

URGENT: FIELD SAFETY NOTICE (Correction)

Specific product codes and lots of Protexis Latex Micro Surgical Gloves

Event-2020-03257

XX October 2020


Attention: Risk Management Director and O.R. Materials Management

Dear Valued Customer:

The purpose of this letter is to inform you that Cardinal Health has issued a new Field Safety Notice for specific production lots of **Cardinal Health™ PROTEXIS™ Latex Micro Surgical Gloves** due to possible holes and donning tears at the folding area around the cuffs. Please see Attachment 1 for affected product codes and lots. The affected products were manufactured between April 2020 and July 2020 and were distributed between April 2020 and September 2020.

Previously, in **July/August** 2020, Cardinal Health initiated a voluntary recall (Event-2020-03063) of specific production lots of Cardinal Health™ PROTEXIS™ Latex Micro Surgical Gloves that were distributed between June 2019 and July 2020. The investigation into this event determined the potential root cause to be a change to the latex maturation time, which was resolved.

However Cardinal Health has since received a limited number of complaints on additional lots and is initiating this new Field Safety Notice (correction) while conducting further investigations. Please note that this new Field Safety Notice (correction) concerns lots other than the ones affected by the recall initiated in **July/August** 2020.

<p>Description of the problem:</p>	<p><u>What is the issue?</u> Cardinal Health™ PROTEXIS™ Latex Micro Surgical Gloves may have possible holes and donning tears at the folding area around the cuffs. Please see photographs below.</p>  <p><u>Why are we sending this Field Safety Notice?</u> Cardinal Health™ PROTEXIS™ Latex Micro Surgical Gloves are disposable devices made of natural rubber latex intended to be worn by operating room personnel as barrier protection from contamination. Use of surgical gloves with holes and/or tears has the potential risk of infection or cross-patient (clinician) exposure to body fluids.</p> <p>Given the unprecedented demand for personal protective equipment (PPE) during the current COVID-19 global health crisis, Cardinal Health recognizes the importance of continuing to supply this product to our healthcare partners and is asking customers to implement the actions described below.</p> <p>Cardinal Health has not received any reports of clinician or patient harm or injury, and the observed defect and complaint occurrence rates for the specific lot numbers are significantly lower than the defect occurrence rate observed for those lot numbers affected by the July/August 2020 recall.</p>
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	<u>What other actions is Cardinal Health taking?</u> Cardinal Health is investigating the root cause of this issue. Corrective actions will be implemented and monitored to ensure that the issue has been corrected.
Actions requested on your part:	<ol style="list-style-type: none">1. INSPECT your inventory for affected product (see attachment 2 for item code and lot location). Retain a copy of this notice with the product.2. COMMUNICATE with all personnel that utilize the product of the risk of possible holes and donning tears at the folding area around the cuffs.3. INSPECT the entire surgical glove for any holes or tears after donning has occurred.<ol style="list-style-type: none">a. If a hole or tear is detected, the glove must be discarded and a new glove must be obtained. Inspect the new glove for holes or tears in the same manner.b. Double-gloving is recommended to provide additional barrier protection.4. NOTIFY any customers to whom you may have distributed or forwarded affected product about this product correction notice.5. RETURN the enclosed acknowledgment form6. MAINTAIN awareness of this notice until all affected product has been utilized.

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



Attachment 1 – Affected Product Codes and Lots

Product Code	Product Description	Affected Lots
2D72NT55X	PROTEXIS™ Latex Micro Surgical Gloves Size 5.5	TS20040247, TS20050050, TS20050051, TS20050261, TS20060112, TS20060113, TS20070125, TS20070289
2D72NT60X	PROTEXIS™ Latex Micro Surgical Gloves Size 6.0	TS20040173, TS20040249, TS20040257, TS20040333, TS20050052, TS20050069, TS20050152, TS20050153, TS20050196, TS20050197, TS20050334, TS20050335, TS20060011, TS20060053, TS20060054, TS20060115, TS20060116, TS20060199, TS20060200, TS20060250, TS20070023, TS20070108, TS20070183
2D72NT65X	PROTEXIS™ Latex Micro Surgical Gloves Size 6.5	TS20040111, TS20040069, TS20040104, TS20040174, TS20040293, TS20050140, TS20050181, TS20050182, TS20050268, TS20050269, TS20050336, TS20050344, TS20050378, TS20060010, TS20060064, TS20060065, TS20060138, TS20060140, TS20060224, TS20060225, TS20060285, TS20060286, TS20070003, TS20070081
2D72NT70X	PROTEXIS™ Latex Micro Surgical Gloves Size 7.0	TS20040204, TS20040260, TS20040312, TS20050113, TS20050157, TS20050289, TS20050290, TS20050391, TS20060093, TS20060152, TS20060153, TS20060204, TS20060237, TS20060238, TS20060296, TS20060304, TS20060305, TS20070020, TS20070107
2D72NT75X	PROTEX IS™ Latex Micro Surgical Gloves Size 7.5	TS20040051, TS20040075, TS20040058, TS20040176, TS20040280, TS20040281, TS20040291, TS20050010, TS20050174, TS20050306, TS20050353, TS20060032, TS20060038, TS20060120, TS20060174, TS20060175, TS20060260, TS20050250
2D72NT80X	PROTEXIS™ Latex Micro Surgical Gloves Size 8.0	TS20040334, TS20040358, TS20040359, TS20050106, TS20050322, TS20060026, TS20060084
2D72NT85X	PROTEXIS™ Latex Micro Surgical Gloves Size 8.5	TS20050169, TS20050262, TS20060005
2D72NT90X	PROTEXIS™ Latex Micro Surgical Gloves Size 9.0	TS20040290, TS20050032, TS20060107

Attachment 2 – Packaging of Affected Product

