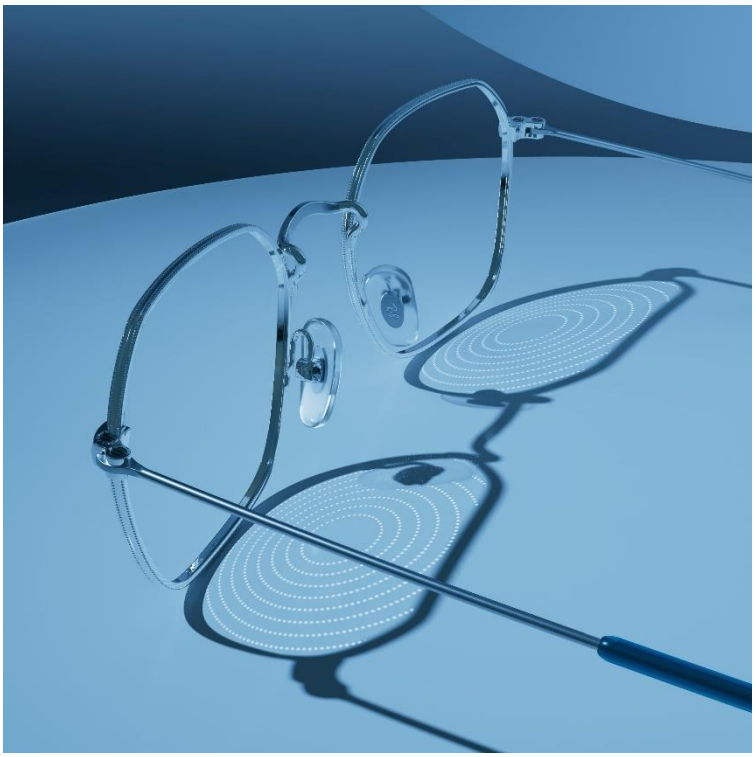
ESSILOR® STELLEST®

spectacle lenses



PROFESSIONAL FITTING AND INFORMATION GUIDE

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Stellest®
essilor

Table of Contents

IMPORTANT: Please read carefully and keep this information for future use. This package insert is intended for the eye care professional, but should be made available to patients upon request. The eye care professional should provide the patient with patient instructions that pertain to the patient's prescribed lens.

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PRODUCT DESCRIPTION

Essilor® Stellest® spectacle lenses are ophthalmic lenses designed to slow myopia progression while correcting refractive error in myopic children.

The Essilor® Stellest® spectacle lens consists of a single vision zone to correct myopic refractive error and a myopia progression control zone made with Highly Aspherical Lenslet Target (H.A.L.T.*) technology. H.A.L.T.* technology consists of 1021 contiguous highly aspherical lenslets spread over 11 rings. The area of the lens without lenslets provides vision correction. Within a single ring lenslets are of the same geometry, but lenslets from each ring have different geometries. The aspherical geometry of the lenslets does not focus light at a single point but instead distributes it across a range in front of the retina (volume of myopic defocus). As the geometry of the lenslets from each ring has been computed so that the created volume is equidistant from a theoretical myopic retina at any eccentricity. A volume of myopic defocus is expected to provide better myopia control compared to a surface of myopic defocus. The volume of myopic defocus created by the lenslets provides the slowing of myopia progression signal.

The prescription (Rx) surfacing is made on the back surface of the lens to obtain the appropriate prescription (to correct myopia and astigmatism). The lenslets are placed on the front surface of the lens and are nearly invisible. A schematic of the uncut lens is outlined below in Figure 1 and a photograph of the lens is shown in Figure 2. The configuration and technological characteristics of the Essilor® Stellest® spectacle lens are described in Table 1.

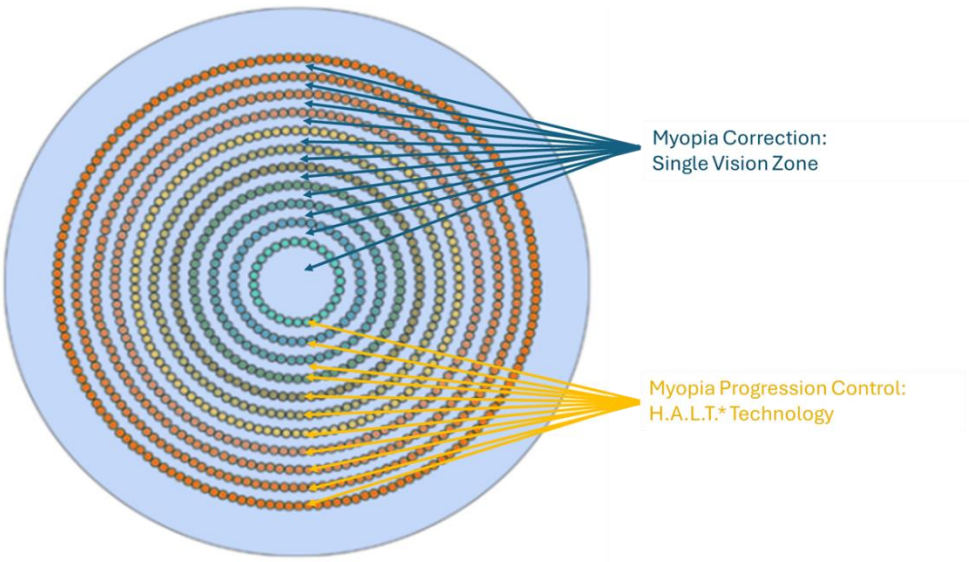

Figure 1: Schematic of the uncut Essilor® Stellest® spectacle lens showing the single vision zone and the zone to slow myopia progression (H.A.L.T. technology), illustrating 1021 contiguous highly aspherical lenslets spread on 11 rings.*

H.A.L.T. is an acronym for Highly Aspherical Lenslet Target and does not imply a "halt" or "stop" of myopia progression.

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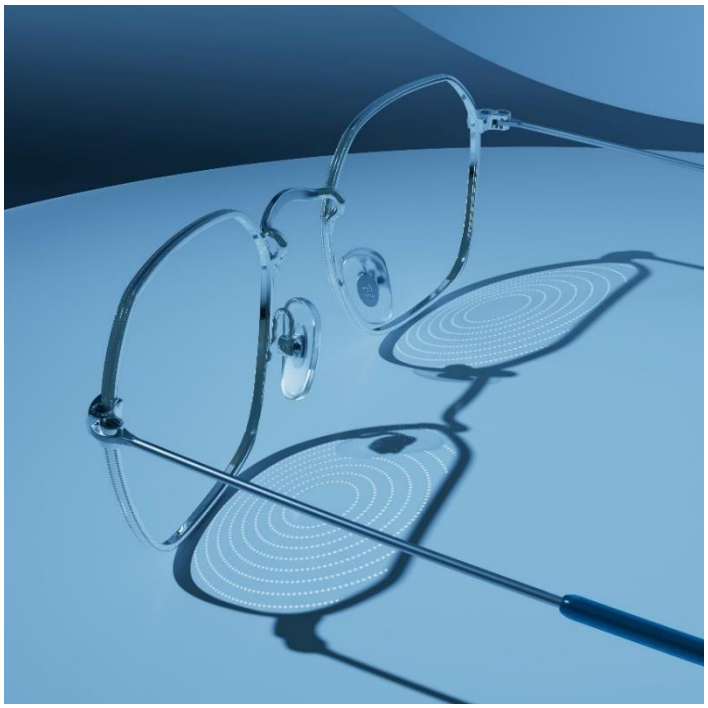

Figure 2: Photograph of the Essilor® Stellest® spectacle lens mounted in a frame, showing the single vision zone and the zone to control myopia progression (H.A.L.T.† technology).

Table 1: Technological Characteristics of the Essilor® Stellest® spectacle lens

Technological Feature	**Description**
Single Vision Zone	No lenslet in the central 9 mm diameter to ensure correct automatic lensometer measurement (Figure 3)
	Concentric rings of distance refractive power
	The single vision zone ensures the correction of refractive error in all gaze directions
Lenslets	Diameter of each lenslet: 1.12 mm
	Aspherical (1021 in total number) (Figure 3)
	All the lenslets in a single ring have the same optical design
	Lenslets from different rings have different optical designs
Rings	Eleven rings of contiguous highly aspherical lenslets (Figure 3)
Coatings	Anti Reflective + Hard coat
Material	Polycarbonate / Index: 1.59 / Abbe number 31 / Specific gravity: 1.20g/cm3
UV cut off	380nm
Impact resistance	Drop ball test according to US FDA regulation 21CFR Part 801.410
Tint	Not available with tint

† *H.A.L.T. is an acronym for Highly Aspherical Lenslet Target and does not imply a "halt" or "stop" of myopia progression.*

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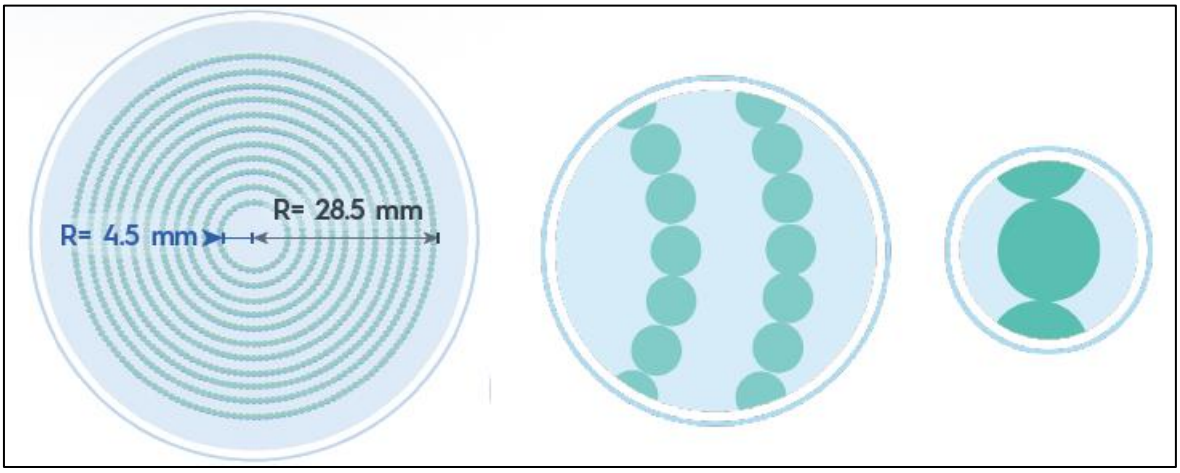

Figure 3: The Essilor® Stellest® spectacle lens showing a central 9 mm single vision zone with no lenslets surrounded by the myopia progression control zone (H.A.L.T.‡ technology) comprising 1,021 contiguous highly aspherical lenslets arranged over 11 rings.

LENS PARAMETERS AVAILABLE

- Sphere: 0.00D to -10.00D in 0.25D steps
- Cylinder: 0.00D to -4.00D in 0.25D steps

MECHANISM OF ACTION

The Essilor® Stellest® spectacle lens consists of a single vision zone and a H.A.L.T.‡ technology zone to slow myopia progression.

Single vision zone: The single vision zone ensures the correction of refractive error in all gaze directions. Light rays passing through this zone are focused on the fovea of the retina, providing sharp vision (Figure 4). This provides myopia correction.

‡ *H.A.L.T. is an acronym for Highly Aspherical Lenslet Target and does not imply a "halt" or "stop" of myopia progression.*

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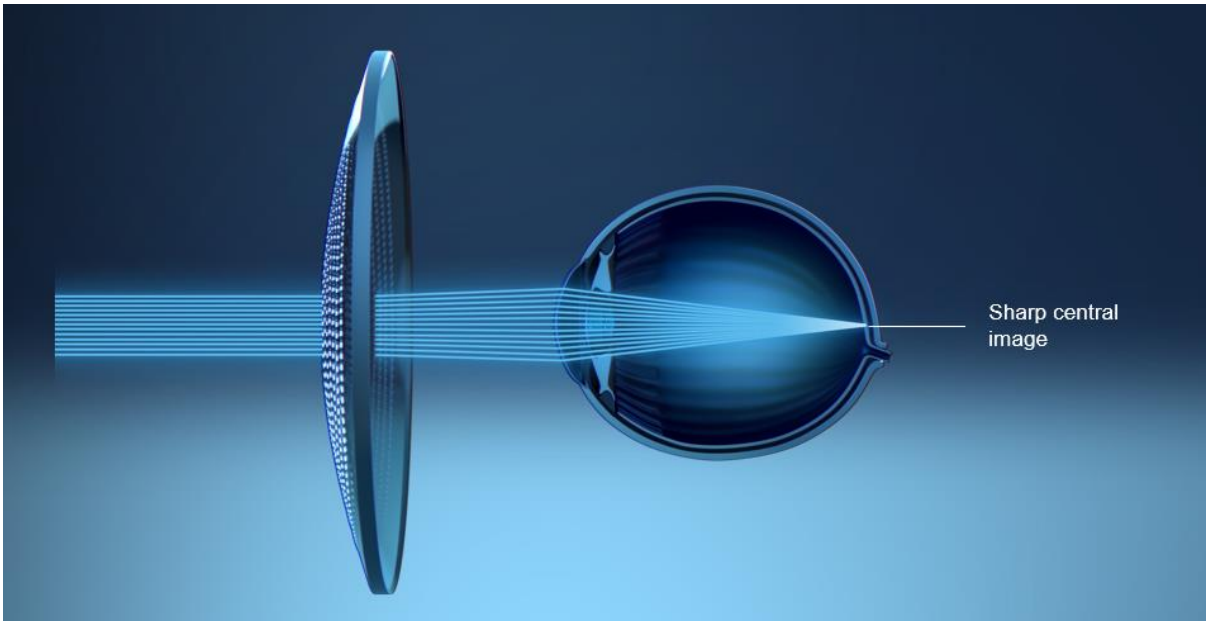

Figure 4: Light rays passing through the single vision zone are focused on the retina providing sharp vision

Myopia progression control zone: The lenslets are of aspherical geometry, designed to not focus light at a single point, but instead distributing it across a range in front of the retina (Figure 5). Light rays passing through these highly aspherical lenslets create a volume of myopic defocus (Figure 6).

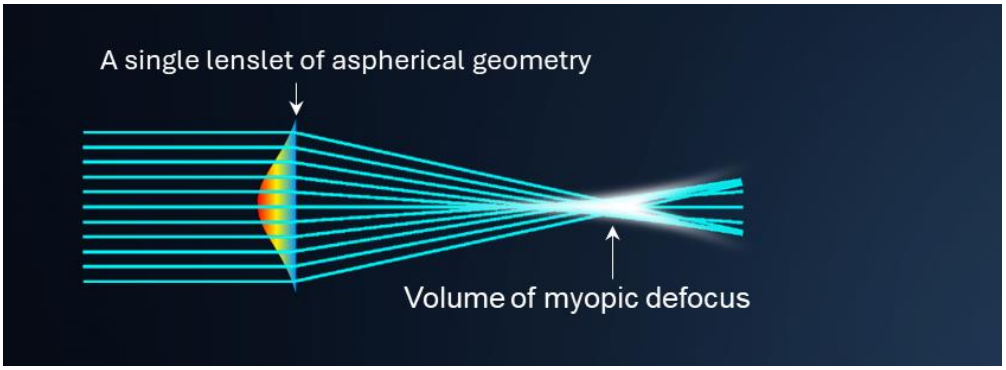

Figure 5: A single lenslet is of aspherical geometry, designed to not focus light at a single point, but instead distributing it across a range in front of the retina

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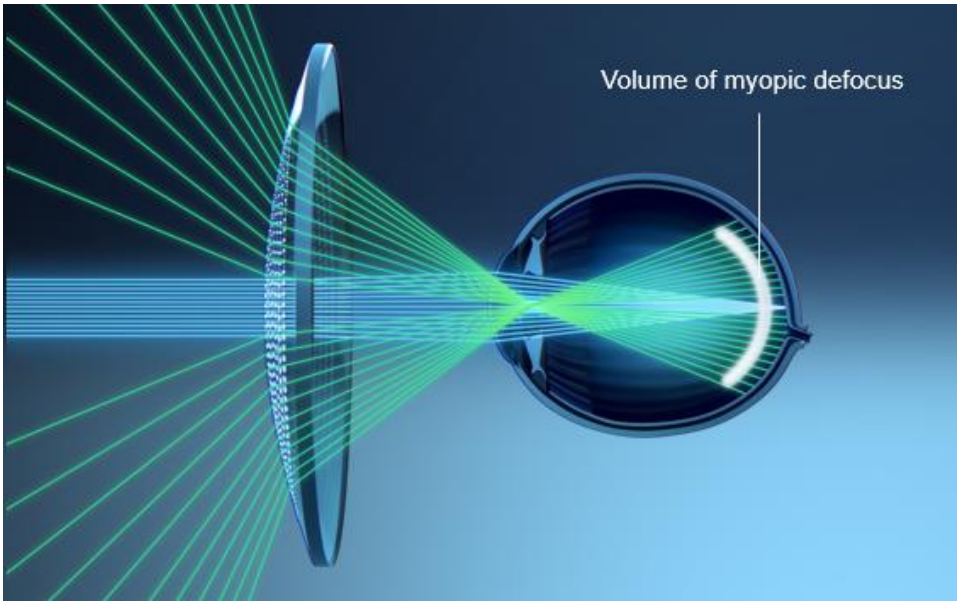

Figure 6: The combination of all the light beams passing through all aspherical lenslets creates a volume of myopic defocus in front of the retina.

INTENDED USE

The Essilor® Stellest® spectacle lens is intended to be worn by a patient in a spectacle frame, to reduce the rate of progression of myopia, and optically correct myopic refractive error for children who have myopia with or without astigmatism.

INDICATIONS FOR USE

The Essilor® Stellest® spectacle lens is indicated for the correction of myopia with and without astigmatism and for slowing the progression of myopia in children with non-diseased eyes, who, at the initiation of treatment, are aged 6-12 years and have spherical equivalent refraction of -0.75 D to - 4.50 D with astigmatism up to 1.50 D.

RECOMMENDED WEARING SCHEDULE

It is recommended that the patient wears their Essilor® Stellest® spectacle lenses for a minimum of 10 hours per day, at least 6 days per week.

SELECTION OF PATIENTS

- The Essilor® Stellest® spectacle lens can be prescribed by eyecare professionals when myopia management is indicated.
- The Essilor® Stellest® spectacle lens is indicated for the correction of myopia with and without astigmatism and for slowing the progression of myopia in children with non-diseased eyes, who, at the initiation of treatment, are aged 6-12 years and have a spherical equivalent refraction of -0.75 D to - 4.50 D, and with astigmatism up to 1.50 D.
- Parental cooperation and informed consent are important.
- Patient compliance is essential to success.

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EYE EXAMINATION RECOMMENDATIONS

Initial patient evaluation should include taking the patient's history, entrance testing, assessment of refractive status, and examination of both external and internal ocular structures. Additional tests can be performed as indicated for each patient, including but not limited to cycloplegic refraction and axial length measurement.

DISPENSING RECOMMENDATIONS

Frame selection

The ideal frame should meet a number of criteria to withstand a child's active lifestyle:

- Light weight
- Flexible
- Solid
- Material resistant to sweat and corrosion
- Adjustability features

Frame Characteristics

Frame choice should be appropriate for the child's age and facial features to allow for comfort and stability.

The frame size matters:

1. Should not be wider than the widest part of the child's face.
2. Choose a frame with a boxed center distance similar to the patient's pupil distance (PD).
3. This reduces the amount of decentration required when gazing and thus reduces edge thickness, giving a lighter, more comfortable pair of glasses with the best cosmetics.
4. Eyes should be centred in the frame. No narrow frames.
5. Minimum 30mm "B" (vertical measurement of frame)
6. Pantoscopic angle of the frame should be close to 0°

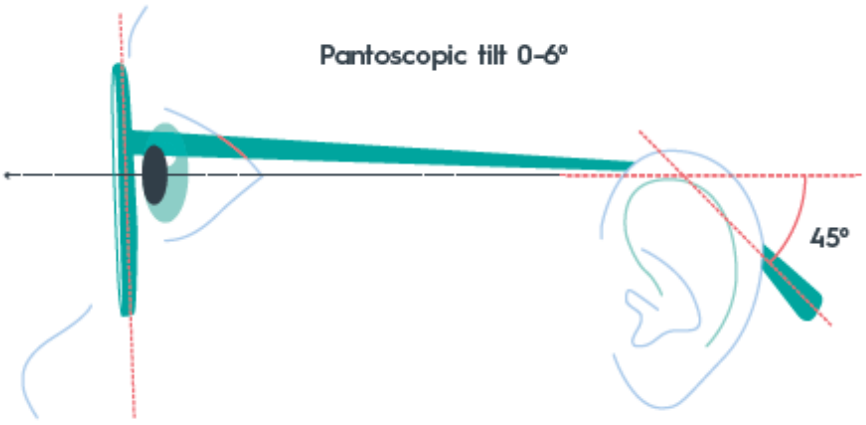

Figure 7: Pantoscopic angle of the frame should be close to 0°

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Check the frame fit:

1. The frame should fit over the eye sockets without extending down the cheeks.
2. If the frame does slip down, the bridge and nose pads may need tightening. If the nose pads are too tight, they can cause discomfort.
3. Be aware of the length of the frame's temples, which should extend just beyond the child's ears.
4. If frames are too tight on the temples, they can cause pressure, which may lead to discomfort, headaches, and frame slippage.
5. If the temples are too long, the spectacles may slip, which may affect comfort and vision.

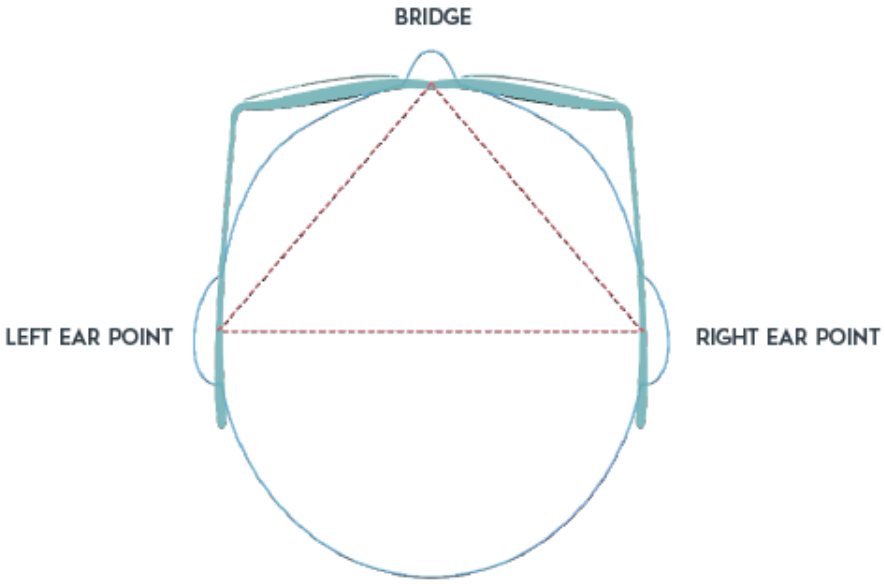

Figure 8: The frame touches in 3 places only to avoid pressure; i) the bridge of the nose; ii) the left ear point; iii) the right ear point

Centration and Fitting

The reference point is the center of the rings of lenslets. It is the point where the prescription is measured and controlled. The reference point should be aligned with the pupil center in the wearer's primary gaze direction to ensure the wearer is looking through the central single vision zone of the Essilor® Stellest® spectacle lens in their primary gaze position. In higher prescriptions, incorrect alignment of the optical center can induce unwanted prismatic effects and visual distortion, potentially affecting comfort, visual quality and lens performance.

A marking (dot) is to be used by the eye care professional as the reference point for centering of the lens. Essilor® Stellest® spectacle lenses should be fitted while the patient is looking straight ahead at a distant object.

- Horizontally: Monocular pupil distances (PD) R/L eye
- Vertically: Monocular heights R/L eye (center of pupils)

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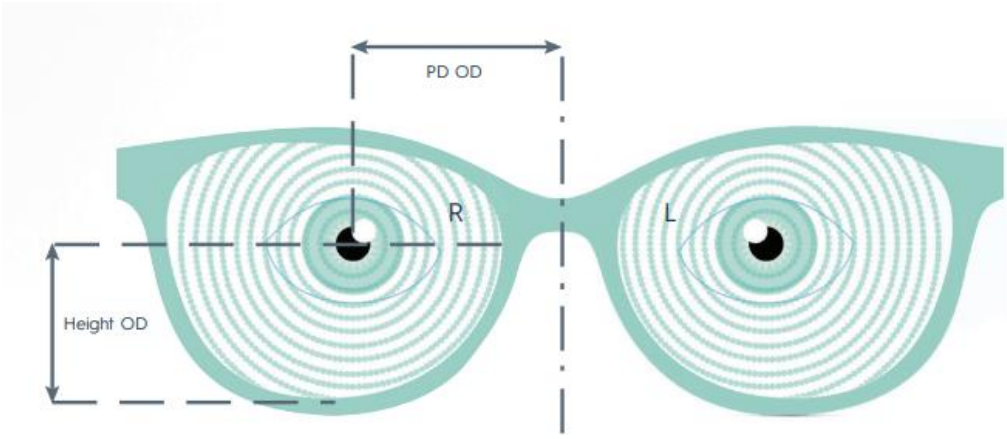

Figure9: *Essilor® Stellest® spectacle lenses are fitted in the horizontal gaze direction with monocular pupil distances (PD) and monocular fitting heights measured for the right (OD) and left (OS) eye.*

Mounting

- Do not put too much pressure to avoid tension in the lens.
- This is the case with any lens material. Cold mounting is always preferred for a plastic frame.

Cleaning

- Do not use any chemical incompatible with polycarbonate, such as acetone, ether, ammonia or trichloroethylene.
- The best cleaning solution is gentle dishwashing liquid/detergent and water. Advise patients/parents to follow these easy steps:
    1. Run the glasses under lukewarm or cool water (avoid hot water)
    2. Apply a drop of gentle dishwashing liquid/detergent on your fingers and lather the lenses, frames and earpieces
    3. Rinse with lukewarm or cool water and dry with a soft, clean cloth

Dispensing and advising

- Frame fit and adjustment check
- 15-minute spectacle trial (e.g., reading, walking), to ensure vision feels clear
- Recommended wearing schedule: It is recommended that the patient wears Essilor® Stellest® spectacle lenses for a minimum of 10 hours per day, at least 6 days per week.
- Adaptation period up to 1 week

RECOMMENDED FOLLOW UP

1. First follow-up visit after 2 weeks (Dispensing Eye Care Professional)
    - Check for adaptation and compliance/wearing time
    - Frame fitting check
    - Ask about vision at distance and near
    - Answer any questions the patient and parents may have
    - If needed, additional visits to adjust the frame

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2. Follow-up every 6 months (Prescribing eyecare professional)
   - Distance & near visual acuity
   - Check compliance/wearing time
   - Objective and subjective refraction and axial length measurement as indicated
   - Best corrected visual acuity

3. Annual comprehensive eye examination
   - Update Essilor® Stellest® spectacle lenses if Rx progression is 0.50D or more

4. Ongoing monitoring should include objective and subjective refraction at 6-month intervals, as indicated by the prescribing eye care professional.

GENERAL WARNINGS AND PRECAUTIONS

General warnings

As spectacles are manufactured based on a precise prescription, the eye care professional should ensure they are correctly fitted and appropriately assessed on the patient.

The Essilor® Stellest® spectacle lens, like any ophthalmic lens, may require an initial adaptation period, typically under one week. During this period, it is advisable to avoid high-impact activities where altered vision could present a risk. If adaptation takes longer or causes significant issues, it is recommended the wearer consults their eye care professional.

The lenses used in the FIN-3101 clinical trial were equipped with a Crizal Easy Pro coating, which does not provide any tint or filtering capabilities.

WARNINGS

Patients should be advised of the following warnings pertaining to Essilor® Stellest® spectacle lenses:

- *The effectiveness of the lens to slow myopia progression was not studied with any tints or filters. Speak to your doctor before adding any tint or filters to the lenses, as it is possible these may impact device effectiveness.*

Precautions

At this point, potential rebound effects (i.e., accelerated myopia progression following discontinuation of Essilor® Stellest® spectacle lens wear compared to single vision lenses) have not been evaluated in U.S. patients.

The effects of Essilor® Stellest® spectacle lenses on reading skill development and on peripheral visual function—including obstacle detection in the periphery—are unknown.

CLINICAL STUDY

FIN-3101 Randomized, Controlled Clinical Trial

Study Description

The FIN-3101 randomized, controlled clinical trial, conducted at nine clinical sites in the USA, enrolled 175 participants between the ages of 6 and 12 years. As per the study inclusion criteria, participants were required to have a manifest spherical equivalent refraction between -0.75 D and -4.50 D. Ultimately, 149 of these subjects received and used the study lenses. This group had a cycloplegic Spherical Equivalent Refraction (cSER) ranging from -0.50 D to -5.00 D and no more than 1.50 D of astigmatism.

Of the 149 participants, 91% (135) completed the 24-month study. The study population was primarily White (63.8%), with significant Asian (20.1%) and Black/African American (19.5%) representation (Table 2). Data were pooled from multiple study sites for this analysis based on three factors: a common protocol, close monitoring of protocol compliance by the Clinical Research Organization (CRO), and common data collection procedures across sites.

Participants and investigators were masked to lens assignment. A masked technician performed objective measurements, minimizing investigator bias.

Table 2: Participant Demographics – Participants dispensed study lenses.

Variable		Total	Test	Control
No. of Subjects		149	74	75
Participant Integer Age (n(%))	6 yrs old	4 (2.7)	2 (2.7)	2 (2.7)
	7 yrs old	10 (6.7)	6 (8.1)	4 (5.3)
	8 yrs old	19 (12.8)	8 (10.8)	11 (14.7)
	9 yrs old	30 (20.1)	16 (21.6)	14 (18.7)
	10 yrs old	35 (23.5)	16 (21.6)	19 (25.3)
	11 yrs old	35 (23.5)	16 (21.6)	19 (25.3)
	12 yrs old	16 (10.7)	10 (13.5)	6 (8.0)
	Mean (SD)	9.7 (1.52)	9.7 (1.59)	9.7 (1.47)
Sex (n(%))	Male	78 (52.3)	34 (45.9)	44 (58.7)
	Female	71 (47.7)	40 (54.1)	31 (41.3)
Ethnicity (n(%))	Hispanic or Latino	34 (22.8)	18 (24.3)	16 (21.3)
	Not Hispanic	115 (77.2)	56 (75.7)	59 (78.7)
Race* (n(%))	White	95 (63.8)	46 (62.2)	49 (65.3)
	East/Southeast Asian	30 (20.1)	14 (18.9)	16 (21.3)
	Black/African American	29 (19.5)	14 (18.9)	15 (20.0)
	South Asian	4 (2.7)	2 (2.7)	2 (2.7)
	American Indian or Alaska Native	2 (1.3)	0 (0)	2 (2.7)

	Native Hawaiian or Other Pacific Islander	1 (0.7)	1 (1.4)	0 (0)

** Proportions do not sum to 100% as subjects selecting more than one race will be counted multiple times.*

Effectiveness Endpoint

The primary statistical analyses for effectiveness were the mean changes in cSER and axial length. Treatment effectiveness was analyzed using all participants' data, with adjustments for missing data. Separate models analyzed changes in cSER and axial length considering factors such as treatment, time, age, sex, and location. The results, summarized as average changes from baseline, were statistically tested. The least-squares-mean cycloplegic refractive error and axial length change-over 2-years are shown below in Table 3.

Table 3: Cycloplegic refractive error and axial length change over 2 years in the FIN-3101 randomized, controlled clinical trial. Difference calculated as Test minus Control. (LS Mean - multiple imputation – ITT (159 subjects))

	Arm	LS Mean (SE)	95% CI	Difference in LS Means (SE)	95% CI of Difference	P-value	% Control
cSER	Essilor® Stellest®	-0.25 D (0.05)	-0.35 to -0.16	0.64 (0.07)	0.50 to 0.79	**<0.0001**	**71%**
	Control	-0.90 D (0.05)	-1.00 to -0.79	-	-		
Axial Length	Essilor® Stellest®	0.21 mm (0.02)	0.17 to 0.25	-0.24 (0.03)	-0.29 to -0.19	**<0.0001**	**53%**
	Control	0.45 mm (0.02)	0.42 to 0.49	-	-		

LS-Means: least-square means, ITT: Intent-to-Treat, SE: standard error, CI: confidence interval.

The differences in both cSER and axial length between the groups were statistically significant. The change in axial length was highly correlated with the change in cSER.

Additional Analysis

Subgroup analysis, stratified by age, revealed significantly less myopia progression in the test group compared to the control group across all age subgroups (6-8, 9-10, and 11-12 years) at 2-years. At 2 years, a cSER reduction of 89%, 62% and 72% was achieved for each of the three age groups, respectively. Subgroup analysis based on baseline myopia (-0.75 to -2.50 D, -2.75 to -4.50 D) showed that both groups with lower and higher myopia showed significantly less myopia progression at 2-years when using the test lenses compared to the control lenses. Subjects in the test group showed a reduction in myopia progression of 71% and 69% in cSER at 2-years for the lower and higher myopia subgroups, respectively.

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Safety Endpoint

At baseline, the mean best-corrected monocular high-contrast distance visual acuities (BCVAs) were -0.02 and -0.03 logMAR for the test and control groups, respectively.

At the 2-year visit, the mean BCVAs were -0.04 logMAR for both groups. None of the subjects from either group showed a *worsening* of visual acuity (VA) of two or more lines compared to baseline BCVA (Table 4)

Table 4: Best corrected distance visual acuity by visit and treatment (n(%)) - Participants dispensed study lenses.

	Baseline		6-Month		12-Month		18-Month		24-Month	
	Test	Control	Test	Control	Test	Control	Test	Control	Test	Control
No. of Eyes	148	150	148	140	146	138	140	130	138	132
>20/20	45 (30%)	60 (40%)	72 (49%)	66 (47%)	66 (45%)	54 (39%)	64 (46%)	63 (48%)	69 (50%)	65 (49%)
20/20	92 (62%)	81 (54%)	69 (47%)	65 (46%)	77 (53%)	74 (54%)	73 (52%)	62 (48%)	65 (47%)	65 (49%)
20/25	11 (7%)	9 (6%)	7 (5%)	9 (6%)	3 (2%)	9 (7%)	3 (2%)	5 (4%)	4 (3%)	2 (2%)
20/30	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (1%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
<20/30	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

Conversion from logMAR to Snellen:
<0.00 = >20/20
0.00 to 0.04 = 20/20 (20/20 – 20/21.9)
0.06 to 0.12 = 20/25 (20/23 – 20/26.4)
0.14 to 0.20 = 20/30 (20/27.6 – 20/31.7)
>0.20 = <20/30

Safety information was collected at each follow-up visit, during which subjects were asked about any symptoms, problems, or complaints related to their spectacles. The incidence of adverse events was low and comparable between the test and control groups. No ocular adverse events were considered lens-related or clinically significant. Reported symptoms, problems, and complaints were infrequent and distributed similarly across groups (Table 5). The “Other symptoms” category in Table 5 includes symptoms such as itchy eyes, squinting, stinging sensations, very infrequent dizziness, rare shadows and afterimages when looking at bright light.

The FIN-3101 randomized, controlled clinical trial demonstrated an acceptable safety profile and positive benefit-risk assessment.

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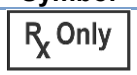
Table 5: Number of participants who were dispensed study lenses who reported symptoms, problems and complaints.

	Test	Control
No. of Subjects	74	75
1. Symptoms		
i. Headache	2 (3%)	4 (5%)
ii. Halos	1 (1%)	2 (3%)
iii. Glare	0 (0%)	0 (0%)
iv. Blurred vision		
▪ Distance	5 (7%)	9 (12%)
▪ Near	2 (3%)	2 (3%)
▪ General	7 (9%)	6 (8%)
v. Double vision	1 (1%)	0 (0%)
vi. Other	3 (4%)	7 (9%)
2. Other		
i. Problems with frames	10 (14%)	10 (13%)
ii. Problems with lenses	4 (5%)	8 (11%)
iii. Other	0 (0%)	2 (3%)

ADDITIONAL PRODUCT INFORMATION

The Essilor® Stellest® spectacle lens is a class 2 product according to FDA regulation. The following symbols may appear on the label.

Symbols

Symbol	Meaning
	Caution: Federal (USA) law restricts this device to sale by or on the order of a licensed practitioner.
	Legal Manufacturer
	Date of Manufacture
	CE Marking (European regulation relating to medical devices).

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MD	Medical Device
REF	Catalogue or Model Number

Legal Manufacturer Information

Essilor International
147 rue de Paris
94220 Charenton le Pont - FRANCE

REPORTING ADVERSE ACTIONS

All serious adverse experiences and adverse reactions in patients wearing Essilor® Stellest® spectacle lenses or experienced with the lenses should be reported to:

Essilor of America,

13675 N. Stemmons Fwy,

Farmers Branch, TX 75234.

(800) 366-6342

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