

# Professional Fitting and Information Guide

**DAILIES TOTAL<sup>1</sup>**<sup>®</sup>  
BREATHABLE ONE-DAY CONTACT LENSES\*

**DAILIES TOTAL1<sup>®</sup> (delefilcon A) Soft Contact  
Lenses For Single-Use, Daily Disposable Wear**

**\*High O<sub>2</sub> Permeable Lenses, Dk=140**

**Rx only**

**Caution: Federal law (USA) restricts  
this device to sale by or on the order  
of a licensed eye care professional**

**Alcon**<sup>®</sup>

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## **INTRODUCTION**

Thank you for prescribing DAILIES TOTAL1® (delefilcon A) daily disposable soft contact lenses. The benefits of a high oxygen transmissible and wettable lens material with a state of the art manufacturing process are combined to make DAILIES TOTAL1® (delefilcon A) lenses. This guide contains important information regarding fitting procedures and aftercare of the DAILIES TOTAL1® (delefilcon A) contact lens patient.

### **Daily Disposability:**

By eliminating the need for lens care, daily disposable lenses offer your patients a major advancement in wearing convenience. The next time you prescribe lenses consider the health and comfort benefits of beginning each wearing period with a new pair of fresh, sterile lenses that are worn once and then discarded.

### **LightStream® Lens Technology:**

DAILIES TOTAL1® (delefilcon A) contact lenses are made from a proprietary silicone hydrogel material with a water content of approximately 33% water. The use of process automation, precision glass and quartz molds and photolithographic edge forming help ensure every lens has the same crisp optics, smooth surface finish and consistent edge quality from lens to lens. DAILIES TOTAL1® (delefilcon A) contact lenses are produced under strictly controlled process conditions and inspected to exacting quality tolerances. As a result, you can be confident your patients will experience consistent vision, comfort, and ease of handling every day.

## **PRODUCT DESCRIPTION**

DAILIES TOTAL1® (delefilcon A) soft contact lenses are available in a spherical lens design. The lens material is a silicone containing hydrogel with approximately 33% water and 67% delefilcon A polymer with phosphatidylcholine. The core lens material containing 33% water transitions through a water gradient to a hydrogel surface layer that exceeds 80% water. This structure enables a silicone hydrogel lens with a water gradient that has:

- Over 80% water at the surface of the lens to mimic the water content of the cornea.
- High level of oxygen transmissibility through the lens.
- Excellent overall comfort.

The lenses contain and release phosphatidylcholine (DMPC), a phospholipid found naturally in the tears. In addition, lenses contain the color additive copper phthalocyanine, a light blue tint which makes them easier to see when handling.

The lenses are packaged in strips of 5 individual blisters containing buffered saline with approximately 0.3% of polymeric wetting agents consisting of copolymers of polyamidoamine and poly(acrylamide-acrylic acid).

### **Lens Properties**

- Refractive Index (hydrated): 1.42
- Light Transmittance:  $\geq 93\%$  (@610 nm, -1.00D)
- Oxygen Permeability (Dk):  $140 \times 10^{-11}$  (cm<sup>2</sup>/sec)  
(ml O<sub>2</sub>/ml x mm Hg),  
measured at 35°C , (intrinsic Dk -  
Coulometric method)
- Water Content 33% by weight in normal saline
- Surface Water Content  $\geq 80\%$

### **Available Lens Parameters<sup>1</sup>**

DAILIES TOTAL1® (delefilcon A) Spherical contact lenses

- Chord Diameter Available: 14.1 mm
- Center Thickness: 0.09 mm @ -3.00D  
(varies with power)
- Base Curve: 8.5 mm
- Spherical Powers Available: -0.50 to -6.00D (0.25D steps)  
-6.50 to -10.00D (0.50D steps)

### **Actions**

When hydrated and placed on the cornea DAILIES TOTAL1® (delefilcon A) soft contact lenses act as a refracting medium to focus light rays on the retina.

### **INDICATIONS (USES)**

DAILIES TOTAL1® (delefilcon A) spherical soft contact lenses are indicated for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes with up to approximately 1.50 diopters (D) of astigmatism that does not interfere with visual acuity.

The lenses are to be prescribed for single use, daily disposable wear. The lenses are not intended to be cleaned or disinfected and should be discarded after a single use.

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

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<sup>1</sup> Check for actual product availability as additional parameters may be introduced over time.

## ***CONTRAINDICATIONS, WARNINGS, PRECAUTIONS AND ADVERSE EFFECTS***

For additional important prescribing and safety information, refer to the Package Insert that is printed in the back of this guide.

## ***ADVERSE EFFECT REPORTING***

If a patient experiences any serious adverse effects associated with the use of DAILIES TOTAL1® (delefilcon A) contact lenses, in the USA please **contact Alcon Medical Safety at 1-800-241-7468.**

## ***FITTING GUIDELINES***

***Please see the appropriate sections of this booklet that contain guidelines for spherical and monovision fitting techniques.***

## **FITTING GUIDELINES (Spherical Lenses)**

### **1. Patient Selection**

The patient characteristics necessary to achieve success with DAILIES TOTAL1® (delefilcon A) spherical lenses are similar to those for other spherical soft contact lenses. A thorough pre-fitting examination should be conducted to ensure the patient is a suitable candidate for soft contact lens wear.

The following procedures should be followed when fitting DAILIES TOTAL1® (delefilcon A) spherical lenses. For additional tips on fitting the monovision patient refer to the section Monovision Fitting Guidelines.

### **2. Pre-fitting Examination**

#### **A pre-fitting examination is necessary to:**

- assess the patient's motivation, physical state and willingness to comply with instructions regarding hygiene and wear schedule
- make ocular measurements for initial contact lens parameter selection
- collect baseline clinical information to which post-fitting examination results can be compared

#### **A pre-fitting examination should include:**

- a thorough case history
- a spherocylindrical refraction
- keratometry
- tear film assessment
- biomicroscopy

### **3. Trial Lens Evaluation**

#### **A. Lens Base Curve Selection**

A well-fitted lens provides good movement, centration and comfort. An optimal fit can be achieved for the vast majority of patients with the single 8.5 mm base curve.

#### **B. Initial Lens Power Selection**

The initial power selection should be as close as possible to the patient's prescription after taking into account spherical equivalent and vertex calculations, if necessary.



### ***Spherical Equivalent Calculation***

To determine initial lens power, convert the spherocylindrical spectacle Rx to its spherical equivalent as follows:

**Spherical Equivalent = Sphere power + 1/2 (Cylinder Power)**

**Example:**    **Spectacle Rx:**                    **-4.50D -1.00 x 180**  
                  **Spherical equivalent:**       **-4.50D + (-0.50D) = -5.00D**

### ***Vertex Distance Conversion***

If the spherical equivalent is greater than  $\pm 4.00D$ , a vertex distance correction is necessary (see Vertex Distance Conversion Chart) to determine the lens power required at the corneal plane.

**Example:**    **Spectacle Rx:**                    **-4.50D -1.00 x 180**  
                  **Spherical equivalent:**       **-4.50D + (-0.50D) = -5.00D**  
                  **Vertex compensation:**    **-4.75 (initial lens power)**

## **C. Lens Fit Assessment**

Allow the lenses to settle on the eyes for approximately **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 in primary and up gaze positions. The **Push-up Test**, as described below, is an additional test of the lens evaluation. The following guidelines will be helpful in fit evaluation:

### ***Characteristics of a Well-fitted Lens***

A well-fitted DAILIES TOTAL1® (delefilcon A) spherical contact lens satisfies the following criteria:

- 1. Good centration and full corneal coverage** in all fields of gaze.
- 2. Sufficient lens movement to allow tear exchange** under the lens during a blink in primary or upward gaze.
- 3. Satisfactory Push-up Test**
  - This test is a reliable indicator of a good fit. With the patient looking straight ahead, place your index finger on the patient's lower lid and nudge the edge of the lens upward while observing lens movement. Then pull the lid back down and observe the return of the lens.
  - A well fitted lens will move freely upward, stopping shortly after passing the limbus and then return freely to its original position.
- 4. Good comfort and stable visual response** (with over refraction).

### ***Characteristics of a Tight (Steep) Lens Fit***

A tight or steep lens fit would display some or all of the following characteristics:

1. Insufficient or no lens movement during a blink in primary or upward gaze.
2. Unsatisfactory Push-up Test
  - **A tight fitting lens will resist movement.**  
If successfully nudged upward, the lens may remain decentered or return slowly to its original position.
3. Good centration.
4. Good comfort.
5. Fluctuating vision between blinks.

### ***Characteristics of a Loose (Flat) Lens Fit***

A loose lens fit would display some or all of the following characteristics:

1. **Reduced comfort**, usually accompanied by lower lid sensation.
2. **Poor centration** with limbal exposure on exaggerated eye movement.
3. **Lens edge standoff.**
4. **Excessive lens movement** during the blink in primary or up-gaze.
5. **Unsatisfactory Push-up Test**
  - A loose fitting lens will move easily but may remain decentered or slip under the upper lid.
6. **Vision may be blurred** after the blink.

An inverted lens may mimic the characteristics of a loose lens. If any of the above signs occur remove the lens and check to make sure it is not inverted.

### ***General Fitting Tips***

- Trial fitting of the individual eye is recommended.
- A well fitting lens will show movement of 0.1 to 0.5 mm.

### ***D. Final Lens Power Determination***

After the characteristics of a well fitted lens have been satisfied, conduct a **spherical over-refraction** to determine the proper lens power to be dispensed.

<b>Example:</b>	<b>Diagnostic lens:</b>	<b>-4.50</b>
	<b>Over-refraction:</b>	<b>-0.25</b>
	<b>Final lens power:</b>	<b>-4.75</b>

## **FITTING GUIDELINES (Monovision)**

### **Patient Selection**

#### **A. Monovision Needs Assessment**

For a good prognosis, the patient should have adequately corrected distance and near visual acuity in each eye. Patients with reduced visual acuity, such as the amblyopic patient, may not be a good candidate for monovision.

Occupational and environmental visual demands should be considered. If the patient requires critical vision (visual acuity and stereopsis), it must be determined by trial whether this patient can function adequately with monovision. Monovision contact lens wear may not be optimal for such activities as:

1. visually demanding situations such as operating potentially dangerous machinery or performing other potentially hazardous activities; and
2. driving automobiles (e.g., driving at night). Patients who cannot pass requirements for a driver's license with monovision correction should not drive with this correction. An additional over-correction can be prescribed to improve vision.

#### **B. Patient Education**

All patients do not function equally well with monovision correction. Patients may not perform as well for certain tasks with this correction as they have with bifocal reading glasses. Each patient must understand that monovision, as well as other presbyopic contact lenses, or other alternatives, can create a vision compromise that may reduce visual acuity and depth perception for distance and near tasks. During the fitting process, it is necessary for the patient to realize the disadvantages as well as the advantages of clear near vision in straight-ahead and upward gaze that monovision contact lenses provide compared to spectacle bifocals.

### **Eye Selection**

Generally, the non-dominant eye is corrected for near vision. The following test for eye dominance can be used:

#### **A) Ocular Preference Determination Methods**

- Method 1 - Determine which eye is the "sight eye". Have the patient point to an object at the far end of the room. Cover one eye. If the patient is still pointing directly at the object, the eye being used is the dominant (sighting) eye.
- Method 2 - Determine which eye will accept the added power for near with the least reduction in distance vision. Place a trial spectacle near ADD lens in front of one eye and then the other while the distance refractive error correction is in place for both eyes. Determine whether the patient functions best with the near ADD lens over the right or left eye.

B) Refractive Error Method

- For anisometropic corrections, it is generally best to fit the more hyperopic (less myopic) eye for distance and the more myopic (less hyperopic) eye for near.

C) Visual Demands Method

- Consider the patient's occupation during the eye selection process to determine the critical vision requirements. If a patient's gaze for near tasks is usually in one direction, correct the eye on that side for near.

**Example:**

A person who places copy to the left side of the desk will usually function best with the near lens on the left eye.

## Special Fitting Considerations

### *Unilateral Lens Correction*

There are circumstances where only one contact lens is required. As an example, an emmetropic patient would only require a near lens while a bilateral myope may require only a distance lens.

- **Examples:**

- **Emmetrope:** A presbyopic emmetropic patient who requires a +1.75 diopter ADD would have a +1.75 lens on the near eye and the other eye left without a lens.
- **Bilateral myope:** A presbyopic patient requiring a +1.50 diopter ADD who is -2.50 diopters myopic in the right eye and -1.50 diopters myopic in the left eye may have the right eye corrected for distance and the left uncorrected for near.

- **Unilateral astigmat:**

- a) Emmetropic in one eye, astigmatic in the other

Spectacle Rx

O.D. Plano

O.S. -1.00 -1.00 x 090

Add: +1.50

Potential Monovision Rx

Uncorrected for distance

+0.50 -1.00 x 090 for near

- b) Myopic in one eye, astigmatic in the other

Spectacle Rx

O.D. -1.50

O.S. -2.00 -1.75 x 090

Potential Monovision Rx

Uncorrected for near

-2.00 -1.75 x 090 for distance

## Amblyopia

The amblyopic patient may not be a good candidate for monovision.

## Astigmatism

Patients with less than 1.50 diopters of astigmatism might be successfully fit in DAILIES TOTAL1® (delefilcon A) spherical lenses.

- Determine which eye to use for the near prescription (see Eye Selection, A-C, above)
- Add the appropriate near add power to the spherical component of the astigmatic prescription for that eye.

Example:	<u>Spectacle Rx</u>	<u>Potential Monovision Rx</u>
	O.D.: -2.50 -0.75 x 180	-2.50 -0.75 x 180 for distance
	O.S.: -3.00 -1.75 x 165	-2.00 -1.75 x 165 for near
	Add: +1.00	
	Dominant eye: O.D.	

## Near Add Determination

Always prescribe the lens power for the near eye that provides optimal near acuity at the midpoint of the patient's habitual reading distance. However, when more than one power provides optimal reading performance, prescribe the least plus (most minus) of the powers.

## Trial Lens Fitting

A trial lens fitting is performed in the office to allow the patient to experience monovision correction. Lenses are fit according to the directions in the *General Fitting Guidelines and Base Curve Selection* described earlier in the guide.

Case history and standard clinical evaluation procedures should be used to determine the suitability of monovision. Determine which eye is to be corrected for distance and which eye is to be corrected for near. Next determine the near ADD. With trial lenses of the proper power in place, observe the reaction to this mode of correction.

Immediately after the correct power lenses are in place, walk across the room and have the patient look at you. Assess the patient's reaction to distance vision under these circumstances. Then have the patient look at familiar near objects such as a watch face or fingernails. Again assess the reaction. As the patient continues to look around the room at both near and distance objects, observe the reactions. Only after these vision tasks are completed should the patient be asked to read print. Evaluate the patient's reaction to large print (e.g., typewritten copy) at first and then graduate to news print and finally smaller type sizes.

After evaluating the patient's performance under the above conditions, tests of visual acuity and reading ability under conditions of moderately dim illumination should be attempted.

An initial unfavorable response in the office, while indicative of a less favorable prognosis, should not immediately rule out a more extensive trial under the usual conditions in which a patient functions.

## **Adaptation**

Visually demanding situations should be avoided during the initial wearing period. A patient may at first experience some mild blurred vision, dizziness, headaches, and feeling of slight imbalance. You should explain the adaptational symptoms to the patient. These symptoms may last for a few minutes or for several weeks. The longer these symptoms persist, the poorer the chance for successful adaptation.

To help in the adaptation process, the patient can be advised to first use the lenses in a comfortable, familiar environment such as in the home.

Some patients feel that automobile driving performance may not be optimal during the adaptation process. This is particularly true when driving at night. Before driving a motor vehicle, it is recommended that patients be a passenger first to make sure that their vision is satisfactory for operating an automobile. During the first several weeks of wear (when adaptation is occurring), it may be advisable for the patient to only drive under optimal driving conditions. After adaptation, and success with these activities, the patient should be able to drive under other conditions with caution.

## **Other Suggestions**

The success of the monovision technique may be further improved by having your patient follow the suggestions below:

- Have a third contact lens (distance power) to use when critical distance viewing is needed.
- Have a third contact lens (near power) to use when critical near viewing is needed.
- Have supplemental spectacles to wear over the monovision contact lenses for specific visual tasks. This is particularly applicable for those patients who cannot meet driver's licensing requirements with a monovision correction.
- Make use of proper illumination when carrying out visual tasks.

Success in fitting monovision can be improved by the following suggestions:

- Reverse the distance and near eyes if a patient is having trouble adapting.
- Refine the lens powers if there is trouble with adaptation. Accurate lens power is critical for presbyopic patients.
- Emphasize the benefits of the clear near vision in straight ahead and upward gaze with monovision.

The decision to fit a patient with a monovision correction is most appropriately left to the eye care professional in conjunction with the patient after carefully considering the patient's needs. All patients should be supplied with a copy

of the **Patient Instruction Booklet**, which contains important instructions for the monovision wearer. You can obtain copies of the instruction book by calling customer service **in the USA at (800) 241- 5999**.

## **DISPENSING VISIT**

To help ensure patient success the following steps should be conducted with each patient, even if they have previously worn contact lenses. Even experienced wearers are prone to develop bad habits over time.

DAILIES TOTAL1® (delefilcon A) lenses are supplied sterile in foil sealed blister pack containers. Open the foil pack by peeling back the foil lidding material and gently slide the lens out of the container with your finger, or pour the lens onto the palm of your clean hand.

Conduct the following steps with each patient, even if they have previously worn contact lenses:

### **A. *Verification of Lens Fit***

Evaluate lens fit and visual response with the lens on the eye. The criteria of a well-fitted lens should be met and the patient's visual acuity should be acceptable. If not, the patient should be refitted with a more appropriate lens.

### **B. *Hygiene and Lens Handling Instructions***

Good hygiene and proper lens handling are important factors in achieving safe, comfortable lens wear. Instruct the patient on hygiene and handling of lenses. Patients who are unable to place and remove lenses should not be provided with them.

### **C. *Lens Wear and Replacement Schedules (see Package Insert)***

Prescribe and explain the daily disposable wear schedule. Explain that lenses are to be discarded after each daily wearing period. Determine the maximum suggested daily wearing period based on the patient's physiological eye condition. There may be a tendency for the patient to over wear their lenses initially. For some patients who have never worn contact lenses consider a wearing schedule that allows for a gradual increase in wearing time.

### **D. *Lens Care Directions (see Package Insert)***

The lenses are not intended to be cleaned or disinfected and should be discarded after a single use. The eye care professional may recommend lens rewetting drops, as needed.

## **E. Additional Instructions**

- **Review the Package Insert**

Provide the patient with all relevant information and precautions on the proper use of the lenses that are prescribed.

- **Provide the Patient Instruction Booklet for DAILIES TOTAL1® (delefilcon A) Contact Lenses.**

Give the patient a copy of the **Patient Instruction Booklet** for DAILIES TOTAL1® (delefilcon A) soft contact lenses. Review the contents so the patient clearly understands the prescribed lens wear, care, and replacement schedule. In the USA you can obtain copies of the instruction book by calling Alcon customer service **at (800) 241-5999**.

## **Follow-Up Examinations**

Follow-up care is extremely important for continued successful contact lens wear. Follow-up care should include:

- Case history, including questions to identify any problems related to contact lens wear
- Management of specific problems, if any, and
- A review with the patient of the lens wearing schedule, replacement schedule and handling procedures.

## **Follow-up Examination Procedures**

- Patients should be instructed to wear lenses prior to a follow-up examination.
- Record patient's symptoms, if any.
- Measure visual acuity monocularly and binocularly with the contact lenses in place.
- Perform an over-refraction to check for residual refractive error.
- With a biomicroscope, evaluate lens fitting.
- Remove the lenses and conduct a thorough biomicroscopic examination with fluorescein. Rinse eyes with saline before re-inserting lenses.
- Evert upper lids to determine condition of tarsal conjunctiva.
- Periodically perform keratometry and spectacle refractions. These results should be recorded to compare to the initial measurements.
- If any observations are abnormal, use professional judgment to manage the problem and restore the eye to optimal conditions. If visual requirements are not satisfied during any follow-up examination, the patient should be re-fitted with a more appropriate lens.



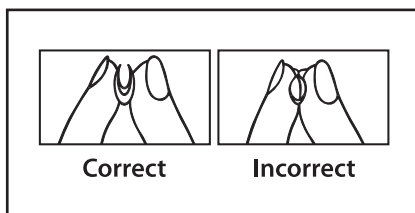
## LENS HANDLING HINTS

### Lens Insertion

- When about to place the lens on the eye, make sure the lens sits up on the placement finger. The finger should be dry so surface tension does not cause the lens to adhere to the finger.
- Check to see that the lens is right side out. A lens that is placed on the eye inside out may not feel comfortable or provide good vision.

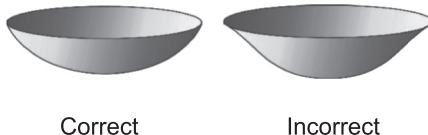
One way to do this is to perform the ‘taco test’ by placing the lens between your thumb and index finger and squeeze the edges together gently.

- If the edges come together, the lens is right side out.
- If the edges turn outward, the lens is wrong side out. Carefully reverse it with your fingers.



Another way is to place the lens on the tip of your index finger and check its shape.

- If the edge appears bowl-shaped, it is right side out.
- If the edge has a lip or flares outward, it is wrong side out and must be reversed.
- Place the lens directly onto the cornea (placing it on the lower sclera can lead to the lens folding after a blink). While continuing to hold both lids in place, the patient should look down to seat the lens. The lids may then be released.



### Lens Removal

- **Wash hands thoroughly** with soap that does not have any oils, lotions or perfumes.
- **Carefully dry hands** with a lint-free towel.

It is important to remind patients to **dry their hands thoroughly** prior to removing their lenses. The surface of DAILIES TOTAL1® lenses is designed to stay very wet and lubricious, or slippery while on the eye. If their fingertips are wet they are likely to slip across the surface of the lens making removal more difficult.

- Slide the lens off the cornea (down or to the side) onto the sclera. This produces a fold in the lens, which assists in removal. With the index finger and thumb, gently pinch the lens off the eye.
- Discard lenses.

### Care for a Sticking Lens

- In the unlikely event that the lens sticks (stops moving) or begins to dry on the eye, instruct the patient to apply several drops of a recommended lubricating solution (used in accordance with package labeling). The patient should wait until the lens begins to move freely on the eye before attempting to remove it. If the lens continues to stick, the patient should **immediately** consult the eye care professional.

## IN OFFICE CARE OF TRIAL LENSES

Eye care professionals should understand and educate contact lens technicians concerning proper use of trial lenses.

- Each contact lens is shipped sterile in a sealed blister pack containing phosphate buffered saline with additives. Hands should be thoroughly washed and rinsed and dried with a lint-free towel prior to handling a lens. In order to insure sterility, the blister pack should not be opened until immediately prior to use.
- DAILIES TOTAL1® (delefilcon A) lenses are for daily disposable wear only and should be discarded after a single use. The **lenses should be disposed of after a single use and not be re-used from patient to patient.**

## ADDITIONAL INFORMATION

For assistance with fitting or clinical questions regarding DAILIES TOTAL1® contact lenses eye care professionals having questions or problems should contact Medical Information Systems in the USA at (800) 241-7468. To order DAILIES TOTAL1® contact lenses contact your Alcon sales representative or call Customer Service, in the USA at (800) 241-5999.



**Important:** This package insert is effective as of July 2012 and applicable to the **DAILIES TOTAL1® (delefilcon A)** contact lenses described below. Please read carefully and keep this information for future use. This package insert is intended for the eye care professional, but should be made available to patients upon request. The eye care professional should provide the patient with appropriate instructions that pertain to the patient's prescribed lenses. Copies of this package insert are available without charge from Alcon by calling Customer Service at 1-800-241-5999 or download from our website at [www.alcon.com](http://www.alcon.com). In addition a Patient Instruction Booklet is available which is recommended to be given to patients.



**CAUTION: Federal (United States) law restricts this device to sale by or on the order of a licensed eye care professional.**

#### PRODUCT DESCRIPTION

**DAILIES TOTAL1® (delefilcon A)** soft contact lenses are made from a lens material that is 33% water and 67% (delefilcon A) polymer, a silicone containing hydrogel with added phosphatidylcholine. The core lens material containing 33% water transitions through a water gradient to a hydrogel surface layer that exceeds 80% water. Lenses contain the color additive copper phthalocyanine, a light blue tint, which makes them easier to see when handling.

#### Lens Properties

- Refractive index hydrated: 1.42
- Light Transmittance: 93% (@ 610 nm, -1.00D)
- Oxygen Permeability (Dk): 140 x 10<sup>-11</sup> (cm<sup>2</sup>/sec)(ml O<sub>2</sub>/ml x mm Hg), measured at 35° C (intrinsic Dk-Coulometric method)
- Water Content: 33% by weight in normal saline
- Surface Water Content: ≥ 80%

#### Lens Parameters

- Diameter Range 13.0 to 15.0 mm
- Spherical Power Range -20.00 to +20.00D
- Base Curve Range 8.0 to 9.2 mm

#### Lens Parameters Available<sup>1</sup>

##### DAILIES TOTAL1® (delefilcon A) spherical

- Chord Diameter : 14.1 mm
- Center Thickness: 0.09 mm @ -3.00D (varies with power)
- Base Curve : 8.5 mm
- Powers: -0.50 to -6.00D (0.25D steps); -6.50 to -10.00D (0.50D steps)

#### ACTIONS

When hydrated and placed on the cornea, **DAILIES TOTAL1® (delefilcon A)** contact lenses act as a refracting medium to focus light rays on the retina.

#### INDICATIONS (Uses)

**DAILIES TOTAL1® (delefilcon A)** spherical soft contact lenses are indicated for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes with up to approximately 1.50 diopters (D) of astigmatism that does not interfere with visual acuity.

The lenses are to be prescribed for single use, daily disposable wear. The lenses are not intended to be cleaned or disinfected and should be discarded after a single use.

#### CONTRAINDICATIONS (REASONS NOT TO USE)

**DO NOT use DAILIES TOTAL1® (delefilcon A) contact lenses when any of the following exists:**

- Inflammation or infection of the anterior chamber of the eye
- Active disease, injury or abnormality affecting the cornea, conjunctiva, or eyelids
- Microbial infection of the eye
- Insufficiency of lacrimal secretion (dry eye) that interferes with contact lens wear
- Corneal hypoesthesia (reduced corneal sensitivity)
- Use of any medication that is contraindicated or interferes with contact lens wear, including eye medications
- Any systemic disease which may be exacerbated by or interferes with contact lens wear
- Allergic reactions or ocular irritation of the ocular surfaces or adnexa that may be caused by or exaggerated by the wearing of contact lenses
- Patient history of recurring eye or eyelid infections, adverse effects associated with contact lens wear, intolerance or abnormal ocular response to contact lens wear
- If eyes become red or irritated

#### WARNINGS

**Advise patients of the following warnings pertaining to contact lens wear:**

- Problems with contact lenses and lens care products could result in serious injury to the eye. It is essential that patients follow their eye care professional's directions and all labeling instructions for proper use of lenses and lens care products. **Eye problems, including corneal ulcers, can develop rapidly and lead to loss of vision.**
- Daily wear lenses are not indicated for overnight wear, and patients should be instructed not to wear lenses while sleeping. Clinical study results<sup>2</sup> have shown that the risk of serious adverse reactions is increased when lenses are worn overnight.
- Studies<sup>2</sup> have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than nonsmokers.
- If a patient experiences eye discomfort, foreign body sensation, excessive tearing, vision changes, or redness of the eye, the patient should be instructed to immediately remove lenses and promptly contact his or her eye care professional. It is recommended that contact lens wearers see their eye care professional regularly as directed.

#### PRECAUTIONS

To prevent damage to the eyes or to the contact lenses, the following precautions should be taken:

##### Special Precautions for the Eye Care Professional:

Due to the small number of patients enrolled in the 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 professional

should consider all characteristics of the lens that can affect lens performance and ocular health, including oxygen permeability, central and peripheral thickness and optic zone diameter.

The potential impact of these factors on the patient's ocular health should be carefully weighed against the patient's need for refractive correction; therefore the continuing ocular health of the patient and lens performance on the eye should be carefully evaluated on initial dispensing and monitored on an ongoing basis by the prescribing eye care professional.

- Fluorescein, a yellow dye, should not be used while the lenses are on the patient's eyes. The lenses absorb this dye and become discolored. Whenever fluorescein is used, the eyes should be flushed thoroughly with sterile saline solution that is recommended for in eye use prior to inserting lenses. Avoid dispensing saline from an aerosol can directly into the eye.
- Before leaving the eye care professional's office, the patient should be able to promptly remove their lenses or should have someone else available who can remove their lenses for them.
- Eye care professionals should instruct the patient to remove the lenses immediately if the eye becomes red or irritated.
- Routine eye examinations are necessary to help assure the continued health of the patient's eyes. Eye care professionals should make arrangements with the patient for appropriate follow-up visits. Alcon recommends that patients see their eye care professional once each year, or more often, as recommended by the eye care professional.
- Diabetics may have reduced corneal sensitivity and thus are more prone to corneal injury and do not heal as quickly or completely as non-diabetics.
- Visual changes or changes in lens tolerance may occur during pregnancy or use of oral contraceptives. Caution patients accordingly.

**Eye Care Professionals should carefully instruct patients about the following safety precautions:**

#### **Handling Precautions:**

- Be sure that before leaving the eye care professional's office the patient is able to promptly remove lenses or have someone else available to remove them.
- Good hygiene habits help promote safe and comfortable lens wear. **Always wash, rinse and thoroughly dry hands with a lint-free towel before handling lenses.**
- **REMOVE A LENS IMMEDIATELY** if an eye becomes red or irritated.
- Always handle lenses carefully. Never use tweezers or other sharp objects such as fingernails to remove lenses from the lens container unless specifically indicated for that use.
- Shake the blister pack gently prior to opening. Remove the lens from the blister pack by carefully pouring the lens onto the palm of your clean hand. Ensure the lens is right side out and that the correct lens for each eye is available. Inspect lenses prior to insertion. Do not insert damaged lenses.
- To insert lenses:
  - Place a lens on the tip of your clean and dry right or left index finger, place the middle finger of the same hand close to lower eyelashes and pull down the lower eyelid.
  - Use the fingers of the other hand to lift the upper eyelid.
  - Place the lens directly on the eye (cornea) and gently roll finger away from the lens.
  - Look down and slowly remove the hand, releasing the lower lid.
  - Look straight ahead and slowly remove the other hand, releasing the upper lid.
  - Blink gently.
- To remove lenses:
  - **Make sure hands are clean and completely dry.**
  - Blink fully several times.
  - While looking up, slide the lens down onto the white part of the eye.
  - Remove the lens by pinching gently between the thumb and forefinger. Do not pinch the eye tissue.
  - If the lens is difficult to grasp, dry fingers once more and try again. Do not use rewetting drops in this instance.
- If a lens decenters on the eye, close the eye and gently massage the eyelid to return the lens to the central position. If the problem persists, consult the eye care professional.
- If a lens tears in the eye it will feel uncomfortable. Advise wearers it is impossible to lose a contact lens or part of a contact lens behind the eye and to remain calm. Lens pieces may be removed by pinching them as for normal lens removal, carefully avoiding pinching the eye tissue. If the lens pieces do not seem to remove easily, rinsing with saline is recommended. If this does not help, the wearer should contact an eye care professional for assistance.

#### **Lens Wearing Precautions:**

- Patients should never exceed the prescribed wearing schedule regardless of how comfortable the lenses feel. Doing so may increase the risk of adverse effects.
- The lens should move freely on the eye at all times. If the lens sticks (stops moving) on the eye, follow the recommended directions in the *Care for a Sticking Lens* section. If non-movement of the lens continues, the patient should be instructed to consult their eye care professional immediately.
- The eye care professional should be consulted about wearing lenses during water sports and water related activities. Exposure to water or other non-sterile liquids while wearing contact lenses in activities such as swimming, water skiing, and hot tubs may increase the risk of ocular infection, including but not limited to Acanthamoeba keratitis.
- Eye irritation, infection, or lens damage may result if cosmetics, lotion, soap, cream, hair spray, deodorant, aerosol products or foreign particles come in contact with lenses.
- Environmental fumes, smoke, and vapors should be avoided in order to reduce the chance of lens contamination or physical trauma to the cornea.
- Lenses should be disposed of each day upon removal from the eye.
- Discard any lens which has become dehydrated or damaged. Replace with a sterile, fresh, new lens.
- Note the correct lens power for each eye to prevent getting them mixed up.
- Always keep a supply of replacement lenses on hand.
- Do not use lenses beyond their expiration date.

#### **Other Topics to Discuss with Patients:**

- Periodic eye examinations are extremely important for contact lens wearers. Schedule and conduct appropriate follow-up examinations to determine ocular response. Alcon recommends that patients see their eye care professional once each year or as recommended by the eye care professional.
- Certain medications may cause dryness of the eye, increased lens awareness, lens intolerance, and blurred vision or visual changes. These include, but are not limited to, antihistamines, decongestants, diuretics, muscle relaxants, tranquilizers, and those for motion sickness. Caution patients using such medications accordingly and prescribe proper remedial measures.
- Visual changes or changes in lens tolerance may occur during pregnancy or use of oral contraceptives. Caution patients accordingly.

#### **Who Should Know that the Patient is Wearing Contact Lenses:**

- Patients should inform their health care practitioners that they are wearing contact lenses.
- Patients should inform their employers that they are wearing contact lenses. Some jobs may require the use of eye protection equipment or may require that contact lenses not be worn.

It is strongly recommended that patients be provided with a copy of the **DAILIES TOTAL1®** (delefilcon A) *Patient Instruction Booklet* available from Alcon and understand its contents prior to dispensing the lenses.

#### ADVERSE EFFECTS

**Patients should be instructed to check eyes regularly to make sure they look well, feel comfortable and vision is clear. Potentially serious complications are usually accompanied by one or more of the following signs or symptoms:**

- Moderate to severe eye pain not relieved by removing the lens
- Foreign body sensation
- Excessive watering or other eye secretions including mucopurulent discharge
- Redness of the eyes
- Photophobia (light sensitivity)
- Burning, stinging or itching or other pain associated with the eyes
- Comfort is less compared to when the lens was first placed on eye
- Poor visual acuity (reduced sharpness of vision)
- Blurred vision, rainbows or halos around objects
- Feeling of dryness

**Patients should be instructed that if any of the above signs or symptoms are noticed, he or she should:**

- **IMMEDIATELY REMOVE THE LENSES.**
- **If the discomfort or problem stops**, discard the lens and replace it with a new one.
- **If the discomfort or problem continues after removing lens(es) or upon insertion of a new lens, IMMEDIATELY remove the lens(es) and contact the eye care professional for identification of the problem and prompt treatment to avoid serious eye damage.**
- **The patient should be informed that a serious condition such as corneal ulcer, infection, corneal vascularization, or iritis may be present, and may progress rapidly. Less serious reactions such as abrasions, infiltrates, and bacterial conjunctivitis must be managed and treated carefully to avoid more serious complications.**
- Additionally, contact lens wear may be associated with ocular changes that require consideration of discontinuation or restriction of wear. These include but are not limited to local or generalized corneal edema, epithelial microcysts, epithelial staining, infiltrates, neovascularization, endothelial polymegathism, tarsal papillary changes, conjunctival injection or iritis.

#### ADVERSE EFFECT REPORTING

If a patient experiences any serious adverse effects associated with the use of **DAILIES TOTAL1®** (delefilcon A) contact lenses, please notify: Alcon Medical Safety in the USA at **1-800-241-7468**.

#### FITTING GUIDE AND PATIENT BOOKLET

Conventional methods of fitting contact lenses apply to **DAILIES TOTAL1®** (delefilcon A) contact lenses. For a detailed description of the fitting techniques, refer to the **DAILIES TOTAL1®** (delefilcon A) Professional Fitting and Information Guide. Both the professional fitting guide and a patient instruction booklet are available free of charge from:

Alcon Laboratories, Inc.  
6201 South Freeway  
Fort Worth, TX, USA 76134 1-800-241-5999

#### LENS WEAR & REPLACEMENT SCHEDULES

##### DAILY WEAR (less than 24 hours, while awake):

- To avoid tendency of the daily wear patient to overwear the lenses initially, stress the importance of adhering to a proper, initial wearing schedule. Normal daily wear of lenses assumes a minimum of 6 hours of non-lens wear per 24 hour period.
- 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 allows more gradual adaptation of the ocular tissues to contact lens wear.
  - The maximum daily wearing time should be determined by the eye care professional based upon the patient's physiological eye condition because individual responses to contact lenses vary. There may be a tendency for patients to overwear the lenses initially. The eye care professional should stress the importance of adhering to the initial maximum wearing schedule. Studies have not been conducted to show that **DAILIES TOTAL1®** (delefilcon A) contact lenses are safe to wear during sleep, therefore patients should be advised to remove their lenses while sleeping. Normal daily wear of lenses assumes a minimum of 6 hours of non-lens wear per 24 hour period. Optimum individual wearing schedule will vary.

**DAILIES TOTAL1®** (delefilcon A) contact lenses are intended to be worn once (daily disposable wear) and then discarded at the end of each wearing period. The patient should be instructed to start the next wearing period with a fresh new lens.

#### EMERGENCY LENS CARE

Cleaning and disinfection of daily disposable lenses is not recommended. The patient should be reminded to have replacement lenses or back-up spectacles available at all times.

#### CARE FOR A STICKING LENS

If the lens sticks (stops moving) or begins to dry on the eye, instruct the patient to apply several drops of a recommended lubricating solution (used in accordance with package labeling). The patient should wait until the lens begins to move freely on the eye before attempting to remove it. It is important that the patient wash and dry their hands thoroughly before removing the lens. If the lens continues to stick, the patient should **IMMEDIATELY** consult the eye care professional.

#### IN OFFICE USE OF TRIAL LENSES

Eye care professionals should educate contact lens technicians concerning proper use of trial lenses.

Each contact lens is shipped sterile in a blister pack containing phosphate buffered saline solution. Hands should be thoroughly washed and rinsed and dried with a lint-free towel prior to handling a lens. In order to ensure sterility, the blister pack should not be opened until immediately prior to use. For fitting and diagnostic purposes lenses should be disposed of after a single use and not be re-used from patient to patient.

#### 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 or fresh saline solution and immediately contact the eye care professional or visit a hospital emergency room without delay.**

#### HOW SUPPLIED

Each lens is packaged in a foil-sealed plastic container containing phosphate buffered saline solution with approximately 0.3% of polymeric wetting agents consisting of copolymers of polyamidoamine and poly(acrylamide-acrylic) acid and is steam sterilized **STERILE**. The package is marked with the base curve, diameter, dioptric power, manufacturing lot number and expiration date.

**The following may appear on labels or cartons:**

Symbol/Sign	Description
	CAUTION: Federal (United States) law restricts this device to sale by or on the order of a licensed eye care professional.
	Steam sterilized
	Use by date (Expiry date)
	Batch code
	Example of two letter language code (English)
 Do Not Reuse	Do Not Reuse
DIA	Diameter
BC	Base curve
D	Diopter (lens power)
	European conformity sign
	See product instructions
	Authorized European Representative European Community
	Manufacturer
	Packaging waste license sign

1. Check for actual product availability as additional parameters may be introduced over time
2. New England Journal of Medicine, September 21, 1989;321 (12), pp.773-783

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Manufactured for Alcon by CIBA Vision

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Duluth, GA, USA 30097

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6201 South Freeway  
Fort Worth, TX, USA 76134

1-800-241-5999

**Alcon**<sup>®</sup>

Date: July 2012

# **VERTEX DISTANCE CONVERSION CHART**

For minus lenses, read left to right; for plus lenses, read right to left.  
(12 mm Vertex Distance)

-	+	-	+	-	+	-	+
4.00	3.87	7.50	6.87	12.00	10.37	19.00	15.50
4.25	4.00	7.62	7.00	12.50	10.75	19.25	15.62
4.50	4.25	7.75	7.12	12.75	11.00	19.25	15.75
4.75	4.50	7.87	7.25	13.00	11.25	19.75	16.00
5.00	4.75	8.00	7.37	13.50	11.50	20.00	16.12
5.12	4.87	8.12	7.50	13.75	11.75	20.25	16.25
5.37	5.00	8.25	7.62	14.00	12.00	20.50	16.50
5.50	5.12	8.50	7.75	14.25	12.25	20.75	16.62
5.62	5.25	8.75	8.00	14.75	12.50	21.00	16.75
5.75	5.37	9.00	8.25	15.00	12.75	21.25	17.00
5.87	5.50	9.25	8.37	15.50	12.75	21.75	17.25
6.00	5.62	9.50	8.62	15.75	13.25	22.25	17.50
6.12	5.75	9.75	8.75	16.25	13.50	22.50	17.75
6.37	5.87	10.00	9.00	16.75	13.75	23.00	18.00
6.50	6.00	10.25	9.12	17.00	14.00	23.50	18.25
6.62	6.12	10.50	9.25	17.25	14.25	23.75	18.50
6.75	6.25	10.75	9.37	17.62	14.37	24.25	18.75
6.87	6.37	11.00	9.62	18.00	14.50	24.75	19.00
7.00	6.50	11.25	9.75	18.12	14.75	25.00	19.25
7.12	6.62	11.50	10.00	18.50	15.00	25.50	19.50
7.37	6.75	11.75	10.25	18.75	15.25	26.00	19.75



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