URGENT: FIELD SAFETY NOTICE (Removal)

Specific product codes and lots of:

- **Hydroline Trumpet Valves**

Event-2018-01390

CardinalHealth

June 11, 2018

Attention: Risk Management Director and O.R. Materials Management
(cc: Chairman Medical Board and relevant Head of Departments)
Dear Valued Customer:

The purpose of this letter is to advise you that Cardinal Health is recalling specific item codes and production lots of Hydroline Trumpet Valves. This Field Safety Corrective Action (FSCA) is being conducted due to an issue in which the valves may not close properly on the below affected products, which could cause continuous suction.

There is a remote possibility that inability to control suction during a procedure may result in loss of carbon dioxide in the abdomen, reduced visibility of the surgical site and potential injury to organs and body tissue. Cardinal Health is not aware of any reports of injury attributed to this issue.

Cardinal Health's records indicate you may have received product associated with this action. Please ensure all lots of the product codes listed below are returned immediately to Cardinal Health and are not used per the instructions outlined in the **Required Actions** section below.

Product Code	Product Description	Affected Lot Numbers
ASU1200	PROBE 5MM X 33CM, DISP FIXED	21706,21707,31751,31748,31750,31753,41719, 41720,61717,61718,61719,71736,71737,91702, 91705,91706,91721
ASU1201	PROBE 5MM X 33CM, DISP FIXED	31712,31711,31713,31714,31764,31765,41711, 41713,41715,41724,41737,41714,41721,41722, 41723,41727,41726,41725,41719,41731,41732, 41730,41728,41733,41734,41735,71738,71739, 71740,71748,71741,71742,81745,71743
ASU1221	TRUMPET VALVE, NO PROBE	21719,41738

This FSCA affects only the specific combinations of item codes and lots listed above.
The applicable regulatory agencies are being notified that Cardinal Health is voluntarily taking this action.
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. **Contact** any other facilities that have been provided with units of affected lots. **Maintain awareness** of this notice until all affected product has been returned to Cardinal Health.
5) **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,

Moazzam Khan
Director, QRA Management