

# ReFlow Recalls Wingman 35 Crossing Catheters due to Tip Separation

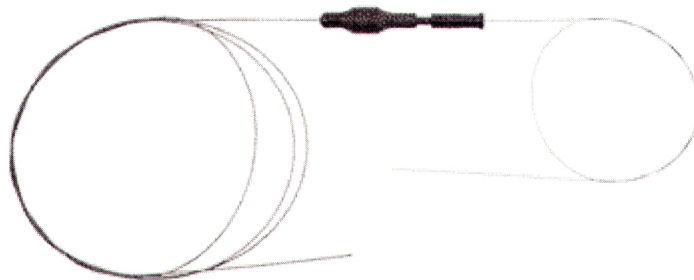
*The FDA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries or death.*

## Recalled Product

- Product Description: Wingman 35 Crossing Catheter, 65cm
- Lot Numbers: 1509154R, 1510024R, 1510204, 1510054R, 1602164, 1604194R, 1605133, 1606273R2, 1701244, 1508264R, 1508265, 1601044, 1603024, 1603214, 1605193, 1508204R, 1508205, 1510074R, 1511304, 1512174, 1602174, 1604213, 1604253, 1605113, 1606203, 161103
- Distribution Dates: March 1, 2015 to March 17, 2017
- Devices Recalled in the U.S.: 2327

## Device Use

The Wingman 35 Crossing Catheter is used with steerable guidewires to access veins and arteries not in the chest or abdomen. It may be used to assist with the placement and exchange of guidewires and other interventional devices and administer drugs or fluids into blood vessels.



## Reason for Recall

Reflow is recalling the Wingman 35 Crossing Catheter due to a risk of the catheter tip splitting or separating. If a catheter tip splits or separates during use, it can enter the patient's bloodstream and can result in serious adverse health consequences such as injury to blood vessel walls, development of blood clots, embolism, heart attack or death.

On March 22, 2017, ReFlow Medical issued a recall notice for lots 1602164 and 1602164R. As of April 19, 2017 ReFlow Medical determined additional lots could be affected, so the recall has been expanded.

## Who May be Affected

- Health care providers using the Wingman 35 Crossing Catheter
- All patients undergoing procedures involving these catheters

## What to Do

On April 20, 2017, ReFlow Medical sent an Urgent: Medical Device Recall letter to all affected customers. The letter asked customers to:

- Identify and collect affected products from inventory and discontinue use.
- Mark the product as "Recalled Product - Recall 2017-001"
- Complete the Customer Response Form even if there is no product to return.
- Return response form by e-mail at [quality@reflowmedical.com](mailto:quality@reflowmedical.com) (<mailto:quality@reflowmedical.com>), fax at 760.290.3216, or mail to:
  - ReFlow ReFlow Medical Attn: Recall Coordinator  
1003 Calle Sombra,  
San Clemente, CA 92673
- ReFlow Medical will send a Returned Good Authorization label and shipping label for the return of recalled devices. Credit for product returns will be issued upon receipt of returned goods.
- Notify any other entities within the organization who were distributed the affected product of this recall. Instruct them to discontinue use and quarantine the affected product.
- If the listed lots have been distributed to other parties, perform a SUB-RECALL to the user accounts using the recall notification and stock response form.

## Contact Information

Customers may contact ReFlow Medical Customer Relations at 1-949-481-0399, Monday through Friday, between 8:00 a.m. and 4:30 p.m. Pacific time or by email at [info@reflowmedical.com](mailto:info@reflowmedical.com) (<mailto:info@reflowmedical.com>) with any questions related to this recall.

## Date Recall Initiated

March 22, 2017

## 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](https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home) (<https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home>) either online, by regular mail or by FAX to 1-800-FDA-0178.

**More in Medical Device Recalls**  
([/MedicalDevices/Safety/ListofRecalls/default.htm](https://www.fda.gov/MedicalDevices/Safety/ListofRecalls/default.htm))

**2017 Medical Device Recalls** ([/MedicalDevices/Safety/ListofRecalls/ucm535289.htm](https://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm535289.htm))

**2016 Medical Device Recalls** ([/MedicalDevices/Safety/ListofRecalls/ucm494341.htm](https://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm494341.htm))