URGENT: FIELD SAFETY NOTICE

Specific product codes and lots of:

- **Yankauer Suction Tubing**
- **Penrose Tubing**
- **Trocar Catheter**
- **Thoracic Catheter**

CardinalHealth

FSCA Reference: FA808

March 2018

Attention: Risk Management Director and O.R. 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, Penrose Tubing, Trocar Catheter and Thoracic Catheter. This Field Safety Corrective Action (FSCA) is being conducted due to the distributor's wrong 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 respective markets; however, some customers may experience differences between this affected product and the CE-Marked product. There are differences in the packaging and labeling of the products. For the Yankauer devices users may notice a difference in the curvature and the angle of bend, in comparison with the CE-Marked devices.

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.

Item	Description	Lot
8888561043	TROCAR CATH 40CM 20FR X10	1724119864
8888504001	YANKAUER FINE X50	1722020264
8888504001	YANKAUER FINE X50	1726918764
8888570531	THORACIC CATH STR 24FR X10	1729115964
8888513804	PENROSE TUBE 30CM 16.0MMX50	173210248
8888515007	PENROSE TUBE 45CM 10.0MMX50	171490133
8888502005	YANKAUER HIGH	1726918664
8888501023	YANKAUER REG W/TT	1712221264
8888501007	YANKAUER REG X50	1726220064
8888561027	TROCAR CATH 23CM 12FR X10	1733919264
8888504001	YANKAUER FINE X50	1721319064
8888501007	YANKAUER REG X50	1725518864
8888501023	YANKAUER REG W/TT	1716015164
8888501007	YANKAUER REG X50	1729719564

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 FSCA affects only the specific combinations of item codes and lots listed above.
This action is being taken with the knowledge of the Competent Authority in your country. We request that you contact Cardinal Health if you have experienced quality problems or adverse events.

As of July 29th 2017, Cardinal Health acquired this product from Medtronic. Some portions of this letter refer to Medtronic due to transition services being performed by Medtronic.

Required Actions:

1. Please quarantine and discontinue use of the affected item codes and lots listed above.
2. Please return affected product as follows:

	Customer with inventory	Customer with zero inventory	Where to send the completed form
Purchased **directly** from *Medtronic	Please complete the attached Returns Verification Form in its entirety. Upon receiving your form, Medtronic Customer Care will contact you to organize the return of your products. You will receive credit for unused device(s) that you return.	Complete form and check the box indicating “no inventory”	E-mail or fax the completed form to the Medtronic contact provided on the verification form.
Purchased from a **distributor**	Complete **all** fields on the form and contact your distributor directly to arrange for return of product	Complete form and check the box indicating “no inventory”	E-mail or fax the completed form to your Distributor & to the Medtronic contact provided on the verification form.

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

Sincerely,

Karl Vahey

Karl Vahey
Vice President, Manufacturing Quality
Cardinal Health
Patient Recovery