Medtronic

URGENT FIELD SAFETY NOTICE

Harmony™ Delivery Catheter System

Model: HARMONY-DCS

GTIN: 00763000582951

Recall

May 2026

Medtronic Reference: FA1565
EU Manufacturer Single Registration Number (SRN): US-MF-000019977

Dear Healthcare Professional/ Risk Manager,

The purpose of this letter is to advise you that Medtronic is recalling certain lots of Harmony™ Delivery Catheter System (DCS) with the lot numbers listed in Appendix A, due to the potential risk of distal tip (nose cone) detachment (separation). This recall does not involve the Harmony transcatheter pulmonary valve (TPV).

Issue Description:
Up until May 14, 2026, Medtronic had received two (2) complaints about Harmony DCS distal tip detachment during the implant procedure. A root cause investigation has identified that, due to a manufacturing issue, Harmony DCS from specific manufacturing lots may have an increased potential for distal tip detachment under certain procedural or anatomical conditions.

Detachment of the distal tip during the implant procedure will require a secondary intervention to remove the tip, either by endovascular retrieval or surgical intervention. Additional potential patient risks associated with this issue may include prolonged procedure time, extended fluoroscopy time, occlusion, tissue damage, pulmonary regurgitation, embolism, and hemorrhage. In both reported complaints, the detached tip was successfully retrieved endovascularly via snaring, with no additional adverse health consequences reported following retrieval.

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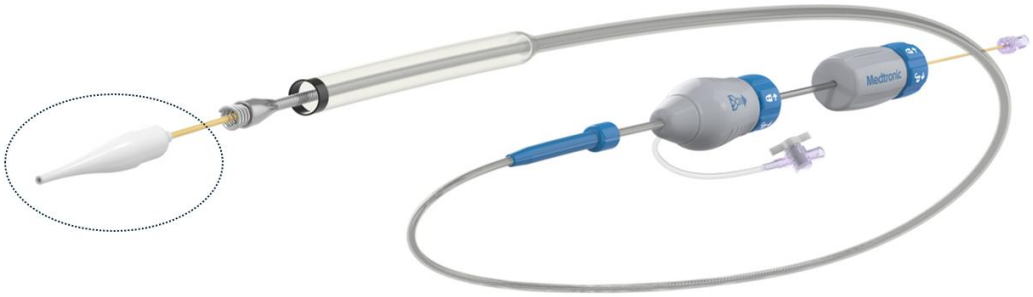

Schematic of the Harmony DCS indicating the point of tip separation.

This recall does not affect patients who have previously undergone Harmony TPV implantation. Because the potential tip detachment is limited to the Harmony-DCS during delivery of the Harmony TPV, there are no additional actions required for patients with a successfully implanted Harmony TPV. These patients should continue to be monitored per your practice's standard clinical follow-up procedures.

Product Scope:

Only the lot numbers listed in Appendix A are subject to this recall. All other Harmony DCS lots currently in your inventory are unaffected and remain safe for use. The underlying manufacturing issue has been resolved; therefore, all future shipments will not be impacted by this recall.

Actions:

Medtronic records indicate that your facility has received one or more of the affected Harmony DCS. As a result, Medtronic requests that you immediately take the following action:

- Review your inventory for affected lot numbers listed in Appendix A.
- If you have unused inventory from the listed lot numbers, immediately quarantine and return the affected products to Medtronic. Your Medtronic sales representative can assist you in the return of unit as necessary.
- Please share this notification with implanters and teams within your organization. If product listed above has been forwarded to another facility, please notify the facility of this Urgent Field Safety Notice.
- Please maintain a copy of this communication in your records.

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 representative.

Sincerely,

Medtronic

Local / OU manager

Enclosed:

- Appendix A: Affected Lot Numbers

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Appendix A: Affected Lot Numbers

Model Number	GTIN	Lot Number
HARMONY-DCS	00763000582951	0012606413, 0012642964, 0012690219, 0012699637, 0012804151, 0012804580, 0013063764, 0013063765