



Avansee™Preset 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.

AvanseePreset

What is AvanseePreset?

AvanseePreset is a fully preloaded IOL system featuring Kowa's successful Avansee lens, and its unique, surgeon-friendly injector. The Avansee lens offers optimum visual acuity with minimal post-operative complications. It is one of the leading lenses in the competitive Japanese IOL market, with over 500,000 sold in Japan since its launch in 2007.

In September 2014 it was launched in Germany, the first time it has been available outside of Japan.

How is it used?

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

What are the key benefits of AvanseePreset?

1. 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 vision 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. In a study simulating 20 years of deterioration, Avansee demonstrated no opacity, whereas six other IOLs investigated (including MA60BM [Acrysof: Alcon], SA60AT [Acrysof: Alcon], AR40e [Sensor: AMO], VA-60BB [Acryfold: HOYA], N4-18B [Nex-Acri: NiDEK], and HP60M [Hydroview: Bausch & Lomb]) demonstrated glistening-like opacity, colouring or granular changes².

2. Very 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.

Avansee is associated with a relatively low rate (<2%) of PCO. In a retrospective study in 4,862 eyes, the proportion of PCO cases requiring Nd:YAG treatment after two years was significantly lower in patients receiving Avansee or AcrySof than in those receiving the rounder-edged Hoya IOL ($p < 0.0001$ for both comparisons)³.

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

Not all square-edged IOLs have the same degree of squareness. Cast-moulded hydrophobic IOLs, such as Avanseer, that are carved without grinding after polymerisation tend to have squarer edges than IOLs that are manufactured using other techniques.

3. Well-established, long term safety profile

Over 500,000 Avanseer lens have been sold in Japan since 2007 with only 22 reports of adverse events, which is 0.0032% of all lenses implanted, giving it a well-established and long term safety profile.

4. Preloaded into a unique, surgeon-friendly injector

The Avanseer lens is preloaded into Kowa's original injector which has a unique, surgeon-friendly design that enables preparation for IOL insertion in two simple steps and single handed implantation with a smooth, even force.

As the AvanseerPreset IOL system is fully preloaded it means that lenses can be loaded without being touched, which reduces the risk of infection and IOL damage.

The use of disposable, preloaded injectors is predicted to grow by 23%⁴ a year over the next 5 years.

What are the key features of the Avanseer Lens?

Optics - Avanseer optics are made from a UV-absorbing, hydrophobic, highly cross-linked, soft acrylic material in yellow or clear. It is cast-moulded and carved without grinding to provide a squarer edge than IOLs manufactured using other techniques

Haptics - Avanseer has modified 3-piece (3P) C-loop haptics made from soft, flexible polyvinylidene fluoride (PVDF). The flexibility of the haptics reduces the risk of breakage during insertion and the haptic softness reduces the risk of damage to the eye after insertion.

Who is Avanseepreset aimed at?

Avanseepreset is aimed at all ophthalmology surgeons who are looking for an aspheric, hydrophobic, monofocal lens that is fully preloaded in a surgeon-friendly 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 – 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): Global initiative for the elimination of avoidable blindness: action plan 2006-2011. 2014.
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- 2) Kawai K, Hayakawa K, Suzuki T. Simulation of 20-year deterioration of acrylic IOLs using severe accelerated deterioration tests. Tokai J Exp Clin Med 2012;37:62-65.
- 3) Adapted from data provided by K Miyake
- 4) '2014 Comprehensive Report on The Global IOL Market', Market Scope, May 2014, Pg 352, Fig 141



AvanseePreset Media Q&A

Questions

A) AvanseePreset

1. What sort of a product is AvanseePreset?

AvanseePreset is a fully preloaded intraocular lens (IOL) system featuring Kowa's successful Avansee lens, over 500,000 of which have been sold in Japan since 2007, and its unique, surgeon-friendly injector.

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

AvanseePreset contains Kowa's original Avansee lens which is glistening free, has a very low PCO rate and, as over 500,000 have been sold in Japan since 2007, has a well-established, long term safety profile.

This lens is preloaded into Kowa's original injector which has a unique, surgeon-friendly design that enables preparation for IOL insertion in two simple steps and single handed implantation with a smooth, even force.

3. Who is the target audience for AvanseePreset?

AvanseePreset is aimed at all ophthalmology surgeons who are looking for an aspheric, hydrophobic, monofocal lens that is fully preloaded in a surgeon-friendly 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 is predicted to grow by 23%¹ a year over the next 5 years and in AvanseePreset we have a unique, surgeon-friendly injector that is well positioned to be part of that growth.

As the AvanseePreset IOL system is fully preloaded it means that lenses can be loaded without being touched, which reduces the risk of infection and IOL damage.

5. What is AvanseePreset's safety record?

Over 500,000 Avansee lens have been sold in Japan since 2007 with only a very small amount of adverse events reported, giving it a well-established and long term safety profile.

6. Have there been any reported problems with this product in Japan?

There have only been 22 reports of adverse events since the Avanse lens was launched in Japan in 2007, which is 0.0032% of all lenses implanted.

7. What will AvansePreset cost?

AvansePreset will be competitively priced and pricing is available to customers on request.

B) Kowa

8. What experience does Kowa have in IOLs?

Kowa has over 60 years of experience in ophthalmic diagnostics and the development of quality optical lenses. In 2007 it launched an IOL business in Japan and used this experience to support it in quickly becoming a leader in the competitive Japanese IOL market, the second largest market in the world. Since 2007 it has sold over 500,000 lenses in Japan.

9. Where is Kowa positioned in the Japanese market?

Kowa is one of the leaders in the competitive Japanese market, the second largest market in the world.

C) Germany

10. Why have you chosen Germany for Kowa's first IOL presence outside of Japan?

Kowa has long recognised the importance of broadening its market base and sees Germany, which is the highest volume IOL market in Europe, as a natural next step. Germany has always demonstrated an openness to new technologies and as Kowa already has an established presence in Germany, through its optical devices division, it is the ideal country in which to launch Kowa's first IOL presence in Europe.

11. Does Kowa have any experience of the German market?

Yes, in 1986 Kowa established its first European office, Kowa Europe GmbH, and later launched an optical devices business here in 2011, Kowa Optimed Europe Ltd., so we are familiar with the German market. To establish our IOL business we have recruited an experienced team, based in Dusseldorf and headed up by Stefan Kremer, who have worked closely with German ophthalmologists.

12. What presence does Kowa's IOL business have in Germany?

We have an office of our European pharmaceutical and medical devices division, Kowa Pharmaceutical Europe Co. Ltd., in Düsseldorf, Germany. This has a General Manager, Stefan Kremer, and a team experienced in the German ophthalmology market.

13. This is a very competitive market, how does Kowa propose to succeed?

In Avanseepreset we have a proven, high quality and successful lens with a unique, surgeon-friendly injector. We are committed to working in partnership with ophthalmology surgeons to ensure we provide not only the best product but also the best possible service.

16. What is the difference between Kowa Optimed Europe Ltd. and Kowa Pharmaceutical Europe Co. Ltd.?

Kowa Optimed Europe Ltd. is the European optical devices division of Kowa and Kowa Pharmaceutical Europe Co. Ltd. is its European pharmaceutical and medical devices division that is launching Avanseepreset.

D) Future Plans

17. What are the long term plans/aspirations for Kowa in Germany?

We are committed to a long term partnership with German ophthalmology surgeons and we will aim to keep providing innovative, quality products and an excellent service.

We are continuously developing our pipeline of enhanced monofocal and premium lenses and we plan to launch further products in Germany using our unique Avanseepreset injector.

18. What are Kowa's plans for the rest of Europe?

Kowa is exploring all opportunities across Europe and investigating how it can best be positioned in other markets.

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References:

- 1) '2014 Comprehensive Report on The Global IOL Market', Market Scope, May 2014, Pg 352, Fig 141



Kowa Media Fact Sheet

The Kowa Group

Overview

Starting life in 1894 as Hattori Kaneshaburo Wholesale Store (a cotton cloth wholesaler), 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 5,819 people worldwide in 88 subsidiary companies and 18 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 60 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 2014

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 – nonmyda

2010 World's 1st 2D/3D Digital Retinal camera – nonmydWX3D

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 500,000 lenses in Japan.

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.

The Future

Kowa is continually developing its pipeline of enhanced monofocal and premium lenses and plans to launch further products in Germany as well as investigating how it can best position itself in 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-mydratic camera – nonmyda
- 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** AvansePreset launched in Germany, the first time Kowa's IOLs have been available outside of Japan

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