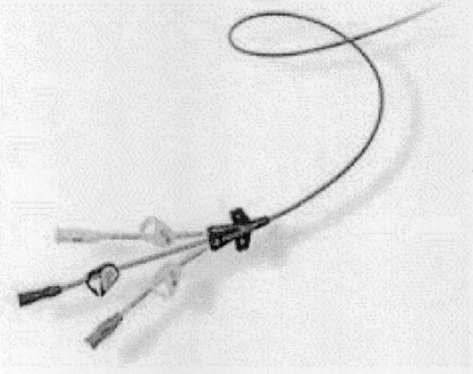
Centurion Recalls Multi-Med Single Lumen Catheters due to Excess Material that May Split or Separate

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:

- Centurion Convenience Kits containing Multi-Med Single Lumen Catheters
- Lot Numbers: 2016062150, 2016062950, 2016070650, 2016081550, 2016051050 2016053150, 2016060750, 2016061550, 2016063050, 2016072050, 2016080250, 2016091950, 2016060750, 2016072650, 2016093050, 2016101050, 2016052050, 2016062850, 2016082350, 2016082650, 2016090250, 2016050950, 2016053150, 2016060750, 2016071250, 2016080350, 2016082950, 2016060850, 2016061650, 2016062050, 2016070550, 2016071950, 2016080250, 2016090750, 2016071350, 2016072050, 2016092650, 2016100650, 2016072950, 2016082450
- Centurion Kit Codes: ECVC1680, ECVC4785, M11620HKIC, M11620HKICNL, M11620HS, M11620KC, M11620KCNL, M12013K, M12013KNL
- Product Code: FOZ
- Distribution Dates: May 23, 2016 to October 18, 2016
- Devices Recalled in the U.S.: 1,000 kits

Device Use

The Multi-Med Catheter is used to sample blood, and administer drugs or fluids. The catheter is inserted into the body through a small puncture made in the skin and into a blood vessel.

Reason for Recall

Centurion is recalling the Centurion Convenience Kits containing Multi-Med Single Lumen Catheters. The catheters have a potential for excess material to remain at the tip of the catheter from the manufacturing process. If this occurs, the excess material may separate from the catheter

during use and could enter the patient's bloodstream. This can result in serious adverse health consequences such as the development of blood clots, embolism of the excess material to vital organs, or death.

Who May be Affected

- Health care providers using these catheters
- All patients undergoing procedures involving these catheters

What to Do

On October 21, 2016, Centurion sent an Urgent Recall Notice letter to all affected customers. The letter asked customers to:

- Identify and stop using the affected products
- Complete and return the response form, attached to recall notice, to the recall coordinator via email via **Lcarpenter@centurionmp.com** or fax 517-546-3356.

Contact Information

Health care professionals and consumers with questions should contact Centurion Medical Products Corporation at (571)-546-5400 with any questions related to this recall.

Date Recall Initiated:

October 21, 2016

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

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