IMPORTANT - PRODUCT RECALL

ATEC Canister Lid
ATEC CANISTER

Dear Hologic Business Partner:

At Hologic, we are committed to continually evaluating and improving the quality and reliability of our products. This letter is to notify you of a potential performance issue of the ATEC Sapphire Breast Biopsy System.

There have been reports of customers receiving ATEC canisters with cracked lids. We wanted to notify you that Hologic is aware of the issue and we need your assistance resolving this problem. Hologic, Ine. is Recalling certain lots of its ATEC Canister. This action is being taken because the canister lid may have cracks. The lot numbers affected by the Recall are as follows: Lot# 20150013 & 20150014.

This issue will be discovered during the inspection of the canister during setup or via a system vacuum error when testing the Eviva or ATEC biopsy needle. This issue does not pose any potential patient harm or other safety issue. However, it may prevent the system from enabling a procedure to continue.

As outlined in the ATEC Sapphire Breast Biopsy System User Reference Guide:

> "In "SET UP" mode, if the "VACUUM READY" light is flashing, indicating an air leak is present, systematically close off openings from the console to the hand piece to determine the source of the vacuum leak."

At this time, we would like to remind our customers that an air leak could be caused by a crack in the canister lid. If a vacuum error occurs, an inspection of the canister and lid should be part of the system evaluation.

Hologic requests that you immediately inventory your supplies of the Recalled product in all appropriate areas and cease use of all affected stock. Please complete the enclosed Recall Response Card indicating whether you have any of the Recalled product on hand, as well as the quantity of product that you have in stock.

It is important that the Recall Response Card be returned even when you have no product in inventory.

Upon receipt of the Recall Response Card, we will be contacting your designated representative to confirm the disposal of product, as well as compensation.

Please be advised that Hologic, Ine. has informed the FDA of this product Recall.

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