

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):
 $19.73 \times 10^{-11} \text{ (cm}^2/\text{s) } \{ \text{mlO}_2/\text{ml} / (\text{ml} \times \text{mmHg}) \}$.

LENS PARAMETERS

NaturalVue Sphere Contact Lenses parameters:

- * Diameter: 12.0mm to 15.0mm
- * Centre 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
- * Centre 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:

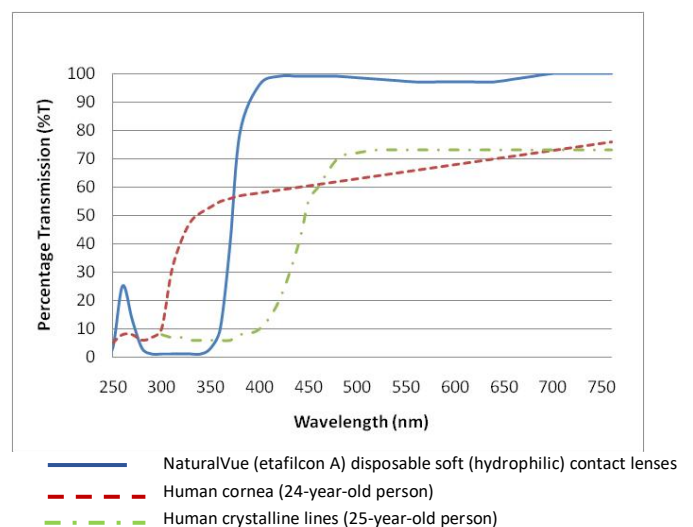
- * Diameter: 12.0mm to 15.0mm
- * Centre Thickness: 0.08 @ -3.00D (varies with power)
- * Base Curve: 7.80mm to 10.00mm
- * Powers: +20.00D to -20.00D
- * ADD Powers: Extended depth of focus (centre distance) design provides a single universal add power effective up to +3.00D

NaturalVue Multifocal Toric Contact Lenses parameters:

- * Diameter: 12.0mm to 15.0mm
- * Centre 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 (centre 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 dioptres. The lenses may be worn by persons who exhibit astigmatism of 2.00 dioptres 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 dioptres and astigmatic corrections from -0.25 to -10.00 dioptres

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 dioptres 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 dioptres 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 dioptres 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 dioptres 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 labelling 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 non-smokers, 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 labelled 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 discoloured. 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 vapours 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 expiry 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, tranquilisers and motion sickness medication. 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 increases 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. Important Treatment Information for Adverse Reactions (See Important Treatment Information for Adverse Reactions.) A serious condition such as infection, corneal ulcer, corneal vascularisation, 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 generalised corneal edema, epithelial microcysts, epithelial staining, infiltrates, neovascularisation, 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 refitted with a lens which fulfils 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 free of charge at www.vtvision.com or by calling Visioneering Technologies, Inc. on:
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 more frequently if directed to do so.

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 wearing 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 (Non-moving) 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 sterilised with steam (moist heat). The blister is labelled with the base curve, diameter, dioptré 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 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 Prinsessegracht 20 2514 The Hague The Netherlands
	CE Mark for Notified Body# 0123

SYMBOL	DESCRIPTION
	Consult instructions for use
	Batch code
	Authorised Representative in the European Community
	CE Mark, indicates product is authorised for sale in the European Community
	Sterilised Using Steam or Dry Heat
	Use by Date Expressed as: CCYY-MM or CCYY-MM-DD CCYY-MM

SYMBOL	DESCRIPTION
	Product to be sold by or on the order of a licensed practitioner.
	UV-Blocking (Indicates the lens is UV blocking)
B.C.	Base Curve (product property)
D	Dioptre (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

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