PACKAGE INSERT

Acuity 100™ (hexafocon A)

Acuity 100™ (hexafocon A) with Tangible® Hydra-PEG® Gas Permeable Contact Lenses

Spherical and Aspheric Lenses for Myopia and Hyperopia

Toric Lenses to Correct Astigmatism

Lenses for the Management of Irregular Corneas

Multifocal Lenses for Presbyopia in Aphakic and Non-Aphakic Persons

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

RX ONLY

CAUTION: Federal (U.S.A) law restricts this device to sale by or on the order of a licensed eye care professional.

DESCRIPTION

The Acuity 100™ (hexafocon A) and Acuity 100™ (hexafocon A) with Tangible® Hydra-PEG® Gas Permeable Contact Lens are available as a spherical, aspheric, prism ballast toric or multifocal design for daily wear only. Semi-scleral and scleral lenses are available for daily wear only. Lenses for the management of irregular corneas are available for daily wear only.

The Acuity 100™ (hexafocon A) and Acuity 100™ (hexafocon A) with Tangible® Hydra-PEG® Gas Permeable Contact Lens is composed of an aliphatic siloxanyl fluoromethacrylate copolymer with a UV light absorber. The lens is available in clear, blue, ice blue, violet, and green tints. The tinted lenses contain the following color additives:

Color	Color Additive
Blue	D & C Green No. 6
Ice Blue	D & C Green No. 6
Violet	D & C Violet No. 2
Green	D & C Green No. 6 Solvent Yellow 18

The Acuity 100™ (hexafocon A) and Acuity 100™ (hexafocon A) with Tangible® Hydra-PEG® Contact Lens is a hemispherical lens with the following dimensions (not all parameter combinations are available in all designs):

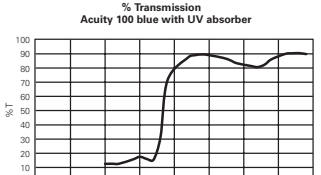
Spherical and Aspheric Contact Lens	
Diameter	7.0 to 21.0 mm
Base Curve	4.00 to 11.5 mm
Powers	-20.00 to +20.00D (in 0.25D steps)
Toric Contact Lens	
Diameter	7.0 to 21.0 mm
Base Curve	4.00 to 11.50 mm
Sphere Powers	-20.00 to +20.00D (in 0.25D steps)
Cylinder Powers	Up to 9.00 Diopters
Multifocal Contact Lens (Centered, Decentered, Crescent)	
Diameter	7.0 to 21.0 mm
Base Curve	4.00 to 11.50 mm
Sphere Power	-20.00 to +20.00D
Add Power	+1.00 to +3.75D

The lenses above can have a center thickness (CT) of 0.07 to 0.65 mm, depending on the design, power and diameter of the lens.

Physical/Optical Properties of Acuity 100™ and Acuity 100™ with Tangible® Hydra-PEG® Contact Lens/ Material:

Hardness, Shore D	80
Specific Gravity	1.27
Refractive Index	1.415
Light Absorbance	(640 nm) 8.5 Blue Tint
Light Absorbance	(640 nm) 5.3 Ice Blue Tint
Light Absorbance	(640 nm) 5.3 Ice Blue Tint
Light Absorbance	(585 nm) 5.3 Violet Tint
Light Absorbance	(640 nm) 4.9 Green
Wetting Angle	56
(Sessile Drop Contact Angle)	<10°
Light Transmittance	
[average % T (380– 780nm)]	89%
Water Content	<1.0% by weight
Oxygen Permeability	
Edge Corrected	111*

*ISO/Fatt Method: Dk Units=x10^{-11} (cm^3 O_2)(cm)/[(sec)(cm^2)(mmHg)]@35°C



Acuity 100™ (hexafocon A) and Acuity100™ (hexafocon A) with Tangible® Hydra-PEG® Contact Lens - Spectral transmittance curve for Acuity 100™ (hexafocon A) Contact Lens - D & C Green No. 6 and UV absorbing agent (sample thickness Acuity 100™ (hexafocon A) lens thickness = 0.12 mm)

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 the eye care professional for more information.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.

ACTIONS

The Acuity 100™ (hexafocon A) and Acuity100™ (hexafocon A) with Tangible® Hydra-PEG® Contact Lenses, when placed on the eye, act as a refracting medium to focus light rays on the retina.

Transmittance of ultraviolet light through the contact lens at the thinnest lenses available (0.12 mm) at powers ranging from -20.00D to 20.00D (thinnest lenses) are as follows:

UV-A (380 nm–315 nm)	30.4%
UV-B (315 nm–280 nm)	16.4%

The Acuity 100™ (hexafocon A) and Acuity 100™ (hexafocon A) with Tangible® Hydra-PEG® Contact Lens is a lathe cut firm gas permeable 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.

The Acuity 100™ (hexafocon A) and Acuity 100™ (hexafocon A) with Tangible® Hydra-PEG® Toric Contact Lens provides a more even surface over the different curvatures of the astigmatic cornea and thus helps to focus light rays on the retina.

The Acuity 100™ (hexafocon A) and Acuity 100™ (hexafocon A) with Tangible® Hydra-PEG® Multifocal Contact Lens provides the necessary optical powers to correct different refractive errors for distance and near requirements.

INDICATIONS (Uses)

The Acuity 100™ (hexafocon A) and Acuity 100™ (hexafocon A) with Tangible® Hydra-PEG® Gas Permeable Contact Lens are indicated for daily wear for the correction of refractive error (myopia, hyperopia, presbyopia and/or astigmatism) in aphakic and non-aphakic persons with non-diseased eyes.

The lens may be prescribed in spherical and aspheric powers ranging from -20.00D to +20.00D for daily wear.

The lenses may be prescribed for daily wear in otherwise non-diseased eyes that require a gas permeable contact lens for the management of irregular corneal conditions such as keratoconus, pellucid marginal degeneration, or following penetrating keratoplasty or refractive (e.g., LASIK) surgery.

The Acuity 100™ (hexafocon A) and Acuity 100™ (hexafocon A) with Tangible® Hydra-PEG® Gas Permeable Contact Lenses are also indicated for therapeutic use in eyes with ocular surface disease (e.g. ocular Graft-versus-Host disease, Sjögren's syndrome, dry eye syndrome and Filamentary Keratitis), limbal stem cell deficiency (e.g. Stevens-Johnson syndrome, chemical radiation and thermal burns), disorders of the skin (e.g. atopy, ectodermal dysplasia), neurotrophic keratitis (e.g. Herpes simplex, Herpes zoster, Familial Dysautonomia), and corneal exposure (e.g. anatomic, paralytic) that might benefit from the presence of an expanded tear reservoir and protection against an adverse environment. When prescribed for therapeutic use for a distorted cornea or ocular surface disease, the lens may concurrently provide correction of refractive error.

The lens may be disinfected using a chemical disinfection system only.

See **WARNINGS** for information about the relationship between wearing schedule and corneal complications.

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE the Acuity 100™ (hexafocon A) and Acuity 100™ (hexafocon A) with Tangible® Hydra-PEG® Contact Lens when any of the following conditions exist:

- Acute and subacute inflammation or infection of the anterior segment 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), except when using a semi-scleral or scleral lens design that maintains a fluid chamber between the cornea/conjunctiva and the contact lens
- Corneal hypoesthesia (reduced corneal sensitivity), except when using a semi-scleral or scleral lens design that maintains a fluid chamber between the cornea/conjunctiva and the contact lens and acts as a protective barrier for the cornea
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses
- Allergic reactions of ocular surfaces or surrounding tissues 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 is to be used to care for the Acuity 100™ (hexafocon A) and Acuity 100™ (hexafocon A) with Tangible® Hydra-PEG® Contact Lens
- Any active corneal infection (bacterial, fungal, or viral)
- If eyes become red or irritated
- Incomplete healing following eye surgery

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 and lens care products, including the lens case.

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

1. Soaking and Storing Your Lenses

Instruction for Use:

Use only fresh multi-purpose (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.

2. Rub and Rinse Time Instruction for Use

Rub and rinse your lenses according to the recommended lens rubbing and rinsing times in the labeling of your multi-purpose solution to adequately disinfect your lenses.

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.

3. Lens Case Care Instruction for Use

Empty and 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 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 you by your eye care professional 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 multi-purpose 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. 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.

5. Discard Date on Multi-purpose Solution Bottle Instruction for Use

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

The discard date refers to the time you can safely use contact lens care product after the bottle has been opened. It is not the same as the expiration date, which is the last date that the product is still effective before it is opened.

WARNING:

Using your multi-purpose solution beyond the discard date could result in contamination of the solution and can lead to severe infection, vision loss or blindness.

To avoid contamination, DO NOT touch tip of container to any surface. Replace cap after using.

To avoid contaminating your solution, DO NOT transfer to other bottles or containers.

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

- Eye Discomfort
- Loss of Vision
- Excessive Tearing
- Eye Redness
- Vision Changes
- 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 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.

WARNINGS:

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

- You should follow the complete recommended lens rubbing and rinsing times in the product labeling to adequately disinfect your lenses and reduce the risk of contact lens contamination. Reduced rubbing or rinsing times may not adequately clean your lenses.
- You should fill your lens case with fresh solution every time you store your lenses, and never "top-off" or re-use solution. You should discard your solution immediately after your lenses have been removed from the lens case. You should not expose or store your lenses in or rinse your lens case with any water, such as tap, bottled, or distilled, or with any non-sterile solution.
- Clean, rinse and air-dry your lens case each time you remove your lenses. In order to permit excess solution to drain, you can flip over your lens case while air drying. Replace your lens case frequently, depending upon your hygiene habits.
- 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 professional's direction 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 daily wear lenses are worn overnight.
- Smoking increases the risk of corneal ulcers for contact lens users, especially when lenses are worn overnight or while sleeping.[1,2]

- 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 professional.
- 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. Persons should continue to use their protective UV-absorbing eyewear as directed.
- Never use tap water.
- Water can harbor microorganisms that can lead to severe infection, vision loss or blindness. If your lenses have been submersed in water such as when swimming in pools, lakes or oceans, you should thoroughly clean and disinfect them before insertion. Ask your eye care professional for recommendations about wearing your lenses during any activity involving water.

[1]CLAO Journal, January 1996; Volume 22, Number 1, pp. 30–37

[2]New England Journal of Medicine, September 21, 1989; 321 (12), pp. 773–783

CAUTION: NON-STERILE. ALWAYS CLEAN AND DISINFECT LENSES PRIOR TO USE.

PRECAUTIONS

Special Precautions for Eye Care Professionals:

- Due to the small number of patients enrolled in clinical investigations of these types of lenses, all refractive powers, design configurations, or lens parameters available in the lens material were not evaluated in significant numbers. Consequently, when selecting an appropriate lens and wear schedule for a patient, the eye care professional should consider all lens characteristics 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 professional.
- The following patients may experience a higher rate of adverse effects associated with contact lens wear:
  - -Patients with a history of acute inflammatory reactions to contact lens wear.
  - -Patients with a history of giant papillary conjunctivitis associated with contact lens wear.
  - -Patients with a history of ocular allergies may need to temporarily discontinue lens wear during certain times of the year.
  - -Patients with a history of non-compliance with contact lens care and disinfection regimen, wearing restrictions, wearing schedule, or follow-up visit schedule.
  - -Patients who are unable or unwilling to understand or comply with any directions, warnings, precautions, or restrictions. Contributing factors may include but are not limited to age, infirmity, other mental or physical conditions, and adverse working or living conditions.
  - -Patients who are unwilling or unable to adhere to a recommended care regimen, or who are unable to insert and remove lenses, should not be provided with them.
- Eye care professionals should instruct the patient to remove the lenses immediately if the eye becomes red or irritated.
- The use of fluorescein is contraindicated in those persons who have a known hypersensitivity to any component.
- The presence of the ultraviolet (UV) light absorber in the Acuity 100™ (hexafocon A) and Acuity 100™ (hexafocon A) with Tangible® Hydra-PEG® Contact Lens material may require equipment enhancement to visualize fluorescein patterns adequately. (Refer to the Professional Fitting and Information Guide for detailed instructions.)

As with any contact lens patient, 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.

- Aphakic and other post-surgical persons should not be fitted with Acuity 100™ (hexafocon A) and Acuity 100™ (hexafocon A) with Tangible® Hydra-PEG® Contact Lenses until the determination is made that the eye has healed completely.
- 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.
- It is advised that wound healing and corneal curvature are stable prior to fitting Acuity 100™ lenses for post-surgical or other compromised corneas.

Eye care professionals should carefully instruct patients about the following care regimen and safety precautions. It is strongly recommended that patients be provided with a copy of the Patient Information Booklet for the Acuity 100™ (hexafocon A) and Acuity 100™ (hexafocon A) with Tangible® Hydra-PEG® Gas Permeable Contact Lens available from Acuity Polymers Inc. and understand its contents prior to dispensing the lenses.

Handling Precautions

- 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.
- Before leaving the eye care professional'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.
- 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.
- Always handle lenses gently and avoid dropping them on hard surfaces.
- Do not touch the lens with fingernails.

- Carefully follow the handling, insertion, removal, cleaning, disinfecting, storing, and wearing instructions in the Patient Instructions for the Acuity 100™ (hexafocon A) and Acuity 100™ (hexafocon A) with Tangible® Hydra-PEG® Contact Lens and those prescribed by the eye care professional.
- Never use tweezers or other tools to remove lenses from the lens container unless specifically indicated for that use.

Solution Precautions

- Always use fresh unexpired lens care 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.
- Always keep the lenses completely immersed in the recommended storage solution when the lenses are not being worn (stored). Prolonged periods of drying may reduce the ability of the lens surface to return to a wettable state.
- Do not use saliva or anything other than the recommended solutions for lubricating or wetting lenses.
- 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 cleaning, wetting, and/or soaking solution and lenses. Keep away from extreme heat.
- Use only a chemical (not heat) lens care system. Use of a heat (thermal) care system can damage the Acuity 100™ (hexafocon A) and Acuity 100™ (hexafocon A) with Tangible® Hydra-PEG® Contact Lenses.

Lens Wearing Precautions

- Never wear lenses beyond the period recommended by the eye care professional.
- If the lens sticks (stops moving) on the eye, follow the recommended directions in 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, immediately consult your eye care professional.
- Avoid all harmful or irritating vapors and fumes while wearing lenses.
- If aerosol products such as hair spray are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.

Lens Case Precautions

- Contact lens cases can be a source of bacterial growth. Lens cases should be emptied, cleaned, rinsed with the sterile contact lens solution recommended by the lens case manufacturer (never use tap water) and allowed to air dry.
- Lens cases should be replaced at regular intervals as recommended by the lens manufacturer or your eye care professional.

TOPICS TO DISCUSS WITH THE PATIENT

- 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.
- Patients should be advised about wearing lenses during water activities and other sports. Exposing contact lenses to water during swimming or while in a hot tub may increase the risk of eye infection from microorganisms.
- Always contact your eye care professional before using any medicine in the eyes.
- Certain medications may cause dryness of the eye, increased lens awareness, lens intolerance, blurred vision or visual changes. These include, but are not limited to, antihistamines, decongestants, diuretics, muscle relaxants, tranquilizers, oral contraceptives and motion sickness medications. Caution patients using such medications accordingly and prescribe proper remedial measures.
- Patients should inform the doctor (health care professional) about being a contact lens wearer.
- Patients should 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.

ADVERSE REACTIONS

- Eyes stinging, burning, itching (irritation) or other eye pain
- Comfort is less than when lens was first placed on eye
- Abnormal 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, 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 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 the eye care professional. 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, the patient should **immediately remove the lenses and consult the eye care professional.**

If the above symptoms continue after removal of the lens, or upon reinsertion of a lens, or upon insertion of a new lens, the patient should immediately remove the lenses and contact his or her eye care professional or physician, who must determine the need for examination, treatment or referral without delay (See Important Treatment Information for Adverse Reactions). A serious condition such as infection, corneal ulcer, corneal vascularization, or iritis may be present and may progress rapidly. Less serious reactions such as abrasions, epithelial stinging or bacterial conjunctivitis must be managed and treated carefully to avoid more serious complications.

During use for the management of irregular corneal conditions, an adverse effect may be due to the original condition or may be due to the effects of wearing a contact lens. There is a possibility that the existing condition might become worse when a lens is used on an eye with an irregular corneal condition. The patient should be instructed to avoid serious eye damage by contacting the eye care professional IMMEDIATELY if there is an increase in symptoms while wearing the lens.

Important Treatment Information for Adverse Reactions

Sight-threatening ocular complications associated with contact lens wear can develop rapidly, and therefore early recognition and treatment of problems are critical. Infectious corneal ulceration is one of the most serious potential complications, and may be ambiguous in its early stage. Signs and symptoms of infectious corneal ulceration include discomfort, pain, inflammation, purulent discharge, sensitivity to light, cells and flare, and corneal infiltrates.

Initial symptoms of a minor abrasion and an early infected ulcer are sometimes similar. Accordingly, such epithelial defect, if not treated properly, may develop into an infected ulcer. In order to prevent serious progression of these conditions, a patient presenting symptoms of abrasions or early ulcers should be evaluated as a potential medical emergency, treated accordingly, and be referred to a corneal specialist when appropriate. Standard therapy for corneal abrasions such as eye patching or the use of steroids or steroid/antibiotic combinations may exacerbate the condition. If the patient is wearing a contact lens on the affected eye when examined, the lens should be removed immediately, and the lens and lens care products retained for analysis and culturing.

FITTING PREPARATION

Acuity 100™ (hexafocon A) and Acuity 100™ (hexafocon A) with Tangible® Hydra-PEG® Contact Lenses should be thoroughly cleaned with the recommended cleaning solution and disinfected/hydrated in the desired soaking/conditioning solution according to the labeled directions for use prior to placement on the eye to insure maximum surface wettability.

FITTING

Conventional methods of fitting gas permeable contact lenses for regular corneas apply Acuity 100™ (hexafocon A) and Acuity 100™ (hexafocon A) with Tangible® Hydra-PEG® Contact Lenses. Special methods are needed for irregular corneas. For a detailed description of the fitting techniques, refer to the Acuity 100™ (hexafocon A) and Acuity 100™ (hexafocon A) with Tangible® Hydra-PEG® Professional Fitting and Information Guide, copies of which are available from:

Acuity Polymers Inc.
1667 Lake Avenue
Building 59, Suite 303
Rochester, NY 14615 USA

1-888-POLYMER (1-888-756-9637)

www.acuitypolymers.com

WEARING SCHEDULE

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

For the management of irregular corneal conditions, close supervision by the eye care professional is necessary. The eye care professional should determine the appropriate wearing time and provide specific instructions to the patient regarding lens care, insertion, and removal.

WARNING:

Patients fitted with Acuity 100™ (hexafocon A) and Acuity 100™ (hexafocon A) with Tangible® Hydra-PEG® contact lenses for the management of keratoconus or other types of irregular cornea should NOT wear their lenses overnight or while sleeping in them. For these patients, wearing lenses while asleep can cause serious adverse reactions or loss of vision. It is essential that the wearing schedule be individually determined by the eye care professional.

Acuity 100™ (hexafocon A) and Acuity 100™ (hexafocon A) with Tangible® Hydra-PEG® contact lenses are indicated for daily wear. The maximum suggested wearing time for these lenses is:

During Waking Hours*

Day	Hours
1	4-8
2	6-10
3	8-14
4	10-15
5	12-all waking hours
6 and after	all waking hours

*If the lenses continue to be well tolerated.

Lenses should be removed daily for cleaning and disinfecting (according to lens care system instructions) before wearing.

LENS CARE DIRECTIONS

Eye care professionals 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

Basic Instructions:

- Always wash and rinse hands before handling contact lenses.
- Always use fresh unexpired lens care solutions.
- Use the recommended chemical (not heat) system of lens care. 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, enzyme (as recommended by the eye care professional) and disinfect lenses according to the schedule prescribed by the eye care professional. The use of an enzyme or any cleaning solution does not substitute for disinfection.

The lens care products listed are recommended by Acuity Polymers Inc. for use with the Acuity 100™ (hexafocon A) and Acuity 100™ (hexafocon A) with Tangible® Hydra-PEG® Contact Lens. See Package Insert for other products that may be used with this lens. Eye care professionals may recommend alternate solutions that are appropriate for the patient's use with his or her lens. Care should be taken not to mix solutions from different companies and/or care systems unless specifically instructed to do so by the eye care professional.

RECOMMENDED LENS CARE SYSTEM	
Solution Purpose	**Lens Care System** **Chemical (Not Heat) Disinfection**
Cleaning	Menicon Unique pH™ Multi-Purpose Solution Boston SIMPLUS® Multi-Action Solution
Rinsing	Menicon Unique pH™ Multi-Purpose Solution, Boston Simplus®, Sterile Saline Solution or other solution recommended by your eye care professional
Disinfection/ Storage	Menicon Unique pH™ Multi-Purpose Solution, Boston Simplus® or other solution recommended by your eye care professional
Lubrication/ Rewetting	Boston® Rewetting Drops
Insertion of semi-scleral & scleral lenses	Sterile Non-preserved solution (Alcon Unisol®) or 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) with a recommended cleaning solution. Rinse the lens thoroughly with recommended 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 the eye care professional.
- 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, the patient should be instructed to consult the package insert or the eye care professional for information on storage of lenses.
- After removing the lenses from the lens case, empty and rinse the lens storage case with sterile contact lens solution as recommended by the lens case manufacturer. (never use tap water); 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 case manufacturer or your eye care professional.
- Eye care professionals may recommend a lubricating/rewetting solution, which can be used to wet (lubricate) lenses while they are being worn to make them more comfortable.
- Acuity 100™ (hexafocon A) and Acuity 100™ (hexafocon A) with Tangible® Hydra-PEG® Contact Lenses cannot be heat (thermally) disinfected.

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 lens manufacturer or the eye care professional.
- Thoroughly rinse lenses with a fresh saline 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 eyes.
- 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 (or follow the instructions on the disinfection solution labeling) 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 the eye care professional. Enzyme cleaning removes protein deposits on the lens. These deposits cannot be removed with regular cleaners. Removing protein deposits is important for the well-being of the patient's lenses and eyes. If these deposits are not removed, they can damage the lenses and cause irritation.

Enzyme cleaning does NOT replace routine cleaning and disinfecting. For enzyme cleaning, the patient should carefully follow the instructions in the enzymatic cleaning labeling as recommended by your eye care professional.

CARE FOR A STICKING (NON-MOVING) LENS:

If the lens sticks (stops moving), the patient should be instructed to apply a few 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 10 minutes, the patient should immediately consult the eye care professional.

EMERGENCIES

The patient should be informed that if chemicals of any kind (household products, gardening solutions, laboratory chemicals, etc.) are splashed into the eyes, the patient should:

FLUSH EYES IMMEDIATELY WITH TAP WATER AND THEN REMOVE LENSES PROMPTLY. CONTACT THE EYE CARE PROFESSIONAL OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.

HOW SUPPLIED

Each Acuity 100™ (hexafocon A) and Acuity 100™ (hexafocon A) with Tangible® Hydra-PEG® Contact Lens is shipped non-sterile in an individual plastic container.

The plastic container, packing slip or invoice is marked with the information for base curve, diopter power, diameter, center thickness, color, UV-absorber, lot number, and other required parameters specified by the design.

REPORTING OF ADVERSE REACTIONS

All serious adverse experiences and adverse reactions observed in patients wearing Acuity 100™ (hexafocon A) and Acuity 100™ (hexafocon A) with Tangible® Hydra-PEG® Contact Lenses should be reported to:

Acuity Polymers Inc.
1667 Lake Avenue
Building 59, Suite 303
Rochester, NY 14615

1-888-POLYMER (1-888-756-9637)

www.acuitypolymers.com

Symbol	Definition
	For sale only by or on the order of a lens care professional.
	Attention, see instructions for use.
	Upper limit of temperature

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