Lithoplasty® balloon catheter for peripheral arterial disease

TECHNOLOGY

Lithoplasty® developed by Shockwave Medical, is a novel lithotripsy-enhanced balloon catheter to treat peripheral arterial disease (PAD). It is designed to break-up calcium deposits and increase the compliance of rigid vascular and valvular lesions prior to low-pressure balloon dilatation. Lithoplasty® is intended for use by cardiologists, interventional radiologists and vascular surgeons, in patients with calcified infra-inguinal vascular stenosis.

Lithoplasty® applies a brief series of mechanical pulses designed to safely travel through soft tissue, to break-up and pre-treat calcium deposits. The integrated balloon is then dilated at low pressures to expand the lesion evenly, potentially minimising acute soft tissue injury that would normally lead to additional interventional treatments or long-term restenosis (a re-blockage).

Lithoplasty® is CE marked and the company anticipates launch for routine clinical use in the UK during 2016.

POTENTIAL FOR IMPACT

PAD is a common condition where a build-up of calcium deposits called atheroma, in the walls of the arteries makes them narrower and restricts the flow of blood. A common symptom is painful aching in leg muscles that is triggered by physical activity, such as walking or climbing stairs.

Treatment includes lifestyle changes such as taking regular exercise, drug therapy and surgical revascularisation. Most people with PAD do not need surgical interventions,
The Lithoplasty® balloon catheter is a device to treat a common condition where there is a build-up of fatty substances on the walls of blood vessels in the legs, which reduces blood flow. Lithoplasty® is a long tube called a catheter and an attached balloon, which are inserted into the groin. The catheter vibrates to break up the fatty substances, then the balloon is blown up to open up the vessel and increase blood flow to the legs and feet.

However, if symptoms become severe, angioplasty may be considered. During this procedure a tiny balloon is inserted into the artery and blown up to widen it, prior to the use of devices to keep the artery open such as drug eluting stents. Advanced PAD is more difficult to treat because calcified calcium deposits limit the expansion of vessels and therefore the effectiveness of current endovascular devices, making current interventions challenging and prone to both procedural and long-term failure.

According to the company, in peripheral vessels, Lithoplasty® could enable more effective angioplasty, less frequent bailout stent usage and enhanced lesion preparation prior to the use of endovascular devices. The company states Lithoplasty® has the potential to improve treatment success through fewer vessel injuries requiring stent placement, fewer re-interventions, as well as reduce overall treatment costs and improve patient outcomes.

The technology is predicted to have an impact on the following domain of the NHS Outcomes Framework (see: www.england.nhs.uk/resources/resources-for-ccgs/out-frwrk): Domain 1 Preventing people from dying prematurely.

**EVIDENCE**

**RELEVANT ARTICLE**


**ONGOING STUDIES**


**INFORMATION FROM**

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