Vexillum (olifilcon B) with Tangible Polymers Spherical

Vexillum (olifilcon B) with Tangible Polymers Toric

Vexillum (olifilcon B) with Tangible Polymers Multifocal

Silicone Hydrogel Soft (Hydrophilic) Contact Lenses

For Daily Wear

Patient Instructions

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

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INTRODUCTION

The Vexillum (olifilcon B) with Tangible Polymers Spherical, Vexillum (olifilcon B) with Tangible Polymers Toric, Vexillum (olifilcon B) with Tangible Polymers Multifocal silicone hydrogel soft (Hydrophilic) contact lenses are daily wear single use contact lenses. Once removed, they are to be discarded. They are not intended to be cleaned and disinfected. You should always carry a spare pair of lenses or glasses with them.

They are different from the rigid contact as they are more soft and flexible. The lens material contains a light blue color additive Reactive Blue Dye #19 and a benzotriazole UV absorbing monomer to block UV radiation. The light blue color makes it more visible. When Vexillum (olifilcon B) with Tangible Polymers Silicone Hydrogel Soft (hydrophilic) Contact Lens placed on the cornea, it acts as a refracting medium to focus light rays on the retina. It may block UV light (class II UV protection) but cannot protect eyes as the UV protection Equipment.

The information and instructions apply only to Vexillum (olifilcon B) with Tangible Polymers silicone hydrogel soft (Hydrophilic) contact lens. For your eye health, it is important to wear your lenses as prescribed by your eye care practitioner. It is also important to keep your eye care practitioner fully aware of your medical history. Your eye care practitioner will tailor a total program of care based on your specific needs.

He or she will review with you all instructions for lens handling, including how to safely and easily open the package. You will receive instruction how to properly insert and remove lenses. This booklet will emphasize those instructions. Discard and replace your contact lenses with a new sterile pair, as prescribed by your eye care practitioner.

WEARING RESTRICTIONS AND INDICATIONS

Vexillum (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.

Vexillum (olifilcon B) with Tangible Polymers **Toric** Silicone Hydrogel Soft Contact Lenses are indicated as daily wear for the correction of ametropia (myopia and hyperopia) with astigmatism in aphakic and non-aphakic persons with non-diseased eyes and whose powers are from -20.00 to

+20.00 diopters and astigmatic corrections are from -0.75 to -2.25 diopters.

Vexillum (olifilcon B) with Tangible Polymers **Multifocal** Silicone Hydrogel Soft Contact lenses are indicated as daily wear for the correction of ametropia (myopia and hyperopia) and emmetropia with presbyopia in aphakic and non-aphakic persons with non-diseased eyes and whose powers are from -20.00 to +20.00 diopters with add powers from +0.75 to +2.75 diopters. The lenses may be worn by persons who exhibit astigmatism of 1.00 diopters 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.

DO NOT WEAR YOUR Vexillum (olifilcon B) with Tangible Polymers SILICONE HYDROGEL SOFT CONTACT LENSES WHILE SLEEPING.

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 activites). 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.

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE Vexillum (olifilcon 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 abnormity 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 exacerbated by wearing contact lens
- Allergic reactions of ocular surface or adnexa that may be induced or exaggerated by the wearing of contact lenses or use of contact lens solutions
- Allergy to any ingredient, such as mercury or Thimerosal, in a solution which is be used to care for Vexillum (olifilcon B) with Tangible Polymers with Tangible Polymers Silicone Hydrogel Soft Contact Lens
- Any active corneal infection (bacterial, fugal, or viral)
- If eye become red or irritated

WARNINGS

PROBLEMS WITH CONTACT LENSES COULD RESULT IN SERIOUS INJURY TO THE EYE.

It is essential that you follow the directions of the eye care practitioner and all labeling instructions for proper use of contact lenses. You should be advised of the following instructions for use and warnings pertaining to contact lens wear:

Water Activity

Instruction for Use:

- Do not expose your contact lenses to water while you are wearing them.

WARNING:

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

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

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

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

- Daily wear lenses are not indicated for overnight wear, and you 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/guidancedocments/ucm223663.htm

PRECAUTIONS

Eye care practitioners should carefully instruct you about the following safety precautions. If the lens is prescribed for disposable use only, you should always discard the lens upon removal, and never place it in the storage case.

- Do not use saliva or anything other than the recommended solutions for lubricating or wetting lenses.
- 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, you should be instructed to **immediately** consult your 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 you Instructions for Vexillum (olifilcon B) with Tangible Polymers Silicone Hydrogel Soft Contact Lens and those 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.
- 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.
- Do not touch the lens with fingernails.
- Inform the doctor (health care practitioner) about being a contact lens wearer.
- 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 you not wear contact lenses.
- As with any contact lens, follow-up visits are necessary to assure the continuing health of your eyes. You should be instructed as to a recommend follow-up schedule.

ADVERSE REACTIONS (PROBLEM AND WHAT TO DO)

You should be informed that the following problems may occur:

- Eyes staining, 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 you notice 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 if your lens is prescribed for daily disposable lens.
- If your lens has dirt, an eyelash, or foreign body on it, or the problem stops and the lens appears undamaged, you should discard the lens upon removal and replace it with a new one.
- If the lens is prescribed for disposable use only, you should always discard the lens upon

removal, and never place it in the storage case.

When any of the above problems occur, a serious condition such as infection, corneal ulcer, neovascularization, or iritis may be present. You 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.

PERSONAL CLEANING FOR LENS HANDLING

1. **Preparing the Lens for Wearing**

   It is essential that you learn and use good hygienic methods in the care and handling of your new lenses. Cleanliness is the first and most important aspect of proper contact lens care. In particular, your hands should be clean and free of any foreign substances when you handle your lenses. The procedures are:

   - Always wash your hands thoroughly with a mild soap, rinse completely, and dry with a lint-free towel before touching your lenses.
   - Avoid the use of soaps containing cold cream, lotion, or oily cosmetics before handling your lenses, since these substances may come into contact with the lenses and interfere with successful wearing.
   - Handle your lenses with your fingertips, and be careful to avoid touching the lens with fingernails. It is helpful to keep your fingernails short and smooth.

   Start off correctly by getting into the habit of always use proper hygienic procedures so that they become automatic.

2. **Opening the lens package**

   The lens packages are individual and maintains sterilely.

   - Shake the lens package first and confirm that the lens is floating in the solution.
   - Tear off the foil closure. To avoid splash, you can stabilize the package on the table then tear off.

   A lens may adhere to the inside surface of the foil, or to the plastic package sometimes. There is no effect about the sterility of the lens and still safe to use. Follow the handling instructions removing and inspecting the lens carefully.

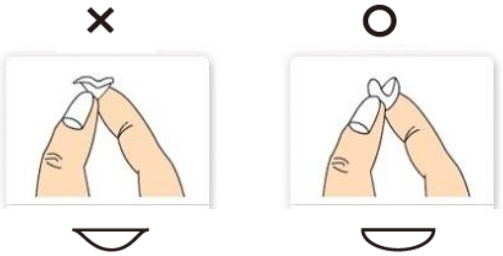
3. **Handling the Lenses**

   - Develop the habit of always working with the same lens first to avoid mixups.

- Remove the lens from its storage cases and examine it to be sure that it is moist, clean, and free of any nicks or tears.

Verify that the lens is not turned inside out by placing it on your forefinger and checking its profile. The lens should appear a natural, curved, bowl-like shape (Right). If the lens edges tend to point outward, the lens is inside out (Left). Another method is to squeeze the lens between the thumb and forefinger gently. The lens will turn to the correct orientation.

4. **Placing the Lens on the Eye**



Start with your right eye.

Once you have opened the lens package, removed and examined the lens, apply the lens to your eye as following steps:

A. Clean your hands throughout.
B. Place the lens on the tip of your forefinger. **Make sure the lens is correctly oriented.**
C. Place the middle finger of the same hand and pull down the lower lid.
D. Use the forefinger or middle finger of the other hand to lift the upper lid.
E. Place the lens on the eye.
F. Release the lids gently and blink. The lens will center automatically.
G. Place the lens on your left eye by the same technique.

There are some other methods of lens wearing. If the above method is difficult for you, please consult your eye care practitioner for alternative methods.

Note: If after placement of the lens, your vision is blurred, check for the following:

- The lens is not centered on the eye (see “centering the Lens” next in this booklet).
- If the lens is centered, remove the lens (see “Removing the Lens” section) and check for the following:
  a. Cosmetics or oils on the lens. Discard the lens and replace a new one.
  b. The lens is on the wrong eye.
  c. The lens is inside out (it would also not be as comfortable as normal).

If your vision is still blurred after checking the above possibilities, remove both lenses and consult your eye care practitioner.

After applied your lenses successfully, you should ask yourself:

- How do the lenses feel in my eye?
- How do my eyes look?
- Do I see well?

If any problems discover, remove your lenses immediately and contact your eye care practitioner.

5. Centering the Lens

Very rarely, a lens that is on the cornea will be displaced onto the white part of the eye during wear. This can also occur during placement and removal of the lens if the correct techniques are not performed properly. To center a lens as follow one of the procedures below.

a. Close your eyelids and gently massage the lens into place through the closed lids.
b. Use finger pressure on the edge of the upper lid or lower lid and gently manipulate the off-centered lens onto the cornea while the eye is open.

6. Removing the Lens

Caution: Always be sure the lens is on the cornea before attempting to remove it. This could be determined by covering the other eye. If vision is blurred, the lens is either on the white part of the eye or not on the eye at all. To locate the lens, inspect the upper area of the eye by looking down into a mirror while pulling the upper lid up. Then, inspect the lower area by pulling the lower lid down.

- Always work with the same side lens first.
- Wash, rinse, and dry your hands thoroughly.

There are two techniques for removing lens: Pinch Method or Forefinger and Thumb Method. Simply follow the procedures recommended by the eye care practitioner.

- Pinch Method
    a. Look up; slide the lens to the lower part of the eye using the forefinger.
    b. Pinch the lens between the thumb and forefinger gently.

c. Remove the lens.

- Thumb Method
  a. Place your hand or a towel under your eye to catch the lens.
  b. Place your forefinger on the center of the upper lid and your thumb on the center of the lower lid.
  c. Press in and force a blink. The lens should fall onto your hand or a towel.
  d. Once you remove the lens, follow the lens care directions recommended by the eye care practitioner immediately.
- Remove the other lens by following the same procedure.

Note: If these methods described above are difficult for you, please consult your eye care practitioner will provide you with an alternative method.

CARING FOR YOUR LENS

You who are prescribed daily disposable lenses should have a spare pair of lenses with you at all times.

1. Basic Instructions:

If you require only vision correction, but will not or unable to place and remove lenses or have someone available to place and remove them, you should not attempt to get and wear contact lenses.

When you first get your lenses, be sure you have to put the lenses on and remove them while you are in your eye care practitioner's office. Your eye care practitioner should instruct you about appropriate and adequate procedures for your use, and provide you with a copy of the Patient Instructions for Vexillum (olifilcon B) with Tangible Polymers silicone hydrogel soft contact lens.

For safe contact lens wear, you should know how to care contact lenses.

- Always wash, rinse and dry hands before handling contact lenses.
- Do not use saliva or anything other than the recommended solutions for lubricating or rewetting your lenses. Do not put lenses in your mouth.
- Never rinse your lenses in water from the tap. There are two reasons for this:
  a. Tap water contains many impurities that can contaminate or damage your lenses and may lead to eye infection or injury.

b. You might lose the lens down the drain.

- Your eye care practitioner may recommend a lubricating/rewetting solution for your use. Lubricating/Rewetting solutions can be used to wet (lubricate) your lenses while you are wearing them to make them more comfortable.

2. Care for a sticking (Nonmoving) lens:

If the lens sticks (stops moving), apply 2 to 3 drops of the recommended lubricating or rewetting solution directly to your eye and wait until the lens begins to move freely on your eye before moving it. If none-movement of the lens continues after 5 minutes, IMMEDIATELY consult your eye care practitioner.

3. **Emergencies**

If chemicals of any kind (household products, gardening solution, laboratory chemicals, etc.) are splashed into your eyes, you should: **Flush eyes with tap water and immediately contact your eye care practitioner or visit a hospital emergency room without delay.**

INSTRUCTIONS FOR THE PRESBOPIC PATIENT (MONOVISION or MULTIFOCAL)

- Presbyopia is a condition in which the natural lenses in the eyes lose some of their elasticity. This occurs normally with aging as the lenses lose some of their ability to change focus for different distances (loss of reading vision).
- Monovision is a method of correction for presbyopia using contact lenses in which one eye is corrected for distance vision and the other is corrected for near vision.
- Multifocal lenses correct presbyopia by providing distance and near vision correction powers within the same lens.

GETTING USED TO MONOVISION CORRECTION (ADAPTATION)

- You should be aware that as with any type of lens correction, there are advantages and compromises to mono-vision contact lens therapy. The benefit of clear near vision in straight ahead and upward gaze that is available with mono-vision may be accompanied by a vision compromises that may reduce your visual acuity and depth perception for distance and near tasks. Some you have experienced difficulty adapting to it. Symptoms, such as mild blurred vision, dizziness, headaches and a feeling of slight imbalance, may last for a brief minute or for several weeks as adaptation takes place. The longer these symptoms persists, the poorer your prognosis for successful adaptation.

- You should avoid visually demanding situations during the initial adaptation period. It is recommended that you first wear these contact lenses in familiar situations, which are not visually demanding. For example, it might be better to be a passenger rather than a driver of an automobile during the first few days of lens wear. It is recommended that you only drive with mono-vision correction if you pass your state drivers licenses requirements with mono-vision correction.
- Some mono-vision you will never be fully comfortable functioning under low levels of illumination, such as driving at night. If this happens, you may want to discuss with your eye care practitioner having additional contact lenses prescribed so that both eyes are corrected for distance when sharp distance binocular vision is required.

If you require very sharp near vision during prolonged close work, you may want to have additional contact lens prescribed so that both eyes are corrected for near when sharp near binocular vision is required.

- Some mono-vision you require supplemental spectacles to wear over the mono-vision correction to provide the clearest vision for critical tasks. You should discuss this with your eye care practitioner.
- It is important that you follow your eye care practitioner’s suggestions for adaptation to mono-vision contact lens therapy. You should discuss any concerns that you may have during and after the adaptation period.

＊The decision to be fit with mono-vision correction is most appropriately left to the eye care practitioner in conjunction with you, after carefully considering and discussing your needs.

WEARING AND APPOINTMENT SCHEDULES

Record here the number of hours your eye care practitioner recommends you wear the lenses each day during the adaption period.

It is essential that you follow your eye care practitioner's directions regarding this important step of building up your wear time.

Prescribed Wearing Schedule

Day	Wearing Time (Hours)
1	
2	
3	
4	
5	
6	
7	
8	
9	
10	
11	
12	
13	
14	

Appointment Schedule

Your appointments are on

Month	Year	Time	Minimum number of hours lenses to be worn at time of appointment Day

PATIENT/EYE CARE PRACTITIONER INFORMATION

Patient/Eye Care Practitioner Information Record

Dr.：

Address：

Phone No.：

Note：

IMPORTANT: In the event that you experience any difficulty wearing your lenses or you do not understand the instructions given to you, **do not wait** for your next appointment. **Telephone your eye care practitioner immediately**.

Manufacturer	Name	VSP Optics
	Address	3333 Quality Drive, Rancho Cordova, CA 95670
	Phone No	(800) 245-6414

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GLOSSARY OF TECHNICAL TERMS

Term	**Definition**
Adnexa	Tissues surrounding the eyeball.
Ametropia	Abnormal vision requiring correction for proper focus.
Anterior chamber	Fluid-filled portion of the eye between the iris and innermost corneal surface.
Aphakic	An eye that does not have its natural lens (example: after cataract surgery).
Astigmatism	A condition where the cornea is not equally curved in all parts of its surface. It is somewhat oval in shape, causing the visual image to be out of focus (blurred).
Conjunctiva	Transparent membrane that lines the eyelids and the white part of the eye.
Conjunctivitis	Inflammation of the conjunctiva.
Continuous Wear	Extended wear for multiple nights in a row.
Cornea	Clear front part of the eye that covers the iris, pupil and anterior chamber.
Corneal erosion	Wearing away of the surface of the cornea.
Corneal ulcer	A sore or lesion on the cornea
Disinfection	A process that kills harmful microorganisms (germs) which can cause serious eye infections
Hydrophilic material	“water loving” or water absorbing substance
Hyperopia	Farsightedness
Hypoesthesia	Reduced corneal sensitivity to touch
Iritis	Inflammation of the interior portion of the eye that includes the iris, and results in redness, pain, blurred vision and sensitivity to light.
Inflammation	Swelling, redness and pain
Monivision	A correction method for presbyopia (loss of reading vision) using contact lenses; one eye is fitted for distance, the other for near vision
Myopia	Nearsightedness
Neovascularization	Blood vessels growing into the cornea
Phakic	An eye that has its natural lens
Presbyopic	A person with Presbyopia
Spherical contact lens	A lens with a continuously rounded curve
Toric contact lens	A lens with two different optical powers at right angles to each other for the correction of astigmatism
Ulcerative keratitis	An infected corneal ulcer