

Sunrise Technologies International, Inc.
PMA P990078 HYPERION™ LTK System
PHYSICIAN LABELING
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HYPERION™ LTK System Physician Labeling

Laser Thermal Keratoplasty (LTK)

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RESTRICTED DEVICE: U.S. Federal Law restricts this device to sale, distribution, and use by or on the order of a physician or other licensed eye care practitioner.

U.S. Federal Law restricts the use of this device to practitioners who have been trained in its calibration and operation, and who have experience in the surgical treatment and management of refractive errors.

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Table of Contents

	<u>Page</u>
1. General Warnings.....	4
2. Device Description	4
3. Indications, Contraindications, Warnings, Precautions, Adverse Events and Complications.....	5
3.1 Indications For Use.....	5
3.2 Contraindications.....	5
3.3 Warnings.....	6
3.4 Precautions	7
3.5 Adverse Events and Complications.....	7
4. Patient Satisfaction, Spectacle/Contact Lens Dependence and Patient Symptoms	8
4.1 Patient Satisfaction	8
4.2 Spectacle and Contact Lens Dependence in Patients Treated Bilaterally.....	10
4.3 Patient Symptoms	10
5. Clinical Study	11
5.1 Introduction.....	11
5.2 Demographics.....	12
5.3 Baseline Parameters	13
5.4 Accountability.....	13
5.5 Safety and Efficacy Results.....	14
5.5.1 Induced Manifest Refraction.....	21
5.5.2 Change in Manifest Refraction Over Time.....	21

6. Statistical Modeling – Effect of Age and Applied Energy on Change in MRSE.....	21
7. Performing The Sunrise LTK Procedure.....	27
7.1 Operating Procedure Summary.....	27
7.2 Post-Procedure.....	29
7.3 Device Labels	30

1. GENERAL WARNINGS

The user is responsible to read all instructions before use of their system. Pay attention to all warnings, contraindications and precautions noted in these instructions, the Operators' Manual, and other related materials. Failure to do so may result in harm to a patient or user of the system.

This labeling is supplied to provide information on the intended clinical use of the Sunrise Technologies HYPERION™ LTK Laser System. For complete information concerning laser system components, laser safety, installation, maintenance and troubleshooting refer to the Operator's Manual.

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

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

2. DEVICE DESCRIPTION

The HYPERION™ LTK System uses a non-contact Ho:YAG laser to perform Laser Thermal Keratoplasty (LTK). This device delivers laser light to precisely heat predetermined areas of the mid-peripheral cornea in order to obtain collagen shrinkage and thereby increase corneal curvature.

The HYPERION™ delivers eight simultaneous spots (0.6mm) on the cornea in a circular pattern; one ring at 6 mm diameter and one at 7 mm diameter for a total of 16 spots. Seven pulses per ring are delivered at a rate of five pulses per second resulting in a treatment time of 2.8 seconds. The pattern can be rotated if necessary.

3. INDICATIONS, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, ADVERSE EVENTS AND COMPLICATIONS

3.1 Indications for use

The Sunrise HYPERION™ LTK System is indicated for:

Temporary reduction of hyperopia in patients with +0.75 to +2.5 diopters of manifest refraction spherical equivalent (MRSE) at the spectacle plane (with cylinder less than or equal to ± 0.75 diopters) who are 40 years of age or older with documented stability of refraction for the prior 6 months, as demonstrated by a change of less than or equal to 0.50D in spherical and cylindrical components of the manifest refraction. The magnitude of correction with this treatment diminishes over time, with some patients retaining some or all of their refractive correction.

3.2 Contraindications

LTK is contraindicated:

- In pregnant or nursing women
- In patients with signs of keratoconus.
- In patients with clinically significant corneal dystrophy or scarring in the 6 or 7 mm central zone.
- In patients with a history of herpetic keratitis.

- In patients with an autoimmune disease, collagen vascular disease, clinically significant atopic syndrome, insulin dependent diabetes or an immune compromised status.

3.3 Warnings

- Based on existing information for the clinical parameters used in the clinical trial, approximately half of the effect seen at 6 months is gone at 2 years including the “initially” intended myopic overcorrection.
- Extrapolating from existing data, Sunrise Technologies has found that the effect of LTK may dissipate in 3-5 years. The effect of the procedure may last substantially longer in some patients.
- The procedure may induce myopia in the early post-treatment period which may cause changes in both near and distance acuity.
- The safety and effectiveness of re-treatment procedures with the Hyperion™ LTK System or other refractive surgical devices have not been established. Limited data suggests that the reduction in refractive error following re-treatment may diminish over time.
- Patient-related warnings:
 - Patients must refrain from wearing contact lenses 2-4 weeks before his or her eye exam (2 weeks prior for soft/permeable lenses; 3 weeks prior for hard lenses). Failure to do so may produce poor surgical results.
 - Patients must be able to fixate on the flashing fixation light. Movement during the procedure could result in undercorrection and/or astigmatism.

3.4 Precautions

- Under-corrections are more likely to occur in younger patients and greater applied energy may be needed.
- Outcomes are affected by age and applied energy. See Section 6.
- The safety and effectiveness of the LTK System has not been determined for use:
 - In patients with progressive hyperopia, ocular disease, corneal abnormality, or trauma in the ablation zone.
 - In patients with glaucoma.
 - In patients under 40 years of age.
 - In long term studies (over 2 years follow-up after procedure).
 - In patients with nystagmus.
 - In patients with cloudy corneas or anterior chambers.
 - In patients with uncontrolled uveitis, severe blepharitis, lagophthalmos or dry eye.

3.5 Adverse Events and Complications

Table 1
Adverse Events After LTK

Corneal Infiltrate or Ulcer	0.0%
Uncontrolled IOP	0.0%
Late Onset of Haze > 6 months with loss of ≥ 2 lines BSCVA	0.0%
Retinal Vascular Accidents	0.0%
Retinal Detachment	0.0%

Table 2
Complications After LTK

	<u>1 Mth</u>	<u>3 Mths</u>	<u>6 Mths</u>	<u>12 Mths</u>	<u>18 Mths</u>	<u>24 Mths</u>
Corneal Edema	0.2%	0.0%	0.0%	0.0%	0.0%	0.0%
Recurrent Corneal Erosion	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Foreign Body Sensation	1.9%	0.4%	0.2%	0.8%	1.1%	0.3%
Pain	0.7%	0.4%	0.0%	0.2%*	0.0%	0.0%

*Isolated single visit; patient seen at 8 post-tx visits but only reported at 12 months

4. PATIENT SATISFACTION, SPECTACLE DEPENDENCE AND PATIENT SYMPTOMS

4.1 Patient Satisfaction

Patient satisfaction was assessed on a patient survey at 6, 12 and 24 months post-treatment using a 5 point grading scale from “very disappointed” to “most satisfied”.

Table 3
Patient Satisfaction

	<u>Very Disappointed</u>			<u>Most Satisfied</u>	
	(1)	(2)	(3)	(4)	(5)
6 Mths	7.7%	6.7%	18.0%	21.5%	46.1%
12 Mths	8.0%	10.9%	18.5%	26.9%	35.7%
24 Mths	14.8%	13.1%	14.8%	9.8%	47.5%

*No patients (0.0%) reported dissatisfaction due to visual symptoms. Primary reasons for dissatisfaction were undercorrection and poorly managed patient expectations (e.g., displeased to lose the immediate post-operative improvement in near visual acuity which occurs due to expected overcorrection, even when aware that near acuity improvement is not a treatment goal).

Patient Satisfaction by Age is given in Table 4.

Table 4
Primary Hyperopia Study - Patient Satisfaction Questionnaire Response Summary by Age Group

Patient Satisfaction	Very Disappointed												Most Satisfied		
	%%			%%			%%			%%			%%		
How satisfied are you with the surgery?	6 mos.	12 mos.	24 mos.	6 mos.	12 mos.	24 mos.	6 mos.	12 mos.	24 mos.	6 mos.	12 mos.	24 mos.	6 mos.	12 mos.	24 mos.
Age Group (Years)															
40-49	14.9%	11.1%	10.0%	4.3%	22.2%	20.0%	34.0%	19.4%	10.0%	17.0%	27.8%	30.0%	29.8%	19.4%	30.0%
50-59	6.8%	7.9%	16.7%	6.8%	9.4%	13.9%	16.4%	19.7%	11.1%	24.7%	26.0%	5.6%	45.2%	37.0%	52.8%
60 & Above	5.6%	6.8%	13.3%	7.8%	8.1%	6.7%	12.2%	14.9%	26.7%	18.9%	28.4%	6.7%	55.6%	41.9%	46.7%

4.2 SPECTACLE AND CONTACT LENS DEPENDENCE IN PATIENTS TREATED BILATERALLY

Table 5
Do You Wear Spectacles or Contact Lenses?

	<u>Pre-TX</u>	<u>6 Mths</u>	<u>12 Mths</u>	<u>24 Mths</u>
Yes	92.3%	31.5%	20.6%	21.1%

*Patients treated bilaterally (both eyes treated) were asked pre-treatment and 6, 12, and 24 months post-treatment if they wore spectacles or contacts lenses. Reason for spectacle/contact lens usage (i.e., for distance vs near vision) not requested.

4.3 PATIENT SYMPTOMS

Patient Subjective Symptoms - (6-24 Months):

No subjective symptom data was collected during the post-treatment period prior to 6 months.

Table 6
Patient Subjective Symptoms-Graded "Present" or "Absent"

<u>Symptom</u>	<u>Pre-Tx</u>	<u>6 Mths</u>	<u>12 Mths</u>	<u>18 Mths</u>	<u>24 Mths</u>
Photophobia	0.0%	0.0%	2.0%	8.7%	6.8%
Itching	0.0%	0.0%	2.0%	0.0%	0.0%
Pain	0.0%	0.0%	2.0%	0.0%	0.0%
Pressure	0.0%	0.0%	0.0%	0.0%	0.0%
Tearing	0.0%	2.0%	0.0%	0.0%	0.0%
Foreign Body Sensation	0.0%	0.0%	2.0%	4.3%	4.5%
Night Vision Difficulty	24.1%	32.6%	28.6%	NR	17.1%

Table 7
Patient Subjective Symptom "Severity"-Graded 0 to +4

<u>Symptom</u>	<u>0</u>	<u>+1</u>	<u>+2</u>	<u>+3</u>	<u>+4</u>
<u>Photophobia:</u>					
<u>Pre-Tx</u>	94.9%	3.0%	1.7%	0.0%	0.4%
<u>6 Mths</u>	89.4%	2.6%	5.4%	1.2%	1.4%
<u>12 Mths</u>	89.5%	4.4%	2.8%	1.2%	2.1%
<u>24 Mths</u>	78.6%	10.7%	7.1%	3.6%	0.0%

Table 8
Patient Subjective Symptom "Incidence"

<u>Symptom</u>	<u>N/R*</u>	<u>None</u>	<u>Very Little</u>	<u>Mild</u>	<u>Moderate</u>	<u>Marked</u>	<u>Severe</u>
Glare:							
<u>Pre-Tx</u>	2.2%	90.3%	1.1%	3.2%	2.5%	0.7%	0.0%
<u>6 Mths</u>	4.4%	83.2%	2.0%	1.6%	5.6%	2.8%	0.4%
<u>12 Mths</u>	8.7%	81.4%	1.7%	2.6%	3.0%	1.7%	0.9%
<u>24 Mths</u>	11.1%	81.5%	3.7%	3.7%	0.0%	0.0%	0.0%

*N/R = Not Reported

<u>Symptom</u>	<u>N/R*</u>	<u>None</u>	<u>Very Little</u>	<u>Mild</u>	<u>Moderate</u>	<u>Marked</u>	<u>Severe</u>
Increased Sensitivity to Light (e.g. halos):							
<u>Pre-Tx</u>	2.9%	91.0%	1.1%	2.5%	1.1%	1.4%	0.0%
<u>6 Mths</u>	3.2%	83.2%	0.8%	2.0%	6.8%	2.4%	1.6%
<u>12 Mths</u>	6.9%	81.4%	0.9%	2.6%	5.6%	1.7%	0.9%
<u>24 Mths</u>	3.7%	85.2%	0.0%	7.4%	0.0%	3.7%	0.0%

*N/R = Not Reported

<u>Symptom</u>	<u>N/R*</u>	<u>None</u>	<u>Very Little</u>	<u>Mild</u>	<u>Moderate</u>	<u>Marked</u>	<u>Severe</u>
Night Vision Problems:							
<u>Pre-Tx</u>	4.3%	88.1%	1.1%	2.2%	2.2%	2.2%	0.0%
<u>6 Mths</u>	3.6%	83.2%	1.6%	2.8%	4.4%	2.4%	2.0%
<u>12 Mths</u>	10.0%	78.4%	0.4%	1.3%	3.9%	4.3%	1.7%
<u>24 Mths</u>	3.7%	92.6%	0.0%	0.0%	0.0%	3.7%	0.0%

*N/R = Not Reported

5. CLINICAL STUDY

5.1 Introduction

The Sunrise Technologies Low to Moderate Hyperopia LTK clinical study was a prospective, non-randomized, unmasked, multi-center clinical study. All subjects were treated using the same algorithm to standardize laser energy, number of laser applications, spot placement and pulse frequency. Applied energy was varied based on the pre-treatment MRSE in a uniform manner. The Treatment Algorithms (that take into consideration Age and Applied Energy) provided in Section 6 were NOT used during this clinical study.

Study inclusion criteria included: at least 40 years of age, unilateral or bilateral hyperopia of +0.75 D to +2.50 D (manifest refraction spherical equivalent) at the spectacle plane with 0.75 D or less manifest cylinder, stable refraction (no more than 0.50 D change in 6 months prior to treatment) and discontinuation of contact lens prior to LTK (2 weeks for soft/permeable lenses; 3 weeks for hard lenses).

Study exclusion criteria included: monocular patients; unstable refraction; nystagmus; prior corneal trauma; ocular surgery or corneal disease; uncontrolled uveitis; severe blepharitis; lagophthalmos or dry eye; pregnant or lactating women; cloudy corneas or anterior chambers; or immunocompromised patients.

5.2 Demographics

Table 9
Demographics
PMA Cohort
612 Eyes Treated of 379 Subjects

Gender			
	Female	226	(59.6%)
	Male	153	(40.4%)
Race			
	American Indian	0	(0.0%)
	Asian	1	(0.3%)
	Black	8	(2.1%)
	Hispanic	16	(4.2%)
	White	354	(93.4%)
Eyes Treated			
	Right	307	(50.2%)
	Left	305	(49.8%)
Age at First Surgery			
	Average	56.1	
	Standard Deviation	7.4	
	Minimum	40	
	Maximum	78	

5.3 Baseline Parameters

Table 10
Pre-Treatment Refractive Parameters

<u>PMA Cohort (MRSE)</u>		
Spherical Equivalent	Number	%
0.75 thru 0.99	26	4.2%
1.00 thru 1.24	57	9.3%
1.25 thru 1.49	102	16.7%
1.50 thru 1.74	107	17.5%
1.75 thru 1.99	126	20.6%
2.00 thru 2.24	91	14.9%
2.25 thru 2.50	103	16.8%
TOTAL	612	100.0%

<u>PMA Cohort (Cylinder)</u>		
Cylinder (diopters)	Number	%
+0.00	242	39.5%
+0.25	115	18.8%
+0.50	171	27.9%
+0.75	82	13.4%
+1.00	2	0.3%
TOTAL	612	100.0%

5.4 Accountability

Table 11
Accountability

<u>Visit</u>	<u># of Eyes</u>	<u>% Accountability</u>
Pre-Treatment	612 eyes	100%
1 Month Post-Treatment	592 eyes	98.3%
3 Months Post-Treatment	571 eyes	95.5%
6 Months Post-Treatment	555 eyes	93.9%
12 Months Post-Treatment	493 eyes	92.5%
18 Months Post-Treatment	267 eyes	92.1%
24 Months Post-Treatment	72 eyes	92.3%

5.5 Safety and Efficacy Results

Table 12 provides a summary of safety and efficacy results over time (1 through 24 months post-treatment) for the PMA Cohort.

Table 13 presents the same parameters at 12 months post-treatment stratified by dioptric power.

Table 14 presents the same parameters at 12 months post-treatment stratified by age groups.

Table 12

Summary of Key Safety
and Efficacy Variables

Sunrise Technologies Inc.
LTK - SL61 / SL72 / SL73 and SF
as of 10/19/1999

PMA Cohort

	1 month	3 month	6 month	12 month	18 month	24 month
Available for Analysis	592	571	555	493	267	72
EFFICACY VARIABLES						
UCVA 20/20 or better	131 / 592 (22.1%) [18.8-25.5%]	181 / 570 (31.8%) [27.9-35.8%]	216 / 554 (39.0%) [34.9-43.1%]	179 / 479 (37.4%) [33.0-41.7%]	90 / 261 (34.5%) [28.7-40.2%]	15/72(20.8%) [11.5-30.2%]
UCVA 20/40 or better	387 / 592 (65.4%) [61.5-69.2%]	447 / 570 (78.4%) [75.0-81.8%]	477 / 554 (86.1%) [83.2-89.0%]	407 / 479 (85.0%) [81.8-88.2%]	214 / 261 (82.0%) [77.3-86.7%]	49/72(68.1%) [57.3-78.8%]
UCVA not reported	0	1	1	14	6	0
DIFFERENCE FROM INTENDED						
± 0.50 D	211 / 544 (38.8%) [34.7-42.9%]	341 / 565 (60.4%) [56.3-64.4%]	356 / 554 (64.3%) [60.3-68.3%]	275 / 481 (57.2%) [52.8-61.6%]	122 / 262 (46.6%) [40.5-52.6%]	24/72(33.3%) [22.4-44.2%]
± 1.00 D	367 / 544 (67.5%) [63.5-71.4%]	502 / 565 (88.8%) [86.3-91.4%]	485 / 554 (87.5%) [84.8-90.3%]	401 / 481 (83.4%) [80.0-86.7%]	194 / 262 (74.0%) [68.7-79.4%]	45/72(62.5%) [51.3-73.7%]
± 2.00 D	521 / 544 (95.8%) [94.1-97.5%]	559 / 565 (98.9%) [98.1-99.8%]	551 / 554 (99.5%) [98.8-100.0%]	474 / 481 (98.5%) [97.5-99.6%]	256 / 262 (97.7%) [95.9-99.5%]	69/72(95.8%) [91.2-100.0%]
MRSE not reported	48	6	1	12	5	0
<u>Undercorrected > 1.00 D</u>	2.4%	4.2%	10.6%	16.4%	25.6%	37.5%
<u>Overcorrected > 1.00 D</u>	30.1%	6.9%	1.8%	0.2%	0.4%	0.0%

Table 12 (Continued)
Summary of Key Safety
and Efficacy Variables

Sunrise Technologies Inc.
LTK - SL61 / SL72 / SL73 and SF
as of 10/19/1999

	PMA Cohort					
	1 month	3 month	6 month	12 month	18 month	24 month
Available for Analysis	592	571	555	493	267	72
SAFETY VARIABLES						
BsCVA worse than 20/40	1 / 573 (0.2%) [0.0-0.5%]	1 / 567 (0.2%) [0.0-0.5%]	0 / 552 (0.0%) [0.0-0.0%]	0 / 481 (0.0%) [0.0-0.0%]	0 / 260 (0.0%) [0.0-0.0%]	0 / 72 (0.0%) [0.0-0.0%]
BsCVA not reported	19	4	3	12	7	0
Loss of 2 lines BsCVA	14 / 573 (2.4%) [1.2-3.7%]	8 / 567 (1.4%) [0.4-2.4%]	14 / 552 (2.5%) [1.2-3.8%]	11 / 481 (2.3%) [1.0-3.8%]	5 / 260 (1.9%) [0.3-3.6%]	0 / 72 (0.0%) [0.0-0.0%]
Loss of > 2 lines BsCVA	14 / 573 (2.4%) [1.2-3.7%]	7 / 567 (1.2%) [0.3-2.1%]	2 / 552* (0.4%) [0.0-0.9%]	1 / 48 ⁺ (0.2%) [0.0-0.6%]	1 / 260 [†] (0.4%) [0.0-1.1%]	0 / 72 (0.0%) [0.0-0.0%]
BsCVA worse than 20/25; 20/20 or better preop	20 / 573 (3.5%) [2.0-5.0%]	15 / 567 (2.6%) [1.3-4.0%]	5 / 552 (0.9%) [0.1-1.7%]	3 / 481 (0.6%) [0.0-1.3%]	4 / 260 (1.5%) [0.0-3.0%]	0 / 72 (0.0%) [0.0-0.0%]
BsCVA value missing preop or postop	19	4	3	12	7	0
Increase >2 D cylinder	19 / 544 (3.5%) [1.9-5.0%]	8 / 566 (1.4%) [0.4-2.4%]	5 / 554 (0.9%) [0.1-1.7%]	1 / 481 (0.2%) [0.0-0.6%]	0 / 262 (0.0%) [0.0-0.0%]	0 / 72 (0.0%) [0.0-0.0%]
Cylinder value missing preop or postop	48	5	1	12	5	0

* SL73-07-341-OS: Cataract development in 1 subject 61 years of age, BsCVA of 20/40

SL61-07-011-OS: Reduced VA at 6 months shows recovery at 12 months, preop BsCVA of 20/10, 6 month BsCVA of 20/20, and 12 month BsCVA of 20/13.

+ SL73-05-305-OD: Vision recorded as 20/32, however, no manifest refraction performed. Patient returned at 18 months post-treatment with BsCVA of 20/16.

† SL73-10-314-OD: Cataract development in 1 subject 63 years of age, BsCVA of 20/40

Table 13

Sunrise Technologies Inc.
LTK - SL61 / SL72 / SL73 and SF
as of 10/19/1999

Summary of Key Safety
and Efficacy Variables at 12 months

Page 1 of 2
01 Nov 1999

Stratified by Preop MRSE; PMA Cohort

	0.75 to 0.99 D	1.00 to 1.24 D	1.25 to 1.49 D	1.50 to 1.74 D	1.75 to 1.99 D	2.00 to 2.24 D	2.25 to 2.50 D
EFFICACY VARIABLES							
UCVA 20/20 or better	11 / 18 (61.1%) [38.6-83.6%]	27 / 47 (57.4%) [43.3-71.6%]	44 / 86 (51.2%) [40.6-61.7%]	28 / 80 (35.0%) [24.5-45.5%]	42 / 96 (43.8%) [33.8-53.7%]	15 / 71 (21.1%) [11.6-30.6%]	12 / 81 (14.8%) [7.1-22.6%] (71.6%)
UCVA 20/40 or better	18 / 18 (100.0) [100.0-100.0%]	45 / 47 (95.7%) [90.0-100.0%]	82 / 86 (95.3%) [90.9-99.8%]	69 / 80 (86.3%) [78.7-93.8%]	85 / 96 (88.5%) [82.2-94.9%]	50 / 71 (70.4%) [59.8-81.0%]	58 / 81 [61.8-81.4%]
UCVA not reported	1	4	2	11	7	8	6
DIFFERENCE FROM INTENDED							
± 0.50 D	14 / 18 (77.8%) [58.6-97.0%]	38 / 47 (80.9%) [69.6-92.1%]	64 / 85 (75.3%) [66.1-84.5%]	56 / 82 (68.3%) [58.2-78.4%]	59 / 96 (61.5%) [51.7-71.2%]	21 / 71 (29.6%) [19.0-40.2%]	23 / 82 (28.0%) [18.3-37.8%]
± 1.00 D	18 / 18 (100.0) [100.0-100.0%]	46 / 47 (97.9%) [93.7-100.0%]	81 / 85 (95.3%) [90.8-99.8%]	77 / 82 (93.9%) [88.7-99.1%]	85 / 96 (88.5%) [82.2-94.9%]	49 / 71 (69.0%) [58.3-79.8%]	45 / 82 (54.9%) [44.1-65.6%]
± 2.00 D	18 / 18 (100.0) [100.0-100.0%]	47 / 47 (100.0) [100.0-100.0%]	85 / 85 (100.0) [100.0-100.0%]	82 / 82 (100.0) [100.0-100.0%]	96 / 96 (100.0) [100.0-100.0%]	68 / 71 (95.8%) [91.1-100.0%]	78 / 82 (95.1%) [90.5-99.8%]
MRSE not reported	1	4	3	9	7	8	5

Table 13 (Continued)

Sunrise Technologies Inc.
LTK - SL61 / SL72 / SL73 and SF
as of 10/19/1999

Summary of Key Safety
and Efficacy Variables at 12 months
Stratified by Preop MRSE; PMA Cohort

	0.75 to 0.99 D	1.00 to 1.24 D	1.25 to 1.49 D	1.50 to 1.74 D	1.75 to 1.99 D	2.00 to 2.24 D	2.25 to 2.50 D
SAFETY VARIABLES							
BsCVA worse than 20/40	0 / 18 (0.0%) [0.0-0.0%]	0 / 47 (0.0%) [0.0-0.0%]	0 / 86 (0.0%) [0.0-0.0%]	0 / 81 (0.0%) [0.0-0.0%]	0 / 96 (0.0%) [0.0-0.0%]	0 / 71 (0.0%) [0.0-0.0%]	0 / 82 (0.0%) [0.0-0.0%]
BsCVA not reported	1	4	2	10	7	8	5
Loss of 2 lines BsCVA	1 / 18 (5.6%) [0.0-16.1%]	1 / 47 (2.1%) [0.0-6.3%]	2 / 86 (2.3%) [0.0-5.5%]	1 / 81 (1.2%) [0.0-3.6%]	2 / 96 (2.1%) [0.0-4.9%]	1 / 71 (1.4%) [0.0-4.1%]	3 / 82 (3.7%) [0.0-7.7%]
Loss of > 2 lines BsCVA	0 / 18 (0.0%) [0.0-0.0%]	0 / 47 (0.0%) [0.0-0.0%]	0 / 86 (0.0%) [0.0-0.0%]	1 / 81 (1.2%) [0.0-3.6%]	0 / 96 (0.0%) [0.0-0.0%]	0 / 71 (0.0%) [0.0-0.0%]	0 / 82 (0.0%) [0.0-0.0%]
BsCVA worse than 20/25; 20/20 or better preop	0 / 18 (0.0%) [0.0-0.0%]	0 / 47 (0.0%) [0.0-0.0%]	0 / 86 (0.0%) [0.0-0.0%]	1 / 81 (1.2%) [0.0-3.6%]	1 / 96 (1.0%) [0.0-3.1%]	0 / 71 (0.0%) [0.0-0.0%]	1 / 82 (1.2%) [0.0-3.6%]
BsCVA value missing preop or postop	1	4	2	10	7	8	5
Increase >2 D cylinder	0 / 18 (0.0%) [0.0-0.0%]	0 / 47 (0.0%) [0.0-0.0%]	0 / 85 (0.0%) [0.0-0.0%]	0 / 82 (0.0%) [0.0-0.0%]	1 / 96 (1.0%) [0.0-3.1%]	0 / 71 (0.0%) [0.0-0.0%]	0 / 82 (0.0%) [0.0-0.0%]
Cylinder value missing preop or postop	1	4	3	9	7	8	5

Table 14

Sunrise Technologies Inc.
LTK - SL61 / SL72 / SL73 and SF
as of 10/19/1999

Summary of Key Safety
and Efficacy Variables at 12 months
PMA Cohort

	Age 40-49	Age 50-59	Age 60 and over
Available for Analysis	69	255	167
EFFICACY VARIABLES			
UCVA 20/20 or better	22 / 66 (33.3%) [22.0-44.7%]	99 / 247 (40.1%) [34.0-46.2%]	58 / 164 (35.4%) [28.0-42.7%]
UCVA 20/40 or better	54 / 66 (81.8%) [72.5-91.1%]	213 / 247 (86.2%) [81.9-90.5%]	138 / 164 (84.1%) [78.6-89.7%]
UCVA not reported	3	8	3
DIFFERENCE FROM INTENDED			
± 0.50 D	33 / 66 (50.0%) [37.9-62.1%]	140 / 250 (56.0%) [49.8-62.2%]	100 / 163 (61.3%) [53.9-68.8%]
± 1.00 D	53 / 66 (80.3%) [70.7-89.9%]	201 / 250 (80.4%) [75.5-85.3%]	145 / 163 (89.0%) [84.1-93.8%]
± 2.00 D	66 / 66 (100.0) [100.0-100.0%]	246 / 250 (98.4%) [96.8-100.0%]	160 / 163 (98.2%) [96.1-100.0%]
MRSE not reported	3	5	4

Table 14 (Continued)

Sunrise Technologies Inc.
LTK - SL61 / SL72 / SL73 and SF
as of 10/19/1999

Summary of Key Safety
and Efficacy Variables at 12 months
PMA Cohort

	Age 40-49	Age 50-59	Age 60 and over
Available for Analysis	69	255	167
SAFETY VARIABLES			
BsCVA worse than 20/40	0 / 66 (0.0%) [0.0-0.0%]	0 / 249 (0.0%) [0.0-0.0%]	0 / 164 (0.0%) [0.0-0.0%]
BsCVA not reported	3	6	3
Loss of 2 lines BsCVA	3 / 66 (4.5%) [0.0-9.6%]	5 / 249 (2.0%) [0.3-3.8%]	3 / 164 (1.8%) [0.0-3.9%]
Loss of > 2 lines BsCVA	0 / 66 (0.0%) [0.0-0.0%]	1 / 249 (0.4%) [0.0-1.2%]	0 / 164 (0.0%) [0.0-0.0%]
BsCVA worse than 20/25; 20/20 or better preop	0 / 66 (0.0%) [0.0-0.0%]	1 / 249 (0.4%) [0.0-1.2%]	2 / 164 (1.2%) [0.0-2.9%]
BsCVA value missing preop or postop	3	6	3
Increase >2 D cylinder	0 / 66 (0.0%) [0.0-0.0%]	1 / 250 (0.4%) [0.0-1.2%]	0 / 163 (0.0%) [0.0-0.0%]
Cylinder value missing preop or postop	3	5	4

5.5.1 Induced Manifest Refraction Cylinder:

Table 15
Induced Cylinder After LTK

	<u>1 Mth</u>	<u>3 Mths</u>	<u>6 Mths</u>	<u>12 Mths</u>	<u>18 Mths</u>	<u>24 Mths</u>
Increase > 2.00 D	3.5%	1.4%	0.9%	0.2%	0.0%	0.0%
Increase > 1.00 D	14.2%	10.3%	9.8%	4.7%	1.9%	4.2%

5.5.2 Change in Manifest Refraction Over Time

Table 16
Change in Manifest Refraction Over Time:
PMA Cohort

	<u>Time Period Intervals</u>					
	<u>1 WK-1M</u>	<u>1 M-3 M</u>	<u>3 M-6 M</u>	<u>6 M-12 M</u>	<u>12 M-18 M</u>	<u>18 M-24 M</u>
<u>Change in MRSE</u>						
≤ +0.25 D	24.2%	17.5%	28.4%	27.7%	25.9%	35.3%
+/- 0.25 D	41.1%	32.5%	51.0%	43.8%	49.0%	61.8%
+/- 0.50 D	66.8%	51.6%	76.3%	70.2%	81.7%	88.2%
+/- 0.75 D	83.3%	69.0%	89.5%	86.5%	93.2%	97.1%
+/- 1.0 D	90.1%	82.0%	94.8%	94.3%	96.8%	100.0%
<u>Mean Change in SE</u>	0.26 D	0.54 D	0.30 D	0.36 D	0.25 D	0.14 D
<u>Mean Rate of Change per month</u>	0.34 D	0.27 D	0.10 D	0.06 D	0.04 D	0.02 D

6. STATISTICAL MODELING-EFFECT OF AGE AND APPLIED ENERGY ON CHANGE IN MRSE

An in-depth modeling analysis was performed to identify those factors that have a statistically significant impact on LTK clinical outcomes. Change in spherical equivalent (or the reduction in hyperopia-MRSE) was analyzed as a continuous variable as a function of AGE, RACE, GENDER, APPLIED ENERGY and CORNEAL CURVATURE at 6, 12, 18 and 24 months post-treatment.

The only variables found to be statistically significant were AGE and APPLIED ENERGY. Increased AGE was directly correlated with an increased effect with older patients having 0.1 to 0.2 D more reduction in hyperopia per decade of increasing age. LTK treatment with 258mJ of APPLIED ENERGY would result in 0.6 to 0.75 D more effect than treatment with 228mJ.

A modeling analysis was then used to develop “best-fit” algorithms or “look-up” tables to predict the change in MRSE for the possible combinations of AGE (40 to 78 years) and APPLIED ENERGY (226 to 258 mJ) at 6, 12, 18, and 24 months post-treatment. This information is provided in the following 4 “look-up” tables.

Table 17
Applied Energy by Age and Predicted Change (MRSE)
Treatment Algorithm for 16 Spot LTK-6 Months (emmetropia endpoint)
Patient Age (YRS)

PreTx	40 - 44	45 - 49	50 - 54	55 - 59	60 - 64	65 - 69	>= 70
MRSE (D)	(mJ)						
0.750	226**	226**	226**	226**	226**	226**	226**
0.875	226**	226**	226**	226**	226**	226**	226**
1.000	226 - 227	226**	226**	226**	226**	226**	226**
1.125	231 - 233	228 - 230	226 - 227	226**	226**	226**	226**
1.250	237 - 240	234 - 237	231 - 234	228 - 231	226 - 228	226**	226**
1.375	243 - 246	241 - 243	238 - 240	235 - 237	232 - 234	229 - 231	226 - 228
1.500	250 - 252	247 - 249	244 - 246	241 - 243	238 - 240	235 - 237	231 - 234
1.625	256 - 258	253 - 255	250 - 252	247 - 250	244 - 247	241 - 244	238 - 241
1.750	258*	258*	256 - 258	253 - 256	250 - 253	248 - 250	244 - 247
1.875	258*	258*	258*	258*	257 - 258	254 - 256	250 - 253
2.000	258*	258*	258*	258*	258*	258*	257 - 258
2.125	258*	258*	258*	258*	258*	258*	258*
2.250	258*	258*	258*	258*	258*	258*	258*
2.375	258*	258*	258*	258*	258*	258*	258*
2.500	258*	258*	258*	258*	258*	258*	258*

*Maximum power (258 mJ) required – Partial correction expected

**Minimum power (226 mJ) required – Overcorrection expected

Table 18
Applied Energy by Age and Predicted Change (MRSE)
Treatment Algorithm for 16 Spot LTK-12 Months (emmetropia endpoint)
Patient Age (YRS)

PreTx	40 - 44	45 - 49	50 - 54	55 - 59	60 - 64	65 - 69	>= 70
MRSE (D)	(mJ)						
0.750	228 - 230	226 - 227	226**	226**	226**	226**	226**
0.875	234 - 236	232 - 234	229 - 231	227 - 229	226**	226**	226**
1.000	240 - 242	238 - 240	236 - 238	233 - 235	231 - 233	228 - 230	226 - 228
1.125	247 - 249	244 - 246	242 - 244	239 - 241	237 - 239	235 - 236	232 - 234
1.250	253 - 255	251 - 253	248 - 250	246 - 248	243 - 245	241 - 243	238 - 240
1.375	258*	257 - 258	255 - 257	252 - 254	250 - 252	247 - 249	244 - 247
1.500	258*	258*	258*	258*	256 - 258	254 - 256	251 - 253
1.625	258*	258*	258*	258*	258*	258*	257 - 258
1.750	258*	258*	258*	258*	258*	258*	258*
1.875	258*	258*	258*	258*	258*	258*	258*
2.000	258*	258*	258*	258*	258*	258*	258*
2.125	258*	258*	258*	258*	258*	258*	258*
2.250	258*	258*	258*	258*	258*	258*	258*
2.375	258*	258*	258*	258*	258*	258*	258*
2.500	258*	258*	258*	258*	258*	258*	258*

*Maximum power (258 mJ) required – Partial correction expected

**Minimum power (226 mJ) required – Overcorrection expected

Table 19
Applied Energy by Age and Predicted Change (MRSE)
Treatment Algorithm for 16 Spot LTK-18 Months (emmetropia endpoint)
Patient Age (YRS)

PreTx	40 - 44	45 - 49	50 - 54	55 - 59	60 - 64	65 - 69	>= 70
MRSE (D)	(mJ)						
0.750	238 - 239	237 - 238	236 - 237	235 - 236	234 - 235	233 - 234	232 - 233
0.875	243 - 244	242 - 243	241 - 242	240 - 241	239 - 240	238 - 239	237 - 238
1.000	248 - 249	247 - 248	246 - 247	245 - 246	244 - 245	243 - 244	242 - 243
1.125	253 - 254	252 - 253	251 - 252	250 - 251	249 - 250	248 - 249	247 - 248
1.250	258*	257 - 258	256 - 257	255 - 256	254 - 255	253 - 254	252 - 253
1.375	258*	258*	258*	258*	258*	258*	257 - 258
1.500	258*	258*	258*	258*	258*	258*	258*
1.625	258*	258*	258*	258*	258*	258*	258*
1.750	258*	258*	258*	258*	258*	258*	258*
1.875	258*	258*	258*	258*	258*	258*	258*
2.000	258*	258*	258*	258*	258*	258*	258*
2.125	258*	258*	258*	258*	258*	258*	258*
2.250	258*	258*	258*	258*	258*	258*	258*
2.375	258*	258*	258*	258*	258*	258*	258*
2.500	258*	258*	258*	258*	258*	258*	258*

*Maximum power (258 mJ) required – Partial correction expected

**Minimum power (226 mJ) required – Overcorrection expected

Table 20
Applied Energy by Age and Predicted Change (MRSE)
Treatment Algorithm for 16 Spot LTK-24 Months (emmetropia endpoint)
Patient Age (YRS)

PreTx	40 - 44	45 - 49	50 - 54	55 - 59	60 - 64	65 - 69	>= 70
MRSE (D)	(mJ)	(mJ)	(mJ)	(mJ)	(mJ)	(mJ)	(mJ)
0.750	258*	251 - 258	243 - 250	234 - 241	226 - 232	226**	226**
0.875	258*	258*	254 - 258	245 - 252	236 - 243	228 - 234	226**
1.000	258*	258*	258*	256 - 258	247 - 254	238 - 245	228 - 237
1.125	258*	258*	258*	258*	258*	249 - 256	239 - 247
1.250	258*	258*	258*	258*	258*	258*	249 - 258
1.375	258*	258*	258*	258*	258*	258*	258*
1.500	258*	258*	258*	258*	258*	258*	258*
1.625	258*	258*	258*	258*	258*	258*	258*
1.750	258*	258*	258*	258*	258*	258*	258*
1.875	258*	258*	258*	258*	258*	258*	258*
2.000	258*	258*	258*	258*	258*	258*	258*
2.125	258*	258*	258*	258*	258*	258*	258*
2.250	258*	258*	258*	258*	258*	258*	258*
2.375	258*	258*	258*	258*	258*	258*	258*
2.500	258*	258*	258*	258*	258*	258*	258*

*Maximum power (258 mJ) required – Partial correction expected

**Minimum power (226 mJ) required – Overcorrection expected

7. Performing the Sunrise LTK Procedure

7.1 Operating Procedure Summary

Equipment Set-up

Prior to the procedure, the system operation must be verified in accordance with the instructions provided in the user manual.

Patients will be treated with two rings of eight spots in the recommended treatment pattern; 8 spots at 6mm; 8 spots at 7 mm; spots radially aligned.

Supplies: Speculum
 Eye shield for fellow eye
 Topical anesthetic -- 0.5% proparacaine

- Instill topical anesthetic to eye being treated as follows:
 - Instill first drop, wait three minutes.
 - Instill second drop, wait three minutes.
 - Instill third drop, wait five minutes.

During this interval, verify the treatment parameters.

NOTE: Systemic analgesics or sedatives may be administered at the surgeon's discretion.

- Place (or tape) shield over fellow eye.
- Insert lid speculum.
- Press Start air-dry timer. Allow the tear film to dry naturally for three minutes.
- Press Start Auto-Cal button and allow automatic calibration to complete.
- Ask patient to fixate on flashing center light.

- Instruct the patient not to move during the treatment. The patient may experience some sensation or pressure, but should not feel any pain during the treatment.

NOTE: It is extremely important for the patient not to move during treatment.

To reduce the likelihood of movement, someone may apply gentle pressure to the back of the patient's head during treatment to help stabilize the head.

- With the patient looking directly at the fixation light located inside the biomicroscope, center the 8 red alignment spots around the pupil and superimpose the 2 green focus spots on the anterior corneal surface.
- Wait for the READY indication to show in the Heads-Up Display and Touch screen display.
- With the patient fixating, and if the treatment spot alignment is correct, press the foot switch and hold it down until the treatment is complete.

NOTE: Laser energy pulses will be stopped prematurely if the foot switch is released before treatment is completed.

7.2 Post-Procedure

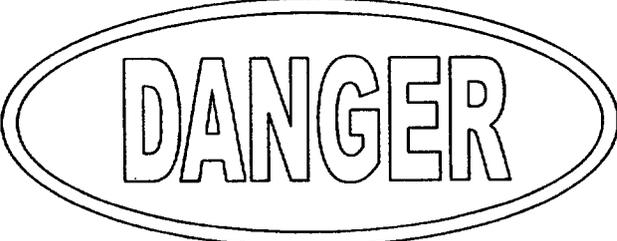
- Post-treatment medications are then applied, and the patient is discharged with instructions for at-home administration of medications:
 - Tobramycin ophthalmic solution 1 drop 4 times daily for 1 week.
 - As needed, diclofenac sodium 1 drop 4 times daily for up to 1 week.
 - Acetaminophen with codeine, 1 or 2 tablets every 4 hours as needed. Alternatively, non-narcotic pain medications according to physician's recommendations.
 - Other medications may be administered as deemed necessary by the physician.
 - Systemic medications that are considered necessary for the patient's welfare may be used.

7.3 Device Labels

Manufacturer's Identification Label

SUNRISE TECHNOLOGIES, INC.	
3400 W. WARREN AVENUE	
FREMONT, CA 94538 U.S.A.	
Model No.	HYPERION™ LTK System
Serial No.	
Manufactured:	
Rated:	120VAC 50/60Hz 15A
THIS PRODUCT COMPLIES WITH 21 CFR 1040.10 AND 1040.11	
MANUFACTURED UNDER U.S. PATENTS PENDING	
0400-0945 REV. 2	

Warning Logotype Label

			
	VISIBLE AND INVISIBLE LASER RADIATION AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION		
	532 nm	0.5mW	CONTINUOUS
	635 nm	0.5mW	CONTINUOUS
	2120 nm	350 mJ	160 μs PULSE
0400-0930 REV 2		CLASS IV LASER PRODUCT	

Hazard Label

DANGER
RISK OF EXPLOSION IF USED IN THE
PRESENCE OF FLAMMABLE ANESTHETICS

Laser Aperture Label

LASER APERTURE



Non-Interlocked Protective Housing Label

**DANGER – Hazardous Electromagnetic
Radiation When Open**

**AVOID EYE OR SKIN EXPOSURE TO DIRECT OR
SCATTERED RADIATION**

Prescription Device Caution Label

**CAUTION: Federal law restricts
this device to sale by or on the
order of a Physician or
Practitioner**

PATIENT INFORMATION BROCHURE

Laser Thermal Keratoplasty (LTK)

HYPERION™ LTK System

This brochure is designed to help you and your ophthalmologist (eye doctor) decide whether or not you should have Laser Thermal Keratoplasty (LTK) for the temporary treatment of farsightedness with some patients retaining some or all of their treatment correction. Please read this entire brochure before deciding on this treatment. Discuss it thoroughly with your ophthalmologist, so that all of your questions have been answered before you agree to LTK.

Sunrise Technologies, International, Inc.

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Fremont, CA 94538

U.S.A.

Telephone: (800) 789-4949

Website: <http://www.sunrise-tech.com>

RESTRICTED DEVICE: U.S. Federal Law restricts this device to sale, distribution, and use by or on the order of a physician or other licensed eye care practitioner. U.S. Federal Law restricts the use of this device to practitioners who have been trained in its calibration and operation, and who have experience in the surgical treatment and management of refractive errors.

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Table of Contents

	<u>Page</u>
1. Introduction.....	3
2. How the Eye Functions.....	4
3. What is Laser Thermal Keratoplasty (LTK)?.....	8
4. Are You a Good Candidate for LTK?	9
5. Benefits of LTK.....	10
6. Risks of LTK.....	11
7. What to Expect:	12
Before the LTK Treatment.....	12
The Day of LTK Treatment.....	13
Immediately After Treatment	14
The First Week Following Treatment.....	15
8. Complications.....	15
Adverse Events Reported.....	16
Complications Reported After LTK.....	16
9. Contraindications (who should not have this procedure).....	17
10. Warnings.....	17
11. Questions to Ask Your Physician.....	18
12. Summary of Important Information.....	21
13. Patient Assistance Information.....	23
14. Glossary of Terms.....	24

1. Introduction

This brochure provides information to help you decide whether or not to have Laser Thermal Keratoplasty (LTK) for the correction of your farsightedness (hyperopia). Please read this brochure carefully and discuss the information with your ophthalmologist and his or her staff. Your ophthalmologist can determine if you are a candidate for LTK.

LTK is NOT required to correct farsightedness. You can wear glasses or contact lenses to correct your vision. There are also other laser procedures, called excimer laser surgery (photorefractive keratectomy or laser assisted in situ keratomileusis) that correct farsightedness.

If you choose to have LTK to correct your farsightedness, you may benefit from having both your eyes treated with LTK during the same appointment. Sometimes, however, it is better to have only one eye treated with LTK. This is something you should discuss with your ophthalmologist.

You are the only one who can decide whether LTK is right for you. The information in this brochure should help you make your decision. Make sure that all of your questions have been answered by your ophthalmologist before deciding to have LTK. Please be aware that certain jobs (such as airplane/military pilots) have special vision requirements that cannot be met by having LTK.

2. How the Eye Functions

Your eye focuses light to form images or “pictures” of everything around you, much like a camera. Your eye changes these images into electrical signals and sends them to the brain.

There are several parts of your eye that help form the images you see. The cornea, (the clear outermost layer of the eye) and lens focus light by bending it as it enters the eye so the light rays form an image on the retina (at the back of the eye). The cornea provides approximately two-thirds of the bending power of the eye, and the lens provides most of the other third. The retina is the part of the eye that sends information to the brain, allowing you to “see” images.

In the normal eye, the cornea and the lens inside of the eye focus rays of light from distant objects so that a sharp image is formed on the retina. When all the light rays meet on the retina, it gives you a clear, sharp image of the object you are looking at. If the light focuses in back of or in front of the retina, the image you see will be blurred. Depending on where the image focuses, you may be nearsighted or farsighted.

The 'Normal' Eye

Emmetropia Distance

Light Is 'Refracted' By
The Cornea & Lens

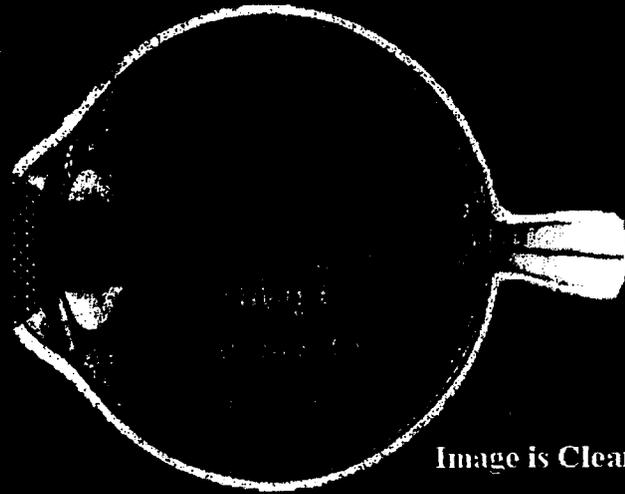


Image is Clear

In the nearsighted (myopic) eye, the curvature (shape) of the cornea is too steep so that light rays are focused in front of the retina. Distant objects are blurred, but near objects are in focus (clear).

The Farsighted Eye

Hyperopia

The Eye Is Too
Short &/Or The
Cornea Too Flat

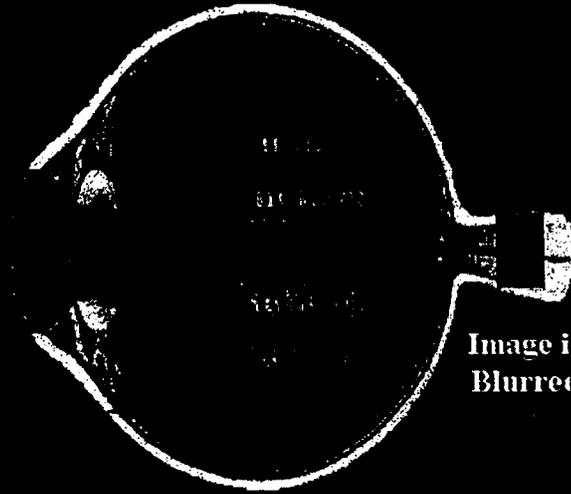


Image is
Blurred

In the farsighted (hyperopic) eye, the curvature (shape) of the cornea is not steep enough so that light rays are not focused on the retina. Distant objects are blurred and near objects are even more blurred.

The Astigmatic Eye

Astigmatism

The Cornea Is Steep
In One Axis & Flat
In The Other



Images Blurred
& Distorted

If the cornea is shaped irregularly, like a football instead of a baseball, light rays bend irregularly. This condition is called astigmatism. Both distant and near vision is blurry. Astigmatism can be combined with nearsightedness or farsightedness.

When you have an eye exam, your ophthalmologist or other eye care professional is able to determine whether you have normal vision or are farsighted, nearsighted, and/or have astigmatism. During the eye exam, your eye care professional will observe where your eye focuses light. And, if your vision is not normal, measure the correction needed by placing a lens in front of your eye. By using different lenses during your exam, your eye care professional can determine the amount of vision correction you need.

If it has been determined that you are farsighted, your ophthalmologist will discuss different treatments with you. To improve your vision, you may choose to wear glasses, contact lenses, or have a surgical procedure, such as laser thermal keratoplasty (LTK), photorefractive keratectomy, or laser assisted in situ keratomileusis, to correct your vision. Because your vision will probably change as you get older, your glasses or contact lens prescription may need to be changed, or you may need to wear glasses when you previously did not need glasses or contact lenses.

3. What is Laser Thermal Keratoplasty?

Laser Thermal Keratoplasty (LTK) is a surgical treatment for farsightedness performed using a holmium YAG laser. The laser produces a beam that heats the tissue in the cornea, causing it to shrink slightly. When the tissue shrinks, the cornea becomes steeper. This allows incoming light to focus on the retina, giving you clearer images.

The goal of LTK is to improve your ability to see objects at a distance.

LTK may be performed on either one or both eyes on the same day or on different days. Please consult with your eye doctor as to what would be best for you.

Clinical studies of the LTK treatment were conducted in the United States during the development of the holmium laser. In these studies, about two out of three (68.1%) of all treated eyes could see distant objects 20/40 or better without glasses 2 years after LTK. In most states, 20/40 or better

vision is the requirement for driving a car without glasses or contacts. Two years after LTK, about two out of three, (69.4%) had a 2 or more line improvement, (2 lines of letters on the eye chart used by the ophthalmologist to measure vision) in their uncorrected vision (vision without glasses or contacts) compared to before LTK treatment. The remainder of the eyes, about one out of three, had less or no improvement at 2 years; fewer than 2 out of 100 patients (2%) were able to read less lines on an eye chart after treatment than before without glasses or contacts. Some patients still needed glasses or contact lenses after LTK.

4. Are You a Good Candidate for LTK?

The Sunrise Hyperion™ LTK is indicated for the temporary reduction of farsightedness. It is temporary because the amount of LTK correction in farsightedness decreases over time, with some patients retaining some or all of their correction. To be eligible for LTK you must meet the following rules:

- Be at least 40 years of age;
- Have farsightedness between +0.75 to +2.50 diopters and astigmatism of less than or equal to 0.75 D;
- Have visual acuity which has changed very little, for example, your glasses prescription has changed no more than 0.50 diopter in the six months before your pre-treatment exam; and,
- Be informed of LTK's risks and benefits compared with other available treatments.

LTK has not been tested in patients who did not meet the above.

Things to Consider:

- LTK may not be the right choice for you if you have unrealistic expectations. As with any surgery, perfect results are not guaranteed with LTK.
- Your vision may continue to change over time.
- Your improved vision caused by LTK may become less or disappear. Based on existing information from the clinical trial, approximately half of the reduction in farsightedness seen at 6 months is gone at 2 years (including the initial “overshoot” that causes nearsightedness in the early post-treatment period)
- Based on data out to 2 years, Sunrise Technologies has found that the effect of LTK may dissipate in 3-5 years. The effect of the procedure may last substantially longer in some patients.
- If your results with LTK are not satisfactory and you desire a second surgical treatment, it is unproven at this time whether re-treatment procedures with LTK or other refractive surgical devices will be successful.
- Your vision may not be perfect and you may need to wear glasses or contact lenses for some activities even after having LTK surgery.
- You may experience improvement in your near vision such as by being able to see objects close up, like reading a book without glasses,

as well as an improvement in distance vision, but most likely this improvement in near vision will go away over time while the improvement in distance vision may last longer.

- The goal of LTK is to improve your ability to see objects at a distance, not improve your ability to see close up objects.

5. Benefits of LTK

LTK performed with the Sunrise Technologies HYPERION™ Laser System has the ability to improve your uncorrected vision, or your vision without glasses or contacts for seeing objects at a distance. Your farsightedness may be reduced with LTK, and this will usually reduce or eliminate your need for contact lenses or glasses for seeing objects at a distance. You may no longer need glasses at all for seeing objects at a distance or find that you need to wear them less during the day or maybe for only certain activities.

6. Risks of LTK

There are several risks you will take if you choose to have the LTK procedure. They are described below. Discuss these risks and what they may mean to you with your ophthalmologist before you decide to have the LTK procedure.

- LTK is a surgical procedure and as such, carries risks.
- If your results with LTK are not satisfactory, you most likely will still be able to see as well with glasses or contacts as you did before treatment. If your results with LTK are not satisfactory and you do

not desire to wear glasses or contacts, you may need a second surgical treatment. It is uncertain whether additional LTK surgery or surgery with other refractive surgical devices will be successful based on the small amount of data that were obtained in the clinical studies.

- You may experience mild discomfort, burning, blurry vision, double vision (seeing 2 or more images of the same object), an itchy or scratchy feeling, tearing, and/or increased sensitivity to light following the LTK. These symptoms are most common in the first 2-4 weeks; rarely some of these symptoms may last 1 to 2 years.
- You may experience a decrease in your ability to see objects or read at a distance or near without glasses or contacts over time.
- Remember, the effect of LTK may not last and you may need glasses or contacts for good distance vision as you did before LTK.

In the clinical study of how successful LTK was in correcting farsightedness, some patients suffered consequences that threatened their vision.

- One eye in 100 eyes lost best corrected vision. The best corrected vision is the best possible vision with glasses. There is no evidence that losses of best corrected vision were due to LTK surgery.
- One eye in 200 eyes developed a cataract, which is clouding of the lens. There is no evidence that development of cataracts were due

to LTK surgery and were probably due to the normal aging process.

- One eye in 200 eyes had an increase in astigmatism after LTK surgery. This astigmatism can be corrected with glasses, hard contact lenses or other types of surgical treatment.

7. What to Expect

Before the LTK Treatment

If you are interested in having LTK, you will need a pre-treatment exam to determine if your eye is healthy and suitable for LTK. This will include a complete eye history and a thorough exam of both eyes. In addition, a map of your cornea will be made by a computer to determine if it is smooth and properly shaped and therefore suitable for treatment by the LTK laser.

WARNING:

If you wear contact lenses, your doctor will ask you to stop wearing them 2 - 4 weeks before your exam. Failure to do so may produce poor surgical results.

- Arrange for someone to drive you home after surgery and to your next appointment. This applies if you have 1 or both eyes treated on the same day.
- You will not be able to drive until you receive permission from your doctor. This applies if you have 1 or both eyes treated on the same day.

The Day of LTK Treatment

Before treatment, you will be given a chance to listen to the laser so you will be familiar with the noise it makes during treatment. Anesthetic (numbing) drops will be placed into your eye to be treated. You will sit up in a chair and look at the instrument that delivers the laser light to your cornea. You will be required to place your chin on a chin-rest, and your forehead will be pressed against a crossbar to keep you from moving unintentionally during the procedure. It is very important for you to hold as still as possible during the laser procedure so that the heat applications with LTK are placed in the proper position on the front of your eye.

The doctor will use a delicate wire device to keep your eye open and eyelids apart during the treatment. You will not feel this small device since your eye will be numb. When your ophthalmologist is ready, he or she will ask you to look directly at a flashing yellow light. You should try to keep both eyes open, without squinting, as this makes it easier to focus on the flashing light. The LTK device, the Sunrise HYPERION™ Laser System will then be used to apply laser energy to 16 spots on your cornea, to gently shrink the tissue for correction of your farsightedness. As the laser energy is applied to your eye, you may experience a sensation of pressure, but you should not feel any pain. The entire laser procedure takes approximately five minutes. The use of the laser, however, takes only about three seconds.

IMPORTANT:

It is very important to keep looking at the flashing yellow light and not move during the procedure, even if the light fades or dims. Movement during the procedure could result in under-correction (only a partial treatment) and/or astigmatism.

Immediately After Treatment

After the laser procedure, you will be allowed to go home, probably within 30 minutes, but you should not drive yourself. The initial effect of the LTK procedure is to produce nearsightedness that may blur distance vision making driving unsafe. Your ophthalmologist may give you eye drops to use when you return home, with instructions on when and how to use the eye drops. You may experience mild pain, discomfort or scratchiness after the LTK procedure. You should not be in any significant pain, but if you do experience pain, be sure to contact your ophthalmologist. He or she may ask you to come in for an examination.

The First Week Following Treatment

At first, when you look in the mirror, you may be able to see the laser “spots” on your cornea during the first 24 to 48 hours after LTK, where the laser energy was applied. These spots are not permanent and you should not be able to see them in the mirror after 48 hours.

IMPORTANT:

Use any drops and lubricants as directed by your doctor. Your surgical results depend on carefully following your doctor’s directions.

8. Complications

The complications and adverse events reported following the LTK procedure are presented below:

<u>Safety</u>	
<u>FDA Safety Criteria</u>	<u>HYPERION™ Results</u>
Loss of more than 2 lines* of best corrected vision on eye chart (best possible vision with glasses or contacts)	4 in 1000 eyes at 6 months 2 in 1000 eyes at 12 months 4 in 1000 eyes at 18 months 0 in 1000 eyes at 24 months
Eyes worse than 20/40 (best possible vision with glasses or contacts); level in most states required to pass driving test	0 in 1000 eyes at 6 months 0 in 1000 eyes at 12 months 0 in 1000 eyes at 18 months 0 in 1000 eyes at 24 months
Eyes with significant astigmatism	2 in 1000 eyes at 12 months 0 in 1000 eyes at 24 months

*2 patients developed cataracts during the study not related to the laser and 2 had a temporary decrease in vision which returned to normal

Adverse Events Reported After LTK in U.S. Study

<u>Adverse Events</u>	
Infection on Front of Eye	None in over 600 eyes
Uncontrolled Pressure in Eye	None in over 600 eyes
Haze on Clear Front Part of Eye With Loss of Vision	None in over 600 eyes
Retinal Vascular Accidents (Stroke in Back of Eye)	None in over 600 eyes
Retinal Detachment (Tearing of the Layer in the Back of the Eye)	None in over 600 eyes

Complications Reported After LTK in U.S. Study

	<u>1 Mth</u>	<u>3 Mths</u>	<u>6 Mths</u>	<u>12 Mths</u>	<u>18 Mths</u>	<u>24 Mths</u>
Corneal Edema ¹	0.2%	0.0%	0.0%	0.0%	0.0%	0.0%
Recurrent Corneal Erosion ²	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Foreign Body Sensation	1.9%	0.4%	0.2%	0.8%	1.1%	0.3%
Pain*	0.7%	0.4%	0.0%	0.2%*	0.0%	0.0%

*Isolated single visit; patient seen at 8 visits after LTK but only reported at 12 months

¹ Corneal Edema: Swelling of front, clear portion of the eye

² Recurrent Corneal Erosion: Painful loss of the outer most layer of the front, clear portion of the eye

9. Contraindications (who should not have LTK treatment)

You should NOT have LTK if:

- You are pregnant or nursing
- You have abnormal thinning and shape of the clear front surface of the eye (keratoconus)
- You have scarring in the center of your cornea
- You have a history of herpetic infection in your eye (cornea)
- You have an autoimmune disease, collagen vascular disease, clinically significant atopic syndrome (serious allergies or asthma), insulin dependent diabetes, or an immunocompromised status.

10. Warnings

Be sure to discuss the following issues with your physician:

- LTK may cause nearsightedness in the early post-treatment period which may cause changes in both near and distance vision.

- Based on existing information from the clinical trial, approximately half of the reduction in farsightedness seen at 6 months is gone at 2 years (including the initial “overshoot” that causes nearsightedness in the early post-treatment period).
- Based on data out to 2 years, Sunrise Technologies has found that the effect of LTK may dissipate in 3-5 years. The effect of the procedure may last substantially longer in some patients.
- If your vision is not improved as much as you expect after the LTK surgery, your ophthalmologist may recommend that you have additional LTK surgery. It is unproven whether additional LTK surgery will be successful based on the small amount of data that were obtained in the clinical studies.

11. Questions to Ask Your Physician

Ask your physician the following questions in order to help you decide whether LTK is right for you:

- What other options are available for correcting farsightedness?

You may choose to wear glasses or contacts to correct your vision. There are also other laser procedures, called excimer laser surgery (photorefractive keratectomy or laser assisted in situ keratomileusis) that correct farsightedness.

- Will I need to limit my activities after treatment? If yes, for how long?

You should have someone drive you home after the procedure. Most people can go back to work and resume their regular routine, the day after treatment.

- What are the benefits of LTK for my amount of farsightedness?

LTK has the ability to improve your ability to see objects at a distance clearly (distance vision). After LTK, you may no longer need glasses at all or find that you need to wear them less during the day or maybe for only certain activities.

- What quality of vision can I expect in the first few months after treatment?

Immediately following the procedure, you will probably be slightly nearsighted in the treated eye(s). Over time your vision will adjust-your distance vision will become clearer and some of your improvement in near vision may lessen.

- If LTK does not correct my vision, what is the possibility that my glasses would need to be stronger than before? Could my need for glasses increase over time?

As part of the normal aging process, farsightedness tends to increase with time, as does the need to wear glasses for reading.

However, LTK does not appear to make farsightedness worse requiring stronger glasses.

- If needed, will I be able to wear contacts after LTK?

Yes, there have been no reports of any difficulties in wearing contacts, if needed, after LTK.

- How is LTK likely to affect my need to wear glasses or contact lenses as I grow older?

As part of the normal aging process, farsightedness tends to increase with time, as does the need to wear glasses for reading. However, LTK does not appear to make farsightedness worse requiring stronger glasses.

- Will my cornea heal differently if injured after having LTK?

It is unknown whether having the LTK procedure will affect the healing process following an injury to the cornea.

- Should I have LTK in my other eye?

Depending on your vision before LTK, your physician may recommend treatment in both eyes or only 1 eye. You should consider the risks and benefits of treatments and decide on what is best for you.

- How long will I have to wait before having surgery on my other eye?

LTK may be performed on both eyes the same day or can be done at different times. This needs to be discussed on an individual

basis with your eye doctor.

- What vision problems might I experience if I have LTK only on one eye?

This will depend on whether you are farsighted in both eyes and the amount of your farsightedness. Discuss with your physician what is most appropriate for your eyes and your lifestyle. Glasses or contacts can be used to correct visual acuity in your other eye.

- What are the costs involved and the follow-up care requirements?

Ask your physician about his or her specific costs. The cost of LTK will involve your pre-treatment exam, the LTK procedure and follow-up care after LTK. Your ophthalmologist may give you eye drops to use when you return home, with instructions on when and how to use the eye drops.

12. Summary of Important Information

- LTK is not reversible.
- LTK is a non-contact procedure. This means there's no cutting or shaving of the cornea.
- The improvement in distance vision (ability to see distant objects clearly) after LTK diminishes over time, with some eyes keeping some or all of their improvement in farsightedness.

- LTK does not eliminate the need for reading glasses, even if you have not worn them before. The key goal of LTK is to improve your ability to see objects at a distance.
- Your vision must be stable for at least 6 months prior to surgery. Your doctor will need to determine that your farsightedness has not changed more than 0.50 diopters in the past six months.
- You would not be a good candidate if you have any medical condition that makes it difficult for you to focus your eye and hold still during treatment.
- LTK is not risk-free. Please review this entire brochure, paying special attention to the risk and benefit sections before agreeing to treatment.
- LTK is not a laser version of photorefractive keratectomy (PRK) or laser assisted in situ keratomileusis (LASIK). Photorefractive keratectomy and laser assisted in situ keratomileusis are completely different procedures.
- Alternatives to LTK include, but are not limited to, glasses, contact lenses, photorefractive keratectomy and laser assisted in situ keratomileusis.
- Certain jobs (such as airplane/military pilots) have special vision requirements that cannot be met by having LTK, photorefractive keratectomy or laser assisted in situ keratomileusis.

- Before considering LTK, you should have a complete eye exam and talk with at least one ophthalmologist about the time required for healing and the benefits, complications, and risks of LTK.

13. Patient Assistance Information

PRIMARY EYE CARE PROFESSIONAL:

Name: _____
Address: _____
Telephone No: _____

PHYSICIAN PERFORMING LTK:

Name: _____
Address: _____
Telephone No: _____

SURGERY LOCATION:

Name: _____
Address: _____
Telephone No: _____

LASER MANUFACTURER:

Sunrise Technologies International, Inc.
3400 W. Warren Road
Fremont, CA 94538
U.S.A.
Tel: (800) 789-4949

14. Glossary of Terms

astigmatism:	Refractive error which prevents an image being sharply focussed on the retina because of different degrees of bending of light by the various meridians of the eye.
cataract:	A cloudiness of the lens of the eye.
cornea:	Transparent front portion of the eye that covers the iris, pupil, and anterior chamber, and provides most of an eye's optical focusing power.
corneal edema:	Swelling of front, clear portion of the eye.
recurrent corneal erosion:	Painful loss of the skin of the front, clear portion of the eye.
diopter:	Unit of measurement of optical strength or refractive power of lenses.
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.
FDA Target Value:	Maximum acceptable number of eyes reporting a complication or adverse event suggested by the U.S. Food and Drug Administration.
halos:	Hazy ring around bright lights seen by some patients with refractive error or optical defects (e.g., cataracts or corneal swelling).
holmium YAG:	A medical laser that produces a beam of light of a single specific wavelength (color) that is used to shrink tissue in the clear front part of the eye (cornea). This is done in a computer-controlled fashion to re-shape the cornea to correct farsightedness. This re-

shaping allows incoming light rays to be more accurately focused on the retina.

keratoconus: Abnormal thinning and shape of the clear front surface of the eye.

**laser assisted in situ
keratomileusis**

This is a surgical procedure in which a flap is created by shaving the thin portion of the clear front part of the eye (cornea) by a surgical cutting instrument. The excimer laser is then used to re-shape the cornea to correct refractive errors of the eye.

lens:

A transparent, colorless body located in the front third of the eyeball, behind the iris (colored portion inside the eye), the function of which is to help bring rays of light to focus on the retina.

LTK:

An acronym for "laser thermal keratoplasty". This is a surgical procedure in which the tissue in the clear front part of the eye (cornea) is re-shaped by a holmium YAG laser in a predetermined manner to correct farsightedness.

**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.

ophthalmologist:

A doctor specializing in refractive, medical, and surgical treatment of eye diseases and disorders.

pupil:

The opening at the center of the iris of the eye for the transmission of light, which varies in diameter depending upon the brightness of the light coming into the eye.

**photorefractive
keratectomy:**

This is a surgical procedure in which a thin portion of the clear front part of the eye (cornea) is removed by the excimer laser in a predetermined manner 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 membranous lining of the rear two-thirds of the eye that converts images from the eye's optical system into electrical impulses sent along the optic nerve for transmission to the brain.

retinal detachments: Tearing of the layer in back of the eye.

retinal vascular accidents: Stroke in back of eye.

thermal: Heat