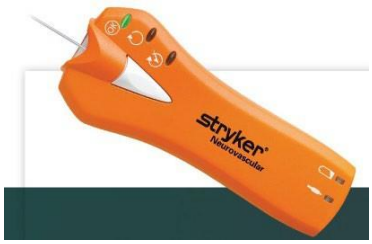
URGENT:
MEDICAL DEVICE RECALL – REMOVAL
Recall Number: RA2026-4297377

InZone Detachment System



Attn: Supply Chain Management/ Recall Coordinator/ Inventory Manager
Date: April 2, 2026

Stryker Neurovascular has initiated a Voluntary Medical Device Recall – Removal on **certain lots** of InZone Detachment System devices. Our records indicate that you have been supplied with the subject devices. **We therefore request that you read this notice carefully and complete the actions requested.**

Product Affected Affected product is listed in Attachment A (InZone Detachment System)

Product Description The InZone Detachment System is a sterile, handheld, single-patient-use device designed for use with Stryker Neurovascular detachable embolization coils. The device consists of an enclosure with a detachment button, four LED indicator lamps, and a funnel inset at its distal end. The device comes pre-loaded with two AAAA batteries. Stryker Neurovascular Detachable Coils are sold separately. For the specific intended use and indications for use of each type of Stryker Neurovascular Detachable Coil, consult the device Instructions for Use packaged with each device.

Product Issue Stryker Neurovascular has identified an issue affecting certain lots of InZone Detachment System devices. Stryker Neurovascular has observed that some devices may experience premature battery drain. When this occurs, the devices may:

- Not power on;
- Power on with faint audible and visual indicators;
- Be unable to detach a coil as intended.

Potential Harms The potential harms associated with the failure to detach the coil include:

• Increased time under anesthesia due to replacement of a defective InZone Detachment System with a backup device.

• Additional measures to safely complete the procedure if a replacement InZone Detachment System is not available, such as removing the coil or using an alternative endovascular or surgical approach.

To date, no patient injuries or deaths have been reported.

Type of Action Stryker Neurovascular has investigated and identified the issue which contributed to the premature battery drain noted with the InZone Detachment System devices. A corrective manufacturing step has been implemented. Replacement devices are available.

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Required Actions

1. Check your internal inventory for affected devices (Attachment A).
2. **Segregate the affected devices in a secure location for return to Stryker.**
3. **Complete the attached Business Reply Form.**
    - Completing this form will allow us to update our records and will also eliminate the need for us to send any further unnecessary communications on this matter.
4. Email the completed form to your local Stryker contact. Product Return and replacement information will be provided to you by your designated Stryker contact.
5. If any of the subject devices have been distributed to other organizations, please forward a copy of this notice to the new users and provide contact details to Stryker Neurovascular so new recipients can be informed appropriately.
6. Maintain awareness of this communication internally until all required actions have been completed within your facility.

Adverse reactions or quality problems experienced with the use of this product should be reported to your local Stryker contact.

Your designated contact person for this action is given below. Should you have any queries concerning this matter please do not hesitate to contact them directly.

Name: _____ Position:_____ email:_____

In line with the recommendations of the Meddev Vigilance Guidance Document Ref 2.12-1 and EU 2017/745, we can confirm that this FSCA has been notified appropriately to the National Competent Authority for your country.

On behalf of Stryker Neurovascular, we thank you sincerely for your help and support in completing this action and regret any inconvenience that may be caused.

Yours sincerely,

Subashiny Prabakaran
Senior RAQA Specialist |ASEAN NV
Stryker Corporation, Malaysia
P: +6010-3794246

Business Reply Form

FSCA identifier: RA 2026-4297377

Account number:
Account name:
Account Address:

Product: InZone Detachment System

Please choose the most appropriate box below and fill out the corresponding table(s):

☐ I no longer have any affected product listed on Attachment A.

☐ I am returning the following unused devices from Attachment A.

☐ I further distributed the devices listed and will forward a copy of this notice to the new users. I will also notify Stryker of the devices' new location.

Catalog Number	GTIN	Product Description	Quantity on Hand	Affected Lot Numbers
M00345100950	04546540697950	INZONE DETACHMENT SYSTEM		

**Stryker assumes that you are sending all unused devices, and other devices are deemed to be used or thrown away at your account.*

I have received the notification from Stryker Neurovascular stating that they have initiated a product field action for the above referenced product, and I acknowledge receipt and review of this URGENT MEDICAL DEVICE Recall - Removal.

Please return this signed and dated form to **your local Stryker representative.**

Note: Your signature indicates that you have received and understand the enclosed notification.

Printed name _____ Title _____

Contact phone number _____ Signature _____ Date _____

Email address _____ Phone Number _____

Attachment A
Recall – Removal InZone

Catalog number	GTIN	Product description
M00345100950	04546540697950	INZONE DETACHMENT SYSTEM

#	Lot number	Expiration Date	Transaction ID	Transaction Date	Qty received	Qty on hand
1	WMP133871	17/10/2026	5209074202	16/1/2025	3	
2	WMP133871	17/10/2026	5209074199	16/1/2025	3	
3	WMP133871	17/10/2026	5209074201	16/1/2025	34	
4	WMP134940	11/12/2026	5413929557	11/6/2025	20	
5	WMP136200	27/2/2027	5518109125	28/8/2025	22	