IMPORTANT: Please read carefully and keep this information for future use. This fitting guide is intended for the eyecare practitioner, but should be made available to the patient upon request.

EYEDIA® SOFT58 (ETAFILCON A) DAILY WEAR SOFT CONTACT LENS (VISIBILITY TINT WITH UV BLOCKER)

Symbols key

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

Symbol	Description
℞ Only	**CAUTION**: Federal Law (USA) restricts this device to sale by or on the order of a **Licensed Eye Care Practitioner**.
STERILE	Sterilized using steam or dry heat
⚠**SINGLE PATIENT USE**	Caution: This is a single patient use device; See Package Insert or Instructions For Use
EXP	Use by date (Expiry date)
BC	Base Curve

Symbol	Description
	Single sterile barrier system
LOT	Batch code (Lot number)
DIA	Diameter
D	Diopter (Lens Power)
UV BLOCKING	Lens contains UV blocking properties.

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

TABLE OF CONTENT

DESCRIPTION OF LENS:

The **eyedia® soft58 (Etafilcon A) Soft (hydrophilic) Contact Lens** is available as a single vision spherical lens. The hydrophilic nature of the material allows the lens to become soft and pliable when immersed in an aqueous solution.

MATERIAL CHARACTERISTICS:

The frequent replacement lens is manufactured from Etafilcon A, a 2-Hydroxyethyl Methacrylate (HEMA) polymer material that is frequent used in contact lens manufacturing. The contact lens contains 58% water by weight when immersed in packaging saline solution. Reactive blue #19, an US FDA approved pigment for contact lenses, is used to provide the handling tint which is incorporated into the contact lens polymer in order to help the patient to handle and relocate the lens if dropped.

The 42% Etafilcon A, 58% Water Content (spherical) – frequent replacement lens acts as a corrective refracting medium (except for plano lenses) to focus light rays onto the retina when placed on the human eye covering the cornea and also aberration control. The lens is intended for frequent replacement use. However, the qualified Eye Care Practitioner is encouraged to determine an appropriate lens replacement schedule based upon the response of the patient.

The hydrophilic characteristics allow aqueous solutions to enter the lens and in its fully hydrated state the lens is approximately 58% water by weight. The physical properties of the lens are:

Refractive Index	1.4050 (wet)
Light Transmission	greater than 95%
Water Content	58 %
Specific Gravity	1.017 (hydrated)
Oxygen Permeability	21.83 $\times 10^{-11}$ (cm^2/sec) (mlO_2/ml × mmHg@ 35°C), (revised Fatt method).

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

Chord Diameter	13.80-14.20mm (Minus power)
	14.30-14.70mm (Plus power)
Center Thickness	0.096mm ± 0.020 mm @ -3.00D
Base Curve	8.30mm (Minus Steep)
	8.70mm (Minus Flat, Plus Flat)
Powers	-10.00 Diopters to +06.00 Diopters
	0.00^ to -6.00 D in 0.25 D increment
	-6.50 to -10.00 D in 0.50 D increment
	+0.25 to +4.00 D in 0.25 D increment
	+4.50 to +6.00 D in 0.50 D increment

Note: ^Plano lens (0.00D – without corrective power) is not being sold in EU. Plano lens is used for the manufacture of cosmetically tinted lenses (colored lenses). Standard Minus Power SKU starts at -0.25D.

ACTIONS:

The 42% Etafilcon A, 58% Water Content (spherical) – frequent replacement lens acts as a corrective refracting medium (except for plano lenses) to focus light rays onto the retina when placed on the human eye covering the cornea and also aberration control. The lens is intended for frequent replacement use. However, the qualified Eye Care Practitioner is encouraged to determine an appropriate lens replacement schedule based upon the response of the patient.

INDICATIONS (USES):

The lenses (except for plano lenses) are intended for the optical correction of refractive ametropia (myopia and hyperopia) in phakic and aphakic person with non-diseased eye who may have 0.75D or less of astigmatism. The lens may be cleaned and disinfected using a chemical lens care system.

Eye Care Practitioners may prescribe the lenses for frequent/ planned replacement wear, within 1 to 30 days, with cleaning, disinfection and scheduled replacement. When prescribed for frequent/ planned replacement wear, the lens may be cleaned, rinsed and disinfected each time it is removed from patient's eye, with an approved chemical lens care system. The **eyedia® soft58 (Etafilcon A) Soft (hydrophilic) Contact Lens** are to be discarded after the recommended wearing period, from 1 to 30 days, as prescribed by the Eye Care Professional.

The target population for the use of this device are adults of 18 years or older. There is no clinical data to support the use of this device by individuals under 18 years of age. Use of this device by individuals less than 18 years of age is at the sole discretion of the eye care professionals (ECP).

CONTRAINDICATIONS (REASONS NOT TO USE):

DO NOT USE the **eyedia® soft58 (Etafilcon A) Soft (hydrophilic) Contact Lens** when any of the following conditions exist:

- Use of eye medication.
- Any eye disease, injury, redness, inflammation, infection or abnormality that affects the cornea, conjunctiva, eyelids or anywhere in or around the eyes.
- Severe insufficiency of lacrimal secretion or inadequate tear fluid (dry eyes).
- Corneal hypoesthesia (reduced corneal sensitivity
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lens. If the patient is diagnosed or has reason to believe that such systemic disease exists, please consult and inform the eye care practitioner for proper evaluation and advice on contact lens wear. These are the common systemic diseases that may affect the eye: Diabetes mellitus; AIDS; Graves' disease; Rheumatoid arthritis, Lupus and other autoimmune conditions; Hypertension and Atherosclerosis; Multiple sclerosis; and Shingles.
- Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lens or use of contact lens solutions.

- Allergy to any ingredient, such as mercury or thimerosal, in a solution which is to be used to care for the **eyedia® soft58 (Etafilcon A) Soft (hydrophilic) Contact Lens** .
- Any active corneal infection (bacteria, fungi, or viral)
- If eyes become red or irritated.
- If patient is unable to follow lens care regimen or unable to obtain assistance to do so due to a sickness.
- Patient history of recurring eye or eyelid infections, adverse effects associated with contact lens wear, intolerance or abnormal ocular response to contact lens wear.
- Poor health affecting the eye such as cold and flu.
- Previous medical intervention which may adversely affect the use of the lens.

CAUTION:

Due to small number of patients enrolled in clinical investigation of lens, 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 Practitioner should consider all characteristics of the lens that can affect lens performance and ocular health, including oxygen permeability, wettability, central and peripheral thickness, and optic zone diameter.

The potential impact of these factors on the patient's ocular health must be carefully weighed against the patient's need for refractive correction. Therefore, the continuing ocular health of the patient and lens performance on the eye should be carefully monitored by the prescribing Eye Care Practitioner.

Read this Professional Fitting Guide carefully. It contains the information you need to know to wear, handle, and care for your **eyedia® soft58 (Etafilcon A) Soft (hydrophilic) Contact Lens** . If you are in doubt about any instructions, please request clarification from your Eye Care Practitioner.

WARNINGS:

Please refer to Warnings in the Package Insert.

PRECAUTIONS:

Please reference Precautions in the Package Insert.

ADVERSE REACTIONS:

Please reference Adverse Reactions in the Package Insert.

PATIENT SELECTION:

Patients selected to wear these lenses should be chosen based on:

- Motivation to wear lenses

- General ocular health
- Ability to follow instructions regarding lens handling and wearing
- Ability to adhere to a recommended care regimen
- Ability to understand the benefits and risk of lens wear

Patients who do not meet the above criteria should not be provided with **eyedia® soft58 (Etafilcon A) Soft (hydrophilic) Contact Lens** . Patient communication is vital. All necessary precautions and warnings should be discussed and understood by the patient *(review Package Insert with the patient.)*

Failure to follow handling and wearing instructions could lead to serious eye infections, which might result in corneal ulcers.

FITTING PROCEDURE FOR THE EYEDIA® SOFT58

1. Pre-fitting Examination

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

2. Parameter Selection

   The preferred fitting method is by use of a trial lens, selecting the steeper base curve as first choice and then evaluate the CRITERIA OF A WELL FITTED LENS**.**

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

Average K Reading	Suggested Lens Design
41.25 and lower	8.9 mm base curve / 14.5 mm Diameter
41.50 to 45.50	8.6 mm base curve / 14.5 mm Diameter
41.75 and higher	8.3 mm base curve / 14.5 mm Diameter (NA for plus lens)

   Lens power can be calculated from spectacle Rx

   Sphere Lenses:

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

   Example:
   Rx at 12mm vertex distance -5.00 -1.00 x180

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

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

CLINICAL ASSESSMENT

1. Criteria of a Well-Fitted Lens
   The criteria of a well fitted lens is one which centers easily after a blink, bridges the limbus and extends onto the sclera about 1.5mm, lags downward about 1 to 2 mm on upward gaze and does not move excessively as a result of blinking or exaggerated eye movements.

   After the trial lens has settled on the eye (5-10 minutes), manipulate the lens using lid pressure and observe for indications of excessive tightness. The lens should move freely and easily with slightest pressure and return to the centered position when released.

   Movement of the lens on the eye is very important in assessing the fit and performance of the lens. In primary gaze, slight vertical post-blinking lens movement should occur. On upward gaze, the lens should sag approximately 1-2mm.

2. Characteristics of a Tight (Steep) Lens

   A tight (steep) lens does not move easily on the cornea with slight pressure.

3. Characteristics of a Loose (Flat) Lens
   A loose (flat) lens sags more than 2.0 mm on upward gaze.

4. . Final Lens Power
   After the characteristics of a well-fitted lens have been satisfied, the spherical over-refraction should be combined with the trial lens power to determine the final lens prescription.
   Example:
   Trial Lens: -5.00D
   Over-refraction: -0.25D
   Final Lens Power: -5.25D
   If vision is acceptable, perform a slit lamp examination to assess adequate fit (centration and movement). If fit is acceptable dispense the lenses instructing the patient to return in one week for assessment.

FOLLOW-UP CARE:

1. Follow-up examinations are recommended by the Eye Care Practitioner, they are necessary to ensure continued successful contact lens wear.

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

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

FOLLOW - UP EXAMINATIONS:

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

NOTE: or at the discretion of the Eye Care Practitioner

At the follow up examinations, the patient should report good subjective quality of vision. Adaptation to the vision with **eyedia® soft58 (Etafilcon A) Soft (hydrophilic) Contact Lens** should occur almost immediately and should definitely be reported within the first (1 week) follow-up visit. At these follow-up visits the practitioner should:

1. Check distance and near acuity with lens in place
2. Over-refract to verify lens prescription
3. Observe the position of lens on the cornea. The lens should be centered and move on upward gaze and with blink.
4. Evert the lids to examine the tarsal conjunctiva and check for incidence of giant papillary conjunctivitis.
5. Remove the lens. Check corneal curvature. There should be no substantial changes in either meridian.
6. Perform a slit-lamp examination with and without Fluorescein. Check for corneal edema, corneal abrasion, vascularization, corneal infiltrates and perilimbal injection. Reinsert the lens only after all residual Fluorescein has dissipated from the eye.
   Clean the lens with a prophylactic surfactant cleaner and examine for deposits, foreign bodies or physical imperfections of the lens surface.

LENS HANDLING (IN-OFFICE CLEANING, DISINFECTING AND STORAGE)

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

Each **eyedia® soft58 (Etafilcon A) Soft (hydrophilic) Contact Lens** is received in the Eye Care Practitioner's office in a sterile blister pack with sterile buffered normal saline solution and labeled to the parameters of the lens contained. To assure sterility, the blister pack should not be opened until ready for use. To open the blister pack, pull back the lid where indicated. Upon removing the cover, the lens may be removed and is ready for use. **eyedia® soft58 (Etafilcon A) Soft (hydrophilic) Contact Lens are not to be reused in diagnostic procedures.** For the full details of lens handling, refer to the Package Insert.

After opening the blister pack, if the lens sticks to the under-surface of the foil and has become partially dried-out, fully immersed the lens in the buffered saline solution that is inside the blister pack and wait for minimum 15 minutes before lens fitting.

1. Cleaning:
   A surfactant cleaner may be used with the **eyedia® soft58 (Etafilcon A) Soft (hydrophilic) Contact Lens** to ensure a clean lens surface. A single procedure is as follows:

   Apply 3 to 4 drops to the lens and then rub the surface of the lens against the palm of one hand with the index finger of the other hand or between thumb and forefinger for 20 seconds.

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

3. Chemical Lens Care Systems:
   A sterile rinsing, storing, and disinfecting multipurpose solution should be used to rinse and chemically disinfect the **eyedia® soft58 (Etafilcon A) Soft (hydrophilic) Contact Lens**. After cleaning the lenses, rinse with liberal amounts of fresh multipurpose solution to remove loosened debris and traces of cleaner. The lens should then be placed in the lens case supplied in the multipurpose solution kit and filled with enough fresh disinfecting solution to completely submerge the lens. To ensure disinfection, the lens must remain in the disinfecting solution for the recommended period of time as written on the multipurpose solution bottle instruction-for-use. Follow the instruction and timings recommended by the lens care solution manufacturer. Before reinsertion, the lens should be rinsed with fresh sterile rinsing solution.

4. Lens Care Directions:
   Please refer to LENS CARE DIRECTIONS in the Package Insert.

5. Storage:
   The **eyedia® soft58 (Etafilcon A) Soft (hydrophilic) Contact Lens** must be stored in the recommended solutions. If exposed to air, the lens will dehydrate. If a lens dehydrates, it should be discarded and replaced with a fresh-sterile lens.

RECOMMENDED WEARING SCHEDULE:

Close professional supervision is recommended to ensure safe and successful contact lens wear. If the patient complains of discomfort, decreased vision, ocular injection or corneal edema, the lens should be removed, and the patient scheduled for examination. The problem may be relieved by putting the patient on a different wearing schedule or possibly by refitting the lens.

Patients tend to over wear the lens initially. It is important that you do not wear the lenses beyond the maximum wearing time. Regular checkups, as determined by the Eye Care Practitioner, are also extremely important.

The maximum suggested wearing schedule for the **eyedia® soft58 (Etafilcon A) Soft (hydrophilic) Contact Lens** is suggested below.

Day	1	2	3	4	5	6
Hours	6	8	10	12	14	Up to 14 hours

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

It is recommended that the **eyedia® soft58 (Etafilcon A) Soft (hydrophilic) Contact Lens** be discarded and replaced with a new lens every after 30 days. When removed between replacement periods lenses must be cleaned and disinfected prior to reinsertion or be discarded and replaced with a fresh lens.

STUDIES HAVE NOT BEEN COMPLETED TO SHOW THAT THE **eyedia® soft55 (Methafilcon A) Soft (hydrophilic) Contact Lens** IS SAFE TO WEAR DURING SLEEP.

RECOMMENDED LENS CARE PRODUCTS

The Eye Care Practitioner should recommend a care system that is appropriate for the **eyedia® soft58 (Etafilcon A) Soft (hydrophilic) Contact Lens** . Each lens care product contains specific instructions for use and important safety information, which should be read and carefully followed.

STORAGE CONDITIONS:

Store lenses at ambient temperature.

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 patients should:

FLUSH EYES IMMEDIATELY WITH TAP WATER AND THEN REMOVE LENSES PROMPTLY. CONTACT THE EYECARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.

HOW SUPPLIED:

Each lens is supplied sterile in blister packs containing buffered saline solution. The blister pack is labeled with the base curve, diopter power, diameter, lot number, and expiration date of the lens. The blister pack is also marked as 'NOT FOR INDIVIDUAL RESALE.

DISPOSAL:

There is no special disposal required for soft contact lens and its blister. The carton packaging, aluminum lidding and polypropylene (PP) plastic case should be placed properly in the waste bin or recycled according to local waste guidance or local regulations.

REPORTING OF ADVERSE REACTIONS:

All serious adverse experiences and adverse reactions observed in patients wearing **eyedia® soft58 (Etafilcon A) Soft (hydrophilic) Contact Lens** or experienced with the lens should be reported to the manufacturer and the competent authority of the member state.

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