



## **VISX STAR™ Excimer Laser Systems Receive FDA Approval for Hyperopic Astigmatism**

*New Indication Adds to Extensive List of Treatments Available Using VISX® Technology*

**OCTOBER 2000** — VISX, Incorporated announced that the U.S. Food and Drug Administration (FDA) approved the use of the STAR Excimer Laser Systems for the treatment of hyperopic astigmatism. This new treatment was added to the comprehensive list of refractive indications approved to treat patients using VISX technology. The indication is also approved for the latest state of the art laser system, the STAR S3 ActiveTrak™.

"We are pleased with the FDA's decision," said Liz Dávila, President and Chief Operating Officer of VISX. "At VISX, we remain focused on advancing laser vision correction technology to provide our customers with the very best products. With each new approval, our customers can treat a wider range of patients and increase their procedure volume."

Results of the clinical trials for the treatment of hyperopia with astigmatism with the VISX STAR Excimer Laser Systems presented to the FDA earlier this year. "Results of the clinical trials greatly exceeded FDA guidance levels," said Richard E. Braunstein, MD, VISX principal investigator. "At six months postoperatively, 96.5% of patients achieved a UCVA of 20/40 or better, while 71.0% achieved 20/25, and 50.2% achieved 20/20 or better. These results are impressive."

The VISX STAR Excimer Laser Systems are indicated for the correction of between +0.5 D and 5 D of sphere with refractive astigmatism from +0.5 D to 4 D with a maximum manifest refraction spherical equivalent of 6 D.

Next week, all VISX certified doctors will receive education and training materials which they need to review, sign and fax back to the VISX education department. New Vision Key® cards™ that include the hyperopic astigmatism indication along with the current indications can be ordered from the Customer Response Center by calling (800) 246-VISX. These cards should be available for shipment in approximately two weeks, and will not obsolete current cards.

The VISX STAR Excimer Laser System is approved for photorefractive keratectomy (PRK) for the reduction or elimination of nearsightedness (0 to -12.0 D) with up to -4.0 D of astigmatism, and hyperopia (farsightedness) between +1.0 and +6.0 D with no more than 1.0 D refractive astigmatism.

The VISX STAR Excimer Laser System is also approved for laser assisted in situ keratomileusis (LASIK) for the reduction or elimination of nearsightedness (0 to -14.0 D) with or without astigmatism ranging from -0.5 to -5.0 D. The VISX Star Excimer laser

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## **VISX STAR™ Excimer Laser Systems Receive FDA Approval for Hyperopic Astigmatism (CONTINUED)**

is also approved for photorefractive keratectomy (PRK) for reduction or elimination of naturally occurring hyperopia between +0.5 and +5.0 D sphere at the spectacle plane with refractive astigmatism from +0.5 to +4.0 D with a MRSE of +6.0 D. Safety and effectiveness data has not been established beyond these limits. Alternatives to PRK or LASIK include eyeglasses, contact lenses, radial keratotomy or automated lamellar keratoplasty.

PRK and LASIK are contraindicated in patients with collagen vascular, autoimmune or immunodeficiency disease, signs of keratoconus, patients taking isotretinoin or amiodarone hydrochloride or are pregnant or nursing. Similarly, neither PRK nor LASIK surgery is recommended in patients with a history of ophthalmic Herpes simplex or Herpes zoster. Caution should be employed in deciding to perform either surgery on patients with systemic disease likely to effect wound healing, such as connective tissue disease, diabetes, severe atopic disease or an immunocompromised status; safety and effectiveness has not been established for these patient populations.

Lower uncorrected visual acuity rates of 20/20 and 20/40 may be anticipated with higher degrees of correction. The safety and effectiveness of the VISX Excimer Laser System have NOT been established: in patients with progressive myopia or astigmatism, ocular disease, corneal abnormality, or previous corneal surgery or trauma in the ablation zone; in patients with corneal neovascularization with 1.0mm of the ablation zone; in patients under 21 years of age with myopia greater than 6.0 D and astigmatism greater than 1.0 D; in patients under 18 years of age; for patients over the long term; in patients with a history of keloid formation; and in patients who are taking sumatriptan.

It is possible following Laser Vision Correction treatment that patients will find it more difficult than usual to see in conditions such as very dim light, rain, snow, fog, or glare. Astigmatic patients under the age of 30 or with large pupils are more likely to experience a degradation in visual performance under these conditions. Additional potential side effects include halos, double images, haze, dryness, headache, redness, over correction, increased refractive astigmatism, visual fluctuations, loss of BSCVA, increased ocular pressure, second surgical intervention, corneal edema, flap/cap trauma, corneal perforation, and infection, corneal infiltration/ulcer, corneal epithelial defect, corneal decompensation, lens abnormality, retinal detachment, and retinal vascular accident.