



Avansee™ Preload1P Media Fact Sheet

Cataracts and Cataract Surgery

What is a Cataract?

A cataract is cloudiness of the lens (the normally clear structure in your eye which focuses the light). Over time the cloudiness can become worse, causing vision to become increasingly blurry, hazy or cloudy. This can result in difficulty performing every-day tasks, such as reading, writing, and driving (especially at night).

Cataracts account for approximately 5% of blindness in Western Europe and almost 50% of blindness worldwide¹. The exact cause of cataracts is unknown, however, they appear to be due to changes in the protein structures within the lens of the eye that occur over many years, eventually leading to a "clouding" of the lens.

How can they be treated?

Currently, the only treatment is surgery. The clouded lens is removed (usually by a process called phacoemulsification) and a synthetic intraocular lens (IOL) is inserted through a small incision. The IOL replaces the natural lens and acts as a refractive medium for the visual correction of aphakia (absence of the eye's natural crystalline lens).

How common is IOL implantation?

IOL implantation is the most frequently performed surgical procedure worldwide. According to industry estimates, nearly 3.6 million IOL implants were performed in Western Europe in 2012, 78% of which were carried out in Germany, France, Italy, Spain and the UK. This number is predicted to rapidly increase as the population continues to age.

Avansee Preload1P

What is Avansee Preload1P?

Avansee Preload1P is a fully preloaded IOL system. It features a specially developed plunger designed specifically for the Avansee 1-piece lens, ensuring correct lens placement with every use. This 1-piece IOL, Kowa's first in Europe, is glistening-free² and has a low PCO rate^{3,4}.

How is it used?

Avansee Preload1P is used to replace the clouded lens during cataract surgery. After surgical insertion into the eye, the lens gently unfolds to restore vision.

All Avansee lenses are manufactured from hydrophobic, highly cross-linked, soft acrylic, and this 1-piece lens can be inserted through 2.2 mm (sclera cornea) and 2.4 mm (cornea) incisions.

What are the key benefits of Avansee Preload1P?

1. Preloaded into a unique, surgeon-friendly injector

Avansee Preload1P has a light-weight, syringe-type injector which allows preparation in 3 simple steps and insertion of the foldable IOL with just one hand. This specially developed plunger has been designed specifically for the Avansee 1-piece lens.

The advanced design of the plunger includes a unique head shape which stabilises the lens attitude and movement during insertion. It has an angled nozzle to ensure it consistently releases the lens in the correct position and the lubricated lining ensures a low delivery force, minimising the risk of lens damage. These features combine to ensure accurate lens placement every time.

The use of disposable, preloaded injectors has been predicted to grow by 23%⁵ a year over the next 2 years.

2. Glistening free

The transparency of IOL optics can deteriorate after implantation due to glistening (small bright spots), which is as a result of the formation of small, fluid-filled vacuoles in the optic material.

Some (but not all) surgeons believe that glistening can have a significant impact on visual function, in particular contrast sensitivity. In cases where visual function is affected by glistening, the lens may need to be removed and replaced with a new one.

The cast-moulded optics of Avansee are made from a stable, uniform and highly cross-linked polymer thereby eliminating glistening. Since its launch in Japan in 2007, no cases of glistening have been reported for Avansee. A study conducted at the David J Apple International Laboratory for Ocular Pathology, Heidelberg, in 2015 showed Kowa's Avansee

IOL to have industry leading optical purity. The study showed the lens to be glistening free with a glistening severity grade of 0 out of 3. This was significantly less than both Alcon's market leading Acrysof lens and Hoya's I-Sert which had glistening severity grades of 3 out of 3².

3. Low PCO rate

Posterior capsule opacification (PCO) is a thickening, opacification and clouding of the posterior lens capsule (often called a secondary cataract). It can be treated with neodymium-yttrium-aluminium-garnet (Nd:YAG) laser capsulotomy. Although effective, the treatment is expensive and carries a risk of retinal detachment, macular oedema, and intraocular pressure elevation.

PCO is caused by hyperplasia and cellular migration of lens epithelial cells (LECs) from the anterior capsule to the posterior capsule following IOL implantation. Compared to round-edged IOLs, IOLs with a square edge to their posterior surface are more likely to induce a sharp bend in the capsular bag, thereby preventing LEC migration and reducing the risk of PCO.

Avansee Preload1P has a 360 degree square edge that extends around the lens to the optic-haptic junction, as well as unique haptics which maintain space and aid adhesion between the anterior and posterior capsules ensuring it has a low PCO rate^{3,4}.

What incision size can it be used for?

This 1-piece lens can be inserted through 2.2 mm (sclera cornea) and 2.4 mm (cornea) incisions.

Who is Avansee Preload1P aimed at?

The Avansee Preload1P is aimed at all ophthalmology surgeons who are looking for a 1 piece, aspheric, hydrophobic, monofocal lens that is fully preloaded in a light-weight, injector and that offers optimum visual acuity with minimal post-operative complications.

Glossary:

Aphakia – Absence or loss of the eye's natural crystalline lens, occurring congenitally or as a result of trauma or surgery

Cataract – Clouding of the eyes' lens, which can block light from entering the eye and focusing clearly

Glistening – Fluid-filled microvacuoles within the IOL which can be seen as small bright spots on the IOLs optics

IOLs – Artificial lenses implanted in the eye to replace the eye's clouded crystalline lens during cataract surgery

PCO – Posterior capsule opacification (PCO) is a thickening, opacification and clouding of the posterior lens capsule (often called a secondary cataract)

Phacoemulsification – Also called "phaco", is a procedure that uses a device with a vibrating, ultrasonic tip to gently break up the cataract and remove it from the eye.

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- 1) WHO. World Health Organization (2007) 'Vision 2020 The Right to Sight: Global Initiative for the Elimination of Avoidable Blindness: action plan 2006-2011'. Pg 11.
- 2) Auffarth G et al., "Evaluation of in vitro glistening formation in different hydrophobic acrylic intraocular lenses". Poster presented at the ESCRS poster sessions on cataract surgery outcomes, Barcelona, Spain, September 2015
- 3) Morgan-Warren PJ and Smith JA. Clin Ophthalmol. 2013; 7:1661–1667
- 4) Auffarth G et al., Ophthalmology 2003; 110:772–80
- 5) '2014 Comprehensive Report on The Global IOL Market', Market Scope, May 2014, Pg 352, Fig 141



Avansee™ Preload1P Media Q&A

Questions

1. What sort of a product is the Avansee Preload1P?

Avansee Preload1P is a fully preloaded IOL system. It features a specially developed plunger designed specifically for the Avansee 1-piece lens, ensuring correct lens placement with every use.

2. How does it compare to other products on the market?

The advanced design of the plunger includes a unique head shape which stabilises the lens attitude and movement during insertion ensuring accurate lens placement every time.

This 1-piece IOL is glistening-free and its lens material has the lowest glistening severity code possible (0) in European laboratory studies¹. It has a 360 degree square edge that extends around the lens to the optic-haptic junction, as well as unique haptics which maintain space and aid adhesion between the anterior and posterior capsules ensuring it has a low PCO rate^{2,3}.

3. Who is the target audience for the Avansee Preload1P?

The Avansee Preload1P is aimed at all ophthalmology surgeons who are looking for a 1 piece, aspheric, hydrophobic, monofocal lens that is fully preloaded in a light-weight, injector and that offers optimum visual acuity with minimal post-operative complications.

4. Why have you chosen to launch a preloaded product?

The use of disposable, preloaded injectors has been predicted to grow by 23%⁴ a year over the next 2 years and in Avansee Preload1P we have a unique, surgeon-friendly injector that is well positioned to be part of that growth.

As the Avansee Preload1P IOL system is fully preloaded it means that lenses can be prepared for implantations without being touched, which reduces the risk of infection and IOL damage.

5. What is the Avansee Preload1P safety record?

A leader in the Japanese IOL market, Kowa's Avansee lenses have been used extensively in Japan since 2007, with a very low incidence of adverse events (0.009%) and serious adverse events (0.0009%)^{5,6}.

6. What will the Avanse Preload1P cost?

The Avanse Preload1P will be competitively priced and pricing is available to customers on request.

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2. Morgan-Warren PJ and Smith JA. *Clin Ophthalmol.* 2013; 7:1661–1667
3. Auffarth G et al., *Ophthalmology* 2003; 110:772–80
4. '2014 Comprehensive Report on The Global IOL Market', Market Scope, May 2014, Pg 352, Fig 141
5. Data on file (DOF/KE/IOL/2016-001)
6. Data on file (DOF/KE/IOL/2016-003)



Kowa Media Fact Sheet

The Kowa Group

Overview

Starting life in 1894 as Hattori Kaneshaburo Wholesale Store (a cotton cloth wholesaler), over 120 years later Kowa Company, Ltd. has grown into a multinational Japanese company. Still privately held, it is actively engaged in a broad variety of manufacturing and trading activities covering the fields of pharmaceuticals, life sciences, information technology, textiles, machinery and consumer products. It employs 6,409 people worldwide in 78 subsidiary companies and 15 associated companies*.

Kowa in Europe

In 1986 Kowa established its first European office, Kowa Europe GmbH, which was followed in 2000 with the launch of a specialty pharmaceutical and medical devices company, Kowa Pharmaceutical Europe Co. Ltd (KPE), located in Wokingham, UK.

In 2011 Kowa strengthened its European presence further with Kowa Optimed Europe Ltd. to provide high technology products manufactured by the Electronics & Optics division of Kowa. It produces products in 4 distinct categories: ophthalmic diagnostic products, lenses (CCTV & Industrial), sporting optics and LEDs.

In 2014 KPE established a branch office in Düsseldorf, Germany, to support the launch of Kowa's first IOL business outside of Japan.

Kowa in Ophthalmology

Ophthalmic Heritage

Kowa has over 70 years of experience in premium ophthalmic diagnostics and medical imaging (fundus cameras, slit lamps etc). A pioneer in this field, it is one of the world's leading suppliers of ophthalmic diagnostic solutions and has set clinical standards for a wide range of ophthalmic conditions.

*as of end of March 2016

Since the launch of its first retinal camera in 1962, Kowa has produced many firsts:

1978 World's 1st combined (Myd & Non- Myd) retinal camera – RC-WFN

1987 World's 1st compact retinal camera – FX-50R

1988 World's 1st Aqueous Flare Cell meter – FC-1000

2001 World's 1st digital built in CCD non-mydratic camera – nonmyd α

2010 World's 1st 2D/3D Digital Retinal camera – nonmyd WX

Optical Heritage

In 1946 Kowa branched out into the optical equipment field and established an Electronics & Optics division. It originally produced eyeglasses for a short period, before switching to higher value products such as binoculars, rifle scopes and spotting scopes. Kowa is now one of the leading manufacturers of high quality lenses for a wide range of applications including CCTV, machine vision, cinematography, aerospace and robotics.

Respected the world over for its quality and precision, Kowa takes particular pride in the craftsmanship needed to create the custom PROMINAR fluorite crystal lenses it offers in its high performance models. The crystal is grown from scratch and then handcrafted to ensure the lenses provide the highest level of optical performance.

Leading IOL Manufacturer

In 2007 Kowa combined its ophthalmic and optical heritage to launch its first intraocular lens (IOL) in Japan, AvanseTM. Aware of the trend towards an increasingly aging population Kowa thought that developing and providing high-quality and safer IOLs would contribute to the quality of life of many cataract patients. Using its experience and expertise it quickly became a leader in the competitive Japanese IOL market, a country that is second only to the United States in IOL revenue. Since 2007 it has sold over 1,000,000 lenses in Japan¹.

Kowa IOLs in Europe

German Launch

Recognising the importance of broadening its market base, in 2014 Kowa launched its fully preloaded IOL system, AvansePreset, in Germany, the first time its IOLs have been available outside of Japan. Germany is the highest volume IOL market in Europe and as Kowa already had an established presence there, through its optical devices division, it was an ideal country in which to launch Kowa's first IOL presence in Europe. This was followed up in 2017 with the launch of the Avanse Preload1P, Kowa's first 1-piece IOL to be available in Europe.

Kowa in Europe

As well as being sold direct in Germany, Kowa's IOL products are also available via distributors in other European countries; Italy, Switzerland and Benelux.

The Future

Kowa is continually developing its pipeline of enhanced monofocal and premium lenses and plans to launch additional products to its current customer base, as well as investigating further expansion into other European markets.

Timeline: Kowa in Ophthalmology

- 1946** Kowa Company, Ltd. branches out into the optical equipment field and establishes its Electronics & Optics business
- 1947** It expands into the pharmaceutical sector and establishes its pharmaceutical business
- 1952** Electronics & Optics division begins the production of its first spotting scopes
- 1955** Launches its first ophthalmic solution for eye disorders, Neosynesis Kowa 5% Eye Solution (Phenylephrine Hydrochloride), ophthalmic drops for the diagnosis or treatment of mydriasis
- 1962** First portable retinal camera, Kowa RC, launched
- 1964** Kowa spotting scopes are the official scopes for sports shooting at the Tokyo Olympic Games
- 1978** World's 1st combined (Myd & Non- Myd) retinal camera – RC-WFN
- 1985** Kowa Optimed Co, Ltd established
- 1986** Establishment of Kowa Europe GmbH provides first European presence
- 1987** World's 1st compact retinal camera – FX-50R
- 1988** Launches the world's first laser flare cell meter, the FC-1000
- 2001** World's 1st digital built in CCD non-mydratiac camera – nonmyd α
- 2007** Kowa's first IOL, Avanse, is launched in Japan
- 2010** Broadens IOL offering with the launch of its first preloaded IOL system, AvansePreset, in Japan
- 2010** Launches the World's first 2D & 3D (simultaneous photographing) digital retinal camera – nonmyd WX
- 2011** Establishment of Kowa Optimed Europe Ltd. focusing on providing high technology products manufactured by the Electronics & Optics division of Kowa including medical equipment, lenses for machine vision and CCTV, sporting optics and latest LED technologies

- 2014** Avanseepreset launched in Germany, the first time Kowa's IOLs have been available outside of Japan
- 2017** Avanseepreload1P launched in Germany. Kowa's first 1-piece IOL to be available in Europe

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