DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 1 1998

Eric P. Ankerud, J.D.
Vice President,
Quality, Regulatory, and Clinical Affairs
Summit Technology, Inc.
21 Hickory Drive
Waltham, MA 02154

Re: P930034/S9
SVS Apex Plus Excimer Laser Workstation and emphasis® disc for myopic astigmatic photorefractive keratectomy (Toric PRK)
Filed: August 14, 1997
Amended: April 30, July 11 and 16, August 14 and 22, December 11, 17 and 23, 1997; by faxes on January 23, February 3, 5, 11, 18, 23, 25, and 26, and March 3, 1998

Dear Mr. Ankerud:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the SVS Apex Plus Excimer Laser Workstation and emphasis® disc. These devices are indicated to perform myopic astigmatic photorefractive keratectomy (Toric PRK):

1. for the reduction or elimination of mild to moderate myopia (-1.00 to <- 6.00 D) and concomitant reduction or elimination of mild to moderate astigmatism (-1.00 to < -4.00 D), in which the combined attempted correction must be < -6.00 D spherical equivalent at the spectacle plane;

2. in patients with documentation of a stable manifest refraction (± 1 D) over the past year; and,

3. in patients who are 21 years of age or older.

We are pleased to inform you that the PMA supplement is approved subject to the conditions described below and in the "Conditions of Approval" (enclosed). You may begin commercial distribution of the device upon receipt of this letter.

The SVS Apex Plus Excimer Laser Workstation and emphasis® disc for Toric PRK will only be enabled for myopia (-1.00 to <- 6.00 D) and astigmatism (-1.00 to < -4.00 D) and an attempted correction of < -6.00 D spherical equivalent at the spectacle plane.

The sale, distribution, and use of these devices are restricted to prescription use in accordance with 21 CFR 801.109 within the meaning of section 520(e) of the Federal Food, Drug, and Cosmetic Act (the act) under the authority of section 515(d)(1)(B)(ii) of the act. FDA has also determined that to ensure the safe and effective use of the device that the device is further restricted within the meaning of section 520(e) under the authority of section 515(d)(1)(B)(ii), (1) insofar as the labeling specify the requirements that apply to the training of practitioners who may use the device as approved in this order and (2) insofar as the sale, distribution, and use must not violate sections 502(q) and (r) of the act.

These restrictions on the use, labeling, promotion, and advertising of the device are applicable to Summit Technology, Inc., as well as device purchasers and users. Summit must notify the purchasers and users of these restrictions and include them in your training programs.

1. Only practitioners who are experienced in the medical management and surgical treatment of the cornea, who have been trained in laser refractive surgery (for myopia and astigmatism) including laser system calibration and operation, may use the device as approved in this order.

2. Prospective patients, as soon as they express an interest in Toric PRK and prior to undergoing surgery, must receive from the treatment provider the Patient Information Booklet (as described in your final submission to this PMA Supplement).

3. Prior to undergoing surgery, prospective patients must be informed of the alternatives for correcting their myopic astigmatism including eyeglasses, contact lenses and other refractive surgeries.

4. Comparison of the safety and effectiveness of this laser with any other method of refractive correction is prohibited. This prohibition is based on the fact that the data submitted for PMA supplemental approval do not compare the clinical outcome of this device with any other method of refractive correction. Such comparisons of safety and effectiveness are misleading and would misbrand your laser in accordance with section 502(a) of the act. All promotion and advertising for this device must include the following information on indications, risks and benefits:

    a. Approval is for the Summit Technology, Inc.'s application for the SVS Apex Plus Excimer Laser Workstation and emphasis® disc to perform myopic astigmatic photorefractive keratectomy (Toric PRK) for the reduction or elimination of mild to moderate myopia (-1.00 to <- 6.00 D) and concomitant

reduction or elimination of mild to moderate astigmatism (-1.00 to < -4.00 D), in which the combined attempted correction must be < -6.00 D spherical equivalent at the spectacle plane; in patients with documentation of a stable manifest refraction (± 1 D) over the past year; and, in patients who are 21 years of age or older.

b. Toric PRK is an elective procedure with the alternatives including eyeglasses, contact lenses, radial keratotomy, astigmatic keratotomy or automated lamellar keratectomy.

c. Approval of the application is based on a U. S. study of 151 eyes followed for six months, together with supplemental safety and effectiveness information from the nine month exam.

d. The study found that of the 151 eyes, 84% were corrected to 20/40 or better, and 48% were corrected to 20/20 or better without spectacles or contact lenses.

e. The study showed the following complications and adverse events occurred in at least 1% of the subjects at six month post-treatment: blurry vision (1.3%), foreign body sensations (1.3%), double vision (2.0%), increase in intraocular pressure (2.0%), halo (3.3%), light sensitivity (3.3%), decrease ≥ 2 lines of the vision with eyeglasses (4.0%), ghost images (4.6%), and glare (8.6%).

f. Long term risks of Toric PRK beyond 9 months have not been studied.

g. This laser is not indicated to correct farsightedness, or myopic astigmatism where the myopia is ≥- 6.00 D, astigmatism is ≥ -4.00 D, or for which the attempted correction is ≥- 6.00 D spherical equivalent. It is not to be used in procedures other than those described in the approved Operator's Manual.

h. Note that the complete name for the approved devices is "SVS Apex Plus Excimer Laser Workstation and emphasis® disc for myopic astigmatic photorefractive keratectomy (Toric PRK) (-1.00 to <- 6.00 D myopia and -1.00 to <4.00 D astigmatism, for a combined attempted correction of < -6.00 D spherical equivalent at the spectacle plane)". An acceptable alternate version of this official name is "Toric PRK laser correction of mild to moderate nearsightedness and astigmatism". The word excimer, ultraviolet, or UV may be used instead of Toric PRK. Names other than those appearing above require approval in a PMA supplement.

In addition to the postapproval requirements in the enclosure, you must report to FDA CDRH's Office of Compliance at the address below of any instances of device tampering or usage outside of the approved indication, and any excimer systems that were exported under an 801(e) order and are now back in the U.S.

OC/Division of Enforcement (HFZ-331)
Center for Devices and Radiological Health
Food and Drug Administration
2098 Gaither Road
Rockville, MD 20850

Failure to comply with the conditions of approval invalidates this approval order. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act.

CDRH will notify the public of its decision to approve your PMA by making available a summary of the safety and effectiveness data upon which the approval is based. The information can be found on the FDA CDRH Internet HomePage located at http://www.fda.gov/cdrh/pmapage.html. Written requests for this information can also be made to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857. The written request should include the PMA number or docket number. Within 30 days from the date that this information is placed on the Internet, any interested person may seek review of this decision by requesting an opportunity for administrative review, either through a hearing or review by an independent advisory committee, under section 515(g) of the Federal Food, Drug, and Cosmetic Act (the act).

You are reminded that, as soon as possible and before commercial distribution of your device, you must submit an amendment to this PMA supplement submission with copies of all approved labeling in final printed form.

All required documents should be submitted in triplicate, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

PMA Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Blvd.
Rockville, Maryland 20850

If you have any questions concerning this approval order, please contact Ms. Quynh Hoang at (301) 594-2018.

Sincerely yours,

Susan Alpert, Ph.D., M.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure: "Conditions of Approval"

Issued: 3-4-98

CONDITIONS OF APPROVAL

APPROVED LABELING. As soon as possible, and before commercial distribution of your device, submit three copies of an amendment to this PMA submission with copies of all approved labeling in final printed form to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration (FDA), 9200 Corporate Blvd., Rockville, Maryland 20850.

ADVERTISEMENT. No advertisement or other descriptive printed material issued by the applicant or private label distributor with respect to this device shall recommend or imply that the device may be used for any use that is not included in the FDA approved labeling for the device. If the FDA approval order has restricted the sale, distribution and use of the device to prescription use in accordance with 21 CFR 801.109 and specified that this restriction is being imposed in accordance with the provisions of section 520(e) of the act under the authority of section 515(d)(1)(B)(ii) of the act, all advertisements and other descriptive printed material issued by the applicant or distributor with respect to the device shall include a brief statement of the intended uses of the device and relevant warnings, precautions, side effects and contraindications.

PREMARKET APPROVAL APPLICATION (PMA) SUPPLEMENT. Before making any change affecting the safety or effectiveness of the device, submit a PMA supplement for review and approval by FDA unless the change is of a type for which a "Special PMA Supplement-Changes Being Effected" is permitted under 21 CFR 814.39(d) or an alternate submission is permitted in accordance with 21 CFR 814.39(e). A PMA supplement or alternate submission shall comply with applicable requirements under 21 CFR 814.39 of the final rule for Premarket Approval of Medical Devices.

All situations which require a PMA supplement cannot be briefly summarized, please consult the PMA regulation for further guidance. The guidance provided below is only for several key instances.

A PMA supplement must be submitted when unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures necessitate a labeling, manufacturing, or device modification.

A PMA supplement must be submitted if the device is to be modified and the modified device should be subjected to animal or laboratory or clinical testing designed to determine if the modified device remains safe and effective.

A "Special PMA Supplement - Changes Being Effected" is limited to the labeling, quality control and manufacturing process changes specified under 21 CFR 814.39(d)(2). It allows for the addition of, but not the replacement of previously approved, quality control specifications and test methods. These changes may be implemented before FDA approval upon acknowledgment by FDA that the submission is being processed as a "Special PMA Supplement - Changes Being Effected." This acknowledgment is in addition to that issued by the PMA Document Mail Center for all PMA supplements submitted. This procedure is not applicable to changes in device design, composition, specifications, circuitry, software or energy source.

10

Alternate submissions permitted under 21 CFR 814.39(e) apply to changes that otherwise require approval of a PMA supplement before implementation of the change and include the use of a 30-day PMA supplement or annual postapproval report. FDA must have previously indicated in an advisory opinion to the affected industry or in correspondence with the applicant that the alternate submission is permitted for the change. Before such can occur, FDA and the PMA applicant(s) involved must agree upon any needed testing protocol, test results, reporting format, information to be reported, and the alternate submission to be used.

POSTAPPROVAL REPORTS. Continued approval of this PMA is contingent upon the submission of postapproval reports required under 21 CFR 814.84 at intervals of 1 year from the date of approval of the original PMA. Postapproval reports for supplements approved under the original PMA, if applicable, are to be included in the next and subsequent annual reports for the original PMA unless specified otherwise in the approval order for the PMA supplement. Two copies identified as "Annual Report" and bearing the applicable PMA reference number are to be submitted to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, Maryland 20850. The postapproval report shall indicate the beginning and ending date of the period covered by the report and shall include the following information required by 21 CFR 814.84:

(1) Identification of changes described in 21 CFR 814.39(a) and changes required to be reported to FDA under 21 CFR 814.39(b).

(2) Bibliography and summary of the following information not previously submitted as part of the PMA and that is known to or reasonably should be known to the applicant:

(a) unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices ("related" devices include devices which are the same or substantially similar to the applicant's device); and

(b) reports in the scientific literature concerning the device.

If, after reviewing the bibliography and summary, FDA concludes that agency review of one or more of the above reports is required, the applicant shall submit two copies of each identified report when so notified by FDA.

ADVERSE REACTION AND DEVICE DEFECT REPORTING. As provided by 21 CFR 814.82(a)(9), FDA has determined that in order to provide continued reasonable assurance of the safety and effectiveness of the device, the applicant shall submit 3 copies of a written report identified, as applicable, as an "Adverse Reaction Report" or "Device Defect Report" to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, Maryland 20850 within 10 days after the applicant receives or has knowledge of information concerning:

(1) A mix-up of the device or its labeling with another article.

(2) Any adverse reaction, side effect, injury, toxicity, or sensitivity reaction that is attributable to the device and

(a) has not been addressed by the device's labeling or

(b) has been addressed by the device's labeling, but is occurring with unexpected severity or frequency.

(3)Any significant chemical, physical or other change or deterioration in the device or any failure of the device to meet the specifications established in the approved PMA that could not cause or contribute to death or serious injury but are not correctable by adjustments or other maintenance procedures described in the approved labeling. The report shall include a discussion of the applicant's assessment of the change, deterioration or failure and any proposed or implemented corrective action by the applicant. When such events are correctable by adjustments or other maintenance procedures described in the approved labeling, all such events known to the applicant shall be included in the Annual Report described under "Postapproval Reports" above unless specified otherwise in the conditions of approval to this PMA. This postapproval report shall appropriately categorize these events and include the number of reported and otherwise known instances of each category during the reporting period. Additional information regarding the events discussed above shall be submitted by the applicant when determined by FDA to be necessary to provide continued reasonable assurance of the safety and effectiveness of the device for its intended use.

REPORTING UNDER THE MEDICAL DEVICE REPORTING (MDR) REGULATION. The Medical Device Reporting (MDR) Regulation became effective on December 13, 1984. This regulation was replaced by the reporting requirements of the Safe Medical Devices Act of 1990 which became effective July 31, 1996 and requires that all manufacturers and importers of medical devices, including in vitro diagnostic devices, report to the FDA whenever they receive or otherwise become aware of information, from any source, that reasonably suggests that a device marketed by the manufacturer or importer:

(1)May have caused or contributed to a death or serious injury; or

(2)Has malfunctioned and such device or similar device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

The same events subject to reporting under the MDR Regulation may also be subject to the above "Adverse Reaction and Device Defect Reporting" requirements in the "Conditions of Approval" for this PMA. FDA has determined that such duplicative reporting is unnecessary. Whenever an event involving a device is subject to reporting under both the MDR Regulation and the "Conditions of Approval" for a PMA, the manufacturer shall submit the appropriate reports required by the MDR Regulation within the time frames as identified in 21 CFR 803.10(c) using FDA Form 3500A, i.e., 30 days after becoming aware of a reportable death, serious injury, or malfunction as described in 21 CFR 803.50 and 21 CFR 803.52 and 5 days after becoming aware that a reportable MDR event requires remedial action to prevent an unreasonable risk of substantial harm to the public health. The manufacturer is responsible for submitting a baseline report on FDA Form 3417 for a device when the device model is first reported under 21 CFR 803.50. This baseline report is to include the PMA reference number. Any written report and its envelope is to be specifically identified, e.g., "Manufacturer Report," "5-Day Report," "Baseline Report," etc. Any written report is to be submitted to:

Food and Drug Administration
Center for Devices and Radiological Health
Medical Device Reporting
PO Box 3002
Rockville, Maryland 20847-3002

Copies of the MDR Regulation (FOD # 336&1336)and FDA publications entitled "An Overview of the Medical Device Reporting Regulation" (FOD # 509) and "Medical Device Reporting for Manufacturers" (FOD #987) are available on the CDRH WWW Home Page. They are also available through CDRH's Fact-On-Demand (F-O-D) at

800-899-0381. Written requests for information can be made by sending a facsimile to CDRH's Division of Small Manufacturers Assistance (DSMA) at 301-443-8818.

P930034/S9

SUMMARY OF SAFETY AND EFFECTIVENESS DATA FOR A SUPPLEMENTAL PREMARKET APPROVAL APPLICATION

I. GENERAL INFORMATION

Device Generic Name: Ophthalmic Excimer Laser System

Device Trade Name: SVS Apex Plus Excimer Laser Workstation and emphasis® disc

Applicant's Name and Address: Summit Technology, Inc.
21 Hickory Drive
Waltham, MA 02154 USA

Premarket Approval Application (PMA) Supplement Number: P930034/S9

Date of Notice of Approval to Applicant: March 11, 1998

The SVS Apex Plus Excimer Laser Workstation was approved on February 7, 1997 for phototherapeutic keratectomy (P910067/S1) and for the limited indication for myopic photorefractive keratectomy using a 6.0 mm ablation zone in patients 21 years of age or older with myopia 1.5 to 7.0 D and concomitant astigmatism ≤ 1.5 D whose refractive change for the one year prior to the laser treatment is within ± 1.0 D (P930034/S2). The sponsor submitted this supplement to expand the indication statement. The updated preclinical and clinical work to support this expanded indication is provided in this summary. For more information on the data which supported the original indications, the original Summaries of Safety and Effectiveness Data to the respective PMA applications should be referenced which can be obtained from the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Drive, rm. 1-23, Rockville, MD 20857 under Docket # 95M-0179 for phototherapeutic keratectomy and #96M-0274 for myopic photorefractive keratectomy.

II. INDICATIONS FOR USE

The SVS Apex Plus Excimer Laser Workstation and emphasis® disc are indicated to perform myopic astigmatic photorefractive keratectomy (Toric PRK):

1. for the reduction or elimination of mild to moderate myopia (-1.00 to <- 6.00 D) and concomitant reduction or elimination of mild to moderate astigmatism (-1.00 to < -4.00 D), in which the combined attempted correction must be < -6.00 D spherical equivalent at the spectacle plane;

10

2. in patients with documentation of a stable manifest refraction (± 1 D) over the past year; and,

3. in patients who are 21 years of age or older.

III. CONTRAINDICATIONS, WARNINGS, AND PRECAUTIONS

A. Contraindications:

Toric PRK treatment should not be performed in patients:

1. with uncontrolled vascular disease or auto-immune diseases because it is well known that these patients have difficulty in corneal healing and are more susceptible to corneal melting;

2. who are pregnant and/or nursing, due to the potential for temporary fluctuation in refraction during this time;

3. with signs of keratoconus since eyes with this condition may have unstable corneas;

4. known to have a previous history of keloid formation because their corneal healing response is less predictable; or,

5. taking Accutane (isotretinoin) or Cordarone (amiodarone hydrochloride)

B. Warnings:

1. Toric PRK should not be performed in patients whose refractive history is unstable since an accurate pretreatment baseline refraction for the calculation of the desired correction can not be obtained.

2. Toric PRK is not recommended in patients with Herpes Simplex Virus or Herpes Zoster since cases of herpes reactivation have been reported after use of the excimer laser. Further clinical experience is necessary regarding the use of the 193 nanometer excimer laser wavelength in patients with these conditions.

C. Precautions:

1. Toric PRK should not be performed in patients who are unable to cooperate during the treatment because of the potential difficulty in aligning the laser beam and keeping the eye steady during the treatment.

2. Prior to initiating epithelium removal, practitioners should arm and test the laser to ensure that it is ready to deliver laser energy.

3. The safety and effectiveness of Toric PRK in patients with a history of glaucoma have not been established.

4. The safety and effectiveness of Toric PRK in patients taking Imitrex (sumatriptan succinate) have not been studied.

5. The safety and effectiveness of Toric PRK in patients who are under 21 years of age have not been established.

6. Although the effects of Toric PRK on visual performance under poor lighting conditions have not been determined, it is possible that post-procedure patients will find it more difficult than usual to see in conditions such as very dim light, rain, snow, fog, or glare from bright lights at night.

7. The long term safety and effectiveness of Toric PRK has not been established.

IV. DEVICE DESCRIPTION

The excimer laser and a new component, the emphasis® disc, are the subject of this PMA supplement.

The excimer laser for Toric PRK differs from the approved one in these characteristics: fluence of 180 mJ/cm^2 at the disc plane and 162 mJ/cm^2 at the corneal plane. Furthermore, these features in the excimer laser are now utilized or activated: a port for sliding in the emphasis® disc cassette and a purging system to remove the plume generated during a disc ablation.

The emphasis® disc contains three components: a single-use PMMA disc that contains the cylinder correction, single-use vacuum tweezer for picking up the PMMA disc, and a re-usable cassette to hold the disc. Ten discs are made available for corrections from -1.0 to -5.0 D cylinder.

17

To perform the combined myopic astigmatic treatment with the excimer laser and disc, sphere correction is delivered through the laser's expanding iris and cylinder correction through the disc. The correction or optical zone is an ellipse of 5.0 mm x 6.5 mm dimension.

V. ALTERNATE PRACTICES AND PROCEDURES

There are currently four other alternatives for the correction of mild to moderate myopic astigmatism:

Automated Lamellar Keratoplasty
Contact Lenses
Radial Keratotomy and Astigmatic Keratotomy
Spectacles

Each alternative has its own advantages and disadvantages. A prospective patient should fully discuss with his/her care provider these alternatives in order to select the correction method that best meets his/her expectation and lifestyle.

VI. MARKETING HISTORY

Since 1987 when the first excimer laser was sold overseas, Summit Technology, Inc. has sold or distributed over 140 laser systems to users in approximately 40 countries in North America, South America, Europe, Middle East, and Far East. The Summit Excimer Laser System has not been withdrawn from any country or market for reasons of safety or effectiveness.

VII. ADVERSE EFFECTS OF THE DEVICE ON HEALTH

During the immediate/early postoperative period, reported problems are primarily associated with postoperative re-epithelialization and early postoperative healing. They include: postoperative pain (first 24 to 48 hours), corneal swelling, double vision, foreign body sensation, shadow images, light sensitivity, tearing and pupil enlargement. These signs and symptoms are temporary in most subjects, usually subsiding within several weeks after surgery.

The adverse reactions and complications reported at the postoperative examinations include: blurry vision, double vision, drooping of eyelid, foreign body sensation, glare, ghost images, halo, haze, elevation of intraocular pressure, light sensitivity, loss of best corrected visual acuity, and overcorrection.

12

A discussion of these adverse events is found in the clinical summary section of this document (section IX).

VIII. SUMMARY OF PRECLINICAL STUDIES

A nonclinical laboratory study, which involved ablating the discs above photopaper, was performed to verify the dimensions of the shape that allows for a simultaneous myopic astigmatic correction. The correction level calculated from these dimensions must be within 10% of that intended to be imparted by the disc.

Another nonclinical laboratory study was performed to evaluate the achieved profiles (depth, width, and radius of curvature) in polymethylmethacrylate. The correction level calculated from these dimensions must be within 10% of that intended to be imparted by the disc.

IX. SUMMARY OF CLINICAL STUDY

The sponsor performed a phase II and a phase III Toric PRK clinical studies in the US under the auspices of an IDE G900143. The phase II study was a preliminary clinical study in which another disc configuration was evaluated. The Phase III study utilized the disc configuration intended for market. Data from the Phase III study therefore served as the basis for the approval decision. Specifically, safety and effectiveness outcomes at 6 month were assessed as stability is reached by that time. Outcomes at 9 months postoperatively were also evaluated for confirmation. The phase III study is described in details as follows.

A. Study Objectives

The Phase III study was conducted to evaluate the safety and effectiveness of the excimer laser and emphasis® disc in improving the uncorrected visual acuity of myopic astigmatic subjects.

B. Study Design

The Phase III study was a prospective, multicenter, single-arm cohort study where the primary control would be the preoperative state of the treated eye *(i.e.,* comparison of pretreatment and post-treatment visual parameters in the same eye).

10

C. Inclusion and Exclusion Criteria

Enrollment in the Phase III study was limited to subjects requiring mild to moderate spherical corrections of -1.00 to -7.00 D and mild to moderate cylindrical corrections of -1.00 to -5.00 D (based on the subject's manifest refraction); preoperative best spectacle corrected visual acuity (BSCVA) of 20/25 or better; preoperative best contact lens over refraction corrected visual acuity that did not differ more than 11 letters from the BSCVA; and refractive stability within $\pm$ 1.00 D for a period of at least one year.

Subjects were not permitted to enroll in the study if they met any of the following exclusion criteria: functionally monocular *(i.e.,* BSCVA of fellow eye worse than 20/40); difference of more than 1.00 D between preoperative manifest refraction spherical equivalent (MRSE) and cycloplegic refraction spherical equivalent; history of glaucoma or a preoperative intraocular pressure of 21 mm Hg or greater; irregular astigmatism; progressive retinal pathology, such as diabetic retinopathy; clinically significant cataract; signs of keratoconus; or previous intraocular or corneal surgery.

D. Study Plan, Patient Assessments, and Efficacy Criteria

All subjects were expected to return for follow-up examinations at 1, 3, and 7 days (only required at 7 days if not re-epithelialized at 3 days), and 1, 3, 6, 9, 12, 18 and 24 months postoperatively.

Subjects were permitted to have second eyes (fellow eyes) treated a minimum of three months after treatment of the first eye. In addition, subjects were eligible for retreatment if they had a stable uncorrected visual acuity (UCVA) of worse than 20/40 and a stable MR-SE of worse than -1.00 D. Retreatment was not permitted until at least six months after the initial treatment.

Preoperatively, the subjects medical and ocular histories were recorded. Immediate postoperatively, re-epithelialization data were collected. During the study, objective parameters measured included best spectacle corrected visual acuity, uncorrected visual acuity, manifest refraction, intraocular pressure, pupil size and status of the cornea, conjunctiva, anterior chamber, lens, vitreous, retina, and externals. These tests were performed preoperatively, and required at selected postoperative visits or in response to an adverse event: contact lens over refraction, contrast sensitivity, corneal topography, cycloplegic refraction, and slit lamp photographs. A patient questionnaire was to be administered to all subjects at preoperatively and postoperatively at 6, 12,18 and 24 months.

15

Success was defined as an uncorrected visual acuity of 20/40 or better and predictability of ± 1.0 D MRSE.

E. Study Period, Investigational Sites, and Demographics

1. Study period and investigational sites

Subjects were treated between May 28, 1996, and February 4, 1997. The database for this PMA supplement reflects data collected through July 25, 1997 and includes 202 eyes of which there are164 first eyes and 38 second eyes. There were seven investigational sites.

Table 1

Principal Investigator/Co-Investigator and Site	Number of eyes treated
Michael Gordon, MD/Perry Binder, MD Vision Surgery and Laser Center San Diego, CA	37
Peter Hersh, MD The Cornea and Laser Vision Institute Teaneck, NJ	25
Edward Manche, MD/Robert Hetland, MD Stanford University Medical Center Stanford, CA	21
Daniel Gold, MD/Bernard Milstein, MD The Eye Clinic of Texas Galveston, TX	32
Jonathan Rubenstein, MD/ Randy Epstein, MD Rush Presbyterian-St. Luke's Eye Center Physicians Ltd. Chicago, IL	18
Vance Thompson, MD Ophthalmology, Ltd Sioux Empire Medical Center Sioux Falls, SD	44
Helen Wu, MD/Roger Steinert, MD Lawrence Memorial Eye Clinic Medford, MA	25
TOTAL	202

2. Demographics

The demographics of this study are very typical for a contemporary refractive surgery trial performed in the US. Of the 202 treated eyes, 58.4% (118/202) were from male subjects and 41.6% (84/202) from

110

female subjects. Furthermore, 97.5% (197/202) were from Caucasians, 0.5% (1/202) were from Blacks, and 2.0% (4/202) were of other races. The right eye was treated in 53.5% (108/202) cases and the left eye was treated in 46.5% (94/202) cases. The mean age of the subjects treated was 39 ± 8.6 years with a range from 19 to 66. From the existing data for this laser for PRK, gender has not been a factor in safety and effectiveness outcomes. Age was a factor in that younger subjects were more predictable.

An analysis of the data revealed that there was only one subject treated in this study under the age of 21. Therefore, the approved indication should be limited to subjects 21 years of age and older.

Table 2: Preoperative Characteristics

UCVA 20/40 or better	0.5% (1/202)
UCVA 20/50 to 20/80	6.9% (14/202)
UCVA 20/100 or worse	92.6% (187/202)
manifest refraction cylinder	-1.94 ±0.81 D; range -1.00 to -6.00 D
manifest refraction sphere	-3.81 ± 1.65 D; range -1.00 to -7.25 D
manifest refraction spherical equivalent	-4.78 ± 1.71 D; range -1.75 to -10.25 D
cycloplegic refraction cylinder	-1.96 ± 0.80 D; range -0.75 to -5.75 D
cycloplegic refraction sphere	-3.63 ± 1.65 D; range -0.50 to -7.00 D
cycloplegic refraction spherical equivalent	-4.62 ± 1.69 D; range -1.38 to -9.63 D

F. Data Analysis and Results

1. Preoperative characteristics

Table 2 contains a summary of the preoperative acuity and refraction. Note that per protocol, subjects with preoperative refractive error greater

than that enabled in the devices can be enrolled in the study as long as the correction that is being sought falls within the range for the study.

2. Postoperative results

a. Accountability

With the exception of the 1 eye not examined at the one month visit, accountability up to six months was at 100%. At nine months, 201 of the 202 eyes were eligible for the exam and of which 131 were examined.

b. Stability of outcome

Paired-difference analysis of MRSE was performed to assess stability (table 3). Only subjects who had every follow-up exam up to six months were included in the analysis.

As shown by table 3, between the 3 and 6 month examinations, 94.6% (191/202) of the 202 eyes (FULL COHORT) had a change in MRSE of ±1.00 D. This is an indication that the FULL COHORT may be stable by 6 months. When the data were further stratified by attempted correction, stability appeared to be demonstrated by the group with attempted corrections of < 7.00 D (COHORT A) in which 97.1% (170/175) had a change in MRSE of ±1.00 D between 3 and 6 months. Other indications that stability may have been reached by COHORT A were that over time, the mean change of MRSE in COHORT A approached and became practically 0, and its confidence interval narrowed.

To identify the time point of stability for COHORT A, the available data for this group at 9 months (table 4) were analyzed. Again, only those who had every follow-up exam up to 9 months were included in the analysis. As can be seen, the mean change of MRSE in COHORT A and its confidence interval did not change beyond 6 month. This second analysis provided further assurance that COHORT A reached stability between 3 and 6 months; and therefore, allowing the evaluation of safety and effectiveness using the 6 month data from COHORT A.

19

Table 3
Change of MRSE
6 months analysis

	Between 1 and 3 Months n/N (%)			Between 3 and 6 Months n/N (%)		
	FULL COHORT	< 7.00 D	≥ 7.00 D	FULL COHORT	< 7.00 D	≥ 7.00 D
± 1.00 D	187/201 (93.0%)	163/174 (93.7%)	24/27 (88.9%)	191/202 (94.6%)	170/175 (97.1%)	21/27 (77.8%)
Mean of Paired-Differences	-0.22 D	-0.20 D	-0.35 D	-0.11 D	-0.06 D	-0.46
SD	0.58	0.57	0.64	0.55	0.49	0.76
95% CI	-0.30 to -0.14 D	-0.28 D to -0.12 D	-0.59 to -0.11 D	-0.19 to -0.03 D	-0.13 D to -0.01 D	-0.75 to -0.17 D

Table 4: COHORT A (< 7.00 D)
Change of MRSE
9 months analysis

	Between 1 and 3 Months	Between 3 and 6 Months	Between 6 and 9 months
± 1.00 D	85/94 (90.4%)	91/94 (96.8%)	93/94 (98.9%)
Mean of Paired-Differences	-0.20 D	-0.04 D	-0.05 D
SD	0.57	0.52	0.39
95% CI	-0.32 D to -0.08 D	-0.15 D to +0.07 D	-0.13 D to +0.03 D

c. Effectiveness results

Effectiveness analysis was performed on the COHORT A which demonstrated stability by 6 months.

i. Correction of Cylindrical Component (scalar and vector analyses)

Table 5 provides an analysis of scalar astigmatism - the amount of correction achieved in terms of its abduction. The Ophthalmic Devices Panel (the Panel), in the January 14, 1997 meeting in which the Panel assessed outcomes from a myopic astigmatic treatment, provided FDA with some guidance as to the acceptable effectiveness rates. The Panel considered 64% as an acceptable mean reduction in absolute cylinder at the point of stability. Therefore, the 70% reduction at 6 months achieved with this device is acceptable.

TABLE 5: COHORT A
Scalar Astigmatism – Achieved Correction

	6 Months n = 175	**9 Months n = 107**
Attempted Cylinder Correction (D)	1.88	1.96
Achieved Cylinder Correction (D)	1.32	1.33
Percent Correction	70.0%	67.9%

When the data are further stratified by attempted correction (table 6), eyes with attempted correction between 4.00 and 5.00 D of cylinder raise significant concern with only 33.3% achieving ±1.00 D of intended. This low percentage could be an artifact of the small n=3, or could be a real finding given the observed trend of reduced percentages of the intended vs. achieved with increase in the attempted correction (91% for 1.00 to 1.90D group, decreasing to

64.3% for 3.00 to 3.90D). In either case, the data in the range of 4.00 to 5.00D do not support approval for this range.

Table 6: COHORT A
Predictability of Cylinder Component by Attempted Correction

PREDICTABILITY	Attempted Correction (D)									
	1.00 - 1.90 (N =100)		2.00 - 2.90 (N =58)		3.00 - 3.90 (N =14)		4.00 - 5.00 (N =3)		TOTAL (N=175)	
	n	%	n	%	n	%	n	%	n	%
OVERCORRECTED	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
± 1.00 DIOPTER	91	91.0	48	82.8	9	64.3	1	33.3	149	85.1
UNDERCORRECTED	9	9.0	10	17.2	5	35.7	2	66.6	26	14.9

The sponsor utilized the Retzlaff method for calculating vectoral change. This method was described in the Journal of Cataract and Refractive Surgery, Volume 19, May, 1993, pages 393-398.

Looking at vector magnitude, the Intended Refractive Correction ("IRC") had a mean of -1.88 D with a median of -1.75, a minimum of -4.75 D and a maximum of -1.00 D, and the Surgically Induced Refractive Correction ("SIRC") had a mean of 1.54 D, a median of 1.30 D, a minimum of 0.25 D and a maximum of 5.25 D. The results for SIRC/IRC were: 81% mean with a standard deviation of 23%, a median of 84%, a minimum of 17% and a maximum of +145%. The Panel has found 82.5% acceptable for correction efficacy (SIRC/IRC) at stability. The 81% achieved by this device is certainly within the same range and is therefore acceptable.

When cylinder correction efficacy (SIRC/IRC for the cylinder component only) were stratified by preoperative diopter of cylinder, 77% efficacy is the lowest achieved by this device for any particular range and is acceptable given that levels as low as 76.6% were found acceptable by the Panel.

Analysis of residual astigmatic error post treatment reveals that only 3.4% (6/175) of eyes in COHORT A had a residual cylinder magnitude $\geq$ 1.0D and absolute shift in axis >30°. The Panel has found 4.0% as an acceptable range for this value in the overall cohort. When residual astigmatic errors were stratified by preoperative diopter of absolute cylinder, it was noted that 2 of the 3 eyes with pre-operative cylinder >4D and $\leq$ 5D had a residual cylinder $\geq$ 1 D and an absolute shift in axis of >30°. This analysis further supported the recommendation for limiting approval indication for this device to attempted cylindrical correction of less than 4.0 D

ii. Correction of Spherical Component

At six months, 55.4% of eyes were within +0.50 D of the intended spherical correction and 80.0 % were within +1.00 D. Although there are no specific benchmarks for only the spherical component, these results are within the benchmarks for MRSE and are therefore acceptable.

iii. Key efficacy outcomes

Key efficacy outcomes of COHORT A stratified by attempted correction MRSE can be found in Tables 5 and 6.

An analysis of tables 7 and 8 revealed that the 6.00 to 6.99D MRSE group has significantly lower rates than the rest of the cohort with only 25% of eyes within $\pm$ 0.5 D MRSE and 41.7 % within $\pm$1.00 D MRSE. These percentages improved by 9 months to 58.3 and 75.0 respectively, but if stability is reached by 6 months, an improvement at 9 months is questioned. The apparent improvement may merely be a function of the smaller denominator (12 eyes) and can be addressed when more data in this range become available. At this point, the efficacy results of the group with attempted correction <6.00 D MRSE (151 eyes at 6 month) warrant an approval consideration. This approvable group will henceforth be called COHORT B.

Table 7: COHORT A
Summary of Key Efficacy Variables at 6 Months
by Attempted Correction (MRSE)

Efficacy Variables	1.0 to 1.99 D n/N (%)	2.0 to 2.99 D n/N (%)	3.0 to 3.99 D n/N (%)	4.0 to 4.99 D n/N (%)	5.0 to 5.99 D n/N (%)	CUM TOTAL <6 D n/N (%)	6.0 to 6.99 D n/N (%)	CUM TOTAL <7 D n/N (%)
UCVA 20/20 or better	3/5 (60.0)	20/29 (69.0)	16/40 (40.0)	18/39 (46.2)	16/38 (42.1)	73/151 (48.3)	6/24 (25.0)	79/175 (45.1)
UCVA 20/40 or better	5/5 (100.0)	26/29 (89.7)	35/40 (87.5)	30/39 (76.9)	31/38 (81.6)	127/151 (84.1)	18/24 (75.0)	145/175 (82.9)
MRSE +/-0.50 D	3/5 (60.0)	21/29 (72.4)	21/40 (52.5)	14/39 (35.9)	15/38 (39.5)	74/151 (49.0)	6/24 (25.0)	80/175 (45.7)
MRSE +/-1.00 D	5/5 (100.0)	26/29 (89.7)	29/40 (72.5)	25/39 (64.1)	26/38 (68.4)	111/151 (73.5)	10/24 (41.7)	121/175 (69.1)

Table 8: COHORT A
Summary of Key Efficacy Variables at 9 Months
by Attempted Correction (MR-SE)

Efficacy Variables	1.0 to 1.99 D n/N (%)	2.0 to 2.99 D n/N (%)	3.0 to 3.99 D n/N (%)	4.0 to 4.99 D n/N (%)	5.0 to 5.99 D n/N (%)	CUM TOTAL <6 D n/N (%)	6.0 to 6.99 D n/N (%)	CUM TOTAL <7 D n/N (%)
UCVA 20/20 or better	2/4 (50.0)	12/17 (70.6)	12/26 (46.2)	7/23 (30.4)	11/25 (44.0)	44/95 (46.3)	6/12 (50.0)	50/107 (46.7)
UCVA 20/40 or better	4/4 (100.0)	17/17 (100.0)	22/26 (84.6)	17/23 (73.9)	21/25 (84.0)	81/95 (85.2)	10/12 (83.3)	91/107 (85.0)
MRSE +/-0.50 D	2/4 (50.0)	13/17 (76.5)	9/26 (34.6)	12/23 (52.2)	9/25 (36.0)	45/95 (47.3)	7/12 (58.3)	52/107 (48.6)
MRSE +/-1.00 D	4/4 (100.0)	17/17 (100.0)	23/26 (88.5)	18/23 (78.3)	16/25 (64.0)	78/95 (82.1)	9/12 (75.0)	87/107 (81.3)

d. Safety Outcomes

Among the parameters assessed in the consideration of safety were: acuity, re-epithelialization rate, intraocular pressure, corneal status, anterior segment status, retinal and vitreal status. Below are the reported rates.

i. Key safety variables

Key safety variables for COHORT A at all postoperative visits and for its subgroup COHORT B at 6 months are given in tables 9 and 10. These data further support the approval of the COHORT B.

Table 9: COHORT A
Summary of Key Safety Variables

	1 Month	3 Months	6 Months	9 Months
	n/N (%)	n/N (%)	n/N (%)	n/N (%)
Safety Variables				
Loss of ≥ 2 lines BSCVA	18/173 (10.4)	13/175 (7.4)	6/175 (3.4)	5/102 (4.9)
BSCVA worse than 20/40	1/173 (0.6)	1/175 (0.6)	0/175 (0.0)	0/102 (0.0)
BSCVA worse than 20/25 if 20/20 or better preop	7/173 (4.0)	3/175 (1.7)	0/175 (0.0)	0/102 (0.0)
Not Reported	1/174	0/175	0/175	5/107

Table 10: COHORT B
Summary of Key Safety Variables at 6 Months by Attempted Correction (MR-SE)

	1.0 to 1.99 D n/N (%)	2.0 to 2.99 D n/N (%)	3.0 to 3.99 D n/N (%)	4.0 to 4.99 D n/N (%)	5.0 to 5.99 D n/N (%)	**CUM TOTAL <6 D** n/N (%)
Safety Variables						
Loss of ≥ 2 lines BSCVA	1/5 (20.0)	0	3/40 (7.5)	1/39 (2.6)	1/38 (2.6)	6/151 (4.0%)
BSCVA worse than 20/40	0	0	0	0	0	0
BSCVA worse than 20/25 if 20/20 or better preoperatively	0	0	0	0	0	0

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ii. Adverse events and complications

Table 11 presents a summary of FDA defined adverse events for the FULL COHORT and COHORT B. The benchmark for adverse events is a rate of less than 1 %. For the approvable cohort B which has a sample size of 151 eyes, a 0 observed rate means that the true rate can be as high as 2.4% (in other words, if this study of 151 eyes were to be repeated over and over again, the observed adverse event rate for each study may be different each time but it will not be higher than 2.4%). Obviously, a rate of 2.4% is higher than the 1.0% benchmark. Since a PRK procedure was performed to support the new indication, and there are prior PRK safety data for this laser, FDA's assessment of the safety of the PRK procedure with this laser was not limited to the data from this specific study. Rather, the data from this specific study were assessed for confirmation.

Table 11: Adverse Events at 6 months

Adverse Event	FULL COHORT	COHORT B
Corneal infiltrate or ulcer	0	0
Persistent central corneal epithelial defect at 1 month or later	0	0
Corneal edema at 1 month or later	0	0
Uncontrolled IOP with increase of > 10 mm Hg above baseline, or any reading above 25 mm Hg	0	0
Late onset of haze beyond 6 months with loss of 2 lines (10 letters) or more BSCVA	NA	NA
Decrease in BSCVA of > 10 letters not due to irregular astigmatism as shown by hard contact lens refraction, at 6 months or later	0.50% (1/202)	0
Retinal detachment	0	0

Table 12 presents a summary of the FDA defined complications at the 6 month exam. The rates as shown do not raise any concern.

Table 12: Complications at 6 months

Complication	FULL COHORT	COHORT B
Corneal edema between 1 week and 1 month after the procedure	0.0%	0.0%
Peripheral corneal epithelial defect at 1 month or later	1.0% (2/202)	0.0%
Recurrent corneal erosion at 1 month or later	0.5% (1/202)	0.0%
Foreign body sensation at 1 month or later	2.0% (4/202)	1.3% (2/151)
Patient discomfort* at 1 month or later	0.5% (1/202)	0.0%
Double images in the operative eye	3.0% (6/202)	2.0% (3/151)
Ghost images in the operative eye	4.5% (9/202)	4.6% (7/151)

*Information was collected regarding patient discomfort not pain as specified in FDA sample table.

e. Retreatments

All retreatment procedures were performed at least 6 months after the initial treatment date with written approval from Summit. The following retreatments were performed through the data collection cutoff date for FULL COHORT: 31 retreatments were performed including 24 sphere-only PRK treatments, 4 Toric PRK treatments, 2 Astigmatic Keratotomies, and 1 Radial Kerototomy with AK. For COHORT A there were 28 retreatments (16%) and for COHORT B there were 20 retreatments (13%).

For COHORT B there were no eyes with BSCVA loss of greater than 2 lines of BSCVA post retreatment and 100% of eyes were within 1.0 D of plano MRSE after retreatment. 84% of COHORT B retreated eyes had UCVA of 20/40 or better. Overall retreatment outcomes for the refractive range of COHORT B do not raise significant safety concerns.

f. Patient satisfaction

The preoperative patient survey was completed by all 202 subjects of FULL COHORT. At 6 months after the Toric treatment the patient survey was completed by 194 subjects; this was the first time after treatment that the patient survey was administered.

At the 6 month visit 72.2% of FULL COHORT stated that they did not wear any corrective lenses compared with 0.0% preoperatively. With regard to the satisfaction with vision without corrective lenses question, preoperatively 92.1% of subjects said they were very to somewhat unsatisfied with their vision without corrective lenses (0 or 1 on a scale of 0 to 5 with 0 for very unsatisfied and 5 for very satisfied); this decreased to 17.5% at 6 months postoperatively. Preoperatively, 6.4% were somewhat to very satisfied with their vision without corrective lenses while this increased to 56.2% at 6 months.

Patients were asked if they could read ordinary newsprint without corrective lenses. Preoperatively, 57.9% could read ordinary newsprint without corrective lenses while this improved to 89.2% of FULL COHORT at 6 months postoperatively.

Patients were asked if they could recognize a friend across the street without corrective lenses. Preoperatively, 6.9% indicated they could recognize a friend across the street without corrective lenses while this improved to 77.8% of FULL COHORT 6 months postoperatively.

g. Device failures

There were two cases in which the device stopped mid-procedure. The cause was determined to be a failure in the plume purging system. Subsequent to a modification of this system, no other cases were observed. No permanent injury has been reported from any of these failures.

X. CONCLUSIONS DRAWN FROM THE CLINICAL STUDY

The data in this application supports reasonable assurance of safety and efficacy of this device for the treatment of myopia from 1.00 up to < 6.00 D of sphere and concomitant correction of cylinder (in the minus form) from 1.00 up to < 4.0 D, and for which a

combined attempted correction must be < 6.00 D spherical equivalent as measured at the spectacle plane.

XII. FDA DECISION

On March 11, 1998, FDA issued an approval order to Summit Technology, Inc.

X. APPROVAL SPECIFICATIONS

Continued approval of the device is contingent upon abiding by the conditions of approval in the approval order.

SUMMIT TECHNOLOGY, INC.

SVS APEX PLUS EXCIMER LASER WORKSTATION
PRACTITIONER INFORMATION

MYOPIC ASTIGMATIC PHOTOREFRACTIVE KERATECTOMY (TORIC PRK)

for the reduction or elimination of mild to moderate myopia (-1.00 to < -6.00 D) and concomitant reduction or elimination of mild to moderate astigmatism (-1.00 to < -4.00 D); the combination of which must result in an attempted correction of < -6.00 D spherical equivalent at the spectacle plane

with the
emphasis® disc

CAUTION: RESTRICTED DEVICE: U.S. Federal law restricts this device to sale, distribution, and use by or on the order of a practitioner. U.S. Federal law restricts the use of this device to practitioners who have been trained in laser refractive surgery including laser system calibration and operation. U.S. Federal law restricts the use of this device to practitioners trained in the medical management and surgical treatment of the cornea. This device is not for use in mobile clinics.

Be certain that all patients are advised of the risks inherent in the use of this medical device and in the outcomes of Toric PRK before applying it to their person!

All patients must have the opportunity to read and understand the Patient Information Brochure for Toric PRK.

All patients must have the opportunity to read, understand and sign an Informed Consent Document for this treatment.

701

Improper use of this device may result in physical harm to a patient! If in doubt about the correct way to operate this medical device, seek help! Pay attention to all warnings, cautions and contraindications in the following practitioner information document and in the Laser Workstation User Manual.

A. Background:

The following practitioner information has been developed based on the experiences of active Summit excimer laser centers to provide recommendations concerning the use of the SVS Apex Plus Excimer Laser Workstation with the emphasis® disc for myopic astigmatic PRK procedures.

The practitioner and staff should read the Summit Technology SVS Apex Plus Excimer Laser Workstation User Manual, the following practitioner information, and the emphasis® disc package insert. **Practitioners must complete all necessary training as outlined by the Company prior to performing patient treatments.**

Summit Technology strongly recommends that new practitioners review the bibliography of peer review journal publications regarding this refractive surgical technique.

B. Directions For Use:

Indications For Use:

The SVS Apex Plus Excimer Laser Workstation and emphasis® disc are indicated to perform myopic astigmatic photorefractive keratectomy (Toric PRK):

1. for the reduction or elimination of mild to moderate myopia (-1.00 to < -6.00 D) and concomitant reduction or elimination of mild to moderate astigmatism (-1.00 to < -4.00 D); the combination of which must result in an attempted correction of < -6.00 D spherical equivalent at the spectacle plane;

2. in patients with documentation of a stable manifest refraction (± 1 D) over the past year; and

3. in patients who are 21 years of age or older.

Contraindications

The SVS Apex Plus Excimer Laser Workstation used in conjunction with the emphasis® disc for Toric PRK is contraindicated for the following:

1. Patients with uncontrolled vascular disease or autoimmune diseases, because it is well known that these patients have difficulty in corneal healing and are more susceptible to corneal melting;

2. Women who are pregnant or nursing, due to the potential for temporary fluctuation in refraction with pregnancy;

3. Patients with signs of keratoconus, since eyes with this condition may have unstable corneas.

4. Patients known to have a previous history of keloid formation, because their corneal healing response is less predictable; and

5. Patients taking Accutane (isotretinoin) or Cordarone (amiodarone hydrochloride).

Warnings:

The following Warnings pertain to the Apex Plus Excimer Laser Workstation used in conjunction with the emphasis® disc for Toric PRK:

1. The treatment should not be performed in patients whose refractive history is unstable since an accurate pretreatment baseline refraction for the calculation of the desired correction can not be obtained.

2. The treatment is not recommended in individuals with Herpes Simplex Virus or Herpes Zoster since cases of herpes reactivation have been reported after use of the excimer laser. Further clinical experience is necessary regarding the use of the 193 nanometer excimer laser wavelength in patients with this condition.

Precautions:

The following Precautions pertain to the Apex Plus Excimer Laser Workstation used in conjunction with the emphasis® disc for Toric PRK:

1. The treatment should not be performed in patients who are unable to cooperate during the treatment because of the potential difficulty in aligning the laser beam and keeping their eye steady during the procedure.

2. Prior to removing the epitheleum, practitioners should arm and test the laser to ensure that it is ready to deliver laser energy.

3. The safety and efficacy of Toric PRK in patients with a history of glaucoma has not been established.

4. The long term safety and efficacy of Toric PRK has not been established.

5. The safety and effectiveness of Toric PRK has not been established in patients who are under 21 years of age.

6. Patients taking Imitrex (sumatriptan succinate).

7. Although the effects of myopic astigmatic photorefractive keratectomy (Toric PRK) on visual performance under poor lighting conditions have not been determined, it is likely that patients will find it more difficult than usual to see in conditions such as very dim light, rain, snow, fog, or glare from bright lights at night.

C. Safety And Effectiveness Considerations:

Benefit/Risk Analysis

The information from the clinical investigation of the Summit Technology Apex Plus Excimer Laser Workstation used in conjunction with the emphasis® disc, provides reasonable assurance of safety and effectiveness.

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Benefits:

The Toric PRK clinical treatment performed with the Apex Plus Excimer Laser Workstation used in conjunction with the emphasis® disc, is effective in reducing myopia of -1.0 to < -6.0 diopters when astigmatism is -1.0 to < -4.0 diopters. Toric PRK allows:

- An improvement in an individual's myopic astigmatic correction which may reduce the patient's myopic astigmatic prescription or decrease the patient's dependence on eyeglasses and/or contact lenses.

- An improvement in an individual's myopic astigmatic correction which could potentially eliminate the patient's dependence on eyeglasses and/or contact lenses.

- Myopic astigmatic individuals may potentially experience the same level of visual function postoperatively without the aid of corrective lenses as experienced preoperatively with maximal correction.

The practitioner and patient should carefully weigh the benefits and risks of the Toric PRK procedure prior to performing the procedure on any one individual.

Risks:

Potential Adverse Reactions and Complications

The majority of adverse reactions/complications after Toric PRK occur in association with the normal healing that takes place after the procedure. Potential adverse effects and complications that may result in conjunction with the performance of the Toric PRK procedure include:

- Anterior stromal reticular haze
- Anisometropia
- Blindness
- Blurred vision
- Corneal decompensation
- Corneal epithelial defect
- Corneal infection
- Corneal scarring

- Corneal transplant
- Corneal thinning
- Corneal ulceration/perforation
- Decrease in best spectacle corrected visual acuity
- Difficulties wearing contact lenses postoperatively
- Diffuse nebulae
- Diffuse superficial punctate keratitis
- Dryness
- Epithelial hyperplasia
- Endophthalmitis
- Endothelial cell loss
- Foreign body sensation
- Glare
- Guttata
- Halo
- Hyphema
- Hypopyon
- Induced astigmatism regular/irregular
- Intraocular infection
- IOP elevation
- Iritis
- Iron lines
- Irregularities or deposits in the cornea (epithelium, stroma, Bowman's layer)
- Itching
- Keratoconus
- Lens opacity/cataract
- Microbial keratitis
- Microcysts
- Night vision difficulties
- Overcorrection
- Pain
- Patient discomfort
- Persistent corneal edema
- Photophobia
- Ptosis
- Reading difficulty
- Unknown long term effects
- Vascularization

The practitioner should make an objective assessment of the potential benefits of the excimer laser myopic astigmatic PRK procedure in light of the potential complications associated with the myopic astigmatic PRK procedure.

The following adverse events and complications were reported in conjunction with Summit Technology's Toric PRK Clinical Investigation:

Immediate/Early Post-treatment Complications:
The following complications have been reported in the first month after Toric PRK. They are associated with the normal post-treatment healing process and include: post-treatment pain (first 24 to 48 hours), corneal swelling, double vision, feeling something is in the eye, shadow images, light sensitivity, tearing and pupil enlargement. These symptoms are temporary and occur in many patients during the early post-treatment period.

Post-treatment Complications and Adverse Events at 6 Months:

The following is a list of the complications and adverse events reported at 6 months during Summit Technology's Toric PRK U.S. clinical trials that occurred in more than 1.0% of patients:

- Retreatment for undercorrection after 6 months (13.9%)
- Glare (8.6%)
- Ghost images (4.6%)
- Decrease in BCVA ≥ 2 lines (4.0%)
- Halo (3.3%)
- Light sensitivity (3.3%)
- Double vision (2.0%)
- Increase in IOP (2.0%)
- Foreign body sensations (1.3%)
- Blurry vision (1.3%)

The following complications and adverse events at 6 months occurred post-treatment in the Toric PRK clinical trials in less than 1.0% of patients:

- Drooping of eyelid (0.7%)
- Overcorrection > 1.0D (0.7%)
- Anterior stromal reticular haze (0.7%)
- Other ocular conditions (subjective comments) (0.7%)
- BCVA worse than 20/40 (0.0%)
- BCVA worse than 20/25, if 20/20 or better preop (0.0%)
- BCVA worse than 20/40, if 20/20 or better preop (0.0%)

D. Ancillary Equipment:

The following items will be needed when performing myopic astigmatic PRK procedures with the Summit Technology SVS Apex Plus Excimer Laser Workstation and emphasis® disc:

1. Sterile eye speculum
2. Gauze pads and tape
3. Carboxypropyl Methylcellulose 1.0% and/or 0.5%
4. Agent to constrict the pupil
5. Small ophthalmic sponges
6. Topical anesthetic
7. Slit Lamp available near the laser system
8. Materials to perform the SVS Apex Plus Excimer Laser Beam Profile and Alignment Test
9. Patient bed or chair capable of performing fine movements (comparable to the chair supplied by Summit Technology)
10. Standard instrument for mechanical epithelium removal (64 Beaver® blade)
11. 7.5 mm optical zone marker.
12. emphasis® "M" discs and suction cups for handling discs
13. emphasis® cassette
14. Vacuum tweezers

E. SVS Apex Plus Excimer Laser Workstation Parameters :

Ablation Zone Size:	System set at 6.5 mm x 5.0 mm
Intended Correction:	Spherical Correction: -1.0 to < -6.0 diopters, in 0.1 diopter increments. Cylindrical Correction: -1.0 to < -4.0 diopters, in 0.25 diopter increments, the combination of which must result in an attempted correction of < -6.00 D sperical equivalent at the spectacle plane
Pulse Energy Density:	180 mJ/cm^2 at the laser disc plane 162 mJ/cm^2 at the corneal plane
Repetition Rate:	System set at 10 Hz.

F. Directions For Use: Myopic Astigmatic (Toric) PRK:

Laser Preparation:

1. Turn on the SVS Apex Plus Excimer Laser Workstation and allow the system to warm up. Refer to the SVS Apex Plus Excimer Laser Workstation User Manual for start up and operating instructions regarding your laser system.

2. If it is the first procedure of the day, the Beam Profile and Alignment Test (refer to the User Manual) should be performed in accordance with Summit Technology's PRK beam profile test instructions. **This daily check should include a test of the emphasis® cassette alignment.**

3. If your test results meet the criteria specified in the beam profile and alignment test instructions proceed with the Toric PRK procedure. If your test results do **not** meet the test criteria; (1) contact Summit's Customer Service Department immediately or your Summit Service Representative and (2) do **not** use the laser on patients because of the potential for improper results.

emphasis® disc preparation:

4. Review the manifest refraction for the eye to be treated.

5. Select the attempted spherical and cylindrical correction to be programmed into the laser system based on the manifest refraction.

6. Select the appropriate "M" disc for treatment as determined by the spherical and cylindrical correction. To select the disc, use the Look-Up Table located at the end of this document or in Chapter 6 of your SVS Apex Plus User Manual. Laser disc selection may also be made by choosing the Toric PRK procedure and programming the desired correction into the laser system. The system will respond with the disc type required.

NOTE: When selecting a disc from the Look-Up Table, take care to ensure that the vertex distance of the manifest refraction you have chosen corresponds to the Look-Up Table you are using. If the vertex distances do not correspond, adjust the spherical and cylindrical values to the corneal plane.

7. Check the chamber of the emphasis® cassette to ensure it is free of obstructions by inserting the suction cup end of the vacuum tweezers into the chamber. Remove any obstructions being careful not to dislodge the O-ring.

CAUTION: Failure to remove obstructions, such as used discs or the disc alignment template, prior to insertion of the treatment disc may cause an undesired clinical result.

8. Open the appropriate disc package **(please retain the disc package for reference to the "M" number and "minimum thickness value, to be entered into the laser system)** and carefully pick up the disc with the vacuum tweezers using the suction cup provided. Check the printed surface to verify that the disc type is the same as was indicated on the external packaging. Place the disc in the cassette with the printed side facing down with the cassette alignment pins engaging the slots on the disc.

WARNING: Do not use the disc if it appears damaged in any way or becomes damaged in insertion into the disc cassette. Using a damaged disc could adversely affect the outcome of the treatment.

NOTE: Avoid contacting the delicate emphasis disc with any object while handling the disc. Do not contaminate the disc by contacting it with any surface. Do not manipulate the disc with anything other than the vacuum tweezers.

9. Slide the disc latch on the cassette to the closed position.

NOTE: Adjust the axis of astigmatism while viewing the emphasis cassette under low magnification. The laser system microscope should not be used for the axis alignment since higher magnification will bend the axis lines on the emphasis cassette which may result in inaccurate axis alignment.

10. To adjust for the axis of the astigmatic correction, push the astigmatic axis adjustment ring toward the body of the cassette to engage the adjustment mechanism and set the disc astigmatic axis to the angle of the patient's astigmatism in the **negative** cylinder format.

29

11. Release the axis adjustment ring to lock in the astigmatic axis selection.

NOTE: The disc must be aligned to the patient's axis of **minus** cylinder.

12. Do not insert the cassette until you are prompted to do so by the laser system software.

Patient Preparation

13. Approximately 30 minutes prior to the procedure, place 1 drop of topical anesthetic and a miotic agent in the operative eye. Additional topical anesthetic should be applied up until the epithelium removal has been initiated.

14. Move the patient to the slit lamp. Using a corneal marking pen, mark the 0° and 180° meridian on the patient's eye at the limbus.

15. Place the patient on the patient chair with the operative eye centered under the excimer laser delivery system.

16. Additional drops of topical anesthetic may be given to the eye **not** scheduled for treatment to relax the reflexes.

17. Patch the patient's eye **not** scheduled for treatment. A patch may also be placed on the side of the head next to the eye to be treated to collect excess fluids.

18. Place the speculum in the eye to be treated.

19. Turn on the HeNe aiming beams.

20. The patient should be instructed to keep his operative eye focused on the flashing green fixation target inside the red fixation ring in the laser downtube.

21. Position the patient with the HeNe aiming beams so that the two central spots intersect on the anterior surface of the cornea centered over the pupil. The 3 and 9 o'clock diverging HeNe beams should appear on the iris equally spaced from the center of the pupil.

20

22. Align the patient rotationally by lowering the patient chair until the HeNe aiming beams are at the limbus. Adjust the position of the patient until the two HeNe aiming beams are aligned with the 0° and 180° marks made on the patient's eye. When the patient is properly positioned, raise the patient chair and align the two HeNe aiming beams as described in step 20.

NOTE: The HeNe aiming beams mark the image plane of the excimer beam. The desired vertical area of effect is located where the two HeNe beams appear as one spot. In order to ensure that the patient is not exposed to hazardous levels of laser energy, the HeNe beams should not be fired at the patient continuously for longer than 390 seconds.

NOTE: Do **not** lean on the operating microscope or the excimer laser system during any portion of the procedure.

Patient Training

Patient training allows patients to become familiar with fixating the eye on the green fixation target as well as introducing the patient to the light, noise and smell produced by the laser system during laser energy delivery. The SVS Apex Plus Workstation provides two patient training sequences: Patient Training A and Patient Training B. Patient Training A is a simulated PRK where the laser energy is delivered on a coating of 1% methylcellulose. Patient Training B is a 25 pulse PTK designed to be delivered on dry epithelium. The patient should be made aware that there is no pain associated with the laser beam striking the cornea.

NOTE: Neither Patient Training A or Patient Training B is a refractive procedure.

Training "A"

1. Program the laser for Patient Training A. Arm and test the laser.

2. Apply 1% methylcellulose to the eye to ensure that the entire cornea is covered. This layer of methylcellulose will inhibit laser ablation of the cornea.

3. Begin firing the laser and closely observe the patient's ability to fixate during laser delivery. If the sound of the ablation changes, stop firing the laser as you may be ablating epithelium.

4. Repeat this procedure 2 to 3 times, as necessary, until the patient fixates adequately during laser delivery.

NOTE: If the patient cannot fixate after two to three training sessions, the practitioner may reschedule the clinical procedure.

Training "B"

1. Patient training B should be performed on dry epithelium. Delivering laser energy to the dry epithelium will produce a circular ablation on the patient's epithelium. This final training session allows the practitioner to ensure that the patient is able to fixate and introduces the patient to the noise, smell and sensation of the laser striking the cornea.

2. Using a small ophthalmic sponge, remove all remaining methylcellulose from the eye and from around the eye speculum.

3. Program the laser for Patient Training B. Arm and test the laser.

4. Make sure that the patient is aligned correctly and begin firing the laser. Closely observe the ability of the patient to fixate during laser delivery. This training will most closely mimic the actual procedure.

NOTE: Do not perform more than one Patient Training B session on the dry epithelium.

OPERATIVE TECHNIQUE:

1. Program the laser for the Toric PRK procedure.

2. Enter the manifest refraction spherical value at the spectacle plane.

3. Enter the manifest refraction cylindrical value at the spectacle plane.

4. Enter vertex distance. (A vertex distance of 00.0 mm may be selected if the entered spherical and cylindrical values were calculated down to the corneal plane.)

NOTE: If the entire sphere, cylinder, and vertex distance values result in a spherical equivalent greater than 5.9 D, the system will respond with "S.E. correction exceeds limit ..." and the user will be prompted to re-enter all values.

5. The system responds with "Insert laser disc type Mtt" where "tt" is the correct disc type determined by the laser system software for the treatment. **This should be the same disc type that has been selected from the Look-Up Table and inserted into the emphasis® cassette.** To confirm that the emphasis® disc prompted by the system software is the same disc type that is installed in the emphasis® cassette, press "Enter" to proceed.

6. Reconfirm that the emphasis® disc installed in the emphasis® cassette is the same disc type requested in step 5 by entering the disc type again.

7. The system responds with "Enter laser disc minimum thickness" This is a value printed on the emphasis® disc label, and is specific to the emphasis® disc installed.

8. The laser system will now calculate the total number of pulses necessary to perform the myopic and astigmatic correction, simultaneously.

9. The laser system will present all parameters entered into the laser system for your review and confirmation. Press Enter to confirm.

10. Check the HeNe alignment again. Align the patient rotationally by lowering the patient chair until the HeNe aiming beams are at the limbus. Adjust the position of the patient until the two HeNe aiming beams are aligned with the 0° and 180° marks made on the patient's eye. When the patient is properly positioned, raise the patient chair and align the two HeNe aiming beams as described in step 20.

11. Arm the Excimer laser. The system will prompt the user to insert the emphasis cassette. Turn the cassette over so that the astigmatic axis indicator faces down. Carefully slide the cassette into the cassette port until it latches into position.

12. Press the TEST button to complete the Arm and Test procedure, BEFORE beginning epithelium removal to ensure that the laser will complete the test mode, allowing the delivery of laser energy.

NOTE: If the laser remains armed for more than 20 minutes without firing, the system will automatically disarm and you will need to clear the laser and rearm and retest the system.

13. Reposition the patient's eye under the laser. Mark the intended optical zone using an 7.5 mm optical zone marker, centered symmetrically around the visual axis.

NOTE: Epithelium removal should occur with the patient under the laser to minimize the time period between epithelium removal and laser ablation. The goal is to remove the epithelium approximately 1 mm beyond the 6.5 mm ablation zone.

NOTE: Do not use alcohol, cocaine or any other substances to remove the epithelium. Application of these substances may influence the ablation rate of the excimer laser energy and could lead to a poor procedural result.

14. Mechanically remove the epithelium in the center of the eye using a standard instrument (such as a 64 Beaver blade) designed for epithelium removal. Take great care not to damage Bowman's layer. The area of epithelium removed should be slightly larger than the area to be treated. Remove the epithelium in a circumferential manner, starting at the outer diameter and moving towards the center. Clean Bowman's layer very carefully to remove all debris with a small ophthalmic sponge.

15. Once the epithelium has been removed, apply 1 drop of 0.5% or 1.0 % methylcellulose to a small ophthalmic sponge and continue cleaning Bowman's layer. The methylcellulose is used to smooth out any surface irregularities commonly present in Bowman's layer. The cleaning should continue with a small, dry ophthalmic sponge until all methylcellulose has been removed.

NOTE: It is important that all epithelium is removed prior to performing the myopic astigmatic PRK procedure. Histology has shown that small particles of epithelium may remain even when they cannot be seen through the operating microscope.

NOTE: No additional drops should be placed on Bowman's layer once the cleaning procedure has been completed. Application of liquids at this time will impact the desired clinical result.

16. Check HeNe alignment again. Align the patient rotationally by lowering the patient chair until the HeNe aiming beams are at the limbus. Adjust the position of the patient until the two HeNe aiming beams are aligned with the 0° and 180° marks made on the patient's eye. When the patient is properly positioned, raise the patient chair and align the two HeNe aiming beams so that the two central spots intersect on the anterior surface of the cornea centered over the pupil. The 3 and 9 o'clock diverging HeNe beams should appear on the iris equally spaced from the center of the pupil.

17. Turn the coaxial illuminator all the way down or off and position the oblique illuminator on the patient's operative eye. The oblique light may be used at a low intensity, so that the HeNe aiming beams appear clearly on the patient's iris and corneal surface.

NOTE: During laser energy delivery, the practitioner should concentrate on the position of the HeNe on the iris. The practitioner should not be distracted by watching the laser energy impacting the cornea.

18. Press the foot pedal until the laser stops firing. The total number of laser pulses for the desired refractive correction should be delivered in one continuous application.

19. The practitioner should observe the procedure through the operating microscope. While the laser is firing, the practitioner should closely observe the fixation of the patient's eye. If the patient's eye moves during the procedure, firing of the laser should be stopped. The patient should be instructed to re-fixate and the treatment resumed. The laser system will keep track of how many pulses have been delivered and how many are remaining.

NOTE: As stated previously, during laser energy delivery, the practitioner should concentrate on the position of the HeNe's on the iris. The practitioner should not be distracted by watching the laser energy impacting the cornea.

NOTE: Do **not** lean on the operating microscope or the excimer laser system during laser delivery.

20. Unlatch the emphasis® cassette. Carefully slide the cassette out of the cassette port.

NOTE: Each emphasis® disc may only be used for one procedure. Do not re-use the disc .

Postoperative Technique:

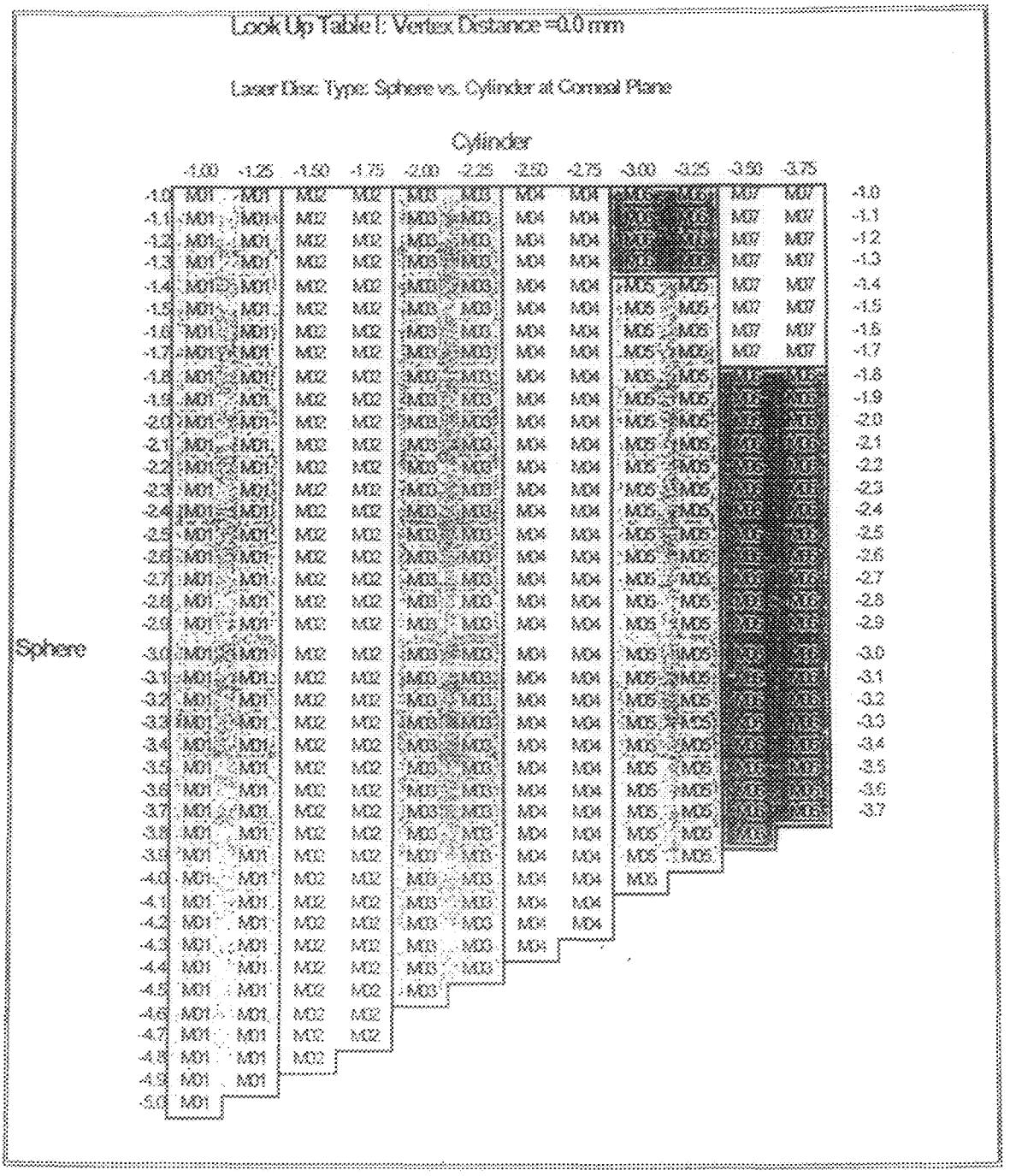
1. Remove the eye speculum.

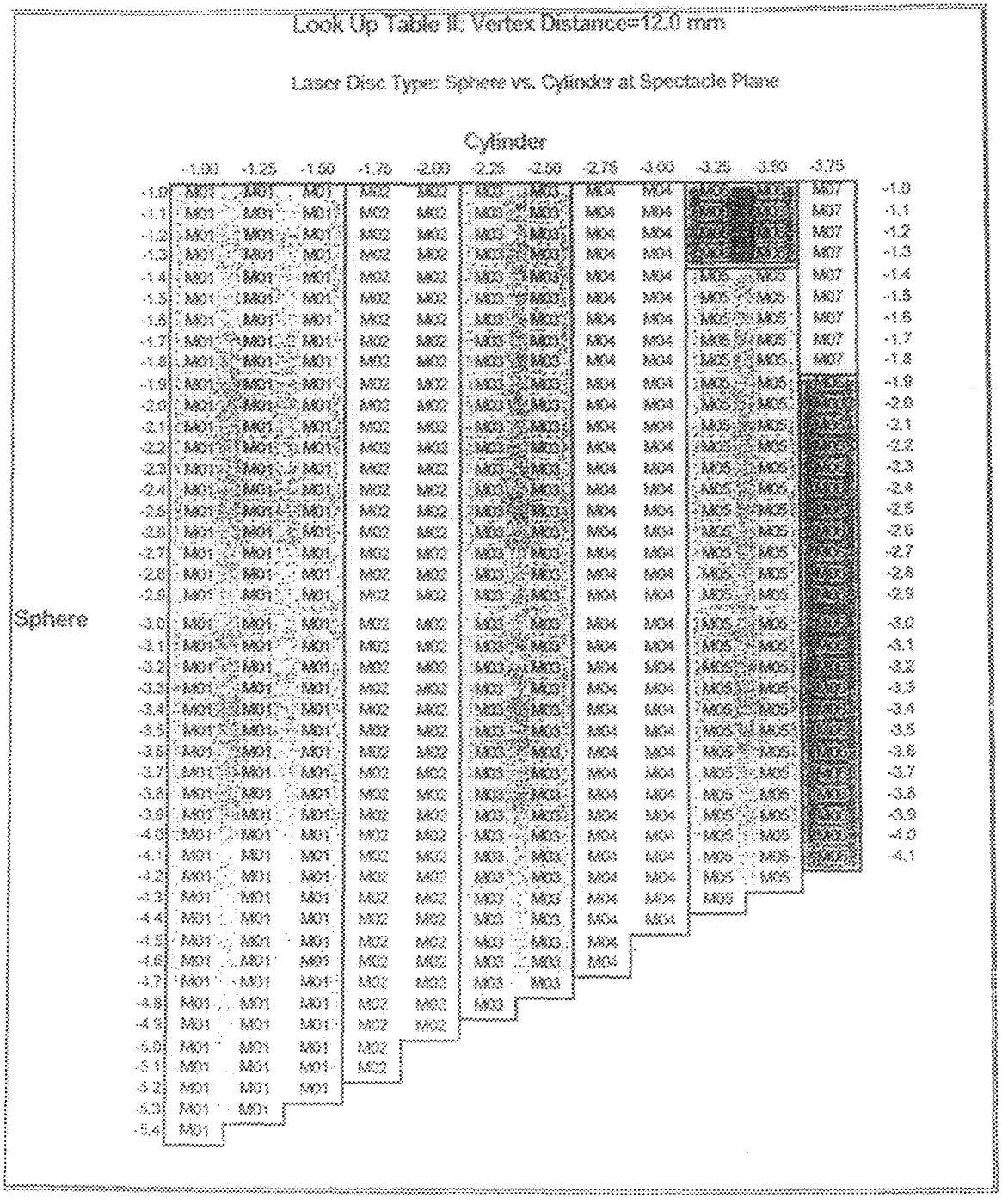
2. All practitioners participating in Summit Technology's clinical investigation inserted a Pro Tek bandage contact lens.

3. Most patients will experience postoperative pain for the first 24 hours after a myopic astigmatic PRK procedure. Postoperative pain medication may be prescribed at the practitioner's discretion.

REABLATION TECHNIQUE:

Reablation treatments for Toric PRK may be used to treat residual myopia with astigmatism or residual myopia. Before performing retreatments status-post Toric PRK, the practitioner must determine the amount of haze present in order to decide on the method of epithelial debridement. If little or no haze is noted, the practitioner may mechanically debride the epithelium. If more marked haze is noted, the practitioner may use the laser for epithelial debridement as described in the Photorefractive Keratectomy Practitioner Information document located in the User Manual.


Look Up Table I: Vertex Distance =0.0 mm
Laser Disc Type: Sphere vs. Cylinder at Corneal Plane
Cylinder
Sphere


Look Up Table II: Vertex Distance=12.0 mm
Laser Disc Type: Sphere vs. Cylinder at Spectacle Plane
Cylinder
-1.00 -1.25 -1.50 -1.75 -2.00 -2.25 -2.50 -2.75 -3.00 -3.25 -3.50 -3.75
Sphere
-1.0 -1.1 -1.2 -1.3 -1.4 -1.5 -1.6 -1.7 -1.8 -1.9 -2.0 -2.1 -2.2 -2.3 -2.4 -2.5 -2.6 -2.7 -2.8 -2.9 -3.0 -3.1 -3.2 -3.3 -3.4 -3.5 -3.6 -3.7 -3.8 -3.9 -4.0 -4.1 -4.2 -4.3 -4.4 -4.5 -4.6 -4.7 -4.8 -4.9 -5.0 -5.1 -5.2 -5.3 -5.4
MD1 MD2 MD3 MD4 MD5 MD6 MD7

PATIENT INFORMATION

MYOPIC ASTIGMATIC PHOTOREFRACTIVE KERATECTOMY (TORIC PRK)

Mild to Moderate Myopia (-1.0 TO <-6.0 diopters)

With Mild to Moderate Astigmatism (-1.0 TO <-4.0 diopters)

Please speak with your doctor regarding Toric PRK for the correction of Myopia and Astigmatism. Use of any machine for a medical treatment requires discussion with a qualified doctor. It is important that you read this booklet and then carefully discuss its contents with your doctor.

Summit Technology, Inc.
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Waltham, Massachusetts 02154
Phone 781-890-1234
Fax 781-890-0313

Doc No. 711168
Rev. C

IMPORTANT INFORMATION

- Toric PRK is a permanent operation to the cornea; it cannot be reversed.
- Alternatives to Toric PRK include eyeglasses, contact lenses, radial keratotomy (RK), automated lamellar keratectomy (ALK), astigmatic keratotomy (AK), or similar non-laser surgical procedures.
- Toric PRK is not a laser version of RK, AK or ALK; it is completely different.
- Applicants for some occupations, such as pilots, may need to meet certain visual acuity standards after having any refractive surgery.
- Refractive error must be stable (within +/-1.0 D) for at least one year before the surgery.
- The following risks of Toric PRK should be noted:
  - transient complications: pain (24-48 hours), corneal swelling, double vision, feeling something in the eye, shadow images, light sensitivity, tearing and pupil enlargement. These problems may last up to several weeks.
  - Complications and adverse events at 6 months occurring in at least 1% of subjects: foreign body sensations (1.3%), blurry vision (1.3%), increase in intraocular pressure (2.0%), double vision (2.0%), light sensitivity (3.3%), halo (3.3%), decrease in vision with glasses of 2 lines or more (4.0%), ghost images (4.6%), and glare (8.6%);
- The following benefits of Toric PRK surgery should be noted:
  - Reduced dependence on eyeglasses or contact lenses.
  - Toric PRK may be an alternative to eyeglasses in some patients who are intolerant of contact lenses.
  - Toric PRK is another alternative to correct nearsightedness and astigmatism.
- Patients considering Toric PRK should:
  - Discuss fully with one or more ophthalmic surgeons the complications of Toric PRK, the risks and the time required for healing, and have a complete eye examination before making a final decision.
  - Read both the Patient Information Booklet and the Informed Consent Document (ICD) provided by your doctor carefully before signing the ICD.

TABLE OF CONTENTS:
What You Need To Know Preoperatively

You are entitled to be informed about the treatment proposed, including the risks of the treatment and alternatives to it. Please read this booklet and then discuss the content with your doctor so that all of your questions are answered to your satisfaction. Informed Consent is the law! Please read the Informed Consent before signing.

INTRODUCTION

The following information is being provided to you because you are thinking about having Myopic Astigmatic Photorefractive Keratectomy (Toric PRK) laser surgery for the correction of mild to moderate (-1.0 to <-6.0 diopters) nearsightedness (myopia) with astigmatism (-1.0 to <-4.0 diopters). The options for correction of myopia and astigmatism now include eyeglasses, contact lenses, the refractive surgical procedures known as radial keratotomy (RK), astigmatic keratotomy (AK), and automated lamellar keratectomy (ALK), and Toric PRK. Toric PRK is a completely different technique than RK, AK and ALK.

Please note that it may be necessary to have both eyes treated with Toric PRK to achieve a satisfactory result. There are cases where it is appropriate to have Toric PRK on only one eye. This educational information is provided to help you make an informed decision about Toric PRK as a method of changing your cornea to correct your nearsightedness. Please read this material completely and discuss any questions with your doctor in order to decide if Toric PRK is right for you. Only a qualified eye doctor can determine whether or not you are suitable for Toric PRK. **You should know that a small percentage of patients treated with the excimer laser have permanent adverse visual effects.**

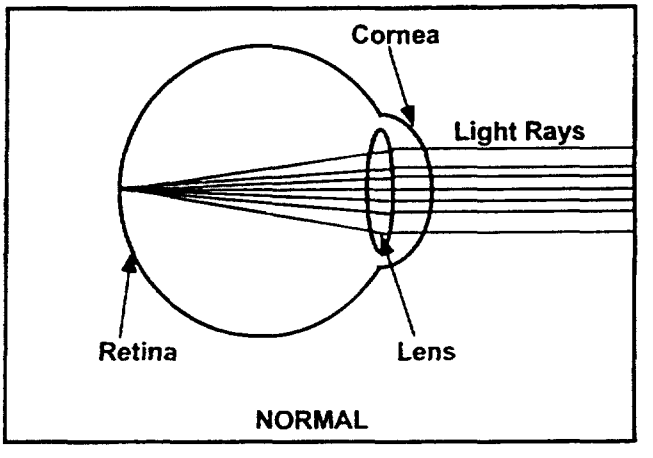
The goal of Toric PRK is to reduce your need for eyeglasses or contact lenses by flattening and reshaping the cornea through Toric PRK laser surgery.

HOW THE EYE FUNCTIONS

Your eye focuses light to form images or "pictures", very much like a video camera. Your eye changes these images into electrical signals, which are then sent back to your brain. If your eye is out of focus, what you see will be blurred.

The cornea at the front of the eye bends (or refracts) the light rays onto your retina. This clear tissue is responsible for two-thirds of the focusing power of your eye. The lens within your eye finishes the job of focusing the light onto your retina.

DIAGRAM 1



THE NEARSIGHTED EYE (MYOPIA)

The excimer laser has been approved for the refractive treatment of mild to moderate myopia (nearsightedness). Myopia is the most common refractive condition affecting one in four people in North America. Myopic individuals are nearsighted; they see near objects clearly, but distant objects are blurry. Myopia occurs when light rays entering the eye are focused in front of your retina instead of directly on it. Nearsightedness can be corrected by eyeglasses, contact lenses, or refractive surgery. The first two options, eyeglasses and contact lenses, can be adjusted through new lenses if your vision changes. The tendency to develop myopia runs in families. Myopia (nearsightedness) usually starts in childhood and typically stabilizes in the late teens or early adulthood.

THE ASTIGMATIC EYE

Myopia frequently occurs with astigmatism. In the astigmatic eye, the front of the cornea is not equally curved; it is slightly oval in shape. Light rays that enter the eye are unequally bent resulting in a distortion of the image. Myopic astigmatism can be corrected by eyeglasses, contact lenses or refractive surgery.

CHECKING YOUR FOCUS

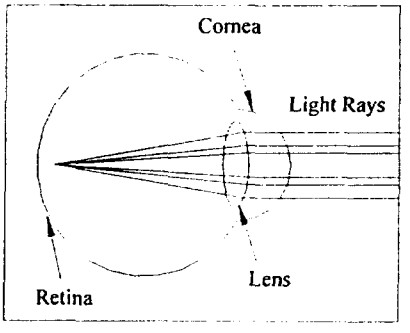
When your doctor checks your vision, he or she considers where the eye focuses light relative to your retina. When your doctor corrects your vision, he or she properly focuses light on the retina. The amount required to correct your vision is in units of diopters (D). Toric PRK can correct up to 6D of myopic astigmatism.

WHAT IS TORIC PRK?

Toric PRK is a surgical treatment for nearsightedness and astigmatism in which an excimer laser flattens and reshapes the front surface of the cornea by removing microscopic amounts of tissue.

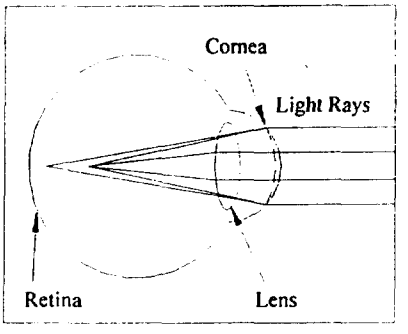
Diagrams 2 and 3 illustrate the nearsighted eye and the astigmatic eye as described on page 6 of this booklet. Diagram 4 illustrates the astigmatic eye following Toric PRK.

DIAGRAM 2



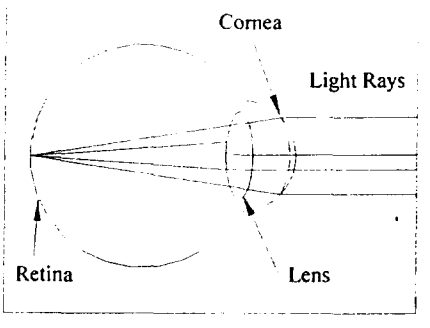
THE NEARSIGHTED EYE

DIAGRAM 3



THE ASTIGMATIC EYE

DIAGRAM 4



ASTIGMATIC EYE
FOLLOWING TORIC PRK

WHAT IS AN EXCIMER LASER?

A laser is an instrument that can produce and control a powerful beam of light. Laser light can be directed and controlled more precisely than normal light, and it can be delivered in extremely brief, intense pulses.

The excimer laser produces a beam of ultraviolet light in pulses that last only a few billionths of a second. Each pulse removes a microscopic amount of tissue by evaporating it, producing very little heat and usually leaves underlying tissue almost the same.

Toric PRK has been studied for four years in the U.S. The procedure is performed using a computerized laser to correct myopia (nearsightedness) and astigmatism. The excimer laser is well-suited for corneal reshaping, because the removal of microscopic amounts of tissue can produce the results you need to correct your nearsightedness and astigmatism.

HOW IS TORIC PRK PERFORMED?

A specially-trained eye doctor uses the beam from the computerized laser to remove microscopic amounts of corneal tissue, precisely reshaping the cornea.

Prior to the laser treatment, some drops are placed on the eye to numb it. Use of the laser beam lasts about 15-60 seconds. The laser removes a microscopic portion of the surface tissue to reshape the cornea. This treatment is performed on one eye at a time. The second eye can be treated if all goes well and vision stabilizes without complications or adverse reactions. Toric PRK of the second eye can be done three months or sooner after the first eye, at the surgeon's discretion.

After this treatment, most people report that they no longer need to wear eyeglasses or contact lenses. In the clinical trials, 84% of people could see 20/40 or better after treatment, reporting that they were able to function normally and even drive without eyeglasses or contact lenses. The remaining people experienced an improvement in vision without eyeglasses or contact lenses, but may still need to wear eyeglasses or contact lense's for some tasks. Toric PRK does not eliminate the need for reading eyeglasses. In some patients, reading eyeglasses may be required after treatment even if they were not worn before treatment. ***Keep in mind that your vision may take months to clear up and stabilize.***

Changes due to refractive surgery are permanent and cannot be undone or easily modified if your vision or focus changes or if the initial surgery is not successful (which occurs in a small percentage of cases).

WHAT YOU NEED TO KNOW PREOPERATIVELY

If you are interested in having Toric PRK you will need to have a pre-treatment examination to determine if your eye condition is right for the treatment.

Your pre-treatment examination will involve a complete medical and eye history, in which both eyes will be examined by a vision and eyeglass check, a microscopic examination, a glaucoma test, and possibly the computerized mapping of your cornea.

Prior to coming to the surgery please talk with your doctor about your normal schedule for taking any prescribed medications. Also, talk with your doctor about the advisability of eating or drinking immediately prior to the surgery. You should arrange for someone to drive you home after the surgery and to your next doctor's appointment. You should not drive until the doctor gives you permission to do so.

THE DAY OF SURGERY

Just prior to the surgery you will be given some drops in your eyes. You will be escorted into the room that contains the laser system. You will see a large machine with an arm sticking out that has the microscope attached to it. Also you may see a computer screen, a surgeon's chair and the reclining patient chair. You will be asked to sit in the patient chair. You will be laying face up toward the microscope and the ceiling. Your eye will be numbed with more drops.

Overall the surgery will take approximately 10-20 minutes, however the use of the laser beam lasts only 15-60 seconds. The doctor will place an instrument between your eyelids to hold them open during the treatment. Try to keep both eyes open without squeezing since this will allow you to relax more. The doctor will ask you to look up through the bottom of the microscope. You will see colored lights in the center of the microscope tube. The fixation light is very important in keeping your eye positioned properly during the laser surgery. **The doctor will instruct you how and when to look at these colored lights.** The doctor will then take you through a practice session with the laser to familiarize you with the sights and sounds of the treatment so that you will be prepared for what to expect during the actual treatment. Remember you and your doctor are a team; cooperate with your doctor to get the best possible result.

After the training session, the treatment will begin with the doctor using a surgical instrument or the laser to remove the outermost layer of the cornea called the epithelium. Only after the doctor has repositioned your head in the chair, refocused the microscope and asked you to fixate on the colored lights will the laser treatment be performed.

After your treatment, your doctor may place some drops or ointment into your eye. Your eye may then be patched for protection and comfort. The treatment itself is painless because of the numbing drops. When these eye drops wear off, your eye will likely hurt for one to two days. The doctor may recommend medicine to make you more comfortable during the immediate post-treatment period.

FIRST DAYS AFTER THE TREATMENT

If a patch is used it is usually removed the next day. You may be sensitive to light and glare and have the feeling that something is in your eye for the first few weeks while the outer layer of your cornea grows back completely. Sunglasses may be worn to make you more comfortable during this time. Initially your eye may be overcorrected making you hyperopic (farsighted). Objects up close may be blurry. This is part of the normal healing process after Toric PRK and it may take up to three months for your vision to stabilize. All eyes get some degree of haze or cloudiness in the cornea following treatment which may or may not interfere with vision. The haziness tends to decrease over time and should eventually disappear completely.

ARE YOU A GOOD CANDIDATE FOR TORIC PRK?

Read this page then check with your doctor.

Be sure to ask your doctor any questions that occur to you.

Anyone who is considering Toric PRK should:

- Be 21 years of age or older;
- Have healthy eyes which are free from retinal problems, corneal scars, and any eye disease;
- Have mild to moderate myopia (nearsightedness) within the range of treatment: - 1.0 to <-6.0 diopters of correction with astigmatism of -1.0 to <-4.0 diopters;
- Discuss with your doctor's **office** how you will pay for the treatment and follow-up care since laser correction is not covered by most health insurance policies;
- Be fully informed about the risks and benefits of Toric PRK as compared to other available treatments for myopia and astigmatism.

Speak to your doctor about your reasons for choosing Toric PRK and if you would make a good candidate.

The most common risks associated with Toric PRK include glare, ghost images, and decrease in vision with eyeglasses of 2 lines or more.

Please see page 14 for a detailed list and definitions of all known risks associated with Toric PRK. It is important to thoroughly discuss all possible risks with your eye doctor.

INDICATIONS AND USE OF THE EXCIMER LASER TO PERFORM TORIC PRK

DEVICE AND TREATMENT

The Summit Technology SVS Apex Plus Excimer Laser Workstation used in conjunction with the emphasis® disc has been designed to correct myopia (nearsightedness) and astigmatism simultaneously by changing the shape of the cornea. This treatment involves the removal of microscopic amounts of corneal tissue (a few microns at a time.)

INDICATIONS FOR USE

SVS Apex Plus Excimer Laser Workstation and emphasis® disc are indicated to perform myopic astigmatic photorefractive keratectomy (Toric PRK):

1. for the reduction or elimination of mild to moderate myopia (-1.00 to <-6.00 D) and concomitant reduction or elimination of mild to moderate astigmatism (-1.00 to <-4.00 D); the combination of which must result in an attempted correction of <-6.00 D spherical equivalent at the spectacle plane;

2. in patients with documentation of a stable manifest refraction (± 1 D) over the past year; and,

3. in patients who are 21 years of age or older.

CONTRAINDICATIONS

The Apex Plus Excimer Laser Workstation used in conjunction with the emphasis® disc for Toric PRK is contraindicated for the following:

- Patients with uncontrolled vascular disease or auto-immune diseases because it is well known that these patients have difficulty in corneal healing and are more susceptible to corneal melting;

- Women who are pregnant or nursing, due to the potential for temporary fluctuation in refraction with pregnancy;

- Patients with signs of keratoconus, since eyes with this condition may have unstable corneas;

- Patients known to have a previous history of keloid formation, because their corneal healing response is less predictable; and
- Patients taking Accutane (isotretinoin) or Cordarone (amiodarone hydrochloride).

WARNINGS

The following Warnings pertain to the SVS Apex Plus Excimer Laser Workstation used in conjunction with the emphasis® disc for Toric PRK:

- The treatment should not be performed in patients whose refractive history is unstable since an accurate pretreatment baseline refraction for the calculation of the desired correction can not be obtained.
- The treatment is not recommended in individuals with Herpes Simplex Virus or Herpes Zoster since cases of herpes reactivation have been reported after use of the excimer laser. Further clinical experience is necessary regarding the use of the 193 nanometer excimer laser wavelength in patients with these conditions.

PRECAUTIONS

The following Precautions pertain to the SVS Apex Plus Excimer Laser Workstation used in conjunction with the emphasis® disc for Toric PRK:

- The treatment should not be performed in patients who are unable to cooperate during the treatment because of the potential difficulty in aligning the laser beam and keeping their eye steady during the treatment.
- Prior to removing the epithelium, the doctor should arm and test the laser to ensure that it is ready to deliver laser energy.
- The safety and efficacy of Toric PRK in patients with a history of glaucoma has not been established.
- The long-term safety and effectiveness of Toric PRK has not been established.
- The safety and effectiveness of Toric PRK has not been established in patients who are under 21 years of age.
- Patients taking Imitrex (sumatriptan succinate).

- Although the effects of myopic astigmatic photorefractive keratectomy (Toric PRK) on visual performance under poor lighting conditions have not been determined, it is likely that patients will find it more difficult than usual to see in conditions such as very dim light, rain, snow, fog, or glare from bright lights at night.

BENEFIT / RISK ANALYSIS

The information from the clinical investigation of the Summit Technology SVS Apex Plus Excimer Laser Workstation used in conjunction with the emphasis® disc, provides reasonable assurance of safety and effectiveness. Following is a summary of the known benefits and risks:

BENEFITS

The Toric PRK clinical treatment performed with the SVS Apex Plus Excimer Laser Workstation used in conjunction with the emphasis® disc, is effective in reducing myopia of -1.0 to <-6.0 diopters when astigmatism is -1.0 to <-4.0 diopters. Toric PRK allows:

- The potential to reduce the patient's overall myopia and astigmatism and reduce dependence on eyeglasses or contact lenses for correction of refractive error.
- An alternative to eyeglasses for some patients intolerant of contact lenses.
- Some patients who are reluctant to wear eyeglasses, for occupational and life-style issues, a new option to reduce or correct their myopia and astigmatism.

The Toric PRK clinical treatment performed with the Summit Technology SVS Apex Plus Excimer Laser Workstation used in conjunction with the emphasis® disc, is an alternative means of correcting myopia and astigmatism with a reasonable assurance of safety and effectiveness.

RISKS

The following adverse events and complications were reported in conjunction with Summit Technology's Toric PRK Clinical Investigation:

- Immediate/Early Post-treatment Complications
  The following complications have been reported in the first month after Toric PRK. They are associated with the normal post-treatment healing process and include: post-treatment pain (first 24 to 48 hours), corneal swelling, double vision, feeling something is in the eye, shadow images, light sensitivity, tearing and pupil enlargement. These symptoms are temporary and occur in many patients during the early post-treatment period.

- Post-treatment Complications and Adverse Events at 6 months
  The following is a list of the complications and adverse events reported at 6 months during Summit Technology's Toric PRK U.S. clinical trials that occurred **in more than 1.0%** of patients:

  - Blurry Vision: Image shapes and sizes appear unclear.
  - Double Vision: Images appear overlapping or twice in the visual field.
  - Foreign Body Sensations: Feeling something is in the eye.
  - Glare: Glare, especially from bright lights may be seen particularly at night after treatment.
  - Ghost Images: Overlap at edges of images.
  - Halo: Halo or hazy rings surrounding bright lights may be seen particularly at night after treatment.
  - Loss of Best Spectacle Corrected Acuity (2 lines or more): A decrease in best corrected visual acuity with eyeglasses.
  - IOP Elevation: An increase in the intraocular (inner eye) pressure (IOP) due to usage of post-treatment medications may occur which is usually corrected by drug therapy or discontinuation of post-treatment medication.
  - Light Sensitivity: Bright lights may cause discomfort.

The following complications and adverse events at 6 months occurred post-treatment in the Toric PRK clinical investigations in **less than 1.0%** of patients: drooping of the eyelid, haze, and overcorrection greater than 1 diopter.

This information is not intended to be a substitute for a thorough discussion with your doctor about whether this treatment is right for you.

Please read this information carefully and then talk to your doctor.

Please read the Informed Consent Document before signing it.

QUESTIONS TO ASK YOUR DOCTOR

- What are the other options for correction of myopia and astigmatism?
- Will I have to limit my activities after the treatment? If yes, for how long?
- What are the benefits of Toric PRK for my level of vision?
- If Toric PRK does not correct my vision, could my vision be worse than before? Could my vision gradually decline?
- Will I be able to wear contact lenses if I still need them after Toric PRK?
- How is Toric PRK likely to affect my need to use eyeglasses or contact lenses when I get old?
- Will my cornea heal differently if I injure it after having Toric PRK?
- If I have both my eyes done, what vision problems will I experience between the treatment of my first eye and second eye?
- What vision problems will I experience if I have Toric PRK only in one eye?

PATIENT ASSISTANCE INFORMATION

Primary Eye Doctor

Name: _____

Address: _____

_____

Telephone No: _____

Treatment Doctor

Name: _____

Address: _____

_____

Telephone No: _____

Treatment Location

Name: _____

Address: _____

_____

Telephone No: _____

Laser Manufacturer

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