



Important safety information

Bridge Plus Occlusion Balloon

The Bridge Plus Occlusion Balloon is indicated for temporary vessel occlusion of the superior vena cava and inferior vena cava in applications including perioperative occlusion and emergency control of hemorrhage. Use of the Bridge Plus 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.

Prior to initiating the procedure, a Bridge Plus Occlusion Balloon Catheter compatible guidewire should be placed through a venous access site and across the length of the superior or inferior vena cava. Attempting to place the guidewire after a tear has occurred may:

- Result in an inability to traverse the superior or inferior vena cava with the guidewire
- Result in the guidewire exiting the vasculature at the tear site
- Result in an inability to place the Bridge Plus 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.

Caution: Federal law restricts this device to sale by or on the order of a physician.

