Artis® PL *E*

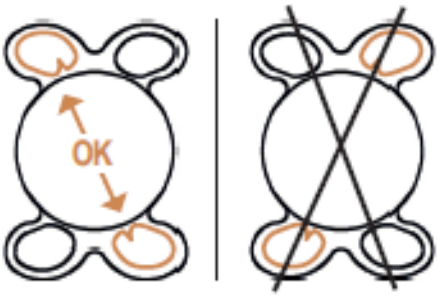
INTRAOCULAR LENS

Hydrophobic acrylic

MONOFOCAL

PRELOADED

Aspherical



Year of CE marking: ARTIS® PL *E* - 2014

www.cristalens-international.com

CE 0459

MADE IN FRANCE

STERILE EO

35°C

5°C

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[EN]

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Availability and accessibility of the instructions for use

The instructions for use of the ARTIS PL *E* device (basic UDI-DI: 37006373IOL01D6) are available free of charge in many languages on the CRISTALENS INDUSTRIE website (www.cristalens-international.com), in the current and previous versions.

To access the electronic format of the instructions for use of the ARTIS PL *E* device:

1. Go to www.cristalens-international.com,
2. Select “HEALTH PROFESSIONAL PORTAL”,
3. Log in or, if you are a first-time visitor to the website, create an account,
4. Click on “CRISTABOX” in the menu at the top of the page, then on “Clinical box”,
5. In the “INSTRUCTIONS FOR USE” section, you can obtain the available instructions for use from a drop-down menu. Select the device concerned (ARTIS PL *E*) and the desired language,
6. Click on the corresponding link to download the PDF file.

To display the instructions for use of the ARTIS PL *E* device, you need an internet browser (such as Apple Safari, Google Chrome, Microsoft Edge, Mozilla Firefox, or Opera) associated with a PDF reader (such as Adobe Acrobat Reader).

A hard copy of the ARTIS PL *E* instructions for use is available on request, free of charge 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 (0)2 96 48 92 92,

- By mail to CRISTALENS INDUSTRIE, 4 rue Louis de Broglie, 22300 LANNION – FRANCE.

The time limit for obtaining a hard copy of the instructions for use is seven (7) calendar days after receipt of the request, or on delivery of the device if the request was made when the order was placed.

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1. Manufacturer's identification

CRISTALENS INDUSTRIE, 4 rue Louis de Broglie 22300 Lannion – France.

2. Device identification

ARTIS PL *E*

Description: This medical device, ARTIS PL *E,* is a monofocal intraocular lens, preloaded in its ACCUJECT™ PRO injection system (ACCUJECT™ PRO 2.1-1P injector manufactured by Medicel AG – SWITZERLAND). It is a monobloc, foldable posterior chamber intraocular lens to be placed in the capsular bag.
This is a sterile, single-use device. It is sterilised with ethylene oxide.

3. Intended use, indications, and contraindications

Intended use: An intraocular lens for implantation by its injector into the capsular bag (posterior chamber of the eye) to replace the natural cataract-diseased crystalline lens.

Indications: Visual correction of aphakia after age-related cataract surgery and compensation of ametropia.

Contraindications: This ARTIS PL *E* device is contraindicated in neonates, premature neonates, infants and children (until 18 years of age).
This ARTIS PL *E* device is also contraindicated in individuals with one or more of the following conditions (non-exhaustive list):

Active intraocular infection,
Active eye disease other than age-related cataract,
Acute ocular or intraocular inflammation,
Acute ocular disease,
Any progressive ocular disease other than age-related cataract,
Nanophthalmos,
Severe optic nerve atrophy,
Inadequate capsular support,
Allergy to ethylene oxide,
Pregnancy or breastfeeding.

If the patient has an acute condition in addition to age-related cataract, the condition should be treated as a priority before considering cataract surgery and implantation of an ARTIS PL *E* intraocular lens.

Special considerations:
Patients with one or more of the following conditions, may not be candidates for implantation of an ARTIS PL *E* monofocal intraocular lens (non-exhaustive list):

Non-age-related cataract (e.g., traumatic, congenital cataract),
A history of intraocular or refractive surgery,
Use of systemic or eye medication that could affect vision,
Ocular or intraocular inflammation,
Intraocular infection,

Glaucoma,
Retinal conditions (e.g. macular degeneration, diabetic retinopathy, retinal detachment or a history of retinal detachment, cystoid macular oedema, macular hole),
Corneal abnormalities (e.g., keratoconus, corneal opacification),
Corneal conditions that compromise visual acuity (e.g., corneal endothelial disease, corneal dystrophies, a history of corneal transplantation),
Choroidal haemorrhage or any other intraocular haemorrhage,
Intraocular hypertension,
Capsular or zonular abnormalities (e.g., zonular laxity, zonulysis) that may affect the postoperative centration or postoperative tilt of the intraocular lens,
Posterior capsule rupture or large capsulorhexis (compromised intraocular lens stability),
Known or suspected radial tears or tear-out at the time of surgery,
Incapacity to confirm the integrity of the capsulorhexis by direct visualisation,
Capsulotomy by a technique other than by a circular incision,
Aniridia,
Collapse of the anterior chamber,
Narrow anterior chamber,
Microphthalmia,
Amblyopia,
Cortico-dependent ocular hypertonia,
Significant loss of vitreous humour,
Anisometropia, aniseikonia,
Large eye, excessive axial eye length (more than 28 mm).

A thorough preoperative evaluation and clinical review should be performed by the surgeon to rigorously assess the benefit/risk ratio prior to implantation of an ARTIS PL *E* monofocal intraocular lens in these patients.

Target population: Adult aphakic patients after age-related cataract surgery.

Target users: Ophthalmic surgeons and ophthalmic operating assistants.

4. Mechanism of action

The ARTIS PL *E* monofocal intraocular lens ensures the function of the natural crystalline lens and provides the appropriate optical power for clear vision at a given distance (by correcting any preoperative myopia or hyperopia) through its spherical equivalent (SE) power.

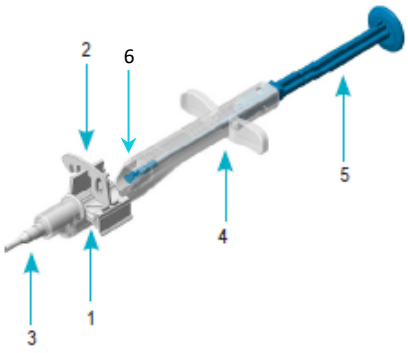
5. Composition of the medical device

Contents: The protective packaging (box) contains the sterile product, these instructions for use, the patient implant card, and the self-adhesive traceability labels.

Each ARTIS PL *E* intraocular lens, preloaded in its injection system, is individually wrapped in sterile packaging that corresponds to a double sterile barrier system (SBS) consisting of a pouch and a blister pack. The entire package is sterilised with ethylene oxide.

The ARTIS PL *E* intraocular lens, held in place in the loading chamber (1) of the injector, is blocked by the lens holder (2) and by the cartridge (3). The injector is also composed of a body (4) and a plunger (5), the end of which is in contact with the intraocular lens and has a silicone cushion (6) (see *Diagram of the injector*).

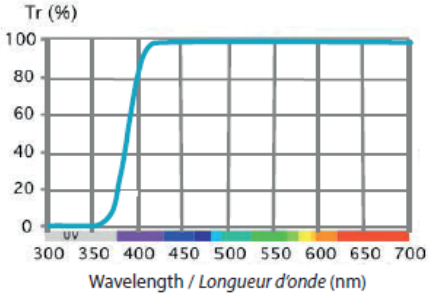
Diagram of the injector



Properties:

Material: Each ARTIS PL *E* intraocular lens is obtained by machining from a hydrophobic acrylic material that is transparent in visible light and has a UV (ultraviolet) filter (see *Transmittance spectrum*). The UV cut-off wavelength is 380 nm (transmission < 10%).
CRISTALENS INDUSTRIE recommends the use of intraocular lenses with equivalent transmission spectra for both eyes.

Transmission spectrum



Materials and substances to which the patient is likely to be exposed (maximum exposure): cross-linked acrylic copolymer CBK 1.8 (intraocular lens material) (≤ 23 mg/device), poly(ethylene glycol) and poly(ethylene glycol) derivatives (CAS 25322-68-3) (≤ 60.4 µg/device), ethylene oxide residues (≤ 0.5 µg/device), glycerol monopalmitate or isomer (CAS 542-44-9) (≤ 29.0 µg/device), glycerol monosterate or isomer (CAS 31566-31-1) (≤ 18.5 µg/device), 2-phenoxyethanol (CAS 122-99-6) (≤ 325.8 µg/device), 2-(2-phenoxyethoxy)-ethanol (CAS 104-68-7) (≤ 46.3 µg/device). No biological effects expected in case of release, even total release, of these substances.

Optic design: monofocal, aspherical, 360° square edges. Modulation Transfer Function: MTF > 0.43 (measured @ 100 c/mm for a 3-mm aperture).

Refractive index: 1.54.

Range of available spherical equivalent (SE) powers: refer to the technical data sheet for the device, available on the CRISTALENS INDUSTRIE website (www.cristalens-international.com) or in hard copy.

Intraocular lens dimensions: refer to the device labelling.

6. Clinical benefit / performance

Claimed clinical performance: Restoration of clear vision at a given distance.

Criteria: measurement of monocular corrected visual acuity at the target distance (mean value ≤ 0.3 LogMAR, with 92.5% of patients having a maximum of 0.3 LogMAR) and measurement of refraction (mean value of the residual refractive error (spherical equivalent (SE)) ≤ 0.5D).

Link to the Summary of Safety and Clinical Performance (SSCP):
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 (37006373IOL01D6 for the ARTIS PL *E* device).
In the absence of 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 (0)2 96 48 92 92.

7. Information to be given to the patient

Before surgery:
There should be a discussion between the surgeon and the patient to assess the patient's level of discomfort and the impact on their quality of life. The patient's needs should also be discussed as the choice of the intraocular lens to be implanted is based on the patient's lifestyle and possibly their preferences.

The patient must be accurately informed by the surgeon, in appropriate language, about monofocal intraocular lenses, their benefits and the contraindications (section "**3. Intended use, indications, and contraindications**"), residual risks (section "**8. Warnings, precautions for use, interactions, interferences, and residual risks**"), possible complications and adverse effects (section "**10. Possible complications and adverse effects**") related to this type of surgery and this type of implant.

All this information makes the patient aware of the risks and benefits so that the benefit/risk ratio of cataract surgery associated with the implantation of an ARTIS PL *E* intraocular lens can be assessed. He/She is then able to make an informed decision.

After surgery:
The patient must be accurately informed by the surgeon, in appropriate language, about the postoperative follow-up and required measures (follow-up required, possible interactions and interferences (section "**8. Warnings, precautions for use, interactions, interferences, and residual risks**"), possible complications and adverse effects (section "**10. Possible complications and adverse effects**"), …) related to this type of surgery and this type of implant.

The surgeon must warn the patient that he must consult urgently in the event of a decrease in visual acuity associated with significant pain in the operated eye in the first few days after surgery.

The surgeon should warn the patient not to rub his/her eyes and to immediately consult a health professional in the following cases or in any other case he/she deems necessary:

Decrease in visual acuity 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.

The surgeon must inform the patient of the name of the implanted device (ARTIS PL *E*) and its manufacturer (CRISTALENS INDUSTRIE). Detailed information on the traceability of the device and CRISTALENS INDUSTRIE is indicated on the implant card given to the patient. He/She must also mention to the patient that the manufacturer's information for patients is available on the CRISTALENS INDUSTRIE website (www.cristalens-international.com).

The surgeon must also inform the patient about the expected lifetime of the device (20 years), the ophthalmological monitoring required throughout this period, and the materials and substances to which he/she might be exposed during this period (refer to section "**5. Composition of the medical device**" in these instructions for use). The surgeon must specifically inform the patient that regular, long-term assessment of the intraocular lens is required, and that it is important to continue follow-up appointments to assess eye

health and ensure proper functioning of the intraocular lens. In addition, the surgeon must inform the patient 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, surgery can be performed to explant the intraocular lens and replace it with another one.
- In the long term and/or beyond the expected 20-year lifetime of the intraocular lens, lens replacement might be considered, particularly if it is damaged, misaligned, opacified, or if the intraocular lens prescription is no longer adapted to the patient's visual needs.

Implant card:

The surgeon or health care facility should complete the patient implant card provided with the device and give it to the patient. The patient should be instructed to always keep the card with him/her as a record of the implant and to present it to any physician he/she may consult later.
An implant card should only be associated with a single eye. If the patient has surgery on both eyes, he/she should be given two implant cards.

All the blank fields on the implant card should be filled out with the patient's identification, the date of surgery (in the format YYYY-MM-DD), the surgeon's name, the name and address of the health care facility, the treated eye and one of the device traceability labels provided with the device should be stuck to the indicated area of the implant card.

Additional patient information is available on the CRISTALENS INDUSTRIE website (www.cristalens-international.com), indicated on the implant card. This information can be updated by the manufacturer.

Notification of serious incidents:

As discussed with the doctor and/or the health care facility where the incident is detected, the patient should report any serious incident concerning the ARTIS PL *E* device 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.

8. Warnings, precautions for use, interactions, interferences, and residual risks

Warnings and precautions for use:

- Do not use after the expiry date. The expiry date indicated on the protective packaging (box) and on the sterile packaging (pouch + blister pack) determines the shelf-life. It is indicated in the format YYYY-MM-DD.
  The device should not be used, nor should the intraocular lens be implanted after the expiry date indicated.
- If the conditions for storage and transport indicated on the protective packaging (box) and in these instructions for use in section "**11. Storage, handling, disposal**" are not respected, or if in doubt about their compliance, use another device.
- Do not use if the protective packaging (box) has been damaged or pre-opened.
  Damage to the protective packaging (box) may be associated with damage to the sterile packaging (pouch + blister pack) even if the sterile packaging appears to be intact.
- Do not use if the sterile packaging (pouch + blister pack) has been damaged or pre-opened.
  Sterility is only valid if the pouch and blister pack show no signs of deterioration.
- Do not use if the device (intraocular lens + injector) is damaged or has any abnormality.
- Do not resterilise by any method.
- Do not reuse. The device (intraocular lens + injector) is for single use only.
- Do not use in patients with one or more of the contraindications listed in section "**3. Intended use, indications, and contraindications**" of these instructions for use.
- It is the responsibility of the surgeon to carry out a careful patient-specific preoperative assessment with sound clinical judgement and risk/benefit assessment before any decision is made concerning cataract surgery.
- For patients with atypical eyes, the surgeon may need to perform additional preoperative measurements.
- In order to achieve optimal performance of the ARTIS PL *E* intraocular lens, CRISTALENS INDUSTRIE recommends gaining experience on intraocular lenses from the ARTIS preloaded monofocal hydrophobic family. It is necessary to master the biometry of the ARTIS PL *E* intraocular lens in order to optimize the A-constant.
- CRISTALENS INDUSTRIE recommends the use of intraocular lenses with equivalent transmission spectra for both eyes.
- Various surgical techniques can be used to implant intraocular lenses. It is up to the surgeon to choose the one that is most appropriate to implant the intraocular lens into the capsular bag.
- Do not remove the intraocular lens from the injection system in which it is preloaded to use it with another injector. It is designed to be implanted only with the ACCUJECT™ PRO injection system provided.
- Do not disassemble, modify, or alter the intraocular lens, the injector or any of its components. Doing so can impair proper functioning and/or the structural integrity of the device, compromise successful implantation of the intraocular lens, and cause complications and adverse effects.
- The use of accessories not approved by CRISTALENS INDUSTRIE can compromise the successful implantation of the intraocular lens and cause complications and adverse effects. The only safe combinations are those indicated in section "**9. Prerequisites for use and instructions for use**".
- The ARTIS PL *E* intraocular lens is to be placed entirely within the capsular bag. Do not implant it, even partially, in any other location.
- CRISTALENS INDUSTRIE recommends making an incision for which the size is adapted to the injector (size of the cartridge tip: 2.1 mm).
- Do not start pushing on the injector plunger or advancing the intraocular lens in the injector unless you are ready for implantation and scrupulously follow the procedure described in section "**9. Prerequisites for use and instructions for use**".
- During implantation, the corneal endothelium can be damaged if it touches the silicone cushion of the injector or the intraocular lens.

- Centre the ARTIS PL *E* intraocular lens very carefully. A non-centred intraocular lens can cause visual disorders.
- Avoid the use of silicone oil. Silicone oil, particularly when used in the surgical treatment of retinal detachment, could touch the intraocular lens if the posterior lens capsule is not intact. This may cause partial and/or localised opacification of the intraocular lens.
- Regular, long-term assessment of the intraocular lens is required. It is important to continue to follow the patient through appointments to assess eye health and ensure proper functioning of the intraocular lens.
  Potential complications include opacification of the posterior capsule (also known as secondary cataract), intraocular lens dislocation, or lens damage. If complications occur, an intervention by the surgeon might be required to correct the problem:
  - In case of opacification of the posterior capsule, 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, surgery can be performed to explant the intraocular lens and replace it with another one.

  In the long term and/or beyond the expected 20-year lifetime of the intraocular lens, lens replacement might be considered, particularly if it is damaged, misaligned, opacified, or if the intraocular lens prescription is no longer adapted to the patient's visual needs.
- Any decision regarding a possible secondary surgery, in particular replacement of the implanted intraocular lens, should be made by the surgeon based on careful assessment of the benefit/risk ratio. Discomfort for the patient 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.

<u>Interactions and interferences:</u>

- The intraocular lens complies with the Nd:YAG laser exposure test according to standard ISO 11979-5.
- The intraocular lens contains no metallic materials.
- No interference, 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, adverse effects related to interactions with other devices during diagnostic investigations, evaluations, therapeutic treatments, or other specific procedures are known.

<u>Residual risks:</u>

- Frequent – at least 1 in 100 patients (≥ 1%): None.
- Probable – less than 1 in 100 patients (< 1%): None.
- Occasional – less than 1 in 1,000 patients (< 0.1%):
  - Increased operating time,
  - Injector failure (jamming, blockage, abnormal behaviour of the intraocular lens).
- Remote – less than 1 in 10,000 patients (< 0.01%):
  - Damage to the intraocular lens (scratching, cracking, breakage of the optics; scratching, cracking, warping, breakage of the haptics),
  - Decentration or dislocation of the intraocular lens,
  - Visual impairment.

- Improbable – less than 1 in 100,000 patients (< 0.001%):
    - Damage to the corneal endothelium with risk of corneal oedema,
    - Endophthalmitis.

In case of reuse, re-sterilisation, repackaging of the device, use of a damaged or pre-opened device (sterility defect), or use of the device after the expiry date, the risks identified are deterioration of the device, contamination, infection, endophthalmitis, inflammation, lesion, disease, and loss of the treated eye.

9. Prerequisites for use and instructions for use

Facilities, training, and qualifications required:
Facility: An environment such as an aseptic operating theatre that complies with at least standard ISO 7 is required to use the ARTIS PL *E* device, regardless of the anaesthesia modality.

Training and qualifications: Only ophthalmic surgeons or ophthalmic operating assistants with the appropriate diplomas and professional training are allowed to use the ARTIS PL *E* device.

Devices, equipment, accessories:
The accessories validated for use with the ARTIS PL *E* device (preloaded intraocular lens) are:

- Sterile balanced salt solution (BSS): sterile saline solution poured into the injector cartridge and on the intraocular lens when preparing the injection.
- A sterile sodium hyaluronate-based ophthalmic viscoelastic device (OVD) such as CRISTAVISC c®, I.SPACE®, PhysioVisc® Integral and ViscoSert (manufactured by Vivacy Laboratories) : a sterile lubricating product injected into the cartridge tip, the injector cartridge and on the intraocular lens when the implantation is being prepared.

For further information on accessories, please refer to the instructions for use provided by their manufacturer.

There are no known restrictions for combination with devices, equipment, or accessories, besides avoiding the use of silicone oil. That is because it could touch the intraocular lens if the posterior lens capsule is not intact, particularly when used in the surgical treatment of retinal detachment, which can cause partial and/or localised opacification of the intraocular lens.

However, the use of devices, equipment, or accessories other than those listed above is not approved by CRISTALENS INDUSTRIE. This can cause deterioration of the lens and/or the injector as well as potential complications during implantation.
Therefore, safe combination cannot be guaranteed. In fact, if the surgeon uses any devices, equipment, or accessories other than those listed above it is entirely his responsibility.

Do not remove the intraocular lens from the injection system in which it is preloaded to use it with another injector. It is designed to be implanted only with the ACCUJECT™ PRO injection system provided.

Calculating the power of the intraocular lens:
Prior to implantation, the surgeon must determine the spherical equivalent (SE) power of the ARTIS PL *E* monofocal intraocular lens to be implanted. It is calculated for each patient based on keratometric and biometric data, formulas in the literature, the experience of each surgeon, and the estimated A-constants indicated on the box or 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 (0)2 96 48 92 92.

These estimates serve as a starting point to calculate the power. They should be optimised by each surgeon according to clinical experience, the surgical techniques, measuring equipment and postoperative results obtained.
In order to achieve optimal performance of the ARTIS PL *E* intraocular lens, CRISTALENS INDUSTRIE recommends gaining experience on intraocular lenses from the ARTIS preloaded monofocal hydrophobic family. It is necessary to master the biometry of the ARTIS PL *E* intraocular lens in order to optimize the A-constant.
The spherical equivalent (SE) power expressed in diopters (D) for each ARTIS PL *E* intraocular lens is indicated on the labelling by the symbol “D”.

Instructions for use:

Procedure for the implantation of the ARTIS PL *E* intraocular lens:

Steps 1 to 13 must be performed under aseptic conditions to ensure the sterility of the device (intraocular lens + injector).

1. Verify the integrity of the protective packaging (box). If it is damaged, use another device.
   Verify the labelling on the protective packaging (box), particularly the model, power, and expiry date of the device.
2. Open the protective packaging (box).
3. Verify the integrity of the sterile packaging (double SBS: pouch + blister pack). If either of the items is damaged, use another device.
   Verify the labelling on the sterile packaging (pouch + blister pack), particularly the model, power, and expiry date of the device.
   If there is any inconsistency between the information on the labelling of the protective packaging (box) and the labelling of the sterile packaging (pouch + blister pack), use another device.
4. Open the pouch and remove the blister pack.
5. Open the blister pack and carefully remove the injector.
6. Carefully examine the intraocular lens and the injector.
   If any damage or abnormality is detected, use another device (intraocular lens + injector).
7. Remove the lens holder that blocks the intraocular lens (fig. 1).
8. Ensure that the intraocular lens is correctly positioned in the loading chamber.
   In case of incorrect positioning (haptics off the tracks, intraocular lens too far forward/backward), carefully reposition the intraocular lens or use another device (intraocular lens + injector).
9. Add sterile balanced salt solution (BSS) into the cartridge and on the intraocular lens (Fig. 2), wait at least 1 minute to allow activation of the injector sliding agent.
10. Add the sterile ophthalmic viscoelastic device (OVD) into the tip of the cartridge, into the cartridge and on the intraocular lens (Fig. 2).
11. Close the wings of the loading chamber (fig. 3). The “click" indicates that the loading chamber is properly closed.
12. Push the plunger slightly forward and ensure that the silicone cushion enters the loading chamber correctly.
    If any anomaly is detected, pull the plunger back slightly and repeat the operation once or use another device (intraocular lens + injector).
13. Then, ensure that the intraocular lens advances normally for about 1 cm.
    If any abnormality is detected, use another device (intraocular lens + injector).
14. Locate the form of the bevel at the end of the cartridge, then position it in the eye incision or at the edge of the incision depending on the choice of surgical technique.
15. Inject the intraocular lens by pushing the plunger in a continuous motion. Once the intraocular lens is completely expelled from the injector, stop pushing.
    If any abnormal behaviour is detected during injection such as strong resistance, stop using the device.

16. Ensure that the intraocular lens is placed in the capsular bag, and that it is correctly positioned by checking the notches (refer to the intraocular lens diagram at the beginning of these instructions for use).
17. Carefully remove the ophthalmic viscoelastic device (OVD) from the eye using standard irrigation and aspiration techniques.
18. Dispose of the packaging and injector as indicated in section "**11. Storage, handling, disposal**" of these instructions for use. Do not reuse the injection system.
19. Fill out the patient implant card and give it to the patient as indicated in section "**7. Information to be given to the patient**".

Fig. 1

Fig. 2

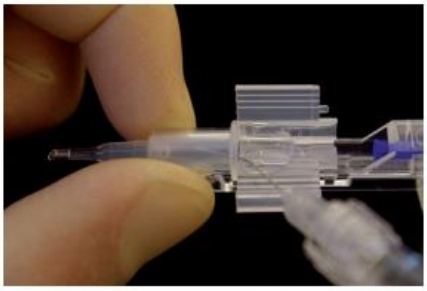


Fig. 3

10. Possible complications and adverse effects

As with any surgical procedure, there is a risk. Possible complications and adverse effects of cataract surgery and/or implantation of an ARTIS PL *E* monofocal intraocular lens may include (but are not limited to) the following:

- Possible complications:
  Opacification of the posterior and/or anterior capsule,
  Decentration or tilt of the intraocular lens,
  Abnormally long and/or complicated surgery,
  Ocular or intraocular inflammation,
  Intraocular infection,
  Corneal oedema,
  Macular oedema,
  Increased intraocular pressure,
  Retinal detachment,
  Hypertonia,
  Pupillary block,
  Capsular block,
  Capsular rupture,
  Hypopion,
  Incision leakage,
  Precipitates on the surface of the intraocular lens,
  Damage to the corneal endothelium,
  Ectasia after refractive surgery (deformation of the cornea by bulging and thinning causing irreversible loss of vision),
  Dislocation of the intraocular lens,
  Refractive error,
  Damage to the intraocular lens (scratching, cracking, breakage of the optics; scratching, cracking, warping, breakage of the haptics),

Injector failure (jamming, blockage, abnormal behaviour of the intraocular lens),
Significant intraoperative vitreous loss,
Vitreous prolapse,
Ocular hypertension,
Temporary or permanent decrease in visual acuity,
Blurred, cloudy vision,
Persistent sensation of haze,
Diplopia (double or triple vision),
Temporary or permanent loss of vision in the treated 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),
Residual ametropia (myopia, hyperopia, astigmatism), induced corneal astigmatism,
Dry eyes,
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,
Eye pain, which is sometimes significant,
Drooping eyelids (ptosis),
Loss of the eye,
Anisometropia, aniseikonia, stereoacuity disorder,
Secondary surgical procedures including, but not limited to intraocular lens repositioning, intraocular lens replacement, vitreous aspiration or iridectomy for pupillary block, incisional leak repair or retinal detachment repair. Any decision regarding a possible secondary surgery, in particular replacement of the implanted intraocular lens, should be made by the surgeon based on careful assessment of the benefit/risk ratio. Discomfort for the patient 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.

- <u>Possible adverse effects:</u>

  <u>Transient:</u>
  Subconjunctival haemorrhage,
  Decreased visual acuity,
  Blurred, cloudy vision,
  Persistent sensation of haze,
  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),
  Coloured vision, distorted colour perception including transient enhancement of the subjective perception of blue,
  Refractive error.

  <u>Permanent:</u>
  Whitening of the intraocular lens,
  Decreased visual acuity,
  Blurred, cloudy vision,
  Persistent sensation of haze,
  Intraocular lens light reflection, pupillary reflections,
  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),
  Opacification of the intraocular lens,
  Glistening,

Refractive error,
Posterior vitreous detachment (physiological phenomenon that occurs more frequently after cataract surgery),
Unrestored accommodation,
Residual ametropia (myopia, hyperopia, astigmatism), induced corneal astigmatism,
Anisometropia, aniseikonia, stereoacuity disorder,
Presbyopia.

Notification of serious incidents:
Any serious incident that occurs in connection with the ARTIS PL *E* device must be reported by the surgeon or the health care facility to CRISTALENS INDUSTRIE, the local contact (distributor) and the competent authority of the country in which the surgeon and/or the patient is established.

To notify CRISTALENS INDUSTRIE:

1. Contact CRISTALENS INDUSTRIE immediately:
   - By e-mail to materiovigilance@cristalens.fr,
   - Via the dedicated form on the website (www.cristalens-international.com) in the “Contact" tab then “Product claim”, or in the user profile then “Claim about a product”.
2. Return the device with all the information required for traceability, under the conditions specified when contact was made.

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.

11. Storage, handling, disposal

Expiry date:
The expiry date on the protective packaging (box) determines the shelf-life. It is indicated in the format YYYY-MM-DD.
The device should not be used, nor should the intraocular lens be implanted after the expiry date indicated on the protective packaging (box).

Conditions for storage and transport:
Protect from sunlight and humidity. Avoid bumping and crushing of the protective packaging (box).
Do not use if the protective packaging (box) has been damaged or opened.
Specific conditions for storage and transport: see symbols on these instructions for use and on the protective packaging (box).
If the conditions for storage and transport are not respected or if there is any doubt concerning their observance, use another device.

Disposal of the device:
The device (injector and intraocular lens), its sterile packaging (pouch + blister pack) and protective packaging (box) must be disposed of in appropriate waste containers according to the rules and recommendations in force in each health care facility, in particular:

- The injector and the intraocular lens, which are healthcare waste that pose a risk of infection.
- The box and instructions for use can be recycled.

The traceability labels are to be used for the patient's medical record and for the implant card.

The implant card should be given to the patient, as indicated in section "**7. Information to be given to the patient**" in these instructions for use.

12. Disclaimer

CRISTALENS INDUSTRIE cannot be held liable for any damage incurred by a patient resulting from:

- The choice or prescription of the intraocular lens.
- The surgical technique or implantation method used by the surgeon.
- The use of devices, equipment, or accessories not considered suitable or considered unsuitable for the device.
- Damage or deterioration of the intraocular lens, detected during surgery and which did not lead to the removal of the intraocular lens.
- Reuse, re-sterilisation or re-packaging of the device, use of a damaged or pre-opened device (sterility defect) or use after the expiry date. The risks identified are deterioration of the medical device, contamination, infection, endophthalmitis, inflammation, injury, disease, loss of the treated eye.
- Non-compliance with these instructions for use.

13. Guarantee

CRISTALENS INDUSTRIE guarantees its intraocular lenses against any manufacturing defect.

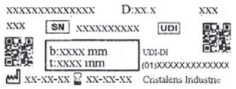
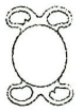
14. Version of the instructions for use

Date of publication and version number of the instructions for use: 2023-04-19, v.1.0.

Symbols and abbreviations used on the labelling and in the instructions for use

	*To be kept dry*
	*Do not use if the packaging is damaged and consult the instructions for use*
	*Double sterile barrier system (double SBS)*
	*Keep out of direct sunlight*
	*Maximum storage and transport temperature*
	*Sterilised using ethylene oxide*

	*Do not reuse / Single use*
	*Do not resterilise*
 www.cristalens-international.com	*Consult the electronic instructions for use*
CE 0459	*CE mark of conformity - Notified body n°0459*
	*Manufacturer*
	*Date of manufacture (format YYYY-MM-DD)*
LOT	*Batch code*
SN	*Serial number*
UDI	*Unique device identifier (UDI)*
UDI-DI	*Unique device identifier (UDI) - "Device" identifier section*
	*Use-by date (format: YYYY-MM-DD)*
 UA.TR.099	*National mark of conformity (Ukraine)*
MD	*Medical device / Name of the device*
	*Patient identification*
	*Health care centre or doctor*

	*Date (surgery)*
	*Treated eye*
	*Patient information website*
	*Traceability label space*
SE	*Spherical equivalent*
D	*Diopter*
Øt	*Total implant diameter (mm)*
Øb	*Implant body diameter (mm)*
	*Intraocular lens (IOL)*
	*Haptics angulation value*