



VISX® Receives FDA Approval For Variable Spot Scanning (VSS) Allowing Larger Treatment Zones

VSS™ Increases Treatment Zone to 8mm

MARCH 2001 — VISX, Incorporated announced today that the U.S. Food and Drug Administration (FDA) has approved the use of variable spot scanning to achieve larger treatment zones for myopia on the VISX STAR S2™ and STAR S3 ActiveTrak™ Excimer Laser Systems.

This new treatment zone increases the ablation area by 51%, extending the myopic treatment to 8 mm, providing additional flexibility when pupil size is a concern.

"For patients with larger pupils, this treatment has an advantage over flying spot laser systems," said Gustavo Tamayo, MD, of the Aruba Eye Institute, who conducted the international study. "This is due to the fact that variable spot scanning, which creates the blend zone, performs these larger treatments without significantly increasing ablation time or depth."

Flying spot scanning treatments, which are limited by a single spot size, have the potential to increase the depth of the ablation by as much as a factor of three.

The VISX STAR™ platform uses an exclusive SmartBeam™ technology which tailors the beam size from 0.65 mm to 6.5mm for the particular area to be treated, sparing precious corneal tissue.

The availability of more treatment options allows doctors to better address the specific needs of each patient. Also, this innovation may help to reduce patient concerns that sometimes delay the decision to have laser vision correction. This new feature is the latest example of VISX's commitment to research and development, which brings VISX certified doctors the most advanced laser vision correction technology.

The VISX STAR™ Excimer Laser System is approved for photorefractive keratectomy (PRK) for the reduction or elimination of:

1. MYOPIA (nearsightedness) between 0 and -12.0 D with up to -4.0 D of astigmatism
2. HYPEROPIA (farsightedness) between +1.0 and +6.0 D with no more than 1.0 D refractive astigmatism
3. HYPEROPIA (farsightedness) between +0.5 and +5.0 D of sphere at the spectacle plane with refractive astigmatism from +0.5 to +4.0D with a maximum manifest refraction spherical equivalent (MRSE) of +6.0D.

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VISX® Receives FDA Approval For Variable Spot Scanning (VSS) Allowing Larger Treatment Zones (CONTINUED)

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. Safety and effectiveness data has not been established beyond these limits. PRK and LASIK are elective procedures with alternatives including eyeglasses, contact lenses and other refractive surgeries.

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 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 hyperopia, with and without astigmatism, and 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.