SUMMIT TECHNOLOGY, INC.

MYOPIC AND MYOPIC ASTIGMATIC LASER IN SITU KERATOMILEUSIS (LASIK)

SVS APEX PLUS EXCIMER LASER WORKSTATION PRACTITIONER INFORMATION

CAUTION: RESTRICTED DEVICE: Federal Law (US) restricts this device to sale, distribution, and use by or on the order of a practitioner. Federal Law (US) restricts the use of this device to practitioners who have been trained in laser refractive surgery including laser system calibration and operation. Federal Law (US) 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 the Myopic LASIK and Toric LASIK procedures before applying it to their person!

All patients must have the opportunity to read and understand the Patient Information brochure for the LASIK treatment of myopia and myopic astigmatism.

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

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 SVS Apex Plus Excimer 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 in conjunction with emphasis "M" discs for treatment of myopia and myopic astigmatism.

The practitioner and staff should read the Summit Technology SVS Apex Plus Excimer Laser Workstation User Manual, the following practitioner information, and the emphasis "M" disc package insert. Practitioners must complete all necessary training as outlined by Summit Technology 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. Indications, Contraindications, Warnings, Precautions:

Indications For Use:

The SVS Apex Plus Excimer Laser Workstation and emphasis"M" discs are indicated to perform LASIK for the reduction or elimination of myopia ranging from 0.0 to -14.0 D with or without astigmatism ranging from -0.5 D to -5.0 D in patients who are 18 years of age or older who have documentation of a stable manifest refraction (± 0.5D) over the past year;

Contraindications:

The SVS Apex Plus Excimer Laser Workstation for Myopic LASIK, and used in conjunction with the emphasis 'M' discs for Toric LASIK 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;

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

Warnings:

The following Warnings pertain to use of the SVS Apex Plus Excimer Laser Workstation to treat myopia with or without astigmatism using the LASIK procedure:

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 these conditions.

3. Poorer visual outcomes may be anticipated for higher degrees of correction.

4. To avoid corneal ectasia the posterior 250 microns of corneal stroma should not be violated by the laser or the microkeratome.

5. The possibility of significant visual symptoms such as glare and haloes may be worse in patients with larger pupil sizes or patients functioning in conditions that produce larger pupils (e.g., driving at night).

Precautions:

The following Precautions pertain to use of the SVS Apex Plus Excimer Laser Workstation to treat myopia with or without astigmatism using the LASIK procedure:

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 the eye steady during the procedure.

2. Prior to cutting the LASIK flap, practitioners should arm and test the laser to ensure that it is ready to deliver laser energy.

3. Since the LASIK Clinical Investigation was conducted over a period of six months, the long-term safety and effectiveness of the Myopic LASIK and Toric LASIK procedures has not been established.

4. The safety and effectiveness of the Myopic LASIK and Toric LASIK procedures has not been established in patients who are under 18 years of age.

5. There is no safety and effectiveness information for refractive LASIK treatments greater than 14 D of myopia or 5 D of astigmatism.

6. Of the eyes treated in these trials, only 26/1013 (3%) of highly myopic eyes had myopia between 12-14 D and only 19/1013 (2%) of astigmatic eyes had astigmatism between 4-5 D. These populations may not have been sufficient to determine the level of effectiveness or the complications and adverse event rates for this refractive error range with the same reliability as for eyes with less severe refractive errors.

7. The safety and effectiveness of the Myopic LASIK and Toric LASIK procedures has not been established in patients who have had prior incisional refractive surgery.

8. The safety and effectiveness of photorefractive keratectomy (PRK) for myopia greater than -7.0D has not been established.

9. Patients taking Imitrex (sumatriptan succinate).

10. Patients with known sensitivity to any of the treatment medications;

11. Patients with a history of glaucoma because of the potential for a strong response to postoperative steroids

12. Although the effects of the Myopic LASIK and Toric LASIK procedures 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. Adverse Events:

Post-Treatment Adverse Events at 6 Months:

The following is a list of the events reported at 6 months during the CRS LASIK Study that occurred in more than 1.0 % of patients:

- Undercorrection >1 D (11.9%)
- Overcorrection > 1 D (4.2%)
- Severe halo (3.5%)
- BSCVA worse than 20/25 if 20/20 or better preop (3.0%)
- Severe visual fluctuations (2.6%)
- Loss in BCVA 2 lines or more (1.9%)
- Severe glare (1.7%)

The following events occurred in 1.0 % or less of the cohort: Corneal Epithelial Defect (Persistent Stain), Increase in IOP, Flap Edema, Epithelial Interface, and Induced Astigmatism >2 D.

The following events may occur, but were not reported: Corneal Infiltrate or Ulcer, Melting of the Flap, Late Onset of Haze, Retinal Detachment, Retinal Vascular Accidents, Drooping of eyelid, Double Vision, Foreign Body Sensations, Anterior Stromal Reticular Haze and Stromal Edema.

Subjective Patient Adverse Events

Some patients experience glare, halos and visual fluctuations before having LASIK surgery. Clinical results have indicated that these symptoms are subjectively improved following LASIK as compared to preoperatively with eyeglasses or contact lenses.

VISUAL SYMPTOM	% of patients reporting before LASIK surgery	% of patients reporting 6 months after surgery
No Glare	**7.8%**	**15.7%**
Severe Glare	[illegible]	[illegible]
No Halo	**12.0%**	**20.9%**
Severe Halo	[illegible]	[illegible]
No visual fluctuations	**21.1%**	**42.6%**
Severe visual fluctuations	[illegible]	[illegible]

The majority of complications after LASIK procedures occur in association with the normal healing that takes place after the procedure. Potential complications that may result in conjunction with the performance of LASIK procedures include:

- Anterior stromal reticular haze
- Anisometropia
- Blindness
- Blurred vision
- Corneal decompensation
- Corneal edema
- 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
- Epithelium in the interface
- Endophthalmitis

- Endothelial cell loss
- Flap not of size/shape intended
- Foreign body sensation
- Ghost images
- 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
- Lost, misplaced or misaligned lap
- Melting of flap
- Microbial keratitis
- Microcysts
- Overcorrection
- Pain
- Patient discomfort
- Persistent corneal edema
- Photophobia
- Ptosis
- Reading difficulty
- Retinal detachment
- Retinal vascular accidents
- Uncontrolled IOP
- Unknown long term effects
- Vascularization

D. Clinical Study Results

Key Safety and Efficacy Variables:
Key safety and efficacy variables are shown at 6 months in Tables 1-5 below:

Table 1

Summary of Key Safety and Efficacy Variables
Spheres Only
6 Months

	Spheres
Efficacy Variable	
UCVA 20/20 or better*	142/257 (55.3%)
UCVA 20/40 or better*	238/257 (92.6%)
MRSE within ± 0.5D	178/303 (58.7%)
MRSE within ± 1.0D	253/303 (83.5%)
Safety Variable	
Loss ≥ 2 lines BSCVA	2/305 (0.7%)
BSCVA worse than 20/40	0/305 (0.0%)
Increase > 2D cylinder	3/315 (1.0%)
BSCVA worse than 20/25 if 20/20 or better preoperatively	6/267 (2.2%)

* For all eyes minus those intentionally undercorrected

Table 2

Summary of Key Safety and Efficacy Variables
Spherocylinders
6 Months

	Spherocylinders
Efficacy Variable	
UCVA 20/20 or better*	172/412 (41.7%)
UCVA 20/40 or better*	378/412 (91.7%)
MRSE within ± 0.5D	279/442 (63.1%)
MRSE within ± 1.0D	372/442 (84.2%)
Safety Variable	
Loss ≥ 2 lines BSCVA	12/446 (2.7%)
BSCVA worse than 20/40	3/446 (0.7%)
Increase > 2D cylinder	0/0 (0.0%)
BSCVA worse than 20/25 if 20/20 or better preoperatively	12/340 (3.5%)

* For all eyes minus those intentionally undercorrected

Table 3

Summary of Key Safety and Efficacy Variables
Spheres Only
6 Months

	0 to <1.0D	1.0D to < 2.0D	2.0D to < 3.0D	3.0D to < 4.0D	4.0D to < 5.0D	5.0D to < 6.0D	6.0D to < 7.0D	7.0D to < 8.0D	8.0D to < 9.0D	9.0D to < 10.0D	10.0D to < 11.0D	11.0D to < 12.0D	12.0D to < 13.0D	13.0D to < 14.0D
Efficacy Variable														
UCVA 20/20 or better*	0	7/12 (58.3%)	20/21 (95.2%)	17/25 (68.0%)	26/40 (65.0%)	24/35 (68.6%)	11/19 (57.9%)	10/27 (37.0%)	13/25 (52.0%)	7/21 (33.3%)	2/14 (14.3%)	1/5 (20.0%)	2/8 (25.0%)	2/5 (40.0%)
UCVA 20/40 or better*	0	12/12 (100.0%)	21/21 (100.0%)	24/25 (96.0%)	39/40 (97.5%)	30/35 (85.7%)	19/19 (100.0%)	24/27 (88.9%)	24/25 (96.0%)	20/21 (95.2%)	11/14 (78.6%)	3/5 (60.0%)	8/8 (100.0%)	3/5 (60.0%)
MRSE within ± 0.5D	0	13/13 (100.0%)	17/20 (85.0%)	18/27 (66.7%)	30/43 (69.8%)	26/40 (65.0%)	13/22 (59.1%)	18/35 (51.4%)	17/34 (50.0%)	10/27 (37.0%)	8/18 (44.4%)	1/7 (14.3%)	4/9 (44.4%)	3/8 (37.5%)
MRSE within ± 1.0D	0	13/13 (100.0%)	19/20 (95.0%)	26/27 (96.3%)	39/43 (90.7%)	33/40 (82.5%)	18/22 (81.8%)	28/35 (80.0%)	29/34 (85.3%)	22/27 (81.5%)	10/18 (55.6%)	3/7 (42.9%)	9/9 (100.0%)	4/8 (50.0%)
Safety Variable														
Loss ≥ 2 lines BSCVA	0	0/13 (0.0%)	0/23 (0.0%)	0/25 (0.0%)	0/43 (0.0%)	0/42 (0.0%)	0/24 (0.0%)	1/35 (2.9%)	1/31 (3.2%)	0/27 (0.0%)	0/18 (0.0%)	0/7 (0.0%)	0/9 (0.0%)	0/8 (0.0%)
BSCVA worse than 20/40	0	0/13 (0.0%)	0/23 (0.0%)	0/25 (0.0%)	0/43 (0.0%)	0/42 (0.0%)	0/24 (0.0%)	0/35 (0.0%)	0/31 (0.0%)	0/27 (0.0%)	0/18 (0.0%)	0/7 (0.0%)	0/9 (0.0%)	0/8 (0.0%)
Increase > 2D cylinder	0	0/13 (0.0%)	0/23 (0.0%)	0/27 (0.0%)	1/45 (2.2%)	0/43 (0.0%)	0/25 (0.0%)	1/35 (2.9%)	1/35 (2.9%)	0/27 (0.0%)	0/18 (0.0%)	0/7 (0.0%)	0/9 (0.0%)	0/8 (0.0%)
BSCVA worse than 20/25 if 20/20 or better preoperatively	0	0/11 (0.0%)	0/23 (0.0%)	0/25 (0.0%)	0/42 (0.0%)	1/40 (2.5%)	0/22 (0.0%)	1/30 (3.3%)	1/27 (3.7%)	0/22 (0.0%)	2/13 (15.4%)	1/5 (20.0%)	0/6 (0.0%)	0/1 (0.0%)

* For all eyes minus those intentionally undercorrected

Table 4

Summary of Key Safety and Efficacy Variables
Spherocylinders Only
6 Months

	0 to <1.0D	1.0D to < 2.0D	2.0D to < 3.0D	3.0D to < 4.0D	4.0D to < 5.0D	5.0D to < 6.0D	6.0D to < 7.0D	7.0D to < 8.0D	8.0D to < 9.0D	9.0D to <10.0D	10.0D to <11.0D	11.0D to <12.0D	12.0D to <13.0D	13.0D to <14.0D
Efficacy Variable														
UCVA 20/20 or better*	2/3 (66.7%)	13/28 (46.4%)	29/53 (54.7%)	20/48 (41.7%)	21/44 (47.7%)	26/52 (50.0%)	14/37 (37.8%)	13/42 (31.0%)	19/40 (47.5%)	6/28 (21.4%)	3/17 (17.6%)	2/6 (33.3%)	4/13 (30.8%)	0/1 (0.0%)
UCVA 20/40 or better*	3/3 (100.0%)	26/28 (92.9%)	50/53 (94.3%)	44/48 (91.7%)	42/44 (95.5%)	51/52 (98.1%)	32/37 (86.5%)	39/42 (92.9%)	38/40 (95.0%)	24/28 (85.7%)	11/17 (64.7%)	5/6 (83.3%)	12/13 (92.3%)	1/1 (100.0%)
MRSE within ± 0.5D	2/3 (66.7%)	18/27 (66.7%)	41/52 (78.8%)	28/49 (57.1%)	39/51 (76.5%)	33/55 (60.0%)	26/39 (66.7%)	32/50 (64.0%)	27/44 (61.4%)	14/31 (45.2%)	8/16 (50.0%)	4/9 (44.4%)	5/13 (38.5%)	2/3 (66.7%)
MRSE within ± 1.0D	2/3 (66.7%)	24/27 (88.9%)	48/52 (92.3%)	41/49 (83.7%)	45/51 (88.2%)	47/55 (85.5%)	34/39 (87.2%)	40/50 (80.0%)	37/44 (84.1%)	23/31 (74.2%)	13/16 (81.3%)	5/9 (55.6%)	10/13 (76.9%)	3/3 (100.0%)
Safety Variable														
Loss ≥ 2 lines BSCVA	0/3 (0.0%)	2/28 (7.1%)	0/53 (0.0%)	2/49 (4.1%)	0/52 (0.0%)	0/55 (0.0%)	0/42 (0.0%)	0/50 (0.0%)	2/43 (4.7%)	1/31 (3.2%)	2/16 (12.5)	3/8 (37.5%)	0/13 (0.0%)	0/3 (0.0%)
BSCVA worse than 20/40	0/3 (0.0%)	1/28 (3.6%)	0/53 (0.0%)	0/49 (0.0%)	0/52 (0.0%)	0/55 (0.0%)	0/42 (0.0%)	0/50 (0.0%)	0/43 (0.0%)	0/31 (0.0%)	1/16 (6.3%)	1/8 (12.5%)	0/13 (0.0%)	0/3 (0.0%)
Increase > 2D cylinder	0/0 (0.0%)	0/0 (0.0%)	0/0 (0.0%)	0/0 (0.0%)	0/0 (0.0%)	0/0 (0.0%)	0/0 (0.0%)	0/0 (0.0%)	0/0 (0.0%)	0/0 (0.0%)	0/0 (0.0%)	0/0 (0.0%)	0/0 (0.0%)	0/0 (0.0%)
BSCVA worse than 20/25 if 20/20 or better preoperatively	0/2 (0.0%)	2/26 (7.7%)	0/47 (0.0%)	0/43 (0.0%)	1/44 (2.3%)	0/46 (0.0%)	1/30 (3.3%)	3/30 (0.0%)	0/33 (0.0%)	2/19 (10.5%)	1/6 (16.7%)	1/2 (50.0%)	1/10 (10.0%)	0/2 (0.0%)

* For all eyes minus those intentionally undercorrected

Retreatments

A summary of the key safety and effectiveness variables for the 38 retreatments occurring during the CRS LASIK Study is shown below in Table 5.

Table 5

CRS LASIK Study
Retreatment Summary of Key Safety and Effectiveness Variables
For Myopia and Myopic Astigmatism

(Last Available Visit after Retreatment Procedure)

Efficacy Variable	n/N (%)
UCVA 20/20 or better*	13/38 (34.2%)
UCVA 20/40 or better*	35/38 (92.1%)
MRSE within ± 0.5D	26/38 (68.4%)
MRSE within ± 1.0D	32/38 (84.2%)
Safety Variable	
Loss ≥ 2 lines BSCVA	0/38 (0%)
BSCVA worse than 20/40	1/38 (2.6%)
Increase > 2D cylinder	1/38 (2.6%)
BSCVA worse than 20/25 if 20/20 or better preoperatively	0/38 (0%)

E. Ancillary Equipment:

The following items will be needed when performing LASIK surgery with the SVS Apex Plus Excimer Laser Workstation:

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. Microkeratome
11. emphasis "M" discs and suction cups for handling discs (for toric procedures only)
12. emphasis cassette (for toric procedures only)
13. Vacuum tweezers(for toric procedures only)

F. SVS Apex Plus Excimer Laser Workstation Parameters:

Clinical Procedure	Range	Zone Size	Pretreatment Variables
Single Zone	Sphere: -0.1 to -7.0D in 0.1D increments	Single zone: 6.0mm	Zone: 2.0 to 4.0mm Pulses: 1% to 15%
Aspheric Multizone	Sphere: -7.1 to -14.0D in 0.1D increments	Inner zone: 5.0 to 5.5mm Outer zone: 6.0 to 6.5mm	Zone: 2.0 to 4.0mm Pulses: 1% to 15%
Extended Toric	Sphere: 0.0 to –14.0D in 0.1D increments Cylinder: -0.5 to –5.0D in 0.25D increments	Short axis: 5.0mm Long axis: 6.5mm	Zone: 2.0 to 4.0mm Pulses: 1% to 15%

Pulse Energy Density: 180 mJ/cm^2 at the laser disc plane
180 mJ/cm^2 at the corneal plane for myopia without astigmatism corrections
162 mJ/cm^2 at the corneal plane for myopia with astigmatism corrections

Repetition Rate: System set at 10 Hz.

G. Directions For Use:

NOTE: The programmed amount indicates the average correction that can be anticipated, but actual use will require individual adjustments of this amount. Tracking of clinical outcomes is recommended to help physicians in determining by what, if any, factor the laser input should be adjusted.

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 Apex Plus 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 treatment. 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 'M' disc preparation (applies to toric procedures only):

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

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

3. 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 the Apex Plus User Manual. Laser disc selection may also be made by choosing the Extended Toric or Extended Toric with pretreatment 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 and use the 0.00 mm Vertex Distance Look-Up Table.

4. 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.

5. 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 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 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.

6. 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.

7. 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. 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.

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

LASIK Procedural Instructions

1. Prepare the microkeratome for use. Check for presence of all necessary components. Perform all required performance checks for the microkeratome.

2. Ensure the availability of donor corneal tissue, should this become necessary (as in traditional LASIK). The donor corneal tissue does not have to be on site at the time of the procedure.

3. The patient should receive drops preoperatively to constrict the pupil in the operative eye.

4. If the Apex Plus and the microkeratome are functional, bring the patient into the treatment room.

5. Place the patient on the patient bed/chair with the operative eye centered under the Apex Plus.

6. Topical anesthetic may be given to the eye **not** to be treated to relax the reflexes.

7. Apply anesthetic drops in the operative eye.

8. Prepare the patient for the surgical procedure, using a sterile drape that will remove the lashes from the operative field.

9. Turn on the helium-neon aiming beams.

10. Select Single Zone or Single Zone with Pretreatment, Aspheric Multizone or Aspheric Multizone with Pretreatment from the menu of the laser system for myopic treatments; or Extended Toric or Extended Toric with Pretreatment from the menu of the laser system for toric treatments.

NOTE: Refer To the "Sample Procedures" in section 6 of the Apex Plus User Manual for screen-by-screen instructions on each treatment procedures.

11. If the Single Zone with Pretreatment, Aspheric Multizone with Pretreatment or Extended Toric with Pretreatment has been selected, enter the pretreatment zone diameter and pretreatment percentage depth. **(Note: the pretreatment default values are 8% depth at 2.5 mm. A different pretreatment zone diameter and percentage depth may be selected.)** Enter the attempted correction and vertex distance into the system as prompted by the system software.

12. The Apex Plus will present all treatment parameters to be used in the procedure for review and confirmation.

NOTE: The system will accept treatment parameters above the indicated range of -14.0 D sphere (Aspheric Multizone and Extended Toric). The system will display the following screens: "No clinical data exist to support treatment above -14.0 D." "Do you wish to proceed with a treatment above -14.0 D? <Press (1) if Yes, press (2) if No>." Contact Summit Customer Support for emphasis disc information.

NOTE: The system will accept treatment parameters below the indicated range of –0.5 D and above the indicated range of -5.0 D cylinder (Extended Toric). The system will display the following screens: "No clinical data exist to support treatments below -0.5 D or above above -5.0 D." "Do you wish to proceed with a treatment below -0.5 D or above -5.0 D? <Press (1) if Yes, press (2) if No>. Contact Summit Customer Support for emphasis disc information.

13. Arm and test the laser BEFORE using the microkeratome to create a flap.

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.

14. Take steps to ensure a particle free environment. Instruments should be kept on a particle free tray. All flush solutions should be enclosed and filtered. Take steps to minimize airborne particles.

15. Insert the eyelid speculum.

16. Stain the optical zone markers with gentian violet including the tangential line and the 2 optical zones.

17. Create a flap using the microkeratome.

18. A pachymeter should be available to check the remaining corneal thickness.

LASIK Operative Instructions

1. Insert the emphasis Cassette (with emphasis disc) into the emphasis Cassette Port (for toric procedures only) located in the Apex Plus downtube.

2. Position the patient under the Apex Plus operating microscope, utilizing the Helium Neon aiming beams. Ensure that the HeNe's appear as one spot on the stromal surface and the 3:00 and 9:00 HeNe's appear on either side of the pupillary margin.

3. Examine the stromal bed under high magnification, looking for any foreign particulate matter. Remove particulate matter with irrigation.

4. Return the microscope to lower power magnification and turn off the coaxial illumination. Turn on the oblique illuminator with the light projected across the area to be treated.

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

6. The physician should observe the procedure through the operating microscope.

NOTE: During laser energy delivery, the physician should concentrate on the position of the HeNe's on the pupillary margin. The physician should not be distracted by watching the laser energy impacting the surface of the cornea.

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 assure 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 laser workstation during laser delivery.

7. Irrigate the bed and flap with filtered balance salt solution (BSS) and wipe both with ophthalmic sponges to remove any debris or cells.

8. The corneal flap should be moist and "float" into position. Gently manipulate the corneal flap to its original position.

9. Allow the flap to dry and adhere to the remaining stroma for 3-5 minutes while dropping 1 drop of antibiotic on the center of the flap every 30 seconds and drying the "gutter" with an ophthalmic sponge.

10. Remove the eye speculum.

11. In reference to postoperative medications during both the immediate postoperative period and for the first several months after the procedure, the physician should refer to the existing peer review literature to determeine the appropriate course of action

12. Cover the operative eye gently with a shield.

G. Extended Toric Lookup Table I

Look Up Table I: Vertex Distance=0.0 mm

Laser Disc Type: Sphere vs. Cylinder at Corneal Plane

Cylinder

Sphere	-0.5	-0.75	-1.00	-1.25	-1.50	-1.75	-2.00	-2.25	-2.50	-2.75	-3.00	-3.25	-3.50	-3.75	-4.00	-4.25	-4.50	-4.75	-5.00	
0.0	M00	M00	M01	M01	M02	M02	M03	M03	M04	M04			M07	M07	M08	M08				0.0
-0.1	M00	M00	M01	M01	M02	M02	M03	M03	M04	M04			M07	M07	M08	M08				-0.1
-0.2	M00	M00	M01	M01	M02	M02	M03	M03	M04	M04			M07	M07	M08	M08				-0.2
-0.3	M00	M00	M01	M01	M02	M02	M03	M03	M04	M04			M07	M07	M08	M08				-0.3
-0.4	M00	M00	M01	M01	M02	M02	M03	M03	M04	M04			M07	M07	M08	M08				-0.4
-0.5	M00	M00	M01	M01	M02	M02	M03	M03	M04	M04			M07	M07	M08	M08				-0.5
-0.6	M00	M00	M01	M01	M02	M02	M03	M03	M04	M04			M07	M07	M08	M08				-0.6
-0.7	M00	M00	M01	M01	M02	M02	M03	M03	M04	M04			M07	M07	M08	M08				-0.7
-0.8	M00	M00	M01	M01	M02	M02	M03	M03	M04	M04			M07	M07	M08	M08				-0.8
-0.9	M00	M00	M01	M01	M02	M02	M03	M03	M04	M04			M07	M07	M08	M08				-0.9
-1.0	M00	M00	M01	M01	M02	M02	M03	M03	M04	M04			M07	M07	M08	M08				-1.0
-1.1	M00	M00	M01	M01	M02	M02	M03	M03	M04	M04			M07	M07	M08	M08				-1.1
-1.2	M00	M00	M01	M01	M02	M02	M03	M03	M04	M04			M07	M07	M08	M08				-1.2
-1.3	M00	M00	M01	M01	M02	M02	M03	M03	M04	M04			M07	M07	M08	M08				-1.3
-1.4	M00	M00	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M07	M07	M08	M08				-1.4
-1.5	M00	M00	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M07	M07	M08	M08				-1.5
-1.6	M00	M00	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M07	M07	M08	M08				-1.6
-1.7	M00	M00	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M07	M07	M08	M08				-1.7
-1.8	M00	M00	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M07	M07	M07	M07				-1.8
-1.9	M00	M00	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M07	M07	M07	M07				-1.9
-2.0	M00	M00	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M07	M07	M07	M07				-2.0
-2.1	M00	M00	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M07	M07	M07	M07				-2.1
-2.2	M00	M00	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M07	M07	M07	M07				-2.2
-2.3	M00	M00	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M07	M07	M07	M07	M07	M07		-2.3
-2.4	M00	M00	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M07	M07	M07	M07	M07	M07		-2.4
-2.5	M00	M00	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M07	M07	M07	M07	M07	M07		-2.5
-2.6	M00	M00	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M07	M07	M07	M07	M07	M07		-2.6
-2.7	M00	M00	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M07	M07	M07	M07	M07	M07		-2.7
-2.8	M00	M00	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M07	M07	M07	M07	M07	M07		-2.8
-2.9	M00	M00	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M07	M07	M07	M07	M07	M07		-2.9
-3.0	M00	M00	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M07	M07	M07	M07	M07	M07		-3.0
-3.1	M00	M00	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M07	M07	M07	M07	M08	M08		-3.1
-3.2	M00	M00	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M07	M07	M07	M07	M08	M08		-3.2
-3.3	M00	M00	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M07	M07	M07	M07	M08	M08		-3.3
-3.4	M00	M00	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M07	M07	M07	M07	M08	M08		-3.4
-3.5	M00	M00	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M07	M07	M07	M07	M08	M08		-3.5
-3.6	M00	M00	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M07	M07	M07	M07	M08	M08		-3.6
-3.7	M00	M00	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M07	M07	M07	M07	M08	M08		-3.7
-3.8	M00	M00	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M07	M07	M07	M07	M08	M08		-3.8
-3.9	M00	M00	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M07	M07	M07	M07	M08	M08		-3.9
-4.0	M00	M00	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M07	M07	M07	M07	M08	M08		-4.0
-4.1	M00	M00	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M07	M07	M07	M07	M08	M08		-4.1
-4.2	M00	M00	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M07	M07	M07	M07	M08	M08		-4.2
-4.3	M00	M00	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M07	M07	M07	M07	M08	M08		-4.3
-4.4	M00	M00	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M07	M07	M07	M07	M08	M08		-4.4
-4.5	M00	M00	M01	M01	M02	M02	M03	M03	M03	M03	M04	M04	M05	M05	M07	M07	M07	M07	M08	-4.5
-4.6	M00	M00	M01	M01	M02	M02	M03	M03	M03	M03	M04	M04	M05	M05	M07	M07	M07	M07	M08	-4.6
-4.7	M00	M00	M01	M01	M02	M02	M03	M03	M03	M03	M04	M04	M05	M05	M07	M07	M07	M07	M08	-4.7
-4.8	M00	M00	M01	M01	M02	M02	M03	M03	M03	M03	M04	M04	M05	M05	M07	M07	M07	M07	M08	-4.8
-4.9	M00	M00	M01	M01	M02	M02	M02	M02	M03	M03	M04	M04	M05	M05	M07	M07	M07	M07	M08	-4.9
-5.0	M00	M00	M01	M01	M02	M02	M02	M02	M03	M03	M04	M04	M05	M05	M07	M07	M07	M07	M08	-5.0
-5.1	M00	M00	M01	M01	M02	M02	M02	M02	M03	M03	M04	M04	M05	M05	M07	M07	M07	M07	M08	-5.1
-5.2	M00	M00	M01	M01	M02	M02	M02	M02	M03	M03	M04	M04	M05	M05	M07	M07	M07	M07	M08	-5.2
-5.3	M00	M00	M01	M01	M02	M02	M02	M02	M03	M03	M04	M04	M05	M05	M07	M07	M07	M07	M08	-5.3
-5.4	M00	M00	M01	M01	M02	M02	M02	M02	M03	M03	M04	M04	M05	M05	M07	M07	M07	M07	M08	-5.4
-5.5	M00	M00	M01	M01	M02	M02	M02	M02	M03	M03	M04	M04	M05	M05	M07	M07	M07	M07	M08	-5.5
-5.6	M00	M00	M01	M01	M02	M02	M02	M02	M03	M03	M04	M04	M05	M05	M07	M07	M07	M07	M08	-5.6
-5.7	M00	M00	M01	M01	M02	M02	M02	M02	M03	M03	M04	M04	M05	M05	M07	M07	M07	M07	M08	-5.7
-5.8	M00	M00	M01	M01	M02	M02	M02	M02	M03	M03	M04	M04	M05	M05	M07	M07	M07	M07	M08	-5.8
-5.9	M00	M00	M01	M01	M02	M02	M02	M02	M03	M03	M04	M04	M05	M05	M07	M07	M07	M07	M08	-5.9
-6.0	M00	M00	M01	M01	M02	M02	M02	M02	M03	M03	M04	M04	M05	M05	M07	M07	M07	M07	M08	-6.0
-6.1	M00	M00	M01	M01	M02	M02	M02	M02	M03	M03	M04	M04	M05	M05	M07	M07	M07	M07	M08	-6.1
-6.2	M00	M00	M01	M01	M02	M02	M02	M02	M03	M03	M04	M04	M05	M05	M07	M07	M07	M07	M08	-6.2
-6.3	M00	M00	M01	M01	M02	M02	M02	M02	M03	M03	M04	M04	M05	M05	M07	M07	M07	M07	M08	-6.3
-6.4	M00	M00	M01	M01	M02	M02	M02	M02	M03	M03	M04	M04	M05	M05	M07	M07	M07	M07	M08	-6.4
-6.5	M00	M00	M01	M01	M02	M02	M02	M02	M03	M03	M04	M04	M05	M05	M07	M07	M07	M07	M08	-6.5
-6.6	M00	M00	M01	M01	M02	M02	M02	M02	M03	M03	M04	M04	M05	M05	M07	M07	M07	M07	M08	-6.6
-6.7	M00	M00	M01	M01	M02	M02	M02	M02	M03	M03	M04	M04	M05	M05	M07	M07	M07	M07	M08	-6.7
-6.8	M00	M00	M01	M01	M02	M02	M02	M02	M03	M03	M04	M04	M05	M05	M07	M07	M07	M07	M08	-6.8
-6.9	M00	M00	M01	M01	M02	M02	M02	M02	M03	M03	M04	M04	M05	M05	M07	M07	M07	M07	M08	-6.9
-7.0	M00	M00	M01	M01	M02	M02	M02	M02	M03	M03	M04	M04	M05	M05	M07	M07	M07	M07	M08	-7.0
-7.1	M00	M00	M01	M01	M02	M02	M02	M02	M03	M03	M04	M04	M05	M05	M07	M07	M07	M07	M08	-7.1
-7.2	M00	M00	M01	M01	M02	M02	M02	M02	M03	M03	M04	M04	M05	M05	M07	M07	M07	M07	M08	-7.2
-7.3	M00	M00	M01	M01	M02	M02	M02	M02	M03	M03	M04	M04	M05	M05	M07	M07	M07	M07	M08	-7.3
-7.4	M00	M00	M01	M01	M02	M02	M02	M02	M03	M03	M04	M04	M05	M05	M07	M07	M07	M07	M08	-7.4
-7.5	M00	M00	M01	M01	M02	M02	M02	M02	M03	M03	M04	M04	M05	M05	M07	M07	M07	M07	M08	-7.5
-7.6	M00	M00	M01	M01	M02	M02	M02	M02	M03	M03	M04	M04	M05	M05	M07	M07	M07	M07	M08	-7.6
-7.7	M00	M00	M01	M01	M02	M02	M02	M02	M03	M03	M04	M04	M05	M05	M07	M07	M07	M07	M08	-7.7
-7.8	M00	M00	M01	M01	M02	M02	M02	M02	M03	M03	M04	M04	M05	M05	M07	M07	M07	M07	M08	-7.8
-7.9	M00	M00	M01	M01	M02	M02	M02	M02	M03	M03	M04	M04	M05	M05	M07	M07	M07	M07	M08	-7.9

REFER TO LOOKUP TABLE II

Extended Toric Look Up Table I (continued)

Look Up Table I: Vertex Distance=0.0 mm

Laser Disc Type: Sphere vs. Cylinder at Corneal Plane

Cylinder

Sphere	-0.50	-0.75	-1.00	-1.25	-1.50	-1.75	-2.00	-2.25	-2.50	-2.75	-3.00	-3.25	-3.50	-3.75	-4.00	-4.25	-4.50	-4.75	-5.00	Sphere
-8.0	M00	M00	M01	M01	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M07	M07	M08	-8.0
-8.1	M00	M00	M01	M01	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M07	M07	M08	-8.1
-8.2	M00	M00	M01	M01	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M07	M07	M08	-8.2
-8.3	M00	M00	M01	M01	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M07	M07	M08	-8.3
-8.4	M00	M00	M01	M01	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M07	M07	M08	-8.4
-8.5	M00	M00	M01	M01	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M07	M07	M08	-8.5
-8.6	M00	M00	M01	M01	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M07	M07	M08	-8.6
-8.7	M00	M00	M01	M01	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M07	M07	M08	-8.7
-8.8	M00	M00	M01	M01	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M07	M07	M08	-8.8
-8.9	M00	M00	M01	M01	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M07	M07	M08	-8.9
-9.0	M00	M00	M01	M01	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M07	M07	M08	-9.0
-9.1	M00	M00	M01	M01	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M07	M07	M08	-9.1
-9.2	M00	M00	M01	M01	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M07	M07	M08	-9.2
-9.3	M00	M00	M01	M01	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M07	M07	M08	-9.3
-9.4	M00	M00	M01	M01	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M07	M07	M08	-9.4
-9.5	M00	M00	M01	M01	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M07	M07	M08	-9.5
-9.6	M00	M00	M01	M01	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M07	M07	M08	-9.6
-9.7	M00	M00	M01	M01	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M07	M07	M08	-9.7
-9.8	M00	M00	M00	M00	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M07	M07	M08	-9.8
-9.9	M00	M00	M00	M00	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M07	M07	M08	-9.9
-10.0	M00	M00	M00	M00	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M07	M07	M08	-10.0
-10.1	M00	M00	M00	M00	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M07	M07	M08	-10.1
-10.2	M00	M00	M00	M00	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M07	M07	M08	-10.2
-10.3	M00	M00	M00	M00	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M07	M07	M08	-10.3
-10.4	M00	M00	M00	M00	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M07	M07	M08	-10.4
-10.5	M00	M00	M00	M00	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M07	M07	M08	-10.5
-10.6	M00	M00	M00	M00	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M07	M07	M08	-10.6
-10.7	M00	M00	M00	M00	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M07	M07	M08	-10.7
-10.8	M00	M00	M00	M00	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M07	M07	M08	-10.8
-10.9	M00	M00	M00	M00	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M07	M07	M08	-10.9
-11.0	M00	M00	M00	M00	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M07	M07	M08	-11.0
-11.1	M00	M00	M00	M00	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M07	M07	M08	-11.1
-11.2	M00	M00	M00	M00	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M07	M07	M08	-11.2
-11.3	M00	M00	M00	M00	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M07	M07	M08	-11.3
-11.4	M00	M00	M00	M00	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M07	M07	M08	-11.4
-11.5	M00	M00	M00	M00	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M07	M07	M08	-11.5
-11.6	M00	M00	M00	M00	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M07	M07	M08	-11.6
-11.7	M00	M00	M00	M00	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M07	M07	M08	-11.7
-11.8	M00	M00	M00	M00	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M07	M07	M08	-11.8
-11.9	M00	M00	M00	M00	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M07	M07	M08	-11.9
-12.0	M00	M00	M00	M00	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M07	M07	M08	-12.0
-12.1	M00	M00	M00	M00	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M07	M07	M08	-12.1
-12.2	M00	M00	M00	M00	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M07	M07	M08	-12.2
-12.3	M00	M00	M00	M00	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M07	M07	M08	-12.3
-12.4	M00	M00	M00	M00	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M07	M07	M08	-12.4
-12.5	M00	M00	M00	M00	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M07	M07	M08	-12.5
-12.6	M00	M00	M00	M00	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M07	M07	M08	-12.6
-12.7	M00	M00	M00	M00	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M07	M07	M08	-12.7
-12.8	M00	M00	M00	M00	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M07	M07	M08	-12.8
-12.9	M00	M00	M00	M00	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M07	M07	M08	-12.9
-13.0	M00	M00	M00	M00	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M07	M07	M08	-13.0
-13.1	M00	M00	M00	M00	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M07	M07	M08	-13.1
-13.2	M00	M00	M00	M00	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M07	M07	M08	-13.2
-13.3	M00	M00	M00	M00	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M07	M07	M08	M08	M08	-13.3
-13.4	M00	M00	M00	M00	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M07	M07	M08	M08	M08	-13.4
-13.5	M00	M00	M00	M00	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M07	M07	M08	M08	M08	-13.5
-13.6	M00	M00	M00	M00	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M07	M07	M08	M08	M08	-13.6
-13.7	M00	M00	M00	M00	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M07	M07	M08	M08	M08	-13.7
-13.8	M00	M00	M00	M00	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M07	M07	M08	M08	M08	-13.8
-13.9	M00	M00	M00	M00	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M07	M07	M08	M08	M08	-13.9
-14.0	M00	M00	M00	M00	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M07	M07	M08	M08	M08	-14.0

Extended Toric Look Up Table II

Look Up Table II: Vertex Distance=12.0 mm

Laser Disc Type: Sphere vs. Cylinder at Spectacle Plane

Cylinder

Sphere	-0.50	-0.75	-1.00	-1.25	-1.50	-1.75	-2.00	-2.25	-2.50	-2.75	-3.00	-3.25	-3.50	-3.75	-4.00	-4.25	-4.50	-4.75	-5.00
0.0	M00	M00	M01	M01	M01	M02	M02	M03	M03	M04	M04	M04	M05	M07	M07	M08	M08	M08	M09
-0.1	M00	M00	M01	M01	M01	M02	M02	M03	M03	M04	M04	M04	M05	M07	M07	M08	M08	M08	M09
-0.2	M00	M00	M01	M01	M01	M02	M02	M03	M03	M04	M04	M04	M05	M07	M07	M08	M08	M08	M09
-0.3	M00	M00	M01	M01	M01	M02	M02	M03	M03	M04	M04	M04	M05	M07	M07	M08	M08	M08	M09
-0.4	M00	M00	M01	M01	M01	M02	M02	M03	M03	M04	M04	M04	M05	M07	M07	M08	M08	M08	M09
-0.5	M00	M00	M01	M01	M01	M02	M02	M03	M03	M04	M04	M04	M05	M07	M07	M08	M08	M08	M09
-0.6	M00	M00	M01	M01	M01	M02	M02	M03	M03	M04	M04	M04	M05	M07	M07	M08	M08	M08	M09
-0.7	M00	M00	M01	M01	M01	M02	M02	M03	M03	M04	M04	M04	M05	M07	M07	M08	M08	M08	M09
-0.8	M00	M00	M01	M01	M01	M02	M02	M03	M03	M04	M04	M04	M05	M07	M07	M08	M08	M08	M09
-0.9	M00	M00	M01	M01	M01	M02	M02	M03	M03	M04	M04	M04	M05	M07	M07	M08	M08	M08	M09
-1.0	M00	M00	M01	M01	M01	M02	M02	M03	M03	M04	M04	M04	M05	M07	M07	M08	M08	M08	M09
-1.1	M00	M00	M01	M01	M01	M02	M02	M03	M03	M04	M04	M04	M05	M07	M07	M08	M08	M08	M09
-1.2	M00	M00	M01	M01	M01	M02	M02	M03	M03	M04	M04	M04	M05	M07	M07	M08	M08	M08	M09
-1.3	M00	M00	M01	M01	M01	M02	M02	M03	M03	M04	M04	M04	M05	M07	M07	M08	M08	M08	M09
-1.4	M00	M00	M01	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M07	M07	M08	M08	M08	M09
-1.5	M00	M00	M01	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M07	M07	M08	M08	M08	M09
-1.6	M00	M00	M01	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M07	M07	M08	M08	M08	M09
-1.7	M00	M00	M01	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M07	M07	M08	M08	M08	M09
-1.8	M00	M00	M01	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M07	M07	M08	M08	M08	M09
-1.9	M00	M00	M01	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M07	M07	M07	M09
-2.0	M00	M00	M01	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M07	M07	M07	M09
-2.1	M00	M00	M01	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M07	M07	M07	M09
-2.2	M00	M00	M01	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M07	M07	M07	M09
-2.3	M00	M00	M01	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M07	M07	M07	M08
-2.4	M00	M00	M01	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M07	M07	M07	M08
-2.5	M00	M00	M01	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M07	M07	M07	M08
-2.6	M00	M00	M01	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M07	M07	M07	M08
-2.7	M00	M00	M01	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M07	M07	M07	M08
-2.8	M00	M00	M01	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M07	M07	M07	M08
-2.9	M00	M00	M01	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M07	M07	M07	M08
-3.0	M00	M00	M01	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M07	M07	M07	M08
-3.1	M00	M00	M01	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M07	M07	M07	M08
-3.2	M00	M00	M01	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M07	M07	M07	M08
-3.3	M00	M00	M01	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M07	M07	M07	M08
-3.4	M00	M00	M01	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M07	M07	M07	M08
-3.5	M00	M00	M01	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M07	M07	M07	M08
-3.6	M00	M00	M01	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M07	M07	M07	M08
-3.7	M00	M00	M01	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M07	M07	M07	M08
-3.8	M00	M00	M01	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M07	M07	M07	M08
-3.9	M00	M00	M01	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M07	M07	M07	M08
-4.0	M00	M00	M01	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M07	M07	M07	M08
-4.1	M00	M00	M01	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M07	M07	M07	M08
-4.2	M00	M00	M01	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M07	M07	M07	M08
-4.3	M00	M00	M01	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M07	M07	M07	M08
-4.4	M00	M00	M01	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M07	M07	M07	M08
-4.5	M00	M00	M01	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M07	M07	M07	M08
-4.6	M00	M00	M01	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M07	M07	M07	M08
-4.7	M00	M00	M01	M01	M01	M02	M02	M03	M03	M03	M03	M04	M04	M05	M05	M06	M06	M06	M07
-4.8	M00	M00	M01	M01	M01	M02	M02	M03	M03	M03	M03	M04	M04	M05	M05	M06	M06	M06	M07
-4.9	M00	M00	M01	M01	M01	M02	M02	M03	M03	M03	M03	M04	M04	M05	M05	M06	M06	M06	M07
-5.0	M00	M00	M01	M01	M01	M02	M02	M03	M03	M03	M03	M04	M04	M05	M05	M06	M06	M06	M07
-5.1	M00	M00	M01	M01	M01	M02	M02	M03	M03	M03	M03	M04	M04	M05	M05	M06	M06	M06	M07
-5.2	M00	M00	M01	M01	M01	M02	M02	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M06	M07
-5.3	M00	M00	M01	M01	M01	M02	M02	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M06	M07
-5.4	M00	M00	M01	M01	M01	M02	M02	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M06	M07
-5.5	M00	M00	M01	M01	M01	M02	M02	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M06	M07
-5.6	M00	M00	M01	M01	M01	M02	M02	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M06	M07
-5.7	M00	M00	M01	M01	M01	M02	M02	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M06	M07
-5.8	M00	M00	M01	M01	M01	M02	M02	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M06	M07
-5.9	M00	M00	M01	M01	M01	M02	M02	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M06	M07
-6.0	M00	M00	M01	M01	M01	M02	M02	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M06	M07
-6.1	M00	M00	M01	M01	M01	M02	M02	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M06	M07
-6.2	M00	M00	M01	M01	M01	M02	M02	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M06	M07
-6.3	M00	M00	M01	M01	M01	M02	M02	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M06	M07
-6.4	M00	M00	M01	M01	M01	M02	M02	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M06	M07
-6.5	M00	M00	M01	M01	M01	M02	M02	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M06	M07
-6.6	M00	M00	M01	M01	M01	M02	M02	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M06	M07
-6.7	M00	M00	M01	M01	M01	M02	M02	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M06	M07
-6.8	M00	M00	M01	M01	M01	M02	M02	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M06	M07
-6.9	M00	M00	M01	M01	M01	M02	M02	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M06	M07
-7.0	M00	M00	M01	M01	M01	M02	M02	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M06	M07
-7.1	M00	M00	M01	M01	M01	M02	M02	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M06	M07
-7.2	M00	M00	M01	M01	M01	M02	M02	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M06	M07
-7.3	M00	M00	M01	M01	M01	M02	M02	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M06	M07
-7.4	M00	M00	M01	M01	M01	M02	M02	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M06	M07
-7.5	M00	M00	M01	M01	M01	M02	M02	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M06	M07
-7.6	M00	M00	M01	M01	M01	M02	M02	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M06	M07
-7.7	M00	M00	M01	M01	M01	M02	M02	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M06	M07
-7.8	M00	M00	M01	M01	M01	M02	M02	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M06	M07
-7.9	M00	M00	M01	M01	M01	M02	M02	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M06	M07

Extended Toric Look Up Table II (continued)

Look Up Table II: Vertex Distance=12.0 mm

Laser Disc Type: Sphere vs. Cylinder at Spectacle Plane

Cylinder

Sphere	-0.50	-0.75	-1.00	-1.25	-1.50	-1.75	-2.00	-2.25	-2.50	-2.75	-3.00	-3.25	-3.50	-3.75	-4.00	-4.25	-4.50	-4.75	-5.00	Sphere
-8.0	M00	M00	M01	M01	M01	M02	M02	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M06	M07	-8.0
-8.1	M00	M00	M01	M01	M01	M02	M02	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M06	M07	-8.1
-8.2	M00	M00	M01	M01	M01	M02	M02	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M06	M07	-8.2
-8.3	M00	M00	M01	M01	M01	M02	M02	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M06	M07	-8.3
-8.4	M00	M00	M01	M01	M01	M02	M02	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M06	M07	-8.4
-8.5	M00	M00	M01	M01	M01	M02	M02	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M06	M07	-8.5
-8.6	M00	M00	M01	M01	M01	M02	M02	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M06	M07	-8.6
-8.7	M00	M00	M01	M01	M01	M02	M02	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M06	M07	-8.7
-8.8	M00	M00	M01	M01	M01	M02	M02	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M06	M07	-8.8
-8.9	M00	M00	M01	M01	M01	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M06	M07	-8.9
-9.0	M00	M00	M01	M01	M01	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M06	M07	-9.0
-9.1	M00	M00	M01	M01	M01	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M06	M07	-9.1
-9.2	M00	M00	M01	M01	M01	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M06	M07	-9.2
-9.3	M00	M00	M01	M01	M01	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M06	M07	-9.3
-9.4	M00	M00	M01	M01	M01	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M06	M07	-9.4
-9.5	M00	M00	M01	M01	M01	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M06	M07	-9.5
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-9.7	M00	M00	M01	M01	M01	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M06	M07	-9.7
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-10.3	M00	M00	M01	M01	M01	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M06	M07	-10.3
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-11.0	M00	M00	M01	M01	M01	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M06	M07	-11.0
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-14.0	M00	M00	M00	M00	M00	M01	M01	M02	M02	M03	M03	M04	M04	M05	M05	M06	M06	M06	M07	-14.0

PATIENT INFORMATION

LASER IN SITU KERATOMILEUSIS (LASIK) SURGERY

SVS Apex Plus Excimer Laser Workstation

CAUTION: Federal Law (US) restricts this device to sale by or on the order of a physician or properly licensed practitioner.

Please speak with your doctor regarding this procedure for the correction of your nearsightedness and your astigmatism, if you have astigmatism. It is important that you read this entire booklet and carefully discuss its contents with your doctor. Ask any questions you may have before you agree to the surgery.

Summit Technology, Inc.
21 Hickory Drive
Waltham, Massachusetts 02451
Phone (781) 890-1234
Fax (781) 890-0313

IMPORTANT INFORMATION

- LASIK surgery is a permanent procedure, it is not reversible.

- Some jobs, such as pilots, have vision requirements that surgical procedures such as LASIK cannot provide and eyeglasses may still be needed after surgery.

- Your vision must be stable for at least 1 year before the surgery. You will need written proof that your nearsightedness has changed less than 0.5 diopter during this time. A diopter is a unit of measurement of optical strength or power.

- LASIK surgery is not a laser version of other surgical procedures such as radial keratotomy (RK); they are completely different procedures.

- Alternatives to LASIK surgery include eyeglasses, contact lenses, RK and photorefractive keratectomy (PRK).

- The following risks of LASIK surgery for the treatment of nearsightedness and astigmatism should be noted:
  - Transient complications: pain (24 to 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.
  - Adverse events at 6 months occurring in at least 1% of subjects: induced astigmatism (1.0%), severe glare (1.7%), decrease in vision with glasses of 2 lines or more (1.9%), severe visual fluctuations (2.6%), loss of one line or more post-op if 20/20 with eyeglasses pre-op (3.0%), severe halo (3.5%), overcorrection of more than 1 diopter (4.2%), undercorrection of more than 1 diopter (11.9%).

- The following benefits of LASIK surgery for the treatment of nearsightedness and astigmatism should be noted:
  - Reduced dependence on eyeglasses or contact lenses.
  - LASIK surgery may be an alternative to eyeglasses in some patients who are intolerant of contact lenses.
  - LASIK surgery is an alternative to correct nearsightedness and astigmatism.
  - In patients with less than or equal to –7.0 diopters of nearsightedness before surgery, 95% had vision of 20/40 or better with eyeglasses or contact lenses after 6 months. In patients with more than –7.0 diopters of nearsightedness before surgery, 86% had vision of 20/40 or better without eyeglasses or contact lenses after 6 months.

- You should have a complete eye examination before considering LASIK surgery. Additionally, you should discuss the complications, risks, and the time required for healing with one or more eye surgeons.

TABLE OF CONTENTS

INTRODUCTION

The following information is being provided to you because you are thinking about having LASIK surgery. The SVS Apex Plus Excimer Laser Workstation is indicated for use in the reduction or elimination of nearsightedness (myopia) ranging from 0.0 to –14.0 diopters with or without astigmatism ranging from –0.5 to –5.0 diopters using Laser In Situ Keratomileusis (LASIK). You must have documentation of a stable refraction (± 0.5 diopter) over the past year and be 18 years of age or older. An excimer laser is a surgical instrument that produces a powerful beam of light that can remove tissue from the eye. Options for correcting nearsightedness (myopia) with or without astigmatism include eyeglasses, contact lenses, and surgical procedures such as radial keratotomy (RK), photorefractive keratectomy (PRK), and LASIK.

If you are nearsighted in both eyes, it may be necessary to have both eyes treated with LASIK surgery. There are cases where it is appropriate to have LASIK surgery performed on only one eye. This patient booklet will help you make an informed decision about LASIK surgery to correct your nearsightedness and if present, your astigmatism . Please read this booklet completely and discuss any questions with your doctor in order to decide if LASIK surgery is right for you. Only a qualified eye doctor can determine whether you are a suitable candidate for LASIK surgery. The goal of LASIK surgery is to reduce your need for eyeglasses or contact lenses by reshaping the cornea through laser surgery.

HOW THE EYE FUNCTIONS

Your eye focuses light to form images or pictures, much like video camera. Your eye changes these images into electrical signals and sends them 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 light rays onto your retina. The cornea is responsible for two-thirds of the focusing power of your eye. The lens within your eye is responsible for the other third as it focuses light onto your retina. (see Diagram 1).

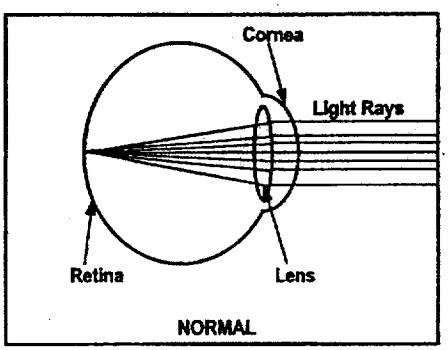

Diagram 1

The Nearsighted Eye (Myopia)

The excimer laser is approved for treatment of mild to high myopia, also known as nearsightedness. Nearsightedness is common, affecting one in four people in North America. Nearsightedness occurs when light rays entering the eye are focused in front of the retina instead of directly on it (see Diagram 2). The tendency to develop nearsightedness runs in families. Nearsightedness usually starts in childhood and typically stabilizes in the late teens or early adulthood. It can be corrected with eyeglasses, contact lenses, or refractive surgery (eye surgery that corrects vision). The first two options, eyeglasses and contact lenses, can be adjusted if your vision changes over time.

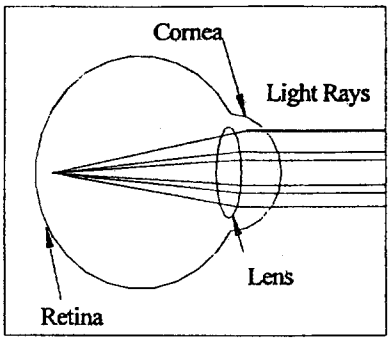

Diagram 2 - Myopic Eye

The Astigmatic Eye

Nearsightedness frequently occurs with astigmatism. In the astigmatic eye, the front of the cornea is not equally curved; it is slightly oval in shape, like a football. Light rays entering the eye bend unequally, resulting in a distorted image (see Diagram 3). Astigmatism can be corrected with eyeglasses, contact lenses, or refractive surgery.

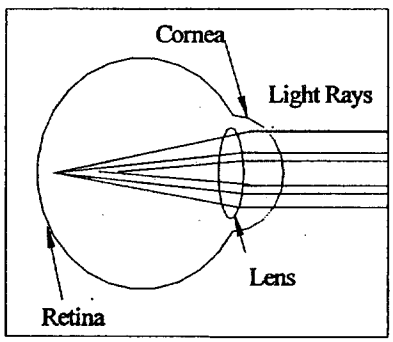

Diagram 3 - Astigmatic Eye

Checking Your Focus

During your eye exam, the doctor observes where your eye focuses light relative to your retina. When your doctor corrects your vision, light is focused properly on the retina. The amount required to correct your vision is measured in units called diopters. LASIK surgery can correct up to -14.0 diopters of nearsightedness and up to -5.0 diopters of astigmatism.

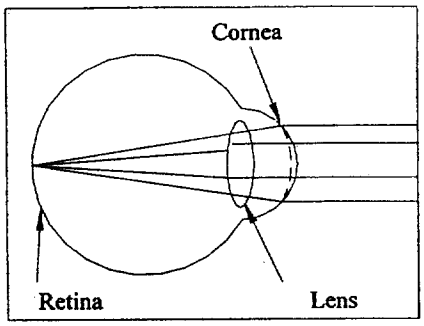

Figure 4 - Eye After LASIK Surgery

WHAT IS LASIK SURGERY?

LASIK surgery is a surgical treatment for nearsightedness and astigmatism. A surgical instrument called a microkeratome creates a flap of corneal tissue. This flap is folded back and the excimer laser removes microscopic amounts of tissue from the cornea underneath the flap. After the laser pulses are delivered, the flap is repositioned.

WHAT IS AN EXCIMER LASER?

An excimer laser is a surgical instrument that produces a powerful beam of light. Laser light is directed and controlled precisely and delivered in 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 from the surface of the cornea, thereby changing the shape of the cornea.

INDICATIONS FOR USE

The SVS Apex Plus Excimer Laser Workstation and emphasis "M" discs are indicated to perform Laser In Situ Keratomileusis (LASIK) for the reduction or elimination of myopia ranging from 0.0 to –14.0 diopters with or without astigmatism ranging from –0.5 to –5.0 diopters in patients who are 18 years of age or older who have documentation of a stable manifest refraction (± 0.5 diopter) over the past year.

CONTRAINDICATIONS

You should **NOT** have LASIK surgery if:

- you have a vascular, auto-immune, or immunodeficiency disease (for example, rheumatoid arthritis, lupus, or AIDS), because it is well known that patients with these diseases have difficulty in corneal healing and are more susceptible to corneal melting
- your nearsightedness is changing
- you are pregnant or nursing, because of the potential for temporary changes in vision under these conditions
- you show signs of keratoconus (a corneal disease), because eyes with this condition may have unstable corneas
- you have a tendency to form scars (keloids), because your corneal healing response is less predictable
- you are taking Accutane (isotretinoin) for treatment of acne or Cordarone (amiodarone hydrochloride) to control heart rhythm

WARNINGS

- You should **NOT** have LASIK surgery if you have had a Herpes simplex or Herpes zoster infection in your eyes, as laser treatment may cause the infection to return
- You should **NOT** have LASIK surgery if you are unable to keep your eye steady during the procedure
- You may have a poorer visual result if you require a high degree of correction.
- Significant visual symptoms such as glare and haloes may be worse if your pupils are large or if you are functioning in conditions, such as driving at night, that will induce larger pupils.

PRECAUTIONS

- You may find it more difficult than usual to see in very dim light, rain, snow, fog, or glare from bright lights at night
- You should talk to your doctor if you are taking Imitrex (sumatriptan succinate) for the treatment of migraine headache.
- You should talk to your doctor if you have a known sensitivity to any of the medications required for the laser procedure.
- You should talk to your doctor if you have a history of glaucoma, because of the potential for a strong response to post operative steroids.
- You should know that since the LASIK clinical investigation was conducted over a period of six months the long term safety and effectiveness of LASIK surgery has not been established.
- You should know that the safety and effectiveness of LASIK surgery in patients under 18 years of age has not been established.
- You should know that the safety and effectiveness of LASIK surgery has not been established in patients who have had prior incisional refractive surgery.
- You should know that there is no safety and effectiveness information for refractive LASIK treatments greater than 14 diopters of myopia or 5 diopters of astigmatism and for PRK greater than 7 diopters.
- You should know that of the eyes treated in the LASIK clinical investigation, only 26/1013 (3%) of highly myopic eyes had myopia between 12-14 diopters and only 19/1013 (2%) of astigmatic eyes had astigmatism between 4-5 diopters. These populations may not have been sufficient to determine the level of effectiveness or the complications and adverse event rates for this refractive error range with the same reliability as for eyes with less severe refractive errors.

RISKS

As with any surgical procedure, there are certain risks and complications associated with LASIK surgery. It is important to discuss these risks with your doctor before you make the decision to have laser surgery. The following adverse events were reported in the clinical study of LASIK surgery using the SVS Apex Plus Excimer Laser Workstation:

- First Month after Surgery

  These symptoms 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.

- First Six Months after Surgery

  At 6 months after treatment the following events, presented in alphabetical order, were reported in patients included in the LASIK clinical study:

  Corneal Epithelial Defect: a slight imperfection (nick) in the outer layer of the cornea

  Epithelial Interface: cells from the outer layer of the cornea which may grow under

  Flap Edema: excess fluid or swelling of the corneal flap

  Flap Wrinkling: a misaligned corneal flap replacement

  Increase in Intraocular Pressure (IOP): increased pressure in the inner eye which may occur from the use of certain post-treatment medications. Increased IOP is usually resolved by drug therapy or discontinuation of post-treatment medication.

  Induced Astigmatism: a change in the shape of the cornea that results in distorted images, possibly requiring the use of eyeglasses or contact lenses

  Loss of Best Spectacle Corrected Visual Acuity: decrease of 2 or more lines of vision on the eye chart while wearing eyeglasses or contact lenses as compared to what your vision was before you had LASIK

  Overcorrection: a correction where some degree of farsightedness may result, possibly requiring the use of eyeglasses or contact lenses

Undercorrection: a correction where some degree of nearsightedness or astigmatism may remain, possibly requiring the use of eyeglasses or contact lenses

- Some patients experience glare, halos and visual fluctuations before having LASIK surgery. Results have indicated that glare, halos and visual fluctuation are better after LASIK than preoperatively with eyeglasses or contact lenses.

VISUAL SYMPTOM	% of patients reporting before LASIK surgery	% of patients reporting 6 months after surgery
No Glare	7.8%	15.7%
Severe Glare	6	1.7%
No Halo	12.0%	20.9%
Severe Halo	3	3.5%
No visual fluctuations	21.1%	42.6%
Severe visual fluctuations	4.0%	2.6%

- The following events were NOT reported in the clinical studies of LASIK surgery using the SVS Apex Plus Excimer Laser Workstation. These events have been known to occur and you should be aware of them. A detailed definition of these events can be found in the glossary at the end of this booklet:

  Anterior stromal reticular haze, corneal infiltrate or ulcer, drooping of eyelid, double vision, foreign body sensations, ghost images, iatrogenic keratoconus, late onset of corneal haze, light sensitivity, melting of the corneal flap, retinal detachment, and retinal vascular accidents.

BENEFITS

- LASIK surgery performed with the SVS Apex Plus Excimer Laser Workstation is effective in reducing or eliminating nearsightedness in the range of –0.1 to –14.0 diopters and nearsightedness with astigmatism in the range of 0.0 to –14.0 diopters (myopia) and –0.5 to –5.0 diopters (astigmatism).
- LASIK surgery may reduce or eliminate dependency on eyeglasses and contact lenses.
- LASIK surgery may reduce overall nearsightedness and astigmatism.
- In patients with less than or equal to –7.0 diopters of nearsightedness before surgery, 95% had vision of 20/40 or better without eyeglasses or contact lenses after 6 months. In patients with more than –7.0 diopters of nearsightedness before surgery, 86% had vision of 20/40 or better without eyeglasses or contact lenses after 6 months.

- LASIK surgery provides an alternative to eyeglasses for some patients intolerant of contact lenses.
- If you are reluctant to wear eyeglasses, for occupational and lifestyle issues, LASIK surgery is a new option to reduce or correct your nearsightedness and astigmatism.

THE LASIK TREATMENT OF NEARSIGHTEDNESS AND ASTIGMATISM PERFORMED WITH THE SVS APEX PLUS EXCIMER LASER WORKSTATION IS AN ALTERNATIVE MEANS OF CORRECTING NEARSIGHTEDNESS AND ASTIGMATISM WITH A REASONABLE ASSURANCE OF SAFETY AND EFFECTIVENESS

Important: Carefully weigh the risks and benefits of LASIK surgery with your doctor before deciding on surgery. Please read the Informed Consent Document before signing it.

ARE YOU A GOOD CANDIDATE FOR LASIK SURGERY?

If you are considering LASIK:

- you should be 18 years of age or older
- you should have healthy eyes which are free from disease or corneal abnormality (for example: scarring or infection)
- you should have nearsightedness (myopia) with or without astigmatism in the range of 0.0 to –14.0 diopters (myopia) and –0.5 to –5.0 diopters (astigmatism)
- your vision has been stable (changed by less than 0.5 diopter) for at least one year before surgery
- you should become familiar with the risks and benefits of LASIK surgery compared with other available treatments for nearsightedness and astigmatism.

Speak with your doctor about your reasons for choosing LASIK surgery and whether you are a suitable candidate for this procedure.

HOW IS LASIK SURGERY 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 start of treatment, some drops are placed on the eye to numb it. Before using the laser, the doctor will use a surgical instrument called a microkeratome, to cut the surface of the eye to create a flap of corneal tissue. The laser is used on the part of the cornea that lies underneath the flap.

The laser treatment uses a laser beam that lasts about 15-60 seconds. The laser removes a microscopic portion of the surface tissue to reshape the cornea. The flap is then placed back over the treated cornea; this may require the use of sutures (stitches). The 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. Treatment 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 investigation of LASIK surgery using the SVS Apex Plus Excimer Laser Workstation, 92 % of the eyes treated had 20/40 or better vision at 6 months after treatment.

LASIK surgery 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.

Important: Keep in mind that your vision may take months to stabilize. LASIK surgery is permanent and cannot be reversed or easily modified if your vision changes or if the initial surgery is not successful (which occurs in a small percentage of cases).

WHAT YOU NEED TO KNOW

Before Surgery

If you are interested in having LASIK surgery, 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.

Before the surgery please talk with your doctor about any medication you take. Also, talk with your doctor about 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.

Important: If you wear contact lenses, it is important to stop wearing them at least two weeks before your pre-surgical examination. Failure to do so may produce poor surgical results.

The Day of Surgery

Overall the surgery will take approximately 10-20 minutes. Just before 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 and a surgical instrument called a microkeratome will first be used to create a flap of tissue at the surface of cornea. You will next be treated with the laser beam; this treatment usually lasts only 15-60 seconds. The doctor will place an instrument between your eyelids to hold them open during the laser treatment. Try to keep both eyes open without trying to shut or squeeze your eyes closed 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 called a microkeratome to create a tissue flap. Only after the doctor has repositioned your head in the chair, refocused the microscope and has asked you to stare at the colored lights will the laser treatment be performed.

Important: It is very important to keep looking directly at the colored fixation lights during the laser treatment. The success of the surgery depends upon you staring at the lights throughout the treatment.

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 this time.

First Days after Surgery

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 your eye heals. Wearing sunglasses will make you more comfortable during this time. Initially, your eye may be overcorrected and objects may be blurry - this is part of the normal healing process. It may take up to three months for your vision to stabilize. All

eyes experience some degree of haze or cloudiness after surgery. The haziness may or may not affect your vision; it tends to decrease as your eyes heal and should eventually disappear completely.

QUESTIONS TO ASK YOUR DOCTOR

- What are the other options for correcting nearsightedness and astigmatism?
- Will I need to limit my activities after the treatment? If yes, for how long?
- What are the benefits of LASIK surgery for my level of vision?
- If LASIK surgery does not correct my vision, could my vision be worse than before surgery? Could my vision gradually decline?
- If needed, will I be able to wear contact lenses after LASIK surgery?
- How is LASIK surgery likely to affect my need to use eyeglasses or contact lenses when I am older?
- Will my cornea heal differently if I injure it after having LASIK surgery?
- If I have LASIK surgery performed on both of my eyes, 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 LASIK surgery on only one eye?

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

PATIENT ASSISTANCE INFORMATION

Primary Eye Doctor

Name: _____

Address: _____

_____

Telephone No: _____

LASIK Surgeon

Name: _____

Address: _____

_____

Telephone No: _____

Treatment Location

Name: _____

Address: _____

_____

Telephone No: _____

Laser Manufacturer

Summit Technology, Inc.
21 Hickory Drive
Waltham, Massachusetts 02451 USA
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GLOSSARY

anterior stromal reticular haze: Corneal haze that occurs at the borders of the treatment area.

astigmatism: Refractive error which prevents light rays from coming to a single point of focus on the retina because of different degrees of bending of light by the eye.

cornea: Transparent front portion of the eye that covers the iris, pupil, and anterior chamber, and provides most of the eye's focusing power.

corneal infiltrate (or ulcer): Abnormal growth of cells into the LASIK cut on the cornea.

corneal swelling: Swollen eye due to inflammation caused by surgery

diopter: Unit of measurement of optical strength or refractive power of lenses.

double vision: Seeing an image as two images

drooping of eyelid: Sagging of the upper eyelid

excimer laser: A medical device that produces a very powerful and pure beam of light of a single specific wavelength (color) that is used to remove tissue from the clear front part of the eye (cornea). This is performed using a computer to re-shape the cornea to correct refractive errors. This re-shaping allows incoming light rays to focus more accurately on the retina.

farsightedness (hyperopia): Condition in which the eye is "underpowered", so that parallel light rays from a distant object strike the retina before coming to a sharp focus; true focal point is said to be "behind the retina". Corrected with additional optical power, supplied by a plus lens or by additional use of the eye's own focusing ability.

foreign body sensations: A feeling that something is in the eye.

ghost images: Seeing a shadow around objects

glare:	Sensation produced by bright lights that is greater than normal and can cause discomfort and annoyance
halos:	A hazy ring around bright lights seen by some patients.
iatrogenic keratoconus:	Keratoconus caused by thinning of the cornea, sometimes resulting from LASIK surgery treatment.
keratoconus:	A hereditary, degenerative corneal disease characterized by generalized thinning and cone-shaped protrusion of the central cornea.
LASIK Surgery:	An acronym for "laser in situ keratomileusis". This is a surgical procedure in which a microkeratome creates a thin flap of cornea and an excimer laser re-shapes the corneal tissue under the flap. This procedure is intended to correct refractive errors of the eye.
late onset of corneal haze:	Foggy cornea causing images to appear smudged or unclear and this happens six months after surgery or later
lens:	A transparent, colorless body located in the front third of the eye which helps bring light rays into focus on the retina.
light sensitivity:	When light hurts your eyes
manifest refraction:	A test in which a series of lenses in graded power are used to determine which lenses provide the sharpest, clearest vision. This test results in the prescription for eyeglasses or contact lenses.
melting of the corneal flap:	The flap created during surgery degrades and may require a corneal transplant
microkeratome:	A surgical instrument used for shaving the cornea during LASIK procedures to create a flap.

nearsightedness (myopia):	"Overpowered" eye in which parallel light rays from a distant object are brought to focus in front of the retina. Requires minus lens correction to "weaken" the eye optically and permit clear distance vision.
pupil:	The opening at the center of the iris of the eye transmits light. The pupil varies in diameter depending upon the brightness of incoming light.
pupil enlargement:	When the diameter of the opening in the eye (pupil) is larger than normal
PRK:	An acronym for "photorefractive keratectomy". This is a surgical procedure in which a thin portion of the clear front part of the eye (cornea) is removed using an excimer laser to re-shape the cornea to correct refractive errors of the eye.
refractive surgery:	Several procedures used for altering the shape of the cornea and thus how it bends light, in order to change or correct the eye's refractive error.
retina:	The thin lining of tissue at the back of the eye that converts images from the eye's optical system into electrical impulses sent to the brain.
retinal detachment:	When the thin lining of tissue at the back of the eye (retina) becomes loose and separates from the back of eye
retinal vascular accidents:	When bleeding occurs in the thin lining of tissue at the back of the eye (retina)
RK:	An acronym for "radial keratotomy". This is a surgical procedure in which radial cuts are made in the cornea. This allows the cornea to flatten and thereby reduces nearsightedness.
shadow images:	Same as ghost images
tearing:	Excessive watering of the eye

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