IMPORTANT: Please read carefully and keep this information for future use.
This fitting guide 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.

clearday™ Beyond and clearday™ Beyond Toric (Avefilcon A) SOFT (hydrophilic) SILICONE HYDROGEL CONTACT LENS

clearday™ Beyond clearday™ Beyond Toric

Symbols key

The table shows the symbols that may appear on label or carton

Symbol	Description
℞ Only	**CAUTION**: Federal Law (USA) restricts this device to sale by or on the order of a **Licensed Eye Care Practitioner**.
STERILE	Sterilized using steam or dry heat
	Caution
	Do not use if the product sterile barrier system or its packaging is compromised.
	Manufacturer
	Date of Manufacture
EC REP	Authorized Representative in European Community
LOT	Batch code (Lot number)
	Use by date (Expiry date)
	Consult instructions for use.
CE 0123	European Conformity Sign
BC	Base Curve
DIA	Diameter
D	Diopter (Lens Power)
	Temperature limits

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

clearlab®

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MATERIAL CHARACTERISTIC

The **clearday™ Beyond** and **clearday™ Beyond Toric (Avefilcon A) Soft (hydrophilic) Silicone Hydrogel Contact Lens** is available as a single vision spherical lens, and as a back surface astigmatic (toric) lens. The hydrophilic nature of this material allows the lens to become soft and pliable when immersed in an aqueous solution.

DESCRIPTION OF LENS

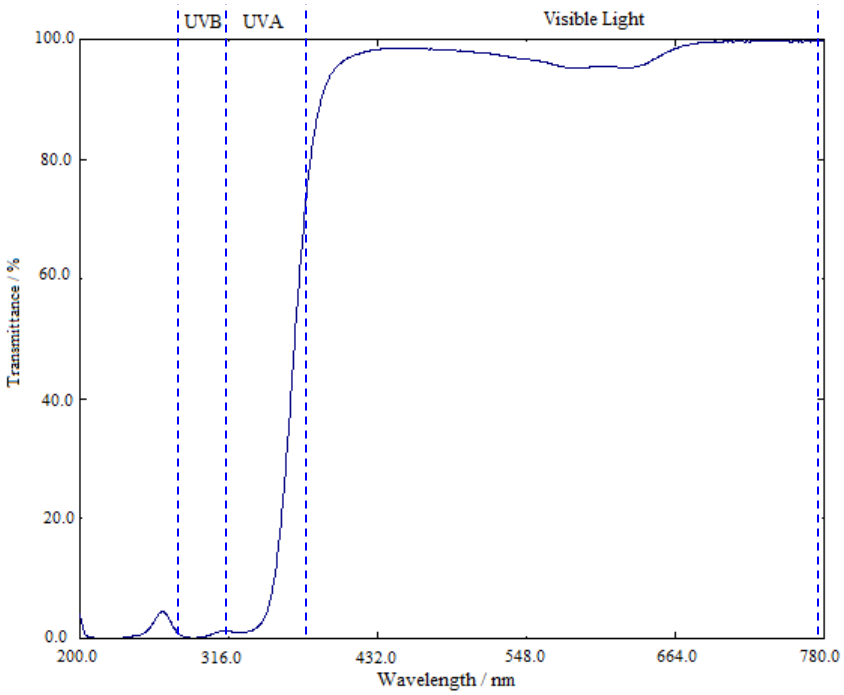
The non-ionic lens material (**Avefilcon A**) is composed of siloxane containing monomer and macromer. It is cross linked with other hydrophilic monomers and dimethacrylate cross linker. The lenses are incorporated with Reactive Blue 19, a US FDA approved dye for contact lens as handling tint. The **clearday™ Beyond** and **clearday™ Beyond Toric (Avefilcon A) Soft (hydrophilic) Silicone Hydrogel Contact Lens** consists of 40% **Avefilcon A** and 60% water by weight when immersed in buffered saline solution. This contact lens contains a UV blocking material that blocks UVB and UVA radiation. A -3.00D lens with center thickness of 0.06mm blocks about 96% of UVB rays and about 55% of UVA rays.

UV radiation blockage provided by **clearday™ Beyond** and **clearday™ Beyond Toric (Avefilcon A**) will increase for thicker lenses.

WARNING:

UV-absorbing contact lenses are NOT substitutes for protective UV-absorbing eyewear such sunglasses, because they do not completely cover the eye and surrounding area. Patients should continue to use UV-absorbing eyewear as directed by a licensed eye care professional.

Figure 1:
Representative UV transmittance profile of -3.00D clearday™ Beyond (Avefilcon A) contact lens.



In the hydrated state, the lens conforms to the curvature of the eye covering the cornea and extending slightly beyond the limbus forming a colorless, transparent optical surface. The hydrophilic properties of the lens require that it be maintained in a fully hydrated state in a solution compatible with the eye. If the lens dries out, it will become hard and appear somewhat warped however, it will return to its proper configuration when completely rehydrated in the proper storage solution.

The hydrophilic characteristics allow aqueous solutions to enter the lens when fully hydrated in phosphate buffered saline; the lens is approximately 60% water by weight. The physical properties of the lens are:

Refractive Index	1.397
Light Transmission	95%
Water Content	60 %
Oxygen Permeability	88 $x10^{-11}$ [(cm ^{2}/sec) x (mlO_2)/(ml x mm Hg)] @ 35 ^oC

The lenses are hemispherical flexible shells which cover the cornea and portion of the adjacent sclera with the following dimensions:

Chord Diameter	:	12.00 – 15.00 mm
Base Curve	:	7.80 – 10.00 mm
Center Thickness	:	0.04 – 0.80 mm

Powers	:	0.0 to -6.00 Diopters(D) in 0.25D increment -6.50 to -20.00 Diopters(D) in 0.50D increment +0.25 to +4.00 Diopters(D) in 0.25D increment +4.50 to +20.00 Diopters(D) in 0.50D increment
Cylinders	:	-0.75D, -1.25D, -1.75D, -2.25D
Axis	:	10^{o} to 180^{o} in 10^{o} increment

ACTIONS

In its hydrated state, the **clearday™ Beyond** and **clearday™ Beyond Toric (Avefilcon A) Soft (hydrophilic) Silicone Hydrogel Contact Lens** when placed on the cornea, act as a refracting media to focus light rays on the retina. The near portion of the aspheric design places the incoming light rays on the retina when viewing reading material as the reading distance.

INDICATIONS:

The **clearday™ Beyond** and **clearday™ Beyond Toric (Avefilcon A) Soft (hydrophilic) Silicone Hydrogel Contact Lens** for daily wear contains a UV Blocker to help protect against transmission of harmful UV radiation to the cornea and into the eye.

The **clearday™ Beyond (Avefilcon A) Soft (hydrophilic) Silicone Hydrogel Contact Lens** is indicated for the optical correction (except for plano lenses) of ametropia (myopia or hyperopia) in aphakic and non-aphakic persons with non-diseased eyes within the limits of the product specification. The lens may be worn by persons who exhibit refractive astigmatism of 0.75 diopters or less where the astigmatism does not interfere with visual acuity.

The **clearday™ Beyond Toric (Avefilcon A) Soft (hydrophilic) Silicone Hydrogel Contact Lens** is indicated for the optical correction (except for plano lenses) of ametropia (myopia or hyperopia) in aphakic and non-aphakic persons with non-diseased eyes within the limits of the product specification. The lens may be worn by persons who exhibit refractive astigmatism of 7.00D diopters or less.

The lens may be cleaned and disinfected using a chemical (not heat) lens care system.

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 is to be cleaned, rinsed and disinfected, each time it is removed from patient's eye, with chemical (not heat) lens care system.

CAUTION:

Due to the small number of patients enrolled in clinical investigation of lens, all refractive powers, design configurations, or lens parameters available in the lens material were not

evaluated in significant numbers. Consequently, when selecting an appropriate lens 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.

WARNINGS:

Please reference Warnings in the Package Insert included at the end of this Fitting Guide.

PRECAUTIONS:

Please reference Precautions in the Package Insert included at the end of this Fitting Guide.

ADVERSE REACTIONS:

Please reference Adverse Reactions in the Package Insert included at the end of this Fitting Guide.

PATIENT SELECTION:

- The **clearday™ Beyond** and **clearday™ Beyond Toric (Avefilcon A) Soft (hydrophilic) Silicone Hydrogel Contact Lens** are indicated for the correction of myopia and hyperopia in aphakic or non-aphakic patients with non-diseased eyes who exhibit no more than 2.00 diopters of astigmatism and can obtain satisfactory visual acuity, in a power range of +20.00 to -20.00 diopters.
- Persons who require only visual correction and who would not or could not adhere to a recommended care regimen of the **clearday™ Beyond** and **clearday™ Beyond Toric (Avefilcon A) Soft (hydrophilic) Silicone Hydrogel Contact Lens** or are unable to place and remove the lenses should not be provide with them. Failure to follow handling and wearing instructions could lead to serious eye infections, which might result in corneal ulcers.
- Patient communication is vital because it relates not only to patient selection, but also to ensuring patient compliance. It is also necessary to discuss the information contained in the Patient Instruction/ Wearer's Guide with the patients at the time of the initial examination.
- Patients selected to wear the **clearday™ Beyond** and **clearday™ Beyond Toric (Avefilcon A) Soft (hydrophilic) Silicone Hydrogel Contact Lens** should be chosen for their motivation to wear contact lenses, general health and cooperation. The eye care practitioner must take care in selecting, examining and instructing patients. Patient hygiene and willingness to follow practitioner instructions are essential to their success.

- A detailed history is crucial to determining patient needs and expectations. Your patient should be questioned regarding vocation, desired lens wearing time (full or part-time) and desired lens usage (reading, recreation or hobbies)
- Initial evaluation of the trial lens should be preceded by a complete eye examination, including acuity with and without correction at both distance and near, keratometry and slit lamp examination.
- All necessary steps in lens care and all precautions and warnings should be discussed and understood by the patient.

Fitting procedure for the

clearday™ Beyond and **clearday™ Beyond Toric (Avefilcon A) Soft (hydrophilic) Silicone Hydrogel Contact Lens**

1) Pre-fitting Examination

A pre-fitting patient history and examination are necessary to:
Determine whether a patient is a suitable candidate for daily wear contact lenses (refer to contradictions)
Collect and record baseline clinical information to which post-fitting examination results can be compared.
Make ocular measurements for initial contact lens parameter selection

2) Parameter Selection

1. Perform a preliminary evaluation to determine distance refraction as well as to rule out contraindications to contact lens wear as described in the Package Insert.
2. Lens Power is determined from the patient's spherical equivalent prescription corrected to the corneal plane.
3. Place the lens onto the eye. Allow the lens to remain on the eye long enough to achieve state of equilibrium. Small variation in the tonicity, pH or the lens solutions and individual tear composition may cause light changes in fitting characteristics.
4. If the initial lens selection covers the patient's cornea fully, provides discernible movement (0.10mm to 0.30mm) after blink, is comfortable for the patient and provides satisfactory visual performance, it is well fitted lens and can be dispensed.
5. Full coverage of the cornea is defined as the lens edge extending beyond the limbal area in all directions. Initial lens evaluation must be done after at least 10 minutes of lens wear to allow the lens to stabilize and any tearing to subside.
6. Following a blink, the lens should move vertically on the patient's eye about 0.10mm to 0.30mm. Using a slit lamp, this movement can be estimated by comparing it with the one millimeter lens peripheral bevel width.
7. When the lenses are dispensed for vision correction, the wearer must be supplied with an appropriate wearing regimen and must fully understand all lens handling and emergency lens care instructions to prevent lens damage as described in the Package Insert and Patient Instruction/ Wearer's Guide.

The preferred fitting method is the selection of a stepper base curve as the first choice and evaluates the criteria of a well fitted lens, using trial lenses. Please refer to **Criteria for a Well-fitted lens** for **CLINICAL ASSESSMENT**.

The alternative method is to determine the K readings and apply the following

Average K Reading	Suggested Lens Design
39.50 - 41.50 and higher	8.6 mm base curve / 14.2 mm Diameter

Lens power can be calculated from spectacle Rx

Sphere Lenses:
First convert the spectacle Rx in minus cylinder form (if applicable), compensate the power of both major meridians for a vertex distance of 0mm and then add half the cylinder power to the sphere

Example:

Rx at 12mm vertex distance	-5.00 -1.00 x180
Power on horizontal meridians	-5.00 @ 12 mm vertex compensate to -4.75 @ 0 vertex
Power on vertical meridians	-6.00 @ 12 min vertex compensate to -5.50 @ 0 vertex
Rx at 0mm vertex distance	-4.75, -0.75 x180

Add half the cylinder to the sphere and round to the higher 0.25 step
(-4.75) + (-0.75/2) = -5.25 final power of the lens

CLINICAL ASSESSMENT:

Allow the lenses to settle on the eyes for approximately 5 to 10 minutes. This allows time for the patient to adapt to the lenses and time for the lens to equilibrate.

Evaluate the fit and movement of the lenses on the eye. The **Push-up Test**, as described below, is an important part of the lens evaluation. The following guidelines will be helpful in fit evaluation:

1. **Criteria of a Well-Fitted Lens**

   The criteria of a well fitted lens is one which centers easily after a blink, bridges the limbus and extends onto the sclera about 1.25mm, lags downward about 1.0 to 1.5 mm on upward gaze and does not move excessively as a result of blinking or exaggerated eye movements

   A well-fitted lens should be able to achieve satisfactory Push-up Test. When the trial lens has settled on the eye (5 – 10 minutes), manipulate the lens using lid pressure and observe for indications of excessive tightness. The lens should move freely and easily with slightest pressure and return to the centered position when released.

Movement of the lens on the eye is very important in assessing the fit and performance of the lens. In primary gaze, slight vertical post-blinking lens movement should occur. On upward gaze, the lens should sag approximately 1 - 1.5 min.

2. Characteristics of a Tight (Steep) Lens

A tight or steep lens should not be dispensed. If a lens fit is judged to be too steep a flatter lens (larger base curve), if available, should be evaluated. Patients with tight (steep) lens fit may experience discomfort and some fluctuation in visions between blinks.

There would be insufficient or no lens movement during a blink in primary or upward gaze. A tight (steep) lens does not move easily on the cornea with slight pressure. In other words, a tight (steep) fitting lens will resist movement. If successfully nudged upward, the lens may remain de-centered or return slowly to its original position.

3. Characteristics of a Loose (Flat) Lens

If a lens fit is judged to be too flat, a steeper lens (smaller base curve), if available, should be evaluated. Patients with loose (flat) lens would experience discomfort, and blurring of vision after each blink.

There would be excessive lens movement during the blink in primary or upward gaze. A loose (flat) fitting lens will move very easily, well beyond the limbus and possibly encroaching upon or going beyond the pupil. It will then return very quickly to its original position and often, return lower than its original position. A loose (flat) lens sags more than 2.0 mm on upward gaze.

CONTRAINDICATION (REASONS NOT TO USE)

DO NOT USE the **clearday™ Beyond** and **clearday™ Beyond Toric (Avefilcon A) Soft (hydrophilic) Silicone Hydrogel 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 abnormality that affects the cornea, conjunctiva, or eyelids.
- Severe insufficiency of lacrimal secretion (dry eyes).
- Corneal hypoesthesia (reduced corneal sensitivity), if not-aphakic.
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lens.
- Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lens or use of contact lens solutions.
- Allergy to any ingredient, such as mercury or thimerosal, in a solution which is to be used to care for the **clearday™ Beyond** and **clearday™ Beyond Toric (Avefilcon A) Soft (hydrophilic) Silicone Hydrogel Contact Lens**.

- Any active corneal infection (bacterial, fungi, or viral)
- If eyes become red or irritated.
- Patients unable to follow lens care regimen or unable to obtain assistance to do so.
- Patient history of recurring eye or eyelid infections, adverse effects associated with contact lens wear, intolerance or abnormal ocular response to contact lens wear.

FOLLOW-UP CARE:

1. Follow-up examinations are recommended by the eye care practitioner, they are necessary to ensure continued successful contact lens wear.
2. Prior to a follow up examination, the contact lens should be worn for at least one continuous hour and the patient should be asked to identify any problems which might be occurring related to contact lens wear.
3. With lenses in place on the eyes, evaluate the fitting performance to assure the criteria of a well-fitted lens continue to be satisfied. Examine the lenses closely for surface deposition and / or damage.
4. After the lens removal, conduct a thorough bio-microscopy examination.
    a. The presence of vertical corneal striate in the posterior central cornea and/ or cornea neovascularization is indicative of excessive corneal edema.
    b. The presence of corneal staining and / or limbal-conjunctival hypereremia can be indicative of an unclean lens, a reaction to solution preservatives, excessive lens wear and/ or a poorly fitting lens.
    c. Papillary conjunctiva1 changes may be indicative of an unclean and/ or damaged lens.

If any of the above observations are considered as abnormal, various professional judgments are necessary to alleviate the problem and restore the eye to its optimal conditions. If any the **Criteria of a Well-Fitted Lens** is not satisfied during any follow-up examinations, the patient should be refitted with a more appropriate lens.

FOLLOW - UP EXAMINATIONS:

- Within one week of lens dispensing
- After three weeks of lens wear
- After seven weeks of lens wear
- After each six month period of lens wear

At the follow up examinations, the patient should report good subjective quality of vision. Adaptation to the vision with **clearday™ Beyond** and **clearday™ Beyond Toric (Avefilcon A) Soft (hydrophilic) Silicone Hydrogel Contact Lens** should occur almost immediately and should definitely be reported within the first (1 week) follow-up visit. At these follow-up visits the practitioner should:

1. Check distance and near acuity with lens in place
2. Over-refract to verify lens prescription
3. Observe position of lens on the cornea. The lens should be centered and move on upward gaze and with blink.

4. Evert the lids to examine the tarsal conjunctiva and check for incidence of giant papillary conjunctivitis.
5. Remove the lens. Check corneal curvature. There should be no substantial changes in either meridian
6. Perform a slit-lamp examination with and without Fluorescein. Check for corneal edema, corneal abrasion, vascularization, corneal infiltrates and perilimbal injection. Reinsert the lens only after all residual Fluorescein has dissipated from the eye.
7. Clean the lens with a prophylactic surfactant cleaner and examine for deposits, foreign bodies or physical imperfections of the lens surface.

LENS HANDLING (in-office cleaning, disinfecting and storage):

Trial lenses should be cleaned, rinsed and disinfected after each use following recommended care instructions with any of the chemical or hydrogen peroxide lens care system approved for use with soft contact lenses. Storage of trial lenses which have been reconditioned should be subjected to re-disinfection procedures on a periodic basis; at least weekly.

Wash and rinse hands thoroughly, making certain that all soap residues have been rinsed away before drying with a lint free towel. It is suggested to wet the lens while in the eye using wetting drops before removal. Always start with the right eye first in order to avoid mixing the lenses. Avoid touching the inside (concave) surface of the lens during handling. It is possible, though not likely, that the lens might be inside out; therefore, check the lens by placing it on the index finger and examine its profile. If the edges of the lens tend to point outward, the lens is inside out. After removing the lens from its container assure that it is clean, clear and wet.

Each **clearday™ Beyond** and **clearday™ Beyond Toric (Avefilcon A) Soft (hydrophilic) Silicone Hydrogel Contact Lens** is received in the eye care practitioner's office in a sterile blister pack with sterile phosphate buffered saline solution and labeled to the parameters of the lens contained. To assure sterility the blister pack should not be opened until ready for use.
To open the blister pack pull back the lid where indicated. Upon removing the cover the lens may be removed and is ready for use.

clearday™ Beyond and **clearday™ Beyond Toric (Avefilcon A) Soft (hydrophilic) Silicone Hydrogel Contact Lenses** are not reused in diagnostic procedures.

CLEANING:

A surfactant cleaner may be used with the **clearday™ Beyond** and **clearday™ Beyond Toric (Avefilcon A) Soft (hydrophilic) Silicone Hydrogel Contact Lens** to ensure a clean lens surface. A single procedure is as follows.
Apply 3 to 4 drops to the lens and then rub the surface of the lens against the palm of one hand with the index finger of the other hand or between thumb and forefinger for 20 seconds.

RINSING:

After cleaning, thoroughly rinse both surfaces of the lens with a steady stream of fresh, sterile rinsing solution.

CHEMICAL (NOT HEAT) LENS CARE SYSTEMS:

A sterile rinsing, storing and disinfecting multipurpose solution should be used to rinse and chemically disinfect the **clearday™ Beyond** and **clearday™ Beyond Toric (Avefilcon A) Soft (hydrophilic) Silicone Hydrogel Contact Lens**. After cleaning the lenses, rinse with liberal amounts of fresh multipurpose solution to remove loosened debris and traces of cleaner. The lens should then be placed in the plastic container supplied in the multipurpose solution kit and filled with enough fresh disinfecting solution to completely submerge the lens. To ensure disinfecting, the lens must remain in the disinfecting solution for the recommended period of time as written on the multipurpose solution bottle. Follow the instruction and timings recommended by the solution manufacturer. Before reinsertion, the lens should be rinsed with fresh sterile rinsing solution.

Lens disinfection with Hydrogen Peroxide lens care systems:

- Neutralized the lens before wearing, when hydrogen peroxide lens care systems is used and carefully follow instructions on solution labeling.
- Use ONLY the lens case provided with the hydrogen peroxide care system as this case may contain neutralizer. Failure to use the specialized case will cause stinging, burning, and damage to the eye. Always follow the recommendations on hydrogen peroxide lens care system labeling**.**

LENS CARE DIRECTIONS:

Please reference LENS CARE DIRECTIONS in the Package Insert.

STORAGE:

The **clearday™ Beyond** and **clearday™ Beyond Toric (Avefilcon A) Soft (hydrophilic) Silicone Hydrogel Contact Lens** must be stored in the recommended solutions. If exposed to air, the lens will dehydrate. If a lens dehydrates, it should be discarded and replaced with a fresh-sterile lens.

RECOMMENDED WEARING SCHEDULE:

Close professional supervision is recommended to ensure safe and successful contact lens wear. If any discomfort, decreased vision, ocular injection or corneal edema, is felt or experienced, the lens should be removed and the patient scheduled with their eye care professional for examination immediately. The problem may be relieved by establishing a different wearing schedule or possibly by refitting the lens.

It may be advisable for patients who have never worn contact lenses previously to be given a wearing schedule that gradually increases wearing time over a few days. This is to allow more gradual adaptation of the ocular tissues to contact lens wear. It is important not to exceed the wearing schedule. Regular check ups, as determined by the eye care practitioner, are also extremely important. Normal daily wear of lenses assumes a minimum of 6 hours of non-lens wear everyday (i.e. for every 24 hours). The maximum suggested wearing schedule for the **clearday™ Beyond** and **clearday™ Beyond Toric (Avefilcon A) Soft (hydrophilic) Silicone Hydrogel Contact Lens** is suggested below.

DAY	1	2	3	4	5	6
HOURS	6	8	10	12	14	All Waking hours

STUDIES HAVE NOT BEEN COMPLETED TO SHOW THAT THE "clearday™ Beyond and **clearday™ Beyond Toric (Avefilcon A) Soft (hydrophilic) Silicone Hydrogel Contact Lens" IS SAFE TO WEAR DURING SLEEP**

FREQUENT/PLANNED REPLACEMENT:

It is recommended that the **clearday™ Beyond** and **clearday™ Beyond Toric (Avefilcon A) Soft (hydrophilic) Silicone Hydrogel Contact Lens** be discarded and replaced with a new lens after 30 days. When removed between replacement periods lenses must be cleaned and disinfected prior to reinsertion, or be discarded and replaced with a fresh lens.

However, patients should adhere to the recommended replacement schedule given by their eye care professional based upon their individual needs and physiological conditions.

RECOMMENDED LENS CARE PRODUCTS:

The eye care practitioner should recommend a care system that is appropriate for the **clearday™ Beyond** and **clearday™ Beyond Toric (Avefilcon A) Soft (hydrophilic) Silicone Hydrogel Contact Lens**. Each lens care product contains specific instructions for use and important safety information, which should be read and carefully followed.

STORAGE CONDITIONS:
Store lenses between 1°C to 45°C.

EMERGENCIES:

The patient should be informed that if any chemical 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 YOUR EYE CARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.

REPORTING OF ADVERSE REACTIONS:

Practitioners should report any adverse reactions to **clearday™ Beyond** and **clearday™ Beyond Toric (Avefilcon A) Soft (hydrophilic) Silicone Hydrogel Contact Lens** within 5 days to the address below.

Additional Package Insert and Patient Instruction/ Wearer's Guide are available from:

Clearlab SG Pte. Ltd.
139 Joo Seng Road,
Singapore 368362
Tel: +65 6749 1090
Fax: +65 6282 3953
Email: Regulatory@clearlab.com
Website: www.clearlab.com

HOW SUPPLIED:

Each lens is supplied sterile in blister packs in phosphate buffered saline solution. The blister pack is marked with the base curve, diameter, dioptric power, manufacturing lot number, expiration date, Single Patient Use, Rx symbol, sterile symbol, and composition of the lens.

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