

Bridge occlusion balloon References

1. Document on file D027562. Bridge can be fully deployed in 14 seconds in an animal model when pre-positioned on a guidewire, or in under two minutes (1 minute, 46 seconds) when not pre-positioned.
2. 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.
3. Document on file, D026197. In an animal model with SVC tears up to 3.5 cm, with 2 pacing leads and 1 ICD lead.
4. Ryan Azarrafiy, BA; Darren C. Tsang, BS; Bruce L. Wilkoff, MD, FHRS; Roger G. Carrillo, MD, MBA, FHRS. The Endovascular Occlusion Balloon for Treatment of Superior Vena Cava Tears During Transvenous Lead Extraction: A Multi-Year Analysis and An Update to Best Practice Protocol. *Arrhythm Electrophysiology* (2019). doi: 10.1161/circep.119.007266.
5. Wazni, O et. al. Lead Extraction in the Contemporary Setting: The LEXIcon Study: A Multicenter Observational Retrospective Study of Consecutive Laser Lead Extractions, *J Am Coll Cardiol*, 55:579-586.
6. Azarrafiy R, Tsang DC, Boyle TA, Wilkoff BL, Carrillo RG, Compliant Endovascular Balloon Reduces the Lethality of Superior Vena Cava Tears During Transvenous Lead Extractions, *Heart Rhythm*. doi:10.1016/j.hrthm.2017.05.005
7. Brunner, Wilkoff et al: *Heart Rhythm* 2014;11:419-25.
8. Darren C. Tsang, Ryan Azarrafiy, Simon Pecha, Hermann Reichenspurner, Roger G. Carrillo, Samer Hakmi. Long Term Outcomes of prophylactic placement of an endovascular balloon in the vena cava for high-risk transvenous lead extractions. *Heart Rhythm* (2017), doi: 10.1016/j.hrthm.2017.08.003.
9. Wilkoff BL, Kennergren C, Love CJ, Kutalek SP, Epstein LM, Carrillo R, et al. Bridge to Surgery: Best Practice Protocol Derived From Early Clinical Experience with the Bridge Occlusion Balloon. *Heart Rhythm* (2017), doi: 10.1016/j.hrthm.2017.07.008.