

URGENT: MEDICAL DEVICE CORRECTION

Evolut Pro, Evolut Pro+, Evolut R aortic valve replacement system, and Melody Transcatheter Pulmonary Valve System Electronic Instructions for Use (eIFUs) Missing on the Medtronic Manual Library Website

07 June 2023 | 20:29 PDT

Attention: Risk Management Director and O.R Materials Management

CC: The Chairman Medical Board and relevant Head of Departments

Dear Customer:

The purpose of this letter is to advise you that Medtronic is issuing a corrective action to address several instances of missing electronic Instructions for Use (eIFUs) for Medtronic products Evolut Pro, Evolut Pro+, Evolut R, and Melody on the Medtronic Manual Library Website. **Medtronic is not requesting any return of product from your facility.**

Issue Description:

During an initiative to standardize the process for releasing eIFU's to the Medtronic Manuals website, Medtronic discovered instances of eIFU's not posted to the website at the time of initial approval of the product, after IFU changes, or release of product new to a geography/country. This issue with posting eIFUs occurred with products specific to certain countries only.

- The issue does not impact the function or therapy delivery of the device
- Based on internal investigation and risk assessment, the issue is assessed to have negligible or no impact on overall patient safety
- There is no change to IFU content
- Medtronic has addressed affected products with missing eIFUs and all eIFUs have been uploaded to the Medtronic Manual Library Website

Current controls in place that mitigate risk:

- Please follow the product's leaflet's contact information or email RS.CSTechSupport@medtronic.com to access eIFUs or to get a paper IFU.

Product Scope:

Product Information (Malaysia)	
Product Names	Model #/CFN
Evolut Pro	ENVPRO-16, EVOLUTPRO-23, EVOLUTPRO-26 EVOLUTPRO-29, L-ENVPRO-16, L-ENVPRO-1623
Evolut Pro+	D-EVPROP23-29, D-EVPROP34, EVPROPLUS-23 EVPROPLUS-26, EVPROPLUS-29, EVPROPLUS-34 L-EVPROP23-29, L-EVPROP34
Evolut R	ENVPRO-14, EVOLUTR-29, EVOLUTR-34
Melody	PB1016, PB1018

Physician Actions:

- Share this information with other physicians in your facility who use the Evolut Pro, Evolut Pro+, Evolut R, or Melody products.
- After review of this information, complete the enclosed Physician Confirmation Form and hand or scan then email back to your local Medtronic field representative.

Additional Information:


Regulatory notification:

Medtronic is communicating this information to the appropriate regulatory agency in your country.

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 local Medtronic field representative.

Sincerely,

DocuSigned by:
Soon Yee Chow

 Signer Name: Soon Yee Chow
Signing Reason: I approve this document
Signing Time: 07 June 2023 | 20:29 PDT
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Quality and Regulatory Affairs Lead
Malaysia

Medtronic

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Customer Confirmation Form

Urgent Medical Device Correction

Evolut Pro, Evolut Pro+, Evolut R Aortic Valve Replacement System, And Melody Transcatheter Pulmonary Valve System Electronic Instructions For Use (eIFUs) Missing On The Medtronic Manual Library Website

Please complete all fields below and return all pages immediately

Customer Contact Details		Medtronic Contact Details	
Distributor/Hospital/Clinic/Patient name:		Name:	
		Contact:	
Address:		Email:	
Phone no:	Email:		

By signing this form I confirm that I have read the Urgent Medical Device Correction or similar Notification Letter, dated 07 June 2023 | 20:29 PDT, from Medtronic regarding Evolut Pro, Evolut Pro+, Evolut R Aortic Valve Replacement System, And Melody Transcatheter Pulmonary Valve System Electronic Instructions For Use (eIFUs) And Uploading Missing eIFUs On The Medtronic Manual Library Website and taken appropriate action.

Please complete and sign the form as indicated below and hand or scan then email back to your local Medtronic field representative.

Name (print): _____ Signature: _____ Stamp: _____ Date:

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For questions, contact your local Medtronic field representative.