Addendum to Patient Information Leaflet for intraocular lenses for Patients residing in Australia

Dear patient,

This Addendum is to provide additional information to the current Patient Information Leaflet for intraocular with respect to the new regulation EP13A.3 of Therapeutic Goods Administration (TGA), Australia.

FOR WHICH INTRAOCULAR LENS MODELS MANUFACTURED BY HUMANOPTICS HOLDING AG IS THIS PATIENT INFORMATION INTENDED FOR?

IOL models:

Monofocal, aspherical: Aspira-aA, Aspira-aAY, Aspira-aXA, Aspira-aXAY

Monofocal toric: Torica-aA, Torica-aAY

Multifocal aspherical: Triva-aA, Triva -aAY, Triva -aXA, Triva -aXAY

Multifocal toric: TrivaT-aA, TrivaT-aAY

INTENDED PERFORMANCE OF IOLS

All IOLs covered by these instructions replace the crystalline lens after surgical removal of the natural lens and are designed to focus light passing through the cornea and pupil onto the retina, like the eye's natural lens.

All models have an aspheric optic design, which is aberration-free (spherical aberration).

Monofocal IOLs provide clear vision at one focal point (usually far focus).

The models with the ending -aXA/-aXAY are designed with a large optic of 7 mm to prevent incoming light to scatter at the edge of the lens optic, thereby minimizing photopic phenomena.

Multifocal IOLs contain a hybrid optic which combines a central diffractive zone with gradual tapering and a peripheral refractive zone in order to create three (Triva) focal points, thereby restoring visual acuity at near (addition +3.5 D at IOL plane), intermediate (addition +1.75 D at IOL plane) and far distance.

Toric IOLs correct corneal astigmatism. Therefore, the IOL meridians of strongest and of weakest refraction are aligned opposite to those of the astigmatic cornea during implantation.

Multifocal toric IOLs combine the principles of multifocal and toric lenses.

All yellow IOLs (-Y) contain a blue light filter that absorbs the high-energy portion of the blue short-wave light.

THE MATERIALS AND SUBSTANCES INCLUDED IN THE DEVICE:

IOLs contains no manufacturing residuals that could pose a risk to the patient.

REPORTING OF SERIOUS INCIDENTS

If a severe adverse event occurs, the doctor must report it to the national / local authorized representative, distributor if sold from a distributor and the manufacturer HumanOptics by calling 49 (0) 9131 50 66 5-0 or via email to mail@humanoptics.com and as well as to the Therapeutic Goods Administration (TGA). Their website is https://www.tga.gov.au/