

Copernic / Copernic RC Safety & Warnings

Contraindications

COPERNIC/COPERNIC RC is contraindicated when, in the medical judgment of the physician, use of such product may compromise the patient's condition.

These medical devices are contraindicated for neonates, premature neonates and infants.

Potential Complications

Potential adverse events associated with the use of balloon catheters or with the endovascular procedures include but are not limited for:

- Access site complications,
- Allergic reaction
- Vessel or aneurysm perforation
- Aneurysm rupture
- Death
- Embolism
- Hematoma
- Hemorrhage
- Infection
- Ischemia
- Neurological deficit
- Stroke
- Transient ischemic attack
- Vasospasm
- Vessel dissection
- Vessel occlusion
- Vessel rupture
- Vessel thrombosis

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 COPERNIC catheter should never be thermoformed because of the risk of damage to the fit between the guide and the catheter which may result.
- The .012'' or .014'' guide-wire should always be humidified before use.
- For exchange procedure use the exchange guide wire HYBRID10D300.
- Never take out the guide-wire by more than 30 cm from the distal end of the catheter: this would jeopardise the balloon water tightness.
- The COPERNIC catheter should be used together with fluoroscopic control and adequate anticoagulating agents.
- Do not drain continuously when the guide-wire is positioned beyond the distal end of the catheter: this could cause the balloon to inflate.
- Never perform injections at a pressure higher than 50 psi: the balloon could inflate at an untimely moment.
- Respect the inflation volumes and never exceed the maximum volume.

- Use only appropriate media for inflating the balloon (by instance: 50/50 volume solution of contrast medium and sterile saline), we recommend the use of lesser viscous contrast liquids so to facilitate inflating and deflating.
- Never move an intravascular device in case of resistance without determining its cause by means of angiography. Moving of intravascular devices in case of resistance can damage the catheter or cause injuries to the patient.
- Never inflate the balloon with air or other gases when it is inside the patient.