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URGENT FIELD SAFETY NOTICE

Medtronic Evolut™ PRO+/FX/FX+ Bioprosthesis

Potential Jar Lid Particulate - IFU Update

Product Name	Bioprosthesis Model Numbers (CFN)	GTIN
Evolut™ PRO+	EVPROPLUS-23	00763000655419; 00763000211073
	EVPROPLUS-26	00763000655426; 00763000211059; 00763000211080
	EVPROPLUS-29	00763000655433; 00763000211066; 00763000211097
	EVPROPLUS-34	00763000655440; 00763000211134; 00763000211141
Evolut™ FX	EVOLUTFX-23	00763000370602
	EVOLUTFX-26	00763000370619
	EVOLUTFX-29	00763000370626
	EVOLUTFX-34	00763000370633
Evolut™ FX+	EVFXPLUS-23	00763000920418
	EVFXPLUS-26	00763000920425
	EVFXPLUS-29	00763000920432; A7630009204301
	EVFXPLUS-34	00763000920449

March 2025

Medtronic Reference: FA1483
EU Manufacturer Single Registration Number (SRN): US-MF-000019985

Dear Health Care Professional/Risk Manager,

Medtronic is issuing this notification to provide important information regarding updates to the Instructions for use (IFUs) and Physician / Health care Practitioner Training related to potential damage to the bioprosthesis container (jar) upon opening.

Medtronic has received reports of users having difficulty opening the jar, which may cause damage to the lid, resulting in the potential for particulate (see Figure 1) transferring from the lid to the jar containing the bioprosthesis. As of January 31, 2025, Medtronic has observed an incidence rate of 0.043% for this jar lid issue. To date, there has been no patient harm nor serious injury reported.

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Medtronic has no evidence of seal degradation and no evidence that the sterility of the bioprosthesis is compromised. If particulate material is observed in the solution upon opening the jar, the bioprosthesis should be discarded and a new unopened device used instead. In accordance with current Instructions for Use (IFU) and training, the bioprosthesis should always be rinsed with 3 rinsing bowls before use.

Figure 1. Example of Jar lid particulates

Please refer to the above table for the affected product models. Medtronic is not requesting return of products at your facility.

Medtronic is conducting a thorough investigation of the events, including manufacturing process mitigations. In the interim, Medtronic has initiated an action to update the applicable IFUs for Evolut PRO+/FX/FX+ as follows:

"Do not use the bioprosthesis if there is any damage to the container (for example, cracked jar or lid, leakage, particulate material, broken or missing seals or jar lid gasket)."

Actions:

Patient Recommendations:

Medtronic does not recommend any further actions for patients already treated with the listed devices and patients should be managed according to the standard of care after a TAVI procedure.

Customer Instructions:

Medtronic records indicate that your facility has received one or more of the listed devices. As a result, Medtronic requests that you immediately take the following actions:

1. Share this notice with all those who need to be aware of this issue within your organization and maintain a copy of this notice in your records.
2. Please complete and return the Customer Acknowledgement Form enclosed with this letter, acknowledging that you have received this information.

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Additional Information:

Medtronic has notified the Competent Authority of your country 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 Field Representative.

Sincerely,

Local / OU Manager

Enclosures: Customer Acknowledgement Form