PACKAGE INSERT

Acuity™ 181 (tisilfocon A) Daily Wear Contact Lenses

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 the patient upon request. The eye care practitioner should provide the patient with the wearer's guide that pertains to the patients prescribed lens.

RX ONLY

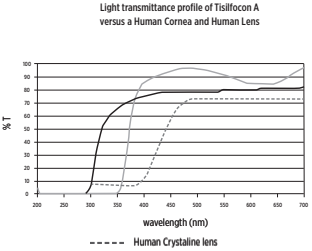
CAUTION: Federal law restricts this device to sale by or on the order of a licensed practitioner.

DESCRIPTION OF LENSES

The **Acuity 181™ (tisilfocon A) and Acuity 181™ (tisilfocon A) with Tangible™ Hydra-PEG® Rigid Gas Permeable Contact Lens** is manufactured from a machine latheable rigid gas permeable material composed of siloxanyl fluoromethacrylate copolymer that is tinted for visibility and available with or without an ultraviolet (UV) light absorber. The lenses may be plasma treated during the manufacturing process.

In the **Acuity 181™ (tisilfocon A) and Acuity 181™ (tisilfocon A) with Tangible™ Hydra-PEG® Rigid Gas Permeable Contact Lenses** with UV Blocker, a Benzophenone UV blocking monomer is used to block >99% of UV Radiation.

The following graph compares the UV transmittance profile of the **Acuity 181™ (tisilfocon A) Rigid Gas Permeable Contact Lenses** (with Benzophenone UV blocking monomer), to that of a cornea and crystalline lens.



Cornea - Human cornea from a 24-year-old person as described in Lerman, S., Radiant Energy and the Eye, MacMillan, New York, 1980, p. 58. Crystalline Lens - Human crystalline lens from a 25-year-old person as described in Waxler, M., Hitchins, V.M., Optical Radiation and Visual Health, CRC Press, Boca Raton, Florida, 1986, p. 19, figure 5.

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 your eye-care practitioner for more information.

WARNING: UV-absorbing contact lenses are NOT a substitute for protective UV-absorbing eyewear such as UV-absorbing goggles or sunglasses because they do not completely cover the eye and surrounding area. You should continue to use UV-absorbing eyewear as directed.

The **Acuity 181™ (tisilfocon A) and Acuity 181™ (tisilfocon A) with Tangible™ Hydra-PEG® Rigid Gas Permeable Contact Lenses** incorporates a visibility tint to make the lens more visible for handling. The tinted lenses contain one or more of the following color additives: D&C Green No. 6, Solvent Yellow No. 18, D&C Violet No. 2 and D&C Red No. 17.

The **Acuity 181™ (tisilfocon A) Rigid Gas Permeable Contact Lens** may be optionally treated to incorporate Tangible® Hydra-PEG®—which is a thin polyethylene glycol (PEG)-based polymer that is covalently bonded to the surface of the contact lens and is designed to enhance the surface properties of the contact lens while retaining the mechanical properties of the underlying material. When treated with Tangible® Hydra-PEG®, the underlying material (tisilfocon A) is encapsulated in a thin layer of polymer that results in measurable improvement of wettability (sessile drop contact angle) compared to untreated lenses. The following table depicts the contact angle of the coated vs. uncoated vs. plasma treated lenses:

	Acuity 181™ (tisilfocon A)		
	Uncoated	Tangible™ Hydra-PEG® Coated	Plasma Treated
Average Sessile Drop Wetting Angle (degrees), n=30	95.4	48.8	19.2
Standard Deviation	3.89	3.64	6.45

The **Acuity 181™ (tisilfocon A) and Acuity 181™ (tisilfocon A) with Tangible™ Hydra-PEG® Rigid Gas Permeable Contact Lens** may be packaged and shipped "dry" or "wet" in a polypropylene contact lens case. The primary container for shipping the **Acuity 181™ (tisilfocon A) and Acuity 181™ (tisilfocon A) with Tangible™ Hydra-PEG® Rigid Gas Permeable Contact Lens** is the deep well lens case. When shipped "wet", the **Acuity 181™ (tisilfocon A) and Acuity 181™ (tisilfocon A) with Tangible™ Hydra-PEG® Rigid Gas Permeable Contact Lens** may be packaged and shipped in the Bausch & Lomb's Boston® Simplus Multi-Action Solution.

The physical properties of the **Acuity 181™ (tisilfocon A) and Acuity 181™ (tisilfocon A) with Tangible™ Hydra-PEG® Rigid Gas Permeable Contact Lens** is as follows:

Refractive Index	1.434
Specific Gravity	1.22
Water Content	< 1.0%
Oxygen Permeability, Dk, ISO/ Fatt Method 10-11 (cm3 O2 x cm/ (cm2 x sec x mmHg)@ 35°C	181
Hardness, Shore D [±2 D]	81
Flex Modulus, MPa	1488
Maximum, Flexural Strength, MPa	55.6
Toughness, J/m3	2.23
Visible Tints (Lenses contain one or more of the following color additives conforming to 21 CFR Part 73 & 74 Subpart D)	D&C Green No. 6, Solvent Yellow No. 18, D&C Violet No. 2, D&C Red No. 17
Wet Shipping Compatible Solution	Bausch & Lomb's Boston Simplus Multi-Action Solution

The **Acuity 181™ (tisilfocon A) and Acuity 181™ (tisilfocon A) with Tangible™ Hydra-PEG® Rigid Gas Permeable Contact Lens** is available, for daily wear, in the Spherical, Aspherical, Toric, Multifocal/Bifocal, Irregular Cornea (Scleral), Orthokeratology design configurations, within the following lensparameters:

SPHERICAL AND ASPHERIC LENS	
PowerRange	-35.00D to +35.00D in 0.25D increments
Diameter	7.0mm to 26.0mm
Base Curve Range	4.00mm to 12.00 mm in 0.01mm increments
MULTIFOCAL/BIFOCAL LENS (CENTERED, DECENTERED, CRESCENT)	
Power Range	-35.00D to +35.00D in 0.25D increments
Diameter	7.0mm to 26.0mm
Base Curve Range	4.00mm to 12.00mm in 0.01mm increments
Segment Heights	-2.00mm to +1.00mm in 0.5 increments
Add Powers	+1.00D to +4.00D in 0.25D increments
Prism Ballast	0.5 to 3.5 prism diopters in 0.5D increments
TORIC LENS	
Power Range	-35.00D to +35.00D in 0.25D increments
Diameter	7.0mm to 26.0mm
Base Curve Range	4.00mm to 12.00mm in 0.01mm increments
Toricity	Up to 10.00 Diopters
SCLERAL CONTACT LENS	
Power Range	-35.00D to +35.00D in 0.25D increments
Diameter	16mm to 26.0mm
NormalizedVaults	2.50mm to 6.00mm

ORTHOKERATOLOGY LENS	
Power Range	-5.00D to +1.50D in 0.25D
Diameter	9.6mm to 11.6mm
Base Curve Range	7.30mm to 10.15mm
Reverse Curve	5.00mm to 9.00mm (Steeper than the base curve)
Alignment Curve 1	7.00mm to 9.0mm (Steeper than the base curve but flatter than the Reverse Curve
Alignment Curve 2	7.25mm to 9.25mm (Steeper than the base curve but flatter than the Alignment Curve 1 and Reserve Curve)
Peripheral Curve	9.00mm to 15.00mm

ACTIONS

When placed on the cornea, the **Acuity 181™ (tisilfocon A) and Acuity 181™ (tisilfocon A) with Tangible™ Hydra-PEG® Daily Wear Contact Lens** acts as a refracting media to focus light rays on the retina.

Acuity 181™ (tisilfocon A) and Acuity 181™ (tisilfocon A) with Tangible™ Hydra-PEG® Daily Wear Contact Lens for orthokeratology produce a temporary reduction of myopia by changing the shape (flattening) of the cornea, which is elastic in nature. Flattening the cornea reduces the focusing power of the eye, and if the amount of corneal flattening is properly controlled, it is possible to bring the eye into correct focus and compensate for myopia. Contact lenses rest directly on the corneal tear layer and can influence the corneal shape. Regular RGP contact lenses are designed to cause little or no effect on the shape of the cornea, but **Acuity 181™ (tisilfocon A) and Acuity 181™ (tisilfocon A) with Tangible™ Hydra-PEG®** for daily wear orthokeratology are designed to flatten the shape of the cornea by applying slight pressure to the center of the cornea. If the central cornea is flattened, this reduces the focusing power of the eye, and if the amount of corneal flattening is sufficient, it is possible to bring the eye into correct focus and compensate for myopia. After the contact lens is removed, the cornea generally retains its altered shape for part or all of the remainder of the day. A Myopic Reduction Maintenance Lens, also referred to as a Retainer Lens (see Wearing Schedule Section) should be worn each day to maintain the corneal flattening or the myopia will revert back to the pretreatment level.

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

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

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 must 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.

INDICATIONS FOR USE

The **Acuity 181™ (tisilfocon A) and Acuity 181™ (tisilfocon A) with Tangible™ Hydra-PEG® SPHERICAL** Rigid Gas Permeable (RGP) Contact Lens is indicated for daily wear for the correction of refractive error in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia.

The **Acuity 181™ (tisilfocon A) and Acuity 181™ (tisilfocon A) with Tangible™ Hydra- PEG®TORIC** Rigid Gas Permeable (RGP) Contact Lens is indicated for daily wear for the correction of refractive error in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia and/or possesses refractive astigmatism not exceeding 10.00 diopters.

The A**cuity 181™ (tisilfocon A) and Acuity 181™ (tisilfocon A) with Tangible™ Hydra- PEG®MULTIFOCAL/ BIFOCAL** Rigid Gas Permeable (RGP) Contact Lens is indicated for daily wear for the correction of refractive error in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia and/ or possesses refractive astigmatism not exceeding 4 diopters and are presbyopic requiring add power of up to +4.00 diopters.

The **Acuity 181™ (tisilfocon A) and Acuity 181™ (tisilfocon A) with Tangible™ Hydra-PEG® IRREGULAR CORNEA** Daily Wear Contact Lens may be prescribed in otherwise non-diseased eyes that require a rigid gas permeable 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 181™ (tisilfocon A) and Acuity 181™ (tisilfocon A) with Tangible™ Hydra-PEG® ORTHOKERATOLOGY** contact lenses are indicated for daily wear in an orthokeratology fitting program for the temporary reduction of myopia of up to 5.00 diopters in non-diseased eyes. To maintain the orthokeratology effect of myopia reduction, lens wear must be continued on a prescribed wearing schedule.

Furthermore, eyes suffering from certain ocular surface disorders may benefit from the physical protection, aqueous hydrated environment and the saline bath provided by scleral lens designs.

Acuity 181™ (tisilfocon A) and Acuity 181™ (tisilfocon A) with Tangible™ Hydra-PEG® (tisilfocon A) SCLERAL lenses are indicated for therapeutic use for the management of irregular and distorted corneal surfaces where the subject:

1. cannot be adequately corrected with spectacle lenses

2. requires a rigid gas permeable contact lens surface to improve vision

3. is unable to wear a corneal rigid gas permeable lens due to corneal distortion or surface irregularities.

Common causes of corneal distortion include but are not limited to corneal infections, trauma, tractions as a result of scar formation secondary to refractive surgery (e.g. LASIK or radial keratotomy) or corneal transplantation. Causes may also include corneal degeneration (e.g. keratoconus, keratoglobus, pellucid marginal degeneration, Salzmann's nodular degeneration) and corneal dystrophy (e.g., lattice dystrophy, granular corneal dystrophy, Reis-Bucklers dystrophy, Cogan's dystrophy).

The **Acuity 181™ (tisilfocon A) and Acuity 181™ (tisilfocon A) with Tangible™ Hydra-PEG® (tisilfocon A) SCLERAL lenses** are indicated for therapeutic use in eyes with ocular surface disease (e.g. ocular Graft-versus-Host disease, Sjogren'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 **Acuity 181™ (tisilfocon A) and Acuity 181™ (tisilfocon A) with Tangible™ Hydra-PEG® (tisilfocon A) (tisilfocon A) SCLERAL lenses** may concurrently provide correction of refractive error.

Eye care practitioners may prescribe the lenses for frequent/planned replacement wear, with cleaning, disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be cleaned and disinfected using a chemical (not heat) lens care system.

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE the **Acuity 181™ (tisilfocon A) and Acuity 181™ (tisilfocon A) with Tangible™ Hydra- PEG® Daily Wear Contact Lens** when any of the following conditions are present:

- Acute and subacute inflammation or infection of the anterior chamber of the eye.
- Any eye disease, injury, or abnormality other than irregular corneal conditions or ocular surface disease conditions as described in the INDICATIONS section that affects the cornea, conjunctiva, or eyelids.
- Aphakic patients should not be fitted with Acuity 181™ (tisilfocon A) and **Acuity 181™ (tisilfocon A) with Tangible™ Hydra-PEG® Daily Wear Contact Lens** until the determination is made that the eye has healed completely.
- Severe insufficiency of lacrimal secretion (dry eyes) except when using a 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 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 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 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 **Acuity 181™ (tisilfocon A) and Acuity 181™ (tisilfocon A) with Tangible™ Hydra-PEG® Daily Wear Contact Lens Daily Wear Contact Lens.**
- Any active corneal infection (bacterial, fungi, or viral).
- Patients unable to follow lens care regimen or unable to obtain assistance to do so.
- If eyes become red or irritated.

WARNINGS:

- PROBLEMS WITH CONTACT LENSES AND LENS CARE PRODUCTS COULD RESULT IN **SEROUS INJURY** TO THE EYE. It is essential that patients follow their eye care practitioner'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**; THEREFORE, 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 see their eye care practitioner as directed.
- 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.

PRECAUTIONS

Special Precautions for eye care practitioner and/or physician:

- **WARNING:** Inspect contact lens packaging for leakage when lenses are wet shipped. If the packaging is damaged or leaking, throw away damaged packaging and replace with a new contact lens container and refill with new cleaning, disinfection and storage solution. Prior to dispensing lenses that have been shipped wet, it is important to THOROUGHLY RINSE all solution from the lens since it will sting and cause irritation if instilled directly in the eye. After rinsing is complete and prior to inserting into patient's eye, apply 2 drops of wetting and rewetting drops to each surface of the lens WITHOUT rubbing the lens. When lenses are shipped/stored wet the solution needs to be replaced with fresh, sterile, and unexpired solution every 30 days from initial manufacture date.
- Clinical studies have demonstrated that contact lenses manufactured from (tisilfocon A) are safe and effective for their intended use. However, the clinical studies may not have included all design configurations or lens parameters that are presently available in this lens material.

  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. The continuing ocular health of the patient and lens performance on the eye should be carefully monitored by the prescribing eye care practitioner.
- For the most accurate fluorescein interpretation, it is recommended that the blue cobalt and the yellow Wratten filter be used. Whenever fluorescein is used in eyes, the eyes should be flushed with a sterile saline solution that is recommended for in eye use.
- Before leaving the eye care practitioner's office, the patient should be able to promptly 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.
- Patients with limbal stem cell deficiency may need to be monitored more closely to prevent progression of the disease, and if any progression of the disease is noted, contact lens wear may have to be reduced or terminated.

Eye care 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 for use with all lenses. Use only recommended solutions that are fresh and sterile. Never use solutions recommended for conventional hard contact lenses only. Chemical disinfection solutions should not be used with heat unless specifically indicated on product labeling for use in both heat and chemical disinfection. Always use **FRESH, STERILE 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. Do not use saliva or anything other than the recommended solution for lubricating or rewetting lenses. Always keep the lenses completely immersed in the recommended storage solution when the lenses are not being worn (stored). Prolonged periods of drying will damage the lenses. Follow the lens care directions for care for a dried out (dehydrated) dry lens if the lens surface does become dried out.
- If the lens sticks (stops moving) on the eye, follow the recommended directions on **Care For 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-base cosmetics are less likely to damage lenses than oil-base.
- Do not touch contact lenses with the fingers or hands if the hands are not free of foreign materials, as microscope scratches of the lenses may occur, causing distorted vision and/or injury to the eye.
- Carefully follow the handling, insertion, removal, cleaning, disinfection, storing and wearing instructions in the patient instructions for the **Acuity 181™ (tisilfocon A) and Acuity 181™ (tisilfocon A) with Tangible™ Hydra-PEG® Daily Wear Contact Lens** and those prescribed by the eye care practitioner.
- Never wear lenses beyond the period recommended by the eye care practitioner.
- If aerosol products such as hair spray are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.
- Always handle lenses carefully and avoid dropping them.
- Avoid all harmful or irritating vapors and fumes while wearing lenses.
- Ask the eye care practitioner about wearing lenses during sporting activities.
- Inform the doctor (health care practitioner) about being a contact lens wearer.
- Never use tweezers or other tools to remove lenses from the lens container unless specifically indicated for that use. Pour the lens into the hand.
- Do not touch the lens with fingernails.
- Always contact the eye care practitioner before using any medicine or medications in the eyes.
- Always inform the employer of being a contact lens wearer. Some jobs may require use of eye protection equipment or may require that the patient not wear contact lens.
- 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 eye.
- Redness of the eye.
- Feeling that something is in the eye such as a foreign body or scratched area.
- Excessive watering (tearing) or the eye.
- Unusual eye secretions.
- 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 discomfort or problems 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 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, the patient should **IMMEDIATELY REMOVE THE LENSES AND CONSULT THE EYE CARE PRACTITIONE R.**

  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 LENS OFF THE EYE AND SEEK IMMEDIATE PROFESSIONAL IDENTIFICATION** of the problem and prompt treatment to avoid serious eye damage.
- During therapeutic use, an adverse effect may be due to the original condition or disease or may be due to the effects of wearing the contact lenses. There is a possibility that the existing disease or condition might become worse when a contact lens is used to treat an already diseased or damaged eye. The patient should be instructed to avoid serious eye damage by contacting the eye care professional IMMEDIATELY if there is any increase in symptoms while wearing the lens.

CLINICAL STUDY RESULTS (for Daily Wear Orthokeratology):*

A total of 138 eyes were enrolled in a clinical study with 110 eyes completing a minimum of 3 months of contact lens wear. Of the completed eyes, a total of 106 eyes showed some reduction in myopic refractive error during the 3-month time period that the RGP contact lenses for orthokeratology were worn. The average reduction was 1.69 diopters with a range from 0.25 to 4.25 diopters. The average amount of myopia that can be expected to be corrected is shown in the following table. These values are only averages and some patients can be expected to achieve more or less than these averages.

AVERAGE REDUCTION IN MYOPIA (Diopters)

INITIAL MYOPIA	REDUCTION MYOPIA
-1.00	0.80
-2.00	1.50
-3.00	2.00
-4.00	2.40

The amount of myopia reduced varied between patients and could not be predicted prior to treatment. There was an insignificant difference between the patients who wore contact lenses prior to the study and those with no previous contact lens experience. RGP contact lenses for orthokeratology provided a temporary full reduction in some patients with up to 3.00 diopters of myopia. For patients with greater than 3.00 diopters of myopia, only a partial reduction of myopia can be expected. The percentage of patients that can be expected to achieve full or partial temporary refractive reduction is shown in the following table:

PERCENT OF EYES THAT ACHIEVED FULL OR PARTIAL TEMPORARY REDUCTION OF MYOPIA

SYSTEM PROCESS	FULL TEMP REDUCTION	UP TO 0.50 D UNDER FULL REDUCTION	FINAL V.A. 20/20 OR BETTER	FINAL V.A. 20/20 OR BETTER
-1.00 D	52%	84%	78%	100%
-1.25 TO -2.00 D	36%	55%	74%	96%
-2.25 TO -3.00 D	18%	35%	48%	472%
-3.25 TO -4.00 D	4%	13%	16%	64%

For the 110 eyes that completed this study, the initial visual acuity by best refraction was 20/20 or better for 104 eyes and 20/40 or better for all 110 eyes. At the final visit, visual acuity with contact lenses was equal to or better than 20/20 for 99 eyes, 20/40 for 109 eyes and one eye had a visual acuity of 20/70. Nine eyes had a one-line drop in visual acuity for contact lenses compared to best refraction, one eye had a two-line drop and three eyes had a three-line drop. In each case, the reduced visual acuity was attributed to residual astigmatism when wearing contact lenses. The percentage of eyes that achieved uncorrected visual acuity of 20/20 or better and 20/40 or better in relation to the initial myopia is given in the above table. A total of 43 (39%) eyes achieved a visual acuity of 20/20 or better and 78 (71%) eyes achieved 20/40 or better.

EFFECTS ON ASTIGMATISM

Either increases or decreases in astigmatism may occur following orthokeratology. Of the 110 eyes (55 patients) which completed the three-month clinical, 8% showed no change in corneal astigmatism, 32% showed a decrease less than one diopter, while 41% showed an increase less than one diopter and 16% showed an increase greater than one diopter.

WEARING TIME

In the study, the average wearing time required for patients who wore RGP contact lenses for orthokeratology for various time periods was as follows:

One week	7.7 hours/day
Two weeks	7.8 hours/day
One month	8.0 hours/day
Three months	8.4 hours/day

There was considerable variability, however, as many patients required several hours more or less than the averages as shown for the three-month time period as follows:

Daily Wear

Time Worn	Percent of patients
0 to 4 hours	25.5%
4.1 to 8 hours	21.8%
to 12 hours	23.7%
to 16 hours	27.2%

*Data based on CONTEX (siflufocon A) 3-month Clinical Study.

FITTING

Conventional methods of fitting contact lenses do and do not apply to **Acuity 181™ (tisilfocon A) and Acuity 181™ (tisilfocon A) with Tangible™ Hydra-PEG® Daily Wear Contact Lens Daily Wear Contact Lens.** For a detailed description of the fitting techniques, refer to **Acuity 181™ (tisilfocon A) and Acuity 181™ (tisilfocon A) with Tangible™ Hydra-PEG® Daily Wear Contact Lens** Professional Fitting and Information Guide and **Acuity 181™ (tisilfocon A) and Acuity 181™ (tisilfocon A) with Tangible™ Hydra- PEG® Daily Wear Contact Lens Daily Wear Contact Lens** Professional Fitting and Information Guide for Daily Wear Orthokeratology, copies of which are available from:

Acuity Polymers. Inc.
1667 Lake Ave
Building 59, Suite 303
Rochester, New York USA
1-888-POLYMER (1-888-756-9637)

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

WEARING SCHEDULE

THE WEARING AND REPLACEMENT SCHEDULES SHOULD BE DETERMINED BY THE EYE CARE PRACTITIONER. Patients tend to over wear 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.

The maximum suggested wearing schedule for the **Acuity 181™ (tisilfocon A) and Acuity 181™ (tisilfocon A) with Tangible™ Hydra-PEG® Daily Wear Contact Lens** Daily Wear Contact Lens is reflected below.

DAY	HOURS
1	3
2	4
3	5
4	6
5	7
6	8
7	9
8	10
9	11
10 – 14	12
15+	All waking hours

STUDIES HAVE NOT BEEN COMPLETED TO SHOW THAT THE ACUITY 181 (TISILFOCON A) DAILY WEAR CONTACT LENS IS SAFE TO WEAR DURING SLEEP. WEARING SCHEDULES SHOULD BE DETERMINED BY THE EYE CARE PRACTITIONER.

LENS CARE DIRECTIONS

Eye care 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:

Basic Instructions:

- Care of contact lenses takes very little time and involves three essential steps – **CLEANING, RINSING AND DISINFECTION.** Each step in itself is important, and one step is not to be replaced by the other. Always wash, rinse and dry hands before handling contact lenses. Always use **FRESH, STERILE UNEXPIRED** lens care solutions. Use the recommended chemical (not heat) lens care system. Different solutions cannot always be used together, and not all solutions are safe for use with all lenses. D**O 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. 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 rewet (lubricate) lenses while they are being worn to make them more comfortable.

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.

SPECIFIC INSTRUCTIONS FOR USE AND WARNINGS:

1. Soaking and Storing the Lenses

Instruction for Use:

Use only fresh multi-purpose (contact lens disinfecting) solution each time the lenses are soaked (stored).

WARNING:

Do not reuse or "top off" old solution left in the 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 the case.

2. Rub and Rinse Time Instruction for Use:

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

WARNING:

Rub and rinse the lenses for the recommended amount of time to help prevent serious eye infections.

Never use water, saline solution, or rewetting drops to disinfect the lenses. These solutions will not disinfect the 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 the lens case according to the directions given by the eye care professional or the labeling that came with the case.

Contact lens cases can be a source of bacterial growth.

WARNING:

Do not store the lenses or rinse the lens case with water or any non-sterile solution. Only use fresh multi-purpose solution to prevent contaminating the

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 the contact lenses to water while wearing them.

WARNING:

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

5. Discard Date on Multipurpose Solution Bottle Instruction for Use:

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

The Discard date refers to the time the patient 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 the 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 the solution, DO NOT transfer to other bottles or containers.

LENS CLEANING, RINSING, DISINFECTION, AND STORAGE:

Clean one lens first (always the same lens first to avoid mix-ups), rinse the lens thoroughly with recommended rinsing solution to remove the cleaning solution, mucus, and film from the lens surface, and put lens into correct chamber of the lens storage case. Then repeat the procedure for the second lens. After cleaning and rinsing, **disinfect** lenses using the system recommended by the manufacture and/or the eye care practitioner. To store lens, 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 practitioner for information on storage of lenses.

LENS CARE REGIMEN:

Patients must adhere to the lens care regimen recommended by their eye care practitioner for the care of Acuity 181™ (tisilfocon A) and **Acuity 181™ (tisilfocon A) with Tangible™ Hydra-PEG® Daily Wear Contact Lens.** Failure to follow this procedure may result in development of serious ocular infections

Care for a sticking (non-moving) lens:

If the lens sticks (cannot be removed), the patient should be instructed to apply 3 to 4 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 15 minutes, the patient should **IMMEDIATELY** consult the eye care practitioner.

STORAGE:

The **Acuity 181™ (tisilfocon A) and Acuity 181™ (tisilfocon A) with Tangible™ Hydra-PEG® Daily Wear Contact Lens** must be stored in the individual plastic case and in the recommended solutions.

Chemical (NOT HEAT) Lens Disinfection:

1. Wash and rinse your hands thoroughly BEFORE HANDLING LENSES.
2. After removal of lenses, CLEAN the lenses by applying three drops of cleaning solution to each surface. Then rub the lens between your fingers for 20 seconds.
3. AFTER CLEANING, thoroughly rinse both surfaces of the lens with a steady stream of fresh, sterile unexpired rinsing solution for approximately 10 seconds.
4. Fill the contact lens case with the recommended disinfection and storage solution and place lenses in the proper cells for the time specified in the solution label.

Note: DO NOT HEAT THE DISINFECTION SOLUTION AND LENSES.

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 rinsing solution prior to placement on the eye should reduce the potential for irritation.

- When using hydrogen peroxide lens care systems, the patient must use ONLY the lens case provided with the hydrogen peroxide care system. This case is specially designed to neutralize the solution. Failure to use the specialized case will result in severe stinging, burning, and injury to the eye. Follow the recommendations on the hydrogen peroxide system labeling exclusively. Following disinfection with a peroxide system, the lenses should be rinsed with sterile saline.

USE OF ENZYMATIC CLEANING PROCEDURE

Boston® ONE STEP Liquid Enzymatic Cleaner or as recommended by an eye care professional, approved for rigid gas permeable contact lenses.

RECOMMENDED SOLUTIONS

the **Acuity 181™ (tisilfocon A) and Acuity 181™ (tisilfocon A) with Tangible™ Hydra-PEG® Daily Wear Contact Lens** should be disinfected using only a chemical (not heat) disinfection system. The following lens care systems are recommended (or other lens care systems as recommended by your eye care practitioner).

RECOMMENDED LENS CARE SYSTEM	
SYSTEM PROCESS	**CHEMICAL (not heat) DISINFECTION SYSTEM**
Daily Cleaning	Bausch & Lomb Boston Simplus® Mult-Action Solution
Cleaning, Disinfecting and Soaking	Bausch & Lomb Boston Simplus® Mult-Action Solution
Rinsing (do not use tap water)	Bausch & Lomb Boston Simplus® Mult-Action Solution
Wetting & Lubricating	Boston® Rewetting Drops
Use With Scleral Contact Lenses	Bausch & Lomb ScleralFil® Preservative Free Saline Solution, or a preservative free sterile saline solution recommended for use with scleral contact lenses

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 IMMEDIATELY CONTACT THE EYE CARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.

HOW SUPPLIED:

Each lens is supplied non-sterile in an individual plastic case. The case, packing slip and invoice are marked with the base curve, dioptric power, toric power, bifocal power, diameter, center thickness, color, UV blocker, lot number and the expiration date.

REPORTING OF ADVERSE REACTIONS:

Practitioners should report any adverse reactions within 5 days to Acuity Polymers. Inc.

Additional Fitting Guides, Package Inserts and Patient Guides are available from:

Acuity Polymers. Inc.
1667 Lake Ave
Building 59, Suite 303
Rochester, New York USA

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

www.acuitypolymers.com

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

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

A100PIV20924