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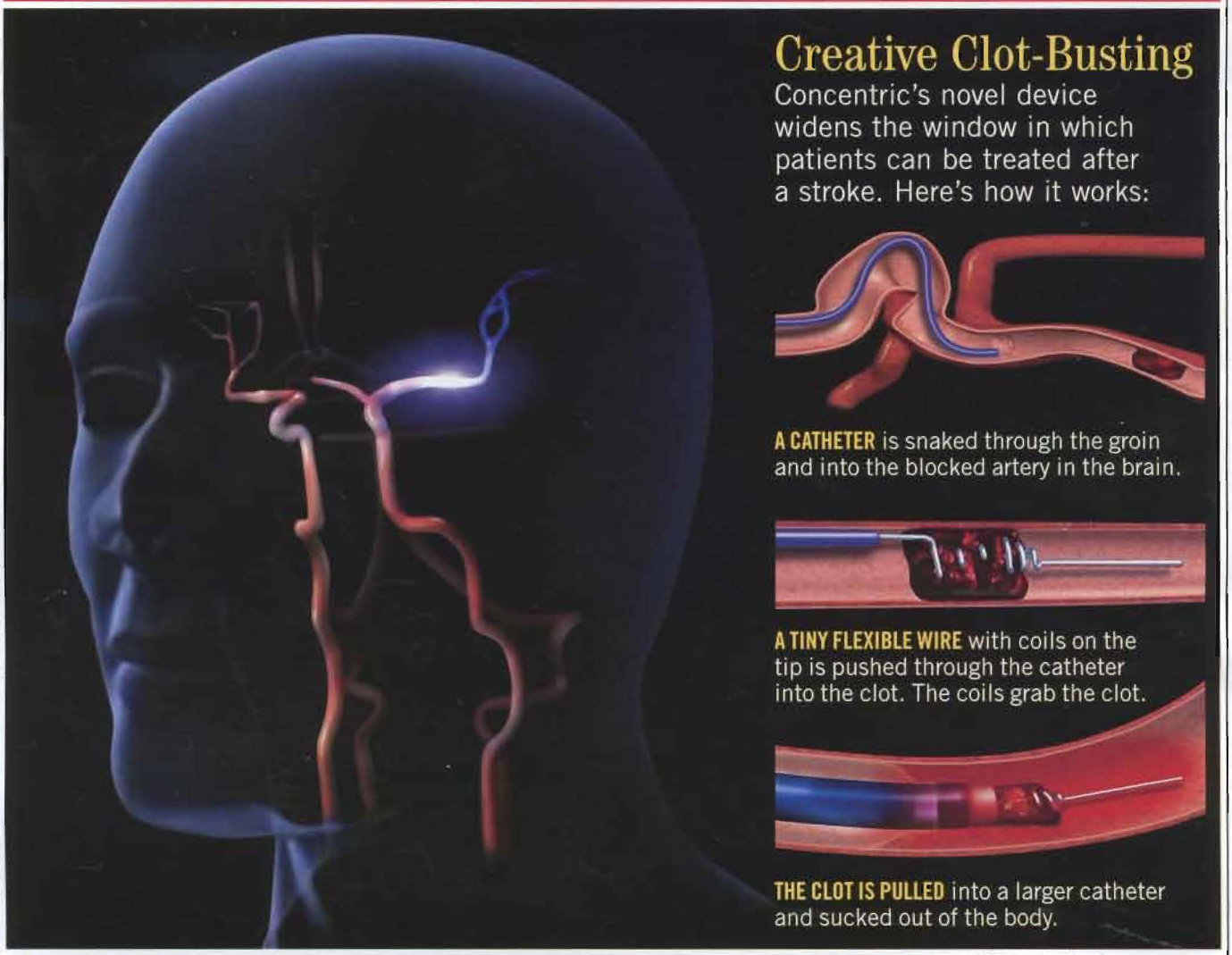

Creative Clot-Busting

Concentric's novel device widens the window in which patients can be treated after a stroke. Here's how it works:

A CATHETER is snaked through the groin and into the blocked artery in the brain.

A TINY FLEXIBLE WIRE with coils on the tip is pushed through the catheter into the clot. The coils grab the clot.

THE CLOT IS PULLED into a larger catheter and sucked out of the body.

CONCENTRIC MEDICAL

HEALTH CARE

SNAKING OUT STROKES

Concentric is testing a corkscrew for clogged arteries

When Bill Schlosberg came down with a crushing headache on Feb. 23, he didn't know he was having a stroke. He made it from his home in Overland Park, Kan., to the emergency room, where doctors eventually pinned down the cause of his pain. Unfortunately, he wasn't eligible for conventional drug treatment to break up the clot blocking an artery in his brain. So they transferred him to a stroke specialty center, where doctors threaded a catheter into the artery and delicately dislodged the

clot. Schlosberg, a 56-year-old engineer who was initially paralyzed by the stroke, regained most of his lost motor function a few days later. "Without this treatment, I don't think I'd be here now," he says.

The tool that saved Schlosberg's life is still being tested, but stroke specialists are already buzzing about it. The device, called the MERCI Retriever, is literally a corkscrew for brain clots. Invented at the University of California at Los Angeles and developed by Concentric Medical Inc. in Mountain View, Calif., it is expected to be submitted for Food & Drug Administration approval by the end of October.

If Concentric's device gets the green light, it could be a godsend for a huge and seriously underserved group of patients. "Ischemic" strokes—those caused by blood clots—account for 85% of the 700,000 strokes diagnosed in the U.S. each year, according to the American Heart Assn. Stroke is the third-leading cause of death. And the paralysis and loss of brain function that often result make it the No. 1 trigger of long-term disability. What's especially disheartening is that there's only one drug approved for treating strokes. And only 2% of patients can get it—largely because it must be given within three hours of onset of stroke, which is notoriously tough to diagnose.

The Concentric device may be usable six or even eight hours into the stroke. "Expanding that time window would be a breakthrough," says Dr. Marilyn Rymer, medical director of the stroke center at Mid America Brain & Stroke Institute at Saint Luke's Health System in Kansas City, Mo., which treated Schlosberg as part of a clinical trial. And it could be a windfall for Concentric: CEO Gary Curtis estimates if he reaches just 20% of stroke patients each year, the company could pull in $850 million in annual sales.

Success is far from certain, however. The stroke field is littered with experimental devices that sounded great but ultimately failed. The problem is, the walls of the blood vessels that feed the brain are tissue-thin and extraordinarily fragile. The slightest tug can cause debilitating—sometimes even fatal—bleeding in the brain. No one has been able to fashion a device strong enough to remove clots yet soft enough to leave arteries unscathed. "It has been a design challenge for years," Curtis says.

The company could face a nervous FDA. The medical-device industry has suffered a series of setbacks this year, including the revelation that Indianapolis-based Guidant Corp. failed to report malfunctions — some leading to deaths—of a device sold for treating abdominal aortic aneurysms. Guidant paid $92.4 million in fines to settle federal felony charges in June. Given such disappointments, the FDA is bound to scrutinize Concentric's safety record before letting hospitals stock up.

Delicate Work

Before the MERCI Retriever, no one had been able to design a device strong enough to remove clots, yet soft enough to leave arteries unscathed

So far, Concentric seems to be on the right path. The Retriever has worked in about 50% of the patients tested. In contrast, the only clot-busting drug approved to treat strokes, Genentech Inc.'s Activase has a 33% success rate. Curtis says less than 5% of patients treated with the device suffered bleeding or other debilitating side effects. Activase has a 6% complication rate. Better yet, there is evidence the two treatments may be complementary: Some of the patients in the Concentric trials were given injections of Activase directly into their brains to dissolve remnants of clots the Retriever couldn't reach.

The secret to the Retriever's clot-busting talent is in its design. It is made of a "shape memory" alloy—the same kind that's used in flexible eyeglass frames. That means it can be molded so it's perfectly straight when it is threaded through a catheter that is inserted into an artery in the brain, but when the wire protrudes from the end of the catheter, it automatically reshapes itself into tiny coils that latch on to the clot (diagram). A balloon at the end of the catheter inflates to stop blood flow temporarily through the artery so the clot can't break free and travel away. The clot is then pulled into a second, larger catheter and sucked out of the body with a syringe. In some cases, the procedure can be done in as little as 20 minutes, whereas Activase, given intravenously, can take an hour or more to dissolve a clot, says Dr. Sidney Starkman, clinical professor of emergency medicine and neurology at UCLA.

The Concentric tool offers more than a time advantage. It may be a lifesaver for patients who can't be given clot-busting drugs because the risk of catastrophic bleeding is too high. People who have recently undergone surgery, for example, can't be treated with Activase. In a trial at UCLA Medical Center, doctors were able to use the Concentric tool on a woman in her 30s who had suffered a stroke two weeks after giving birth by cesarean section. She arrived at the hospital unable to speak or move on her right side. With one tug of the Retriever, "she was made normal immediately," Starkman says.

If Concentric wins the FDA's consent, the company will face a whole new set of hurdles. It will have to train stroke specialists, most of whom have never used medical devices for this purpose before. And at first, the device may be available only in a handful of specialty neurology centers. Concentric has pulled in $25 million in venture capital so far, but execs say they will need to raise another round to properly launch the product. Despite the challenges, Curtis says, "we're excited. There is no choice for some of these patients. To provide that for them would be the greatest high there is." Certainly medicine could use another powerful weapon against one of its most sinister foes.

By Arlene Weintraub in Los Angeles