Medtronic

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Urgent Field Safety Notice
EnVeo™ R and EnVeo™ PRO Delivery Catheter
Manufactured before 11-JUL-2020 or in lot 10281657
Recall

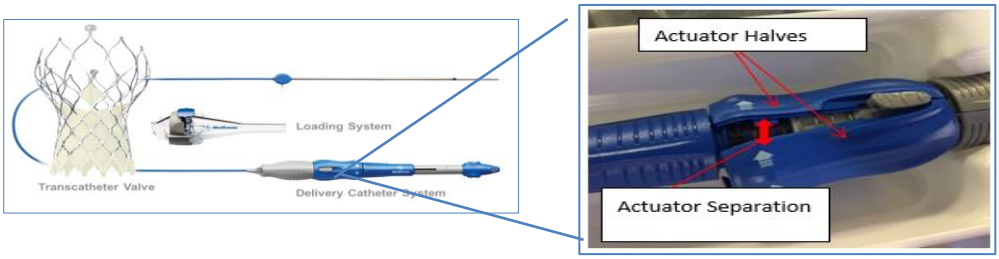
June 2021

Medtronic reference: FA977

Dear Healthcare Professional,

The purpose of this letter is to advise you that Medtronic is voluntarily recalling EnVeo™ R and EnVeo™ PRO Delivery Catheters with manufacturing lot 10281657 or a manufacturing date before 11-JUL-2020. Medtronic is taking this action to reduce the potential for actuator separation within the subset. Actuator separation may occur during valve loading on the delivery system, advancement, deployment or recapture of the valve. Through March 2021, the reported rate of actuator separation on the original design version was 0.18% out of 270,071 sold worldwide. If the actuator separates during a procedure, it could lead to procedure delays, hypotension, secondary procedure, or tissue damage.

The actuator is an external component of the handle of the EnVeo™ R and EnVeo™ PRO Delivery Catheters.



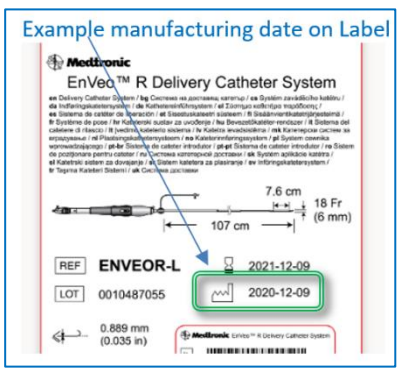
Medtronic implemented an updated design of the actuator component, which has demonstrated an improved performance. Medtronic is proactively replacing the remaining product manufactured before 11-JUL-2020 with product utilizing the updated design. The valve itself and its performance are not impacted by this component update.

There are no additional actions required for patients where the original design version was used during a procedure.

Customer Instructions:

Medtronic records indicate that your facility has received one or more of the EnVeo R and EnVeo PRO Delivery Catheter manufactured before 11-JUL-2020 or in lot 10281657. As a result, Medtronic requests that you immediately take the following actions:

1. Identify and quarantine all unused affected product manufactured before 11-JUL-2020 or in lot 10281657.
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.



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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 Field Representative at 01 511 1400

Sincerely,

Bethany Moxon
Associate Regulatory Affairs Specialist – UK and Ireland