

# URGENT: FIELD SAFETY NOTICE (Correction)

## Specific product codes and lots of:

- Protexis Neoprene Surgical Gloves

Event-2018-01753



31 October 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 initiating a product labeling correction for specific item codes and production lots of Protexis Neoprene Surgical Gloves. This Field Safety Corrective Action (FSCA) is being conducted due to incorrect breakthrough (i.e., permeation) times for two chemotherapy drugs (Carmustine and Thiotepa) stated on the “wallet” (primary packaging). Additionally, breakthrough time for Mitomycin was added to the same label in error. Refer to table below for technical data comparison.

	Breakthrough Time (in minutes)	
	Affected Wallet Labeling	Correct Values
<b>Carmustine</b>	60.1	0.20
<b>Thiotepa</b>	110.5	82.2
<b>Mitomycin</b>	>240	N/A

The incorrect permeation times for Carmustine and Thiotepa poses the potential risk of chemical exposure to users. In addition to localized skin irritation, blistering and burn-like effects, systemic symptoms can occur with prolonged or repeated exposure. To mitigate risk, clinicians should assess the drug toxicity and exposure time prior to handling. It is recommended that two common clinical practice standards be utilized: double gloving and changing gloves every 30 minutes. Cardinal Health has not received any related complaints for the affected product to date.

Cardinal Health’s records indicate you may have received product associated with this action. Please ensure the **Required Actions** are completed for the affected product codes and lots for this action.

Product Code	Product Description	Lot Numbers
2D73DP55	Protexis Neoprene Surgical Glove Size 5.5	TS18060249, TS18070244, TS18080021, TS18080344, TS18090280
2D73DP60	Protexis Neoprene Surgical Glove Size 6.0	TS18060125, TS18060250, TS18060328, TS18070031, TS18070245, TS18070392, TS18080025, TS18080345, TS18080444, TS18090119, TS18090281
2D73DP65	Protexis Neoprene Surgical Glove Size 6.5	TS18050409, TS18060149, TS18060240, TS18060312, TS18070036, TS18070106, TS18070306, TS18070371, TS18080026, TS18080348, TS18080445, TS18090113, TS18090159, TS18090212, TS18090282
2D73DP70	Protexis Neoprene Surgical Glove Size 7.0	TS18050417, TS18060144, TS18060234, TS18060314, TS18070120, TS18070307, TS18070379, TS18080022,

		TS18080349, TS18080446, TS18090120, TS18090155, TS18090211, TS18090288
2D73DP75	Protexis Neoprene Surgical Glove Size 7.5	TS18060009, TS18060145, TS18060251, TS18060322, TS18070037, TS18070122, TS18070312, TS18070380, TS18080033, TS18080350, TS18090125, TS18090154, TS18090213, TS18090290
2D73DP80	Protexis Neoprene Surgical Glove Size 8.0	TS18060134, TS18060230, TS18060323, TS18070039, TS18070313, TS18070372, TS18080027, TS18080351, TS18090164, TS18090218, TS18090289
2D73DP85	Protexis Neoprene Surgical Glove Size 8.5	TS18060015, TS18060329, TS18070121, TS18070314, TS18080034, TS18080352, TS18090219
2D73DP90	Protexis Neoprene Surgical Glove Size 9.0	TS18060016, TS18070126, TS18070315, TS18080353, TS18090220

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. **INSPECT your inventory for the affected product code and lot number (listed on package).**
2. **AFFIX enclosed warning label on the principal display panel on affected dispenser packs in your inventory. If additional labels are needed, please contact [XXXXXX].**
  - a. **NOTE: If wallets are removed from the dispenser pack into another storage location at your facility, the warning label or this notice should accompany the affected product to inform users of the correct breakthrough times.**
3. **NOTIFY any internal parties and/or customers to whom you may have distributed, or forwarded affected product of this Field Safety Notice (Correction) and the correct permeation times.**
4. **COMPLETE the enclosed Acknowledgement Form and return immediately to Cardinal Health.**

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,



Karl Vahey  
Vice President, Manufacturing Quality