

# Vascular Solutions, Inc. Recalls Langston Dual Lumen Catheter Due to Risk of Separation During Use

*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

- Vascular Solutions, Inc. Langston Dual Lumen Catheter
- Lot Numbers: Lots distributed between July 12, 2019 and March 10, 2020
  - See full list
- Model Number: Model 6F 5540
- Manufacturing Dates: June 22, 2019 to December 02, 2019
- Distribution Dates: July 12, 2019 to March 10, 2020
- Devices Recalled in the U.S.: 4,304
- Date Initiated by Firm: March 16, 2020

## Device Use

The Vascular Solutions, Inc. Langston Dual Lumen Catheter is used for the rapid delivery of dye (contrast material) into a patient's blood vessels during medical imaging tests (angiographic studies) to allow clinicians to see internal body structures. The device also measures pressure within the blood vessel.



## Reason for Recall

Vascular Solutions, Inc. is recalling the Langston Dual Lumen Catheter because there is a potential the inner catheter may separate during use. If the inner catheter separates, it could cause serious health conditions including additional surgical procedures to remove the separated section, damage to the blood vessel or death. If the inner catheter separates outside of the patient's body, the dye could spray the doctor and lead to an infection that may require the doctor to receive treatment.

There have been 8 complaints and no reports of injury or death.

## Who May be Affected

- Health care providers using the Langston Dual Lumen Catheter
- Patients undergoing angiography procedures using the Langston Dual Lumen Catheter

## What to Do

From March 26-31, 2020, Vascular Solutions, Inc. contacted their customers by mail or email informing them of the affected device, model, and lot numbers and provided the following instructions:

- Secure and remove all unused affected devices
- Complete the Recall Acknowledgement Form

Teleflex (Vascular Solutions, Inc.'s parent company) will destroy any unused recalled devices.

## Contact Information

Customers who have questions about the notice should contact Vascular Solutions at 1-888-240-6001 Monday through Friday, between the hours of 8:00 a.m. and 5:00 p.m. Central Time or by email at [cs@teleflex.com](mailto:cs@teleflex.com) (<mailto:cs@teleflex.com>).

## Full List of Affected Devices

651278 651457 651920 652097 652176 652459  
652628 652777 653053 653319 653443 653565  
653776 653863 654010 654190 654340 654514  
654657 654889 654890 655128 655287 655460  
655465 655738 655869 656191 656533 656554  
656727 656801 657030 657243 657517 657627  
657680 657866 658018 658151 658250 658438  
658541 658671 658824 658984 659122 659217  
659362 659443 659630 659855 660075 660199  
660288 660397 660590 660717 660823 660910  
661139 661257 661474 662824

## Additional Resources:

- Medical Device Recall Database Entry (<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=180664>)
- Related FDA recall classification notices (<http://wayback.archive-it.org/7993/20170112083837/http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm404054.htm>)  
[↗](http://www.fda.gov/about-fda/website-policies/website-disclaimer) (<http://www.fda.gov/about-fda/website-policies/website-disclaimer>)

## How do I report a problem?

Health care professionals and consumers may report adverse reactions or quality problems (<https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home>) they experienced using these devices to MedWatch: The FDA Safety Information and Adverse Event Reporting Program

using an online form, regular mail, or FAX.