Instructions for Use
SYNFLATE® Vertebral Balloon

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

SYNFLATE® Vertebral Balloon
Synflate is used for balloon-based vertebral body augmentation procedures. It consists of the Synflate vertebral balloon and a vacuum syringe. The Synflate balloon includes two lumens, one for insertion of a stiffening wire and a second for balloon inflation. The balloon includes two radiopaque markers for X-ray visualization.

These instructions for use contain information about the following products:

03.804.700S	Synflate Vertebral Balloon, small
03.804.701S	Synflate Vertebral Balloon, medium
03.804.702S	Synflate Vertebral Balloon, large

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
Balloon catheter: Thermoplastic Polyurethane
Stiffening wire: Stainless Steel
Radiopaque marker: Platinum/Iridium

Intended Use
The Synflate System is intended for the reduction of fractures and/or creation of a void in cancellous bone in the spine (T5-L5). It is intended to be used in combination with a legally-marketed bone filler adequately indicated for use in vertebroplasty or vertebral body augmentation procedures.

Note: Refer to the manufacturer's directions accompanying the bone filler for specific information on its use, indications, contraindications, precautions, warnings, potential adverse events, undesirable side effects and residual risks.

Indications
– Painful vertebral compression fractures
– Osteolytic lesions located within the vertebral body

Contraindications
– Fracture involvement of the posterior wall and/or pedicles
– Lesions requiring open anterior column reconstruction
– Vertebral dimensions or fracture pattern do not allow safe placement and inflation of the balloon
– Acute and chronic systemic or localized spinal infections
– Allergies to contrast media

Patient Target Group
The Synflate System 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 Synflate is used as intended and according to the instructions for use and labeling, it is expected to provide clinical benefit such as reduction of back pain.

Performance Characteristics of the Device
Synflate 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; embolization of fat, thrombus or instrument or implant debris which could lead to symptomatic pulmonary embolism or other pulmonary and/or vascular or organ injury; rupture and collapse of the inflated balloon catheter and retention of fragments in the vertebral body and/or contrast agent exposure and possible subsequent allergic reaction or anaphylaxis; neurological damage, excessive bleeding, damage to vessels, soft tissue or organs; dural tear or spinal fluid leak; early and late infections, cardiac arrest, haematoma and impaired wound healing, rebounding fragments of the vertebral body that cause damage to the spinal cord or the nerve roots and can thus result in radiculopathy, paresis or paralysis, fracture of the endplate and/or sidewall of the vertebral body due to over inflation of a non-mobile fracture, rupture of the aorta, pedicle fracture, tumor extravasation.

Sterile Device

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.

Warnings and Precautions
– The product may only be used 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 manufacturer is not responsible for any complications arising from incorrect diagnosis, choice of incorrect bone filler, incorrectly combined components and/or operating techniques, the limitations of treatment methods, or inadequate asepsis.
– Do not leave the balloon implanted; the balloon material is not implant grade material.

Preoperative planning
Place the patient in the prone position on a lumbar support.
– The patient should be checked for allergy to the contrast medium.
– Before using the Synflate System, ensure that the balloon size is suitable for the specific procedure.

Patient positioning
– The operating room (OR) table should allow free manipulation of the C-arm over the operative site in both planes.
– The Synflate System may only be used under fluoroscopic control with high quality imaging.

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

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 positional and dimensional assessments.

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 positional and dimensional 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.

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 insert or advance the working sleeve in the bone without the trocar. This could damage the working sleeve and obstruct balloon insertion.
– Do not redirect the instrument assembly without removing it and re-accessing the vertebral body.

b) Guide wire access
– Under fluoroscopy, while advancing the cannulated trocar, ensure that neither the guide wire nor the cannulated trocar breaches the anterior wall of the vertebral body at any time.
– Make sure that the opening on the plastic handle of the cannulated trocar is cleared at all times while advancing the cannulated trocar in order to avoid obstruction of the guide wire passage.
– Only hammer on the blue plastic handles of the access instrumentation.
– The guide wire will extend out the back of the handle. Advance the instruments carefully to avoid injury to the physician's hand.
– Be sure to maintain the position of the guide wire to prevent it from advancing or backing out inadvertently.
– Do not insert or advance the working sleeve in the bone without the trocar. This could damage the working sleeve and obstruct balloon insertion.
– 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.
– True AP and lateral images are required to ensure accurate assessments.

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.

Creation of access channel and determination of balloon size (The access channel for the Synflate balloon is created using the plunger.)
– Do not use a hammer to drive the drill forward. The drill may aggressively advance with rotation.
– Always use fluoroscopy when advancing the drill or plunger. It is essential to avoid overdriving the drill or plunger tip into vascular structures beyond the anterior cortical wall of the vertebral body.
– 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.
– If no plunger grooves are visible under fluoroscopy, adjust the working sleeve and/or the plunger if possible. If the instrumentation cannot be safely adjusted to reveal at least one groove, then the Synflate balloon procedure will not be possible and an alternative augmentation procedure should be used.

Preparation of inflation system
– It is essential to observe the manufacturer's instructions on the indications, use and safety measures for the contrast agent.
– Only inflate the balloon with liquid, water-soluble, ionic or non-ionic contrast medium (Synflate 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.
– 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 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 white wings will return automatically to the locked position.

Preparation of balloon catheter and inflation of balloon
– Expansion of balloons, pressure and volume on the inflation system have to be monitored carefully.
– The pressure of the Synflate balloon may not exceed the maximum inflation pressure of 30 atm. A manometer is used to monitor the pressure.
– The inflation volumes of the Synflate balloons must not exceed the maximum volumes specified in the section "Additional Device-Specific Information".
– The balloons may leak if they are filled beyond their maximum volume or pressure.
– The performance of the balloon catheter may be adversely affected if it comes into contact with bone splinters, bone cement and/or surgical instruments.
– Do not use air or other gases to inflate the Synflate balloon catheters.
– Never expose the balloon catheter to organic solvents (e.g. alcohol).
– The inflation characteristics of Synflate are altered by inflation inside bone.
– For bilateral procedures, it is important to ensure balloon inflation does not induce misalignment (e.g. unsymmetrical height restoration). However, it may be desirable to inflate the balloons to different volumes to prevent or correct misalignment.

Deflation and retrieval of balloon
– Only reinsert the stiffening wire when balloon is outside the patient.
– Prior to reinserting the catheter back into the white cover sleeve, rinse the balloon to remove any residues with saline solution. Do not clean the balloon by methods of direct contact (e.g. wiping). Since the first inflation may stretch the balloon material, the length may become larger than the original length. Therefore, always insert the catheter under fluoroscopic control.

Injection of bone filler
– 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.
– Do not use the grey colored biopsy kit for cement application.
– Check the compatibility of the bone filler with the injection needle prior to bone filler application.
– Closely monitor the bone filler injection under fluoroscopy to reduce the risk of bone filler leakage. Severe leakage can cause death or paralysis. If bone filler leakage is observed during the procedure, stop injecting and consider the following: wait for the injected bone filler to harden, reposition the needle, adjust the needle direction, or stop the procedure. If desired, continue bone filler injection slowly, and carefully evaluate for further leakage. If further leakage is observed, cease bone filler injection.
– The timing of the release of the bone filler is dependent on the bone filler selection. Its preparation, injection and setting times vary by product, refer to the system's instructions prior to surgery and plan accordingly. If the injection needle with the working sleeve is removed too early, there may be a risk of pulling cement fibers into the muscle tissue. If the injection needle is removed too late, the injection needle may become stuck or difficult to remove.
– For bilateral approach, leave both injection needles inserted while applying the bone filler to avoid backflow into the working sleeve.

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

Combination of Medical Devices
Synflate is intended to be used in combination with a legally-marketed bone filler adequately indicated for use in vertebroplasty or vertebral body augmentation procedures. Refer to the manufacturer's directions accompanying the bone filler for specific information on its use, indications, contraindications, precautions, warnings, potential adverse events, undesirable side effects and residual risks.
Synflate is intended to be used with Access Kits (10 G & 4.7 mm), Biopsy Kit and inflation system. Please refer to the associated product information for details on its use, precautions, warnings, potential adverse events, undesirable side effects and residual risks.
Alternate instrumentation must not be used with the Synflate System.
Synthes has not tested compatibility with devices provided by other manufacturers and assumes no liability in such instances.

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. Do not use if the package is damaged.

Additional Device-Specific Information
The Synflate vertebral balloon is available in three sizes.

Article no.	Balloon Length	Initial Length	Max. ∅*	Max. Length*	Max. Vol.	Max. Pressure
03.804.700S Small	10 mm	14 mm	16.3 mm	18.1 mm	4 ml	30 atm 440 PSI
03.804.701S Medium	15 mm	19 mm	16.1 mm	23.3 mm	5 ml	30 atm 440 PSI
03.804.702S Large	20 mm	24 mm	16.3 mm	28.9 mm	6 ml	30 atm 440 PSI

* At maximum inflation volume in water bath at 37 °C. Depending on the bony structure dimensions (diameter and length) may vary inside the vertebral body.

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

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