CT LUCIA 602

ZEISS 3-piece IOL (Formerly EC-3 PAL)

Technical Specifications

CT LUCIA 602

ZEISS 3-piece IOL (Formerly EC-3 PAL)

	CT LUCIA® 602
Optic Design	Monofocal, aspheric
Material	Hydrophobic acrylic with Polyvinylidene fluoride (PVDF) monofilament haptics
Optic Diameter	6.0 mm
Total Diameter	13.0 mm
Haptic Angulation	5°
Lens Design	Three-piece
Incision Size	2.8 mm
Company Labeled A-Constant	117.7
Diopter Range	From +4.0 to +34.0 D, 0.5 D increments
ACD	4.8
Abbe	50
Implantation in	Bag
Injector / Cartridge Set	ZEISS R28 IOL Delivery System with ZEISS Z28 Cartridge IOL Delivery System for diopter range +4.0 to +34.0 D

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CT LUCIA 202 / CT LUCIA 602

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ZEISS

Description

Carl Zeiss Meditec Production's CT LUCIA 202 is a UV light-absorbing posterior chamber hydrophobic acrylic lens designed to be implanted in the capsular bag following extracapsular cataract extraction. The optic is biconvex design. It is made from an optically clear hydrophobic acrylic material which incorporates an UV-absorbing component. The lens is available in diopter ranges between 4.0 to 34.0D in 0.5D increments. It is also available with an aspheric optic, the CT LUCIA 602. Clinical studies have not been conducted with the CT LUCIA 602 to assess the effect of the added aspheric surface on spherical aberration, visual acuity and contrast sensitivity.

Indications

Carl Zeiss Meditec Production's CT LUCIA 602 and 202 IOLs are 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 phacoemulsification.

Contraindications

Outside of general contraindications for ocular surgery, the following specific contraindications apply: Uncontrolled glaucoma, microphthalmia, chronic severe uveitis, retinal detachment, corneal decompensation, diabetic retinopathy, iris atrophy, perioperative complications, potential foreseeable post-operative complications and other conditions which an ophthalmic surgeon might identify based on their experience.

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. Endothelial corneal dystrophy.
9. Operative vitreous loss.
10. Aniridia.
11. Implantation of posterior chamber lenses in the anterior chamber has been shown to be unsafe and should not be performed with posterior chamber lenses.
12. The requirement for a secondary iridectomy for pupillary block may be prevented by one or more iridectomies at the time of IOL implantation. This preventative measure is better known for anterior chamber and iris fixation models. It has also been determined to apply to posterior chamber models.
13. Marked microphthalmos.
14. Recurrent anterior or posterior segment inflammation of unknown etiology.
15. Rubella cataract.

Warnings

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

1. Improper handling of this lens may cause damage to the haptics and the optics.
2. Patients in whom the intraocular lens may affect the ability to observe, diagnose, or treat posterior segment diseases.
3. 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).
4. A distorted eye due to previous trauma or developmental defect in which appropriate support of the IOL is not possible.
5. Circumstances that would result in damage to the endothelium during implantation.
6. Suspected microbial infection.
7. Recurrent ocular disease (e.g., uveitis, diabetic retinopathy, or glaucoma,).
8. The long-term effects of intraocular lens implantation have not been determined. Therefore, physicians should continue to monitor implant patients postoperatively.

Precautions

1. Do not autoclave the intraocular lens.
2. Do not resterilize by any method.
3. Store at room temperature.
4. Do not freeze or leave in sunlight.
5. Use only sterile balanced salt solution for rinsing or soaking of lens.
6. 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.

Adverse Events

The incidents of adverse events reported in 354 subjects during the CT LUCIA 202 IOL pivotal clinical trial were statistically equal to or less than the rates reported in control populations (FDA Grid and ISO 11979-7) for posterior chamber lenses. Refer below to Table 3 for the adverse events reported in the pivotal clinical trial.

Clinical Trial

The CT LUCIA 202 IOL clinical study was a single-arm, prospective, multi-center, international clinical investigation at 14 sites. A total of 354 subjects received the implant in one eye and followed for one year to evaluate clinical performance of the CT LUCIA 202 IOL. The study objectives were to evaluate the safety and effectiveness of the CT LUCIA 202 IOL following primary implantation for the visual correction of aphakia when the cataractous lens was removed by phacoemulsification with a continuous curvilear capsulorhexis. Table 1 outlines the subject demographics for the all subjects entered in the clinical investigation.

Table 1: Demographics

Number of Subjects		354 Enrolled Subjects
Gender	**n**	**%**
Female	219	61.9
Male	135	38.1
Race	**n**	**%**
Asian	0	0.0
Black	1	0.3
Caucasian	351	99.1
Mixed	1	0.3
Other	1	0.3
Age (Years)	**n**	**%**
< 60	20	5.6
60 to <70	76	21.5
70 to < 80	177	50.0
≥ 80	81	22.9
Age (Years)		
Mean (±SD), N	73.5 (±8.0), 354	
Range	50.0 – 95.0	

Safety and Effectiveness Results

The CT LUCIA 202 IOL showed an excellent safety and effectiveness profile in the pivotal clinical investigation. Cataract removal with CT LUCIA 202 IOL implant was attempted in 354 subjects and all procedures were successfully completed. The analysis of safety was based on adverse event rates compared to historical controls as listed in the FDA GRID and in ISO 11979-7 of cataract surgery followed by the implantation of a posterior chamber IOL. There were no serious or unanticipated device-related adverse events in any of the 354 patients implanted with the CT LUCIA 202 IOL. There were no reports of glistening from any subject at any follow-up visit in the one-year study. The cumulative and persistent adverse events, the key safety outcomes for the CT LUCIA 202 IOL study are presented below in Tables 2 and 3.

Table 2: Cumulative Adverse Events*

Cumulative Adverse Events	CT LUCIA 202 (%)	Historical (%)
Secondary Surgical Intervention	2.0	0.8
Open operative side-port (incision to relieve elevated IOP)	0.6	N/A
Lens Removal	0.6	N/A
Repair Retinal Detachment	0.3	N/A
"Piggyback" procedure	0.3	N/A
Epi-Retinal membrane removal	0.3	N/A
Cystoid Macular Edema	1.1	3.0
Hyphema	0.3	2.2
Retinal Detachment	0.3	0.3
Endophthalmitis	0.0	0.1
Hypopyon	0.0	0.3
IOL Dislocation	0.0	0.1
Pupillary Block	0.0	0.1

*Cumulative: Occurring at any time during the study.

Table 3: Persistent Adverse Events*

Persistent Adverse Events	CT LUCIA 202 (%)	Historical (%)
Cystoid Macular Edema	0.3	0.5
Corneal Edema	0.0	0.3
Iritis	0.0	0.3
Elevated IOP Requiring Treatment	0.0	0.4

*Persistent: Present at the One-Year Visit for any subject.

Best Corrected Visual Acuity at One Year

CT LUCIA 202 IOL effectiveness was based on the analysis of visual acuity data. The rates for both overall and best-case 20 / 40 or better visual acuity for the cohort population exceed the FDA grid values. Table 4 lists the one-year postoperative best corrected visual acuity results for all subjects implanted with the CT LUCIA 202 IOL and completing One-Year follow-up. Table 5 presents the best corrected visual acuity data for the best-case subjects. Both tables include the corresponding FDA Grid values.

Table 4: Best Corrected Visual Acuity – All Patient

Visual Acuity One Year	Age (in Years)							
	< 60		60 to < 70		70 to < 80		≥ 80	
	n	%	n	%	n	%	n	%
20 / 20 or better	14	73.7	45	67.2	114	68.3	38	53.5
20 / 25 or better	17	89.5	59	88.1	152	91.0	57	80.3
20 / 32 or better	18	94.7	63	94.0	164	98.2	68	95.8
20 / 40 or better	18	94.7	66	98.5	166	99.4	71	100
FDA Grid for % of 20 / 40 or better	97.9 %		95.7 %		93.4 %		86.5 %	
χ^2 test p-value for H0: p=FDA Grid	P=0.8625		P=0.4062		P=0.003		P=0.0016	
Fisher's exact test for comparing percentages of 20 / 40 or better among the age groups	P=0.1556							
20 / 41 to 20 / 63	0	0.0	1	1.5	1	0.6	0	0.0
20 / 64 to 20 / 100	0	0.0	0	0.0	0	0.0	0	0.0
20 / 101 to 20 / 200	1	5.3	0	0.0	0	0.0	0	0.0
Worse than 20 / 200	0	0.0	0	0.0	0	0.0	0	0.0
N[1]	19		67		167		71	
N (missing)[2]	0		0		0		0	
Total[3]	19		67		167		71	

[1] N = Number of available subjects with 1-Year VA for the corresponding age group.

[2] N (missing) = Number of available subjects with missing 1-Year VA for the corresponding age group.

[3] Total = Number of available subjects at 1-Year for the corresponding age group.

Table 5: Best Corrected Visual Acuity – Best Case Patients

Visual Acuity One Year	Age (in Years)							
	< 60		60 to < 70		70 to < 80		≥ 80	
	n	%	n	%	n	%	n	%
20 / 20 or better	13	72.7	43	68.3	110	68.8	37	56.1
20 / 25 or better	16	88.9	57	90.5	148	92.5	54	81.8
20 / 32 or better	17	94.4	61	96.8	158	98.8	65	98.5
20 / 40 or better	17	94.4	62	98.4	160	100	66	100
FDA Grid for % of 20 / 40 or better	98.5%		96.5%		97.5%		94.8%	
χ^2 test p-value for H0: p=FDA Grid	P=0.6547		P=0.6242		P=0.0764		P=0.1042	
Fisher's exact test for comparing %s of 20 / 40 or better among the age groups	P=0.0274							
20 / 41 to 20 / 63	0	0.0	1	1.6	0	0.0	0	0.0
20 / 64 to 20 / 100	0	0.0	0	0.0	0	0.0	0	0.0
20 / 101 to 20 / 200	1	5.6	0	0.0	0	0.0	0	0.0
Worse than 20 / 200	0	0.0	0	0.0	0	0.0	0	0.0
N[1]	18		63		160		66	
N (missing)[2]	0		0		0		0	
Total[3]	18		63		160		66	

[1] N = Number of available subjects with 1-Year VA for the corresponding age group.

[2] N (missing) = Number of available subjects with missing 1-Year VA for the corresponding age group.

[3] Total = Number of available subjects at 1-Year for the corresponding age group.

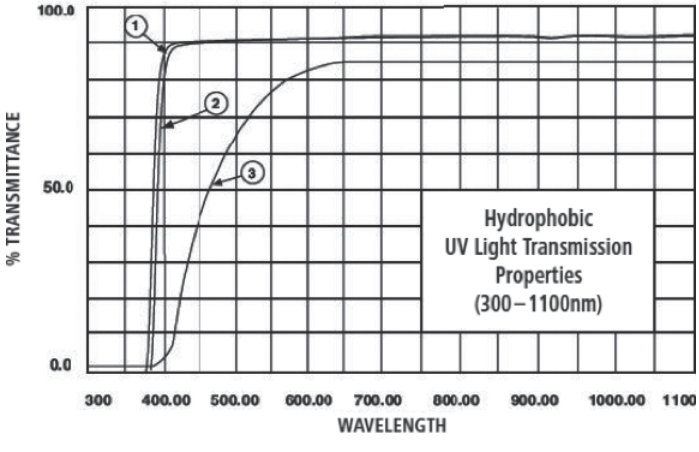
Detail Device Description Lens

- Material.....Hydrophobic acrylic with UV-absorber
- Refractive Index.....1.49
- Power.....4.0 to 34.0 diopter powers in 0.5 diopter increments
- Optic diameter 6.0mm
- Center thickness.....0.8927mm (+20.0D)
- Light Transmittance.....Please refer to the graph in Figure 1
- Specific Gravity .....1.09 g / cc
- Overall Length.....13.0mm

Haptics (Multipiece)

- Configuration.....Modified-C
- Material.....Polyvinylidene fluoride (PVDF) monofilament
- Color .....blue
- Haptic Angulation.....5 degrees

Firgure 1



Percent transmission as a function of wavelength for a 10 diopter lens (1), 30 diopter lens (2) and a 54-year-old natural lens (3). The 54-year-old natural lens data was taken from E.A. Boettner, Spectral Transmission of the Eye – Italic, Final Report. USAF Contract AF41 (609) – 2966, USAF Aerospace Medical Division, Brooks Air Force Base, Texas, July 1967. (The cut-off wavelengths and the spectral transmittance curves represent the range of transmittance values of IOLs made with this material).

Instructions for Use

1. Use of the lenses is especially appropriate in patients who cannot tolerate contact lenses, those who would not be candidates for cataract spectacles, or for patients requiring an intraocular lens for occupational or other reasons.
2. A variety of surgical techniques may be employed during the implantation of an intraocular lens. The surgeon should select a procedure which is appropriate for the patient. If lens is to be implanted in a folded configuration, it must be used within 3 minutes of being folded.
3. It is recommended that the use of the intraocular lens be initially limited to one eye.
4. Check the label on the lens box for proper lens model, dioptric power and expiration date.
5. Open the package and verify dioptric power of the lens.
6. To remove the lens, open the pouch and transfer the case to a sterile environment. Carefully open the case to expose the lens. When removing the lens from the case, DO NOT grasp the optical area with forceps. Prior to the actual folding process, the lens should be handled by the haptic portion only. Rinse the lens thoroughly using sterile intraocular irrigating solution. DO NOT rinse the lens in solutions other than sterile intraocular irrigating solutions.
7. To minimize the occurrence of marks on the lens due to folding, all instrumentation should be scrupulously clean.
8. Carl Zeiss Meditec Production, LLC recommends using a forceps with round edges and smooth surfaces.
9. Orient lens for insertion (See *Figure 2*).

How to orient lens for insertion

After removing lens from tray, make sure top haptic points left while loading the lens for implantation. When you are looking down on the lens after implantation, the top haptic should still point left. This ensures that the 5° angulation of the lens is oriented toward the anterior.

Figure 2

Lens Power Calculation

The power of the lens to be implanted should be determined preoperatively. The labeled A-constant listed on the outer label is presented as a guideline and is a starting point for implant power calculations. Physicians should develop their own A-constant based upon their clinical experience, surgical techniques, measuring equipment, and post-operative results.

The following references provide lens power calculation methods

(A) Binkhorst, RD. *Intraocular Lens Power Calculation Manual*, New York, 1978.
(B) Retzlaff J, Sanders D, Kraft M. *A Manual of Implant Power Calculation.*

Patient Implant Identification Card

The Implant Identification Card is provided to the patient. This helps in obtaining information for future follow-ups related to adverse reactions and adverse events.

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 toll-free number in the US, 1(877) 644-4657 or by contacting the local Carl Zeiss Meditec Production, LLC representative. This information is being requested from all implant surgeons in order to document potential long-term effects of intraocular lens implantation.

How Supplied

Carl Zeiss Meditec Production's CT LUCIA 602 / 202 is supplied sterile, non-pyrogenic in its own sterilization pouch. Sterility is assured provided the sterilization pouch seal has not been compromised or the pouch has not been punctured.

Expiration Date

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

Return / Exchange Policy

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

Contact Details

For information on more quality ophthalmic products, call, fax 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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Symbols used on packaging

Standard / Source	Symbol	Reference Number	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 15223-1:2012		5.1.1	Manufacturer	Indicates the medical device manufacturer as defined in applicable medical device regulations.
ISO 15223-1:2012		5.1.4	Use-by date	Indicates the date after which the medical device is not to be used.
ISO 15223-1:2012	2	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 15223-1:2012		5.4.3	Consult instructions for use	Indicates the need for the user to consult the instructions for use.
ISO 15223-1:2012	SN	5.1.7	Serial Number	Indicates the manufacturer's serial number so that a specific medical device can be identified.
ISO 15223-1:2012	STERILE EO	5.2.3	Sterilized using ethylene oxide	Indicates a medical device that has been sterilized using ethylene oxide
ISO 15223-1:2012	2	5.2.6	Do not resterilize	Indicates a medical device that is not to be resterilized.