

SPI Safety & Warnings

Contraindications

- Vascular anatomy incompatible with the catheter to be introduced
- Vasospasms
- Anastomose over a dangerous area of diameter larger than the spiral diameter
- Intolerance of occlusion of affected vessel
- Arteriovenous shunt of high flow intensity
- False aneurysm with a risk of hemorrhage
- These medical devices are contraindicated for neonates, premature neonates and infants.

Potential Complications

Vascular occlusion procedures should not be attempted by physicians unfamiliar with all possible complications.

Complications specific to embolization procedures may occur at any time during or after the procedure and may include, but are not limited to, the following:

- Ischemia at an undesired location
- Stroke or cerebral infarction
- Pushable coil migration into normal vessels adjacent to the lesion
- Pulmonary embolism
- Vessel dissection, perforation, rupture and haemorrhage
- Neurological deficits
- Injury to normal vessels or tissue
- Infection
- Free spirals are made of Platinum / Tungsten alloy and very rare cases of Tungsten allergy have been reported.
- Vasospasm
- Death

Precautions for Use



Do not use if the pouch is open or damaged. These products are sterile when the packaging is not damaged.

- These products are intended for single use only. Do not reuse. Any reuse of the device cause a high risk of microbiological contamination for the patient as well as a risk of loss of the device characteristics.
- Do not resterilize.
- Store in a dry place at room temperature and away from light.
- Do not use the product after the expiry date.
- These products must be used by specialist physicians in interventional neuroradiology and / or specialist physicians in interventional radiology.
- Never use the spiral which appears deformed (is extended or lost its shape memory) prior to or during manipulation.
- Never drive or move the set forcefully without prior verifying and identifying the cause of resistance by means of angiography. Forceful movements with the set may cause damage to the set and to patient's vessels.
- In case of spiral blocking in catheter, remove the whole set (catheter, spiral, pusher).

MRI SAFETY AND COMPATIBILITY INFORMATION

Until now, no report had mentioned side effects associated to magnetic resonance imaging procedures (MRI) performed on patients implanted with platinum coils in their vascular systems. However, coils and MRI compatibility was not demonstrated and the image distortion degree arising from the coils presence was not measured.