

Solaris Vascular Stent Graft

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General description of Solaris Vascular Stent Graft

Solaris Vascular Stent Graft consists of a stent graft and its delivery system. The stent graft is self-expandable made of a super elastic metal alloy (nitinol) encapsulated with PTFE membrane along the entire length, except at the ends of the stent prosthesis where radiopaque, tantalum markers are located to delineate the ends of the stent. The delivery system is Pull Back and OTW (Over the Wire) type that consists of concentric tubes.

- The compatible guidewire is 0.035".
- Solaris Vascular Stent Graft is a Class IIb medical device.
- Product is sterilized by Ethylene Oxide.

Solaris Vascular Stent Graft Unique features:

Solaris Stent Graft:

- **PTFE membrane by electrospinning. Providing durability and multidirectional tear resistance.**
- High flexibility with less shorting due the Nitinol stent design that combine the balanced distance between crown stents and the connection bar.
- Double PTFE membrane encapsulating the Nitinol stent structure.
- 3 Tantalum markers on each proximal and distal end.
- Uncovering distal and proximal ends for guarantee a better wall positioning of the stent graft, avoiding infolding membrane.

Delivery System:

- **Unique 130cm working length Delivery system with Hydrophilic coating.**
- **Atraumatic radiopaque flexible tip.**
- **Delivery system with anti jumping system that allows to hold the Solaris stent graft during the deployment process gaining accurate and precision implant.**
- Marker band in the external sheet for a better visualization of the delivery system.
- Simple pull back delivery system.
- Braided and multi-durometer external sheet for a proper support and navigability of the delivery system.

Indications for use

- In the treatment of in-stent restenosis in the venous outflow of hemodialysis patients dialyzing by either an arteriovenous (AV) fistula or AV graft.
- In the treatment of stenosis in the venous outflow of hemodialysis patients dialyzing by an AV graft.
- Restenosis or reocclusion (except vessels on the Central Circulatory System* and Central Nervous System**)
- Dissection (except vessels on the Central Circulatory System and Central Nervous System)
- Residual stenosis with impaired perfusion (pressure gradient) following balloon dilatation, especially in stages III and IV according to Fontaine; (except vessels on the Central Circulatory System and Central Nervous System)
- Detached arteriosclerotic plaque material and luminal obstruction following balloon dilatation. (except vessels on the Central Circulatory System and Central Nervous System)
- Occlusion after thrombolysis or after aspiration and before dilatation. (except vessels on the Central Circulatory System and Central Nervous System).

**Central Circulatory System* - pulmonary arteries, ascending aorta, aortic arch, descending aorta to aortic bifurcation, coronary arteries, common carotid artery, external carotid artery, internal carotid artery, cerebral arteries, brachycephalic trunk, coronary veins, pulmonary veins, superior vena cava and vena cava Inferior*

***Central Nervous System** - the brain, the meninges, and the spinal cord.*

