PACKAGE INSERT

Acuity 200™ (fluoroxyfocon A)

Spherical & Aspherical Contact Lenses for Myopia and Hyperopia

Multifocal Contact Lenses for Presbyopia

Toric Lenses to Correct Astigmatism in Non-Aphakic and Aphakic Persons

Spherical & Aspherical Scleral Contact Lenses for Myopia, Hyperopia, and Presbyopia

Gas Permeable Contact Lenses for Daily Wear

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 care practitioner should provide the patient with the patient instructions that pertain to the patient's prescribed lens.

℞ ONLY CAUTION: Federal Law restricts this device to sale by or on the order of a licensed practitioner.

Acuity 200™

DESCRIPTION

Acuity 200™ (fluoroxyfocon A) contact lenses are manufactured from a gas permeable contact lens material composed of siloxanyl fluoromethacrylate copolymer. Acuity 200 is available with or without an ultraviolet absorber (MHB).

The Acuity 200 (fluoroxyfocon A) Rigid Gas Permeable Contact Lens is available in a spherical, aspheric, toric or multifocal design for daily wear only. Semi-scleral and scleral lenses are available for daily wear only.

Spherical Lens Designs	
Power Range	-20.00D to +20.00D in 0.25D increments
Diameter	7.0mm to 21.0mm
Base Curve Range	4.00mm to 11.50mm in 0.01mm increments
Multical Lens Designs (Centered, Decentered, Crecent)	
Power Range	-20.00D to +20.00D in 0.25D increments
Diameter	7.0mm to 21.0mm
Base Curve Range	4.00mm to 11.50mm in 0.01mm increments
Segment Heights	-2.00D to +1.00mm in 0.5 increments
Add Powers	+1.00D to +3.75D in 0.5D increments
Prism Ballast	0.5 to 3.5 prism diopters in 0.5D increments
Toric Lens Designs	
Power Range	-20.00D to +20.00D in 0.25D increments
Diameter	7.0mm to 21.0mm
Base Curve Range	4.00mm to 11.50mm in 0.01mm increments
Toricity	Up to 9.00 Diopters
Scleral Contact Lens Designs	
Power Range	-20.00D to +20.00D in 0.25D increments
Diameter	16.0mm to 21.0mm
Normalized Vaults	2.50mm to 6.00mm

The lenses described in the first column can have a center thickness of 0.07 mm to 0.65 mm that will vary with lens design, power and diameter.

Physical/Optical Properties of Acuity 200 Contact Lens/Material:

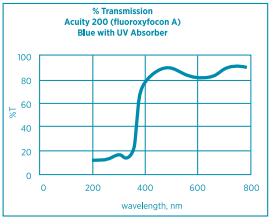
The tinted lenses contain the following color additives:

Color	Color Additive
Blue	D & C Green No. 6
Ice Blue	D & C Green No. 6
Orange	D & C Red #17 Solvent Yellow No. 18
Green	D & C Green No. 6 Solvent Yellow No. 18
Specific Gravity	1.18
Refractive Index	1.430
Light Transmittance*	

Tint	Transmittance
Blue	89%
Ice Blue	91%
Orange	90%
Green	87%
Surface Character	Hydrophobic
Wetting Angle	48°
Wetting Angle w/Hydra-PEG	10°
Water Content	<1%
Oxygen Permeability:	
Edge Corrected	200**

*Average CIE Luminous Y Transmittance (381 nm–780 nm) (lens center thickness = 0.65 mm)

**ISO/Fatt Method: DK Units = x 10–11 (cm3 O2)(cm)/[(sec)(cm2)(mmHg)] @ 35°C



Acuity 200– 0.15 mm thick Acuity 200 (Blue)

Note: Long term exposure to ultraviolet (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.

WARNING: UV-absorbing contact lenses are NOT substitutes for protective UV-absorbing eyewear such as UV-absorbing goggles or sunglasses. Persons should continue to use their protective UV-absorbing eyewear as directed.

ACTIONS

Acuity 200 Contact Lenses when placed on the cornea act as a refracting medium to focus light rays on the retina. The Acuity 200 semi-scleral and scleral contact lens when placed on the conjunctiva, vaults over the cornea and acts as a refracting medium to focus light rays on the retina.

Acuity 200 Contact Lenses are lathe cut firm contact lens with spherical or aspheric back surfaces. The posterior curve is selected to properly fit an individual eye, and the anterior curve is selected to provide the necessary optical power to correct refractive error. A peripheral curve system on the posterior surface allows tear exchange between the lens and the cornea.

Acuity 200 Contact Lenses provide a more even surface over the different curvatures of the astigmatic cornea and thus helps to focus light rays on the retina.

Acuity 200 Contact Lenses provide the necessary optical powers to correct different refractive errors for distance and near requirements.

Practitioner Note: Acuity 200 Contact Lenses are not sterile when shipped from the Authorized Acuity Manufacturer. Prior to dispensing, clean, and disinfect the lens(es) according to the appropriate lens care regimen.

INDICATIONS (USES)

Acuity 200 (fluoroxyfocon A) Contact Lenses are indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia, astigmatism, and presbyopia) in aphakic and non-aphakic persons with non-diseased eyes. The lenses may be disinfected using a chemical disinfection (not heat) system only.

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE Acuity 200 Contact Lenses when any of the following conditions exist:

- Acute or subacute inflammation of the anterior chamber of the eye
- Any eye disease, injury, or abnormality, other than irregular corneal conditions as described in the INDICATIONS section, that affects the cornea, conjunctiva, or eyelids
- Severe insufficiency of lacrimal secretion (dry eyes)
- Corneal hypoesthesia (reduced corneal sensitivity), if non-aphakic
- Any systemic disease that 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 using contact lens solutions
- Allergy to any ingredient in a solution which is to be used to care for the Acuity 200 Contact Lens material.
- Any active corneal infection (bacterial, fungal, or viral)
- Red or irritated eyes

WARNINGS

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

- 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 these daily wear 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 be instructed to **IMMEDIATELY REMOVE LENSES AND PROMPTLY CONTACT HIS OR HER EYE CARE PRACTITIONER.**

PRECAUTIONS

- Never reuse the solution. You may store the lenses in the unopened container until ready to dispense, up to a maximum of thirty days from the date of filling (see lens shipping carton label). If the lenses are stored for longer periods of time, they should be cleaned and disinfected with Boston SIMPLUS® Multi-Action Solution or Menicon Unique-pH® Multi-Purpose Solution.
- Patients may experience a reduction in visibility while wearing these lenses in conditions of low illumination for the following color and center thickness:

Lens Type/Color	Center Thickness
Acuity 200 Blue	>0.65 mm
Acuity 200 Ice Blue	>0.65 mm
Acuity 200 Green	>0.55 mm
Acuity 200 Orange	>0.65 mm

Special Precautions for Eye Care Practitioners:

- When wet shipped, Acuity 200 Contact Lenses are packaged non sterile in a preserved aqueous solution, either Boston SIMPLUS® Multi-Action Solution or Boston ADVANCE® Conditioning Solution. Boston SIMPLUS® Multi-Action Solution contains poloxamine, hydroxyalkyl phosphonate, boric acid, sodium borate, sodium chloride, hydroxypropylmethyl cellulose, glucam,and preserved with polyaminopropyl biguanide (0.0005%), chlorhexidine gluconate (0.003%). Boston ADVANCE® Conditioning Solution contains polyaminopropyl biguanide (0.0005%), chlorhexidine gluconate (0.003%), and edetate disodium (0.05%) as preservatives. If the patient has experienced a prior history of allergy to any of the ingredients in Boston SIMPLUS® Multi-Action Solution or Boston ADVANCE® Conditioning Solution, remove the lens from the solution and soak for 24 hours in unpreserved saline solution prior to cleaning, disinfecting, and dispensing.
- 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 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 continuing ocular health of the patient and lens performance on the eye should be carefully monitored by the prescribing eye care practitioner.
- Patients who wear 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.
- Aphakic patients should not be fitted with Acuity 200 Contact Lenses until the determination is made that the eye has healed completely.
- Before leaving the eye care practitioner's office, the patient should be able to properly 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.
- The presence of the UV-absorber in the Acuity 200 Contact Lens material may require equipment enhancement to visualize fluorescein patterns adequately. (Refer to the Professional Fitting and Information Guide for detailed instructions.) Eye care practitioners should carefully instruct patients about the following care regimen and safety precautions:
- Different solutions often cannot be used together, and not all solutions are safe for use with all lenses. Use only recommended
  - Do not heat the conditioning/storage solution and/or lenses. Keep them 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 (not heat) lens care system. Use of a heat (thermal) care system can warp Acuity 200 Contact Lenses.
  - 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 the recommended storage solution when the lenses are not being worn (stored).
- If the lens sticks (stops moving) on the eye, the patient should be instructed to follow the recommended directions on Care for a Sticking (Non-Moving) 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-based cosmetics are less likely to damage lenses than oil-based products.
- Do not touch contact lenses with the fingers or hands if the hands are not free of foreign materials, as microscopic scratches on the lenses may occur, causing distorted vision and/or injury to the eye.
- Carefully follow the handling, insertion, removal, cleaning, disinfecting, storing, and wearing instructions in the Patient Information Booklet for the Acuity 200 Contact Lenses and in 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 gently and avoid dropping them on hard surfaces.
- Avoid all harmful or irritating vapors and fumes while wearing lenses.
- Patients should be advised about wearing lenses during sporting and water related activities. Exposure to water while wearing contact lenses in activities such as swimming, water skiing, and hot tubs may increase the risk of ocular infection including, but not limited to, Acanthamoeba keratitis.
- Instruct patient to inform his or her doctor (health care professional) that the patient wears contact lenses.
- Never use tweezers or other tools to remove lenses from the lens case unless specifically indicated for that use. To remove the lens from the case, pour the solution containing the lens into the palm of your hand.
- Do not touch the lens with fingernails.
- Instruct the patient to contact his or her eye care practitioner before using any medicine in the eyes.
- Instruct the patient to inform his or her employer that he or she wears contact lenses. 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 recommended 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 the eye
- Feeling of something 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, 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, the lens should not be placed back on the eye. Place the lens in the lens case and contact the 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, the patient should thoroughly clean, rinse, and disinfect the lenses; then reinsert them. After reinsertion, if the problem continues, **IMMEDIATELY REMOVE THE LENSES AND CONSULT THE EYE CARE 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

For detailed descriptions of the conventional fitting techniques and special fitting considerations for the Acuity 200 Contact Lenses, refer to the Acuity 200 Professional Fitting and Information Guide, copies of which are available from:

Customer Service
Acuity Polymers, Inc.
1667 Lake Avenue
Rochester, NY 14615 USA
www.acuitypolymers.com
1-888-POL-YMER

Professional Fitting Guides are also available through your Authorized ACUITY Manufacturer.

WEARING SCHEDULE

The wearing and replacement schedules should be determined by the eye care practitioner. Patients tend to overwear the lenses initially. The eye care practitioner should emphasize the importance of adhering to the initial maximum wearing schedule. Regular checkups, as determined by the eye care practitioner, are also extremely important. Acuity 200 Contact Lenses are indicated for **daily wear.**

LENS CARE DIRECTIONS

Eye care practitioners should review lens care directions with the patient, including both basic lens care information and specific instructions on the lens care regimen recommended for the patient.

General Lens Care (First Clean and Rinse, Then Disinfect Lenses)

1. Rub and Rinse Time

Instruction for Use:

Follow the complete recommended lens rubbing and rinsing times in the labeling of your solution used for cleaning, disinfecting, and soaking your lenses to adequately disinfect your lenses and reduce the risk of contact lens infection.

WARNING:

- Rub and rinse your lenses for the recommended amount of time to help prevent serious eye infections.
- **Never use water**, saline solution, or rewetting drops to disinfect your lenses. These solutions will not disinfect your lenses. Not using the recommended disinfectant can lead to severe infection, vision loss or blindness.

2. Soaking and Storing Your Lenses

Instruction for Use:

Use only fresh contact lens disinfecting solution each time you soak (store) your lenses.

WARNING:

DO NOT REUSE or "top-off" old solution left in your lens case since solution reuse reduces effective lens disinfection and could lead to severe infection, vision loss or blindness. "Topping-off" is the addition of fresh solution to solution that has been sitting in your case.

3. Lens Case Care

Instruction for Use:

- Clean contact lens cases with digital rubbing using fresh, sterile disinfecting solutions/contact lens cleaner. **Never use water**. Cleaning should be followed by rinsing with fresh, sterile disinfecting solutions **(never use water)** and wiping the lens cases with a fresh, clean tissue is recommended. Never air-dry or recap the lens case lids after use without any additional cleaning methods. If air-drying, be sure that no residual solution remains in the case before allowing it to air-dry.
- Replace your lens case according to the directions given to you by your eye care practitioner or the labeling that came with your case.

- Contact lens cases can be a source of bacterial growth.

WARNING:

Do not store your lenses or rinse your lens case with water or any non-sterile solution. Only use fresh solution so you do not contaminate your lenses or lens case. Use of non-sterile solution can lead to severe infection, vision loss or blindness.

4. 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. Exposure to water while wearing contact lenses in activities such as swimming, water skiing, and hot tubs may increase the risk of ocular infection, including, but not limited to, Acanthamoeba keratitis. If your lenses have been submersed in water, you should thoroughly clean and disinfect them before insertion. Ask your eye care practitioner (professional) for recommendations about wearing your lenses during any activity involving water.

5. Discard Date on Solution Bottle

Instruction for Use:

Discard any remaining solution after the recommended time period indicated on the bottle of solution used for disinfecting and soaking your contact lenses.

WARNING:

Using your solution beyond the discard date could result in contamination of the solution and can lead to SEVERE INFECTION, VISION LOSS OR BLINDNESS.

6. Basic Instructions

Always wash, rinse, and 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 often cannot 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, or if advised by the eye care practitioner.**
- 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. The lens case must be emptied and refilled with fresh, sterile recommended storage and disinfection solution prior to disinfecting the lenses.

  Eye care 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.

  The lens care products listed below are recommended by Bausch + Lomb for use with Acuity 200 Contact Lenses. Eye care practitioners may recommend alternate products that are appropriate for the patient's use with his or her lens(es).

LENS CARE TABLE: For Acuity 200 Contact Lenses

Product Purpose	Lens Care System
Clean	• Menicon Unique pH • Boston Simplus Multi-Action Solution
Disinfect	• Menicon Unique pH • Boston Simplus Multi-Action Solution
Store	• Menicon Unique pH • Boston Simplus Multi-Action Solution
Rinse	• Menicon Unique pH • Boston Simplus Multi-Action Solution
Lubricate/Rewet	• Boston Rewetting Drops
Insertion of semi-scleral & scleral lenses	Sterile Non-preserved solution as recommended by your eye care professional

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), and rinse the lens thoroughly as recommended by your eye care practitioner to remove the cleaning solution, mucus, and film from the lens surface. Follow the instructions provided in the cleaning solution labeling. Put that lens into the correct chamber of the lens case. Then repeat the procedure for the second lens.
- After cleaning, disinfect lenses using the above recommended system by your eye care practitioner and/or the manufacturer. Follow the instructions provided in the disinfection solution labeling.
- To store lenses, disinfect and leave them in the closed/unopened case until ready to wear. If lenses are not to be used immediately following disinfection, you should consult the Package Insert or your eye care practitioner for information on storage of your 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 again after a few weeks, ask your eye care practitioner for a recommendation on how to store your lenses.
- Acuity 200 Contact Lenses cannot be heat (thermally) disinfected.
- After removing your lenses from the lens case, empty and rinse the lens case with solution(s) recommended by the lens case manufacturer or the eye care practitioner, then allow the lens case to air-dry. When the case is used again, refill it with fresh storage solution. Lens cases should be replaced 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 for your use. Lubricating/Rewetting solutions can be used to wet (lubricate) your lenses while you are wearing them to make them more comfortable.
- Your eye care practitioner may recommend a Weekly Enzymatic Cleaner which can be used to effectively remove protein deposits from your Acuity 200 Contact Lenses.

7. Care for a Sticking (Non-Moving) Lens

If the lens sticks (stops moving/cannot be removed), apply one to three drops of a recommended lubricating or rewetting solution directly to your 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, you should **IMMEDIATELY CONSULT YOUR EYE CARE PRACTITIONER.**

8. Emergencies
If chemicals of any kind (household products, gardening solutions, laboratory chemicals, etc.) are splashed into your eyes, you should: **FLUSH YOUR EYES IMMEDIATELY WITH TAP WATER, THEN REMOVE YOUR LENSES PROMPTLY, IF POSSIBLE, AND IMMEDIATELY CONTACT YOUR EYE CARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.**

HOW SUPPLIED

Each lens is supplied (non-sterile) in a plastic lens case, dry or in solution (Menicon Unique pH Multi-Purpose Solution or Boston SIMPLUS® Multi-Action Solution). The case is labeled with the base curve, diopter power, diameter, center thickness, color, UV-absorber (if present), and lot number. Additional parameters of add power, segment height, prism ballast, and truncation may be included for bifocal lenses.

REPORTING OF ADVERSE REACTIONS

All serious adverse reactions observed in patients wearing Acuity 200 Contact Lenses or adverse experiences with the lenses should be reported to:

Customer Service
Acuity Polymers, Inc.
1667 Lake Avenue
Rochester, NY 14615 USA
1-888-POLYMER (1-888-756-9637)

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