Medtronic

Cardiac and Vascular Group (CVG)
Structural Heart
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November 20, 2020

In reference to:

Product Id	Product Description	Serial No/Lot No	Event Date	Reference Nos (mPXR)
BB841	Affinity Fusion™ Oxygenator and Cardiotomy/Venous Reservoir (CVR) with Balance™ Biosurface	LN: 13326113 (Not Returned)	October 9, 2020	704004478 (765459)
		LN: 13326113 (Not Returned)	October 9, 2020	704056602 (774562)
		SN: 8401046107 LN: 13326113	October 14, 2020	704013984 (767165)

Thank you for informing Medtronic of your experience with the above referenced products. The information we received indicated post use of a Fusion cardiotomy venous reservoir (CVR), as the ECC circuit was being transferred to the waste bin, the venous inlet port of the CVR became detached. Minimal force was required to detach it.

Another reservoir with the same lot number was checked and found loose; it was described as looser than usual but did not come out when mild force was applied. No external damage was noted to the packaging or external cardboard carton. A third occurrence was also reported.

Analysis Summary:

Product Id: BB841 **Serial No:** 8401046107 **Lot No:** 13326113
Visual inspection showed the venous inlet tube was installed when received (see photos below). The customer provided video showing the venous inlet port was easily removed and installed; however, it was not evident from the video that the venous inlet port was loose/separated from the device prior to the demonstration.

The venous inlet tube was removed from the lid. The outer diameter (OD) of the venous inlet tube that secures into the lid was measured against the specification. The following measurements of 1.816 inches in one direction and 1.820 inches in the other direction were recorded, (specification is 1.818 +/- 0.005 inches).
The diameter of the shoulder that snaps into the lid measured 0.870 inches (specification is 0.872 +/- 0.005 inches).

Conclusion:

Medtronic Quality Engineers confirmed the venous down tube dislodged from the lid based on the customer provided pictures. Returned product analysis found the associated dimensions for venous tube and lid retention features to be within specification. The retention feature of the venous inlet tube is designed to withstand a foreseeable force encountered during transportation or during use, such as when the tubing is knocked or pulled.

Based on the Venous Inlet dislodgement occurrences, a potential cause was identified during production and corrective actions were taken. The potential cause for the Venous Inlet dislodgement was determined to be the manual method at which the lubricant is applied to the Venous Inlet O-ring, leading to inconsistences in the amount. To mitigate the inconsistences in the amount of lubricant applied, production implemented an automated method to apply lubricant to the Venous O-ring. These devices were manufactured prior to corrective actions. We will continue to monitor this product for similar events.

Thank you for your time and concern in reporting this event. We appreciate the opportunity to evaluate product performance, as this is a valuable source of information for improving reliability and design. If we may be of further assistance, please contact your Medtronic Representative and they will work with our team.

Sincerely,

Mary Berg

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