

A Balloon-based Vertebral Augmentation System

SYNFLATE®

Vertebral Balloon

Surgical Technique

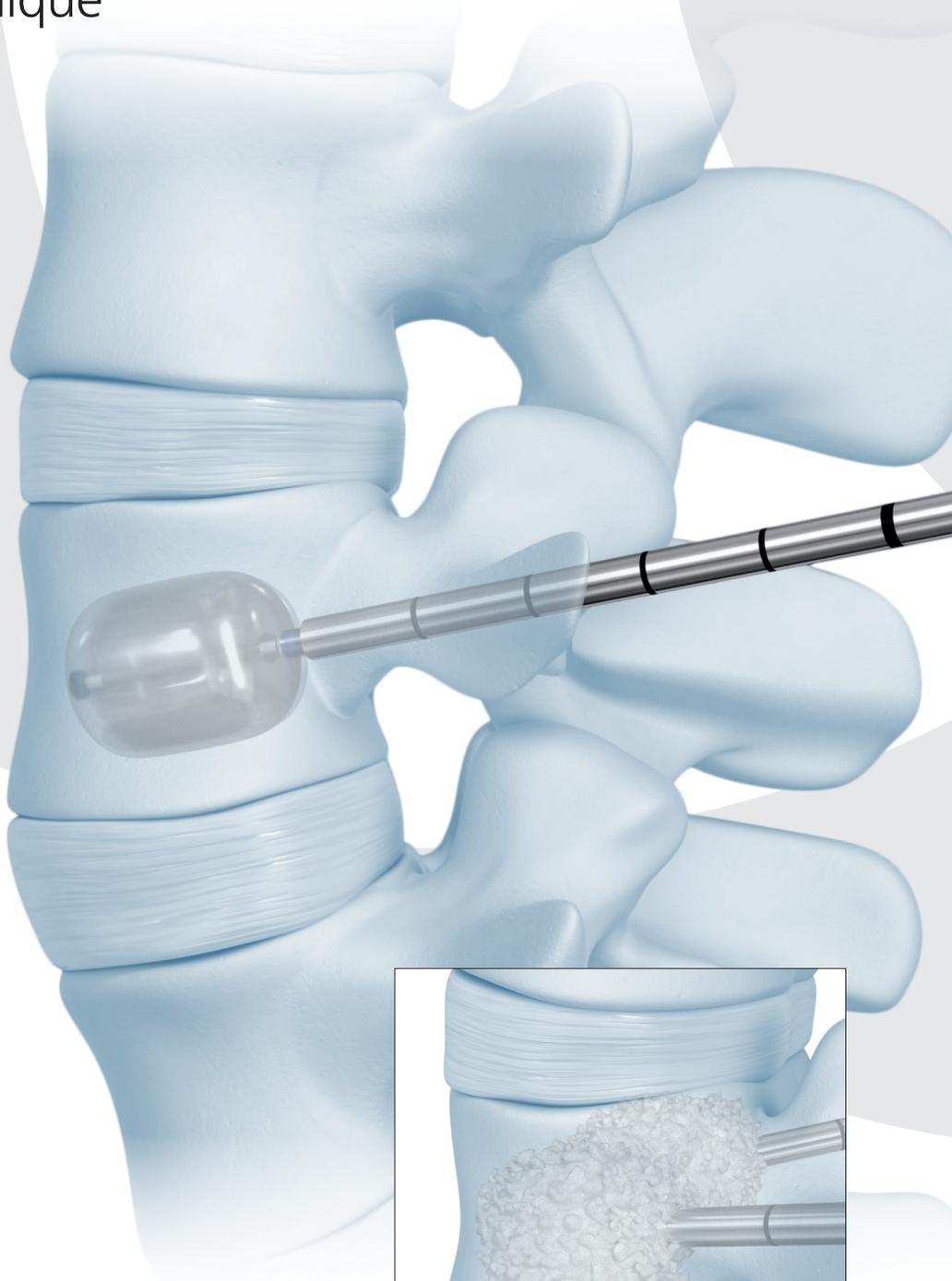


 Image intensifier control

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.depuyshnthes.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.depuyshnthes.com/hcp/reprocessing-care-maintenance>

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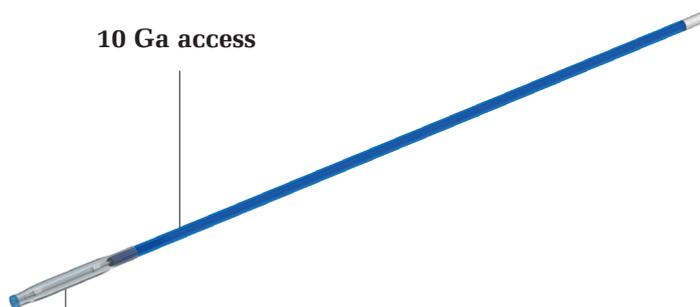
SYNFLATE® Vertebral Balloon



Two radiopaque markers

For X-ray visualization of the balloon to facilitate placement

10 Ga access

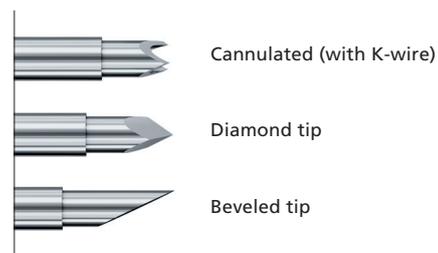


3 balloon sizes

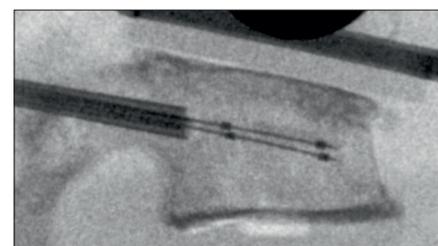
with a pre-inflation profile of 3.2mm

Insertion of the Synflate Vertebral Balloon

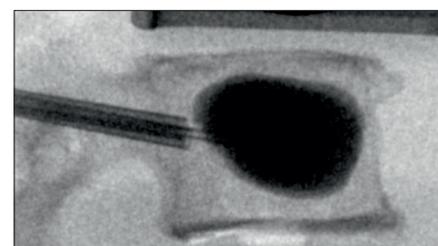
Three different options for access trocars



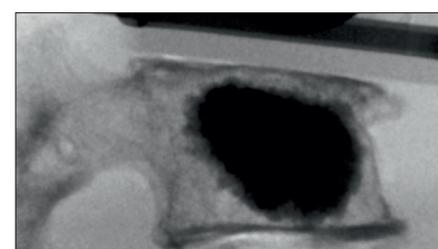
Access the Vertebral Body



Insertion of the Synflate Vertebral Balloon



Inflation of Synflate Vertebral Balloon



Injection of the bone filler (here Vertecem V+ Cement)

Inflation port with valve

One-step Catheter preparation using the vacuum syringe enclosed in the packaging



Additional port for the stiffening wire

Stiffening wire gives rigidity. Optional removal for inflation upon surgeons preference

Cover sleeve

3 balloon sizes with a pre-inflation profile of 3.2mm



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}

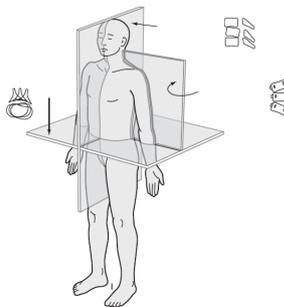
Stability

Stabilization to achieve a specific therapeutic outcome



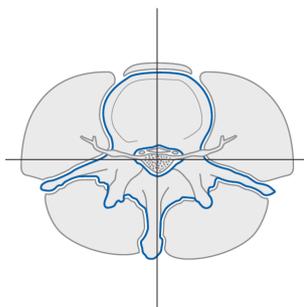
Alignment

Balancing the spine in three dimensions



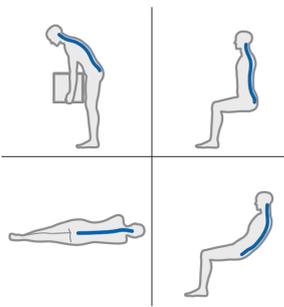
Biology

Etiology, pathogenesis, neural protection, and tissue healing



Function

Preservations and restoration of function to prevent disability



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Preoperative Planning

Planning of balloon placement

The placement of the SYNFLATE® Vertebral Balloon(s) should be planned based on the AP and lateral image which helps to identify the proper insertion path.

Preplanning of appropriate balloon size

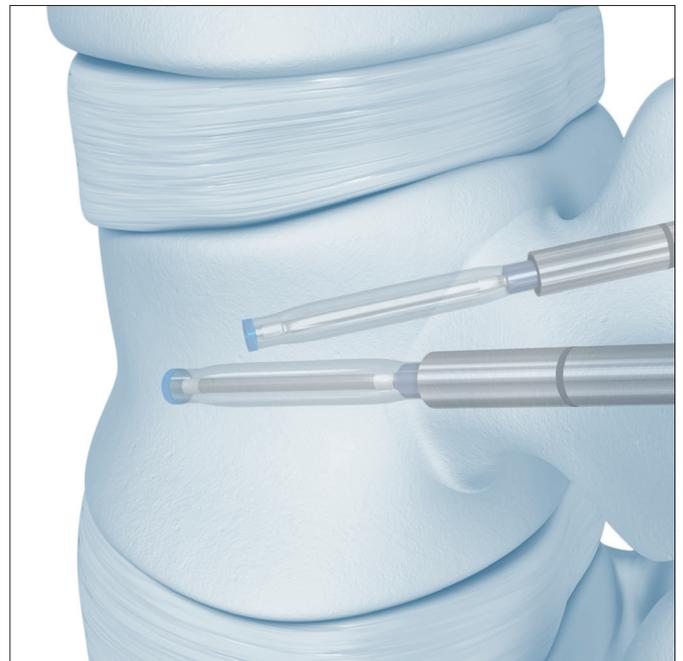
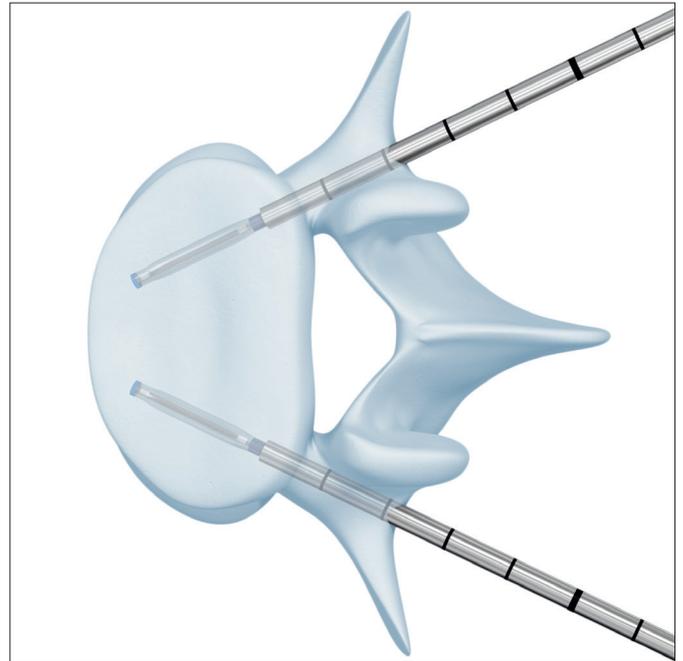
The balloon size for the procedure can be roughly approximated by using MRI or radiographs during pre-operative planning.

Precaution: Before using the Synflate system, ensure that the balloon size is suitable for the specific procedure.

Intraoperative x-ray imaging

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

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



Anatomical landmarks

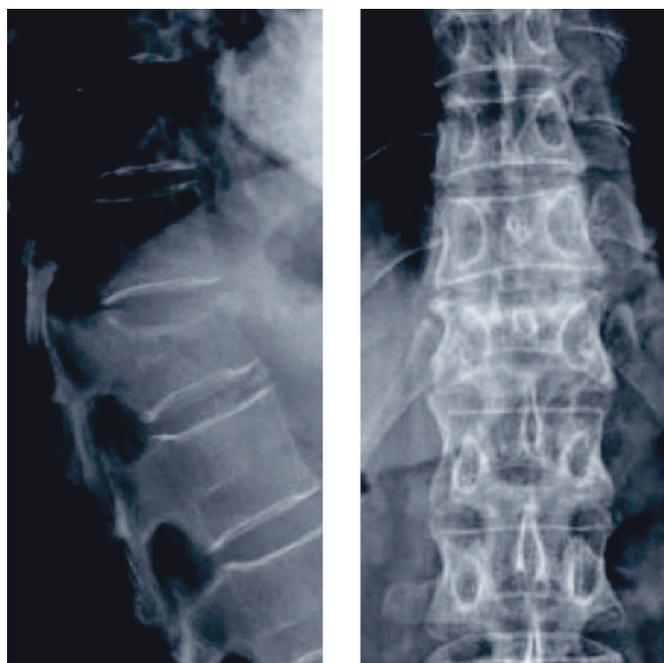
For vertebral augmentation with Synflate, it is recommended to place two balloons per vertebra. Some anatomical situations may require the use of one balloon only.

If two balloons are used, make sure they are positioned in a symmetrical, paramedian way within the affected vertebral body to achieve optimum reduction of the spinal fracture without damaging the lateral vertebral body edges.

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

The following landmarks should be defined on the spine:

- Both pedicles
- Spinous process
- Endplates
- Posterior wall of vertebral body



Patient Positioning

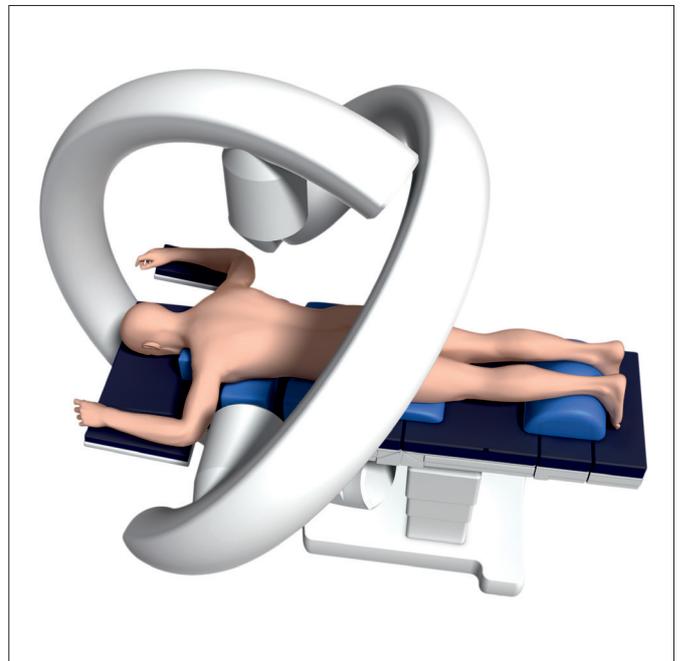
Place the patient in the prone position on a lumbar support. The table must be radiolucent to allow imaging of the targeted/affected levels in both planes.



- Biplanar fluoroscopy is recommended for the most efficient use of imaging. A single, freely mobile C-arm may also be used. Set up the table, patient and fluoroscopy to facilitate AP and lateral imaging throughout the procedure.

Precautions:

- The 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

Instrument options

03.804.514S	Access Kit, 10 G, Diamond Tip, with side-opening, Double Pack, sterile
03.804.515S	Access Kit, 10 G, Beveled Tip, with side-opening, Double Pack, sterile
03.804.519S	Access Kit, 10 G, Diamond Tip, with side-opening, Single Pack, sterile
03.804.520S	Access Kit, 10 G, Beveled Tip, with side-opening, Single Pack, sterile
03.804.521S	Access Drill, 10 G, sterile

Alternative Instrument

03.804.612S	Access Kit 4.7
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The access instruments (guide wire or trocar) can be inserted through either a transpedicular or extrapedicular approach.

Option A. Transpedicular

- 1 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.

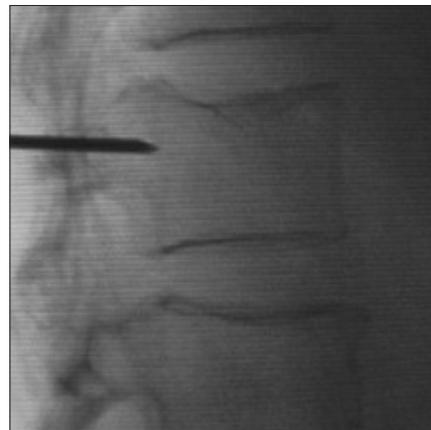
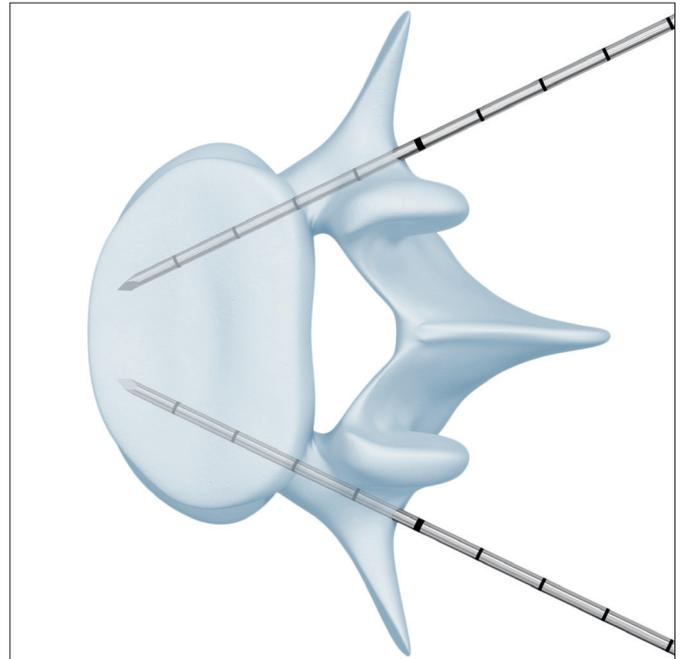
Make a skin incision.

- 2 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 positional and dimensional assessments.

If considering a transpedicular approach, ensure that the diameter of the pedicle is large enough to be punctured by the chosen access system or by the 4.7mm access instrumentation respectively.



Option B. Extrapedicular

- 1 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.

- 2 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 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.

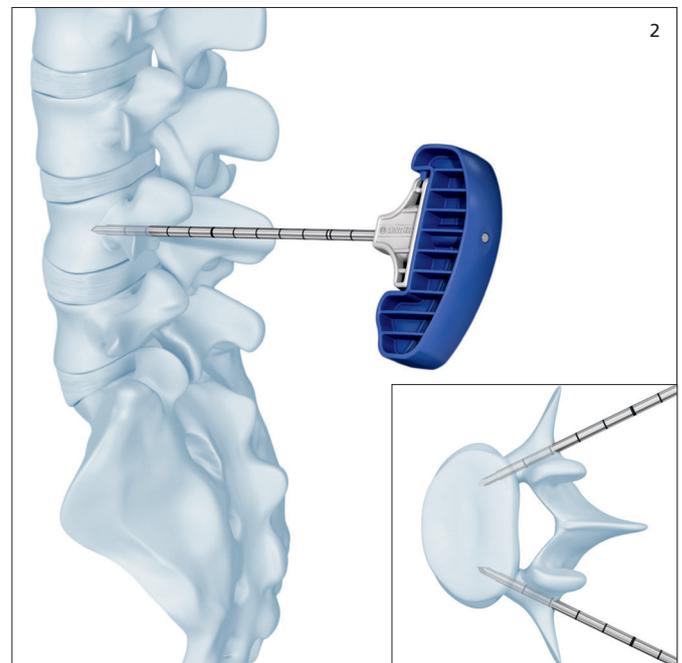
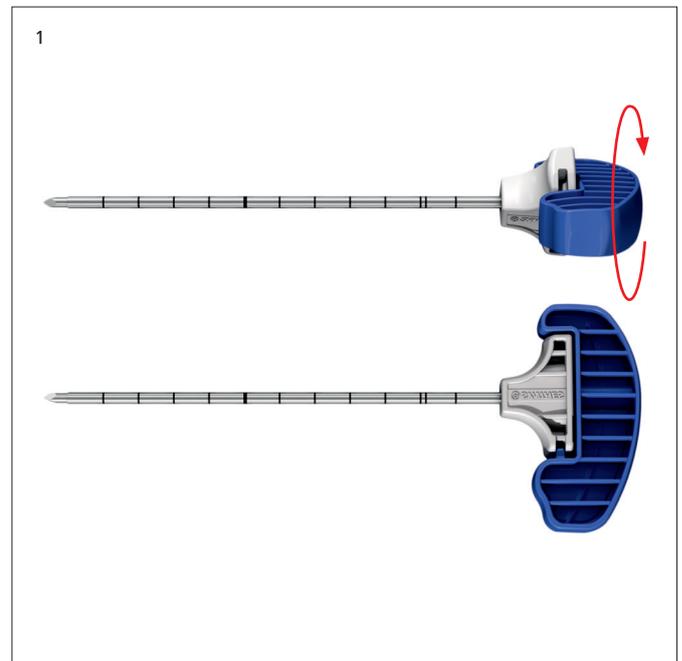
Option A. Trocar

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.

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

- Under fluoroscopy, insert the trocar instrumentation until the end of the working sleeve is tightly seated approximately 3 mm into the vertebral body (2). The end of the working sleeve can be identified by locating the step in diameter between trocar and the working sleeve.



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

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.

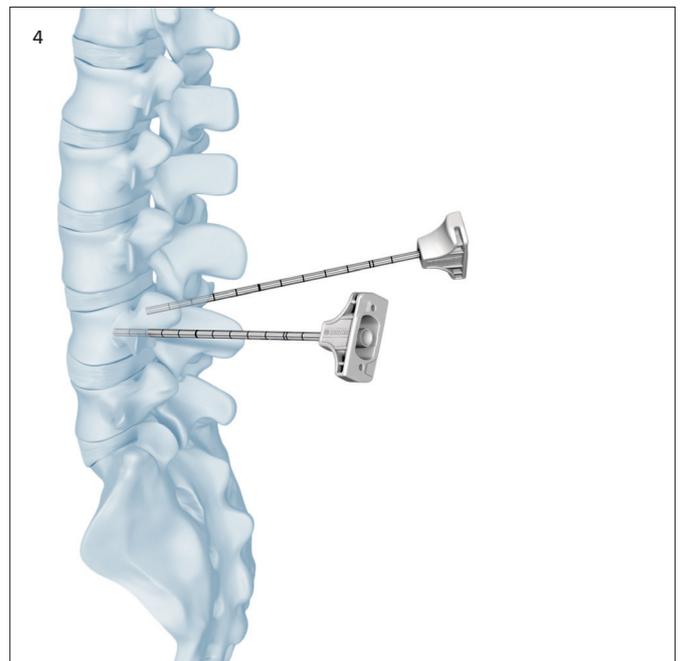
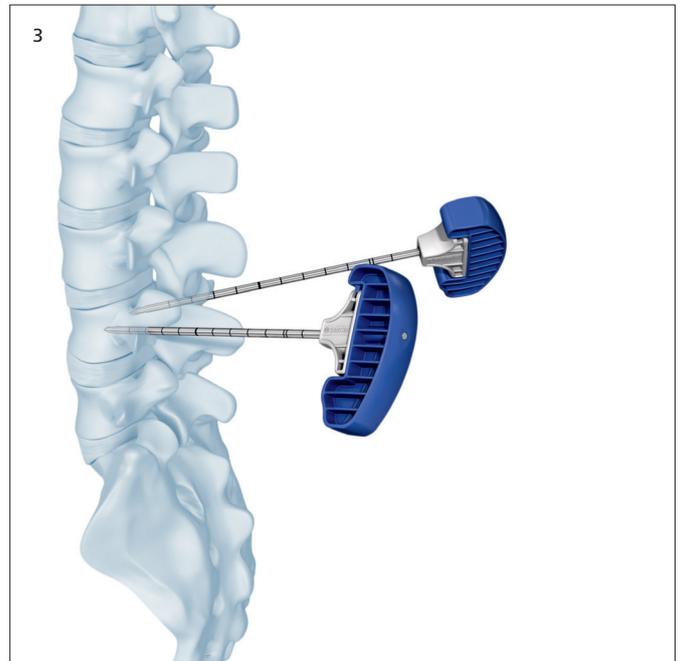
- ① Confirm proper positioning of the access instrumentation under fluoroscopy in both AP and lateral view.

Warnings:

- 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.

For bilateral procedures, repeat on the contralateral side (3).

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



Option B. Guide Wire

The guide wire option is available in the double pack access kits only.

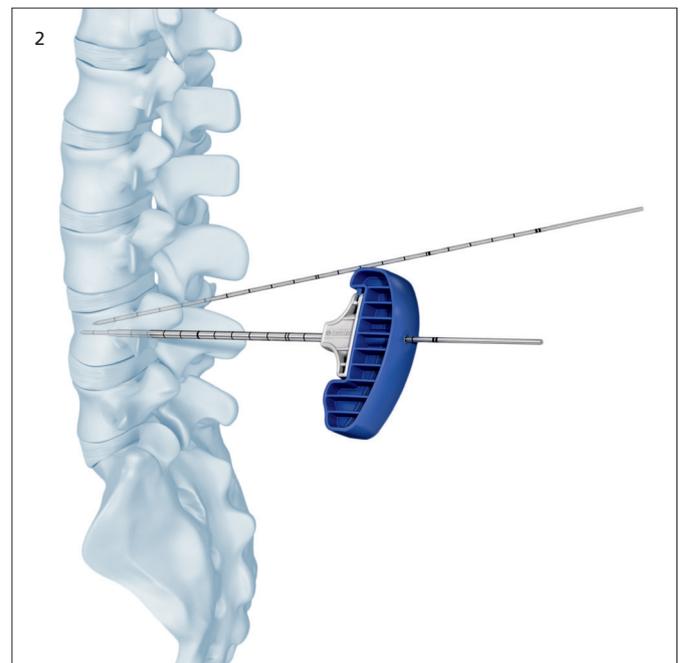
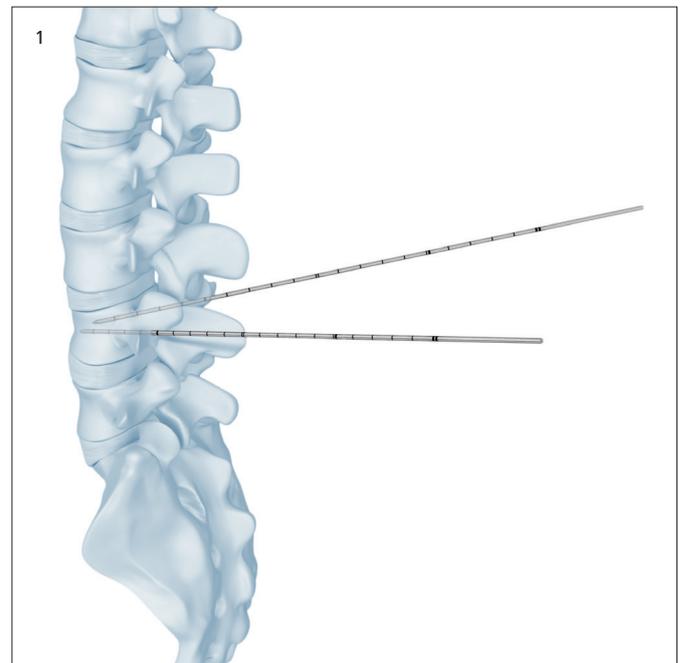
Insert the guide wire to create the access path, and position appropriately (1). Insert the working sleeve and cannulated trocar assembly over the guide wire and into the vertebral body (2).

- ① 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:

- ① • 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.
- 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 Confirm proper positioning of the access instrumentation under both AP and lateral fluoroscopy.

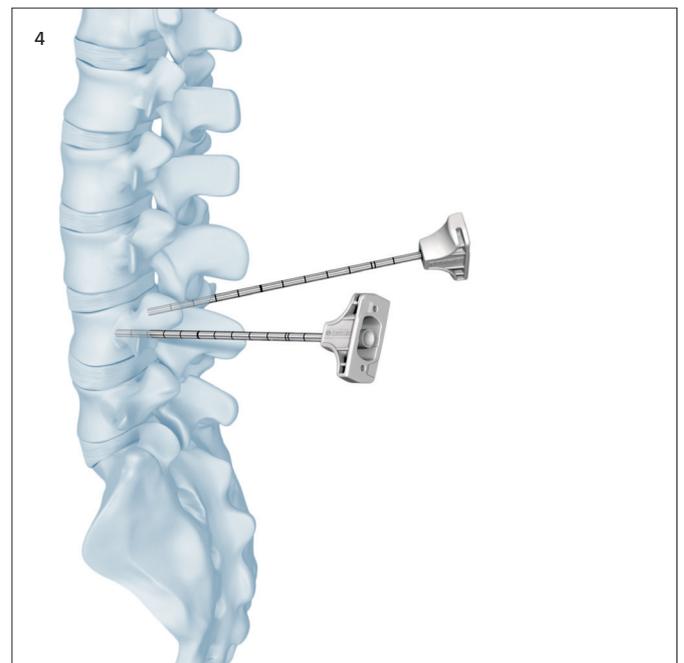
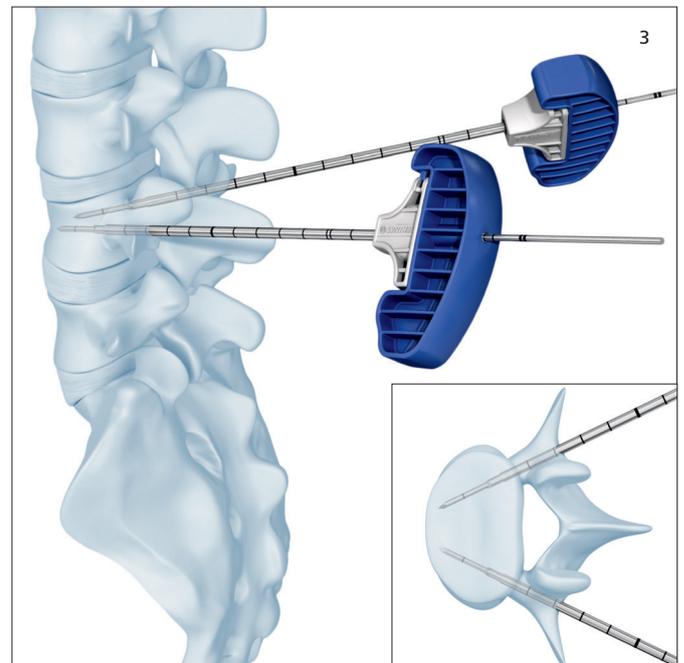
Warning: Do not insert or advance the working sleeve in the bone without the trocar. This could damage the working sleeve and obstruct balloon insertion.

For bilateral procedures, repeat on the contralateral side (3).

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

Warnings:

- Do not redirect the instrument assembly without removing it and re-accessing the vertebral body.
- Do not use excessive force on the guide wire to avoid potentially deforming the guide wire.



Biopsy

After placement of the working sleeve (see chapters Approach and Access before), an optional biopsy can be taken using the biopsy kit.

Instruments

03.804.522S Biopsy Kit, 10 G, sterile

Alternative Instrument

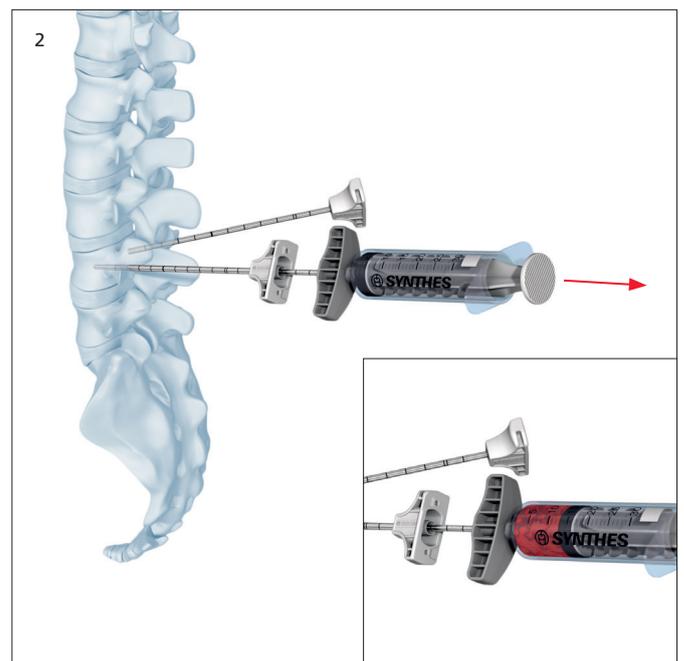
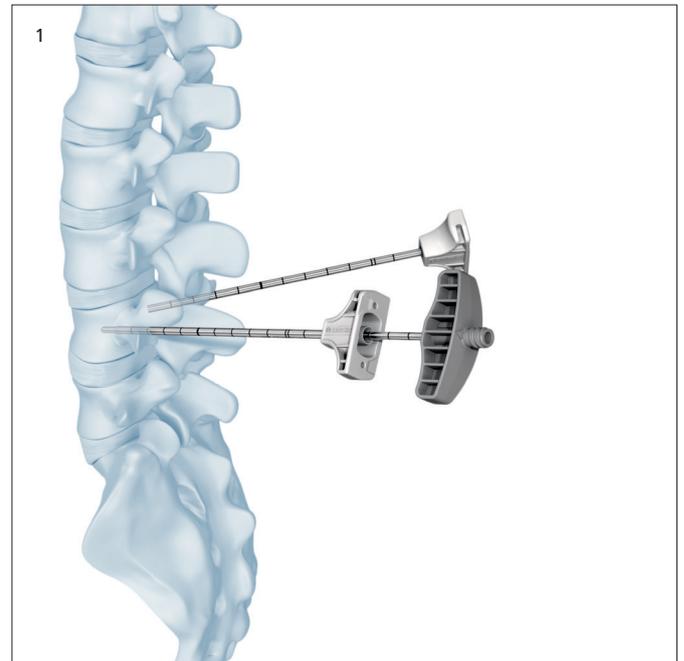
09.804.613S Biopsy Kit 4.7*

Remove plunger from the biopsy needle.

- 1 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).
- 2 Under fluoroscopy, advance the biopsy needle further and rotate it at least one full turn (360°). This will help to remove the biopsy.
- 3 **Warning: Do not insert the biopsy needle beyond the anterior cortical wall of the vertebral body, as this could damage vascular structures.**

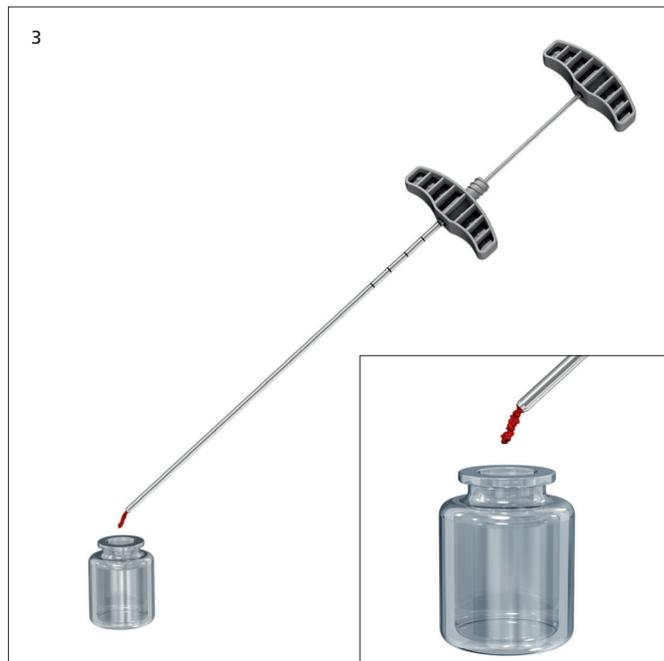
Attach a luer lock syringe to the biopsy needle and create a vacuum to retain the bone biopsy in the needle (2). Remove the biopsy needle with the attached syringe from the working sleeve.

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



* Only if Access Kit 4.7 (Art. No. 03.804.612S) is used for access creation.

Release the vacuum, remove the syringe and use the biopsy plunger to push the collected bone tissue out of the biopsy needle (3).



Creation of Access Channel and Determination of Balloon Size

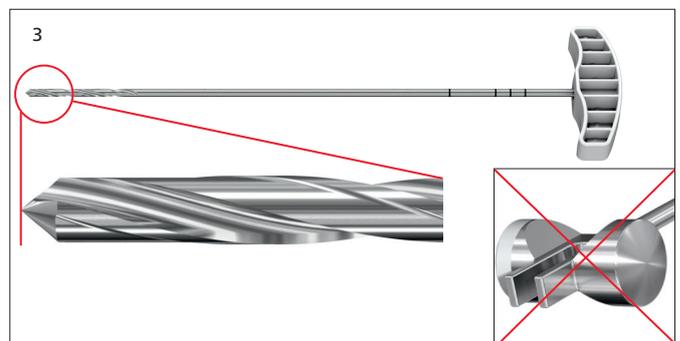
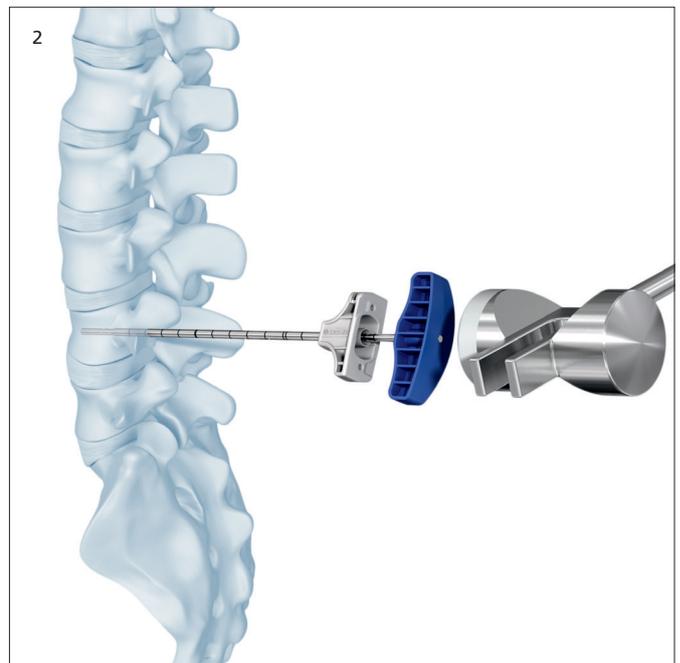
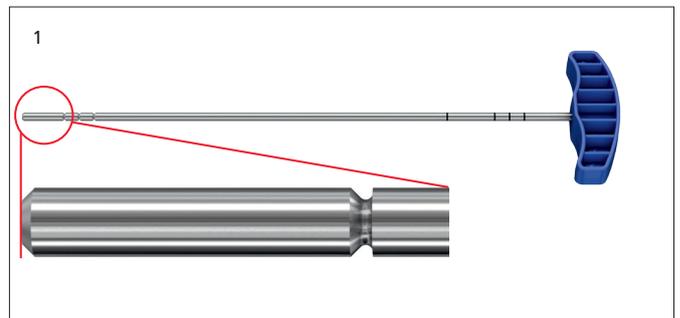
The plunger has two important uses:

- a) To create an access channel for balloon insertion
- b) To determine the appropriate balloon size

1. Create access channel

- 1 The access channel for the Synflate balloon is created using the plunger (1).
- 2 Under lateral fluoroscopy, insert the plunger through the working sleeve and into the vertebral body. The plunger may be advanced by hand or gently hammering on the blue handle (2).

As an additional option, the plunger can be removed and the access channel can be created with the access drill (3). Advance the drill slowly by turning the handle clockwise. Remove the drill and insert the plunger to size and verify balloon position. It is also possible to use the access drill prior to the use of the plunger.



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

Note: The distal (first) marking on the plunger and drill indicates when the tip leaves the working sleeve whereas the three following markers show the initial lengths of the balloon sizes S/M/L, respectively.

- ⓘ **Warning:** 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.

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.

For bilateral procedures, repeat on the contralateral side.

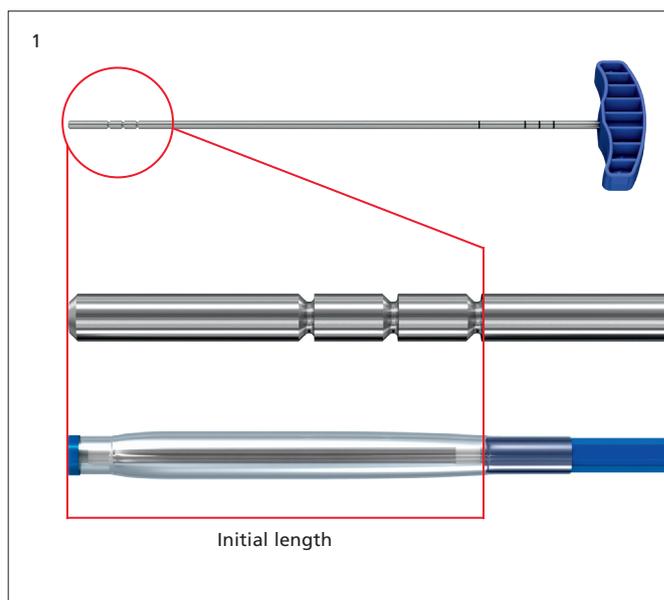
2. Determine balloon size

The Synflate Vertebral Balloon is available in three sizes.

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

The plunger has three grooves towards the distal tip that correspond to the three initial lengths of the Synflate balloons: small, medium and large. In (1), an example of a large size balloon is shown. Its initial length corresponds to the distance between tip and third groove of the plunger.

Note: If the Access Kit 4.7 (Art. No. 03.804.612S) is used, be aware that the initial length of each balloon is smaller than the distance between tip and the corresponding groove of the plunger.



*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.

- Once the plunger has been positioned appropriately (2), use lateral fluoroscopy to determine the maximum Synflate balloon size (3).

From distal tip, the first groove visible outside the working sleeve:

Synflate Vertebral Balloon, Small

From distal tip, the second groove visible outside the working sleeve:

Synflate Vertebral Balloon, Medium

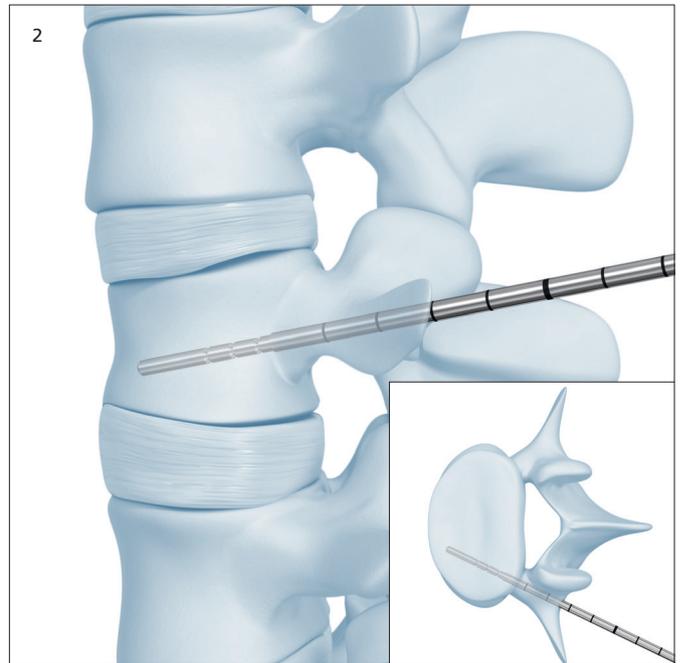
From distal tip, the third groove visible outside the working sleeve:

Synflate Vertebral Balloon, Large

Precaution: 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.

For bilateral procedures, repeat on the contralateral side.

Technique tip: When using two single packs for bilateral procedures, two plungers are available which can be used simultaneously on both sides to check alignment of the access channel.



In this case 3 grooves are visible allowing for a maximum balloon size of large

Preparation of Inflation System

Instrument

03.804.4135 Inflation System, sterile

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

It is necessary to prepare one inflation system per balloon.

The 3-way-valve contained in the package will not be used for the Synflate procedure.

Fill the inflation system with saline solution and a liquid contrast medium.

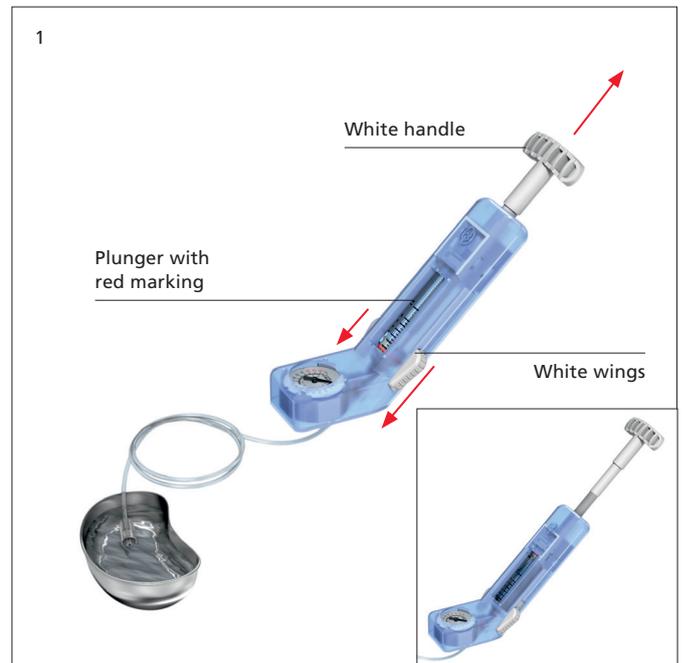
Precaution: It is essential to observe the manufacturer's instructions on the indications, use, and safety measures for the contrast agent.

- **Note:** It is essential to fill the inflation system with saline/contrast agent mixture to ensure visibility of the Synflate balloon during inflation.

Precaution: 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.

Prepare the contrast medium mixture in a cup (about 15 ml per inflation system) and place the end of the flexible tube of the inflation system in the solution. Push forward on the white wings on the inflation system and pull back on the handle until the plunger bottoms out (1, inset).

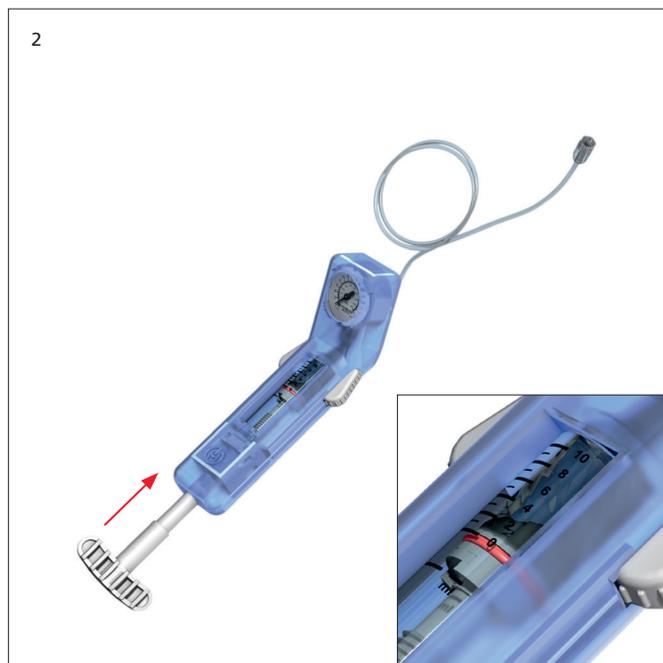
Precaution: Patients should be checked for allergy to the contrast medium.



With the handle pointing downwards, tap the unit to clear the gauge portion of the inflation system of air (2). Rotate the handle clockwise to expel all the air in the barrel. Continue turning the handle clockwise, until solution starts to emerge and the leading edge of the red mark on the plunger reaches the zero mark (2, inset).

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 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

Instruments

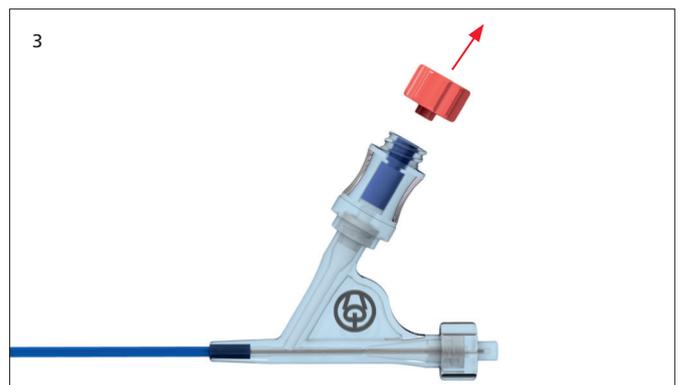
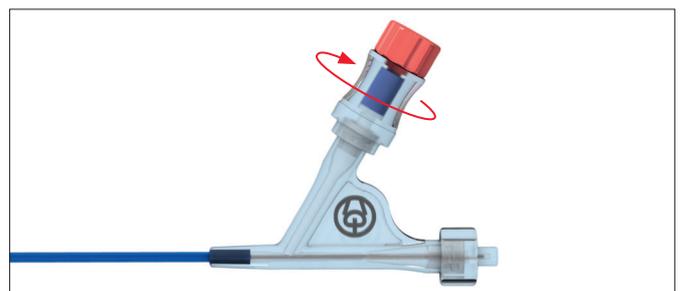
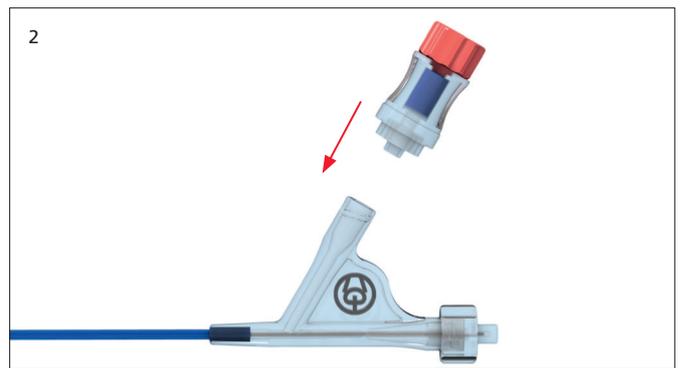
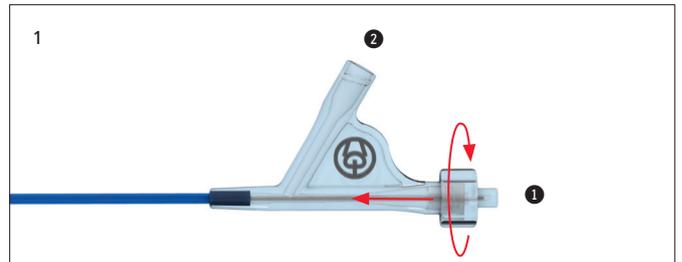
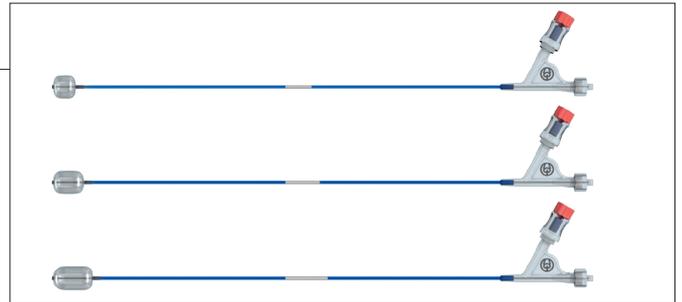
03.804.700S	Synflate Vertebral Balloon, small, sterile
03.804.701S	Synflate Vertebral Balloon, medium, sterile
03.804.702S	Synflate Vertebral Balloon, large, sterile

The Synflate vertebral balloon catheter is designed on a double lumen principle. This includes the inner lumen with the stiffening wire ❶ and the outer lumen ❷ which delivers the inflation medium to the balloon (1). Both lumens are independent and therefore it is the surgeon's choice to remove the stiffening wire during inflation. If removed keep stiffening wire for further reuse.

To prepare the Synflate balloon catheter, remove the Synflate catheter from the sterile packaging.

Note: Since the stiffening wire is NOT attached, make sure not to loose it while removing the catheter from the package and make sure to attach it tightly to the inner lumen luer (1). If the stiffening wire sticks, gently push it towards the luer lock by a back- forward movement.

If not mounted already attach the valve with the red cap tightly to the outer lumen (2). Remove the red cap from the side arm of the luer (3).



It is mandatory to create a vacuum in the balloon catheter prior to its insertion into the working sleeve. For this, remove the enclosed vacuum syringe from the package, connect it to the side luer of the Y-connector and draw a vacuum by drawing back the syringe plunger until bottomed out (4). Make sure that the syringe is tightened well on the side luer in order to maintain the vacuum.

In this position, the syringe plunger can be blocked by turning it a quarter turn up to marking (5).

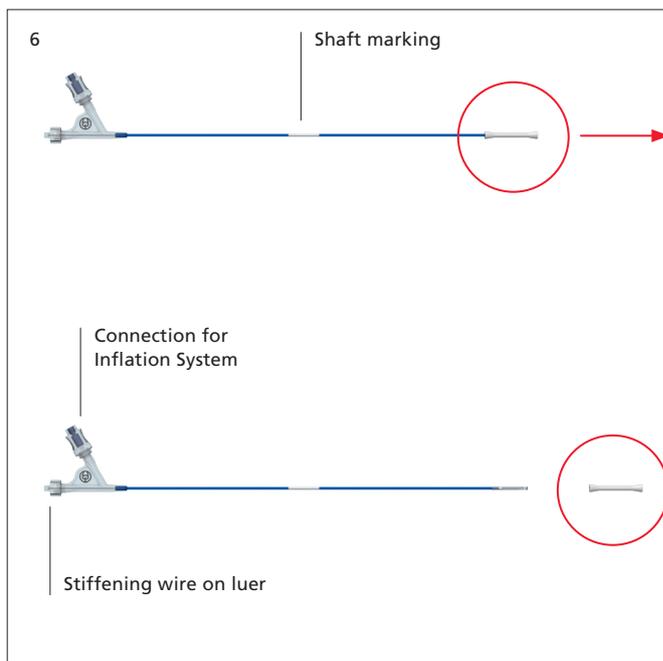
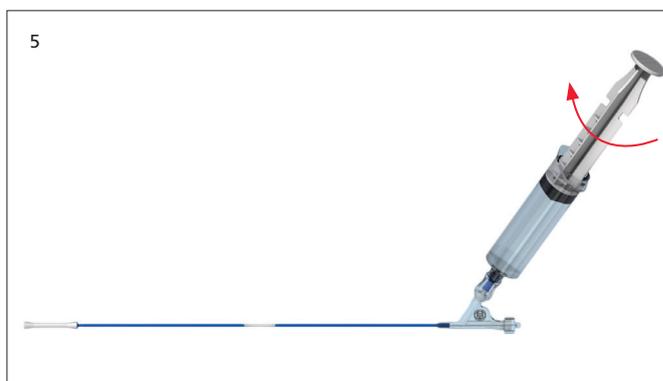
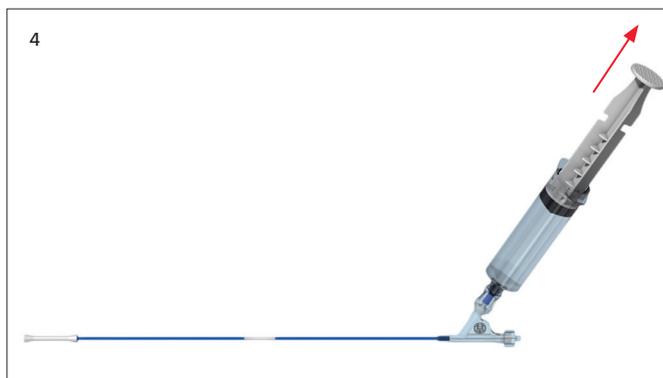
Remove the whole syringe from the side luer. The vacuum in the catheter is kept by the valve.

Remove the white cover sleeve from the balloon (6). This cover sleeve can be used later for folding back the balloon after catheter removal for reuse.

Note: Do not slide the cover sleeve towards the luer lock since this may lubricate the shaft reducing the grip for catheter introduction.

A white marking on the balloon catheter shaft indicates the initial length of the balloon (6).

Note: The Synflate balloon catheter may be reused once within one surgery.



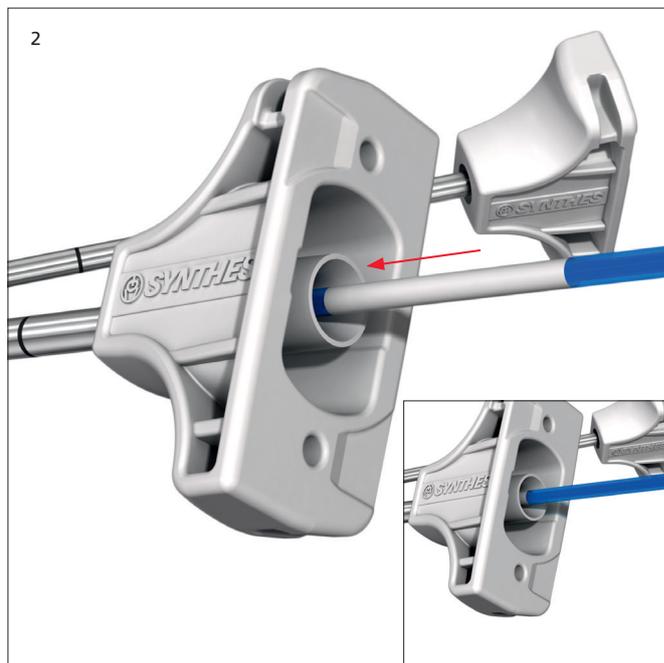
Inflation of Balloon

1. Insert balloon

1. Insert the balloon catheter under lateral fluoroscopy (1). The balloon is completely outside the working sleeve when the proximal end of the white marking of the catheter shaft disappears into the working sleeve (2, inset).

Notes:

- Check the balloon position by identifying the markers of the balloon under fluoroscopy in AP and lateral view.
- If it is not possible to completely insert the balloon catheter so that the white marking of the catheter shaft disappears, it may be necessary to clear the path again using the plunger.
- For insertion, the catheter stiffening wire must always be mounted to the catheter.
- If the balloon experiences high friction in the working sleeve, the catheter can be pulled back and forth for lubrication resulting in a decreased insertion force.

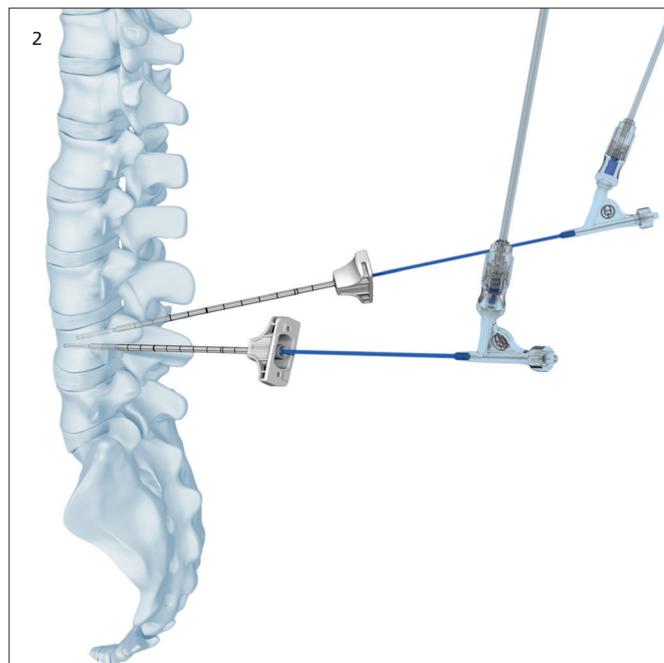
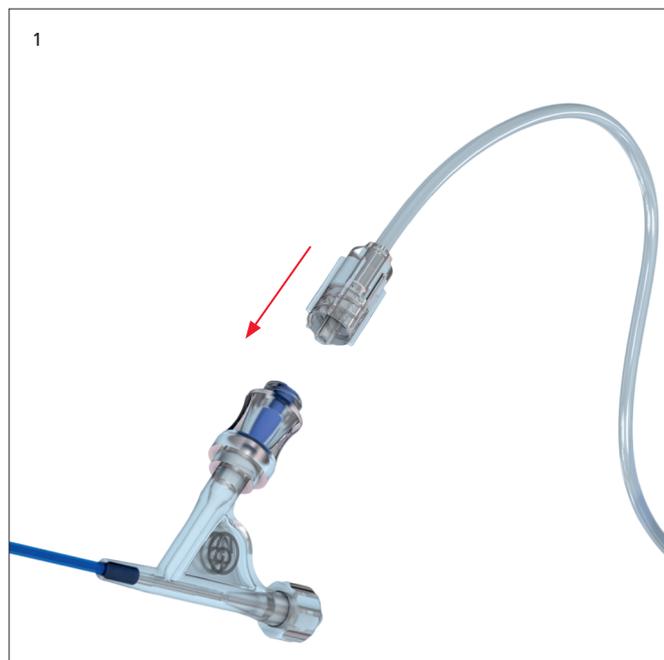


2. Connect the inflation system(s)

Connect the inflation system to the side port of the catheter (1,2).

Notes:

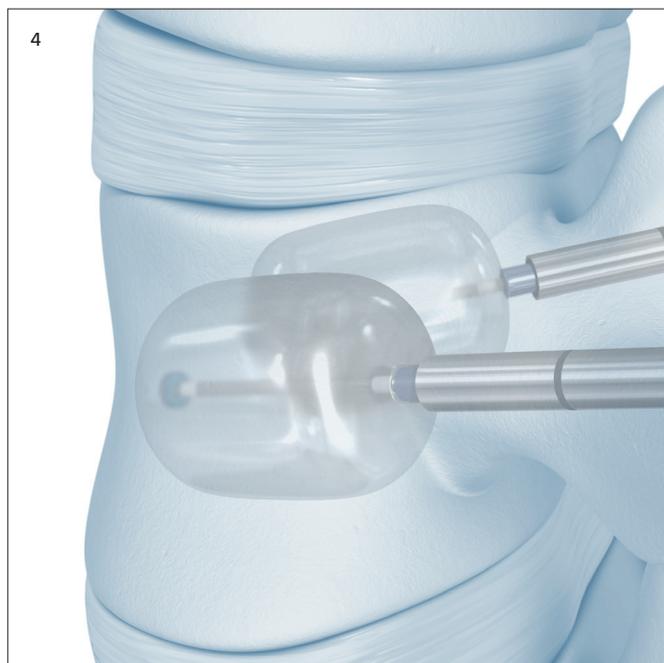
- Do not connect the inflation system prior to catheter insertion since this may hamper the insertion.
- Do not connect the inflation system to the connection of the stiffening wire.



3. Inflate balloon

- To inflate the balloon (4), slowly rotate the handle of the inflation system clockwise while monitoring the pressure and volume. Monitor the balloon inflation under fluoroscopy.

Proceed with inflation slowly, stopping every few seconds to allow the bone to adjust to the pressure/volume changes.



Stop increasing inflation in any of the following cases:

- The desired outcome is reached
- The pressure reaches 30 atm (440 psi)
- The maximum balloon volume is achieved
 - 4.0 ml for the small balloon
 - 5.0 ml for the medium balloon
 - 6.0 ml for the large balloon
- Any part of the inflated balloon length touches the cortical bone

Precaution: Expansion of balloons, pressure and volume on the inflation system have to be monitored carefully (5).

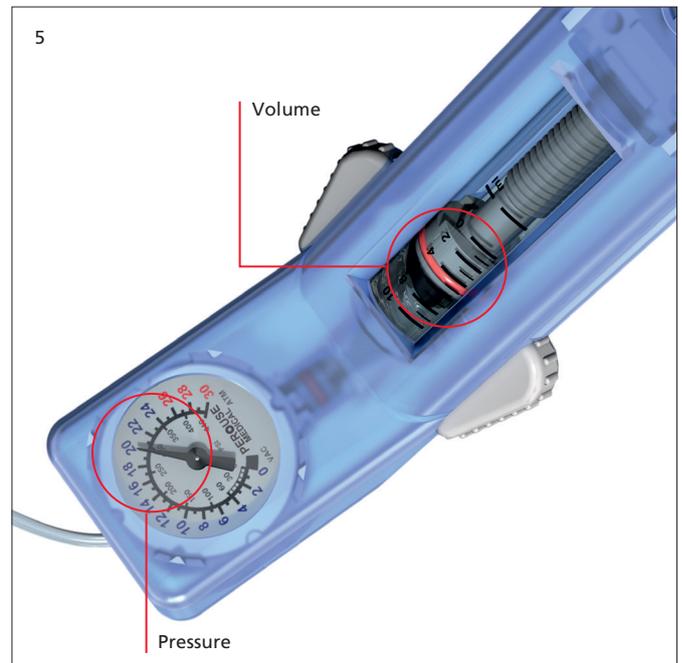
Precautions:

- 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.

Warning: The balloon material is not implant grade material.

For bilateral procedures, inflate each balloon alternately in increments.

Precaution: 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

Gradually decrease the pressure by turning the handle of the inflation system counterclockwise (1), until the manometer indicates approximately 10 atm (150 psi). Slide the white wings forward while pulling the handle all the way back (2) slowly and wait a few seconds to fully deflate the balloon and draw a vacuum. Release the wings with the handle pulled all the way back, to seal the vacuum.

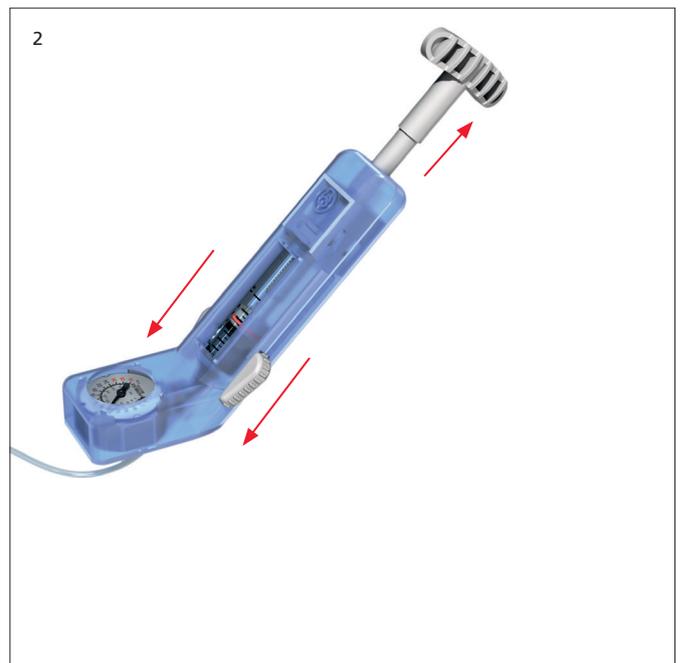
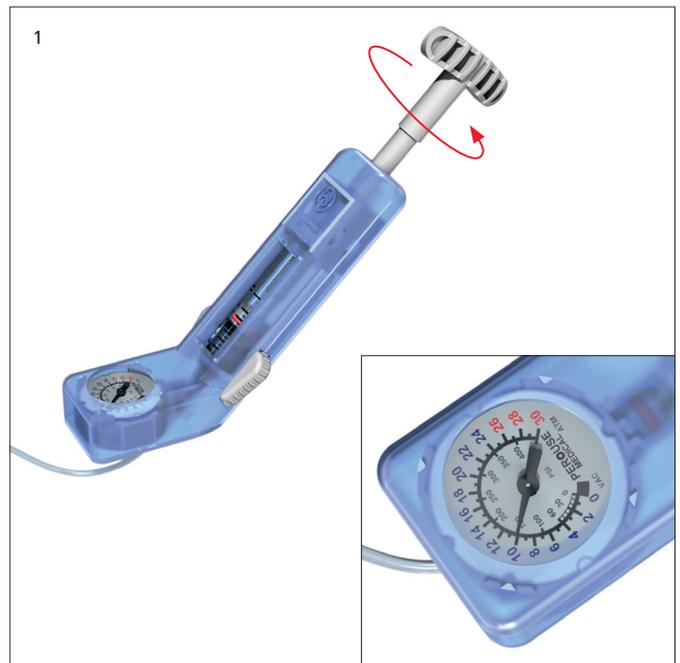
Notes:

- Hold the working sleeve in place and pull firmly on the catheter to retrieve the balloons.
- If the balloon does not deflate, check the connections to the inflation system, draw a vacuum again, or assemble the vacuum syringe to draw a vacuum and deflate the balloon.
- If it becomes difficult to remove the balloon catheter through the working sleeve, twist the catheter while firmly pulling the catheter.

If removal is still difficult, remove the balloon catheter(s) along with the working sleeve(s), then re-access the vertebral body using the working sleeve with the trocar assembly. Once the re-access is completed, remove the trocar.

Precaution: Only reinsert the stiffening wire when balloon is outside the patient.

For bilateral procedures, deflate and retrieve each balloon alternately in increments.

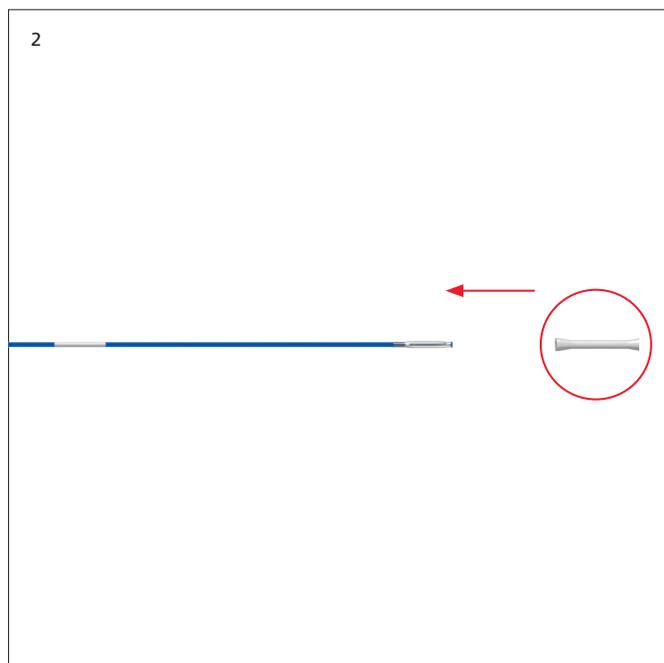


① Reuse of balloon catheter

The Synflate balloon catheter may be reused once within one surgery.

For balloon catheter reuse, remove the inflation system and carefully insert the catheter back into the white cover sleeve to properly refold the balloon (2). Then start over with the balloon catheter preparation see pages 24 and 25.

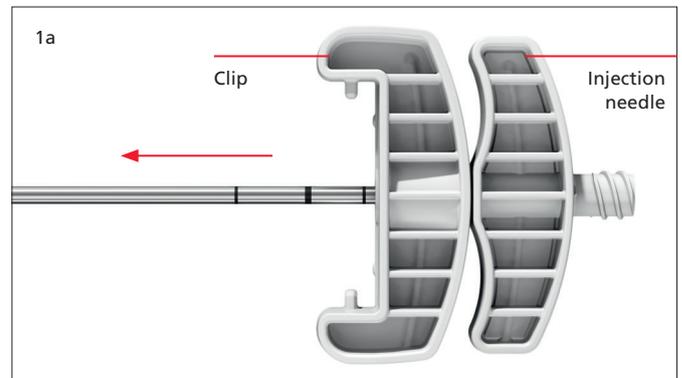
Precautions: Prior to reinserting the catheter back into the white cover sleeve, rinse the balloon to remove any residues with saline solution. Do not clean the balloon by methods of direct contact (e.g. wiping). Since the first inflation may stretch the balloon material, the length may become larger than the original length. Therefore always insert the catheter under fluoroscopic control.



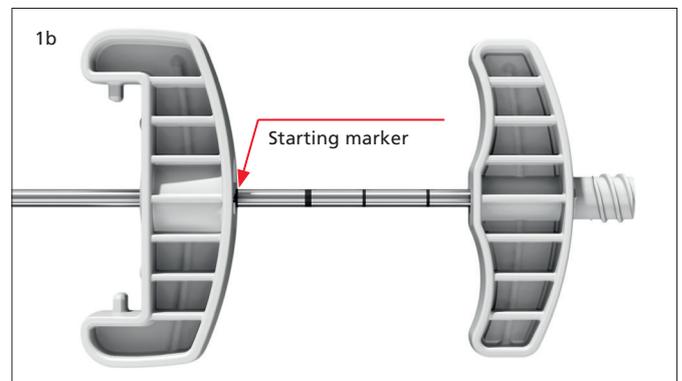
Injection of Bone Filler

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.



Insertion of injection needle

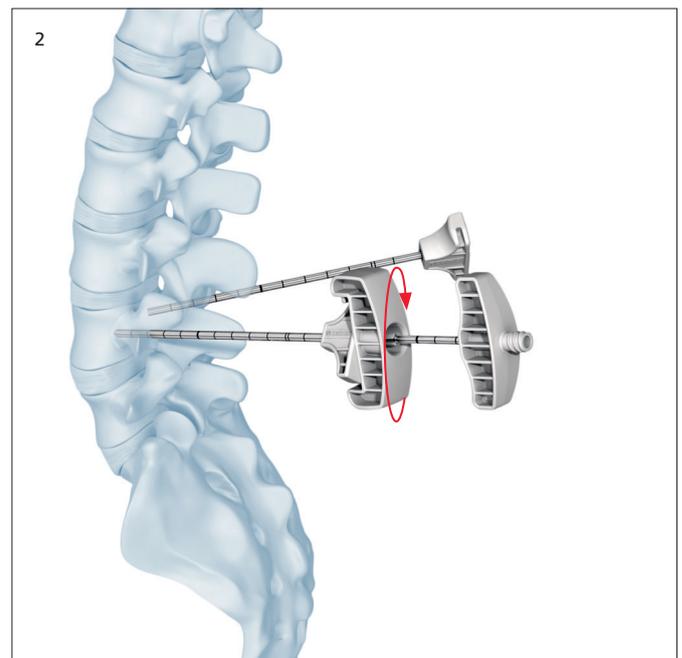
- Under fluoroscopy, insert the injection needle with clip into the working sleeve (2) and fix the clip to the working sleeve.

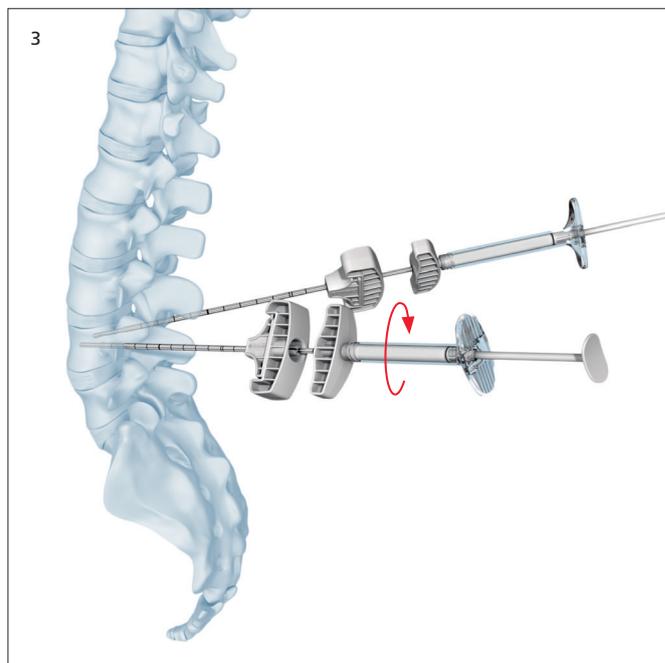
Warning: Do not use the grey colored biopsy kit for cement application.

Precaution: Check the compatibility of the bone filler with the injection needle prior to bone filler application.

The filling volume of the injection needle is 1 ml.

Note: If the Access Kit 4.7 mm is used, the filling volume of the injection needle is 1.8 ml.

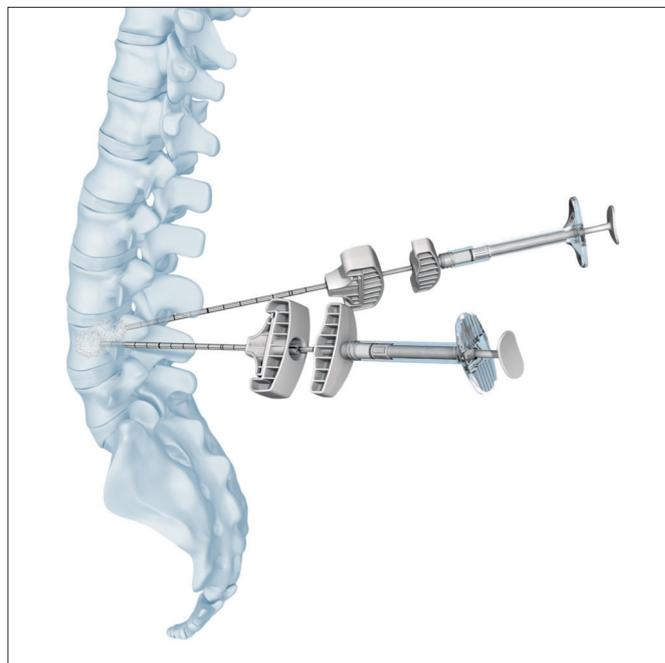




- Under lateral fluoroscopy, inject the bone filler. The direction of the bone filler flow can be changed by orienting the handle of the injection needle with the side-opening. Make sure to apply the appropriate amount of bone filler according to the surgical situation.

Notes:

- Check the position of the side-opening while injecting the bone filler. The arrow on the handle of the injection needle indicates the position of the side opening.
- If using a bilateral approach, alternately fill both sides in increments. It is important to see the filling behavior of both needles. Once the filling of one side is accomplished, the lateral view of the opposite side may be hidden by the cement, which makes monitoring the flow more difficult.



- ⓐ **Warning:** Closely monitor the 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.

Optional injection needle cleaning can be performed using the cleaning stylet contained in the single pack access kit.

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

Warning: The timing of the release of the 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.

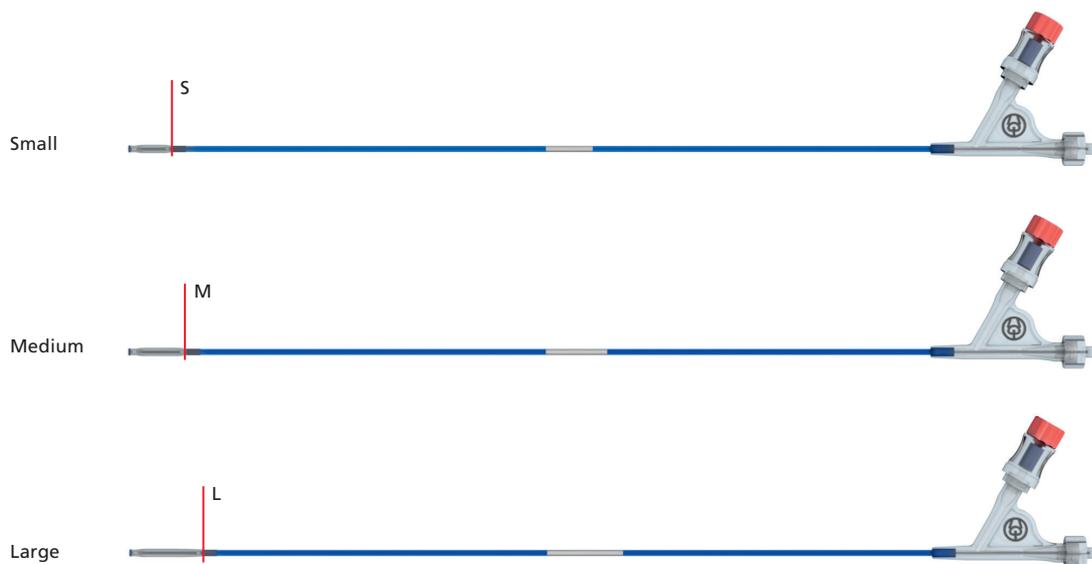
Precaution: For bilateral approach, leave both injection needles inserted while applying the bone filler to avoid backflow into the working sleeve.

Close the wound.



Implants and Instruments

Art. No.	Description	Max. volume	Balloon length
03.804.700S	Synflate Vertebral Balloon, small, sterile	4 ml	10 mm
03.804.701S	Synflate Vertebral Balloon, medium, sterile	5 ml	15 mm
03.804.702S	Synflate Vertebral Balloon, large, sterile	6 ml	20 mm



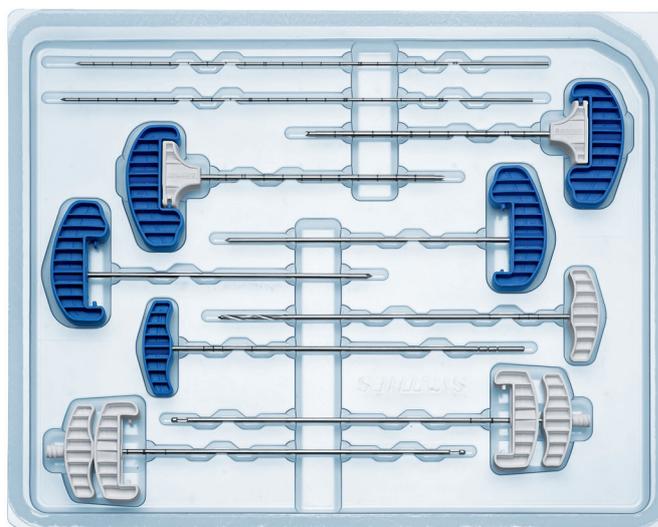
03.804.514S Access Kit, 10 G, Diamond Tip, with side-opening, Double Pack, sterile

03.804.515S Access Kit, 10 G, Beveled Tip, with side-opening, Double Pack, sterile

Instruments for double access with trocar or Kirschner wire.

Set includes:

- 2 × guide Wire
- 2 × Working Sleeve with cannulated trocar
- 2 × Trocar (diamond or beveled)
- 1 × Access Drill
- 2 × Cement needle with clip



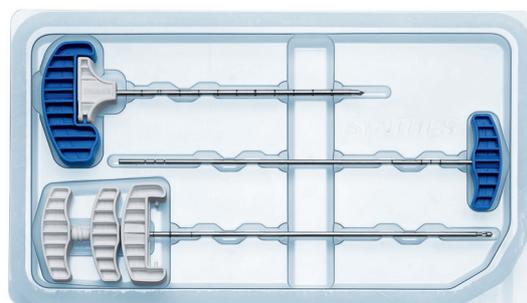
03.804.519S Access Kit, 10 G, Diamond Tip, with side-opening, Single Pack, sterile

03.804.520S Access Kit, 10 G, Beveled Tip, with side-opening, Single Pack, sterile

Instruments for monolateral access with trocar. Includes a cleaning stylet for the injection needle.

Set includes:

- 1 × Working Sleeve with trocar (diamond or beveled)
- 1 × Plunger
- 1 × Injection needle with clip and cleaning stylet



03.804.521S Access Drill, 10 G, sterile (optional together with Single Pack Access Kits)



03.804.522S Biopsy Kit, 10G, sterile (optional)



03.804.413S Inflation System, sterile



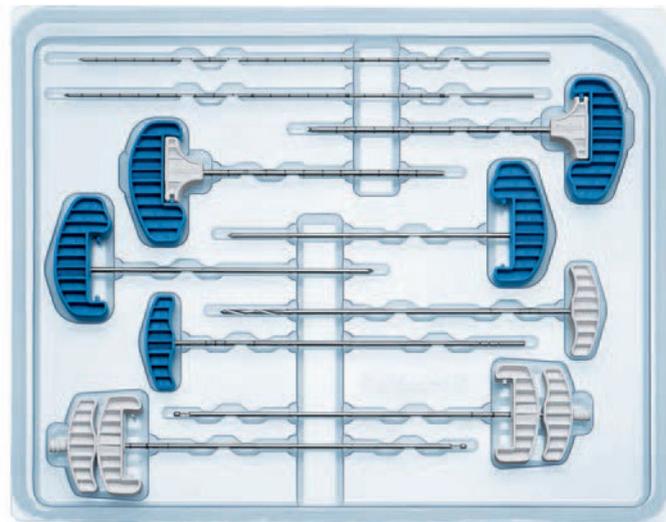
Alternative Instruments

03.804.6125 Access Kit 4.7 mm

Instruments for double access with trocar or Kirschner wire.

Set includes:

- 2 × Guide Wire
- 2 × Working Sleeve with cannulated trocar
- 2 × Trocar (Diamond Tip)
- 1 × Access Drill
- 1 × Plunger
- 2 × Cement needle with clip



03.804.6135 Biopsy Kit 4.7 mm

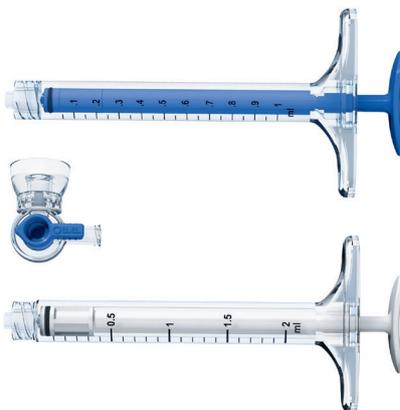


PMMA-based Bone Cements

07.702.0165 Vertecem V+ Cement Kit, sterile



03.702.2155 Vertecem V+ Syringe Kit, sterile



2839-99-002 Adaptor: Confidence Reservoir to Standard Luer



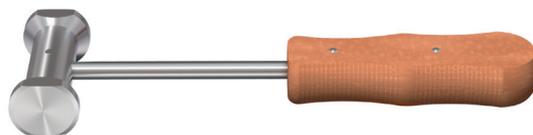
2839-07-000 CONFIDENCE Needleless Kit 7 cc

2839-13-000 CONFIDENCE Needleless Kit 11 cc



Optional Instruments

399.410 Hammer 300 g



292.210S Kirschner Wire Ø 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.depuy-synthes.com/ifu

Bibliography

- ¹ Aebi M, Arlet V, Webb JK, (2007): AOSPINE Manual (2 vols), Stuttgart, New York: Thieme.
- ² Aebi M, Thalgott JS, Webb JK (1998): AO ASIF Principles in Spine Surgery. Berlin: Springer.

