

Field Corrective Action # FA1466 Plan

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Medtronic


Neurovascular

Pipeline Vantage 027 Recall & Pipeline Vantage 021 Correction (IFU Update)


Regional Field Corrective Action Plan

(based on D01333718 Rev C)

Plan developed by

Name	Title	Signature & Date
Sheena Loren Lao	Quality Systems Specialist	<p>Signed by:</p>  <p>Signer Name: Sheena Loren Lao Signing Reason: I am the author of this document Signing Time: 01 February 2025 10:46 CST D5C434423B0F425BB95CC6303C359E43</p>

FCA Package Approval (Denotes approval of FCA Plan and all communication documents)

Name	Title	Signature & Date
Chloe Tan	QARA Director Southeast Asia	<p>Signed by:</p>  <p>Signer Name: Chloe Tan Signing Reason: I approve this document Signing Time: 02 February 2025 21:29 SGT 90D0724C9B1C402A99B286449A1644B8</p>

1. Executive Summary

The purpose of this document is to outline the intended Global Field Corrective Action (FA) plan for initiating communications to consignees, retrieving affected product, and completing effectiveness checks for Pipeline™ Vantage Embolization Device with Shield Technology™ (“Pipeline Vantage”) due to adverse braid behaviors for Pipeline Vantage. The approval of this plan will initiate the following voluntary actions:

- Removal (retrieval) of unused inventory of Pipeline Vantage 027 devices (PED3-027-XXX-XX)
- Correction to the IFU of the Pipeline Vantage 021 devices (PED3-021-XXX-XX)

Product Hold Order (D01321689) was initiated on 21-Dec-2024 to contain the affected product.

CAPA PR 675853 was opened.

Risk assessment details are available in Pipeline Vantage Adverse Braid Behaviors, document # D01254978.

2. Background

2.1. Device Description and Intended Use

The Pipeline™ Vantage Embolization Device with Shield Technology™ consists of a permanent implant with a guidewire-based delivery system. The Pipeline™ Vantage Embolization Device with Shield Technology™ is a braided, multi-alloy, mesh cylinder woven with cobalt-chromium-nickel and platinum wires. [...] The woven wires of the device provide approximately 30% metal coverage of the arterial wall surface area. The implant is designed for placement in a parent vessel across the neck of an intracranial aneurysm (IA). The expanded or unconstrained diameter is 0.25mm larger than the labeled diameter. Shield Technology is a surface-modification that is not derived from animal or human sources.

US FDA INTENDED USE / INDICATIONS FOR USE: The Pipeline™ Vantage Embolization Device with Shield Technology™ is indicated for the endovascular treatment of adults (22 years of age or older) with large or giant wide-necked intracranial aneurysms (IAs) in the internal carotid artery from the petrous to the superior hypophyseal segments.

The Pipeline™ Vantage Embolization Device with Shield Technology™ is also indicated for use in the internal carotid artery up to the terminus for the endovascular treatment of adults (22 years of age or older) with small and medium wide-necked (neck width \geq 4 mm or dome-to-neck ratio $<$ 2) saccular or fusiform intracranial aneurysm (IAs) arising from a parent vessel with a diameter \geq 2.0 mm and \leq 5.0 mm.

CE Mark Indications for Use: The Pipeline™ Vantage Embolization Device with Shield Technology is intended for the endovascular embolization of cerebral aneurysms.

2.2. Problem Description and Technical Summary

Field reports of serious adverse events with braid deformation triggered a quality investigation on Pipeline Vantage. This investigation is focused on braid deformation and/or incomplete wall apposition issues

including incomplete/failure to open, fishmouth, collapse, twist, flatten, ribbon, hump, and migration. The hazards under investigation include:

- Hazard 1: **Intra-procedure** braid deformation/incomplete wall apposition
- Hazard 2: **Post-procedure** braid deformation/incomplete wall apposition

A review of the available data from 1) the INSPIRE-A registry and 2) post-market surveillance data (i.e. complaints) was conducted. Performance of Pipeline Vantage was compared against the previous generation Pipeline Shield flow divertor as appropriate, to assess relative performance.

Medtronic also conferred with an independent Physician Safety Advisory Panel as well as the US FDA. As a collective outcome of these activities, Medtronic is voluntarily pursuing the actions outlined in this field action plan.

The details of the investigation and the risk assessment are captured in Issue Impact Assessment (IIA) D012554978.

2.3. Actions to be taken

- A voluntary FCA 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.
 - Medtronic will retrieve Pipeline Vantage with compatibility to 0.027" inner diameter microcatheters (part numbers PED3-027-XXX-XX)
 - Medtronic will communicate a correction (Update to IFU) to Pipeline Vantage with compatibility to 0.021" inner diameter microcatheters (part numbers PED3-021-XXX-XX).
- Consignees will be asked to confirm receipt of FCA notification.
- Consignees will be asked to return all unused affected sold Pipeline Vantage 027 devices with part numbers PED3-027-XXX-XX within their possession.
- Medtronic field representatives will assist with retrieving consigned product from consignee locations.
- Reconciliation of returned product will be managed per PHO.
- Communication Waves:
 - This FCA will include a single wave of communication for removal of unused inventory of Pipeline Vantage 027 devices.
 - This FCA will include multiple waves of communication for the Pipeline Vantage 021 devices. Waves of communication will occur every month for newly identified consignee that receive Pipeline Vantage 021 devices with the existing IFU. For tracking purposes, the initial communication is considered Wave 1. The wave communications will end upon

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implementation and release of product with the updated IFU and depletion of Pipeline Vantage 021 product with the old IFU.

Additional Medtronic Actions:

- Field representatives may assist consignees with the return of unused product (sold part numbers PED3-027-XXX-XX) and the timely return of the consignee signed Consignee Confirmation Form.
- Medtronic is implementing changes to the IFU for the Pipeline Vantage 021 with part numbers PED3-021-XXX-XX
- 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:

CFN	Product Description	GTIN
PED3-027-350-16	STENT PED3-027-350-16	00847536030794
PED3-027-350-16	STENT PED3-027-350-16	00847536035294
PED3-027-400-14	STENT PED3-027-400-14	00847536036697
PED3-027-400-14	STENT PED3-027-400-14	00847536030879
PED3-027-400-14	STENT PED3-027-400-14	00847536035379
PED3-027-400-16	STENT PED3-027-400-16	00847536036703
PED3-027-400-16	STENT PED3-027-400-16	00847536030886
PED3-027-400-16	STENT PED3-027-400-16	00847536035386
PED3-027-400-20	STENT PED3-027-400-20	00847536036727
PED3-027-400-20	STENT PED3-027-400-20	00847536030909
PED3-027-400-20	STENT PED3-027-400-20	00847536035409
PED3-027-450-16	STENT PED3-027-450-16	00847536036802
PED3-027-450-16	STENT PED3-027-450-16	00847536030985
PED3-027-450-16	STENT PED3-027-450-16	00847536035485
PED3-027-450-20	STENT PED3-027-450-20	00847536036826
PED3-027-450-20	STENT PED3-027-450-20	00847536031005
PED3-027-450-20	STENT PED3-027-450-20	00847536035508
PED3-027-500-20	STENT PED3-027-500-20	00847536036925
PED3-027-500-20	STENT PED3-027-500-20	00847536031098
PED3-027-500-20	STENT PED3-027-500-20	00847536035607
PED3-027-500-40	STENT PED3-027-500-40	00847536036963
PED3-027-500-40	STENT PED3-027-500-40	00847536031135
PED3-027-500-40	STENT PED3-027-500-40	00847536035645
PED3-027-600-20	STENT PED3-027-600-20	00847536037144
PED3-027-600-20	STENT PED3-027-600-20	00847536031302
PED3-027-600-20	STENT PED3-027-600-20	00847536035829
PED3-027-350-14	STENT PED3-027-350-14	00847536030787
PED3-027-350-14	STENT PED3-027-350-14	00847536035287

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CFN	Product Description	GTIN
PED3-027-350-20	STENT PED3-027-350-20	00847536030817
PED3-027-350-20	STENT PED3-027-350-20	00847536035317
PED3-027-400-12	STENT PED3-027-400-12	00847536036680
PED3-027-400-12	STENT PED3-027-400-12	00847536030862
PED3-027-400-12	STENT PED3-027-400-12	00847536035362
PED3-027-400-25	STENT PED3-027-400-25	00847536036734
PED3-027-400-25	STENT PED3-027-400-25	00847536030916
PED3-027-400-25	STENT PED3-027-400-25	00847536035416
PED3-027-450-12	STENT PED3-027-450-12	00847536036789
PED3-027-450-12	STENT PED3-027-450-12	00847536030961
PED3-027-450-12	STENT PED3-027-450-12	00847536035461
PED3-027-450-14	STENT PED3-027-450-14	00847536036796
PED3-027-450-14	STENT PED3-027-450-14	00847536030978
PED3-027-450-14	STENT PED3-027-450-14	00847536035478
PED3-027-550-20	STENT PED3-027-550-20	00847536037021
PED3-027-550-20	STENT PED3-027-550-20	00847536031180
PED3-027-550-20	STENT PED3-027-550-20	00847536035706
PED3-027-450-30	STENT PED3-027-450-30	00847536036840
PED3-027-450-30	STENT PED3-027-450-30	00847536031029
PED3-027-450-30	STENT PED3-027-450-30	00847536035522
PED3-027-450-25	STENT PED3-027-450-25	00847536036833
PED3-027-450-25	STENT PED3-027-450-25	00847536031012
PED3-027-450-25	STENT PED3-027-450-25	00847536035515
PED3-027-500-14	STENT PED3-027-500-14	00847536036895
PED3-027-500-14	STENT PED3-027-500-14	00847536031067
PED3-027-500-14	STENT PED3-027-500-14	00847536035577
PED3-027-500-16	STENT PED3-027-500-16	00847536036901
PED3-027-500-16	STENT PED3-027-500-16	00847536031074
PED3-027-500-16	STENT PED3-027-500-16	00847536035584
PED3-027-500-25	STENT PED3-027-500-25	00847536036932
PED3-027-500-25	STENT PED3-027-500-25	00847536031104
PED3-027-500-25	STENT PED3-027-500-25	00847536035614
PED3-027-500-30	STENT PED3-027-500-30	00847536036949
PED3-027-500-30	STENT PED3-027-500-30	00847536031111
PED3-027-500-30	STENT PED3-027-500-30	00847536035621
PED3-027-550-30	STENT PED3-027-550-30	00847536037045
PED3-027-550-30	STENT PED3-027-550-30	00847536031203
PED3-027-550-30	STENT PED3-027-550-30	00847536035720
PED3-027-600-40	STENT PED3-027-600-40	00847536037182
PED3-027-600-40	STENT PED3-027-600-40	00847536031340
PED3-027-600-40	STENT PED3-027-600-40	00847536035867
PED3-027-600-50	STENT PED3-027-600-50	00847536037205

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CFN	Product Description	GTIN
PED3-027-600-50	STENT PED3-027-600-50	00847536031364
PED3-027-600-50	STENT PED3-027-600-50	00847536035881
PED3-021-300-12	STENT PED3-021-300-12	00847536036345
PED3-021-300-12	STENT PED3-021-300-12	00847536030527
PED3-021-300-12	STENT PED3-021-300-12	00847536035010
PED3-021-300-20	STENT PED3-021-300-20	00847536030565
PED3-021-300-20	STENT PED3-021-300-20	00847536035058
PED3-021-300-20	STENT PED3-021-300-20	00847536036383
PED3-021-350-20	STENT PED3-021-350-20	00847536036543
PED3-021-350-20	STENT PED3-021-350-20	00847536030725
PED3-021-350-20	STENT PED3-021-350-20	00847536035218
PED3-021-350-16	STENT PED3-021-350-16	00847536030701
PED3-021-350-16	STENT PED3-021-350-16	00847536035195
PED3-021-350-16	STENT PED3-021-350-16	00847536036529
PED3-021-250-12	STENT PED3-021-250-12	00847536030404
PED3-021-250-12	STENT PED3-021-250-12	00847536034891
PED3-021-250-12	STENT PED3-021-250-12	00847536036222
PED3-021-250-14	STENT PED3-021-250-14	00847536030411
PED3-021-250-14	STENT PED3-021-250-14	00847536036239
PED3-021-250-14	STENT PED3-021-250-14	00847536034907
PED3-021-300-14	STENT PED3-021-300-14	00847536030534
PED3-021-300-14	STENT PED3-021-300-14	00847536036352
PED3-021-300-14	STENT PED3-021-300-14	00847536035027
PED3-021-250-10	STENT PED3-021-250-10	00847536036215
PED3-021-250-10	STENT PED3-021-250-10	00847536030398
PED3-021-250-10	STENT PED3-021-250-10	00847536034884
PED3-021-350-25	STENT PED3-021-350-25	00847536030732
PED3-021-350-25	STENT PED3-021-350-25	00847536035225
PED3-021-350-25	STENT PED3-021-350-25	00847536036550
PED3-021-250-20	STENT PED3-021-250-20	00847536030442
PED3-021-250-20	STENT PED3-021-250-20	00847536034938
PED3-021-250-20	STENT PED3-021-250-20	00847536036260
PED3-021-350-12	STENT PED3-021-350-12	00847536030688
PED3-021-350-12	STENT PED3-021-350-12	00847536035171
PED3-021-350-12	STENT PED3-021-350-12	00847536036505
PED3-021-350-14	STENT PED3-021-350-14	00847536030695
PED3-021-350-14	STENT PED3-021-350-14	00847536035188
PED3-021-350-14	STENT PED3-021-350-14	00847536036512
PED3-027-350-12	STENT PED3-027-350-12	00847536030770
PED3-027-350-12	STENT PED3-027-350-12	00847536035263
PED3-027-550-40	STENT PED3-027-550-40	00847536031227
PED3-027-550-40	STENT PED3-027-550-40	00847536037069

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CFN	Product Description	GTIN
PED3-027-550-40	STENT PED3-027-550-40	00847536035744
PED3-027-550-50	STENT PED3-027-550-50	00847536031241
PED3-027-550-50	STENT PED3-027-550-50	00847536037083
PED3-027-550-50	STENT PED3-027-550-50	00847536035768
PED3-027-350-25	STENT PED3-027-350-25	00847536030824
PED3-027-350-25	STENT PED3-027-350-25	00847536035324
PED3-027-400-30	STENT PED3-027-400-30	00847536030923
PED3-027-400-30	STENT PED3-027-400-30	00847536035423
PED3-027-400-30	STENT PED3-027-400-30	00847536036741
PED3-027-450-40	STENT PED3-027-450-40	00847536031043
PED3-027-450-40	STENT PED3-027-450-40	00847536035546
PED3-027-450-40	STENT PED3-027-450-40	00847536036864
PED3-027-600-30	STENT PED3-027-600-30	00847536031326
PED3-027-600-30	STENT PED3-027-600-30	00847536035843
PED3-027-600-30	STENT PED3-027-600-30	00847536037168
PED3-021-325-16	STENT PED3-021-325-16	00847536030626
PED3-021-325-16	STENT PED3-021-325-16	00847536035119
PED3-021-325-16	STENT PED3-021-325-16	00847536036444
PED3-021-325-12	STENT PED3-021-325-12	00847536030602
PED3-021-325-12	STENT PED3-021-325-12	00847536035096
PED3-021-325-12	STENT PED3-021-325-12	00847536036420
PED3-021-325-14	STENT PED3-021-325-14	00847536030619
PED3-021-325-14	STENT PED3-021-325-14	00847536035102
PED3-021-325-14	STENT PED3-021-325-14	00847536036437
PED3-021-325-20	STENT PED3-021-325-20	00847536030640
PED3-021-325-20	STENT PED3-021-325-20	00847536035133
PED3-021-325-20	STENT PED3-021-325-20	00847536036468
PED3-021-275-12	STENT PED3-021-275-12	00847536030466
PED3-021-275-12	STENT PED3-021-275-12	00847536034952
PED3-021-275-12	STENT PED3-021-275-12	00847536036284
PED3-021-275-16	STENT PED3-021-275-16	00847536030480
PED3-021-275-16	STENT PED3-021-275-16	00847536034976
PED3-021-275-16	STENT PED3-021-275-16	00847536036307
PED3-021-275-14	STENT PED3-021-275-14	00847536030473
PED3-021-275-14	STENT PED3-021-275-14	00847536034969
PED3-021-275-14	STENT PED3-021-275-14	00847536036291
PED3-021-275-20	STENT PED3-021-275-20	00847536030503
PED3-021-275-20	STENT PED3-021-275-20	00847536036321
PED3-021-275-20	STENT PED3-021-275-20	00847536034990
PED3-027-550-16	STENT PED3-027-550-16	00847536031166
PED3-027-550-16	STENT PED3-027-550-16	00847536035683
PED3-027-550-16	STENT PED3-027-550-16	00847536037007

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PED3-027-600-16	STENT PED3-027-600-16	00847536031289
PED3-027-600-16	STENT PED3-027-600-16	00847536035805
PED3-027-600-16	STENT PED3-027-600-16	00847536037120
PED3-021-250-16	STENT PED3-021-250-16	00847536030428
PED3-021-250-16	STENT PED3-021-250-16	00847536034914
PED3-021-250-16	STENT PED3-021-250-16	00847536036246
PED3-021-300-16	STENT PED3-021-300-16	00847536030541
PED3-021-300-16	STENT PED3-021-300-16	00847536035034
PED3-021-300-16	STENT PED3-021-300-16	00847536036369
PED3-027-400-18	STENT PED3-027-400-18	00847536036710
PED3-027-450-18	STENT PED3-027-450-18	00847536036819
PED3-027-500-18	STENT PED3-027-500-18	00847536036918
PED3-021-350-18	STENT PED3-021-350-18	00847536036536
PED3-021-325-18	STENT PED3-021-325-18	00847536036451
PED3-027-600-18	STENT PED3-027-600-18	00847536037137
PED3-027-550-18	STENT PED3-027-550-18	00847536037014
PED3-021-275-18	STENT PED3-021-275-18	00847536036314
PED3-021-250-18	STENT PED3-021-250-18	00847536036253
PED3-021-300-18	STENT PED3-021-300-18	00847536036376
Grand Total		

Rationale for Scope of this FCA:

Pipeline Vantage adverse braid behaviors have the potential to occur intra-procedurally or at any time after implantation. All Pipeline Vantage devices sold since launch are considered impacted and are in scope of this FCA.

The table below provides an overview of the distribution and inventory status for affected units in scope of this FCA as of 16-Jan-2025.

Country	Sold	Consigned	Trunk	Grand Total	# of Consignees
Bangladesh	5	0	0	5	1
Malaysia	22	44	14	80	15
Philippines	6	0	0	6	3
Singapore	132	0	15	147	17
Thailand	116	199	0	315	24
Vietnam	327	0	0	327	2
Grand Total	608	243	29	880	62

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

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Product affected by this issue and identified as in Medtronic Control is not in scope of FCA consignee activities and is listed in the table below as of 16-Jan-2025 :

Out of Scope				
	Warehouse	Trunk Stock	Inactive Devices (scrapped, disposed, returns, etc.)	Total
US	10,529	5,352	5,352	30,340
OUS	7,781	1,326		

3. Communication Plan

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

- Consignee Notification and Confirmation Form
- Redline IFU Update
- List of affected Pipeline vantage 027 devices for retrieval
- Medtronic Representative Confirmation Form (UTC)
- Internal Q&A
- Field Presentation for use during field call

3.1. Consignee Communications

3.1.1. Regional Consignees

- Medtronic will send the Consignee Notification 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.
- 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.

Recipient/ Audience	Document Description	Distribution Dates	Distribution Method	Communication Owner
Consignees with Affected product	Consignee Notification and Confirmation Form Redline IFU Update List of affected Pipeline vantage 027 devices for retrieval	Beginning 03- Feb-2025 <i>Or starting on the date approved by country's regulatory authority, whichever comes later.</i>	Mail, Other Regionally Approved Method	Local Sales and Marketing

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3.2. Regulatory Body Communications

Note: See section 5.1 *FCA Plan Execution* for regulatory reporting actions.

3.2.1. 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.

3.2.2. Regional Regulatory Body Reporting

This FCA will be reported Regulatory Authorities regionally as required and/or applicable per local regional requirements.

4. FCA Effectiveness Check 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 and in accordance with local regulatory requirements. Additional regional plans may be developed that further outline actions required for completing FCA activities.

5. Field Action Plan Activity and Timing

5.1. FCA Plan Execution (Including Closure)

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

Activity	Responsible	Plan Date dd-mmm-yyyy
Report to local regulatory authority (if applicable)	Country RA	<i>within the required timeline of local regulations</i>
WAVES (if applicable)	OU Quality / Scoping Specialist/ Execution/ Center-Led FCA QA/ Local Sales and Marketing	See date detail in Wave Dates Table below.

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Activity	Responsible	Plan Date dd-mmm-yyyy
Initiate consignee communications and confirmations; including special accounts.	Local Sales and Marketing	Beginning 03-Feb-2025 <i>Or starting on the date approved by country's regulatory authority, whichever comes later.</i> See date detail in Wave Dates Table below.
Second communication attempt	Local Sales and Marketing	See date detail in Wave Dates Table below.
Third communication attempt	Local Sales and Marketing	See date detail in Wave Dates Table below
Retrieval of Trunk Stock and/or consignment	Local Sales and Marketing	02-Apr-2025
Completion of 3 rd attempt notifications (see Effectiveness Checks/Closure Criteria)	Local Sales and Marketing	See date detail in Wave Dates Table below.
Reconciliation of all communication attempts	Center-Led FCA QA	See date detail in Wave Dates Table below.

Wave Dates Table

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	Bounding Provided (No later than)	Finalize and Reconcile Scope	1 st Attempt (Beginning)	2 nd Attempt (No later than)	3 rd Attempt (No later than)	Confirmation of Consignee Communication completed
Responsible	OU Quality	Scoping Specialist	Local Sales and Marketing	Local Sales and Marketing	Local Sales and Marketing	
Initial (Wave 1)	01-Jan-2025	16-Jan-2025	03-Feb-2025	20-Mar-2025	5-May-2025	Wave 1: 19-Jun-2025
Wave 2	17-Feb-2025	24-Feb-2025	01-Mar-2025	23-Apr-2025	16-Jun-2025	Waves 2-4: 07-Aug-2025
Wave 3	17-Mar-2025	24-Mar-2025	31-Mar-2025	13-May-2025	25-Jun-2025	
Wave 4	16-Apr-2025	23-Apr-2025	30-Apr-2025	2-Jun-2025	4-Jul-2025	
Wave 5	16-May-2025	23-May-2025	30-May-2025	22-Jul-2025	12-Sep-2025	Waves 5-8: 06-Nov-2025
Wave 6	16-Jun-2025	23-Jun-2025	29-Jun-2025	11-Aug-2025	23-Sep-2025	
Wave 7	15-Jul-2025	22-Jul-2025	29-Jul-2025	29-Aug-2025	3-Oct-2025	
Wave 8	14-Aug-2025	21-Aug-2025	28-Aug-2025	19-Sep-2025	13-Oct-2025	
Wave 9	15-Sep-2025	22-Sep-2025	27-Sep-2025	24-Nov-2025	19-Jan-2026	Waves 9-12: 19-Mar-2026
Wave 10	13-Oct-2025	20-Oct-2025	27-Oct-2025	13-Dec-2025	30-Jan-2026	
Wave 11	12-Nov-2025	19-Nov-2025	26-Nov-2025	5-Jan-2026	9-Feb-2026	
Wave 12	12-Dec-2025	19-Dec-2025	26-Dec-2025	22-Jan-2026	19-Feb-2026	

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Activity	Responsible	Plan Date dd-mmm-yyyy
Consignment and sold product Retrieval Due Date (as applicable)	Local Sales and Marketing	20-Aug-2025
Reconciliation of Product Retrieval Completed (see Effectiveness Checks/Closure Criteria)	Center-Led FCA QA	20-Aug-2025
Country/Region Closure Forms due upon confirmation <i>and product return reconciliation</i> – all affected Countries/Regions	Center-Led FCA QA	10-Jun-2026*
Confirm FCA Status reporting aligns with Country/Region closure form	Global FCA Execution Specialists	24-Jun-2026*
Final Disposition of the PHO	OU Quality	20-Jul-2026*
Reconcile final disposition of affected product	OU Quality / Global FCA Execution Specialists / Center-Led FCA QA	20-Oct-2026*

* If an extension was initiated / an update was made by global team, refer to the latest revision of the global plan for this FCA.

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, sold, or consigned product has been returned or reconciled (globally).
- 100% of Country/Region Closure Forms are completed and returned to the Global Execution Specialist.