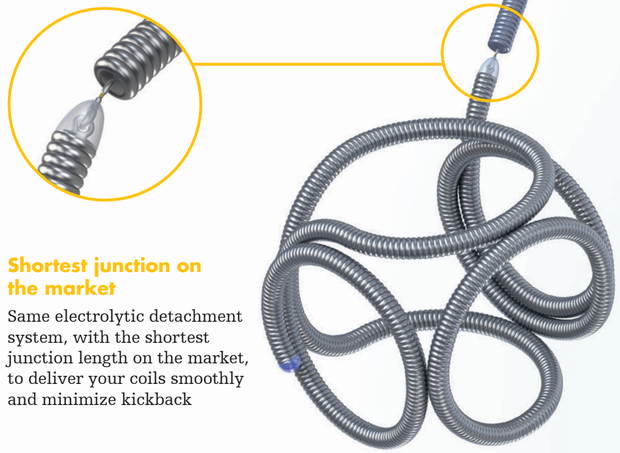
stryker

InZone®
Detachment System

The smarter **InZone® Detachment System***

Improved user experience in detaching

Target®
Detachable Coils



Shortest junction on the market

Same electrolytic detachment system, with the shortest junction length on the market, to deliver your coils smoothly and minimize kickback

The only detachment device that is designed to:

- Offer information interactive technology
- Detect if the coil is likely detached when the cycle is complete†

† Verify under fluoroscopy that the coil has detached by slowly pulling back on the delivery wire and monitoring the fluoro image to make sure the coil does not move
* Compared to previous version

Designed for:

Higher detachment rate

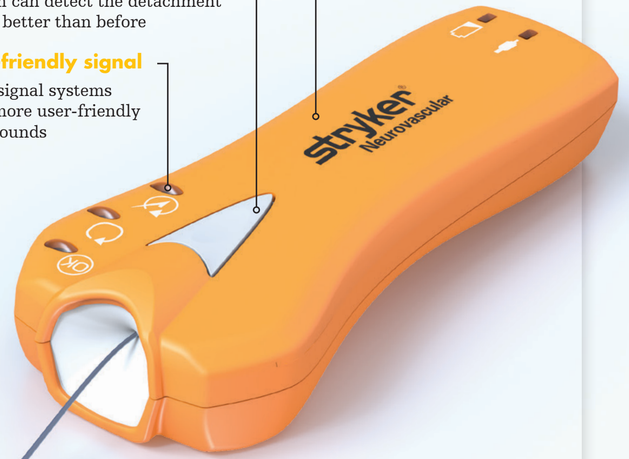
InZone Detachment System can smartly monitor the detachment status and optimize the current flow time to detach coils with one attempt for most cases

Improved signal accuracy

The smarter InZone Detachment System can detect the detachment status better than before

User-friendly signal

Same signal systems with more user-friendly beep sounds



LED summary

	**System ready**	Solid green 1 beep	Ready to detach
	**Current flow**	Solid green No sound	Current flowing
	**Cycle complete**	Solid green 3 short beeps	Detachment likely signal†
		Flashing green 1 long beep	Non-detachment likely signal†
	**Low battery**	Flashing yellow No sound	System battery is low (Replace device)

How to use

Detachment preparation

- Slide the InZone Detachment System funnel over the proximal end of the delivery wire until the wire is completely inserted

Detachment activation

- Once the system ready light is on, press and release the detachment button to begin the detachment process
- While current is flowing, the current flow indicator will illuminate solid green

Detachment cycle complete

- The cycle complete indicator will illuminate green when InZone Detachment System detects the cycle is complete
- Always check under fluoro after the cycle is complete

Detachment tips

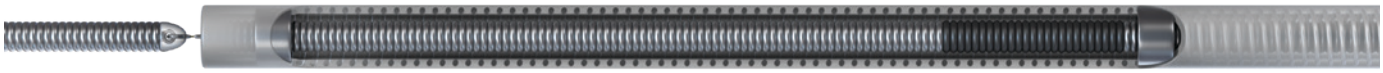
- Check the detachment status after every completed cycle.
- The electrolytic detachment system needs a favorable electrolytic environment.
- Remember the acronym **F.A.T.:**

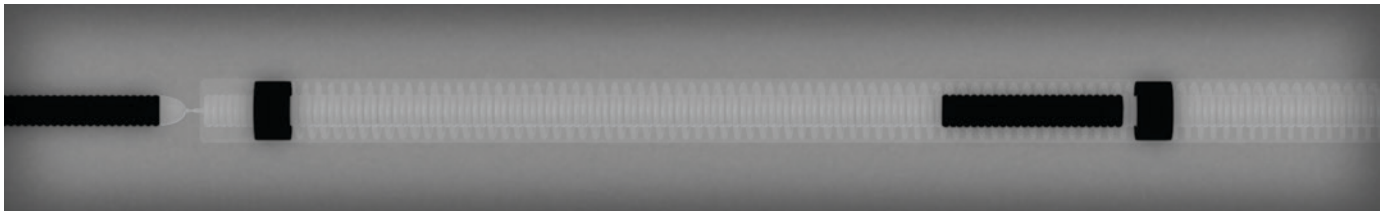
F

Check the flush line
It is critical that a continuous infusion of appropriate flush solution be maintained.

A

Align properly
This is the ideal alignment practice when the proximal marker of the delivery wire is just beyond the proximal marker of the 2-tip microcatheter.





T

Thrombus removal
Continuous flush can reduce the potential for thrombus formation.

Product package

New design with a corner flag
New serial number starts with T
Same product number (451009-5)

SN Serial Number T123456

Description	Product number
InZone Detachment System	451009-5

InZone Detachment System

See package insert for complete indications, contraindications, warnings and instructions for use.

RX ONLY

Indications for use

The InZone Detachment System is intended for use with all versions of Stryker Neurovascular detachable coils in the embolization of intracranial aneurysms and other vascular malformations of the neuro and peripheral vasculature.

Contraindications

None known.

Potential adverse events

No adverse events are associated with the use of the InZone Detachment System as a stand alone device. Failure to detach might result in prolongation of the procedure or additional intervention. Refer to Stryker Neurovascular Detachable Coil Directions for Use for adverse events associated with the use of Stryker Neurovascular detachable coils. Please be aware that potential adverse effects may arise even with the proper use of medical devices. Accordingly, this device should only be used by persons qualified in the procedures for which it is indicated.

Please notify your Stryker Neurovascular representative immediately if a device malfunctions or patient complication or injury is experienced or suspected associated with the use of this device. Please make every attempt to retain any suspect device, its associated components and their packaging for return to Stryker Neurovascular.

Warnings

Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Stryker Neurovascular representative.

- For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.
- After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.
- This device should only be used by physicians who have received appropriate training in interventional neuroradiology or interventional radiology and preclinical training on the use of this device as established by Stryker Neurovascular.
- The InZone Detachment System can only be used with Stryker Neurovascular detachable coils (Target and GDC) and the IZDS Connecting Cable. DO NOT SUBSTITUTE any components or devices from other manufacturers or injury to the patient or user could result.
- Advancing the coil delivery wire beyond the microcatheter tip once the coil has detached may increase the risk of aneurysm or vessel rupture.
- Sliding the detachment system with too much force or failing to tighten the microcatheter RHV prior to detachment may cause the delivery wire to kink or result in displacement of the coil and/or microcatheter tip in the vessel, which could lead to failed detachment, suboptimal coil position postdetachment, vessel perforation, aneurysm perforation, pseudoaneurysm, or aneurysm rupture. Do not advance the InZone Detachment System over the coil delivery wire against significant resistance.
- After use, the InZone Detachment System (excluding packaging) should be handled and processed as biohazardous material. After use, dispose of the InZone Detachment System unit in accordance with hospital, administrative, and/or local government policy for the handling, processing, and disposal of biohazardous materials. Dispose of packaging, delivery wires, introducer sheaths, IZDS Connecting Cable (UPN M00345110250, if applicable), and needle (if applicable) in accordance with hospital, administrative, and/or local government policy.
- The use of cables and/or other medical devices other than the IZDS Connecting Cable specified may result in increased emissions or decreased immunity of the InZone Detachment System.
- The InZone Detachment System should not be used adjacent to or stacked with other equipment; if adjacent or stacked use is necessary, the InZone Detachment System should be observed to verify normal operation in the configuration in which it will be used.
- No modification of the equipment is allowed.

Cautions

- Federal Law (USA) restricts this device to sale by or on the order of a physician.
- Prior to beginning a procedure, confirm that there are enough detachment systems on the shelf to complete the anticipated number of detachments required. In addition, one extra InZone Detachment System is required as backup for all procedures. Verify that the InZone Detachment Systems to be used are within their indicated shelf life.
- One extra IZDS Connecting Cable (UPN M00345110250) and sterile 20- or 22-gauge uncoated stainless steel hypodermic needle are required as backup for all procedures using the InZone Detachment System to detach GDC Detachable Coils. Verify that the cables and needles to be used are within their indicated shelf life.
- While it is essential to sufficiently tighten the microcatheter RHV around the coil delivery wire prior to using the InZone Detachment System, over-tightening the RHV could cause the delivery wire to kink.
- Batteries are pre-loaded into the InZone Detachment System. Do not attempt to replace batteries or open the enclosure.
- Increased detachment times may occur when:
  - Other embolic agents are present.
  - Detachment zone is in contact with the coil mass.
  - Delivery wire and microcatheter markers are not properly aligned.
  - Thrombus is present on the coil detachment zone.
  - The IZDS Connecting Cable has been resterilized. The IZDS Connecting Cable is supplied for one use only and should be discarded after each procedure (Only applicable when detaching GDC Detachable Coils).
- If device is set down, take care to gently place it in a stable position so that it does not slide off of the delivery wire during detachment. If device is held, take care to gently hold it in a stable position so that it does not slide off of the delivery wire during detachment.
- In some ECG equipment, perturbations may be observed immediately before illumination of the CYCLE COMPLETE indicator on the InZone Detachment System.
- Because coils are not always detached following completion of a cycle, ALWAYS verify under fluoroscopy that the coil has detached by slowly pulling back on the delivery wire while monitoring the fluoro image to make sure there is no movement of the coil. In the unlikely event the coil moves (indicating it is still attached to the delivery wire), check and adjust the flush system, flush the system to clear any contrast that may exist around the detachment zone, check and adjust the grounding setup (only applicable when detaching GDC Detachable Coils), realign the delivery wire with the microcatheter, tighten the RHV, and repeat the detachment procedure.
- Needle must not be coated.
- If the patient experiences pain at the site of the needle, or if detachment times are increasing, replace the needle with a new needle at a new insertion site.
- The IZDS Connecting Cable is intended for single patient use only. Do not resterilize and/or reuse. Resterilization could corrode the connecting cable, resulting in increased detachment times.
- Disconnection or poor connection of any part of the grounding setup after the detachment system indicates SYSTEM READY may result in an inability to detach GDC Detachable Coils.
- The safety and performance characteristics of the InZone Detachment System when used with another manufacturer's devices (whether coils, coil delivery devices, catheters, guidewires and/or other accessories), have NOT been established. Due to the potential incompatibility of non-Stryker Neurovascular components with the InZone Detachment System, the use of another manufacturer's device(s) with the InZone Detachment System is not recommended.
- The InZone Detachment System needs special precautions regarding EMC. Use of the InZone Detachment System should be according to the EMC information provided within the Directions for Use.
- Portable and mobile RF communications equipment may affect the performance of the InZone Detachment System.

This document is intended solely for the use of healthcare professionals.

A physician must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. Stryker does not dispense medical advice and recommends that physicians be trained in the use of any particular product before using it in a procedure. The information presented is intended to demonstrate the breadth of Stryker product offerings. A physician must always refer to the package insert, product label and/or instructions for use before using any Stryker product. Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your Stryker representative if you have questions about the availability of Stryker products in your area.

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NZ **New Zealand Sponsor Address**
Stryker New Zealand Ltd
PO Box 17136
Greenlane 1546
Auckland
New Zealand

AUS **Australian Sponsor Address**
Stryker Australia Pty Ltd
8 Herbert Street
St Leonards, NSW 2065
Australia

Stryker Neurovascular
47900 Bayside Parkway
Fremont, CA 94538

stryker.com

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