

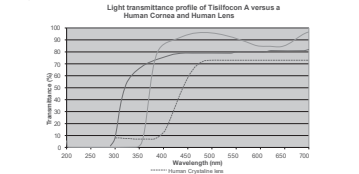
PACKAGE INSERT
Acuity Polymers
Acuity 181 (Biflatoon A) Daily Wear Contact Lenses
CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A LICENSED PRACTITIONER

IMPORTANT: Please read carefully and keep this information for future use. This package insert is intended for the eye care practitioner and 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.

DESCRIPTION OF LENSES:
The Acuity 181™ (Biflatoon A) and Acuity 181™ (Biflatoon A) with Tangible™ Hydra-PEG® Rigid Gas Permeable Contact Lenses is manufactured from a machine latheable rigid gas permeable material composed of siloxane polymers. It is intended for use with or without an ultraviolet (UV) light absorber. The lenses may be plasma treated during the manufacturing process.

In the Acuity 181™ (Biflatoon A) and Acuity 181™ (Biflatoon A) with Tangible™ Hydra-PEG® Rigid Gas Permeable Contact Lenses with UV Blocker, a Benzophenone UV blocking monomer is used to block >98% of UV Radiation.

The following graph compares the UV transmittance profile of the Acuity 181™ (Biflatoon 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, 2nd Ed., McGraw-Hill, New York, 1960, p. 58. Crystalline Lens** - Human crystalline lens from a 25-year-old person as described in **Waxler, M., Michels, 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 (diet and habits of outdoor activities). UV-absorbing contact lenses help provide protection against harmful UV radiation. Human clinical studies have shown 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. Use with 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™ (Biflatoon A) and Acuity 181™ (Biflatoon A) with Tangible™ Hydra-PEG® Rigid Gas Permeable Contact Lenses incorporates a wettability 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, Sunset Yellow No. 18, D&C Violet No. 2, and D&C Red No. 17.

The Acuity 181™ (Biflatoon A) and Acuity 181™ (Biflatoon A) with Tangible™ Hydra-PEG® Rigid Gas Permeable Contact Lenses 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 (Biflatoon 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:

	Uncoated	Tangible™ Hydra-PEG® Coated	Plasma Treated
Average Sessile Drop Wetting Angle (degrees)	55.4	101.8	112.2
Standard Deviation	3.89	3.04	6.45

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

The physical properties of the Acuity 181™ (Biflatoon A) and Acuity 181™ (Biflatoon A) with Tangible™ Hydra-PEG® Rigid Gas Permeable Contact Lenses are as follows:

	Acuity 181™ (Biflatoon A)
Specific Gravity	1.22
Refractive Index	1.42
Oxygen Permeability, DK, BOFatt Method (Dk) (cm ² x 10 ⁻⁹ cm ³ x sec x cm ² x mmHg @ 35°C)	181
Hardness, Shore D (10 D)	81
Flex Modulus, MPa	1808
Maximum Flexural Strength, MPa	4.68
Toughness, J/m ²	2.25
Tensile Tests (Lenses contain one or more of the following color additives conforming to CFR Part 73.8.14 Subpart D)	D&C Green No. 6, Sunset Yellow No. 18, D&C Violet No. 2, D&C Red No. 17
Wet Shipping Compatible Solution	Bausch & Lomb's Boston Simplex

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

	SPHERICAL AND ASPHERIC LENS
Power Range	-35.00D to +35.00D in 0.25D increments 7.0mm to 26.0mm
Diameter	30.00mm to 12.00mm in 0.01mm increments
Base Curve Range	4.00mm to 12.00mm in 0.01mm increments
	MULTIFOCAL/BIFOCAL LENS (CENTRAL, LUCIDAL, PERIPHERAL, OR SCENT)
Power Range	-35.00D to +35.00D in 0.25D increments
Diameter	30.00mm 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
Rising 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 16mm to 26.0mm
Diameter	2.50mm to 6.00mm
	ORTHOKEATOLOGY LENS
Power Range	-5.00D to +1.50D in 0.25D increments
Diameter	6.0mm to 11.0mm
Base Curve Range	7.00mm to 10.00mm
Reverse Curve	5.00mm to 8.00mm (Steeper than the base curve)
Alignment Curve 1	7.00mm to 9.00mm (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 Reverse Curve)
Peripheral Curve	9.00mm to 15.00mm

ACTIONS: When used on the cornea, the Acuity 181™ (Biflatoon A) and Acuity 181™ (Biflatoon A) with Tangible™ Hydra-PEG® Rigid Gas Permeable Contact Lenses acts as a refracting media to focus light rays on the retina.

The Acuity 181™ (Biflatoon A) and Acuity 181™ (Biflatoon A) with Tangible™ Hydra-PEG® Rigid Gas Permeable Contact Lenses for orthokeratology provide a temporary reduction of myopia by changing the shape (battening) of the cornea, which is elastic in nature. Battening the cornea reduces the focusing power of the eye, and the amount of corneal flattening is properly controlled. It is possible to bring the eye into correct focus and compensate for myopia. Contact lenses used directly on the cornea help and can influence the corneal shape. Rigid Gas Permeable (RGP) contact lenses are designed to cause little or no effect on the shape of the cornea, but Acuity 181™ (Biflatoon A) and Acuity 181™ (Biflatoon 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 returns to 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 pre-treatment level.

CAUTION 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 materials involved 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™ (Biflatoon A) and Acuity 181™ (Biflatoon A) with Tangible™ Hydra-PEG® SPHERICAL, Rigid Gas Permeable (RGP) Contact Lenses 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™ (Biflatoon A) and Acuity 181™ (Biflatoon A) with Tangible™ Hydra-PEG® TORIC Rigid Gas Permeable (RGP) Contact Lenses is indicated for daily wear for the correction of refractive error in aphakic and not aphakic persons with myopia or hyperopia and/or possesses refractive astigmatism not exceeding 10.00 diopters.

The Acuity 181™ (Biflatoon A) and Acuity 181™ (Biflatoon A) with Tangible™ Hydra-PEG® MULTIFOCAL/BIFOCAL Rigid Gas Permeable (RGP) Contact Lenses 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™ (Biflatoon A) and Acuity 181™ (Biflatoon A) with Tangible™ Hydra-PEG® IRREGULAR CORNEA Daily Wear Contact Lenses 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™ (Biflatoon A) and Acuity 181™ (Biflatoon 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, lenses 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™ (Biflatoon A) and Acuity 181™ (Biflatoon A) with Tangible™ Hydra-PEG® Rigid Gas Permeable (RGP) Contact Lenses are indicated for therapeutic use for the management of irregular and distorted corneal surfaces where the subject:

- cannot be adequately corrected with spectacle lenses
- requires a rigid gas permeable contact lens surface to improve vision
- 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 common 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-Bücklers dystrophy, Cogan's dystrophy).

The Acuity 181™ (Biflatoon A) and Acuity 181™ (Biflatoon A) with Tangible™ Hydra-PEG® (Biflatoon A) SCLERAL lenses are 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 lens reservoir and protection against an adverse environment. When prescribed for therapeutic use for a distorted cornea or ocular surface disease, the Acuity 181™ (Biflatoon A) and Acuity 181™ (Biflatoon A) with Tangible™ Hydra-PEG® (Biflatoon 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™ (Biflatoon A) and Acuity 181™ (Biflatoon A) with Tangible™ Hydra-PEG® Daily Wear Contact Lenses 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 anomaly other than irregular corneal conditions or ocular surface disease as described in the INDICATIONS section that affects the cornea, conjunctiva, or eyelids.
- Aphakic patients should not be fitted with Acuity 181™ (Biflatoon A) and Acuity 181™ (Biflatoon A) with Tangible™ Hydra-PEG® Daily Wear Contact Lenses if 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 and acts as a protective barrier for the cornea if non-aphakic.
- Any systemic disease that may affect the eye or be exacerbated by wearing contact lenses.
- Allergic reactions or ocular surface conditions or adverse that may be induced or exacerbated by wearing contact lenses or use of contact lenses.
- Along to any ingrowth, such as neovascularization, in a solution which is to be used to care for Acuity 181™ (Biflatoon A) and Acuity 181™ (Biflatoon A) with Tangible™ Hydra-PEG® Daily Wear Contact Lenses.
- Any active corneal infection (bacterial, viral, or fungal).
- Patients unable to follow the 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 SERIOUS INJURY TO THE EYE. The eye care practitioner should ensure 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 and eye. PROBLEMS, INCLUDING CORNEAL LACERS, 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: Infection has been associated with contact 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. After removing contact 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 inhaled directly in the eye. Prior to rinsing in 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/wetted 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 Biflatoon 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.

The most accurate corneal curvature interpretation, it is recommended that the blue coat and the yellow fixation filter used. Whenever fluorescein is used in the eyes, the eyes should be flushed with a sterile saline solution that is recommended for eye use. Before leaving the eye care practitioner's office, patients 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 for continued 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 indicate use FRESH, STERILE UNEXPIRED lens care solutions. Always follow directions in the package inserts for the use of contact lens solutions. Sterile unexpired solutions, when used, should be discarded after the time specified in the labeling directions. Do not use saline 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 dry out (dehydrated) dry lens if the lens surface does become dried out.
- If the lens sticks (slips moving) on the eye, follow the recommended directions on Care For Sticking (non-moist) Lenses. The lens should move freely on the eye and 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.
- 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™ (Biflatoon A) and Acuity 181™ (Biflatoon A) with Tangible™ Hydra-PEG® Daily Wear Contact Lenses 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 try 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 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 eye.
- Fearing that something is in the eye such as a foreign body or scratched area.
- Excessive watering (tearing) of the eye.
- Unusual eye sensations.
- Redness of the eye.
- Reduced sharpness of vision (poor visual acuity).
- Burred 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 stop, 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 practitioner. If the lens has an air, 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 PRACTITIONER.

When any of the above problems occur, a serious condition such as infection, corneal ulcer, neovascularization, or iris may be present. The patient should be instructed to KEEP LENS OFF THE EYE AND SEEK IMMEDIATE PROFESSIONAL IDENTIFICATION. 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 1.89 diopters with a range from 0.25 to 4.25 diopters. The average amount of myopia that can be expected to be reduced 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.

INITIAL MYOPIA (diopters)	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 produced a percentage reduction in myopia of 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

INITIAL MYOPIA	FULL TEMP. REDUCTION	UP TO 0.50 D UNDER FULL REDUCTION	MYOPIA VA 20/20 OR BETTER	FINAL VA 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%	72%
-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 89 eyes, 20/40 for 108 eyes and one eye had a visual acuity of 20/70. Nine eyes had a corrected visual acuity for contact lenses that was equal to or better than 20/20. 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 18% 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:

	Percent of patients
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%
8.1 to 12 hours	23.7%
12.1 to 16 hours	27.2%

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

FITTING:
Conventional methods of fitting contact lenses do and do not apply to Acuity 181™ (Biflatoon A) and Acuity 181™ (Biflatoon A) with Tangible™ Hydra-PEG® Rigid Gas Permeable Contact Lenses. For a detailed description of the fitting techniques, refer to Acuity 181™ (Biflatoon A) and Acuity 181™ (Biflatoon A) with Tangible™ Hydra-PEG® Rigid Gas Permeable Contact Lenses Professional Fitting and Information Guide and Acuity 181™ (Biflatoon A) and Acuity 181™ (Biflatoon A) with Tangible™ Hydra-PEG® Rigid Gas Permeable Contact Lenses Professional Fitting and Information Guide for Daily Wear Orthokeratology, copyright Acuity Polymers, Inc.

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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™ (Biflatoon A) and Acuity 181™ (Biflatoon A) with Tangible™ Hydra-PEG® Rigid Gas Permeable Contact Lenses Daily Wear Contact Lenses is reflected below.

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

STUDIES HAVE BEEN COMPLETED TO SHOW THAT THE ACUTY 181 (BIFLATOON 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. DO NOT ALTERNATE OR MIX LENS CARE SYSTEMS UNLESS INDICATED ON SOLUTION LABELING.

Do not use saline 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:
a. Soaking and Storing the Lenses:
Instruction for Use:
Use only fresh multi-purpose (contact lens disinfecting) solution each time the lenses are soaked (stored).

WARNINGS:
Do not reuse a "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" the addition of fresh solution to solution that has been sitting the case.

b. **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.

c. **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.

d. **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 submerged 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.

e. **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™ (Bisfilcon A)** and **Acuity 181™ (Bisfilcon 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™ (Bisfilcon A)** and **Acuity 181™ (Bisfilcon 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™ (Bisfilcon A) and Acuity 181™ (Bisfilcon 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).

SYSTEM PROCESS	CHEMICAL (not heat) DISINFECTION SYSTEM
Daily Cleaning	Bausch & Lomb Boston Simplus® Multi-Action Solution
Cleaning, Disinfecting and Soaking	Bausch & Lomb Boston Simplus® Multi-Action Solution
Rinsing (do not use tap water)	Bausch & Lomb Boston Simplus® Multi-Action Solution
Wetting & Lubricating	Boston® Rewetting Drops
Use With Scleral Contact Lenses	Bausch & Lomb ScleralFit® 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.
1607 Lake Ave
Building 59, Suite 303
Rochester, New York USA
(585) 468-9409

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

PATIENT INSTRUCTION / WEARER'S GUIDE

Acuity 181™ (Biflacoen A) and Acuity 181™ (Biflacoen A) with Tangible™ Hydra-PEGO® Daily Wear Contact Lens

CAUTION: FEDERAL LAWRESTRICTS THIS DEVICE TO SALEBY OR ON THE ORDER OF A LICENSED PRACTITIONER

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CONGRATULATIONS:

You have just received your new Acuity 181™ (Biflacoen A) and Acuity 181™ (Biflacoen A) with Tangible™ Hydra-PEGO® Daily Wear Contact Lens. This booklet has been prepared to help you care for it. Please read it carefully and follow the instructions so that you receive full satisfaction from your lens.

PRACTITIONER: _____

ADDRESS: _____

TELEPHONE: _____

Lens Parameters	TYPE	POWER	DIAM.	BC	LOT #
Right Lens					
Left Lens					

Disinfection Solution: _____

Rinsing Solution: _____

Daily Cleaner: _____

Lubricating Solution: _____

Enzymatic Cleaner: _____

INTRODUCTION:

Read this Wearer's Guide carefully. It contains the information you need to know to wear, handle, and care for your Acuity 181™ (Biflacoen A) and Acuity 181™ (Biflacoen A) with Tangible™ Hydra-PEGO® Daily Wear Contact Lens. If you are in doubt about any instructions, request clarification from your eye care practitioner.

You are cautioned, however, to follow the initial wearing time schedule prescribed by your practitioner and not to overwear the lenses simply because they remain comfortable. Your eye care practitioner will determine your appropriate wearing schedule.

The life of your Acuity 181™ (Biflacoen A) and Acuity 181™ (Biflacoen A) with Tangible™ Hydra-PEGO® Daily Wear Contact Lens will depend to a large extent on how you handle and care for them. Use with all precision devices, proper use will assure you the benefits of convenience, comfort, and confidence in your lenses.

WEARING RESTRICTIONS AND INDICATIONS FOR USE:

The Acuity 181™ (Biflacoen A) and Acuity 181™ (Biflacoen A) with Tangible™ Hydra-PEGO® 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™ (Biflacoen A) and Acuity 181™ (Biflacoen A) with Tangible™ Hydra-PEGO® 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 Acuity 181™ (Biflacoen A) and Acuity 181™ (Biflacoen A) with Tangible™ Hydra-PEGO® 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 4.00 diopters and are presbyopic requiring add power of up to +4.00 diopters.

The Acuity 181™ (Biflacoen A) and Acuity 181™ (Biflacoen A) with Tangible™ Hydra-PEGO® 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™ (Biflacoen A) and Acuity 181™ (Biflacoen A) with Tangible™ Hydra-PEGO® ORTHOKERATOLOGY contact lenses are indicated for daily wear in an orthokeratology fitting program for the correction 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™ (Biflacoen A) and Acuity 181™ (Biflacoen A) with Tangible™ Hydra-PEGO® (Biflacoen A) SCLERAL lenses are indicated for therapeutic use for the management of irregular and distorted corneal surfaces where the subject:

- cannot be adequately corrected with spectacle lenses
- requires a rigid gas permeable contact lens surface to improve vision
- 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, trauma 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-Bücklers dystrophy, Congenital dystrophy).

The Acuity 181™ (Biflacoen A) and Acuity 181™ (Biflacoen A) with Tangible™ Hydra-PEGO® (Biflacoen A) SCLERAL lenses are 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., stony ectodermal dysplasia), neurotrophic keratitis (e.g., Herpes simplex, Herpes zoster, Familial Dysautonomia), and corneal exposure (e.g., anatomic, paralytic) that 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™ (Biflacoen A) and Acuity 181™ (Biflacoen A) with Tangible™ Hydra-PEGO® (Biflacoen 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.

The Acuity 181™ (Biflacoen A) and Acuity 181™ (Biflacoen A) with Tangible™ Hydra-PEGO® Daily Wear Contact Lens described in this booklet should be removed from your eyes for routine cleaning and disinfecting as prescribed by your eye care practitioner.

DO NOT WEAR Acuity 181™ (Biflacoen A) and Acuity 181™ (Biflacoen A) with Tangible™ Hydra-PEGO® Daily Wear Contact Lens WHILE SLEEPING.

CONTRAINDICATIONS (REASONS NOT TO USE):

DO NOT USE the Acuity 181™ (Biflacoen A) Daily Wear Contact Lens when any of the following conditions exist:

- Acute and subacute inflammation or infection of the anterior chamber of the eye.
- Any eye disease, injury, or abnormally other than irregular corneal conditions or ocular surface conditions as described in the INDICATIONS section that affects the cornea, conjunctiva, or eyelids.
- Aphakic persons should not be fitted with Acuity 181™ (Biflacoen A) and Acuity 181™ (Biflacoen A) with Tangible™ Hydra-PEGO® 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.
- Any systemic disease that may affect the eye or be exacerbated by wearing contact lenses.
- Corneal hypesthesia (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 allergic reactions of ocular surfaces or adhesion that may be induced or exaggerated by wearing contact lenses or use of contact lens solutions.
- Always to be kept in mind, such as mercury or thimerosal, in a solution which is to be used to care for the Acuity 181™ (Biflacoen A) and Acuity 181™ (Biflacoen A) with Tangible™ Hydra-PEGO® Daily Wear Contact Lens.
- Any active corneal infection (bacterial, fungal, or viral).
- You are unable to follow the lens care regimen or unable to obtain assistance to do so.
- If eye becomes red or itched.

WARNINGS:

- PROBLEMS WITH CONTACT LENSES AND LENS CARE PRODUCTS COULD RESULT IN SERIOUS INJURY TO THE EYE. It is essential that you follow your 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.
- You must use your eye care practitioner as directed.
- Daily wear lenses are not indicated for overnight wear, and you are instructed not to wear the Acuity 181™ (Biflacoen A) and Acuity 181™ (Biflacoen A) with Tangible™ Hydra-PEGO® Daily Wear Contact Lens 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:

- CAUTION – Non-sterile. Clean and condition lenses prior to use.
- 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 chemical disinfection only. Always use FRESH, STERILE UNEXPURED lens care solutions. Always follow directions in the package inserts for the use of the contact lens solutions. Sterile unopened 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 wetting 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.

- 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 no 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 distortion 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™ (Biflacoen A) and Acuity 181™ (Biflacoen A) with Tangible™ Hydra-PEGO® 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, makeup should be removed before inserting the lenses of the patient's eyes. The patient should be instructed also a recommended follow-up schedule.

ADVERSE REACTIONS:

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.
- 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 eye.
- Reduced sharpness of vision (poor visual acuity).
- Irritated vision, rainbows, or halos around objects.
- Sensitivity to light (photophobia).
- Dry eyes.

If you notice any of the above, IMMEDIATELY REMOVE YOUR LENSES.

- If discomfort or problems stops, then look closely at the eye. If the lens is in way damage, DO NOT PUT THE LENS BACK ON YOUR EYE. Place the lens in the storage case and contact your eye care practitioner. If the lens has dried, or other foreign body on it, or the problem stops and the lens appears undamaged, you should thoroughly clean, rinse, and discard the lenses; then reinsert them. After reinsertion, if problems continues, you should IMMEDIATELY REMOVE THE LENSES AND CONSULT YOUR EYE CARE PRACTITIONER.

When any of the above problems occur, a serious condition such as infection, corneal ulcer, neovascularization, or vititis may be present. 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.

PERSONAL CLEANLINESS AND LENS HANDLING

Before Handling Your Lenses:

Cleanliness is an important aspect of contact lens care.

Before handling your lenses, always wash and rinse your hands thoroughly and dry them with a lint-free towel. Do not use soaps, lotions, cold creams, or perfumes that leave a residue on your hands. Avoid using medications, creams, deodorants, make-up, after shave lotions, or similar items prior to touching your lenses. When hair spray is used, the eye must be kept closed until the spray has settled. Take care in handling your lenses. Always avoid touching your lenses with your fingernails or other sharp objects. NEVER WORK DIRECTLY OVER A SINK WITH THE DRAIN OPEN, AS THE LENS MAY BE LOST.

- Handling and Placing the Lenses on the eye:
- To avoid the possibility of lens mix-ups, always start with the same lens first.
 - Before inserting the lens, rinse well with fresh, sterile rinsing solution. Then place the lens on the tip of the index finger of your dominant hand.
 - Look straight ahead and raise the upper lid with your other index finger.
 - While looking ahead, and keeping both eyes open, place the lens on the upper white part of the eye.
 - Slowly release upper lid, and gently close your eye.
 - The lens should center automatically, or it can be moved on center by gentle fingertip pressure through the lids.
 - Repeat the above procedure for the second lens.
 - If the lens appears to be stuck on your eye, apply a few drops of a recommended lubricating solution to the eyes and blink a few times. If the lens does not move freely on your eye, contact your eye care practitioner for further instructions.
- There is no single "right way" of putting on lenses. If you find this method of lens placement difficult, your eye care practitioner will suggest another method or provide additional information.

Removing the Lenses:

Preparation:

- Wash and rinse your hands thoroughly.
- Dry hands with a lint-free towel.
- Check that the lens is centered on the cornea before attempting to remove the lens. Check your vision by covering one eye. If vision is blurry, the lens is off-center. Re-center the lens before attempting to remove it.

- Removal:
- To avoid the possibility of lens mix-ups, always begin with the same lens.
 - Look up and keep both eyes open.
 - Using the middle finger of your dominant hand, gently pull down the lower lid of the first eye. Using the tip of your index finger of the same hand, gently pull at the corner of your lower/lower lids, the lens should fall out.
 - Gently "pinch" the lens between the index finger and the thumb and remove.
 - Repeat the procedure for the second eye.
 - If the lens cannot be easily moved, apply a few drops of lubricating solution to the eyes, blink a few times, and when the lens moves freely on the eye, remove in the manner described above. If the lens still cannot be moved, contact your eye care practitioner for further instruction.
 - Upon removal, clean each lens with a contact lens cleaner per the procedures described under the heading, CARING FOR YOUR LENSES. Rinse well with rinsing solution and place in the lens storage case filled with fresh storage solution.

IMPORTANT: Always avoid touching your lenses with your fingernails. Use only your fingertips.

If you find this method difficult, your eye care practitioner will suggest another method or provide additional instruction.

NEVER WORK DIRECTLY OVER A SINK WITH THE DRAIN OPEN, AS THE LENS MAY BE LOST.

If the lens is chipped, do not put the lens back on your eye. Return the lens to the storage case with fresh solution and contact your eye care practitioner.

CARING FOR YOUR LENSES

Basic Instructions:

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

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

If you require only vision correction but will not or cannot adhere to a recommended care regimen for your lenses or are unable to place and remove lenses or have someone available to place and remove them, you should not attempt to get and wear contact lenses. When you first get your lenses, be sure you learn to comfortably put the lenses on and remove them while you are in your eye care practitioner's office. At that time, you will be provided with a recommended cleaning and disinfection regimen and the instructions and warnings for lens care, handling, cleaning, and disinfection. Your eye care practitioner should instruct you about appropriate and adequate procedures and products for your use and provide you with a copy of the Wearer's Guide for the Acuity 181™ (Biflacoen A) and Acuity 181™ (Biflacoen A) with Tangible™ Hydra-PEGO® Daily Wear Contact Lens.

For safe contact lens wear, you should know and always practice your lens care routine: Always wash, rinse, and dry hands before handling contact lenses.

- Always use fresh, sterile unexpired lens care solutions.
- Use the recommended system of lens care and carefully follow instructions on solution labeling.
- Different solutions cannot always be used together, and not all solutions are safe for use with all lenses. DO NOT ALTERNATE OR MIX LENS CARE SYSTEMS UNLESS INDICATED ON SOLUTION LABELING.

- Do not use saliva or anything other than the recommended solutions for lubricating or rewetting lenses. Do not put lenses in the mouth.
- Never rinse your lenses in water from the tap. There are two reasons for this:
 - a. Tap water contains many impurities that can contaminate or damage your lenses and may lead to eye infection or injury.
 - b. You might lose the lens down the drain.
- The eye care practitioner should recommend a care system that is appropriate for the Acuity 181™ (Biflacoen A) and Acuity 181™ (Biflacoen A) with Tangible™ Hydra-PEGO® Daily Wear Contact Lens. Each lens care product contains specific directions for use and important safety information, which should be read and carefully followed.
- Clean one lens first (always the same lens first to avoid mix-ups), rinse the lens thoroughly with recommended rinsing or disinfecting solution to remove the cleaning solution, mucus, and film from the lens surface, and put lens into contact 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 manufacturer and/or your 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, you should consult the package insert or your eye care practitioner for information on storage of lenses.
- Always keep your lenses completely immersed in a recommended disinfecting/desinfecting solution when the lenses are not being worn. If you discontinue wearing your lenses, but plan to begin wearing them after a few weeks, ask your eye care practitioner for a recommendation on how to store your lenses.
- The Acuity 181™ (Biflacoen A) and Acuity 181™ (Biflacoen A) with Tangible™ Hydra-PEGO® Daily Wear Contact Lens can be disinfected using only a chemical (NOT HEAT) disinfecting system.
- Contact lens cases can be a source of bacteria growth. After removing the lenses from the case, empty and rinse the lens storage case with solution as recommended by the lens case manufacturer, then allow the lens case to air dry. When the case is used again, refill it with storage solution. Replace lens case at regular intervals as recommended by the lens 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.

Specific Instructions for Use and Warnings:

a. 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.

b. 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.

c. 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 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.

d. 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 submerged 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 (professionals) for recommendations about wearing your lenses during any activity involving water.

e. 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 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.

care for a Sticking (non-moving) Lens:

If the lens sticks (cannot be removed), you should apply 3 to 4 drops of the recommended lubricating or rewetting solution directly to the eye and wait the lens begins to move freely on the eye before removing it. If the lens continues after 15 minutes, you should IMMEDIATELY consult your eye care practitioner.

Chemical (NOT HEAT) Lens Disinfection:

Wash and rinse your hands thoroughly BEFORE HANDLING LENSES.

- 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.
- AFTER CLEANING, thoroughly rinse both surfaces of the lens with a steady stream of fresh, sterile unexpired rinsing solution for approximately 10 seconds.
- Fill 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 DISINFECTING 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, 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 specified case may 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.

INSTRUCTIONS FOR MONOVISION AND MULTIFOCAL WEARERS

You should be aware that as with any type of lens correction, there are advantages and compromises to monovision contact lens therapy and multifocal contact lenses. The benefit of clear near vision in straight ahead and upward gaze that available with monovision and multifocal contact lenses may be accompanied by visual compromises that may reduce your visual acuity and depth perception for distance and near tasks. Some patients have experienced difficulty adapting to it. Symptoms, such as mild blurred vision, dizziness, headaches and a feeling of slight imbalance, may last for a brief minute or for several weeks as adaptation takes place. The longer these symptoms persist, the poorer your prognosis for successful adaptation. You should avoid visually demanding situations during the initial adaptation period. It is recommended that you first wear these contact lenses in similar situations which are not visually demanding. For example, it might be better to be a passenger rather than a driver of an automobile during the first few days of lens wear. It is recommended that you only drive with monovision or multifocal correction if you pass your state driver license requirements with the correction.

- Some monovision or multifocal patients will not be fully comfortable functioning under "low levels of illumination, such as driving at night. If this happens, you may want to discuss with your eye care practitioner having additional contact lenses prescribed so that both eyes are corrected for distance when sharp distance binocular vision is required.
- If you require very sharp near vision during prolonged close work, you may want to have additional contact lenses prescribed so that both eyes are corrected for near when sharp near binocular vision is required.

- Some monovision or multifocal patients require supplemental spectacles to wear over the monovision or multifocal correction to provide the clearest vision for critical tasks. You should discuss this with your eye care practitioner.
- It is important that you follow your eye care practitioner's suggestions for adaptation to monovision contact lens therapy and multifocal contact lenses. You should discuss any concerns that you may have during and after the adaptation period.
- The decision to be fit with monovision or multifocal correction is most appropriately left to the eye care practitioner in conjunction with you, after carefully considering and discussing your needs.

LENS DEPOSITS AND 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.

Lens Case Cleaning and Maintenance:

Contact lens cases can be a source of bacteria growth. After removing the lenses from the case, empty and rinse the lens storage case with solution as recommended by the lens case manufacturer, then allow the lens case to air dry. When the case is used again, refill it with disinfecting solution. Replace lens case at regular intervals as recommended by the lens case manufacture or your eye care practitioner.

EMERGENCIES:

If any chemicals of any kind (household products, gardening solutions, laboratory chemicals, etc.) are splashed into the eyes, you should:

FLUSH EYES IMMEDIATELY WITH TAP WATER AND IMMEDIATELY CONTACT YOUR EYE CARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.

WHEN TO CALL YOUR EYE CARE PRACTITIONER

Certain symptoms may be early indicators of potentially serious problems. A careful examination of your lens, and professional examination of your eyes, may be required. Remove the lens following the instructions outlined in this guide, and call your eye care practitioner if:

- 1) Your eyes become red and feels irritated or "gritty".
- 2) You notice a change in your vision or see rainbows or halos around objects.
- 3) You experience discomfort and/or sensitivity to lights.

A good general policy is:

"IF IN DOUBT... TAKE THE LENS OUT," and contact your eye care practitioner.

Learn and Use Proper lens Care Habits:

- 1) Follow Instructions.
- 2) Handle Lenses Properly.
- 3) Learn How to Put On and Take Off Your Lenses.
- 4) Keep Your Lenses Clean.
- 5) Disinfection is a Necessary Security.

WEARING SCHEDULE:

THE WEARING AND REPLACEMENT SCHEDULES SHOULD BE DETERMINED BY YOUR EYE CARE PRACTITIONER.

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

<u>DAY</u>	<u>HOURS</u>
1	3
2	4
3	5
4	6
10	7
11	8
12	9
13	10
14	11
10 – 14	12
15+	All waking hours

STUDIES HAVE NOT BEEN COMPLETED TO SHOW THAT THE ACUITY 181™ (BISLOCON A) AND ACUITY 181™ (BISLOCON A) WITH TANGIBLE™ HYDRA-PEG® DAILY WEAR CONTACT LENS IS SAFE TO WEAR DURING SLEEP.

WEARING SCHEDULES SHOULD BE DETERMINED BY THE EYE CARE PRACTITIONER.

APPOINTMENT SCHEDULE:

Your appointments are on:

Month Year Time Day

IMPORTANT:

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

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