CRISTALENS

ArtisSymbiose®
BINOCULAR PHASE CONTINUITY

АРТІС СИМБІОЗ

INTRAOCULAR LENS
LENTILLE INTRAOCULAIRE
INTRAOKULARLINSE
LENTE INTRAOCULAR
LENTE INTRAOCULARE
İNTRAOKÜLER LENS
ІНТРАОКУЛЯРНА ЛІНЗА
عدسة داخلية
ИНТРАОКУЛЯРЛЫ ЛИНЗА
LENTE INTRAOCULAR
ИНТРАОКУЛЯРНАЯ ЛИНЗА
THỦY TINH THỂ NHÂN TẠO

Hydrophobic acrylic
Acrylique hydrophobe
Hydrophobes Acrylat
Acrílico hidrófobo
Acrilico idrofobo
Hidrofobik akrilik
للماء كاره أكريليك
Гідрофобна акрилова
Acrílico hidrofóbico
Гидрофобты акрилді
Acrylic kỵ nước

DIFFRACTIVE MULTIFOCAL EXTENDED DEPTH OF FOCUS WITH BINOCULAR COMPLEMENTARITY AND VARIABLE TORICITY

MULTIFOCAL DIFFRACTIF A PROFONDEUR DE CHAMP ETENDUE ET COMPLEMENTAIRE EN BINOCULARITÉ AVEC TORICITE VARIABLE

MULTIFOKAL-DIFFRAKTIV ERWEITERTE TIEFENSCHÄRFE MIT BINOKULARER KOMPLEMENTÄRITÄT UND VARIABLER TORIZITÄT

MULTIFOCAL DIFRACTIVA CON PROFUNDIDAD DE FOCO EXTENDIDA Y COMPLEMENTARIA EN LA BINOCULARIDAD CON TORICIDAD VARIABLE

MULTIFOCALE DIFFRACTIVA A PROFONDITÀ DI FUOCO CONTINUA E COMPLEMENTARE IN BINOCULARITÀ CON TORICITÀ VARIABILE

DİFRAKTİF, MULTİFOKAL, ODAK DERİNLİĞİ UZUN, BİNOKÜLER TAMAMLAYICILI VE DEĞİŞKEN TORİSİTELİ

ДИФРАКЦІЙНА МУЛЬТИФОКАЛЬНА VARIÁ- VEL РОЗШИРЕНОЇ ГЛИБИНИ ФОКУСУ З БІНОКУЛЯРНОЮ КОМПЛЕМЕНТАРНІСТЮ Й ЗМІННОЮ ТОРИЧНІСТЮ

متعددة البؤر الانكسارية ذات عمق مجال ممتد ومكمّل في الرؤية بالعينين مع حيدية متغيّرة

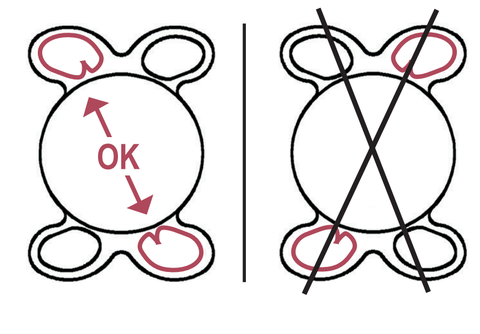
ДИФРАКТИВНАЯ МУЛЬТИФОКАЛЬНАЯ С УВЕЛИЧЕННОЙ ГЛУБИНОЙ ПОЛЯ ЗРЕНИЯ И ДОПОЛНИТЕЛЬНОЙ БИНОКУЛЯРНОСТЬЮ С ПЕРЕМЕННОЙ ТОРОИДАЛЬНОСТЬЮ

MULTIFOCAL DIFRATIVA COM PROFUNDIDADE DE CAMPO AUMENTADA E BINOCULARIDADE COMPLEMENTAR COM TORICIDADE VARIÁVEL

ТОРИКАЛЫҚ НҰСҚАЛАРЫ ӘР ТҮРЛІ ЖӘНЕ БИНОКУЛЯРЛЫҚПЕН ТОЛЫҚТЫРЫЛҒАН, ФОКУС ТЕРЕҢДІГІ КЕҢЕЙТІЛГЕН МУЛЬТИФОКАЛЬДІ ДИФРАКЦИЯЛЫҚ

KINH DA TIEU DIỂM KHUẾCH TAN VỚI DỘ SAU TRƯỜNG ẢNH MỞ RỘNG, TINH BỔ SUNG HAI MẮT VA DỘ CONG BIẾN DỔI

PRELOADED
PRÉCHARGÉ
VORGELADEN
PRECARGADA
PRECARICATA
ÖNCEDEN YÜKLENMİŞ
ПОПЕРЕДНЬО ЗАВАНТАЖЕНА
محمّلة سلفاً
ПРЕДВАРИТЕЛЬНО ЗАГРУЖЕННАЯ
PRÉ-CARREGADA
АЛДЫН АЛА ЖҮКТЕЛГЕН
ĐÃ ĐƯỢC LẮP SẴN



Year of CE marking affixing: Année d'apposition du marquage CE : Jahr der Anbringung der CE-Kennzeichnung: Año de colocación del marcado CE: Anno di apposizione della marcatura CE: CE işaretinin alındığı yıl: Рік нанесення CЄ маркування: سنة وضع الوسم CE: Год нанесения маркировки CE: Ano da aposição da marcação CE: CE таңбалау жылы: Năm cấp dấu CE:	ARTIS SYMBIOSE® – 2018

Storage
Stockage
Lagerung
Almacenamiento
Stoccagio
Saklama
Зберігання
التخزين
Хранение
Conservação
Сақтау
Bảo quản
40° C
5° C

MADE IN FRANCE

CE 0459

STERILE EO

2 STERILIZE

Référence : IFU-1007 v8.0 - Edition : 21/04/2026

EN

Description

This medical device is a diffractive multifocal extended depth of focus intraocular lens, with binocular complementarity and variable toricity, preloaded in its injection system ACCUJECT PRO*. It is sterile and is for single use.

This ARTIS SYMBIOSE intraocular lens is indicated for the replacement of a cataractous natural crystalline lens, for visual correction of aphakia after cataract surgery, as well as to compensate for presbyopia to allow the patient to benefit from continuous functional vision at all distances and fitted to the corneal astigmatism. It is a one-piece and posterior chamber foldable diffractive multifocal extended depth of focus intraocular lens, with binocular complementarity. It is designed for implantation in the capsular bag and to provide the function of the natural crystalline lens and appropriate optical power to achieve a sharp distance vision by its spherical equivalent power (SEQ) and its UV (UltraViolet) filter, as well as to compensate for presbyopia through its addition and, when necessary, to correct the corneal astigmatism of the patient's eye through its cylindrical (or torical) power.

Intraocular lens properties

Each ARTIS SYMBIOSE intraocular lens is obtained by machining a hydrophobic acrylic material that incorporates a filter to protect the retina from UV radiation (see *Transmission spectrum*).

The UV cut-off wavelength is 370 nm (transmission < 10%).

CRISTALENS Industrie recommends using intraocular lenses with equivalent transmission spectra in both of a patient's eyes.

Optics: diffractive multifocal extended depth of focus, with binocular complementarity, aspherical, biconvex, 360° square edges, diffractive pattern on the anterior face, toricity on the posterior face.

Refractive index: 1.54.

Available spherical equivalent (SEQ) power range: refer to the technical documentation.

Available additions profiles range:

- The "MID" profile ARTIS SYMBIOSE diffractive multifocal extended depth of focus intraocular lens, with binocular complementarity, which preserves distance vision, is intended to promote intermediate vision while providing continuity through near vision.
- The "PLUS" profile ARTIS SYMBIOSE diffractive multifocal extended depth of focus intraocular lens, with binocular complementarity, which preserves distance vision, is intended to promote near vision while providing continuity through intermediate vision.

CRISTALENS Industrie recommends combining, for each patient, a "MID" profile ARTIS SYMBIOSE intraocular lens in one eye and a "PLUS" profile ARTIS SYMBIOSE intraocular lens in the contralateral eye, in order to ensure complementary binocular vision between intermediate vision and near vision.

Available cylindrical power range: refer to the technical documentation.

Intraocular lens dimensions: refer to labelling.

Content

The protective packaging contains the sterile product, these instructions for use, the patient card and self-adhesive traceability labels.

Each ARTIS SYMBIOSE 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 sterilized with ethylene oxide.

The ARTIS SYMBIOSE intraocular lens, held in place in the injector loading chamber (1), is blocked by the clip (2) and the cartridge (3). Moreover, the injector is composed of a body (4) and a plunger (5) (see *Injector's drawing*).

Indications & Claimed clinical performances

This ARTIS SYMBIOSE posterior chamber diffractive multifocal extended depth of focus intraocular lens, with binocular complementarity, is indicated for the replacement of a cataractous natural crystalline lens, for visual correction of aphakia after cataract surgery, as well as to compensate for presbyopia to allow the patient to benefit from continuous functional vision at all distances and fitted to the corneal astigmatism. It is designed for implantation in the capsular bag, to provide the natural crystalline lens function and appropriate optical power to achieve a sharp distance vision, compensate for presbyopia and, when necessary, correct the corneal astigmatism of the patient's eye.

Clinical performance, clinical benefit, and safety claims:

The clinical performance targeted by the ARTIS SYMBIOSE device is the restoration of sharp distance and intermediate to near vision, obtained by the complementarity of the "MID" and "PLUS" addition profiles with:

- A value of binocular uncorrected distance visual acuity ≤ 0.3 LogMAR on average.
- 92.5% of patients with binocular corrected distance visual acuity of 0.3 LogMAR maximum.
- A value of binocular uncorrected intermediate and near visual acuity ≤ 0.3 LogMAR on average.
- A value of binocular continuous uncorrected visual acuity from 40 to 90 cm ≤ 0.3 LogMAR on average.
- An absolute value of residual refractive error (spherical equivalent (SE)) ≤ 0.5D on average.
- An absolute value of residual astigmatism ≤ 0.75 D on average.

The ARTIS SYMBIOSE device offers a clinical benefit to the patient by improving its visual acuity. The intended maximum benefit is the correction of cataract and the achievement of satisfactory visual acuity without spectacles at near, intermediate, and far distances.

The targeted safety claim for the ARTIS SYMBIOSE device is a secondary cataract surgery rate for intraocular lens removal (lens exchange, lens explantation) of < 0.5%.

Special considerations in patient selection

This ARTIS SYMBIOSE intraocular lens is contraindicated in newborns, premature babies, infants and children. ARTIS SYMBIOSE diffractive multifocal extended depth of focus intraocular lens, with binocular complementarity, implantation may not be suitable in patients with any of the following conditions (non-exhaustive list):

Dry eye (e.g. Meibomian gland dysfunction);
Expected postoperative residual astigmatism greater than 0.75D;
Irregular corneal astigmatism, significant irregular corneal aberration;
Strabismus, absence of binocular vision;
Pupil abnormality (non-reactive, tonic, abnormally shaped or with a dilatation less than 3.5 mm under mesopic/scotopic conditions);
Monophthalmia;
Non-age-related cataract (e.g. traumatic cataract);
History of intraocular or refractive surgery;
Use of systemic or ocular drugs that might affect the vision;
Ocular or intraocular inflammation;
Intraocular infection;
Glaucoma;
Retinal disorders (e.g. macular degeneration, diabetic retinopathy, history of retinal detachment, cystoid macular oedema, colour blindness, macular hole);
Corneal disorders compromising visual acuity (e.g. corneal endothelial diseases, corneal dystrophy, cornea guttata, history of corneal transplantation);
Choroidal haemorrhage or any other intraocular haemorrhage;
Intraocular hypertension;
Capsular or zonular anomalies (e.g. zonular laxity, zonulysis) which may affect the postoperative centring or the postoperative tilt of the intraocular lens;
Posterior capsule rupture or wide capsulorhexis (compromised intraocular lens stability);
Aniridia;
Anterior chamber collapse;
Narrow anterior chamber;
Microphthalmia;
Amblyopia.

Thorough preoperative evaluation and careful clinical analysis have to be performed by the surgeon to rigorously assess the benefit/risk ratio before an ARTIS SYMBIOSE diffractive multifocal extended depth of focus intraocular lens, with binocular complementarity, is implanted in such patients.

Precautions for use

- Do not use after the expiration date.
- Do not use if the packaging has been damaged or opened. Sterility is only guaranteed if the packaging shows no sign of damage.
- Do not use if the intraocular lens or the injector is damaged or shows any defect.
- Do not resterilize using any method.
- Do not reuse.
- Various surgical techniques can be used to implant an intraocular lens. It is up to the surgeon to select the most appropriate.
- CRISTALENS Industrie recommends using an incision size matching the injector.
- Avoid the use of silicon oil. Silicon oil, particularly when used in the surgical treatment of retinal detachment, may come in contact with the intraocular lens if the posterior capsule of the crystalline lens is not intact.
- The ARTIS SYMBIOSE diffractive multifocal extended depth of focus intraocular lens, with binocular complementarity, is not recommended in patients who have had a corneal surgery.
- The ARTIS SYMBIOSE diffractive multifocal extended depth of focus intraocular lens, with binocular complementarity, is not recommended in patients with a naturally large pupil (diameter above 4 mm).
- In patient with atypical eyes (including unusually large eyes as in common in high myopia), the surgeon may need to make appropriate additional preoperative measurements (e.g. of the posterior cornea).
- CRISTALENS Industrie recommends targeting emmetropia for distance vision.
- Center the ARTIS SYMBIOSE diffractive multifocal extended depth of focus intraocular lens, with binocular complementarity, very carefully. A non-centered intraocular lens may lead to vision problems.
- The superimposition of focused and unfocused images is having predictable effects on vision. These may look like halos or radial lines in dim conditions. Some effects may regress after adaptation to multifocality.
- In low-light conditions, visual acuity is lower with an extended depth of focus multifocal intraocular lens than with a monofocal intraocular lens. Patients with an extended depth of focus multifocal intraocular lens should therefore be careful when driving at night or in poor visibility conditions.
- To maximize patient satisfaction and adaptation, both eyes – as opposed to just one – should be fitted with multifocal lenses.
  Refer to the *"Intraocular lens properties"* section for Cristalens Industrie's recommendations about combining ARTIS SYMBIOSE diffractive multifocal extended depth of focus intraocular lenses, with binocular complementarity.
- 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 **"Instructions for use"**.

In the presence of astigmatism correction (cylinder other than zero), the following precautions for use have to be added to the previous list:

- Carefully align the ARTIS SYMBIOSE intraocular lens having a torical component with the axis of placement defined on the cornea. Any misalignment of the intraocular lens will compromise the correction of astigmatism.
- Misalignment of the ARTIS SYMBIOSE intraocular lens having a torical component by more than 30° with respect to its axis of placement will exacerbate postoperative astigmatism instead of correcting it. In this case, the intraocular lens will have to be realigned. It is recommended that this is carried out between one week and one month after implantation.
- It is strongly recommended to use the Toric Calculator provided by CRISTALENS Industrie to determine the cylindrical power as well as the axis of placement of the ARTIS SYMBIOSE diffractive multifocal extended depth of focus intraocular lens having a torical component, with binocular complementarity, to be implanted.

Notification of serious incidents:

Any serious incident that occurs in connection with the ARTIS SYMBIOSE device must be reported by the doctor and/or the health care facility where the incident is detected, or by the patient, to CRISTALENS INDUSTRIE, the local contact (distributor), the health professional who performed the procedure, 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):
     - For the doctor and/or the health care facility: in the "Contact» tab then "Product claim", or in the user profile then "Claim about a product".
     - For the patient: in the "Contact» tab then "Information request".
2. Provide all the necessary information requested at the time of contact, in particular traceability information, and if applicable return the device 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.

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 SYMBIOSE 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 SYMBIOSE device.

Devices, equipment, accessories:

The accessories validated for use with the ARTIS SYMBIOSE 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.
- CRISTALENS TORIC CALCULATOR (developed by CRISTALENS INDUSTRIE and available on the website www.cristalens-international.com) – only for the toric version of the ARTIS SYMBIOSE device: a software used by the surgeon preoperatively to determine the cylindrical dioptric power and the axis of placement of the toric intraocular lens.

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.

In addition, regarding diffractive technologies, interpret results with caution when using autorefractors or wavefront aberrometers that use infrared light or when performing duochrome tests.

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.

Operating method to implant the intraocular lens:

In the presence of astigmatism correction (cylinder other than zero), the following information must be taken into account before the ARTIS SYMBIOSE diffractive multifocal extended depth of focus intraocular lens, with binocular complementarity, is implanted:

The ARTIS SYMBIOSE intraocular lens having a torical component must be precisely oriented along a predetermined axis to ensure optimum correction of corneal astigmatism.

Marks on the toric intraocular lens indicate the position of its flat meridian (the meridian with the lowest dioptric power). At the end of surgery, these must be perfectly aligned with the axis of placement identified on the cornea. For optimum outcome, this placement axis must be established prior to surgery using the Cristalens Toric Calculator (available on the website www.cristalens-international.com).

Before surgery, the axis of placement of the ARTIS SYMBIOSE intraocular lens having a torical component in the patient's eye should be identified in the following way:

1. Just before the surgery with the patient sitting down, define the axis of reference in the eye as precisely as possible using a suitable marker. This axis of reference could be the horizontal axis of the eye (0°-180°) and/or its vertical axis (90°-270°).
2. Before insertion of the implant in the eye, use the axis of reference to identify, using a suitable marker, the axis of placement for the toric intraocular lens, established beforehand using the Cristalens Toric Calculator (www.cristalens-international.com).

Operating method to implant the ARTIS SYMBIOSE diffractive multifocal extended depth of focus intraocular lens, with binocular complementarity:

1. Check all labelling, especially model, additions profile, powers and expiration date.
   Check the packaging completely. If the packaging is damaged, use another intraocular lens.
2. Open the pouch and take out the blister using aseptic technique to maintain sterile conditions.
   Open the blister on the sterile area and carefully remove the injector.
3. Meticulously examine the intraocular lens and injector.
   If any damage or anomaly is noticed, use another intraocular lens.
4. Remove the clip (fig. 1).
5. Check that the intraocular lens is correctly positioned in the loading chamber.
   If it is mispositioned (haptics off the rails, intraocular lens too far forward or back), carefully reposition the intraocular lens or use another intraocular lens.
6. Pour sterile saline solution (BSS) into the cartridge and onto the intraocular lens (fig. 2), wait at least 1 minute.
7. Insert sterile viscoelastic product in the cartridge tip, in the cartridge and place some on the intraocular lens (fig. 2).
8. Close the wings of the loading chamber (fig. 3). The "click" indicates the correct closure of the loading chamber.
9. Push the plunger and ensure that the intraocular lens advances normally about 1 cm.
10. Identify the taper at the cartridge tip and then insert it through the eye incision.
11. Inject the intraocular lens by continuously pushing on the plunger.
    If any problem is detected during injection such as a strong resistance, stop using the device.
12. Ensure that the intraocular lens is inside the capsular bag, and in the right position by checking the notches.
13. Dispose of the packaging and injector. Do not reuse the injection system.

In the presence of astigmatism correction (cylinder other than zero), the following steps must be considered after the ARTIS SYMBIOSE diffractive multifocal extended depth of focus intraocular lens, with binocular complementarity, is implanted:

14. After insertion of the ARTIS SYMBIOSE intraocular lens having a torical component into the capsular bag, rotate the implant until the marks present on the intraocular lens are perfectly aligned with the previously defined axis of placement.
15. At the end of surgery, check carefully that the ARTIS SYMBIOSE intraocular lens having a torical component is indeed positioned along its axis of placement.

Possible adverse effects and complications

As with any surgical procedure, there is a risk. Possible complications and adverse events following cataract surgery and/or implantation of an ARTIS SYMBIOSE diffractive multifocal extended depth of focus intraocular lens, with binocular complementarity, include (non-exhaustive list):

Posterior and/or anterior capsule opacification;
Decentration or luxation of the intraocular lens;
Ocular or intraocular inflammation;
Intraocular infection;
Corneal oedema;
Macular oedema;
Intraocular pressure rise;
Retinal detachment;
Glaucoma;
Pupillary block;
Capsular block;
Capsular rupture;
Wound leak;
Hypopyon;
Dysphotopsia;
Precipitates on the intraocular lens surface;
Glistening;
Refractive error;
Damage to the intraocular lens (scratch, crack, break of the optic; scratch, crack, deformation, break of the haptics);
Injector failure (jamming, block, abnormal behaviour of the intraocular lens);
Secondary surgical interventions including, but not limited to: intraocular lens repositioning, intraocular lens replacement, vitreous aspiration or iridectomy for pupillary block, wound leak repair, retinal detachment procedure.

In the presence of astigmatism correction (cylinder other than zero), the following adverse event must be added to the previous list:
Intraocular lens rotation.

Interactions

- The intraocular lens passed the Nd-YAG laser exposure test according to the ISO 11979-5 standard.
- The intraocular lens contains no metal.
- No direct interactions with drugs are known. However, current or previous treatments with alpha1-adrenergic receptors antagonists may increase the risk of complications associated with cataract surgery (Intraoperative Floppy Iris Syndrome (IFIS)).
- No adverse events related to interactions with other investigational or specific treatment devices are known.

Patient information

Before surgery, the patient should be given appropriate information about diffractive multifocal extended depth of focus intraocular lenses, with binocular complementarity, and about the contraindications and possible complications and adverse events, postoperative follow-up and required measures (follow-up required, possible interactions and interferences) to this type of surgery and this type of implant.

In the presence of astigmatism correction (cylinder other than zero), the patient should also be given appropriate information about toric intraocular lenses and about the contraindications and possible complications and adverse events, postoperative follow-up and required measures (follow-up required, possible interactions and interferences) to this type of surgery and this type of implant.

Following the operation, the surgeon must warn the patient that in the event of decreased performance of the operated eye, the patient must consult an ophthalmologist without delay.

Calculation of the intraocular lens power

Prior to implantation, the surgeon must determine the spherical equivalent power as well as the additions profile and the cylindrical power of the ARTIS SYMBIOSE diffractive multifocal extended depth of focus intraocular lens, with binocular complementarity, to be implanted:

- Calculation of spherical equivalent (SEQ) power: it is calculated for each patient based on keratometric and biometric data, using formulae available from the literature, the surgeon's experience, and estimated A-constants indicated on the box. These estimates serve as a starting point for the power calculation. They will have to be optimized by each surgeon based on clinical experience, surgical techniques, measuring equipment and achieved postoperative results.
  Cristalens Industrie recommends optimizing A-constant with intraocular lenses of the ARTIS preloaded monofocal hydrophobic family.
  The spherical equivalent (SEQ) power, expressed in diopters, of each ARTIS SYMBIOSE intraocular lens is displayed on the labelling with the symbol "D".
- Choice of the additions profile: the choice of the additions profile determines the promoted near vision zone. Therefore, the surgeon must match the choice of the implants to the patient's lifestyle and (possibly) preferences.
  Refer to the *"Intraocular lens properties"* section for information about available additions profiles range for the ARTIS SYMBIOSE diffractive multifocal extended depth of focus intraocular lens, with binocular complementarity, and related recommendations from Cristalens Industrie.
  The additions profile for each ARTIS SYMBIOSE intraocular lens is specified on the labelling as "MID" or "PLUS".
- Calculation of cylindrical (or toric) power: it is calculated for each patient based on keratometric and biometric data, taking into account the size and position of the incision to be made by the surgeon.
  In order to determine the cylindrical power of the ARTIS SYMBIOSE diffractive multifocal extended depth of focus intraocular lens having a torical component, with binocular complementarity, to be implanted as well as its axis of placement, CRISTALENS Industrie provides the surgeon with the Cristalens Toric Calculator (www.cristalens-international.com) and recommends using it to achieve optimum outcome.
  The cylindrical (or toric) power, expressed in diopters, of each ARTIS SYMBIOSE intraocular lens having a torical component is displayed on the labelling with the symbol "Cyl".
  Correction of astigmatism in the corneal plane (calculated for an average eye and based on an intraocular lens of median spherical equivalent power) as a function of the cylindrical power in the plane of each ARTIS SYMBIOSE intraocular lens having a torical component in CRISTALENS Industrie's standard range is given in Table 1.

Expiration date

The expiration date indicated on the box determines the limit for use. It is indicated in the format YYYY-MM-DD.

The intraocular lens must not be implanted after the expiration date indicated on the packaging.

Storage and transport conditions

Protect from sunlight and moisture. Avoid shocks and crushing of the box.

Specific storage conditions: see symbols on these instructions for use and on the box.

Disposal of the device

The device (injector, packaging and intraocular lens) must be disposed of in adapted special collector in accordance with the rules and recommendations in force at each health care facility:

The injector and intraocular lens constitute infectious clinical waste.

The box and instructions for use can be recycled.

Disclaimer

CRISTALENS Industrie cannot be held responsible for any damage incurred by a patient resulting from:

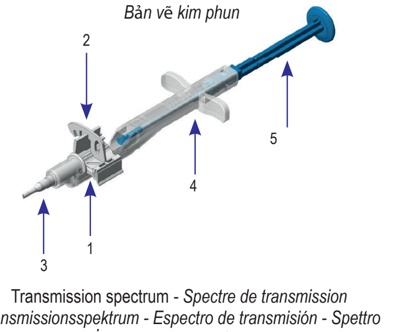
- Surgical technique or implantation method used by the surgeon.
- An integrity fault, a deterioration of the intraocular lens, noticed during the surgery but not leading to the removal of the damaged intraocular lens.
- Choice or prescription of the intraocular lens.
- Reuse of the device, resterilization, repackaging, use of a damaged or already opened device (compromised sterility), or use after its expiration date. The identified risks are: damage to the medical device, contamination, infection, endophthalmitis, inflammation, injury, illness, operated eye loss.
- Non-compliance of these instructions for use.

Guarantee

CRISTALENS Industrie guarantees its intraocular lenses against any manufacturing defect.

* Injector ACCUJECT PRO™ manufactured by Medicel AG – SWITZERLAND

Injector's drawing - *Schéma de l'injecteur*
Darstellung des Injektors - Esquema del inyector
Schema dell'iniettore - Enjektör çizimi - Малюнок інжектора -
الرسم التخطيطي للحاقن *- Схема инжектора -*
Esquema do injetor - Инжектор диаграмма
Bản vẽ kim phun



Transmission spectrum - *Spectre de transmission*
Transmissionsspektrum - Espectro de transmisión - Spettro di trasmissione - İletim spektrumu - Спектр пропускання - طيف النفاذ *- Спектр пропускания - Espectro de transmissão -*
Өткізгіштік спектрі - Phổ truyền dẫn

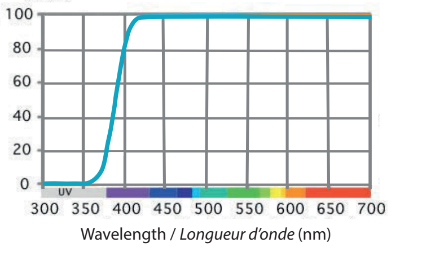


Fig. 1 / Şek. 1 / Мал. 1 / الشكل 1 / 1-сур. / Рис.1 / Hình 1

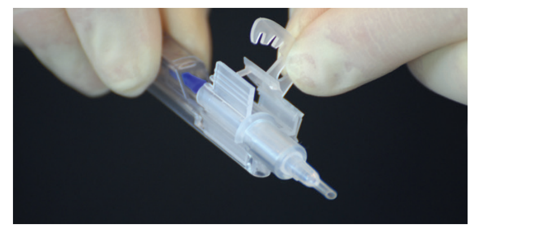


Fig. 2 / Şek. 2 / Мал. 2 / الشكل 2 / 2-сур. / Рис.2 / Hình 2

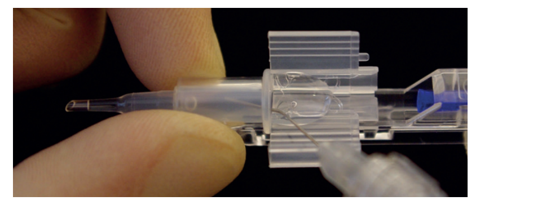


Fig. 3 / Şek. 3 / Мал. 3 / الشكل 3 / 3-сур. / Рис.3 / Hình 3

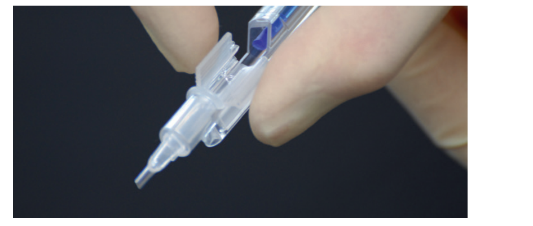
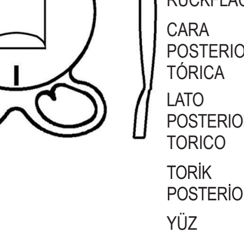


Table 1 - *Tableau 1 - Tabelle 1 - Tabla 1 - Tabella 1 - Tablo 1 -*
Таблиці 1 - الجدول 1 - Таблица 1 - Tabela 1 - 1 кесте - Bảng 1

IOL model *Modèle de la LIO* *Modell der IOL* *Modelo de la LIO* *Modello della LIO* *IOL modeli* *Модель ІОЛ* نموذج العدسة الداخلية الحيدية *Модель ИОЛ* *Modelo da LIO* *ИОЛ моделі* *Chủng loại IOL*	**IOL cylindrical power (in diopters)** *Puissance cylindrique de la LIO (en dioptries)* *Zylinderstärke der IOL (in Dioptrien)* *Potencia cilíndrica de la LIO (en dioptrías)* *Potere cilindrico della LIO (in diottrie)* *IOL silindir gücü (diyoptri cinsinden* *Циліндрична сила ІОЛ (в діоптріях)* القوة الإسطوانية للعدسة الداخلية الحيدية (في ديوبتر) *Цилиндрическая сила ИОЛ (в диоптриях)* *Potência cilíndrica da LIO (em dioptrias)* *ИОЛ цилиндрлік куаты (диоптриямен)* *Công suất loạn thị của IOL (biểu thị bằng độ khúc xạ)*	**Correction at corneal plane (in diopters)** *Correction au plan de la cornée (en dioptries)* *Korrektur auf Hornhautebene (in Dioptrien)* *Corrección en el plano de la córnea (en dioptrías)* *Correzione a livello della cornea (in diottrie)* *Korneal düzlemde düzeltme (diyoptri cinsinden)* *Корекція в площині рогівки (в діоптріях)* تصحيح مستوى القرنية (بالديوبتر) *Коррекция плоскости роговицы (в диоптриях)* *Correção no plano da córnea (em dioptrias)* *Қасаң қабықтың жазықтығында түзету (диоптриямен)* *Độ điều chỉnh ở mặt phẳng giác mạc (biểu thị bằng độ khúc xạ)*
ARTIS SYMBIOSE T0.25	0.25 D	0.18 D
ARTIS SYMBIOSE T0.50	0.50 D	0.36 D
ARTIS SYMBIOSE T0.75	0.75 D	0.53 D
ARTIS SYMBIOSE T1.00	1.00 D	0.72 D
ARTIS SYMBIOSE T1.25	1.25 D	0.90 D
ARTIS SYMBIOSE T1.50	1.50 D	1.08 D
ARTIS SYMBIOSE T1.75	1.75 D	1.26 D
ARTIS SYMBIOSE T2.00	2.00 D	1.44 D
ARTIS SYMBIOSE T2.25	2.25 D	1.61 D
ARTIS SYMBIOSE T2.50	2.50 D	1.79 D
ARTIS SYMBIOSE T2.75	2.75 D	1.97 D
ARTIS SYMBIOSE T3.00	3.00 D	2.15 D
ARTIS SYMBIOSE T3.25	3.25 D	2.32 D
ARTIS SYMBIOSE T3.50	3.50 D	2.50 D
ARTIS SYMBIOSE T3.75	3.75 D	2.68 D

In the presence of astigmatism correction (cylinder other than zero):
En présence de correction d'astigmatisme (cylindre différent de zéro) :
Bei Vorhandensein einer Astigmatismuskorrektur (Zylinder ungleich Null):
En presencia de corrección de astigmatismo (cilindro distinto de cero):
In presenza di correzione dell'astigmatismo (cilindro diverso da zero):
Astigmatizma düzeltmesi varlığında (sıfır haricinde silindir):
При необхідності корекції астигматизму (циліндр, більший від нуля):
في وجود تصحيح اللابؤرية (اسطوانة مختلفة عن الصفر):
При наличии коррекции астигматизма (цилиндр отличен от нуля):
Na presença de correção de astigmatismo (cilindro diferente de zero):
Астигматизмді түзету үшін (цилиндр нөлге тең емес):
Trong trường hợp có điều chỉnh loạn thị (độ trụ khác 0):



Marked axis (flat meridian)
Axe marqué (méridien plat)
Markierte Achse (méridien plat)
Eje marcado (meridiano plano)
Asse segnato (meridiano piatto)
İşaretli eksen (düz meridyen)
Позначена вісь (плоский меридіан)
المحور المحدد (الخط القطبي المسطح)
Отмеченная ось (плоский меридиан)
Eixo marcado (meridiano plano)
Таңбаланған өс (тегіс меридиан)
Trục được đánh dấu (kinh tuyến phẳng)
TORIC POSTERIOR SURFACE
FACE POSTERIEURE TORIQUE
TORISCHE RÜCKFLÄCHE
CARA POSTERIOR TÓRICA
LATO POSTERIORE TORICO
TORİK POSTERİOR YÜZ
ТОРИЧНА ЗАДНЯ СТОРОНА
وجه خلفي حيدي
ТОРОИДАЛЬНАЯ ЗАДНЯЯ ПОВЕРХНОСТЬ
FACE POSTERIOR TÓRICA
АРТҚЫ ЖАҒЫ ТОРИКАЛЫ
MẶT TORIC PHÍA SAU

CRISTALENS INDUSTRIE
4 rue Louis de Broglie
22300 LANNION - FRANCE
Tel : +33 (0)2 96 48 92 92
www.cristalens-international.com

• Нарушения целости, повреждения интраокулярной линзы, замеченного во время операции, но не ведущего к удалению поврежденной интраокулярной линзы.
• Выбора или назначения интраокулярной линзы.
• Повторного использования изделия, рестерилизации, переупаковки, использования поврежденного или уже открытого изделия (нарушения стерильности) или использования после истечения срока годности. Выявленными рисками являются: повреждение медицинского изделия, заражение, инфекция, эндофтальмит, воспаление, травма, болезнь, потеря оперированного глаза.
• Несоблюдение данной инструкции по использованию.

Гарантия
CRISTALENS INDUSTRIE гарантирует отсутствие производственного брака у своих интраокулярных линз.

* Инжектор ACCUJECT PRO™ производства Medicel AG – ШВЕЙЦАРИЯ

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ТОО «TESM Company»
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050012, город АЛМАТЫ - РЕСПУБЛИКА КАЗАХСТАН
Тел.: 007 727 260 13 11
Факс: 007 727 260 13 18
Моб: 007 701 808 33 39
mukhtar.slamkulov@gmail.com

VI

Mô tả sản phẩm

Thiết bị y tế này là thủy tinh thể nhân tạo mở rộng độ sâu tiêu cự đa tiêu nhiễu xạ, với tính chất bổ sung thị giác hai mắt và công suất loạn thị đa dạng, đặt sẵn trong dụng cụ đặt thủy tinh thể ACCUJECT PRO. Thiết bị này vô trùng và chỉ dùng một lần.

Thủy tinh thể nhân tạo ARTIS SYMBIOSE được chỉ định để thay thế thể thủy tinh tự nhiên của mắt nhằm điều chỉnh thị lực cho bệnh nhân không còn thể thủy tinh (aphakia) sau phẫu thuật đục thủy tinh thể, đồng thời bù trừ lão thị (presbyopia), cho phép bệnh nhân đạt được thị lực liên tục ở mọi khoảng cách và điều chỉnh loạn thị giác mạc. Đây là thủy tinh thể nhân tạo một mảnh, gập được đặt vào hậu phòng, đa tiêu nhiễu xạ mở rộng độ sâu tiêu cự, với tính chất bổ sung thị giác hai mắt. Nó được thiết

Symbols used on labelling – *Symboles utilisés sur l'étiquetage – Auf die Etikettierung verwendete Symbole – Símbolos utilizados en el etiquetado – Simboli utilizzati sull'etichettatura – Etikette kullanılan semboller – Символи, які використовуються на маркуванні –* الرموز المستخدمة في البطاقة التعريفية *– Símbolos utilizados na etiqueta – Символы, использованные в маркировке - Таңбалауда қолданылатын белгілер – Biểu tượng*

☂	Keep dry *Craint l'humidité* *Vor Nässe schützen* *Mantener seco* *Teme l'umidità* *Kuru tutun* *Зберігати в сухому місці* يخشى الرطوبة *Ылғалға төзімді* *Proteger da humidade* *Хранить в сухом месте* *Giữ sản phẩm khô ráo*
⊘	Do not use if package is damaged *Ne pas utiliser si l'emballage est endommagé* *Nicht verwenden, wenn die Verpackung beschädigt ist* *No utilizar si el envase está dañado* *Non utilizzare se la confezione é dannegiata* *Ambalaj hasarlıysa kullanmayın* Не використовувати, якщо упаковку пошкоджено عدم الاستخدام إذا كان الغلاف تالفاً *Қаптама зақымдалған жағдайда, қолданбаңыз* *Não utilizar se a embalagem estiver danificada* *Не использовать, если упаковка повреждена* *Không được sử dụng nếu bao bì bị hư hỏng*
☀	Keep away from sunlight *Conserver à l'abri de la lumière du soleil* *Vor Sonnenlicht schützen* *Mantener alejado de la luz solar* *Tenere al riparo dalla luce del sole* *Güneş ışığından uzak tutun* Зберігати в темному місці يحفظ بعيداً عن ضوء الشمس *Жарықтан қорғалған жерде сақтау керек* *Conservar ao abrigo da luz do sol* *Беречь от солнечного света* *Tránh ánh nắng mặt trời*
Storage Stockage 40° C 5° C	Storage temperature limits Limites de température de stockage *Lagerungstemperaturbegrenzung* *Límites de temperatura de almacenamiento* *Limiti di temperatura di stoccaggio* *Saklama sıcaklığı sınırları* Температурне обмеженні при зберіганні حدود درجات حرارة التخزين *Сақтаған кездегі температуралық шектері* *Limites de temperaturas de conservação* *Температурный предел для хранения* *Giới hạn nhiệt độ bảo quản*
STERILE EO	Sterilized using ethylene oxide *Stérilisé avec de l'oxyde d'éthylène* *Mit Ethylenoxid sterilisiert* *Esterilizado con óxido de etileno* *Sterilizzato con ossido di etilene* *Etilen oksit ile sterilize edilmiştir* Стерилізовано оксидом етилену معقم بأكسيد الإيثيلين *Этилен тотығымен зарарсыздандырылған* *Esterilizado com óxido de etileno* *Стерилизован оксидом этилена* *Tiệt trùng bằng ethylene oxide*
⊘ 2	Do not reuse *Ne pas réutiliser* *Nicht wiederverwenden* *No reutilizar* *Non riutilizzare* *Yeniden kullanmayın* Повторно використовувати заборонено عدم إعادة الاستخدام *Қайта қолдануға болмайды* *Não reutilizar* *Не использовать повторно* *Không được tái sử dụng*
⊘ 2 STERILIZE	Do not resterilize *Ne pas restériliser* *Nicht resterilisieren* *No reesterilizar* *Non risterilizzare* *Yeniden sterilize etmeyin* Повторно стерилізувати заборонено عدم إعادة التعقيم *Қайта зарарсыздандыруға болмайды* *Não reesterilizar* *Не рестерилизовать* *Không được tiệt trùng lại*
ℹ	Consult instructions for use *Consulter les instructions d'utilisation* *Gebrauchsanweisung beachten* *Consulte las instrucciones de uso* *Consultare le istruzioni per l'uso* *Kullanma talimatlarına bakın* Ознайомлення з інструкцією з використання الاطلاع على تعليمات الاستخدام *Пайдалану бойынша нұсқаулықты қараңыз* *Consultar as instruções de utilização* *Ознакомьтесь с инструкцией по пользованию* *Đọc kỹ hướng dẫn sử dụng*
CE 0459	CE marking of conformity – Notified body n°0459 *Marquage de conformité CE – Organisme notifié n°0459* *CE-Konformitätskennzeichnung – Benannte Stelle n°0459* *Marcado CE de conformidad – Organismo notificado n°0459* *Marcatura CE di conformità – Organismo notificato n°0459* *CE uygunluk işareti – Onaylı kuruluş no 0459* Знак відповідності CЄ – нотифікований орган №0459 وسم المطابقة CE - الهيئة المبلّغة رقم 0459 *CE сәйкестігін таңбалау - Нотификациялы органның сәйкестендіру нөмірі 0459* *Marcação de conformidade CE — Organismo notificado n.º 0459* *Маркировка соответствия CE – Уполномоченный орган №0459* *Biểu tượng đạt Tiêu chuẩn CE – Cơ quan cấp phép số 0459*
	Manufacturer *Fabricant* *Hersteller* *Fabricante* *Produttore* *Üretici* Виробник الصانع *Өндіруші* *Fabricante* *Производитель* *Nhà sản xuất*
SN	Serial number *Numéro de série* *Seriennumber* *Número de serie* *Numero di serie* *Seri numarası* Серійний номер رقم السلسلة *Сериялық нөмірі* *Número de série* *Серийный номер* *Số seri*
⧗	Use-by date *Date limite d'utilisation* *Verwendbar bis* *Fecha de caducidad* *Data di scadenza* *Son kullanma tarihi* Використати до (дата) تاريخ إنتهاء الصلاحية *Жарамдылық мерзімі* *Data limite de utilização* *Срок годности* *Ngày hết hạn sử dụng*
UA.TR.099	Mark of conformity with technical regulations (Ukraine) – Conformity assessment body n°UA.TR.099 (UKRMEDCERT) *Marque de conformité aux règlements techniques (Ukraine) – Organisme d'évaluation de la conformité n°UA.TR.099 (UKRMEDCERT)* *Zeichen der Konformität mit technischen Vorschriften (Ukraine) - Konformitätsbewertungsstelle Nr. UA.TR.099 (UKRMEDCERT)* *Marca de conformidad con los reglamentos técnicos (Ucrania) - Organismo de evaluación de la conformidad n°UA.TR.099 (UKRMEDCERT)* *Marchio di conformità ai regolamenti tecnici (Ucraina) - Organismo di valutazione della conformità n°UA.TR.099 (UKRMEDCERT)* *Teknik düzenlemelere uygunluk işareti (Ukrayna) - Uygunluk değerlendirme kuruluşu n°UA.TR.099 (UKRMEDCERT)* *Знак відповідності технічним регламентам (Україна) - Орган з оцінки відповідності №UA.TR.099 (УКРМЕДСЕРТ)* *(UKRMEDCERT)* علامة المطابقة مع اللوائح الفنية (أوكرانيا) - هيئة تقييم المطابقة رقم 099 *Техникалық регламенттерге сәйкестік белгісі (Украина) – Сәйкестікті бағалау органы n°UA. TR.099 (UKRMEDCERT)* *Marca de conformidade com as regulamentações técnicas (Ucrânia) - Organismo de avaliação da conformidade n.ºUA.TR.099 (UKRMEDCERT)* *Знак соответствия техническому регламенту (Украина) -. Орган по оценке соответствия №UA. TR.099 (УКРМЕДСЕРТ)* *Biểu tượng đạt tiêu chuẩn quy định kỹ thuật (Ukraine) – Cơ quan đánh giá quy chuẩn số UA.TR.099 (URKMEDCERT)*
	Date of manufacture *Date de fabrication* *Herstellungsdatum* *Fecha de fabricación* *Data di fabbricazione* *Üretim tarihi* Дата виготовлення تاريخ الصنع *Өндірілген күні* *Data de fabrico* *Дата производства* *Ngày sản xuất*