



Field Safety Notice

Dear Beckman Coulter Customer,

This letter is to inform you of a potential malfunction and hence hazard to patients when using the attached *in-vitro* diagnostics medical device.

We, hereby, enclosed the manufacturer's notification letter of this field corrective action with detailed information on the issue, impact, action need to be taken and resolution on this issue.

If you have sold this medical device and it is no longer in your possession, we kindly ask that you forward this safety notice to the new owner of this medical device. Please inform us about the new owner of the medical device.

The **Medical Device Authority** will be informed of this notice.

Sincerely Yours,

Nur Aishah
Regulatory Affairs Specialist

Contact person of this notification	... Alice Wong.....
Department	... Marketing.....
Telephone	... 6012-296 0320.....
Fax	... 603 7772 0551.....
E-mail	... awong02@beckman.com

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December 8, 2022

IMPORTANT PRODUCT NOTICE*

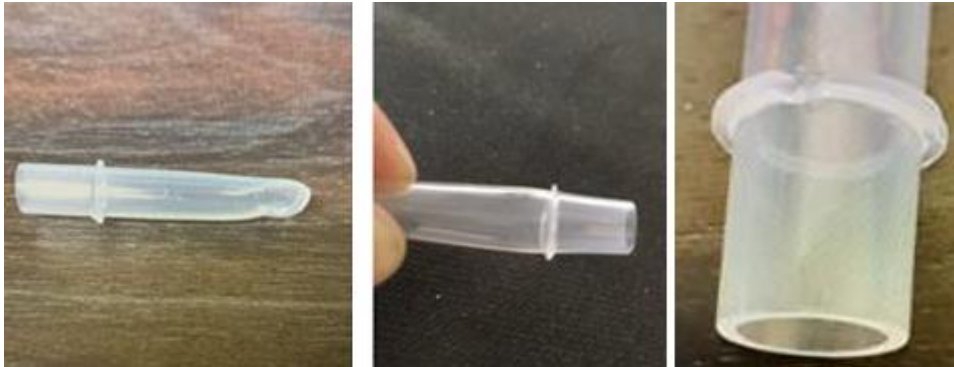
UniCel DxI Reaction Vessels (RV)

REF	LOT	
386167	N576933, N576929, N584314, N584315, N576928, N584316, N588527, N588526, N584318, N576926	NA

- * Includes the UniCel DxI 600, UniCel DxI 800, UniCel DxC 600i, UniCel DxC 660i, UniCel DxC 680i, UniCel DxC 860i, and UniCel DxC 880i systems.

Dear Beckman Coulter Customer,

This letter contains important information regarding UniCel DxI reaction vessels (RVs). Patient results are not impacted by UniCel DxI Reaction Vessel deformation.

<p>ISSUE:</p>	<ul style="list-style-type: none"> Beckman Coulter has determined that the RV kit lot numbers listed in the table above may contain RVs that were deformed during the manufacturing process. RVs may appear crushed or deformed. A damaged RV may cause a system failure that stops sample processing. The instrument will enter the Not Ready mode and post an event to the Event Log. <p>Examples of damaged RVs:</p> 
<p>IMPACT:</p>	<ul style="list-style-type: none"> There is no impact to patient results. Error or Failure event messages may occur if deformed RVs are loaded onto a UniCel DxI instrument including: <ul style="list-style-type: none"> Bulk Feeder device Bulk Feeder pusher motion Bulk Feeder jammed

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	<ul style="list-style-type: none"> ○ Dispense chute jammed ○ PnP device ○ PnP motion ○ RV supply carriage device ○ RV supply motion <ul style="list-style-type: none"> ● The system will enter the Not Ready mode if any of these events occur, which may delay sample processing and reporting results. ● If you experience this issue, attempt reinitialize the instrument. ● If this does not resolve the issue, please contact support. ● Please refer to the UniCel DxI Reference Manual, onboard Help menu, or a Beckman Coulter representative for assistance with troubleshooting these events.
ACTION:	<p>Check your inventory of UniCel DxI RVs for the lots listed above and take the following actions:</p> <ul style="list-style-type: none"> ● Continue using UniCel DxI RV lots listed in the preceding table only if your lab has insufficient inventory of any alternate lots. ● Contact Beckman Coulter as soon as possible for a replacement supply of RVs. <p>Discard all affected RV lots according to your local regulations after establishing a sufficient inventory of unaffected RVs.</p>
RESOLUTION:	<ul style="list-style-type: none"> ● Beckman Coulter has discontinued shipping the UniCel DxI RV lots listed in the preceding table. ● Beckman Coulter is working to ensure that future supplies of UniCel DxI RVs are free of this deformity.

Please share this information with your laboratory staff and retain this notification as part of your laboratory Quality System documentation. If you have forwarded any of the affected product(s) listed above to another laboratory, please provide them a copy of this letter.

Please complete and return the enclosed Response Form within 10 days so we are assured you have received this important communication.

If you have any questions regarding this notice, please contact:

From our website: <http://www.beckmancoulter.com>

- Outside the United States and Canada, contact your local Beckman Coulter representative.

For replacement/reimbursement, please contact

- Your local Beckman Coulter Representative.

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We apologize for any inconvenience that this caused your laboratory.

Sincerely,

DocuSigned by:

Rachel Davison



Signer Name: Rachel Davison

Signing Reason: I approve this document

Signing Time: 07-Dec-2022 | 2:29:46 PM PST

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Rachel Davison
Vice President, Quality & Regulatory Affairs
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Enclosure: Response Form, Product Request form

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