

## Instructions for Wearers of

**FLOSI** (wilofocoon A), **ONSI-56** (onsifocoon A) or **TYRO-97** (hococon A) Rigid Gas Permeable Spherical, Aspheric, Toric and Bifocal Contact Lenses and Contact Lenses for the Management of Irregular Corneal Conditions (TYRO & ONSI Only)

These Instructions for Wearers apply to all FLOSI (wilofocoon A), ONSI-56 (onsifocoon A) or TYRO-97 (hococon A) Rigid Gas Permeable Spherical, Aspheric, Toric and Bifocal Contact Lenses and Contact Lenses for the Management of Irregular Corneal Conditions (TYRO & ONSI Only)

### CAUTION:

Federal (USA) law restricts this device to sale by or on the order of a licensed practitioner. See package insert for additional information.

## Instruction for Wearers

RECOMMENDED LENS CARE SOLUTIONS: A CHEMICAL (NOT HEAT) LENS CARE DISINFECTION SYSTEM SPECIFICALLY RECOMMENDED FOR USE WITH FLUORO SILICONE ACRYLATE LENSES SHOULD BE USED.

### IMPORTANT:

If you experience any difficulty wearing your lenses or you do not understand the instructions given you, DO NOT WAIT for your next appointment. TELEPHONE YOUR EYE-CARE PRACTITIONER IMMEDIATELY.

The FLOSI (wilofocoon A), ONSI-56 (onsifocoon A) or TYRO-97 (hococon A) Rigid Gas Permeable Spherical, Aspheric, Toric and Bifocal Contact Lens

### INTRODUCTION:

This instruction booklet is for wearers of the FLOSI (wilofocoon A), ONSI-56 (onsifocoon A) or TYRO-97 (hococon A) Rigid Gas Permeable Spherical, Aspheric, Toric and Bifocal Contact Lenses.

We would like to stress the importance of following the instructions given you by your practitioner, as well as those provided in this booklet. If you have any questions or concerns regarding your lenses and their care, please consult your practitioner for clarification.

### WEARING RESTRICTIONS AND INDICATIONS:

The FLOSI (wilofocoon A), ONSI-56 (onsifocoon A) or TYRO-97 (hococon A) Rigid Gas Permeable Spherical, Aspheric, Toric and Bifocal Contact Lens is indicated for daily wear for the correction of visual acuity in not-aphakic persons with non-diseased eyes that are myopic, hyperopic or presbyopic and which may exhibit corneal astigmatism.

The lenses may be disinfected only by using chemical disinfection.

The FLOSI (wilofocoon A), ONSI-56 (onsifocoon A) or TYRO-97 (hococon A) Rigid Gas Permeable Spherical, Aspheric, Toric and Bifocal Contact Lenses should be disinfected using a chemical (not heat) lens care disinfection system **specifically recommended for use with fluoro silicone acrylate lenses**.

The FLOSI (wilofocoon A), ONSI-56 (onsifocoon A) or TYRO-97 (hococon A) Rigid Gas Permeable Spherical, Aspheric, Toric and Bifocal Contact Lenses described in this booklet should be removed from your eyes for routine cleaning and disinfecting as prescribed by your eye-care practitioner. DO NOT WEAR YOUR DAILY WEAR CONTACT LENSES WHILE SLEEPING.

### CONTRAINDICATIONS:

**DO NOT USE** the FLOSI (wilofocoon A), ONSI-56 (onsifocoon A) or TYRO-97 (hococon A) Rigid Gas Permeable Spherical, Aspheric, Toric and Bifocal Contact Lenses if you have any of the following conditions:

- Acute or subacute inflammation of the cornea, the iris or the anterior chamber of the eye.
- Any eye disease, injury, or abnormality that affects the cornea, conjunctiva or eyelids.
- Insufficiency of lacrimal secretion (dry eyes).

Corneal hypesthesia (reduced corneal sensitivity)

- Any systemic disease, which may affect the eye or be exaggerated by wearing contact lenses.
- Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lenses or use of contact lens solutions.
- Allergy to any ingredient, such as mercury or thimerosal, in a solution which must be used to care for the FLOSI (wilofocoon A), ONSI-56 (onsifocoon A) or TYRO-97 (hococon A) Rigid Gas Permeable Spherical, Aspheric, Toric and Bifocal Contact Lenses.
- Any active corneal infection: bacterial, fungal or viral.
- If eyes become red or irritated.

### WARNINGS:

Problems with contact lenses and contact lens care products could result in serious injury to your eye. It is essential that you follow your eye care practitioner's directions and all labeling instructions for proper use of lenses and lens care products. Eye problems, including corneal ulcers, can develop rapidly and lead to loss of vision.

Daily wear lenses are not indicated for overnight wear, and you should not wear your 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.

If you experience eye discomfort, excessive tearing, vision changes, or redness of the eye, immediately remove your lenses and promptly contact your eye-care practitioner.

ALL CONTACT LENS WEARERS MUST RETURN FOR PERIODIC CHECK-UP VISITS AS RECOMMENDED BY THEIR EYE CARE PRACTITIONER.

### PRECAUTIONS:

**CAUTION:** Non-sterile. Clean and condition lenses prior to use.

- Patients who wear aspheric contact lenses to correct presbyopia may not achieve the best corrected visual acuity for either far or near vision. Visual requirements vary with the individual and should be considered when selecting the most appropriate type of lens for each patient.
- Before leaving your eyecare practitioner's office, you should be able to remove lenses promptly or should have someone else available who can remove the lenses for you.
- Different solutions cannot always be used together and not all solutions are safe for use with all lenses. Use only recommended solutions.
- Do not heat the wetting/soaking solution and lenses. Keep away from extreme heat.
- Do not use heat or thermal lens care systems. Heat disinfection will damage the lens.
- Always use **fresh unexpired** lens care solution.
- **Always use a lens care system for your** FLOSI (wilofocoon A), ONSI-56 (onsifocoon A) or TYRO-97 (hococon A) **Rigid Gas Permeable Spherical, Aspheric, Toric and Bifocal Contact Lenses which has been recommended for use with fluorosilicone acrylate contact lenses**.
- CONVENTIONAL HARD CONTACT LENS SOLUTIONS ARE NOT INDICATED FOR USE WITH THE FLOSI (wilofocoon A), ONSI-56 (onsifocoon A) or TYRO-97 (hococon A) RIGID GAS PERMEABLE SPHERICAL, ASPHERIC, TORIC AND BIFOCAL CONTACT LENSES AND SHOULD NOT BE USED.
- Always use FRESH rinsing and storage solutions.
- Always follow directions in the package inserts for the use of contact lens solutions.
- Sterile unpreserved solutions, when used, should be discarded after the time specified in the labeling directions.
- Do not use saliva or anything other than the recommended solutions for lubricating or wetting lenses.
- Always keep the lenses completely immersed in a recommended storage solution when the lenses are not being worn (stored). Prolonged periods of drying will reduce the ability of the lens surface to return to a wettable state. Follow the lens care directions for Care for a Dried Out (Dehydrated) Lens if the lens surface

does become dried out.

- If the lens sticks (stops moving) on your eye, follow the recommended directions on "Care for a Sticking Lens". The lens should move freely on your eye for the continued health of your eye. If non-movement of the lens continues, immediately consult your eyecare practitioner.
- Always wash and rinse your hands before handling lenses. Do not get cosmetics, lotions, soaps, creams and deodorants 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 your contact lenses with your fingers or hands if your hands are not free of foreign materials, as microscopic scratches of the lenses may occur, causing distorted vision and/or injury to your eye.
- Carefully follow the handling, insertion, removal, cleaning, disinfecting, storing and wearing instructions in this booklet and those prescribed by your eyecare practitioner.
- Never wear lenses beyond the period recommended by your eye-care practitioner.
- If you use aerosol products such as hair spray 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 your lenses.
- Ask the eyecare practitioner about wearing lenses during sporting events.
- Inform your doctor (health care practitioner) about being a contact lens wearer.
- Never use tweezers or other tools to remove your lenses from the lens container unless specifically indicated for that use. Pour the lens into the hand.
- Do not touch the lens with fingernails.
- Always consult your eye care practitioner before using any medicine in your eyes.
- Always inform your employer that you wear contact lenses. 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 continuing health of the patient's eyes. Your eye-care practitioner will recommend a follow-up schedule.

### ADVERSE EFFECTS

The following problems may occur:

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

If you notice any of the above:

- 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. Place the lens in the storage case and contact your eye care practitioner.
- If the lens has dirt, an eyelash, or other foreign body on it or the problem stops and the lens appears undamaged, thoroughly clean, rinse, and disinfect the lens with recommended solutions, and then reinsert it.
- After reinsertion, if the problem continues, immediately remove the lens and consult your eye care practitioner.
- When any of the above symptoms or problems occur, a serious condition such as infection, corneal ulcer, neovascularization, or iritis may be present. Keep the lens off the eye and seek immediate professional identification of the problem and prompt treatment to avoid serious eye damage.

### PERSONAL CLEANLINESS FOR LENS HANDLING

### PREPARING THE LENS FOR WEARING

1. All contact lenses are susceptible to breaking and damage if handled improperly. Before handling your lenses always wash your hands thoroughly with a mild soap. Rinse hands well before handling lenses. Never use soap containing deodorants, oils, lotions or cosmetics.
2. Work over a flat surface that has been covered with a towel or cloth. Avoid dropping or setting your lenses on surfaces other than your lens case. Never use tweezers or other instruments to remove lenses from the case. If necessary, wet your finger with a drop of storing solution to retrieve a dropped lens.

### LENS APPLICATION:

Using whichever hand is most comfortable, follow these steps to apply the lens:

1. Place the lens on the tip of the index finger and apply several drops of a recommended lubricating solution.
2. Using the middle finger, pull down the lower lid of your right eye.
3. Using the middle or index finger of your other hand, raise the upper lid.
4. Gently bring the lens up to the eye. The lens should center itself, do not push the lens to the center.
5. Release the eyelids and blink. You should have proper vision in that eye.
6. If the lens is comfortable and you have proper vision, proceed with the left lens.

There are a variety of techniques for inserting lenses and if you have difficulty with this one, your practitioner can explain an alternate method to you.

If your vision is blurred or you have unusual discomfort in either eye, remove the lens, clean by rubbing several drops of a recommended cleaning solution on both surfaces of the lens. Then rinse the lens in a recommended rinsing solution and reinsert.

### CENTERING A LENS:

To re-center a lens which has become displaced, wash, thoroughly rinse and dry your hands; then follow one of the three (3) procedures listed below:

1. Look in the direction of the displaced lens - the lens will usually slide toward the center of the eye and re-center itself on the cornea.
2. Close your eyelids and gently massage the lens into place through the closed lid, using your index finger.
3. Gently slide the displaced lens onto the cornea while the eye is open, using finger pressure on the edge of the upper or lower lid.

### LENS REMOVAL:

When removing lenses, the same precautions discussed in the section on Preparation should be exercised. Wash hands and have available your lens case and a recommended cleaning and storing solution.

1. Place your head several inches above the flat surface over which you are working. Cup one hand under your eye in order to catch the lens.
2. With the other hand, place the index finger at the outer corner of the eye and open your eye as wide as possible.
3. While looking straight ahead, pull the corner of your eye outward and slightly upward and blink briskly. The lens should dislodge and fall into your palm.

There are a variety of techniques for removing lenses, and if you have difficulty with this one, your practitioner can explain an alternate method to you.

### CARING FOR YOUR LENSES (CLEANING, RINSING, DISINFECTING, ENZYMING, STORAGE AND REWETTING/LUBRICATING):

#### Basic Instructions

For continued safe and comfortable wearing of your lenses, it is important that you first clean and rinse, then disinfect your lenses after each removal, using the care regimen recommended by your eye-care practitioner. Cleaning and rinsing are necessary to remove mucus, secretions, films, or deposits; which may have accumulated during wearing. The ideal time to clean your lenses is immediately after removing them. Disinfecting

is necessary to destroy harmful germs.

You should adhere to a recommended care regimen. Failure to follow the regimen may result in development of serious ocular complications as discussed in the WARNINGS section above.

If you require only vision correction but will not or cannot adhere to a recommended care regimen for your lenses or are 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 to put the lenses on and remove them while you are in your eye-care practitioner's office. At that time, you will be provided with a recommended cleaning and disinfection regimen and instructions and warnings for lens care, handling, cleaning, and disinfection. Your eye-care practitioner should instruct you about appropriate and adequate procedures and products for your use, and provide you with a copy of the Patient Instructions for the FLOSI (wilofocoon A), ONSI-56 (onsifocon A) or TYRO-97 (hoyocon A) Rigid Gas Permeable Spherical, Aspheric, Toric and Bifocal Contact Lenses.

For safe contact lens wear, you should know and always practice your lens care routine:

- Always wash, rinse, and dry your hands before handling contact lenses.
- Always use fresh unexpired lens care solution.
- Use the recommended system of lens care and carefully follow instructions on solution labeling. Different solutions cannot always be used together, and not all solutions are safe for use with all lenses. Do not alternate or mix lens care systems unless indicated on solution labeling.
- Always remove, clean, rinse, enzyme and disinfect your lenses according to the schedule prescribed by your eye-care practitioner. The use of an enzyme or any cleaning solution does not substitute for disinfection.

**NOTE: DO NOT HEAT YOUR FLOSI (wilofocoon A), ONSI-56 (onsifocon A) or TYRO-97 (hoyocon A) RIGID GAS PERMEABLE SPHERICAL, ASPHERIC, TORIC AND BIFOCAL 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.

The following solutions have been used in clinical trials with the onsifocon A material. Your eye care practitioner may recommend alternative lens care products.

#### Contact Lens Care System

##### Clean

- OPTIMUM Cleaning/Disinfecting/Storage Solution

##### Rinse

- Tap water

##### Disinfect/Store

- OPTIMUM

##### Cleaning/Disinfecting/Storage Solution Rinse

- Rinse thoroughly as recommended by your eye-care practitioner

##### Lubricate/Rewet

- OPTIMUM by Lobob® Wetting/Rewetting Drop

##### Extra Strength Cleaner

- OPTIMUM by Lobob® "Extra Strength" Cleaner

The Package Insert accompanying each solution and the package label of each product provide detailed instructions on how the solutions are to be used in caring for contact lenses. Read and follow those instructions carefully. The FLOSI (wilofocoon A), ONSI-56 (onsifocon A) or TYRO-97 (hoyocon A) Rigid Gas Permeable Spherical, Aspheric, Toric and Bifocal Contact Lenses should only be disinfected by chemical systems of disinfection **specifically recommended for use with fluorosilicone acrylate lenses.**

- Note:** Some solutions may have more than one function, which will be indicated on the label. Read the label on the solution bottle and follow instructions.
- Clean one lens first (always the same lens first to avoid mix-ups), rinse the lens thoroughly with recommended saline or disinfecting solution to remove the cleaning solution, mucus, and film from the lens surface, and put that lens into the correct chamber of the lens storage case. Then repeat the procedure for the second lens.

- After cleaning, disinfect lenses using the system recommended by the manufacturer and/or eye-care practitioner.
- To store lenses, disinfect and leave them in the closed/unopened case until ready to wear. If the lenses are not to be used immediately following disinfection, the patient should be instructed to consult the package insert or the eye-care practitioner for information on storage of lenses.
- Always keep your lenses completely immersed in a recommended disinfecting/conditioning solution when the lenses are not being worn. If you discontinue wearing your lenses, but plan to begin wearing them after a few weeks, ask your eye-care practitioner for a recommendation on how to store your lenses.
- FLOSI (wilofocoon A), ONSI-56 (onsifocon A) or TYRO-97 (hoyocon A) Rigid Gas Permeable Spherical, Aspheric, Toric and Bifocal Contact Lenses **cannot** be heat (thermally) disinfected.
- After removing the lenses from the lens case, empty and rinse the lens storage case with solution as recommended by the lens case manufacturer; then allow the case to air dry. When the case is used again, refill it with storage solution. Replace lens case at regular intervals as recommended by the lens case manufacturer or your eye-care practitioner.
- Your eye-care practitioner may recommend a lubricating/rewetting solution which can be used to wet (lubricate) lenses while they are being worn to make them more comfortable.

#### CARE FOR A STICKING (NONMOVING) LENS:

If the lens sticks (stops moving) or cannot be removed, the patient should be instructed to apply 5 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 30 minutes, the patient should immediately consult their eye-care practitioner.

#### Chemical (Not Heat) Disinfection:

- Clean the contact lenses with a recommended cleaning solution and thoroughly rinse them with a recommended rinsing solution.
- After cleaning, to disinfect, carefully follow the instructions accompanying the disinfecting solution in the care regimen recommended by the eyecare practitioner.
- Thoroughly rinse lenses with a fresh solution recommended for rinsing before inserting and wearing or follow the instructions on the disinfection solution labeling.
- Do not heat the disinfection solution and lenses.
- Leave the lenses in the unopened storage case until ready to put on the eye.
- Caution:** Lenses that are chemically disinfected may absorb ingredients from the disinfecting solution, which may be irritating to the eyes. A thorough rinse in fresh sterile saline solution prior to placement on the eye should reduce the potential for irritation.

#### LENS DEPOSITS AND USE OF ENZYMATIC CLEANING PROCEDURE:

Enzyme cleaning may be recommended by your eye-care practitioner. Enzyme cleaning removes protein deposits on the lens. These deposits cannot be removed with regular cleaners. Removing protein deposits is important for the wellbeing of your lenses and eyes. If these deposits are not removed, they can damage the lens and cause irritation.

Enzyme cleaning does NOT replace routine cleaning and disinfecting. For enzyme cleaning, you should carefully follow the instructions in the enzymatic cleaning labeling.

#### LENS CASE CLEANING AND MAINTENANCE:

Contact lens cases can be a source of bacterial growth. You should empty, clean, and rinse your lens case with solutions recommended by the lens case manufacturer, and allow the case to air dry. Lens cases should be replaced at regular intervals, as recommended by the lens case manufacturer or your eye-care practitioner.

#### EMERGENCIES:

If chemicals of any kind (household products, gardening solutions, laboratory chemicals, etc.) are splashed onto your eyes, you should: **FLUSH EYES IMMEDIATELY WITH TAP WATER AND IMMEDIATELY CONTACT YOUR EYECARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.**

#### INSTRUCTIONS FOR THE MONOVISION WEARER:

- You should be aware that as with any type of lens correction, there are advantages and disadvantages and compromise to monovision contact lens therapy. The benefit of clear near vision in straight ahead and upward gaze that is available with monovision may be accompanied by a vision compromise that may reduce your visual acuity and depth perception for distance and near tasks. Some patients 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 persist, 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 monovision if you pass your state driver's license requirements with monovision correction.
- Some monovision patients 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 lenses prescribed so that both eyes are corrected for near when sharp near binocular vision is required.
- Some monovision patients require supplemental spectacles to wear over the monovision correction to provide the clearest vision for critical tasks. You should discuss this with your eyecare practitioner.
- It is important that you follow your eyecare practitioner's suggestions for adaptation to monovision contact lens therapy. You should discuss any concerns that you may have during and after the adaptation period.
- The decision to be fit with a monovision correction is most appropriately left to the eyecare practitioner in conjunction with you, after carefully considering and discussing your needs.

#### INSTRUCTIONS FOR THE ASPHERIC MULTIFOCAL WEARER:

- You should be aware that as with any type of lens correction, there are advantages and disadvantages and compromise to multifocal contact lens therapy. The benefits of near, intermediate and far vision that are available with multifocal vision may be accompanied by a vision compromise that may reduce your visual acuity and depth perception for distance and near tasks. Some patients 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 persist, 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 multifocal vision if you pass your state driver's license requirements with multifocal correction.
- Some multifocal vision patients 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 your 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 lenses prescribed so that your eyes are corrected for near when sharp near binocular vision is required.
- Some multifocal patients require supplemental spectacles to wear over the multifocal 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 multifocal 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 a multifocal correction is most appropriately left to the eye-care practitioner in conjunction with you, after carefully considering and discussing your needs.

#### WEARING AND APPOINTMENT SCHEDULE:

Prescribed Daily Wearing Schedule			
Day	Wear time (hrs)		
1	_____.		
2	_____.		
3	_____.		
4	_____.		
5	_____.		
6	_____.		
7	_____.		
Appointment Schedule			
Minimum number of hours lenses to be worn at time of appointment: <u>1 hour</u>			
Your appointments are on _____			
Month	Year	Time	Day
Name and address of lens manufacturer: _____			