Instructions for Use
VBS – Vertebral Body Stenting System

This instruction for use is not intended for distribution in the USA.

Not all products are currently available in all markets.

Manuals are subject to change;
the most current version of each manual is always available online.
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DePuy Synthes
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Instructions for Use

VBS – Vertebral Body Stenting System
VBS is used for balloon-based vertebral body augmentation procedures. VBS is available in three sizes small/medium/large (S/M/L). VBS consists of a Vertebral Body Stent mounted on a balloon catheter. Additionally VBS is offered in a double pack containing one VBS and one corresponding Vertebral Body Balloon (VBB) catheter. The balloon catheters include a stiffening wire and a radiopaque marker for X-ray visualization.

These instructions for use contain information about the following products:
09.804.500S
09.804.501S
09.804.502S
09.804.600S
09.804.601S
09.804.602S

Important note for medical professionals and operating room staff: These instructions for use do not include all the information necessary for selection and use of a device. Please read the instructions for use and the Synthes brochure "Important Information" carefully before use. Ensure that you are familiar with the appropriate surgical procedure.

For accompanying information, such as Surgical Techniques, please visit www.jnjmedtech.com/en-EMEA/product/accompanying-information or contact local customer support.

Materials
Stent material: L605 Cobalt Chromium Tungsten Nickel Alloy (Cobalt – 20% Chromium – 15% Tungsten – 10% Nickel) according to ASTM F90
Balloon catheter: Thermoplastic Elastomer
Stiffening wire: Stainless Steel, Polyoxymethylene (POM)
Radiopaque marker: Stainless Steel

Intended Use
The VBS System is intended for use in vertebral body augmentation from T5-L5 in skeletally mature patients. 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, indications, contraindications, precautions, and warnings potential adverse events, undesirable side effects and residual risks.

[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.

Indications
- Painful vertebral compression fractures involving the anterior column of the spine.
- Painful vertebral burst fractures involving the middle and/or posterior columns of the spine, in combination with internal fixation.
- Treatment of vertebral bony defects caused by osteolytic processes.

Contraindications
- Lesions requiring open anterior column reconstruction
- If vertebral dimensions or fracture pattern do not allow safe placement and inflation of the balloon
- Acute or chronic systemic or localized spinal infections
- Allergies to contrast media

Patient Target Group
VBS is intended for use in skeletally mature patients. These products are to be used with respect to the intended use, indications, contraindications and in consideration of the anatomy and health condition of the patient.

Intended User
These instructions for use alone do not provide sufficient background for direct use of the device or system. Instruction by a surgeon experienced in handling these devices is highly recommended.

Surgery is to take place according to the instructions for use following the recommended surgical procedure. The surgeon is responsible for ensuring that the operation is carried out properly. It is strongly advised that the surgery is performed only by operating surgeons who have acquired the appropriate qualifications, are experienced in spinal surgery, are aware of general risks of spinal surgery, and are familiar with the product-specific surgical procedures.

This device is intended to be used by qualified health care professionals who are experienced in spinal surgery e.g. surgeons, physicians, operating room staff, and individuals involved in preparation of the device.

All personnel handling the device should be fully aware that these instructions for use do not include all the information necessary for selection and use of a device. Please read the instructions for use and the Synthes brochure "Important Information" carefully before use. Ensure that you are familiar with the appropriate surgical procedure.

Expected Clinical Benefits
When the vertebral body augmentation procedure such as VBS is used as intended and according to the instructions for use and labeling, it is expected to provide reduction of back pain.

A summary of safety and clinical performance can be found at the following link (upon activation): https://ec.europa.eu/tools/eudamed

Performance Characteristics of the Device
VBS is a vertebral body augmentation device designed to improve vertebral body height intra-operatively until cement is injected and cured, when used according to the instructions for use and labeling.

Potential Adverse Events, Undesirable Side Effects and Residual Risks
As with all major surgical procedures, there is a risk of adverse events. Possible adverse events may include: problems resulting from anesthesia and patient positioning; excessive bleeding; abnormal wound healing or scar formation; functional impairment of the musculoskeletal system; complex regional pain syndrome (CRPS); ongoing pain; damage to adjacent bones, discs, organs, or other soft tissues; dural tear or spinal fluid leak; device-related complications including deformation, loosening, wear or intraoperative breakage and unintentional retention of procedural instruments and/or implant components. Intraoperative rupture and collapse of the inflated balloon may also result in contrast agent exposure and the possibility of allergic reaction. Ruptured or broken balloon or instrument fragments may be irretrievable and retained in the patient after failure.

Embolization of fat, thrombus or instrument or implant debris may also occur, and this could lead to symptomatic pulmonary embolism or other pulmonary and/or vascular or organ injury.

Additional complications are possible, and these include damage to nerves; early and late infections; allergic or other systemic reaction to the instrument or implant materials; hematoma formation and impaired wound healing.

Rebounding fragments of the vertebral body may cause compression of neurologic structures and risk of radiculopathy, paresis or paralysis; or death (cardiovascular instability, stroke, or cardiac arrest are possible after exposure to bone cement).

Sterile Device

STERILE EO Sterilized using ethylene oxide

Store sterile devices in their original protective packaging, and do not remove them from the packaging until immediately before use.

Do not use when packaging is damaged.

Prior to use, check the product expiration date and verify the integrity of the sterile packaging. Do not use if the package is damaged or date of expiration has passed.

Do not resterilize

Resterilization of the device can result in product not being sterile, and/or not meeting performance specifications and/or altered material properties.

Single Use Device

Do not re-use

Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.

Re-use or clinical reprocessing (e.g. cleaning and resterilization) may compromise the structural integrity of the device and/or lead to device failure which may result in patient injury, illness or death.
Furthermore, re-use or reprocessing of single use devices may create a risk of contamination e.g. due to the transmission of infectious material from one patient to another. This could result in injury or death of the patient or user.

Contaminated implants must not be reprocessed. Any Synthes implant that has been contaminated by blood, tissue, and/or bodily fluids/matter should never be used again and should be handled according to hospital protocol. Even though they may appear undamaged, the implants may have small defects and internal stress patterns that may cause material fatigue.

Warnings and Precautions
- It is strongly advised that the VBS System is implanted only by operating surgeons who have acquired the appropriate qualifications, are experienced in spinal surgery, are aware of general risks of spinal surgery, and are familiar with the product-specific surgical procedures. The operating surgeon must have knowledge of the device limitations, which are detailed in the contraindications as well as warnings and precautions listed below.
- Implantation is to take place as per the instructions for the recommended surgical procedure. The surgeon is responsible for ensuring that the operation is carried out properly.
- The manufacturer is not responsible for any complications arising from incorrect diagnosis, choice of incorrect implant, incorrectly combined implant components and/or operating techniques, the limitations of treatment methods, or inadequate asepsis.
- Consider the use of supplemental fixation in cases where cortical disruption might lead to segmental instability.
- Be aware of vulnerable patient populations (such as younger patients) and carefully consider the potential risks associated with using this medical device in such groups.

Preoperative planning
- Before using the VBS System ensure that the size is suitable for the specific procedure. See section “Additional Device-Specific Information” for more details.
- It is important, to treat only patients with non-consolidated fractures.
- Warning: The patient has to be checked for allergy or hypersensitivity to the contrast medium and stent material, i.e. any of the metal components of the CoCrWNi alloy.
- The balloon pressure of the VBS and VBB may not exceed the maximum inflation pressure of 30 bar/atm. A manometer is used to monitor the pressure.
- The inflation balloon volumes of the VBS and VBB must not exceed the maximum volumes specified in the section “Additional Device-Specific Information”.

Preparation
- It is essential to fill the Inflation System with saline/contrast medium mixture to ensure visibility of the VBS balloon catheter during inflation.
- 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.
- It is essential to observe the manufacturer’s instructions on the indications, use and safety measures for the contrast agent.
- 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.
- 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.

Patient positioning and approach
Place the patient in the prone position on a lumbar support.
The access instruments (guide wire or trocar) can be inserted through either a transpedicular or extrapedicular approach.
Option A. Transpedicular approach
- 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 anteroposterior (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.

Option B. Extrapedicular approach
- 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.
- 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 access
- 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.
- Do not redirect the instrument assembly without removing it and re-accessing the vertebral body.

Option B. Guide wire
- 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.
- 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.

Biopsy
After placement of the working sleeve, an optional biopsy can be taken using the biopsy kit.
- Do not insert the biopsy needle beyond the anterior cortical wall of the vertebral body, as this could damage vascular structures.

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

Optional: Use of VBB
The VBS System can optionally be used with a Vertebral Body Balloon (VBB).
Unpacking the VBB catheter
- Only use VBB of the same size together with the corresponding VBS.

Insertion of the VBB catheter
- 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. Make sure to position the VBB according to the anticipated VBS position.

Connecting VBB catheter to inflation system and creating vacuum
- It is important to ensure that all Luer connectors are securely attached. Loose connections may result in inaccurate filling volumes and pressures.
- 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.
- If vacuuming on the patient, use absorbent cotton to soak up any expelled excess solution.

Inflation of VBB
- It is essential to use AP and lateral fluoroscopy to track VBB expansion via the balloon contrast media solution inflation fluid.
- 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.
- 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.
– In case of contrast medium leakage, pull vacuum, insert stiffening wire and remove balloon, don't reuse balloon.
– 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.

Retrieve balloon catheters
– The VBB catheter can be re-used once within one surgery. Make sure by visual inspection that the VBB catheter has not been damaged.
– Do not use a VBB catheter when visual damage is observed, or when a leak is evident.
– Do not leave the balloon implanted; the balloon material is not implant grade material.

Using the VBS catheter
– The fracture must be mobile in order for height restoration to be possible. In order to simulate stent expansion use optional VBB.

Connecting VBS catheter to inflation system and creating vacuum
– It is important to ensure that all Luer connectors are securely attached. Loose connections may result in inaccurate filling volumes and pressures.
– 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.
– If vacuuming on the patient, use absorbent cotton to soak up any expelled excess solution.

Deployment of stents
Insert and deploy stents
– 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.
– 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.
– 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.
– 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.
– Do not inflate the balloons beyond their maximum volume or pressure. If this is done, they may leak.
– VBS maximum volumes differ from VBB maximum volumes.
– In case of contrast medium leakage, pull vacuum, insert stiffening wire and remove balloon. Do not reuse the balloon.
– 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.

Retrieve balloon catheters
– 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.
– Do not leave the balloon implanted; the balloon material is not implant grade material.

Cement augmentation
Preparation of injection needle
– Move the clip to the starting marker position. In this position, the distal tip of the injection needle is in line with the distal end of the working sleeve after insertion.

Insertion of injection needle
– 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.

Inject PMMA based bone cement
– Use of the VBS system in combination with PMMA-based bone cement to treat compression fractures, burst fractures, or osteolytic vertebral body defects may result in unintended leakage of cement through known or unknown vertebral body defects. Severe leakage can cause nerve injury, paralysis, or death. Closely monitor the bone cement injection under fluoroscopy to reduce the risk of cement leakage. If bone cement leakage is observed during the procedure, STOP injecting and consider the following: wait for the bone cement to harden, reposition the needle, adjust the needle direction, or stop the procedure. If desired, continue bone cement injection slowly, and carefully evaluate for further leakage. If further leakage is observed, cease bone cement injection.
– Cement should be injected until it infiltrates the surrounding cancellous bone around the cavity created by the balloon or the stent.
– Closely monitor the PMMA based bone cement injection under fluoroscopy to reduce the risk of PMMA based bone cement leakage. Severe leakage can cause nerve injury, paralysis, or death. 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.

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

For more information, please refer to the Synthes brochure "Important Information".

Combination of Medical Devices
The VBS system is intended to be used in combination with a legally-marketed PMMA 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, indications, contraindications, precautions, and warnings potential adverse events, undesirable side effects and residual risks.

The Access Kit (03.804.612S, 03.804.613S) and the Inflation System are designed to be used with the VBS System, please refer to the Instructions for Use for the Access Kit and Inflation System for additional details regarding these devices.

Alternate instrumentation must not be used with the VBS System.

Synthes has not tested compatibility with devices provided by other manufacturers and assumes no liability in such instances.

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

Magnetic Resonance Environment
MR Conditional:
Non-clinical testing of the worst-case scenario has demonstrated that the implants of the VBS system are MR conditional. These articles can be scanned safely under the following conditions:
– Static magnetic field of 3 Tesla or less.
– Spatial gradient field of 72 mT/cm (720 Gauss/cm).
– Maximum whole body averaged specific absorption rate (SAR) of 3 W/kg for 15 minutes of scanning.

Based on non-clinical testing, the VBS implant will produce a temperature rise not greater than 1.5°C at a maximum whole body averaged specific absorption rate (SAR) of 3 W/kg, as assessed by calorimetry for 15 minutes of MR scanning in a 3 Tesla MR scanner.

MR Imaging quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the VBS device.

Treatment before Device is Used
Sterile Device:
The devices are provided sterile. Remove products from the package in an aseptic manner.
Store sterile devices in their original protective packaging.
Do not remove them from the packaging until immediately before use.
Prior to use, check the product expiration date and verify the integrity of the sterile packaging by visual inspection:
– Inspect the entire area of sterile barrier package including the sealing for completeness and uniformity.
– Inspect the integrity of the sterile packaging to ensure there are no holes, channels or voids.
Do not use if the package is damaged or expired.

Additional Device-Specific Information

Dimensions of 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

Dimensions of Vertebral Body Stent with Balloon

	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

Special Operating Instructions

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.

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.

Preparation
Instrument preparation
– 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.
  – Connect inflation system to connector:
    Attach the tube of the inflation system with the Luer connector to the supplied 3-way connector. Rotate the knob on the 3-way connector to position the "off" indicator towards the lateral outlet.
  – Fill inflation system:
    Fill the inflation system with saline solution and a liquid contrast medium.
– 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.
– 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.
– The inflation system has now been prepared accordingly and can be set aside. Repeat for the second inflation system.

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.
  – 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 and 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
– 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.
– 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.

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.

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.
– Under fluoroscopy, insert the trocar instrumentation 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 trocar to gently advance the trocar instrumentation.
– Confirm proper positioning of the access instrumentation under fluoroscopy in both AP and lateral view.
– Repeat on the contralateral side.
– Hold the working sleeve(s) in place and carefully remove the trocar(s) leaving the working sleeve(s) in the vertebral body.

Option B: Guide wire
– Insert the guide wire to create the access path, and position appropriately. Insert the working sleeve and cannulated trocar assembly over the guide wire and into the vertebral body.
– 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.
– Confirm proper positioning of the access instrumentation under both AP and lateral fluoroscopy.
– Repeat on the contralateral side.
– 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.

Biopsy
- After placement of the working sleeve, an optional biopsy can be taken using the biopsy kit.
- 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.
- Under fluoroscopy, advance the biopsy needle further and rotate it at least one full turn (360°). This will help to remove the biopsy.
- 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.
- Use the biopsy plunger to push the collected bone tissue out of the biopsy needle.

Create access channel
- Guide the drill and afterwards the blunt plunger through the working sleeves to create an access channel for the stents.
- The plunger can be driven forward with light hammer blows.
- Repeat on the contralateral side.

Determine length of stent
- The vertebral body stents and balloons are available in three sizes. See section "Additional Device-Specific Information" for more details.
- The plunger has three grooves towards the distal tip that correspond to the three stent lengths.
- 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
- 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.

Unpacking the VBB catheter
- Remove the VBB catheter from the sterile packaging.
- Slide back the white cover sleeve towards the Luer connector and attach it properly to the Luer. 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.
- The shaft marker indicates when balloon is fully inserted; use fluoroscopy while inflating with contrast media.

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.
- Repeat for the contralateral side.
- Simultaneous dilatation of bilateral inserted VBBs is recommended.
- Make sure to position the VBB according to the anticipated VBS position.

Connecting VBB catheter to inflation system and creating vacuum
- 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.
- 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".
- Close the balloon catheter with the 3-way connector by positioning the "off" indicator towards the catheter. This retains the vacuum inside the catheter.
- 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 at "0".
- This flushes out the excess saline solution/contrast medium mixture and air through the lateral opening of the three-way connector.
- Suspend the 3-way connector over a receptacle for all steps that involve expelling 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.

Inflation of VBB
- Simultaneous dilatation of bilateral devices is recommended.
- 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. When the pressure reaches and increases beyond 26 atm (382 psi), continue dilatation gradually. Wait a few seconds then slowly continue until the desired VBB diameter is reached.
- Stop balloon expansion when any of the following happens:
  - 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.
  - Pressure reaches 30 atm (440 psi).
  - VBB volume reaches maximum 4.0 ml for VBB small, 4.5 ml for VBB medium or 5.0 ml for VBB large.
- To pull the vacuum and release the pressure push in the white wings and pull the handle back.

Retrieve balloon catheters
- Slowly turn the handles of the inflation systems counter-clockwise to draw the liquid out of the balloon catheter. Once the pressure has reached 10 atm (147 psi), push the white wings forward, slowly pull the handle back all the way, and release the white wings. This draws and holds a vacuum in the catheter.
- Aerate the VBB catheter by first positioning the "off" indicator towards the catheter and second turn back towards the lateral side opening.
- 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. 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.
- 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 and reinsert stiffening wire to gently straighten the balloon.

Using the VBS catheter
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.

Connecting VBS catheter to inflation system and creating vacuum
- Connect the prepared inflation system with the selected VBS balloon catheters using the Luer connector.
- 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".
- Close the balloon catheter with the 3-way connector by positioning the "off" indicator towards the catheter. This retains the vacuum inside the catheter.
- 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 at "0".
- This flushes out the excess saline solution/contrast medium mixture and air through the lateral opening of the three-way connector.
- Suspend the 3-way connector over a receptacle for all steps that involve expelling 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.

Deployment of stents
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.
– Repeat on the contralateral side.
– 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 approximately 12 atm (176 psi). Match the expansion bilaterally by tracking the fluid volume on the scales. When the pressure reaches 26 atm (382 psi) continue dilatation gradually. Wait a few seconds then slowly continue until the desired stent diameter is reached.
– Stop balloon inflation when any of the following happens:
  – 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.
  – Pressure reaches 30 atm (440 psi).
  – VBS volume reaches maximum 4.5 ml for VBS small, 5.0 ml for VBS medium or 5.5 ml for VBS large
– 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.

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. Once the pressure has reached 10 atm (147 psi), push the white wings forward, slowly pull the handle back all the way, and release the white wings. 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.

Cement augmentation
Preparation of injection needle
– Remove the injection needle assembled with the clip from package.

Insertion of injection needle
– Under fluoroscopy, insert the injection needle with clip into the working sleeve and fix the clip to the working sleeve.
– The filling volume of the injection needle is 1.8 ml.

Inject PMMA based bone cement
– Connect a cement delivery system via the Luer lock. 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.

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.
– Close the wound.

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 vertebral body stent with balloons is available in three sizes. See section "Additional Device-Specific Information" for more details.

Disposal
Any Synthes implant that has been contaminated by blood, tissue, and/or bodily fluids/matter should never be used again and should be handled according to hospital protocol.

Devices must be disposed of as a healthcare medical device in accordance with hospital procedures.

Implant Card & Patient Information Leaflet
If supplied with the original packaging, provide the implant card as well as the relevant information according to the patient information leaflet to the patient. The electronic file containing the patient information can be found at the following link: ic.jnjmedicaldevices.com

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