# PATIENT INFORMATION BROCHURE

# FINEVISION HP Trifocal IOL

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## Introduction

This brochure is intended to help you to understand your treatment and the technology behind your intraocular implant. Your physician, surgeon, or general practitioner can also provide more information about the product and your operation. Information about your implant is always available on the manufacturer's website:

www.bvimedical.com and www.ifu.bvimedical.com

## What is Cataract?

Cataract is a natural and normal aging process where the eye's lens becomes cloudy, making it difficult to see clear images. Cataract is a widespread condition and is a major cause of blindness. Cataract formation is not preventable and causes progressive blurring of the eye lens, affecting your daily activities.

## What are the Symptoms of Cataracts?

When cataracts are mild, you might not have any symptoms. But as they develop, cataracts can cause changes in your vision:

- Cloudy or blurry vision
- Colors look faded
- You can't see well at night
- Lamps, sunlight, or headlights seem too bright
- You see a halo around lights
- You see double (this sometimes goes away as the cataract gets bigger)
- You have to change the prescription for your glasses or contact lenses often

Talk with your eye doctor if you have any of these symptoms—they could also be signs of other eye problems.

## What Causes Cataracts?

After age 40, the proteins in the lens of your eye naturally start to break down. Most cataracts happen because of these natural changes.
Doctors and researchers are still studying why cataracts form. They have found some factors other than aging that make cataracts more likely, including:

- A family history of cataracts
- Diabetes
- A serious eye injury
- Eye surgery to treat glaucoma or another eye condition
- Taking steroids—medicines used to treat some health problems, like arthritis or allergies
- Radiation treatment for cancer or other diseases

Research has also found some things make cataracts form faster, including:

- Smoking
- Drinking too much alcohol
- Spending too much time in the sun, especially without sunglasses.

## What is Corneal Astigmatism?

Astigmatism is a common eye condition that causes blurry vision. In a normal eye, the cornea (the clear front part of the eye) is round and allows light rays entering the eye to focus at a single point on the back of the eye (retina) to form a clear image. In an eye with corneal astigmatism, the cornea is oval shape. As a result, the light rays do not focus at the same point on the retina. This may cause some parts of an object to be unclear and may also lead to eye discomfort and headaches. During a comprehensive eye exam, your eye doctor can tell you if you have corneal astigmatism.

## What are the Treatment Options?

Eye surgery is the only treatment option for cataracts. During the surgery, your clouded, opacified lens is removed and is replaced with an intraocular lens (IOL). The physician chooses the IOL before the surgery, based on a non-invasive eye exam and testing. This implanted IOL acts as your new lens, mimicking and possibly restoring the full properties of the removed lens. During cataract surgery, the IOL (your implant) is inserted with an injector similar to a syringe. The procedure is minimally invasive and requires a very small incision into your eye.
There is no need for post-surgical stiches. The surgery is ambulatory/performed as an out-patient procedure and complications are rare. You will only be asked to take some medicine and to protect your eye from contaminations. Eyedrops are also given, as common practice, prior to surgery. After surgery, you may be able to go home the very same day.

Discuss what visual quality you need with your physician. These needs are important; take all the time you need to discuss the procedure, your implant choice, and your expectations with respect to your lifestyle.

## What Happens After Cataract Surgery?

Your eye doctor will explain how to protect your eye after cataract surgery. They'll give you eye drops to help your eye heal, and you may need to wear a special eye shield or glasses. You may also need to avoid some activities for a few weeks e.g., touching your eye, bending over, or lifting heavy things. Your eye may feel a bit itchy or uncomfortable and sensitive to light and touch. After 1 or 2 days, your eye should feel better.

Call your eye doctor right away if you notice any of these problems after surgery:

- Vision loss
- Bad pain that won't go away even if you take medicine for it
- Very red eyes
- Floaters—flashes of light or a lot of small dark spots or squiggly lines that float across your vision

Most people are completely healed 8 weeks after their surgery. Your eye doctor will schedule checkups to make sure your eye is healing correctly.

## Risks Associated with Cataract Surgery.

As with any surgery, there are risks and potential complications associated with routine cataract surgery and IOL implantation. General surgery risks include reactions to medicines, bleeding, infection, inflammation, tissue damage, tissue swelling of the front or the back of the eye, redness, scratchiness of the eye, sensitivity to light, and increased eye pressure. If your lens is not in the correct position, your vision may also be affected and the normal flow of fluid within the eye may be blocked. You may require additional surgery to treat these side effects, and there is a small chance that your vision could be made worse by the operation. Please discuss these risks with your eye doctor.

## Which Kind of IOLs are Available for This Procedure?

There are many different IOLs to choose from. Your eye doctor will discuss your IOL options with you.

## Monofocal IOLs

Monofocal IOLs are one of the most widely used IOL types. They provide clear vision for one specific distance—either near, intermediate, or far. Individuals who prefer a monofocal IOL often opt for clear distance vision and rely on reading glasses or other corrective measures for close-up tasks. Monofocal IOLs do not correct for corneal astigmatism.

Advantages:

- Monofocal IOLs provide predictable results and so they are an excellent choice for patients with straightforward vision needs.

- Monofocal IOLs have a lower risk of visual issues like halos and glare, making them suitable for night driving.

**Monofocal Toric IOLs**

Monofocal toric IOLs are designed to address astigmatism. These types of IOLs lenses have a toric shape, which allows them to work with the irregular curvature of the cornea in astigmatic eyes.
Advantages:

- Significantly reduces astigmatism, improving the overall quality of vision.
- Reduces dependence on glasses for distance vision.
- Enhances contrast sensitivity, leading to sharper and clearer vision, especially in low-light conditions.

**Multifocal IOLs**

Multifocal lenses allow individuals to see clearly at different distances. These types of IOLs can correct presbyopia, a condition that affects near vision as people age.
Advantages:

- Improved quality of life due to their ability to perform a wide range of activities.

These lenses do not correct for corneal astigmatism.

**Multifocal Toric IOLs**

In addition to the potential benefits of Multifocal IOLs, Multifocal Toric IOLs also correct corneal astigmatism. There is a chance you may still need glasses for distance, intermediate, and/or near vision.

**Key Points to Remember Regarding Your Choice.**

Discuss your lifestyle and your expectations regarding your visual quality needs with your physician. Ask your treating physician if you need any additional information. There are many types of intraocular lenses on the market, but if you want better vision at intermediate and near viewing distances and distance vision comparable to a monofocal IOL,FINEVISION HP Trifocal IOL is a suitable choice.

**What Are the Characteristics of Your Intraocular Lens?**
The FINEVISION HP Trifocal IOL lens discussed in this brochure is a trifocal lens, which means it improves vision at intermediate and near viewing distances with distance vision comparable to a monofocal IOL. It is made from an acrylic hydrophobic material designed by PhysIOL. The material also filters out ultraviolet and blue light to better simulate the filtering that your natural lens provided. The material is biocompatible (it will not interact with the tissues in your eye) and should not interact with surrounding electrical systems (e.g., Magnetic Resonance Imaging technology, used during body scans).

**What are the Potential Benefits of Your Implanted Intraocular Lens?**

The type of lens you have been implanted offers the following benefits:

- Restores visual quality lost during cataract progression.
- Provides distance vision comparable to the monofocal IOL (e.g., television watching, driving, sports, and outdoors activities)
- Improves vision at intermediate viewing distance (e.g., computer and tablet work, cooking)
- Improves vision at the near viewing distance (e.g., reading, sewing, handiwork, shaving, and applying make-up).

You may require some adaptation time. This specific lens has been designed to prioritize far and near visual quality.

- The FINEVISION HP Trifocal IOL has been designed to diminish visual disturbances caused by the diffractive technology.
- Reduced post-surgery complications when compared with previous IOL materials.

**What are the Risks Related to Your Surgery and Implant?**

Adverse effects may occur following your cataract surgery. These adverse effects are rare and are outweighed by the potential benefits of restoring your vision. Surgery risks include:

- Reactions to medicines
- Reactions to the surgical procedure
- Possible vision changes. There is a small chance that your vision could be impaired by the operation, especially if bleeding, inflammation or infection occurs. Some of the complications may require a secondary surgery to reposition, exchange, or remove the IOL. If you experience any undesirable effects, contact your treating physician, the Competent Health Authorities of your country, or the manufacturer (Physiol SA, contact information available at the end of this brochure).

**Potential Side Effects Associated with FINEVISION HP Trifocal IOL**

Some side effects are associated with IOLs that provide a broader range of vision than a monofocal IOL. These side effects include visual disturbances such as glare, rings around lights, starbursts, and a decreased ability to distinguish objects from their background, especially in dim lighting. These side effects may make it more difficult to see in some situations.

**Clinical Study Summary:**

A study was done in the U.S. to test a new eye lens called the FINEVISION HP Trifocal IOL (this version does not correct astigmatism). Here's what the study found:

**Vision Results:**

- The FINEVISION HP Trifocal IOL helped people see far away just as well as the regular lens.
- It was even better for seeing things up close and at middle distances—like when reading a book or using a computer.
- This means people who get the FINEVISION HP Trifocal IOL may have sharper vision at all distances.

**Safety and Side Effects:**

- Both the FINEVISION HP Trifocal IOL and the regular AcrySof lenses were safe.
- Serious side effects were very rare—less than 1 out of 100 people**.**

Here are some of the side effects they looked for:

- Swelling in the back of the eye (macular edema): Happened in about 1% of people in both groups. It can cause blurry vision but didn't happen often.
- Eye infections (endophthalmitis), severe inflammation (hypopyon) and persistent inflammation (iritis): These did not happen in either group.
- Retinal detachment (when the back part of the eye pulls away): Happened in a few people with the FINEVISION HP Trifocal IOL, but not with the AcrySof lens. This is a serious issue but is related to the surgery, not the lens itself.
- Extra procedures after surgery: A few people needed more treatment, like removing leftover lens pieces or using a laser. This happened a little more often with the FINEVISION HP Trifocal IOL.
- Other problems like lens movement, high eye pressure, or fluid in the cornea were very rare in both groups.

**Visual Disturbances**

Reports of visual disturbances for this lens compared to a monofocal IOL are shown in Tables 1, 2, and 3. Most visual symptoms—such as glare, hazy or blurred vision, image distortion, double or multiple images, trouble focusing, difficulty judging distance or depth, and vision fluctuations—occurred at similar or slightly lower rates in the FINEVISION HP Trifocal IOL group compared to the control group. However, two symptoms—starbursts and halos—were reported more frequently by participants with the FINEVISION HP Trifocal IOL than those with the monofocal control lens.

## Table 1: Frequency of each visual disturbance at 1 year post-op

| | FINEVISION HP (%) | | | | | Monofocal (%) | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Visual Disturbance** | **N** | **Never** | **Occasionally** | **Quite Often** | **Very Often** | **N** | **Never** | **Occasionally** | **Quite Often** | **Very Often** |
| Glare | 315 | 38.4% [121/315] | 47.3% [149/315] | 11.1% [35/315] | 3.2% [10/315] | 159 | 38.4% [61/159] | 51.6% [82/159] | 8.2% [13/159] | 1.9% [3/159] |
| Haloes | 315 | 22.2% [70/315] | 39.0% [123/315] | 21.0% [66/315] | 17.8% [56/315] | 159 | 70.4% [112/159] | 23.3% [37/159] | 3.8% [6/159] | 2.5% [4/159] |
| Starbursts | 315 | 50.2% [158/315] | 31.4% [99/315] | 11.7% [37/315] | 6.7% [21/315] | 159 | 61.6% [98/159] | 30.8% [49/159] | 5.7% [9/159] | 1.9% [3/159] |
| Hazy Vision | 315 | 67.9% [214/315] | 24.4% [77/315] | 5.1% [16/315] | 2.5% [8/315] | 159 | 67.3% [107/159] | 24.5% [39/159] | 5.7% [9/159] | 2.5% [4/159] |
| Blurred Vision | 315 | 61.3% [193/315] | 32.7% [103/315] | 4.8% [15/315] | 1.3% [4/315] | 159 | 50.9% [81/159] | 38.4% [61/159] | 8.2% [13/159] | 2.5% [4/159] |
| Distortion | 315 | 90.5% [285/315] | 8.6% [27/315] | 1.0% [3/315] | 0.0 % | 159 | 91.8% [146/159] | 5.7% [9/159] | 2.5% [4/159] | 0.0% |
| Double or multiple images | 315 | 88.6% [279/315] | 10.5% [33/315] | 0.6% [2/315] | 0.3% [1/315] | 159 | 88.7% [141/159] | 9.4% [15/159] | 1.3% [2/159] | 0.6% [1/159] |
| Fluctuation in Vision | 315 | 48.3% [152/315] | 42.5% [134/315] | 7.3% [23/315] | 1.9% [6/315] | 159 | 50.3% [80/159] | 44.0% [70/159] | 3.8% [6/159] | 1.9% [3/159] |
| Focusing Difficulties | 315 | 44.1% [139/315] | 47.9% [151/315] | 5.4% [17/315] | 2.5% [8/315] | 159 | 39.6% [63/159] | 46.5% [74/159] | 9.4% [15/159] | 4.4% [7/159] |
| Difficulty Judging Distance or Depth Perception | 315 | 73.7% [232/315] | 19.0% [60/315] | 4.4% [14/315] | 2.9% [9/315] | 159 | 66.0% [105/159] | 25.8% [41/159] | 6.3% [10/159] | 1.9% [3/159] |

Note: Percentages are based on the number of subjects (N) seen at Visit 5 (Day 360 to 420) for the respective treatment group for the population being analyzed.

## Table 2: Severity of each visual disturbance at 1 year post-op excluding subjects who reported frequency of "Never"

| | FINEVISION HP (%) | | | | | | Monofocal (%) | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Visual Disturbance** | **N** | **Not at all** | **Mild** | **Moderate** | **Severe** | **Missing** | **N** | **Not at all** | **Mild** | **Moderate** | **Severe** | **Missing** |
| Glare | 194 | 4.1 % [8/194] | 67.0 % [130/194] | 24.7 % [48/194] | 3.6 % [7/194] | 0.5 % [1/194] | 98 | 6.1 % [6/98] | 59.2% [58/98] | 31.6% [31/98] | 3.1% [3/98] | 0.0% |
| Haloes | 245 | 3.3 % [8/245] | 52.7% [129/245] | 33.9% [83/245] | 9.8% [24/245] | 0.4% [1/245] | 47 | 6.4% [3/47] | 70.2% [33/47] | 21.3% [10/47] | 2.1% [1/47] | 0.0% |
| Starbursts | 157 | 8.3% [13/157] | 54.8% [86/157] | 31.2% [49/157] | 5.7% [9/157] | 0.0% | 61 | 8.2% [5/61] | 65.6% [40/61] | 23.0% [14/61] | 3.3% [2/61] | 0.0% |
| Hazy Vision | 101 | 7.9% [8/101] | 65.3% [66/101] | 24.8% [25/101] | 1.0% [1/101] | 1.0% [1/101] | 52 | 7.7% [4/52] | 71.2% [37/52] | 15.4% [8/52] | 5.8% [3/52] | 0.0% |
| Blurred Vision | 122 | 7.4% [9/122] | 73.0% [89/122] | 17.2% [21/122] | 2.5% [3/122] | 0.0% | 78 | 3.8% [3/78] | 66.7% [52/78] | 24.4% [19/78] | 5.1% [4/78] | 0.0% |
| Distortion | 30 | 13.3% [4/30] | 73.3% [22/30] | 13.3% [4/30] | 0.0% | 0.0% | 13 | 7.7% [1/13] | 69.2% [9/13] | 23.1% [3/13] | 0.0% | 0.0% |
| Double or multiple images | 36 | 8.3% [3/36] | 83.3% [30/36] | 8.3% [3/36] | 0.0% | 0.0% | 18 | 11.1% [2/18] | 61.1% [11/18] | 16.7% [3/18] | 11.1% [2/18] | 0.0% |
| Fluctuation in Vision | 163 | 9.2% [15/163] | 69.9% [114/163] | 17.8% [29/163] | 2.5% [4/163] | 0.6% [1/163] | 79 | 8.9% [7/79] | 75.9% [60/79] | 12.7% [10/79] | 2.5% [2/79] | 0.0% |
| Focusing Difficulties | 176 | 12.5% [22/176] | 69.9% [123/176] | 14.8% [26/176] | 2.8% [5/176] | 0.0% | 96 | 2.1% [2/96] | 71.9% [69/96] | 21.9% [21/96] | 4.2% [4/96] | 0.0% |
| Difficulty Judging Distance or Depth Perception | 83 | 8.4% [7/83] | 68.7% [57/83] | 19.3% [16/83] | 3.6% [3/83] | 0.0% | 54 | 1.9% [1/54] | 68.5% [37/54] | 27.8% [15/54] | 1.9% [1/54] | 0.0% |

Note: Percentages are based on the number of subjects (m) seen at Visit 5 (Day 360 to 420) who did not report a frequency of "Never" for the visual disturbance and treatment group for the population being analyzed.

**Table 3: Bothersomeness of each visual disturbance at 1 year post-op excluding subjects who reported frequency of "Never"**

| | FINEVISION HP (%) | | | | | | Monofocal (%) | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Visual Disturbance** | **N** | **Not at all** | **A little** | **Quite** | **Very** | **Missing** | **N** | **Not at all** | **A little** | **Quite** | **Very** | **Missing** |
| Glare | 194 | 15.5% [30/194] | 67.5% [131/194] | 10.8% [21/194] | 5.7% [11/194] | 0.5% [1/194] | 98 | 17.3% [17/98] | 62.2% [61/98] | 15.3% [15/98] | 5.1% [5/98] | 0.0% |
| Haloes | 245 | 23.7% [58/245] | 47.3% [116/245] | 18.0% [44/245] | 10.6% [26/245] | 0.4% [1/245] | 47 | 25.5% [12/47] | 59.6% [28/47] | 12.8% [6/47] | 2.1% [1/47] | 0.0% |
| Starbursts | 157 | 24.2% [38/157] | 46.5% [73/157] | 21.7% [34/157] | 7.6% [12/157] | 0.0% | 61 | 21.3% [13/61] | 65.6% [40/61] | 9.8% [6/61] | 3.3% [2/61] | 0.0% |
| Hazy Vision | 101 | 15.8% [16/101] | 63.4% [64/101] | 16.8% [17/101] | 4.0% [4/101] | 0.0% | 52 | 21.2% [11/52] | 57.7% [30/52] | 13.5% [7/52] | 7.7% [4/52] | 0.0% |
| Blurred Vision | 122 | 12.3% [15/122] | 68.0% [83/122] | 16.4% [20/122] | 3.3% [4/122] | 0.0% | 78 | 12.8% [10/78] | 57.7% [45/78] | 20.5% [16/78] | 9.0% [7/78] | 0.0% |
| Distortion | 30 | 23.3% [7/30] | 60.0% [18/30] | 16.7% [5/30] | 0.0% | 0.0% | 13 | 15.4% [2/13] | 53.8% [7/13] | 30.8% [4/13] | 0.0% | 0.0% |
| Double or multiple images | 36 | 22.2% [8/36] | 66.7% [24/36] | 8.3% [3/36] | 2.8% [1/36] | 0.0% | 18 | 11.1% [2/18] | 61.1% [11/18] | 16.7% [3/18] | 11.1% [2/18] | 0.0% |
| Fluctuation in Vision | 163 | 23.9% [39/163] | 63.8% [104/163] | 8.6% [14/163] | 3.1% [5/163] | 0.6% [1/163] | 79 | 16.5% [13/79] | 63.3% [50/79] | 13.9% [11/79] | 6.3% [5/79] | 0.0% |
| Focusing Difficulties | 176 | 21.0% [37/176] | 61.9% [109/176] | 11.9% [21/176] | 4.5% [8/176] | 0.6% [1/176] | 96 | 12.5% [12/96] | 66.7% [64/96] | 15.6% [15/96] | 5.2% [5/96] | 0.0% |
| Difficulty Judging Distance or Depth Perception | 83 | 10.8% [9/83] | 68.7% [57/83] | 14.5% [12/83] | 6.0% [5/83] | 0.0% | 54 | 5.6% [3/54] | 74.1% [40/54] | 13.0% [7/54] | 7.4% [4/54] | 0.0% |

Note: Percentages are based on the number of subjects (N) seen at Visit 5 (Day 360 to 420) who did not report a frequency of "Never" for the visual disturbance and treatment group for the population being analyzed.

## Should You Take Precautions?

Follow your physician's recommendations about the medication and post-surgery care. This might also involve precautions regarding daily activities where you might hurt your eye. You may also be requested to perform a careful self-assessment in case of any discomfort. Trifocal lenses, the type of lens you have been implanted with, may cause some visual disturbances in low-light conditions. Please exercise caution when driving at night or in poor visibility conditions.

## Required Exams and Follow-Ups

If you have been enrolled in a clinical trial related to the IOL, you have signed consent forms and are asked to comply with exams and follow-ups as described in the clinical investigation protocol. Otherwise, exams and follow-ups will be determined by your treating physician and according to your hospital's standard practice.

## Are There any Contraindications to This Intraocular Lens?

Contraindications include:

- The presence of pre-existing eye diseases that could be aggravated by the implant, and/or
- Diseases where the implant may interfere with treatment or examination.
- Eye infection
- Eye inflammation
- Previous damage to your eye caused by external trauma or previous surgery
- Eye diseases such as glaucoma or inherited cataract.
- Significant preoperative astigmatism (blurriness at all distances due to the imperfect curvature of the eye cornea) or patients who are expected to develop astigmatism post-operatively

Your treating physician will assess any contraindications and evaluate whether the lens can be implanted. If you have any pre-existing conditions related to your eye, please refer to your physician.

Always follow your doctor's instructions.
Use the following web site for reporting adverse events and complaints involving these intraocular lenses:

URL: https://www.bvimedical.com/contact-complaint/

Expected lifetime of the device
The expected lifetime of the device is set at 20 years