URGENT:

UPDATE MEDICAL DEVICE RECALL – REMOVAL

Recall Number: RA2026-4297377



Please read the message below before proceeding to the recall notice.

Stryker Neurovascular is providing an update to the InZone™ Detachment System recall initiated in April 2026. This update continues the recall by including additional affected lot numbers. Please review the attached list of affected lot numbers to determine whether any product at your facility is impacted.

This notification completes Stryker Neurovascular's planned, phased communication of the affected product scope.

Stryker Neurovascular appreciates your prompt attention and continued cooperation.

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InZone Detachment System



Attn: Supply Chain Management/ Recall Coordinator/ Inventory Manager
Date: XXXXX, 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

Catalog Number	UDI DI	Product Description	Impacted lots
M00345100950	08858250000263RM	INZONE DETACHMENT SYSTEM	Listed in Attachment A

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.

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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.

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.
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 Medical Device Coordination Group Guidance document ref MDCG 2023-3 rev 2 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,

Business Reply Form

FSCA identifier: RA2026-4297377

Account number: Click or tap here to enter text.
Account name: Click or tap here to enter text.
Account Address: Click or tap here to enter text.

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 Neurovascular of the devices' new location.

Refer to Attachment A (Page 4) for the list of affected lot numbers

Catalog Number	UDI DI	Product Description	Quantity on Hand	Affected Lot Numbers
M00345100950	08858250000263RM	INZONE DETACHMENT SYSTEM		

**Stryker assumes that you are sending all unused devices, and other devices are deemed to be used or disposed 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 _____

Attachment A

InZone – Affected lots

Click or tap here to enter text.

Catalog number	UDI DI	Product description
M00345100950	08858250000263RM	INZONE DETACHMENT SYSTEM

Catalog Number	Product Description	Impacted lots
M00345100950	INZONE DETACHMENT SYSTEM	**WMP137431**
M00345100950	INZONE DETACHMENT SYSTEM	**WMP137432**
M00345100950	INZONE DETACHMENT SYSTEM	**WMP137459**
M00345100950	INZONE DETACHMENT SYSTEM	**WMP137460**
M00345100950	INZONE DETACHMENT SYSTEM	**WMP137484**
M00345100950	INZONE DETACHMENT SYSTEM	**WMP137513**
M00345100950	INZONE DETACHMENT SYSTEM	**WMP137537**
M00345100950	INZONE DETACHMENT SYSTEM	**WMP137553**
M00345100950	INZONE DETACHMENT SYSTEM	**WMP137578**
M00345100950	INZONE DETACHMENT SYSTEM	**WMP137579**
M00345100950	INZONE DETACHMENT SYSTEM	**WMP137600**
M00345100950	INZONE DETACHMENT SYSTEM	**WMP137646**
M00345100950	INZONE DETACHMENT SYSTEM	**WMP137688**
M00345100950	INZONE DETACHMENT SYSTEM	**WMP137997**
M00345100950	INZONE DETACHMENT SYSTEM	**WMP138019**
M00345100950	INZONE DETACHMENT SYSTEM	**WMP138045**
M00345100950	INZONE DETACHMENT SYSTEM	**WMP138093**
M00345100950	INZONE DETACHMENT SYSTEM	**WMP138094**
M00345100950	INZONE DETACHMENT SYSTEM	**WMP138131**
M00345100950	INZONE DETACHMENT SYSTEM	**WMP138349**
M00345100950	INZONE DETACHMENT SYSTEM	**WMP138350**
M00345100950	INZONE DETACHMENT SYSTEM	**WMP138403**
M00345100950	INZONE DETACHMENT SYSTEM	**WMP138458**
M00345100950	INZONE DETACHMENT SYSTEM	**WMP138486**
M00345100950	INZONE DETACHMENT SYSTEM	**WMP138889**
M00345100950	INZONE DETACHMENT SYSTEM	**WMP138953**
M00345100950	INZONE DETACHMENT SYSTEM	**WMP138995**
M00345100950	INZONE DETACHMENT SYSTEM	**WMP139032**
M00345100950	INZONE DETACHMENT SYSTEM	**WMP139034**
M00345100950	INZONE DETACHMENT SYSTEM	**WMP139070**
M00345100950	INZONE DETACHMENT SYSTEM	**WMP139778**
M00345100950	INZONE DETACHMENT SYSTEM	**WMP139779**
M00345100950	INZONE DETACHMENT SYSTEM	**WMP139882**
M00345100950	INZONE DETACHMENT SYSTEM	**WMP139883**
M00345100950	INZONE DETACHMENT SYSTEM	**WMP139923**
M00345100950	INZONE DETACHMENT SYSTEM	**WMP139925**

Catalog Number	Product Description	Impacted lots
M00345100950	INZONE DETACHMENT SYSTEM	**WMP140096**
M00345100950	INZONE DETACHMENT SYSTEM	**WMP140160**
M00345100950	INZONE DETACHMENT SYSTEM	**WMP140161**
M00345100950	INZONE DETACHMENT SYSTEM	**WMP140201**
M00345100950	INZONE DETACHMENT SYSTEM	**WMP140266**
M00345100950	INZONE DETACHMENT SYSTEM	**WMP140298**
M00345100950	INZONE DETACHMENT SYSTEM	**WMP140595**
M00345100950	INZONE DETACHMENT SYSTEM	**WMP140655**
M00345100950	INZONE DETACHMENT SYSTEM	**WMP140726**
M00345100950	INZONE DETACHMENT SYSTEM	**WMP140758**
M00345100950	INZONE DETACHMENT SYSTEM	**WMP140779**
M00345100950	INZONE DETACHMENT SYSTEM	**WMP140835**
M00345100950	INZONE DETACHMENT SYSTEM	**WMP140862**
M00345100950	INZONE DETACHMENT SYSTEM	**WMP140901**
M00345100950	INZONE DETACHMENT SYSTEM	**WMP140925**
M00345100950	INZONE DETACHMENT SYSTEM	**WMP141023**
M00345100950	INZONE DETACHMENT SYSTEM	**WMP141050**
M00345100950	INZONE DETACHMENT SYSTEM	**WMP141163**
M00345100950	INZONE DETACHMENT SYSTEM	**WMP141248**
M00345100950	INZONE DETACHMENT SYSTEM	**WMP141279**
M00345100950	INZONE DETACHMENT SYSTEM	**WMP141309**
M00345100950	INZONE DETACHMENT SYSTEM	**WMP141385**
M00345100950	INZONE DETACHMENT SYSTEM	**WMP141485**
M00345100950	INZONE DETACHMENT SYSTEM	**WMP141486**
M00345100950	INZONE DETACHMENT SYSTEM	**WMP141912**
M00345100950	INZONE DETACHMENT SYSTEM	**WMP142145**
M00345100950	INZONE DETACHMENT SYSTEM	**WMP142170**
M00345100950	INZONE DETACHMENT SYSTEM	**WMP142244**
M00345100950	INZONE DETACHMENT SYSTEM	**WMP142314**
M00345100950	INZONE DETACHMENT SYSTEM	**WMP142331**
M00345100950	INZONE DETACHMENT SYSTEM	**WMP142587**
M00345100950	INZONE DETACHMENT SYSTEM	**WMP142648**
M00345100950	INZONE DETACHMENT SYSTEM	**WMP142649**
M00345100950	INZONE DETACHMENT SYSTEM	**WMP142665**
M00345100950	INZONE DETACHMENT SYSTEM	**WMP142777**
M00345100950	INZONE DETACHMENT SYSTEM	**WMQ003560**