

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

Hummingbird Med Devices Inc. Recalls Hummi Micro-Draw Blood Transfer Device Due to Potential for Parts to Disconnect

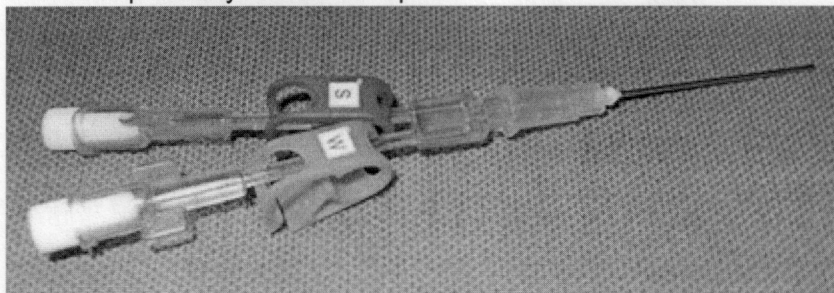
The FDA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries or death.

Recalled Product:

- ABG-HM-1 Hummi Micro-Draw Blood Transfer Device
- Lot numbers: 15180, 15286, 15287, 15300, 15305
- Manufacturing dates: June 29, 2015 to December 2, 2015
- Distribution dates: October 26, 2015 to November 18, 2015
- Devices recalled in the U.S.: 37, 750 units in California, Kentucky, Maryland and Illinois

Device Use

The Hummi Micro-Draw Blood Transfer Device is a blood collection device with a Y-shaped connector attached to a yellow cannula hub (tube). It connects to a catheter to collect small volume blood samples from infants, including premature ones. The collected blood is transferred from the device to a syringe or other container for transport and processing. The device is primarily used in hospitals.



Hummi Micro-Draw Blood Transfer Device

Reason for Recall

Hummingbird Med Devices Inc. is recalling the Hummi Micro-Draw Blood Transfer Device because the Y-shaped connector and the yellow tube may disconnect from each other prior to or during use. This could lead to blood or fluid leakage. Blood or fluid loss may result in serious adverse health consequences, including death.

Who May be Affected

- Patients who are having blood drawn through this device
- Health care professionals using this device to draw blood

What to do

On October 1, 2015, Hummingbird Med Devices Inc. sent notification letters to affected customers informing them that:

1. The firm recommends not using the identified lots;
2. A local distributor or sales representative will be contacting them to arrange a return of the identified lot for credit and replacement;
3. Replacement product should be available within 10 days of October 30, 2015; and
4. During the period of product unavailability customers should return to previous methods for blood drawing.

On November 19, 2015, the firm expanded this recall to include additional lots of the device. The firm sent a second notification letter to affected customers with the same instructions as in the October 30, 2015 letter, but stated that the replacement product would be available mid-December 2015.

The firm requested a Reply Form be completed and returned via fax at 949-583-2775.

Date Recall Initiated:

October 1, 2015

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>) either online, by regular mail or by FAX to 1-800-FDA-0178.

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>)