PHILIPS

Bridge

Occlusion balloon

Bridge best practice protocol[1] summary

Consensus from 30 extracting physicians

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SVC tears during lead extraction are very rare, occurring in less than 0.5% of procedures.[1]

The Philips Bridge occlusion balloon™ was designed to provide hemostasis in the rare event of an SVC tear, allowing time for surgical repair and increasing survivability. The best practices protocol was published in *Heart Rhythm*.[1] It is the consensus of 30 high-volume extracting physicians for the deployment of Bridge.

Prepare

1. 0.035" stiff guidewire placed
2. Introducer sheath inserted
3. Pre-filled syringe and Bridge immediately available

Practice

4. Bridge familiarity
5. Bridge competence
6. Bridge prophylaxis

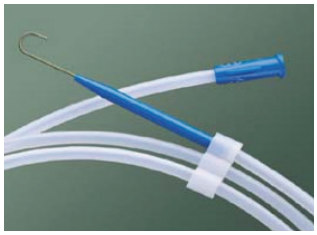
Perform

7. **Immediate** deployment when SVC tear is **suspected**, including tamponade and/or hemothorax

Prepare

Every patient, every extraction. You cannot predict, but you can prepare.

In the rare event of an SVC tear, minimizing the time to Bridge deployment and surgical repair is crucial. Before extraction, operators should ensure all patients are prepped for potential emergent deployment and all necessary items are immediately available and prepared.



0.035" Stiff guidewire placed

- Insert guidewire from the right femoral vein to the right internal jugular. Alternative access may include the left femoral vein and right or left subclavian vein. The use of ultrasound to facilitate access to the femoral vein is highly recommended.
- Clamp the wire just outside the introducer and/or to the drape cloth to prevent movement.

Introducer sheath inserted

- 12F introducer required for Bridge delivery.
- Alternatively, a 6F peelaway with 12F pre-loaded on the wire may be utilized.
  - **6F sheath considerations:** Bridge cannot be staged in the inferior vena cava (IVC), increases the risk of dislodgement of the guidewire, and delays the deployment of Bridge.

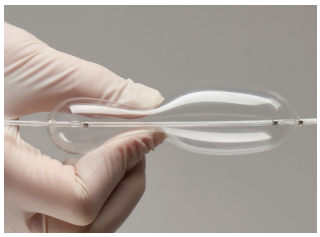
Pre-filled syringe & Bridge immediately available

- Pre-filled 60cc syringe (**12cc contrast & 48cc saline**) with a 2-way stopcock attached.

"With SVC perforations, time is of the essence. Any scenarios that may delay deployment of Bridge should be avoided."[1]

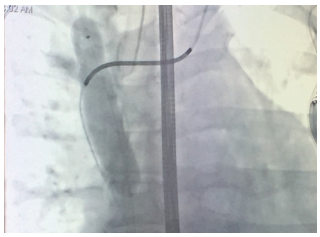
Practice

It is not recommended to deploy Bridge for the first time in an emergency situation. “Field experience with Bridge is critical for understanding best practices for successful clinical outcomes.”[1]



Bridge familiarity and competence

- Several practice deployments may be necessary to develop comfort with Bridge and the workflow. Bridge can be deflated after test deployment and withdrawn to the IVC until extraction is complete.
- All team members should be familiar with the device and the steps for deployment.

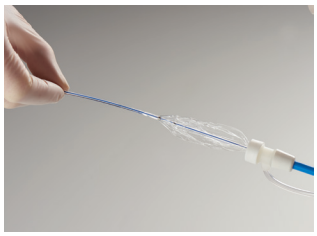


Bridge prophylaxis

- In addition to familiarity and competence, prophylactic deployment of Bridge may be considered for:
  - High-risk patients
  - Increase in perceived risk during the procedure
  - Lower volume extractors
- Situations that may be considered higher risk and warrant staging Bridge in the IVC:
  - Female patients
  - Low BMI (<25)
  - ICD leads
  - Low left ventricular ejection fraction
  - Difficult case with multiple extraction tools already used
  - Multiple indwelling leads (>4)
  - Combined age of leads is >10 years old

Perform

Immediate deployment of Bridge in the SVC when a tear is suspected is critical; a delay can result in patient mortality.



Immediate deployment

- Deploy Bridge as soon as an SVC tear is suspected, including cardiac tamponade, hemothorax, or both. (Bridge is not designed to provide hemostasis for injuries in the heart, but it is not possible to be certain of the location of the tear before opening the chest.)
- Inflate Bridge with 30-60cc of fluid (12cc contrast/48cc saline) and close the stop cock valve.
- Maintain guidewire placement to prevent balloon migration.
- The availability of Bridge in no way obviates the need for emergent cardiothoracic surgical backup. Delay to definitive treatment is potentially life-threatening.

Bridge Occlusion Balloon Important Safety Information

The Bridge Occlusion Balloon is indicated for use for temporary vessel occlusion of the superior vena cava in applications including perioperative occlusion and emergency control of hemorrhage. Use of the Bridge Occlusion Balloon in procedures other than those indicated is not recommended.

The adverse events associated with an occlusion balloon procedure include, but are not limited to allergic reactions, death, embolization, hematoma, hemorrhage, sepsis/infection, short-term hemodynamic deterioration, thromboembolic episodes, vascular thrombosis, vessel dissection, vessel perforation, vessel spasm.

In order to facilitate rapid delivery, it is recommended that a guidewire is in place in the superior vena cava prior to beginning the lead extraction procedure. Attempting to place the guidewire after a tear has occurred 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

Delay or prevent the ability to achieve occlusion

This information is not intended to replace a discussion with your healthcare provider on the benefits and risks of this procedure to you.

Refer to spectranetics.com for Bridge IFU.

1. Wilkoff BL, Kennergren C, Love CJ, Kutalek SP, Epstein LM, Carrillo R, 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

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