Notices and Alerts

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Occasionally, the U.S. Food & Drug Administration sends product alerts, or companies announce product recalls or notices. As a service to members, SVS will post links to these notices here.

LivaNova PLC
Stöckert 3T heater/cooler device
Oct. 13, 2016 - The Centers for Disease Control and Prevention (CDC) is advising hospitals to notify patients who underwent open-heart (open-chest) surgery involving a Stöckert 3T heater-cooler that the device was potentially contaminated, possibly putting patients at risk for a life threatening infection. New information indicates that these devices, manufactured by LivaNova PLC (formerly Sorin Group Deutschland GmbH), were likely contaminated with the rare bacteria Mycobacterium chimaera during manufacturing. Hospitals should advise potentially exposed patients to seek medical care if they are experiencing symptoms such as night sweats, muscle aches, unexplained weight loss, fatigue, or unexplained fever. In addition, hospitals that use or have used this device are strongly encouraged to make and execute a plan to communicate with potentially exposed patients and to increase awareness among healthcare providers. **Read more here** .

Vascular Solutions
Twin-Pass Dual Access Catheter
Oct. 4, 2016 - Vascular Solutions, Inc., has issued a nationwide recall of Twin-Pass Dual Access catheters because of a potential for excess manufacturing material to remain at the tip of the catheter or within the distal portion of the rapid exchange lumen. The excess material may separate from the catheter during use and pose a potential risk of embolism, which could result in serious injury or death. No injuries have been reported in association with this issue to date.

The recalled products were manufactured from October 2014 to August 2016 and were distributed from October 2014 to September 2016. The recalled products are all unexpired lots of Model Numbers 5200, 5210, and 5230. **Read more here**.