CONTRAINDICATIONS (REASON NOT TO USE): DO NOT USE the FLOSI (wilofocon A) rigid Gas Permeable Spherical, Aspherical, Toric and Bifocal Contact Lens when any of the following conditions exist:
1. Acute or subacute inflammation or infection of the anterior chamber of the eye.
2. Any eye disease, injury or abnormality that effects the cornea, conjunctiva or eyelids.
3. Severe insufficiency of lacrimal secretion (dry eyes).
4. Corneal hypothermia (reduced corneal sensitivity) if not aphakic.
5. Any systemic disease which may affect the eye or be exacerbated by wearing contact lenses.
6. Allergic reactions of ocular surfaces or adnexa which may be induced or exaggerated by wearing contact lenses or use of contact lens solutions.
7. Allergy to any ingredient, such as mercury or Thimerosal, in a solution which is to be used to care for the FLOSI (wilofocon A) Rigid Gas Permeable Spherical, Aspherical, Toric and Bifocal Contact Lenses.
8. Any active corneal infection (bacterial, fungal or viral).
9. If eyes become red or irritated.

WARNINGS: Patients should be advised of the following warnings pertaining to contact lenses: Problems with contact lenses and lens care products could result in serious injury to the eye. It is essential that patients follow their eye care practitioner’s directions and all labeling instructions for proper use of lenses and lens care products, including the lens case. Eye problems including corneal ulcers, can develop rapidly and lead to loss of vision. 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 lenses are worn overnight. Studies have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than nonsmokers. If a patient experiences eye discomfort, excessive tearing, vision changes, or redness of the eye the patient should immediately remove the lenses and promptly contact his or her eye care practitioner.

PRECAUTIONS:
CAUTION: Non-sterile. Clean and condition lenses prior to use. Special Precautions for eye care practitioners: Due to the small number of patients enrolled in the clinical investigation all 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 practitioner 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 continued ocular health of the patient and lens performance on the eye should be carefully monitored by the prescribing eye care practitioner. Fluorescein, a yellow dye, may be used in the fitting of FLOSI (wilofocon A) rigid Gas Permeable Spherical, Aspherical, Toric and Bifocal Contact Lenses and for the evaluation of corneal integrity. Eyecare practitioners should carefully instruct patients about the following care regimen and safety precautions:

DIFFERENT SOLUTIONS CANNOT ALWAYS BE USED TOGETHER, AND NOT ALL SOLUTIONS ARE SAFE TO USE WITH ALL LENSES. USE ONLY RECOMMENDED SOLUTIONS. ALWAYS USE FRESH UNEXPIRED LENS CARE SOLUTIONS. ALWAYS FOLLOW DIRECTIONS IN THE PACKAGE INSERT FOR THE USE OF CONTACT LENS SOLUTIONS. USE ONLY A CHEMICAL LENS CARE SYSTEM. USE OF A HEAT (THERMAL) CARE SYSTEM CAN DAMAGE THE FLOSI (wilofocon A) Rigid Gas Permeable Spherical, Aspherical, Toric and Bifocal Contact Lens. STERILE UNPRESERVED SOLUTIONS, WHEN USED, SHOULD BE DISCARDED AT 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 LENS CARE PROFESSIONAL INFORMED OF THE LENSES IN USE. WHEN WINTERING 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 LENSES ARE WORN OVERNIGHT. STUDIES HAVE SHOWN THAT CONTACT LENS WEARERS WHO ARE SMOKERS HAVE A HIGHER INCIDENCE OF ADVERSE REACTIONS THAN NONSMOKERS. IF A PATIENT EXPERIENCES EYE DISCOMFORT, EXCESSIVE TEARING, VISION CHANGES, OR REDNESS OF THE EYE THE PATIENT SHOULD IMMEDIATELY REMOVE THE LENSES AND PROMPTLY CONTACT HIS OR HER EYE CARE PRACTITIONER.

WARNING: 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 lenses were first placed on eye.

Different solutions cannot always be used together, and not all solutions are safe to use with all lenses. Use only recommended solutions. Do not heat the wetting-soaking solution and lenses. Keep away from extreme heat. Always use fresh unexpired lens care solutions. Always follow directions in the package inserts for the use of contact lens solutions. Use only a chemical lens care system. Use of a heat (thermal) care system can damage the FLOSI (wilofocon A) rigid Gas Permeable Spherical, Aspherical, Toric and Bifocal Contact Lens. Sterile unpreserved solutions, when used, should be discarded at 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 lens care professional informed of the lenses in use. When wintering 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 lenses are worn overnight. Studies have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than nonsmokers. If a patient experiences eye discomfort, excessive tearing, vision changes, or redness of the eye the patient should immediately remove the lenses and promptly contact his or her eye care practitioner.
Feeling of something in the eye such as a foreign body or 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 the patient notices any of the above, he or she should be instructed to:

**IMMEDIATELY REMOVE YOUR 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 your eye.
Place the lens in the storage case and contact your eyecare practitioner. If the lens has dirt, an eyelash, or other foreign object on it, or if the problem stops and the lens appears undamaged, the patient should thoroughly clean, rinse and disinfect the lens, then reinsert them. If the problem continues, the patient should IMMEDIATELY remove the contact lenses and consult the eyecare practitioner.
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 the lens off the eye and seek immediate professional identification of the problem and prompt treatment to avoid serious eye damage.

**FITTING:** Conventional methods of fitting rigid contact lenses apply to the FLOSI (wilofocon A) rigid Gas Permeable Spherical, Aspherical, Toric and Bifocal Contact Lenses. For a description of fitting techniques, refer to the Fitting Guide for FLOSI (wilofocon A) rigid Gas Permeable Spherical, Aspherical, Toric and Bifocal Contact Lenses. Copies are available from: The Lagado Corporation, 2890 South Tejon Street, Englewood, CO 80110

**WEARING SCHEDULE:** The FLOSI (wilofocon A) rigid Gas Permeable Spherical, Aspherical, Toric and Bifocal Contact Lenses are indicated for daily wear. The maximum suggested wearing time for the lenses is:

**DAILY WEAR (LESS THAN 24 HOURS WHILE AWAKE)**
Day 1 2 3 4 5 6 7 8 9 10 15 All hours awake
Studies have not been completed to show that the FLOSI (wilofocon A) rigid Gas Permeable Spherical, Aspherical, Toric and Bifocal Contact Lenses is safe to wear during sleep. The wearing and replacement schedule should be determined by the eyecare practitioner. Patients tend to overwear the lenses initially. The eyecare practitioner should emphasize the importance of adhering to the initial maximum wearing schedule. Regular checkups, as determined by the eyecare practitioner, are also extremely important.

**LENSES CARE DIRECTIONS:** Eyecare practitioners should review with the patient lens care directions, including both basic lens care information and specific instructions on the lens care regimen recommended for the patient. General Lens Care (To First Clean and Rinse, Then Disinfect Contact Lenses) Basic Instructions:
Always wash, rinse, and then dry hands before handling contact lenses. Always use fresh unexpired lens care solutions. Use the recommended system of lens care, chemical (not heat) 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. Do not use saliva or anything other than the recommended solutions for lubricating or rewetting lenses. Do not put lenses in the mouth. Lenses should be cleaned, rinsed, and disinfected each time they are removed.
Cleaning and rinsing are necessary to remove mucus and film from the lens surface. Disinfecting is necessary to destroy harmful germs. Always remove, clean, rinse and enzyme (as recommended by the eyecare practitioner) and disinfect lenses according to the schedule prescribed by the eyecare practitioner. The use of an enzyme or any cleaning solution does not substitute for disinfection.
The lens care products listed below are recommended by the Lagado Corporation for the use with FLOSI (wilofocon A) rigid Gas Permeable Spherical, Aspherical, Toric and Bifocal Contact Lenses. Eyecare practitioners may recommend alternate products that are appropriate for the patient’s use with his or her lenses.

**Lens Care Table:**

<table>
<thead>
<tr>
<th>Product Type</th>
<th>Lens Care Product</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product Purpose Lens Care System (chemical - not heat)</td>
<td>Clean Lobob Optimum Cleaner</td>
</tr>
<tr>
<td>Rinse Lobob Optimum Wetting &amp; Soaking Solution</td>
<td>Disinfect Lobob Optimum Wetting &amp; Soaking Solution</td>
</tr>
<tr>
<td>Store Lobob Optimum Wetting &amp; Soaking Solution</td>
<td>Lubricate/Rewet Lobob Optimum Rewetting Solution</td>
</tr>
</tbody>
</table>

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 the 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 the eyecare practitioner.
To store lenses, disinflect and leave them in the closed/unopened case until ready to wear. If lenses are not to be used immediately following disinfection, the patient should be instructed to consult the package insert or the eyecare practitioner for information on storage of lenses. After removing lenses from the lens case, empty and rinse the lens storage case with solution as recommended by the lens care manufacturer, then allow the lens 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 care manufacturer or eyecare practitioner.
Eyecare practitioners may recommend a lubricating/rewetting solution which can be used to wet (lubricate) lenses while they are being worn to make them more comfortable.

**REPORTING ADVERSE REACTIONS:** All serious adverse experiences and adverse reactions observed in patients wearing FLOSI (wilofocon A) rigid Gas Permeable Spherical, Aspherical, Toric and Bifocal Contact Lenses must be immediately reported to the manufacturer.

The Lagado Corporation
2890 South Tejon Street
Englewood, CO 80110