IFU_CT LUCIA 202, 602
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Rev.005

Instructions for use
CT LUCIA 202, CT LUCIA 602

EN

1 Products to which these instructions for use apply

These instructions for use apply to the following products:

Model	Performance characteristics	Packaging color code	Basic UDI-DI
CT LUCIA 202	Spherical, monofocal, blocks UV light	Ultralight grey	4049336_P01_M02_R2B_WN
CT LUCIA 602	Aspheric, monofocal, corrects spherical aberrations, blocks UV light	Medium grey	

2 Device description

One sterile, foldable hydrophobic, acrylic, monofocal, posterior chamber intraocular 3-piece intraocular lens (IOL).

CT LUCIA 202 and CT LUCIA 602 are made of an optically clear, hydrophobic acrylic material (terpolymer of butyl acrylate), ethyl methacrylate (EMA) and n-benzyl-n-isopropylacrylamide (BPA) cross-linked with ethylene glycol dimethacrylate (EGDMA) which incorporates a component that absorbs UV light. The haptic is made of polyvinylidene fluoride monofilament.

See label on the cardboard box for lens type, lens type attributes and refractive power. The overall 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 the cut-off wavelengths of the IOLs.

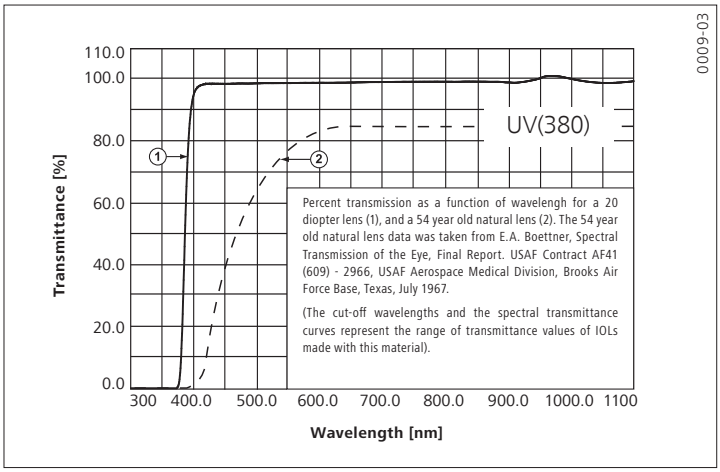


Fig. 1: Light transmission curve for CT LUCIA 202 and CT LUCIA 602

3 Packaging

This ZEISS IOL is supplied sterile, packed in a polypropylene case sealed inside a sterilization pouch. The lens is sterilized with ethylene oxide (EO).

4 Intended purpose of the device

Intended purpose:

This ZEISS intraocular lens is intended for implantation in the capsular bag to replace the human crystalline lens.

Indication:

This ZEISS intraocular lens is indicated for the visual correction of aphakia secondary to the removal of the crystalline lens in patients with cataract.

Patient target group:

aphakic adult patients (18 years old or older).

Intended users:

IOLs shall be handled by health professionals and implanted by physicians.

5 Warnings, undesirable side effects and residual risks

The complications listed below may occur following implantation of any intraocular lens and may require treatment or in severe cases can lead to secondary surgery for which the surgeon should carefully evaluate the risk/benefit ratio.

Possible complications linked to surgery for crystalline lens removal and intraocular lens implantation include, but are not limited to, those listed below:

- inflammatory reaction (e.g. vitritis, iritis, iridocyclitis, hypopyon, cyclitic membrane)
- ocular infection (endophthalmitis, microbial keratitis)
- toxic anterior segment syndrome
- wound leakage
- iris prolapse
- pupillary block
- raised intraocular pressure (IOP) requiring treatment
- corneal edema
- corneal endothelial damage
- retinal detachment
- cystoid macular edema

Possible complications related to the intraocular lens include:

- secondary cataract
- decentration of the lens
- deviation from target refraction

6 Precautions

The safety and effectiveness of the IOLs have not been demonstrated in extracapsular IOL implantation (with or without scleral or intrascleral haptics fixation) and in patients with the following pre-existing ocular conditions and intraoperative complications listed below. Careful pre- and perioperative evaluation and sound clinical judgment should be used by the surgeon to determine the risk/benefit ratio before implanting a lens in a patient with one or more of the conditions below:

- perioperative complications (such as posterior capsule rupture, zonular damage, vitreous loss, significant anterior chamber bleeding, or choroidal hemorrhage)
- uncontrollable positive intraocular pressure or glaucoma
- aniridia
- microphthalmos or macrophthalmos

7 Precautions for use and storage

- Store the product at ambient temperature.
- Store the product away from moisture and light.
- Do not freeze the product.
- Do not use the product if the package is damaged.
- Do not use the product if the package is wet.
- Do not use the product if the package was unintentionally opened before use.
- Do not use the product beyond the expiration date.
- Do not reuse any of the parts.
- Do not resterilize the product.
- Reuse and/or resterilization may compromise device performance, which could cause serious harm to the patient's health and safety.
- Do not implant IOLs which are not compliant with the patient's specific biometrical parameters.

8 Lens power calculation for IOLs

We recommend using Z CALC, the online calculator for all ZEISS IOLs, in addition to the IOL power calculation formula on the biometric devices (e.g. IOLMaster). Z CALC can be accessed at https://zcalc.meditec.zeiss.com. Please note that a thorough evaluation of the actual conditions in terms of diagnostics, surgical instruments and the chosen algorithm for calculation is crucial to achieving the expected postoperative results.

You will find the A-constants for the individual IOL types on the label of the cardboard box. Only the use of individually optimized lens constants [1][2] can compensate for the systematic deviations within the predictable range of

postoperative refraction. For questions or further information, please contact your local distributor.

[1] HAIGIS, W. Optimized IOL constants for the ZEISS IOLMaster calculated from patient data on file.

[2] https://iolcon.org/lensesTable.php. Last retrieved 2019-02-28

9 Instructions for use

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. 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. Higher diameter injector systems with an incision size greater than 2.7mm are recommended for all 3-piece hydrophobic lenses. Alternatively, incision forceps can be used. ZEISS recommends using a forceps with round edges and smooth surfaces.
3. Open the package and verify dioptric power of the lens.
4. 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.
5. Use only scrupulously clean instrumentation during IOL folding to minimize the occurrence of marks/deposits on the lens.
6. After removing lens from lens holder, make sure the leading haptic points on the left side (see figure 2). Figure 3 shows the incorrect orientation of the lens.

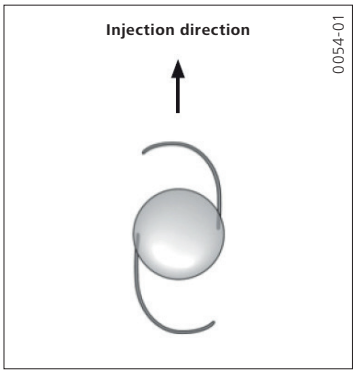


Fig. 2: How to orient lens for insertion

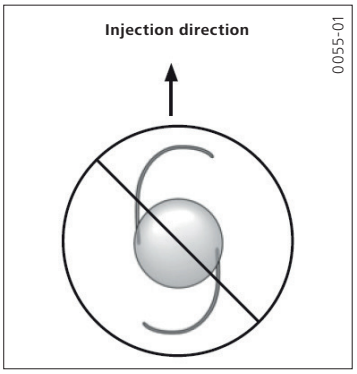


Fig. 3: Incorrect orientation of the lens for insertion

Devices intended for use together with the IOL

The IOL should be implanted with a suitable injector. A compatibility chart can be found on our website: www.zeiss.com/injectors. Devices other than those listed in the chart have not been tested and cannot be recommended. Alternatively, the IOL can be implanted with forceps.

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.

10 Clinical benefits

The clinical benefit of the implantation of an IOL for cataract patients is the prevention of blindness.

This ZEISS IOL provides functional far vision, improves patients' quality of life and reduces their dependence on glasses.

11 Safety and clinical performance

For products registered under Regulation (EU) 2017/745, the summary of safety and clinical performance is published in the European Database on Medical Devices (Eudamed). The URL of the public website of Eudamed is: https://ec.europa.eu/tools/eudamed. The SSCP is linked to the Basic UDI-DI listed in section 1.

12 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 seen in future. The implant card is to be completed with the patient data and provided with a self-adhesive label containing the identification information of the implant.

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 healthcare institution / provider.

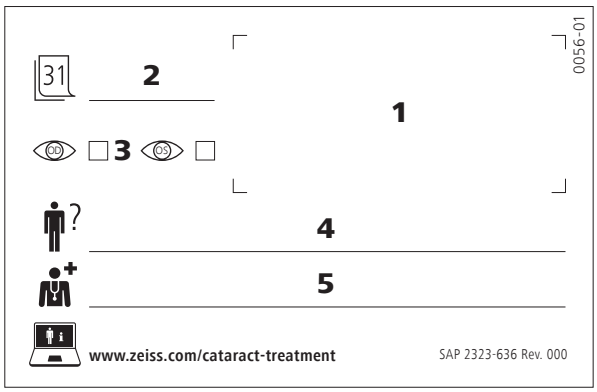


Fig. 4: Implant card

Patient information is made available on the internet. The link to access the information is printed on the implant card.

13 Reporting

Adverse events that suggest that the lens may have caused a serious incident should be reported to your ZEISS representative and to the competent regulatory authority.

14 Return/exchange policy

To return or exchange a product, please contact the manufacturer or your local distributor.

15 Limitation of warranty and liability

The implantation of an intraocular lens is a surgical procedure and carries several risks associated with eye surgery. Carl Zeiss Meditec 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 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.
2. incorrect prescription, selection and/or use of the intraocular lens for a particular patient.

16 Symbols used on labeling

STERILE EO	Sterilized using ethylene oxide		Keep away from sunlight
SN	Serial number		Consult instructions for use
	Do not re-use		Keep dry
	Do not resterilize		Do not use if package is damaged
	Use-by date		Date of manufacture
ØT	Overall Diameter		Manufacturer
Øbody	Body Diameter	A Opt	A-constant
MD	Medical device (followed by the device name)		Indicates the sterile barrier system with a protective packaging inside
	IOL was implanted in the right eye.		IOL was implanted in the left eye
	Person identification (Patient)		Health care center or doctor
	Patient information website		Date (of implantation)
UDI	Unique Device Identifier	**UDI-DI**	UDI Device Identifier

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