

**Company**

Alcon

**Drug or Device Name**

AcrySof™ IQ Vivity™ Extended Vision Intraocular Lens (IOL)

**Category**

Medical Technology

**Compound/Technical Name**

N/A

**Trade Name**

AcrySof™ IQ Vivity™ Extended Vision Intraocular Lens (IOL)

**Date of Approval**

02/26/2020

**Therapeutic Categories**

Ophthalmology Cataracts Cataract surgery

**Indications**

The AcrySof™ IQ Vivity™ Extended Vision IOL Model DFT015 is indicated for primary implantation for the visual correction of aphakia in adult patients with < 1.00 D of preoperative corneal astigmatism, in whom a cataractous lens has been removed by extracapsular cataract extraction. The lens mitigates the effects of presbyopia by providing an extended depth of focus.<sup>1</sup>

**Background**

Cataracts are the most common cause of vision loss globally with over 28M cataract surgeries performed globally each year.<sup>2</sup> But there is a looming boom in the aging population. By 2025, approximately 5.4M cataract surgeries will be performed in the U.S. and by 2050, that number is expected to double.<sup>3,4</sup> Globally, the number of surgeries is anticipated to reach over 60M by 2045.<sup>2</sup> Cataracts are the cloudiness of the natural lens of the eye that can lead to vision loss and decreased quality of life. During cataract surgery, the lens is replaced with an artificial lens known as an intraocular lens (IOL). IOLs can now correct patients' vision at the time of surgery to help achieve their vision goals.<sup>5</sup> More spectacle independence hasn't always been an option for all patients, only those who are candidates for diffractive IOLs. A diffractive IOL splits light, creating distinct images at certain distances which improves vision. However, there can be side effects to diffractive IOLs, including halos and glares. Because of this, 2 to 3 out of every 10 patients are disqualified from diffractive IOLs and typically receive a traditional monofocal IOL, which only corrects distance vision and does not have the visual disturbance profile (e.g., halos and glares) of a diffractive IOL. This includes patients with glaucoma or other conditions, leaving many without an advanced IOL option that is right for them.<sup>6</sup> Diffractive lenses can also require significant surgeon training to implant as landing 20/20 vision can be difficult with the calculations, measurements and anatomical considerations, leaving many surgeons hesitant to implant diffractive IOLs to avoid patient dissatisfaction.<sup>6</sup> To address the unmet needs, Alcon saw an opportunity to develop a non-diffractive IOL that mitigates glares and halos, which could be easier to implant like a monofocal lens and land 20/20 vision.<sup>6</sup>

**Development**

Alcon has a strong commitment to research and development efforts and prioritizes finding solutions that address the unmet needs of surgeons and patients to help people See Brilliantly. The creation of Vivity was a monumental R&D effort as Alcon embarked on the journey to develop the first and only non-diffractive extended depth of focus IOL. The team considered the lifestyle needs of patients that were previously disqualified from diffractive lens options. They evaluated the compromises patients have had to make with multifocal lenses and the impact it has on achieving their

vision goals, specifically for fewer visual disturbances. For the aging population, Alcon wanted to offer a solution that allowed patients to have clearer vision while doing the things they love, such as watching children play, working on a computer, reading and driving a car. Vivity is unique due to its visual benefits of being a presbyopia correcting IOL (PC-IOL) while having a monofocal-like disturbance profile (i.e., limited halos and glares). To achieve these visual benefits, Alcon's R&D team developed Vivity by leveraging an innovative, patented technology called X-WAVE™. X-WAVE technology features two smooth surface transition elements in the central 2.2mm of the IOL. The first surface transition element is a slightly elevated smooth plateau that is about 1 micron in height which stretches the focal range. The second surface transition element is a small curvature change which shifts the wavefront to the anterior side of the retina to utilize all available light energy. These two smooth surface transition elements work together to stretch and shift without splitting light creating an extended focal range.<sup>7</sup> This process is something that has never been done in an IOL, setting Vivity apart from other IOL offerings.

### Innovation

The AcrySof® IQ Vivity® lens is the first of its kind, non-diffractive extended depth of focus IOL with Alcon's proprietary X-WAVE™ technology.<sup>8</sup> X-WAVE allows Vivity to have a clinically proven monofocal visual disturbance profile and unsurpassed clarity.<sup>9-12</sup> Vivity is designed to provide a superior halo profile compared to diffractive extended depth of focus (EDOF) lenses, making it accessible to patients who weren't candidates for diffractive multifocal lenses. By introducing Vivity, Alcon has been able to bring more surgeons into the fold of implanting advanced technology IOLs allowing more patients the option of correcting their vision at the time of cataract surgery. Alcon ensured Vivity could be implemented by even more surgeons, not just the most advanced surgeons. Now, more surgeons can offer Vivity to their patients who are interested in restoring their visual performance and improving their lifestyle, and therefore expand access to this offering. Over 363K eyes have been implanted with Vivity in the US alone – many who would have otherwise received a standard monofocal IOL. Patients are exceedingly satisfied with their results. 94% and 92% of Vivity patients reported very good or good vision at distance and arm's length, respectively, without glasses in bright light, with vision of 20/20 at distance, greater than 20/25 at intermediate and 20/32 at near. <sup>13</sup> Statistics aside, what is most remarkable are the quality of life improvements that coincide with Vivity. With improved vision, patients may no longer need readers and are less likely to experience injuries, such as hip fractures that result from falls.<sup>14</sup> Vivity showcases the impact of ATIOLs and what the future of cataract surgery means for patients. With greater access to IOL options, more patients can experience renewed vision and freedom to do the activities they love the most. \*Results from a prospective, randomized, parallel group, subject- and assessor-masked, multisite trial of 107 subjects bilaterally implanted with the AcrySof® IQ Vivity™ IOL and 113 with the AcrySof® IQ IOL with 6 months' follow-up

### Pubmed

References: 1. AcrySof™ IQ Vivity™ Extended Vision Intraocular Lens (IOL) (Model DFT015), AcrySof™ IQ Vivity™ Toric Extended Vision IOLs (DFT315, DFT415, DFT515), AcrySof™ IQ Vivity™ Extended Vision UV Absorbing IOL (DAT015), and AcrySof™ IQ Vivity™ Toric Extended Vision UV Absorbing IOLs (DAT315, DAT415, DAT515) - P930014/S126 | FDA 2. Lindstrom, Richard L. (2021). Future of cataract surgery seems promising. Healio.) 3. Cataract Data and Statistics. National Eye Institute. Accessed December 21, 2020. <https://www.nei.nih.gov/learn-about-eye-health/resources-for-health-educators/eye-health-data-and-statistics/cataract-data-and-statistics>. 4. Blindness and vision impairment (who.int) 5. Cataracts Overview. Mayo Clinic. 02 Sept 2021. <https://www.mayoclinic.org/diseases-conditions/cataracts/symptoms-causes/syc-20353790#:~:text=A%20cataract%20is%20a%20clouding,frosty%20or%20fogged%20Dup%20window>. 6. 2021 Capital Markets Day. Alcon. 24 March 2021. <https://investor.alcon.com/news-and-events/events-and-presentations/event-details/%2021/2021-Capital-Markets-Day/default.aspx> 7. US-VIV-2000073 Vivity View MOA 8. Alcon Data on File. TDOC-0055576. 09 Apr 2019. 9. Clareon Vivity IOL Directions for Use. 10. Alcon Data on File. TDOC-0055576. 09 Apr 2019. 11. Bala C, et al. Multi-country clinical outcomes of a new nondiffractive presbyopia-correcting intraocular lens. J Cataract Refract Surg. 2022;48(2):136-143. 12. Werner L, Thatthamla I, Ong M, et al. Evaluation of clarity characteristics in a new hydrophobic acrylic IOL in comparison to commercially available IOLs. J Cataract Refract Surg. 2019;45(10):1490-1497. 13. AcrySof® IQ Vivity™ Extended Vision IOL DFU. Alcon Laboratories, Inc.; 2020. 14. Cataract surgery may help lower hip fracture risk. Harvard Health Publishing. 1 Oct 2012. <https://www.health.harvard.edu/diseases-and-conditions/cataract-surgery-may-help-lower-hip-fracture-risk#:~:text=Cataract%20surgery%20can%20help%20prevent%20hip%20fractures%20that,continue%20reading%20this%20article%2C%20you%20must%20log%20in>. PubMed Links Extended depth-of-focus (EDOF) AcrySof® IQ Vivity® intraocular lens implant: a real-life experience - PubMed (nih.gov) Optical Bench Analysis of 2 Depth of Focus Intraocular Lenses - PubMed (nih.gov) The Effect of Spectacle-Induced Low Myopia in the Non-Dominant Eye on the Binocular Defocus

Curve with a Non-Diffractive Extended Vision Intraocular Lens - PubMed (nih.gov) Profile of a new extended range-of-vision IOL: a laboratory study - PubMed (nih.gov) Optical and Clinical Outcomes of an Extended Range of Vision Intraocular Lens - PubMed (nih.gov) Quantitative biometric cutoffs for the choice of the intraocular lens power calculation formula for a recently introduced nondiffractive extended depth-of-focus intraocular lens - PubMed (nih.gov) Nondiffractive wavefront-shaping extended depth-of-focus intraocular lens: visual performance and patient-reported outcomes - PubMed (nih.gov) Enhanced Depth-of-focus Intraocular Lenses: Latest Wavefront-shaped Optics versus Diffractive Optics - PubMed (nih.gov) Effect of minimonovision in bilateral implantation of a novel non-diffractive extended depth-of-focus intraocular lens: Defocus curves, visual outcomes, and quality of life - PubMed (nih.gov) Unilateral implantation of a new non-diffractive extended range-of-vision IOL in a young patient with Curschmann-Steinert myotonic dystrophy - PubMed (nih.gov) The Vivity Extended Range of Vision IOL vs the PanOptix Trifocal, ReStor 2.5 Active Focus and ReStor 3.0 Multifocal Lenses: A Comparison of Patient Satisfaction, Visual Disturbances, and Spectacle Independence - PubMed (nih.gov) Visual outcomes of a new nondiffractive extended depth-of-focus intraocular lens targeted for minimonovision: 3-month results of a prospective cohort study - PubMed (nih.gov) Clinical Outcomes in a United States Registration Study of a Novel Extended Depth of Focus Intraocular Lens with a Nondiffractive Design - PubMed (nih.gov) Evaluation of Quality of Vision and Visual Outcomes with Bilateral Implantation of a Non-Diffractive Extended Vision Intraocular Lens with a Target of Slight Myopia in the Non-Dominant Eye - PubMed (nih.gov) Presbyopia correction after previous Intracor treatment: Combined implantation of a small-aperture and a non-diffractive extended-depth-of-focus lens - PubMed (nih.gov) Profile of a new extended range-of-vision IOL: a laboratory study - PubMed (nih.gov) Optical and Clinical Outcomes of an Extended Range of Vision Intraocular Lens - PubMed (nih.gov)

**Attachments**

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