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, Inc. 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 provide the following information to us via this web link: www.hologic.com/canister-recall

- *We have no inventory on hand*
- *We have inventory on hand and will dispose of the following quantity _____ of the affected lot number 20150013 and quantity of _____ 20150014*

Customer information:

Lab/Medical Office/Hospital/Distributor Name: _____
Address: _____
Contact Person:_____
Phone Number:_____
Date:_____

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

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

Sincerely,

Dan Phelan
Director, Regulatory Affairs
Hologic, Inc.

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