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6th January 2020

URGENT: FIELD SAFETY NOTICE – VT-RAP-19-02-001 (Rev02)

EnCor® Breast Biopsy Probe
Impacted Product Codes/Lot Numbers - Refer to Table 1, Page 3
Type of Field Action: Advisory
UPDATED INFORMATION

Attention: Clinical Personnel, Risk Managers, Biomedical Personnel

This letter contains important information which requires your **immediate** attention.

Dear Customer,

BD issued an advisory Field Safety Notice (VT-RAP-19-02-001) in May 2019 related to the **EnCor® Breast Biopsy Probe** (figure 1). BD has identified an additional 10 lot numbers as being potentially affected by this issue. Your organisation has been identified as receiving these impacted lot number(s) which are listed in Table 1, page 3.

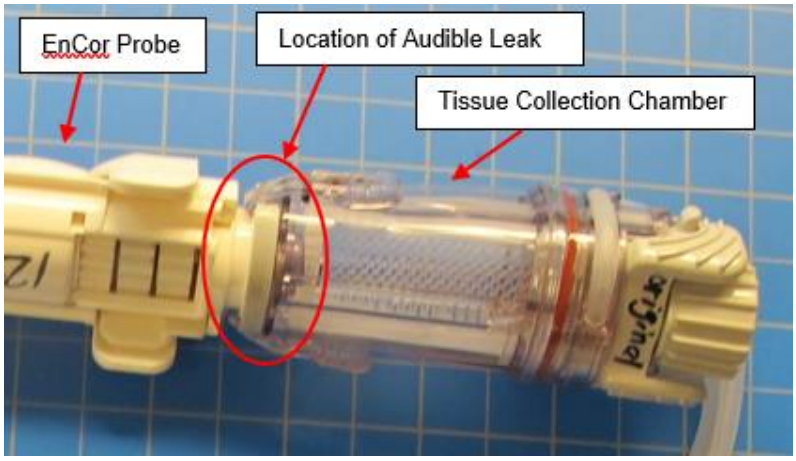

Figure 1: EnCor® Breast Biopsy Probe

Description of the Problem

The EnCor® Breast Biopsy Probe is used to acquire tissue for diagnostic sampling of breast abnormalities. Based on customer feedback, BD has identified that the product codes/ lot numbers listed in Table 1 on Page 3, may be at risk of experiencing a leak at the location referenced in the figure above, which could result in:

1. The sample chamber filling with blood with the potential to leak onto the driver and/or driver gears during the procedure and/or,

2. Minimal suction which has the potential to result in a minimal or no tissue sample obtained.

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As a result of this feedback and to mitigate this occurrence, BD is recommending the following instructions for the impacted product codes/lot numbers:

1. After calibrating the ENCOR® Breast Biopsy Probe, press and hold the VAC button on the ENCOR® Breast Biopsy Driver or the VAC button on the foot pedal. Inspect the probe and listen for any abnormal hissing sounds at the connection between the ENCOR® Breast Biopsy Probe and the Tissue Collection Chamber.

2. If any abnormal hissing sounds are heard, gently rotate the Tissue Collection Chamber a quarter turn in either direction until the hissing sound abates.

3. If the hissing sound remains, remove the Tissue Collection Chamber by depressing the wings on the chamber body and pull back on the Tissue Collection Chamber. Then reconnect the Tissue Collection Chamber by gently pushing it back on the ENCOR® Breast Biopsy Probe until the wings click back onto the probe body.

4. If the hissing sound is still present, replace the device and repeat the steps above. If the issue persists, please contact your local BD representative.

Advice on action to be taken:

1) Distribute this notice to all those who need to be aware of the update to the impacted lots of the EnCor® Breast Biopsy Probe within your organisation.

2) If you have further distributed the product, please identify those users and notify them at once of this advisory Field Safety Notice.

3) Complete the Customer Response Form on Page 3 and return it to *<<insert contact details>>* **as soon as possible or no later than January 30th, 2020**.

There is no requirement for customers to return any EnCor® Breast Biopsy probe to BD. These products can continue to be used in accordance with the guidance in this safety notice.

Should you have any questions or require assistance relating to this Field Safety Corrective Action, please contact your local BD representative at *<<insert contact details>>.*

We confirm that the appropriate regulatory agencies have been informed of these actions.

BD is committed to advancing the world of health. Our primary objectives are patient and user safety and providing you with quality products. We apologize for any inconvenience this issue may have caused you and thank you in advance for helping us to resolve this matter as quickly and effectively as possible.

Yours sincerely,

William David
Senior Director, Quality Compliance EMEA

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Customer Response Form – VT-RAP-19-02-001 (Rev02)

EnCor® Breast Biopsy Probe

Impacted product codes/Lot numbers - refer to Table 1 below

Please read in conjunction with the advisory Field Safety Notice VT-RAP-19-02-001 (Rev02) and return the completed and signed form as soon as possible or **no later than January 30th, 2020 to** *<<insert contact details>>.*

REF	LOT		REF	LOT
ECP017G	VTCT0268		ECPMR0110G	VTCW0468
	VTCT0269		ECPMR0110GBT	VTCV0370
	VTCT0270		ECPMR017G	VTCT0272
	VTCT0271			
	VTCU0340			VTCV0384
	VTCU0341			

Table 1: Product under scope of this Field Safety Notice

By signing below, you confirm this notice has been read, understood and that all recommended actions have been implemented as required.

Name of Hospital / Facility covered by this response:	
Department *(if applicable)*:	
Address:	
Postcode:	**City:**
Contact Name:	
Job Title:	
Contact Telephone Number:	**Contact E-mail Address:**
Signature:	**Date:**

Please return your completed Acknowledgement Form to: *<<insert contact details>>.*