

Sonic Safety & Warnings

Contraindications

SONIC micro-catheter is contraindicated when, in the medical judgment of the physician, use of such product may compromise the patient's condition.

Not intended for use in the coronary vasculature.

The SONIC micro-catheters are contraindicated for neonates, premature neonates and infants.

Potential Complications

Potential complications include, but are not limited to:

- Puncture site hematoma,
- Vessel perforation or dissection,
- Vasospasm,
- Hemorrhage,
- Pain and tenderness,
- Infection,
- Thromboembolic episodes,
- Neurological deficits including stroke,
- Vascular thrombosis,
- Death.

Precautions for Use



- Do not use if the pouch is open or damaged. These products are sterile when the packaging is not damaged.
- This product is 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.
- The instructions for use of products to be flushed out through SONIC micro-catheters must be respected.
- Be careful not to damage or detach the « Fusecath » during manipulation of the SONIC.
- NEVER allow the reflux to overpass the 3rd marker during the use of a DMSO-based embolization product (or the 2nd marker with a cyanoacrylate-based product). Any overpassing may lead to a jailing of the micro-catheter and its rupture during a removal attempt.
- To minimize the risk of uncontrolled Fusecath detachment:
- Exchange the micro-catheter for a new one after 1 hour of unsuccessful navigation.
- During navigation, always check that the distal tip of the micro-catheter is not kinked before passing the microguidewire through it.
- Avoid any traction on the distal end of the micro-catheter.
- Do not use a cannula or needle to introduce the end of the micro-catheter into a connector.
- Use the appropriate guidewire (see the guidewire indicated on the label) to rigidify the micro-catheter.
- Never surpass the maximum working pressure of use of 7 bars (100PSI) indicated on the label. At the slightest resistance during injection, immediately stop the injection and pull out the micro-catheter.
- Never use a guidewire that is not mentioned on the label.
- Select tip size based on angioarchitecture. Do not place micro-catheter such that the detached tip could interfere with permeable vessels.
- Never force an intravascular device against resistance without having first checked the cause by angiographic control. Forcing against resistance may damage the micro-catheter or induce lesions in the patient.

MRI SAFETY AND COMPATIBILITY INFORMATION
- The SONIC micro-catheter is MR unsafe.