

URGENT: FIELD SAFETY NOTICE – PI-21-3959

BARD® MARQUEE® Disposable Core Biopsy Instruments and Kits

REF & Lot Numbers: Refer to Attachment 1

Type of Action: Product Removal

Attention: Clinical Personnel, Risk Managers, Biomedical Personnel

This letter contains important information which requires your immediate attention.

Dear Customer,

BD is issuing this Field Safety Notice to remove specific lots of BARD® MARQUEE® Disposable Core Biopsy Instruments and Kits. The specific product code (REF) / lot number combinations affected by this product removal are outlined in Attachment 1. According to our distribution records your organisation may have received the impacted product.

Description of the Problem

Through customer feedback, BD has discovered the specific lots of BARD® MARQUEE® Disposable Core Biopsy Instruments and Kits listed in Table 1 above have a potential fault in the Penetration Depth Switch (refer to Figure 1). The events that BD have received reported that the Penetration Depth Switch, depicted in the image below; used to select the desired penetration depth of tissue biopsies, detached from the device during use.

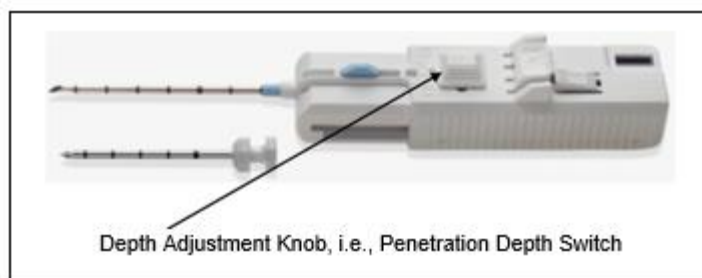


Figure 1; BARD® MARQUEE® Disposable Core Biopsy Instrument

A Penetration Depth Switch detachment may result in (1) prolongation of the biopsy procedure as the user obtains a replacement device, (2) undershooting the lesion unexpectedly, compromising the sample quality and potentially leading to a misdiagnosis or (3) if the penetration is overshoot, the device may pierce adjacent tissue and/or organs causing injury. Medical or surgical intervention may be required. No specific patient follow-up activities are recommended for affected devices already used to take a biopsy. However, any clinical considerations, including further diagnostic testing to ensure adequate sampling has been obtained and/or if any inadvertent injury may have occurred should be at the discretion of the medical doctor.



To date, there have been no reported patient injuries associated with the reported Penetration Depth Switch detachments.

Advice on actions to be taken by the customer:

1. Inspect your inventory, locate and quarantine any units of the impacted devices listed in Table 1.
2. If you have further distributed the product, please identify those facilities, notify them at once of this product removal and have them destroy the affected product.
3. Destroy any unused units of the affected product and complete the customer response form on page 3 indicating:
 - the quantities destroyed **OR**
 - that your organisation does not have any impacted units left in inventory
4. Return the completed Customer Response Form to bdukfieldaction@bd.com **as soon as possible or no later than March 12th, 2021.**

Should you have any questions or require assistance relating to this Field Safety Notice, please contact your Local BD representative at customer.Services@bd.com

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,

Lorna Darrock
Senior Manager, Post Market Quality EMEA



Customer Response Form – PI-21-3959

BARD® MARQUEE® Disposable Core Biopsy Instruments and Kits

REF & Lot Numbers: Refer to Attachment 1

Please read in conjunction with Field Safety Notice PI-21-3959 and return, completed and signed, as soon as possible or **no later than March 12th, 2021**, to bdukfieldaction@bd.com

- **I confirm this notice has been read, understood and that all recommended actions have been implemented as required.**

Tick the appropriate box below

☐ We do **not** have any of the affected product as listed in Attachment 1 in our possession. *(Please complete the table below with your contact information and return to the email address listed above)*

OR

☐ We have units of the affected product as listed in Attachment 1 in our possession and I confirm that the units have been destroyed *(Please complete Attachment 1 with the quantity of units destroyed. Then complete the table below with your contact information and return both documents to the email address listed above)*

Account/Organisation Name:	
Department (if applicable):	
Address:	
Postcode:	City:
Contact Name:	
Job Title:	
Contact Telephone Number:	Contact E-mail Address:
Signature:	Date:

This form must be returned to BD before this action can be considered closed for your account.



Attachment 1 – Affected Product Code / Lot Number Combinations

Product code / REF	Lot / Serial Number	Quantity Destroyed	Product code / REF	Lot / Serial Number	Quantity Destroyed
MQ1210			MQ1620		
	1353340			1353723	
	1353342		MQ1810		
	1358065			1353492	
MQ1213				1359991	
	1353402			1369267	
	1359984		MQ1816		
MQ1410				1353722	
	1353404		MQ1820		
	1356409			1364093	
	1356410		MQ1825		
	1356886			1353721	
	1356888			1355807	
	1359149			1359994	
	1359150		MQK1213		
	1359151			1364072	
	1359988		MQK1410		
	1363604			1358408	
	1364076			1358414	
	1364077		MQK1416		
	1364078			1347094	
	1368474		MQK1610		
	1369045			1357859	
MQ1413			MQK1810		
	1357081			1353725	
	1369273		MQK1816		
MQ1610				1364089	
	1356414		MQK2010		
	1364079			1369272	
	1369264		MQK2016		
MQ1616				1360030	
	1356999				