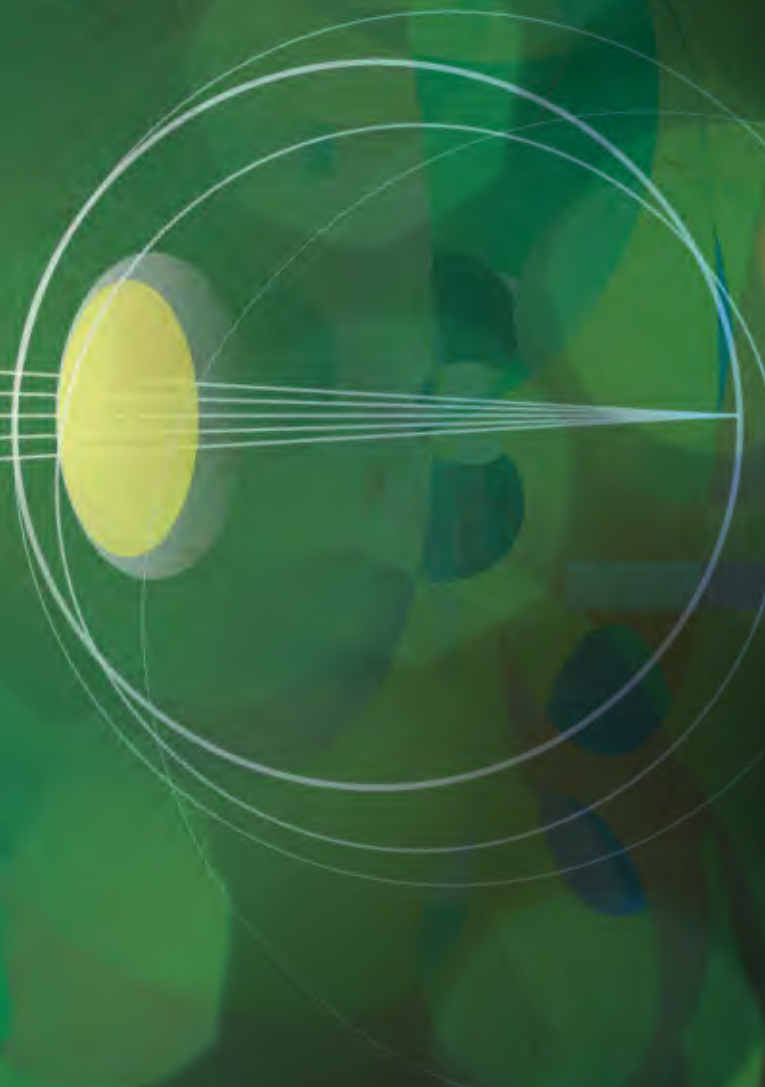


Clareon[®] IOL: A New Monofocal Platform

Highlights from Alcon's Satellite Symposium, held on October 9, 2017, at the XXXV Congress of the ESCRS, Lisbon, Portugal.



Presenters

Rudy Nuijts, Maastricht University Medical Center, Maastricht, The Netherlands (Moderator)

Liliana Werner, John A. Moran Eye Center, University of Utah, Salt Lake City, Utah, USA

Gerd Auffarth, International Vision Correction Research Centre (IVCRC), David J. Apple International Laboratory for Ocular Pathology, University of Heidelberg, Heidelberg, Germany

Stephen Lane, Clinical Professor of Ophthalmology at the University of Minnesota and Medical Director of Associated Eye Care in Stillwater, Minnesota, USA; and Chief Medical Officer of Alcon

This supplement solely reflects the views, opinions and experiences of presenters who participated in the ESCRS congress in Lisbon on October 9, 2017. Data presented are representative of each participating surgeons' own experience, and do not arise from formal clinical studies. Trademarks are the property of their respective owners.

Clareon® IOL: A New Monofocal Platform

Cataract surgery is constantly advancing and evolving, and one key area of innovation is the intraocular lens (IOL) design and biomaterial. Alcon is a company which has a vast history of manufacturing and developing best in class IOLs. Recently, Alcon has achieved 100 million implantations of the AcrySof® platform, one of the world's most frequently implanted IOLs (1). Alcon is also a customer centric company and listens to feedback from cataract surgeons about the improvements they would like to see in the next generation of IOLs – specifically, high biocompatibility and even greater optical clarity. Hence, Alcon has developed a next generation of IOLs: Clareon®.

Clareon® is an advanced monofocal IOL that is made from a new hydrophobic acrylic material and enhanced manufacturing process, along with the trusted AcrySof® platform features (2; see Box 1). These two key innovations enable the Clareon® precision edge design (3), which bestows several benefits, including significantly lower edge glare (4) and low incidences of posterior capsule opacification (PCO) – and subsequent YAG rates (2). Previous studies in Europe and Japan performed with the same Clareon® IOL material have shown Nd:YAG rates of 1.5 and 0 %, respectively (2), which is comparable to current AcrySof® data (2.2 %) (5).

AutonoMe™ Clareon® was presented at the XXXV annual Congress of the ESCRS in Lisbon, Portugal, where leading cataract surgeons overviewed data on Clareon® bio-optics, biomechanics and biomaterial features, and also introduced the AutonoMe™ pre-loaded IOL delivery device.

Box 1 – Clareon®: A New Monofocal IOL Platform

Key Bio-optics Features

- Precision edge design to minimize potential for edge glare and positive dysphotopsias, as well as guarding against PCO and minimizing Nd:YAG procedures (2-4)
- Fully usable 6 mm biconvex aspheric optic (6)
- UV and blue light filtering (2)
- Refractive index: 1.55 (2)

Key Biomechanics Features

- STABLEFORCE™ Haptics for low axial displacement, decentration

and tilt (7)

- Rapid and controlled unfolding, with haptics that remain planar (8)

Key Biomaterial Features

- Unsurpassed optical clarity (9-12)*
- Manufactured using an advanced process (12)
- Resistant to phase separation (9)
- Amongst the lowest level of surface haze, subsurface nanoglistenings (SSNGs), and glistenings of competitive monofocal IOLs (9-12)*

<i>Lens Specifications</i>	<i>Clareon®</i>
Optic type	Asymmetric biconvex optic
Asphericity	-0.2 µm (anterior surface)
Optic material	Hydrophobic acrylic
Optic diameter	6.0 mm diameter
Overall length	13.0 mm
IOL powers (equivalent diopters)	+6.0 to +30.0 D (in 0.5 D increments)
Haptic angulation	0° planar
Haptic configuration	STABLEFORCE™ modified IOL haptics
Photoprotection	UV and blue light filtration
Refractive index	1.55
Suggested A-constant (SKR-T)	119.1 (PCI-Optical)

PCI, partial coherence interferometer.

Precision edge design (3)



*Based on aggregate results from in vitro evaluations of haze, SSNGs and glistenings compared to TECNIS® OptiBlue® ZCB00V (Abbott), TECNIS® ZCB00 (Abbott), Eternity Natural Uni® W-60 (Santen), Vivinex® XY-1 (HOYA) and enVista® MX60 (B&L; Bausch & Lomb). ®Trademarks are the property of their respective owners.

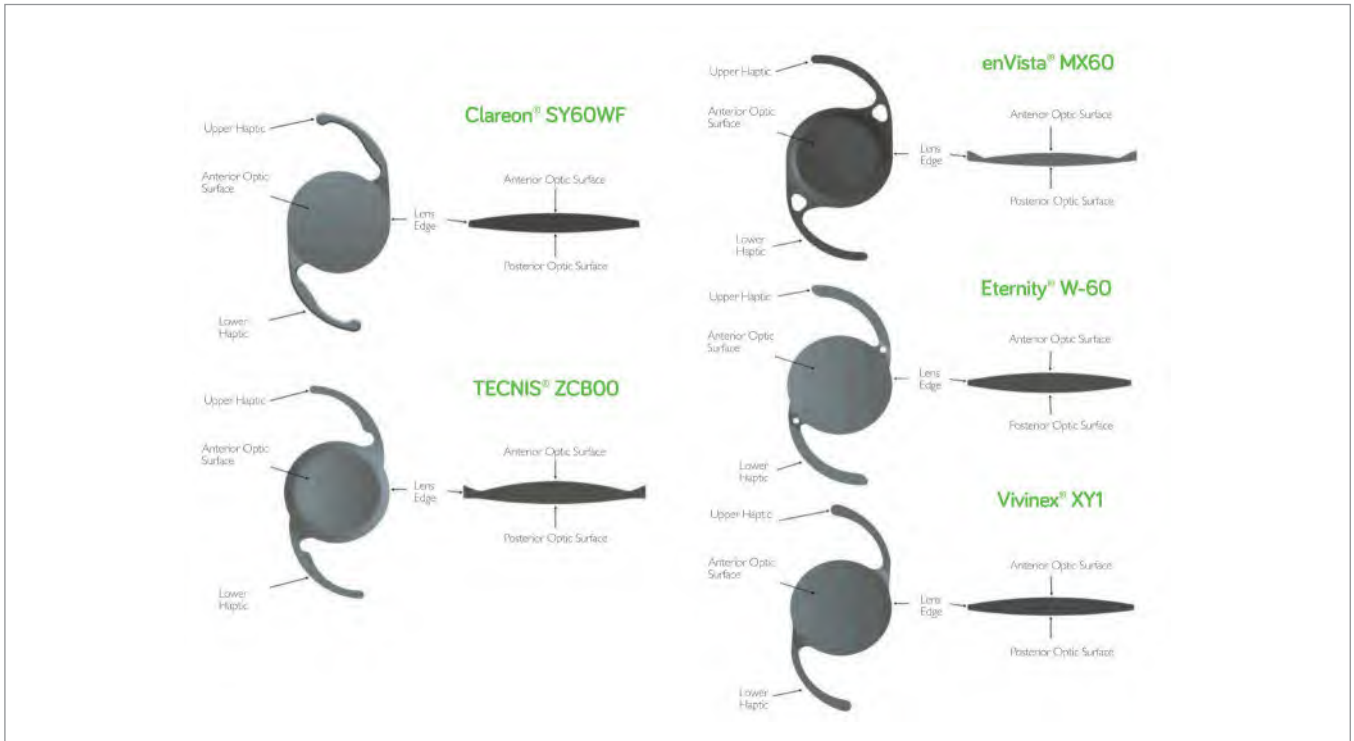


Figure 1. Reverse engineering and SolidWorks 3D software IOL models based on high-resolution images and direct lens measurements for the five IOLs studied.

Biooptics – delivering sharp, crisp vision (2)

Liliana Werner was the first to present the bio-optical properties of Clareon®, and focused on positive dysphotopsia and glare type phenomena. IOLs can induce stray light artifacts or veiling glare into the eye (13), and Dr. Werner explained that “glare and photic phenomena can be affected by the edge profile of the lens as well as by additional components of the IOL (14).” Clareon® has an advanced design, including a fully usable 6 mm aspheric optic (6) and the ‘precision edge design’ – which helps mitigate edge glare (3,4).

Dr. Werner overviewed an *in vitro* study in which Clareon® was compared with four commercially available single piece hydrophobic monofocal IOLs (Eternity®, Santen; enVista®, Bausch + Lomb; TECNIS®, Johnson and Johnson Vision; and Vivinex® iSert®, HOYA

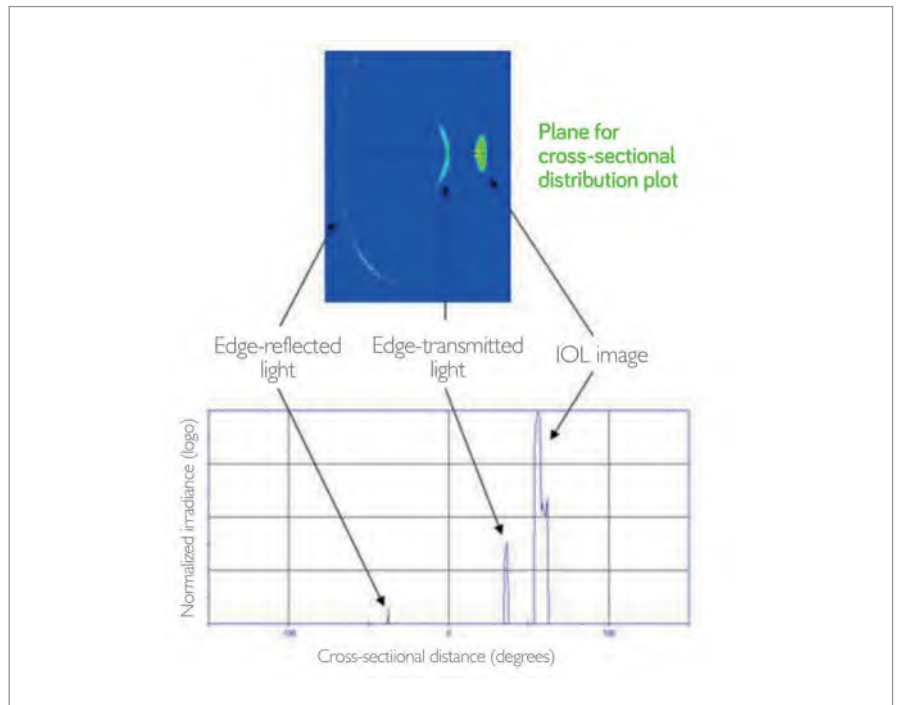


Figure 2. Non-Sequential ray trace model eye simulation from analysis of Clareon® IOL

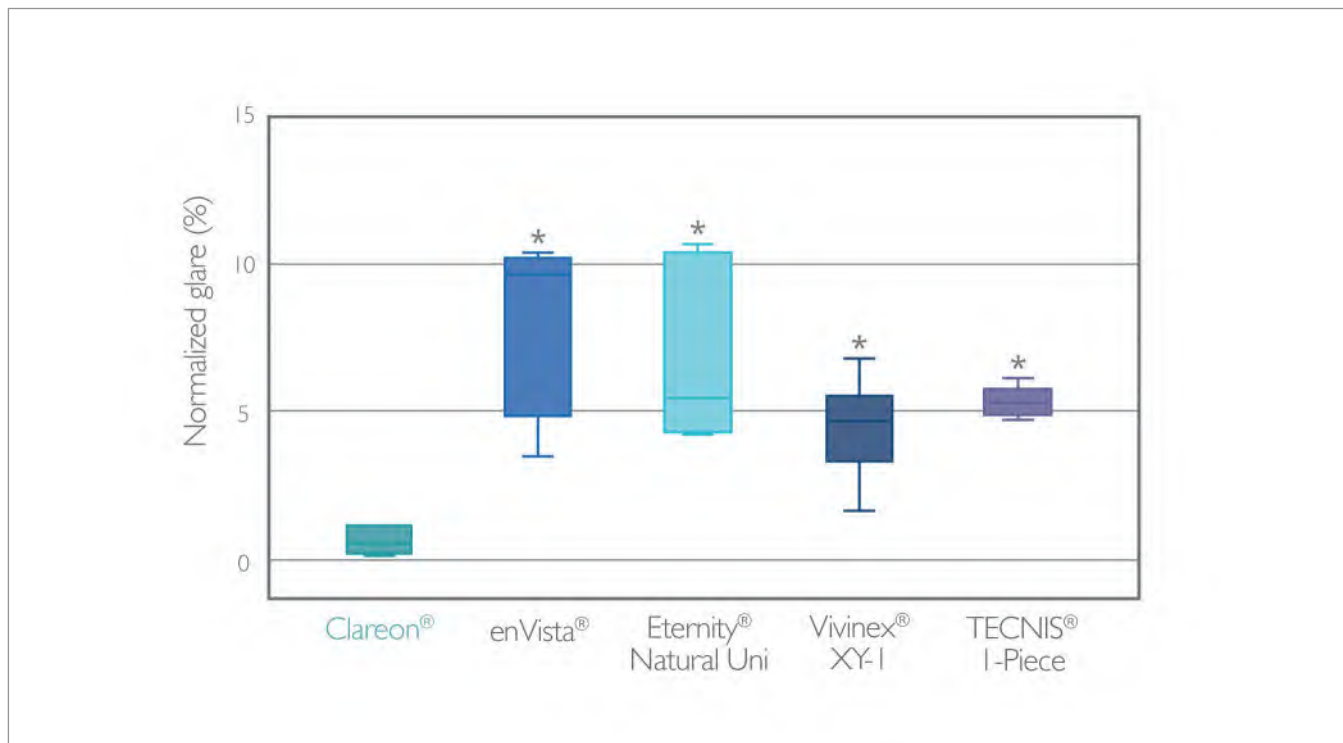


Figure 3. Distribution of normalized glare/main beam ratio comparison at a 55° illumination angle *in vitro* (n = 5 IOLs per group). Evaluated in a schematic model eye and *in vitro* evaluation of positive dysphotopsia or glare types photic phenomena. Optical ray trace simulations of incoming light were generated based on a collimated light source with a wavelength of 550 nm for various off-axis angles of illumination (n=5 IOLs per group, +25.0 D). The simulation analyses were verified using a laboratory glare bench-top measurement system, whereby glare components formed from off-axis illumination of IOLs fitted into an artificial eye model were measured (15).

Surgical Optics IOLs) (15). The aim of this study was to evaluate the photic phenomena for all these IOLs. First, SolidWorks was used to create IOL models for this study (Figure 1).

The assessment of glare type photic phenomenon was done using a non-sequential ray trace program in a schematic model eye. The results of the simulations were verified by an *in vitro* glare bench method. From model eye simulations, Clareon® was the only tested IOL that produced only focused images (Figure 2). Vivinex® iSert® XYI showed focused images similar to those observed with the Clareon®, however there was an additional edge-transmitted glare component. Both TECNIS and enVista lenses produced dispersed images and

glare characteristics, whilst Eternity® W-60 showed a high edge reflected glare characteristic, a feature that Dr. Werner ascribed as being “likely because of its sharp edge geometry.”

Results from the laboratory bench images and glare intensity profiles were consistent with the model eye simulation data and verified that Clareon® showed significantly lower glare than the other tested lenses at large angles, such as 50° and 55° angles (Figure 3) of incidence.

Dr. Werner concluded that lenses with modified anterior edge curvature, for example, the precision edge design of Clareon®, and a full optic profile without peripheral design features demonstrated the lowest level – or absence – of glare components over a wide range of incident

angles. Further clinical studies are needed to confirm if these differences observed *in vitro* are clinically significant.

Biomechanics – maximizing refractive predictability

Following implantation, the mechanical stability of IOLs can affect clinical outcomes. For example, axial IOL displacement can lead to refractive errors and other complications, such as pigmentary dispersion syndrome or pupillary IOL capture. Postoperative optic tilt and decentration can also be problematic as they can affect lens performance (16). Typically, lenses are designed for an average capsular size which is 10 mm (17).

“Results verified that Clareon® showed significantly lower glare than the other tested lenses at 50° and 55° angles of incidence.”

Multiple studies have shown that the AcrySof® IQ monofocal IOL exhibits excellent IOL positioning stability and precise centration, with consistent axial lens position and refractive outcome predictability (18–21).

Dr. Werner described a study performed by Dr. Stephen Lane et al. (22) that compared the Clareon® IOL with AcrySof®, enVista, TECNIS, and Vivinex iSert IOLs. Ten of each lens (+ 20.0 D) were tested in deionized water at 35°C for axial displacement, optic tilt and decentration. For assessments of axial displacement, lenses were compressed to the following diameters: 11.0, 10.5, 10.0, 9.5 and 9.0 mm, and the effects of the compression on the axial displacement and corresponding power change were measured. Optic decentration and optic tilt were each measured at 10 mm of compression.

Clareon® and AcrySof® showed significantly lower ($P < 0.001$) axial displacement at 10 mm compression (Figure 4a) compared with all other tested lens models.

When the IOLs were compressed at different diameters, Clareon® and AcrySof® showed the lowest axial

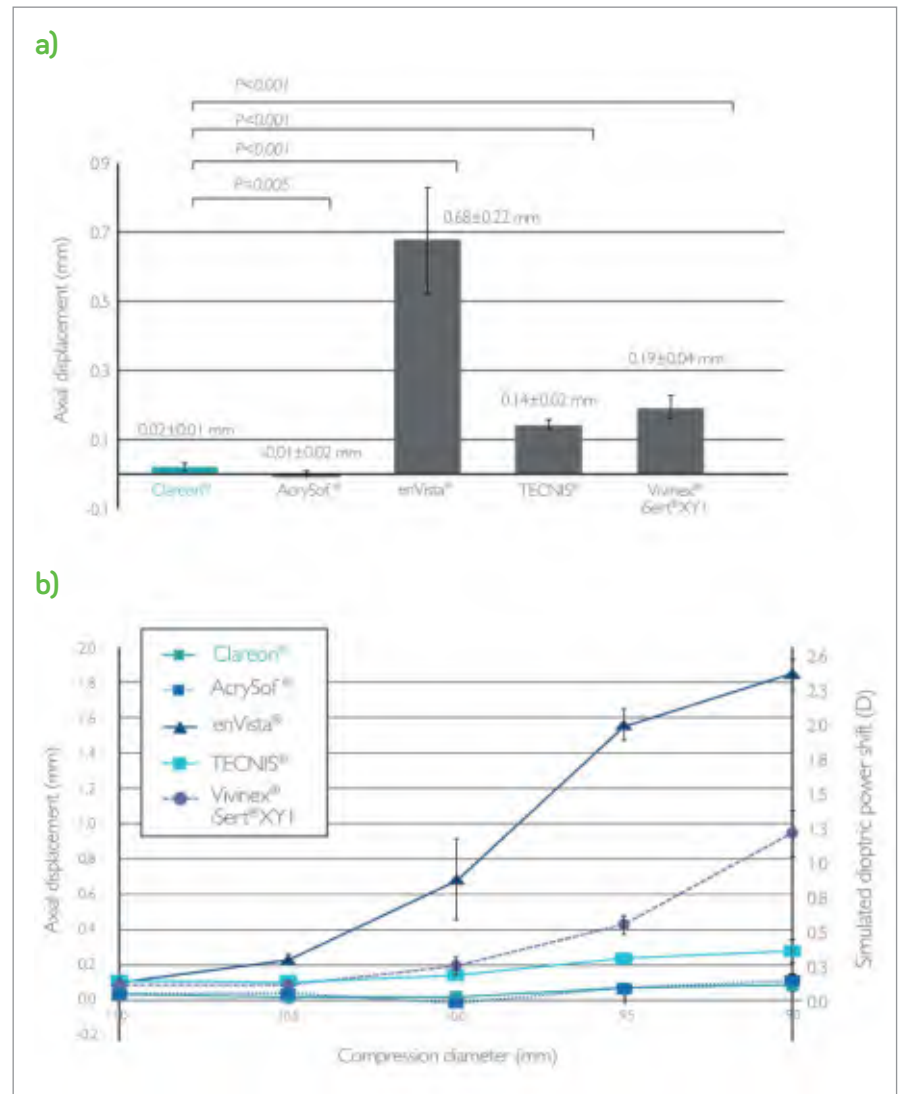


Figure 4. Axial displacement at 10 mm compression (a) and axial displacement and simulated dioptric power shifts for five compression diameters (b) of Clareon® and AcrySof® compared with other commercially available monofocal IOLs. P-values for axial displacement vs. Clareon®.

displacement and simulated dioptric power shifts at the corneal plane at all 5 compression diameters studied (Figure 4b).

Dr. Werner showed example images of the lenses in their compressed (9 mm) and uncompressed states (Figure 5), commenting, “You can appreciate that some designs have much higher axial displacement.”

In terms of optic decentration and

optic tilt, Dr. Werner highlighted the great performance of all IOLs evaluated, with decentrations being within 0.06 mm and tilt no greater than 1.2° for all IOLs tested (Figure 6). Mean Clareon® optic decentration was found to be 0.04 ± 0.02 mm, which is lower than the maximum 0.6 mm (sum of the mean and two standard deviations) specified by the International Organization for Standardization (ISO; 23). Similarly,

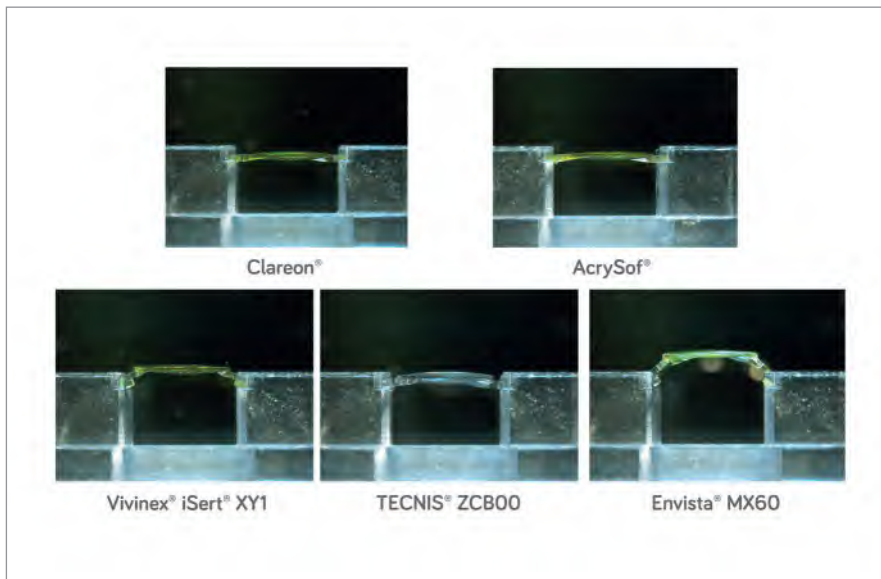


Figure 5. Example images of IOLs compressed at 9.0 mm overall diameter.

“Both Clareon and AcrySof lenses are very stable and have a similar intraocular performance in the capsular bag.”

Clareon® was well below the maximum ISO-specified value of 5° optic tilt (sum of the mean and two standard deviations; 23), with a mean value of $0.5 \pm 0.2^\circ$ reported in this study.

Concluding her presentation, Dr. Werner noted, “Such studies are important because the impact of axial displacement and associated refractive outcomes on IOL selection need to be evaluated clinically, as the capsular bag changes post-operatively.”

Biomaterial - a new hydrophobic acrylic

Gerd Auffarth presented the outcomes from in vitro evaluations of the new Clareon® IOL compared to TECNIS®, EnVista® and Vivinex® lenses (24).

Prof. Auffarth tested the IOLs under ‘tough’ conditions at the David J. Apple lab in Heidelberg. The IOLs studied were subjected to an accelerated aging process to induce glistening formation (25). Lenses were immersed in a saline solution at 45°C for 24 hours, before being cooled to 37°C over a 2.5 hour-period. “This may not seem like a huge temperature difference, but it has a huge impact on lenses,” explained Prof. Auffarth. Glistening formation was

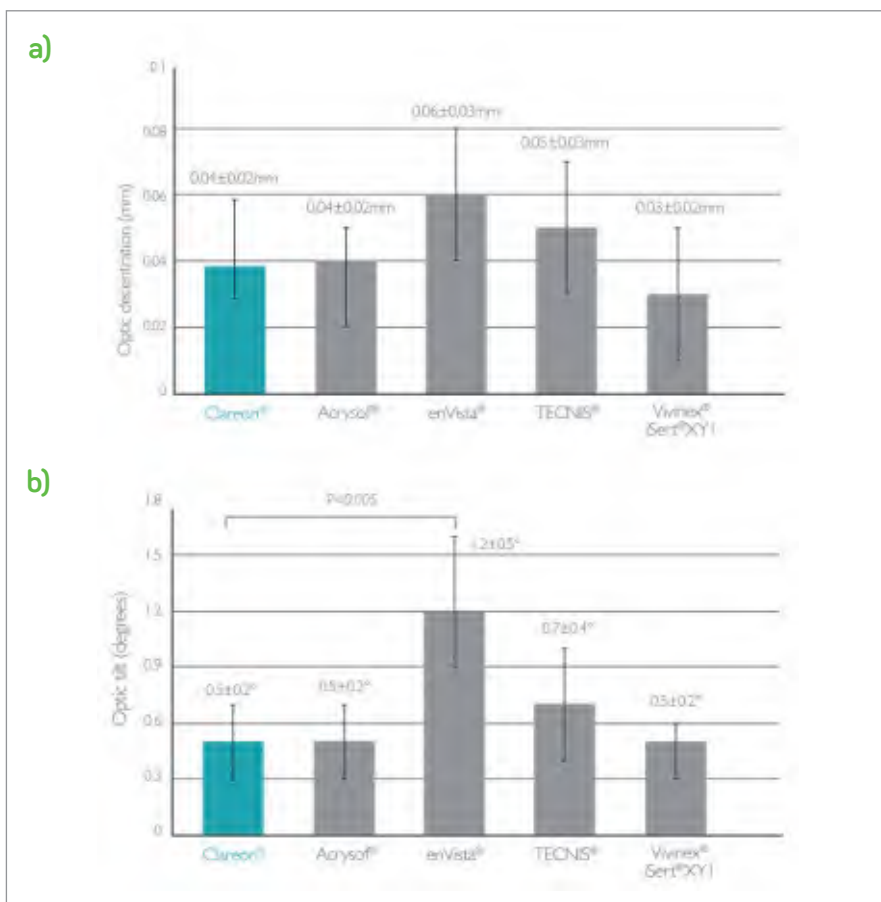


Figure 6. Optic decentration (a) and optic tilt (b) of all tested IOLs. P-value for optic tilt, Clareon® vs. enVista®.

analyzed (at 37°C) through microscopic imaging of the center of the lens where data on glistening size, volume and count were collected.

All lenses displayed a low number of glistenings. Clareon® had a mean number of 4.09 glistening microvacuoles/mm², a number that characterizes Clareon® as Grade 0 on the Miyata glistenings scale (26). “As a lens is generally considered glistening free if it has less than 25 microvacuoles/mm², this means that Clareon® is glistening free,” explained Prof. Auffarth. “With this accelerated type of testing we can say that there is little danger that the lens will develop glistenings over time.”

Prof. Auffarth moved on to address how the new biomaterial in Clareon® interacts in the eye, and described results from two studies in which Clareon® interaction with an ophthalmic viscosurgical device (OVD) (27,28) and silicone oil was assessed (29,30).

Using ProVisc® OVD no significant difference was observed in OVD removal times for Clareon® and AcrySof® (24). For the silicone oil adhesion study, the IOLs were immersed in NaCl solution (0.9%) for 12 hours, before being immersed in silicone oil for 12 hours more (Siluron 5000, Geuder). Then, they were washed with distilled water, and examined using light microscopy to quantify the percentage of silicone oil adhesion.

The results were comparable between the two lenses (Figure 7). “The percentage coverages obtained for Clareon® and AcrySof® are much lower than what we were seeing 15 years ago with previous silicone and hydrophobic material IOLs, which had around 20–25 percent adhesion,” said Prof. Auffarth. “We were quite surprised how improved the Clareon® and AcrySof® materials are in terms of their adhesion to silicone oil, and I think that there would be no problems with these lenses should the



Figure 7. Silicone oil coverage of (a) AcrySof® (9%) and (b) Clareon® (8%) following experimental studies on silicone oil adhesion and removal.

patient need future retinal surgery.”

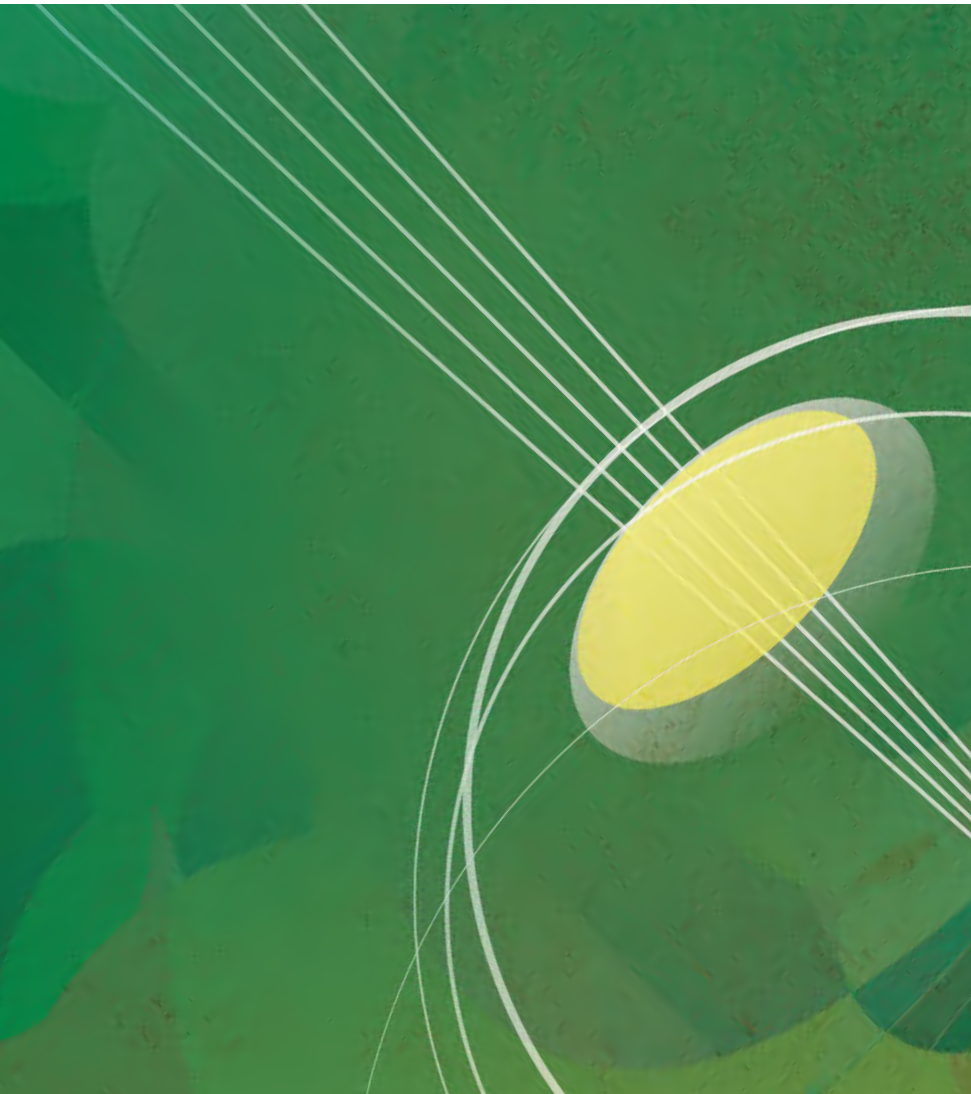
Prof. Auffarth also analyzed Clareon® and AcrySof® IOLs implanted in human autopsy eyes with Miyake-Apple posterior view technique in order to evaluate the behavior of these two lenses in the capsular bag (24). They showed that both the Clareon® and AcrySof® lenses are very stable and have a similar intraocular performance in the capsular bag, with Clareon® showing a slightly larger arc of contact and less pronounced striae and ovalization.

Prof. Auffarth summarized the presentation, stating that the Clareon® biomaterial has an extremely low incidence of glistenings, and compares favorably with the AcrySof® lens in terms

of OVD removal time, silicone oil adhesion and intraocular capsular bag performance.

Clinical experience with implanting the Clareon® IOL

Rudy Nuijts began implanting Clareon® lenses in patients in July 2017, and shared the Maastricht University Eye Clinic's surgical experience with the new lens in a cohort of 99 eyes (69 patients). Reflecting on their experiences with Clareon® lens handling compared with the AcrySof®, Prof. Nuijts said, “We found that the IOL handles less ‘stiffly’ during the cartridge manipulation and loading, and there is a quicker unfolding of the optic and haptics in the eye.” He added, “There was also



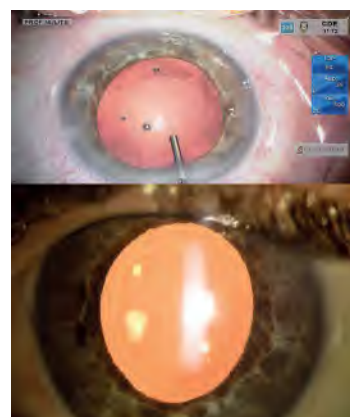
less 'stickiness' of the haptics on the optic, as you can sometimes see with the AcrySof®." Based on Prof. Nuijts's early experience they identified a four second difference in unfolding time between the Clareon® and AcrySof® lenses (30 [± 13.5] seconds vs. 34 [± 15.7] seconds, respectively). Prof. Nuijts stated that the unfolding time of other commercially available hydrophobic lenses has been shown to range between 30 and 120 seconds.

Turning to clinical outcomes following Clareon® implantation, Prof. Nuijts

noted that their studies were based on an academic cohort rather than a selective clinical study population: 31 of 99 eyes had comorbidities, including age-related macular degeneration (AMD), brunescant/mature cataract, high myopia, amblyopia and Fuch's endothelial dystrophy; and four of these 31 eyes had received prior radial keratotomy or LASIK. One month after Clareon® IOL implantation, 100 % of eyes (n=40) had a monocular corrected distance visual acuity (CDVA) greater than 20/40, and 64.3 % had a CDVA greater than 20/20.

Box 2 – Case Study of Clareon® Implantation

- 80 year old female with decreased OD vision (CDVA +1.50 -0.25x 54°: 0.6)
- Slit lamp examination showed cortical cataract 2+ OD
- Prediction for SRK/T A-constant:
 - 119.1 = +0.29 D
 - 119.2 = +0.37 D
- Clareon® was implanted in the right eye (+21 D) through a 2.2 mm incision



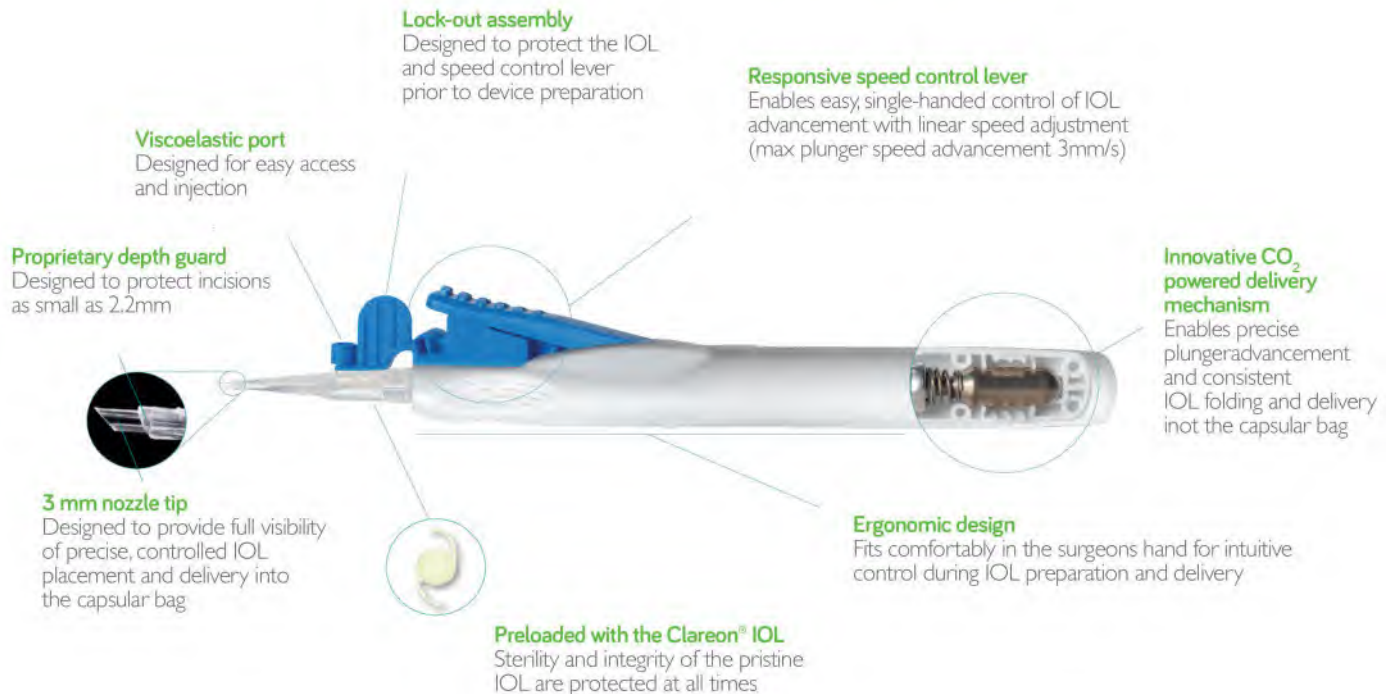
- Postoperative results were as follows:
 - Day 1 – CDVA (+0.50 D): 0.6
 - Week 1 – UDVA 1.0
 - Month 1 – UDVA 1.2
- Slit lamp examination showed clear pseudophakia

"We were very pleased with these good visual outcomes, especially considering that one third of the eyes in our cohort had comorbidities," said Prof. Nuijts. An example of a routine cataract case can be seen in Box 2.

Prof. Nuijts concluded that Clareon® has a shorter unfolding time than AcrySof®, and that the estimated

Box 3 – Key Features of AutonoMe™ (2)

- Single-use
- Innovative, automated lens advancement with the use of the speed-controlled lever
- IOL delivery speed up to 3.0 mm/s
- Length: 16.51 cm
- Outer diameter: 15.24 mm



A-constant for Clareon® is 119.1 – which simply involves adding 0.2 to the personalized AcrySof IQ® A-constant. Prof. Nuijts also highlighted: “We have seen no surface haze or glistenings in this early post-operative period.”

AutonoMe™ IOL Delivery System - An automated approach to delivery

“AutonoMe™ (Box 3) is the first and only automated, disposable, pre-loaded delivery system in the ophthalmology

market,” said Dr. Lane.

AutonoMe™ is the next evolution of IOL delivery advancements from Alcon, following a series of innovative designs including the MONARCH® series of injectors and pre-loaded injectors, such as the AcrySert® and UltraSert® (Figure 8).

The key feature that sets AutonoMe™ devices apart is the delivery control mechanism (31, 32), which has evolved from the screw-type mechanism of the MONARCH® devices and the syringe-type system in the UltraSert® (where pressure is exerted by the surgeon) to

the automated lever delivery system in AutonoMe™, which features an innovative CO₂-powered delivery mechanism (2). “It’s actually a pretty simple system,” said Dr. Lane. “The CO₂ cartridge is really what provides the mechanism for automated lens advancement, as it provides the power to move the piston down the shaft and deliver the lens.” Delivery speed is controlled by a responsive speed control lever; the surgeon only needs to use one fingertip as speed is determined by the level of depression, meaning that the second hand can remain free

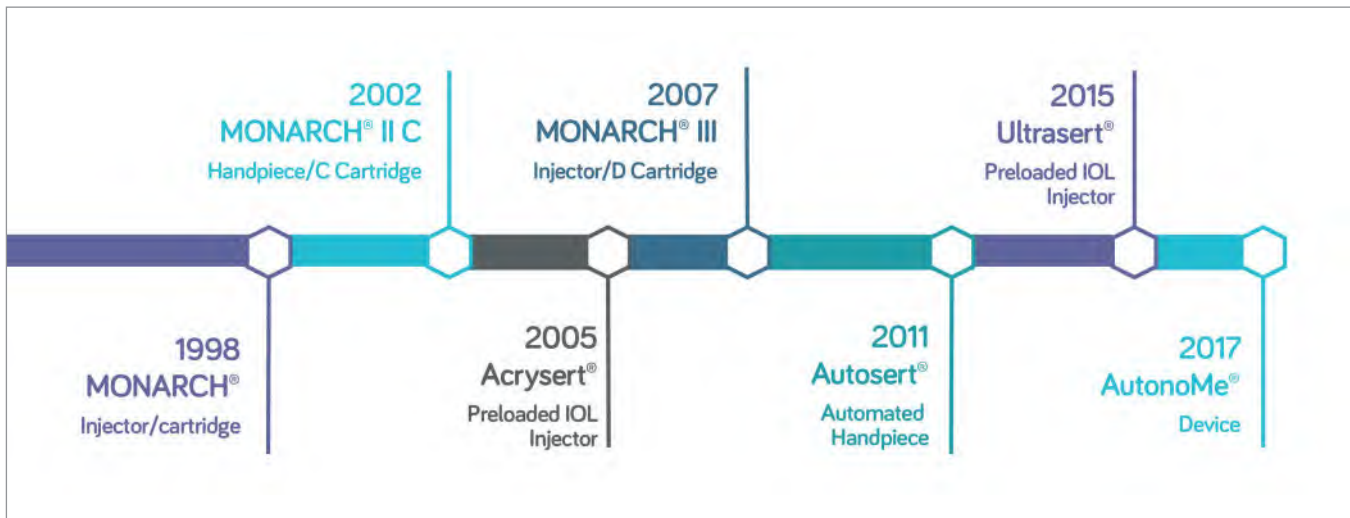


Figure 8. Timeline of Alcon IOL delivery advancements.

during lens delivery to stabilize the eye if needed. The CO₂-powered delivery mechanism also enables precise plunger advancement, as well as consistent IOL folding and delivery into the capsular bag (32).

Dr. Lane summarized the preparation steps (2) with the device (see Box 4 – Using AutonoMe™) and highlighted the three pillars to take away from the innovative AutonoMe™ system. “Firstly, it is very easy to use (31),” he said. “It allows single-handed delivery, and utilizes a very innovative, automated delivery system with a CO₂-powered cartridge and responsive speed control lever that allows the surgeon to stop or start – and vary the speed of – the delivery.” The second pillar relates to the intuitive (31) and ergonomic nature of AutonoMe™. “It is designed for comfortable, ergonomic hand positions,” he said. “It is not a ‘one type fits all’ situation – the surgeon can adapt the device to his or her particular technique.” The third pillar is related to control (32): “All surgeons like control throughout all phases of the surgery, and AutonoMe™ enables precise delivery into the capsular bag, whilst protecting incisions as small as 2.2 mm and providing

full IOL visibility during the delivery.”

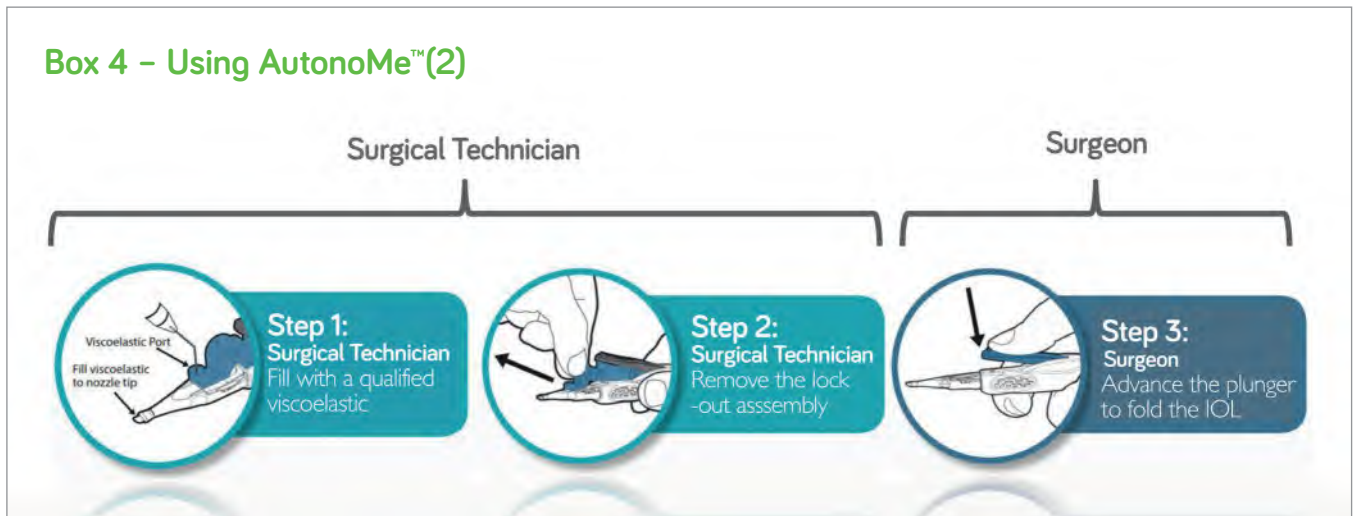
Dr. Lane concluded that “The Clareon® AutonoMe™ delivers the ultimate IOL insertion experience which I believe will change the way we deliver IOLs into the eye”. “It is the first and only automated disposable pre-loaded delivery device that is easy and intuitive (31,32) – and allows for predictable IOL delivery of a true and pristine premium IOL with a new hydrophobic biomaterial and advanced manufacturing process that achieves – along with the precision edge design – unsurpassed optical clarity.” (3, 9-12)

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Box 4 – Using AutonoMe™(2)



Consult the Clareon® AutonoMe™ DFU (2) for complete preparation and delivery inspection, as well as a list of Alcon-qualified viscoelastics

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