Target Detachable Coil

RX ONLY

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

Intended use / indications for use

Target Detachable Coils are intended to endovascularly obstruct or occlude blood flow in vascular abnormalities of the neurovascular and peripheral vessels. Target Detachable Coils are indicated for endovascular embolization of:

• Intracranial aneurysms
• Other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae
• Arterial and venous emboliations in the peripheral vasculature

Contraindications

None known.

Potential adverse events

Potential complications include, but are not limited to: allergic reaction, aneurysm perforation and rupture, arrhythmia, death, edema, embolus, headache, hemorrhage, infection, ischemia, neurological/ intracranial sequelae, post-embolization syndrome (fever, increased white blood cell count, discomfort), TIA/stroke, vasospasm, vessel occlusion or closure, vessel perforation, dissection, trauma or damage, vessel rupture, vessel thrombosis. Other procedural complications including but not limited to: anesthetic and contrast media risks, hypotension, hypertension, access site complications.

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. Do not reprocess or resterilize.
• MR temperature testing was not conducted in arteriovenous malformations or fistulae models.
• The safety and performance characteristics of the Target Detachable Coil System (Target Detachable Coils, InZone Detachment Systems, delivery systems and accessories) have not been demonstrated with other manufacturer’s devices (whether coils, coil delivery devices, coil detachment systems, catheters, guidewires, and/or other accessories). Due to the potential incompatibility of non Stryker Neurovascular devices with the Target Detachable Coil System, the use of other manufacturer’s device(s) with the Target Detachable Coil System is not recommended.
• To reduce risk of coil migration, the diameter of the first and second coil should never be less than the width of the ostium.
• In order to achieve optimal performance of the Target Detachable Coil System and to reduce the risk of thromboembolic complications, it is critical that a continuous infusion of appropriate flush solution be maintained between a) the femoral sheath and guiding catheter, b) the 2-tip microcatheter and guiding catheter, and c) the 2-tip microcatheter and Stryker Neurovascular guidewire and delivery wire. Continuous flush also reduces the potential for thrombus formation on, and embolization of infarct around, the detachment zone of the Target Detachable Coil.
• Do not use the product after the “Use By” date specified on the package.

Cautions / precautions

• Federal Law (USA) restricts this device to sale by or on the order of a physician.
• Besides the number of InZone Detachment System units needed to complete the case, there must be an extra InZone Detachment System unit as back up.
• Removing the delivery wire without grasping the introducer sheath and delivery wire together may result in the detachable coil sliding out of the introducer sheath.
• Failure to remove the introducer sheath after inserting the delivery wire into the RHV of the microcatheter will interrupt normal infusion of flush solution and allow back flow of blood into the microcatheter.
• Some low level overhead light near or adjacent to the patient is required to visualize the fluoro-saver marker; monitor light alone will not allow sufficient visualization of the fluoro-saver marker.
• Advance and retract the Target Detachable Coil carefully and smoothly without excessive force. If unusual friction is noticed, slowly withdraw the Target Detachable Coil and examine for damage. If damage is present, remove and use a new Target Detachable Coil.
• If it is necessary to reposition the Target Detachable Coil, verify under fluoroscopy that the coil moves with a one-to-one motion. If the coil does not move with a one-to-one motion or movement is difficult, the coil may have stretched and could possibly migrate or break. Gently remove both the coil and microcatheter and replace with new devices.
• Increased detachment times may occur when:
  – Other embolic agents are present.
  – Delivery wire and microcatheter markers are not properly aligned.
  – Thrombus is present on the coil detachment zone.
• Do not use detachment systems other than the InZone Detachment System.