

Essilor[®] Stellest[®]

spectacle lenses

PATIENT AND CAREGIVER GUIDE

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Myopia and myopia management

Myopia, also known as nearsightedness or shortsightedness, is a condition in which people can see clearly up close, but objects farther away appear blurred.¹ It commonly occurs when a person's eye is too long.¹ It typically develops in children of school age and tends to progress until adulthood.

Traditional single vision spectacles and conventional contact lenses correct vision but do not slow myopia progression. Myopia management, a more comprehensive approach, includes preventing or delaying myopia onset, correcting vision, slowing and monitoring myopia progression, and management of long-term eye health.²

As part of myopia management, Essilor® Stellest® spectacle lenses are designed to both correct vision and help slow myopia progression in children.

Myopia management with Essilor® Stellest® spectacle lenses

Essilor® Stellest® spectacle lenses offer two benefits:

1. Correct myopia through the single vision zone.
2. Slow myopia progression with Highly Aspheric Lenslet Target (H.A.L.T.*) technology, which consists of 1021 lenslets arranged over 11 rings. The lenslets create a volume of myopic defocus, acting as a signal to slow myopia progression and eye elongation (Figure 1).



Figure 1: Photograph of the Essilor® Stellest® spectacle lens in a frame, showing the single vision zone (no lenslets) and the zone designed to slow myopia progression using H.A.L.T. technology, which consists of 1,021 lenslets arranged over 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.

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 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.

Recommendations for Essilor® Stellest® spectacle lenses

Advice for parents to support their child's success with Essilor® Stellest® spectacle lenses

Collecting your child's new Essilor® Stellest® spectacle lenses

When your child collects their glasses with Essilor® Stellest® spectacle lenses, the eye care professional will ensure they fit comfortably and sit in the right position. They will also check that your child's vision feels clear. If at any time your child experiences discomfort or their vision does not feel right, please return to your eye care professional.

Wearing time

Encourage your child to wear their Essilor® Stellest® spectacle lenses consistently. It is recommended that your child wears the lenses for a minimum of 10 hours per day for at least 6 days per week.

Taking care of the lenses and frame

Guide your child in daily lens care. Teach them to clean their glasses with a microfiber cloth whenever needed, and to store them properly in their case before bedtime. This will help protect the lenses and ensure long-term comfort and efficacy.

When cleaning the lenses, the best cleaning solution is gentle dishwashing liquid/detergent and water. 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

Do not use any chemical incompatible with polycarbonate, such as acetone, ether, ammonia or trichloroethylene.

Follow-up visits

Regular follow-up visits are essential to ensure your child receives the full benefits of Essilor® Stellest® spectacle lenses. The prescribing eye care professional will recommend how often these visits should occur and advise on the timing of the next check-up. Following this schedule is important to maintain optimal vision correction and help slow the progression of myopia.

Breakage or damage

If your child's lenses become scratched or damaged, or if their glasses break or no longer fit properly between visits, return to your eye care professional for adjustment or repair.

General warnings and precautions

General warnings

As spectacles are manufactured based on a prescription from an eye care professional, an 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, which, typically is less than one week. During this period, it's 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 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

Some aspects of potential effects of the Essilor® Stellest® spectacle lenses, such as whether the eye grows faster once lens wear stops (rebound effect), on side (peripheral) vision including obstacle detection, or effects on learning to read, have not been studied in the context of US children.

Clinical study

The Essilor® Stellest® FIN-3101 Randomized, Controlled Clinical Trial

Study Description

The Essilor® Stellest® FIN-3101 clinical trial was conducted at nine medical centers in the United States. The study was designed to assess the safety and effectiveness of Essilor® Stellest® spectacle lenses in slowing the progression of myopia (nearsightedness) in children compared to standard single vision lenses. A total of 175 children between the ages of 6 and 12 were enrolled in the clinical trial. All participants had a prescription ranging from -0.75 D to -4.50 D, with no more than 1.50 D of astigmatism.

Of the children enrolled in the clinical trial, 149 received either Essilor® Stellest® spectacle lenses or standard single vision lenses. Most children (91% or 135 participants) completed the full two-year trial. The trial included children from a range of backgrounds, including White (63.8%), Asian (20.1%) and Black/African American (19.5%) (Table 1).

Table 1: 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.

To ensure results were consistent and reliable, the trial followed the same protocol at all participating sites and was overseen by an independent Clinical Research Organization (CRO). The children did not know which type of lenses they were given, and their eye examinations were carried out by a technician who was also unaware of the lens assignments. This helped prevent any bias in the results.

Effectiveness of Essilor® Stellest® spectacle lenses in slowing myopia progression

The clinical trial measured how children’s myopia progressed over two years by looking at two main factors: the change in the children’s eyeglass prescription and the growth of the eye (axial length change). These changes were compared between children wearing Essilor® Stellest® spectacle lenses and those wearing standard single vision lenses.

The analysis also considered factors such as the child’s age, sex, and location.

Change in prescription: Over two years, children wearing Essilor® Stellest® spectacle lenses had an average prescription change of -0.25 D, compared with -0.90 D for children wearing single vision lenses. This means Essilor® Stellest® spectacle lenses slowed the progression of myopia by about 71% compared with single vision lenses.

Eye growth: Children wearing Essilor® Stellest® spectacle lenses had an average eye growth of 0.21 mm, compared with 0.45 mm for those wearing single vision lenses. This corresponds to a 53% reduction in eye growth with Essilor® Stellest® spectacle lenses.

Additional Analysis

The trial also looked at how the lenses worked in different age groups and for children with different levels of myopia.

- **By age:** Children were grouped into three age groups (6–8 years, 9–10 years, and 11–12 years). In all age groups, children wearing Essilor® Stellest® spectacle lenses had significantly slower progression of myopia compared with those wearing single vision lenses. After two years, Essilor® Stellest® spectacle lenses reduced the increase in prescription by 89%, 62%, and 72% for the three age groups, respectively.
- **By prescription at enrollment:** Children were also grouped by how strong their prescription was at the start of the clinical trial (low myopia: -0.75 to -2.50 D; higher myopia: -2.75 to -4.50 D). In both groups, Essilor® Stellest® spectacle lenses slowed

myopia progression compared with single vision lenses, with a 71% reduction for the lower-prescription group and 69% for the higher-prescription group.

These results show that the lenses were effective across different ages and levels of myopia.

Safety

At the 2-year visit, the average vision was the same for those wearing Essilor® Stellest® spectacle lenses and those wearing single vision lenses.

The clinical trial monitored for any side effects or unexpected reactions. At each visit, participants were asked about any problems, symptoms, or complaints while wearing their glasses. Table 2 summarizes these reports, with the category “other symptoms” including symptoms such as such as itchy eyes, squinting, stinging sensations, very infrequent dizziness, rare shadows and afterimages when looking at bright light. In general, very few issues were reported, and the number was similar whether participants wore Essilor® Stellest® spectacle lenses or regular single vision lenses. None of the issues were serious or caused by the lenses.

Overall, the FIN-3101 Essilor® Stellest® spectacle lens clinical trial showed that the lenses were safe for children and provided clear benefits.

Table 2: Number of participants who were dispensed the 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%)

References

1. Flitcroft DI, He M, Jonas JB, et al. IMI – Defining and Classifying Myopia: A Proposed Set of Standards for Clinical and Epidemiologic Studies. *Invest Ophthalmol Vis Sci.* 2019;60(3):M20–M30. doi:10.1167/iovs.18-25957.

2. Flitcroft DI, Bullimore MA, Gifford KL, et al. IMI – Myopia Correction, Myopia Control and Myopia Management: Definitions and Recommended Usage. *Invest Ophthalmol Vis Sci.* 2025;66(6):41. doi:10.1167/iovs.66.6.41.