IFU_ACRYLAT_EN
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Instructions for use
Hydrophilic acrylic intraocular lens

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 SPHERIS 204, CT SPHERIS 209M	Spherical, monofocal	Ultralight grey	4049336_P01_M01_R2B_VF
CT ASPHINA 404, CT ASPHINA 409M, CT ASPHINA 409MP	Aspheric, monofocal	Purple red	
CT ASPHINA 509M, CT ASPHINA 509MP		Medium grey	
AT LARA 829MP	Extended Depth of Focus (EDoF)	Light green	4049336_P04_M01_R2B_Y6
AT LISA 809M, AT LISA 809MP	Bifocal	Magenta	
AT LISA tri 839MP	Trifocal	Cyan	
AT TORBI 719M, AT TORBI 719MP	Toric	Orange	4049336_P02_M01_R2B_WC
AT LARA toric 929M, AT LARA toric 929MP	EDoF toric	Green	4049336_P03_M01_R2B_X9
AT LISA toric 909M	Bifocal toric	Purple	
AT LISA tri toric 949M, AT LISA tri toric 949MP	Trifocal toric	Indigo	

2 Device description

One sterile, foldable, hydrophilic, acrylic, posterior chamber intraocular lens (IOL) with a hydrophobic surface.

ZEISS hydrophilic acrylic IOLs are made of from highly purified acrylate copolymer of 2-hydroxyethyl methacrylate (HEMA) and ethoxyethyl methacrylate (EOEMA) with 25% water content, which incorporates a chemically bound organic component (0.5%) that absorbs UV light.

See label on the cardboard box for lens type, lens type attributes and refractive power. The overall diameter of the lens is 11 mm and the body diameter is 6 mm. The spectral transmittance curve (figure 1) represents the transmittance values of the IOL. The 10% cut-off wavelength is 370 nm.

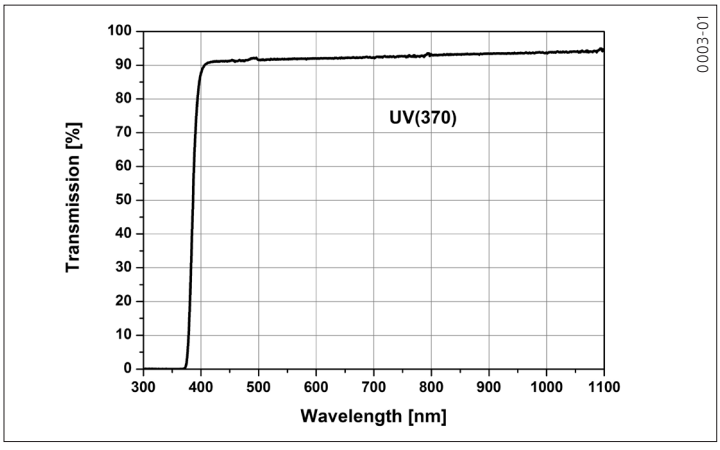

Fig. 1: Spectral transmission of hydrophilic acrylic IOL of 20 diopters

3 Packaging

This ZEISS IOL is supplied sterile. The lens is steam-sterilized.

There are two different packaging versions. IOL models preloaded in loading chambers are compatible with the BLUEMIXS 180 injectors, while non-preloaded IOLs in glass vials are compatible with conventional cartridge injectors:

1. BLUEMIXS 180 compatible IOLs are preloaded into a loading chamber that is designed for use with the BLUEMIXS 180 injector. The loading chamber is held open by a lens holder. Both the loading chamber and lens holder are made of medical-grade plastic. Each IOL in the loading chamber is sealed in a blister pack containing ultrapure water. The blister pack is sealed in a sterile pouch.
2. IOLs packaged in glass vials are designed to be implanted using conventional cartridge injectors. Each IOL is supplied in a sterile vial filled with ultrapure water. The vial is sealed in a sterile peel pouch.

4 Intended purpose of the device

Intended purpose:

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

Indication:

This ZEISS IOL is indicated for the visual correction of aphakia secondary to the removal of the crystalline lens in patients with cataracts. ZEISS LISA and LARA IOLs are also indicated for non-cataractous, presbyopic patients who seek greater independence from glasses for intermediate and/or near distances. ZEISS toric IOL are also indicated for the correction of regular corneal astigmatism.

Patient target group:

Aphakic adult patients (18 years old or older).

Intended users:

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

5 Warnings, undesirable side effects and residual risk

The complications listed below may occur following implantation of any IOL 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 IOL 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
- elevated intraocular pressure requiring treatment
- corneal edema
- corneal endothelial damage
- retinal detachment
- cystoid macular edema
- salt precipitation in/on the lens. A correlation may exist between the use of exogenous material (such as air or gas during corneal surgery or vitrectomy) and subsequent salt precipitation in/on the IOL. The mechanism and the incidence are unknown.

Possible complications related to IOLs include:

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

Possible complications related to toric IOLs:

- Rotation of toric IOLs from their intended axis can reduce their astigmatic correction function. Misalignment greater than 30 degrees can increase postoperative refractive cylinder values. If necessary, lens repositioning should occur as early as possible prior to lens encapsulation.

Possible undesirable side effects related to LISA and LARA IOLs:

- Patients may have a contrast sensitivity reduction in low light conditions (compared to monofocal IOLs) and may need to take extra care when driving at night.
- Patients who have recently undergone IOL implantation may experience visual disturbances (such as halos, glare, starburst), in particular in night-time conditions. These disturbances typically diminish over time as patients adapt to the multifocal IOLs.

6 Precautions

The safety and effectiveness of the IOLs have not been demonstrated 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

Particular caution should be exercised when considering the implantation of LISA and LARA IOLs:

- progressive or unstable eye disease
- macular degeneration
- severe optic nerve atrophy
- retinal conditions or predisposition to retinal conditions, previous history of or predisposition to retinal detachment or proliferative diabetic retinopathy
- LISA and LARA IOLs may slightly decrease the level of retinal detail during examination or treatment. This could make retinal laser surgery and the diagnosis of some conditions more challenging.
- progressive diseases of the anterior segment of the eye (e.g. rubeosis iridis, essential iris atrophy)
- chronic anterior or posterior segment inflammation such as uveitis
- corneal changes affecting visual acuity (such as endothelial corneal dystrophy or previous corneal transplant)
- non-senile cataract (such as rubella or congenital cataract)

Particular caution should be exercised when considering the implantation of toric IOLs:

- significant irregular astigmatism

7 Precautions for use and storage

- 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 use the product if the package is damaged.
- Do not use the product if the package was unintentionally opened before use.
- Do not use the product beyond the expiration date.
- Store the product between +2 °C (35.6 °F) and +45 °C (113 °F).
- IOLs should be at room temperature at the time of surgery to avoid temporary clouding of the lens optic after implantation.
- Store the product away from moisture and sunlight.
- Do not use the product if the package is wet.
- Do not use the storage liquid from the blister pack for intraocular irrigation.
- Do not implant IOLs which are not compliant with the patient's specific biometrical parameters.
- Avoid decentration and tilt of the optical axis of the lens (risk of high-order aberrations).
- When inserting the lens with an injector system, the lens may form fold lines. These lines are reversible and are therefore not a reason to explant the lens.
- For toric IOLs: The reference axis of the cornea (normally 0°) must be identified prior to implantation. Corneal marking should be done under topical anesthesia with the patient in a sitting position or using the ZEISS cataract suite.
- For toric IOLs: Pay special attention to the labeling as the dioptric power for toric IOLs can be stated either as "sphere (SPH) and cylinder (CYL)" or "spherical equivalent (SE) and cylinder (CYL)", please check the label carefully.

8 Lens power calculation for monofocal and multifocal IOL

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

Please follow the instructions that are relevant to your product.

Preparatory steps for BLUEMIXS 180 compatible lenses

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. In a sterile environment, open the peel pouch and remove the blister pack. Verify the diopter of the lens again.
3. Inspect the blister pack. Make sure it is not damaged and the seal is not broken. Before opening the blister pack, gently tap on the cover to remove drops of the storage liquid from the inside of the cover.
4. Slowly and continuously peel off the cover while holding the blister pack in a horizontal position.
5. Remove the loading chamber containing the lens from the blister pack. Do not remove the lens holder at this time!
6. For detailed descriptions, refer to the instructions for use supplied with the BLUEMIXS 180 injector.

Preparatory steps for lenses packaged in glass vials

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. In a sterile environment, open the peel pouch and remove the vial. Verify the diopter of the lens again.
3. Open the vial and remove the lens, maintaining sterile conditions. ZEISS acrylic IOLs are foldable in a hydrated condition.
4. IOLs with two circular marks on the haptic should be placed in the cartridge with one circular mark in the upper left corner and one in the bottom right corner, as shown in figure 2. Figure 3 shows the correct position of the marks of the IOL in the capsular bag.

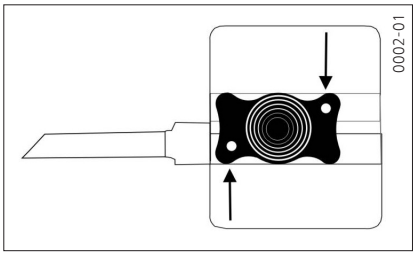

Fig. 2: Example of the IOL position in a cartridge

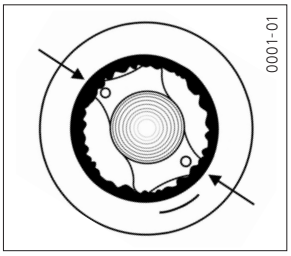

Fig. 3: IOL position in the capsular bag

Implanting steps

1. To ensure that the lens is implanted while in a hydrated state, the IOL should be injected immediately after preparation of the injector.
2. Use only sterile intraocular irrigating solutions to hydrate the IOL.
3. Once the IOL is in place, thoroughly remove all viscoelastic from the eye, both in front and behind the IOL, using routine irrigation and aspiration.
4. Toric IOL: The flatter curvature (flatter meridian) is marked with two opposing lines that provide orientation for correct positioning in the capsular bag. To obtain a correct position, align the orientation marks of the IOL (flat curvature) with the steeper meridian of the cornea. Residual viscoelastic may allow the lens to rotate causing misalignment of the toric IOL from the intended axis of placement.

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 (used or unused) are classified as medical (clinical) waste that harbors a potential infection or microbial hazard and must be disposed of accordingly.

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.

LISA IOLs provide functional near vision.

LISA trifocal and LARA IOLs provide functional intermediate vision.

ZEISS toric IOLs correct corneal astigmatism.

11 Safety and clinical performance

For products registered under Regulation (EU) 2017/745, the summary of safety and clinical performance (SSCP) 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 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 healthcare institution / provider.

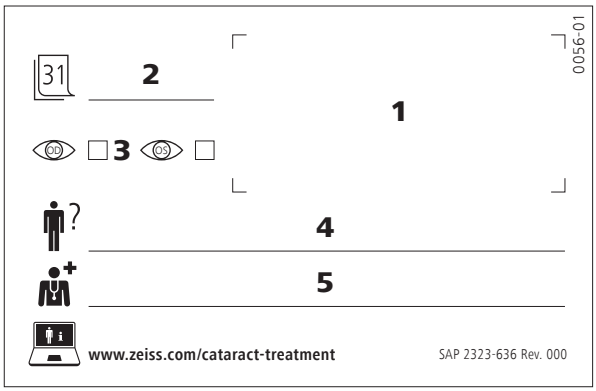

Fig. 4: Implant card

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 IOL 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 IOL for a particular patient.

16 Symbols used on labelling

STERILE	Sterilized using steam		Keep away from sunlight
SN	Serial number		Consult instructions for use
	Temperature limit		Keep dry
	Do not re-use		Do not use if package is damaged
	Do not resterilize		Date of manufacture
	Use-by date		Manufacturer
ØT	Overall Diameter	A Opt	A-constant
Øbody	Body Diameter	t	Toric optic
near add	Near addition power (multifocal IOL)	int add	Intermediate addition power (multifocal IOL)
MD	Medical device (followed by the device name)		Indicates the sterile barrier system with a protective packaging inside
OD	IOL was implanted in the right eye.	OS	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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