Patient Information Leaflet
Name : POD F GF
Device Commercial Name: FINEVISIONHP

Introduction

This brochure has been written to aid you in the understanding of your treatment and of the technology behind your intraocular implant. Your physician, surgeon or general practitioner is also able to help you should you need any more information regarding the product, the reason(s) behind your operation or even about details regarding the surgery itself. Finally, more information about your implant is always available on the website of the manufacturer: https://www.bvimedical.com/products/iol/

What is Cataract?

Cataract is a natural and normal process affecting your eye and occurring with age. Cataract is possibly associated with presbyopia, a condition in which the natural lens in your eyeyour eye might progressively lose its ability to accommodate, making it difficult to see close objects. Cataract is the clouding of the eye natural lens and leads to a eduction of visual quality. The eye is functioning as a camera and should the lens become clouded, you would be unable to perceive clear images. It is a widespread and almost inevitable eye-ageing process which is the root cause in about 50% of all blindness-affected patients . The cataract formation cannot be avoided and causes progressive blurring of the eye lens, affecting all your daily activities.

What are the treatment options?

Surgery of the eye remains the only available option nowadays for treating cataract. However, the surgery itself is very common, well-controlled, very often ambulatory and not painful.

It consists in the removal of your clouded, opacified lens and its replacement with an intraocular device, which is called an “Intraocular lens” (IOL). The implant is carefully chosen by your physician prior the surgery, after thorough, non-invasive examination of your eye with adequate and relevant tests. This implant acts as your natural lens, mimicking and possibly restoring the full natural properties of the removed lens.

During cataract surgery, the artificial intraocular lens (your implant) is inserted with a standard injector similar to a syringe. The procedure is minimally invasive and requires only a very small incision into your eye. There is consequently no need for post-surgical stiches. The surgery is ambulatory, generally occurring without complications and does not require hospitalization. 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.

Your personal needs regarding your visual quality are very important and you should discuss them with your physician. You should take all the time you need to discuss the procedure, your implant choice and your expectations regarding your lifestyle.

Key points to remember regarding your choice

Discussing with your physician about your lifestyle and your expectations regarding your visual quality and needs is of the highest importance. You should always refer to your treating physician whenever you are in need of any further details. There are many types of intraocular lenses on the market, but if reduced dependence on glasses and the possibility to see from far, intermediate and near distance are your desired outcomes, the POD F GF (FINEVISIONHP ) is a suitable choice.

What are the characteristics of your intraocular lens?

The lens discussed in this informative brochure is called POD F GF FINEVISIONHP, based on the Finevision technology. It is a trifocal lens, which means it allows you to see clearly from far, intermediate and near distances with less spectacle dependence. It is made from an acrylic hydrophobic material. The material has been specifically designed by Physiol SA with the added property of ultraviolet and blue light filtration. Those filters were selected to better simulate the natural physiologic properties of your eye lens removed during cataract surgery. The material is also completely tolerated by the eye natural tissues (biocompatible) and it has been thoroughly checked and validated during all required standardized tests. No specific interactions of your implant with surrounding electrical systems (For example, Magnetic Resonance Imaging technology, used during body scans) is expected.

What are the potential benefits of your implanted intraocular lens?

Several benefits might be expected with the type of lens you have been implanted with:

- First of all, the main goal of any intraocular lens is to restore your visual quality lost during cataract progression: recovery of a certain level of independency regarding your daily activities is the main advantage of such procedure.
- The Trifocal technology has been designed to restore your far (such as television watching, car driving, sports and outdoors activities), intermediate (for daily

activities, such as computer & tablet work, cooking) and near vision (such as reading, sewing, handiwork, shaving and applying make-up) with less spectacle dependence. Due to this technology, you may however require some adaptation time. It is to note that this specific lens has been designed to favorize the visual quality at far and near distances.

- All trifocal intraocular lenses using diffractive technology may cause some visual disturbances, those being intrinsically related to the multifocal technology. However, the POD F GF has been specifically designed to diminish those visual effects.
- The material that has been chosen for the POD F GF is aimed at reducing post-surgery complications that were documented with previous IOL lens materials. It may also reduce some visual effects known could occur with other materials.

What are the risks related to your surgery and implant?
Several adverse effects may occur following your lens surgical replacement. However, you have to know that with any surgical procedure (related to the cataract or not), there are risks involved. These risks are rare and are outweighed by the potential benefits of restoring your vision.
Surgery risks include reactions to medicines, reactions to the surgical procedure itself and 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 -as in any intraocular lens surgical implantation procedure- a secondary surgical intervention for intraocular lens, repositioning, exchange or explantation. Should you experience any undesirable effects, you can contact your treating physician, the Competent Health Authorities of your country or possibly also the manufacturer (Physiol SA, contact information available at the end of this brochure).
In addition, you may present some side effects due to the design of your implanted lens. These side effects may make it more difficult to see while driving at night or for you to complete other tasks in a room with low lighting. They present as glare, rings around lights, and blurred vision. Those inconveniences may diminish overtime as your brain will progressively get adapted to interpreting perceived images trough your intraocular lens.
Should you take precautions?
Your surgery will be performed as per standard of care and your surgeon is well-versed into this type of technology and surgery. He is provided with the adequate instruction for use related to your lens implantation. The lens has been chosen to optimally fit your vision requirements.
As a measure of precaution, you should strictly follow your physicians 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.
It is to note that trifocal lenses, the type of lens you have been implanted with, may cause some visual disturbances in low-light conditions. You should thus exercise caution when driving at night or in poor visibility conditions.
Required exams and follow-ups
If you have been enrolled into a clinical trial related to the device, you have signed consent and are asked to comply with exams and follow-ups as designed by the clinical investigation protocol. Otherwise, exams and follow-ups will be determined by your treating physician and per your hospital standard practice.
Are there any contra-indications to this intraocular lens?
Contraindications to the device implantation are the presence of pre-existing eye diseases that could be aggravated by the implant, and/or diseases where the implant may interfere with the possibilities of treatment or examination. Your treating physician will proceed to the assessment of those and will evaluate the possibility of the lens implantation. Should you be aware that you may present any pre-existing conditions related to your eye, please refer to your physician.
Contraindications may include eye infection, eye inflammation, previous damage to your eye caused by external trauma or previous surgery, eye diseases such as glaucoma or inherited cataract.
Finally, patients with significant preoperative astigmatism (blurriness at all distances due to the imperfect curvature of the eye cornea) or those who are expected to present astigmatism post-operatively are contraindicated as they may not obtain optimal visual performances.
Manufacturer Information
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+32 (0)4 361 05 49 - https://www.bvimedical.com/wp-content/uploads/2021/10/Leaflet-POD-F-GF.pdf

Expected lifetime of the device
The expected lifetime of the device is set at 20 years.
Reporting Serious Event
Always follow your doctor's instructions. Any serious event that you experience in relation to the device, you

can report to the manufacturer or the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems

Sponsor Information
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