

## Lombard takes on the heavyweights with US approval of aortic graft



[Elizabeth Cairns](#)

It has been a long time coming, but Lombard Medical Technologies has obtained US FDA approval for its Aorfix device for the endovascular treatment of abdominal aortic aneurysms. The relatively tiny company will now go up against medtech giants Medtronic, Cook Group and W L Gore & Associates in a market worth around \$1.2bn worldwide.

In a small section of the patient population, Lombard will not just compete with these companies but will look to outdo them. Crucially, Aorfix can be used to treat patients who cannot be addressed by current grafts on the market; it is the only product approved for cases where the artery above the aneurysm bends particularly sharply. The company's stock jumped over 30% today.

### Hard graft

An abdominal aortic aneurysm (AAA) is a bulge in the aorta, usually below the renal arteries but above where the aorta branches into the two iliac arteries that take blood to the legs. The bulge is often more pronounced on one side, distorting the angle at which the aorta joins it. This area is called the neck of the aneurysm.

All other endovascular stent grafts are approved for neck angulations of up to 60 degrees; Aorfix will be the first in the US to be indicated for use in cases where the angulation is as great as 90 degrees. This population, which Lombard says makes up around 20% of all AAA patients, is currently treated with risky open surgery or the other, less flexible grafts used off-label.

Lombard must therefore now turn its efforts to getting the graft to doctors. The UK company has decided against forming a partnership to sell the device, chief executive Simon Hubbert says, and will instead take on more sales staff to target a few busy grafting centres in the US.

Done right, an in-house launch could see Lombard gain a decent share of the US market. Julie Simmonds, an analyst at Canaccord Genuity, points out that Aorfix's indication means that off-label use of competitor devices in the harder-to-treat patients could leave surgeons open to litigation in the case of graft failure. If Lombard can communicate this to the right doctors in the right places it will have more than a foot in the door.

But three large firms control 75% of the endovascular AAA repair market, and they really are big companies – in terms of market cap, Medtronic is a thousand times the size of Lombard. The underdog has an edge in the shape of its graft's broad indication. It must now put all its efforts into maximising the advantage.

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