Spectranetics Corp. Recalls Bridge Occlusion Balloon Catheter Due to Risk of Blocked Guidewire Lumen Preventing Balloon Utilization

The FDA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries or death

Recalled Product(s):

- Spectranetics Corp. Bridge Occlusion Balloon Catheter
- Model/Item Numbers: 590-001
- Lot Numbers: FMN17B13A, FMN17C08A, FMN17C28A, FMN17D07A, FMN17D12A, FMN17D19A, FMN17D27A, FMN17E02A, FMN17E23A, FMN17E31A, FMN17E31B, FMN17F06A, FMN17F20A, FMN17F21A, FMN17G12A, FMN17G18A, FMN17H03A, FMN17H03A, FMN17H03A, FMN17H10A, FMN17H29A
- Manufacturing Dates: February 13, 2017 to July 18, 2017
- Distribution Dates: February 24, 2017 to July 31, 2017
- Devices Recalled in the U.S.: 1,900+

Device Use
Spectranetics' Bridge Occlusion Balloon Catheter is a device intended to temporarily block the superior vena cava (SVC) when emergency control of hemorrhage is required.

The Bridge Occlusion Balloon catheter is constructed of a compliant balloon mounted on a dual lumen shaft. The guidewire lumen is used to pass the catheter over a guide wire.

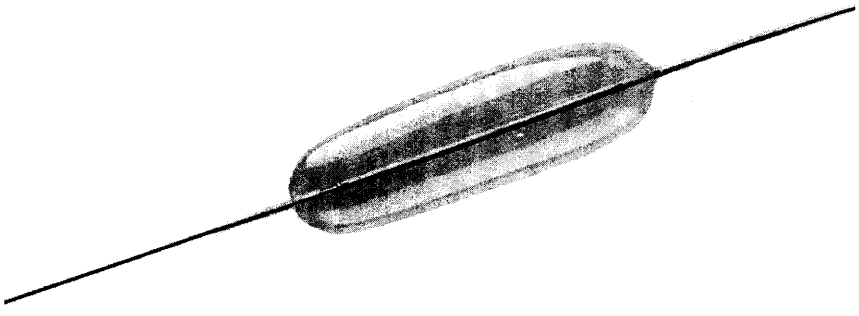

Image of a Spectranetics Bridge Occlusion Balloon Catheter

Reason for Recall
Spectranetics is recalling its Bridge Occlusion Balloon Catheter due to the possibility of a blocked guidewire lumen in some device units. If a device with a blocked guidewire lumen were to be used during the procedure, the device would not be positioned correctly and hemorrhage would not be controlled. This would delay life-saving treatment, which may result in immediate and serious adverse health consequences, including death.

Who May be Affected

- Hospitals and health care professionals performing lead extraction surgery using a Spectranetics Bridge Occlusion Balloon Catheter manufactured between February 13, 2017 and July 18, 2017.

- Patients undergoing lead extraction surgery using a Spectranetics Bridge Occlusion Balloon Catheter manufactured between February 13, 2017 and July 18, 2017.

What to Do
On August 7, 2017, Spectranetics sent affected customers an "Urgent Medical Device Recall" notice informing them of the device's risks. The notice directed physicians to confirm that the guidewire lumen is open and unblocked prior to start of the procedure, and to have back up units on hand should they be needed during the procedure.

Spectranetics also sent affected customers an updated notice on August 21, 2017 to notify them that all bridge devices have the potential for guidewire blockage. The updated notice recommended that physicians:

- Place a guide wire through the venous access site and across the length of the SVC prior to the start of the procedure.
- Consider removing the Bridge device from its packaging and placing the catheter over the guidewire prior to the start of the procedure to ensure a patent lumen.
  - If the guidewire lumen is obstructed, discard that device and test another until a working device has been identified. Return defective devices to Spectranetics.
- Be aware that all Bridge inventory will continue to have the potential for a guidewire lumen blockage until Spectranetics has implemented a permanent solution.
- Bring extra Bridge inventory into the procedure so that there is a back-up device on hand, should it be determined that the existing unit has a blocked guidewire lumen.
- Always follow appropriate complication prevention and management protocols as they relate to patient preparation and surgical back up for lead extraction procedures.
- Complete and return to Spectranetics the "Acknowledgement and Receipt Form" that accompanied the Urgent Medical Device Recall notice.
  - A Spectranetics Sales Representative will be in contact to facilitate the return and replacement of any remaining inventory once new inventory with an implemented fix is available.

On September 7, 2017, Spectranetics sent affected customers an additional notification informing them that follow-up distribution of the device is limited to a 30-day period.

Contact Information
Customers with questions regarding this recall may contact Spectranetics' Customer Service at 1-(800)-231-0978, and select "Option 2".

Date Recall Initiated
August 7, 2017

How do I report a problem?
Health care professionals and consumers may report adverse reactions or quality problems they experienced using these devices to **MedWatch: The FDA Safety Information and Adverse Event Reporting Program (/Safety/MedWatch/HowToReport/ucm2007306.htm)**. Health care professionals employed by facilities that are subject to **FDA's user facility reporting requirements (/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm2005737.htm)** should follow the reporting procedures established by their facilities.

More in Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/default.htm)
2017 Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/ucm535289.htm)
2016 Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/ucm480134.htm)