



**CAUTION:** This reusable medical device is to be sold by and/or prescribed by a properly licensed practitioner.

**IMPORTANT:** These Instructions for Use are intended for the Eye Care Professional. Prior to dispensing the product, the Eye Care Professional should provide the patient with instructions for appropriate use.

**NOTICE TO THE USER AND/OR PATIENT:** Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

GTIN (UDI-DI)	Title
00810084980002	DOT-20-365-090 (DOT 0.2) Spectacle Lens
00810084980019	DOT-20-365-090 AR (DOT 0.2) Spectacle Lens with Anti-Reflective Coating
00810084980026	DOT-20-365-105 T8 (DOT 0.2) Photochromic Spectacle Lens
00810084980033	DOT-20-365-090 AR and T8 (DOT 0.2) Photochromic Spectacle Lens with Anti-Reflective Coating

**DESCRIPTION:** SightGlass Vision (SGV) Diffusion Optics Technology (DOT) prescription spectacle lenses are available with or without anti-reflective coating (AR) and/or photochromic (i.e. Transitions® Signature® Gen 8™). The spectacle lens contains light scattering features and an approximately 5 mm clear aperture that is designed to be aligned to the patient's pupillary axis. The prescribed lenses are fitted into a spectacle frames for multiple uses.

**LENS MATERIAL:** DOT spectacle lenses are made from Trivex lens material have a hard, anti-scratch coating. The lenses are available with or without an embedded photochromic layer and/or an anti-reflective coating.

**LENS PARAMETERS:**

- Trivex Finished Single Vision DOT Lenses with or without an Anti-Reflective Coating:
  - Diameter: 70 mm
  - Sphere powers (D): 0.00 to -8.00
  - Cylinder powers (DC): 0.00 to -2.00
- Made-to-order Trivex Finished Single Vision DOT Lenses with or without an Anti-Reflective Coating:
  - Diameter: 50 mm to 76 mm
  - Sphere powers (D): 0.00 to -12.00
  - Cylinder powers (DC): 0.00 to -4.00
- Made-to-order Trivex Photochromic Finished Single Vision DOT Lenses with or without an Anti-Reflective Coating:
  - Diameter: 50 mm to 76 mm
  - Sphere powers (D): 0.00 to -12.00
  - Cylinder powers (DC): 0.00 to -4.00

**INDICATIONS (Uses):**

- DOT spectacle lenses are indicated for the correction of refractive ametropia (myopia and/or astigmatism) and for the reduction in the rate of myopic progression in phakic children who are aged 6 to 13 years old with non-diseased eyes.
- DOT spectacle lenses should be worn constantly for all activities except for those outlined in WARNINGS (a minimum of 10 hours per day).

**CONTRAINDICATIONS (Reasons not to use):**

Do not use DOT spectacle lenses when any of the following conditions exists:

- Amblyopia in either eye
- Any ocular or systemic conditions that could influence refractive development or status (e.g., keratoconus, congenital glaucoma, ocular trauma, diabetes, Marfan syndrome or other connective tissue disorder, Down syndrome, family history of poor night vision)

**WARNINGS:**

Patients should be advised of the following warnings pertaining to DOT spectacle lens wear:

- Do not wear DOT spectacle lenses when playing high impact sports such as football, baseball, basketball, soccer, or other high impact sports
- DOT photochromic spectacle lenses are not intended for use as protection against artificial light sources, such as sun lamps, lasers, etc.
- The patient should be told to never stare directly at the sun or at an eclipse with or without DOT photochromic spectacle lenses
- If a patient experiences eye discomfort or headaches, they should be instructed to discontinue use of the DOT spectacle lenses and return to their Eye Care Professional
- The treatment zone of SightGlass Vision DOT spectacle lenses provides an optical correction that slightly reduces contrast. Under certain circumstances (such as low light levels), this optical design can cause the following visual symptoms for some patients:
  - Reduced image contrast;
  - Halos or glare around bright lights;
  - Hazy vision.
- Not all patients function equally well with this type of correction, which can create a vision compromise that may cause difficulties with certain visually-demanding tasks. Patients should exercise extra care if performing potentially hazardous activities.

**POTENTIAL COMPLICATIONS:**

General risks related to any spectacles:

- Headache
- Eye strain
- Dizziness
- Eye discomfort
- Eye or face injury (e.g., patient gets hit with an object while wearing spectacle lenses)

Possible/potential incremental risks due to DOT lenses:

- Glare
- Halos
- Blurred/hazy vision
- Other (e.g., teasing)

**SPECTACLE DISPENSING:**

- 1) Eye Care Professional (ECP) performs the steps to refract the patient and determines if a patient is good candidate for DOT spectacles lenses.
- 2) Patient obtains a prescription for spectacle lenses.
- 3) ECP assists patient in frame selection, measures monocular pupillary distance and optical (or pupil) center heights to ensure proper fit of DOT spectacle lenses in the selected frame.
- 4) ECP orders spectacle lenses to be placed into selected frames.
- 5) Lab prepares the DOT spectacle lenses for selected frames per ECP order..
- 6) ECP adjusts spectacles frames and dispenses glasses.
- 7) ECP provides patient/parent(s)/guardian(s) with access to a patient User Guide.

**CLEANING OF DOT LENSES:**

- 1) DOT spectacle lenses can be cleaned using mild dish soap, water, and a clean, microfiber cloth.
- 2) DOT spectacle lenses can also be cleaned using spectacle lens cleaner and a clean, microfiber cloth.
- 3) DOT spectacle lenses can also be cleaned using premoistened lens wipes (e.g., lens cleaning wipes).

**PERFORMANCE CHARACTERISTICS:**

The CYPRESS clinical study (NCT03623074) is a multi-center, randomized, controlled, double-masked, parallel-group clinical trial designed to evaluate the safety and efficacy of DOT spectacle lenses vs. control lenses. Two hundred and fifty-six (256) myopic subjects aged 6 to 10 years at screening, who met criteria were randomized and dispensed lenses across 14 sites. The co-primary endpoint included change from baseline measures of axial length and cycloplegic autorefractation. Subjects are being followed for a total of 36 months, with pre-planned interim analyses at 12- and 24-months.

**24-Month Results:**

Subjects were 58% female with an average age of 8.1 years (SD ± 1.2 years) at screening. At baseline, the mean spherical equivalent refraction (SER) was -2.01 D (SD ± 0.9 D) using manifest refraction, mean cycloplegic autorefractation was -1.94 D (SD ± 1.0 D) and the mean axial length (AL) was 24.02 mm (SD ± 0.77 mm). The mean difference in SER progression for DOT 0.2 vs. control was 0.41 D (p<0.0001) representing a 47% reduction. The difference in AL progression for DOT 0.2 vs. control was 0.12 mm (p=0.0041). All measures of visual acuity were clinically stable and there were no adverse events related to the test lenses through Month 24.

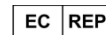
**LABELING:**

The following symbols are used on the DOT lens packaging.

Symbol	Definition
	Prescription only
	Manufactured by
	Authorized Representative
	CE Mark



SightGlass Vision, Inc.  
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LBL-C02-IFU-01 r9

# LBL-C02-IFU-01 DOT-20-XXX-YYY DOT 0.2 Spectacle Lenses (DOC-1377) Ver. 9

## Approved By:

[\(CO-565\) CO-565\\_LBL-C02-IFU-01 r9](#)

## Description

- Removed EU from title

## Justification

- IFU to serve as global IFU

<b>Assigned To:</b>	<b>Initiated By:</b>	<b>Priority:</b>	<b>Impact:</b>
Rachel McClaran	Rachel McClaran	Medium	Minor

## Version History:

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Rachel McClaran	October 29, 2021 10:22 AM PDT	<a href="#">CO-565</a>	9	Published
Rachel McClaran	August 30, 2021 8:03 AM PDT	<a href="#">CO-498</a>	8	Superseded
Rachel McClaran	April 15, 2021 10:33 AM PDT	<a href="#">CO-355</a>	7	Superseded
Rachel McClaran	March 23, 2021 3:21 PM PDT	<a href="#">CO-337</a>	6	Superseded
Rachel McClaran	February 11, 2021 3:05 PM PST	<a href="#">CO-295</a>	5	Superseded
Rachel McClaran	June 17, 2020 10:29 AM PDT	<a href="#">CO-157</a>	4	Superseded
Rachel McClaran	May 5, 2020 2:43 PM PDT	<a href="#">CO-110</a>	3	Superseded
Kaylee Zampardi	October 14, 2019 5:00 PM PDT	Not Available	2	Superseded
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