Catchview Safety & Warnings

Contraindications

The use of CATCHView is contraindicated under these circumstances:

- Patients with known hypersensitivity to nickel-titanium.
- Patients with stenosis proximal to the thrombus site that may preclude safe recovery of the CATCH+ and CATCHView.
- Patients with angiographic evidence of carotid dissection.
- These devices are contraindicated for neonates, premature neonates and infants.

Potential Complications

The majority of the side effects are either associated with the clinical progression liable to occur in the patient or the risks associated with any endovascular brain surgery.

This list is for informational purposes and is not exclusive:

- Hematoma and haemorrhage at puncture site
- Perforation, rupture, dissection or other arterial lesions
- Vessel spasms
- Change in mental status
- Neurologic deterioration including stroke and death
- Ischemia
- Infection
- Air embolism
- Intracranial Haemorrhage
- Vascular occlusion
- Pseudo aneurysm formation
- Post procedure bleeding
- Distal embolization including to a previously uninvolved territory
- Adverse reactions to antiplatelet / anticoagulation agents or contrast media
- Device(s) deformation, collapse, fracture or malfunction.
- Thrombosis (acute and subacute)
- Arterio-venous fistula
- Clot migration

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 catheter and the CATCH+/CATCHView system must be used along with fluoroscopic monitoring and the appropriate anticoagulant agents.
- Follow the instructions for the systems used and substances injected.
- Take care not to touch the "stent" during the various handling operations such as removal from packaging or insertion into the guide catheter; this could displace or damage it.
- Do not pass through a stent with the CATCH+/CATCHView device because there is an important risk of displacing the stent.
- Perfuse the guide catheter throughout the procedure.
- A dedicated neurointerventional team **and a rigorous patient selection** is critical to achieve good clinical outcomes.
- **The adopted selection criteria should be based on the recent published guidelines**.

Warnings

WARNING: IF EXCESSIVE RESISTANCE IS ENCOUNTERED DURING THE DELIVERY OF THE CATCH+/CATCHVIEW, DISCONTINUE THE DELIVERY AND IDENTIFY THE CAUSE OF THE RESISTANCE. ADVANCEMENT OF THE CATCH+/CATCHVIEW AGAINST RESISTANCE MAY RESULT IN DEVICE DAMAGE AND/OR PATIENT INJURY.

WARNING: IF EXCESSIVE RESISTANCE IS ENCOUNTERED DURING RECOVERY OF THE CATCH+/CATCHVIEW, DISCONTINUE THE RECOVERY AND IDENTIFY THE CAUSE OF THE RESISTANCE. DO NOT PERFORM MORE THAN THREE RECOVERY ATTEMPTS IN THE SAME VESSEL USING CATCH+/CATCHVIEW.

WARNING: DO NOT USE EACH CATCH+/CATCHVIEW FOR MORE THAN TWO FLOW RESTORATION RECOVERIES.

WARNING: ADVANCING THE MICROCATHETER WHILE THE DEVICE IS ENGAGED IN CLOT MAY LEAD TO EMBOLIZATION OF DEBRIS. DO NOT ADVANCE THE MICROCATHETER AGAINST ANY RESISTANCE. DO NOT REPOSITION MORE THAN TWO TIMES.