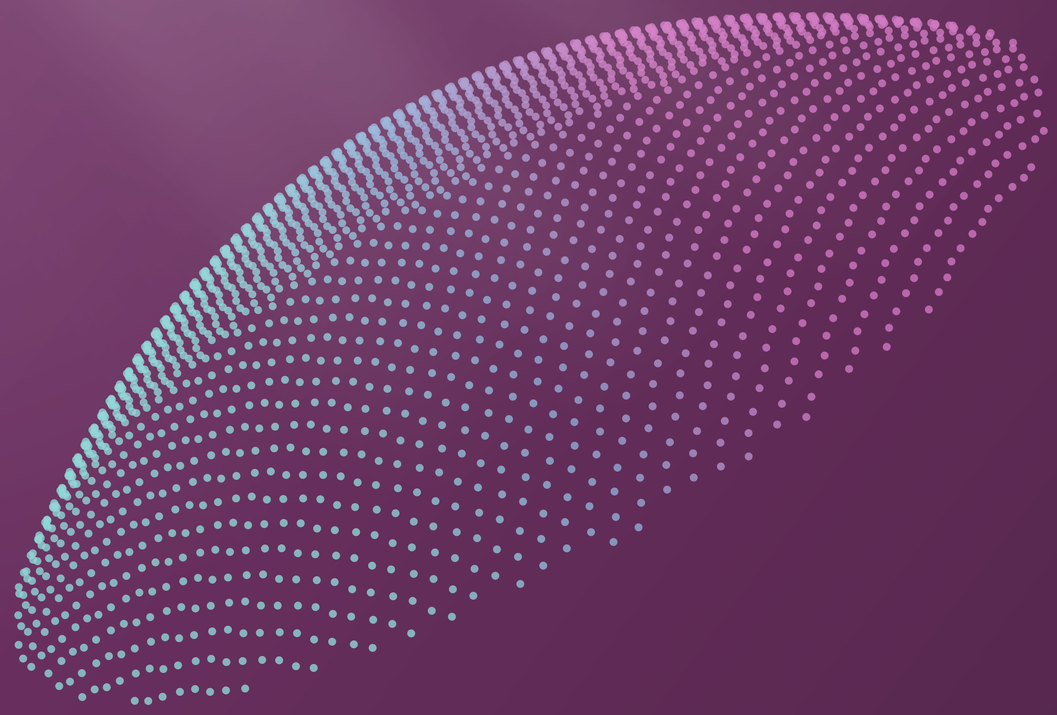
Light Adjustable Lens™

Light Adjustable Lens +™



Changing the Shape of Cataract Surgery

The Light Adjustable Lens™ (LAL®/LAL+™) is the first and only lens that can be adjusted in the eye, after cataract surgery. Precise UV light treatments adjust the shape of the Light Adjustable Lens, giving your patients truly custom vision that is literally transformative.

Imagine what the Light Adjustable Lens could do for your practice.

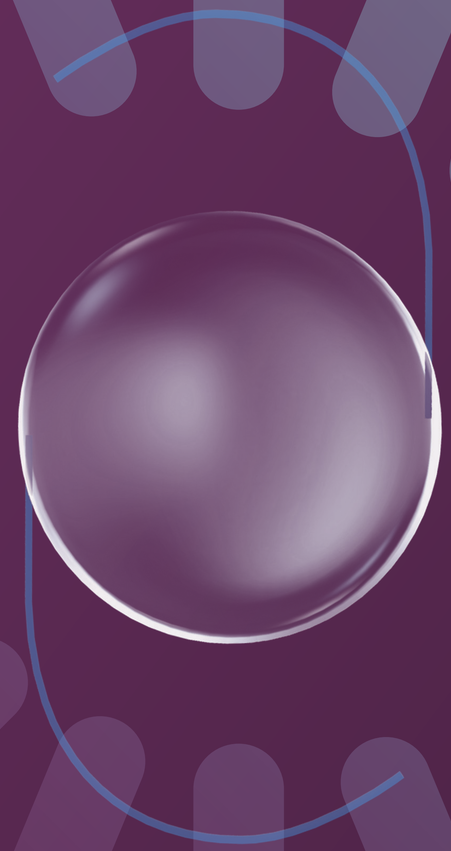
About the LAL and LAL+ | Fixed vs Adjustable Lenses | Redefining the Patient Journey | Outcomes and Economics | The Technology | Join the Transformation | References

Light Adjustable Lens full indications for use and Important Safety Information

Light Adjustable Lens+ full indications for use and Important Safety Information

The World's First Adjustable Intraocular Lens

- Custom vision driven by patient preferences and needs
- Delivers LASIK-level refractive outcomes[1,2]
- No reduction in contrast compared to a monofocal IOL[1]
- No increase in glare and halo compared to a monofocal IOL[1]
- Empowers a wide group of patients and doctors
- Higher practice revenue and profit[3]



Light Adjustable Lens full indications for use and Important Safety Information

Light Adjustable Lens+ full indications for use and Important Safety Information

Current premium intraocular lens (IOL) offerings do not meet the demands of ophthalmologists or their patients.

Ophthalmologists go to great lengths to consistently meet patients' rising expectations.[4]

Preoperative Diagnostics
- Biometry
- Topography
- OCT Imaging

Intraoperative Tools
- Femtosecond Lasers
- Aberrometry
- Alignment Tools

Additional Procedures
- LASIK Enhancement
- IOL Exchange

Fixed IOLs rely on preoperative refraction estimations.

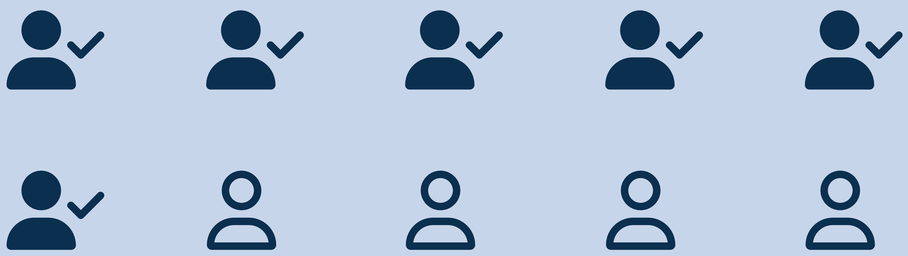
Residual refractive errors are common even after premium cataract surgery.

As a result, surgeons struggle with “multifocal anxiety syndrome.”

Jim Davies, MD

“I would get a grinding feeling in my stomach wondering ‘do I really want to recommend this?’ If we don’t have a good result, I feel it, but not nearly as much as my patients who will deal with it 24/7.”

Only 6 out of 10 cataract patients achieve their target vision with fixed IOLs.[5]



ERROR SOURCE[6]

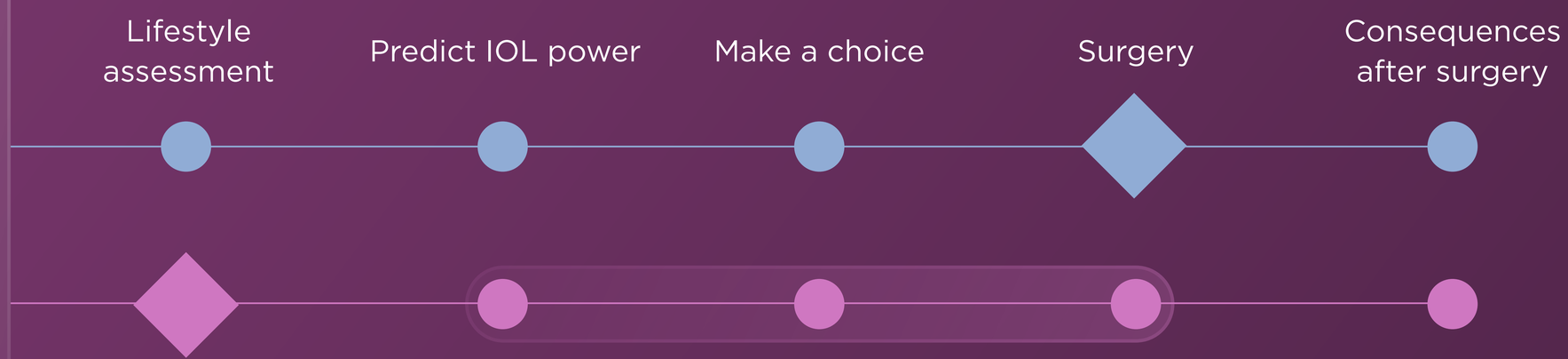
35%	Postop IOL position
15%	Postop corneal power
17%	Axial length

Redefining the Patient Journey

The Light Adjustable Lens has revolutionized cataract surgery, moving the important decisions about final lens power to its ideal place: after surgery. This way, the process is now more precise than ever, accounting for lens shift and refractive changes during the healing process, to achieve the best possible outcome.

Fixed Lens

Tries to predict lens power for patients *before* surgery



Light Adjustable Lens

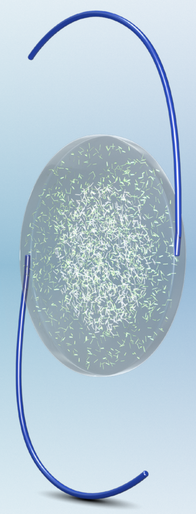
Adjusts the lens to fit the patient *after* surgery

How Adjustability Works

Non-surgical light treatments are performed in the clinic.

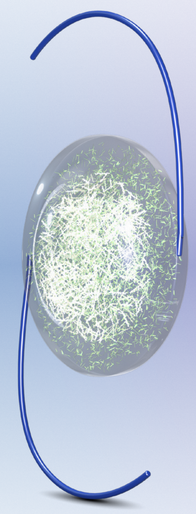
Adjustment Beam

Light from the RxSight® LDD is directed by the surgeon to the Light Adjustable Lens



Photopolymerization

Macromers in the path of the light are photo-polymerized

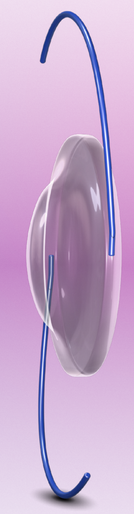


Diffusion and Power Change

Unpolymerized macromers move into the polymerized area, causing precise shape and power change

Lock-In Beam

The entire lens is exposed to light to polymerize all the remaining macromers



Final Result

The outcome is a precise change in the Light Adjustable Lens power to match the patient's individual prescription

Light treatments are painless, non-invasive, and take approximately 90 seconds.

Initial light treatment
At least 17 days after surgery.

Secondary light treatment
At least 3 days after initial light treatment.

Additional light treatments
If required. At least 3 days after each prior light treatment.

Light Adjustable Lens full indications for use and Important Safety Information

Light Adjustable Lens+ full indications for use and Important Safety Information

Only Adjustability Will Do

Practices love the Light Adjustable Lens for its accuracy, quality of vision, and unparalleled customization.

Accuracy

With adjustability in your workflow, you can measure refraction postoperatively, rather than make predictions before surgery.

Quality

The LAL demonstrates no loss of contrast or increased visual symptoms compared to a standard monofocal IOL.[1]

Customization

Adjustments driven by real-life patient trials: patients can experience their vision firsthand before customizing the lens to meet their needs.

2X

the number of eyes with 20/20 vision or better without glasses[1]

Powerful Practice Economics[3]

More patients choose a premium option when the Light Adjustable Lens is available to them.

44% of LAL patients would have received a non-premium monofocal IOL

Lens category	% of LALs coming from category	Net additional revenue per LAL
Toric IOL	29%	$368
Presbyopia-correcting IOL	28%	$225
Monofocal IOL	**44%**	**$1,504**
Blended net additional revenue		**$2,097**

91% of surveyed practices anticipate growing LAL procedure volumes

Procedure	Average selling price	LAL premium over category
Toric IOL	$2,528	$1,890
Presbyopia-correcting IOL	$3,612	$805
LAL	$4,417	—

$327K

Average incremental annual revenue

Surveyed practices averaged 156 LALs per year. At $2,097 per LAL, that's $327,132 in additional revenue.

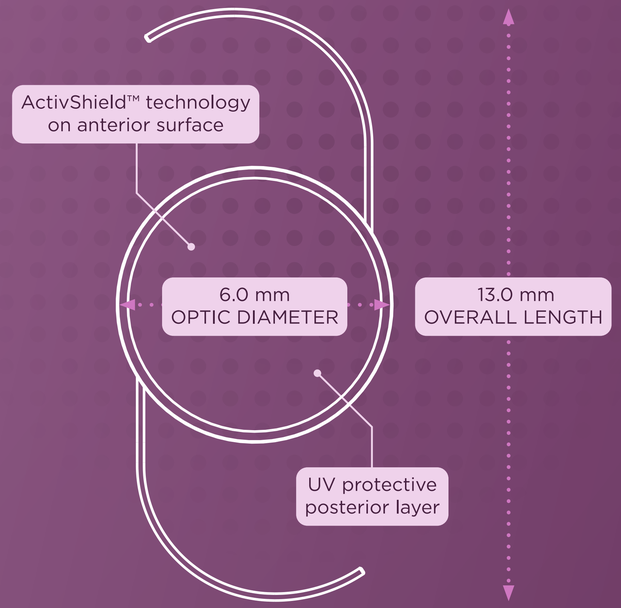
$805

Light Adjustable Lens premium over a presbyopia-correcting IOL

Light Adjustable Technology

Light Adjustable Lens™

Light Adjustable Lens +™



The LAL and the LAL+ are built on the same platform. The LAL+ has a modified aspheric anterior surface that creates a small continuous increase in central lens power, which is designed to slightly extend the depth of focus.

Optic body:
- Photoreactive UV-absorbing silicone
- Biconvex
- Anterior surface with rounded edge
- Posterior surface with squared edge
- 6 mm diameter

Haptics:
- Blue core PMMA monofilament
- Modified C
- Haptic angle of 10°
- 13 mm total diameter

Light Delivery Device™ (LDD™)

Includes all components needed for lens customization:

- Anterior segment biomicroscope
- Patient chin and headrest
- Computer system for planning and performing light treatments
- UV light projection system

RxSight Insertion Device

Proprietary insertion device specially designed for the Light Adjustable Lens

Light Adjustable Lens full indications for use and Important Safety Information

Light Adjustable Lens+ full indications for use and Important Safety Information

Don’t Get Left in the Dark

96% willingness to recommend[7]

80% would choose the LAL for themselves, over any other lens[7]

“Patient satisfaction is through the roof! With the Light Adjustable Lens, patients can test drive their new vision and I can fine tune it to meet their individual needs, in much the same way that a fine suit or a wedding dress can be custom tailored for just one person. There is simply nothing else like it.”

KIPER NELSON, MD
Southern Eye Center

“The Light Adjustable Lens has such excellent accuracy and quality of vision. We are able to optimize our patient’s vision after the LAL is placed, after the procedure. We love the lens almost as much as our patients.”

STEVE SLADE, MD
Slade & Baker Vision

“Not only did we return our investment in the LAL in under five months, but it has allowed us to invest more in our most important resource: our staff. We’ve generated enough revenue to give generous wage increases we might not have been able to provide otherwise.”

MARIANNE SLOAN, MBA
Four Corners Eye Clinic

Light Adjustable Lens™

Light Adjustable Lens +™

Be Part of the Transformation

Bring adjustability to your practice.
Learn more at RxSight.com

INDICATIONS FOR USE AND IMPORTANT SAFETY INFORMATION

INDICATIONS: The Light Adjustable Lens™ (LAL®) and Light Delivery Device™ (LDD™) system is indicated for the reduction of residual astigmatism to improve uncorrected visual acuity after removal of the cataractous natural lens by phacoemulsification and implantation of the intraocular lens in the capsular bag in adult patients with preexisting corneal astigmatism of ≥ 0.75 diopters and without preexisting macular disease. The system also reduces the likelihood of clinically significant residual spherical refractive errors.

CONTRAINDICATIONS: The Light Adjustable Lens is contraindicated in patients who are taking systemic medication that may increase sensitivity to ultraviolet (UV) light as the LDD treatment may lead to irreversible phototoxic damage to the eye; patients who are taking a systemic medication that is considered toxic to the retina (e.g., tamoxifen) as they may be at increased risk of retinal damage during LDD treatment; patients with a history of ocular herpes simplex virus due to the potential for reactivation from exposure to UV light; patients with nystagmus as they may not be able to maintain steady fixation during LDD treatment; and patients who are unwilling to comply with the postoperative regimen for adjustment and lock-in treatments and wearing of UV protective eyewear.

WARNINGS: Careful preoperative evaluation and sound clinical judgment should be used by the surgeon to decide the risk/benefit ratio before implanting an IOL in a patient with any of the conditions described in the Light Adjustable Lens and LDD Professional Use Information document. Caution should be used in patients with eyes unable to dilate to a pupil diameter of ≥ 7 mm to ensure that the edge of the Light Adjustable Lens can be visualized during LDD light treatments; patients who the doctor believes will be unable to maintain steady fixation that is necessary for centration of the LDD light treatment; patients with sufficiently dense cataracts that preclude examination of the macula as patients with preexisting macular disease may be at increased risk for macular disease progression; and patients at high risk for future vitreoretinal disease that may require silicone oil as part of therapy. The Light Adjustable Lens must be implanted in the correct orientation with the back layer facing posteriorly.

PRECAUTIONS: The long-term effect on vision due to exposure to UV light that causes erythropsia (after LDD treatment) has not been determined. The implanted Light Adjustable Lens MUST undergo a minimum of 2 LDD treatments (1 adjustment procedure plus 1 lock-in treatment) beginning at least 17-21 days post-implantation. All clinical study outcomes were obtained using LDD power adjustments targeted to emmetropia post LDD treatments. The safety and performance of targeting to myopic or hyperopic outcomes have not been evaluated. The safety and effectiveness of the Light Adjustable Lens and LDD have not been substantiated in patients with preexisting ocular conditions and intraoperative complications. Patients must be instructed to wear the RxSight-specified UV protective eyewear during all waking hours after Light Adjustable Lens implantation until 24 hours post final lock-in treatment. Unprotected exposure to UV light during this period can result in unpredictable changes to the Light Adjustable Lens, causing aberrated optics and blurred vision, which might necessitate explantation of the Light Adjustable Lens.

ADVERSE EVENTS: The most common adverse events (AEs) reported in the randomized pivotal trial included cystoid macular edema (3 eyes, 0.7%), hypopyon (1 eye, 0.2%), and endophthalmitis (1 eye, 0.2%). The rates of AEs did not exceed the rates in the ISO historical control except for the category of secondary surgical interventions (SSI); 1.7% of eyes (7/410) in the Light Adjustable Lens group had an SSI ($p < .05$). AEs related to the UV light from the LDD include phototoxic retinal damage causing temporary loss of best spectacle corrected visual acuity (1 eye, 0.2%), persistent induced tritan color vision anomaly (2 eyes, 0.5%), persistent induced erythropsia (1 eye, 0.3%), reactivation of ocular herpes simplex Infection (1 eye, 0.3%), and persistent unanticipated significant increase in manifest refraction error (≥ 1.0 D cylinder or MRSE) (5 eyes, 1.3%).

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

Please see the Professional Use Information document for a complete list of contraindications, warnings, precautions, and adverse events.

Light Adjustable Lens full indications for use and Important Safety Information

Light Adjustable Lens+ full indications for use and Important Safety Information

INDICATIONS FOR USE AND IMPORTANT SAFETY INFORMATION

INDICATIONS: The Light Adjustable Lens+™ (LAL+™) and Light Delivery Device™ (LDD™) system is indicated for the reduction of residual astigmatism to improve uncorrected visual acuity after removal of the cataractous natural lens by phacoemulsification and primary implantation of the intraocular lens in the capsular bag in adult patients with preexisting corneal astigmatism of ≥ 0.75 diopters and without preexisting macular disease. The system also reduces the likelihood of clinically significant residual spherical refractive errors.

CONTRAINDICATIONS: The LAL+ is contraindicated in patients who are taking systemic medication that may increase sensitivity to ultraviolet (UV) light as the LDD treatment may lead to irreversible phototoxic damage to the eye; patients who are taking a systemic medication that is considered toxic to the retina (e.g., tamoxifen) as they may be at increased risk of retinal damage during LDD treatment; patients with a history of ocular herpes simplex virus due to the potential for reactivation from exposure to UV light; patients with nystagmus as they may not be able to maintain steady fixation during LDD treatment; and patients who are unwilling to comply with the postoperative regimen for adjustment and lock-in treatments and wearing of UV protective eyewear.

WARNINGS: Careful preoperative evaluation and sound clinical judgment should be used by the surgeon to decide the risk/benefit ratio before implanting an IOL in a patient with any of the conditions described in the LAL+ and LDD Professional Use Information document. Caution should be used in patients with eyes unable to dilate to a pupil diameter of ≥ 7 mm to ensure that the edge of the LAL+ can be visualized during LDD light treatments; patients who the doctor believes will be unable to maintain steady fixation that is necessary for centration of the LDD light treatment; patients with sufficiently dense cataracts that preclude examination of the macula as patients with preexisting macular disease may be at increased risk for macular disease progression; and patients at high risk for future vitreoretinal disease that may require silicone oil as part of therapy. The LAL+ must be implanted in the correct orientation with the back layer facing posteriorly.

PRECAUTIONS: The safety and effectiveness of the LAL+ has not been substantiated in clinical trials. The effects of the LAL+ optical design on the quality of vision, contrast sensitivity, and subjective visual disturbances (glare, halo, etc.) have not been evaluated clinically. Surgeons must weigh the potential benefits of the modified optical design of the LAL+ against the potential for risks associated with degradation in vision quality and the lack of clinical data to characterize the impact of the LAL+ optical design on contrast sensitivity and subjective visual disturbance. These considerations may be especially relevant to patients with certain pre-existing ocular conditions (prior corneal refractive surgery, irregular corneal astigmatism, severe corneal dystrophy, macular disease, or optic nerve atrophy, etc.) or intraoperative conditions (posterior capsular rupture, complications in which the IOL stability could be compromised, inability to place IOL in capsular bag, etc.). The long-term effect on vision due to exposure to UV light that causes erythropsia (after LDD treatment) has not been determined. The implanted LAL+ MUST undergo a minimum of 2 LDD treatments (1 adjustment procedure plus 1 lock-in treatment) beginning at least 17-21 days post-implantation. All clinical study outcomes were obtained using LDD power adjustments targeted to emmetropia post-LDD treatments. The safety and performance of targeting to myopic or hyperopic outcomes have not been evaluated. The safety and effectiveness of the LAL+ and LDD have not been substantiated in patients with preexisting ocular conditions and intraoperative complications. Patients must be instructed to wear the RxSight-specified UV protective eyewear during all waking hours after LAL+ implantation until 24 hours post final lock-in treatment. Unprotected exposure to UV light during this period can result in unpredictable changes to the LAL+, causing aberrated optics and blurred vision, which might necessitate explantation of the LAL+. When performing refraction in patients implanted with the LAL+, confirmation of refraction with maximum plus manifest refraction technique is recommended.

ADVERSE EVENTS: The most common adverse events (AEs) reported in the randomized pivotal trial of the parent LAL included cystoid macular edema (3 eyes, 0.7%), hypopyon (1 eye, 0.2%), and endophthalmitis (1 eye, 0.2%). The rates of AEs did not exceed the rates in the ISO historical control except for the category of secondary surgical interventions (SSI); 1.7% of eyes (7/410) in the LAL group had an SSI ($p < .05$). AEs related to the UV light from the LDD include phototoxic retinal damage causing temporary loss of best spectacle corrected visual acuity (1 eye, 0.2%), persistent induced tritan color vision anomaly (2 eyes, 0.5%), persistent induced erythropsia (1 eye, 0.3%), reactivation of ocular herpes simplex Infection (1 eye, 0.3%), and persistent unanticipated significant increase in manifest refraction error (≥ 1.0 D cylinder or MRSE) (5 eyes, 1.3%).

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

Please see the Professional Use Information document for a complete list of contraindications, warnings, precautions, and adverse events.

Light Adjustable Lens full indications for use and Important Safety Information

Light Adjustable Lens+ full indications for use and Important Safety Information

References

1. RxSight P160055: FDA Summary of Safety and Effectiveness Data. 2017.
2. Sandoval HP, Donnenfeld ED, Kohnen T, et al. Modern laser in situ keratomileusis outcomes. *J Cataract Refract Surg*. 2016;42(8):1224-1234.
3. RxSight 2023 Economic Survey.
4. Market Scope 2019 Annual Survey of Cataract Surgeons.
5. Market Scope 2020 IOL Market Report: A Global Analysis for 2019 to 2025.
6. Norrby S. Sources of error in intraocular lens power calculation. *J Cataract Refract Surg*. 2008;34(3):368-376.
7. RxSight 2023 Customer Survey.

Light Adjustable Lens full indications for use and Important Safety Information

Light Adjustable Lens+ full indications for use and Important Safety Information