

Date

URGENT: MEDICAL DEVICE RECALL

DELIVERY CONFIRMATION REQUIRED

Attn:
Facility Name
Address

Customer ID#

Subject: Voluntary Recall of TomoSPOT® and Designed for Digital Skin Markers

Beekley Medical has issued a voluntary recall of specific lots of **TomoSPOT® and Designed for Digital® Skin Markers** shipped between February 2, 2018 and May 31, 2018. Our records indicate your facility ordered and received this product.

This recall is due to the possibility of imaging artifact that may mimic calcifications on patient's mammograms.

- 1) Please check your inventory for the affected lots on Page 3.
- 2) Complete & sign the Acknowledgement on Page 3 and fax to +1-860-584-2739 or scan and email to abosco@beekley.com.
- 3) **If any inventory DOES remain at your facility**, please contact Beekley Medical's Customer Care Team at +1-860-583-4700 between 8:00 AM and 5:30 PM EST to request a shipping label to return and exchange product.
- 4) **If product has been distributed**, please contact Amy Bosco, Global Business Development Senior Manager +1-860-583-4700 x 411 or abosco@beekley.com.

The US FDA has been apprised of this recall. If any issues occurred as a result of the use of products from the affected lots, please contact Kate Chase, Quality Assurance & Regulatory Manager at +1-860-583-4700 x 434.

We appreciate your prompt attention to this matter. Beekley Medical is committed to providing quality products and service to its customers and we sincerely apologize for any inconvenience this situation may have caused you.

Sincerely,



Ayn S. LaPlant
President & CEO

To identify the Lot number, please refer to the bar code on the product package (see an example in the picture below).



The Lot number is identified above, circled in pink.

Date

Attn:
Facility Name
Address

Customer ID#

Subject: TomoSPOT® and Designed for Digital Skin Markers Inventory Acknowledgement

This statement is to acknowledge that our facility received the affected lots listed below.

Lot Number	# of Boxes Received	# of Boxes In Stock	# of Boxes Distributed

Signed: _____

Printed name: _____

Title: _____

Date: _____

Please fax this page to +1-860-584-2739 or scan and email to abosco@beekley.com immediately.
Thank you again for your prompt attention to this matter; we appreciate your support and thank you for your time.

Sincerely,
Beekley Medical