CT LUCIA 621P

Technical Specifications (US only)

ZEISS

Seeing beyond

Instructions for Use
CT LUCIA 621P

℞ ONLY

1. Products to which these instructions for use apply

These instructions for use apply to the following product:

Model	Performance characteristics	Packaging color code
CT LUCIA 621P	Aspheric, monofocal	Medium grey

2. Device description

One sterile, foldable, heparin-coated*, hydrophobic, acrylic, monofocal, posterior chamber intraocular lens (IOL) pre-loaded in an injector.

CT LUCIA 621P is made of Acrylmex, an optically clear, hydrophobic acrylic copolymer of butyl acrylate, ethyl methacrylate, and N-benzyl-N-isopropylacrylamide crosslinked with ethylene glycol dimethacrylate.

See label on the cardboard box for lens type, lens type attributes and refractive power. The total diameter of the lens is 13 mm and the body diameter is 6 mm. The spectral transmittance curve (figure 1) represents the transmittance values and cut-off wavelengths of the IOL.

Detail Lens Description:

- Material.....Hydrophobic acrylic (Acrylmex Clear), with benzotriazole UV-absorber
- Coating.....Heparin
- Refractive Index.....1.49
- Power.....0.0 to +34.0 diopter powers in 0.5 diopter increments
- Optic Diameter.....6.0 mm
- Light Transmittance.....Please refer to the graph in Figure 1
- Overall Diameter.....13.0 mm
- Haptic Design.....Modified C-loop
- Haptic Angulation.....Step-vaulted, 0 degrees

***NOTE:** The heparin coating on the lens surface has no pharmacological, immunological or metabolic action.

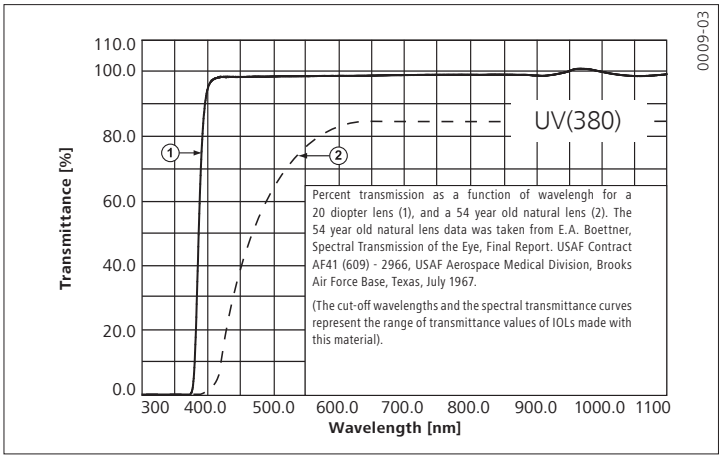


Fig. 1: Light transmission curve for CT LUCIA 621P

3. How supplied

The lens is supplied sterile, non-pyrogenic and preloaded in a single-use injector. Sterility is assured provided the tray seal has not been compromised or tray has not been punctured.

4. Intended Use

Carl Zeiss Meditec Production's CT LUCIA 621P IOL is intended for primary implantation in the capsular bag of the eye for the visual correction of aphakia in adult patients in whom a cataractous lens has been removed by extracapsular cataract extraction.

5. Warnings

Physicians considering lens implantation under any of the following circumstances should weigh the potential risk / benefit ratio:

1. IOL should be placed entirely in the capsular bag. Do not place the lens in the ciliary sulcus.
2. Patients in whom the intraocular lens may affect the ability to observe, diagnose, or treat posterior segment diseases.
3. Patients in whom neither the posterior capsule nor the zonules are intact enough to provide support for the IOL.
4. Surgical difficulties at the time of cataract extraction, which might increase the potential for complications (e.g. persistent bleeding, significant iris damage, uncontrolled positive pressure, or significant vitreous prolapse or loss).
5. A distorted eye due to previous trauma or developmental defect in which appropriate support of the IOL is not possible.
6. Circumstances that would result in damage to the endothelium during implantation.
7. Suspected microbial infection.
8. Patients with recurrent severe anterior or posterior segment inflammation or ocular disease that would be significantly worsened with the implantation of an intraocular lens.
9. Pupillary block may be prevented by one or more iridectomies at the time of IOL implantation based on the surgeon's assessment.

6. Caution

Patients with any of the following conditions may not be suitable candidates for implantation of the posterior chamber lens:

1. Chronic uveitis, iritis, iridocyclytis or rubeosis iridis.
2. Congenital bilateral cataracts.
3. Excessive vitreous pressure.
4. Medically uncontrollable glaucoma.
5. Ruptured posterior capsule or zonular separations.
6. Patients with only one eye with potentially good vision.
7. Proliferative diabetic retinopathy.
8. Retinal detachment.
9. Endothelial corneal dystrophy, corneal decompensation.
10. Iris atrophy.
11. Aniridia.
12. Marked microphthalmos.
13. Recurrent anterior or posterior segment inflammation of unknown etiology.
14. Rubella cataract.

7. Precautions

1. Do not implant in the anterior chamber.
2. Do not re-sterilize by any method.
3. Improper handling of this lens may cause damage to the haptics and the optics.
4. Store at room temperature.
5. Do not freeze or leave in sunlight.
6. Use only sterile balanced salt solution for rinsing or soaking of lens.
7. A high level of surgical skill is required for intraocular lens implantation. A surgeon should have observed and / or assisted on numerous surgical implantations and successfully completed one or more courses on intraocular lens implantation before attempting to implant intraocular lenses.

8. Clinical Investigation

A prospective, multicenter, open-label clinical study in adult subjects requiring cataract surgery with IOL implantation was performed to support the safety and effectiveness of the ZEISS CT LUCIA 611P IOL. The results of that study are applicable to the ZEISS CT LUCIA 621P IOL and are provided below to describe the performance characteristics.

Bench studies have demonstrated equivalent performance between the CT LUCIA 621P IOL and the CT LUCIA 611P IOL. The data presented in this section are applicable to both IOLs. The CT LUCIA 621P has a monofocal, biconvex* optic design with both anterior and posterior surfaces being aspheric while the CT LUCIA 611P is monofocal, biconvex where only the anterior surface is aspheric. Both lenses are a one-piece design made of same Acrylmex material with modified C-loop haptic body and square edge optic body. In addition, the CT LUCIA 621P diopter range was expanded beyond the +4.0 D to +34.0 D range to include 0.0 D to +3.5 D.

A total of 339 subjects received the implant in one eye and followed for 12 months postoperative. Demographics for subjects enrolled in the clinical investigation is presented in Table 1.

** For low diopter group 0 D to +3.5 D, the lens surface is not biconvex.*

Table 1: Demographics

	All Subjects (N=339)
Age (Years)	
N	339
Mean (SD)	69.1 (8.10)
Median	69.0
Min, Max	40,93
Sex: n (%)	
Male	131 (38.6)
Female	208 (61.4)
Race: n (%)	
American Indian/Alaska Native	1 (0.3)
Asian	9 (2.7)
Black/African American	29 (8.6)
Native Hawaiian or Other Pacific Islander	0
White	299 (88.2)
Multi-Racial	1 (0.3)
Other	0
Ethnicity: n (%)	
Hispanic/Latino	18 (5.3)
Not Hispanic/Latino	321 (94.7)

Best Corrected Distance Visual Acuity (BCDVA):

The primary effectiveness endpoint[1] for the proportion of eyes achieving BCDVA of 0.3 logMAR (20/40) or better at 12-Month was 99.4% (308/310). Table 2 presents the primary effectiveness endpoint[1] and the distribution of BCDVA across visits.

Table 2: Primary Effectiveness Endpoint & Distribution of BCDVA by Visit

	1-Week (N=338) n (%)	**1-Month (N=335) n (%)**	**6-Month (N=324) n (%)**	**12-Month (N=310) n (%)**
≤ 0.0 logMAR	192 (56.8)	217 (64.8)	227 (70.1)	219 (70.6)
> 0.0 to 0.3 logMAR	137 (40.5)	113 (33.7)	93 (28.7)	89 (28.7)
≤ 0.3 logMAR[2]	329 (97.3)	330 (98.5)	320 (98.8)	308 (99.4)[1]
> 0.3 logMAR	9 (2.7)	5 (1.5)	4 (1.2)	2 (0.6)

1. Primary Effectiveness Endpoint. 2. Total of two preceding rows

Uncorrected Distance Visual Acuity (UCDVA):

Secondary effectiveness endpoint for the percentage of eyes with UCDVA ≤ 0.0 logMAR (20/20 or better) at 12-Month was 35.8% (111/310). At 12-Month, 92.9% (288/310) of eyes had UCDVA of ≤ 0.3 logMAR (20/40 or better). Table 3 presents the distribution of UCDVA across visits.

Table 3: UCDVA by Postoperative Visit

	1-Week (N=338) n (%)	**1-Month (N=335) n (%)**	**6-Month (N=324) n (%)**	**12-Month (N=310) n (%)**
≤ 0.0 logMAR	84 (24.9)	90 (26.9)	108 (33.3)	111 (35.8)
> 0.0 to 0.3 logMAR	223 (66.0)	208 (62.1)	182 (56.2)	177 (57.1)
≤ 0.3 logMAR[1]	307 (90.8)	298 (89.0)	290 (89.5)	288 (92.9)
> 0.3 logMAR	31 (9.2)	37 (11.0)	34 (10.5)	22 (7.1)

1. Total of two preceding rows

Manifest Refraction Spherical Equivalent (MRSE):

Between 1-Week and 12-Month postoperative, MRSE showed excellent stability over time, with a mean of 0.00 D, -0.07 D, -0.07 D, and -0.03 D MRSE at 1-Week, 1 Month, 6 Month, and 12 Month, respectively. Mean MRSE over time for subjects/eyes implanted with the CT LUCIA 611P are presented in Table 4.

Table 4: MRSE Over Time

	1-Week	**1-Month**	**6-Month**	**12-Month**
MRSE Over Time				
n	338	335	325	310
Mean (SD)	-0.0018 (0.47728)	-0.0675 (0.47165)	-0.0677 (0.46099)	-0.0270 (0.44966)
Median	0.0000	0.0000	0.0000	0.0000
Min, Max	-2.000, 2.500	-1.500, 1.750	-2.125, 1.500	-1.500, 1.750
MRSE Change from1-Week				
n	-	334	324	309
Mean (SD)	-	-0.0656 (0.44101)	-0.0707 (0.44948)	-0.0288 (0.44854)
Median	-	0.0000	0.0000	0.0000
Min, Max	-	-3.250, 1.250	-2.275, 1.250	-2.500, 1.375

Adverse Events (AE):

The incidence of cumulative and persistent adverse events compared favorably to the ISO 11979-7 Safety and Performance Endpoint (SPE) rates. Only the cumulative rate for Secondary Surgical Intervention[4] (SSI) (n = 13) exceeded the ISO 11979-7 SPE rate ($p < 0.0001$). Persistent adverse events at 12 months did not exceed the ISO 11979-7 SPE rate. Cumulative and persistent adverse events reported in the clinical investigation are presented in Table 5. None of the reported SSIs were related to the study device; 11 were reported as related to the study procedure (paracentesis, anterior chamber washout, YAG vitreolysis, IOL removal, and intravitreal injection of triamcinolone); and two (2) were reported as unrelated to the study device or study procedure (pars plana vitrectomy). There were no reports of unanticipated adverse device effects with the CT LUCIA 611P IOL.

Table 5: Cumulative and Persistent Adverse Events

	Observed AE Rate (N=339) n (%)[1]	**SPE Rate (%)[2]**	**p-value[3]**	**Threshold Rate (%)[4]**
Cumulative				
Cystoid macular edema	8 (2.4)	3.0	0.7988	6.0
Hypopyon	0	0.3	NE	1.6
Endophthalmitis	0	0.1	NE	0.9
Lens dislocated from posterior chamber	0	0.1	NE	0.9
Pupillary block	0	0.1	NE	0.9
Retinal detachment	1 (0.3)	0.3	0.6389	1.6
Secondary surgical intervention[5]	13 (3.8)	0.8	<0.0001	2.6
Persistent				
Corneal stroma edema	0	0.3	NE	1.6
Cystoid macular edema	3 (0.9)	0.5	0.2413	2.0
Iritis	0	0.3	NE	1.6
Raised IOP requiring treatment	0	0.4	NE	1.6

1. Observed AE rate is calculated as 100 multiplied by the number of eyes with the specific treatment-emergent event divided by the number of implanted eyes in the full analysis set.

2. The ISO standard SPE rate in ISO 11979-7:2006(E) - Table B.2.

3. p-value based on a 1-sided exact binomial test comparing the proportion of eyes with the event to the ISO standard SPE rate. The null hypothesis: observed AE rate ≤ SPE rate for the specific AE.

4. The threshold rate is the minimum rate detectable as statistically significantly greater than the SPE rate (with approximately 80% power using an exact binomial test with a one-sided alpha level of 0.05), based on the population of 339 subjects.

5. Secondary surgical interventions reported: paracentesis due to elevated IOP from baseline (n = 7); pars plana vitrectomy with membrane stripping/peel due to retinal detachment and macular pucker (n = 2); anterior chamber washout due to cortical remnants post cataract extraction (n = 1); YAG vitreolysis due to vitreous strand (n = 1); IOL removal due to weakened capsular bag (n = 1); and intravitreal injection of triamcinolone due to macular edema (n = 1).

Posterior Capsule Opacification (PCO) & Nd:YAG Capsulotomy Rate:

At 12-Month, 187 subjects (66.2%, 198/299) had no reported findings of PCO, while 76 (25.4%, 76/299), 17 (5.7%, 17/299), and eight (2.7%, 8/299) subjects had reported findings of trace, mild, and moderate/severe, respectively. Of the 134 subjects with reported findings of PCO at any visit during the clinical investigation, 15 subjects (11.2%, 15/134) were diagnosed with clinically significant PCO requiring Nd:YAG, of which 11 subjects (8.2%, 11/134) underwent Nd:YAG capsulotomy on or prior to the 12-Month visit. Nd:YAG capsulotomywas not performed in 96.8% (328/339) of subjects in the study; the overall rate of Nd:YAG capsulotomy for every implanted subject is 3.2% (11/339). All 11 reported BCDVA of 0.1 logMAR or better at the 12-Month visit.

IOL Glistenings:
The same Acrylmex material used for the CT LUCIA 621P has been demonstrated to be glistening-free during a prospective, multi-center investigation of the CT LUCIA 611P. Investigators were instructed to observe and grade glistenings at both the 6 and 12-month postoperative visits. There were no findings of glistenings of any grade for any subject at either visit in the investigation.

9. Lens Power Calculation
The power of the lens to be implanted should be determined preoperatively based on the surgeon's experience, preference, and intended lens placement. The labeled A constant listed on the packaging's outer label is presented as a guideline and is a starting point for calculating the required lens power. Physicians should develop their own A-constant based upon their clinical experience, surgical techniques, measuring equipment, and post-operative results. Lens power calculation methods are described in the following references[1,2]:

NOTE: An optimized A-constant of 120.1[3] was used for the preoperative calculation of the recommended lens power in the clinical investigation for the parent lens, the CT LUCIA 611P IOL.

1. https://www.doctor-hill.com/iol-main/formulas.htm

2. Connell BJ, Kane JX. Comparison of the Kane formula with existing formulas for intraocular lens power selection. BMJ Open Ophthalmol. 2019;4(1):e000251. Published 2019 Apr 1. doi:10.1136/bmjophth-2018-000251.

3. https://iolcon.org/lensesTable.php. Last retrieved 2019-02-28

10. Instructions for Use
Preparatory steps

1. Check the label on the lens box to ensure that you have the correct lens model and dioptric power and that the product is not past its expiration date.
2. Three different injector configurations are used to inject IOLs from the complete dioptric power range. Confirm an appropriate incision for the corresponding injector configuration prior lens implantation.

   Correlation between dioptric power and injector configuration:

Dioptric Power Range	Injector configuration
0.0D to +24.0D	Injector configuration 2.2
+24.5D to +30.0D	Injector configuration 2.4
+30.5D to +34.0D	Injector configuration 2.6

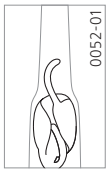
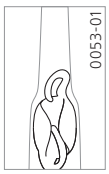
3. Prior to use, ensure that both the Ophthalmic Viscosurgical Device (OVD) and the preloaded instrument are at least 65°F (18°C).
4. Remove the tray from the box outside the sterile area. Remove the tray lid in the sterile area and then remove the pre-loaded ZEISS injector from the tray.
5. Verify that the lens is centered and secure in the IOL chamber (figure 2).
6. Cover the whole lens and blue plunger tip (figure 3) with a generous amount of ophthalmic viscoelastic. Avoid touching the lens and blue plunger tip.
7. Close the wings of the IOL chamber (figure 4).

   IMPORTANT: Allow the lens to remain in this position until the surgeon is ready to implant it into the eye.

Implantation steps

8. Advance the lens to the intermediate position. Gently push the plunger forward until an audible "click" is heard (figures 5 and 6).

   IMPORTANT: The lens should be implanted immediately.
9. Before implantation, please check to ensure that the IOL is correctly oriented:

Drawing	Possible haptic configuration	Possible IOL behavior	Recommendation
 0050-01	Both haptics are tucked into the optic (ideal scenario).	Correct position (no risk).	Proceed.
 0051-01	Plunger overriding trailing haptic.	The haptic could become pinned between the cartridge and the plunger cushion, and the IOL could become stuck in the injector tip. There is a risk that the haptic might tear.	Do not proceed.
 0052-01	Leading haptic twisted.	The leading haptic may become twisted and may point downward and/or to the right; the optic may begin to roll counter-clockwise and even roll upside down.	Rotate the injector clockwise (bevel to the left) to ensure that the leading haptic is correctly positioned in the capsular bag and proceed as normal.
 0053-01	Leading haptic is looped but not over the optic.	Haptic can swing out and is slightly off-axis but pointing in the correct direction.	Proceed.

10. Injection: With loading chamber wings facing upwards, slowly advance the lens until it has been released from the injector. If delivery is incomplete, apply additional force to the thumb flange to release the lens (figure 7).
11. Carefully position the lens in the capsular bag.
12. Discard the device. Do not reuse the injector.

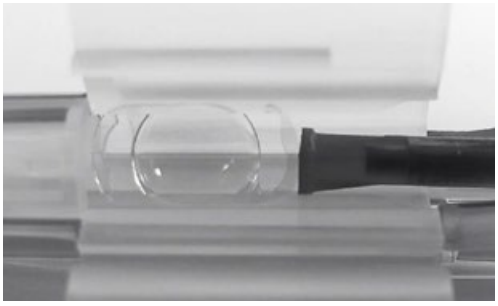

0011-01

Fig. 2: Lens in the IOL chamber

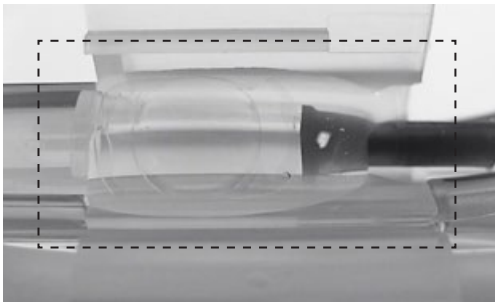
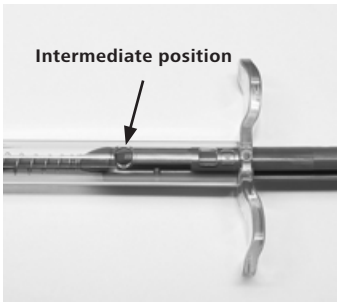

0012-01

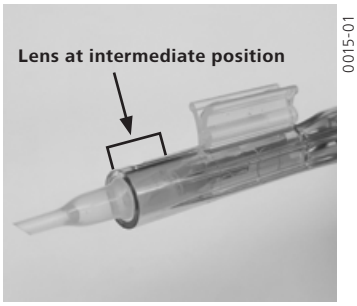
Fig. 3: OVD coverage area (rectangle)


0013-01

Fig. 4: Closed wings of the IOL chamber



0014-01



0015-01

Fig. 5, Fig. 6: Intermediate position

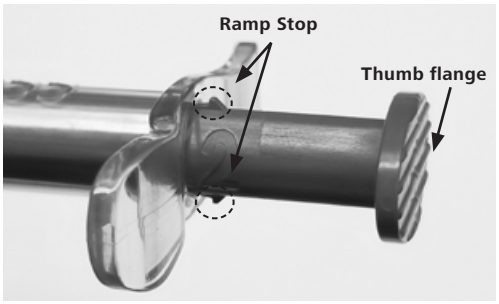


Fig. 7: Ramp stop and thumb flange

Devices intended for use with the IOL

The CT LUCIA 621P IOL is to be implanted with the supplied injector.

Disposal

Discarded IOLs and injectors, both used and unused, are classified as medical (clinical) waste with a potential infection or microbial hazard; their disposal must comply with national regulations.

11. Implant card and patient information

The implant card included in the package is to be completed and given to the patient together with instructions to keep this card as a permanent record of the implant and to show the card to any eye care professional consulted in the future.

How the implant card is filled out by the healthcare facility / healthcare provider

1. Add the label supplied in the packaging on the implant card. Do not use the label marked "For ZEISS order".
2. Fill in the date of implantation.
3. Indicate if the IOL was implanted in the left or right eye.
4. Fill in the name of the patient or a patient ID.
5. Fill in the name and address of the health care center/doctor.

Date (of implantation): _____

Place implant identification label here

IOL was implanted:

☐ in the right eye ☐ in the left eye

Person identification (Patient): _____

Health care center/doctor: _____

Patient information website: **www.zeiss.com/cataract-treatment**

Fig. 8: Implant card

Information for patient is made available on the internet. The link to access the information is printed on the implant card.

12. Reporting

All serious adverse events and / or potentially sight-threatening complications, that may reasonably be regarded as lens related and that were not previously expected in nature, severity or degree of incidence are to be reported to Carl Zeiss Meditec Production, LLC. on a tollfree number in the US, (877) 644-4657 or by contacting the local Carl Zeiss Meditec Production, LLC. representative. This information is being requested from all implant surgeons to document potential long-term effects of intraocular lens implantation.

13. Return/exchange policy

For return and / or exchange policy information, please contact the Carl Zeiss Meditec Production, LLC. office (contact details provided below).

14. Expiration Date

The expiration date is clearly indicated on the outside of the box.

15. Limitation of warranty and liability

The implantation of an IOL is a surgical procedure and carries several risks associated with eye surgery. Carl Zeiss Meditec Production, LLC. has provided information and recommendations with respect to such risks as well as methods and techniques of implantation of the lens. The physician should provide patients with all relevant information in this respect. In particular, Carl Zeiss Meditec Production, LLC. excludes any and all liability in connection with injuries or losses that may be suffered by the patient due to:

1. the implantation method or technique used by the physician if the physician did not comply with the recommendations of Carl Zeiss Meditec Production, LLC.
2. incorrect prescription, selection and/or use of the IOL for a particular patient.

16. Symbols used on labeling

Standard / Source	Symbol	Reference	Title of Symbol	Description of Symbol per Standard
FDA Guidance "Alternative to Certain Prescription Device Labeling Requirements", issued 1/21/2000	℞ ONLY	N/A	N/A	**Caution:** Federal (USA) law restricts this device to sale by or on the order of a physician.
ISO 15223-1:2021 Medical Devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements		5.1.1	Manufacturer	Indicates the medical device manufacturer as defined in applicable medical device regulations.
ISO 15223-1:2021 Medical Devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements		5.1.3	Date of manufacture	Indicates the date when the medical device was manufactured.
ISO 15223-1:2021 Medical Devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements		5.1.4	Use-by date	Indicates the date after which the medical device is not to be used.
ISO 15223-1:2021 Medical Devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements		5.4.2	Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
ISO 15223-1:2021 Medical Devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements		5.4.3	Consult Instructions for Use	Indicates the need for the user to consult the instructions for use.
ISO 15223-1:2021 Medical Devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	SN	5.1.7	Serial Number	Indicates the manufacturer's serial number so that a specific medical device can be identified.
ISO 15223-1:2021 Medical Devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	STERILE EO	5.2.3	Sterilized using ethylene oxide	Indicates a medical device that has been sterilized using ethylene oxide

ISO 15223-1:2021 Medical Devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements		5.2.6	Do not resterilize	Indicates a medical device that is not to be resterilized.
ISO 15223-1:2021 Medical Devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements		5.2.8	Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened.
ISO 15223-1:2021 Medical Devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements		5.3.2	Keep away from sunlight	Indicates a medical device that needs protection from light sources.
ISO 15223-1:2021 Medical Devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements		5.3.4	Keep dry	Indicates a medical device that needs to be protected from moisture.
EN ISO 11979-4:2008 + A1:2012 Ophthalmic implants — Intraocular lenses — Part 4: Labelling and information	ØT	N/A	Overall Diameter	N/A
EN ISO 11979-4:2008 + A1:2012 Ophthalmic implants — Intraocular lenses — Part 4: Labelling and information	Øbody	N/A	Body Diameter	N/A
ISO 15223-1:2021 Medical Devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	UDI	5.7.10.	Unique device identifier	Indicates a carrier that contains Unique Device Identifier information
EN ISO 11979-4:2008 + A1:2012 Ophthalmic implants — Intraocular lenses — Part 4: Labelling and information	A Opt	N/A	A-constant	N/A

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Contact Details:
For information on more quality ophthalmic products, call or email for a full Carl Zeiss Meditec Production, LLC. catalog. Or visit our website and explore our catalog online: www.zeiss.com/med

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ZEISS CT LUCIA 621P

Technical Specifications

Seeing beyond

	CT LUCIA® 621P – fully preloaded
Optic Design	Monofocal, aspheric (aberration correcting)
Material	Hydrophobic acrylic with heparin-coated[1] surface
Optic Diameter	6.0 mm
Total Diameter	13.0 mm
Haptic	Step vaulted
Lens Design	Single-piece
Incision Size	2.2 – 2.6 mm (depending on diopter)
Diopter Range	From 0.0 to +34.0 D, 0.5 D increments
Company Labeled A-Constant[2]	120.2
ACD[2]	6.29
Abbe Number	51
Refractive Index	1.49
Implantation in	Capsular bag
Injector/Cartridge Set	BLUESERT™ 2.2 Injector for diopter range 0.0 to +24.0 BLUESERT 2.4 Injector for diopter range +24.5 to +30.0 BLUESERT 2.6 Injector for diopter range +30.5 to +34.0

[1] The heparin coating on the lens surface has no pharmacological, immunological or metabolic action.

[2] For optimized A Constants and ACD Constants refer to IOLCon: https://iolcon.org/lensesTable.php. Last retrieved 2019-02-28

en-US_32_022_0165III CZ-IV/2023 United States Edition: Only for sale in selected countries.

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