

Bifurcation Stent

Opportunity

A dedicated bifurcation stent to effectively treat patients requiring percutaneous coronary interventions in more than one branch has been developed. It is a patent protected novel design.

There is a recognised need, driven by clinicians, for a simple stenting solution for patients with bifurcation disease to improve patient outcomes.

We are looking for an experienced commercial partner to gain a CE mark. A prototype has already been developed and successfully tested in animals (£2 million from the Medical Research Council, 2016).

The problem

There are over three million percutaneous coronary interventions (PCIs) performed worldwide per annum. Between 15 and 20 per cent (some sources report up to 30 per cent) of these patients have bifurcation disease where there is disease affecting an important side branch. This equates to approximately 500,000 patients.

Conventional cylindrical stents cannot easily

cover both main and side branches. Common practice for the clinician is to opt to stent only the main branch, as some of the angles and access do not lend themselves to current stent products.

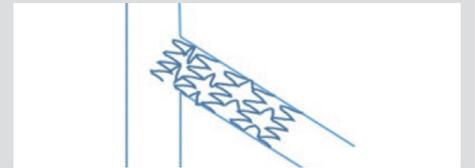
There is currently no widely adopted solution. Other developed devices in this arena have been shown either to not work or not be operator-friendly.

Our solution

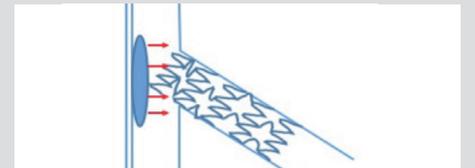
The dedicated bifurcation stent design has a highly malleable distal end, capable of being moulded to the ostium of the bifurcation, which retains circumference and does not

collapse when positioned. The dedicated bifurcation stent can be deployed across the range of angles and shapes of typical bifurcations with similar

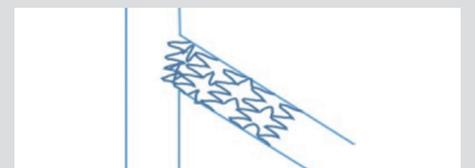
Figure 1



Side branch stent deployed within the side branch



Malleable end of the stent collapsed with 3.0mm balloon inflation in the main branch



Malleable end longitudinally collapsed to appose to the side branch ostium

The Market

The total coronary stent market is estimated to be worth US\$7 billion (2015). Approximately, over 500,000 patients per year have bifurcation coronary lesions that require

stenting of the side branch. This patient population is set to grow due to longevity and lifestyle factors, such as obesity and type 2 diabetes.

apposition characteristics and represents a novel and user-friendly method of performing a two-stent strategy in bifurcation disease (see figure 1).

Based on these figures, the bifurcation market potential of our stent is approximately £250 million.

Market status

This innovation requires £2.06 million of investment to:

- Gain a CE mark by end of 2018
- Produce a GMP-standard stent for trial
- Develop drug elution to the contemporary standard. This will not be a complex process, due to its simple design.
- Conduct a first-in-man trial with 10 patients who have coronary bifurcation disease, to demonstrate safety and meet the Food and Drug Administration (FDA) criteria
- Carry out a post-CE mark study of 30 patients with data collected suitable for FDA
- Production runs for EU market

Technology readiness

- The stent is technically optimised.
- Work is on-going to ensure best visibility in-vivo (placing platinum markers at each end of the stent).
- Early studies on developing a drug-eluting version are planned (to allow for clinical standards to be met).

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