PROFESSIONAL FITTING AND INFORMATION GUIDE

NaturalVue (etafilcon A) Daily Disposable Soft (Hydrophilic) Contact Lenses

CAUTION: THIS DEVICE FOR SALE BY OR ON THE ORDER OF A LICENSED PRACTITIONER

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INTRODUCTION

NaturalVue (etafilcon A) Daily Disposable Soft (Hydrophilic) Contact Lenses are made from etafilcon A with a water content of 58% by weight.

For a complete listing of lens parameters, please refer to LENS PARAMETERS section below.

This Fitting and Information Guide has been developed to provide the Eye Care Professional with information covering characteristics of the NaturalVue (etafilcon A) Daily Disposable Soft (Hydrophilic) Contact Lenses, and to illustrate fitting procedures. Please read carefully and keep this information for future use.

See Instructions for Use for Actions, Contraindications, Warnings, Precautions, Adverse Reactions and Patient Lens Care Directions.

DESCRIPTION

NaturalVue (etafilcon A) Daily Disposable Soft (Hydrophilic) Contact Lenses are made of a hydrophilic copolymer of 2-hydroxyethyl methacrylate (2-HEMA) and Methacrylic Acid (MAA). When hydrated, the lenses consist of 42% (etafilcon A) and 58% water by weight when immersed in normal buffered saline. The lens polymer contains a UV absorbing compound with a blue visibility-handling tint, which is color additive “reactive blue19” per 21 CFR part 73.3121. A benzotriazole UV absorbing monomer is used to block UV radiation. The UV Blocking averages 98% in the UVB range of 280 nm to 315 nm and 84% in the UVA range of 316 nm to 380 nm. The etafilcon A name has been adopted by the United States Adopted Names Council (USAN).

WARNING:
UV absorbing contact lenses aren’t substitutes for protective UV absorbing eyewear, for example UV absorbing goggles or sunglasses, because they don’t completely cover the eye and surrounding area. Patients should continue to use UV absorbing eyewear as directed.

LENS PARAMETERS

NaturalVue (etafilcon A) Daily Disposable Soft (Hydrophilic) Contact Lenses are available in a sphere, toric, multifocal and multifocal toric designs, which cover the cornea and a portion of the adjacent sclera with the following dimensions:

Sphere
* Diameter: 12.0mm to 15.0mm
* Center Thickness: 0.08 @ -3.00D (varies with power)
* Base Curve: 7.80mm to 10.00mm
* Powers: +20.00D to -20.00D

Toric
* Diameter: 12.0mm to 15.0mm
* Center Thickness: 0.08 @ -3.00D (varies with power)
* Base Curve: 7.80mm to 10.00mm
* Powers: +20.00D to -20.00D
* Cylinder: -0.25D to -10.00D
* Axis: 0˚ to 180˚ in 5˚ increments

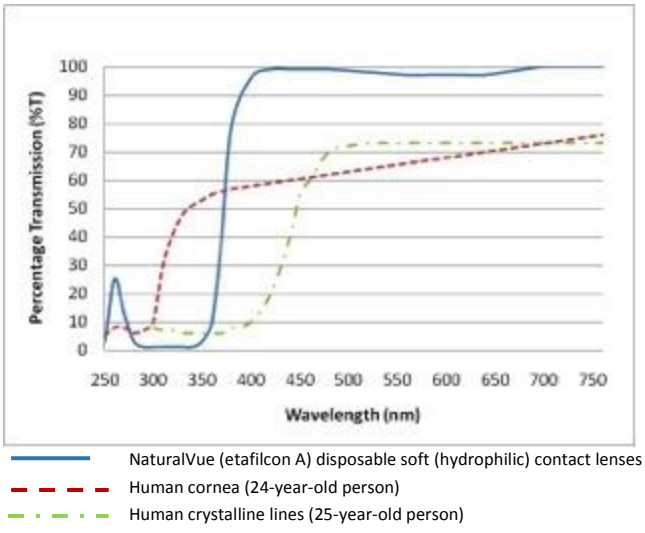
Multifocal
* Diameter: 12.0mm to 15.0mm
* Center Thickness: 0.08 @ -3.00D (varies with power)
* Base Curve: 7.80mm to 10.00mm
* Powers: +20.00D to -20.00D
* ADD Powers: Extended depth of focus (center distance) design provides a single universal add power effective up to +3.00D

Multifocal Toric
* Diameter: 12.0mm to 15.0mm
* Center Thickness: 0.08 @ -3.00D (varies with power)
* Base Curve: 7.80mm to 10.00mm
* Powers: +20.00D to -20.00D
* Cylinder: -0.25D to -10.00D
* Axis: 0˚ to 180˚ in 5˚ increments
* ADD Powers: Extended depth of focus (center distance) design provides a single universal add power effective up to +3.00D

The physical/optical properties of the lens are:
Refractive index: 1.402
Light Transmittance: 95% minimum
Water Content: 58%
Oxygen Permeability (Dk): $19.73*10^{-11}$ $(cm^2/s)\{ml O_2 ml/ (ml \times mmHg)\}$.

TRANSMITTANCE CURVES

Typical Transmittance Profile of –3.00D NaturalVue (etafilcon A) Daily Disposable Soft (Hydrophilic) Contact Lenses with UV blocker versus a human cornea from a 24 year-old person and a human crystalline lens from a 25 year-old person.



Notes:
1. Lerman, S., Radiant Energy and the Eye, MacMillan, New York, 1980, p. 58, Figure 2-21.
2. Waxler, M., Hitchins, V.M., Optical Radiation and Visual Health, CRC Press, Boca Raton, Florida, 1986, p. 19, Figure 5.

WARNING:
UV absorbing contact lenses aren't substitutes for protective UV absorbing eyewear, for example UV absorbing goggles or sunglasses, because they don't completely cover the eye and surrounding area. You should continue to use UV absorbing eyewear as directed.

ACTIONS

In the hydrated state, the NaturalVue (etafilcon A) Contact Lenses, when placed on the cornea, acts as a refracting medium to focus light rays on the retina.
The visibility tinting of the NaturalVue (etafilcon A) Daily Disposable Soft (Hydrophilic) Contact Lenses allows the lens to become visible to the wearer when the lens is not on the eye. The NaturalVue (etafilcon A) Contact Lenses blocks 84% of UVA radiation and 98% UVB radiation average across the spectrum. (Please refer to accompanying transmittance curve graph)

Note: **Long term exposure to UV radiation is a part of the risk factors associated with cataracts.** Exposure is according to a number of factors, for instance environmental conditions (altitude, geography, cloud cover) and personal factors (extent and nature of outdoor activities). UV-absorbing contact lenses help provide protection against harmful UV radiation. However, clinical studies have not been done to demonstrate that wearing UV-absorbing contact lenses reduces the risk of developing cataracts or other eye disorders. Consult your Eye Care Professional for more information.

INDICATIONS

Sphere

NaturalVue (etafilcon A) Sphere Daily Disposable Soft (Hydrophilic) Contact Lenses are indicated for daily wear for the correction of ametropia (myopia and hyperopia) in aphakic and/or non-aphakic persons with non-diseased eyes in powers from +20.00 to -20.00 diopters. The lenses may be worn by persons who exhibit astigmatism of 2.00 diopters or less that does not interfere with visual acuity.

Toric

NaturalVue (etafilcon A) Toric Daily Disposable Soft (Hydrophilic) Contact Lenses are indicated for daily wear for the correction of ametropia (myopia and hyperopia with astigmatism) in aphakic and/or non-aphakic persons with non-diseased eyes in powers from -20.00 to +20.00 diopters and astigmatic corrections from -0.25 to -10.00 diopters

Multifocal

NaturalVue (etafilcon A) Multifocal Daily Disposable Soft (Hydrophilic) Contact Lenses are indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia), and/or presbyopia, and myopia progression control in aphakic and/or non-aphakic persons with non-diseased eyes in powers from -20.00 to +20.00 diopters and with non-diseased eyes who may require a reading addition of up to +3.00D. The lenses may be worn by persons who exhibit astigmatism of 2.00 diopters or less that does not interfere with visual acuity.

Multifocal Toric

NaturalVue (etafilcon A) Multifocal Toric Daily Disposable Soft (Hydrophilic) Contact Lenses are indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia), and/or presbyopia, and myopia progression control in aphakic and/or non-aphakic persons with non-diseased eyes in powers from -20.00 to +20.00 diopters and with non-diseased eyes who may require a reading addition of up to +3.00D. The lenses may be worn by persons who exhibit astigmatism of 10.00 diopters or less.

NaturalVue (etafilcon A) Daily Disposable Soft (Hydrophilic) Contact Lenses help protect against transmission of harmful UV radiation to the cornea and into the eye.

The lenses are intended for single-use disposable wear. Lenses should be discarded after removal from the eye.

CONTRAINDICATIONS, WARNINGS, PRECAUTIONS AND ADVERSE REACTIONS

Refer to Instruction for Use for CONTRAINDICATIONS, WARNINGS, PRECAUTIONS and ADVERSE REACTIONS.

GENERAL FITTING GUIDELINES

Please see the appropriate sections of this booklet that contain guidelines for Sphere, Toric, Multifocal, and Multifocal Toric fitting techniques.

SELECTION OF PATIENTS

• NaturalVue (etafilcon A) Daily Disposable Soft (Hydrophilic) Contact Lenses are indicated for daily wear for vision correction of refractive ametropia (myopia and hyperopia), and/or astiagmatism, and/or presbyopia, and/or myopia progression control in aphakic and/or non-aphakic persons with non-diseased eyes.
• The lens is intended for single-use disposable wear.
• Persons who require vision correction and who would not or could not adhere to a recommended wear and care regimen for NaturalVue (etafilcon A) Daily Disposable Soft (Hydrophilic) Contact Lenses or are unable to place and remove the lenses should not be provided with them. Failure to follow handling and wearing instructions could lead to serious eye infections that might result in corneal ulcers.
• Patient communication is vital because it relates not only to patient selection, but also to ensuring patient compliance. It is also necessary to discuss the information contained in the Patient Information Booklet with the patient at the time of the initial examination.
• Patients selected to wear NaturalVue (etafilcon A) Daily Disposable Soft (Hydrophilic) Contact Lenses should be chosen for their motivation to wear contact lenses, general health and cooperation. The Eye Care Professional must take care in selecting, examining and instructing contact lens patients. Patient hygiene and willingness to follow practitioner instructions are essential to their success.
• A detailed history is crucial to determining patient needs and expectations. Your patient should be questioned regarding vocation, desired lens-wearing time (full or part-time), and desired lens usage (reading, recreation or hobbies).
• Initial evaluation of the trial lens should be preceded by a complete eye examination, including visual acuity with and without correction at both distance and near, keratometry and slit lamp examination.
• It is normal for the patient to experience mild symptoms such as lens awareness, variable vision, occasional tearing (watery eyes) and slight redness during the adaptation period. Although the adaptation period varies for each individual, generally within one week these symptoms will disappear. If these symptoms persist, the patient should be instructed to contact their Eye Care Professional.

FITTING PROCEDURE

• Perform a preliminary evaluation to determine distance refraction as well as to rule out contraindications to contact lens wear as described in the Instructions for Use.
• Lens power is determined from the patient's spherical equivalent prescription corrected to the corneal plane (i.e., corrected for the vertex distance used for the refraction)
•Make the initial base curve selection if more than one is available. In clinical tests, the NaturalVue (etafilcon A) SPHERE Daily Disposable Soft (Hydrophilic) Contact Lenses in the 8.5mm/14.2mm parameters have performed successfully on eyes with a range of keratometry readings. However, corneal curvature measurements should be performed to establish the patient's baseline ocular status. Trial lenses should be placed on each of the patient's eyes and evaluated after the patient has adjusted to the lenses.
• Place the lens on the eye. Allow the lens to remain on the eye long enough to achieve a state of equilibrium. Small variations in the tonicity, pH or the lens solutions and individual tear composition may cause slight changes in fitting characteristics.
• If the initial lens selection covers the patient's cornea fully, provides discernible movement (0.10mm to 0.30mm after blink) or is mobile using the push-up test, is comfortable for the patient and provides satisfactory visual performance, it is a well-fitted lens and can be dispensed. (See Criteria for a Well-Fitted Lens under CLINICAL ASSESSMENT).
• Full coverage of the cornea is defined as the lens edge extending beyond the limbal area in all directions. Initial lens evaluation should be done after at least 10 minutes of lens wear to allow the lens to stabilize and any tearing to subside.
• Following a blink, the lens should move vertically on the patient's eye about 0.10mm to 0.30 mm. Using a slit lamp, this movement can be estimated by comparing it with the one-millimeter lens peripheral bevel width.
• The Push-up Test is also a reliable indicator of a well-fit lens. With the patient looking straight ahead, use your index finger on the patient's lower lid to 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.
• When lenses are dispensed for vision correction, the wearer must be supplied with an appropriate wearing regimen and must fully understand all lens handling and emergency lens care instructions to prevent lens damage as described in the Instructions for Use.

CLINICAL ASSESSMENT

- Criteria for a Well-Fitted Lens
  - sufficient lens movement to allow tear exchange under the lens during a blink in either primary or upward gaze
  - good centration in primary gaze and full corneal coverage in all fields of gaze
  - satisfactory results on the push-up test
  - good comfort and a stable visual response (with over-refraction if needed)

- Characteristics of a Tight Lens

A tight lens fit should not be dispensed. A tight lens fit would display some or all of the following characteristics:

- insufficient or no lens movement during a blink in either primary or upgaze
- unsatisfactory results on the push-up test showing a lens that resists movement, remains decentered or returns slowly to its original position
- good comfort

- fluctuating vision between blinks

• Characteristics of a Loose Lens

A loose lens fit should not be dispensed. A loose lens fit would display some or all of the following characteristics:

- Excessive movement in either primary or upgaze
- poor centration in primary and upgaze
- unsatisfactory results on the push-up test showing a lens that moves very easily, remains decentered or returns very quickly to its original position or even drops down lower than its original position
- reduced comfort
- vision may be blurred after the blink

FITTING GUIDELINES – Toric

FITTING PROCEDURE

• Perform a preliminary evaluation to determine distance refraction as well as to rule out contraindications to contact lens wear as described in the Instructions for Use.

• Lens power is determined from the patient's sphero-cylindrical prescription corrected to the corneal plane (i.e., corrected for the vertex distance used for the refraction)

• Make the initial base curve selection if more than one is available. In clinical tests, the NaturalVue (etafilcon A) Toric Daily Disposable Soft (Hydrophilic) Contact Lenses in the 8.3mm/14.5mm parameters have performed successfully on eyes with a range of keratometry readings. However, corneal curvature measurements should be performed to establish the patient's baseline ocular status. Trial lenses should be placed on each of the patient's eyes and evaluated after the patient has adjusted to the lenses.

• Place the lens on the eye. Allow the lens to remain on the eye long enough to achieve a state of equilibrium. Small variations in the tonicity, pH or the lens solutions and individual tear composition may cause slight changes in fitting characteristics.

• If the initial lens selection covers the patient's cornea fully, provides discernible movement (0.10mm to 0.30mm after blink) or is mobile using the push-up test, is comfortable for the patient and provides satisfactory visual performance, it is a well fitted lens and can be dispensed. (See Criteria for a Well-Fitted Lens under CLINICAL ASSESSMENT).

• Full coverage of the cornea is defined as the lens edge extending beyond the limbal area in all directions. Initial lens evaluation should be done after at least 10 minutes of lens wear to allow the lens to stabilize and any tearing to subside.

• Following a blink, the lens should move vertically on the patient's eye about 0.10mm to 0.30 mm. Using a slit lamp, this movement can be estimated by comparing it with the one-millimeter lens peripheral bevel width.

• The Push-up Test is also a reliable indicator of a well-fit lens. With the patient looking straight ahead, use your index finger on the patient's lower lid to 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.

• When lenses are dispensed for vision correction, the wearer must be supplied with an appropriate wearing regimen and must fully understand all lens handling and emergency lens care instructions to prevent lens damage as described in the Instructions for Use.

CLINICAL ASSESSMENT

- Criteria for a Well-Fitted Lens
  - sufficient lens movement to allow tear exchange under the lens during a blink in either primary or upward gaze
  - good centration in primary gaze and full corneal coverage in all fields of gaze
  - satisfactory results on the push-up test
  - good comfort and a stable visual response (with over-refraction if needed)

- Characteristics of a Tight Lens

A tight lens fit should not be dispensed. A tight lens fit would display some or all of the following characteristics:

  - insufficient or no lens movement during a blink in either primary or upgaze
  - unsatisfactory results on the push-up test showing a lens that resists movement, remains decentered or returns slowly to its original position
  - good comfort
  - fluctuating vision between blinks

- Characteristics of a Loose Lens

A loose lens fit should not be dispensed. A loose lens fit would display some or all of the following characteristics:

  - Excessive movement in either primary or upgaze
  - poor centration in primary and upgaze
  - unsatisfactory results on the push-up test showing a lens that moves very easily, remains decentered or returns very quickly to its original position or even drops down lower than its original position
  - reduced comfort
  - vision may be blurred after the blink

Determination of the Final Lens Power

When the diagnostic lens has its axis aligned in the same meridian as the patient's refractive axis, a sphero-cylindrical over-refraction may be performed and visual acuity determined. However, in the case of crossed axes, such as when the diagnostic lens axis is different from the spectacle cylinder axis, it is not advisable to over-refract because of the difficulty in computing the resultant power.

In fitting toric contact lenses, one should generally prescribe the full power in the sphere.
In the cylinder, however, any lens rotation may impact the patient's vision, so generally start with the lower of two cylinder powers if the exact cylinder power is not available. To determine the final lens power:

For the Sphere:

If sphere alone or combined sphere and cylinder Rx >±4.00D, compensate each meridian separately for vertex distance. If sphere alone or combined sphere and cylinder Rx ≤±4.00D, vertex compensation is not necessary.

For the Cylinder:

Adjust the axis by the rotational angle of the diagnostic trial lens using the LARS (Left Add Right Subtract) method. If possible, select a cylinder that is within 0.50D from the refractive cylinder remembering to compensate the spherical power as needed.

Case Examples

EXAMPLE 1:

Manifest (spectacle refraction):
O.D. -3.50 -1.25 X 170 20/20
O.S. -3.00 -1.00 X 170 20/20
Choose a diagnostic trial lens for each eye with an axis as close to 170° as possible. Place the lens on each eye and allow a minimum of 10 minutes for it to equilibrate, based on the patient's initial response to the lens.
Check the orientation of the axis mark. If the bottom axis mark is in the 6 o'clock position on both eyes, choose the appropriate cylinder as listed previously. The Final Lens Power to dispense and order would be:
O.D. -3.50 -1.25 x 170
O.S. -3.00 -0.75 x 170

EXAMPLE 2:
Manifest (spectacle refraction):
O.D. -2.00 -1.00 X 100 20/20
O.S. -3.75 -2.00 X 100 20/20
Choose a diagnostic lens of -2.00 -0.75 x 100 for the right eye and -3.75 -1.75 x 100 for the left eye, the nearest lenses available to the spherical power and axis needed. Place the lens on each eye and allow a minimum of 10 minutes for it for it to equilibrate, based on the patient's initial response to the lens.
Check the orientation of the axis mark. If the bottom axis mark is in the 6 o'clock position on both eyes, choose the appropriate cylinder as listed previously. The Final Lens Power to dispense and order would be:
O.D. -2.00 -0.75 x 100
O.S. -3.75 -1.75 x 100.

FITTING GUIDELINES – Multifocal

FITTING PROCEDURE

• NaturalVue (etafilcon A) Multifocal Daily Disposable Soft (Hydrophilic) Contact Lenses uses a unique extended depth of focus design, which allows a single universal 'ADD' power to provide optimal intermediate and near vision for a large range of reading additions, while maintaining clear distance vision. NaturalVue (etafilcon A) Multifocal Contact Lenses are easy to fit, as the starting lens powers are the same as the patient's distance spherical contact lens powers (i.e. vertex corrected spherical equivalent lens powers).

• Perform a preliminary evaluation to determine distance and near refraction as well as to rule out contraindications to contact lens wear as described in the Instructions for Use.

- Ideal Candidates:
  - refractive cylinder ≤ 1.00D
  - 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 (since spectacles would also generally contain a cylindrical correction) 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 > 1.00D (any axis) 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 (< -1.50D) and has not been habitually corrected
  - Highly satisfied, adapted monovision or highly satisfied, adapted current multifocal contact lens wearers
  - Any other contraindications to successful contact lens wear such as tear abnormality or lid margin disease

Initial Lens Selection

- Start with a current refraction performed at the time of the initial lens fitting:
- Determine ocular dominance using your preferred method. The dominance determination will help with any small power adjustments that may be needed.
- The initial diagnostic trial lens power is determined from the patient's spherical equivalent DISTANCE prescription corrected to the corneal plane (i.e., corrected for the vertex distance used for the refraction). It is important to get the distance vision clear with this lens design, and refracting to the 20/15 line is recommended.
- Make the initial base curve selection if more than one is available. In clinical tests, NaturalVue (etafilcon A) Multifocal Contact Lenses in the 8.3mm/14.5mm parameters have performed successfully on eyes with a range of keratometry readings. However, corneal curvature measurements should be performed to establish the patient's baseline ocular status. Trial lenses should be placed on each of the patient's eyes and evaluated after the patient has adjusted to the lenses.
- Place the lens on the eye. Allow the lens to remain on the eye long enough to achieve a state of equilibrium. Small variations in the tonicity, pH or the lens solutions and individual tear composition may cause slight changes in fitting characteristics.
- If the initial lens selection covers the patient's cornea fully, provides discernible movement (0.10mm to 0.30mm after blink) or is mobile using the push-up test, is comfortable for the patient and provides satisfactory visual performance, it is a well fitted lens and can be dispensed. (See Criteria for a Well-Fitted Lens under CLINICAL ASSESSMENT).
- Full coverage of the cornea is defined as the lens edge extending beyond the limbal area in all directions. Initial lens evaluation should be done after at least 10 minutes of lens wear to allow the lens to stabilize and any tearing to subside.
- Following a blink, the lens should move vertically on the patient's eye about 0.10mm to 0.30 mm. Using a slit lamp, this movement can be estimated by comparing it with the one-millimeter lens peripheral bevel width.
- The Push-up Test is also a reliable indicator of a well-fit lens. With the patient looking straight ahead, use your index finger on the patient's lower lid to 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.

CLINICAL ASSESSMENT

- Criteria for a Well-Fitted Lens
  - sufficient lens movement to allow tear exchange under the lens during a blink in either primary or upward gaze
  - good centration in primary gaze and full corneal coverage in all fields of gaze
  - satisfactory results on the push-up test
  - good comfort and a stable visual response (with over-refraction if needed)

- Characteristics of a Tight Lens

A tight lens fit should not be dispensed. A tight lens fit would display some or all of the following characteristics:

  - insufficient or no lens movement during a blink in either primary or upgaze
  - unsatisfactory results on the push-up test showing a lens that resists movement, remains decentered or returns slowly to its original position
  - good comfort
  - fluctuating vision between blinks

- Characteristics of a Loose Lens

A loose lens fit should not be dispensed. A loose lens fit would display some or all of the following characteristics:

  - Excessive movement in either primary or upgaze
  - poor centration in primary and upgaze
  - unsatisfactory results on the push-up test showing a lens that moves very easily, remains decentered or returns very quickly to its original position or even drops down lower than its original position
  - reduced comfort
  - vision may be blurred after the blink

Evaluation of the Lenses

- At the end of the settling period, ask the patient to assess vision at distance, intermediate and near under binocular conditions.

*__Best Success Tip:__ Use real world assessments (e.g., looking out a window, checking cell phone, reading a magazine, reading a watch, etc.).

- Record monocular and binocular distance and near visual acuities.
- Assess lens fit and movement.

*__Best Success Tip:__ The lens is designed to provide a well-centered, minimal movement fit. A gentle nudge of the lens with the push-up test should show the lens to move upon push-up even if it is not moving with a blink.

Over-Refraction and Lens Changes

Conduct an over-refraction by plusing one eye with a loose +1.00D trial lens while over-refracting the other eye (with the handheld trial lenses or flippers) to a final end point. Repeat with the other eye, then remove +1.00D and recheck vision with final over-refraction in normal room lighting.

***Best Success Tip:** The most important power selection needed to get a successful fit with this design, is the power to obtain clear distance vision. Even if the patient does not show an over refraction at distance (i.e., the patient does not respond positively that an over refraction improves their vision), if their distance vision is not clear, change the on eye diagnostic lens power by adding -0.25 to the dominant eye to clear up distance vision. If the patient is still having distance vision not as clear as desired, then add another -0.25 D to the on eye diagnostic lens power in the dominant eye, then add -0.25D to the on eye diagnostic lens power in the non-dominant eye only if needed. Once distance vision is clear, the intermediate and near vision will improve as well.

- If a lens change is required based on over-refraction or based on patient assessment that distance vision is not clear, change the on eye diagnostic lens(s) repeat the vision assessment after a 10-minute settling period. If vision is acceptable for both distance and near, check lens fit, and proceed with dispensing.
- Vision generally improves over the first 1-2 days with the NaturalVue (etafilcon A) Multifocal lens. A follow-up visit at 2-5 days is recommended to check that the patient is able to perform most daily visual tasks.

Improving Vision

It is important to remember two things with this multifocal contact lens design:

1. The initial diagnostic trial lens power is determined from the patient's spherical equivalent DISTANCE prescription corrected to the corneal plane (i.e., corrected for the vertex distance used for the refraction).

2. The most important power to get a successful fit with this lens design is the power needed to obtain clear distance vision. It is important to get the distance vision clear with this lens design before fine-tuning the intermediate or near vision. It is highly recommended that the NaturalVue Multifocal calculator be used to most efficiently determine the starting lens powers (www.naturalvuecalculator.com)

- If this optimal lens power does not provide acceptable vision at either distance or near, and no over-refraction is found to provide improvement in distance vision, follow these guidelines:
- **Distance Vision and Distance Symptom Complaints:** Add -0.25D to the on eye diagnostic lens power, starting with the **DOMINANT** eye and then adding another -0.25D to the on eye diagnostic lens power on the DOMINANT eye if needed, then -0.25D to the on eye diagnostic lens power to the NON-DOMINANT eye only if needed. If the patient demonstrates an over refraction or lens power change of greater than -0.50D, recheck the original distance refraction. NOTE: Post-LASIK patients with a flat central cornea, may require more extra minus power than what is described here due to the physical fit of the lens over the flat central cornea.
    - If the patient reports some difficulty with distance vision, but over refraction does not appear to improve vision, change the on eye diagnostic lens power by -0.25D in the **Dominant** eye and recheck both distance and near vision.

- **Near Vision and Near Symptom Complaints:** Add +0.25D to the on eye diagnostic lens power, starting with the **NON-DOMINANT** eye, and then adding another +0.25D to the on eye diagnostic lens power to the NON-DOMINANT eye, and then +0.25D to the on eye diagnostic lens power to the DOMINANT eye only if needed, to further improve near vision.
    - If the patient reports some difficulty with near vision, but over refraction does not appear to improve vision, dispense a lens with +0.25D to the on eye diagnostic lens power in the **Non-Dominant** eye and recheck both distance and near vision.

FITTING GUIDELINES – Multifocal Toric

NaturalVue (etafilcon A) Multifocal Toric Daily Disposable Soft (Hydrophilic) Contact Lenses use a unique extended depth of focus design, which allows a single universal ADD power to provide optimal intermediate and near vision for a large range of reading additions while maintaining clear distance vision. The NaturalVue (etafilcon A) Multifocal Toric Contact Lenses are easy to fit, as the starting lens powers are the same as the patient's distance toric contact lens powers.

To fit the NaturalVue (etafilcon A) Multifocal Toric Contact Lenses, follow the guidelines for fitting the NaturalVue (etafilcon A) Toric Contact Lenses to determine the initial distance contact lens powers needed.

Once clear distance vision is obtained, follow the guidelines for fitting the NaturalVue (etafilcon A) Multifocal Contact Lenses for fine-tuning the intermediate and/or near power.

RECOMMENDED WEARING SCHEDULE

The prescribing Eye Care Professional for each individual patient, based upon a full examination and patient history as well as the practitioner's experience and professional judgment should determine the wearing schedule. Patients should be given a wearing schedule and carefully instructed on the handling and care of their lenses as discussed in the Instructions for Use. Also be sure to complete the personal wearing/replacement schedule record in the patient information booklet. Eye Care Professionals may prescribe the lens for single-use daily disposable wear. The lens is intended for single-use, daily disposable wear. (See the factors discussed in the WARNINGS section.)

Follow up examinations are necessary to ensure continued successful contact lens wear and to ascertain the effects of the lenses on the eyes. The following schedule is a suggested guideline for daily wear contact lenses:

- 24 hours post-dispensing
- 7 days
- 1 month
- 3 months
- every 6 months thereafter

HANDLING OF LENSES

- Always wash, rinse and dry hands before handling contact lenses.
- All traces of soap, perfumes, hair sprays, creams and lotions should be removed from your hands and around the eyes.
- Keep your nails trimmed and clean – long fingernails can tear or split contact lenses.
- Avoid picking up lenses with your fingernails – they can only be held safely between the fingertips or with soft plastic tipped tweezers specially designed for contact lenses.
- Do not touch your lenses with sharp, pointed objects (fingernails, pens, etc).
- Make sure lenses do not get caught on the edge of storage cases. Tapping the lens case on the table before screwing the top on will help completely submerse the contact lenses in solution.
- Never allow lenses to dry out and never try to insert them when they are in a dehydrated state.
- Do not use the lens if the pack is open or damaged.
- Never use expired lenses or solutions.
- **Verify that the lens is right side out.** The lens should assume a natural, curved, bowl-like shape. If the lens edges tend to point outward, the lens is inside out. Another method is to gently squeeze the lens between the thumb and forefinger. The edges should turn inward. If the lens is inside out, the edges will turn slightly outward.

LENS PLACEMENT

To avoid confusion, make it a habit of inserting the same lens first. Check the lens is clean and moist – if not, rinse with contact lens care saline or multipurpose solution. DO NOT ever rinse a contact lens with tap water or saliva.

Check the lens is not inside out. And then follow these steps to apply the lens to your eye:

- Balance the lens on the tip of your forefinger.
- Pull the lower lid down with the middle finger of the same hand.
- Hold the upper lid firmly from above with the middle finger of the other hand. Make sure the finger is placed just where the eyelid meets the eyelashes.
- The eye is now wide open and the cornea exposed.
- Place the lens directly on the eye. Move your eyes around to help center the lens.
- Release the lower and then the upper lid. Look down and gently close the eyes. Rub the top lid lightly to rub out any trapped air bubbles.
- If the lens is not properly centered on the cornea, gently manipulate by using fingertips and eyelids.

LENS REMOVAL

- Rewet the contact lenses with a few drops of solution to help the lens slide off the eye, especially if they are a little dry.
- Place index finger on the lens.
- Look up.
- Slide lens to white part of the eye using index finger.
- Gently squeeze the lens between thumb and forefinger to remove the lens.

PATIENT LENS CARE DIRECTIONS

Daily disposable (single use) lenses are discarded upon removal from the eye **each day**.

• Patients should be instructed to have a spare pair of lenses with them at all times.

Clinical studies have shown that there is an increased risk of adverse effects for soft contact lenses that are reused versus those that are discarded after each use.

LUBRICATING/REWETTING LENSES ON-EYE

The Eye Care Professional may recommend a lubricating/rewetting solution that can be used to wet (lubricate) lenses while they are being worn to make them more comfortable.

CARE FOR A NON-MOVING LENS

Refer to Instructions for Use for Care for A Sticking (Nonmoving) Lens.

REPORTING OF ADVERSE REACTIONS

If any serious adverse events or a patient experiences associated with the wear of NaturalVue (etafilcon A) Daily Soft (Hydrophilic) Contact Lenses, please notify: Visioneering Technologies, Inc. 10745 Westside Way Rd, Suite 200, Alpharetta, GA 30009. Tel: 00-1-844-VTI-LENS (00-1-844-884-5367), www.vtivision.com

HOW SUPPLIED

Each lens is supplied sterile in a blister pack containing buffered saline solution, and is sterilized with steam (moist heat). The blister is labeled with the base curve, diameter, diopter power, manufacturing lot number, and expiration date of the lens. (ADD, cylinder and axis will be included as appropriate.)

Lenses are supplied in cartons containing 10, 30 or 90 lenses.

INSTRUCTIONS FOR USE (Package Insert)

naturalVue® (etafilcon A)

NaturalVue (etafilcon A) Daily Disposable Soft (Hydrophilic) Contact Lenses

CAUTION

This product for sale by or on the order of a licensed practitioner.

IMPORTANT

This Instructions for Use 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 and recommended wearing schedule.

DESCRIPTION

The NaturalVue (etafilcon A) Daily Disposable Soft (Hydrophilic) Contact Lenses are available in a spheric, toric, multifocal and multifocal toric designs.

NaturalVue (etafilcon A) Daily Disposable Soft (Hydrophilic) Contact Lenses are made of a hydrophilic copolymer of 2-hydroxyethyl methacrylate (2-HEMA) and Methacrylic Acid (MAA). When hydrated, the lenses consist of 42% (etafilcon A) and 58% water by weight when immersed in normal buffered saline. The lens polymer contains a UV absorbing compound with a blue visibility-handling tint, which is color additive "reactive Blue19" per 21 CFR part 73.3121. A benzotriazole UV absorbing monomer is used to block UV radiation. The UV Blocking averages 98% in the UVB range of 280 nm to 315 nm and 84% in the UVA range of 316 nm to 380 nm. The etafilcon A name has been adopted by the United States Adopted Names Council (USAN).

LENS PROPERTIES

Refractive index: 1.402
Light Transmittance: 95 % minimum.
Water Content: 58%
Oxygen Permeability (Dk):

$19.73*10^{-11}$ $(cm^2/s)\{ml O_2 ml/ (ml \times mmHg)\}$.

LENS PARAMETERS

NaturalVue Sphere Contact Lenses parameters:
* Diameter: 12.0mm to 15.0mm
* Center Thickness: 0.08 @ -3.00D (varies with power)
* Base Curve: 7.80mm to 10.00mm
* Powers: +20.00D to -20.00D

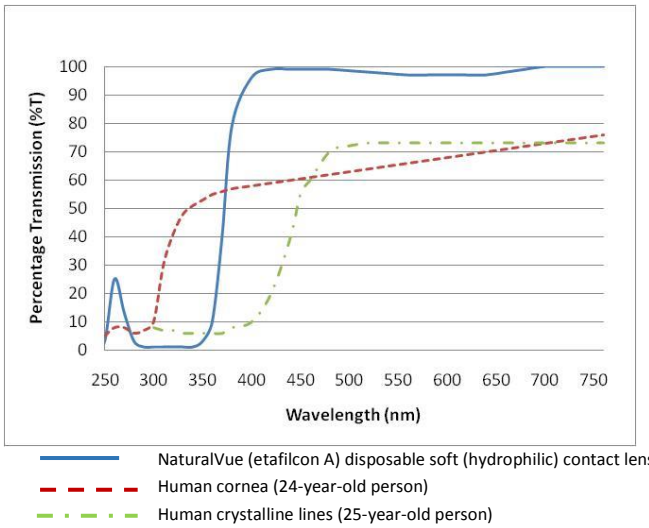
NaturalVue Toric Contact Lenses parameters:
* Diameter: 12.0mm to 15.0mm
* Center Thickness: 0.08 @ -3.00D (varies with power)
* Base Curve: 7.80mm to 10.00mm
* Powers: +20.00D to -20.00D
* Cylinder: -0.25D to -10.00D
* Axis: 0° to 180° in 5° increments

NaturalVue Multifocal Contact Lenses parameters:
* Diameter: 12.0mm to 15.0mm
* Center Thickness: 0.08 @ -3.00D (varies with power)
* Base Curve: 7.80mm to 10.00mm
* Powers: +20.00D to -20.00D
* ADD Powers: Extended depth of focus (center distance) design provides a single universal add power effective up to +3.00D

NaturalVue Multifocal Toric Contact Lenses parameters:
* Diameter: 12.0mm to 15.0mm
* Center Thickness: 0.08 @ -3.00D (varies with power)
* Base Curve: 7.80mm to 10.00mm
* Powers: +20.00D to -20.00D
* Cylinder: -0.25D to -10.00D
* Axis: 0° to 180° in 5° increments
* ADD Powers: Extended depth of focus (center distance) design provides a single universal add power effective up to +3.00D

TRANSMITTANCE CURVE

Typical Transmittance Profile of –3.00D NaturalVue (etafilcon A) Daily Disposable Soft (Hydrophilic) Contact Lenses with UV blocker versus a human cornea from a 24 year-old person and a human crystalline lens from a 25 year-old person.



Notes:
1. Lerman, S., Radiant Energy and the Eye, MacMillan, New York, 1980, p. 58, Figure 2-21.
2. Waxler, M., Hitchins, V.M., Optical Radiation and Visual Health, CRC Press, Boca Raton, Florida, 1986, p. 19, Figure 5.

WARNING:

UV absorbing contact lenses aren't substitutes for protective UV absorbing eyewear, for example UV absorbing goggles or sunglasses, because they don't completely cover the eye and surrounding area. You should continue to use UV absorbing eyewear as directed.

ACTIONS

In the hydrated state, the NaturalVue (etafilcon A) Contact Lenses, when placed on the cornea, act as a refracting medium to focus light rays on the retina.
The visibility tinting of the NaturalVue (etafilcon A) Contact Lenses allow the lens to become visible to the wearer when the lens is not on the eye. The NaturalVue (etafilcon A) Contact Lenses block 84% of UVA radiation and 98% UVB radiation average across the spectrum. (Please refer to accompanying transmittance curve graph)

Note: **Long term exposure to UV radiation is a part of the risk factors associated with cataracts.** Exposure is according to a number of factors, for instance environmental conditions (altitude, geography, cloud cover) and personal factors (extent and nature of outdoor activities). UV-absorbing contact lenses help provide protection against harmful UV radiation. However, clinical studies have not been done to demonstrate that wearing UV-absorbing contact lenses reduces the risk of developing cataracts or other eye disorders. Consult your Eye Care Professional for more information.

INDICATIONS

Sphere
NaturalVue (etafilcon A) Sphere Daily Disposable Soft (Hydrophilic) Contact Lenses are indicated for daily wear for the correction of ametropia (myopia and hyperopia) in aphakic and/or non-aphakic persons with non-diseased eyes in powers from +20.00 to -20.00 diopters. The lenses may be worn by persons who exhibit astigmatism of 2.00 diopters or less that does not interfere with visual acuity.

Toric
NaturalVue (etafilcon A) Toric Daily Disposable Soft (Hydrophilic) Contact Lenses are indicated for daily wear for the correction of ametropia (myopia and hyperopia with astigmatism) in aphakic and/or non-aphakic persons with non-diseased eyes in powers from -20.00 to +20.00 diopters and astigmatic corrections from -0.25 to -10.00 diopters

Multifocal
NaturalVue (etafilcon A) Multifocal Daily Disposable Soft (Hydrophilic) Contact Lenses are indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia), and/or presbyopia, and myopia progression control, in aphakic and/or non-aphakic persons with non-diseased eyes in powers from -20.00 to +20.00 diopters and with non-diseased eyes who may require a reading addition of up to +3.00D. The lenses may be worn by persons who exhibit astigmatism of 2.00 diopters or less that does not interfere with visual acuity.

Multifocal Toric
NaturalVue (etafilcon A) Multifocal Toric Daily Disposable Soft (Hydrophilic) Contact Lenses are indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia), and/or presbyopia, and myopia progression control, in aphakic and/or non-aphakic persons with non-diseased eyes in powers from -20.00 to +20.00 diopters and with non-diseased eyes who may require a reading addition of up to +3.00D. The lenses may be worn by persons who exhibit astigmatism of 10.00 diopters or less.

NaturalVue (etafilcon A) Daily Disposable Soft (Hydrophilic) Contact Lenses help protect against transmission of harmful UV radiation to the cornea and into the eye.

The lenses are intended for single-use disposable wear. Lenses should be discarded after removal from the eye.

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE the NaturalVue Lens when any of the following conditions exist:
• Acute and subacute inflammation or infection of the anterior chamber of the eye.
• Any eye disease, injury, or abnormality that affects the cornea, conjunctiva, or eyelids.
• Severe insufficiency of lacrimal secretion (dry eyes).
• Corneal hypoesthesia (reduced corneal sensitivity).
• Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses.
• Allergic reactions of ocular surfaces or adnexa (surrounding tissue) that may be induced or exaggerated by wearing contact lenses or use of contact lens solutions.
• Any active corneal infection (bacterial, fungal, or viral).
• If eyes become red or irritated.
• Use of any medication that is contraindicated or interferes with contact lens wear, including ocular medications.
• Allergy to any ingredient in the contact lens material.
• History of recurrent eye or eyelid infections, adverse effects associated with contact lens wear, intolerance or an unusual response to contact lens wear.
• The patient is unable or unwilling to follow the Eye Care Professionals' directions for removal and disposal of the lenses or unable to obtain assistance to do so.

WARNINGS

Advise patient of the following warnings pertaining to contact lens wear:
• Problems with contact lenses 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.
• Eye problems, including a sore or lesion on the cornea (corneal ulcers), can develop rapidly and lead to loss of vision.
• Studies have shown that contact lens wearers who are smokers have a higher risk incidence of adverse reactions than nonsmokers, especially when lenses are worn overnight or while sleeping.
• If a patient experiences eye discomfort, such as foreign body sensation, excessive tearing, vision changes, or redness of the eye or other problems, the patient should immediately remove lenses and promptly contact his or her Eye Care Professional.
• 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 lenses are worn overnight.
• Non-compliance with the manufacturer's labeled lens care instruction may put the patient at significant risk of developing a serious eye infection.
• Tap water, distilled water, homemade saline solutions or saliva should NOT be used at any time with contact lenses. The use of tap and distilled water has been associated with Acanthamoeba keratitis, a corneal infection that is resistant to treatment and cure.

PRECAUTIONS

Special Precautions for Eye Care Professional:
• Due to the small number of patients enrolled in clinical investigation of lenses, all refractive powers, design configurations, or lens parameters available in the lens material are not evaluated in significant numbers. Consequently, when selecting an appropriate lens design and parameters, the Eye Care Professional should consider all characteristics of the lens that can affect lens performance and ocular health, including oxygen permeability, wettability, central, and peripheral thickness, and optic zone diameter.
The potential impact of these factors on the patient's ocular health should be carefully weighed against the patient's need for refractive correction; therefore, the continuing ocular health of the patient and lens performance on eye should be carefully monitored by the prescribing Eye Care Professional.
• Fluorescein, a yellow dye, should not be used while the patient is wearing the lenses, because the lenses will absorb this dye and become discolored. Whenever fluorescein is used in eye, flush the eyes with sterile saline solution. Wait at least 10 minutes before reinserting the lenses. If it is not possible to flush the eyes, wait at least 1 hour before wearing the lenses. If inserted too soon, the lenses may absorb remaining fluorescein.
• Before leaving the Eye Care Professional's office, the patient should be able to promptly remove lenses or should have somebody else available who can remove the lenses for him or her.
• Eye Care Professionals should instruct the patient to remove the lenses immediately if the eyes become red or irritated.

Eye Care Professionals should carefully instruct patients about the following safety precautions, including the need for routine eye examinations being necessary to help assure the continued health of the patient's eyes:
• If the lens sticks (stops moving) on the eye, follow the recommended directions in Care for a Sticking Lens. The lens should move freely on the eye for the continued health of the eye. If non-movement of the lens continues, you should immediately consult your Eye Care Professional.
• Always wash, rinse and thoroughly dry hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, deodorants, aerosol products or hair sprays in the eyes or on the lenses. It is best to put on lenses before putting on make-up. Water-base cosmetics are less likely to damage lenses than oil-base products.
• Do not touch contact lenses with the fingers or hands if the hands are not free of foreign materials, as microscopic scratches of the lenses may occur, causing distorted vision or injury to the eye.
• Exposure to water 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.
• Ask the Eye Care Professional about wearing contact lenses during sporting activities.
• Never wear lenses beyond the period recommended by the Eye Care Professional.
• If aerosol products such as hair spray are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.
• Always handle lenses gently and avoid dropping them.
• Avoid all harmful or irritating vapors and fumes while wearing lenses.
• Aphakic patients should not be fitted with lenses until the determination is made that the eye has healed completely from surgery.
• Never use tweezers or other tools to remove lenses from the lens blister pack unless specifically indicated for that use. Pour the lens into the hand.
• Do not touch the lens with fingernails.
• Always discard lenses after the recommended wearing schedule prescribed by the Eye Care Professional. Since these lenses are daily disposable (single use), the lenses must be discarded after removal from the eye.
• Always contact the Eye Care Professional before using any medicine in the eyes.
• Always inform the employer of being a contact lens wearer. Some jobs may require use of eye protection

equipment or may require that the patient not wear contact lenses.
• As with any contact lens, follow-up visits are necessary to ensure the continuing health of the patient's eyes. The patient should be instructed as to a recommended follow-up schedule.
• Patients should never exceed the prescribed wearing schedule regardless of how comfortable the lenses feel. Doing so increases the risk of adverse effects.
• Do not use lenses past the expiration date.
•Certain medications may cause dryness of the eye, increased lens awareness, lens intolerance, 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.
•Patients who are pregnant or oral contraceptive users could develop visual change or change in lens tolerance when using lenses.
• Do not use if the sterile blister package is opened or damaged.
• Diabetics may have reduced corneal sensitivity and may be more prone to corneal injury and do not heal as quickly or completely as non-diabetics.
• Patients should be instructed to never allow anyone to wear their lenses. They have been prescribed to fit their eyes and to correct their vision to the degree necessary. Sharing lenses greatly increase the chance of eye infections.

ADVERSE REACTIONS (Problems and What To Do)

The patient should be informed that the following problems may occur when wearing contact lenses:
• Your eye stinging, burning, itching (irritation), or other eye pain.
• Comfort is less compared to when lens was first placed on eye.
• There may be a feeling of something in the eye (foreign body, scratched area).
• Excessive watering (tearing) of the eyes.
• Unusual eye secretions.
• Redness of the eyes.
• Reduced sharpness of vision (poor visual acuity).
• Blurred vision, rainbows, or halos around objects.
• Sensitivity to light (photophobia).
• Feeling of dryness.
• Foreign body sensation.

If the patient notices any of the above, he or she should be instructed to:
• Immediately remove lenses.
• If the discomfort or problem stops, then look closely at the lens. If the lens is in any way damaged, do not put the lens back on the eye. If the lens has dirt, an eyelash, or other foreign body on it, or the problem stops and the lens appears undamaged; the patient should thoroughly clean and rinse the lens, then reinsert it. After reinsertion, if the problem continues, the patient should immediately remove the lens and consult the Eye Care Professional.
• If the above symptoms continue after removal of the lens, or upon insertion of a new lens, the patient should immediately remove the lens and contact his or her Eye Care Professional, who must determine the need for examination, treatment or referral without delay. (See Important Treatment Information for Adverse Reactions.) A serious condition such as infection, corneal ulcer, corneal vascularization, or iritis may be present, and may progress rapidly. Less serious reactions such as abrasions, epithelial staining or bacterial conjunctivitis must be managed and treated carefully to avoid more serious eye damage. Additionally, contact lens wear may be associated with ocular changes which 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.
• Patients should be reminded to keep a spare pair of lenses with them at all times.

Important Treatment Information for Adverse Reactions

Sight-threatening ocular complications associated with contact lens wear can develop rapidly, and therefore early recognition and treatment of problems are critical. Infectious corneal ulceration is one of the most serious potential complications, and may be ambiguous in its early stage. Signs and symptoms of infectious corneal ulceration include discomfort, pain, inflammation, purulent discharge, sensitivity to light, cells and flare and corneal infiltrates.
Initial symptoms of a minor abrasion and an early infected ulcer are sometimes similar. Accordingly, such epithelial defect, if not treated properly, may develop into an infected ulcer. In order to prevent serious progression of these conditions, a patient presenting symptoms of abrasions or early ulcers should be evaluated as a potential medical emergency, treated accordingly, and be referred to a corneal specialist when appropriate. Standard therapy for corneal abrasions such as eye patching or the use of steroids or steroid/antibiotic combinations may exacerbate the condition. If the patient is wearing a contact lens on the affected eye when examined, the lens should be removed immediately.

FITTING

• The lens must move adequately on the eye for a suitable fit. If the fit is judged to be too tight, the patient must be refit into a lens which provides the criteria of a well-fitted lens.
•Fitting techniques for other contact lenses may not be applicable to the fitting of these lenses.

• Copies of Professional Fitting and Information Guide for NaturalVue (etafilcon A) Contact Lenses are available without charge at www.vtivision.com or calling Visioneering Technologies, Inc. at:
Tel: 00-1-844-VTI-LENS x102
(00-1-844-884-5367 x102).

WEARING SCHEDULE

It is recommended that contact lens wearers see their Eye Care Professional twice each year or if directed, more frequently.
Daily Wear (Less than 24 hours, while awake):
There may be a tendency for the **NEW** daily wear patient to over-wear the lenses initially. Initial daily wearing schedule should be stressed to these patients.
The wearing schedule should be determined by the Eye Care Professional. The maximum suggested wearing time is:

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

NaturalVue Lenses are only indicated for daily wear (less than 24 hours, while awake). **NaturalVue Lenses should NOT be worn for 24 hours or greater**, including while asleep, as studies have not been completed to show that the lenses are safe to wear during sleep.

REPORTING OF ADVERSE REACTION

If any serious adverse event or patient experience associated with the wear of NaturalVue (etafilcon A) Daily Soft (Hydrophilic) Contact Lenses occurs, please notify:
Visioneering Technologies, Inc.
10745 Westside Way, Suite 200
Alpharetta, GA 30009 USA
Tel: 00-1-844-VTI-LENS x102
(00-1-844-884-5367 x102).

LENS CARE DIRECTIONS

• **Daily disposable (single use)** lenses are discarded upon removal from the eye **each day**.
• Patients should be instructed to have a spare pair of lenses with them at all times.
Clinical studies have shown that there is an increased risk of adverse effects for soft contact lenses that are reused versus those that are discarded after each use.

Care for a Sticking (Nonmoving) Lens:
If the lens sticks (cannot be moved), you should use a lubricating or rewetting solution in your eye. You should apply 3 to 4 drops of the recommended lubricating or rewetting solution directly to the eye and wait until the lens begins to move freely on the eye before removing it. If non-movement of the lens continues after 15 minutes, you should IMMEDIATELY consult your Eye Care Professional.

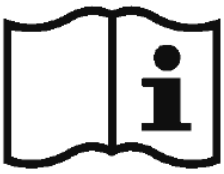
Storage:
• Unopened lenses are sterile and should not be used if the container is broken or the seal has been damaged.

Emergencies:
The patient should be informed that if chemicals of any kind (household products, gardening solutions, laboratory chemicals, etc.) are splashed into the eyes, the patient should:
FLUSH EYES IMMEDIATELY WITH TAP WATER AND THEN REMOVE LENSES PROMPTLY. CONTACT THE EYE CARE PROFESSIONAL OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.

HOW SUPPLIED

Each lens is supplied sterile in a blister pack containing buffered saline solution, and is sterilized with steam (moist heat). The blister is labeled with the base curve, diameter, diopter power, manufacturing lot number, and expiration date of the lens. (ADD, cylinder and axis will be included as appropriate.)
Lenses are supplied in cartons of 10, 30 or 90 lenses.

	Manufactured by: Visioneering Technologies, Inc. 10745 Westside Way, Ste 200 Alpharetta, GA 30009 USA Tel: 00-1-844-VTI-LENS x102 (00-1-844-884-5367 x102) www.vtivision.com
Australian Sponsor	Emergo Australia Level 20, Tower II Darling Park 21 Sussex Street Sydney, NSW, 2000 Australia
	Emergo Europe Prinssessegracht 20 2514 The Hague The Netherlands
	CE Mark for Notified Body# 0123

SYMBOL	DESCRIPTION
	Consult instructions for use
	Batch code
	Authorized Representative in the European Community
	CE Mark, indicates product is authorized for sale in the European Community
	Sterilized Using Steam or Dry Heat
	Use by Date Expressed as: CCYY-MM or CCYY-MM-DD CCYY-MM
	Product to be sold by or on the order of a licensed practitioner.

SYMBOL	DESCRIPTION
	UV-Blocking (Indicates the lens is UV blocking)
B.C.	Base Curve (product property)
D	Diopter (Lens Power, product property)
DIA.	Diameter (product property)
	Do not re-use
	Manufacturer
	Do not use if package is damaged
CYL	Cylinder Power
Axis	Axis
ADD	ADD

Revision Date: February 2018