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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Instructions for Use

VBS – Vertebral Body Stenting System
The VBS System consists of the Vertebral Body Stent (VBS), the optional Vertebral Body Balloon (VBB), the Access Kit, and the Inflation System.

These instructions for use contain information about the following products:

– 09.804.500S – 502S, Vertebral Body Stent (VBS), containing: one stent, one balloon-catheter and one stiffening wire
– 09.804.600S – 602S, Vertebral Body Stent with Vertebral Body Balloon (VBB), containing: one stent, two balloon-catheters and two stiffening wires

The Access Kit (03.804.612S) is used to prepare the operative access in the vertebral body. Subsequently, the Vertebral Body Stent is inserted into the vertebral body using a simultaneous bilateral approach. The Inflation System (03.804.413S) is then used to inflate the balloon, thereby expanding the stent. Once the vertebral body is restored to the desired height, the balloon is deflated and removed from the vertebral body. The stent remains in situ and stabilizes the cavity that has been created. The Access Kit (03.804.612S) is then used to inject the PMMA based bone cement. As an option when using 09.804.600S–602S the enclosed VBB allows an in situ preparation of the vertebral body prior to the use of VBS.

Refer to the Instructions for Use for the Access Kit and Inflation System for additional details regarding these devices. Additionally, please adhere to the Instructions for Use for the specific PMMA based bone cement used during the procedure.

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.

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 the reduction of painful vertebral compression fractures and/or creation of a void in cancellous bone in the spine for the treatment of levels ranging from 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
– Treatment of osteolytic lesions located within the vertebral body

Contraindications
– Fracture involvement of the posterior wall and/or pedicles
– 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.
- Implantation is to take place with 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.

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.
- The patient has to be checked for allergy 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
– 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 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.

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 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, and 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, and the sealing, for completeness and uniformity.
– Inspect for the absence of holes, channels or voids of the sterile barrier package and the sealing.
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

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 available, 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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