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HEALTH

Refractec Gets FDA Approval For Its Presbyopia Treatment

Radio Waves Are Used To Treat Close-Vision Woes Afflicting the Middle-Aged

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Refractec Inc. is set to announce today that it has received Food and Drug Administration approval to market a procedure that uses radio frequency energy to treat presbyopia, the close-vision problem that afflicts nearly everyone by age 50.

The procedure, conductive keratoplasty, known as CK, uses radio waves to reshape the cornea and bring near vision back into focus. Refractec plans to market CK as a safe and painless surgery that doesn't require any cutting or removal of tissue. It can be performed in only a few minutes in a doctor's office.

Presbyopia results from the hardening of the eye's lens with advancing age, a problem that forces middle-age people to rely on reading glasses to order from a restaurant menu or check their watch. Refractec, a closely held 10-year-old company in Irvine, Calif., estimates that 90 million baby boomers either have the condition or will develop it over the next 10 years.

The procedure costs patients between $1,500 and $2,000 per eye. It is typically performed in just one eye, restoring close-up vision without compromising distance vision.

Daniel S. Durrie, a refractive surgeon in Overland Park, Kan., and lead investigator on the studies reviewed by the FDA, said 30,000 procedures have been performed over the past five years without any safety problems. "This is the first FDA approval for a surgical treatment for presbyopia," he added.

Dr. Durrie, a paid consultant to Refractec, cautions that not every baby boomer is a candidate for CK, especially people with thin corneas. Some people won't be totally freed from their reading glasses after the surgery. Patients may need additional treatments as they grow older and their vision continues to deteriorate. "We can turn the clock back, but we can't keep it from ticking," he said.

Two years ago, Refractec won FDA approval to market CK for farsightedness, or hyperopia, a less common condition than presbyopia. Once a procedure is approved for a specific procedure, physicians are allowed to use it "off label" for other indications and many refractive surgeons have been performing CK on their presbyopic patients.

The latest FDA approval is important because it allows Refractec and independent surgeons who own its technology to begin marketing CK for presbyopia.

The technology, including training, requires about a $50,000 investment by the surgeon.

The procedure is performed using a probe thinner than a human hair that releases radiofrequency energy. The radio waves are applied in a circular pattern to shrink small areas of corneal tissue. The treatment pattern acts like a belt tightening around the cornea, increasing its curvature to bring near vision back into focus.

Refractec has so far raised about $35 million from venture capitalists and other investors.

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