Information for patients or non-specialists

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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* 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 use of the medical device for your situation (ARTIS PL *E*, ARTIS T PL *E* 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.

Contents

I Identification of the devices and general information

I.1 Trade name of the devices

ARTIS PL *E*

ARTIS T PL *E*

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:

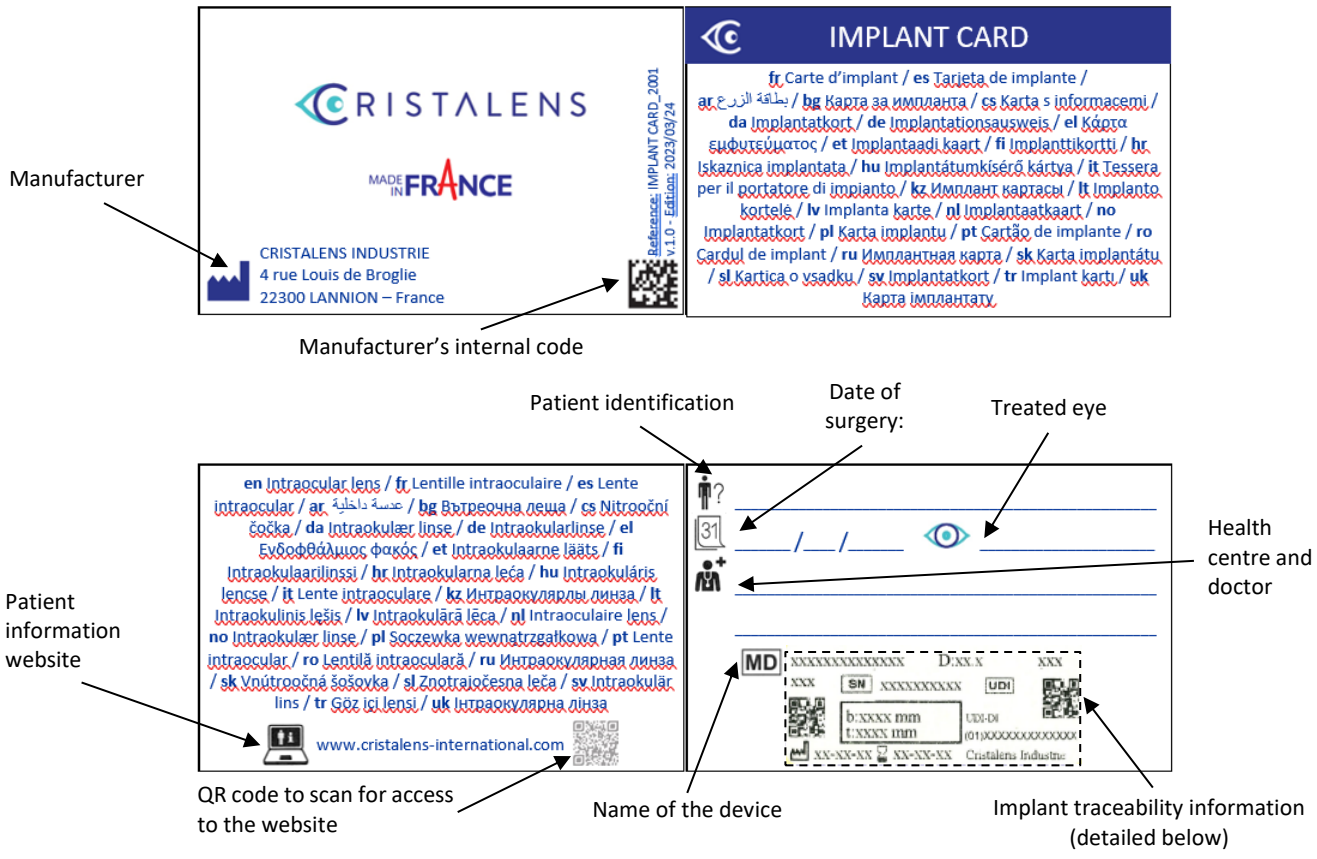
- ARTIS PL *E* / ARTIS T PL *E*: 37006373IOL01D6
- ARTIS SYMBIOSE: 37006373IOL02D8.

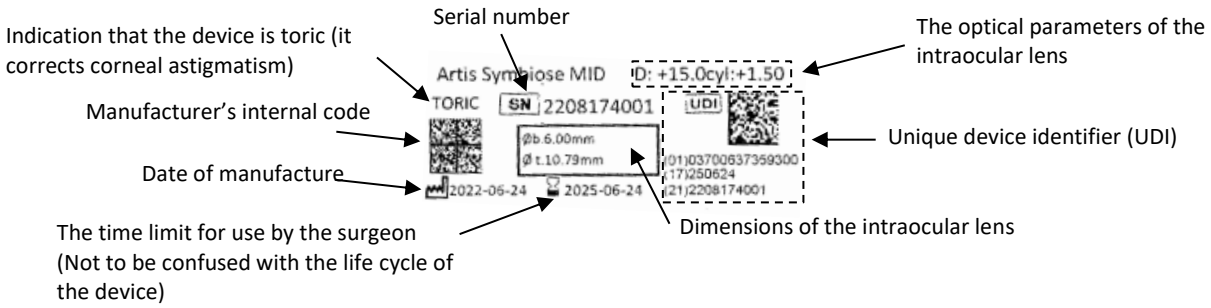
I.4 Implant card

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* 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 lens which has become opaque due to cataract. Using the injector, this intraocular lens is inserted into the capsular bag that surrounds the eye lens.

Figure 2. Diagram of the eye

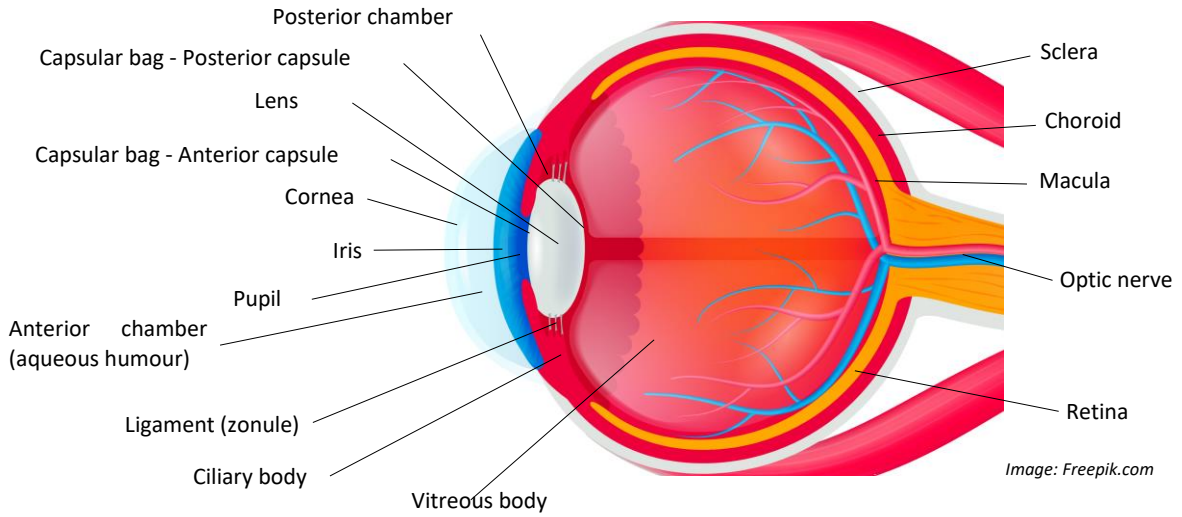


Image: Freepik.com

II.2 Indications and patient categories

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

The ARTIS T PL *E* device is 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 a lens in the eye. This can occur after cataract surgery where the opacified lens is surgically removed from the eye and is replaced by an intraocular implant. The lens is a key structure of the eye that helps converge light rays onto the retina to create a clear 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, hyperopia or, astigmatism.

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 lens of the eye, which makes it more difficult to focus (accommodation) on near objects.

Patients who are eligible for ARTIS PL *E*, ARTIS T PL *E* or ARTIS SYMBIOSE implantation are adults who have had their natural 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* and ARTIS SYMBIOSE 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 SYMBIOSE**	**ARTIS PL *E***	**ARTIS T PL *E***	**ARTIS SYMBIOSE**
Neonates, premature neonates, infants, and children (until 18 years of age)	X	X	X			
Active intraocular infection	X	X	X			
Any active ocular disease other than age-related cataract	X	X	X			
Acute ocular or intraocular inflammation	X	X	X			
Acute ocular disease	X	X	X			
Any progressive ocular disease other than age-related cataract	X	X	X			
Nanophthalmos *(abnormally small eye, extremely small, often underdeveloped eye that may lack normal eye structures)*	X	X	X			
Severe optic nerve atrophy *(severely damaged optic nerve, optic nerve fibres destroyed)*	X	X	X			
Inadequate capsular support *(limited capacity of the lens capsule to maintain the intraocular lens in a stable position after surgery)*	X	X	X			
Allergy to ethylene oxide *(a gas commonly used as a sterilising agent for medical devices)*	X	X	X			
Pregnancy or breastfeeding	X	X	X			
Glaucoma *(a chronic eye disease that gradually damages the optic nerve)*			X	X	X	
Choroidal haemorrhage or any other intraocular haemorrhage *(the choroid is a layer of vessels beneath the retina)*			X	X	X	
Intraocular hypertension *(abnormally high intraocular pressure)*			X	X	X	
Aniridia *(partial or total absence of the iris)*			X	X	X	
Amblyopia *(the brain is unable to correctly interpret images from both eyes)*			X	X	X	
Retinal diseases (e.g., macular degeneration *(disease of the macula, the area in the centre of the retina, characterised by progressive loss of central vision)*, diabetic retinopathy *(ocular complication of diabetes that affects the retina by damaging the supplying blood vessels)*, retinal detachment or a history of retinal detachment, cystoid macular oedema *(fluid build-up in the macula)*, macular hole *(hole/tear in the macula)*)			X	X	X	
Corneal abnormalities (e.g., keratoconus *(progressive, conical deformity of the central part of the cornea which becomes thinner and more curved than normal)*, corneal opacification *(loss of corneal transparency)*)			X	X	X	
A large eye, an eye with an excessive axial length (greater than 28 mm) (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)			X	X	X	
Microphthalmia *(abnormally small eye)*			X	X	X	
Non-age-related cataract (e.g., traumatic cataract, congenital cataract)				X	X	X

A history of intraocular or refractive surgery				X	X	X
Use of systemic or eye medicines that could affect vision *(systemic medicines are absorbed through the circulatory system and have a whole-body effect, unlike topical medicines which are applied locally)*				X	X	X
Ocular or intraocular inflammation				X	X	X
Intraocular infection				X	X	X
Corneal diseases that compromise visual acuity (e.g., corneal endothelial diseases *(affect the endothelium, the inner layer of the cornea)*, corneal dystrophies *(rare genetic diseases that affect the structure and function of the cornea)*, a history of corneal transplants/grafting)				X	X	X
Capsular or zonular abnormalities that can affect the postoperative centring or tilt of the intraocular lens *(the lens zonule is a fibrous structure that holds the lens in place in the eye)*				X	X	X
Posterior capsule rupture or a wide capsulorhexis (compromised intraocular lens stability) *(the posterior capsule is a thin membrane surrounding the lens and which is attached to the zonule of the eye. It holds the lens in place) (capsulorhexis is a surgical technique whereby a precise round opening is made in the anterior capsule of the eye during cataract surgery)*				X	X	X
Known or suspected radial tears or tear-out at the time of surgery *(radial cracks that form in the outer part of the eye lens)*				X	X	X
Incapacity to confirm the integrity of the capsulorhexis by direct visualisation				X	X	X
Capsulotomy by a technique other than a circular incision *(capsulotomy: surgical technique in which an incision is made in the lens capsule)*				X	X	X
Anterior chamber collapse *(reduced intraocular pressure resulting in a loss of volume in the front part of the eye, between the cornea and the iris)*				X	X	X
Narrow anterior chamber *(the area between the cornea in front and the iris in the back is smaller than usual)*				X	X	X
Response to corticosteroids that increase intraocular pressure				X	X	X
Significant loss of vitreous humour *(a gelatinous, transparent substance that fills the interior of the eye, between the 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)*				X	X	X
Anisometropia *(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)*, aniseikonia *(difference in size between the two eyes)*				X	X	X
Irregular corneal astigmatism *(corneal astigmatism where the shape of the cornea is abnormal)*, significant irregular corneal aberration *(an optical anomaly that occurs when light is distorted as it passes through the unevenly shaped cornea)*					X	X
Dry eyes (e.g., Meibomian gland dysfunction *(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*))						X
Expected residual postoperative astigmatism greater than 0.75D *(some degree of astigmatism persists after intraocular lens implantation)*						X

Strabismus *(misalignment of the eyes)*, absence of binocular vision *(the brain cannot correctly interpret images from both eyes)*						X
Pupil abnormality (unresponsive *(no reaction to stimuli)*, a tonic pupil *(larger than usual with abnormal reaction to light)*, an abnormally shaped pupil or one which dilates less than 3.5 mm in moderate/low light)						X
Monophthalmia *(absence of one eye)*						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* 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 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, and ARTIS SYMBIOSE intraocular lenses

Figure 4. Injector

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

The safety and performance that are claimed are expected to endure as long as the ARTIS PL *E*, ARTIS T PL *E* and ARTIS SYMBIOSE devices are functional, i.e., during 20 years.

Each of these devices is CE marked. The CE marking indicates that the individual product 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* 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):

- Cross-linked acrylic 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 monosterate or isomer (≤ 18.5 micrograms/device),

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- 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* and ARTIS SYMBIOSE devices replace the opacified natural lens and ensure its function by projecting clear 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* device is a monofocal intraocular lens. This means that it provides clear 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* device is a toric monofocal intraocular lens. This means that it provides clear 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 clear 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 clear vision and not one or more distances of clear 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 allows to obtain a clear, continuous vision from near to intermediate, as well as clear distance vision.

In fact, the ARTIS SYMBIOSE device provides the appropriate optical power for clear 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, clear 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* or ARTIS SYMBIOSE intraocular lens is implanted through the injector in which 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 computer 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* and ARTIS SYMBIOSE devices (the toric version) 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* 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* 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 SYMBIOSE	What is done to reduce these risks
Adverse effects related to the device				
Whitening of the intraocular lens (permanent)	X	X	X	Appropriate design and manufacture of the device, postoperative follow-up
Subconjunctival haemorrhage *(the conjunctiva is the transparent membrane that covers the white part of the eye)* (temporary)	X	X	X	Use of appropriate surgical techniques to minimise intraoperative trauma, prevention, and management of intraoperative hypertension
Decrease in visual acuity *(decrease in the eye's capacity to see objects or details clearly)* (temporary or permanent)	X	X	X	Preoperative assessment, use of appropriate surgical techniques, postoperative follow-up with management of complications
Blurred, cloudy vision (temporary or permanent)	X	X	X	Appropriate design and manufacture of the device
Persistent sensation of haze (temporary or permanent)	X	X	X	Postoperative follow-up for detection and treatment, management of any oedema, inflammation, haemorrhage, or opacification
Intraocular lens light reflection, pupillary reflections (permanent)	X	X	X	Appropriate design and manufacture of the device, identification of any risk factors during the preoperative assessment, appropriate positioning of the intraocular lens in the eye
Positive or negative dysphotopsia (*perception of bright or dark arcs of light at the periphery of the visual field due to unwanted light reflections in the optics of the intraocular lens*) (temporary or permanent),	X	X	X	Appropriate design and manufacture of the device, identification of any risk factors during the preoperative assessment, choice of the appropriate device, patient "education" because a period of adaptation is required
Coloured vision, distorted colour perception including enhancement of the subjective perception of blue (temporary)	X	X	X	Appropriate design and manufacture of the device, choice of the appropriate device, patient "education" because a period of adaptation is required
Intraocular lens opacification (permanent)	X	X	X	Appropriate design and manufacture of the device, postoperative follow-up
Glistening *(small bubbles inside the intraocular lens that create a shiny or flickering effect)* (permanent)	X	X	X	Appropriate design and manufacture of the device, postoperative follow-up
Refractive error *(a small refractive error (myopia, hyperopia, etc.)) may remain after surgery. This could result in blurred or distorted vision which may require further vision correction)* (temporary or permanent)	X	X	X	Appropriate design and manufacture of the device, quality control including optical control of all intraocular lenses
Posterior vitreous detachment (physiological phenomenon that occurs more frequently after cataract surgery) (permanent)	X	X	X	Use of appropriate surgical techniques to minimise intraoperative trauma, postoperative follow-up for rapid detection and treatment
Unrestored accommodation *(after removal of the natural lens, the eye loses its ability to accommodate: the eye muscles can no longer contract or relax properly, which may make it impossible to focus on near or distant objects)* (permanent)	X	X	X	Informing the patient about the optical performance of the device, choice of the appropriate device
Persistent postoperative ametropia (myopia, hyperopia, astigmatism), surgery-induced corneal astigmatism (permanent)	X	X	X	Appropriate design and manufacture of the device, quality control including optical control of all intraocular lenses

Known risks and complications	ARTIS PL *E*	ARTIS T PL *E*	ARTIS SYMBIOSE	What is done to reduce these risks
Anisometropia *(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)*, aniseikonia *(difference in size between the two eyes)*, stereoacuity problem *(stereoacuity: ability of the eyes to perceive depth and distinguish objects at different distances)* (permanent)	X	X	X	Appropriate design and manufacture of the device, choice of the appropriate device, patient "education" because a period of adaptation is required
Presbyopia *(progressive loss of the ability to see at close range due to ageing of the eyes. A common visual disorder that occurs in people over the age of 40, usually caused by a loss of flexibility in the lens of the eye, which makes it more difficult to focus (accommodate) on near objects)* (permanent)	X	X		Informing the patient about the optical performance of the device, choice of the appropriate device
Persistent postoperative corneal astigmatism (under or over corrected, increased) (permanent)		X	X (toric version)	Appropriate device manufacture, quality control including optical control of all intraocular lenses
Loss of contrast sensitivity *(decrease in the eye's ability to distinguish differences in contrast)* (permanent)			X	Appropriate design and manufacture of the device
Perception of light halos *(light circles around light sources)*, glare, stars, streaks *(straight or curved lines that may appear in the field of vision)*, radial lines *(light rays that propagate from light sources and create a fan-like radial effect around the source)* around light sources, especially in low light (temporary or permanent)			X	Appropriate design and manufacture of the device, choice of the appropriate device, patient "education" because a period of adaptation is required
Binocularity neuroadaptation disorder *(difficulty of the brain to adapt to learn to interpret new images captured by the eyes and to adjust the perception of vision accordingly)* (temporary or permanent)			X	Appropriate design and manufacture of the device, patient "education" because a period of adaptation is required
Complications related to surgery				
Opacification of the posterior and/or anterior capsule *(the capsule that holds the intraocular lens in place becomes opaque)*	X	X	X	Use of appropriate surgical techniques, choice of the appropriate device, appropriate design and manufacture of the device, quality control of the device, postoperative follow-up
Intraocular lens that is not centred correctly (decentring) or that moves from the normal position and becomes completely detached from the fixation in the eye (dislocation)	X	X	X	Use of appropriate surgical techniques, precise positioning of the intraocular lens in the eye, identification of any risk factors during the preoperative assessment, choice of the appropriate device, protection of the treated eye, compliance with the surgeon's instructions after surgery
Abnormally long and/or complicated surgery	X	X	X	Identification of any risk factors during the preoperative assessment, use of appropriate surgical techniques
Ocular or intraocular inflammation	X	X	X	Sterile device, surgery under aseptic conditions, identification of any risk factors during the preoperative assessment, appropriate anti-inflammatory and antibiotic treatments

Known risks and complications	ARTIS PL *E*	ARTIS T PL *E*	ARTIS SYMBIOSE	What is done to reduce these risks
Intraocular infection	X	X	X	Device sterility, preloaded intraocular lens, surgery under aseptic conditions, preventive antibiotic treatments
Corneal oedema *(the cornea, the clear, curved surface of the eye, becomes swollen due to water retention)*	X	X	X	Use of appropriate surgical techniques, postoperative follow-up
Macular oedema *(the macula, the area in the centre of the retina, becomes swollen due to fluid build-up)*	X	X	X	Identification of any risk factors during the preoperative assessment, appropriate anti-inflammatory and concomitant treatments
Increased intraocular pressure *(abnormally high intraocular pressure)*	X	X	X	Preoperative assessment, postoperative follow-up, appropriate medicine for pressure control if required
Retinal detachment	X	X	X	Use of appropriate surgical techniques, postoperative follow-up
Hypertonia *(increased pressure inside the eye)*	X	X	X	Identification of any risk factors during the preoperative assessment, appropriate surgical and medicinal treatments
Pupillary block *(the pupil, the central black part of the eye, cannot dilate normally)*	X	X	X	Use of appropriate surgical techniques to prevent iris bombé, use of mydriatics (drugs that dilate the pupil) before and during surgery
Capsular block *(the capsule surrounding the lens becomes opaque or contracts, preventing optimal light entry into the eye)*	X	X	X	Use of appropriate surgical techniques, postoperative follow-up
Capsular tear *(the capsule surrounding the lens tears)*	X	X	X	Use of appropriate surgical techniques, postoperative follow-up
Hypopyon *(build-up of pus or inflammatory fluid in the front part of the eye, in the anterior chamber, can be caused by an eye infection or inflammation)*	X	X	X	Sterile device, rapid and appropriate treatment of intraocular infections, appropriate anti-inflammatory, and antibiotic treatments
Incision leakage *(a situation where a small amount of fluid leaks from the surgical incision made on the surface of the eye)*	X	X	X	Use of appropriate surgical techniques, postoperative follow-up
Deposits on the surface of the intraocular lens	X	X	X	Appropriate design and manufacture of the device, identification of any risk factors during the preoperative assessment, use of appropriate surgical techniques
Damage to the corneal endothelium *(the endothelium is the inner layer of the cornea)*	X	X	X	Use of appropriate surgical techniques
Ectasia *(progressive corneal deformity, with outward conical bulging)*	X	X	X	Rigorous preoperative assessment of corneal thickness and topography, choice of corneal surgery, patient “education” on the risks related to rubbing the eyes
Partial or complete displacement of the intraocular lens (dislocation)	X	X	X	Use of appropriate, precise surgical techniques, identification of any risk factors during the preoperative assessment, choice of the appropriate device, protection of the treated eye, compliance with the surgeon’s instructions after surgery

Known risks and complications	ARTIS PL *E*	ARTIS T PL *E*	ARTIS SYMBIOSE	What is done to reduce these risks
Refractive error *(a small refractive error (myopia, hyperopia, etc.) may remain after surgery. This could result in blurred or distorted vision which may require further vision correction)*	X	X	X	Meticulous preoperative assessment (including measurements), choice of the appropriate device, precise surgical technique, appropriate positioning of the intraocular lens in the eye, appropriate design and manufacture of the device, training surgeons in the use of the device, educating surgeons in optical parameters, precautions, and proper use of the device (labelling and instructions for use), postoperative follow-up
Damage to the intraocular lens (scratching, cracking, breakage of the optics; scratching, cracking, warping, breakage of the haptics),	X	X	X	Appropriate design and manufacture of the device, quality control of the device including the injector, training surgeons in the use of the device, informing surgeons of the controls and proper use of the device (instructions for use)
Injector failure (jamming, blockage, abnormal behaviour of the intraocular lens)	X	X	X	Appropriate design and manufacture of the device, quality control of the device including the injector, training surgeons in the use of the device, educating surgeons in the proper use of the device (instructions for use)
During surgery, significant loss of vitreous humour *(a gelatinous, transparent substance that fills the interior of the eye, between the 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)*	X	X	X	Use of appropriate surgical techniques to minimise intraoperative trauma, preparation of vitreous substitutes to manage vitreous loss if necessary
Vitreous prolapse *(part of the vitreous humour moves forward out of the normal position and pushes against the retina)*	X	X	X	Use of appropriate surgical techniques to minimise intraoperative trauma, protection of the treated eye, compliance with the surgeon's instructions after surgery, identification of any risk factors during the preoperative assessment, prevention, and management of intraocular hypertension
Ocular hypertension	X	X	X	Preoperative assessment, postoperative follow-up, appropriate medicine for pressure control if required
Temporary or permanent decrease in visual acuity *(decrease in the eye's capacity to see objects or details clearly)*	X	X	X	Preoperative assessment, use of appropriate surgical techniques, postoperative follow-up with management of complications
Blurred, cloudy vision	X	X	X	Meticulous preoperative assessment (including measurements), choice of the appropriate device, precise positioning of the intraocular lens in the eye, postoperative follow-up with management of complications
Persistent sensation of haze	X	X	X	Postoperative follow-up for detection and treatment, management of any oedema, inflammation, haemorrhage, or opacification
Double or triple vision *(seeing double or triple images)*	X	X	X	Identification of any risk factors during the preoperative assessment, use of appropriate surgical techniques, precise positioning of the intraocular lens in the eye, postoperative follow-up with management of complications

Known risks and complications	ARTIS PL *E*	ARTIS T PL *E*	ARTIS SYMBIOSE	What is done to reduce these risks
Temporary or permanent loss of vision in the treated eye	X	X	X	Use of appropriate surgical techniques, sterile device, preloaded intraocular lens, surgery under aseptic conditions, management of complications that could lead to loss of vision, consultation with a specialist surgeon, if necessary, appropriate anti-inflammatory and antibiotic treatments, postoperative follow-up
Positive or negative dysphotopsia *(perception of bright or dark arcs of light at the periphery of the visual field due to unwanted light reflections in the optics of the intraocular lens)*	X	X	X	Appropriate design and manufacture of the device, identification of any risk factors during the preoperative assessment, appropriate positioning of the intraocular lens in the eye, choice of the appropriate device, patient "education" because a period of adaptation is required
Persistent postoperative ametropia (myopia, hyperopia, astigmatism), surgery-induced corneal astigmatism (permanent)	X	X	X	Meticulous preoperative assessment (including measurements), choice of the appropriate device, precise surgical technique, appropriate positioning of the intraocular lens in the eye, appropriate design and manufacture of the device, training surgeons in the use of the device, educating surgeons in optical parameters, precautions, and proper use of the device (labelling and instructions for use), postoperative follow-up
Dry eyes	X	X	X	Use of artificial tears, prescription of medicines to improve tear production if necessary
Eye redness or sensitivity, tearing, itching, stinging, "burning", discomfort that feels like having a foreign body in the eye or a grain of sand under the eyelid	X	X	X	Appropriate management of postoperative inflammation, infection monitoring and treatment, if necessary, treatment of dry eyes, postoperative follow-up with management of complications
Eye pain, which is sometimes significant	X	X	X	Prescription of analgesics, management of complications that may cause pain, postoperative follow-up to assess and treat pain
Droopy eyelids	X	X	X	Preoperative assessment, use of appropriate surgical and anaesthetic techniques, postoperative follow-up with management of complications, consultation with a specialist surgeon, if necessary
Loss of the eye	X	X	X	Use of appropriate surgical techniques, sterile device, preloaded intraocular lens, surgery under aseptic conditions, management of complications that could lead to eye loss, consultation with a specialist surgeon, if necessary, appropriate anti-inflammatory and antibiotic treatments, postoperative follow-up
Anisometropia *(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)*, aniseikonia *(difference in size between the two eyes)*, stereoacuity problem *(stereoacuity: ability of the eyes to perceive depth and distinguish objects at different distances)*	X	X	X	Appropriate design and manufacture of the device, choice of the appropriate device, patient "education" because a period of adaptation is required, choice of the appropriate device, appropriate positioning of the intraocular lens in the eye

Known risks and complications	ARTIS PL *E*	ARTIS T PL *E*	ARTIS SYMBIOSE	What is done to reduce these risks
Additional surgical procedures for intraocular lens repositioning or replacement, vitreous aspiration or iridectomy *(making a small opening in the iris)* to treat pupillary block, repair of incisional leakage, repair of retinal detachment	X	X	X	Precise initial surgery, postoperative follow-up, appropriate treatment of complications, reassessment of the benefit/risk ratio with the additional procedure
Rotation of the intraocular lens *(the intraocular lens rotates on itself; it shifts from the axis on which it was positioned)*		X	X (toric version)	Meticulous preoperative assessment (including measurements), choice of the appropriate 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 surgeons in the use of the device, educating surgeons in optical parameters, precautions, and proper preparation and use of the device (labelling and instructions for use), postoperative follow-up
Persistent postoperative corneal astigmatism (under or over-corrected, increased).		X	X (toric version)	Meticulous preoperative assessment (including measurements), choice of the appropriate device, precise surgical technique, appropriate positioning of the intraocular lens in the eye, training surgeons in the use of the device, educating surgeons in optical parameters, precautions, and proper use of the device (labelling and instructions for use), postoperative follow-up
Additional surgery to realign the intraocular lens on the implantation axis		X	X (toric version)	Precise initial surgery, postoperative follow-up, appropriate treatment of complications, reassessment of the benefit/risk ratio with the additional procedure

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,* 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*, 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 life cycle 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 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 operated eye 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.

Be aware that for certain complications, an 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 life cycle of the ARTIS PL *E*, ARTIS T PL *E,* 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.

The ARTIS T PL *E* and ARTIS SYMBIOSE devices (the toric version): 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 (clear 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 damaging the implanted intraocular lens.
- The devices manufactured by CRISTALENS INDUSTRIE contain no metal.
- There are no known interferences 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.
- There are no known direct drug interactions. 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)).
- There are no known interferences and/or adverse effects related to interactions with other devices during diagnostic examinations, evaluations, therapeutic treatments, or other specific procedures.

Notification 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* or ARTIS SYMBIOSE) to CRISTALENS INDUSTRIE, the local contact (distributor) if their details are known, the health professionnal 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 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 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 lens is removed and the anterior capsule is left intact. A wide incision is made in the cornea to access the lens and remove the central part. The peripheral part of the 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 lens and create a precise anterior capsule to facilitate 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* and ARTIS SYMBIOSE are for surgical use only.

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

END OF DOCUMENT