Leo+ Safety & Warnings

Contraindications

Use of the LEO+ stent is contraindicated in the following cases:

- Patients with active bacterial infection.
- Patients in whom anticoagulant, antiplatelet therapy or thrombolytic drugs are contraindicated.
- Patients with known hypersensitivity to nickel-titanium.
- Patients with anatomy that does not permit passage or deployment.
- Patients who never received antiplatelet agents before surgery.
- Patients resistant to treatment with antiplatelet and / or anticoagulants.
- These devices are contraindicated in newborns, premature newborns and infants.

Potential Complications

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

- Death
- Renal disease
- Septicemia / Infection
- Embolism
- Stroke
- Pharmacotherapeutic reactions, allergic reactions including, but not limited to, contrast, Nitinol metal, and medications
- Perforation, rupture, dissection or other arterial lesion
- Disseminated intravascular coagulation
- Haemorrhage
- Arrhythmia
- Tearing or dissection of the intima
- Neurologic deficit
- Aneurysm recanalisation
- Migration / embolisation of stent
- Thrombosis
- Circulatory deficit

- Cardiac failure and ischaemia

- Arterial-venous fistula

- Tissue necrosis

- Incorrect positioning of stent

- Vessel occlusion, or new stenosis or new narrowing at implantation site

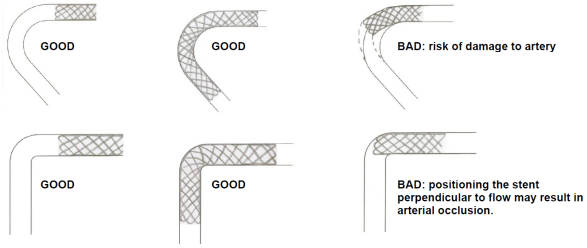
- Haematoma

- Pain and sensitivity

- Pyrogenic reaction

Precautions for Use

-  Do not use if the pouch is open or damaged. These products are sterile when the packaging is not damaged.
-  The stents are non-pyrogenic.
- 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.
- LEO+ stent must be used by specialist physicians in interventional neuroradiology and / or specialist physicians in interventional radiology.
- Carefully determine the diameter of the vessel (±0.2mm) at the location defined for the stent, as well as the length of the aneurysm neck (see imaging unit manufacturer's recommendations).
- Refer to product labelling for the maximum or minimum diameter of the artery according to the nominal size of stent.
- The length of the stent must be selected so as to overlap each side of the neck of the aneurysm, at least 1.5 time the diameter of the expanded vessel.
- IMPORTANT: The ends of the stent must always be located in a straight segment of the artery. The length of the stent and its position must be chosen accordingly.



- An incorrect positioning of stent could create complications.

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.

- Pharmacological treatment including platelet suppressive agents, anticoagulants and vasodilators is essential to successful placement and follow-up.

- Do not use if the patient is not responding to inhibitor of platelet aggregation.

- Large aneurysms (15 to 25 mm) and giant aneurysms (>25mm) present a high hemorrhagic risk. The deployment of the LEO+ stent along with embolization coils in sac enlargements is important because it could reduce this risk.

- The microcatheter and the stent should be used in conjunction with fluoroscopic control and appropriate anticoagulants.

- Never attempt to reload the stent.

- Never move an intravascular device when there is resistance. Use angiography to determine the cause. Moving the stent 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 throughout the procedure.

- The stent can only be used with the catheter supplied in the boxes or indicated on the label.

- Be careful not to touch the stent during the various manoeuvres including removal from package and stent use, as this could result in damage to the stent and delivery system.

MRI information. The **LEO+ stent was** determined to be MR-conditional according to the terminology specified in the American Society for Testing and Materials (ASTM) International,
Designation: F2503-05. Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance environment. ASTM International, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, Pennsylvania, 2005.

Non-clinical testing demonstrated that the LEO+ stent is MR Conditional. A patient with this device can be scanned safety under the following conditions:

Static Magnetic Field
-Static magnetic field of 3-Tesla or less
-Maximum spatial gradient magnetic field of 720-Gauss/cm or less

MRI-Related Heating
In non–clinical testing, the LEO+ stent produced the following temperature rises during MRI performed for 15-min in 1.5-Tesla (1.5 Tesla/64-MHz, Magnetom, Siemens Medical Solutions, Malvern, PA. Software Numaris/4, Version Syngo MMR 2002B DHHS) and 3-Tesla (3-Tesla/128-MHz, Excite,
Software G3.0-052B, General Electric Healthcare, Milwaukee, WI) MR systems, as follows:

Highest temperature change	MRI Condition
+ 2.0°C	1.5-T/64-MHz
+ 2.1°C	3-T/128-MHz

Therefore, the MRI-related heating experiments for the LEO+ stent at 1.5-Tesla and 3-Tesla using a transmit/receive RF body coil at the MR system reported whole body averaged SARs of 2.9-W/kg (i.e., associated with a calorimetry value of 2.1-W/kg) and 3.0-W/kg (i.e., associated with a calorimetry true value of 2.8-W/kg), respectively, indicated that the greatest amount of heating that occurred in association with these specific conditions was equal or less than 2.0°C at 1.5-Tesla and 2.1° at 3-Tesla.

Artifact Information
MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of the following items for the LEO+ stent. Therefore, optimization of MR imaging parameters to compensate for the presence of these devices may be necessary.

Pulse sequence	T1-SE	T1-SE	GRE	GRE

Signal Void Size	486-mm2	52-mm2	831-mm2	79-mm2
Imaging Plane	parallel	perpendicular	parallel	perpendicular

Warnings

Warning: Do not remove the distal metal part of the introducer.

Warning: Do not shape the tip of the delivery wire.

Warning: Do not deploy the stent from the introducer (even partially).

Caution: Make sure that there is solid contact and that the distal metal portion and the microcatheter hub meet correctly

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

Warning: Ensure that all elements are in perfect contact and that the introducer tube is aligned and in good contact within the interior of the microcatheter hub

Warning: If resistance is felt wherever during the 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 while resheathing the stent, do not continue to resheath. Withdraw the catheter slightly to unsheath the stent (without exceeding the recapture limit), and then attempt to resheath the stent again.

Caution: The stent may only be fully resheathed once.

Figure 5: Positioning and deployment of the stent in the aneurism

Caution: In order to keep the stent from moving after deployment, neither move nor remove the delivery wire without ensuring that the stent is completely detached.

Warning: do not torque more than 360°) and allow the time for the distal portion to pivot between each rotation then push the micro catheter forward again until it reaches the stent. Repeat these steps if necessary.

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.