

URGENT MEDICAL DEVICE RECALL

BARD® MARQUEE® Disposable Core Biopsy Instruments and Kits

February 11, 2021

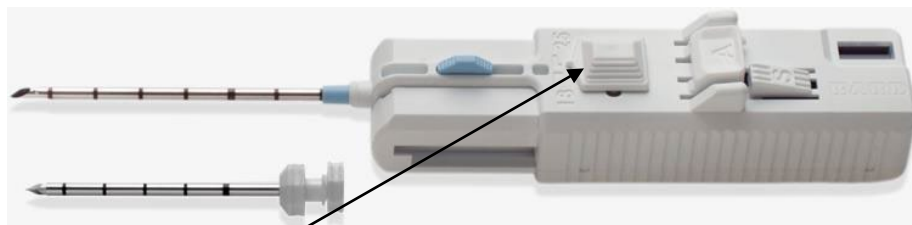
Catalog Numbers	Lot Number
MQ1210, MQ1213, MQ1410, MQ1413, MQ1416, MQ1610, MQ1616, MQ1620, MQ1810, MQ1816, MQ1820, MQ1825, MQK1210, MQK1213, MQK1410, MQK1413, MQK1416, MQK1610, MQK1810, MQK1816, MQK1820, MQK1825, MQK2010, MQK2016	Refer to Attachment A for Product Descriptions and Lot Specific details

For the Attention of: Recall Coordinator, Director of Nursing, Director of Purchasing, Director of Risk Management

Bard Peripheral Vascular Inc., a wholly owned subsidiary of Becton Dickinson and Company (BD), is conducting a voluntary recall of the BARD® MARQUEE® Disposable Core Biopsy Instruments and Instrument Kits referenced in the table above.

Description of the problem and health hazard(s):

BD has received reports that the Penetration Depth Switch, depicted in the image below; used to select the desired penetration depth of the biopsy needle for soft tissue biopsies, detaches from the device during use.



Depth Adjustment Knob, i.e., Penetration Depth Switch

The Penetration Depth Switch detachments may result in (1) prolongation of the biopsy procedures as the user obtains a replacement device, (2) undershooting the lesion unsuspectedly, compromising the sample quality and potentially leading to a misdiagnosis (3) or 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 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 these Penetration Depth Switch detachments.

You are receiving this notice because our records indicate that your facility was shipped one or more units starting May 18, 2020 through current date.



Please Take the Following Actions:

1. Please check all inventory locations within your institution for the catalog/lot number combination listed in this recall notice and destroy all affected product remaining in your possession.
2. Share this recall notice with any users of the product, within your facilities, to ensure they are also aware of this recall.
3. If you purchased this product from a distributor, contact your distributor for further instructions.
4. Complete and return the attached Customer Response Form to the BD contact noted on the form confirming acknowledgement of the recall notification, whether or not you have any affected product, so that BD may acknowledge your receipt of this notification and process any applicable replacement orders.
5. Report any adverse health consequences experienced with the use of this product to BD. Events may also be reported to the FDA's MedWatch Adverse Event Reporting program:

Web: MedWatch website at www.fda.gov/medwatch

Phone: 1-800-FDA-1088 (1-800-332-1088)

Mail: MedWatch, HF-2, FDA, 5600 Fisher's Lane, Rockville, MD 20852-9787

Actions Taken by BD:

1. BD will process replacement orders for all customers affected by the recall following receipt of the completed Customer Response Form.
2. Depending on the specific product code, there may be delays in the fulfillment of replacement orders. BD understands that supply interruptions can impact our customers' ability to provide the best care for their patients and takes this matter very seriously, as such we fulfill orders as quickly as possible.
3. BD has implemented actions to prevent recurrence of this product issue.

Contact Information: If you require further assistance please contact:

BD Customer Support:	Contact Information
North American Regional Complaint Center:	1-844-8BD- LIFE (1-844-823-5499) Say "Recall" when prompted M-F 8am -5pm CT

Electronic version of the information in this notice can be found at <https://www.bd.com/en-us/recall-notifications>

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 and thank you in advance for helping us to resolve this matter as quickly and effectively as possible.

Sincerely,

J.D. Meler, M.D.
Vice President, Medical Safety & Governance

Gail Griffiths
Sr. Director, Post Market Quality



CUSTOMER RESPONSE FORM
BARD® MARQUEE® Disposable Core Biopsy Instruments and Kits

Please assist BD by promptly returning this form to:

BD Regulatory Compliance

Email: BDRC14@bd.com

Fax No.: 312-949-0338

Facility: _____
 Please use full, current facility name. Do not use initials.

Street Address: _____

City: _____ State: _____ Zip: _____

Recall Response Form Completed By:	
Name:	
Title:	
Telephone No.	
Fax No.	
Email Address	

Please check all that apply:

- I have read and understood the attached notice and taken appropriate actions.
- We do not have any of the affected product(s) on hand.
- I certify that I have destroyed all affected product indicated below as available inventory at the time of receipt of this notification and request replacement.

Product Name	Catalog No.	Lot No.	Quantity in Eaches
Bard® MARQUEE® Disposable Core Biopsy Instruments and Kits			
Bard® MARQUEE® Disposable Core Biopsy Instruments and Kits			
Bard® MARQUEE® Disposable Core Biopsy Instruments and Kits			
Bard® MARQUEE® Disposable Core Biopsy Instruments and Kits			
Bard® MARQUEE® Disposable Core Biopsy Instruments and Kits			

Please assist BD with assuring these communications are delivered to the appropriate person/function within your facility if that is not you.

Person/function responsible for the receipt and management of all recalls at your facility:

Name: _____
 Phone: _____
 Email: _____
 Fax: _____

Attachment A: Affected Product

Catalog Number	Product Description	Lot Number	UDI (GTIN, DI + PI)	Exp. Date
MQ1210	Bard® Marquee® Disposable Core Biopsy Instrument Kit, 12G x 10cm	0001353340	(01)801741097119(17)230328(10)0001353340	3/28/2023
MQ1210	Bard® Marquee® Disposable Core Biopsy Instrument Kit, 12G x 10cm	0001353342	(01)801741097119(17)230328(10)0001353342	3/28/2023
MQ1210	Bard® Marquee® Disposable Core Biopsy Instrument, 12g x 10cm	0001353401	(01)801741097119(17)230328(10)0001353401	3/28/2023
MQ1210	Bard® Marquee® Disposable Core Biopsy Instrument, 12g x 10cm	0001356645	(01)801741097119(17)230328(10)0001356645	3/28/2023
MQ1210	Bard® Marquee® Disposable Core Biopsy Instrument, 12g x 10cm	0001358065	(01)801741097119(17)230328(10)0001358065	3/28/2023
MQ1210	Bard® Marquee® Disposable Core Biopsy Instrument, 12g x 10cm	0001359983	(01)801741097119(17)230428(10)0001359983	4/28/2023
MQ1210	Bard® Marquee® Disposable Core Biopsy Instrument, 12g x 10cm	0001369253	(01)801741097119(17)230628(10)0001369253	6/28/2023
MQ1213	Bard® Marquee® Disposable Core Biopsy Instrument Kit, 12G x 13CM	0001353402	(01)801741097126(17)230328(10)0001353402	3/28/2023
MQ1213	Bard® Marquee® Disposable Core Biopsy Instrument, 12g x 13cm	0001359984	(01)801741097126(17)230428(10)0001359984	4/28/2023
MQ1213	Bard® Marquee® Disposable Core Biopsy Instrument, 12g x 13cm	0001369256	(01)801741097126(17)230628(10)0001369256	6/28/2023
MQ1410	Bard® Marquee® Disposable Core Biopsy Instrument Kit, 14g x 10cm	0001353403	(01)801741097133(17)230328(10)0001353403	3/28/2023
MQ1410	Bard® Marquee® Disposable Core Biopsy Instrument, 14g x 10cm	0001353404	(01)801741097133(17)230328(10)0001353404	3/28/2023
MQ1410	Bard® Marquee® Disposable Core Biopsy Instrument, 14g x 10cm	0001356410	(01)801741097133(17)230328(10)0001356410	3/28/2023
MQ1410	Bard® Marquee® Disposable Core Biopsy Instrument, 14g x 10cm	0001356409	(01)801741097133(17)230328(10)0001356409	3/28/2023
MQ1410	Bard® Marquee® Disposable Core Biopsy Instrument, 14g x 10cm	0001356886	(01)801741097133(17)230328(10)0001356886	3/28/2023
MQ1410	Bard® Marquee® Disposable Core Biopsy Instrument, 14g x 10cm	0001356888	(01)801741097133(17)230328(10)0001356888	3/28/2023
MQ1410	Bard® Marquee® Disposable Core Biopsy Instrument, 14g x 10cm	0001359150	(01)801741097133(17)230428(10)0001359150	4/28/2023
MQ1410	Bard® Marquee® Disposable Core Biopsy Instrument, 14g x 10cm	0001359152	(01)801741097133(17)230428(10)0001359152	4/28/2023
MQ1410	Bard® Marquee® Disposable Core Biopsy Instrument, 14g x 10cm	0001359149	(01)801741097133(17)230428(10)0001359149	4/28/2023
MQ1410	Bard® Marquee® Disposable Core Biopsy Instrument, 14g x 10cm	0001359151	(01)801741097133(17)230428(10)0001359151	4/28/2023
MQ1410	Bard® Marquee® Disposable Core Biopsy Instrument, 14g x 10cm	0001359988	(01)801741097133(17)230428(10)0001359988	4/28/2023
MQ1410	Bard® Marquee® Disposable Core Biopsy Instrument, 14g x 10cm	0001363603	(01)801741097133(17)230528(10)0001363603	5/28/2023
MQ1410	Bard® Marquee® Disposable Core Biopsy Instrument, 14g x 10cm	0001363604	(01)801741097133(17)230528(10)0001363604	5/28/2023
MQ1410	Bard® Marquee® Disposable Core Biopsy Instrument, 14g x 10cm	0001364078	(01)801741097133(17)230528(10)0001364078	5/28/2023
MQ1410	Bard® Marquee® Disposable Core Biopsy Instrument, 14g x 10cm	0001364076	(01)801741097133(17)230528(10)0001364076	5/28/2023
MQ1410	Bard® Marquee® Disposable Core Biopsy Instrument, 14g x 10cm	0001364077	(01)801741097133(17)230528(10)0001364077	5/28/2023
MQ1410	Bard® Marquee® Disposable Core Biopsy Instrument, 14g x 10cm	0001368474	(01)801741097133(17)230528(10)0001368474	5/28/2023

Catalog Number	Product Description	Lot Number	UDI (GTIN, DI + PI)	Exp. Date
MQ1410	Bard® Marquee® Disposable Core Biopsy Instrument, 14g x 10cm	0001369045	(01)801741097133(17)230628(10)0001369045	6/28/2023
MQ1410	Bard® Marquee® Disposable Core Biopsy Instrument, 14g x 10cm	0001369046	(01)801741097133(17)230628(10)0001369046	6/28/2023
MQ1413	Bard® Marquee® Disposable Core Biopsy Instrument Kit, 14G x 13CM	0001357081	(01)801741097140(17)230328(10)0001357081	3/28/2023
MQ1413	Bard® Marquee® Disposable Core Biopsy Instrument, 14g x 13cm	0001369273	(01)801741097140(17)230628(10)0001369273	6/28/2023
MQ1416	Bard® Marquee® Disposable Core Biopsy Instrument Kit, 14G x 16CM	0001357079	(01)801741097157(17)230328(10)0001357079	3/28/2023
MQ1610	Bard® Marquee® Disposable Core Biopsy Instrument Kit, 16G x 10CM	0001353246	(01)801741097164(17)230328(10)0001353246	3/28/2023
MQ1610	Bard® Marquee® Disposable Core Biopsy Instrument, 16g x 10cm	0001356414	(01)801741097164(17)230328(10)0001356414	3/28/2023
MQ1610	Bard® Marquee® Disposable Core Biopsy Instrument, 16g x 10cm	0001359989	(01)801741097164(17)230428(10)0001359989	4/28/2023
MQ1610	Bard® Marquee® Disposable Core Biopsy Instrument, 16g x 10cm	0001364079	(01)801741097164(17)230528(10)0001364079	5/28/2023
MQ1610	Bard® Marquee® Disposable Core Biopsy Instrument, 16g x 10cm	0001369264	(01)801741097164(17)230628(10)0001369264	6/28/2023
MQ1616	Bard® Marquee® Disposable Core Biopsy Instrument Kit, 16G x 16CM	0001356999	(01)801741097171(17)230328(10)0001356999	3/28/2023
MQ1616	Bard® Marquee® Disposable Core Biopsy Instrument, 16g x 16cm	0001359990	(01)801741097171(17)230428(10)0001359990	4/28/2023
MQ1620	Bard® Marquee® Disposable Core Biopsy Instrument Kit, 16G x 20CM	0001353723	(01)801741097188(17)230328(10)0001353723	3/28/2023
MQ1810	Bard® Marquee® Disposable Core Biopsy Instrument Kit, 18G x 10CM	0001353492	(01)801741097195(17)230328(10)0001353492	3/28/2023
MQ1810	Bard® Marquee® Disposable Core Biopsy Instrument, 18g x 10cm	0001359991	(01)801741097195(17)230428(10)0001359991	4/28/2023
MQ1810	Bard® Marquee® Disposable Core Biopsy Instrument, 18g x 10cm	0001364091	(01)801741097195(17)230528(10)0001364091	5/28/2023
MQ1810	Bard® Marquee® Disposable Core Biopsy Instrument, 18g x 10cm	0001369267	(01)801741097195(17)230628(10)0001369267	6/28/2023
MQ1816	Bard® Marquee® Disposable Core Biopsy Instrument Kit, 18G x 16CM	0001353722	(01)801741097201(17)230328(10)0001353722	3/28/2023
MQ1820	Bard® Marquee® Disposable Core Biopsy Instrument Kit, 18G x 20CM	0001364092	(01)801741097218(17)230528(10)0001364092	5/28/2023
MQ1820	Bard® Marquee® Disposable Core Biopsy Instrument, 18g x 20cm	0001364093	(01)801741097218(17)230528(10)0001364093	5/28/2023
MQ1820	Bard® Marquee® Disposable Core Biopsy Instrument, 18g x 20cm	0001369270	(01)801741097218(17)230628(10)0001369270	6/28/2023
MQ1825	Bard® Marquee® Disposable Core Biopsy Instrument Kit, 18G x 25CM	0001353721	(01)801741097225(17)230328(10)0001353721	3/28/2023
MQ1825	Bard® Marquee® Disposable Core Biopsy Instrument, 18g x 25cm	0001355807	(01)801741097225(17)230328(10)0001355807	3/28/2023
MQ1825	Bard® Marquee® Disposable Core Biopsy Instrument, 18g x 25cm	0001359994	(01)801741097225(17)230428(10)0001359994	4/28/2023
MQ1825	Bard® Marquee® Disposable Core Biopsy Instrument, 18g x 25cm	0001364090	(01)801741097225(17)230528(10)0001364090	5/28/2023
MQK1210	Bard® Marquee® Disposable Core Biopsy Instrument Kit, 12G x 10CM	0001353400	(01)801741097263(17)230328(10)0001353400	3/28/2023
MQK1210	Bard® Marquee® Disposable Core Biopsy Instrument Kit, 12g x 10cm	0001353399	(01)801741097263(17)230328(10)0001353399	3/28/2023
MQK1210	Bard® Marquee® Disposable Core Biopsy Instrument Kit, 12g x 10cm	0001356646	(01)801741097263(17)230328(10)0001356646	3/28/2023

Catalog Number	Product Description	Lot Number	UDI (GTIN, DI + PI)	Exp. Date
MQK1210	Bard® Marquee® Disposable Core Biopsy Instrument Kit, 12g x 10cm	0001359178	(01)801741097263(17)230428(10)0001359178	4/28/2023
MQK1210	Bard® Marquee® Disposable Core Biopsy Instrument Kit, 12g x 10cm	0001364069	(01)801741097263(17)230528(10)0001364069	5/28/2023
MQK1210	Bard® Marquee® Disposable Core Biopsy Instrument Kit, 12g x 10cm	0001364070	(01)801741097263(17)230528(10)0001364070	5/28/2023
MQK1210	Bard® Marquee® Disposable Core Biopsy Instrument Kit, 12g x 10cm	0001366667	(01)801741097263(17)230528(10)0001366667	5/28/2023
MQK1210	Bard® Marquee® Disposable Core Biopsy Instrument Kit, 12g x 10cm	0001369252	(01)801741097263(17)230628(10)0001369252	6/28/2023
MQK1210	Bard® Marquee® Disposable Core Biopsy Instrument Kit, 12g x 10cm	0001371860	(01)801741097263(17)230628(10)0001371860	6/28/2023
MQK1213	Bard® Marquee® Disposable Core Biopsy Instrument Kit, 12G x 13cm	0001364072	(01)801741097270(17)230528(10)0001364072	5/28/2023
MQK1213	Bard® Marquee® Disposable Core Biopsy Instrument Kit, 12g x 13cm	0001369259	(01)801741097270(17)230628(10)0001369259	6/28/2023
MQK1410	Bard® Marquee® Disposable Core Biopsy Instrument Kit, 14G x 10cm	0001353727	(01)801741097287(17)230328(10)0001353727	3/28/2023
MQK1410	Bard® Marquee® Disposable Core Biopsy Instrument Kit, 14g x 10cm	0001356411	(01)801741097287(17)230328(10)0001356411	3/28/2023
MQK1410	Bard® Marquee® Disposable Core Biopsy Instrument Kit, 14g x 10cm	0001356412	(01)801741097287(17)230328(10)0001356412	3/28/2023
MQK1410	Bard® Marquee® Disposable Core Biopsy Instrument Kit, 14g x 10cm	0001358408	(01)801741097287(17)230428(10)0001358408	4/28/2023
MQK1410	Bard® Marquee® Disposable Core Biopsy Instrument Kit, 14g x 10cm	0001358409	(01)801741097287(17)230428(10)0001358409	4/28/2023
MQK1410	Bard® Marquee® Disposable Core Biopsy Instrument Kit, 14g x 10cm	0001358414	(01)801741097287(17)230428(10)0001358414	4/28/2023
MQK1410	Bard® Marquee® Disposable Core Biopsy Instrument Kit, 14g x 10cm	0001359999	(01)801741097287(17)230428(10)0001359999	4/28/2023
MQK1410	Bard® Marquee® Disposable Core Biopsy Instrument Kit, 14g x 10cm	0001358413	(01)801741097287(17)230428(10)0001358413	4/28/2023
MQK1410	Bard® Marquee® Disposable Core Biopsy Instrument Kit, 14g x 10cm	0001364084	(01)801741097287(17)230528(10)0001364084	5/28/2023
MQK1410	Bard® Marquee® Disposable Core Biopsy Instrument Kit, 14g x 10cm	0001364085	(01)801741097287(17)230528(10)0001364085	5/28/2023
MQK1410	Bard® Marquee® Disposable Core Biopsy Instrument Kit, 14g x 10cm	0001364082	(01)801741097287(17)230528(10)0001364082	5/28/2023
MQK1410	Bard® Marquee® Disposable Core Biopsy Instrument Kit, 14g x 10cm	0001364080	(01)801741097287(17)230528(10)0001364080	5/28/2023
MQK1410	Bard® Marquee® Disposable Core Biopsy Instrument Kit, 14g x 10cm	0001364081	(01)801741097287(17)230528(10)0001364081	5/28/2023
MQK1410	Bard® Marquee® Disposable Core Biopsy Instrument Kit, 14g x 10cm	0001367194	(01)801741097287(17)230528(10)0001367194	5/28/2023
MQK1410	Bard® Marquee® Disposable Core Biopsy Instrument Kit, 14g x 10cm	0001367195	(01)801741097287(17)230528(10)0001367195	5/28/2023
MQK1410	Bard® Marquee® Disposable Core Biopsy Instrument Kit, 14g x 10cm	0001367196	(01)801741097287(17)230528(10)0001367196	5/28/2023
MQK1410	Bard® Marquee® Disposable Core Biopsy Instrument Kit, 14g x 10cm	0001368556	(01)801741097287(17)230528(10)0001368556	5/28/2023
MQK1410	Bard® Marquee® Disposable Core Biopsy Instrument Kit, 14g x 10cm	0001368555	(01)801741097287(17)230528(10)0001368555	5/28/2023
MQK1410	Bard® Marquee® Disposable Core Biopsy Instrument Kit, 14g x 10cm	0001368760	(01)801741097287(17)230528(10)0001368760	5/28/2023
MQK1410	Bard® Marquee® Disposable Core Biopsy Instrument Kit, 14g x 10cm	0001369292	(01)801741097287(17)230628(10)0001369292	6/28/2023

Catalog Number	Product Description	Lot Number	UDI (GTIN, DI + PI)	Exp. Date
MQK1413	Bard® Marquee® Disposable Core Biopsy Instrument Kit, 14G x 13CM	0001360001	(01)801741097294(17)230428(10)0001360001	4/28/2023
MQK1416	Bard® Marquee® Disposable Core Biopsy Instrument Kit, 14G x 16CM	0001347094	(01)801741097300(17)230228(10)0001347094	2/28/2023
MQK1416	Bard® Marquee® Disposable Core Biopsy Instrument Kit, 14g x 16cm	0001357065	(01)801741097300(17)230328(10)0001357065	3/28/2023
MQK1610	Bard® Marquee® Disposable Core Biopsy Instrument Kit, 16G x 10CM	0001357859	(01)801741097317(17)230328(10)0001357859	3/28/2023
MQK1610	Bard® Marquee® Disposable Core Biopsy Instrument Kit, 16g x 10cm	0001364088	(01)801741097317(17)230528(10)0001364088	5/28/2023
MQK1610	Bard® Marquee® Disposable Core Biopsy Instrument Kit, 16g x 10cm	0001369278	(01)801741097317(17)230628(10)0001369278	6/28/2023
MQK1810	Bard® Marquee® Disposable Core Biopsy Instrument Kit, 18G x 10CM	0001353725	(01)801741097348(17)230328(10)0001353725	3/28/2023
MQK1810	Bard® Marquee® Disposable Core Biopsy Instrument Kit, 18g x 10cm	0001360028	(01)801741097348(17)230428(10)0001360028	4/28/2023
MQK1810	Bard® Marquee® Disposable Core Biopsy Instrument Kit, 18g x 10cm	0001369289	(01)801741097348(17)230628(10)0001369289	6/28/2023
MQK1816	Bard® Marquee® Disposable Core Biopsy Instrument Kit, 18G x 16CM	0001364089	(01)801741097355(17)230528(10)0001364089	5/28/2023
MQK1816	Bard® Marquee® Disposable Core Biopsy Instrument Kit, 18g x 16cm	0001369284	(01)801741097355(17)230628(10)0001369284	6/28/2023
MQK1820	Bard® Marquee® Disposable Core Biopsy Instrument Kit, 18G x 20CM	0001369290	(01)801741097362(17)230628(10)0001369290	6/28/2023
MQK1825	Bard® Marquee® Disposable Core Biopsy Instrument Kit, 18G x 25CM	0001353724	(01)801741097379(17)230328(10)0001353724	3/28/2023
MQK1825	Bard® Marquee® Disposable Core Biopsy Instrument Kit, 18g x 25cm	0001360029	(01)801741097379(17)230428(10)0001360029	4/28/2023
MQK2010	Bard® Marquee® Disposable Core Biopsy Instrument Kit, 20G x 10CM	0001369272	(01)801741097386(17)230628(10)0001369272	6/28/2023
MQK2016	Bard® Marquee® Disposable Core Biopsy Instrument Kit, 20G x 16CM	0001360030	(01)801741097393(17)230428(10)0001360030	4/28/2023
MQK2016	Bard® Marquee® Disposable Core Biopsy Instrument Kit, 20g x 16cm	0001369276	(01)801741097393(17)230628(10)0001369276	6/28/2023