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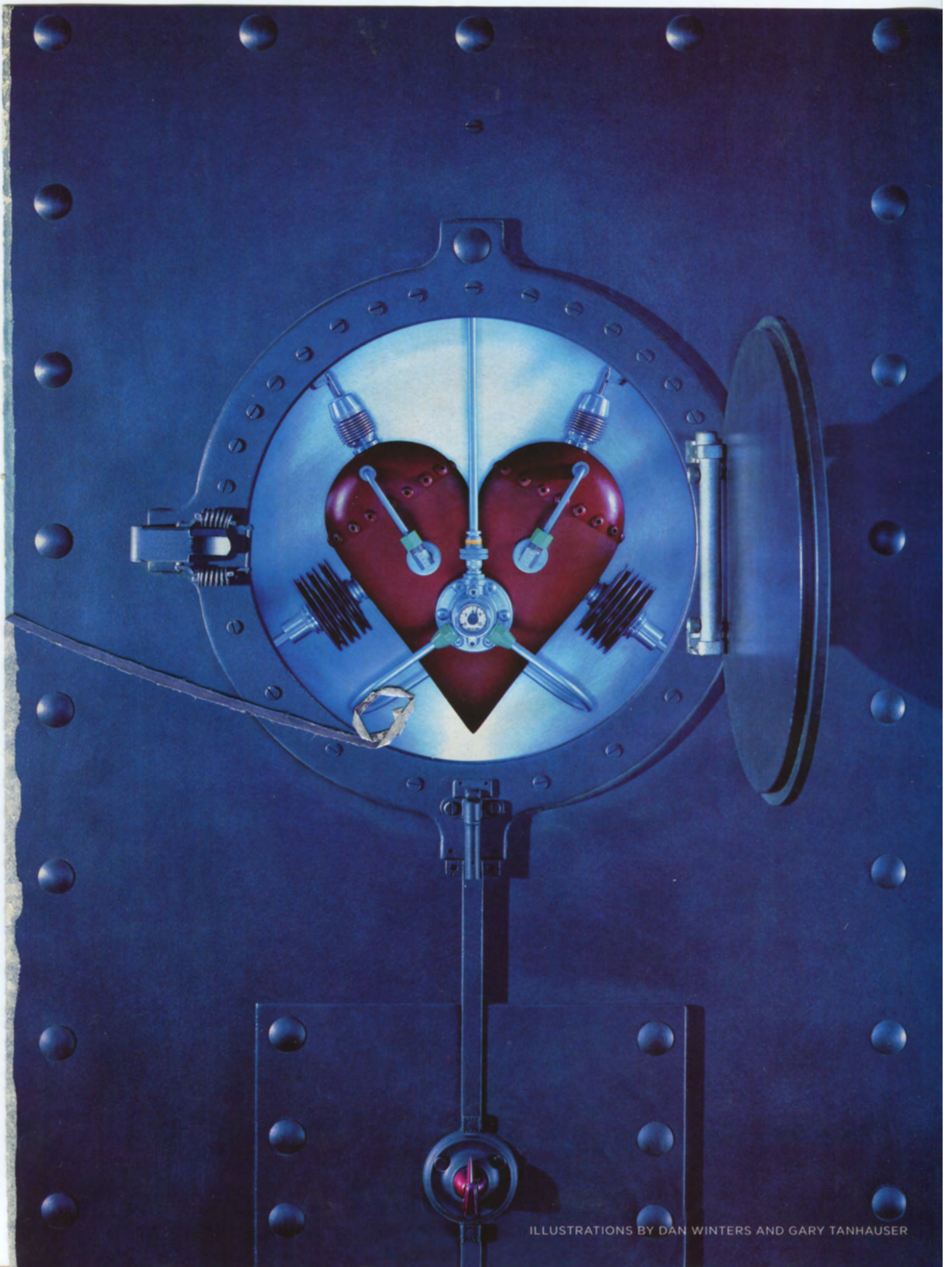
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MACHINE

BY JOHN SEDGWICK

MADE OF TITANIUM and polyurethane, it's about the size of an old-fashioned alarm clock, weighs two pounds and looks like the tiny offspring of a carburetor and a sousaphone. It's an artificial heart, the AbioCor, and any day now, in the medical equivalent of a Mars landing, the device will be implanted by a team of surgeons into the chest of a patient who would die without it. • You'll know when it happens; stuff like this is big news. It'll take place in one of five medical centers, from Boston to Los Angeles, that is now, as I write this, prepping for the big event. Amazingly, the "installation" itself will take only about a half hour. "You just have four connections to make," says Eric Rose, M.D., the surgeon-in-chief of cardiac surgery at Columbia-Presbyterian Medical Center. "The left and right atria, the pulmonary artery and the aorta. That's about it." The hard part will come later, of course, dealing with any bugs. But if the device performs the way its maker, the biotech firm Abiomed of Danvers, Massachusetts, expects, it will be an astonishing achievement, the first significant melding of man and machine. • It does sound like something out of a cyborg movie. The AbioCor is remarkably simple: two chambers with a pump in between to push blood out, first

AS YOU READ THIS, THE NEWEST GENERATION OF ARTIFICIAL HEART IS ABOUT TO BE IMPLANTED INTO THE CHEST OF A GRATEFUL RECIPIENT. THIS VERSION CAN BE RECHARGED BY PLUGGING IT INTO A WALL SOCKET OR A CAR CIGARETTE LIGHTER. ALL OF WHICH RAISES VITAL QUESTIONS FOR SURGEONS AND POETS ALIKE—NOT TO MENTION INVESTORS, WHO WILL KEENLY WATCH TWO COMPANIES VIE FOR WHAT COULD BE A \$7 BILLION MARKET



ILLUSTRATIONS BY DAN WINTERS AND GARY TANHAUSER



from one side, then the other. An electronic "brain" stashed inside the patient's abdomen will both monitor the pump's functions and transmit data to command central at the patient's health center. The patient will carry a cell phone so headquarters can reach him if anything goes wrong.

It's the power supply that gets interesting. The human heart is fueled by the very blood it pumps. But the AbioCor is electrically powered by a four-pound camcorder-type lithium-ion battery that a man will wear on his belt and a woman will most likely carry in her purse. The electrical energy is passed through the skin by a slim plastic-coated disk that works much like the recharger for an electric toothbrush. On the receiving side, a companion patch will be imbedded probably in the abdomen, where surgeons can more easily remove it for replacement. An extra battery that lasts up to an hour will be tucked inside the chest so the user can take a shower or a swim without shorting out the system. (In addition, an alarm will alert him when the juice is getting low.) To go easy on battery power, the user can plug himself into a wall socket if he's going to be sitting indoors awhile. In a car, he can run his heart off a cigarette lighter.

If you're getting the creeps about now—wall socket? cigarette lighter?—you've stumbled onto one of the big reasons Abiomed is the only company in the world still in the artificial-heart business. Bionic bones, joints, hands—sure. But hearts? They're an impressive bit of biophysics, definitely, pumping roughly once a second, day in, day out, for life, perhaps several billion heartbeats altogether, each one sending just under a half cup of life-sustaining, oxygen-rich blood through a vast network of veins, arteries and capillaries that, if laid out end to end, would reach around the globe twice. But you don't have to be a country-and-western singer to realize the heart is more than a marvel of engineering. There is an emotional component here, some music. We speak of broken hearts, aching hearts, bleeding hearts, tender hearts, brave hearts. Even more than the brain, the heart is somehow us. We pledge our hearts, cross our hearts, follow our hearts. Literally and figuratively, the heart is at our very center, pumping the hot blood that brings vitality to our limbs and loins. It is the one internal organ we can actually feel; its thumping provides the driving rhythm of our lives.

In ancient Chinese medicine, there are 300 types of pulses. The AbioCor would have just one, of course, produced by the steady, methodical chug of its patented dual-chamber system. In going forward with its device, Abiomed is betting the world will accept that the heart is just a pump, no more. While Abiomed's CEO, David Lederman, is charmed by the quaint notions about the heart's significance to the self, he insists that anything the heart knows comes from the brain. He dismisses heartcentrics as dreamy mystics. "That's all psychological," he says. Then he gets a glint in his eye. "Of all the organs, it's the brain that produces the most pleasure."

So why have all the other companies abandoned the

field? "It takes courage to do this," he says. "And people simply don't have the courage to do such things anymore." A burly engineer with heavy traces of his Colombian roots in his accent, Lederman has been Abiomed's CEO since the company began, in 1981. He notes that the country's artificial-heart program got its first big push in the '60s and that it came out of the same daring impulse that landed an American on the moon. "Back then the country thought there were some goals worth pursuing," he says. "We lack that courage today."

Abiomed is located in spanking-new offices in Danvers, on Massachusetts's north shore. By a quirk, its chief competitor in the artificial-

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heart business is located about twenty miles down the highway, in Woburn. That company is Thermo Cardiosystems, and it dates back much further, to 1965. Like Abiomed, it set out to build a totally artificial heart but veered off in favor of producing

only a doughnut-size supplementary implant called an LVAD (left ventricular-assist device), which takes over the heavy lifting of the left ventricle but leaves the heart intact. "We don't subscribe to the artificial-heart theory," says Thermo Cardiosystems CEO Michael Kleine, a tall, imposing figure who comes to this job from a career in health care. "Been there, done that." After years of experimentation, the company rejected the program for a combination of spiritual and pragmatic reasons. They decided that individuals would never surrender their hearts if they could possibly avoid it. Plus, the risk of relying solely on a mechanical heart was too great. "Once you take the heart out, it's over," says Kleine. "There is no putting it back. If you've got a totally artificial heart, that's what you've got."

A number of surgeons share this belief. Indeed, the desire for a backup system is so great that on occasion surgeons performing a transplant will leave in the original heart, just in case. This is termed a heterotopic transplant, and it can confuse nurses who might feel two pulses. For now, the FDA has cleared Thermo Cardiosystems' LVAD, the HeartMate, only as a "bridge-to-transplant" device, a means to buy time while waiting for a human heart to become available for transplant. But the company is currently finalizing HeartMates II and III, which are intended to last far longer, as part of a plan to make its devices permanent.

The new versions of the HeartMate will be about the size of your thumb, much smaller than the original. But, curiously, they achieve this reduction in size by sacrificing the original thumping "pulsatile" mechanism for a continuous-flow system that involves a corkscrew whirling at high speed generating no distinct pulse at all. Left to themselves, the new hearts, in short, will not beat but hum. So, no thudding at the sight of your lover, no blip-blip-blip

after a hard run, no pounding at a sudden fright. That, obviously, is going to take some getting used to. Thermo Cardiosystems recently added an option, a piece of software that can be installed in the new HeartMates for users who would like to have a pulse after all.

Close as Abiomed and Thermo Cardiosystems are geographically, they couldn't be farther apart in just about every other respect. Total artificial heart vs. partial; a mechanism that produces a beat vs. one in which the beat is an "extra." Even their anticlotting strategies diverge. Abiomed has opted for supersmooth surfaces everywhere the blood touches so clots will not form, whereas Thermo Cardiosystems has gone for textured interiors in which the blood's platelets and other cells lay down a layer of living tissue that the body recognizes as its own. But their fundamental dispute is over the value of the human heart itself, with Thermo Cardiosystems regarding the heart as "what we love with," in Kleine's words, and Abiomed viewing it as little more than a kidney that handles blood function.

For all this, I hadn't quite realized the bitterness of the struggle between the two companies until I showed up at David Lederman's office, heard him list all the people I had spoken to and realized how distressed he was about what they'd been telling me. How he learned all this I do not know. Then he flipped on his own tape recorder so that I wouldn't misquote him as he went after Thermo Cardiosystems like an attack ad. He slammed the current HeartMate's audible chug-like beat, saying it would drive anyone "insane." He jeered at the future HeartMate's lack of an inherent beat-producing mechanism, saying that the tidal flow of blood through the body has an important scrubbing effect. "We don't have to prove that pulsatile flows are good and will work," he says. "The ones who have to prove it are the ones who have the rotary pumps." He scoffed at the LVAD as a bridge to transplant and even implied Thermo Cardiosystems had used that FDA designation as a way of keeping their patients from, as he said, "dying on their device."

For his part, Kleine claimed that, for all the excitement of Abiomed's first implant, it was still going to take the company years to secure FDA approval for general use of the product. Plus, he questioned why anyone would go for such an iffy technology when the HeartMate had a proven record. He suggested that physicians who went ahead with the AbioCor might be sued if their patients then had a

stroke. "If I'm an attorney, I get you on the witness stand and I go, 'Doctor, were you aware that there was a device on the market with a much lower risk of stroke?' I'm not trying to put the threat of liability out there," Kleine concludes sweetly. "But if I'm David Lederman, and I'm Abiomed, then I've got to be able to alleviate that concern." But he doubted that the AbioCor would ever pass muster with a guy at a bar. "I'd be blown off my barstool if he said he'd rather give up his heart [than try to keep it with a HeartMate]," Kleine argues. "That's a no-brainer."

The debate between Abiomed and Thermo Cardiosystems is hardly academic. There are lives on the line, and, of course, there's money too. Both companies are publicly traded, and although Abiomed's stock has done considerably better than Thermo Cardiosystems', investors in both are still waiting for the big financial score that always seems at least one quarter away. Meanwhile, the potential payoff continues to grow. As baby boomers age, their hearts are often the first body part to go. About 730,000 Americans die every year from heart disease, by far the leading cause of death in the United States. The primary cause of heart disease, congestive heart failure, was called an "ongoing epidemic" in a recent editorial in the *Archives of Internal Medicine*. Five million Americans are currently in some stage of the disease. Half of those who die of heart failure do so too suddenly for any intervention. But some portion of the

remaining 365,000 might be saved by a new heart—either a transplant, an LVAD or an entirely artificial heart like Abiomed's. Just what portion is a subject of dispute. LVAD partisans claim their product will retain greater market share because candidates need not be free of other life-threatening diseases. But even at the higher health standard, Abiomed is projecting 100,000 customers per year. Multiply that by the initial \$75,000 price tag for an AbioCor and you can see what all the fuss is about.

At this point, transplants continue to be the first choice for patients in need, but the supply of available hearts is dwindling due to the increased use of seat belts and motorcycle helmets by younger Americans, whose hearts are the most coveted. Indeed, the market is so

tight that older, decayed hearts are sometimes being patched up like old tires for recycling. Still, for every 60,000 people suffering from end-stage congestive heart failure, only 2,500 will receive a transplant.

Despite the obvious need, a grisly specter haunts the effort to produce an artificial heart—the memory of the last artificial heart to claim the world's attention, the ill-fated Jarvik-7. That one was first and most famously implanted in the chest of a Washington State dentist named Barney Clark in 1982, and he lived on it for nearly four months—enduring convulsions, kidney failure, respiratory trouble and a host of other ailments before finally being released from his



■ **PUMPING GOLD** The new artificial heart from Abiomed will cost about \$75,000, and the company predicts 100,000 customers per year.

misery. That Jarvik-7 was mostly outside the body. It consisted largely of a 375-pound console the size of a washing machine; the patient was attached to it by wires that passed through his skin. (All the recipients were male.) The Jarvik-7 was an audacious bit of engineering and a huge improvement over the first artificial heart, the primitive Cooley device that was tried briefly in 1969. But the Jarvik-7 nonetheless had its problems; chief among them were that it chained the patient to the console, it produced nasty infections where the wires passed through the skin, and it kicked out multitudes of stroke-causing blood clots. "There are things that are worse than death, and this was one of them," concluded George J. Annas, a bioethicist at Boston University who spoke to the last Jarvik-7 patient before the man died. The experience was so ghastly for the patient that it looked for a time as if the artificial heart would join the SST and the nuclear power plant in the pantheon of high-tech devices that are smart but dumb. *The New York Times* editorialized that the artificial heart was the Dracula of medical technology and hoped that a stake would be driven through it.

But medical science persisted. The same miniaturization process that has shrunk mainframes down to PalmPilots has allowed heart pumps to be placed entirely inside the chest. The consumer-electronics explosion has led to batteries that are smaller and longer lasting. Decades of testing have greatly increased reliability. And the blood-clot problem has seemingly been solved, certainly by the HeartMate and possibly by the AbioCor (the device was tested extensively in calves before its pending human trial). And now, almost twenty years after Barney Clark, we stand rather nervously on the edge of a new era.

To get a sense of what the future might be, I spent a little time last summer with Arthur Kastner, a 56-year-old former magazine publisher from Long Island who had been using a HeartMate for more than two months. Before that he had been suffering from the classic symptoms of congestive heart failure: His heart was unable to pump enough blood to keep fluid from backing up in his lungs. He could see his gut swell, and he could tell just how badly he was doing when he weighed himself. At one point, he was bloated with more than eighty pounds of fluid. He desperately needed a new heart, but with no transplant available, his doctors at Columbia-Presbyterian did the next best thing: They implanted a HeartMate, one of more than 2,000 that have, with little fanfare, been inserted into Americans with ailing hearts since 1996.

As Kastner sat with me in the hospital cafeteria after a visit to the doctor, he wore a fisherman's vest to carry the two batteries that powered his LVAD. I could hear the pump pounding away. It sounded a bit like a pneumatic pile driver, a steady chug, chug, chug. He lifted up the vest to show me the thick cable that emerged from his belly and contained two small tubes—one to vent the exhaust from the system, the other to link the battery to his HeartMate. It was stunning to see the spot, the crude

intersection of man and machine.

It had been an adjustment to live with an LVAD. Kastner is a peaceful, gentle fellow, but he did get irked when people stared at him, puzzled by the sound of his heartbeat. His wife said she can now tell when he's anxious, because she can hear his heart speed up. And it had been racing the night before, when the battery recharger at home mysteriously went dead. A hospital nurse from New Jersey had had to drive more than an hour in the middle of the night to bring him a replacement system. "I almost flipped out," Kastner said. As he waited for a heart transplant, he developed a more self-serving view of the young idiots he some-

times saw careening down the highway in souped-up cars. "I wonder if they're my blood type," he said.

But, if anything, with his partly artificial heart, Kastner found himself getting more emotional, not less. Just the sight of an old friend was enough to bring him to tears.

And I was struck by his obvious tenderness toward his wife. It gave me a different view of the heart. Literally, of course, it is inside us. But the metaphorical heart is outside. It is not an organ but a network of relationships. It is the sum of our love.

At Abiomed over the summer, I had a chance to see the artificial hearts in their last stages of testing, before the first one is implanted. I was amazed to see just how high-tech the enterprise is. It reminded me of my first visit to a chip manufacturer almost twenty years ago, when computer chips were still a novelty and the expression "clean room" inspired a certain awe. Here, several dozen AbioCors were being put through their paces—subjected to the equivalent of marathons while being bathed in a saline solution that approximates the corrosive effects of being immersed in blood. Some of the AbioCors jiggled away in what looked like a Waring blender; others were hooked up to computer monitors. The AbioCors seemed so coldly mechanical, so widgety, I thought of them as hard drives, maybe, or automatic garage-door openers. Anything but hearts.

But electronic devices surround us everywhere we go. The world is thickening with them, and they are pressing in. Yes, the first one that gets into the very center of us will be a shock. But is a man without a human heart heartless? I wonder. Even poor Barney Clark, dazed as he was, was able to tell his wife he loved her. A heart is what you think it is. The first implantation of the AbioCor into the chest of that first patient may well be a snap, just as Rose says. I expect it will be a far more difficult operation to insert it into our minds. But it will happen. Even if our hearts turn artificial, our love will still be real. ■

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John Sedgwick is a *GQ* writer-at-large. His novel, *The Dark House* (HarperCollins), was published last summer.