

The logo for Nexus, featuring the word "nexus" in a lowercase, italicized, sans-serif font. The letters are white with a thin black outline. To the right of the text is a decorative graphic consisting of several overlapping, curved, metallic-looking bands that resemble a spring or a coil, rendered in shades of gray.

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## Nexus™ Detachable Coils

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# Nexus™ Detachable Coils

## Instructions for use

### CAUTION

- Federal (USA) law restricts this device to sale, distribution, and use by or on the order of a physician.
- This device should be used only by physicians with a thorough understanding of angiography and percutaneous neurointerventional procedures.



It is important to read the instructions for use with careful attention to cautions, notes and warnings prior to using this product.

STERILE EO

STERILE: This device is sterile and non-pyrogenic. Sterilized using ethylene oxide gas. Do not use if sterile packaging has been compromised or damaged.



This device is intended for SINGLE USE ONLY.  
**DO NOT RESTERILIZE AND/OR REUSE.**

LOT

Lot Number

REF

Catalog Number



Use By Date



Maximum Storage Temperature is 50° C (122° F)

### DESCRIPTION OF DEVICE

The Nexus™ Detachable Coil are platinum alloy coils, enlaced with absorbable polymer microfilaments attached to a stainless steel guiding system with a radiopaque positioning coil. Nexus™ Detachable Coils are designed for use with the Detachment System, specifically designed for coil detachment. The Detachment System is sold separately.

### DEVICE COMPATIBILITY

The following devices are required for use with the Nexus™ Detachable Coil:

- 0.010" Coil Size - Nexus™ Coils should only be delivered through 0.010" Type microcatheter with two marker bands.
- Detachment System

Other accessory products (required to perform a procedure)

6-8F Guide Catheter\*  
Microcatheter (see above)\*  
Guidewires compatible with microcatheter\*  
Continuous saline/heparin saline flush set\*  
Rotating haemostatic valves (RHV)\*  
3-Way stopcock\*  
1-Way stopcock\*  
IV pole\*  
Femoral Sheath\*  
20 or 22 gauge sterile needle\*  
9 V Alkaline Battery\*

\*Not provided as part of the system, chosen based upon physician experience and preference

### INDICATIONS FOR USE

The Nexus™ Detachable Coils are intended for the endovascular embolization of intracranial aneurysms that – because of their morphology, their location, or the patient's general medical condition – are considered by the treating neurosurgical team to be a) very high risk for management by traditional operative techniques, or b) be inoperable. The Nexus™ Detachable Coils are also intended for the embolization of other neurovascular abnormalities, such as arteriovenous malformations and arteriovenous fistulae.

### POTENTIAL COMPLICATIONS

Potential complications include, but are not limited to:

- Puncture site hematoma
- Vessel perforation
- Vasospasm
- Hemorrhage
- Thromboembolic episodes
- Neurological deficits including stroke and possibly death
- Vascular thrombosis
- Ischemia

## WARNING

The Nexus™ Detachable Coil, the dispenser coil, and the introducer sheath are supplied in a sterile and non-pyrogenic, unopened and undamaged package. The package should be checked for potential damage. Damaged Nexus™ Detachable Coils must not be used, as it may result in patient injury.

The Nexus™ Detachable Coils are intended for one use only. After use do not resterilize and/or 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 sterilize Detachment System.

Do not use if sterile packaging has been compromised or damaged.

Increased detachment times may occur if the end of guiding system and the proximal marker band are not aligned properly.

Damaged guiding system and/or coils may affect coil delivery to, and stability inside, the vessel or aneurysm, possibly resulting in coil migration or stretching.

Do not rotate the guiding system during or after delivery of the coil into the aneurysm. Rotating the guiding system during or after coil delivery into the aneurysm may result in a stretched coil or premature detachment of the coil from the guiding system, which could result in coil migration.

Verify that the distal shaft of the microcatheter is not under stress before Nexus™ Detachable Coil detachment. Axial compression or tensile forces could be stored in the microcatheter causing the tip to move during Nexus™ Detachable Coil delivery. Microcatheter tip movement could cause the aneurysm or vessel to rupture.

Advancing the guiding system beyond the microcatheter tip once the coil has been deployed and detached involves risk of aneurysm or vessel perforation.

**If undesirable movement of the Nexus™ Detachable Coil can be seen under fluoroscopy following coil placement and prior to detachment, remove the coil and replace with another more appropriately sized Nexus™ Detachable Coil. Movement of the coil may indicate the coil could migrate once it is detached. Angiographic controls should also be performed prior to detachment to ensure that the coil mass is not protruding into the parent vessel.**

Do not use power sources other than the battery operated power supply, the Detachment System, specifically built for Nexus™ Detachable Coils.

High quality, digital subtraction **fluoroscopic road mapping is mandatory** to achieve safe catheterization of the aneurysm or vessel and correct placement of the first coil. *With smaller aneurysms this is particularly important.*

If Nexus™ Detachable Coil repositioning is necessary, take special care to retract coil under fluoroscopy in a one-to-one motion with the guiding system. If the coil does not move with a one-to-one motion, or repositioning is difficult, the coil has been stretched and could possibly break. Gently remove and discard both the catheter and coil.

Due to the delicate nature of the Nexus™ Detachable Coil, the tortuous vascular pathways that lead to certain aneurysms and vessels, and the varying morphologies of intracranial aneurysms, a coil may occasionally stretch while being maneuvered. Stretching is a precursor to potential malfunctions such as coil breakage and migration.

If resistance is encountered while withdrawing a Nexus™ Detachable Coil, which is at an acute angle relative to the catheter tip, it is possible to avoid coil stretching or breaking by carefully repositioning the distal tip of the catheter at the ostium of the aneurysm, or just slightly inside the parent artery.

Take care not to puncture gloves or sterile drape while handling guiding system.

Multiple embolization procedures may be required to achieve the desired occlusion of some aneurysms or vessels.

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.

## PRECAUTIONS

Handle the Nexus™ Detachable Coil with care to avoid damage before or during treatment.

Do not advance the Nexus™ Detachable Coil against a noted resistance until the cause of the resistance is cleared by fluoroscopy. This may lead to the destruction of the coil and/or catheter or perforation of the vessel.

It is essential to confirm catheter compatibility of the Nexus™ Detachable Coil. The outer diameter of the Nexus™ Detachable Coil should be checked to ensure that the coil will not block the catheter.

The dispenser coil and the introducer sheath are not intended to make contact within the patient.

Do not use the Nexus™ Detachable Coil after the expiration date printed on the product label.

In order to achieve optimal performance of the Nexus™ Detachable Coil and to reduce the risk of thromboembolic complications, it is critical that a continuous infusion of appropriate flush solution be maintained.

Advance and retract Nexus™ Detachable Coils slowly and smoothly, especially in tortuous anatomy. Remove the coil if unusual friction or "scratching" is noted. If friction is noted in a second coil, carefully examine both the coil and the catheter for possible damage such as catheter shaft buckling or kinking, or improperly fused joint.

Do not advance the coil with force if the coil becomes lodged within or outside microcatheter.

Determine the cause of resistance and remove the system when necessary. If resistance is encountered when withdrawing the guiding system, draw back on the infusion catheter simultaneously until the delivery wire can be removed without resistance.

If resistance is noted during coil delivery, remove the system and check for possible damage to the catheter.

## STORAGE

Store products in a cool, dry place with the maximum storage temperature not exceeding 50° C (122° F). A temperature indicator is located on each unit box and pouch. If the product is exposed to temperatures greater than 50° C (122° F), the temperature indicator on the box and/or pouch will change to red.

## WARNING

Do not use the product if the temperature indicator on either the pouch or the carton box is red. A red indicator means the product has been exposed to tem-

perature greater than 50° C (122° F). Use of the product which has been exposed to temperature greater than 50° C (122° F), may compromise patient safety.

## PREPARATIONS FOR USE

1. In order to achieve optimal performance of the Nexus™ Detachable Coil and to reduce the risk of thromboembolic complication, it is advised that a continuous saline flush be maintained between a) the femoral sheath and the guiding catheter, b) the microcatheter and guiding catheter and c) the microcatheter and the guidewire and the Nexus™ Detachable Coil.
2. Place the appropriate guiding catheter following recommended procedures. Connect a rotating haemostatic valve (RHV) to the hub of the guiding catheter. Attach a 3-way stopcock to the side arm of the RHV, then connect a line for the continuous flush.
3. Attach a second RHV to the hub of the microcatheter. Attach a 1-way stopcock to the side arm of the RHV, then connect a line for continuous flush.  
  
For All Nexus™ Detachable Coils:  
One drop from the pressure bag every 3-5 seconds is suggested.
4. Check all fittings so that air is not introduced into guiding catheter or microcatheter during continuous flush.

## DIAGNOSTIC MR IMAGING

The Nexus™ Detachable platinum alloy coil has been shown to be compatible with diagnostic magnetic resonance imaging (MRI) at field strengths up to and including 1.5 Tesla.

## DIRECTIONS FOR USE

1. Slowly and simultaneously remove the Nexus™ Detachable Coil and introducer sheath from the dispenser coil. Inspect proximal guiding system for irregularities. If irregularities exist, replace with a new Nexus™ Detachable Coil.
2. Slowly advance the Nexus™ Detachable Coil out of the introducer sheath into the palm of your gloved hand and inspect for irregularities at the detachment zone and for loss of coil memory. Due to potential risks of irregularities, a visual proof should be performed. If irregularities exist, replace with a new Nexus™ Detachable Coil.
3. Gently immerse the Nexus™ Detachable Coil and its detachment zone in heparinized saline. Take care not to stretch the coil during this procedure, in order to preserve the coil memory. While still immersed in the heparinized saline, gently retract the distal tip of the coil into the introducer sheath.

4. Insert the distal end of the introducer sheath through the rotating haemostatic valve (RHV) and into the hub of the microcatheter until the sheath is firmly seated. Tighten the RHV around the introducer sheath to prevent back flow of blood, but not so tight as to damage the coil during its introduction into the catheter.
5. Transfer the Nexus™ Detachable Coil into the microcatheter by advancing the guiding system in a smooth, continuous manner. Once the flexible portion of the guiding system has entered the catheter shaft, loosen the RHV and remove the introducer sheath over the guiding system's proximal end. Once completed, tighten the RHV around the guiding system. Leaving the introducer sheath in place will interrupt normal infusion of flushing solution and allow back flow of blood into the microcatheter.
6. Visually verify that the flushing solution is infusing normally. Once confirmed, loosen the RHV enough to advance the guiding system, but not enough to allow back flow of blood into the guiding catheter.
7. Advance the Nexus™ Detachable Coil under fluoroscopy and position carefully at the desired site. If coil placement is unsatisfactory, slowly withdraw by pulling on the guiding system, then slowly advance again to reposition the coil. If the coil size is inappropriate, remove and replace with appropriately sized coil.
8. Continue to advance the Nexus™ Detachable Coil until the positioning coil of the guiding system is just distal of the proximal marker of the microcatheter (See Figure 1). Tighten RHV to prevent movement of the guiding system.

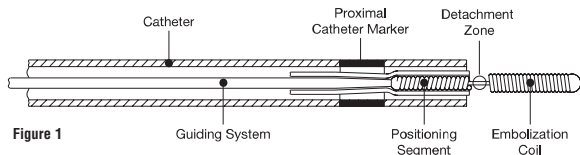


Figure 1

9. When the Nexus™ Detachable Coil has been placed as desired, proceed with detachment per the following:
  - a. Insert a sterile needle (size 20 G or 22 G = 0.7 mm or 0.9 mm, respectively) at the shoulder (M. deltoideus) or at the patient's groin.
  - b. Insert the bayonet plug of the sterile Cable Set into the terminal of the Detachment System (See the Instructions For Use of the Detachment System).

- c. Clip the connector end of the sterile black cable onto the sterile needle.
  - d. Clip the connector end of the sterile red cable onto the proximal end of the guiding system. Ensure that the guiding system is resting on a dry, clean surface.
  - e. Confirm again under fluoroscopy that the positioning coil of the guiding system is just distal of the proximal marker of the microcatheter.
  - f. Switch "ON" the Detachment System. (See the Instructions For Use of the Detachment System).
  - g. A continuous acoustic sound and "Detach" indicator flashes on the Detachment System, which indicates the detachment of the coil.
  - h. Successful detachment must be verified by fluoroscopic monitoring that the coil has detached. Slowly pull back the guiding system while watching the fluoroscope to make sure the coil does not move. In the unlikely event the coil moves, allow more time for detachment. If necessary, advance the guiding system to re-establish the coil and catheter marker alignment. Start the Detachment System again to resume detachment process. Verify coil detachment as above.
  - i. Once coil detachment has been detected and fluoroscopically confirmed, disconnect the connector of the red cable from the guiding system, and slowly withdraw the guiding system from the catheter.
  - j. Switch off the Detachment System.
  - k. Repeat the above steps if additional coil placement is required.
  - l. If the patient experiences pain at the site of the patient return electrode, or if detachment times are increasing, replace the needle with a new needle at a new insertion site.
  - m. Once the procedure is complete, discard the Cable Set and store Detachment System in a clean, dry and secure place. The Detachment System may be cleaned with a damp cloth.
  - n. Dispose of the batteries in accordance with hospital, administrative and/or local government policy. Remove the batteries when the Detachment System is not in use.
- Warning:** Dispose of the Cable Sets in accordance with hospital, administrative and/or local government policy.