

Information for patients or non-specialists

Version: 3

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The aim of this document is to provide the public with access to an updated summary of the main aspects of the medical devices concerned: ARTIS PL E, ARTIS T PL E, ARTIS PRIME, and ARTIS SYMBIOSE. The information presented below is for patients or non-specialists.

The purpose is not to provide advice on the treatment of any disease. If you have any questions concerning your health status or the medical device used in your situation (ARTIS PL E or ARTIS T PL E or ARTIS PRIME or ARTIS SYMBIOSE), please contact your healthcare professional. This document does not replace an implant card or instructions for use as a source of information on the safe use of the medical device concerned.

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I Identification of the devices and general information

I.1 Trade name of the devices

ARTIS PL E
ARTIS T PL E
ARTIS PRIME
ARTIS SYMBIOSE

I.2 Manufacturer's name and address

Name: CRISTALENS INDUSTRIE
Address: 4 rue Louis de Broglie, 22300 Lannion – France
Telephone: +33 2 96 48 92 92

I.3 Unique Device Identifier (“Basic UDI-DI”)

Unique Device Identifiers are numeric or alphanumeric codes used to specifically, and unambiguously identify individual devices and improve their traceability. The basic UDI-DI code (UDI for Unique Device Identifier, DI for Device Identifier) is the primary identifier of a device model:

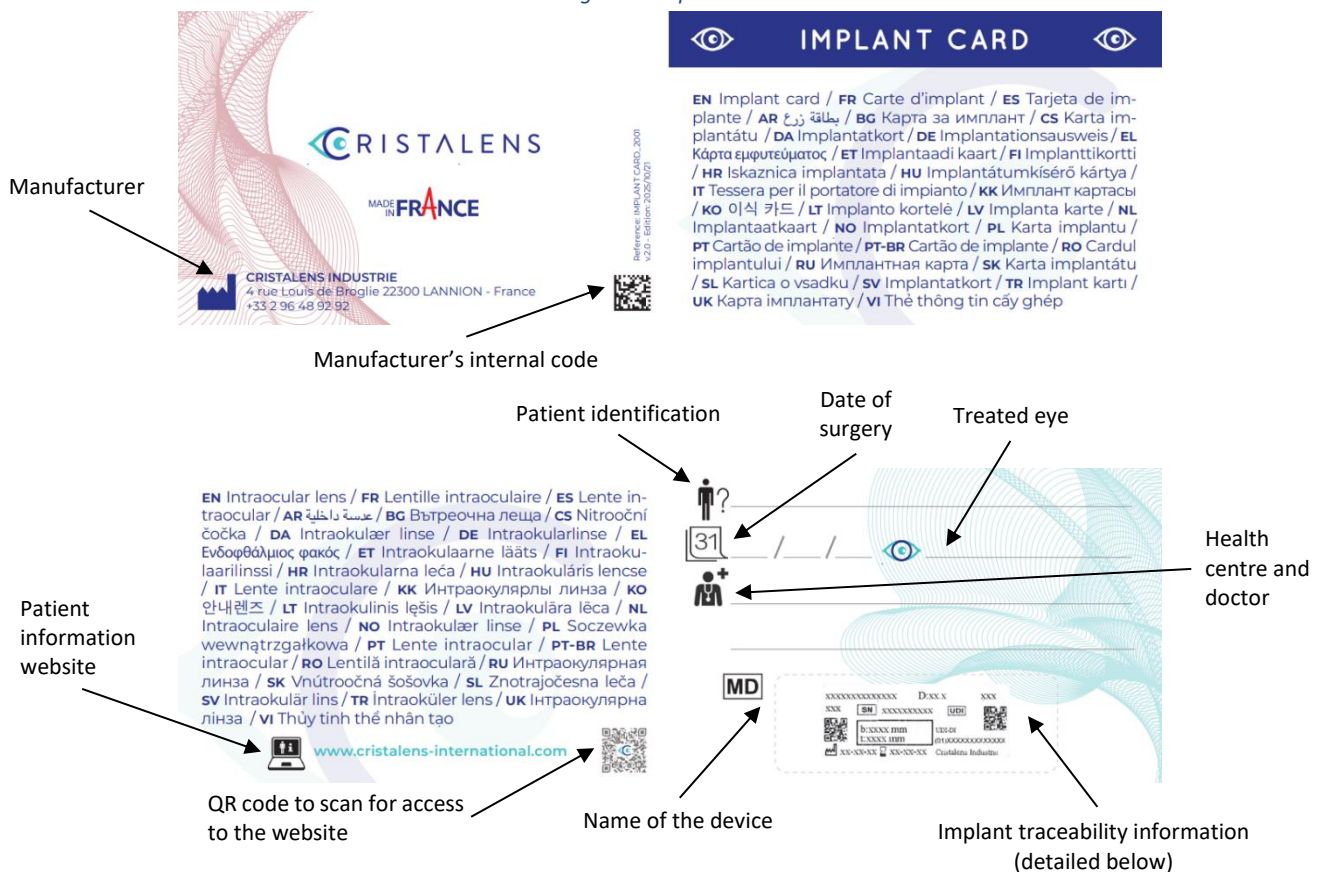
- ARTIS PL E / ARTIS T PL E / ARTIS PRIME: 37006373IOL01D6
- ARTIS SYMBIOSE: 37006373IOL02D8.

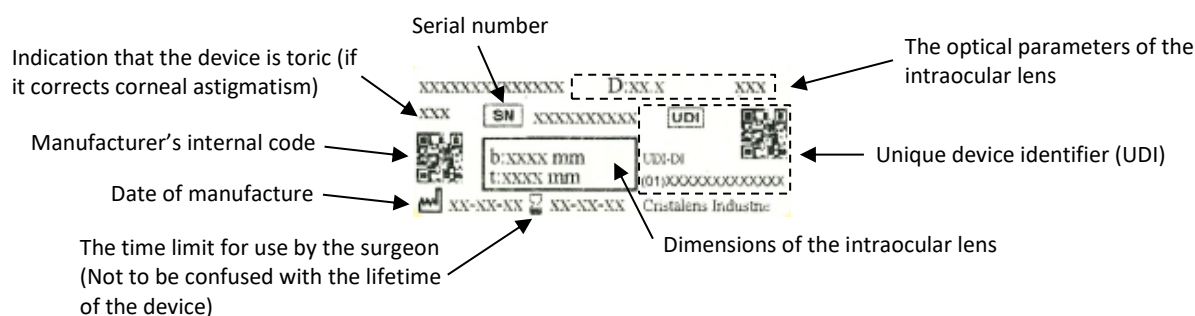
I.4 Implant card

After cataract surgery during which an intraocular lens manufactured by CRISTALENS INDUSTRIE is implanted in your eye, you should receive a patient implant card completed by the surgeon or the health care facility.

This card shows the type of intraocular lens implanted in your eye and appears as follows:

Figure 1. Implant card





You should always have this card with you so that your implant can be traced and so that it can be presented to any physician you may consult later.

An implant card should only be associated with a single eye. In case of surgery on both eyes, you should be given two implant cards.

I.5 Summary of Safety and Clinical Performance (SSCP)

The purpose of the Summary of Safety and Clinical Performance (SSCP) is to provide the public with access to an updated summary of clinical data and other information on the safety and clinical performance of the medical device. The SSCP is one of the means to achieve the objectives of the Medical Device Regulation (MDR), namely, to improve transparency and provide adequate access to information.

The SSCP is available in the European Medical Devices Database (EUDAMED – <https://ec.europa.eu/tools/eudamed>), where it is linked to the Basic UDI-DI attributed to the device.

If you do not have access to EUDAMED, the SSCP is available on request from CRISTALENS INDUSTRIE:

- Via the contact form on the website (www.cristalens-international.com).
- By e-mail to contact.ci@cristalens.fr.
- By telephone at +33 2 96 48 92 92.

II Intended use of the devices

II.1 Intended medical use

The ARTIS PL E, ARTIS T PL E, ARTIS PRIME and ARTIS SYMBIOSE devices are comprised of an intraocular lens and an injector. The intraocular lens is an artificial lens designed to replace the natural crystalline lens which has become opaque due to cataract. Using the injector, this intraocular lens is inserted into the capsular bag that surrounds the crystalline lens.

Figure 2. Diagram of the eye

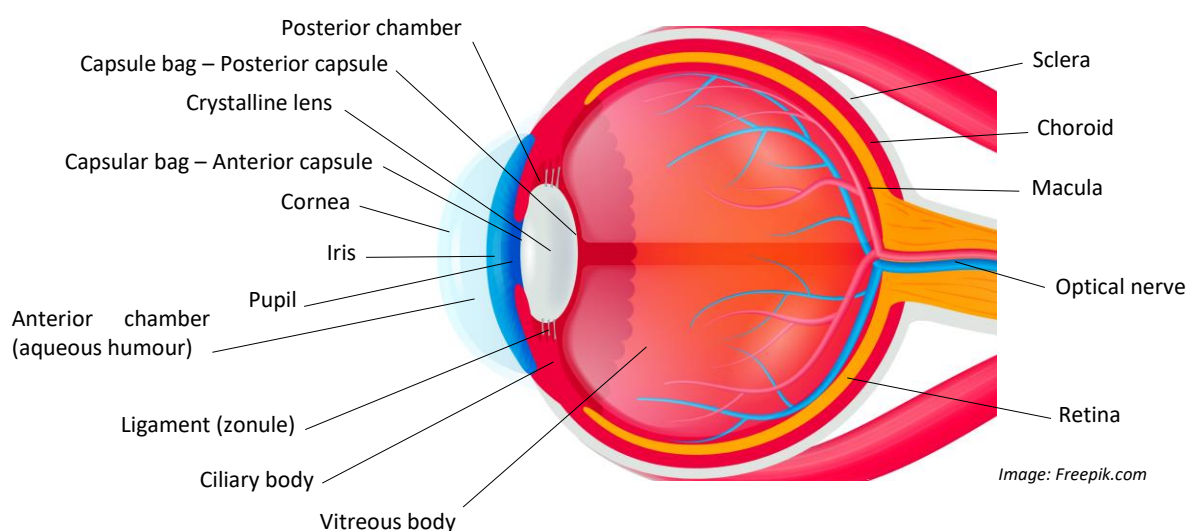


Image: Freepik.com

II.2 Indications and patient categories

ARTIS PL E, ARTIS T PL E, ARTIS PRIME and ARTIS SYMBIOSE devices are indicated for the visual correction of aphakia after age-related cataract surgery and for compensation of ametropia.

The ARTIS T PL E and ARTIS PRIME (toric version) devices are also indicated for the correction of corneal astigmatism.

The ARTIS SYMBIOSE device is also indicated for the compensation of presbyopia. If necessary, it can also correct corneal astigmatism.

Aphakia is a medical term that describes the absence of the crystalline lens in the eye. This can occur after cataract surgery where the opacified crystalline lens is surgically removed from the eye and is replaced by an intraocular implant. The crystalline lens is a key structure of the eye that helps converge light rays onto the retina to create a sharp image. Surgical removal can lead to blurred vision and difficulty seeing objects clearly. Vision must then be corrected.

Ametropia is a medical term for a vision defect in which the eye fails to focus light properly on the retina, leading to blurred or distorted vision. This can occur in case of myopia or hyperopia.

Myopia is a condition where distant objects appear blurred because the light is focused in front of the retina rather than on it. Conversely, hyperopia is a condition where close objects appear blurred because the light is focused behind the retina rather than on it.

Corneal astigmatism is caused by an irregularity in the curvature of the cornea, which is the transparent surface at the front of the eye. In a normal eye the cornea is round and uniform, but in people with corneal astigmatism the curvature is irregular, which causes blurred and/or distorted vision. Objects may appear distorted and/or blurred at all distances.

Presbyopia is a progressive loss of near vision due to ageing of the eyes. It is a common visual disorder that occurs in people over the age of 40 years. Presbyopia is usually caused by a loss of flexibility in the crystalline lens of the eye, which makes it more difficult to focus (to accommodate) on near objects.

Patients who are eligible for implantation of ARTIS PL E, ARTIS T PL E, ARTIS PRIME, and ARTIS SYMBIOSE devices implantation are adults who have had their natural crystalline lens removed after age-related cataract surgery.

II.3 Contraindications and limitations of use

There are certain cases in which ARTIS PL E, ARTIS T PL E, ARTIS PRIME, and ARTIS SYMBIOSE devices should not be used, and certain circumstances require special attention and may require additional explanations.

If you have an acute disease in addition to age-related cataract, the disease should be treated as a priority before considering cataract surgery and implantation of an intraocular lens. *An acute disease is an illness or medical condition that occurs suddenly and develops rapidly, but which usually lasts for a short time.*

A thorough preoperative evaluation and clinical review should be performed by the surgeon to meticulously assess the benefit/risk ratio prior to intraocular lens implantation in patients with one or more of the conditions listed below in "Table 1 - Contraindications and circumstances requiring special consideration" (non-exhaustive list).

Table 1 - Contraindications and circumstances requiring special consideration

	Contraindications				Circumstances requiring special consideration			
	ARTIS PL E	ARTIS T PL E	ARTIS PRIME	ARTIS SYMBIOSE	ARTIS PL E	ARTIS T PL E	ARTIS PRIME	ARTIS SYMBIOSE
Neonates, premature neonates, infants, and children (until 18 years of age)	X	X	X	X				
Active ocular infection	X	X	X	X				
Any active ocular disease other than age-related cataract	X	X	X	X				
Acute ocular inflammation	X	X	X	X				
Acute ocular disease	X	X	X	X				
Any progressive ocular disease other than age-related cataract	X	X	X	X				
Nanophthalmos (<i>abnormally small eye, extremely small, often underdeveloped eye that may lack normal eye structures</i>)	X	X	X	X				
Severe optic nerve atrophy (<i>severely damaged optic nerve, optic nerve fibres destroyed</i>)	X	X	X	X				
Inadequate capsular support (<i>limited capacity of the crystalline lens capsule to maintain the intraocular lens in a stable position after surgery</i>)	X	X	X	X				
Allergy to ethylene oxide (<i>a gas commonly used as a sterilising agent for medical devices</i>)	X	X	X	X				
Pregnancy or breastfeeding	X	X	X	X				
Glaucoma (<i>a chronic eye disease that gradually damages the optic nerve</i>)				X	X	X	X	
Retinal conditions (e.g., macular degeneration (<i>disease of the macula, the area in the centre of the retina, characterised by progressive loss of central vision</i>), diabetic retinopathy (<i>ocular complication of diabetes that affects the retina by damaging the supplying blood vessels</i>), retinal detachment or a history of retinal detachment, cystoid macular oedema (<i>fluid build-up in the macula</i>), macular hole (<i>hole/tear in the macula</i>))				X	X	X	X	
Corneal abnormalities (e.g., keratoconus (<i>progressive, conical deformity of the central part of the cornea which becomes thinner and more curved than normal</i>), corneal opacification (<i>loss of corneal transparency</i>))				X	X	X	X	
Haemorrhage (for example, choroidal haemorrhage or any other intraocular haemorrhage) (<i>the choroid is a layer of vessels beneath the retina</i>)				X	X	X	X	
Intraocular hypertension (<i>abnormally high intraocular pressure</i>)				X	X	X	X	
Aniridia (<i>partial or total absence of the iris</i>)				X	X	X	X	
Microphthalmia (<i>abnormally small eye</i>)				X	X	X	X	

Amblyopia (<i>the brain is unable to correctly interpret images from both eyes</i>)				X	X	X	X	
A large eye, an eye with an excessive axial length (greater than 28 mm) (<i>axial length is the distance measured from the front surface of the cornea, the transparent part at the front of the eye, to the retina, the light-sensitive part at the back of the eye</i>)				X	X	X	X	
Non-age-related cataract (e.g., traumatic cataract, congenital cataract)					X	X	X	X
A history of intraocular or refractive surgery					X	X	X	X
Use of systemic or eye medicines that could affect vision (<i>systemic medicines are absorbed through the circulatory system and have a whole-body effect, unlike topical medicines which are applied locally</i>)					X	X	X	X
Ocular inflammation					X	X	X	X
Ocular infection					X	X	X	X
Corneal conditions that compromise visual acuity (e.g., corneal endothelial diseases (<i>affect the endothelium, the inner layer of the cornea</i>), corneal dystrophies (<i>rare genetic diseases that affect the structure and function of the cornea</i>), a history of corneal transplants/grafting)					X	X	X	X
Capsular or zonular abnormalities that can affect the postoperative centring or tilt of the intraocular lens (<i>the crystalline lens zonule is a fibrous structure that holds the crystalline lens in place in the eye</i>)					X	X	X	X
Posterior capsule rupture or a wide capsulorhexis (compromised intraocular lens stability) (<i>the posterior capsule is a thin membrane surrounding the crystalline lens and which is attached to the zonule of the eye. It holds the crystalline lens in place</i>) (<i>capsulorhexis is a surgical technique used to remove the central anterior part of the crystalline lens capsule from the eye during cataract surgery</i>)					X	X	X	X
Known or suspected radial tears or tear-out at the time of surgery (<i>radial cracks that form in the outer part of the crystalline lens</i>)					X	X	X	X
Incapacity to confirm the integrity of the capsulorhexis by direct visualisation (<i>capsulorhexis is a surgical technique used to remove the central anterior part of the crystalline lens capsule from the eye during cataract surgery</i>)					X	X	X	X
Capsulotomy by a technique other than a circular incision (<i>capsulotomy is a surgical technique in which an incision is made in the crystalline lens capsule</i>)					X	X	X	X
Anterior chamber collapse (<i>reduced intraocular pressure resulting in a loss of volume in the front part of the eye, between the cornea and the iris</i>)					X	X	X	X

Narrow anterior chamber (<i>the area between the cornea in front and the iris in the back is smaller than usual</i>)					X	X	X	X
Response to corticosteroids that increase intraocular pressure					X	X	X	X
Significant loss of vitreous humour (<i>a gelatinous, transparent substance that fills the interior of the eye, between the crystalline lens and the retina, and which gives the eye its round shape. It plays an important role in the transmission of light to the retina</i>)					X	X	X	X
Anisometropia (<i>significant difference between the powers of the two eyes. The two eyes have different vision because one eye is stronger or weaker than the other</i>), aniseikonia (<i>difference in size between the two eyes</i>)					X	X	X	X
Irregular corneal astigmatism (<i>corneal astigmatism where the shape of the cornea is abnormal</i>), significant irregular corneal aberration (<i>an optical anomaly that occurs when light is distorted as it passes through the unevenly shaped cornea</i>)						X	X	X
Dry eyes (e.g., Meibomian gland dysfunction (<i>sebaceous glands in the upper and lower eyelids which produce an oily substance which mixes with tears to lubricate the surface of the eye and prevent this tear film from evaporating too quickly</i>))								X
Expected residual postoperative astigmatism greater than 0.75D (<i>some degree of astigmatism persists after intraocular lens implantation</i>)								X
Strabismus (<i>misalignment of the eyes</i>), absence of binocular vision (<i>the brain cannot correctly interpret images from both eyes</i>)								X
Pupil abnormality (unresponsive (<i>no reaction to stimuli</i>), a tonic pupil (<i>larger than usual with abnormal reaction to light</i>), an abnormally shaped pupil or one which dilates less than 3.5 mm in moderate/low light)								X
Monophthalmia (<i>absence of one eye</i>)								X
Naturally dilated pupil (diameter greater than 4 mm)								X

III Description of the devices

III.1 General description of the devices and materials in contact with the patient's tissues and organs

ARTIS PL E, ARTIS T PL E, ARTIS PRIME, and ARTIS SYMBIOSE devices are intraocular lenses preloaded in their ACCUJECT™ PRO injection system. This means they are pre-positioned in the injector during manufacture to minimise handling of the lenses before implantation.

They are posterior chamber intraocular lenses to be placed in the capsular bag. They are made from a single piece of material with no removable components and are foldable so that they can be inserted into the eye through a small incision in the cornea of approximately 2 mm, which reduces the risk of postoperative complications. These are sterile, single-use devices.

In general, intraocular lenses have two basic characteristics:

- The optical part is the round part of the lens that focuses an image through its optical power(s).
- Structures called haptics are attached to the side of the optic. They help to maintain the position of the intraocular lens in the eye.

In general, intraocular lenses have a total diameter of 10 to 14 mm, and a thickness of less than 1 mm.

Figure 3. ARTIS PL E, ARTIS T PL E, ARTIS PRIME, and ARTIS SYMBIOSE intraocular lenses

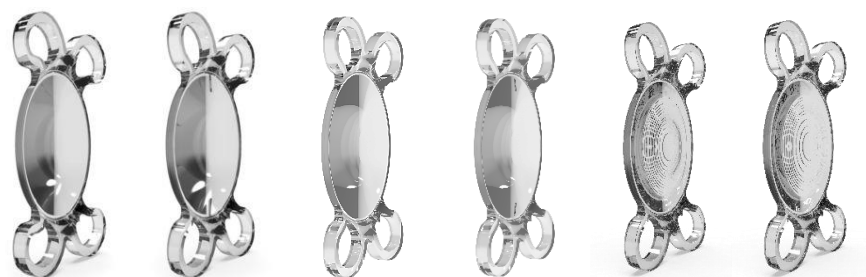


Figure 4. Injector



ARTIS PL E, ARTIS T PL E, ARTIS PRIME, and ARTIS SYMBIOSE devices are made of a transparent hydrophobic acrylic material with an ultraviolet (UV) filter. This material has been in use for over 10 years and its compatibility with the human body is regularly tested.

ARTIS PL E, ARTIS T PL E, ARTIS PRIME, and ARTIS SYMBIOSE devices have a claimed lifespan of 20 years, during which time the safety and claimed performance of the devices are guaranteed.

Each of these devices is CE marked. The CE marking indicates that the device meets the legal requirements applicable at the time it is placed on the market. This means that the device fulfils its function and can be safely used.

III.2 Presence of drugs and substances in the devices

The ARTIS PL E, ARTIS T PL E, ARTIS PRIME, and ARTIS SYMBIOSE devices contain no:

- Animal products,
- Blood products, or products of human origin,
- Medicines,
- Latex,
- Phthalates,
- Metal.

During the life cycle of the devices, patients may be exposed to the following materials and substances (maximum exposure):

- Polyphenoxyethyl acrylate copolymer CBK 1.8 (intraocular lens material) (≤ 23 milligrams/device),
- Poly(ethylene glycol) and poly(ethylene glycol) derivatives (≤ 60.4 micrograms/device),
- Ethylene oxide residues (≤ 0.5 micrograms/device),
- Glycerol monopalmitate or isomer (≤ 29.0 micrograms/device),
- Glycerol monostearate or isomer (≤ 18.5 micrograms/device),
- 2-phenoxyethanol (≤ 325.8 micrograms/device),
- 2-(2-phenoxyethoxy)ethanol (≤ 46.3 micrograms/device).

In the event of release, even total release of these substances, no impact on your body or health is expected.

III.3 Mode of action of the devices

The ARTIS PL E, ARTIS T PL E, ARTIS PRIME, and ARTIS SYMBIOSE devices replace the opacified natural crystalline lens and ensure its function by projecting sharp images onto the retina.

Distance vision is the ability to see objects at a certain distance from several metres away. It is important for activities such as driving, observing scenery, participating in outdoor and other sports, etc.

Intermediate vision is the ability to see objects at a general distance of 60 cm to 1 metre. It is important for activities such as gardening, reading a computer screen, etc.

Near vision is the ability to see objects at a short distance, generally at less than 40 cm. It is important for activities such as reading a book, writing, sewing, etc.

The ARTIS PL E and ARTIS PRIME (non-toric version) devices are monofocal intraocular lenses. This means that it provides sharp vision at a single distance, usually for distance vision, due to the optical power. If necessary, it can also help to correct any pre-existing myopia or hyperopia.

The ARTIS T PL E and ARTIS PRIME (toric version) devices are toric monofocal intraocular lenses. This means that it provides sharp vision at a single distance, usually for distance vision, due to the optical power. If necessary, it can also help to correct any pre-existing myopia or hyperopia. In addition, the toric power corrects corneal astigmatism.

When vision is corrected at only one distance, this means that you will probably need glasses to see clearly at other distances.

The ARTIS SYMBIOSE device is a multifocal intraocular lens with extended depth of focus and binocular complementarity. It is available in a non-toric and a toric version to correct corneal astigmatism:

- A multifocal lens provides sharp vision at several distances (e.g., a bifocal lens that corrects at 2 distances (near and far) or a trifocal lens that corrects at 3 distances (near, intermediate, and far)).
- A lens with an extended depth of focus provides a range of sharp vision and not one or more distances of sharp vision. This type of lens uses advanced optical technology to extend the depth of focus, i.e., the distance at which objects appear clearly.
- Binocular complementarity means that the combination of two lenses (one in each eye) allows them to work together, to complement each other.

The technology of the ARTIS SYMBIOSE device makes it possible to obtain sharp and continuous near to intermediate vision, as well as sharp distance vision.

In fact, the ARTIS SYMBIOSE device provides the appropriate optical power for sharp distance vision and helps to correct any pre-existing myopia or hyperopia, if necessary. It compensates for presbyopia with one of its two additional power profiles, which provide a depth of focus that contributes to near or intermediate vision. The complementarity of the 2 profiles in binocular vision provides continuous, sharp vision. The toric power of the toric version also corrects corneal astigmatism.

With a multifocal intraocular lens, glasses are normally worn less frequently than with a monofocal intraocular lens. However, compromises may be necessary (see *Warnings and precautions*).

III.4 Description of the accessories

An ARTIS PL E, ARTIS T PL E, ARTIS PRIME or ARTIS SYMBIOSE intraocular lens is implanted via the injector where it is preloaded. Sterile balanced salt solution is used to hydrate the device during preparation, and the device must be lubricated prior to use with sterile viscoelastic ophthalmic fluid to facilitate sliding and insertion of the intraocular lens.

A calculator software specifically developed by CRISTALENS INDUSTRIE is also used to calculate the toric power and to determine the positioning axis of the ARTIS T PL E, ARTIS PRIME (toric version) and ARTIS SYMBIOSE (toric version) devices for each patient.

The surgeon should follow the implantation procedure specified by CRISTALENS INDUSTRIE to the letter. Once all these steps have been completed, the chosen device (ARTIS PL E, ARTIS T PL E, ARTIS PRIME or ARTIS SYMBIOSE) is implanted.

IV Risks and warnings

Important: Contact your healthcare professional if you think you are experiencing any side effects from the device or its use, or if you are concerned about risks.

This document does not replace a consultation with a healthcare professional.

IV.1 Risks and side effects

As with any surgical procedure, there are risks and potential complications, and adverse effects associated with cataract surgery and intraocular lens implantation.

Problems may be temporary or may affect vision permanently.

A few patients may wish to have their intraocular lens removed. This may be due to optical/visual symptoms related to the lens.

As with all intraocular lenses, if you have unexpected results, you may need to continue wearing glasses or you may need a second surgery.

Complications and adverse effects related to the ARTIS PL E, ARTIS T PL E, ARTIS PRIME, and ARTIS SYMBIOSE devices and the associated surgery, as well as the means used to reduce the risks, are listed below in "Table 2 - Complications and adverse effects" (non-exhaustive list).

Table 2 - Complications and adverse effects

Known risks and complications	ARTIS PL E	ARTIS T PL E	ARTIS PRIME	ARTIS SYMBIOSE	What is being done to reduce these risks
Complications and adverse effects related to cataract surgery or to the medical device					
Intraoperative events					
Cataract operation complication: for example, abnormally long and/or complicated surgery	X	X	X	X	Identification of possible risk factors during preoperative evaluation, use of appropriate surgical techniques
Damage to the intraocular lens (scratching, cracking, breakage of the optics; scratching, cracking, warping, breakage of the haptics (<i>structures attached to the edge of the optic, helping to maintain the position of the intraocular lens in the eye</i>))	X	X	X	X	Appropriate design and manufacture of the device, quality control of the device including the injector, training of surgeons in the use of the device, information of surgeons about the controls and the proper use of the device (instructions for use)
Surgical failure	X	X	X	X	Use of appropriate surgical techniques, compliance with the instructions for use of the device
Capsular rupture (<i>the capsule surrounding the crystalline lens tears</i>), zonular damage (<i>the crystalline lens zonule is a fibrous structure that holds the crystalline lens in place in the eye</i>)	X	X	X	X	Use of appropriate surgical techniques, postoperative follow-up
Vitreous loss (<i>vitreous is the gelatinous and transparent substance which fills the inside of the eye, between the crystalline lens and the retina, and gives the eye its round shape. It plays an important role in the transmission of light to the retina</i>)	X	X	X	X	Use of appropriate surgical techniques to minimize intraoperative trauma, preparation of vitreous substitutes to manage vitreous loss if necessary
Corneal suture	X	X	X	X	Use of appropriate surgical techniques to minimize intraoperative trauma
Capsular bag tear (<i>the capsule surrounding the crystalline lens tears</i>)				X	Use of appropriate surgical techniques, postoperative follow-up
Zonular detachment (<i>the crystalline lens zonule is a fibrous structure that holds the crystalline lens in place in the eye</i>)				X	Use of appropriate surgical techniques, postoperative follow-up
Vitreous prolapse (<i>part of the vitreous moves out of its normal position and passes towards the front of the eye. Vitreous is the gelatinous and transparent substance which fills the inside of the eye, between the crystalline lens and the retina, and gives the eye its round shape. It plays an important role in the transmission of light to the retina</i>)				X	Use of appropriate surgical techniques, postoperative follow-up

Known risks and complications	ARTIS PL E	ARTIS T PL E	ARTIS PRIME	ARTIS SYMBIOSE	What is being done to reduce these risks
Capsulorhexis rupture (<i>capsulorhexis is a surgical technique used to remove the central anterior part of the crystalline lens capsule from the eye during cataract surgery</i>)				X	Use of appropriate surgical techniques
Intra- or postoperative events					
Pupillary block (<i>the pupil, the central black part of the eye, cannot dilate normally</i>)	X	X	X	X	Use of proper surgical techniques to prevent bulging of the iris, use of mydriatics (medicines that dilate the pupil) before and during surgery
Corneal endothelium damage: for example, Descemet's membrane detachment, corneal abrasion (<i>the endothelium is the inner layer of the cornea</i>)	X	X	X	X	Use of appropriate surgical techniques
Postoperative events					
Pigment dispersion syndrome (<i>tiny particles of pigment, which normally cover the back of the iris (the coloured part of the eye), come loose and float around inside the eye. These particles can build up and block the normal drainage of fluid in the eye, which can lead to increased eye pressure and potentially cause glaucoma if not monitored or treated</i>)	X	X	X	X	Appropriate design and manufacture of the device, appropriate choice of the device, precise and appropriate positioning of the intraocular lens in the eye, training of surgeons in the use of the device, information of surgeons about the controls and the proper use of the device (instructions for use), use of appropriate surgical techniques
Eye pain	X	X	X	X	Prescription of analgesics, management of complications that may cause pain, postoperative follow-up to assess and treat pain
Wound secretion, wound leak (<i>leakage from the incision, situation where a small amount of fluid leaks from the surgical incision created on the surface of the eye</i>)	X	X	X	X	Use of appropriate surgical techniques, postoperative follow-up

Known risks and complications	ARTIS PL E	ARTIS T PL E	ARTIS PRIME	ARTIS SYMBIOSE	What is being done to reduce these risks
Inflammation, infection, including cystoid macular oedema (<i>accumulation of fluid in the macula</i>), macular oedema (<i>the macula, an area in the center of the retina, becomes swollen due to fluid buildup</i>), uveitis (<i>inflammation of the uvea, which consists of the iris, ciliary body, and choroid</i>), iritis (<i>inflammation of the iris</i>), endophthalmitis (<i>severe inflammation of the interior of the eye, involving the vitreous humour and sometimes the aqueous humour, often caused by bacterial or fungal infections</i>), vitritis (<i>inflammation of the vitreous humour</i>), corneal oedema (<i>the cornea, the clear, bulging surface of the eye, becomes swollen due to fluid retention</i>), toxic anterior segment syndrome (TASS) (<i>rare but serious non-infectious inflammatory condition characterized by a sudden onset of inflammation in the anterior segment of the eye</i>), Tyndall (<i>proliferation of anterior chamber cells</i>), hypopyon (<i>accumulation of pus or inflammatory fluid in the front part of the eye, in the anterior chamber, which can be caused by infection or inflammation of the eye</i>)	X	X	X	X	Sterile device, prompt and appropriate treatment of intraocular infections, intraocular lens in preloaded format, surgery under aseptic conditions, identification of possible risk factors during the preoperative evaluation, preventive antibiotic treatments, use of appropriate surgical techniques, postoperative follow-up, appropriate postoperative anti-inflammatory treatments, appropriate antibiotics treatments, and concomitant treatments
Transient or persistent increased intraocular pressure (<i>abnormally high intraocular pressure</i>)	X	X	X	X	Preoperative evaluation, identification of possible risk factors during the preoperative evaluation, postoperative follow-up, appropriate surgical and medicinal treatments, especially appropriate medication for pressure control if necessary
Visual disturbances: for example, dysphotopsia (<i>abnormal perception of light (excessive light or lack of light) causing disturbing light phenomena</i>), colour misperception, amblyopia (<i>the brain fails to correctly interpret images from both eyes</i>), diplopia (<i>seeing double images</i>), photophobia (<i>eye discomfort in bright light</i>)	X	X	X	X	Appropriate design and manufacture of the device, identification of possible risk factors during the preoperative evaluation, appropriate choice of the device, use of appropriate surgical techniques, appropriate and precise positioning of the intraocular lens in the eye, "education" of the patient because adaptation time is necessary, postoperative follow-up with management of complications

Known risks and complications	ARTIS PL E	ARTIS T PL E	ARTIS PRIME	ARTIS SYMBIOSE	What is being done to reduce these risks
Visual impairment: reduced visual acuity (<i>decreased ability of the eye to see objects or details clearly</i>), blurred vision, residual ametropia (myopia, hyperopia, astigmatism, refractive error) (<i>a small refractive error (myopia, hyperopia, etc.) may remain after the surgery. This can lead to blurred or distorted vision which may require additional treatment to correct the sight</i>)	X	X	X	X	Appropriate design and manufacture of the device, quality control including optical control of all intraocular lenses, careful preoperative assessment (including measurements), appropriate choice of the device, precise surgical technique, precise and appropriate positioning of the intraocular lens in the eye, use of appropriate surgical techniques, postoperative follow-up with management of complications, training of surgeons in the use of the device, information of surgeons about the optical parameters, precautions, and proper use of the device (labelling and instructions)
Explantation, exchange of the intraocular lens	X	X	X	X	Appropriate design and manufacture of the device, quality control including optical control of all intraocular lenses, careful preoperative assessment (including measurements), sterile device, intraocular lens in preloaded format, surgery under aseptic conditions, identification of possible risk factors during the preoperative evaluation, preventive antibiotic treatments, appropriate choice of the device, precise and appropriate surgical technique, precise and appropriate positioning of the intraocular lens in the eye, use of appropriate surgical techniques, postoperative follow-up with management of complications, training of surgeons in the use of the device, information of surgeons about the optical parameters, precautions, and proper use of the device (labelling and instructions)
Repositioning other than following intraocular lens rotation	X	X	X	X	Precise initial surgery, postoperative follow-up, appropriate treatment of complications, reassessment of the benefit/risk ratio with the additional intervention
Secondary procedure (other than removal or repositioning of the intraocular lens, e.g. laser retouch, cortical matter removal (<i>removal of residues from the crystalline lens cortex, the peripheral part of the crystalline lens, located between the central nucleus and the capsule</i>), keratectomy (<i>removal of part of the cornea</i>), vitrectomy (<i>removal of all or part of the vitreous</i>))	X	X	X	X	Precise initial surgery, postoperative follow-up, appropriate treatment of complications, reassessment of the benefit/risk ratio with the additional intervention

Known risks and complications	ARTIS PL E	ARTIS T PL E	ARTIS PRIME	ARTIS SYMBIOSE	What is being done to reduce these risks
Capsular bag dislocation (<i>the capsule surrounding the crystalline lens loses its support and moves from its normal position</i>)				X	Use of appropriate surgical techniques, precise positioning of the intraocular lens in the eye, identification of possible risk factors during the preoperative evaluation, appropriate choice of the device, protection of the eye that was operated on, compliance with the instructions given by the surgeon after surgery
Inflammation, infection, including posterior synechia (<i>inflammatory adhesions between the posterior surface of the iris and the anterior crystalline lens capsule</i>)				X	Sterile device, prompt and appropriate treatment of intraocular infections, intraocular lens in preloaded format, surgery under aseptic conditions, identification of possible risk factors during the preoperative evaluation, preventive antibiotic treatments, use of appropriate surgical techniques, postoperative follow-up, appropriate postoperative anti-inflammatory treatments, appropriate antibiotics treatments, and concomitant treatments
Visual disturbances: for example, visual fluctuation, dry eyes (as visual disturbance), focusing difficulties, depth perception, flashes, stereoacuity problem (<i>stereoacuity: ability of the eyes to perceive depth and distinguish objects at different distances</i>), loss of contrast sensitivity (<i>reduced ability of the eye to distinguish differences in contrast</i>), accommodation not restored				X	Appropriate design and manufacture of the device, identification of possible risk factors during the preoperative evaluation, appropriate choice of the device, use of appropriate surgical techniques, appropriate and precise positioning of the intraocular lens in the eye, "education" of the patient because adaptation time is necessary, postoperative follow-up with management of complications
Visual impairment: blurred, hazy, cloudy vision, foggy sensation, binocularity neuroadaptation disorder (<i>difficulty of the brain to adapt to learning how to interpret new images captured by the eyes and to adjust the perception of vision accordingly</i>)				X	Appropriate design and manufacture of the device, quality control including optical control of all intraocular lenses, careful preoperative assessment (including measurements), appropriate choice of the device, precise surgical technique, precise and appropriate positioning of the intraocular lens in the eye, use of appropriate surgical techniques, postoperative follow-up with management of complications, training of surgeons in the use of the device, information of surgeons about the optical parameters, precautions, and proper use of the device (labelling and instructions)
Capsular microfolds (<i>fine ripples or small folds in the capsule surrounding the crystalline lens</i>)				X	Use of appropriate surgical techniques, appropriate design and manufacture of the device, appropriate choice of the device, quality control of the device, postoperative follow-up
Complications and adverse effects related to the medical device					
Intraoperative events					

Known risks and complications	ARTIS PL E	ARTIS T PL E	ARTIS PRIME	ARTIS SYMBIOSE	What is being done to reduce these risks
Injector failure (jamming, blockage, abnormal behaviour of the intraocular lens)	X	X	X	X	Appropriate design and manufacture of the device, quality control of the device including the injector, training of surgeons in the use of the device, information of surgeons about the proper use of the device (instructions for use)
Stuck haptics, haptic adhesions (<i>structures attached to the edge of the optic, helping to maintain the position of the intraocular lens in the eye</i>)	X	X	X	X	Appropriate design and manufacture of the device, quality control of the device including the injector, training of surgeons in the use of the device, information of surgeons about the proper use of the device (instructions for use)
Mispositioned haptics (<i>structures attached to the edge of the optic, helping to maintain the position of the intraocular lens in the eye</i>)	X	X	X	X	Appropriate design and manufacture of the device, quality control of the device including the injector, training of surgeons in the use of the device, information of surgeons about the proper use of the device (instructions for use)
Postoperative events					
Tilt of the implant (<i>intraocular lens that moves from its normal positioning axis</i>)	X	X	X	X	Use of appropriate surgical techniques, precise positioning of the intraocular lens in the eye, identification of possible risk factors during the preoperative evaluation, appropriate choice of the device, training of surgeons in the use of the device, information of surgeons about the proper use of the device (instructions for use), compliance with the instructions given by the surgeon after surgery
Decentration of the implant (<i>intraocular lens not correctly centered</i>)	X	X	X	X	Use of appropriate surgical techniques, precise positioning of the intraocular lens in the eye, identification of possible risk factors during the preoperative evaluation, appropriate choice of the device, training of surgeons in the use of the device, information of surgeons about the proper use of the device (instructions for use), protection of the eye that was operated on, compliance with the instructions given by the surgeon after surgery
Dislocation, luxation of the implant (<i>intraocular lens that moves from its normal position and completely detaches from its attachment in the eye</i>)	X	X	X	X	Use of appropriate surgical techniques, precise positioning of the intraocular lens in the eye, identification of possible risk factors during the preoperative evaluation, appropriate choice of the device, protection of the eye that was operated on, compliance with the instructions given by the surgeon after surgery
Tearing of the implant (including haptic breakage/tear (<i>structures attached to the edge of the optic, helping to maintain the position of the intraocular lens in the eye</i>))	X	X	X	X	Appropriate design and manufacture of the device, quality control of the device including the injector, training of surgeons in the use of the device, information of surgeons about the controls and the proper use of the device (instructions for use)

Known risks and complications	ARTIS PL E	ARTIS T PL E	ARTIS PRIME	ARTIS SYMBIOSE	What is being done to reduce these risks
Anterior capsule contraction, anterior fibrosis (<i>condition that can occur after phacoemulsification and intraocular lens implantation whereby the anterior capsulotomy excessively contracts and becomes fibrotic (capsulotomy is a surgical technique in which an incision is made in the crystalline lens capsule)</i>)	X	X	X	X	Use of appropriate surgical techniques, appropriate design and manufacture of the device, appropriate choice of the device, quality control of the device, postoperative follow-up
Glistening (<i>small bubbles inside the intraocular lens creating a shiny or sparkling effect</i>)	X	X	X	X	Appropriate design and manufacture of the device, postoperative follow-up
Discolouration (including opacification, calcification (<i>deposits of calcium phosphate accumulate on the surface of the intraocular lens</i>), whitening)	X	X	X	X	Appropriate design and manufacture of the device, postoperative follow-up
Intraocular lens rotation (<i>the intraocular lens rotates on itself; it moves from the axis along which it was positioned</i>)		X	X (toric version)	X (toric version)	Careful preoperative assessment (including measurements), appropriate choice of the device, use of appropriate surgical techniques, precise surgical technique, appropriate positioning of the intraocular lens in the eye, appropriate design and manufacture of the device, training of surgeons in the use of the device, information for surgeons about optical parameters, precautions and proper preparation and use of the device (labelling and instructions), postoperative follow-up
Repositioning following intraocular lens rotation (<i>additional surgery to realign the intraocular lens on its implantation axis</i>)		X	X (toric version)	X (toric version)	Precise initial surgery, postoperative follow-up, appropriate treatment of complications, reassessment of the benefit/risk ratio with the additional intervention
Capsular phimosis (<i>shrinkage and whitening of the anterior capsule opening</i>), retraction of the rhexis (<i>progressive contraction of capsulorhexis (capsulorhexis is a surgical technique used to remove the central anterior part of the crystalline lens capsule from the eye during cataract surgery)</i>)				X	Use of appropriate surgical techniques, appropriate design and manufacture of the device, appropriate choice of the device, quality control of the device, postoperative follow-up
Complications and adverse effects related to cataract surgery					
Intraoperative events					
Miosis (<i>constriction or narrowing of the pupil</i>)	X	X	X	X	Use of appropriate surgical techniques
Angle trauma (<i>deformation of the iridocorneal angle, where the aqueous humour is absorbed</i>)	X	X	X	X	Use of appropriate surgical techniques

Known risks and complications	ARTIS PL E	ARTIS T PL E	ARTIS PRIME	ARTIS SYMBIOSE	What is being done to reduce these risks
Capsulorhexis tear-out (<i>the capsulorhexis begins to extend peripherally, radial cracks that form in the outer part of the crystalline lens (capsulorhexis is a surgical technique used to remove the central anterior part of the crystalline lens capsule from the eye during cataract surgery)</i>)	X	X	X	X	Use of appropriate surgical techniques
Posterior capsular plaque (<i>lesion resulting from posterior migration of the epithelium and development of pseudo-fibrous transformation in the crystalline lens epithelium</i>)	X	X	X	X	Use of appropriate surgical techniques
Iris defect, iris atrophy (<i>reduction or disappearance of iris tissue</i>)				X	Use of appropriate surgical techniques
Radial tear (<i>radial cracks that form in the outer part of the crystalline lens</i>)				X	Use of appropriate surgical techniques
Retinal injury (<i>trauma to the retina that occurred during cataract surgery</i>)				X	Use of appropriate surgical techniques
Intra- or postoperative events					
Haemorrhage: Anterior chamber haemorrhage, conjunctival haemorrhage (<i>the conjunctiva is the transparent membrane that covers the white part of the eye</i>), eye haemorrhage, vitreous haemorrhage (<i>vitreous is the gelatinous and transparent substance which fills the inside of the eye, between the crystalline lens and the retina, and gives the eye its round shape. It plays an important role in the transmission of light to the retina</i>), iris bleeding	X	X	X	X	Use of appropriate surgical techniques to minimize intraoperative trauma, prevention and management of intraoperative hypertension
Haemorrhage: Microhaemorrhages				X	Use of appropriate surgical techniques to minimize intraoperative trauma, prevention and management of intraoperative hypertension
Postoperative events					
Posterior capsule opacification (PCO) (also called secondary cataract) (<i>the capsule that holds the intraocular lens in place becomes opaque</i>)	X	X	X	X	Use of appropriate surgical techniques, appropriate design and manufacture of the device, appropriate choice of the device, quality control of the device, postoperative follow-up
Anterior capsule opacification (ACO) (<i>the capsule that holds the intraocular lens in place becomes opaque</i>)	X	X	X	X	Use of appropriate surgical techniques, appropriate design and manufacture of the device, appropriate choice of the device, quality control of the device, postoperative follow-up

Known risks and complications	ARTIS PL E	ARTIS T PL E	ARTIS PRIME	ARTIS SYMBIOSE	What is being done to reduce these risks
Retinal detachment (<i>the retina, thin layer at the back of the eye, is pulled away from its normal position</i>)	X	X	X	X	Use of appropriate surgical techniques, postoperative follow-up
Retinal tear (<i>hole that forms in the outer part of the retina, the thin layer at the back of the eye</i>)	X	X	X	X	Use of appropriate surgical techniques, postoperative follow-up
Retained cortical matter (<i>presence of crystalline lens cortex, the peripheral part of the crystalline lens, located between the central nucleus and the capsule, that has unintentionally remained within the eye following cataract surgery</i>)	X	X	X	X	Use of appropriate surgical techniques, postoperative follow-up
Iris injury, damage	X	X	X	X	Use of appropriate surgical techniques, postoperative follow-up
Iridocele (<i>iris prolapse, trauma, through an abnormal opening or defect in the eye's tissues</i>)	X	X	X	X	Use of appropriate surgical techniques, postoperative follow-up
Inflammation, infection, including punctate keratitis, keratitis (<i>inflammation of the cornea</i>), corneal ulcer, herpetic keratitis, bullous keratitis, conjunctivitis (<i>inflammation of the conjunctiva, clear membrane that covers the white part of the eye (sclera) and lines the inner surface of the eyelids</i>), allergic conjunctivitis, viral conjunctivitis, conjunctival hyperaemia (<i>enlargement or dilation of blood vessels in the conjunctiva, leading to a red or bloodshot appearance of the eyes</i>), conjunctival oedema (chemosis), blepharitis (<i>chronic inflammation of the eyelids, specifically affecting the eyelid margins where the eyelashes grow</i>), hordeolum (<i>stye, localised and painful swelling or lump that forms on the eyelid</i>), eye irritation	X	X	X	X	Sterile device, intraocular lens in preloaded format, surgery under aseptic conditions, identification of possible risk factors during the preoperative evaluation, preventive antibiotic treatments, postoperative anti-inflammatory treatments, and appropriate antibiotics, monitoring for infection and treatment

Known risks and complications	ARTIS PL E	ARTIS T PL E	ARTIS PRIME	ARTIS SYMBIOSE	What is being done to reduce these risks
Comorbidity for which cataract surgery is a risk factor for onset/development: Age-related macular degeneration (AMD), macular degeneration (<i>a disease of the macula, an area in the centre of the retina, characterized by progressive loss of central vision</i>), other macular conditions (including maculopathy, macular hole (<i>hole/tear in the macula</i>), macular fibrosis (<i>fibrous or scar tissue in the macula</i>), macular scar, epiretinal/epimacular membrane), dry eye, watery eyes, pinguecula (<i>common, non-cancerous growth on the conjunctiva, appears as a yellowish or white bump on the conjunctiva near the cornea</i>), diabetic retinopathy (<i>an eye complication from diabetes affecting the retina by damaging the blood vessels that irrigate it</i>), eyelid ptosis (<i>droopy eyelids</i>), trichiasis (<i>eyelashes grow in an abnormal direction, typically inwards towards the eye, causing them to rub against the cornea and conjunctiva</i>), Descemet folds (<i>Descemet's membrane irregularities or undulations, membrane situated between the stroma and the endothelium</i>), arcus lipoides (<i>presence of a white or greyish ring around the outer edge of the cornea</i>), iris atrophy, corneal disorder, corneal degeneration, corneal dystrophy (<i>rare genetic diseases that affect the structure and function of the cornea</i>) (includes keratoconus (<i>gradual, conical deformation of the central part of the cornea which becomes thinner and more curved than normal</i>), Fuchs dystrophy (<i>progressive and degenerative disease of the corneal endothelium</i>)), iris hypopigmentation, vital dye staining of the cornea (<i>highlights specific structures or abnormalities on the cornea</i>), vitreous disorder (<i>vitreous is a gelatinous and transparent substance which fills the inside of the eye, between the crystalline lens and the retina, and gives the eye its round shape. It plays an important role in the transmission of light to the retina</i>), vitreous floaters, vitreous degeneration, vitreous detachment (<i>physiological phenomenon occurring more frequently after cataract surgery</i>)	X	X	X	X	Use of appropriate surgical techniques to minimize intraoperative trauma, postoperative follow-up to detect and treat early, use of artificial tears, prescription of drugs to improve tear production if necessary, preoperative evaluation, use of appropriate surgical and anaesthetic techniques, postoperative follow-up with management of complications, consultation with a specialised surgeon if necessary
Retinal degeneration (<i>condition in which the retina deteriorates due to the gradual loss of retinal cells</i>)				X	Use of appropriate surgical techniques, postoperative follow-up

Known risks and complications	ARTIS PL E	ARTIS T PL E	ARTIS PRIME	ARTIS SYMBIOSE	What is being done to reduce these risks
Headaches				X	Use of appropriate surgical techniques, postoperative follow-up
Diseases of the ocular surface such as discomfort of the external canthus (<i>irritation on the outside of the eye, small area at the outer corner of the eye, near the temple</i>), white deposit in the internal canthus (<i>small area at the inner corner of the eye, near the nose</i>), discomfort in the eyelids, eyelid eczema, swollen eyelids, burning sensation, foreign body sensation in the eyes, sand grain sensation, itching				X	Use of appropriate surgical techniques, postoperative follow-up
Inflammation, infection, including papillary conjunctivitis (<i>inflammation of the conjunctiva, clear membrane that covers the white part of the eye (sclera) and lines the inner surface of the eyelids</i>), rhinoconjunctivitis, chalazion (<i>lump (ball) in the eyelid</i>), ocular hyperaemia (<i>increased blood flow in the eye</i>), iridocyclitis (<i>chronic or acute inflammatory reaction of the iris (iritis) and ciliary body (cyclitis)</i>)				X	Sterile device, intraocular lens in preloaded format, surgery under aseptic conditions, identification of possible risk factors during the preoperative evaluation, preventive antibiotic treatments, postoperative anti-inflammatory treatments, and appropriate antibiotics, monitoring for infection and treatment
Comorbidity for which cataract surgery is a risk factor for onset/development: keratoconjunctivitis sicca (<i>chronic bilateral drying of the conjunctiva and cornea due to a qualitative or quantitative alteration in the lachrymal film</i>), lacrimal deficiency, corneal folds, corneal dystrophy (<i>rare genetic diseases that affect the structure and function of the cornea</i>) (includes cornea guttata (<i>presence of small drop-shaped growths on the corneal endothelium membrane</i>)), myodesopsia (<i>benign vision disorder, also known as floating body or flying flies</i>), unstable tear film, dysfunction of the Meibomius glands (<i>sebaceous glands located in the epidermis of the eyelids</i>), meibomitis (<i>chronic inflammation of the sebaceous glands that line the upper and lower eyelids</i>)				X	Use of appropriate surgical techniques to minimize intraoperative trauma, postoperative follow-up to detect and treat early, use of artificial tears, prescription of drugs to improve tear production if necessary, preoperative evaluation, use of appropriate surgical and anaesthetic techniques, postoperative follow-up with management of complications, consultation with a specialised surgeon if necessary

IV.2 Warnings and precautions

Before surgery:

The surgeon should have a discussion with you to assess your level of discomfort and the impact on your quality of life. Your needs should also be discussed as the choice of the intraocular lens to be implanted is based on your lifestyle and possibly your preferences.

The surgeon should inform you of your options. He/she should accurately inform you in appropriate language about the types of intraocular lenses that could be implanted, their benefits, as well as any possible contraindications, residual risks, complications, and adverse effects related to these types of implants and to cataract surgery associated with the implantation of an intraocular lens.

All this information is to make you aware of the risks and benefits so that you can assess the benefit/risk ratio of cataract surgery associated with the implantation of an ARTIS PL E, ARTIS T PL E, ARTIS PRIME or ARTIS SYMBIOSE intraocular lens. You are then able to make an informed decision.

It should be noted that you will be assessed before any decision is made concerning cataract surgery. Among other things, this assessment makes it possible to:

- Verify whether you have any eye disease besides age-related cataract. In fact, the choice of device and the result obtained after implantation could depend on the health of your eye before surgery.
- Become aware of any medical condition or medicinal treatment that could affect your surgery or vision. Certain pre-existing diseases or conditions could put you at greater risk of complications after cataract surgery (for example, a more difficult recovery).
- Measure your eye to choose the correct power of the intraocular lens to be implanted. If you wear contact lenses, your healthcare professional may ask you to remove them before the examination.

Plan to have someone accompany you home after surgery.

After surgery:

The surgeon should accurately inform you in appropriate language about the postoperative follow-up and required measures (required monitoring, possible interactions and interferences, possible complications, and adverse effects, etc.) related to cataract surgery and the type of intraocular lens implanted.

He/she should also give you an implant card that specifies the name of the device used (ARTIS PL E, ARTIS T PL E, ARTIS PRIME or ARTIS SYMBIOSE), the traceability, the contact details for CRISTALENS INDUSTRIE, as well as the date and place of the surgery.

The surgeon should also inform you about the expected lifetime of the device, the ophthalmological monitoring required throughout this period, and the materials and substances to which you might be exposed.

In fact, regular, long-term assessment of the intraocular lens is required. It is important to continue follow-up appointments to assess your eye health and ensure proper functioning of your intraocular lens.

Consult your healthcare professional if you have any questions or concerns after a cataract surgery.

It should be noted that improvements in vision are different for each person. It may take some time to get used to your intraocular lens. Many patients start to feel better after 1 or 2 days. Some are stable after 1 to 2 weeks. In some cases, it takes 4-6 weeks to recover from surgery.

After surgery and during the recovery period, strictly follow your surgeon's instructions. Do not rub your eyes and avoid any activity that could harm your eye. Your healthcare professional will tell you which activities to avoid.

Seek urgent medical attention if there is a decrease in visual acuity associated with significant pain in the eye that was operated on in the first few days after surgery.

Contact a healthcare professional immediately if you experience any of the following symptoms after surgery (or in any other situation you consider appropriate):

- Decreased vision in the treated eye compared to the day after surgery,
- Pain in the treated eye,
- Significant increase in redness in the treated eye,
- Swelling of the eyelid and/or stuck eyelids,

- Significant discomfort due to a visual disorder (perception of spots, flying flies, dark veil, sparks, etc.),
- Accidental direct contusion.

These symptoms could indicate potentially serious postoperative complications.

It should be noted that, for certain complications, intervention by the surgeon might be required to correct the problem:

- In case of opacification of the posterior capsule (also called secondary cataract), a procedure called Nd-YAG laser capsulotomy could be performed to restore visual clarity.
- In case of decentration, tilt or dislocation of the intraocular lens, surgery can be performed to reposition it.
- In case of damage to the intraocular lens or intolerance to multifocality, surgery can be performed to explant the intraocular lens and replace it with another one.

Moreover, in the long term and/or beyond the expected 20-year lifetime of the ARTIS PL E, ARTIS T PL E, ARTIS PRIME or ARTIS SYMBIOSE device, intraocular lens replacement might be considered, particularly if it is damaged, misaligned, opacified, or if the intraocular lens prescription is no longer adapted to your visual needs.

Any decision regarding a possible secondary surgery, such as replacement of the implanted intraocular lens, should be made by the surgeon based on a careful assessment of the benefit/risk ratio. Discomfort experienced and the performance of the intraocular lens should be weighed against the risks associated with a repeat surgery. Expert surgical skills may be required, particularly if the intraocular lens is to be replaced after several months or years.

The ARTIS T PL E, ARTIS PRIME (toric version) and ARTIS SYMBIOSE (toric version) devices: A toric intraocular lens will only correct corneal astigmatism if placed in the correct position. Therefore, misalignment of the intraocular lens in relation to the positioning axis could result in significant impairment of your eye's ability to see objects or details clearly, and thus require realignment of the intraocular lens. It is recommended to perform this realignment as soon as notified and up to one month after implantation.

Due to the optical design of multifocal intraocular lenses, which include the ARTIS SYMBIOSE device, some effects could be greater than with a monofocal intraocular lens and could make vision more difficult in certain situations:

- Visual effects can be expected due to the superposition of multi-focused (sharp and precise) and unfocused (blurred) images. These could occur as halos (light circles around light sources), glare, stars, streaks (straight or curved lines that may appear in the field of vision), or radial lines (light rays that propagate from light sources and create a fan-like radial effect around the source), especially at night or in low light. Some of these effects can be mitigated after a period of adaptation to multifocality.
- Increased sensitivity to light is noted. This is neither a complication nor an adverse effect, but an unavoidable and usually temporary effect after surgery, which disappears after a period of adaptation to multifocality.
- In low light, the sharpness of vision with a multifocal intraocular lens could decrease compared to vision with a monofocal intraocular lens due to reduced contrast sensitivity (decreased ability of the eye to distinguish differences in contrast). Therefore, patients with a multifocal intraocular lens implant should be vigilant when driving at night or when visibility is poor. Performing tasks in low light or in a dimly lit room could be more difficult after surgery (e.g., additional, or stronger lighting could be required to read small print).

Interactions and interferences:

- Intraocular lenses manufactured by CRISTALENS INDUSTRIE comply with the Nd-YAG laser exposure test. Posterior capsule opacification can be treated by Nd-YAG laser capsulotomy, when necessary, without affecting the safety and performance of the implanted intraocular lens.
- The devices manufactured by CRISTALENS INDUSTRIE do not contain metallic materials.
- Silicone oil, particularly when used in the surgical treatment of retinal detachment, could touch the intraocular lens if the posterior crystalline lens capsule is not intact. This may cause partial and/or localised opacification of the intraocular lens.
- No interference and/or adverse effects from exposure to temperature or humidity, external influences or, reasonably foreseeable environmental conditions such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharges, or radiation associated with diagnostic and therapeutic procedures are known.
- No direct drug interactions are known. However, in some cases current or previous treatments with alpha-1 adrenergic receptor antagonists can increase the risk of intraoperative complications associated with cataract surgery (Intraoperative Floppy Iris Syndrome (IFIS)).

- No interference and/or adverse effects related to interactions with other devices during diagnostic examinations, evaluations, therapeutic treatments, or other specific procedures are known.

Reporting of serious incidents:

As discussed with the doctor and/or the health care facility where the incident is detected, you should report any serious incident concerning the device (ARTIS PL E, ARTIS T PL E, ARTIS PRIME or ARTIS SYMBIOSE) to CRISTALENS INDUSTRIE, the local contact (distributor) if their details are known, the healthcare professional who performed the procedure, and the competent authority in the patient's country.

To inform CRISTALENS INDUSTRIE:

1. Contact CRISTALENS INDUSTRIE immediately:
 - By e-mail to materiovigilance@cristalens.fr,
 - Via the dedicated "Information request" form on the website (www.cristalens-international.com) in the "Contact" tab.
2. Provide all the necessary information requested at the time of contact, in particular traceability information indicated on the implant card.

Note: A serious incident is any incident that directly or indirectly resulted in, may have resulted in, or may result in:

- a) The death of a patient, user, or any other person,
- b) Serious temporary or permanent deterioration in the health status of a patient, user, or any other person,
- c) A serious threat to public health.

IV.3 How risks were controlled or managed

See "Table 2 – Adverse effects" above.

V Medical alternatives to the devices

Important: If you are planning to have alternative treatments, you should contact your healthcare professional who will be able to take your wishes and personal situation into consideration.

V.1 General description of the alternatives

There are non-surgical alternatives that can help to improve the symptoms of cataract. Here are the options for avoiding or delaying the procedure:

- Wearing glasses or contact lenses to correct vision,
- Using magnifiers, reading lights or other vision aids to read and perform detailed tasks.

However, these options do not treat the cataract itself and cannot prevent its progression.

When alternative methods cease to be sufficiently effective and the cataract seriously affects your quality of life, surgery is indicated.

The most common surgical technique for cataract surgery is phacoemulsification. It consists of making a small incision in the cornea and then breaking up and aspirating the opacified crystalline lens using an ultrasound probe called a phacoemulsifier. However, if the clinical situation lends itself to another technique, the surgeon may propose one of the following:

- Intracapsular cataract extraction (ICCE): a wide incision is made in the sclera (white part of the eye) to remove the entire crystalline lens including the surrounding capsule. It was commonly used before the advent of modern techniques but is now only practised in rare cases.
- Extracapsular cataract extraction (ECCE): the opacified crystalline lens is removed and the anterior capsule is left intact. A wide incision is made in the cornea to access the crystalline lens and remove the central part. The peripheral part of the crystalline lens is removed using a curettage or aspiration technique.
- Femtosecond laser-assisted cataract surgery (FLACS): an advanced surgical technique that uses an ultra-fast laser to create a precise incision in the cornea, fragment the opacified crystalline lens and create a precise anterior capsule to facilitate crystalline lens ablation.

The surgeon will then choose the type of device that is most likely to successfully treat your individual situation. Several types of intraocular lenses (monofocal, multifocal, toric, extended depth of focus) are described in the section *Mode of action of the devices*.

VI Suggested profiles for professional users

ARTIS PL E, ARTIS T PL E, ARTIS PRIME, and ARTIS SYMBIOSE devices are for surgical use only.

Their use is reserved solely to qualified cataract operators with the required training and experience.

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