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## Are Migraines All in Your Heart?

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Doctors treating patients with a congenital heart defect have found an unexpected side effect of their work -- repairing the heart condition apparently relieves migraines. Now, a company that developed a device to fix the heart defect is seeking approval to use it specifically as a migraine treatment.

[Cierra](#), of Redwood City, California, manufactures the PFX Closure System, a device that uses energy to close the heart defect known as a patent foramen ovale, or PFO -- an opening in the heart.

Doctors thread the device through a vein in the groin and snake it up the torso until it enters the upper right chamber of the heart. There, the device lands on the PFO, applies suction to hold it closed, and directs radio-frequency energy at the closure site, essentially "welding" the tissue together.

The device is in the midst of clinical trials in Europe, and

Cierra president and CEO Erik Engelson expects it to be approved as a PFO treatment in Europe by mid-2006. The company also plans to launch a clinical trial of the device in migraine patients in the United States next year.

"This will be a pivotal trial for the migraine indication," Engelson says. "We're looking at a pharmaceutical-sized market for a medical device." If approved for use in the United States, he predicts, the treatment could be an industry in the range of \$2 billion.

Cierra's system is the first to close PFOs without leaving behind a device implanted in heart tissue, and this was a key factor in developing a treatment specifically for the migraine condition, Engelson says.

"Migraine patients tend to be otherwise healthy and young," he says. "Implanting something permanent in these individuals didn't seem to be the appropriate level of risk, whereas leaving nothing behind seemed to be a better approach."

While rare, those risks may include blood clots or bacteria forming on the devices, according to [Dr. Jonathan Tobis](#), director of interventional cardiology research and professor of medicine at the University of California at Los Angeles. "The severe risks appear to be minimal, but there is always concern that the side effect of a drug or procedure could be worse than the disease itself," he says.

Cardiologists currently close PFOs with one of two

implantable devices, and only perform the procedure in the case of [cryptogenic stroke](#), which occurs when a patient has no known stroke risk factors such as heart disease. Many of these patients also suffer from migraines, and in a majority of cases, their headaches disappear after having the heart defect fixed, Tobis and his colleagues [report](#).

But cardiologists still haven't found an explanation for the connection between PFO closure and migraine relief, and they point out the relation remains a correlation, and not a cause-and-effect relationship. "It's an unproven hypothesis -- that's a leap of faith right now," says Dr. Carey Kimmelstiel, associate professor of medicine at Tufts University and director of the Cardiac Catheterization Laboratory at Tufts-New England Medical Center. Kimmelstiel's own [research](#) also has pointed to the correlation between PFO and migraine.

Tobis concurs. "It's all too premature," he says, adding that even if trials do support the connection that PFO closure relieves migraines, further trials will need to assess which devices on the market are best suited for that treatment.

Still, Tobis remains optimistic that countless migraine sufferers will have a new treatment option in the future. "I'm confident that this approach will work," he says of closing PFOs in migraine patients. "In the future, millions could be treated for migraines in this way."

Kimmelstiel takes a more cautious view. "Nobody dies of

migraine," he says. "You're putting tubes in people's hearts, and these can be complicated procedures."



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