

Patient's Name: \_\_\_\_\_

Medicare # (HICN): \_\_\_\_\_

## Notice of Exclusion from Medicare Benefits

- Medicare does **not** pay for all of your health care costs. Medicare only pays for covered benefits. Some items and services are not Medicare benefits and Medicare will not pay for them.
- When you receive an item or service that is not a Medicare benefit, **you are responsible to pay for it**, personally or through any other insurance that you may have.

The purpose of this notice is to help you make an informed choice about whether or not you want to receive these items or services, knowing that you will have to pay for them yourself. **Before you make a decision about your options, you should read this entire notice carefully.**

- Ask us to explain, if you don't understand why Medicare won't pay.
- Ask us how much these items or services will cost you  
(Estimated Cost: \$\_\_\_\_\_)

### Medicare will not pay for:

- 1) Added diagnostic tests beyond those required for standard cataract surgery that are necessary for presbyopia correction.
- 2) Refractive keratoplasty for the purpose of reducing dependence on eyeglasses or contact lenses (*e.g.*, limbal relaxing incisions, corneal relaxing incisions, LASIK, etc.).

### Because it does not meet the definition of any Medicare benefit.

Medicare has established a specific policy\* concerning presbyopia-correction that declares these items and services to be not covered and the financial responsibility of the beneficiary.

\* CMS Ruling No 05-01 (May 3, 2005), and Transmittal 636 (August 5, 2005)

### Medicare will only pay for:

Standard cataract surgery including the required examinations, testing, follow-up care, and a conventional IOL. You do not need an Acrysof® ReSTOR® IOL and the related services; implantation of this type of IOL is not medically necessary and completely optional. The major difference between cataract surgery with a traditional IOL versus cataract surgery with a presbyopia-correcting IOL is the degree of dependence on eyeglasses thereafter; it's probably less with the Acrysof® ReSTOR® IOL. In addition to the cost of non-covered items and services, you are responsible for the usual co-payments and deductibles associated with covered services (*i.e.*, cataract surgery).

I understand and agree.

\_\_\_\_\_  
Signature of patient or person acting on patient's behalf

\_\_\_\_\_  
Date

Patient's Name: \_\_\_\_\_

## Notice of Exclusion from Health Plan Benefits

You need to make a choice about having cataract surgery with a presbyopia-correcting IOL (Acrysof® ReSTOR® IOL). Some aspects of this surgery are covered by your health care service plan, however some other aspects are not covered benefits and consequently your health plan will not pay for them. When you receive an item or service that is not a covered benefit, you are responsible to pay for it.

The purpose of this notice is to help you make an informed choice about whether or not you want to receive these items or services, knowing that you will have to pay for them yourself. Before you make a decision about your options, you should read this entire notice carefully. ***Ask us to explain, if you don't understand why your health care service plan won't pay.***

Your doctor has recommended cataract surgery with an Acrysof® ReSTOR® IOL after determining that you are a good candidate for the procedure, and we expect that your health care service plan will pay for cataract surgery but not for the additional cost of the Acrysof® ReSTOR® IOL and the extended care for the surgery. You do not need an Acrysof® ReSTOR® IOL and the related services; it is optional. The major difference between cataract surgery with a traditional IOL versus cataract surgery with a presbyopia-correcting IOL is the degree of dependence on eyeglasses thereafter; it's probably less with the Acrysof® ReSTOR® IOL.

### Cataract Surgery with Acrysof® ReSTOR® IOL

	FACILITY	PHYSICIAN
<b>COVERED</b>	Cataract Surgery	Cataract Surgery
<b>NOT COVERED</b>	Deluxe component of presbyopia-correcting IOL	Extended care for refractive error

Extended care for refractive error includes one or more of the following services.

- Refraction to determine refractive error
- Contact lens trial fitting to assess refractive error
- Wavefront aberration testing to assess refractive error
- Corneal topography associated with refractive surgery
- Corneal pachymetry associated with refractive surgery
- Routine eye care, wellness care, or preventive care (*e.g.*, to cope with refractive error)
- Refractive keratoplasty for the purpose of reducing dependence on eyeglasses or contact lenses (*e.g.*, limbal relaxing incisions, corneal relaxing incisions, LASIK, etc.)

You are responsible for the usual copayments and deductibles associated with covered services (*i.e.*, cataract surgery). You are also responsible for all of the fees associated with non-covered items and services. The extra charge for the deluxe component of an Acrysof® ReSTOR® IOL is \$\_\_\_\_\_ and the charge for the extended care for refractive error is \$\_\_\_\_\_.

### Beneficiary Agreement

Accordingly, the undersigned accepts full financial responsibility for the non-covered services described above.

\_\_\_\_\_  
Signature of patient or person acting on patient's behalf

\_\_\_\_\_  
Date

Patient's Name: \_\_\_\_\_

**VERY IMPORTANT: READ EVERY WORD!**  
**PRESBYOPIC IOL EXPECTATION FORM**

Sugarland Eye & Laser Center has explained to me that the purpose of upgrading to a presbyopic IOL is to decrease my dependence on glasses. I have been told that my vision may not be perfect 20/20 at both distances, intermediate and near. No guarantee of 20/20 uncorrected vision has been given or implied.

*Initials:* \_\_\_\_\_

Sugarland Eye & Laser Center has explained to me that to achieve my best potential with my near vision, which it will take a minimum of three (3) months and it may require a second procedure with an Eximer laser or an Intraocular lens to obtain my best uncorrected distance vision. There may be additional charges for these procedures.

*Initials:* \_\_\_\_\_

Sugarland Eye & Laser Center has explained to me that lower power glasses may be needed to see fine print, read a book, perform complex near vision tasks or perform complex computer tasks. In some instances glasses may still be needed for distance and near visual tasks.

*Initials:* \_\_\_\_\_

Sugarland Eye & Laser Center has told me that there is a 20% - 30% chance of needing low power reading glasses 100% of the time for near vision. If my distance vision is 20/25 or better uncorrected with the presbyopic intraocular lens, there is an approximately 20% - 30% chance of needing low power reading glasses.

*Initials:* \_\_\_\_\_

Sugarland Eye & Laser Center has explained to me that LASIK or PRK may be needed to enhance my uncorrected vision. This will not occur until at least 3-6 months following my initial surgery. The charge for LASIK or PRK is not included with a cataract surgery presbyopic lens upgrade.

*Initials:* \_\_\_\_\_

This line may not be perfectly clear when read, but over 70% of patients should be able to read this line without spectacles.

*Initials:* \_\_\_\_\_

*Patient Signature:* \_\_\_\_\_

*Date:* \_\_\_\_\_

*Witness Signature:* \_\_\_\_\_

*Date:* \_\_\_\_\_

Patient's Name: \_\_\_\_\_

**ReSTOR® PRE-OPERATIVE INFORMATION**  
**Post-Operative Expectations**

The ReSTOR® Vision Enhancement process is a true cosmetic surgical process. A movie star doesn't look like a movie star the first day or even the first month after cosmetic surgery. You must realize that ReSTOR® Vision Enhancement represents a surgical intervention and time needs to be allowed for healing to take place. Please do not expect sharp vision the first day or even the first week after surgery. During this time, your doctor expects for you to have blurry vision, glare, halos, and light sensitivity. You may have little to no capacity for near vision the first two weeks after surgery. The ReSTOR® lens is designed for bilateral (both eyes) implantation and you will not see best visual outcome until surgery is performed on both eyes. Similar to a movie star undergoing cosmetic surgery, you may not see your optimal visual outcome until three to four months after *bilateral* (both eyes) surgery. In the event that you desire excimer laser enhancements to fine tune your vision, your doctor will determine the proper timing for the laser enhancement. Excimer laser enhancement is usually not advised until three months after your initial surgery.

In the FDA trials, over 97% of patients with bilateral ReSTOR® implantation could see well enough to be legal to drive without glasses and to see menu sized print at near. This is referred to as functional vision and should be considered the goal with ReSTOR®. This does not imply that you will be able to read interstate road signs in a strange city, while driving on a rainy night without corrective lenses. Nor does it mean that you will be able to read the stock quotes without corrective lenses. In a survey conducted during the FDA study, over 80% of patients stated they wore glasses none of the time. This means that approximately 20% of patients still wore corrective lenses part of the time or all of the time. The size type being read is 12 point and should be a reasonable expectation for uncorrected near vision in the majority of patients. It should be noted that 20-25% of patients reported nighttime visual complaints such as glare and halos at night during the FDA trials. No lenses required removal secondary to these complaints. Please realize that the ReSTOR® Vision Enhancement process is a surgical procedure to decrease the dependence on corrective eyewear. The ReSTOR® Vision Enhancement process in no way guarantees or implies that "perfect 20/20 vision" will be obtained for distance or near.

Despite our best computer models for lens implant calculations, approximately 15% of our patients desire an excimer laser enhancement procedure for residual nearsightedness, farsightedness, or astigmatism. In some instances your surgeon may advise you to expect an enhancement preoperatively. The cost of an excimer laser enhancement is not included in the ReSTOR® price. Over 98% of patients having lens implants combined with LASIK obtained 20/25 or better uncorrected distance vision at Sugarland Eye & Laser Center. Even with near perfect distance vision, please realize that approximately 20% of patients will still require eyewear to enhance their near vision.

I have read the information regarding ReSTOR® post-operative expectations. I have had all my questions answered with regard to postoperative expectations.

Patient Signature: \_\_\_\_\_

Date: \_\_\_\_\_

Witness Signature: \_\_\_\_\_

Date: \_\_\_\_\_

Patient's Name: \_\_\_\_\_

**Addendum to Informed Consent for Cataract Surgery  
For Patients Opting for Implantation of Multifocal Intraocular Lens**

Patients who have cataracts may have, or will eventually develop, an age-related condition known as presbyopia. Presbyopia is the reason that reading glasses become necessary typically after age 40, even for people who have excellent distance and near vision without glasses. Presbyopic individuals require bifocals or separate (different prescription) reading glasses in order to see clearly at a close range. There are several options available to you to achieve distance and near vision after cataract surgery.

- **MONOFOCAL IOL:** You can choose to have a monofocal (single focus) IOL (intraocular lens) implanted for distance vision and wear separate reading glasses.
- **MONOVISION:** Your surgeon could implant IOL's with two different powers, one for near and one for distance. This combination of a distance eye and a reading eye is called monovision, and could allow you to read without glasses.
- **MULTIFOCAL IOL:** Your surgeon could implant a "multifocal IOL." These IOL's, more recently approved by the Food and Drug Administration (FDA), can provide distance vision AND near vision.

**CHOOSE ONE OF THESE OPTIONS AND CROSS OUT THE OTHER TWO**

1) Monofocal IOL

I wish to have a cataract operation with a monofocal IOL on my \_\_\_\_\_ (state "right" or "left" eye).

2) Monovision with 2 IOLs Option

I wish to have a cataract operation with two different-powered IOLs implanted to achieve monovision.

I wish to have my \_\_\_\_\_ (state "right" or "left") eye corrected for distance vision.

I wish to have my \_\_\_\_\_ (state "right" or "left") eye corrected for near vision.

3) Multifocal IOL Option

I wish to have a cataract operation with a Acrysof ReSTOR multifocal IOL implant on my \_\_\_\_\_ (state "right" or "left") eye.

By signing below, I certify that I have been given an opportunity to ask questions about my condition, alternatives, procedures, and risks involved. I believe I have sufficient information to give this addendum to my informed consent. This form has been fully explained to me, I have read it or had it read to me, the blank spaces have been filled in, and I understand its content.

Date: \_\_\_\_\_ Time: \_\_\_\_\_ AM/PM

Patient Signature: \_\_\_\_\_

Witness Signature: \_\_\_\_\_



Patient's Name: \_\_\_\_\_

**UPGRADE TO A HIGH-TECHNOLOGY ACRYSOF RESTOR INTRAOCULARE LENS**

**Authorization to Perform Non-Covered Services**

1. I have requested that my physician perform cataract surgery and upgrade to an Acrysof ReSTOR intraocular lens instead of the traditionally monofocal intraocular lens. I have requested this upgrade for the correction or presbyopia.
2. I understand that the surgical correction of presbyopia is considered a cosmetic elective surgical procedure and is not an included service with traditional cataract surgery.
3. The upgrade to the AcrySof ReSTOR IOL is not an covered benefit by my insurance company and will not paid for by my insurance company.
4. I understand that Sugarland Eye & Laser Center will bill my insurance company for standard cataract surgery.
5. I will pay Sugarland Eye & Laser Center and the surgical center an additional amount for the AcrSof ReSTOR IOL upgrade. The amount I will pay is \$\_\_\_\_\_ to Sugarland Eye & Laser Center and \$\_\_\_\_\_ to the surgical center prior to the day of the surgery.
6. My signature below indicates that I agree to accept responsibility for payment for the upgrade, and will not seek payment for the upgrade from my insurance company.
7. If excimer laser vision enhancement is determined to be medically appropriate to satisfy my visual expectations, the laser may be scheduled at my surgeon's discretion. I understand additional payments will be needed for exciser laser vision enhancement.

*Patient Signature:* \_\_\_\_\_

*Date:* \_\_\_\_\_

*Witness Signature:* \_\_\_\_\_

*Date:* \_\_\_\_\_