

Urgent Field Safety Notice

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	See Table 1
Perfusion Tubing Packs built with the affected Affinity Pixie™ CVR	BB10H89R4, BB7W03R8, HY10J00R6, HY11B40R1, M448036B, M483203D, M484901D, M490817B	220265395, 220911945, 220768819, 220911913, 220798975, 220781539, 220887101, 220906731, 220886950

February 2021

Medtronic reference: FA955

Dear Risk Manager/Physician,

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 27, 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.
2. Return all unused affected product in your inventory to Medtronic. Your local Medtronic Representative can assist you as necessary in initiating the return of this product.

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. The Competent Authority of your country has been notified of this action.

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 representative at <XXXX>.

Sincerely,

Local / BU Manager

Table 1: Affinity Pixie™ Oxygenator And Cardiotomy/Venous Reservoir With Balance™ Biosurface Affected Lot Numbers

Affinity Pixie™ Oxygenator And Cardiotomy/Venous Reservoir With Balance™ Biosurface	
Model	BBP241
13337110, 13337512, 13337675, 13339043, 13339133, 13339290, 13339452, 13339527, 13340434, 13340766, 13340871, 13342814, 13344059, 13344325, 13344487, 13344594, 13344819, 13346440, 13346564, 13346733, 13347774, 13347907, 13347974, 13348151, 13348285, 13348521, 13348909, 13348974, 13349141, 13349283, 13349388, 13349517, 13349775, 13352832, 13352983, 13353163, 13353438, 13353541, 13353701, 13353800	