Nellix® EndoVascular Aneurysm Sealing System for abdominal aortic aneurysm repair

TECHNOLOGY

The Nellix® EndoVascular Aneurysm Sealing System (EVAS) has been developed by Endologix, Inc., for the endovascular repair of infrarenal abdominal aortic aneurysms (AAA). The system is designed to completely seal the aneurysm sac.

The Nellix® EVAS comprises of two catheters with ePTFE graft-covered balloon expandable stents and attached endobags, an external console for managing the catheters, a cartridge containing a polyethylene glycol (PEG)-based polymer and a dispenser.

During the procedure, two Nellix® catheters are inserted into each femoral artery along guide wires and advanced through the aneurysm, before being attached to the console. The balloons are then inflated to expand the stents and the biostable polymer is injected through a catheter fill system into the endobags under pressure monitoring. As the polymer is injected, the endobags fill outwards into the blood lumen space, sealing the aneurysmal sac. The delivery system is then removed, and the aneurysmal sac is entirely sealed by the implant from the infrarenal aorta to the iliac arteries.

The Nellix® EVAS received a CE mark in February 2013 and the company are planning to further commercialise the system in the UK in 2014.

POTENTIAL FOR IMPACT

An aneurysm is a bulge in a blood vessel wall. Aneurysms are particularly problematic in the abdominal aorta where they are usually asymptomatic and can rupture, causing massive internal bleeding, which is often fatal. The UK has a national abdominal aortic aneurysm screening programme for men aged 65 years.

Preventative surgery is usually recommended for patients who are thought to be at a high...
risk of their AAA rupturing because of its size and/or position. Most commonly, surgical treatment involves the insertion of a synthetic stent graft to replace the weakened arterial wall. This can be performed with open or minimally-invasive endovascular repair (EVAR) surgery. However, not all patients are suitable for surgery.

The company claim that a key innovative feature of this device is that the entire aneurysmal sac is sealed. With other EVAR devices, a graft is fixed to the proximal neck of the aortic aneurysm and distal iliac arteries. The aneurysmal sac is therefore left intact, which can be subject to blood flow from collateral vessel (endoleak). Other issues with current procedures include stent migration and lateral movement. The company claim that complete sealing of the sac prevents such problems, thus reducing complications and the need for second procedures. This may also reduce patient morbidity and anxiety, in addition to saving NHS costs.

The company also anticipate that the Nellix® EVAS is applicable to more patients than other EVAR devices as the consistent procedural approach is less reliant on the anatomy of individual patients. They claim it has the potential to address some of the limitations with current EVAR devices, such as short and/or irregular necks or severe associated iliac aneurysm disease. This may benefit the NHS by reducing procedure time and the training period typically associated with EVAR procedures for clinicians. Simplified post-implant surveillance with duplex ultrasound is also expected to reduce surveillance costs and nephrotoxic morbidity associated with the currently used contrast CT scanning.

If proven to be effective, the Nellix® EVAS may increase the number of patients suitable for treatment with endovascular surgery and reduce costs to the NHS associated with post-EVAR reintervention.

**EVIDENCE**

**PUBLISHED PAPERS AND ABSTRACTS**


ONGOING STUDIES

ClinicalTrials.gov. Multicentre, observational registry to assess outcomes with the Nellix® System for abdominal aortic aneurysm repair (EVAS-Global).


INFORMATION FROM

This Alert is based on information from the company and a time-limited internet search.