

URGENT MEDICAL DEVICE RECALL**Affinity Pixie™ Oxygenator And Cardiotomy/Venous Reservoir With Balance™ Biosurface and Perfusion Tubing Packs built with the affected Affinity Pixie™ CVR**

Product Name	Model Number	Lot Numbers
Affinity Pixie™ Oxygenator And Cardiotomy/Venous Reservoir With Balance™ Biosurface	BBP241	13340434
Perfusion Tubing Packs built with the affected Affinity Pixie™ CVR	BB10H89R4, HY10J00R6, HY11B40R1	220265395, 220768819, 220911913

February 2021

Dear Risk Manager,

The purpose of this letter is to advise you that Medtronic is voluntarily recalling a specific subset of Affinity Pixie™ Oxygenator And Cardiotomy/Venous Reservoir With Balance™ Biosurface (Model BBP241) single use devices and Perfusion Tubing Packs built with the affected Affinity Pixie™ CVR due to potentially elevated level of bacterial endotoxin. Patients exposed to elevated levels of bacterial endotoxins may develop an acute inflammatory response.

Through January 14, 2021, Medtronic has received zero (0) complaints involving this issue.

There are no additional actions required for patients where the Affinity Pixie Oxygenator And Cardiotomy/Venous Reservoir With Balance Biosurface or Perfusion Tubing Packs built with the affected Affinity Pixie™ CVR were used during a procedure. These patients should continue to be monitored in accordance with your medical facility's standard care protocols.

Customer Instructions:

Medtronic records indicate that your facility has received one or more of the listed Affinity Pixie Oxygenator And Cardiotomy/Venous Reservoir With Balance Biosurface and/or Perfusion Tubing Packs built with the affected Affinity Pixie™ CVR. As a result, Medtronic requests that you immediately take the following actions:

1. Identify and quarantine all unused affected product as listed in the above table and enclosed Customer Notification Detail Report.
2. Return all unused affected product in your inventory to Medtronic. Contact Medtronic Customer Service at 800-854-3570 to initiate a product return. Your local Medtronic Representative can assist you as necessary in initiating the return of this product.
3. Complete the enclosed Customer Confirmation Form and email to rs.cfqfca@medtronic.com.

Please forward this notice to all who need to be aware within your organization and to any organization where the affected product may have been transferred. Medtronic will notify all applicable regulatory agencies about this matter.

Per your facility's standard medical device complaint procedures, report any adverse reactions or quality problems if the

quality issue described above has been observed. Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online: www.fda.gov/medwatch/report.htm
- Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form or submit by fax to 1-800-FDA-0178.

We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter. If you have any questions regarding this communication, please contact your Medtronic Field Representative.

Sincerely,

A handwritten signature in black ink, appearing to read 'Eliezer De Jesus Hernandez', written in a cursive style.

Eliezer De Jesus Hernandez
Vice President, Quality
Coronary Structural Heart
Medtronic