Edwards Lifesciences Recalls Swan-Ganz Thermodilution Catheter Due to Incorrect Assembly Causing Reversal of Lumens

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):

- Edwards Lifesciences Swan-Ganz Thermodilution Catheter
- Model Numbers: 131F7, 131F7J, 131F7P, 131VF7P, 151F7
- Lot Numbers: 61321177, 61176373, 61227528, 61321254, 61176369, 61176314, 61176370, 61176367, 61176374, 61321241, 61311580
- Manufacturing Dates: December 26, 2017, to April 19, 2018
- Distribution Dates: January 20, 2018, to August 20, 2018
- Devices Recalled in the U.S.: 1,426

Device Use

Edwards Lifesciences 131F7, 131F7J, 131F7P, 131VF7P, 151F7 Swan-Ganz Thermodilution Catheters provide a diagnostic tool for physicians to quickly measure blood pressures inside the veins, heart, and arteries and to measure blood flow and blood oxygen levels when used with a compatible cardiac output computer. These catheters are often used in patients who are undergoing complex surgery, such as open heart surgery, or require intensive, invasive monitoring to guide their care during serious illness.

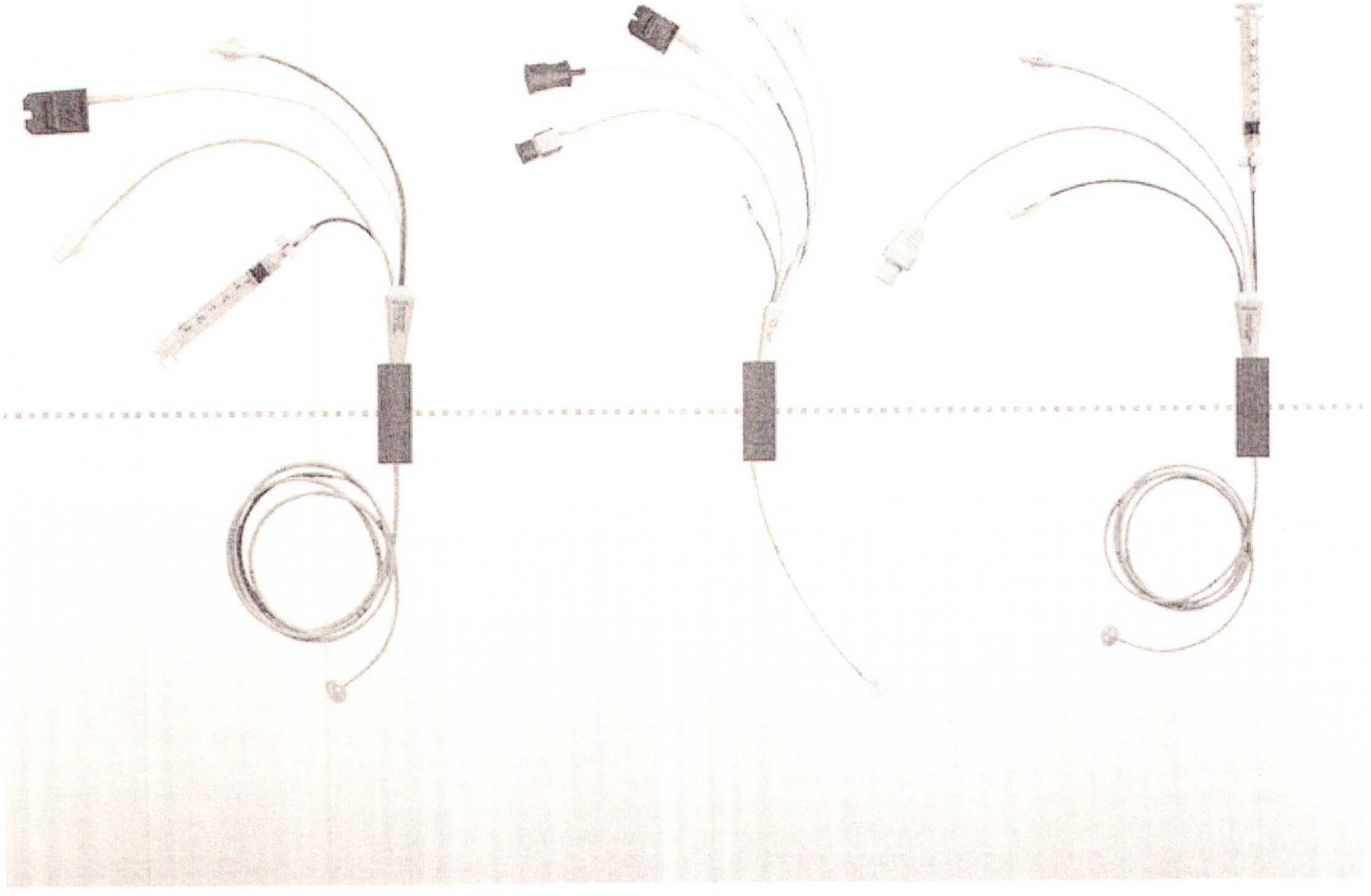

Image of Edwards Lifesciences Swan-Ganz Thermodilution Catheters

Reason for Recall

Edwards Lifesciences is recalling 131F7, 131F7J, 131F7P, 131VF7P, 151F7 Swan-Ganz Thermodilution Catheters manufactured December 26, 2017, to April 19, 2018 due, to incorrect assembly and reversal of the catheter tubes (lumens). If the lumens are reversed the clinician may note inaccurate pulmonary artery and central venous pressure values and waveforms. This may result in unintended treatment, which may result in adverse health consequences.

The inaccurate waveforms and pressure values may also misguide a physician during placement of the catheter, increasing the risk of blood vessel perforation. This exposes the patient to a reasonable likelihood of a serious adverse health consequence or death.

Who May be Affected

- Hospitals and health care professionals using an Edwards Lifesciences Swan-Ganz Thermodilution Catheters, manufactured December 26, 2017 to April 19, 2018 to diagnose or treat patients with a hemodynamic condition.
- Patients receiving testing or treatment for a blood flow or heart condition with an Edwards Lifesciences Swan-Ganz Thermodilution Catheters manufactured December 26, 2017 to April 19, 2018.

What to Do

On December 12, 2018, Edwards Lifesciences sent affected customers an "Urgent Recall Notification Letter" informing of affected model/lot numbers.

The notice requested that customers return any unused units that are currently in their inventory with the affected model and lot numbers. Once returned, replacement product will be shipped to customers at no charge. Edwards Lifesciences prepopulated a "Customer Acknowledgement" form, attached to the notification, with the affected lots and requested that customers follow the instructions on the form to complete the recall process.

Contact Information

Customers with questions may contact Edward Lifesciences Technical Support Department at 1-(800)-822-9837 option 1.

Date Recall Initiated

December 21, 2018

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)

2019 Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/ucm629347.htm)

2018 Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/ucm590900.htm)

2017 Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/ucm535289.htm)

2016 Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/ucm480134.htm)