Cook Incorporated Recalls Advance Enforcer 35 Focal Force PTA Balloon Catheter Due to Balloons Bursting Below the Rated Burst Pressure

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:** Advance Enforcer 35 Focal-Force PTA Balloon Catheter 6mm x 4cm
- **Model Numbers:**
  - 5FR/50cm, Catalog Number ASB5-35-50-6-4, REF Number G35248
  - 5FR/80cm, Catalog Number ASB5-35-80-6-4, REF Number G35252
  - 5FR/135cm, Catalog Number ASB5-35-135-6-4, REF Number G35257
- **Lot Numbers:** 9234424, 9331618, 9212015, 9243035, 9320430, 9386804, 9338194, 9234423, 9278982, 9209468, 9248603, 9320429
- **Manufacturing Dates:** October 3, 2018 to December 17, 2018.
- **Distribution Dates:** October 29, 2018 to March 21, 2019.
- **Devices Recalled in the U.S.:** 33
- **Date Initiated by Firm:** May 24, 2019

Device Use

The Advance Enforcer 35 Focal-Force PTA Balloon Catheter is used by healthcare providers for opening blocked or narrowed arteries that supply blood to the leg (percutaneous transluminal angioplasty (PTA) (https://medlineplus.gov/ency/article/007393.htm)). This catheter is not for use in the brain or heart.

Reason for Recall

Multiple complaints were received for balloons bursting below the rated burst pressure. While there were no reports of malfunctions, deaths, or injury reported for this balloon issue, there is a high occurrence rate. Potential adverse events that may occur if an affected product is used include a delay in the procedure, additional intervention, vessel injury, balloon fragmentation in the patient, and death.

Who May be Affected

- Healthcare professionals using the Advance Enforcer 35 Focal-Force PTA Balloon Catheter

- Patients undergoing procedures involving the Advance Enforcer 35 Focal-Force PTA Balloon Catheter

What to Do

On May 24, 2019, Cook Medical, the customer relations department of Cook Inc., sent an Urgent Medical Device Recall notification letter to customers. The letter asked customers to:

- Examine your inventory immediately to determine if you have affected product(s), and quarantine affected product(s). Immediately cease all distribution and use of these products.
- Return the affected product(s) to Cook Medical with a copy of the Acknowledgement and Receipt Form to receive a product credit. NOTE: Unaffected products that are returned will not be credited.
- Please complete the Acknowledgement and Receipt Form within 5 business days. Even if you do not have affected product(s) on hand, you must still complete the Acknowledgement and Receipt Form and return it via fax (812.339.7316) or by email to FieldActionsNA@CookMedical.com (mailto:FieldActionsNA@CookMedical.com). If you have a product to return, contact Stericycle at phone number 855-205-2627 to obtain a credit and reference event number 10082.
- Share the notification letter with appropriate personnel, including down to the user level, within your organization or with any organization where the potentially affected devices have been transferred.
- Immediately report adverse events to Cook Medical Customer Relations by phone at 800.457.4500 or 812.339.2235, Monday through Friday between 7:30 am and 5:00 pm (Eastern Time) or by email to CustomerRelationsNA@CookMedical.com (mailto:CustomerRelationsNA@CookMedical.com).

Contact Information

Customers with questions may contact Cook Medical with any questions or concerns regarding this recall at 812-339-2235.

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-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda). Health care professionals employed by facilities that

are subject to FDA's user facility reporting requirements (/medical-devices/postmarket-requirements-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities) should follow the reporting procedures established by their facilities.

More Information

- Class 1 Device Recall Advance Enforcer 35 Focal-Force PTA Balloon Catheter 6mm x 4cm, 5FR/80cm (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=172993)
- Class 1 Device Recall Advance Enforcer 35 Focal-Force PTA Balloon Catheter 6mm x 4cm, 5FR/135cm (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=172994)
- Class 1 Device Recall Advance Enforcer 35 Focal-Force PTA Balloon Catheter 6mm x 4cm, 5FR/50cm (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=172992)