

## CustomVue™ Treatments for Monovision in Presbyopic Patients with Low to Moderate Myopia and Myopic Astigmatism

1

## Introduction

- FDA Labeling
- Pre-Operative Examination
- Surgical Technique

2

## IMPORTANT INFORMATION

- CustomVue™ Monovision treatments will require the installation of the WaveScan™ software version 3.9 Upgrade.
- **Prior** to performing CustomVue Monovision treatments you **MUST** be certified to use WaveScan™ software version 3.9.
  - THIS IS NOT A CERTIFICATION FOR MONOVISION OR 3.9 SOFTWARE

3

## CustomVue™ Treatments for Monovision in Presbyopic Patients

## FDA Labeling

4

## FDA Labeling *Indications*

- The STAR S4 IR™ Excimer Laser System with Variable Spot Scanning (VSS™) and the WaveScan® System is indicated for wavefront-guided laser assisted in situ keratomileusis (LASIK) to achieve monovision by the targeted retention of myopia (-1.25 to -2.00 D) in the non-dominant eye of presbyopic myopes:
  - 40 years or older who may benefit from increased spectacle independence across a range of distances with useful near vision

5

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  - With myopic astigmatism up to -6.00 D MRSE
  - With cylinder up to -3.00 D

6

## FDA Labeling

### Indications

- The STAR S4 IR™ Excimer Laser System with Variable Spot Scanning (VSS™) and the WaveScan® System is indicated for wavefront-guided laser assisted in situ keratomileusis (LASIK) to achieve monovision by the targeted retention of myopia (-1.25 to -2.00 D) in the non-dominant eye of presbyopic myopes:
  - **with a successful preoperative trial of monovision or history of monovision experience**

7

## FDA Labeling

### Contraindications

- Laser refractive surgery is contraindicated in:
  - Patients with collagen vascular, auto-immune or immunodeficiency diseases
  - Women who are pregnant or nursing
  - Patients with signs of keratoconus or abnormal corneal topography
  - Patients who are taking the following medications:
    - Isotretinoin (Accutane®)
    - Amiodarone hydrochloride (Cordarone®)

Accutane is a registered trademark of Hoffman-La Roche, Inc.  
Cordarone is a registered trademark of Sanofi

8

## FDA Labeling

### Warnings

- LASIK is not recommended in patients who have:
  - Diabetes
  - A history of Herpes simplex or Herpes zoster keratitis
  - Significant dry eye that is unresponsive to treatment
  - Severe allergies

9

## FDA Labeling

### Precautions

- To avoid corneal ectasia, the posterior 250 microns of the corneal stroma should not be violated by the laser or the microkeratome
- Pre-operative ultrasonic pachymetry must be performed.

**Patient pachymetry - (Non-nomogram adjusted depth of treatment + flap thickness) = > 250 microns**

10

## FDA Labeling

### Precautions

- The safety and effectiveness of this laser for LASIK correction have NOT been established in patients with:
  - Progressive myopia, hyperopia, myopic or hyperopic astigmatism or mixed astigmatism
  - Ocular disease, corneal abnormality, previous corneal or intraocular surgery, or trauma in the ablation zone
  - A history of glaucoma
  - Residual corneal thickness < 250 microns at the completion of the ablation
  - The use of medication: Sumatriptan (Imitrex®)

Imitrex is a registered trademark of Glaxo Group Limited Corporation

11

## FDA Labeling

### Precautions

- The safety and effectiveness of the STAR S4 IR™ System have not been established for wavefront-guided LASIK surgery in patients with:
  - **Targeted residual myopia of > -2.00D**
  - **Treatments > -6.0D MRSE or > -3.00D of astigmatism.**
  - Retreatment with CustomVue™ LASIK
    - There may be significant differences between the WaveScan defocus term and the MRSE in post op myopic astigmatism patients

12

## FDA Labeling Precautions

- The safety and effectiveness of the STAR S4 IR™ System have NOT been established for wavefront-guided monovision LASIK surgery in patients:
  - With corneal neovascularization within 1 mm of the ablation zone
  - Under 40 years of age
  - Over the long term (>1 year after surgery)
  - Who were wearing contact lenses unless they had evidence of stability
  - With prior intraocular or corneal surgery of any kind

13

## FDA Labeling Precautions

- Difference between WaveScan™ and manifest sphere or cylinder powers must be within +/- 0.50D, and cylinder axes within 15 degrees.
- Difference between manifest and cycloplegic sphere or cylinder powers must be within +/- 0.50D, and cylinder axes within 15 degrees.
- Difference between WaveScan and cycloplegic sphere or cylinder powers must be within +/- 0.50D, and cylinder axes within 15 degrees.

14

## FDA Labeling Precautions

- The safety and effectiveness of wavefront-guided LASIK surgery has only been established with a minimum optical zone of 6.0 mm and an ablation zone of 8.0 mm for myopic astigmatism
- No minimum optical zone diameters other than 6 mm were studied in the U.S. wavefront-guided clinical trial for CustomVue Monovision.

15

## FDA Labeling Precautions

- It is important to maintain a carefully controlled surgical environment
- All CustomVue™ treatments should be performed with
  - Relative Humidity between 40-45%
  - Temperature between 68 - 72° F

16

## FDA Labeling Precautions

- The effects of laser refractive surgery on visual performance under poor lighting conditions have not been determined.
- It is possible, following LASIK treatment, that a patient 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.
- Visual performance possibly could be worsened by large pupil sizes or decentered pupils.

17

## FDA Labeling Precautions

- The anticipated post-operative keratometry value in any meridian must be  $\geq 33$  D
- Anticipated post-operative keratometry values can be calculated by multiplying the MRSE by 0.8, and subtracting that value from the average pre-operative keratometry value.
  - In other words:  
$$[(K1 + K2) \times 0.5] - (MRSE \times 0.8) \geq 33$$

18

## FDA Labeling

- All patients must be given the opportunity to read and understand the Patient Information Booklet and to have all their questions answered to their satisfaction before giving consent for Laser Assisted In Situ Keratomileusis (LASIK).
- All surgeons should read the Professional Use Information prior to performing the CustomVue™ procedure.

19

## Pre-operative Evaluation

20

## Pre-operative Examination

- Patients must be clearly informed of all alternatives for the correction of presbyopia with myopic astigmatism.
  - These alternative corrections include but are not limited to spectacles, contact lenses, and other refractive surgeries.

21

## Pre-operative Examination

- Consideration should be given to the following in determining the appropriate patients for CustomVue™ monovision treatment:
  - Preoperative assessment of the patient's acceptance of monovision visual symptoms.
  - Patients new to monovision should undergo a one-week contact lens trial with their individualized monovision prescription.
  - Patients should evaluate their vision over a range of vision tasks during the trial period.

22

## Pre-operative Examination

- Contact Lens Use:
  - Soft contact lenses - discontinue lens wear at least **two** weeks prior to examination **and** treatment
  - Hard (PMMA) or RGP lenses - discontinue lens wear at least **three** weeks prior to examination **and** treatment with stable keratometry and refraction
    - 3 central keratometry readings and MR taken at 1 week intervals. The last two readings must not differ by > 0.5D.
    - Any patient with keratometry or a clinical picture that is suggestive of keratoconus is specifically contraindicated as described above
  - The WaveScan™ measurements should be stable prior to the treatment

23

## Pre-operative Examination Monovision Contact Lens Trial

- Instruct patient to remove monovision lenses and schedule their full, pre-operative examination in  $\geq 7$  days
- If pre-op indicates eligibility instruct the patient to keep the CLs out and schedule surgery at least 7 days later
- **On the day of surgery and before treatment:**
  - Repeat and confirm that Ks and MR do not differ significantly from pre-op ( $\leq 0.50$  D)
  - Surgery should not proceed if refractive change exceeds this criteria

24

## Pre-operative Examination

- WaveScan™ System
  - WaveScan exams with 6.0 mm wavefront diameters are preferred for treatments
    - The minimum diameter of the wavefront measurement must be  $\geq 5.0$  mm to calculate a CustomVue™ treatment
    - Measurements with a wavefront diameter  $< 5.0$  mm will be unavailable for selection

25

## Pre-operative Examination

- Visual Acuity
  - UCVA, BSCVA
- Refraction
  - Manifest Refraction –
    - Pushed plus technique
    - Astigmatism - Jackson Cross Cylinder - maximize magnitude of cylinder

26

## Pre-operative Examination

- WaveScan™ Refractive Parameters:
  - SE up to -6.50D
  - Cylinder up to -3.50D
- Physician Adjustment
  - -0.75D to +2.75D

27

## Pre-operative Examination

### *Refraction Techniques*

- Cycloplegic Refraction (1% cyclopentolate)
- True cycloplegia eliminates accommodation
  - allows evaluation of the refractive error free from the influence of accommodation

28

## Pre-operative Examination

- Keratometry
  - **K1 is the flat K**
  - **K2 is the steep K**
  - **K2 Axis is the axis of the steep K**
- Pupillary Exam
  - Bright and dim illumination measurement

29

## Pre-operative Examination

- Corneal Topography - **necessary** in all patients
  - R/O Keratoconus **or any other abnormality**
  - R/O CL related abnormalities
  - Verify post-operative results
- Pre-operative corneal mapping is essential on all patients to exclude topographical abnormalities.
- This is especially important when astigmatism or steep keratometry readings are present, which may indicate the presence of keratoconus or other irregularities.

30

## Pre-operative Examination

- Slit Lamp Exam
  - The lens must be evaluated, especially in the older patient, to assure that nuclear sclerosis or any other lens opacity is not present prior to laser surgery.
- Tonometry
- Pachymetry
  - Ultrasonic pachymetry required for LASIK
- Dilated Media and Fundus Exam
  - Myopic patients will have a higher incidence of retinal pathology, and indirect ophthalmoscopy through a dilated pupil is essential.

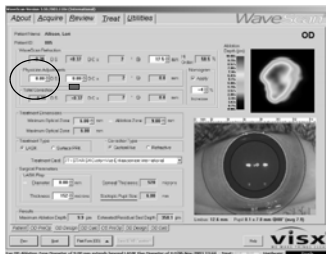
31

## Surgical Planning Surgical Technique

32

## Designing the CustomVue Treatment

The amount of monovision is programmed in the Physician Adjustment Field on the Design Screen. ■



33

## Programming a CustomVue Monovision Treatment

- Example
  - Non-dominant eye of patient with -3.50DS
  - Wish to leave patient with 2.00D of residual myopia
  - Program +2.00D in Physician Adjustment field on the Design Screen
    - By programming +2.00D, there will be 2.00D less myopia treated.
    - Therefore, the patient will have 2.00D of myopia remaining after the CustomVue Monovision treatment.

34

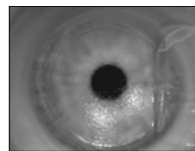
## CustomVue™ Treatments

- The U.S. FDA Multi-Center Clinical Trial for CustomVue Monovision involved the use of a nomogram adjustment.
- For your convenience, this nomogram adjustment has been **incorporated** into the released version of WaveScan™ software 3.9.
- As a result, it is strongly recommended that you **DO NOT** use a percentage nomogram adjustment or a physician adjustment for your initial CustomVue treatments with WaveScan software 3.9.
- A careful retrospective analysis of your results is required prior to the implementation of a percentage nomogram adjustment or physician adjustment.

35

## Environmental Conditions

- Control of environmental conditions during CustomVue™ treatments is important
- In the U.S. FDA Multi-Center Clinical Trial
  - Temperature ranged from 68°F to 72°F
  - Relative humidity ranged from 40% to 45%
- Stability of temperature and humidity is important



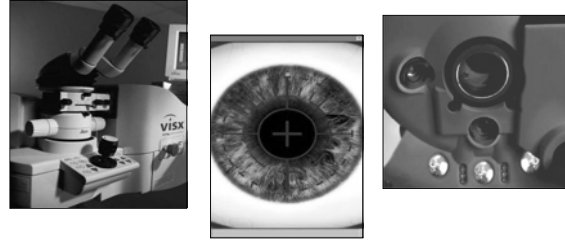
36

## CustomVue™ Treatments

### *Performing the Patient Treatment*

37

## Optimizing CustomVue™ Results *Surgical Technique*



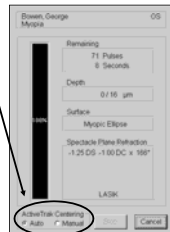
Keep operative pupil between 5 mm and 7.5 mm  
(as close as possible to the WaveScan™-  
generated treatment pupil diameter)

38

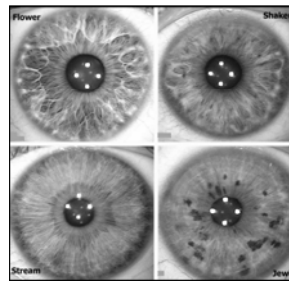
## CustomVue™ Treatments

### *STAR S4 IR™ Excimer Laser System*

- The surgeon must use the automatic centering mode
- Treatment center is set by the STAR S4 IR System
- The surgeon chooses the automatic centering mode on the Ablation Status Screen
- The repetition rate varies from 5 to 20Hz



## CustomVue™ Ablations Iris Registration



- Iris pattern is unique to each eye
- Iris Registration aligns the preoperative WaveScan™ System images and intraoperative STAR S4 IR™ System iris images

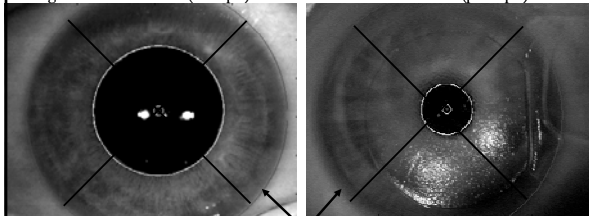
40

## CustomVue™ Ablations Iris Registration

As the pupil changes size, its centroid may not remain stationary, relative to the outer iris boundary

Diagnostic measurement (mesopic)

LVC Treatment (photopic)



Outer Iris Boundary

41

## CustomVue™ Monovision *Surgical Technique*

- Do not use a Chayet drain or similar device
- Create and lift flap
- Dry exposed stromal bed if there is fluid accumulation
- Engage ActiveTrak™ System and Iris Registration System
- Perform ablation
- Interrupt ablation only if there is fluid accumulation
- Replace flap

42

Comparison of CustomVue™ High Myopic Astigmatism, Mixed Astigmatism, Hyperopic and Myopic Treatments

43

Comparison of FDA Approved CustomVue™ Procedures


44

Comparison of FDA Approved CustomVue™ Procedures

			X	
			X	

45

Comparison of FDA Approved CustomVue™ Procedures

			X	
			X	

46

Comparison of FDA Approved CustomVue™ Procedures


47

Comparison of FDA Approved CustomVue™ Procedures

			X	
			X	

48