Bridge™
Occlusion Balloon

Instructions for Use

Spectranetics®

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Caution: Federal (USA) law restricts this device to sale by or on the order of a physician with appropriate training.

1. Device Description

The Bridge Occlusion Balloon Catheter is designed for temporary vessel occlusion of the superior vena cava in applications including perioperative occlusion and emergency control of hemorrhage associated with vascular tears that may occur during lead extraction procedures.

The Bridge Occlusion Balloon Catheter is not designed for use as vascular flow-directed catheter (Swan-Ganz type).

Balloon Catheter Construction

The Bridge Occlusion Balloon Catheter is constructed of a compliant balloon mounted on a multi-lumen catheter shaft. Radiopaque markers are placed within the balloon segment of the catheter to provide visual reference points for balloon positioning within the vessel.

To allow for large inflation volume, the balloon is mounted on a non-tapered catheter shaft. The Bridge Occlusion Balloon Catheters have two lumens that are connected to a proximal hub. The hub port, marked BALLOON, is connected to the balloon inflation lumen. The unmarked hub port is connected to the central lumen of the catheter, which terminates at the distal tip. This lumen is used to pass the catheter over a guidewire.

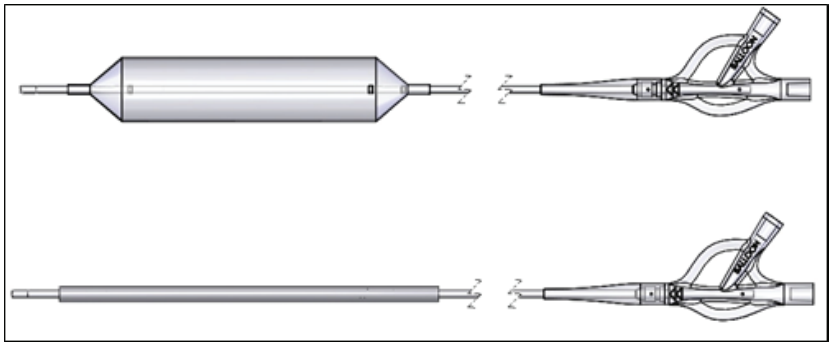


Figure 1: Bridge Occlusion Balloon Catheter (top) with Balloon Protector (bottom)

Table 1: Bridge Occlusion Balloon Catheter Specifications

Cat. #	Catheter Length (cm)	Balloon Diameter (nominal) (mm)	Balloon Length (nominal) (mm)	Maximum OD (Crossing Profile) (mm/in)	Minimum Tip ID (mm/in)	Maximum Inflation Volume (cc)
590-001	90	20	80	4mm/0.157″	0.9mm/0.035″	60

Note: Because the Bridge Occlusion Balloon Catheter has a large liquid capacity, it may take as long as 56 seconds to deflate through the balloon inflation lumen. Use a 60 ml (60 cc) syringe to inflate or deflate.

Table 2: Compliance Chart

Inflation Volume (cc)	Balloon Diameter (mm)
20	18.8
25	19.4
30	21.3
35	23.4
40	25.2
45	26.9
50	28.6
55	29.9
60	31.1

2. Indications for Use

The Bridge Occlusion Balloon Catheter is indicated 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.

3. Contraindications

None known.

4. Warnings

- 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.
- 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
  - delay or prevent the ability to achieve occlusion
- 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.
- Maintain guidewire position throughout the procedure; do not remove the guidewire while the balloon is inflated.
- Failure to observe recommended inflation techniques may result in the 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, rupture of the balloon, or introduction of air emboli.
- Do not exceed the Maximum Inflation Volume. Over inflation may result in damage to the vessel, rupture of the balloon, or introduction of air emboli.
- Occlusion of the superior vena cava beyond 30 minutes is not recommended as this may increase the risk of adverse physiologic or neurologic complications.
- Do not resterilize or reuse this device, as these actions can compromise device performance or increase the risk of cross-contamination due to inappropriate reprocessing.
- Reuse of this single use device could lead to serious patient injury or death and voids manufacturer warranties.
- Use of the device with prolonged dwell times has been associated with the risk of thrombus developing on the balloon. The workflows recommended should be followed in order to reduce thrombotic risk.

5. Precautions

- A thorough understanding of the technical principles, clinical applications, and risks associated with occlusion procedures is necessary before using this product.
- Monitor the positioning and inflation of this device with fluoroscopic guidance.
- Carefully monitor the patient's hemodynamics and vital signs throughout the procedure.
- The Bridge Occlusion Balloon Catheter is not intended for use
  - with high pressure or powered injectors
  - as an infusion catheter
- To avoid balloon damage or rupture, lead extraction tools (such as extraction sheaths) should be removed from the superior vena cava area prior to placing the Bridge Occlusion Balloon Catheter.
- If surgical repair of a venous tear requires suturing, use caution to avoid puncturing the balloon.
- Do not use the Bridge Occlusion Balloon Catheter if the sterile barrier is broken or damaged.
- Do not use the Bridge Occlusion Balloon Catheter if any component has been damaged.

6. Potential Adverse Events

The adverse events associated with an occlusion balloon procedure include, but are not limited to the following:

- allergic reactions
- death
- embolization
- hematoma
- hemorrhage
- sepsis/infection
- short-term hemodynamic deterioration
- thromboembolic episodes
- vascular thrombosis
- vessel dissection
- vessel perforation
- vessel spasm

7. How Supplied

7.1. Sterilization

- For single use only. Not for re-sterilization or reprocessing.
- Ethylene Oxide Sterilized.
- Non-pyrogenic.
- Sterility guaranteed if package is unopened and undamaged.
- Store device at room temperature in a dry place (below 60° C / 140° F) until use.

7.2. Inspection Prior to Use

- Before use, visually inspect the sterile package to ensure that seals have not been broken. All equipment to be used for the procedure, including the Bridge Occlusion Balloon Catheter, should be examined carefully for defects or damage.
- Do not use the Bridge Occlusion Balloon Catheter if it is damaged, unintentionally opened, or if the Use by Date has been exceeded.

8. Compatibility

The recommended Bridge Prep Kit (sold separately) includes a compatible 0.035 inch stiff guidewire, 12 French introducer sheath, syringe and stopcock for Bridge deployment.

8.1. Guidewire Selection

The Bridge Occlusion Balloon Catheter is compatible with 0.035 inch guidewires. Stiff or super stiff guidewires are recommended.

8.2. Introducer Sheath Selection

For introduction, a 12 French (or larger) introducer sheath is recommended.

9. Prophylactic Directions for Use

Note: Prophylactic use of Bridge should be considered if preferred by the physician, the patient is deemed to be high risk, physician performs a low volume of lead extraction procedures per year, the physician is new at lead extraction procedures or if there is an intra-procedural increase in the perceived risk.

9.1. Device and Procedural Preparation

1. Prior to use, carefully examine the unit to verify that the sterile package and product have not been damaged.
2. Place a compatible guidewire through a venous access site and across the length of the superior vena cava. Use a compatible introducer sheath that is capable of maintaining hemostasis at the insertion site. Consider flushing the introducer sheath before inserting into the patient to prevent excessive friction.

Caution: If using a hydrophilic coated wire, be aware that a non-hydrated wire will have increased friction.

3. Prepare a 60cc luer lock syringe with an 80:20 ratio of saline to contrast media for balloon inflation. Ensure the contrast solution is well mixed.
4. Connect a stopcock to the filled syringe.

9.2. Device Placement

Note: Prophylactic placement of the Bridge Occlusion Balloon is recommended after all lead extraction preparation has been completed and just before the use of any extraction sheaths in order to minimize balloon dwell time.

1. Using sterile technique, open the sterile package. Remove the Bridge Occlusion Balloon Catheter from the supplied tray.
2. Remove the balloon protector from the distal portion of the catheter.
3. Introduce the Bridge Occlusion Balloon Catheter percutaneously through a compatible introducer sheath and over a compatible guidewire. No balloon or guidewire lumen preparation is needed before insertion.

Caution: Care should be exercised when both introducing and removing the catheter to avoid undue stress which may damage the balloon catheter.

Warning: Failure to observe recommended inflation techniques may result in the formation of contrast crystals which could prevent deflation.

4. To ensure access to the superior vena cava area is not obstructed, advance the Bridge Occlusion Balloon Catheter under fluoroscopic guidance until the proximal marker band is located at the junction of the superior vena cava and right atrium. Mark the remaining length of the catheter exiting the introducer sheath so the position of the balloon can be quickly re-attained in the event of an SVC tear.

Note: If the superior vena cava area cannot be accessed femorally, consider alternate approaches or techniques.

5. Connect the prepared balloon inflation syringe with stopcock to the balloon inflation port of the catheter hub. A 60 ml (60cc) syringe is recommended for inflation and deflation of the Bridge Occlusion Balloon Catheter (Refer to compliance chart in Table 2).

Note: Consider test inflating the balloon to measure the amount of contrast solution necessary for proper inflation and occlusion. After test inflating, deflate the balloon and ensure all contrast is removed from the balloon by the attached syringe.

6. Retract the Bridge Occlusion Balloon Catheter from the superior vena cava into the inferior vena cava until needed.
7. Maintain guidewire position during balloon advancement, placement, and retraction.

Note: Follow proper medical technique for maintaining the patency of the introducer sheath. If there are no medication drips being infused through the sidearm port of the introducer, connect the sidearm port to 0.9% NS and infuse at 10-30 mL/hr to KVO ('keep vein open") in order to prevent catheter occlusion.

9.3. Application of Therapy

1. If an SVC tear is suspected, advance the balloon to the SVC and verify the placement of the most proximal marker band at the SVC-right atrial junction. Fluoroscopic monitoring of the balloon during inflation is recommended.
2. Inflate the balloon using the 60cc syringe until conformance of the balloon to the vasculature is achieved under fluoroscopy.

Note: When a tear is present, a larger volume of contrast solution than previously measured, not to exceed 60cc, may be needed in order to achieve acceptable occlusion.

Caution: If the balloon ruptures, immediately discontinue use.

Caution: If the balloon migrates towards the atrium during inflation, deflate the balloon and reposition. Mitigate any further unintended balloon movement.

Warning: Do not remove the guidewire while the balloon is inflated.

3. Close the stopcock to the balloon inflation port when the desired inflation volume is reached.
4. Contrast injection via a superior venous access site may be used to confirm proper inflation and occlusion. Stabilization of the patient's hemodynamics/vital signs can also be used as an indicator of acceptable occlusion.

Note: Transfusion of blood products and administration of pharmaceutical agents should be performed via an inferior access site to facilitate delivery and systemic distribution.

5. Continue to monitor the stability of the patient via hemodynamics and vital signs until occlusion is no longer required.

9.4. Device Removal

1. Once all intended leads have been removed and patient maintains hemodynamic stability, the balloon can be removed from the vasculature. If the balloon is inflated, open the stopcock to the balloon inflation port and apply suction to the balloon lumen using a 60cc syringe until full deflation has been achieved.
2. Confirm deflation of the balloon under fluoroscopy and remove from vasculature.

Caution: If resistance is felt when removing the catheter through the introducer sheath, stop and remove them as a complete unit to prevent damage to the catheter or vessel.

10. Emergent Directions for Use

Note: In emergent situations quick access to and deployment of the Bridge Occlusion Balloon Catheter is important for minimizing deployment time.

10.1. Device and Procedural Preparation

1. Prior to use, carefully examine the unit to verify that the sterile package and product have not been damaged.
2. Place a compatible guidewire through a venous access site and across the length of the superior vena cava. Use a compatible introducer sheath that is capable of maintaining hemostasis at the insertion site. Consider flushing the introducer sheath before inserting into the patient to prevent excessive friction.

Note: It is recommended to use a stiff or super stiff guidewire for maintaining access to the superior vena cava area and to allow for expedient insertion of the Bridge Occlusion Balloon Catheter when needed.

Caution: If using a hydrophilic coated wire, be aware that a non-hydrated wire will have increased friction.

3. Prepare a 60cc luer lock syringe with an 80:20 ratio of saline to contrast media for balloon inflation. Ensure the contrast solution is well mixed.
4. Connect a stopcock to the filled syringe.

10.2. Device Placement

1. Using sterile technique, open the sterile package. Remove the Bridge Occlusion Balloon Catheter from the supplied tray.
2. Remove the balloon protector from the distal portion of the catheter.
3. Introduce the Bridge Occlusion Balloon Catheter percutaneously through a compatible introducer sheath and over a compatible guidewire. No balloon or guidewire lumen preparation is needed before insertion.

Caution: Care should be exercised when both introducing and removing the catheter to avoid undue stress which may damage the balloon catheter.

Warning: Failure to observe recommended inflation techniques may result in the formation of contrast crystals which could prevent deflation.

4. To ensure access to the superior vena cava area is not obstructed, advance the Bridge Occlusion Balloon Catheter under fluoroscopic guidance until the proximal marker band is located at the junction of the superior vena cava and right atrium.

Note: If the superior vena cava area cannot be accessed femorally, consider alternate approaches or techniques.

5. Connect the prepared balloon inflation syringe with stopcock to the balloon inflation port of the catheter hub. A 60 ml (60cc) syringe is recommended for inflation and deflation of the Bridge Occlusion Balloon Catheter (Refer to compliance chart in Table 2).

10.3. Application of Therapy

1. Advance the balloon to the SVC and verify the placement of the most proximal marker band at the SVC-right atrial junction. Fluoroscopic monitoring of the balloon during inflation is recommended.
2. Inflate the balloon using the 60cc syringe until conformance of the balloon to the vasculature is achieved under fluoroscopy. Inflation should not exceed 60cc.

Caution: If the balloon ruptures, immediately discontinue use.

Caution: If the balloon migrates towards the atrium during inflation, deflate the balloon and reposition. Mitigate any further unintended balloon movement.

Warning: Do not remove the guidewire while the balloon is inflated.

3. Close stopcock to the balloon inflation port when the desired inflation volume is reached.
4. Contrast injection via a superior venous access site may be used to confirm proper inflation and occlusion. Stabilization of the patient's hemodynamics/vital signs can also be used as an indicator of acceptable occlusion.

Note: Transfusion of blood products and administering of pharmaceutical agents should be performed via an inferior access site to facilitate delivery and systemic distribution.

10.4. Device Removal

1. When occlusion is no longer required and the patient maintains hemodynamic stability, fully deflate the balloon by opening the stopcock to the balloon inflation port and applying suction to the balloon lumen until full deflation has been achieved.

Note: A 60 ml (60cc) syringe is recommended for deflation.

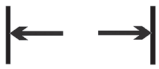
2. Confirm deflation of the balloon under fluoroscopy and remove from vasculature.

Caution: If resistance is felt when removing the catheter through the introducer sheath, stop and remove them as a complete unit to prevent damage to the catheter or vessel.

11. Warranty

Manufacturer warrants that the Bridge Occlusion Balloon Catheter is free from defects in material and workmanship when used by the stated "Use By" date and when package is unopened and undamaged immediately before use. Manufacturer's liability under this warranty is limited to replacement or refund of the purchase price of any defective Bridge Occlusion Balloon Catheter. Manufacturer will not be liable for any incidental, special, or consequential damages resulting from use of the Bridge Occlusion Balloon Catheter. Damage to the Bridge Occlusion Balloon caused by misuse, alteration, improper storage or handling, or any other failure to follow these Instructions for Use will void this limited warranty. **THIS LIMITED WARRANTY IS EXPRESSLY IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING THE IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.** No person or entity, including any authorized representative or reseller of Manufacturer, has the authority to extend or expand this limited warranty and any purported attempt to do so will not be enforceable against Manufacturer.

12. Non Standard Symbology

Sheath Compatibility 	**Balloon Outer Diameter** 	**Working Length** 
Guidewire Compatibility 	**Balloon Length** 	**Quantity** QTY
Non-Pyrogenic 		
Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.		**Rx ONLY**

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