



The ARTIS T PLE intraocular lens is indicated for the replacement of a cataractous natural crystalline lens. It is a one-piece and posterior chamber foldable monofocal toric intraocular lens. It is designed for implantation in the capsular bag and is provided to function the focal refractive index by its spherical equivalent power (SEQ) and its UV (ultraviolet) filter, as well as to correct the corneal astigmatism of the patient's eye through its cylindrical or toric power.

Intraocular lens properties
Each ARTIS T PLE intraocular lens is obtained by machining a transparent acrylic material that incorporates a filter to protect the retina from UV radiation (high transmission spectrum).

The UV cut-off wavelength is 370 nm (transmission < 10%).
CRISTALINS has a refractive index of 1.553, which allows transmission spectra in both of its patient's eyes.

Optical properties
Aspherical, biconvex, 360° square edges, biconvex on the posterior face.
Modulation Transfer Function: MTF > 0.4 (Modulation @ 100 c/mm at 3-nm aperture).

Reflective index: 1.54
Spherical equivalent (SEQ) power range refers to the technical documentation.
Available equivalent power range refers to the technical documentation.
Intraocular lens dimensions: refer to labeling.

Content
The product packaging contains the sterile product, these instructions for use, the patient card and self-test instructions (label).

Each ARTIS T PLE 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 T PLE intraocular lens, held in place in the injector loading chamber (1), is locked by the CR-Q and the cartridge (3). Moreover, the injector is composed of a body (4) and a plunger (5) (see injector's drawing).

Indications & claimed clinical efficacy
The ARTIS T PLE intraocular lens is indicated for the replacement of a cataractous natural crystalline lens by a foldable intraocular lens (IOL) in order to correct refractive error. The ARTIS T PLE intraocular lens is designed for implantation in the capsular bag, to provide the natural optical function and to correct the corneal astigmatism and/or the refractive error.

Clinical performance, clinical benefit, and safety claims
The clinical performance targeted by the ARTIS T PLE device is the restoration of sharp distance vision.

> 92 % of patients with monocular corrected distance visual acuity of 0.3 LOGMAR maximum.
An absolute value of visual interference (visual quality) of 0.7 or less, improving the visual quality.
An absolute value of visual degradation of 0.75 D or average.

The ARTIS T PLE intraocular lens is designed to improve the visual quality of the patient. The intended maximum effect is the correction of astigmatism and the achievement of satisfactory visual quality without spectacles at all least one target distance.

The ARTIS T PLE intraocular lens is designed to be a secondary cataract surgery rate for intraocular lens removal (lens exchange, lens explantation) < 0.5 %.

Special considerations in patient selection
The ARTIS T PLE intraocular lens is contraindicated in neonates, premature babies, infants and adults. ARTIS T PLE intraocular lens implantation may not be suitable in patients with any of the following conditions (non-exclusive list):

Irregular corneal astigmatism; irregular irregular corneal aberration;
Non-eye-related ocular (e.g. traumatic) cataract;
History of intraocular or extraocular surgery;
Use of systemic or ocular drugs that might affect the vision;

Ocular or intraocular inflammation;
Cataract infection;
Glaucoma;

Retinal disorders (e.g. macular degeneration, diabetic retinopathy, history of retinal detachment, ciliary muscular edema, macular hole);
Corneal disorders compromising visual acuity (e.g. corneal endothelial diseases, corneal dystrophy, intraocular hypertension);
Chronic hereditary or any other anterior chamber hemorrhage;

Intraocular hypertension;
Capsular or zonular anomalies (e.g. corneal zonular zonulysis) which may affect the postoperative visual quality;
Posterior capsule rupture or wide opacifications (compromised intraocular lens stability);

Anterior chamber collapse;
Narrow anterior chamber;
Narrow angle glaucoma;
Anterior uveitis;
Anisophoria;

Thorough preoperative evaluation and careful clinical analysis have to be performed by the surgeon or ophthalmologist, the best contact institution, the health care provider and the patient.

The cylindrical (or toric) power, expressed in diopters, of each ARTIS T PLE intraocular lens is indicated on the label.

Precautions for use
Do not use the packaging as a means of transport or storage. Sterility is only guaranteed if the packaging shows no sign of damage.

Do not use the ARTIS T PLE intraocular lens if the injector is damaged or shows any defect.
Do not reenter using any method.

Various surgical methods can be used to implant and intracapsular the lens. It is up to the surgeon to choose the most appropriate.

CRISTALINS provides recommendations using an incision size matching the lens.
Avoid the use of silicon oil. Silicon oil including any use related to the surgical treatment of retinal diseases or contact with the lens or the capsular bag may lead to an increase in the risk of posterior capsule and lens adhesion.

In patient with astigmatism, make appropriate additional prescriptive measurements (e.g. of the posterior cornea).

CRISTALINS provides recommendations for the use of the ARTIS T PLE intraocular lens in combination with the use of placement with excimer refractive surgery 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 CRISTALINS Industrie to determine the cylindrical power as well as the use of placement of the ARTIS T PLE intraocular lens to be implanted.

The use of accessories not approved by CRISTALINS Industrie can compromise the successful implantation of the intraocular lens and cause complications and adverse events. The only valid combinations are those indicated in section "Instructions for use".

Modification of astigmatism
Any anterior incident that occurs in connection with the ARTIS T PLE device must be reported by the doctor and/or the health care facility where the incident is detected, or by the patient, to CRISTALINS Industrie, in order to ensure the safety of the patient and the health care facility, and the competent authority of the country in which the surgeon and/or the patient is established.

To notify CRISTALINS INDUSTRIE
Contact CRISTALINS INDUSTRIE immediately.
By e-mail to: mailto:marketing@crystalins.ch.

For the patient in the "Contact" box "Information required".
For the doctor and/or the health care facility in the "Contact" box "Product claim", or in the "user profile" then "Claim about a product".

2. Provide all the necessary information regarding at the time of contact, in particular transparency (transparency) of the intraocular lens and the use of the ARTIS T PLE intraocular lens.

Note: A serious incident or any incident that directly or indirectly resulted in, may have resulted in, or may result in:
The death of a patient, user, or any other person;

Serious temporary or permanent deterioration in the health status of a patient, user, or any other person;
A serious threat to public health.

Instructions for use
Facilities, location and installation required:
As an aspheric contact lens as an aspheric contact lens that complies with the standards ISO 7

is required to use the ARTIS T PLE device, regardless of the anaesthesia method.

As an aspheric contact lens, the ARTIS T PLE intraocular lens is designed for implantation in the capsular bag, to provide the natural optical function and to correct the corneal astigmatism and/or the refractive error.

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