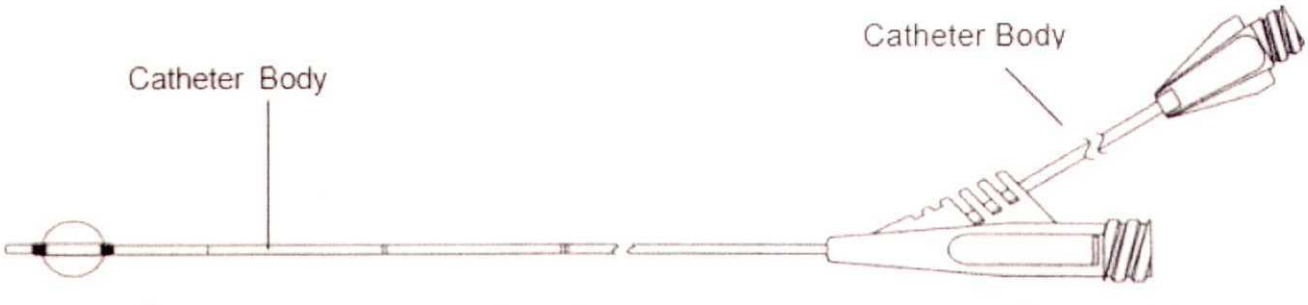
Applied Medical Recalls Python Embolectomy, BARD Embolectomy, and OTW Latis Cleaning Catheters Due to Risk of Separation During Use

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

- Python Embolectomy Catheters, Bard Embolectomy Catheters, and the OTW Latis Cleaning Catheters
- Model Numbers:
  - Python Embolectomy Catheters: A4E01, A4E02, A4E03, A4E04, A4E05, A4E06, A4E08, A4E09
  - Bard Embolectomy Catheters: CE0340DR, CE0380DR , CE0440DR,CE0480DR CE0540DR, CE0580DR, CE0680DR
  - OTW Latis Cleaning Catheters: A4GW6
- Manufacturing Dates: July 23, 2015 to November 8, 2018
- Distribution Dates: August 25, 2015 to March 1, 2019
- Devices Recalled in the U.S.: 19,400
- Date Initiated by Firm: October 24, 2019

Device Use



The Python Embolectomy Catheters, Bard Embolectomy Catheters, and OTW Latis Cleaning Catheters are latex balloon catheters used for temporary blockage, closing of a blood vessel, or infusion of fluids.

Reason for Recall

Applied Medical is recalling their Python Embolectomy Catheters, Bard Embolectomy Catheters, and OTW Latis Cleaning Catheters because there is a risk of the catheter tip detaching during use. If the tip detaches, pieces of the catheter could break off into the patient's body.

If this occurs, there is also the potential for serious health consequences including additional surgical procedures to remove the tip, damage to the blood vessel, or death.

There have been 46 complaints regarding this device issue since 2015. The FDA has received three medical device reports (MDRs) and no reports of death or injury.

Who May be Affected

- Health care providers using affected Python Embolectomy, Bard Embolectomy, and the OTW Latis Cleaning Catheters
- Patients undergoing procedures using affected catheters

What to Do

On November 08, 2019, Applied Medical sent an Urgent: Medical Device Recall Letter to all affected customers with the following instructions:

1. Check your inventory for the recalled product.
2. Complete the Recall Notification Confirmation Form to acknowledge the recall and indicate if your facility is returning or has already used product from the lot listed above.
3. If no product is being returned, please indicate on the Recall Notification Confirmation Form.
4. If you are a distributor, please notify all the facilities that received the affected product of this recall. Please also complete Page 4 of the Recall Notification Confirmation Form.
5. Return the Recall Notification Confirmation Form to Applied Medical by email to recall60810330@appliedmedical.com (mailto:recall60810330@appliedmedical.com) or by fax to 949-713-8908.
6. Return affected product and a copy of the Recall Notification Confirmation Form to Applied Medical (Product Return Instructions are on Page 5).

Contact Information

For product return questions, please contact Jaclene Rios-Simpson, Senior Manager, Customer Relations at 949-713-8688 or jrios@appliedmedical.com (mailto:jrios@appliedmedical.com). For regulatory questions, please contact Lauren Contursi, at 949-713-8767 or

lcontursi@appliedmedical.com (mailto:lcontursi@appliedmedical.com).

Additional Resources:

- Python Embolectomy Recall Database Entry (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=179984)
- BARD Embolectomy Recall Database Entry (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=180041)
- OTW Latis Cleaning Catheters Recall Database Entry (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=180042)

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.