

1st May 2019

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

EnCor® Breast Biopsy Probe
Impacted product codes/ lot numbers - Refer to Appendix 1

Attention: Clinical Personnel, Risk Managers, Biomedical Personnel

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

Dear Customer,

BD is issuing an advisory Field Safety Notice related to the **EnCor® Breast Biopsy Probe** (figure 1). The EnCor® Breast Biopsy Probe is used to acquire tissue for diagnostic sampling of breast abnormalities. Appendix 1 contains a full list of impacted product codes/lot numbers. According to our distribution records your organisation may have received these devices.

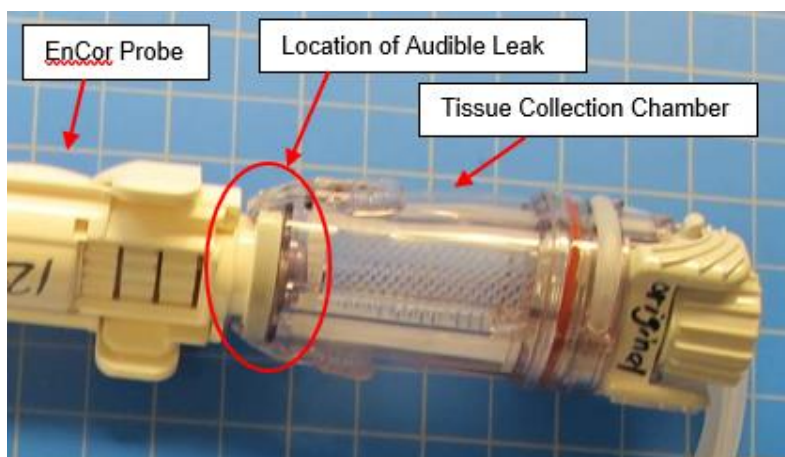


Figure 1: EnCor® Breast Biopsy Probe

Description of the Problem

Based on customer feedback, BD has identified that the product codes/ lot numbers listed in Appendix 1, 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.

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) Complete the Customer Acknowledgement Form and return it to BD using the instructions provided no later than the 31st May 2019.

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



Appendix 1: Affected Product Codes and Lot Numbers

Product Code	Lot Number	Product Code	Lot Number
ECP0110G	VTCT0306	ECP017G	VTCU0347
	VTCT0307		VTCU0348
	VTCU0359		VTCV0372
	VTCU0360		VTCV0376
	VTCU0361		VTCV0377
	VTCW0454		VTCV0380
	VTCW0455		VTCV0381
	VTCW0456		VTCW0448
	VTCX0482		VTCW0450
	VTCX0483		VTCW0457
ECP0110GV	VTCT0273		VTCW0461
	VTCT0308		VTCW0466
	VTCT0309		VTCX0488
	VTCU0351		VTCX0491
	VTCU0352		VTCX0492
	VTCW0451		VTCX0494
	VTCW0452		VTCX0495
	VTCW0453		VTCX0496
	VTCX0485		VTCX0500
	VTCX0486		VTCY0557
	VTCX0487	VTCZ0650	
	VTCY0550	ECP017GV	VTCV0414
	VTCZ0642		VTCW0469
	VTCZ0643		VTCW0470
	VTCZ0644		VTCY0566
	VTCZ0645		VTCZ0640
ECP0112G	VTCT0275		VTCZ0648
ECP0112GV	VTCW0467		VTCZ0649



Field Safety Notice Customer Acknowledgement Form
EnCor® Breast Biopsy Probe
Impacted product codes/Lot numbers - refer to Appendix 1

Please read in conjunction with Field Safety Notice VT-RAP-19-02-001 and return completed form as soon as possible or **no later than the 31st May 2019.**

Name of Hospital / Facility	
Hospital / Facility Address	
Email Address	
Telephone Number	
Name	
Signature	
Date	

Please confirm the following by checking the box:

I have read and understood the contents of this Field Safety Notice.

AND complete one of the following boxes:

I will distribute this Field Safety Notice to all those who need to be made aware.

OR

I confirm that our facility **does not have any** of the affected devices listed in this Field Safety Notice.

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