Catheter

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

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.

The VBB can be reused once within one surgery.

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 the proximal and distal balloon shoulder segments) when the white marking range is completely inserted into the working sleeve.

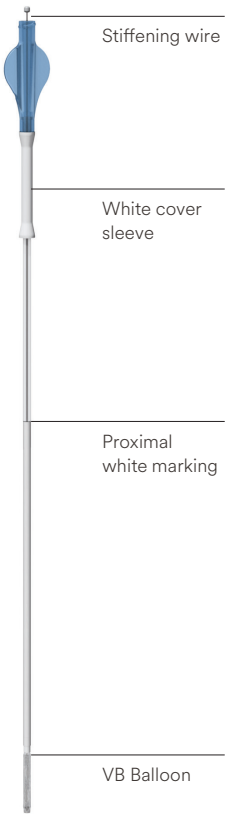
▲ Warning:

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

The shaft marker indicates when balloon is fully inserted; use fluoroscopy while inflating with contrast media.

1

2



2. Insertion of the VBB catheter

Insert the VBB catheter under lateral fluoroscopy.

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 (1).

▲ Precaution:

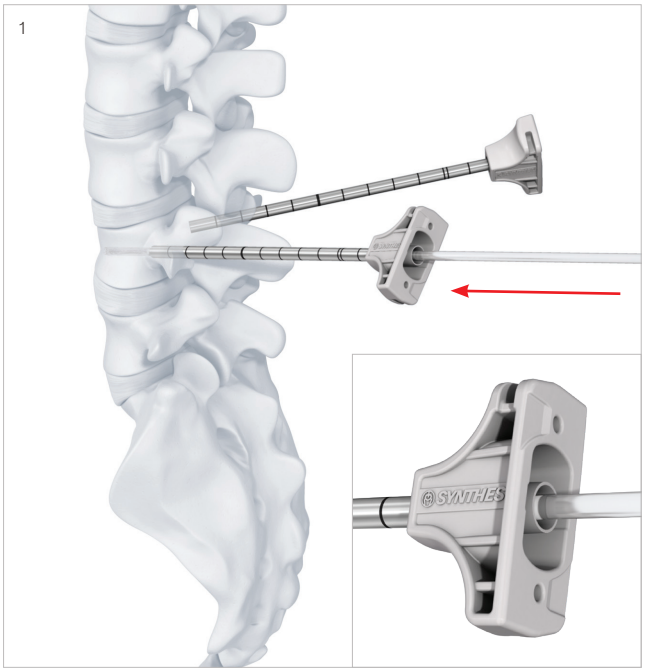
Check the position under fluoroscopic control and confirm the desired position under AP view. It is important that the whole balloon portion is positioned completely inside the vertebra and that these inflatable segments have completely passed through the working sleeve (2). Make sure to position the VBB according to the anticipated VBS position.

Repeat for the contralateral side.

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

Make sure to position the VBB according to the anticipated VBS position.

1



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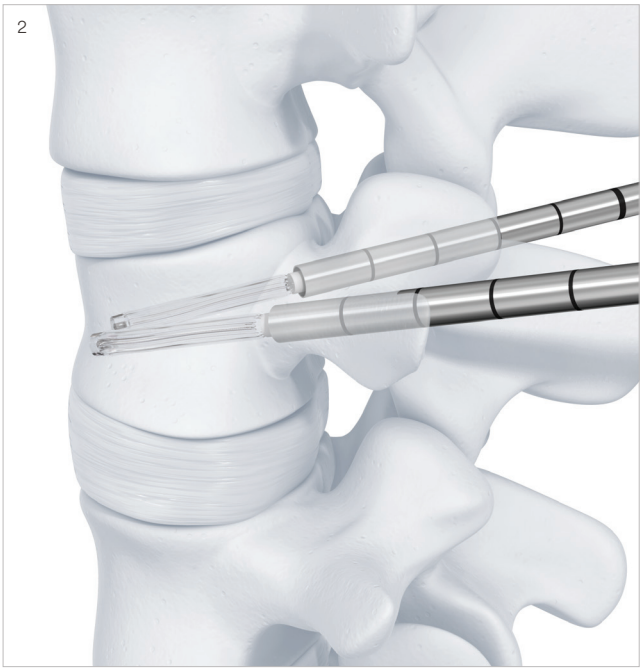


3. Connecting VBB catheter to inflation system and creating vacuum

Instrument	
03.804.413S	Inflation System

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

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).

▲ Warning:

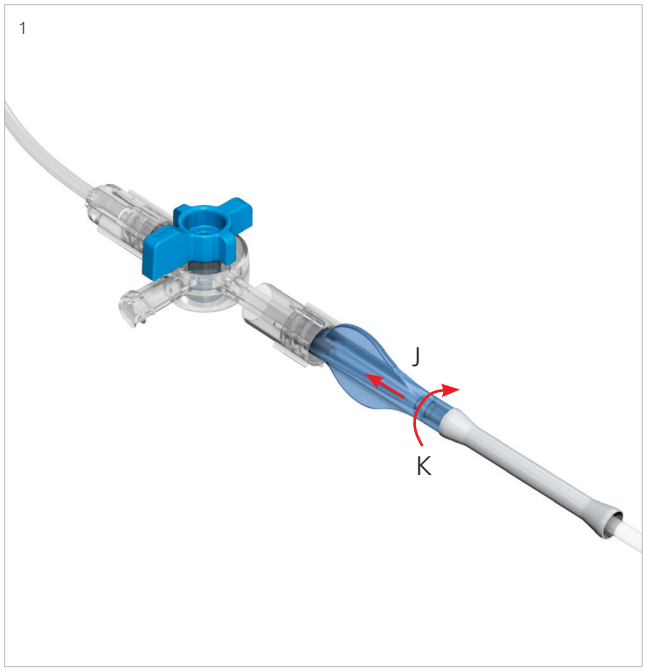
It is important to ensure that all Luer connectors are securely attached. Loose connections may result in inaccurate filling volumes and pressures.

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.

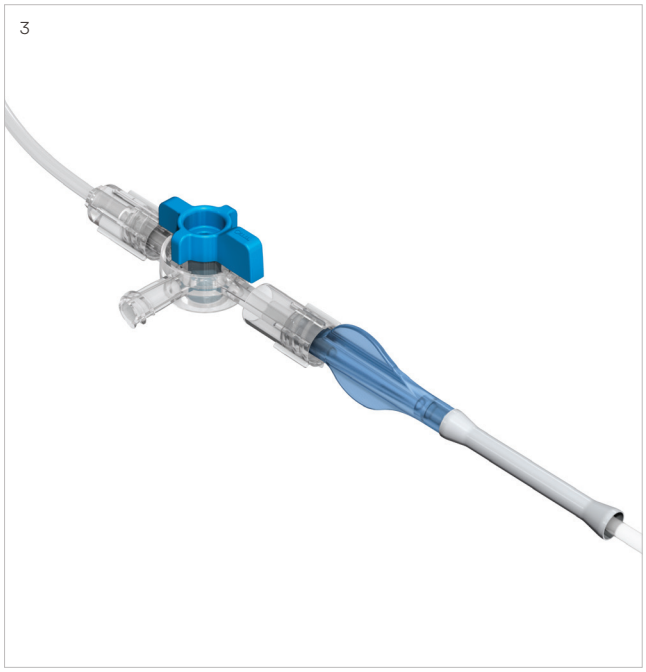
1



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).

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).

4

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

Suspend the 3-way connector over a receptacle for all steps that involve expelling excess solution.

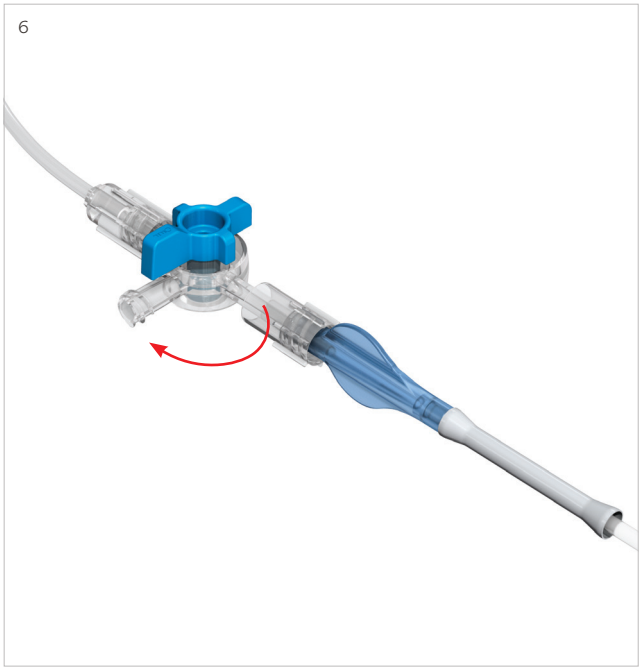
▲ Precaution:

If vacuuming on the patient, use absorbent cotton to soak up any expelled excess solution.

5

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).

6



Inflation of VBB

1. Inflation of VBB

Simultaneous dilatation of bilateral devices is recommended for optimal performance.

▲ Warning:

It is essential to use AP and lateral fluoroscopy 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. Match the expansion bilaterally by tracking the fluid volume on the syringe body with the black volume markers positioned in ml increments (1). 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).

Stop balloon expansion when any of the following happens:

1. Desired vertebral body height or angle is reached. The maximum stent diameter is 15 mm for VBB Small and 17 mm for both VBB Medium and VBB Large.
2. Pressure reaches 30 atm (440 psi)
3. VBB volume reaches maximum
   – 4.0 ml for VBB Small
   – 4.5 ml for VBB Medium
   – 5.0 ml for VBB Large

▲ Precaution:

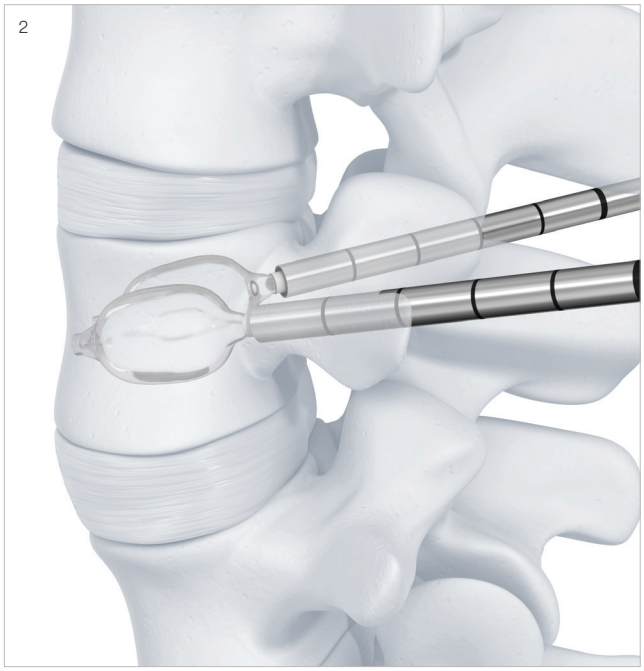
The VBB expansion pressure and volume on the inflation system must be monitored carefully on the inflation system's phosphorescent manometer (units: bar/atm, PSI) and syringe body with black volume markers (units: ml/cc), respectively.

▲ Warnings:

- **Do not fill the balloons over their maximum volume or pressure. If this is done, they may leak.**
- **VBB maximum volumes differ from VBS maximum volumes.**

1

2



▲ Warning:

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

To pull the vacuum and release the pressure push in the white wings and pull the handle back.

▲ Precautions:

- **Do not use air or other gases to inflate the balloon catheters.**
- **Never expose the balloon catheter to organic solvents (e.g. alcohol).**
- **The efficacy of the balloon catheter may be adversely affected if it comes into contact with bone splinters, bone cement, and/or surgical instruments.**

2. Retrieve balloon catheters

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.

1

2

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.

Carefully insert the stiffening wire into the VBB catheter under fluoroscopic 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.

▲ Precaution:

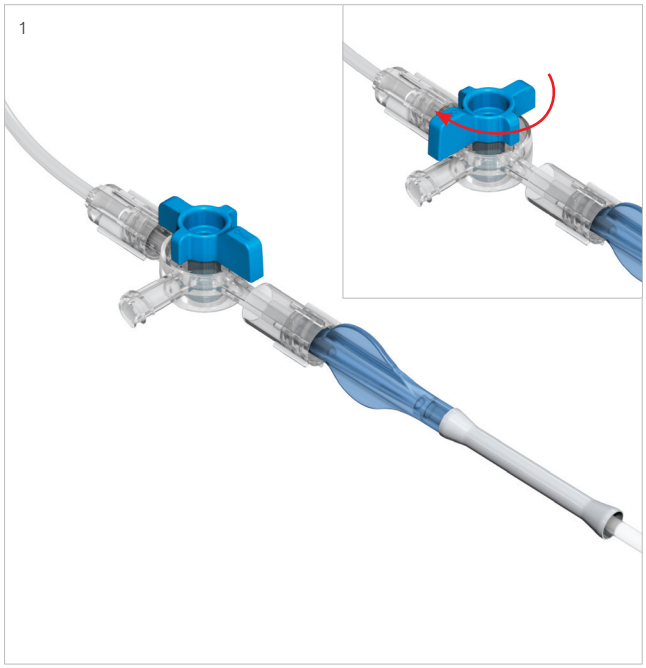
The VBB catheter can be re-used once within one surgery. Make sure by visual inspection that the VBB catheter has not been damaged.

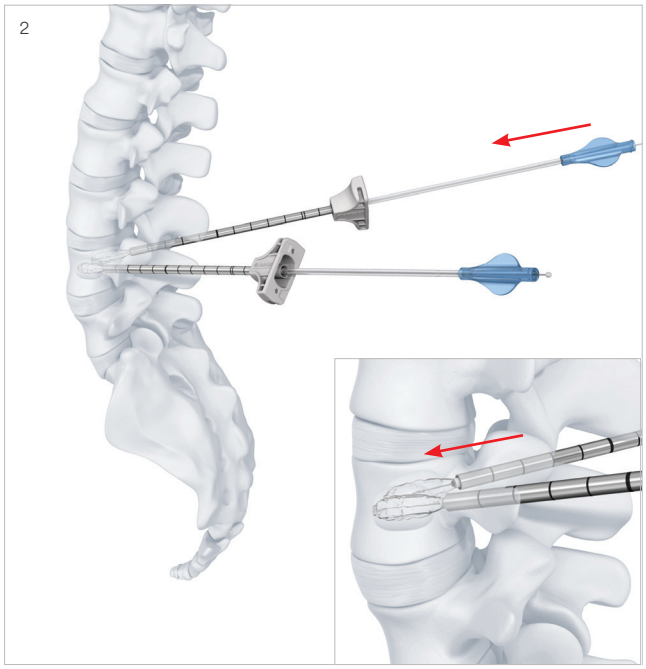
▲ Warning:

Do not use a VBB catheter when visual damage is observed, or when a leak is evident.

▲ Warning:

The balloon-catheter material is not implant grade material.





If the VBB catheter is planned to be reused within the same surgery, cover the refolded balloon of the VBB catheter with the white cover sleeve (3) and reinsert stiffening wire to gently straighten the balloon.

3

Using the VBS Catheter

▲ Precaution:

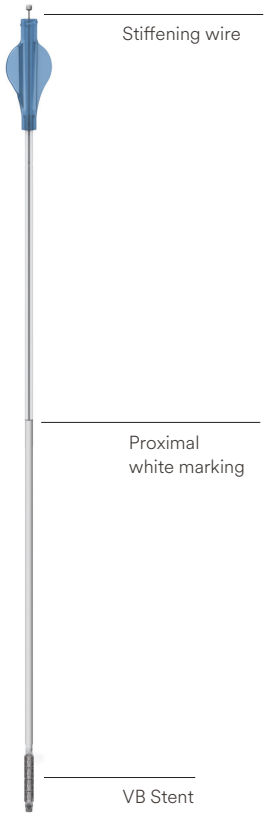
The fracture must be mobile in order for height restoration to be possible. In order to simulate stent expansion use optional VBB (page 19).

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 and both the proximal and distal balloon shoulder segments) when the white marking range is completely inserted into the working sleeve.



2. Connecting VBS catheter to inflation system and creating vacuum

Instrument	
03.804.413S	Inflation System

Connect the prepared inflation system with the selected VBS balloon-catheters using the Luer connector (1).

▲ Precaution:

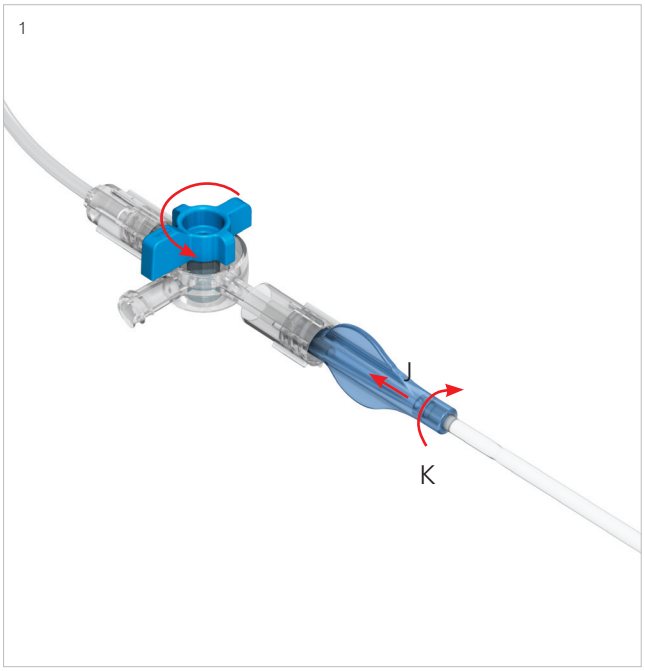
It is important to ensure that all Luer connectors are securely attached. Loose connections may result in inaccurate filling volumes and pressures.

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.

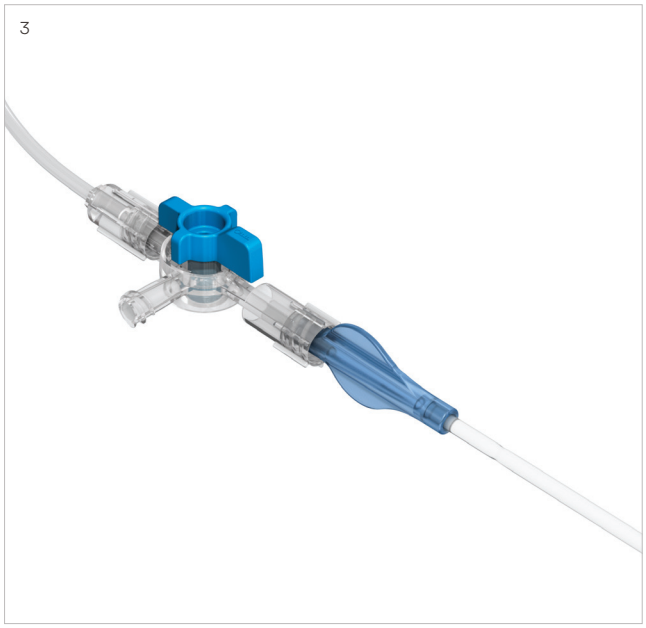
1



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).

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).

4

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

Suspend the 3-way connector over a receptacle for all steps that involve expelling excess solution.

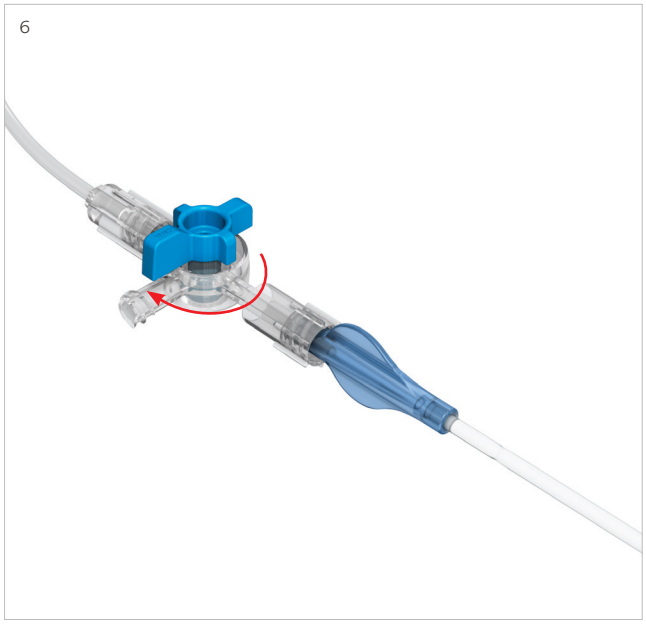
▲ Precaution:

If vacuuming on the patient, use absorbent cotton to soak up any expelled excess solution.

5

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).

6



Deployment of Stents

1. Insert and deploy stents

Insert the balloon catheter with the attached stent under lateral fluoroscopy. 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 (1).

▲ Precaution:

Check the position under fluoroscopic control and confirm the desired position under AP view. 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 (2).

Repeat on the contralateral side.

▲ Warning:

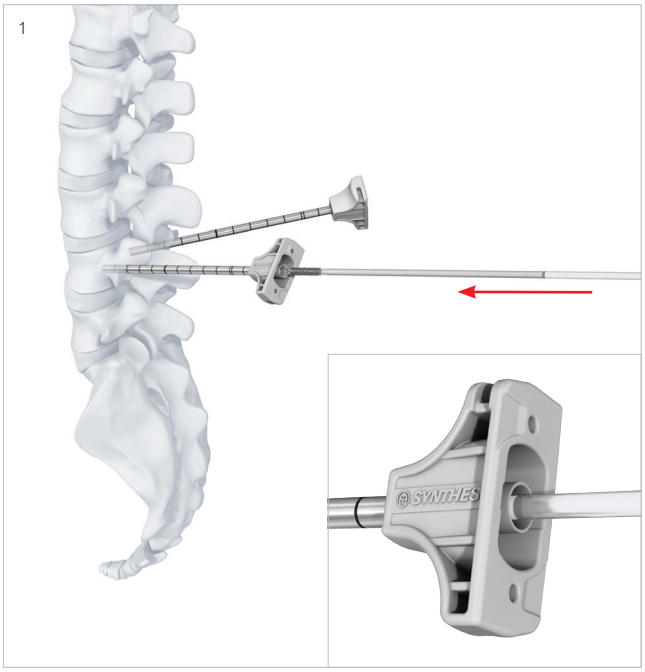
Simultaneous dilatation of bilateral devices is essential for optimal device performance. Once stent expansion has begun the stent cannot be undeployed or repositioned. The system has been validated by simultaneously implanting two stents to ensure optimal intraoperative load capacities.

▲ Warning:

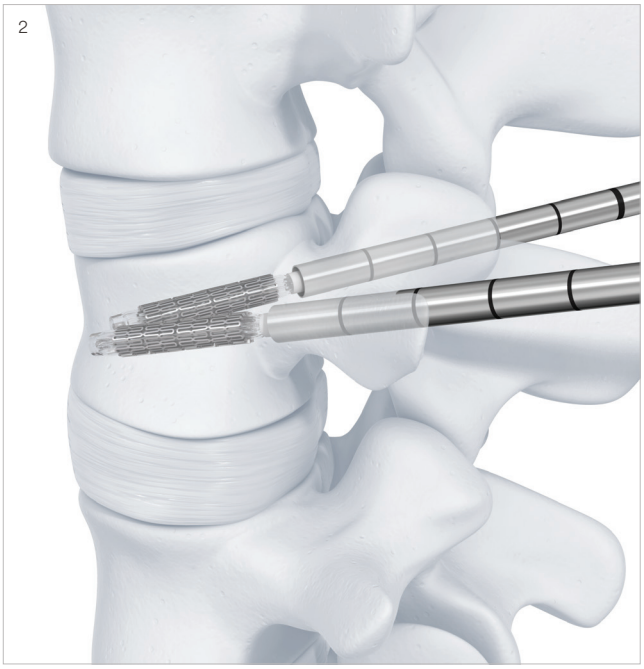
It is essential to use AP and lateral fluoroscopy to track stent expansion and balloon shoulder inflation via the radiopacity of the stent and the balloon contrast medium solution, respectively.

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

1



2



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).

Stop balloon inflation when any of the following happens:

1. Desired vertebral body height or angle is reached. The maximum stent diameter is 15 mm for VBS Small and 17 mm for both VBS Medium and VBS Large.
2. Pressure reaches 30 atm (440 psi)
3. VBS volume reaches maximum
   – 4.5 ml for VBS Small
   – 5.0 ml for VBS Medium
   – 5.5 ml for VBS Large

▲ Precaution:

The VBS expansion pressure and volume on the inflation system must 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.

▲ Warning:

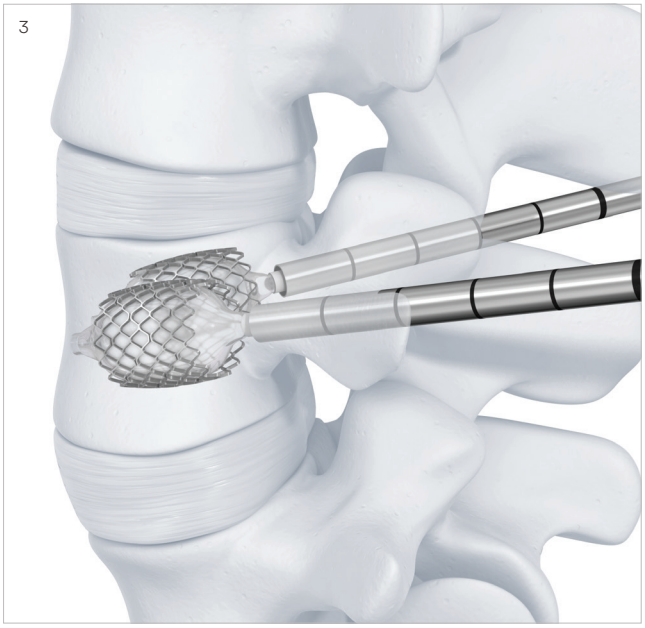
In case of contrast medium leakage, pull vacuum, insert stiffening wire and remove balloon. Do not reuse the balloon.

To pull the vacuum and release the pressure push in the white wings and pull the handle back.

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

2

3



▲ Precautions:

- Do not use air or other gases to inflate the balloon catheters.
- Never expose the balloon catheter to organic solvents (e.g. alcohol).
- The efficacy of the balloon catheter may be adversely affected if it comes into contact with bone splinters, bone cement, and/or surgical instruments.

2. 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 fluoroscopy.

- 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 fluoroscopy.
- Stop insertion when the proximal end of the white range on the catheter shaft is aligned with the top of the working sleeve.
- Check the position under fluoroscopic 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.

1

2

▲ Precaution:

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:

The balloon material is not implant grade material.

Cement Augmentation

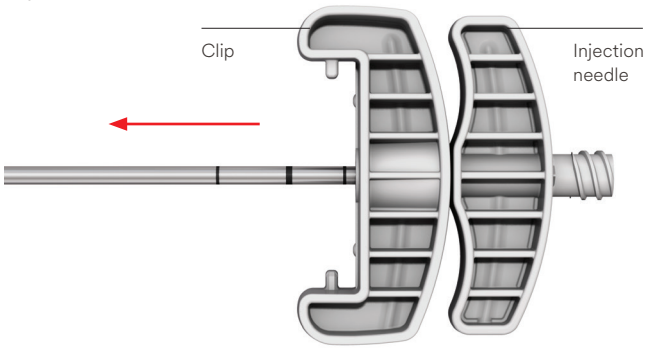
1. Preparation of injection needle

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

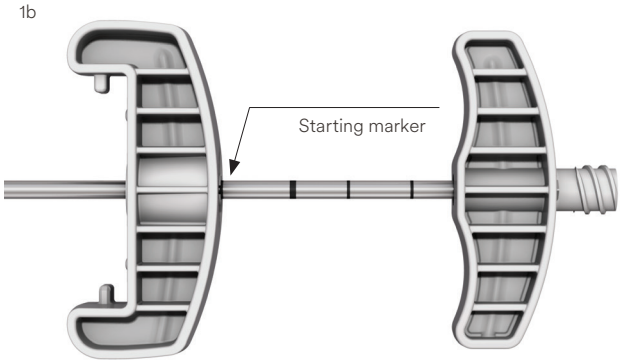
▲ Precaution:

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.

1a



1b



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.

▲ Warning:

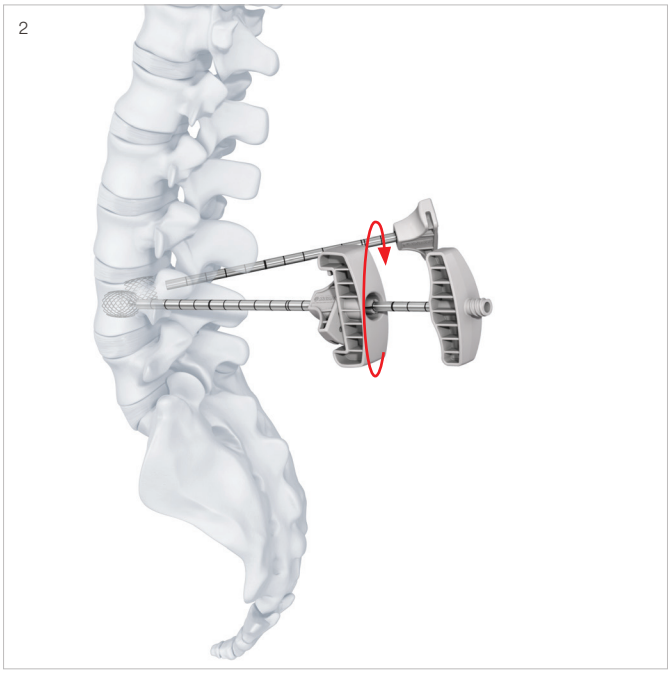
Do not use the grey colored biopsy kit for cement application.

▲ Precaution:

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.

2



3. Inject PMMA based bone cement

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.

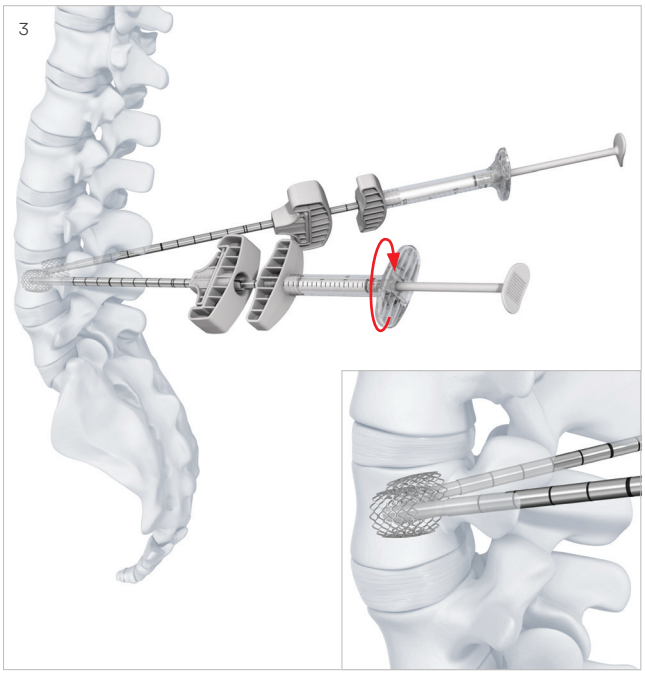
Under lateral fluoroscopy, inject the PMMA based bone cement bilaterally. Fill the anterior vertebral body first and as the trocar is gradually pulled back fill the posterior. The direction of the PMMA based bone cement flow can be changed by orienting the handle of the injection needle with the side-opening. Make sure to apply the appropriate amount of PMMA based bone cement according to the surgical situation. The side-opening cement outflow window can be closed by turning the cannula.

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. It is recommended to monitor proper filling behavior on both sides under fluoroscopy in AP view.

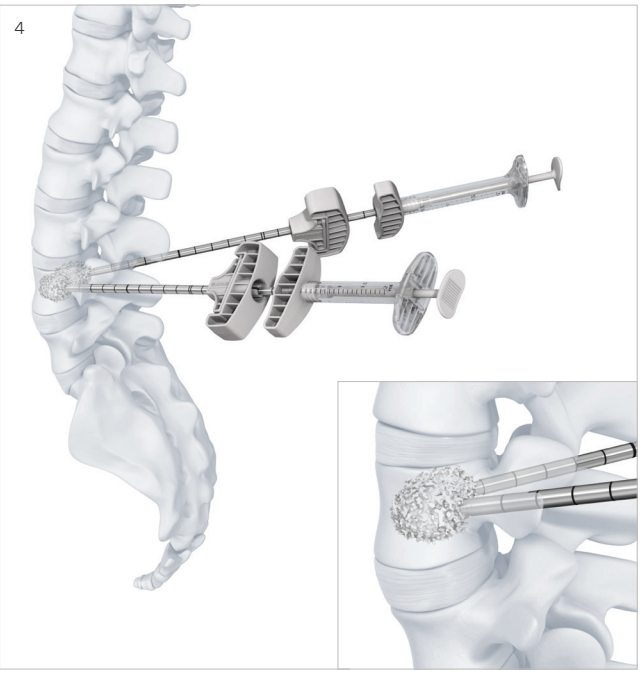
▲ Warning:

Cement should be injected until it infiltrates the surrounding cancellous bone around the cavity created by the balloon or the stent (4).

3

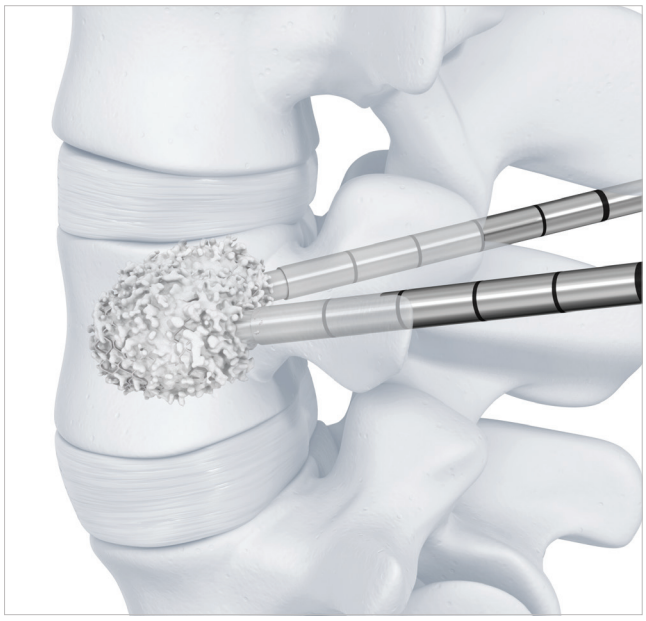


4



▲ 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 to the removal of the 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 into the muscle tissue. If the injection needle is removed too late it may be difficult to remove.

▲ Precaution:

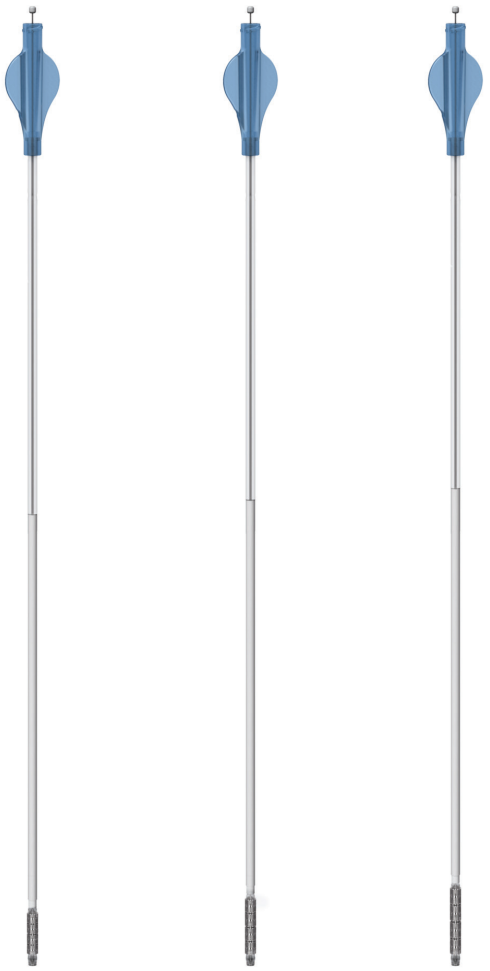
Leave both injection needles inserted while applying the PMMA based bone cement to avoid backflow into the working sleeve.

Close the wound.

Implants and Balloon-Catheters

Vertebral Body Stent

	09.804.500S VBS Small	09.804.501S VBS Medium	09.804.502S VBS Large
Release (initial) length	22 mm	27 mm	31 mm
Stent length expanded	13 mm	15 mm	20 mm
Max ∅ expanded	15 mm	17 mm	17 mm
Max volume	4.5 ml	5.0 ml	5.5 ml
Max pressure	30 atm	30 atm	30 atm



Vertebral Body Stent with Balloon

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

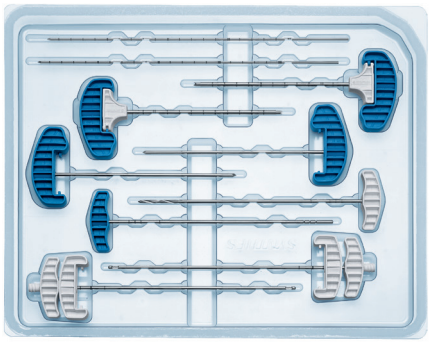
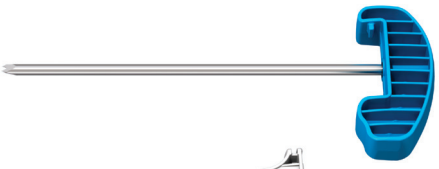
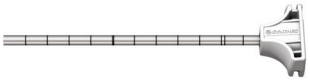
The respective sizes are Small, Medium and Large:

09.804.600S	VBS Small with Balloon
09.804.601S	VBS Medium with Balloon
09.804.602S	VBS Large with Balloon

The dimensions of the VBB are listed in the table below (for VBS dimensions see the table on page 40).

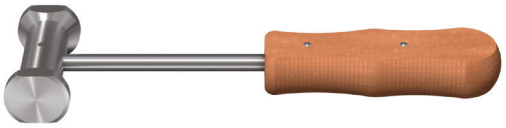
	Small Balloon	Medium Balloon	Large Balloon
Release (initial)	22 mm	27 mm	31 mm
Max ∅ expanded	15 mm	17 mm	17 mm
Max volume	4.0 ml	4.5 ml	5.0 ml
Max pressure	30 atm	30 atm	30 atm

Instruments

03.804.612S	Access Kit 4.7 mm	
	2 x Cement needle with Clip	
	2 x Guide Wires, with Depth Markings	
	2 x Trocar	
	2 x Cannulated trocar	
	2 x Vertebral Body Stent Access Working Sleeve	
	1x Vertebral Body Stent Access Drill	
	1x Vertebral Body Stent Access Plunger	
03.804.613S	Biopsy Kit 4.7 mm, (optional)	
03.804.413S	VBS Inflation System	

Optional Instruments

399.410	Hammer, 300 g
292.210S	Kirschner Wire ∅ 2.0 mm with trocar tip, length 280 mm, Stainless Steel, sterile



Indications and Contraindications

Please refer to the corresponding Instructions for Use for specific information on Intended use, Indications, Contraindications, Warnings and Precautions, Potential Adverse Events, Undesirable Side Effects and Residual Risks. Instructions for Use are available at www.e-ifu.com and/or www.depuysynthes.com/ifu.

Bibliography

1. Aebi M, Thalgott JS,Webb JK (1998): AOASIF Principles in Spine Surgery. Berlin: Springer-Verlag.

2. Aebi M, Arlet V, Webb JK (2007). AOSPINE Manual (2 vols), Stuttgart, New York: Thieme.

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