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## **Tiny Blood Pumps for Failing Hearts**

A new heart aid could be implanted without invasive surgery.

By Jocelyn Rice

For a patient with end-stage heart failure, an implantable pump that helps circulate the blood can mean added months or even years of life. Now [CircuLite](#) is developing an implantable pump that weighs just one-sixth as much as its smallest predecessor. About the size of a AA battery, it could ultimately be implanted through a catheterization procedure that is far less invasive than the operations used to place today's pumps. It could thus be used to treat patients in earlier stages of heart failure, for whom implantation surgery had previously been too risky.

Invented more than two decades ago, the earliest support pumps--or ventricular assist devices (VADs)--kept patients tethered to a large external console and a blood-thinning machine. A second generation of VADs, still widely in use, has spinning rotors that continuously draw in blood. Third-generation devices are much smaller, using magnetic or hydrostatic forces to float the rotor within the blood. That eliminates friction between the pump's parts, which in earlier generations led to breakdowns and blood clots. But implanting these devices still requires sawing through the breastbone and placing the patient on heart-lung bypass.

CircuLite's pump, called Synergy, uses a combination of magnetic and hydrostatic forces to suspend the rotor. But it differs from a VAD in that it sucks blood from a different chamber of the heart and returns it through a different artery. Because it is designed for patients in an earlier stage of heart failure, whose hearts can still pump a modest amount of blood on their own, the Synergy pump gets by on a smaller, less powerful motor. Unlike implantable VADs, which rest deep inside the chest cavity, the Synergy pump is small enough to be placed near the skin's surface.

"It's a very small, very well engineered device," says [Yoshifumi Naka](#), director of the Mechanical Circulatory Support Program at [Columbia University Medical Center](#).

The device began clinical testing in Europe in June 2007 and has been implanted in nine patients so far. All nine have survived to date, and five have successfully gone on

to heart transplants. CircuLite estimates that U.S. clinical trials will begin in early 2009.

The pump itself may sit just beneath the skin, but its inflow tube extends much deeper, into the left atrium of the heart. Currently, in the European studies, the surgeon goes between ribs to place the tube. This "mini-thoracotomy" is faster and safer than the full sternotomy required for most other implantable pumps, but heart-lung bypass is still required.

When the device goes to market in Europe--and in its second round of United States clinical trials--it will be implanted using an even less invasive procedure. Instead of opening the chest and inserting the inflow tube directly into the left atrium, the surgeon will use a catheter to snake it through a large vein into the right atrium, and then through the heart's inner wall to the left atrium.

Ultimately, the Synergy will target a patient population not usually given VADs. These patients--in late stage-three and early stage-four heart failure, often called the "lost stages"--do not respond to drugs but are not yet sick enough to warrant an invasive, risky surgery. "They really have no other option," says [Paul Southworth](#), CEO of CircuLite. "The few patients who get VADs or transplants get them by getting sicker." Earlier intervention will drastically improve quality of life for these patients, says Columbia's Naka.

The CircuLite pump is powered by a roughly four-pound battery pack worn at the waist. Southworth says that future versions will have an even smaller battery, about the size of a Razr cell phone. Patients with the implant can live at home with relatively few lifestyle restrictions. "They want to play with their kids or their grandchildren, or garden, or do the things that they did before," says Southworth, "so it's important that they have something unobtrusive."

Although trials of the device have so far aimed to keep end-stage heart-failure patients alive while they await transplants, Synergy was not designed as a so-called bridge-to-transplant device. Providing a modest boost in blood output from the heart, it is ultimately meant to support patients with chronic heart failure in the long term--over many years--perhaps obviating the eventual need for a transplant. Preliminary results from the European trials suggest that the pump may even allow the failing heart to heal itself by giving it a rest.

"It allows the heart to rest and potentially recover," says Southworth, "and it

supplements the heart where it's unable to pump the required blood."

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