

## Silk Vista Safety & Warnings

### Contraindications

The use of stent silk vista is contraindicated in the following cases:



- Patients with active bacterial infection.
- Patients in whom anticoagulant, antiplatelet or thrombolytic treatments are contraindicated.
- Patients with known hypersensitivity to nickel-titanium.
- Patients whose anatomy prevents passing or deploying it.
- Patients who never received antiplatelet agents before surgery.
- Patients resistant to treatment with antiplatelet and / or anticoagulants.
- Patients which are newborns, premature newborns and infants.

### Potential Complications

Complications and undesirable effects can include, but are not limited to:

- Death
- Septicemia / Infection
- Embolism
- Stroke
- Adverse reactions to antiplatelet / anticoagulation agents or contrast media, Nitinol metal
- Perforation, rupture, dissection or other arterial lesion
- Hemorrhage
- Neurologic deficit
- Aneurysm recanalization
- Aneurysm rupture post-treatment
- Migration
- Thrombosis, in stent thrombosis
- In stent stenosis
- Cardiac failure and ischemia
- Tissue necrosis
- Poor stent positioning
- Vessel occlusion
- Hematoma
- Pain and sensitivity
- Pyrogenic reaction

### Precautions for Use

-  Do not use if the package is open or damaged. These products are sterile when the packaging is not damaged.
-  The stents are non-pyrogenic.
- These stents are intended for single use only. Do not reuse. Any reuse of the device causes a high risk of microbiological contamination for the patient as well as a risk of loss of the device performance.
- Do not resterilize these devices.
- Store in a dry place at room temperature and away from light.
- Do not use the product after the expiry date.
- The silk vista stent and placement systems must be used by specialist physicians trained in interventional neuroradiology and in the treatment of intracranial aneurysms.
- Carefully determine the diameter of the vessel at the location defined for the stent, as well as the length of the aneurysm neck.
- **Avoid any excessive application of forward tension onto the freely open portion of the stent silk vista.**
- **Warning: Based on the current available literature, the use in bifurcation aneurysm is not recommended.**

**Safety and effectiveness of stent-in-stent placement and side branch occlusion has not been clinically assessed.**

- The appropriate anti platelet and anti-coagulation therapy should be administered in advance according to standard medical practice.
- The mesh density of the stent does not allow a micro-catheter to place coils through it. The micro-catheter for coiling must be placed in the aneurysm sac before deploying the stent. After deployment, the catheter will be located between the stent and the artery wall. Once coil placement is achieved, the catheter must be withdrawn very carefully to prevent any risk of stent displacement.
- Large (15 to 25mm) and giant (>25mm) aneurysms present an important haemorrhagic risk. The implantation of a stent silk vista in association with embolization coils in the aneurysm sac is particularly important since it could reduce this risk.
- The catheter and its stent should be used in conjunction with fluoroscopic control.
- Never attempt to reload the stent.
- Never move an intravascular device when there is resistance. Use angiography to determine the cause. Moving the silk vista when there is resistance can damage the device and/or the vessel.
- Follow the instructions for use for the devices and products used during the procedure.
- Maintain constant catheter perfusion during the entire procedure.
- The stent silk vista must only be used with the size of microcatheter indicated on the label of the stent.
- Be careful not to touch the stent during the various manipulations, as this could result in damage to the stent and its delivery system.



**MRI information. Non clinical testing has demonstrated “Flow diverter” SILK VISTA stent range is “MR Conditional” in accordance with the ASTM F2503-13 standard definitions [1].**

A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Patient implanted with one stent only and with uncompromised thermoregulation.
- Horizontal bore MRI system with a static magnetic field of 1.5 Tesla or 3 Tesla.
- Gradient magnetic fields lower or equal to 19T/m.
- $B_0^* |dB_0/dr|$  product lower or equal to 48T<sup>2</sup>/m.
- RF whole body transmit/receive coil use only.
- Whole body averaged SAR (Specific Absorption Rate) limited to Normal operating mode (WB-SAR ≤2W/kg).
- During non-clinical testing, the “Flow diverter” SILK VISTA stent produced a maximal temperature rise of  $4.6 \pm 1.0^\circ\text{C}$  at 1.5T for a measured WB-SAR of  $2.15 \pm 0.81$  W/kg and a maximal temperature rise of  $3.5 \pm 1.0^\circ\text{C}$  at 3T for a measured WB-SAR of  $2.15 \pm 0.88$  W/kg both after 15 minutes of continuous scanning.
- MR image quality may be compromised if the imaging area of interest is in the exact same area of the implant.

[1] ASTM F2503 – 13, 2013, “Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment,” ASTM International, West Conshohocken, PA, 2013. DOI: 10.1520/F2503-13.

### Warnings

**Warning:** Do not deploy the stent out of the introducer (even partially).

**Warning:** Ensure that all elements are in contact and that the introducer tube is aligned and in contact within the microcatheter hub.

**Warning:** If resistance is felt wherever during the stent procedure, withdraw the unit and exchange it for a new device.

**Warning:** Ensure that this movement is done freely in the artery to prevent any risk of perforation.

**Caution:** If resistance is felt during resheathing of the stent, do not continue.

Withdraw the catheter slightly to unsheath the stent (without exceeding the recapture limit), and then attempt to resheath again.

**Caution:** The stent may be fully resheathed once.

**Caution:** To prevent silk vista dislodgement after deployment do not move or retrieve the delivery wire without first checking that the silk vista is fully detached.

**IMPORTANT:** The ends of the stent must always be located in the straight segments of the artery. The length of the stent and its position must be chosen accordingly.

**Warning:** Based on the current available literature, the use in bifurcation aneurysm is not recommended.

Safety and effectiveness of stent-in-stent placement and side branch occlusion has not been clinically assessed.