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FAA Approves Use of Conductive Keratoplasty For Pilots

U.S. Airmen Can Now Take Advantage of Leading Nonlaser Vision Correction Procedure to Improve Near Vision

Irvine, CA - Monday, October 03, 2005 - Ophthalmic device manufacturer Refractec Inc. announced today that the Federal Aviation Administration has established the protocol for airplane pilots wanting to reduce their dependence on glasses by having the NearVision CK (conductive keratoplasty) treatment.

"Certification by the FAA as a vision correction procedure for pilots validates the safety and value of CK as a refractive treatment," said Mitchell B. Campbell, president of Refractec, Inc. "Only the safest and most effective procedures obtain an FAA protocol and we're thrilled that pilots can now enjoy the benefits of NearVision CK."

FAA Protocol for Conductive Keratoplasty

U.S. pilots who are considering having conductive keratoplasty to improve their vision may now do so without losing their aeromedical certification for flying. First, before considering CK, the pilot should check with his or her employer (if employed by the airlines) and/or flight medical examiner to determine if CK is an appropriate treatment option and if post-CK vision meets their individual requirements for flying.

For details on certification requirements and the complete protocol for CK, please visit the Federal Aviation Administration website at www.faa.gov or click here: http://www.faa.gov/about/office_org/headquarters_offices/avs/offices/aam/ame_guide/media/protocols.pdf.

In 2004, Refractec's NearVision CK became the leading nonlaser refractive procedure in the U.S. and is the fastest growing vision procedure since the introduction of LASIK. To date, more than 125,000 CK treatments have been performed worldwide and more than 800 physicians are certified to perform NearVision CK.

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NearVision CK Shows Promise for Post-LASIK Baby Boomers with 'Aging Eyes'

**Preliminary Phase-Three Trial Results Demonstrate Excellent Safety and Visual Outcomes Achieving A 96 Percent Satisfaction Rating among Post-LASIK Patients
Additional Clinical Trial of NearVision CK with LightTouch Technique Begins**

Chicago, IL - Monday, October 17, 2005 - Ophthalmic device manufacturer Refractec Inc. today announced the preliminary clinical results presented at the American Academy of Ophthalmology (AAO) meeting here affirming the safety and efficacy of its NearVision CK (conductive keratoplasty) treatment for presbyopic patients with a history of LASIK surgery.

Greek for "aging eye," presbyopia is a progressive condition that causes near vision to fade with age. Some 90 million Americans age 40 and over either have presbyopia or will develop it in the next decade, and many have had LASIK surgery to correct other vision problems earlier in their lives.

"Those baby boomers who were among the first to enjoy the benefits of LASIK to correct the vision problems of their youth now face the gradual reduction of near vision as they age," said Dr. Daniel S. Durrie, M.D., lead investigator of the study, who presented his findings at the AAO Annual Meeting in Chicago. "Fortunately for these post-LASIK patients, initial results from this study indicate NearVision CK may be a good treatment option."

NearVision CK is a quick (three-minute) treatment that uses radio waves, instead of a laser or a scalpel, to bring near vision back into focus without cutting or removing any tissue. Boasting one of

the highest safety profiles in the refractive market, NearVision CK already has U.S. Food and Drug Administration approval for the treatment of presbyopia and hyperopia (farsightedness). Refractec is seeking expanded approval to improve near vision in post-LASIK patients.

The Phase Three multicenter post-LASIK clinical trial will involve 150 patients who, other than suffering from presbyopia, had normal vision. Preliminary results of the first 23 patients compiled one month after the treatment showed excellent safety (no flap complications or adverse events) and outstanding visual outcomes for the entire range of vision:

- 96 percent of patients could read J3 (phonebook-sized print) or better
- 96 percent of patients achieved binocular intermediate vision of 20/20 or better, compared to 65% pre-operatively
- All of the patients — 100 percent — achieved a binocular UCVA of 20/25 or better at distance
- More than 90 percent achieved binocular UCVA vision to read J2-sized print or smaller
- These results contributed to an enthusiastic response from patients, with 96 percent reporting being satisfied or very satisfied with their post-operative vision.

The clinical trial, now underway, involves more patients at additional centers, and includes longer-term follow-up data. Researchers hope to complete enrollment of the study in mid-2006.

"NearVision CK already plays an important role in the refractive practice, offering patients and surgeons a minimally invasive option for the treatment of presbyopia," said Mitchell B. Campbell, Refractec's president and chief executive officer. "We are confident that the results of this Post-LASIK study will demonstrate our technology's ability to address the needs of presbyopic patients with a history of vision procedures."

Clinical Trial of NearVision CK with LightTouch Begins

Also at the AAO meeting, Refractec announced the launch of an Investigational Device Exemption (IDE) study, recently approved by the FDA, of NearVision CK with LightTouch. The announcement marks an important phase in the company's efforts to obtain supplemental pre-market approval for LightTouch, a neutral-compression technique that delivers even more consistent, repeatable results.

As the LightTouch technique enhances the absorption of the radiofrequency energy, it appears that we can generate results with fewer spots," said Durrie, who also is lead investigator of the LightTouch IDE study. "My initial work with LightTouch indicates that it may reduce the frequency of CK-induced astigmatism and achieve more immediate vision correction — similar to the 'wow factor' that many patients report post-LASIK."