Intraocular Lens – Patient Information Leaflet

The information in this document must be provided to the patient receiving the implanted intraocular lens (IOL). This document is designed to assist in understanding what the device is so that patients can ask relevant clinical questions from their healthcare team. It also helps to direct them in cases where any device-related serious incidents need to be reported.

This leaflet relates to the list of IOLs in the Appendix attached.

Intended Purpose:

The IOL is intended to replace the clouded natural lens during a cataract surgery.

Intended Performance:

The IOL is designed to focus light entering your eye so that you may see clearly. The IOL is surgically positioned in the lens capsule within your eye. It replaces the function of the natural crystalline lens, which is removed prior to implanting the IOL.

Undesirable Side Effects:

Depending on the IOL model implanted, you may need to wear glasses in order to see clearly at different distances.

Potential risks during or following cataract surgery with implantation of an IOL may include, but are not limited to:

1. Endophthalmitis (inflammation of two or more adjacent coats of the eye) /intraocular infection
2. Hypopyon – a medical condition involving inflammatory cells in the eye
3. Hyphema – blood collecting inside the front of the eye
4. IOL dislocation
5. Cystoid macular oedema – accumulation of ‘cyst-like’ sacs of fluid in the macula, the centre of the retina
6. Pupillary block – blockage of normal flow of fluid in the eye
7. Retinal detachment/tear
8. Persistent corneal stromal oedema – persistent build up of fluid in the cornea
9. Persistent inflammation
10. Persistent raised intraocular pressure requiring treatment
11. Acute corneal decompensation – temporary functional deterioration of the cornea
12. Secondary intraocular surgical intervention - including implant repositioning, removal, Anterior Chamber Tap (controlled drainage of fluid from the eye) performed later than one week after cataract surgery, or other surgical procedure
13. Any other adverse incident that leads to permanent visual impairment or requires surgical or medical intervention to prevent permanent visual impairment

Warnings and Precautions:

1. Before the surgery, if you wear contact lenses, your healthcare team may ask you to stop wearing them before being tested for the IOL.
2. Before the surgery, inform your healthcare team if you have any health conditions that may affect your surgery or vision. Examples include high blood pressure, diabetes, and heart disease.
3. After the surgery, you may begin to see better within 1 to 2 days. Some are stable at 10 to 14 days. Some may take 4 to 6 weeks to recover from surgery. Improvements in vision are different for each person.
4. Please follow the directions from your healthcare team following implantation, in order to minimise the likelihood of IOL movement and infection.
5. You may experience unwanted visual symptoms such as glare and rings around lights at night. Image quality such as contrast may also vary between IOL models. Caution should be taken when driving at night or in poor visibility conditions.
6. Call your healthcare team immediately if you experience any itching, pain, flashing lights, “floaters”, redness, severe headache, nausea/vomiting, light sensitivity, or watery eyes after surgery.

Recommended Monitoring:

1. You will return home after the surgery. Your healthcare team will give you antibiotic eye drops and medicines to speed up healing and to prevent infection. Take all prescribed medicines and apply eye drops as instructed by your healthcare team.
2. You will be given a date and time for a follow-up visit. It is typically the next day. Your healthcare team will examine you several more times following your surgery. It may take you some time to get used to your new IOL.
3. This device is for permanent implantation and not intended for removal once implanted. However, if you notice any pain, redness, discomfort, or if your vision deteriorates over time, you should contact your healthcare team to see how they can assist.

Materials Used:

Refer to Appendix attached.

All IOLs are supplied sterile.

Reporting of Serious Incidents:

Any serious incident that occurs in relation to the device should be reported to Johnson & Johnson Surgical Vision’s Customer Service by calling 1800 266 111 or via email to surgicalvisionanz@its.jnj.com. It should also be reported to the Therapeutic Goods Administration. Their website is https://www.tga.gov.au/.

Australia Sponsor:
AMO Australia Pty Ltd, 17 Khartoum Rd, Macquarie Park, NSW 2113, Australia

Legal Manufacturer:
Johnson & Johnson Surgical Vision, Inc.
31 Technology Drive, Suite 200, Irvine, CA 92618 USA
www.jnj.com

Appendix: List of IOLs

IOL Model Name / Material	IOL Model Number
TECNIS Synergy™ OptiBlue™ IOL / soft acrylic with yellow dye and UV blocker	ZFR00V
TECNIS Symfony™ Extended Range of Vision IOL / soft acrylic	ZXR00
TECNIS Symfony™ Extended Range of Vision Toric IOL / soft acrylic	ZXT100-600
TECNIS Eyhance™ IOL / soft acrylic	ICB00
TECNIS™ 1-Piece IOL / soft acrylic	ZCB00
TECNIS™ Toric 1-Piece IOL / soft acrylic	ZCT100-800
TECNIS™ Foldable Acrylic IOLs with OptiEdge Design / soft acrylic with polymethylmethacrylate	ZA9003
SENSAR™ Foldable IOL with OptiEdge Design / soft acrylic with polymethylmethacrylate	AR40e/E/M
TECNIS™ 1-Piece IOL with TECNIS Simplicity™ Delivery System / soft acrylic	DCB00
TECNIS Eyhance™ IOL with TECNIS Simplicity™ Delivery System / soft acrylic	DIB00
TECNIS Synergy™ Toric II OptiBlue IOL /soft acrylic with yellow dye and UV blocker	ZFW100-600
TECNIS Eyhance™ Toric II IOL / soft acrylic	ICU100-800
TECNIS™ Toric II 1-Piece IOL / soft acrylic	ZCU100-800
TECNIS Eyhance™ Toric II IOL TECNIS Simplicity™ Delivery System / soft acrylic	DIU100-800

Please be advised that not all SENSAR™ and TECNIS™ platform families of intraocular lenses (IOLs) are currently listed, and PILs for EU MDR-compliant IOL devices are available at www.ic.jnjmedicaldevices.com.