SynCardia aims to bring artificial hearts to new patients

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The success of ventricular assist devices, used to help failing hearts pump blood, has been notable over recent years and the main players are fighting hard over market share. The picture for artificial hearts – devices that take the place of donor organs in a patient whose native heart has been excised – is very different.

Here the worldwide market is served by just one company: SynCardia Systems. The Tucson, Arizona firm is not the only company to have achieved FDA approval but its only rival, Abiomed, has retired from the market.

“Last year we implanted 161 hearts – double what we did in 2011,” SynCardia’s Don Isaacs tells EP Vantage. “I see this doubling and doubling [each year].”

Destination

The SynCardia temporary total artificial heart, to give the device its official name, is CE marked in Europe and was approved in the US in 2004 for bridge-to-transplant (BTT), allowing it to be used to tide patients over until they can receive a donor heart.

“It replaces the exact same components as a heart transplant: the left and right ventricles and the four heart valves,” Mr Isaacs says. “It is 70cc in size and weighs about 160g – about half the normal weight of the heart. The benefit of our heart is that when you remove the dying ventricles there’s space allocated for the total artificial heart. And when a donor heart is available there is sufficient space to accommodate it.”

But the company is gearing up to gain expanded approval for the device as destination therapy, whereby it could be permanently implanted. The potential recipients would be patients who are too sick to undergo a second operation.

This approval would come through the FDA’s humanitarian use device pathway from the FDA, which, while it only requires proof of the device’s safety according to Mr Isaacs, will oblige SynCardia to conduct another trial.

“We’re optimistic that we’ll get approval to proceed with the study this year,” says Mr Isaacs. He could not say how many patients would have to be enrolled; the pivotal BTT trial was conducted in 81 patients.

Bells and whistles

The company is in an almost unique position in that its one competitor has backed off, ceding well-nigh the entire market to SynCardia. Abiomed’s AbioCor heart reached the market in the US in 2006 but only one of its devices have been implanted since then. The firm has all but abandoned AbioCor in favour of its Impella
ventricular assist device, says Aimee Genzler, a spokesperson for Abiomed.

“I can't say that we have stopped manufacturing [forever] as I don't know what the future holds. [But work on AbioCor] has pretty much completely stopped because all of our focus is going into the Impella family,” Ms Genzler says.

The complexity of the AbioCor may have been its downfall. It is larger than the average human heart, limiting its potential population: “It could only be implanted in very broad-chested, large men,” Ms Genzler says.

“The AbioCor heart ... weighs 900-1,100g,” Mr Isaacs says. “All the bells and whistles are implanted within the human being.”

SynCardia’s implant is relatively streamlined, but the electronics and motors have to go somewhere. Formerly, patients were tethered to a console that could not leave the hospital, but a new driver that fits into a custom backpack is approved in Europe and Canada and is expected to gain US approval any day.

The SynCardia heart also beats AbioCor on the crucial measure of price. With a price tag of precisely $124,700, it is half the price of AbioCor. And it is reimbursed - the Centers for Medicare and Medicaid have covered it since 2008 and “a clear majority” of private insurers do too.

There is another company working towards this marketplace, although it is still in early trials. French company Carmat is conducting early human trials, but its device is unlikely to reach Europe before 2016 and US approval will not come until some years later.

Funding development

If SynCardia sold 161 hearts last year at nearly $125,000 apiece it ought to have seen revenues of around $20m; being private it does not disclose financial reports. But still the company felt the need to raise $14m in a series F round in December.

Mr Isaacs says that the company would be profitable if it were not for its ongoing R&D efforts. The company is working on a new model: at just 50cc in size it would increase the number of available patients.

“We are very close to going into study with our 50cc heart,” Mr Isaacs says. “The 70cc heart covers the majority of men and a minority of women and adolescents; with the 50cc heart we believe our sales will probably triple because it'll allow us to accommodate almost all men and women and many teenagers and children.

“That's where we've been using our funding – to expand our ability to serve the population. Combine 70cc with 50cc, combine destination therapy with bridge to transplant, and we cover the marketplace.”

The obvious question on the corporate side is how long the firm will remain independent. A larger company active in the cardiology space such as Medtronic or St Jude Medical could be interested - but if this happens, it might take time, Mr Isaacs says.
“In today’s climate [buyers] want to see a company that is clearly through their development stages,” he says. “Approvals for destination therapy and of the 50cc heart will allow us to have a better value to a larger company at some point in the future.”

Demand for heart transplants outstrips supply by a long way – in the US alone around 3,400 patients a year require transplants and only around 2,300 donor organs are available. This gives an addressable market worth over $130m, a figure that could get potential acquirers interested.

The total lack of competition – at least until Carmat’s device reaches market – will only increase the company’s appeal.