

Target[®]
Detachable Coil

Directions for Use

2

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Target[®]

Detachable Coil

Rx ONLY

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

Carefully read all instructions prior to use. Observe all warnings and cautions noted throughout these instructions. Failure to do so may result in complications.

WARNING

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.

1. DEVICE DESCRIPTION

Target Detachable Coils are stretch resistant, electrolytically detachable coils consisting of a platinum-tungsten alloy coil attached to a stainless steel delivery wire.

Target Detachable Coils are specifically designed for use with Stryker Neurovascular's InZone[®] Detachment System, M00345100950 (sold separately).

Target Detachable Coils are compatible with Stryker Neurovascular 2-tip marker microcatheters (min. internal diameter 0.41 mm [0.016 in], max. internal diameter 0.48 mm [0.019 in]).

2. 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

3. CONTRAINDICATIONS

None known.

4. WARNINGS

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 catheters, 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.

5. CAUTIONS

- 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 (Figure 3) 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.
- Do not use detachment systems other than the InZone Detachment System, M00345100950.

5.1 Magnetic Resonance Imaging (MRI) Safety Information (Neurovascular Use)

Non-clinical testing and analysis have demonstrated the Target Detachable Coils are MR Conditional. A patient with this device can be safely scanned immediately after placement of the coils in an MR system meeting the following conditions:

- Static magnetic field of 3.0 T or less
- Maximum spatial gradient magnetic field of 2500 gauss/cm (25 T/m)
- Maximum MR system reported, head specific absorption rate (SAR) < 3.2 W/kg and whole body averaged SAR < 2 W/kg (Normal operating mode)

Under the scan conditions defined above, the Target Detachable Coils are expected to produce a maximum temperature rise of less than or equal to 4°C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 12 mm from the Target Detachable Coils when imaged with a gradient echo pulse sequence and a 3.0 T MRI system.

Target Detachable Coils are made from non-magnetic platinum-tungsten alloy and should not migrate in the magnetic field. The health state of the patient or the presence of other implants may require reduction of the MRI limits.

Magnetic Resonance Imaging (MRI) Safety Information (Peripheral Use)

Non-clinical testing and analysis have demonstrated the Target Detachable Coils are MR Conditional. A patient with this device can be safely scanned immediately after placement of the coils in an MR system meeting the following conditions:

- Static magnetic field of 3.0 T or less
- Maximum spatial gradient magnetic field of 2500 gauss/cm (25 T/m)
- Maximum MR system reported, head specific absorption rate (SAR) < 3.2 W/kg and whole body averaged SAR < 1 W/kg (Normal operating mode)

Under the scan conditions defined above, the Target Detachable Coils are expected to produce a maximum temperature rise of less than 7.4°C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 13 mm from the Target Detachable Coils when imaged with a gradient echo pulse sequence and a 3.0 T MRI system.

Target Detachable Coils are made from non-magnetic platinum-tungsten alloy and should not migrate in the magnetic field. The health state of the patient or the presence of other implants may require reduction of the MRI limits.

6. 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

7. CLINICAL USE INFORMATION

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.

7.1 Materials Recommended

Caution: Besides the number of InZone® Detachment System units needed to complete the case, there must be an extra InZone Detachment System unit as backup.

In addition to the Target® Detachable Coils and necessary InZone Detachment Systems, M00345100950 (one for backup), the following items are required:

- 5F (min. internal diameter 1.35 mm [0.053 in]) or 6F (min. internal diameter 1.63 mm [0.064 in]) non-tapered guiding catheter to facilitate Stryker Neurovascular 2-tip microcatheter access to the vessel
- Continuous flush setup with two rotating hemostatic valves (RHVs), three bags of appropriate flush, one 3-way stopcock, and one 1-way stopcock
- Stryker Neurovascular 2-tip marker microcatheters (min. internal diameter 0.41 mm [0.016 in], max. internal diameter 0.48 mm [0.019 in])
- Stryker Neurovascular 0.25 mm (0.010 in) or 0.36 mm (0.014 in) or 0.41 mm (0.016 in) steerable guidewire

7.2 Pre-procedure

Endovascular embolization should be done in an angiography procedure room. High quality, digital subtraction fluoroscopic road mapping is mandatory to achieve safe catheterization of the aneurysm or vessel and correct placement of the coils.

7.3 Preparation

Warning: 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.

7.3.1 Coil Size & Microcatheter Selection

Correct coil size increases Target Detachable Coil effectiveness and patient safety. Occlusive efficiency is, in part, a function of compactness and overall mass. In order to choose the appropriate coil size for a lesion, examine pre-embolization angiograms. The appropriate coil size should be chosen based upon angiographic assessment of the diameter of the vessel, aneurysm dome and/or ostium.

Warning: To reduce risk of coil migration, the diameter of the first and second coil should never be less than the width of the ostium.

7.3.2 Continuous Flush Setup

Warning: 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 catheters, 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.

1. Attach an RHV to the hub of the guiding catheter. Attach a 3-way stopcock to the side arm of the RHV and then connect a line for continuous infusion of appropriate solution.
2. Attach a second RHV to the hub of the 2-tip microcatheter. Attach a 1-way stopcock to the side arm of the RHV and then connect a line for continuous flushing of appropriate solution. One drop from the pressure bag every 3-5 seconds through an empty microcatheter is suggested.
3. Check that all fittings are secure so that air is not introduced into the guiding catheter or 2-tip microcatheter during continuous flush.

Prior to starting the procedure, confirm that there are enough InZone Detachment System units to complete the case plus one backup unit.

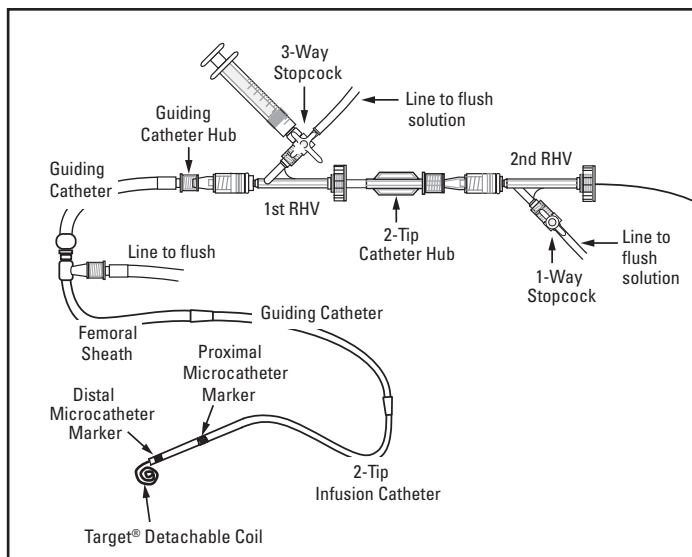


Figure 1. Continuous flush setup

7.3.3 Lesion Preparation

Carefully catheterize the lesion to be treated. The access system should include a guiding catheter of sufficient inner diameter (ID) to accept a 2-tip microcatheter and to permit adequate contrast infusion around the 2-tip microcatheter for fluoroscopic road mapping. Measure the size of the aneurysm to be treated and select an appropriately sized Target Detachable Coil.

7.3.4 Target Detachable Coil Preparation

1. Verify the packaging is intact. Do not use a Target Detachable Coil if packaging is damaged.

Warning: Do not use the product after the “Use By” date specified on the package.

2. Within the sterile field, open pouch containing the packaging hoop and remove the hoop from the pouch.
3. Locate the proximal end of the introducer sheath between the white wire retainer and orange sheath retainer.
4. Carefully grasp the wire and introducer sheath together and remove the delivery wire from the white wire retainer and orange sheath retainer, taking care not to kink the delivery wire (See Figure 2).

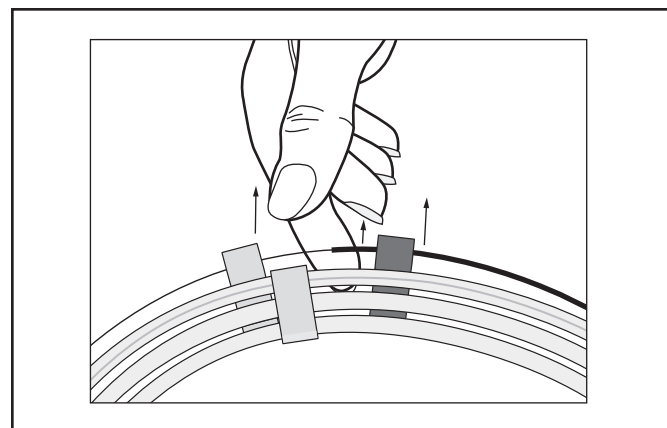


Figure 2. Carefully remove the Target Detachable Coil delivery wire and sheath together from retainers

5. While grasping the wire and introducer sheath together, slide the Target Detachable Coil straight out of the packaging hoop taking care not to damage the delivery wire (See Figure 2).

Warning: 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.

Caution: Removing the delivery wire without grasping the introducer sheath and delivery wire together (Figure 2) may result in the detachable coil sliding out of the introducer sheath.

7.4 Target Detachable Coil Delivery Procedure

1. Inspect the proximal section of the delivery wire for irregularities, such as kinks or roughness. If irregularities exist, replace with a new Target Detachable Coil.

Warning: 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.

Warning: Utilization of damaged coils may affect coil delivery to, and stability inside, the vessel or aneurysm, possibly resulting in coil migration and/or stretching.

- Open the RHV on the microcatheter and insert the tapered distal end of the introducer sheath through the RHV and into the hub of the 2-tip infusion microcatheter until the sheath is firmly seated. A slight buckling of the introducer sheath indicates proper positioning. Tighten the RHV around the introducer sheath to prevent the back flow of blood, but not so tight as to damage the coil during its introduction into the catheter.
- Transfer the Target® Detachable Coil into the catheter by advancing the coil delivery wire in a smooth, continuous motion. This procedure is best accomplished by two people, one to maintain the introducer sheath inside the RHV and 2-tip infusion catheter hub and one to hold the sheath straight and advance the coil.
- Insert the delivery wire until the proximal end of the delivery wire is 2 inches away from the proximal end of the introducer sheath.
- Loosen the RHV, hold the delivery wire in place and remove the introducer sheath over the delivery wire's proximal end making sure the coil does not come out with the sheath.

Caution: 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.

- Once completed, tighten the RHV around the delivery wire. Do not discard the introducer sheath until after the Target Detachable Coil has been positioned and detached.
- Visually verify that the flush solution is infusing normally. Once confirmed, loosen the RHV enough to advance the delivery wire, but not so much as to compromise the continuous infusion.
- Locate the fluoro-saver marker on the delivery wire.

Warning: 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.

Caution: 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.

Warning: If the fluoro-saver marker is not visible, do not advance the coil without fluoroscopy.

- Advance the coil through the microcatheter until the distal end of the fluoro-saver is flush with the proximal end of the RHV and turn on fluoroscopy.

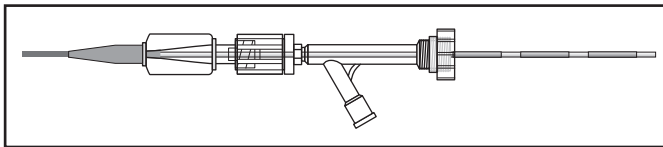


Figure 3. Fluoro-saver marker

- Advance the Target Detachable Coil under fluoroscopy and position carefully at the desired site. If the Target Detachable Coil placement is unsatisfactory, slowly withdraw by pulling on the delivery wire, and then slowly advance again to reposition the coil. If the coil size is inappropriate, remove and replace with appropriately sized coil (Section 7.3.1 Coil Size & Microcatheter Selection).

Caution: 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.

Caution: 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.

Warning: Do not rotate the delivery wire during or after delivery of the coil into the aneurysm. 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.

- Continue to advance the Target Detachable Coil until the radiopaque proximal marker on the delivery wire is exactly distal to the proximal marker on the 2-tip microcatheter (see Figure 4 below). Tighten the RHV to prevent movement of the delivery wire.

Caution: Increased detachment times may occur when delivery wire and microcatheter markers are not properly aligned.

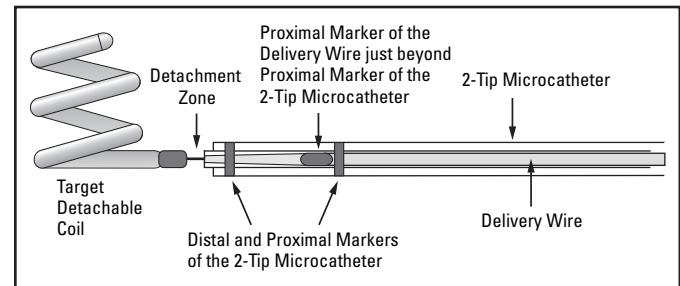


Figure 4. Optimal Alignment of Radiopaque Markers

Warning: 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.

12. After Target® Detachable Coil placement and prior to coil detachment, verify under fluoroscopy that the coil is not protruding into the parent vessel. If any coil protrusion can be seen, reposition the coil until there are no signs of coil protrusion. If the coil cannot be placed without protrusion, remove the coil and replace it with another more appropriately sized coil (one with a smaller secondary diameter).

Warning: 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.

13. After Target Detachable Coil placement and prior to coil detachment, verify under fluoroscopy that there is no undesirable movement of the coil. If any undesirable movement can be seen, remove the coil and replace it with another more appropriately sized coil (one with a larger secondary diameter).

Warning: 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.

7.5 Target Detachable Coil Detachment Procedure

Note: Refer to the InZone® Detachment System Directions for Use (available within InZone Detachment System packaging) for coil detachment instructions.

1. Proceed with detachment per instructions in the InZone Detachment System DFU.

Warning: 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.

Caution: Do not use detachment systems other than the InZone Detachment System, M00345100950.

Caution: 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.
-

2. Once cycle complete has been signaled, verify under fluoroscopy that the coil has detached by performing the following:

- Remove the InZone Detachment System from the delivery wire and loosen the microcatheter RHV.
 - Under fluoroscopy, slowly pull back on the delivery wire making sure that the coil does not move.
-

Warning: Advancing the delivery wire beyond the microcatheter tip once the coil has been detached involves risk of aneurysm or vessel perforation.

3. If the coil moves during delivery wire retraction, perform the following:

- Confirm that flush is set up properly
- Advance the delivery wire to reposition the coil and establish appropriate wire and microcatheter marker alignment.
- Tighten the RHV around the delivery wire

- Follow instructions in the InZone Detachment System DFU to detach the coil
- Verify coil separation under fluoroscopy as above. Repeat as necessary up to 4 times.
- If the coil does not detach after trying 4 times, remove the coil and replace it with a new Target Detachable Coil and repeat the steps outlined above (starting from Section 7.3.4).

4. Once coil detachment has been fluoroscopically confirmed, slowly withdraw the delivery wire from the microcatheter.

5. If additional coil placement is required, repeat the steps outlined above (starting from Section 7.3.4).

6. Once the procedure is over, discard any used materials, including the detachment system, and packaging.

Warning: 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.

Warning: After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

8. HOW SUPPLIED

Do not use if package is opened or damaged.

Do not use if labeling is incomplete or illegible.

Sterile: This device is sterilized and non-pyrogenic using an ethylene oxide (EO) process.

Contents: One (1) Target Detachable Coil.

Handling and Storage

Store in a cool, dry, dark place.

WARRANTY

Stryker Neurovascular warrants that reasonable care has been used in the design and manufacture of this instrument. **This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose.** Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond Stryker Neurovascular's control directly affect the instrument and the results obtained from its use. Stryker Neurovascular's obligation under this warranty is limited to the repair or replacement of this instrument and Stryker Neurovascular shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. Stryker Neurovascular neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. **Stryker Neurovascular assumes no liability with respect to instruments reused, reprocessed or resterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments.**



Catalog Number
Número de catálogo
Numéro de catalogue
Bestell-Nr.
Numero di catalogo
Catalogusnummer
Referência



Consult instructions for use.
Consultar las instrucciones de uso.
Consulter le mode d'emploi.
Gebruiksaanwijzing beachten.
Consultare le istruzioni per l'uso.
Raadpleeg instructies voor gebruik.
Consulte as Instruções de Utilização



Contents
Contenido
Contenu
Inhalt
Contenuto
Inhoud
Conteúdo



EU Authorized Representative
Representante autorizado en la UE
Représentant agréé UE
Autorisierter Vertreter in der EU
Rappresentante autorizzato per l'UE
Erkend vertegenwoordiger in EU
Representante Autorizado na U.E.



Legal Manufacturer
Fabricante legal
Fabricant légal
Berechtigter Hersteller
Fabbricante legale
Wettelijke fabrikant
Fabricante Legal



Lot
Lote
Lot
Charge
Lotto
Partij
Lote



Product Number
Número del producto
Référence
Produktnummer
Codice prodotto
Productnummer
Número do Produto



Recyclable Package
Envase reciclable
Emballage recyclable
Wiederverwertbare Verpackung
Confezione riciclabile
Recyclebare verpakking
Embalagem Reciclável



Use By
Fecha de caducidad
Date limite d'utilisation
Verwendbar bis
Usare entro
Uiterste gebruiksdatum
Validade



Australian Sponsor Address
Dirección del patrocinador australiano
Adresse du promoteur australien
Adresse des australischen Sponsors
Indirizzo sponsor australiano
Adres Australische sponsor
Endereço do Patrocinador Australiano



For single use only. Do not reuse.
Para un solo uso. No reutilizar.
À usage unique. Ne pas réutiliser.
Für den einmaligen Gebrauch. Nicht wieder verwenden.
Esclusivamente monouso. Non riutilizzare.
Uitsluitend bestemd voor eenmalig gebruik. Niet opnieuw gebruiken.
Apenas para uma única utilização. Não reutilize.



Do Not Resterilize
No reesterilizar
Ne pas restériliser
Nicht erneut sterilisieren
Non riesterilizzare
Niet opnieuw steriliseren
Não reesterilize



Do not use if package is damaged.
No usar si el envase está dañado.
Ne pas utiliser si l'emballage est endommagé.
Bei beschädigter Verpackung nicht verwenden.
Non usare il prodotto se la confezione è danneggiata.
Niet gebruiken als de verpakking is beschadigd.
Não utilize se a embalagem estiver danificada.



Magnetic Resonance Conditional
Resonancia magnética, condicional
Résonance magnétique - Sous réserve
Magnetresonanz, bedingt
Risonanza magnetica - Con riserva
MRI-veilig onder bepaalde voorwaarden
Ressonância magnética - utilização condicional



Sterilized using ethylene oxide.
Esterilizado por óxido de etileno.
Stérilisé à l'oxyde d'éthylène.
Mit Ethylenoxid sterilisiert.
Sterilizzato con ossido di etilene.
Gesteriliseerd met ethyleenoxide.
Esterilizado por óxido de etileno.



**Australian
Sponsor Address**

Stryker Australia Pty Ltd
8 Herbert Street
St Leonards, NSW 2065
Australia



**Legal
Manufacturer**

Stryker Neurovascular
47900 Bayside Parkway
Fremont, CA 94538
USA
USA Customer Service 855-91 NEURO (916-3876)



**Do not use if package
is damaged.**



**Recyclable
Package**

CE 0086

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2016-07



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