Implants keep the blood flowing

Engineers have developed a host of devices that keep a patient's heart pumping and blood flowing.

Problems with the heart and circulatory system cause almost one out of three deaths in the U.S., including about 150,000 people under the age of 65 every year. Some folks believe the cure is the truly artificial heart, complete with an implantable power supply. But biomedical engineers know such a device is far in the future. Instead, these engineers are working on a host of implants that could stave off problems or at least let patients survive the cure. Here are some recent innovations.

Pumping up the heart

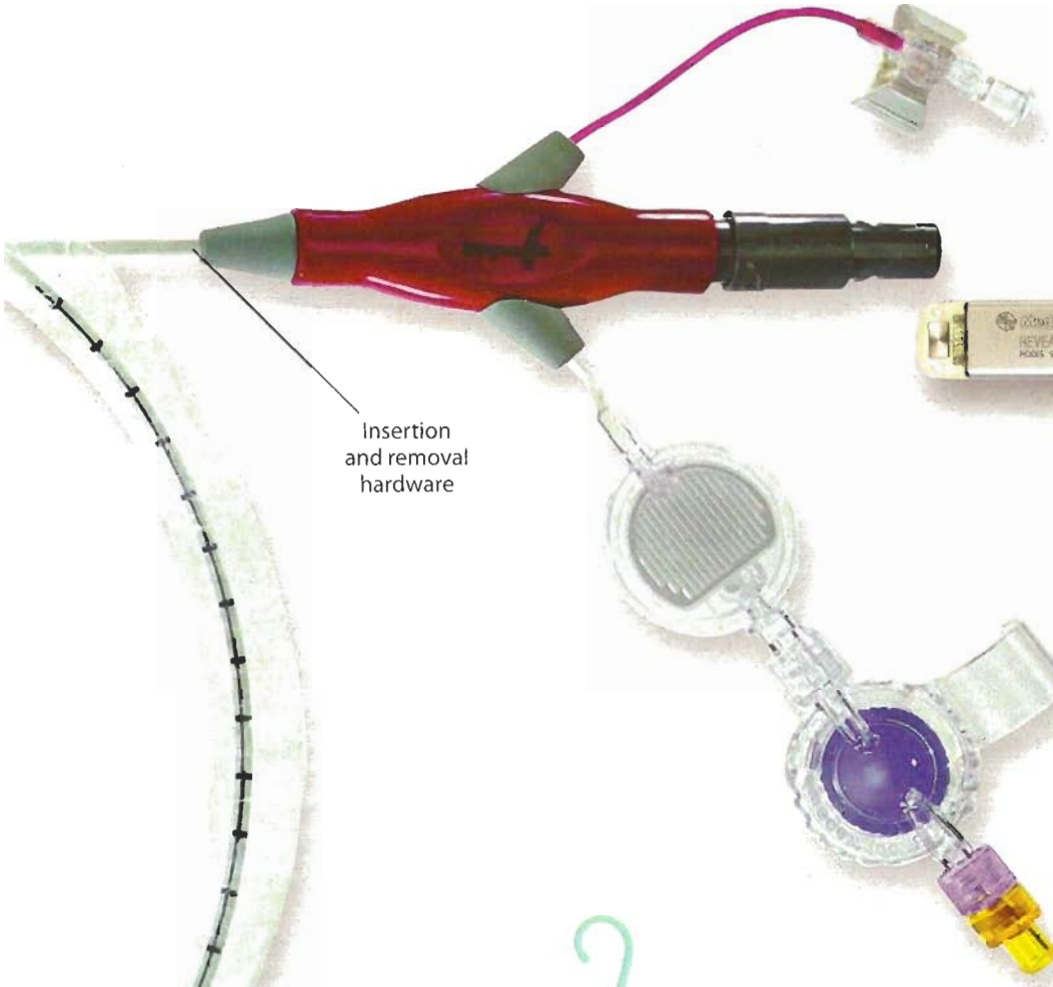
Although artificial hearts are not in the foreseeable future, there is a need to keep blood flowing while doctors operate on patients' hearts and try out new procedures to heal or repair damage. Older heart-lung machines keep blood flowing but also require the heart be stopped, an unnecessary and dangerous requirement for modern, minimally invasive surgeries.

One device approved for use during heart surgeries lasting up to six hours is the Implella 2.5 from **Abiomed Inc.**, Danvers, Mass. Although only four inches long and 0.12-inches wide, it can pump 2.5 l/min. This is enough to relieve the heart of its load and keep the patient alive.

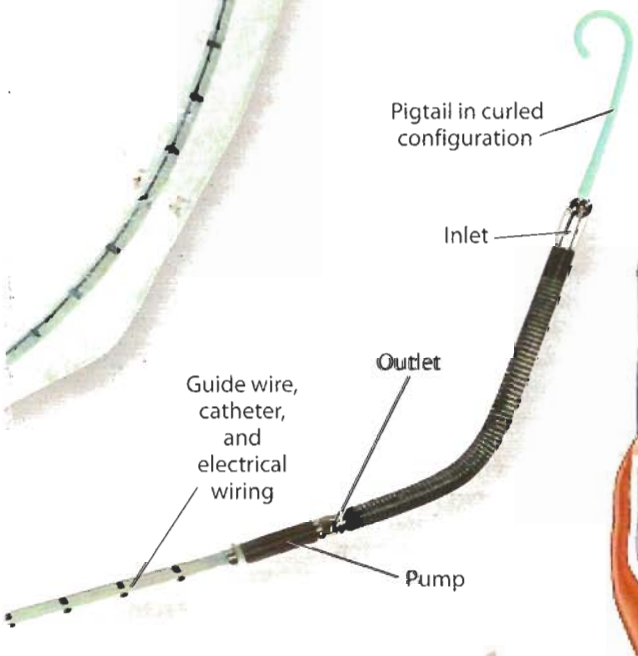
Surgeons insert the Impella 2.5 into the heart's left ventricle using a catheter snaked up through the femoral artery. It stays attached to the catheter so it can be easily removed after the surgery. But the catheter is backed off a bit after insertion. Slightly retracting the catheter removes it from inside the hollow "pigtail" section. With the support of the catheter gone, the pigtail reverts to its curled shape (hence its name). The curl keeps the inlet end of the pump sitting in the ventricle and not migrating toward the mitral valve and left atrium.

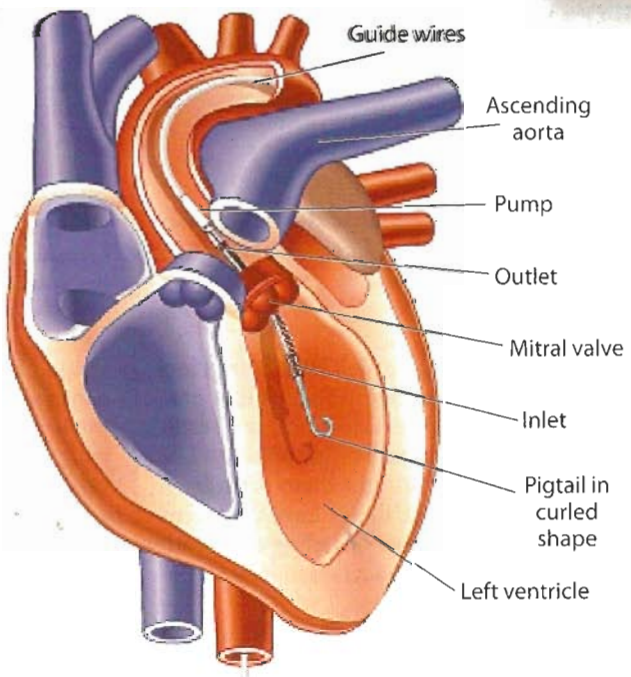
An encapsulated motor located in the part of the Impella outside the left atrium spins a microaxial pump at up to 51,000 rpm, pulling blood through the heart and dumping it in the left ascending aorta. Blood travels through the pump's spinning blades but not the motor. Blood's relatively high viscosity would damage the motor. So a solution of water and 20% dextrose keeps blood out of the motor.

The Impella is powered externally, with electricity travelling through a wire bundled with the catheter. A console controls the pump's output, letting surgeons insert the Impella, bring it up to speed, then keep it there. In case of power outages, a battery in the console provides back-up power. When the operation is complete, the surgeon reverses the process, lowering the rpms until the heart assumes the full load, then backing the pump out through the heart and femoral artery. The



The implantable Reveal XT (left) monitors heart activity for up to three years and records up to 44 min of EEG data that can be examined later by a cardiologist. Like a loop recorder, it can reuse memory space by rerecording over previous data. The patient interacts with the implant by using a Patient Assistant.





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Resources

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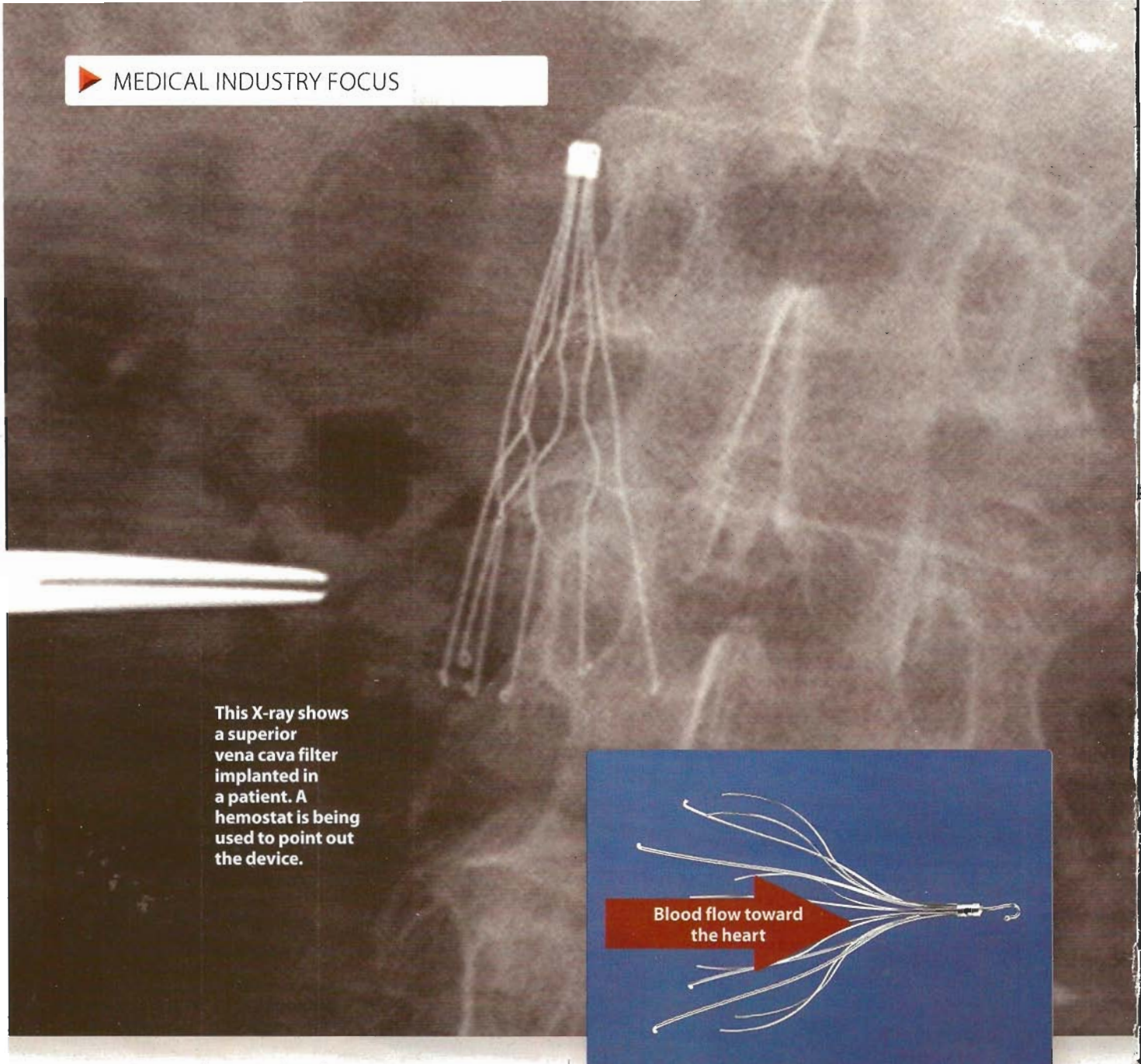


This X-ray shows a superior vena cava filter implanted in a patient. A hemostat is being used to point out the device.

This superior vena cava filter is shown in its expanded form, with hooks out ready to snag the inside walls of the vein. The hook used to insert and remove the clot-catching device can be see at the top.

one-time use device is then thrown away.

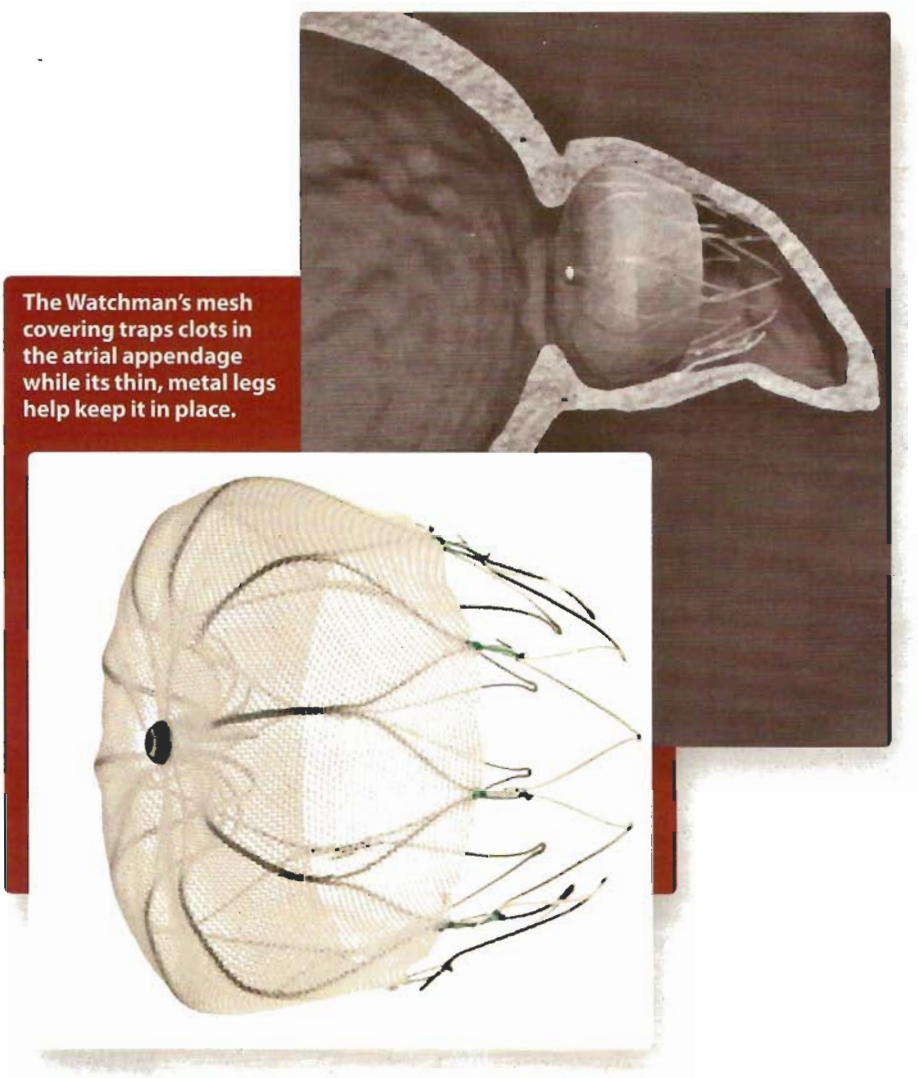
The company also makes versions of the Impella designed to be inside a patient's heart for up to seven days to aid recovery from surgery or disease.

Clot stoppers

A common threat to many people's health are clots or thrombosis. They form naturally in the healing process much like scabs, but inside the body, or as a result of sluggish blood flow due to disease or immobility. The most common way to prevent or fight them is through blood-thinning drugs. But these drugs have problems of their own and can lead to internal bleeding and death — so engineers have come up with several ingenious devices that lessen their impact.

One group of these devices is called superior vena cava filters which are made by several companies including **C.R. Bard Inc.**, Murray Hill, N.J. The devices look like a collapsed umbrella without the fabric. The funnel-shaped object is placed in the superior vena cava, the major vein taking unoxygenated blood to the heart from the lower extremities. The filters collapse for insertion, which is done usually through the right or left femoral vein or the jugular vein with the surgeon monitoring the action on an X-ray machine. Once properly position, the filter is pushed off of the catheter or guide wire and out from its protective covering. A clasp releases the hook on the upstream end. Released of its covering, the filter expands to its natural shape and small hooks grab onto the inside walls of the vein to hold it in place. The entire operation takes about an hour.

For as long as the filter is in place, a decision left to the



The Watchman's mesh covering traps clots in the atrial appendage while its thin, metal legs help keep it in place.

patient's cardiologist, it catches and holds clots, preventing them from travelling to the heart or lungs. When appropriate, the device is removed, with the surgeon gently pulling the filter back into its covering then using the catheter to get the filter out through one of the patient's major veins. Other versions of the filter are left in place permanently. Any clots these devices ensnare are broken down by the blood constantly flowing around them.

These filters are universally made of metal, letting doctors see them on X-rays and CAT scans, But ferrous metals can interfere with MRIs. So versions such as the G2 X filter from Bard are made of nickel and titanium and do not interfere with MRIs.

One variation on the vena cava filter is called the Watchman from **Atritech Inc.** in Plymouth, Minn. It is for people with atrial fibrillation, a condition afflicting about two million Americans. Atrial fibrillation makes the heart's upper chambers beat too fast, causing blood to stagnate and clot in an a thumb-sized area of the heart called the left atrial appendage. Like the appendix, everyone has an atrial appendage but no one really knows its function other than as an extension of the left atrium.

The Watchman traps clots in the appendage, preventing them from causing problems by ending up in the brain, kidneys, lungs, or other organs. The device looks much like a high-altitude balloon, with a mesh covering over a slim, metal framework

Doctors first determine the size the appendage using data from an MRI, CAT scan, or x-ray, and specify a Watchman that provides a tight fit. Then the doctors guide the device into place through a catheter inserted in a the left or right femoral vein. An X-ray camera provides video of the entire event so the physician knows when the device is in the right place.

The Watchman is implanted permanently with any clots trapped behind it slowly dissolved by blood which freely flows through the device's mesh covering.

Monitoring the heart

The heart is a relatively simple muscle but controlling it is complicated. As a result, many people have abnormal heart rhythms. These conditions, such as asystole,

bradyarrhythmia, and tachyarrhythmia, can cause severe health problems. But diagnosing these conditions is difficult because the unusual heartbeats come and go. So it's rare that a doctor is readily available to listen or give the patient an EEG when these cardiac conditions manifest themselves. To solve this problem, biomedical engineers have developed implantable cardiac monitors, such as the Reveal XT from **Medtronic**, Minneapolis, that can monitor heart functions for up to three years,

The battery-powered device is about the size of a memory stick (9 cc in volume) and weighs 15 grams. To implant it, a surgeon forms a small pocket below the skin of the upper chest, inserts the Reveal and sutures it in place. Two electrodes on the surface of the unit pick up electrical signals generated by the heart. Unlike pacemakers or implantable defibrillators, there's no need to physically attach wires to the heart.

Once in place, the device constantly monitors the heart. If it detects abnormal heartbeats (such as those outside preprogrammed norm), it begins recording up to 27 minutes of EEG data. The patient can also initiate up to 22.5 minutes of data recording using a handheld Patient Assistant (PA) if he suspects his heartbeat has become irregular. The PA also downloads data from the implant using two-way RF transmission. Software in the PA then checks the data and signals the patient to call his doctor if the EEG data meets arrhythmia criteria.

The patient can send data to his doctor over the Medtronic Carelink Network or his physician will use a Medtronic 2090 Programmer to download data or reprogram the implant during office visits.

Reveal XT has several features that make it significantly better than the implanted loop recorders. For example, it can operate for three years, up to twice as long as older loop recorders. And external loop recorders, those worn on a belt, are usually only used for two to three days. Advanced programming lets the Reveal XT better detect and classify a range of arrhythmias while noise reversion and overrange-detection algorithms reduce the number of false-positives. It also poses no known hazards to patients undergoing an MRI. And a more intuitive user interface let patients of all ages safely and effectively use the heart monitor. **MD**