

**Unity BioSync (olifilcon B) with Tangible Polymers Spherical
Silicone Hydrogel Soft (hydrophilic) Contact Lenses
For Daily Wear
Professional Fitting and Information Guide**

**CAUTION : FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER
OF A LICENSED PRACTITIONER.**

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TABLE OF CONTENTS

INTRODUCTION1

PRODUCT DESCRIPTION1

LENS PARAMETERS AVAILABLE2

ACTIONS2

INDICATIONS3

CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, AND ADVERSE REACTIONS3

SELECTION OF PATIENTS.....3

GENERAL FITTING PROCEDURE.....3

1. Pre-Fitting Examination3

2. Initial Lens Power Selection4

3. Initial Base Curve Selection4

4. Initial Lens Evaluation.....4

5. Final lens Power Determination.....5

FOLLOW-UP CARE5

IN OFFICE CARE OF TRIAL LENSES.....6

RECOMMENDED WEARING SCHEDULE.....6

MONOVISION FITTING GUIDELINES6

HANDLING OF UNITY BIOSYNC SOFT CONTACT LENSES.....11

PATIENT LENS CARE DIRECTIONS11

CHEMICAL LENS DISINFECTION11

CARE FOR A DEHYDRATED LENS.....11

CARE FOR A STICKING LENS.....11

REPORTING OF ADVERSE REACTIONS.....11

HOW SUPPLIED12

PACKAGE INSERT13

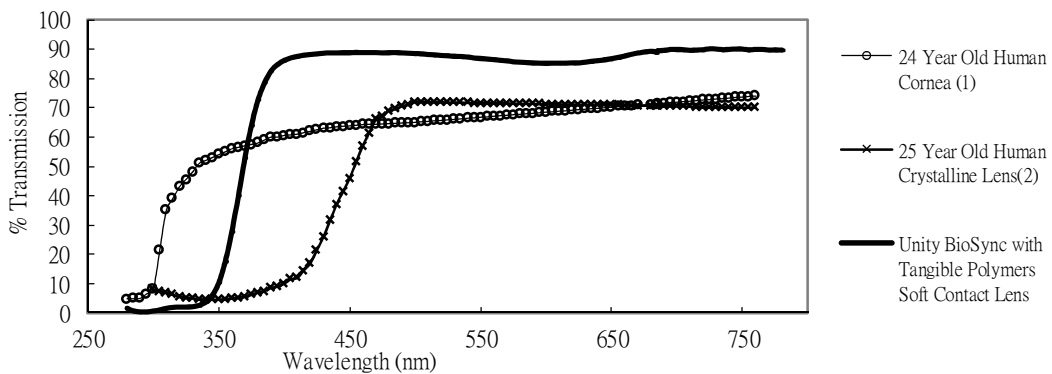
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INTRODUCTION

The Unity BioSync (olofilcon B) with Tangible Polymers Spherical silicone hydrogel soft (hydrophilic) contact lenses are made from a silicone hydrogel material containing 47% water and 53% olofilcon B. For a complete listing of available lens parameters, please refer to LENS PARAMATER AVAILABLE on page 2.

PRODUCT DESCRIPTION

Unity BioSync (olofilcon B) with Tangible Polymers Spherical Silicone Hydrogel Soft Contact Lenses are spherical contact lenses. The lens material contains a light blue color additive Reactive Blue Dye #19 for handling visibility and a benzotriazole UV absorbing monomer to block UV radiation. The UV transmission (the thinnest lens measured by spectrophotometry as stated in ISO 18369) is less than 50% in the UVA range of 316 - 380 nm and less than 5% in the range of UVB range of 280-315 nm.



* The data was obtained from measurements taken through the central 3~5 mm portion for the thinnest marketed lens (-3.00 D Unity BioSync with Tangible Polymers Silicone Hydrogel soft contact lens, 0.08 mm center thickness). The wavelength range is recorded at no more than 5nm increments.

1. Lerman, S., Radiant Energy and the Eye, MacMillan, New York, 1980, p. 58, figure 2-21
2. Waxler, M. Hitchins, V.M., Optical Radiation and Visual Health, CRC Press, Boca Raton, Florida, 1986, p.19, figure.

WARNING: UV-absorbing contact lenses are NOT substitutes for protective UV-absorbing eyewear such as UV-absorbing goggles or sunglasses because they do not completely cover the eye and surrounding area. You should continue to use UV-absorbing eyewear as directed.

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NOTE:

Long term exposure to UV radiation is one of the risk factors associated with cataracts.

Exposure is based on a number of factors such as environmental conditions (altitude, geography, cloud cover) and personal factors (extent and nature of outdoor activities). UV-absorbing contact lenses help provide protection against harmful UV radiation. However, clinical studies have not been done to demonstrate that wearing UV-absorbing contact lenses reduces the risk of developing cataracts or other eye disorders. Consult your eye-care practitioner for more information.

LENS PARAMETERS AVAILABLE

Unity BioSync (olifilcon B) with Tangible Polymers SPHERICAL Soft Contact Lenses characteristics:

- Diameter : 14.1 mm
- Base Curve : 8.8 mm
- Center Thickness : 0.08 mm for -3.00D (varies with power)
- Power : +8.00 to -10.00 D

The physical/optical properties of the lens are:

- Specific gravity : 1.069
- Refractive Index : 1.410
- Light Transmittance : 94%
- Surface Character : Hydrophilic
- Water Content : 47%
- Oxygen Permeability : 120×10^{-11} (cm²/sec)(mlO₂/ml x mmHg), (Polarographic method)

ACTIONS

The Unity BioSync (olifilcon B) with Tangible Polymers silicone hydrogel soft contact lens when placed on the cornea acts as a refracting medium to focus light rays on the retina. The UV transmission (the thinnest lens measured by spectrophotometry as stated in ISO 18369) is less than 50% in the UVA range of 316 - 380 nm and less than 5% in the range of UVB range of 280-315 nm. The radiation blockage of the lenses will increase for thicker lenses.

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INDICATIONS

The Unity BioSync (olofilcon B) with Tangible Polymers **Spherical** Silicone Hydrogel Soft Contact Lenses are indicated as daily wear single use soft contact lens for the correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who exhibit refractive astigmatism of 1.00D or less where the astigmatism does not interfere with visual acuity.

Eye care practitioners may prescribe the lens for daily wear (disposable use) single use. The lenses are to be discarded upon removal. Therefore, no cleaning or disinfecting is required.

CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, AND ADVERSE REACTIONS

See Package Insert.

SELECTION OF PATIENTS

The patient's need and characteristics necessary to fit with Unity BioSync (olofilcon B) with Tangible Polymers Silicone Hydrogel Soft Contact Lenses should be assessed. A thorough pre-fitting examination should be conducted to ensure the patient is a suitable candidate for soft contact lens wear. The following procedures should be followed when fitting Unity BioSync (olofilcon B) with Tangible Polymers Silicone Hydrogel Soft Contact Lenses.

GENERAL FITTING PROCEDURE

1. Pre-Fitting Examination

A pre-fitting patient history and examination are necessary to:

- Determine whether a patient is a suitable candidate for daily wear contact lens (consider patient hygiene and mental and physical)
- Make ocular measurement for initial contact lens parameter selection
- Collect and record baseline clinical information to which post-fitting examination result can be compared

A pre-fitting examination should include a case history, a spherocylindrical refraction, keratometric readings, tear assessment, and biomicroscopy of the anterior segment.

2. Initial Lens Power Selection

The initial power selection should be as close as possible to the patient's prescription after taking into account spherical equivalent and vertex calculations, if necessary. Remember to compensate for vertex distance if the refraction is greater than $\pm 4.00D$.

3. Initial Base Curve Selection

A well-fitted lens provides good movement, centration and comfort. The following trial lens should be selected regardless of keratometry readings. However, corneal curvature measurements should be performed to establish the patient's baseline ocular status.

- **Unity BioSync (olofilcon B) with Tangible Polymers Spherical silicone hydrogel soft contact lens: 8.8 mm/14.1 mm**

4. Initial Lens Evaluation

• Criteria of a Well Fitted Lens:

A well-fit Unity BioSync (olofilcon B) with Tangible Polymers Silicone Hydrogel Soft Contact Lenses best satisfies the following criteria:

- Full corneal coverage.
- Good centration (concentric about the visible iris).
- Satisfactory lens sag (in up gaze 0.10 to 1.00mm is ideal) with the blink.
- The lens moves freely when manipulated with digital pressure against the lower lid.
- Satisfactory comfort response by the patient.
- Satisfactory vision response by the patient.

• Characteristics of a Tight (Steep) Lens:

A tight or steep fit may provide insufficient or no lens movement during a blink in primary or up gaze, resist movement if nudged upward with the index finger and/or cause fluctuating vision between blinks. **If the contact lens is deemed to be steep fitting, do not dispense to the patient.** A flatter lens (larger base curve) should be evaluated if available.

• Characteristics of a Loose (Flat) Lens:

A loose or flat fit may exhibit reduced comfort, decentration, and excessive movement during the blink or in primary up gaze, and/or edge standoff. **If the contact lens is deemed to be flat fitting, do not dispense to the patient.** A steeper lens (smaller base curve) should be evaluated if available.

5. Final lens Power Determination**FOLLOW-UP CARE**

1. Follow-up examinations, as recommended by the eye care practitioner, are necessary to ensure continued successful contact lens wear.
2. Prior to a follow-up examination, the contact lenses should be worn for at least four continuous hours and the patient should be asked to identify any problems which might be occurring related to contact lens wear.
3. With lenses in place on the eyes, evaluate fitting performance to assure that CRITERIA OF A WELL FITTED LENS continue to be satisfied. Examine the lenses closely for surface deposition and/or damage.
4. After the lens removal, conduct a thorough biomicroscopy examination.
 - The presence of vertical corneal striae in the posterior central cornea and/or corneal neovascularization is indicative of excessive corneal edema.
 - The presence of corneal staining and/or limbal-conjunctival hyperemia can be indicative of an unclean lens, a reaction to solution preservatives, excessive lens wear, and/or a poorly fitting lens.
 - Papillary conjunctival changes may be indicative of an unclean and/or damaged lens,

If any of the above observations are judged abnormal, various professional judgments are necessary to alleviate the problem and restore the eye to optimal conditions. If the CRITERIA OF A WELL FITTED LENS are not satisfied during any follow-up examination, the patient should be re-fitted with a more appropriate lens.

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IN OFFICE CARE OF TRIAL LENSES

Eye care practitioners should educate contact lens technicians concerning proper use of trial lenses.

Each contact lens is shipped sterile in a sealed blister pack containing borate buffered saline. Hands should be thoroughly washed and rinsed and dried with a lint free towel prior to handling a lens. In order to insure sterility, the vial should not be opened until immediately prior to use.

For fitting and diagnostic purposes, the **lenses should be disposed of after a single use and not be re-used from patient to patient.**

RECOMMENDED WEARING SCHEDULE

Although many practitioners have developed their own initial wearing schedule, the following sequence is recommended as a guideline. Patients should be cautioned to carefully follow the wearing schedule recommended by the eye care practitioner regardless of how comfortable the lenses feel.

Table with 2 columns: Day, Wearing Time (Hours). Rows: 1 (6), 2 (8), 3 (10), 4 and after (all waking hours or according to practitioner recommendation)

MONOVISION FITTING GUIDELINES

1. Patient Selection

A. Monovision Needs Assessment

For a good prognosis the patient should have adequately corrected distance and near visual acuity in each eye. The amblyopic patient or the patient with significant astigmatism (greater than -1.50 diopters) in one eye may not be a good candidate for monovision with the Unity BioSync (olifilcon B) with Tangible Polymers Silicone Hydrogel Soft (hydrophilic) Contact Lenses.

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Occupational and environment visual demands should be considered. If the patient requires critical vision (visual acuity and stereopsis) it should be determined by trial whether this patient can function adequately with monovision. Monovision contact lens wear may not be optimal for such activities as:

- (1) Visually demanding situations such as operating potentially dangerous machinery or performing other potential hazardous activities; and
- (2) Driving automobiles (eg. driving at night). Patients who cannot pass their state driver’s license requirements with monovision correction should be advised not to drive with this correction, or may require that additional over-correction be prescribed.

B. Patient Education

All patients do not function equally well with monovision correction. Patients may not perform as well for certain tasks with this correction as they have with bifocal reading glasses. Each patient should understand that monovision, as well as other presbyopic contact lenses, or other alternative, can create a vision compromise that may reduce visual acuity and depth perception for distance and near tasks. During the fitting process it is necessary for the patient to realize the disadvantages as well as the advantages of clear near vision in straight ahead and upward gaze that monovision contact lenses provide.

2. Eye Selection

Generally, the non-dominant eye is corrected for near vision. The following test for eye dominance can be used.

A. Ocular Preference Determination Methods

Method 1 – Determine which eye is the “sight eye”. Have the patient point to an object at the far end of the room. Cover one eye. If the patient is still pointing directly at the object, the eye being used is the dominant (sighting) eye.

Method 2 – Determine which eye will accept the added power with the least reduction in vision. Place a trial spectacle near add lens in front of one eye and then the other while the distance refractive error correction is in place for both eyes. Determine whether the patient functions best with the near add lens over the right or left eye.

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B. Refractive Error Method

For anisometropic corrections, it is generally best to fit the more hyperopic (less myopic) eye for distance and the more myopic (less hyperopic) eye for near.

C. Visual Demands Method

Consider the patient's occupation during the eye selection process to determine the critical vision requirements. If a patient's gaze for near tasks is usually in one direction correct the eye on that side of near.

Example:

A secretary who places copy to the left side of the desk will usually function best with the near lens on the left eye.

3. Special Fitting Consideration

Unilateral Lens Correction:

There are circumstances where only one contact lens is required. As an example, an emmetropic patient would only require a near lens while a bilateral myope may require only a distance lens.

Example:

A presbyopic patient who requires a +1.75 diopters add would have a +1.75 lens on the near eye and the other eye left without a lens.

A presbyopic patient requiring a +1.50 diopters add who is -2.50 diopters myopic in the right eye and -1.50 diopters myopic in the left eye may have the right eye corrected for distance and the left uncorrected for near.

4. Near Add Determination

Always prescribe the lens power for the near eye that provides optimal near acuity at the midpoint of the patient's habitual reading distance. However, when more than one power provides optimal reading performance, prescribe the least plus (most minus) of the powers.

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5. Trial Lens Fitting

A trial fitting is performed in the office to allow the patient to experience monovision correction. Lenses are fit according to the directions in the general fitting guidelines and base curve selection described earlier in the guide.

Case history and standard clinical evaluation procedure should be used to determine the prognosis. Determine which eye is to be corrected for distance and which eye is to be corrected for near. Next determine the near add. With trial lenses of the proper power in place observe the reaction to this mode of correction.

Immediately after the correct power lenses are in place, walk across the room and have the patient look at you. Assess the patient's reaction to distance vision under these circumstances. Then have the patient look at familiar near objects such as a watch face or fingernails. Again assess the reaction. As the patient continues to look around the room at both near and distance objects, observe the reactions. Only after these vision tasks are completed should the patient be asked to read print. Evaluate the patient's reaction to large print (eg. typewritten copy) at first and then graduate to news print and finally smaller type sizes.

After the patient's performance under the above conditions is completed, tests of visual acuity and reading ability under conditions of moderately dim illumination should be attempted.

An initial unfavorable response in the office, while indicative of a guarded prognosis, should not immediately rule out a more extensive trial under the usual conditions in which a patient functions.

6. Adaptation

Visually demanding situations should be avoided during the initial wearing period. A patient may at first experience some mild blurred vision, dizziness, headaches, and a feeling of slight imbalance. You should explain the adaptation symptoms to the patient. These symptoms may last for a brief minute or for several weeks. The longer these symptoms persist, the poorer the prognosis for successful adaptation.

To help in the adaptation process the patient can be advised to first use the lenses in a comfortable familiar environment such as in the home.

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Some patients feel that automobile driving performance may not be optimal during the adaptation process. This is particularly true when driving at night. Before driving a motor vehicle, it may be recommended that the patient be a passenger first to make sure that their vision is satisfactory for operating an automobile. During the first several weeks of wear (when adaptation is occurring), it may be advisable for the patient to only drive during optimal driving conditions. After adaptation and success with these activities, the patient should be able to drive under other conditions with caution.

7. Other suggestions

The success of monovision technique may be further improved by having your patient follow the suggestions below:

- Having a third contact lens (distance power) to use when critical distance viewing is needed.
- Having a third contact lens (near power) to use when critical near viewing is needed.
- Having supplemental spectacles to wear over the monovision contact lenses for specific visual tasks may improve the success of monovision correction. This is particularly applicable for those patients who cannot meet state licensing requirements with a monovision correction.
- Make sure of proper illumination when carrying out visual tasks.

Success in fitting monovision can be improved by the following suggestions:

- Reverse the distance and near eyes if a patient is having trouble adapting.
- Refine the lens powers if there is trouble with adaptation. Accurate lens power is critical for presbyopic patients.
- Emphasize the benefits of the clear near vision in straight ahead and upward gaze with monovision.

The decision to fit a patient with a monovision correction is most appropriately left to the eye care practitioner in conjunction with the patient after carefully considering the patient's needs.

All patients should be supplied with a copy of the Unity BioSync (olifilcon B) with Tangible Polymers silicone hydrogel soft contact lenses Patient Instruction.

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HANDLING OF UNITY BIOSYNC SOFT CONTACT LENSES

Wash and rinse hands thoroughly, making certain all soap residues have been rinsed away before drying with a lint-free towel. It is suggested to wet the lens while in the eye using lubricating and rewetting drops before removal of the lens. Care should be used not to pinch the lens when removing it from the eye. Pinching the lens can reduce the life of the lens.

Always start with the right lens first in order to avoid mixing the lenses. In removing the lenses, try to avoid touching the inside (concave) surface of the lens. It is possible, though not likely, that the lens might be inside out; therefore, check the lens by placing it on the index finger and examine its profile. If the edges of the lens tend to point outward, the lens is inside out. After removing the lens from its container assure that it is clean, clear and wet.

PATIENT LENS CARE DIRECTIONS

Please see package insert.

CHEMICAL LENS DISINFECTION

Please see package insert.

CARE FOR A DEHYDRATED LENS

Please see package insert.

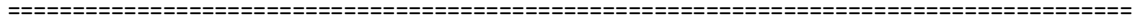
CARE FOR A STICKING LENS

Please see package insert

REPORTING OF ADVERSE REACTIONS

All serious adverse experiences and adverse reactions observed in patients wearing UNITY BIOSYNC Soft Contact Lens or experienced with the lenses should be reported to:

Distributed By Name Plexus Optix Inc.
Address 3333 Quality Drive, Rancho Cordova, CA 95670
Phone No 1 (800) 245-6414



HOW SUPPLIED

Each lens is supplied sterile in a blister pack containing borate buffered isotonic saline solution. The blister is labeled with the base curve, diameter, sphere power, UV absorber, lot number and expiration date.

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DO NOT USE IF THE BLISTER PACKS IS BROKEN OR THE SEAL HAS DAMAGED.

PACKAGE INSERT

IMPORTANT

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

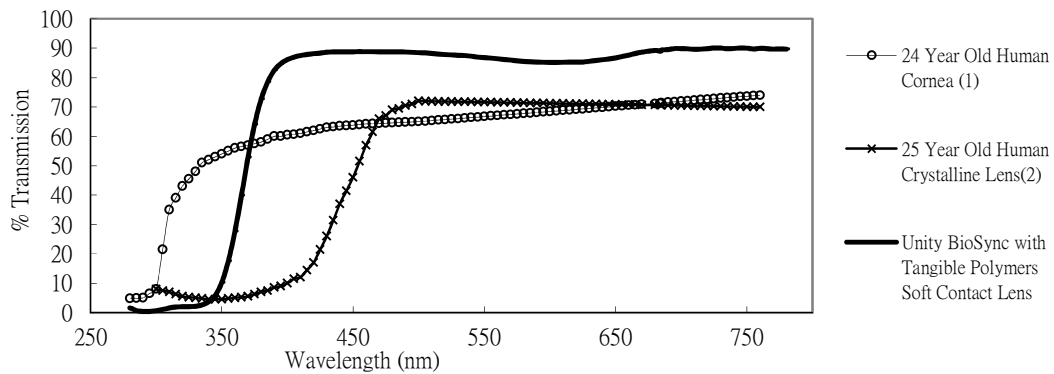
CAUTION : FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A LICENSED PRACTITIONER.

**Unity BioSync (olofilcon B) with Tangible Polymers Silicone Hydrogel Soft (hydrophilic)
Contact Lens
for Not-aphakic/Aphakic
to correct refractive ametropia (Spherical)**

PRODUCT DESCRIPTION

Unity BioSync (olofilcon B) with Tangible Polymers Spherical Silicone Hydrogel Soft Contact Lenses are spherical lenses. The lens material (olofilcon B), silicone hydrogel, is a copolymer of NVP and Siloxan macromer. Lens contain color additive Reactive Blue Dye #19, a light blue handling tint, which makes lens more visible and assists in handling. A benzotriazole UV absorbing monomer is added to block UV radiation. The UV transmission (the thinnest lens measured by spectrophotometry as stated in ISO 18369) is less than 50% in the UVA range of 316 - 380 nm and less than 5% in the range of UVB range of 280-315 nm.

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* The data was obtained from measurements taken through the central 3~5 mm portion for the thinnest marketed lens (-3.00 D Unity BioSync (olifilcon B) with Tangible Polymers silicone hydrogel soft contact lens, 0.08 mm center thickness). The wavelength range is recorded at no more than 5nm increments.

1. Lerman, S., *Radiant Energy and the Eye*, MacMillan, New York, 1980, p. 58, figure 2-21
2. Waxler, M. Hitchins, V.M., *Optical Radiation and Visual Health*, CRC Press, Boca Raton, Florida, 1986, p.19, figure.

WARNING: UV-absorbing contact lenses are NOT substitutes for protective UV-absorbing eyewear such as UV-absorbing goggles or sunglasses because they do not completely cover the eye and surrounding area. You should continue to use UV-absorbing eyewear as directed.

NOTE:

Long term exposure to UV radiation is one of the risk factors associated with cataracts.

Exposure is based on a number of factors such as environmental conditions (altitude, geography, cloud cover) and personal factors (extent and nature of outdoor activities). UV-absorbing contact lenses help provide protection against harmful UV radiation. However, clinical studies have not been done to demonstrate that wearing UV-absorbing contact lenses reduces the risk of developing cataracts or other eye disorders. Consult your eye-care practitioner for more information.

LENS PARAMETERS AVAILABLE

Unity BioSync (olifilcon B) with Tangible Polymers Silicone Hydrogel Soft (hydrophilic) Contact Lenses characteristics is summarized as follow:

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Unity BioSync (olifilcon B) with Tangible Polymers SPHERICAL Soft Contact Lenses characteristics:

- Diameter : 14.1 mm
- Base Curve : 8.8 mm
- Center Thickness : 0.08 mm for -3.00D (varies with power)
- Power : +8.00 to -10.00 D

The physical/optical properties of the lens are:

- Specific gravity : 1.069
- Refractive Index : 1.410
- Light Transmittance : 94%
- Surface Character : Hydrophilic
- Water Content : 47%
- Oxygen Permeability : 120×10^{-11} (cm²/sec)(mlO₂/ml x mmHg), (Polarographic method)

ACTIONS

The Unity BioSync (olifilcon B) with Tangible Polymers Silicone Hydrogel Soft Contact Lens when placed on the cornea acts as a refracting medium to focus light rays on the retina. The UV transmission (the thinnest lens measured by spectrophotometry as stated in ISO 18369) is less than 50% in the UVA range of 316 - 380 nm and less than 5% in the range of UVB range of 280-315 nm. The radiation blockage of the lenses will increase for thicker lenses.

INDICATIONS (USES)

The Unity BioSync (olifilcon B) with Tangible Polymers **Spherical** Silicone Hydrogel Soft Contact Lenses are indicated as daily wear single use soft contact lens for the correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who exhibit refractive astigmatism of 1.00D or less where the astigmatism does not interfere with visual acuity.

Eye care practitioners may prescribe the lens for daily wear (disposable use) single use. The lenses are to be discarded upon removal. Therefore, no cleaning or disinfecting is required.

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CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE Unity BioSync (olofilcon B) with Tangible Polymers Silicone Hydrogel Soft Contact Lenses when any of the following conditions exists:

- Acute or subacute inflammation or infection of the anterior chamber of the eye
- Any eye disease, injury or abnormality that affect the cornea, conjunctiva, or eyelids
- Severe insufficiency of lacrimal secretion (dry eye)
- Corneal hypoesthesia (reduced corneal sensitivity), if not-aphakic
- Any systemic disease that may affect the eye or be exacerbated by wearing contact lens
- Allergic reactions of ocular surface or adnexa that may be induced or exaggerated by the wearing contact lenses or use of contact lens solutions
- Allergy to any ingredient, such as mercury or Thimerosal, in a solution which is to be used to care for the UNITY BIOSYNC Soft Contact Lens
- Any active corneal infection (bacterial, fungal, or viral)
- If eye become red or irritated

WARNINGS

PROBLEMS WITH CONTACT LENSES AND LENS CARE PRODUCTS COULD RESULT IN SERIOUS INJURY TO THE EYE.

It is essential that the patient follows the directions of the eye care practitioner and all labeling instructions for proper use of contact lenses.

Patients should be advised of the following instructions for use and warnings pertaining to contact lens wear:

Water Activity

Instruction for Use:

- Do not expose the contact lenses to water while wearing them.

WARNING:

Water can harbor microorganisms that can lead to severe infection, vision loss or blindness. If the lenses have been submersed in water when swimming in pools, lakes or oceans, they should be discarded and replaced with a new pair. Ask eye care practitioner (professional) for recommendations about wearing the lenses during any activity involving water.

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EYE PROBLEMS, INCLUDING CORNEAL ULCERS, CAN DEVELOP RAPIDLY AND LEAD TO LOSS OF VISION; IF EXPERIENCE:

- **Eye Discomfort,**
- **Excessive Tearing,**
- **Vision Changes,**
- **Loss of Vision,**
- **Eye Redness,**
- **Or Other Eye Problems**

PATIENTS SHOULD BE INSTRUCTED TO IMMEDIATELY REMOVE THE LENSES, AND PROMPTLY CONTACT EYE CARE PRACTITIONER.

- Daily wear lenses are not indicated for overnight wear, and patients should be instructed not to wear lenses while sleeping. Clinical studies have shown that the risk of serious adverse reactions is increased when these lenses are worn overnight.
- Studies have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than nonsmokers.

<http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm223663.htm>

PRECAUTIONS

Special Precautions for Eye care Practitioners;

- Due to the small number of patients enrolled in clinical investigation of lenses, all refractive powers, design configurations, or lens parameters available in the lens material are not evaluated in significant numbers. Consequently, when selecting an appropriate lens design and parameters, the eye care practitioners should consider all characteristics of the lens that can affect lens performance and ocular health, including oxygen permeability, wettability, central and peripheral thickness, and optic zone diameter.
- The potential impact of these factors on the patient's ocular health should be carefully weighed against the patient's need for refractive correction; therefore, the continuing ocular health of the patient and lens performance on the eye should be carefully monitored by the prescribing eye care practitioner.
- Aphakic patients should not be fitted with Unity BioSync (olifilcon B) with Tangible Polymers silicone hydrogel soft contact lenses until the determination is made that the eye

Package Insert

has healed completely.

- Fluorescein, a yellow dye, should not be used while the lenses are on the eyes. The lenses absorb this dye and become discolored. Whenever fluorescein is used in eyes, the eyes should be flushed with a sterile saline solution that is recommended for in-eye use.
- Before leaving the eye care practitioner's office, the patient should be able to promptly remove lenses or should have someone else available who can remove the lenses for him or her.
- Eye care practitioners should instruct the patient to **remove the lenses immediately if the eye becomes red or irritated.**

Unity BioSync (olofilcon B) with Tangible Polymers silicone hydrogel soft contact lenses are daily wear single use lenses, the lenses should be discarded after each use.

- If the lens sticks (stops moving) on the eye, follow the recommended directions on Care for a Sticking lens. The lens should move freely on the eye for the continued health of the eye. If non-movement of the lens continues, the patient should be instructed to immediately consult his or her eye care practitioner.
- Always wash and rinse hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, deodorants, or sprays in the eyes or on the lenses. It is best to put on lenses before putting on makeup. Water-base cosmetics are less likely to damage lenses than oil-base products.
- Do not touch contact lenses with the fingers or hands if the hands are not free of foreign materials, as microscopic scratches of the lenses may occur, causing distorted vision and/or injury to the eye.
- Carefully follow the handling, insertion, removal, and wearing instructions in the Patient Instructions for the Unity BioSync (olofilcon B) with Tangible Polymers Silicone Hydrogel Soft Contact Lens prescribed by the eye care practitioner.
- Never wear lenses beyond the period recommended by the eye care practitioner.
- If aerosol products such as hair spray are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.
- Always handle lenses carefully and avoid dropping them.
- Avoid all harmful or irritating vapors and fumes while wearing lenses.
- Ask the eye care practitioner about wearing lenses during sporting activities.
- Inform the doctor (health care practitioner) about being a contact lens wearer.
- Never use tweezers or other tools to remove lenses from the lens container unless specifically indicated for that use. Pour the lens into the hand.

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- Do not touch the lens with fingernails.
- Always contact the eye care practitioner before using any medicine in the eyes.
- Always inform the employer of being a contact lens wearer. Some jobs may require use of eye protection equipment or may require that the patient not wear contact lenses.
- As with any contact lens, follow-up visits are necessary to assure the continuing health of the patient's eyes. The patient should be instructed as to a recommend follow-up schedule.

ADVERSE REACTIONS

The patient should be informed that the following problems may occur:

- Eyes stinging, burning, itching (irritation), or other eye pain
- Comfort is less than when lens was first placed on eye
- Feeling that something is in the eye such as a foreign body or scratched area
- Excessive watering (tearing) of the eyes
- Unusual eye secretions
- Redness of the eyes
- Reduced sharpness of vision (poor visual acuity)
- Blurred vision, rainbows, halos around objects
- Sensitivity to light (photophobia)
- Dry eyes

If the patient notices any of above, he or she should be instructed to:

- **Immediately remove lenses.**
- If the discomfort or problem stops, then look closely at the lens. If the lens is in any way damaged, DO NOT put the lens back on the eye. Discard the lens and contact the eye care practitioner.
- If the lens has dirt, an eyelash, or foreign body on it, or the problem stops and the lens appears undamaged, the patient should discard the lens upon removal and replace it with a new one.

When any of the above problems occur, a serious condition such as infection, corneal ulcer, neovascularization, or iritis may be present. The patient should be instructed to **keep lens off the eye and seek immediate** professional identification of the problem and prompt treatment to avoid serious eye damage.

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FITTING

Conventional methods of fitting contact lenses apply to Unity BioSync (olifilcon B) with Tangible Polymers Silicone Hydrogel Soft Contact Lens. For a detailed description of the fitting techniques, refer to the Unity BioSync (olifilcon B) with Tangible Polymers Silicone Hydrogel Soft Contact Lens Professional Fitting and Information Guide, copies of which are available from:

Plexus Optix Inc.
3333 Quality Drive
Rancho Cordova, CA 95670
(800) 245-6414
www.unitycontactlenses.com

LENS WEAR SCHEDULE

The wearing schedule should be determined by the eye care practitioner. Patients tend to over wear the lenses initially. The eye care practitioner should emphasize the importance of adhering to initial maximum wearing schedule. Regular checkups, as determined by the eye care practitioner, are also extremely important.

VISCO VISION INC. recommends that the lens be discarded upon removal. The patient should have a spare pair of lenses with him or her at all times.

CARE FOR A DRIED OUT (DEHYDRATED) LENS

If any Unity BioSync (olifilcon B) with Tangible Polymers Silicone Hydrogel Soft Contact Lens is exposed to air for 15 minutes while off the eye, it may become dry and brittle. Please discard the dehydrated lens and use a fresh new one.

CARE FOR A STICKING LENS

If the lens sticks (stops moving), the patient should be instructed to apply 2 to 3 drops of the recommended lubricating or rewetting solution directly to the eye and wait until the lens begins to move freely on the eye before removing it. If non-movement of the lens continues after 5 minutes, the patient should immediately consult the eye care practitioner.

Package Insert

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EMERGENCIES

The patient should be informed that if chemicals of any kind (household products, gardening solution, laboratory chemicals, etc.) are splashed into the eyes, the patient should: **Flush eyes with tap water and immediately contact the eye care practitioner or visit a hospital emergency room without delay.**

HOW SUPPLIED

Each lens is supplied sterile in a blister pack containing borate buffered isotonic saline solution. The blister is labeled with the base curve, diameter, sphere power (spherical lens), UV absorber, lot number and expiration date.

DO NOT USE IF THE BLISTER PACKS IS BROKEN OR THE SEAL HAS DAMAGED.

REPORTING OF ADVERSE REACTIONS

All serious adverse experiences and adverse reactions observed in patients wearing Unity BioSync (olifilcon B) with Tangible Polymers Silicone Hydrogel Soft Contact Lens or experienced with the lenses should be reported to:

Distributed By	Name	Plexus Optix Inc.
	Address	3333 Quality Drive, Rancho Cordova, CA 95670
	Phone No	1 (800) 245-6414

Print Date: -