

Professional Fitting and Information Guide

**DAILIES TOTAL1*
and
DAILIES TOTAL1* Multifocal
(delefilcon A) Soft Contact Lenses
For Single-Use, Daily Disposable Wear
Water Gradient One-Day Contact Lenses**

Rx only

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

Alcon[®]
a Novartis company

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Introduction

Thank you for prescribing DAILIES TOTAL1* and DAILIES TOTAL1* Multifocal (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* and DAILIES TOTAL1* Multifocal (delefilcon A) lenses. This guide contains important information regarding fitting procedures and aftercare of the DAILIES TOTAL1* and DAILIES TOTAL1* Multifocal (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* and DAILIES TOTAL1* Multifocal (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. 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* and DAILIES TOTAL1* Multifocal soft contact lenses are made a silicone containing hydrogel that is approximately 33% water and 67% delefilcon A polymer with added 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): 140×10^{-11} (cm²/sec)
(ml O₂/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 Parameters¹

- 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
 - Powers Available: -0.50 to -6.00D (0.25D steps); -6.50 to -12.00D (0.50D steps)
+0.50 to +6.00D (0.25D steps)

- DAILIES TOTAL1* Multifocal (delefilcon A)**
- Chord Diameter: 14.1 mm
 - Center Thickness: 0.09 mm @ -3.00D (varies with power)
 - Base Curve: 8.5 mm
 - Powers: -0.25 to -10.00D (0.25D steps); plano to +6.00D (0.25D steps)
ADD: LO, MED, HI

¹Check for actual product availability as additional parameters may be introduced over time.

Actions

When hydrated and placed on the cornea 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.

DAILIES TOTAL1* Multifocal (delefilcon A) soft contact lenses are indicated for the optical correction of refractive ametropia (myopia and hyperopia) and/or presbyopia in phakic or aphakic persons with non-diseased eyes who may require a reading addition of +3.00 (D) or less and who may have 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.

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* or DAILIES TOTAL1* Multifocal (delefilcon A) contact lenses, in the USA please **contact Alcon Medical Safety at 1-800-757-9780.**

FITTING GUIDELINES

Please see the appropriate sections of this booklet that contain guidelines for spherical, multifocal 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 upward 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.

Example:	Diagnostic lens:	-4.50
	Over-refraction:	-0.25
	Final lens power:	-4.75

FITTING GUIDELINES (Multifocal)

The **DAILIES TOTAL1* Multifocal** (delefilcon A) soft contact lens is a progressive aspheric simultaneous vision soft contact lens, intended to correct presbyopia with or without additional ametropia, available in three ADD powers; low (LO), medium (MED) and high (HI). For each lens the near and intermediate powers are concentrated primarily in the central portion of the optical zone while the distance power is contained in the surrounding portion. The continuous changes in power across the surface of the lens allow patients requiring a reading addition of up to + 3.00D to see clearly at far, intermediate, and near distances.

Achieving high success with DAILIES TOTAL1* Multifocal (delefilcon A) contact lenses is dependent on several factors, including the patient's motivation, expectations and visual wearing environment, as well as your skill in optimizing the lens powers to balance binocular performance at distance and near. The information in this guide is designed to provide you with the tools to manage your presbyopic patients through each stage of the process from the initial case history to post-fitting follow-up.

1. Pre-fitting Examination

A pre-fitting examination is necessary to:

- determine whether a patient is a suitable candidate for DAILIES TOTAL1* Multifocal (delefilcon A) contact lenses
- make ocular measurements and assessments 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
- detailed assessment of patient's individual visual demands
- understanding of patient's objectives for lens wear and expectations
- a distance spherocylindrical refraction, near add determination and measurement of pupil diameter
- keratometry
- tear assessment
- biomicroscopy

Note: The importance of a thorough case history should not be underestimated. The information gained through careful listening and probing will help greatly in satisfying each patient's unique needs.

2. Patient Selection

The eye care professional should weigh several factors when considering patient selection for a DAILIES TOTAL1* Multifocal (delefilcon A) soft contact lens fitting. When fitting a lens intended to correct for presbyopia, it is especially important to evaluate the particular visual needs, objectives, lifestyle and expectations of the individual patient. Prospective candidates may include current contact lens wearers, former wearers, and persons with no previous wear history. For former wearers it is important to determine the cause for discontinuation.

There are two general categories of candidates based on anticipated usage: those who seek to wear their lenses as their principal means

of vision correction, and those who wish to integrate the use of their contact lenses with spectacles. The integrative user often seeks to wear their lenses for sports or other occasional activities while reverting to spectacles under poor lighting or otherwise demanding vision conditions. In general, even the part-time user does not require more than a few moments re-adaptation time following an interval of no lens wear.

While candidates with greater than 1.00 diopter of refractive error have often been thought of as better candidates than those with low error or emmetropia, this is a generalization that often does not hold true for a given individual. Success is influenced by many factors and the eye care professional is encouraged to offer DAILIES TOTAL1* Multifocal (delefilcon A) contact lenses to all interested presbyopic patients who satisfy the standard requirements for soft contact lens wear.

To summarize patient selection, the characteristics of "ideal candidates" and those that will be more difficult to fit" are listed below:

Ideal Candidates

- Refractive cylinder < 1.00D.
- Attainable visual demands that do not depend upon resolving very fine (smaller than 20/20 letters) details at *both* distance and near for extended periods while wearing DAILIES TOTAL1* Multifocal contact lenses.
- Emphasis on tasks where it is advantageous to have objects simultaneously in focus over a large range of viewing distances.
- Expectations consistent with actual everyday visual demands.
- Motivated to wear lenses and understands that vision may not *always* be as sharp as with spectacles for some distances or lighting conditions.
- Unable to adapt to monovision correction.

Less than Ideal Candidates

- Critical or very fine visual demands at both distance and near.
- Refractive cylinder $\geq 1.00D$ (any axis) in one or both eyes or against-the-rule refractive cylinder $> 1.00D$ in one or both eyes.
- Monocular distance acuities poorer than 20/20 with spherical equivalent refractive correction.
- Myopic anisometropia where the refractive error for one of the two eyes is low ($\leq 1.50D$) and has not been habitually corrected.
- Pupil size larger ($> 4\text{ mm}$) or smaller ($< 3\text{ mm}$) than norm for presbyopic population under natural illumination conditions.
- Abnormal binocular sensory function (e.g., amblyopia or strabismus).
- Expectation to discard and never use spectacles again, including reading glasses, even for special tasks or viewing conditions.
- Highly satisfied monovision wearers.
- Any other contraindications to successful contact lens wear such as tear abnormality or lid margin disease.

3. **Initial Lens Selection**

A. Initial Base Curve Selection

DAILIES TOTAL1* Multifocal (delefilcon A) contact lenses are available in a single 8.5 mm base curve.

B. Initial Lens Power Selection

Note: A careful maximum plus spherocylindrical refraction and nearpoint add determination should be conducted prior to selecting a DAILIES TOTAL1* Multifocal (delefilcon A) trial lens. Autorefractive findings should be refined manually to rule out effects of instrument myopia and ensure proper control of residual accommodation.




The DAILIES TOTAL1* Multifocal lens design makes selecting the initial lens power easy. You need only manipulate the distance power. **The optimum starting point is with a power that is equal to or more plus or less minus than the vertex corrected spherical equivalent spectacle refraction.**

C. Initial ADD Selection

Note: A careful nearpoint ADD determination should be conducted prior to selecting a DAILIES TOTAL1* Multifocal (delefilcon A) trial lens

The DAILIES TOTAL1* Multifocal (delefilcon A) 3 ADD SYSTEM allows personalized fitting for presbyopic patients. The table below makes initial ADD selection easy.

DAILIES TOTAL1* MULTIFOCAL ADD SELECTION

SPECTACLE ADD	BOTH EYES
Up to +1.25	
+1.50 to +2.00	
+2.25 to +2.50	

Example 1:	OD	OS
Spherical Rx:	-4.50 -0.75 x 90	-4.00D
Spherical equivalent (least minus);	-4.75D	-4.00D
Vertex corrected power:	-4.50D	-4.00D
Spectacle Add:		+0.75D
Eye Dominance:		OD
Initial Trial Lens:	-4.50 LO	-4.00 LO

Example 2:	OD	OS
Spherical Rx:	+4.25 -0.25 x 180	+4.00 D -0.50 x 180
Spherical equivalent (least minus):	+4.25D	+3.75D
Vertex corrected power:	+4.50D	+3.75D
Spectacle Add:		+2.00D
Eye Dominance:		OS
Initial Trial Lens:	+4.50 MED	+3.75 MED

4. Initial Lens Fitting Evaluation

- Insert the lenses selected in Section 3 (above). If the exact power is not available, choose the next closest least minus/most plus lens power in your trial set.
- 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 with the patient's tears.
- Evaluate the fit 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 evaluating the physical fit of the lens:

Characteristics of a Well-fitted Lens

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

- Full corneal coverage and good centration (no limbal exposure). A lens that is decentered > 1 mm, particularly temporal, is less likely to give adequate vision.
- Lens movement of 0.1 to 0.5 mm should be present to allow tear exchange under the lens during a blink in primary gaze or upward gaze and to avoid variable vision.

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.**
- Good comfort.
 - Acceptable visual acuity with over-refraction.

Characteristics of a Tight (Steep) Lens Fit

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

1. Good centration.
2. Insufficient or no lens movement during a blink in primary gaze or upward gaze.
3. Excessive conjunctival drag (visible movement of the conjunctival vessels when the lens moves during a blink or during the push-up test). Note: presbyopes often have loose conjunctiva, some conjunctival movement is occasionally seen and may not be a sign of a tight fit. See Push-up Test below.

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.**

4. Good comfort.
5. Blurred vision between blinks.

Characteristics of a Loose (Flat) Lens Fit

If a lens fit is judged to be too flat a steeper lens (smaller base curve), if available, should be evaluated. A loose lens fit would display some or all of the following characteristics:

1. Decentration.
2. Excessive lens movement during the blink in primary or upward gaze.

Push-up Test:

- **A loose 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 times return lower than its original position.**

3. Reduced comfort.
4. Lens edge standoff.
5. Blurred vision immediately after the blink.

5. Initial Lens Visual Evaluation

While lenses are settling, it is helpful to take the patient from the exam room to a “real-world” setting such as a room with an outside view. Once an acceptable fit has been achieved, the visual performance of the lenses may be evaluated. Visual acuity is tested at distance. If necessary, a spherical over-refraction should be performed using a trial frame or hand held lenses rather than a phoropter. This technique is essential when fitting multifocal lenses because it allows the patient to maintain the head posture and direction of gaze (relationship between eye and head) that he or she would naturally use during everyday tasks. This ensures that the visual performance of the lens is being assessed under conditions where the on-eye positioning matches that which will occur when the lens is being used, for example, for near work activities. In addition, pupil size will not be artificially increased

by the reduction in light associated with looking through the aperture of the phoropter cells, or decreased by proximal cues associated with the nearness of the instrument.

6. Fitting Procedures

Step 1. After the trial lenses have settled for approximately 10 minutes, measure distance acuity while the patient is viewing the chart binocularly (i.e., simultaneously with both eyes). Next, evaluate the patient's subjective impression of the near vision when trying to read typical everyday material (e.g., a newspaper, magazine, and cell phone). Lighting and reading distance should be what is normal for the patient.

Step 2. If distance or near vision is unsatisfactory, perform a **binocular distance** over-refraction, as follows. Use hand-held trial lenses and encourage plus. For example, if a Plano and +0.25D over-refraction yields the same results, use the +0.25D endpoint. Re-check visual acuity and visual quality as described in Step 1 above. If over-refraction is other than plano, go immediately to new trial lenses, keeping ADD the same.

Step 3. If distance and near vision are satisfactory, dispense lenses and remind patient to use good light when reading fine print or use additional reading glasses if needed. It is helpful to let the patient experience the lenses in their natural environment before further procedures for enhancing vision are performed.

Step 4. Enhanced Near Vision. If near vision is unsatisfactory, determine the dominant eye by the following method. Determine the eye with **greatest plus acceptance** by placing +1.50 handheld trial lens over each eye alternately while patient views in the distance with both eyes open. Consider the eye for which binocular vision blurs **least** with the +1.50 to be the non-dominant eye. Other methods to determine the dominant eye are appropriate.

Step 4A: Check the patient's binocular acuity with +0.50 over the non-dominant eye to determine if near vision is improved and distance vision is still acceptable. If so, place a new trial lens with the same ADD on the non-dominant eye, **adjusting the distance power by +0.50.**

Enhanced near vision, Step A		
SPECTACLE ADD	DOMINANT EYE	NON-DOMINANT EYE (PLUS ACCEPTED)
Up to +1.25	LO	LO with additional +0.50
+1.50 to +2.00	MED	MED with additional +0.50
+2.25 to +2.50	HI	HI with additional +0.50

Next, re-check visual acuity and visual quality as described in Step 1 above. If satisfactory, dispense new distance lens power for the non-dominant eye. If near vision is still unsatisfactory, proceed to Step B:

Step 4B: If near vision is still unsatisfactory, adjust ADD as shown below.

Enhanced near vision, Step B		
SPECTACLE ADD	DOMINANT EYE	NON-DOMINANT EYE (PLUS ACCEPTED)
Up to +1.25	MED	MED
+1.50 to +2.00	MED	HI
+2.25 to +2.50	HI	MED

Note: It is common to question the rather non-intuitive step we suggest for enhancing vision at near in the HI ADD range, where the suggestion is to “back off” to a MED ADD for the non-dominant eye, the same suggestion we make for enhancing distance vision (below). The reason for this is that after establishing (in Step A) that increasing plus is not helpful, the next most common reason for blur at near (or distance) is unacceptable ghosting that degrades the image quality. Backing down to the MED ADD in one eye can often relieve that and actually improve vision at near.

Step 5: Enhanced Distance Vision. If distance over-refraction did not improve visual acuity, adjust ADD according to the chart below.

SPECTACLE ADD	DOMINANT EYE	NON-DOMINANT EYE (PLUS ACCEPTED)
+1.50 to +2.00	LO	MED
+2.25 to +2.50	HI	MED

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

<u>Spectacle Rx</u>	<u>Potential Monovision Rx</u>
O.D. Plano	Uncorrected for distance
O.S. -1.00 -1.00 x 090	+0.50 -1.00 x 090 for near
Add: +1.50	

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

<u>Spectacle Rx</u>	<u>Potential Monovision Rx</u>
O.D. -1.50	Uncorrected for near
O.S. -2.00 -1.75 x 090	-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* brand (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 overwear 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. Specific Instructions for Presbyopic Patients

Specific instructions, explanations and demonstrations are important for optimizing patient success with multifocal contact lenses. The following information and instructions have proven useful in advising patients who wear DAILIES TOTAL1* Multifocal (delefilcon A) soft contact lenses.

- A contact lens that contains different powers for distance and near involves greater technological and optical complexity than does a bifocal or multifocal spectacle lens. This is because the contact lens moves with the eye, rather than having the eye move up and down while the lens remains suspended in a frame. While the contact lens therefore gives an unobstructed field of view and greater freedom regarding where to look, these advantages may mean that the sharpness of vision may not always be exactly the same as what would be experienced with spectacles.
- Although many individuals use DAILIES TOTAL1* Multifocal (delefilcon A) contact lenses for full-time wear, it is not unusual to find that there may be some activities where one prefers to wear spectacles, or where the disadvantages associated with spectacles are outweighed by other issues. This is an entirely normal and natural response to the challenges presented by presbyopia.
- Situations where vision with multifocal contact lenses may be less sharp or otherwise "different" than what is experienced with spectacles often involve low illumination (e.g., a semi-dark room), reduced visibility (e.g., outdoor conditions of fog or heavy rain), or isolated sources of very bright light (e.g., headlights of an oncoming vehicle on a narrow country road). **Patients should be instructed to make use of good light when reading fine print.**
- Patients should be aware that it might be advisable to refrain from wearing their lenses while driving, flying an airplane or operating heavy machinery while wearing their lenses until they gain some experience with the lenses in a similar visual environment.
- Small changes in lens power can often make a significant difference in the quality of the vision experienced with multifocal contact lenses. Such changes can be best tailored to

individual needs and environmental conditions that the patient will personally encounter on a day-to-day basis. Confidence and assurance that such refinements, if needed, can be achieved are important for patient motivation during the initial period of lens wear.

F. 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* and DAILIES TOTAL1* Multifocal (delefilcon A) Contact Lenses.**

Give the patient a copy of the **Patient Instruction Booklet** for DAILIES TOTAL1* and DAILIES TOTAL1* Multifocal (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

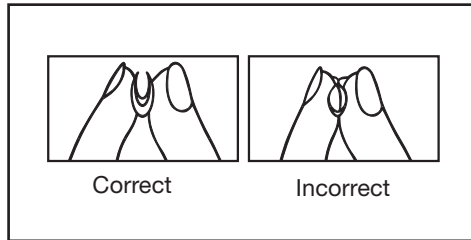
- When about to place the lens on the eye, make sure the lens sits up on the placement finger. The finger should be dry so surface tension does

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.

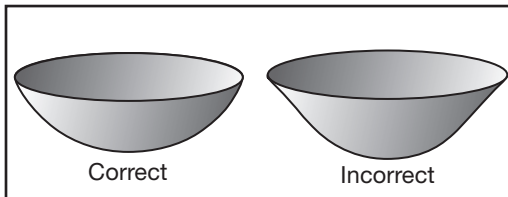
One way to do this is to perform the 'taco test' by placing the lens between your thumb and index finger and squeeze the edges together gently.

- 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 clean, lint-free towel.

It is important to remind patients to **dry their hands thoroughly** prior to removing their lenses. The surface of DAILIES TOTAL1* brand 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.
- 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* and DAILIES TOTAL1* Multifocal 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* and DAILIES TOTAL1* Multifocal contact lenses contact your Alcon sales representative or call Customer Service, in the USA at (800) 241-5999.

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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IMPORTANT: This package insert is effective as of March 2016 and applicable to the 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. In addition, a Patient Instruction Booklet is available which is recommended to be given to patients.



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

PRODUCT DESCRIPTION

DAILIES TOTAL1* and DAILIES TOTAL1* Multifocal (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, -1,000
- Oxygen Permeability (Dk): 140×10^{-11} cm²/sec/ml O₂/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 Available¹

- 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: +5.50 to -6.00D (0.25D steps); -6.50 to -12.00D (0.50D steps) +0.50 to +6.00D (0.25D steps)
- DAILIES TOTAL1* Multifocal (delefilcon A)**
- Chord Diameter: 14.1 mm
 - Center Thickness: 0.09 mm @ -3.00D (varies with power)
 - Base Curve: 8.5 mm
 - Powers: +6.00D to -10.00D (0.25D steps) ADD: 1.0, MED: 1H

NOTE: Hereafter, **DAILIES TOTAL1* spherical lenses and DAILIES TOTAL1* Multifocal contact lenses** will simply be referred to as **delefilcon A contact lenses** unless product distinction is necessary.

ACTIONS

When hydrated and placed on the cornea, **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 anisometropia (myopia and hyperopia) in phakic or aphakic persons with non-dissipated eyes with up to approximately 1.50 diopters (D) of astigmatism that does not interfere with visual acuity.

DAILIES TOTAL1* Multifocal (delefilcon A) soft contact lenses are indicated for the optical correction of refractive anisometropia (myopia and hyperopia) and/or presbyopia in phakic or aphakic persons with non-dissipated eyes who may require a reading addition of +3.00 (D) or less and who may have 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 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 hypesthesia (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. Serious 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 have shown that the risk of serious adverse reactions is increased when contact lenses are worn overnight².
- Studies³ 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 properly 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, and 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.
- Patients who wear contact lenses to correct presbyopia may not achieve the best possible corrected visual acuity for either far or near vision. Visual requirements vary with the individual and should be considered when selecting the most appropriate type of lens for each patient.
- 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 ulcers and do not heal as quickly or completely as non-diabetics.
- Visual changes of 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 has 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.
 - Do not use of blister package is damaged or not sealed completely. This may result in product contamination which can lead to a serious eye infection.
 - Ensure that the correct lens for each eye is available. Shake the blister pack gently prior to opening. Remove the lens from the blister pack by carefully pulling the lens onto the palm of your clean hand. Ensure the lens is right side out. Inspect lenses prior to insertion. Do not insert damaged lenses.
 - To insert lenses:
 - Wash and rinse hands thoroughly and dry completely with a clean, lint free towel before handling 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:
 - Wash and rinse hands thoroughly and dry completely with a clean, lint free towel before handling 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 detaches on the eye, it may be possible to recenter it by:
 - Closing the eye and massaging the lens into place, or
 - Looking in the direction of the lens and blinking gently, or
 - Gently pushing the off-centered lens onto the cornea with light finger pressure on the edge of the upper or lower eyelid.
 - 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 their eye care professional for assistance.
- Lens Wearing Precautions:**
- Patients should never overcome 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*.
- Never allow contact lenses to come into contact with non-sterile liquids (including tap water and saliva) as microbial contamination can occur, which may lead to permanent eye damage.
- 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 eyes.
- 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 carry spare lenses with you or have back-up spectacles available.
- Do not share lenses with anyone as this may spread micro-organisms which could result in serious eye health problems.
- 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 mood 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 **DALIES TOTAL¹** and **DALIES TOTAL¹ Multifocal Contact Lenses** (defleflon 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

WHAT TO DO IF A PROBLEM OCCURS

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 localized 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 **DALIES TOTAL¹** brand (defleflon A) contact lenses, please notify: Alcon Medical Safety in the USA at 1-800-757-9780.

FITTING GUIDE AND PATIENT BOOKLET

Conventional methods of fitting contact lenses apply to defleflon A contact lenses. For a detailed description of the fitting techniques, refer to the **DALIES TOTAL¹** and **DALIES TOTAL¹ Multifocal Contact Lenses** (defleflon 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 76134-2099 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 defleflon 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.

- Defleflon 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, diopter power and ADD power (multifocal lenses), manufacturing lot number and expiration date.

The following may appear on the labels or cartons:

Symbol/Signs/Abbreviations	Description
	CAUTION: Federal law (United States) restricts this device to use by or on the order of a licensed eye care professional.
	Steam sterilized
	Use by date (Expiry date)
	Batch code
	Do not reuse
	Do not use if blister package is damaged
	Example of two letter language code (English)
	Diameter
	Base curve
	Power
	Diopter (lens power)
	Addition power
	European conformity sign
	Caution
	See product instructions
	Authorized Representative European Community
	Manufacturer
	Packaging waste license sign

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Manufacturer:
Alcon Laboratories, Inc.
6201 South Freeway
Fort Worth, TX, USA 76134-2099
www.alcon.com
1-800-241-5999

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¹ Check for actual product availability as additional parameters may be introduced over time

² Schein, OD, Glynis RJ, Poggio EC, Seddon JM, Kenyon KR. The Relative Risk of Ulcerative Keratitis Among Users of Daily Wear and Extended Wear Soft Contact Lenses. *W Eng J Med.* 1989; 32(9):1107-112-783

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