

**U.S. Food and Drug Administration**  
Protecting and Promoting *Your* Health

# **Stryker Sustainability Solutions (formerly Ascent Healthcare Solutions) Recalls Flush Angiographic Catheter Due to Tip Separation**

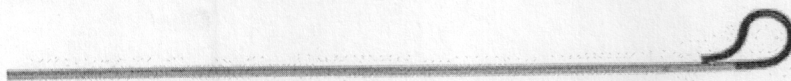
*The FDA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries or death.*

## **Recalled Product:**

- Angiodynamics Soft Vu Omni Flush Angiographic Catheter
- Model/Item Numbers: 10732203
- Lot Numbers: 8248U, 119965U, 158623U, 175183U, 179688U, 191185U, 210813U, 225911U, 225918U, 225919U, 253202U, 277726U, 302844U, 309329U, 325680U, 343908U, 352756U, 352761U, 359352U, 363987U, 366572U, 369818U, 375883U, 772102U, 773196U, 773216U, 775985U, 7710750U
- Manufacturing Dates: November 7, 2003 to October 18, 2008
- Distribution Dates: January 5, 2004 to December 3, 2008
- Devices Recalled in the U.S.: 167 in Texas, Utah, Pennsylvania, California, Vermont, Maine, Washington, Virginia, New York, Maryland, Connecticut

## **Device Use**

The Soft-Vu Omni Flush Angiographic Catheter is used to inject contrast dye into blood vessels in preparation for a cardiac angiogram, a type of X-ray used to diagnose heart conditions. The catheter is inserted into the body through a small puncture made in the skin and into a blood vessel.



*Image of the Angiodynamics Soft Vu Omni Flush Angiographic Catheter*

## **Reason for Recall**

Stryker Sustainability Solutions (formerly Ascent Healthcare Solutions), is recalling Angiodynamics Soft Vu Omni Flush Angiographic Catheters due to reports of separation of the tip of the catheter from the main body. Tip separation leads to loss of device function, possible surgical intervention to retrieve a separated segment, or other complications such as blocking blood flow to bodily organs.

Tip separation can also lead to internal organ injury and cause stroke, kidney failure, and

intestinal failure among other serious adverse health consequences, including death.

### Who May be Affected

- Hospitals and health care professionals using the Angiodynamics Soft Vu Omni Flush Angiographic Catheter
- Patients undergoing cardiovascular angiographic procedures involving these catheters

### What to Do

On June 1, 2016, Stryker Sustainability Solutions sent a Customer Notification letter to customers informing them of the high possibility of tip separation during use. The letter also asked customers to:

- Discontinue use of the affected lots of the recalled products
- Check their inventories for affected lots of the unused products
- Ship all affected products found back to Stryker
- Acknowledge receipt of the letter by returning the enclosed Device Recall Effectiveness Check form by postal mail, or by contacting their Stryker Sustainability Sales Representative by email at [ssspfa@stryker.com \(mailto:ssspfa@stryker.com\)](mailto:ssspfa@stryker.com)
- Report adverse reactions or quality problems experienced with the use of the product to the Stryker Sustainability Solutions Complaint Hotline at (888) 888-3433, Ext. 5555, or to the FDA through:
  - [MedWatch Online \(http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm\)](http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm)
  - Phone: 800-FDA-1088

### Date Recall Initiated

June 1, 2016

[More in Medical Device Recalls \(/MedicalDevices/Safety/ListofRecalls/default.htm\)](#)

[2016 Medical Device Recalls \(/MedicalDevices/Safety/ListofRecalls/ucm480134.htm\)](#)

[2015 Medical Device Recalls \(/MedicalDevices/Safety/ListofRecalls/ucm429489.htm\)](#)

[2014 Medical Device Recalls \(/MedicalDevices/Safety/ListofRecalls/ucm384921.htm\)](#)

