Cardiac Surgery (CS)
Catheter not retaining shape
DLP™ Left Heart Vent Catheters
Global Field Corrective Action Plan

FCA Plan Approvals (Denotes approval of FCA Plan and all communication documents)

Name	Title	Signature	Date
Weiping Zhong	Senior Dir. of Risk Management Center of Expertise		
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Change History Information

Revision	Change History
A	Original approved Field Corrective Action Plan.
B	An immediate Field Corrective Action (FCA) was authorized on July 31, 2025, following the approval of FA1501 Rev A on July 18, 2025: On July 22, 2025, external feedback was received recommending the addition of "death" as a cascading harm. As a result, the OU decided to halt the communications initially scheduled for July 30, 2025, to incorporate "death" into the risk assessment and customer letter, while also avoiding back-to-back communications that could potentially confuse customers. Additionally, the FCA strategy was updated from "notification only" to "retrievals" due to the risk assessment shifting from Risk Zone 1 to Risk Zone 2. Although the communication letter was revised to reflect these changes, it had not yet been approved in accordance with the enterprise FCA process and procedures.

Revision	Change History
	However, given the urgency expressed by regulatory authorities in certain regions (US and ANZ), immediate action was authorized for countries requiring expedited notifications. Meanwhile, FA1501 Rev B was planned and approved to fully address these updates and ensure comprehensive compliance. Updates include: Section 1: • Added retrieving affected products • Added rationale for Immediate action • Updated CAPA number Section 2.2: • Updated CAPA number • Updated complaint data through 28-JUL-2025. • Updated patient risk instances Section 2.3: • Clarified immediate action for US and ANZ only • Added consignees return of affected product • Added Reconciliation of product will be managed by PHO • Added Field representatives assist with returned product Section 2.4: • Added Belarus, Iraq, and Iran to scope and updated quantities accordingly. • Added Jake Miller, Margaret Flood, and Vivian Carlson to the planning team. Removed Melissa Harper Section 3: • Indicated each appendix that was updated in this revision. Section 3.1.1: • Indicated that this is immediate action for US Consignees • Updated table based on Immediate, Recall, and updated distribution dates Section 3.1.2: • Clarified immediate action for ANZ only • Updated table based on Immediate (ANZ only), Recall, and updated distribution dates Section 3.3.1.3: • Updated to clarify regulatory authorities in Singapore, Philippines, and Vietnam Section 3.3.1.8: • Updated to reportable in Canada and Type II

Revision	Change History
	Section 5.1: • Updated Target Completion Dates for activities Section 5.1.1: • Updated dates for Management Review Section 5.1.2: • Updated dates for plan approval Section 5.3: • Updated plan dates for execution Section 5.4: • Added activities and dates for retrieval of trunk stock, consignment and sold product, and reconciliation. • Updated plan dates for execution and closure activities Section 6.1: • Added closure criteria of affected trunk or consigned product Section 6.2: • Updated CAPA number for closure • Added reconciliation and disposition of affected product

1. Executive Summary

The purpose of this document is to outline the intended Global Field Corrective Action (FCA) plan for initiating communications to consignees, retrieving affected product, and completing effectiveness checks for DLP™ Left Heart Vent Catheters due to the catheter resisting shape retention when being bent. The approval of this plan will initiate the FCA.

Rationale:

An immediate Field Corrective Action (FCA) was authorized on 31-JUL-2025, by Laura McCabe (VP Quality, Cardiac Surgery) and documented by email to Scott Cundy (SVP Chief Quality Officer), following the approval of FA1501 Rev A on July 18, 2025: On July 22, 2025, external feedback was received recommending the addition of "death" as a cascading harm. As a result, the OU decided to halt the communications initially scheduled for July 30, 2025, to incorporate "death" into the risk assessment and customer letter, while also avoiding back-to-back communications that could potentially confuse customers.

Additionally, the FCA strategy was updated from "notification only" to "retrievals" due to the risk assessment shifting from Risk Zone 1 to Risk Zone 2. Although the communication letter was revised to reflect these changes, it had not yet been approved in accordance with the enterprise FCA process and procedures.

However, given the urgency expressed by regulatory authorities in certain regions (US and ANZ), immediate action was authorized for countries requiring expedited notifications. Meanwhile, FA1501 Rev B was planned and approved to fully address these updates and ensure comprehensive compliance.

- Product Hold Order (PHO) D01399517 was approved on 09-MAY-2025 to contain affected product.
- CAPA # 716825 was opened.
- Risk assessment details are available in DLP Left Heart Vent Catheter not retaining shape, document # D01308381.

Product quantities affected by this issue and those in scope of this FCA are shown below:

Device Status Description	Qty
Total distributed affected devices in scope of this field action	101010
Total affected devices within Medtronic control and not in scope of this field action	6450
Total affected devices released from manufacturing	107460

2. Background

2.1. Device Description and Intended Use

This catheter is intended for use in venting the left heart during cardiopulmonary bypass surgery up to six hours or less. The Malleable PVC Left Heart Vent consists of a flexible plastic tube with a perforated distal segment. A malleable thin wire within the catheter tube permits precise shaping. Depth markings on the tube indicate insertion depth.

2.2. Problem Description and Technical Summary

Since March 2024, there has been an increase in complaints reported for the DLP Malleable Left Heart Vent Catheter for the catheters resisting shape retention when being bent. The catheters are intended to be malleable and retain a bend in the shaft. Examples of allegations specific to this complaint type include:

- Does not hold its shape.
- The device can be bent but the repulsive force was strong and the sensation was strong.
- Although it could be bent, there was a strong repulsive force and it felt like it would return to its original shape.
- The wire is stiff and unable to maintain its shape.
- The device was not maintaining the desired shape.
- The device was difficult to bend, stiffer than usual.

An investigation into the complaints identified a potential root cause traced back to a change at the sub-tier supplier (Fort Wayne Metals) to remove the annealing step in the 304 stainless steel wire (02729: Wire, Stainless Steel, 0.027 x 5.0 and 02728: Wire, Stainless Steel, 0.022 x 5.0). This wire is within the catheter (CFNs 12110, 12113 and 12115) and is intended to be malleable to permit precise shaping of the catheter. Annealing is a critical process for shape retention properties of the wire, which enables the catheter to retain its shape when bent.

It was determined that the primary supplier, Argon Medical updated their specification to Fort Wayne Metals to align with an update to ASTM A313-18. This update removed the annealing process to attain the tensile strength listed in the standard. The change did not go through the Supplier Change Request (SCR) process for Medtronic's review and approval. The first receipt of non-annealed material at Argon Medical was determined to be April 2023 and finished product was shipped from Medtronic Grand Rapids beginning in June 2023 (production at Medtronic Grand Rapids began in May 2023).

Additional information related to the root cause investigation and corrective actions will be documented in CAPA 716825.

Complaints:
Medtronic has received a total of forty one (41) complaints (product events) between June 2023* through July 28, 2025. The total quantity of complaint devices (complaint quantity) received is fifty nine (59).

As of Date: 28-JUL-2025	Total Number of Complaints Related to Issue (Product Events): 41 Total Number of Complaint Devices (Quantity): 59		
Complaint Region	**Number of Complaints**	**Number of Complaint Products**	**Number of Complaints with Regulatory Reports**
US	14	20	14
International	27	39	27

* The first shipment of finished devices containing non-annealed wire from Medtronic Grand Rapids was in June 2023.
Complaints that contained regulatory reports were reported for device malfunction where the chance of death or serious injury is not remote if to recur.

Patient Risk:

Based on the observed complaint data:

- All of the 19 instances of prolonged procedure led to no patient consequence. Therefore, the probability of the hazardous situation of Prolonged Procedure leading to the harm of No Consequence to patient is 1.
- All of the 37 instances of procedure delay did not involve patient contact. Therefore, the probability of the hazardous situation of Procedure Delay (prior to use) leading to the harm of No Patient Involvement is 1.
- 2 instances of tissue damage resulted in vessel perforation with the category of Major based on patient outcome. Therefore, the probability of the hazardous situation of tissue damage leading to the harm of vessel perforation, major is 1.

2.3. Actions to be taken

- A voluntary immediate FCA (US and ANZ only) will be implemented to communicate the issue to all consignees who have received affected product according to Medtronic records. See 3.1 Consignee Communications for details.
- Consignees will be asked to confirm receipt of FCA notification.
- Consignees will be asked to return all unused affected sold product within their possession.
- Reconciliation of returned product will be managed per PHO D01399517.

Additional Medtronic Actions:

- Field representatives may assist consignees with the return of unused product (sold) and the timely return of the consignee signed Consignee Confirmation Form.
- Other associated Corrective/Preventive Actions established in associated CAPA.

2.4. Distributed product in scope of this FCA by Country and Quantity

The scope of this FCA includes products listed below:

Lot #	Model #/ CFN	Product Name	GTIN	Qtys
2023051188	12113	SUCTION 12113 LV VENT 13FR	20643169881338	600
2023051189	12115	SUCTION 12115 LV VENT 15FR	20643169880935	240
2023060142	12113	SUCTION 12113 LV VENT 13FR	20643169881338	400
2023060144	12113	SUCTION 12113 LV VENT 13FR	20643169881338	380
2023060145	12115	SUCTION 12115 LV VENT 15FR	20643169880935	280
2023060431	12113	SUCTION 12113 LV VENT 13FR	20643169881338	580
2023060432	12115	SUCTION 12115 LV VENT 15FR	20643169880935	380
2023060762	12113	SUCTION 12113 LV VENT 13FR	20643169881338	580
2023061146	12113	SUCTION 12113 LV VENT 13FR	20643169881338	540
2023061146	12113	SUCTION 12113 LV VENT 13FR	00673978176475	20
2023061147	12115	SUCTION 12115 LV VENT 15FR	20643169880935	460
2023070147	12113	SUCTION 12113 LV VENT 13FR	20643169881338	280
2023070147	12113	SUCTION 12113 LV VENT 13FR	00673978176475	20
2023070148	12113	SUCTION 12113 LV VENT 13FR	20643169881338	260
2023070148	12113	SUCTION 12113 LV VENT 13FR	00673978176475	15
2023070149	12113	SUCTION 12113 LV VENT 13FR	20643169881338	260
2023070149	12113	SUCTION 12113 LV VENT 13FR	00673978176475	20
2023070150	12113	SUCTION 12113 LV VENT 13FR	20643169881338	260
2023070150	12113	SUCTION 12113 LV VENT 13FR	00643169881334	20
2023070151	12113	SUCTION 12113 LV VENT 13FR	20643169881338	300
2023070490	12113	SUCTION 12113 LV VENT 13FR	20643169881338	520
2023070490	12113	SUCTION 12113 LV VENT 13FR	00643169881334	40
2023070491	12115	SUCTION 12115 LV VENT 15FR	20643169880935	300
2023070979	12113	SUCTION 12113 LV VENT 13FR	20643169881338	560
2023070980	12115	SUCTION 12115 LV VENT 15FR	20643169880935	420
2023080156	12113	SUCTION 12113 LV VENT 13FR	20643169881338	560
2023080157	12115	SUCTION 12115 LV VENT 15FR	20643169880935	420
2023080407	12115	SUCTION 12115 LV VENT 15FR	20643169880935	280
2023080408	12115	SUCTION 12115 LV VENT 15FR	20643169880935	380
2023080797	12113	SUCTION 12113 LV VENT 13FR	20643169881338	380
2023080798	12113	SUCTION 12113 LV VENT 13FR	20643169881338	520

2023080798	12113	SUCTION 12113 LV VENT 13FR	00673978176475	20
2023080799	12115	SUCTION 12115 LV VENT 15FR	20643169880935	560
2023080800	12115	SUCTION 12115 LV VENT 15FR	20643169880935	180
2023081130	12113	SUCTION 12113 LV VENT 13FR	20643169881338	80
2023081131	12113	SUCTION 12113 LV VENT 13FR	20643169881338	520
2023081131	12113	SUCTION 12113 LV VENT 13FR	00643169881334	17
2023081132	12113	SUCTION 12113 LV VENT 13FR	20643169881338	600
2023081133	12115	SUCTION 12115 LV VENT 15FR	20643169880935	540
2023081134	12115	SUCTION 12115 LV VENT 15FR	20643169880935	280
2023081547	12113	SUCTION 12113 LV VENT 13FR	20643169881338	380
2023081548	12113	SUCTION 12113 LV VENT 13FR	20643169881338	380
2023081548	12113	SUCTION 12113 LV VENT 13FR	00673978176475	20
2023081549	12115	SUCTION 12115 LV VENT 15FR	20643169880935	380
2023090234	12113	SUCTION 12113 LV VENT 13FR	20643169881338	380
2023090235	12113	SUCTION 12113 LV VENT 13FR	20643169881338	380
2023090236	12115	SUCTION 12115 LV VENT 15FR	20643169880935	380
2023090427	12113	SUCTION 12113 LV VENT 13FR	20643169881338	580
2023090429	12115	SUCTION 12115 LV VENT 15FR	20643169880935	380
2023090675	12113	SUCTION 12113 LV VENT 13FR	20643169881338	180
2023090979	12113	SUCTION 12113 LV VENT 13FR	20643169881338	360
2023090980	12113	SUCTION 12113 LV VENT 13FR	20643169881338	380
2023091017	12115	SUCTION 12115 LV VENT 15FR	20643169880935	340
2023091104	12113	SUCTION 12113 LV VENT 13FR	20643169881338	580
2023091105	12113	SUCTION 12113 LV VENT 13FR	20643169881338	460
2023091105	12113	SUCTION 12113 LV VENT 13FR	00643169881334	80
2023091106	12113	SUCTION 12113 LV VENT 13FR	20643169881338	380
2023091106	12113	SUCTION 12113 LV VENT 13FR	00643169881334	20
2023091107	12115	SUCTION 12115 LV VENT 15FR	20643169880935	360
2023091108	12115	SUCTION 12115 LV VENT 15FR	20643169880935	380
2023100097	12115	SUCTION 12115 LV VENT 15FR	20643169880935	320
2023100098	12115	SUCTION 12115 LV VENT 15FR	20643169880935	360
2023100098	12115	SUCTION 12115 LV VENT 15FR	00643169880931	20
2023100243	12113	SUCTION 12113 LV VENT 13FR	20643169881338	260
2023100243	12113	SUCTION 12113 LV VENT 13FR	00643169881334	40
2023100244	12113	SUCTION 12113 LV VENT 13FR	20643169881338	340
2023100641	12113	SUCTION 12113 LV VENT 13FR	20643169881338	380
2023100641	12113	SUCTION 12113 LV VENT 13FR	00673978176475	19
2023100642	12113	SUCTION 12113 LV VENT 13FR	20643169881338	380
2023100643	12115	SUCTION 12115 LV VENT 15FR	20643169880935	420
2023100644	12115	SUCTION 12115 LV VENT 15FR	20643169880935	380
2023101024	12113	SUCTION 12113 LV VENT 13FR	20643169881338	280
2023101025	12113	SUCTION 12113 LV VENT 13FR	20643169881338	320

2023101025	12113	SUCTION 12113 LV VENT 13FR	00643169881334	60
2023101026	12115	SUCTION 12115 LV VENT 15FR	20643169880935	380
2023101027	12115	SUCTION 12115 LV VENT 15FR	20643169880935	360
2023101365	12113	SUCTION 12113 LV VENT 13FR	20643169881338	560
2023101365	12113	SUCTION 12113 LV VENT 13FR	00643169881334	20
2023101366	12113	SUCTION 12113 LV VENT 13FR	20643169881338	940
2023101367	12115	SUCTION 12115 LV VENT 15FR	20643169880935	340
2023101367	12115	SUCTION 12115 LV VENT 15FR	00643169880931	20
2023101368	12115	SUCTION 12115 LV VENT 15FR	20643169880935	260
2023110168	12115	SUCTION 12115 LV VENT 15FR	20643169880935	280
2023110247	12113	SUCTION 12113 LV VENT 13FR	20643169881338	300
2023110308	12113	SUCTION 12113 LV VENT 13FR	20643169881338	520
2023110308	12113	SUCTION 12113 LV VENT 13FR	00643169881334	40
2023110312	12113	SUCTION 12113 LV VENT 13FR	20643169881338	560
2023110312	12113	SUCTION 12113 LV VENT 13FR	00643169881334	20
2023111663	12115	SUCTION 12115 LV VENT 15FR	20643169880935	400
2023111663	12115	SUCTION 12115 LV VENT 15FR	00643169880931	40
2023111663	12115	SUCTION 12115 LV VENT 15FR	00681490463423	20
2023111700	12115	SUCTION 12115 LV VENT 15FR	20643169880935	440
2023111701	12115	SUCTION 12115 LV VENT 15FR	20643169880935	480
2023111702	12115	SUCTION 12115 LV VENT 15FR	20643169880935	440
2023111703	12115	SUCTION 12115 LV VENT 15FR	20643169880935	440
2023111703	12115	SUCTION 12115 LV VENT 15FR	00643169880931	20
2023120176	12115	SUCTION 12115 LV VENT 15FR	20643169880935	420
2023120177	12115	SUCTION 12115 LV VENT 15FR	20643169880935	440
2023120178	12115	SUCTION 12115 LV VENT 15FR	20643169880935	440
2023120179	12115	SUCTION 12115 LV VENT 15FR	20643169880935	460
2023120708	12110	SUCTION 12110 LV VENT 10FR	20643169880676	220
2023120708	12110	SUCTION 12110 LV VENT 10FR	00643169880672	40
2023120709	12110	SUCTION 12110 LV VENT 10FR	20643169880676	480
2023120710	12110	SUCTION 12110 LV VENT 10FR	20643169880676	480
2023120711	12110	SUCTION 12110 LV VENT 10FR	20643169880676	440
2023120712	12110	SUCTION 12110 LV VENT 10FR	20643169880676	500
2023120719	12115	SUCTION 12115 LV VENT 15FR	20643169880935	260
2023120719	12115	SUCTION 12115 LV VENT 15FR	00681490463423	20
2023121041	12110	SUCTION 12110 LV VENT 10FR	20643169880676	460
2023121041	12110	SUCTION 12110 LV VENT 10FR	00643169880672	20
2023121042	12110	SUCTION 12110 LV VENT 10FR	20643169880676	360
2023121046	12115	SUCTION 12115 LV VENT 15FR	20643169880935	300
2023121046	12115	SUCTION 12115 LV VENT 15FR	00681490463423	40
2023121249	12113	SUCTION 12113 LV VENT 13FR	20643169881338	500
2023121250	12113	SUCTION 12113 LV VENT 13FR	20643169881338	680

2023121250	12113	SUCTION 12113 LV VENT 13FR	00643169881334	20
2023121251	12113	SUCTION 12113 LV VENT 13FR	20643169881338	360
2023121251	12113	SUCTION 12113 LV VENT 13FR	00673978176475	78
2023121251	12113	SUCTION 12113 LV VENT 13FR	00643169881334	40
2023121252	12113	SUCTION 12113 LV VENT 13FR	20643169881338	460
2023121253	12113	SUCTION 12113 LV VENT 13FR	20643169881338	480
2023121254	12113	SUCTION 12113 LV VENT 13FR	20643169881338	420
2023121255	12113	SUCTION 12113 LV VENT 13FR	20643169881338	480
2023121256	12115	SUCTION 12115 LV VENT 15FR	20643169880935	240
2024010194	12115	SUCTION 12115 LV VENT 15FR	20643169880935	440
2024010195	12115	SUCTION 12115 LV VENT 15FR	20643169880935	480
2024010196	12115	SUCTION 12115 LV VENT 15FR	20643169880935	480
2024010197	12115	SUCTION 12115 LV VENT 15FR	20643169880935	440
2024010198	12115	SUCTION 12115 LV VENT 15FR	20643169880935	480
2024010199	12115	SUCTION 12115 LV VENT 15FR	20643169880935	180
2024010200	12115	SUCTION 12115 LV VENT 15FR	20643169880935	420
2024010201	12115	SUCTION 12115 LV VENT 15FR	20643169880935	500
2024010202	12115	SUCTION 12115 LV VENT 15FR	20643169880935	440
2024010202	12115	SUCTION 12115 LV VENT 15FR	00681490463423	20
2024010470	12113	SUCTION 12113 LV VENT 13FR	20643169881338	400
2024010471	12113	SUCTION 12113 LV VENT 13FR	20643169881338	540
2024010472	12113	SUCTION 12113 LV VENT 13FR	20643169881338	480
2024010472	12113	SUCTION 12113 LV VENT 13FR	00643169881334	20
2024010473	12113	SUCTION 12113 LV VENT 13FR	20643169881338	460
2024010474	12113	SUCTION 12113 LV VENT 13FR	20643169881338	460
2024010474	12113	SUCTION 12113 LV VENT 13FR	00643169881334	20
2024010475	12113	SUCTION 12113 LV VENT 13FR	20643169881338	480
2024010475	12113	SUCTION 12113 LV VENT 13FR	00673978176475	20
2024010476	12113	SUCTION 12113 LV VENT 13FR	20643169881338	380
2024010476	12113	SUCTION 12113 LV VENT 13FR	00643169881334	60
2024010477	12113	SUCTION 12113 LV VENT 13FR	20643169881338	340
2024011016	12113	SUCTION 12113 LV VENT 13FR	20643169881338	380
2024011016	12113	SUCTION 12113 LV VENT 13FR	00673978176475	20
2024011203	12110	SUCTION 12110 LV VENT 10FR	20643169880676	340
2024011203	12110	SUCTION 12110 LV VENT 10FR	00643169880672	50
2024011204	12110	SUCTION 12110 LV VENT 10FR	20643169880676	260
2024011214	12113	SUCTION 12113 LV VENT 13FR	20643169881338	480
2024011215	12115	SUCTION 12115 LV VENT 15FR	20643169880935	380
2024011216	12115	SUCTION 12115 LV VENT 15FR	20643169880935	340
2024011216	12115	SUCTION 12115 LV VENT 15FR	00681490463423	20
2024011217	12115	SUCTION 12115 LV VENT 15FR	20643169880935	360
2024011218	12115	SUCTION 12115 LV VENT 15FR	20643169880935	340

2024011219	12115	SUCTION 12115 LV VENT 15FR	20643169880935	360
2024011219	12115	SUCTION 12115 LV VENT 15FR	00681490463423	20
2024011220	12115	SUCTION 12115 LV VENT 15FR	20643169880935	380
2024011221	12115	SUCTION 12115 LV VENT 15FR	20643169880935	300
2024011221	12115	SUCTION 12115 LV VENT 15FR	00681490463423	40
2024020135	12110	SUCTION 12110 LV VENT 10FR	20643169880676	580
2024020136	12110	SUCTION 12110 LV VENT 10FR	20643169880676	470
2024020137	12110	SUCTION 12110 LV VENT 10FR	20643169880676	580
2024020138	12110	SUCTION 12110 LV VENT 10FR	20643169880676	560
2024020138	12110	SUCTION 12110 LV VENT 10FR	00673978176468	20
2024020139	12110	SUCTION 12110 LV VENT 10FR	20643169880676	600
2024020140	12110	SUCTION 12110 LV VENT 10FR	20643169880676	560
2024020141	12110	SUCTION 12110 LV VENT 10FR	20643169880676	520
2024020141	12110	SUCTION 12110 LV VENT 10FR	00673978176468	20
2024020471	12110	SUCTION 12110 LV VENT 10FR	20643169880676	980
2024020472	12110	SUCTION 12110 LV VENT 10FR	20643169880676	380
2024020473	12110	SUCTION 12110 LV VENT 10FR	20643169880676	1040
2024020474	12110	SUCTION 12110 LV VENT 10FR	20643169880676	860
2024020474	12110	SUCTION 12110 LV VENT 10FR	00643169880672	20
2024020474	12110	SUCTION 12110 LV VENT 10FR	00673978176468	80
2024020475	12110	SUCTION 12110 LV VENT 10FR	20643169880676	900
2024020475	12110	SUCTION 12110 LV VENT 10FR	00643169880672	20
2024020475	12110	SUCTION 12110 LV VENT 10FR	00673978176468	20
2024020806	12110	SUCTION 12110 LV VENT 10FR	20643169880676	760
2024020806	12110	SUCTION 12110 LV VENT 10FR	00643169880672	60
2024020806	12110	SUCTION 12110 LV VENT 10FR	00673978176468	20
2024030359	12110	SUCTION 12110 LV VENT 10FR	20643169880676	980
2024030360	12110	SUCTION 12110 LV VENT 10FR	20643169880676	480
2024030360	12110	SUCTION 12110 LV VENT 10FR	00643169880672	20
2024030361	12110	SUCTION 12110 LV VENT 10FR	20643169880676	920
2024030361	12110	SUCTION 12110 LV VENT 10FR	00643169880672	20
2024030361	12110	SUCTION 12110 LV VENT 10FR	00673978176468	79
2024030367	12115	SUCTION 12115 LV VENT 15FR	20643169880935	880
2024030367	12115	SUCTION 12115 LV VENT 15FR	00681490463423	20
2024030368	12115	SUCTION 12115 LV VENT 15FR	20643169880935	780
2024030368	12115	SUCTION 12115 LV VENT 15FR	00643169880931	1
2024030833	12110	SUCTION 12110 LV VENT 10FR	20643169880676	980
2024030833	12110	SUCTION 12110 LV VENT 10FR	00673978176468	40
2024030834	12110	SUCTION 12110 LV VENT 10FR	20643169880676	890
2024030834	12110	SUCTION 12110 LV VENT 10FR	00643169880672	1
2024030835	12110	SUCTION 12110 LV VENT 10FR	20643169880676	900
2024030835	12110	SUCTION 12110 LV VENT 10FR	00673978176468	80

2024030841	12115	SUCTION 12115 LV VENT 15FR	20643169880935	880
2024030842	12115	SUCTION 12115 LV VENT 15FR	20643169880935	880
2024031088	12110	SUCTION 12110 LV VENT 10FR	20643169880676	540
2024031088	12110	SUCTION 12110 LV VENT 10FR	00643169880672	20
2024031093	12113	SUCTION 12113 LV VENT 13FR	20643169881338	980
2024031094	12113	SUCTION 12113 LV VENT 13FR	20643169881338	940
2024031095	12113	SUCTION 12113 LV VENT 13FR	20643169881338	960
2024040067	12113	SUCTION 12113 LV VENT 13FR	20643169881338	1000
2024040068	12113	SUCTION 12113 LV VENT 13FR	20643169881338	1000
2024040068	12113	SUCTION 12113 LV VENT 13FR	00643169881334	20
2024040069	12113	SUCTION 12113 LV VENT 13FR	20643169881338	400
2024040070	12113	SUCTION 12113 LV VENT 13FR	20643169881338	940
2024040071	12113	SUCTION 12113 LV VENT 13FR	20643169881338	980
2024040245	12113	SUCTION 12113 LV VENT 13FR	20643169881338	580
2024040245	12113	SUCTION 12113 LV VENT 13FR	00643169881334	20
2024050074	12110	SUCTION 12110 LV VENT 10FR	20643169880676	1000
2024050075	12110	SUCTION 12110 LV VENT 10FR	20643169880676	960
2024050076	12110	SUCTION 12110 LV VENT 10FR	20643169880676	460
2024050403	12110	SUCTION 12110 LV VENT 10FR	20643169880676	900
2024050404	12110	SUCTION 12110 LV VENT 10FR	20643169880676	260
2024050761	12110	SUCTION 12110 LV VENT 10FR	20643169880676	480
2024050762	12110	SUCTION 12110 LV VENT 10FR	20643169880676	900
2024050763	12110	SUCTION 12110 LV VENT 10FR	20643169880676	920
2024050763	12110	SUCTION 12110 LV VENT 10FR	00643169880672	20
2024051075	12110	SUCTION 12110 LV VENT 10FR	20643169880676	900
2024051076	12110	SUCTION 12110 LV VENT 10FR	20643169880676	920
2024051265	12110	SUCTION 12110 LV VENT 10FR	20643169880676	720
2024060283	12110	SUCTION 12110 LV VENT 10FR	20643169880676	440
2024060284	12110	SUCTION 12110 LV VENT 10FR	20643169880676	900
2024060284	12110	SUCTION 12110 LV VENT 10FR	00643169880672	18
2024060285	12110	SUCTION 12110 LV VENT 10FR	20643169880676	900
2024060529	12110	SUCTION 12110 LV VENT 10FR	20643169880676	740
2024060793	12113	SUCTION 12113 LV VENT 13FR	20643169881338	280
2024070340	12110	SUCTION 12110 LV VENT 10FR	00673978176468	59
2024070340	12110	SUCTION 12110 LV VENT 10FR	20763000946436	60
2024071120	12110	SUCTION 12110 LV VENT 10FR	00673978176468	247
2024071120	12110	SUCTION 12110 LV VENT 10FR	20763000946436	580
2024071121	12110	SUCTION 12110 LV VENT 10FR	00673978176468	20
2024071121	12110	SUCTION 12110 LV VENT 10FR	20763000946436	460
2024071122	12110	SUCTION 12110 LV VENT 10FR	20763000946436	920
2024071122	12110	SUCTION 12110 LV VENT 10FR	00763000946432	1
2024080225	12110	SUCTION 12110 LV VENT 10FR	20763000946436	360

2024080225	12110	SUCTION 12110 LV VENT 10FR	00763000946432	20
2024080465	12110	SUCTION 12110 LV VENT 10FR	00673978176468	20
2024080465	12110	SUCTION 12110 LV VENT 10FR	20763000946436	720
2024080690	12110	SUCTION 12110 LV VENT 10FR	20763000946436	980
2024081023	12110	SUCTION 12110 LV VENT 10FR	20763000946436	740
2024081024	12110	SUCTION 12110 LV VENT 10FR	20763000946436	1020
2024090228	12110	SUCTION 12110 LV VENT 10FR	20763000946436	740
2024090229	12110	SUCTION 12110 LV VENT 10FR	20763000946436	680
2024090470	12110	SUCTION 12110 LV VENT 10FR	00673978176468	45
2024090470	12110	SUCTION 12110 LV VENT 10FR	20763000946436	560
2024090471	12110	SUCTION 12110 LV VENT 10FR	20763000946436	400
2024090767	12110	SUCTION 12110 LV VENT 10FR	20763000946436	640
2024090768	12110	SUCTION 12110 LV VENT 10FR	20763000946436	340
2024100621	12110	SUCTION 12110 LV VENT 10FR	20763000946436	180
2024100622	12110	SUCTION 12110 LV VENT 10FR	20763000946436	760
202307C112	12113	SUCTION 12113 LV VENT 13FR	20643169881338	20
202307C113	12115	SUCTION 12115 LV VENT 15FR	20643169880935	40
202308C248	12113	SUCTION 12113 LV VENT 13FR	20643169881338	40
202308C249	12113	SUCTION 12113 LV VENT 13FR	20643169881338	60
202308C250	12115	SUCTION 12115 LV VENT 15FR	20643169880935	60
202309C022	12113	SUCTION 12113 LV VENT 13FR	20643169881338	20
202309C023	12115	SUCTION 12115 LV VENT 15FR	20643169880935	20
202310C057	12113	SUCTION 12113 LV VENT 13FR	20643169881338	40
202310C058	12113	SUCTION 12113 LV VENT 13FR	20643169881338	40
202311C008	12115	SUCTION 12115 LV VENT 15FR	20643169880935	40
202311C009	12115	SUCTION 12115 LV VENT 15FR	20643169880935	20
202312C203	12113	SUCTION 12113 LV VENT 13FR	20643169881338	40
202312C204	12110	SUCTION 12110 LV VENT 10FR	20643169880676	60
202312C205	12110	SUCTION 12110 LV VENT 10FR	20643169880676	60
202312C206	12115	SUCTION 12115 LV VENT 15FR	20643169880935	60
202312C207	12115	SUCTION 12115 LV VENT 15FR	20643169880935	20
202312C208	12115	SUCTION 12115 LV VENT 15FR	20643169880935	40
202401C008	12115	SUCTION 12115 LV VENT 15FR	20643169880935	20
202401C295	12110	SUCTION 12110 LV VENT 10FR	20643169880676	40
202401C296	12110	SUCTION 12110 LV VENT 10FR	20643169880676	20
202402C086	12113	SUCTION 12113 LV VENT 13FR	20643169881338	40
202402C088	12115	SUCTION 12115 LV VENT 15FR	20643169880935	40
202403C085	12113	SUCTION 12113 LV VENT 13FR	20643169881338	40
202403C086	12113	SUCTION 12113 LV VENT 13FR	20643169881338	20
202403C087	12113	SUCTION 12113 LV VENT 13FR	20643169881338	20
202403C101	12115	SUCTION 12115 LV VENT 15FR	20643169880935	20
202403C102	12115	SUCTION 12115 LV VENT 15FR	20643169880935	20

202403C144	12110	SUCTION 12110 LV VENT 10FR	20643169880676	60
202403C145	12110	SUCTION 12110 LV VENT 10FR	20643169880676	60
202403C146	12110	SUCTION 12110 LV VENT 10FR	20643169880676	40
202405C079	12110	SUCTION 12110 LV VENT 10FR	20643169880676	40
202405C080	12110	SUCTION 12110 LV VENT 10FR	20643169880676	20
202406C057	12113	SUCTION 12113 LV VENT 13FR	20643169881338	40
202406C058	12115	SUCTION 12115 LV VENT 15FR	20643169880935	20
202406C064	12110	SUCTION 12110 LV VENT 10FR	20643169880676	20
202406C065	12110	SUCTION 12110 LV VENT 10FR	20643169880676	40
202406C066	12110	SUCTION 12110 LV VENT 10FR	20643169880676	60
202407C109	12113	SUCTION 12113 LV VENT 13FR	20643169881338	20
202409C128	12110	SUCTION 12110 LV VENT 10FR	20643169880676	40
Grand Total				**101010**

Rationale for Scope of this FCA:

Based on information from the supplier, the first lot of non-annealed wire was shipped to Medtronic in April 2023. Production at Medtronic Grand Rapids began in May 2023 and the first lot of finished devices was shipped from Medtronic in June 2023. The last lot of devices that was shipped prior to identification of this issue was October 2024. Therefore, the scope of this issue is all DLP Left Heart Vent Catheters using the non-annealed wire manufactured between May 2023 and October 2024 (finished good lot numbers 2023051188 through 202409C128).

The table below provides an overview of the distribution and inventory status for affected units in scope of this FCA as of 24-JUN-2025 as described in the Global Item List.

Country	Customer Consigned	Sold to Customer	Total	Number of Consignees
Algeria	0	560	560	1
Argentina	0	60	60	1
Australia	0	1,120	1120	11
Austria	0	1,000	1000	4
Azerbaijan	0	80	80	1
Bahrain	0	500	500	1
Bangladesh	0	100	100	1
Belarus	0	280	280	1
Belgium	0	440	440	7
Bosnia And Herzegovina	0	80	80	1
Brazil	0	2,440	2440	10
Brunei Darussalam	0	20	20	1
Bulgaria	0	140	140	2
Cambodia	0	1,020	1020	1
Canada	0	1,360	1360	12

Chile	0	285	285	5
China	0	1,240	1240	7
Colombia	0	440	440	10
Costa Rica	0	400	400	1
Croatia	0	20	20	1
Cyprus	0	160	160	1
Czech Republic	0	400	400	2
Denmark	0	560	560	4
Dominican Republic	0	20	20	1
Ecuador	0	20	20	1
Egypt	0	380	380	1
Estonia	0	20	20	1
Finland	0	560	560	4
France	0	4,300	4300	22
Georgia	0	260	260	1
Germany	0	8,320	8320	33
Greece	0	420	420	8
Honduras	0	100	100	1
Hungary	0	80	80	2
Iceland	0	40	40	1
India	0	3,360	3360	20
Iran, Islamic Republic Of	0	373	373	1
Iraq	0	620	620	1
Ireland	0	480	480	3
Israel	0	120	120	4
Italy	0	1,441	1441	18
Japan	0	1,202	1202	14
Jordan	0	280	280	1
Kazakhstan	0	1,000	1000	8
Kenya	0	460	460	1
Kosovo	0	20	20	1
Kuwait	0	40	40	1
Latvia	0	20	20	1
Lebanon	0	20	20	1
Libya	0	640	640	1
Luxembourg	0	320	320	3
Malaysia	0	240	240	4
Martinique	0	120	120	1
Mexico	0	280	280	2
Morocco	0	40	40	1
Netherlands	0	760	760	8

New Zealand	0	240	240	2
Nigeria	0	200	200	2
Northern Ireland	0	500	500	2
Norway	0	1,420	1420	3
Oman	0	140	140	1
Pakistan	0	160	160	3
Panama	0	20	20	1
Papua New Guinea	0	40	40	1
Philippines	1	30	31	2
Poland	20	920	940	10
Portugal	0	300	300	5
Puerto Rico	0	340	340	1
Qatar	0	40	40	1
Reunion	0	140	140	1
Romania	40	550	590	8
Russia	0	2,880	2880	12
Rwanda	0	400	400	1
Saudi Arabia	0	400	400	6
Serbia	0	120	120	2
Singapore	0	40	40	1
Slovakia	0	40	40	1
Slovenia	0	60	60	1
South Africa	0	240	240	6
South Korea	0	700	700	3
Spain	0	2,460	2460	27
Sweden	0	800	800	3
Switzerland	0	680	680	1
Taiwan	1	3,280	3281	7
Thailand	0	437	437	14
Tunisia	0	80	80	1
Turkey	0	750	750	11
Uganda	0	40	40	1
United Arab Emirates	0	400	400	1
United Kingdom	0	2,080	2080	19
United States	0	38,900	38900	261
Uruguay	0	120	120	1
Uzbekistan	0	160	160	1
Vietnam	0	1,780	1780	2
Grand Total	**62**	**100948**	**101010**	**683**

Note: Number of consignees by country will be finalized at time of FCA closure.

Product affected by this issue and identified as in Medtronic Control is not in scope of FCA consignee activities is listed in the table below as of 24-JUN-2025:

Country	Scrapped Previous to FCA	Warehouse (WH)	Trunk Stock	Grand Total
Domestic	986	663	0	6450
Foreign		4791	10	

Country	Trunk Stock Qty
Romania	10

2.5. Planning Team Members

Department	Name
Global FCA Coordinator	David Melchior
Global FCA Execution Specialist	Amy Mullen (Execution), Stephen Lodge (Scoping)
PHO Coordinator	Carrie Allen
Quality	Alejandra Chavez (OU Lead), (Bounding) Yuvraj Karnik (IIA Author)
Regulatory Affairs	Diane Howell
Legal	Della Boutrous
Marketing	Bob LeBlanc, Yolanda Shepard, Jake Miller
Medical Safety	Sherif Ibrahim, MD, and Ray Hernandez, RN

Department	Name
Regional/Country FCA Coordinator of each affected region	EMEA: Frans Ramakers, Lora Simons, Dorien Vreuls, Pilar Mestrom SEA: Sheena Lao ANZ: Tasheena Gul Korea: Junho Park, Hyemin Kim China: Amanda He Hong Kong: Owen Chan Canada: Sarah Clinton, Rachel Mattison LATAM: Jessica Bautista Taiwan: Lesley Chiang, Aileen Liu Japan: Okoshi Kaori, Shirato Gaku, Kawai Koichi, Shirota Hazuki, Suzuki Keita, Kimura Eiki India: Abhay Buurhanpurkar
Complaints Management	Elaine Doran, Stacy Ruemping
Patient and/or Technical Services	Alan Crescini, Matthew Pikus
Clinical	Pieter Kappetein, Morgan Judkins
Media Relations	Becky Dvorak
Sales Operations	Paul Lohman, Rachael Berns
Supply Chain/Customer Care	Sean Peterlin
Customer Service	Margaret Flood, Vivian Carlson
CAPA Owner	Carlo Gutierrez
Finance	Nathan Chambers

3. Communication Plan

FCA communication documents, included as attachments and approved with this plan, are:

- Appendix A: Consignee Notification (Updated)
- Appendix B: Consignee Confirmation Form (Consignee sign) (Updated)
- Appendix C: Medtronic Representative Confirmation Form (UTC)

- Appendix D: Internal Messaging Guide (IMG) (Updated)
- Appendix E: Field Presentation for use during field call (Updated)
- Appendix F: Clinical Assessment

3.1. Consignee Communications

3.1.1. U.S. Consignees

- Medtronic will send the immediate Consignee Notification, Consignee Detail Report, and Consignee Confirmation Form via 2-Day UPS to each listed consignee.
- Distributors are responsible for forwarding the Urgent Medical Device Correction Letter to those consignees to which they have distributed (forwarded) impacted product.
- Follow-up communications to consignees (with assistance from field representatives as necessary) will be made until all Consignee Confirmation Forms have been received, or three unsuccessful attempts to obtain the signed confirmation form are documented.

Recipient/ Audience	Document Description	Distribution Dates	Distribution Method	Communication Owner
Consignees with Affected DLP™ Left Heart Vent Catheters **(Immediate)**	**Appendix A: Consignee** Notification (Urgent Medical Device Recall Letter) **Appendix B:** Consignee Confirmation Form	**Attempt #1**: Beginning 06-AUG-2025 **Attempt #2:** Beginning 17-SEP-2025 **Attempt #3:** Beginning 29-OCT-2025	Mail, Other	Attempt 1 and 2: FCA Enterprise Attempt 3: OU/Sales Ops

3.1.2. Regional Consignees

- Medtronic will send the immediate Consignee Notification (ANZ only) and Consignee Confirmation Form (or equivalent record) via a regionally approved method (e.g., courier, registered mail, hand delivery, electronic system) to each listed consignee.
    - For countries that follow EU MDR: The devices in scope of this field action are MDD devices therefore UDI is not available or relevant and will not be provided in the consignee notification.

- For countries that follow EU MDR: The SRN will be noted in the consignee notification.

- Distributors are responsible for forwarding the Urgent Medical Device / Field Safety Notice Letter to those consignees to which they have distributed (forwarded) impacted product. Where the distributor is the owner of the product license, distributors are responsible to notify the Regulator of the FCA. The distributor needs to complete the confirmation form acknowledging that the actions are executed.
- Follow-up communications to consignees (with assistance from field representatives as necessary) will be made until all Consignee Confirmation Forms (or equivalent record) have been received, or three unsuccessful attempts to obtain the signed confirmation certificate are documented. Within Australia and Switzerland, a total of 4 attempts is required to inform customers.

Region	Recipient/ Audience	Document Description	Distribution Dates	Distribution Method	Communication Owner
ANZ only **(Immediate)**	Consignees with Affected DLP™ Left Heart Vent Catheters	**Appendix A:** Consignee Notification (Urgent Medical Device Recall Letter/Urgent Field Safety Notice for Europe) **Appendix B:** Consignee Confirmation Form	**Attempt #1:** Beginning 06-AUG-2025 **Attempt #2:** Beginning 17-SEP-2025 **Attempt #3:** Beginning 29-OCT-2025 **Attempt #4**: (Australia Only) Beginning 19-DEC-2025	Mail, Other Regionally Approved Method	Regional R/As
EMEA; SEA; Korea; China; Hong Kong;	Consignees with Affected DLP™ Left Heart Vent Catheters	**Appendix A:** Consignee Notification (Urgent Medical Device Recall Letter/Urgent Field Safety Notice for Europe)	**Attempt #1:** No later than 20-AUG-2025	Mail, Other Regionally Approved Method	Regional R/As

Region	Recipient/ Audience	Document Description	Distribution Dates	Distribution Method	Communication Owner
Canada; LATAM; Taiwan; Japan; India		**Appendix B:** Consignee Confirmation Form	**Attempt #2:** No later than 01-OCT-2025 **Attempt #3:** No later than 12-NOV-2025 **Attempt #4**: (Switzerland Only) No later than 19-DEC-2025		

3.2. Regulatory Body Communications

Note: See section 5.4 *FCA Plan Execution* for regulatory reporting actions.

3.3. Regulatory Body Reporting

This FCA will be reported to Notified Bodies and Regulatory Authorities regionally as required and/or applicable per local regional requirements. Refer to Global FCA Regulatory Reporting Matrix, D01372169.

3.3.1.1. U.S. FDA Reporting

This FCA has been determined to be reportable according to CFR 21 CFR 806 as it was initiated (1) to reduce a Risk to Health posed by the device; or (2) To remedy a violation of the act caused by the device which may present a Risk to Health. This FCA will be reported to the FDA Division office using 115-F367 within 10 working days of the date when this Global FCA plan is approved or the date immediate action is authorized, whichever occurs first. Status reports will be submitted to the FDA using 115-F369, *806 Status and Closure Report* as required.

3.3.1.2. EMEA

This FCA will be reported to the Dutch Competent Authority (IGJ) when pre-notifying this FCA (FA1501). IGJ will take the role of Coordinating Competent Authority per EU MDR 2017-745, article 87-89 for this field action. Additionally, this FCA will be pre-notified to the Competent Authority in the United Kingdom

(UK): MHRA. Finally, this FCA will be reported to all of the affected regulated countries within EMEA as per the scoping list.

The initiation and closure of the FSCA will be reported to Competent Authorities in EEA + CH + TR + UK using the FSCA reporting form and the IIA.
Countries outside EEA + CH+ TR + UK will determine locally if reporting is needed based on local regulations.
This FCA will be reported to Notified Body TÜV SÜD 0123 under EU MDR 2017-745.

3.3.1.3. SEA

This FCA is reportable in affected regulated countries in Southeast Asia, including Malaysia (Medical Device Authority), Philippines (Food and Drug Administration), Singapore (Health Sciences Authority), Thailand (Thai Food and Drug Administration), and Vietnam (Ministry of Health).

3.3.1.4. ANZ

This FCA is reportable in Australia to Therapeutic Goods Administration (TGA) and in New Zealand to Medsafe.

3.3.1.5. Korea

This FCA is reportable for Korea.

3.3.1.6. China

This FCA is reportable for Greater China.

3.3.1.7. Hong Kong

This FCA is not reportable under Department of Health Medical Device Division.

3.3.1.8. Canada

This FCA is reportable to Health Canada as described under CMDR Sections 63-65 SOR/98-282. This recall has been classified as a health hazard classification:

- Type II: A situation where the use of (or exposure to) a device being recalled may cause temporary adverse health consequences or where the probability of serious adverse health consequences is remote.]

3.3.1.9. LATAM

This FCA is reportable in Argentina to the local regulatory agency ANMAT (National Administration of Drugs, Food and Medical Technology), in Brazil to the local regulatory agency ANVISA (Brazilian Health Surveillance Agency/General office of Medical Device), in Colombia to the local regulatory agency INVIMA (National Institute for Surveillance of Drugs and Food), in Costa Rica to the local regulatory agency Ministry of Health, in Ecuador to the local regulatory agency ARCSA (National Agency for Health Regulation, Control and Surveillance), in Mexico to the local regulatory agency COFEPRIS (Federal Commission for the Protection against Sanitary Risks), in Panama to the local regulatory agency MINSA (Ministry of Health) National Directorate of Medical Devices of the Ministry of Health of Panama, in

Uruguay to the local regulatory agency MSP (Ministry of Public Health-Technology Assessment Departments).

Note: Puerto Rico is included in the U.S. report to the FDA.

3.3.1.10. Taiwan

This FCA is reportable under [Enforcement Rules of Medical Devices Act Article 25]: In the event that a medical device may cause harm to the health of human body, the medical device license holders or those who completed the listing, according to the provisions of Paragraph 1 of Article 49 of the Act, shall use the electronic system designated by the central competent authority to report within 7 days after the day of discovery; when necessary, such report can be done in writing, through e-mail, facsimile or telephone.

3.3.1.11. Japan

This FCA will be reported locally in alignment with the regulatory requirements described in D01372169, Global FCA Regulatory Reporting Requirements Matrix.

3.3.1.12. India

This FCA is reportable, and regulatory reporting is mandatory in India.

4. FCA Effectiveness Check Methods

U.S. Effectiveness Checks Methods:

- For each consignee that is affected, a completed and signed confirmation (written Consignee Confirmation Form or electronic) by the consignee is required as proof of receipt of the FCA communication; or 3 documented attempts of communication utilizing at least 2 different methods.

International Confirmation and Effectiveness Check Methods:

Each region or country is required to execute consignee communication and effectiveness check methods in alignment with the global plan. Additional regional plans may be developed that further outline actions required for completing FCA activities.

Within Australia and Switzerland, a total of 4 attempts is required to inform customers.

5. Field Action Plan Activity and Timing

5.1. FCA Plan Development

This section identifies key activities with owners and target completion dates for developing the FCA plan and communication document drafts.

Activity	Responsible	Target Completion Date dd-mmm-yyyy
Product Bounding- Per D00035679, Product Bounding Request for a Potential Field Corrective Action or OU specific bounding process, provide completed Bounding list of all affected products released from manufacturing (including Product/Model No. and name, UPN/GTIN, Serial Numbers, Lot Numbers with quantities) impacted by the FCA to Global FCA Scoping Specialist	Alejandra Chavez	12-JUN-2025
Confirm the PHO and FCA bounding match and provide email evidence to Global FCA Scoping Specialist	Alejandra Chavez	12-JUN-2025
Provide Approved Risk Assessment Document (HRA)	Alejandra Chavez and Yuvraj Karnik	Rev A: 12-JUN-2025 Rev B: 31-JUL-2025
Notify Clinical Management (as applicable for clinical study product)	Clinical Rep	24-JUN-2025
Identify/confirm affected global clinical studies (as applicable for clinical product)	Clinical Rep	25-JUN-2025
Confirm Clinical Study Impact, conduct impact analysis (as applicable for clinical product)	Clinical Rep	25-JUN-2025
Global Scoping/ Item List- Finalize and reconcile scope of FCA including identifying affected product locations and devices within scope of FCA notifications. Create reconciled item list and consignee list.	Stephen Lodge	Rev A: 25-JUN-2025 Rev B: 31-JUL-2025
Distribute reconciled item list to impacted International regions and cc: OU Quality & FCA Scoping Specialist	David Melchior	Rev A: 25-JUN-2025 Rev B: 31-JUL-2025
Provide feedback on any gaps/changes need to the global item list	Regional FCA Coordinators	26-JUN-2025
Identify availability of alternate or replacement product (for each affected region)	Alejandra Chavez	25-JUN-2025

Activity	Responsible	Target Completion Date dd-mmm-yyyy
Check for other Healthcare Organization contractual business requirements for FCA notifications and take appropriate action (e.g. Kaiser Healthcare)	Stephen Lodge	25-JUN-2025
Verify if reportable/regulated in affected regions. Identify Notified Bodies to be notified.	Regional FCA Coordinators	Rev A: 25-JUN-2025 Rev B: 05-AUG-2025
Complaints Confirmation (Update number of complaints received for Adverse Events as of a specific date, for use in consignee letter)	Elaine Doran	Rev A: 25-JUN-2025 Rev B: 05-AUG-2025
Determine Communication Strategy	Alejandra Chavez	Rev A: 12-JUN-2025 Rev B: 01-AUG-2025
Pre-notification to Coordinating Competent Authority in the EU or other regulatory authorities	Regional FCA Coordinator	Rev A: 01-JUL-2025 Rev B: 08-AUG-2025

5.1.1. Management Review

This section defines the timing and those involved for management review of FCA documents identified in this FCA plan.

Revision	Activity	Names	Send for Review (date) dd-mmm-yyyy	Target Response Date dd-mmm-yyyy
A	Management Review of draft FCA Plan and Communication Documents	Laura McCabe Weiping Zhong Karim Bandali Sherif Ibrahim, M.D. Pieter Kappetein	15-JUL-2025	16-JUL-2025
B	Management Review of draft FCA Plan and Communication Documents	Laura McCabe Weiping Zhong Karim Bandali Sherif Ibrahim, M.D. Pieter Kappetein	05-AUG-2025	07-AUG-2025

5.1.2. Global FCA Plan Approval

This section defines the timing and those involved for approval of FCA documents identified in this FCA plan.

Revision	Activity	Names	Send for Review (date) dd-mmm-yyyy	Target Response Date dd-mmm-yyyy
A	Approval of FCA Plan	Weiping Zhong - Sr Director Risk Management Quality COE Karim Bandali – President and VP Cardiac Surgery Laura McCabe – VP Quality, Cardiac Surgery Sherif Ibrahim, M.D – Senior Medical Safety Director	18-JUL-2025	18-JUL-2025
B	Approval of FCA Plan	Weiping Zhong - Sr Director Risk Management Quality COE Karim Bandali – President and VP Cardiac Surgery Laura McCabe – VP Quality, Cardiac Surgery Sherif Ibrahim, M.D – Senior Medical Safety Director	12-AUG-2025	13-AUG-2025

5.2. Distribution of Approved Plan and Communication Documents

Upon approval, the FCA plan and approved documents will be distributed according to the distribution list (DL) below.

Recipients	Responsible Target Completion Date
All Field Action Team Members identified in Field Action Plan	David Melchior-Upon Plan Approval
All Reviewers identified in Field Action Plan	
All Approvers identified in Field Action Plan	
All Regional FCA Coordinator / QA responsible for FCA reporting	
DL FCA Global Communications	
rs.governmentaccountsfcanotifications@medtronic.com	
DL Investor Relations	
Anne Smith - FCA Program Manager	
Brian Wertish, VP Customer Quality Services	
Chris Harrold -VP Core Quality Services - CSQ LT & CoE	
Christina Zhong - CP Clinical/Medical GRC - GC Clinical Research	
DL Customer Quality Leadership Team	
Eishi Usami, VP Fin Japan	
Elena Plyasunova - Russia Country Leader	
Kelly Meyer, Executive Administrative Assistant - National Accounts	
Lisa Woodward Clark - VP Core Quality Services	
Majid Kaddoumi - SVP, President EurAsia Regions	
My Chang, Sr Regulatory Affairs Director, QRA North Asia	
Olaf Hedrich, MD - VP Corporate Medical Safety	
Padraic Curran, VP Quality Systems	
Robert Clifton - VP and President Medtronic Canada	
Rok Yoo - Sr. Director, Marketing leader/Korea	
Schleen Archambeau, Sr. Credit Services Manager	
Scott Cundy, SVP/Chief Quality Officer	

Recipients	Responsible Target Completion Date
Senthilkumar Jayachandran, Senior Quality Systems Director - Enterprise FCA/PHO	
Trevor Gunn, MD – VP, International Relations	
Weiping Zhong - Senior Director – Quality Core Services, Risk Management Center of Expertise	
Dan Sweeney - VP Sales US CS	
David Kim - VP R&D Cardiac Surgery	
Della Boutrous - Lead Counsel CS	
Karim Bandali - VP & President CS	
Laura McCabe- VP Quality Cardiac Surgery	
Lucas VanDeWiele - VP Ops CS	
Ming Xu - Sr China Commercial Director CS	
Nathan Chambers - Sr Finance Director CS	
Prof Pieter Kappetein, M.D., Ph.D. - VP Clinical/Medical EMEA	
Sherif Ibrahim, M.D – Senior Medical Safety Director	
Tetsuya Takahashi - VP Japan Commercial CS & Aortic	
rs.phycommunications@medtronic.com	
DL CV Controller - FCA	

5.3. Prepare for FCA Plan Execution

This section outlines activities to prepare for distribution of FCA documents and FCA plan execution.

Activity	Responsible	Plan Date dd-mmm-yyyy
Submit PHO Request form to update the UIF PHO type to “FA” (as applicable)	Alejandra Chavez	21-JUL-2025
After OU approval is received, update PHO UIF status to “FA” (as applicable)	Carrie Allen	21-JUL-2025

Activity	Responsible	Plan Date dd-mmm-yyyy
Initiate Translation of the Customer Letter	Regional FCA Coordinator	During Planning of the FCA
Complete draft of Regional FCA plan/documents and submit for review/approval (as applicable)	Regional FCA Coordinator	Upon global plan approval, as needed
Review/approve Regional FCA plan(s) (as applicable)	Regional FCA Coordinator, Quality Leadership	Upon request from region
Complete MDR/Vigilance Reporting per Regional Requirements	MDR/Regional FCA Coordinator	Upon global plan approval, as needed
Finalize Consignee lists and prepare communication documents for printing and Mailing/Delivery – International Field/Consignees; Includes approved/certified translations where required	Regional / Country FCA Coordinator	Upon global plan approval, as needed
Finalize U.S. Consignee list and prepare communication documents for printing and Mailing/Delivery or Electronic notification – U.S. Field/Consignees	Stephen Lodge	01-AUG-2025
Share approved FCA information internally across functions listed in section 2.5	FCA team members listed in section 2.5 for each function and listed below (as applicable)	Upon Plan Approval
Send Communication packages to US Field	OU Quality/Marketing/Sales Ops	06-AUG-2205
Conduct conference call(s) / PowerPoint presentation with U.S. Field	OU Quality/ Marketing/ Sales Ops	06-AUG-2025
Conduct conference call(s) / PowerPoint presentation with International Field	Regional FCA Coordinators	No later than 20-AUG-2025

Activity	Responsible	Plan Date dd-mmm-yyyy
Provide draft 115-F367, *806 Letter*	David Melchior	11-AUG-2025

5.4. FCA Plan Execution (Including Closure)

This section outlines FCA plan execution activities with owners and plan dates.

Activity	Responsible	Plan Date dd-mmm-yyyy
Initiate consignee communications and confirmations; including special accounts.	Regional FCA Coordinator/ Scoping Specialist	Beginning 06-AUG-2025 US & ANZ No later than 20-AUG-2025 OUS
Notify Applicable Notified Bodies (e.g., BSI, TUV	EMEA Regional Coordinator or OU Quality	Beginning 19-AUG-2025
Notify Regional Regulatory Authorities (as applicable)	Regional FCA Coordinator per local region requirements	Beginning 19-AUG-2025
Submit 806 Report to FDA	David Melchior	Rev A: 21-JUL-2025 Rev B: 14-AUG-2025

Activity	Responsible	Plan Date dd-mmm-yyyy
Provide status reports to FDA according to FDAs response to the 806 Report(s) initial recall report	Global FCA Execution Specialists	Monthly (upon receipt for FDA confirmation
Update FCA Team with FDA classification as applicable	Global FCA Coordinator	Upon receipt of the FDA Classification
Periodic update <every two weeks> of progress reports for notification confirmations (i.e. via FAST update, sales, etc.)	Regional, Country FCA Coordinator/ Global FCA Execution Specialists	Beginning August 2025
Second communication attempt <mailing or other>	Scoping Specialist / Regional FCA Coordinator	Beginning 17-SEP-2025 (US & ANZ) 01-OCT-2025 OUS
Third communication attempt <mailing or other> – U.S. Sales Representative Involvement	Sales Ops/OU Quality/Regional FCA Coordinator	Beginning 29-OCT-2025 (US & ANZ) 12-NOV-2025 OUS

Activity	Responsible	Plan Date dd-mmm-yyyy
Australia, Switzerland Only - Fourth communication attempt <mailing or other> – Sales Representative Involvement	Sales Ops/OU Quality/Regional FCA Coordinator	Beginning 19-DEC-2025
Retrieval of Trunk Stock	Country FCA Coordinator / Sales Ops/ Customer Care Supply Chain	19-JAN-2026
Completion of 3rd / 4th attempt notifications (see Effectiveness Checks/Closure Criteria)	Sales Ops/OU Quality/Regional Coordinator	27-MAR-2026
Consignment and sold product Retrieval Due Date	Regional, Country FCA Coordinator / Sales Ops/ Customer Care Supply Chain	17-APR-2026

Activity	Responsible	Plan Date dd-mmm-yyyy
Reconciliation of Product Retrieval Completed (see Effectiveness Checks/Closure Criteria)	OU Quality / Regional FCA Coordinator / Sales Ops / Customer Care/ Global FCA Execution Specialists	01-MAY-2026
Country/Region Closure Forms due upon confirmation *and product return reconciliation* – all affected Countries/Regions	Global FCA Execution Specialists/ Regional FCA Coordinator	29-MAY-2026
Confirm FCA Status reporting aligns with Country/Region closure form	Global FCA Execution Specialists	12-JUN-2026

Activity	Responsible	Plan Date dd-mmm-yyyy
Target FCA Field Activities Completion Date (All Activities Complete (AAC))	Global FCA Execution Specialists	13-JUL-2026
Alert PHO owner (OU Quality) and Enterprise PHO coordinator that FCA activities are complete	Global FCA Execution Specialists	20-JUL-2026
OU to provide rework evidence to FCA Execution team	OU Quality	20-JUL-2026
Target Final Disposition of the PHO	OU Quality	27-JUL-2026
Notify FDA prior to Scrap or Rework of product	FCA Execution Specialist	27-JUL-2026
Reconcile final disposition of affected product	Enterprise PHO Coordinator	25-JAN-2027
Notify Enterprise FCA of CAPA closure or extension date	OU Quality	19-MAY-2026
Target CAPA closure date	CAPA Owner	20-JUL-2026
Notify OU VP of Quality (or designee) of final FCA closure	Global FCA Execution Specialists	26-FEB-2027

6. Closure Criteria/ Effectiveness

6.1. FCA Activities Completion Criteria/ Effectiveness Checks:

- Confirmation that 100% identified consignees were notified of the issue and/or despite three documented attempts, consignee was not located or did not provide a response (documented on Country/Region Closure Form).
- 100% of affected trunk or consigned product has been returned or reconciled (globally).
- 100% of Country/Region Closure Forms are completed and returned to the Global Execution Specialist.

6.2. FCA Final Closure Criteria:

In addition to activities outlined in section 6.1:

- Closure Report Submitted to Regulatory Authorities as required.
- CAPA 716825 record is closed
- PHO is closed (if applicable).
- Final reconciliation and disposition of affected product is achieved.
- Notification to most senior OU Quality leader, of final FCA closure.