

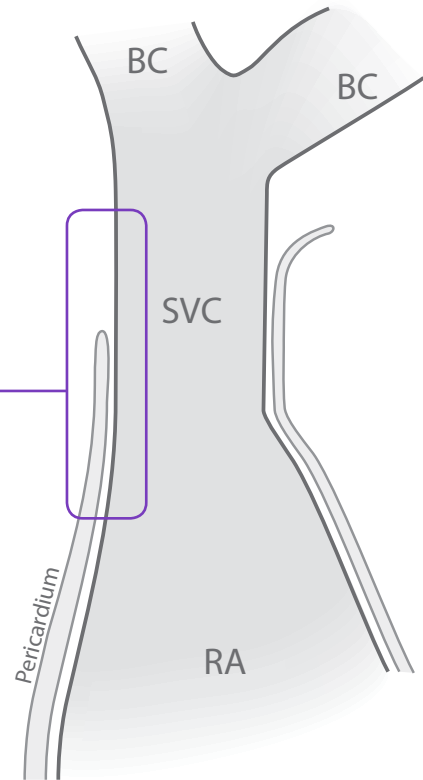
SVC Anatomy & Bridge™ Deployment

Bridge™ Occlusion Balloon has proven to be a life-saving technology.¹ Procedural planning that considers superior vena cava (SVC) anatomy in relation to the pericardium can help ensure successful deployment and utilization.

SVC Tears Can Be Intra- and Extra-Pericardial

- The pericardium extends above the right atrium and covers between 30-45% of the SVC.
- TEE may identify an intra-pericardial tear, but not recognize the tear also extends above the pericardium in the SVC.
- Tears that extend into both areas can bleed into pericardium and the right chest.
- Bleeding in the pericardium should not rule out a tear that extends higher in the SVC.

Diagram of the pericardium covering about 1/3 of the SVC. The right atrium (RA) and brachiocephalic vein (BC, also known as the innominate vein) are also shown for reference.

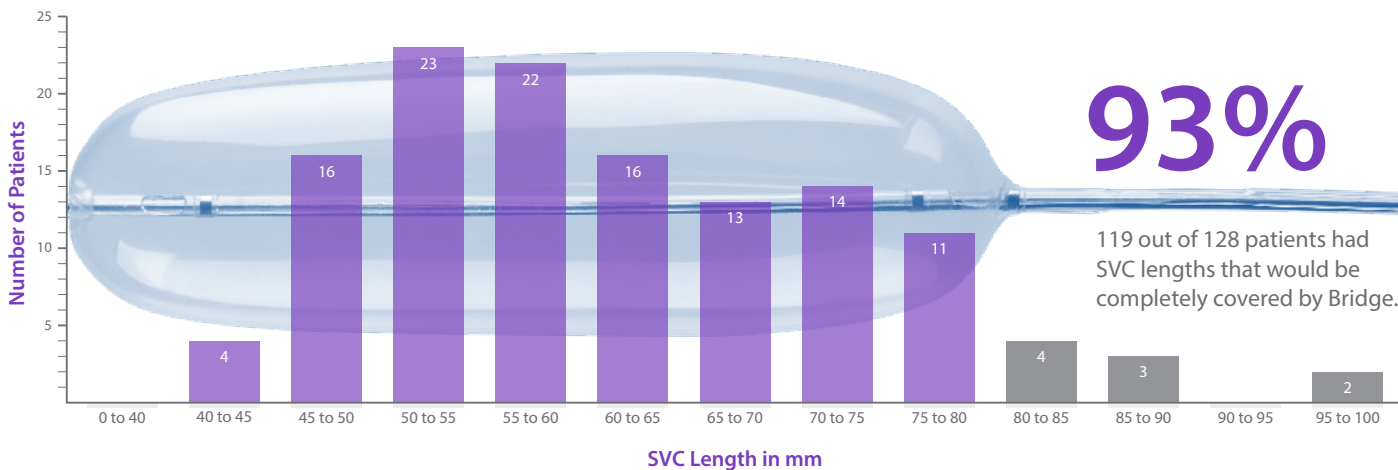


“When in doubt, inflate Bridge.”

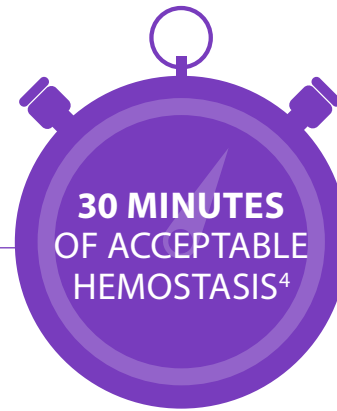
- Dr. Roger Carrillo, MD. University of Miami

SVC lengths of patient population at University of Miami

93% of patients would be completely covered by the Bridge Balloon. The remaining 7% of patients would be mostly covered by the 8cm Bridge Balloon. Courtesy of Roger Carrillo, MD.



Bridge is designed to cover the entire length of the SVC, including tears in the intra- and extra-pericardial space.



"I cannot overstate that this is a tool that saves lives.¹"

- Dr. Roger Carrillo, MD., University of Miami

Important Safety Information

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.



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References

1. Elrod, Jodia. Use of Bridge™ Occlusion Balloon in Lead Extraction: Interview with Dr. Roger Carrillo. EP Lab Digest. November, 2016.
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 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.
4. Document on file, D026197. In an animal model with SVC tears up to 3.5 cm, with 2 pacing leads and 1 ICD lead.