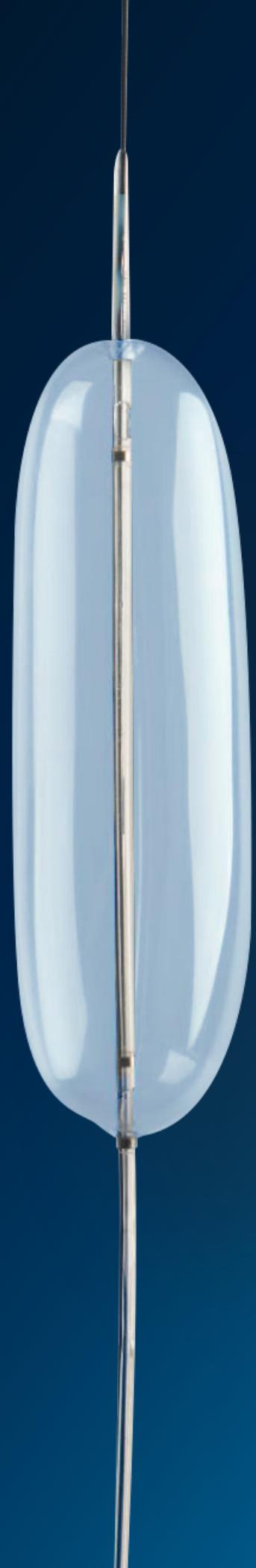


PHILIPS

Bridge

Occlusion balloon



Bridge to surgery

Introducing the Philips Bridge occlusion balloon for lead extraction.

When an SVC tears, **every second counts.**

SVC tears during lead extraction are very rare, occurring in less than 0.5% of procedures.¹ When they do occur, the Bridge occlusion balloon maintains **acceptable hemostasis for at least 30 minutes,**⁵ giving you time to stabilize your patient and transition to surgery.



At Philips, we believe in managing every lead, **safely, predictably and responsibly.**

Through research and development of new tools and techniques as well as the most comprehensive physician training programs in lead management, Philips constantly innovates for safety. The Bridge occlusion balloon is the latest addition to the broadest portfolio of laser and mechanical lead management solutions available. SVC tears during lead extraction are rare, occurring in less than 0.5% of procedures.¹ But when they happen, every second counts. Bridge maintains acceptable hemostasis for at least 30 minutes, providing time to stabilize the patient and transition to surgery.

Laser lead extraction is proven to be a safe and effective way to manage cardiac implanted electronic device (CIED) leads. Multiple clinical studies demonstrate 97.7% clinical success rate in lead removal with only 1.4% of patients experiencing a major adverse event during extraction.^{6,7}



Deploys in under
2 minutes²



Stops on average
90% of blood loss⁴



30 minutes of
acceptable hemostasis⁵

A bridge to **control**

Maintain control and transition to surgery.
The Bridge occlusion balloon can be deployed in less than two minutes via a pre-placed guidewire.² Bridge is easy to use, with no additional balloon preparation required. Radiopaque markers guide proper placement. Bridge is designed to cover the entire length and diameter of the SVC in 90% of patients.³

A bridge to **safety**

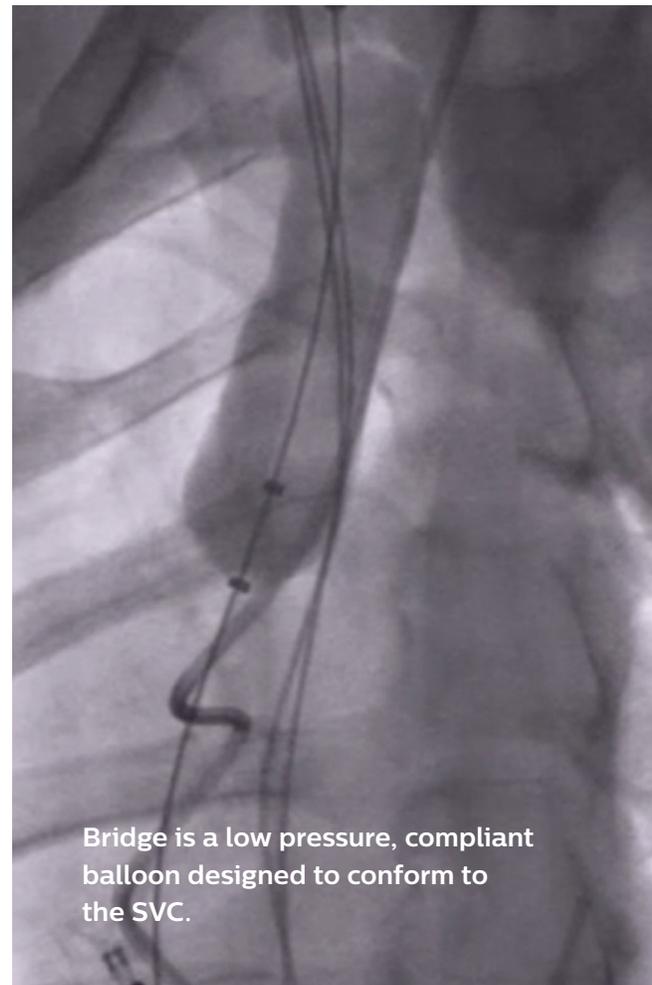
Once deployed, the Bridge occlusion balloon can dramatically reduce blood loss. In an animal model of an SVC tear, Bridge reduced blood loss by up to 90% on average in tears up to 3.5 cm, with two pacing leads and one ICD lead in place.⁴ With proper Bridge utilization, SVC tear survival in patients has gone from 56.4% to 91.7%.¹

A bridge to **stability**

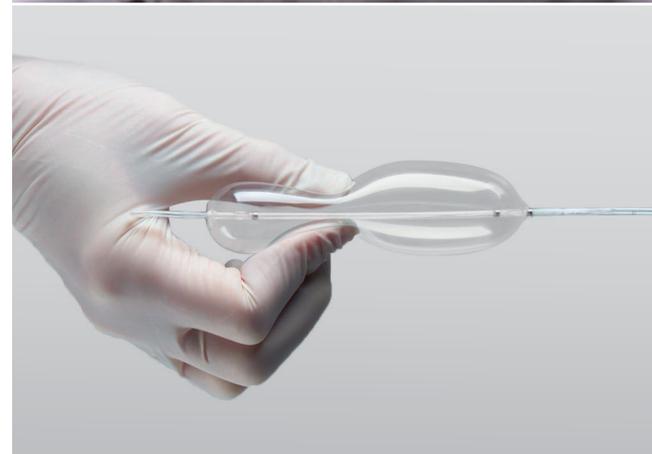
Bridge occlusion balloon can provide at least 30 minutes of acceptable hemostasis⁵ - time to stabilize your patient and transition to surgery. With Bridge, the surgical team can approach the repair in a controlled setting with a clear field of view.

Bridge occlusion balloon is the most significant breakthrough in lead management since the laser was introduced 20 years ago.

With proper Bridge utilization, SVC tear survival has gone from 56.4% to 91.7%¹



Bridge is a low pressure, compliant balloon designed to conform to the SVC.



Bridge occlusion balloon catheter specifications

| | |
|--|--|
| Catalog #: | 590-001 |
| Catheter length : | 90cm |
| Balloon diameter: (nominal) | 20mm |
| Balloon length : (nominal) | 80mm |
| Maximum OD : (crossing profile) | 4mm/0.157" |
| Minimum tip ID: | 0.9 mm/0.035" |
| Maximum inflation volume : | 60cc |
| Bridge prep kit specifications | |
| Catalog #: | 591-001 |
| Description: | Bridge occlusion balloon compatible guidewire, introducer sheath sets, syringe and stopcock. |

References

1. Roger G. Carrillo, MD; Darren C. Tsang, BS; Ryan Azarrafiy, BA; Thomas A. Boyle, BS. Multi-Year Evaluation of Compliant Endovascular Balloon in Treating Superior Vena Cava Tears During Transvenous Lead Extraction. EHRA late-breaking trial, March 19, 2018.
2. Document on file D027562. Bridge can be fully deployed in under one minute (53 seconds) in an animal model when pre-positioned on a guidewire, or in under two minutes (1 minute, 46 seconds) when not pre-positioned.
3. Document on file D027563. The balloon will cover the length and diameter of the SVC in 90% of the population as determined by analysis of 52 patients (N=52, % Male=48.1, Average Age 47.1 ± 16.5, Age Range 63 (18 to 81 years), Average Height 170.8cm ± 10.6, Height Range 40.6cm (152.4 to 193cm), Average BMI 29.8 ± 7.2, BMI Range 32.1 (18.2 to 50.3)).
4. Document on file D027561. When deployed, the Bridge occlusion balloon reduces blood loss by up to 90%, on average, in an animal model of an SVC tear. Testing was conducted in a heparinized porcine model which has shorter SVC length than is typical in humans. A balloon design scaled for use specifically in the porcine model was used in generating this data.
5. Document on file, D026197. In an animal model with SVC tears up to 3.5 cm, with 2 pacing leads and 1 ICD lead.
6. Wilkoff, B.L., et al. (1999). Pacemaker lead extraction with the laser sheath: Results of the Pacing Lead Extraction with Excimer Sheath (PLEXES) Trial. Journal of the American College of Cardiology, 33(6).
7. Wazni, O. et. al. Lead Extraction in the Contemporary Setting: The LExCon Study: A Multicenter Observational Retrospective Study of Consecutive Laser Lead Extractions, J Am Coll Cardiol, 55:579-586.

Summary of safety and effectiveness – Bridge occlusion balloon catheter

Indications

The Bridge occlusion balloon catheter is indicated for use for temporary vessel occlusion of the superior vena cava in applications including perioperative occlusion and emergency control of hemorrhage. Any use for procedures other than those indicated in these instructions is not recommended.

Contraindications

None known.

Warnings

Do not position the Bridge occlusion balloon catheter in a manner that would obstruct the right atrium. Obstruction of the atrium could lead to arrhythmias and/or hemodynamic compromise.

Prior to initiating the lead extraction procedure, a Bridge occlusion balloon catheter compatible guidewire should be placed through a venous access site and across the length of the superior vena cava. Attempting to place a compatible guidewire after a venous tear occurs may:

result in an inability to traverse the superior vena cava with the guidewire, result in the guidewire exiting the vasculature at the tear site, result in an inability to place the Bridge occlusion balloon catheter or delay or prevent the ability to achieve occlusion.

Lead extraction should be performed at institutions with cardiothoracic surgical capabilities by physicians knowledgeable in the techniques and devices for lead or catheter removal. Complication prevention and management protocols should be in place and routinely practiced. It is strongly suggested that the recommendations for lead management of the Heart Rhythm Society (HRS) and European Heart Rhythm Association (EHRA) be followed for best results.

Failure to observe recommended inflation techniques may result in formation of contrast crystals which could prevent deflation. Do not over-inflate the Bridge occlusion balloon catheter after fully occluding the vessel. Over inflation may result in damage to the vessel. Do not exceed the maximum inflation volume. Over inflation may result in damage to the vessel or rupture of the balloon. Occlusion of the superior vena cava beyond 30 minutes is not recommended as this may increase the risk of adverse physiologic or neurologic complications.

Refer to the IFU for additional information.

