# stryker

Target Detachable Coils

# A trusted partner for the toughest cases

# The toughest cases require the strongest partnerships

When operating in uncertain times, it's good to have a partner you can trust. For the most difficult and urgent cases like ruptured aneurysms, we're right by your side.

By listening to leading interventionalists, we are continuously making our Target Coils better. Our products are designed for performance and always advancing based on the needs of your patients and the evolution of your practice.

For 10 years—and for countless reasons—we're an innovative partner you can trust.

## Timeline

Revolutionary, yesterday and today

Our legacy began in 1990, when GDC Coil—named after Dr. Guglielmi completely revolutionized the treatment of intracranial aneurysms. In 2010, we introduced Target Coil—the next chapter in the GDC story.



\*An estimated patient number based on internal data.

#### **Advancements**

Full coverage for every case

By listening to leading interventionalists, we create new advancements, giving you the functional benefits you expect.



#### **Softness**

The most softness levels on the market

As your trusted partner, we offer four levels of coil softness. With choices ranging from stability to softness, we'll help you handle your most challenging cases.



#### **Shapes**

Target Coils come in three different shapes

Our variety of shapes are designed to help you frame securely, fill uniformly and finish by seeking voids within the aneurysm.

#### Target 360 Coils

Target 3D Coils

#### **Target Helical Coils**







## **Shapes** Target 360 Coils

The gold standard in complex coil shape technology, the 360 shape provides uniform distribution, concentric filling and neck coverage.

#### **Open center**

The 360 shape is designed to seek the outer wall and leave an open center, allowing for concentric filling

### **2D distal loop**

The first 1.5 loops are 25% smaller than the stated secondary coil diameter, designed to reduce coil herniation

# **Open loop configuration**

Open loops conform to multiple aneurysm shapes while minimizing compartmentalization



#### **Shapes** Target 3D Coils

A complementary complex coil option offers a secure foundation for consistent framing.

#### 90 degree angles

The coil rotates 90 degrees at each small loop, creating a three-dimensional shape

### **Small loop**

The small loops add body to the coil and help maintain its shape

# Large loop

The large loops appose the vessel wall, providing stability within the aneurysm



# **Shapes** Target Helical Coils

A versatile shape for every case.

### **Helical shape**

Provide versatility to physicians with a wide range of sizes and softness to support every case for framing, filling, and finishing intracranial aneurysms and embolising vascular malformations



#### Diameters

Explore our primary diameters

Target XL Coils provide 2x more fill and 40% more width than Target 10-size Coils.

#### **Target 10-size**





# **2x the fill**





Advance and deploy with confidence

#### Smooth

- Consistent and smooth delivery
- Great tactile feedback

### **Stable**

- Exceptional microcatheter stability
- Maintain access from frame to finish



The Target Detachable Coil's short flexible junction is designed to deliver smoothly, minimizing kickback during coil delivery



#### **Smoothness enhanced**

The hybrid delivery wire features a balanced design of the proximal hypotube, and the distal coil optimizes flexibility and pushability to yield a one-to-one feel

From frame to finish, we have you covered

#### **Frame securely**

**Target 360 Coils** Open loop configuration conforms to different aneurysm shapes and minimizes compartmentalization



**Target 3D Coils** Alternating large and small loops create a stable frame



## **Fill uniformly**

Target 360 Coils are designed to seek the outer wall of the aneurysm and leave an open center to minimize compartmentalization



# **Finish softly**

Target Nano 360 Coils fill small spaces and conform to the final spaces within aneurysms



A decade of continuous improvement

We continuously improve our Target Coil technology, giving you an advanced coil for every case.

# Reinforced sheath

# Eases microcatheter insertion

- Provides greater stability
- 3.5x thicker
- Easily seats into the microcatheter hub

Previous sheath

Current sheath

#### Stronger proximal contact

#### Improves interaction with InZone Detachment System

- Provides greater stability
- Transition is 10x stronger
- Facilitates handling and insertion into the InZone Detachment System



Previous design: micro-welded together



#### Current design: tube over tube

#### Shorter detachment zone

#### Decreases detachment cycle time

- Shortens detachment zone (by 65%) by ablating less insulating material
- No changes to junction length







Current design (0.00085in)

Delivering solutions

Our improvements provide the tools for a variety of cases.

# Bi-lobe ACA aneurysm treated with Target Coils

No.

Images courtesy of Alessandro Pedicelli, MD

#### Small ruptured aneurysm in pericallosal treated with Target Coils





Images courtesy of Brian Jankowitz, MD

#### **Testimonial**

Here for you and the patients you save



#### You're there for your patients. And we're here for you.

Contact your sales representative or email us at <u>nvcustomercare@stryker.com</u> for more information.

#### **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 embolizations 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. 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.
- Patients with hypersensitivity to 316LVM stainless steel may suffer an allergic reaction to this implant.
- 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 crystallization of infusate around, the detachment zone of the Target Detachable Coil.

- Do not use the product after the "Use By" date specified on the package.
- Reuse of the packaging hoop or use with any coil other than the original coil may result in contamination of, or damage to, the coil.

Damaged delivery wires may cause detachment failures, vessel injury or unpredictable distal tip response during coil deployment. If a delivery wire is damaged at any point during the procedure, do not attempt to straighten or otherwise repair it. Do not proceed with deployment or detachment. Remove the entire coil and replace with undamaged product.

- Utilization of damaged coils may affect coil delivery to, and stability inside, the vessel or aneurysm, possibly resulting in coil migration and/or stretching.
- The fluoro-saver marker is designed for use with a Rotating Hemostatic Valve (RHV). If used without an RHV, the distal end of the coil may be beyond the alignment marker when the fluoro-saver marker reaches the microcatheter hub.
- If the fluoro-saver marker is not visible, do not advance the coil without fluoroscopy.
- Do not rotate delivery wire during or after delivery of the coil. Rotating the Target Detachable Coil delivery wire may result in a stretched coil or premature detachment of the coil from the delivery wire, which could result in coil migration.
- Verify there is no coil loop protrusion into the parent vessel after coil placement and prior to coil detachment. Coil loop protrusion after coil placement may result in thromboembolic events if the coil is detached.
- Verify there is no movement of the coil after coil placement and prior to coil detachment. Movement of the coil after coil placement may indicate that the coil could migrate once it is detached.

- Failure to properly close the RHV compression fitting over the delivery wire before attaching the InZone Detachment System could result in coil movement, aneurysm rupture or vessel perforation.
- Verify repeatedly that the distal shaft of the catheter is not under stress before detaching the Target Detachable Coil. Axial compression or tension forces could be stored in the 2-tip microcatheter causing the tip to move during coil delivery. Microcatheter tip movement could cause the aneurysm or vessel to rupture.
- Advancing the delivery wire beyond the microcatheter tip once the coil has been detached involves risk of aneurysm or vessel perforation.
- The long term effect of this product on extravascular tissues has not been established so care should be taken to retain this device in the intravascular space.

#### **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 friction or resistance is still noted, carefully remove the Target Detachable Coil and microcatheter and examine the microcatheter for damage.

 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.

 $\bullet$  Do not use detachment systems other than the InZone Detachment System.



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