

SYNFLATE™ Vertebral Balloon

For the reduction of fracture and/or creation
of a void in the cancellous bone in the spine

- Low profile 10G access
- High lifting forces
- Three sizes to fit varying patient anatomy



- **Three Balloon Sizes**

Accommodates varying patient anatomy

- **10G Access**

Allows access through smaller pedicles

- **Shaft Marker**

Indicates proper advancement into access cannula and vertebral body

- **Two Radiopaque Markers**

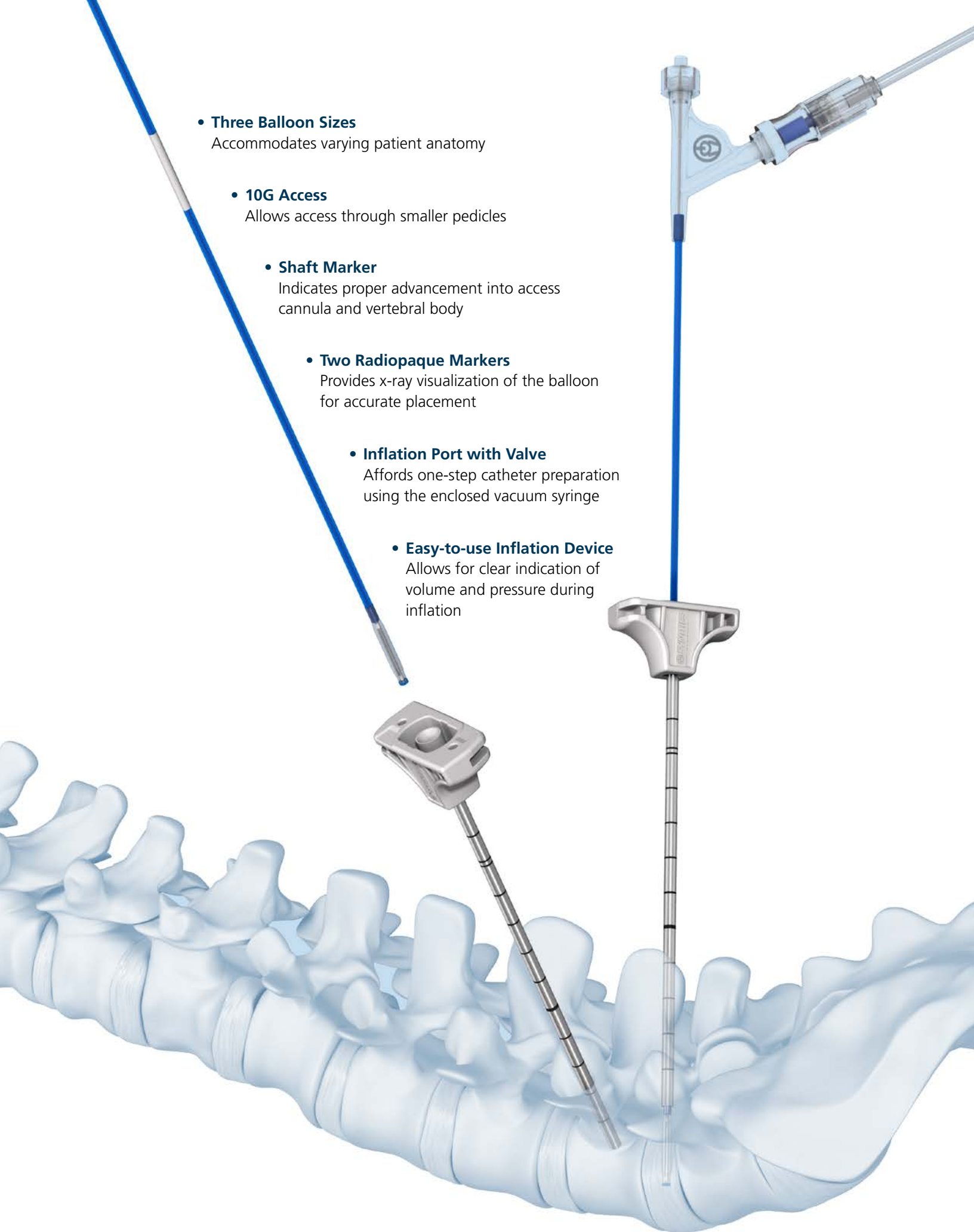
Provides x-ray visualization of the balloon for accurate placement

- **Inflation Port with Valve**

Affords one-step catheter preparation using the enclosed vacuum syringe

- **Easy-to-use Inflation Device**

Allows for clear indication of volume and pressure during inflation

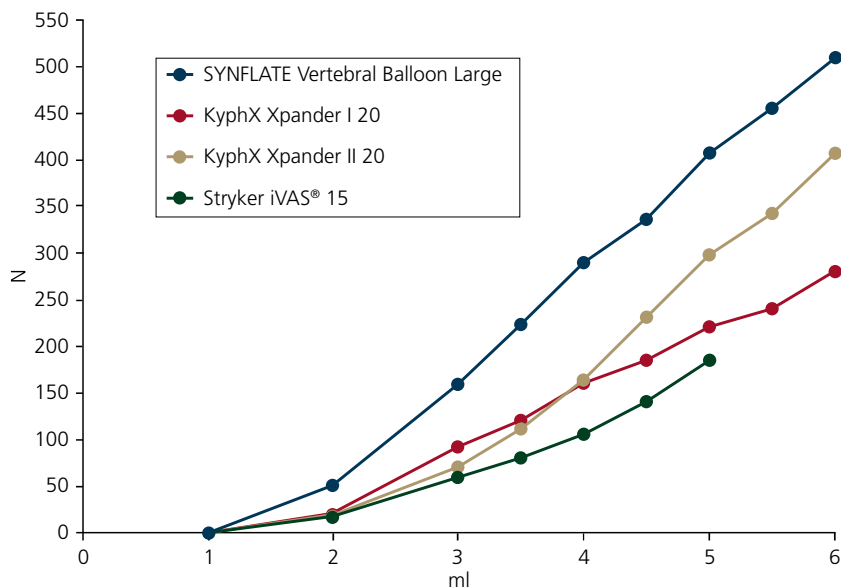


SYNFLATE Vertebral Balloon

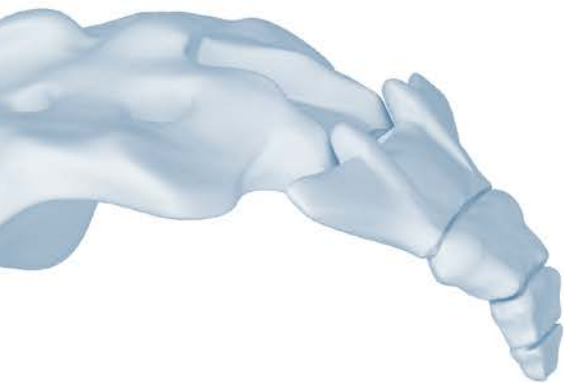
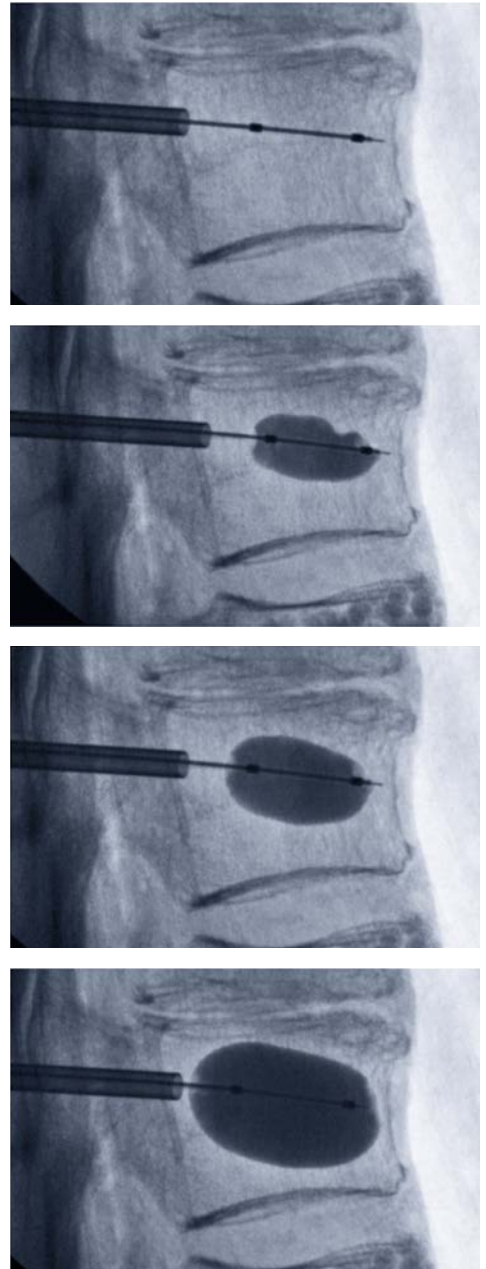
SYNFLATE™ Vertebral Balloon is a semi-compliant balloon. Its material stiffness has been optimized to provide controlled and predictable inflation. Due to its stiffness, there is reduced risk of inadvertently following the path of least resistance, e.g. following a fracture line. Instead, forces are more evenly distributed in all directions, providing strong lifting forces compared to the standard elastic balloons on the market. At its maximum rated volume, SYNFLATE Vertebral Balloon can generate almost twice as much Lifting Force as KyphX Xpander® I.

Balloon Lifting Force

@37°C (6mm plate distance)



Bench Test results may not necessarily be indicative of clinical performance.
A sample size of one piece was used in all tests. Data on file at DePuy Synthes: 0000076076, 0000076077



• Variety of Access and Cement Injection Tips

Provides options to meet physician preference and clinical needs

Access Instrument Tips:

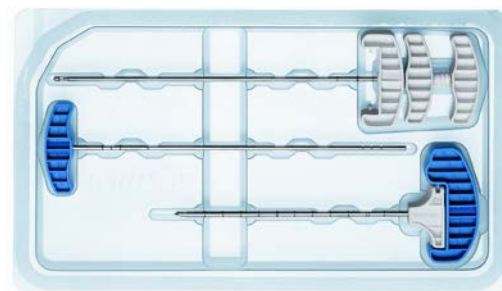


Cement Injection Tips:



Instruments

03.804.413S	Inflation System, Sterile
03.804.517S	10G Access Kit, Diamond/End, Sterile
03.804.518S	10G Access Kit, Beveled/End, Sterile
03.804.519S	10G Access Kit, Diamond/Side, Sterile
03.804.520S	10G Access Kit, Beveled/Side, Sterile
03.804.521S	Access Drill 10G, Sterile
03.804.522S	Biopsy Kit, 10G, Sterile



SYNFLATE Vertebral Balloons, Sterile

		Pre-inflated Length	Max Vol	Max Pressure
03.804.700S	SYNFLATE Balloon, Small	10mm	4.0ml	30 atm / 440 psi
03.804.701S	SYNFLATE Balloon, Medium	15mm	5.0ml	30 atm / 440 psi
03.804.702S	SYNFLATE Balloon, Large	20mm	6.0ml	30 atm / 440 psi



Indications

The SYNFLATE Vertebral Balloon System is intended to be used for the reduction of fractures and/or creation of a void in cancellous bone in the spine. This includes use during percutaneous vertebral augmentation. The system is to be used with cleared spinal polymethylmethacrylate (PMMA) bone cements indicated for use during percutaneous vertebral augmentation procedures, such as kyphoplasty.

Contraindications

- Instability of posterior wall and/or pedicles
- Systemic or local spinal infection
- Severe bleeding
- Known allergies to bone cement
- Pregnancy
- Fractures in which more than 75% of vertebral height is lost
- Any known severe allergy to contrast material
- When safe placement and inflation of the balloon is not possible due to vertebral dimensions or fracture pattern
- Refer to the SYNFLATE System package insert for complete system information including descriptions, indications, contraindications, and warnings
- Refer to specific Instructions for Use of the cement being used for complete system specific information including indications, contraindications, warnings, precautions, and adverse reactions related to bone cement.

Limited Warranty and Disclaimer: DePuy Synthes Spine products are sold with a limited warranty to the original purchaser against defects in workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed.

WARNING: In the USA, these products have labeling limitations. See package inserts for complete information.

CAUTION: USA Law restricts these devices to sale by or on the order of a physician.

To order in the U.S. call, Johnson & Johnson Health Care Systems Inc. Customer Support Services at 800-255-2500.

Not all products are currently available in all markets.



Manufactured or distributed in the United States by:

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