

# **ZEISS Intraocular Lenses (IOLs)**

Patient Information



Seeing beyond

# Table of contents

1	Introduction	3
2	What is cataract and how does it impact your vision?	4
3	What is an Intraocular Lens (IOL)?	6
4	Different types and performance of the IOL	7
5	How to prepare for the cataract surgery	9
6	What to expect during the cataract surgery?	9
7	What to consider after cataract surgery?	11
8	Follow-up examination	12
9	Undesirable side effects, warnings and residual risk	12
10	Warnings about risks that could arise from the interactions of the IOL with other equipment	14
11	Reporting of serious incidents	14
12	Glossary	15
13	Device model and manufacturer	17

# 1 Introduction

Dear Patient,

Have you recently been diagnosed with a cataract? Or have you already undergone cataract surgery? Then this information is what you need. In this patient leaflet you will find useful information about cataracts, different treatment options, as well as how to prepare for the surgery and what to consider after the procedure.

If you have just been confronted with a cataract diagnosis, don't worry. You are not alone. Cataract is a common eye-condition, affecting most people at some point in time. Fortunately, there are advanced medical options available today to effectively treat cataracts. They can also help correct other vision disorders you may have, allowing you to see clearly without visual aids.

In this patient information you will learn more about modern technologies and the various types of intraocular lenses offered by Carl Zeiss Meditec AG, the global provider of medical solutions. This information may help you understand your treatment options and facilitate consultation with your eye doctor.

## 2 What is a cataract and how does it impact your vision?

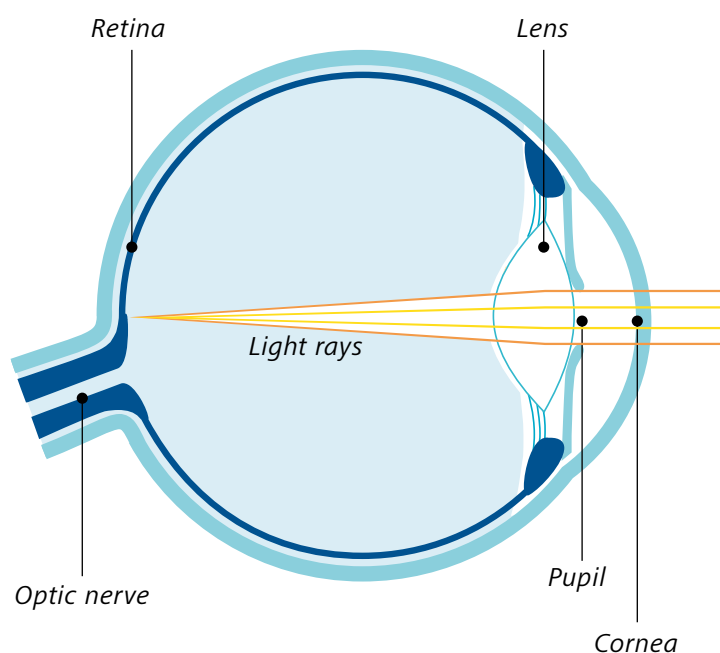
Good vision greatly contributes to our personal well-being and to our ability to do the things we enjoy. However, as we grow older, our eyesight naturally starts to diminish. Cataracts are a common cause for this gradual deterioration. Left untreated, a cataract can increasingly begin to restrict daily activities and the overall quality of life. What's more, cataracts are frequently accompanied by other common eye conditions such as nearsightedness, farsightedness, astigmatism and presbyopia.

A cataract is a medical condition that affects most people sooner or later. It is the most common eye disease and a part of the normal aging process. After the age of 50, it is quite probable that the human eye starts to develop some form of this ocular disease.

A cataract appears as the consequence of the change in the protein structure in the natural lens of the eye. Over time, the lens becomes increasingly cloudy – gradually causing the main symptoms of cataracts.

Common symptoms of cataracts include:

- Gradual deterioration of vision
- Hazy or cloudy sight
- Faded color and contrast perception
- Increased sensitivity to bright light
- Frequent changes of glasses prescription

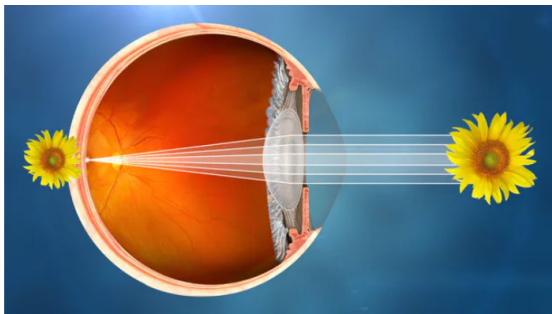


*The anatomy of the eye*

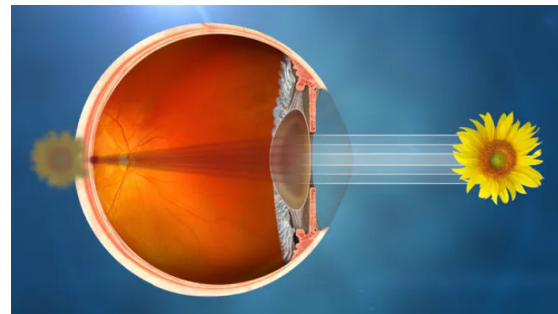
The cataract affects the part of the eye called the crystalline lens. The natural function of the eye's lens is to collect the light entering the pupil, and bend it onto the retina, the back part of the eye, where a clear image is formed. The lens is elasticated and can adapt its shape in order to focus on objects both close up and at long range. This means that when we look at objects nearby, the lens curves to enable clear vision. But when it comes to objects that are further away, it becomes flat – again, enabling us to see clearly. This process of the lens changing its shape to focus on objects at different distances is called “accommodation”.

With increasing age the natural lens of the eye loses its ability to change shape and thus to accommodate, causing age-related vision disorders such as presbyopia, the condition producing difficulty reading small print and making close objects appear blurry. With a cataract, additionally, the naturally clear lens of the eye becomes less and less transparent, resulting gradually in blurry vision. When a cataract starts to affect your vision, the clouded natural lens must be surgically removed and replaced by an artificial lens.

#### Healthy vision



#### Vision impaired by cataract



*Vision simulation without and with cataract.*

### 3 What is an Intraocular Lens (IOL)?

Intraocular lenses are artificial lenses used in modern cataract surgery. They are implanted in the capsular bag to replace the human crystalline lens, which is clouded by the cataract. Intraocular lenses are intended for adult patients (18 years old or older) with cataract.

Intraocular lenses are amazing pieces of technology – both in terms of corrective power and the quality of vision provided. Different types of intraocular lens are available today. Carl Zeiss Meditec (CZM) is one of the main manufacturers of the modern intraocular lenses. ZEISS IOLs have safely been implanted in hundreds of thousands of patients worldwide.

ZEISS intraocular lenses have a diameter of 11 mm or 13 mm and are made of a soft, transparent and biocompatible synthetic material with UV blocking properties. ZEISS offers hydrophilic<sup>1</sup> (absorbing water) as well as hydrophobic<sup>2</sup> (repelling water) types of IOLs. An IOL is neither visible nor perceptible in the eye by the implanted patient. Intraocular lenses do not contain substances that could pose a risk to you as a patient.



*ZEISS IOL size compared to an almond*

ZEISS IOLs are implanted to remain in your eye for your lifetime. Normally the patient has no impact on the lifetime of the implant, neither do external factors. However, some preconditions may impact the perceived quality of vision. See Chapter 9 for an overview of factors that might potentially influence your visual perception after surgery. In most cases, apart from the routine checks by your ophthalmologist, no special precautionary measures are necessary.

**1** ZEISS hydrophilic acrylic IOLs are made from highly purified acrylate copolymer of 2 hydroxyethyl methacrylate (HEMA) and ethoxyethyl methacrylate (EOEMA) with 25% water content, which incorporates a chemically bound organic component (0.5%) that absorbs UV light.

**2** ZEISS hydrophobic acrylic IOLs are made from hydrophobic acrylic material with UV-absorber or with a blue light absorber. These IOLs are heparin coated. The heparin coating is a fragment of heparin with no pharmacological, immunological or metabolic action used in IOL surface coating.

## 4 Different types and performance of the IOL

There are different types of intraocular lens with different optical designs available on the market today. ZEISS offers the following IOL types:

- ✓ Monofocal IOLs
- ✓ Multifocal IOLs (bifocal and trifocal IOLs)
- ✓ EDoF (Extended Depth of Focus) IOLs

**Monofocal lenses** with one focal distance are the most common type of intraocular lens (IOL) for cataract patients. When light enters the eye through a monofocal lens, it is bent to a single focus point on the retina to improve sight at one distance. Light cannot be focused from both distant as well as near objects with this type of lens. It means that a monofocal lens can correct vision at one distance, providing good vision for either near, or far distance. Typically, monofocal IOLs are selected such that they provide sharp distance vision. For activities requiring close-up vision like reading, patients will require spectacles in addition.

Standard types of monofocal IOLs are spherical, i.e. equally rounded over the entire surface. However, the natural crystalline lens of the eye has a slightly aspheric (not evenly rounded) shape. This shape enables it to precisely focus the light rays entering the eye on one point of the retina. The result is a clearer, crisper image. Modern monofocal IOLs are also available in an aspheric shape.

**Multifocal lenses** comprise bifocal and trifocal IOLs.

**Bifocal intraocular lenses** have two focal distances at which they provide sharp vision: for near and far distances. They allow patients to become less dependent on glasses. For intermediate distances such as computer work patients still might need to use visual aids.

**Trifocal IOLs** provide sharp vision for close, intermediate and far distances, without gaps in between. They are designed to enable a high degree of independence from glasses for patients leading an active life and wishing to do without visual aids. Trifocal lenses work by bending the light entering the eye from near, intermediate and far distances, and focusing this light onto a single focal point on your retina. This enables you to focus on objects at different distances simultaneously, providing near, intermediate and distant vision.

Multifocal intraocular lenses provide a high degree of spectacle independence; however, they can also involve some compromises.

A side effect connected with multifocal IOLs is light phenomena (dysphotopsia), which might be perceived when looking into bright light sources, particularly in a dark environment (e.g. at night) and comprises:

- Glare
- Halos, which might appear as rings around light sources

A further consequence of the multifocality is a slightly lower sensitivity to very small image contrasts. This is due to the lens splitting light from different distances on the retina. If you suffer from eye diseases, such as glaucoma, diabetic retinopathy, diabetic macular oedema, or macular degeneration, you may, therefore, not be a suitable candidate for bifocal or trifocal lenses. If you suffer from one of these diseases, you can discuss alternative options with your ophthalmologist.

**EDoF (Extended Depth of Focus) intraocular lenses** enable sharp vision ranging from far to intermediate distances, such as a computer monitor. For close-up activities such as reading fine print and precision work, patients implanted with EDoF lenses may need to wear reading glasses. However, they will experience fewer visual disturbances at night, which are sometimes caused by bright light sources with multifocal IOLs (see explanation in the previous paragraph on multifocal IOLs). EDoF lenses thus represent an attractive combination of more spectacle independence than monofocal IOLs and fewer potential side effects as explained for multifocal IOLs.

For patients with corneal astigmatism, a special type of intraocular lens can be implanted. "Toric" IOLs, as they are called, correct the distorted light rays passing through the astigmatic cornea. Astigmatism occurs when the cornea at the front of the eye has an irregular (slightly oval) shape. It causes objects at different distances to appear skewed or distorted. It is common at any age. The toric intraocular lens focuses all incoming light properly onto your retina to reduce or eliminate astigmatism while treating cataracts at the same time.

Toric IOLs are also available with multifocal and EDoF IOLs.

Your doctor will decide together with you which type of intraocular lens is the best for you.



## 5 How to prepare for the cataract surgery

The cataract surgery is preceded by thorough eye examinations and measurements in the eye clinic. Afterwards the appointment for the procedure is scheduled with your doctor.

On the day of your operation, there are a few things you should keep in mind:

- Do not wear any lotion, make-up, after-shave, or perfume.
- Wear normal and relaxing clothes.
- Eat a light meal no later than a few hours before the procedure, as prescribed by the surgeon/anesthetist, and stay hydrated to ensure a stable circulation for the procedure.
- Arrange someone to pick you up from the clinic in order to get you home safely.
- It might be necessary to have somebody to stay with you for the next 24 hours.

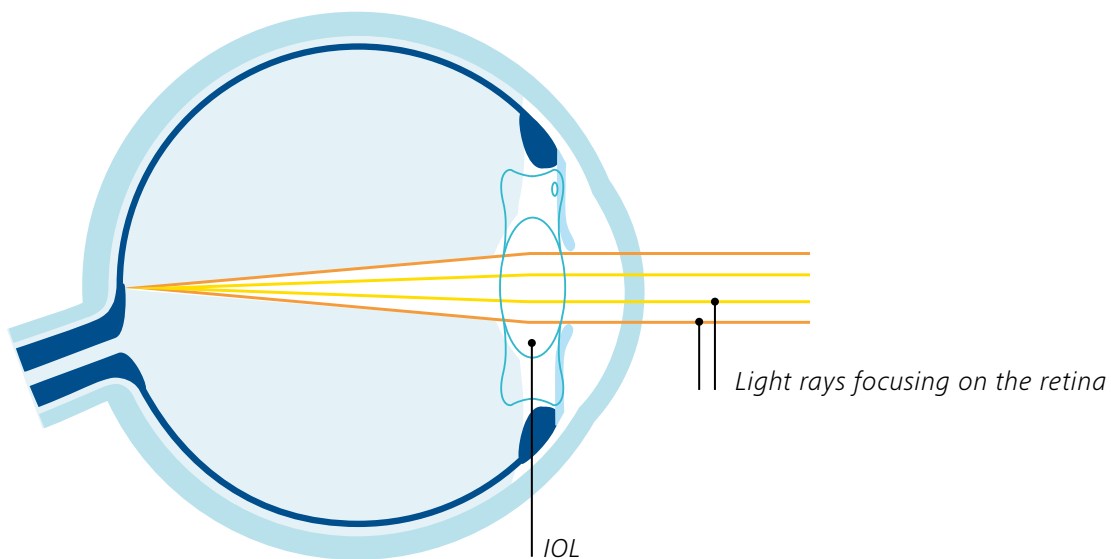
## 6 What to expect during the cataract surgery?

Cataract surgery has proven to be a safe and effective treatment method for many years. As the most common surgical procedure in the world, it is a routine treatment usually performed on an out-patient basis. It takes between 15 to 30 minutes. The surgery is performed on one eye at a time. The second eye is usually treated a few days to a few weeks later.

### Typical steps of the cataract surgery:

- *Biometric Measurement*: Firstly, a few days or weeks prior to the surgery the eye is precisely measured to determine the correct diopter power that is needed for the intraocular lens.
- *Anesthesia*: Directly before the procedure, you will be given an injection, or drops of anesthesia, to numb the eye and to ensure the procedure is painless. An eyelid holder is used to prevent you from blinking during surgery. Furthermore, your eyelids and the surrounding skin will be disinfected.
- *Incision of the Cornea*: The surgeon makes a small incision of approximately 2 mm in your cornea to insert the IOL.
- *Protection of the Inner Eye*: A jelly-like substance called "Ophthalmic Viscosurgical Device" (OVD) is injected in the eye. OVDs protect the corneal endothelium (the innermost layer of the cornea) and other tissues during surgery by minimizing the interaction between tissues and instruments.

- *Opening the Capsular Bag for Precise Placement:* With a thin scalpel, the surgeon creates a small opening in the capsular bag, where the natural lens is located.
- *Phacoemulsification:* The cataract lens is softened and broken into smaller pieces. It is removed, using gentle suction.
- *IOL Insertion:* The intraocular lens is then carefully positioned in the capsular bag where the original lens was located before. Normally the eye heals the incision itself.
- *Post-Operation Eye Protection:* Usually, the surgeon will place a protective patch over your eye.



*Position of the implanted IOL in the eye after cataract surgery*

## 7 What to consider after cataract surgery?

### What are the first steps after surgery?

The recovery time after cataract surgery is relatively short – it can take a few days, but may also take up to one month. It depends on the patient. You will immediately notice a significant vision improvement following the operation.

### Make sure to follow these instructions after your surgery:

- Get someone to drive you home after surgery.
- Try to take a long nap after surgery to keep your eyes closed and rested.
- Resist the urge to rub your eyes if they feel itchy.
- If you are feeling any discomfort or slight pain, ask your doctor for eye drops or an over-the-counter mild pain reliever.
- Explain your symptoms to your doctor in the check-up after the surgery.

### What care measures are typical after surgery?

You might be told to wear an eye patch or similar protection for a few days after surgery and to avoid rubbing or pressing your eye. Your doctor may also prescribe eye drops or other medication to prevent infection and inflammation and/or to control eye pressure. Make sure you use these medications exactly as prescribed.

### What activities should be avoided?

The doctors may advise you to relax and avoid strenuous activities such as bending over, lifting things or exercising, as well as not to overexert your eyes in general for a few weeks. You should avoid rubbing your eye or putting extra pressure on it (when sneezing, for instance). The first week after surgery, you should avoid swimming or using a bath/hot tub to reduce the risk of infection. Moreover, don't expose your eye to irritants such as grime, dust and wind, and refrain from washing your hair.

Working at your computer or watching TV for a short amount of time should be possible within a few hours after your surgery. However, you should avoid reading and other activities that may stress your eyes in the first days after the surgery.

## 8 Follow-up examination

Usually, your doctor wants to look at your eye within 24 hours after surgery. Your vision and eye pressure will be checked, and instructions will be given on how to use the prescribed eye drops. Your vision might be blurry right after surgery, but it should improve during the first few days after your treatment. Additional examinations are typically scheduled over the following weeks to monitor the healing process until vision has fully stabilized. If you need cataract surgery in both eyes, your surgeon will usually wait at least a few days, or even up to weeks, for your first eye to recover before performing the procedure on the second eye. If correcting glasses are still needed after the surgery, they should be prescribed only four to six weeks after the surgery. Depending on the type of intraocular lens, one to four follow-up appointments within the first month after surgery are customary. The final follow-up appointment will take place about a month after the cataract surgery. Generally, a visit to an ophthalmologist every one or two years is advised.

## 9 Undesirable side effects, warnings and residual risk

### Visual light phenomena

Some patients may experience some visual phenomena such as glare or halos right after cataract surgery, especially in poor lighting conditions. Halos are bright circles that surround a light source, like headlights. Glare, on the other hand, is light that enters your eye interfering with your vision and is more likely to appear in daytime.

Visual disturbances occur, for example, when driving at night or when there's artificial light in the dark. These phenomena typically diminish a few weeks to a few months after cataract surgery, because the brain automatically adapts to the intraocular lens and compensates for it. Most patients do not feel disturbed by the light phenomena.

Consult your ophthalmologist for a check-up if you notice light phenomena even after the healing process has finished.

To reduce the risk of complications after cataract surgery, be sure to follow the instructions your surgeon gives you and report any unusual symptoms immediately. Before surgery, there will be a medical briefing held with the surgeon and the anesthetist.

### **Decentration or deviating diopter power of the lens:**

Decentration of the lens may occur in rare occasions (possibly even after years) and lead to visual disturbances and glare, which can be corrected surgically.

If the IOL does not have the exact appropriate diopter power, the visual acuity might not be exactly as can be expected. Reasons for such a deviation might be that the IOL does not end up in the exact plane in your eye as predicted based on the biometric measurements or imprecise calculation of the IOL power. If such deviations occur they are small and without significant effect in the majority of cases. In rare cases of stronger deviations they can be corrected either with glasses or surgically.

Inform your doctor if you experience:

- a strong pain in your eye
- recurring redness of the eye
- unusual headache or nausea
- considerable vision deterioration
- light flashes, or huge increase of floaters in your eye

These are some complications that can occur with a very low probability right after surgery:

### **Infections and minor complications**

Just like any surgical procedure, there is a risk of your eye becoming infected but very few people experience serious cataract surgery complications.

If you develop an infection, you may need to take eye drops for treatment. Please see an ophthalmologist if your eye begins to swell or you experience any other undesirable effects. Other potential cataract surgery complications are minor and may include:

- Swelling
- Increased pressure in the eye
- Droopy eyelid

Minor complications usually clear up with medication and more healing time. Be sure to report any change to your ophthalmologist immediately. He or she can check your eye to see how the healing process is going and if you need any medication.

### **Posterior capsule opacification**

A posterior capsule opacification (PCO) is one of the most common cataract surgery complications. PCO occurs due to remaining cells from the removed crystalline lens starting to proliferate after cataract surgery. These proliferating cells grow over the back surface of the IOL causing your vision to become less crisp again. Although some people call PCO a “secondary cataract” due to the similar symptoms, it is not. Once a cataract is removed, it does not come back.

Fortunately, a PCO can easily be treated with a YAG laser. Your ophthalmologist can perform this procedure in his office. It is very effective, painless and takes only a few minutes.

Most people can expect their vision to improve within a day. If you are struggling with continuous bad vision after your cataract surgery, contact your ophthalmologist to discuss the next possible steps together.

## **10 Warnings about risks that could arise from the interactions of the IOL with other equipment**

No risks are known that could arise from the interactions of an intraocular lens with other equipment. No special precautions need to be taken.

### **Security with Magnetic Resonance Imaging (MRI)**

Patients with an implanted ZEISS IOL do not have to fear any hazard while a magnetic resonance imaging scan (MRI) is performed. ZEISS IOLs are made of an acrylic material which does not conduct electricity, does not include any metal and is not magnetic.

## **11 Reporting of serious incidents**

Any serious incident that occurs in relation to the intraocular lens should be reported to your doctor (in the first instance), to the local ZEISS representative or to the legal manufacturer as shown in the details below.

## 12 Glossary

Here you will find an explanation of the most frequently used terms in the document:

### ***IOL, Intraocular Lens***

An artificial lens made of a soft, synthetic, and biocompatible material used to replace the natural lens in a cataract surgery.

### ***Hydrophilic Materials***

Materials with an affinity for water.

### ***Hydrophobic Materials***

Materials that naturally repel water.

### ***Monofocal IOL***

IOL with one focal plane – either for near or for far vision.

### ***Bifocal IOL***

IOL with two focal planes – for near and far vision.

### ***Trifocal IOL***

IOL with three focal planes – for near, intermediate and far vision.

### ***EDoF IOL***

Extended Depth of Focus IOL with an extended range of vision reaching from far to intermediate distances.

### ***Toric IOL***

IOL with a special shape, used to correct corneal astigmatism.

### ***Presbyopia***

An eye condition that occurs as the eye naturally ages, usually from the age of 40 upwards: the lens loses its elasticity and can thus no longer properly focus clearly on close objects. This makes reading, especially at close range, much more difficult.

### ***Glaucoma***

An eye disease that can be described as damage to the nerve connecting the eye to the brain (called the optic nerve) mostly due to high eye pressure (intraocular pressure), which influences your visual field and visual acuity.

**Cataract**

An age-related eye condition that appears as the consequence of the change in the protein structure in the natural lens of the eye. Over time, the lens becomes increasingly cloudy.

**PCO (posterior capsular opacification)**

A phenomenon that occurs due to remaining cells from the removed lens starting to proliferate after cataract surgery. These proliferating cells grow over the IOL's back surface causing your vision to become cloudy again.

**MRI (magnet resonance imaging)**

A test that uses powerful magnets, radio waves, and a computer to make detailed pictures inside your body.

**YAG laser**

A special laser used in medicine, a.o. to treat PCO after cataract surgery. YAG is an acronym for the crystal used to generate laser light – it is made of yttrium aluminum garnet.

**Capsular bag**

A sack-like cellular membrane surrounding the crystalline lens.



## 13 Device model and manufacturer

The patient information included in this document relates to the following ZEISS IOL models:

<b>Model</b>	<b>Performance characteristics</b>
CT SPHERIS 204 CT SPHERIS 209M	Spherical, monofocal
CT ASPHINA 404 CT ASPHINA 409M CT ASPHINA 409MP	Aspheric, monofocal
CT ASPHINA 509M CT ASPHINA 509MP	
AT LARA 829MP	Aspheric, EDoF*
AT LISA 809M	Aspheric, bifocal
AT LISA tri 839MP	Aspheric, trifocal
AT TORBI 709M AT TORBI 709MP AT TORBI 719M AT TORBI 719MP	Aspheric, toric
AT LARA toric 929M AT LARA toric 929MP	Aspheric, EDoF* toric
AT LISA toric 909M	Aspheric, bifocal toric
AT LISA tri toric 939M AT LISA tri toric 939MP AT LISA tri toric 949M AT LISA tri toric 949MP	Aspheric, trifocal toric
CT LUCIA 621P CT LUCIA 621PY CT LUCIA 611P CT LUCIA 611PY CT LUCIA 602	Aspheric, monofocal
CT LUCIA 221P CT LUCIA 211P CT LUCIA 202	Spherical, monofocal
AT ELANA 841P	Aspheric, trifocal

\* Extended Depth of Focus

The mentioned IOL models are all manufactured by:

**Carl Zeiss Meditec AG**

Goeschwitzer Strasse 51-52

07745 Jena, Germany

[www.zeiss.com/meditec](http://www.zeiss.com/meditec)

Email: [info@zeiss.com](mailto:info@zeiss.com)



Sources:

- ZEISS Patient Website EN\_32\_174\_0158I, [www.zeiss.com/cataract-treatment](http://www.zeiss.com/cataract-treatment)
- ZEISS Instructions for Use
- <https://flexikon.doccheck.com/de/YAG-Laser>
- <https://www.webmd.com/a-to-z-guides/what-is-a-mri#1>

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