URGENT FIELD SAFETY NOTICE

Specific product codes and lots of:

- **Yankauer Suction Tubing**
- **Foley Catheter**
- **Thoracic Catheter**
- **Oxygen Tubing**

15 April 2019

Manufacturers Reference: FA808

Attention: Risk Management Director and Materials Management

Dear Valued Customer:

The purpose of this letter is to advise you that Cardinal Health is recalling specific item codes and production lots of Yankauer Suction Tubing, Foley Catheter, Thoracic Catheter and Oxygen Tubing. This Field Safety Corrective Action (FSCA) is being conducted due to the distributor's shipment of product that is not CE-Marked to customers in the European Union**.** This product is currently distributed by a third-party on behalf of Cardinal Health.

The products meet specifications for their intended markets; however, some customers may notice differences between this affected product and the CE-Marked product. Specifically, for the Yankauer devices, users may notice a difference in the curvature and the angle of bend. Also, although functionally equivalent to the CE Marked version, the non CE-Marked Right Angle Thoracic Catheter varies in radial positioning and overall length dimensions. During use, these differences could require a user to adjust insertion technique, which could cause a delay of treatment, with the potential for complications when treating pneumothorax, hemothorax and pleural effusion. The CE Marked and non CE-Marked versions of the products also have differences in packaging and labelling.

Cardinal Health requests that you quarantine and return any unused products of the items/lots detailed below. Unused products from the affected item codes and lots should be returned as described in the Required Actions section below.

If you have distributed the products listed above, please promptly forward the information from this letter to those recipients. All unused products from the affected item codes and lots must be returned.

This action is being taken with the knowledge of the [Insert name of local Competent Authority]. We request that you contact Cardinal Health if you have experienced quality problems or adverse events.

Required Actions:

1) Immediately check your inventory to confirm whether you have any units from affected product codes in your possession. **Identify and set aside** any units from the affected product codes in a manner that ensures the affected product will not be used. Check all storage and usage locations.
2) **Review, complete, sign and return** the enclosed Acknowledgement Form in accordance with the directions on the form.
3) **Return** all affected product, or contact your local sales representative to facilitate return of the affected product. Your sales representative will inform you of the product replacement or credit options.
4) **Share** this letter with others in your facility who need to be made aware of this recall.
5) **Contact** any other facilities that have been provided with units of affected lots.
6) **Maintain awareness** of this notice until all affected product has been returned to Cardinal Health.
7) **Keep** a copy of this notice with any affected product until returned.

We apologize for this inconvenience. If you have any questions or concerns, please do not hesitate to contact your local sales representative or local sales office.

Sincerely,

William Crates
Vice President, Distribution Quality
Cardinal Health

Attachment 1: Affected Product List

Item	Item Description	Lot Number(s)
8887605122	FOLY CATH 100 SLCON 5CC 12FR	7188187
8887605163	FOLY CATH 100 SLCON 5CC 16FR	7223254, 7303057
8887605205	FOLY CATH 100 SLCON 5CC 20FR	7286243, 7292620
8887630245	FOLY CATH 100 SLCON 30CC 24FR	7279217
8888230201	2302 OXYGEN TUBE 100 FT	1730715364, 1821301864
8888501007	FLEXIBLE YANKAUER REGULAR CAPA	1726918564
8888501023	YANKAUER REG W/TT	1712221264
8888504001	FLEXIBLE YANKAUER FINE CAPACIT	1726918764
8888570549	STR THOR CATH 28FR	1732521364
8888571059	R ANG THOR CATH 32FR	1733221364