



Cardinal Health  
Medical Segment  
7200 Cardinal Place  
Dublin, OH 43017

[cardinalhealth.com](http://cardinalhealth.com)

January 15, 2020

Dear Valued Customer:

As we communicated earlier this week, Cardinal Health has become aware of an issue related to the environmental conditions at a facility that manufactures certain AAMI Level 3 surgical gowns for Cardinal Health. We have initiated an investigation, placed a hold on potentially affected product inventory, and are working with the U.S. Food and Drug Administration (FDA) to address this issue. Cardinal Health intends to initiate a product recall and will provide you with instructions soon. Today's update is the latest step in keeping you informed as we move through this process.

The safety of our products is a responsibility we take very seriously. As such, we decided to issue the voluntary product hold. Our decision was based on quality issues identified at this contract manufacturer's facility. At this time, we cannot provide sterility assurances with respect to the gowns or the packs containing the gowns because of the potential for cross-contamination. Our communications with the FDA confirm our direction that the affected products and packs containing the affected products should not be used.

Consistent with our previous communication, this inventory hold affects certain lots of bulk non-sterile and single-sterile Cardinal Health™ surgical gowns and Presource® procedure packs that include these surgical gowns. We are advising customers to discontinue use and segregate all affected surgical gowns and procedure packs that include these affected surgical gowns from your current inventory. To clarify questions we've received, please note that procedure packs with work order numbers (lot numbers) not listed on the spreadsheet provided by your sales representative are not affected by this hold and are good for use.

We are doing everything we can to mitigate disruption for our customers. Our sales representatives are in process of contacting every affected customer to provide specific details and identify alternatives, and we have deployed additional employees to support their efforts working with customers to segregate product. Our Global Sourcing and Inventory Planning teams are working with our internal and external manufacturing sites to ramp up volume where possible. For procedure packs currently in production, we will include gowns with similar fit, form and function, where possible, with no change in cost, or run without the product or suggest an alternate, comparable single-sterile gown.

We recognize the criticality of our gowns and procedure packs to performing surgeries, and we apologize for the challenges this supply disruption will cause. Cardinal Health puts the safety of patients and healthcare workers first. We are committed to keeping you informed as we work with the FDA to address this issue. We are sharing the best information we have at this time and will share updates as we move through this process.

Sincerely,

A handwritten signature in black ink that reads "Carl E. Hall Jr." in a cursive style.

Carl E. Hall Jr.  
Vice President / General Manager  
Presource & Distribution Services

A handwritten signature in black ink that reads "Emily Gallo" in a cursive style.

Emily Gallo  
U.S. Category Vice President  
Medical Products