

PRODUCT RECALL

PI-24-5080-FA

BD Magnum Biopsy Needle

30 August 2024,

Dear Customer,

CC: Chairman Medical Board and relevant head of department

Type of Field Action: Recall

Affected Product

Product Name	Catalog	Lot No.	UDI-DI	Expiration Date	Package Size
Magnum 14g x 10cm	MN1410	REJP3295	(01)00801741084249(17)270131(10)REJP3295	01/31/2027	Box of 10
Magnum 14g x 10cm	MN1410	REJP2228	(01)00801741084249(17)270131(10)REJP2228	01/31/2027	Box of 10
Magnum 16g x 10cm	MN1610	REJN0587	(01)00801741084287(17)261231(10)REJN0587	12/31/2026	Box of 10
Magnum 20g x 10cm	MN2010	REJQ1160	(01)00801741084386(17)270228(10)REJQ1160	02/28/2027	Box of 10
Magnum 16g x 16cm	MN1616	REJP3289	(01)00801741084300(17)270131(10)REJP3289	01/31/2027	Box of 10
Magnum 14g x 20cm	MN1420	REHX2867	(01)00801741084270(17)260930(10)REHX2867	09/30/2026	Box of 10
Magnum 14g x 10cm	MN1410	REJN2583	(01)00801741084249(17)261231(10)REJN2583	12/31/2026	Box of 10
Magnum 18g x 20cm	MN1820	REJS1418	(01)00801741084355(17)270430(10)REJS1418	04/30/2027	Box of 10
Magnum 14g x 10cm	MN1410	REJQ2851	(01)00801741084249(17)270228(10)REJQ2851	02/28/2027	Box of 10
Magnum 14g x 10cm	MN1410	REJQ0831	(01)00801741084249(17)270228(10)REJQ0831	02/28/2027	Box of 10

Description of the Problem:

BD has identified through internal inspections, that the packaging of the Magnum™ Biopsy Needle may have been damaged by indentations unintentionally made during manufacture, potentially compromising the sterile barrier that may be hard to detect by the end user.

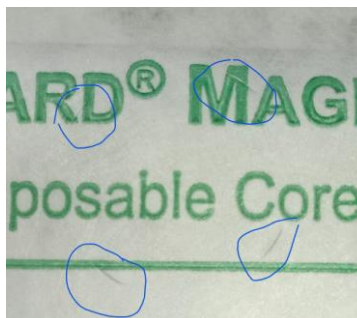


Figure 1: Magnified Image of pouch and location pattern of Tyvek cuts.



Clinical Risk Statement:

Use of contaminated devices could result in infection potentially leading to inflammation, fever, tissue injury, and sepsis, and requiring further medical management. In patients in whom the Magnum™ Biopsy System has already been used, no additional monitoring is recommended.

Complaint & Adverse Event Statement:

There have been no customer complaints or adverse events for this issue.

Actions for Clinical Users:

- 1) Healthcare facilities and providers should cease use of the affected product and discard.
- 2) In patients in whom the Magnum™ Biopsy System has already been used, no additional monitoring is recommended.

Action To be Taken by BD:

- 1) BD is investigating and has implemented appropriate measures to prevent recurrence of this product issue.
- 2) BD will provide credit note upon receipt of a completed customer response form.

Product Distribution Time Frame:

BD distributed the affected lots from 10 April 2024 through 13 June 2024. Our records indicate you may have received product from the affected lot.

Please Take the Following Actions:

- 1) Please immediately discontinue the use and quarantine any of the unused inventory.
- 2) Share this notification with all users within your facility network to ensure they are also aware of this medical device recall.
- 3) If you purchased this product from a distributor, please contact your distributor for further return instructions and credit resolution.
- 4) Complete the attached Customer Response Form and return it to your distributor and/or BD contact noted on the form indicating whether you have any of the affected lots so that BD may acknowledge your receipt of this notification.
- 5) Indicate on the Customer Response Form the quantity for the affected lots identified at your facility and confirm that this product inventory was quarantined for return.
- 6) Report any adverse health consequences experienced with the use of this product to BD.



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Singapore 609930
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bd.com

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,

Karena Han
Quality Manager, Southeast Asia



CUSTOMER RESPONSE FORM
PI-24-5080-FA
BD Magnum Biopsy Needle

Please fill in the information below so that we may acknowledge your receipt of this notification. Simply complete and return the completed form to **SEA_Quality** SEA_Quality@bd.com / **distributor / local BD representative** by **24 September 2024**.

Please tick as appropriate.

- I have read and understood the attached notice & will share this Urgent Product Recall with all users within my facility. I shall clarify with the appointed distributor/ BD representative for clarification (s) to this Urgent Product Recall
- We do not have affected product(s) in our inventory.
- We have affected product(s) in inventory and will return to my distributor/local BD representative for destruction.

Product Description	Catalog No.	Lot No.	Quantity (eaches) received)	Quantity (eaches) sold/used	Remaining Quantity (eaches) in inventory to be *returned



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Completed by:

Name:	
Signature:	
Date:	
Facility / Address / Telephone Number:	