

Package Insert for Focus® NIGHT & DAY™ (Iotrafilcon A) Soft Contact Lenses



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

Important:

This package insert is effective as of [insert Month, year] and applicable to the Focus® NIGHT & DAY™ (Iotrafilcon A) contact lens described below. Please read carefully and keep this information for future use.

This package insert is intended for the eye care professional, but should be made available to patients upon request. The eye care professional should provide the patient with appropriate instructions that pertain to the patient's prescribed lenses. Copies of this package insert are available without charge from CIBA Vision Corporation by calling CIBA Vision Customer Service at 1-800-241-5999 or download from our website at www.cibavision.com. CIBA Vision makes available a *Patient Instruction Booklet*, which is recommended to be given to patients.

PRODUCT DESCRIPTION

Focus® NIGHT & DAY™ (Iotrafilcon A) soft contact lenses are made from a lens material that is approximately 24% water and 76% Iotrafilcon A, a fluoro-silicone containing hydrogel which is surface treated.

• **Lens Properties**

- Specific Gravity: 1.08
- Refractive Index (hydrated): 1.43
- Light Transmittance: ≥ 99%
- Oxygen Permeability (Dk): 140×10^{-11} (cm²/sec)(ml O₂/ml x mm Hg), measured at 35° C (intrinsic Dk - Coulometric method)
- Water Content: 24% by weight in normal saline

• **Lens Parameters**

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

• **Lens Parameters Available**

FOCUS® NIGHT & DAY™ (spherical)

- Chord Diameter Available: 13.8 mm
- Center Thickness: 0.080 mm @ -3.00D (varies with power)
- Base Curve Available: 8.4mm, 8.6 mm
- Powers Available: [-0.25D to -8.00D (0.25D steps); -8.50D to -10.00D (0.50D steps); +0.25D to +6.00D (0.25D steps)]

Focus® NIGHT & DAY™ TORIC

- Chord Diameter Available: 14.2 mm
- Center Thickness: 0.080 mm @ -3.00D (varies with power)
- Base Curve Available: 8.8 mm
- Powers Available: -0.25D to -8.00D (0.25D steps); -8.50D to -10.00D (0.50D steps); +0.25D to +6.00D (0.25D steps)
-1.00, -1.75, -2.50 cylinder, Full circle (10° steps)

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Focus® NIGHT & DAY™ PROGRESSIVES

- Chord Diameter Available: 13.8 mm
- Center Thickness: 0.080 mm @ -3.00D (varies with power)
- Base Curve Available: 8.6 mm, 8.9 mm
- Powers Available: -0.25D to -9.00D (0.25D steps)
+0.25D to +8.00D (0.25D steps)
Single progressive add. Effective range up to 3.00D

NOTE: Hereafter, Focus® NIGHT & DAY™, Focus® NIGHT & DAY™ TORIC, and Focus® NIGHT & DAY™ PROGRESSIVES will be referred to as Focus NIGHT & DAY unless product distinction is necessary.

ACTIONS

When hydrated and placed on the cornea, Focus® NIGHT & DAY™ (Iotrafilcon A) contact lenses act as a refracting medium to focus light rays on the retina.

INDICATIONS (USES)

- Focus® NIGHT & DAY™ (Iotrafilcon A) soft contact lenses are indicated for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes with up to approximately 1.50 diopters of astigmatism.
- Focus® NIGHT & DAY™ TORIC (Iotrafilcon A) soft contact lenses are indicated for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes with 6.00 diopters (D) or less of astigmatism.
- Focus® NIGHT & DAY™ PROGRESSIVES (Iotrafilcon A) soft contact lenses are indicated for the optical correction of refractive ametropia (myopia and hyperopia) and/or presbyopia in phakic or aphakic persons with non-diseased eyes who may require a reading addition of +3.00 diopters (D) or less and who may have up to approximately 1.50 diopters of astigmatism.
- The lenses may be prescribed for daily wear or extended wear for up to 30 nights of continuous wear, with removal for disposal, or cleaning and disinfection prior to reinsertion, as recommended by the eye care professional.

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

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT use Focus® NIGHT & DAY™ (Iotrafilcon A) contact lenses when any of the following exists:

- Inflammation or infection of the anterior chamber of the eye
- Active disease, injury or abnormality affecting the cornea, conjunctiva, or eyelids
- Microbial infection of the eye
- Insufficiency of lacrimal secretion (dry eye) that interferes with contact lens wear
- Corneal hypoesthesia (reduced corneal sensitivity)
- Use of any medication that is contraindicated or interferes with contact lens wear, including eye medications
- Any systemic disease which may be exacerbated by or interferes with contact lens wear

- Allergic reactions of ocular surfaces or adnexa that may be caused by or exaggerated by wearing contact lenses
- Allergy to any ingredient in a solution which must be used to care for the contact lenses
- Patient history of recurring eye or eyelid infections, adverse effects associated with contact lens wear, intolerance or abnormal ocular response to contact lens wear
- If eyes become red or irritated

WARNINGS

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

- **Serious eye injury, scarring of the cornea, and loss of vision may result from problems associated with wearing contact lenses and using contact lens care products.** To reduce these risks, emphasize to the patient the need for strict compliance with the lens care regimen including hand washing, proper lens disinfection, cleaning of the lens case, wearing restrictions, wearing schedules, and follow-up visit schedules.
- **Eye problems, including corneal ulcers, can develop rapidly and lead to loss of vision.** Instruct patients at the dispensing visit and subsequent visits to **immediately** remove their lenses and **promptly** contact their eye care practitioner if they should experience eye discomfort, foreign body sensation, excessive tearing, vision changes, redness of the eye or other problems with their eyes.
- **Non-compliance with the manufacturer's labeled lens care instructions may put the patient at significant risk of developing a serious eye infection.**
- **Tap water, distilled water, or homemade saline solution should NOT be used as a substitute for any component in the lens care process.** The use of tap and distilled water has been associated with Acanthamoeba keratitis, a corneal infection that is resistant to treatment and cure.
- **Smoking increases the risk of corneal ulcers for contact lens users,^{1,2} especially when lenses are worn overnight or while sleeping.**
- **The risk of microbial keratitis has been shown to be greater among users of extended wear contact lenses than among users of daily wear contact lenses.² The long term risk of microbial keratitis has not been determined for this lens. Post-marketing studies are in progress.**

PRECAUTIONS

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

Special Precautions to the Eye Care Professional:

- When selecting an appropriate lens and wear schedule for a patient, the eye care professional should consider all lens characteristics that can affect lens performance and ocular health, including oxygen permeability, wettability, central and peripheral thickness, and optic zone diameter. All refractive powers, design configurations, or lens parameters were not evaluated in clinical trials. At the extremes of the power range (above +10.00 or -15.00) oxygen transmissibility is slightly below the established threshold level required to prevent overnight corneal edema³. The prescribing eye care professional should carefully assess the potential impact of these factors and carefully monitor the continuing ocular health of the patient and lens performance on the eye.

¹ CLAO Journal, January 1996; Volume 22, Number 1, pp. 30-37

² New England Journal of Medicine, September 21, 1989; 321 (12), pp. 773-783

³ Investigative Ophthalmology and Visual Science, October 1984; Vol 25, pp.1161-1167

- The following patients may not be suitable extended wear contact lens candidates, and/or may experience a higher rate of adverse effects associated with contact lens wear:
 - ◊ Patients with a history of acute inflammatory reactions to contact lens wear.
 - ◊ Patients with a history of giant papillary conjunctivitis associated with contact lens wear.
 - ◊ Patients with a history of ocular allergies may need to temporarily discontinue lens wear during certain times of the year.
 - ◊ Patients with a history of non-compliance with contact lens care and disinfection regimen, wearing restrictions, wearing schedule, or follow-up visit schedule.
 - ◊ Patients who are unable or unwilling to understand or comply with any directions, warnings, precautions, or restrictions. Contributing factors may include but are not limited to age, infirmity, other mental or physical conditions, and adverse working or living conditions.
 - ◊ Patients who would not, or could not, adhere to a recommended care regimen, or who are unable to place and remove lenses, should not be provided with them.
- Aphakic patients should not be fitted with Focus NIGHT & DAY Contact Lenses until the determination is made that the eye has healed completely.
- Diabetics may have reduced corneal sensitivity and thus are more prone to corneal injury and do not heal as quickly or completely as non-diabetics.
- Fluorescein, a yellow dye, should not be used while the lenses are on the eyes. The lenses absorb this dye and become discolored. Whenever fluorescein is used in eyes, the eyes should be flushed with a sterile saline solution that is recommended for in-eye use.
- Patients who wear aspheric contact lenses to correct presbyopia may not achieve the best corrected visual acuity for either far or near vision. Visual requirements vary with the individual and should be considered when selecting the most appropriate type of lens for each patient.

Eye care professionals should carefully instruct patients about the following care regimen and safety precautions:

Handling Precautions:

- Be sure that before leaving the eye care professional's office the patient is able to promptly remove lenses or have someone else available to remove them.
- Good hygiene habits help promote safe and comfortable lens wear. **Always wash and rinse hands before handling lenses.**
- **REMOVE A LENS IMMEDIATELY** if an eye becomes red or irritated.
- Carefully follow the handling, insertion, removal, cleaning disinfecting, storing and wearing instructions in the Patient Instructions for Focus NIGHT & DAY Contact Lens.
- Always handle lenses carefully. If a lens is dropped small particles or fibers may adhere to the lens surface which can irritate the eye. Lenses should be cleaned and disinfected prior to insertion or replaced with a sterile, fresh new lens.
- Never use tweezers or other sharp objects such as fingernails to remove lenses from the lens container unless specifically indicated for that use. Pour the lens into the hand.

Lens Wearing Precautions:

- Patients should never exceed the prescribed wearing schedule regardless of how comfortable the lenses feel. Doing so may increase the risk of adverse effects.
- The lens should move freely on the eye at all times. If the lens sticks (stops moving) on the eye, follow the recommended directions in the *Care for a Sticking Lens* section. If non-movement of the lens continues, the patient should be instructed to consult their eye care professional immediately.
- The eye care professional should be consulted about wearing lenses during sporting and water related activities. 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.
- Eye irritation, infection, or lens damage may result if cosmetics, lotion, soap, cream, hair spray, deodorant, aerosol products or foreign particles come in contact with lenses.

- Environmental fumes, smoke, and vapors should be avoided in order to reduce the chance of lens contamination or physical trauma to the cornea.
- Lenses should be disposed of and replaced according to the eye care professional's recommendations.
- Note the correct lens power for each eye to prevent getting them mixed up.
- Always keep a supply of replacement lenses on hand.
- Do not use lenses beyond the expiration date.

Solution Precautions:

- Eye injury due to irritation or infection may result from lens contamination. To reduce the risk of contamination, review the appropriate manufacturer's labeled lens care instructions with the patient (see Lens Care Directions).
- Only use fresh, unexpired lens care solutions recommended for use with soft contact lenses and follow directions in the product package inserts.
- If a lens is exposed to air while off the eye it may become dry, brittle, and permanently damaged. If this should occur, the lens should be discarded and replaced with a new one to avoid possible irritation or injury to the eye. Always keep the lenses completely immersed in the recommended storage solution when lenses are not being worn.
- Do not use thermal (heat) disinfection and do not heat lens care products.
- Saliva or anything other than the recommended solution for lubricating or wetting lenses should not be used with the lenses.

Lens Case Precautions:

- Contact lens cases can be a source of bacterial growth and require proper use, cleaning and replacement at regular intervals as recommended by the lens case manufacturer or eyecare professional.

Other Topics to Discuss with Patients:

- Periodic eye examinations are extremely important for contact lens wearers. Schedule and conduct appropriate follow-up examinations to determine ocular response, especially for extended wear patients.
- 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.
- Visual changes or changes in lens tolerance may occur during pregnancy or use of oral contraceptives. Caution patients accordingly.

Who Should Know That the Patient is Wearing Contact Lenses:

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

It is strongly recommended that patients be provided with a copy of the Focus® NIGHT & DAY™ *Patient Instruction Booklet* available from CIBA Vision and understand its contents prior to dispensing the lenses.

ADVERSE DEVICE EFFECTS

The most commonly observed adverse device effects observed in the clinical study of Focus® NIGHT & DAY™ lenses were conjunctivitis, infiltrative keratitis, and non-infectious peripheral ulcer (See CLINICAL STUDY RESULTS for details).

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Potentially serious complications are usually accompanied by one or more of the following signs or symptoms:

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

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

- **IMMEDIATELY REMOVE THE LENSES.**
- **If the discomfort or problem stops, then look closely at the lens(es):**
 - If the lens(es) is in any way damaged, DO NOT put the lens(es) back on the eye. Discard damaged lens(es), and contact the eye care professional.
 - If the lens(es) have dirt, an eye lash or other foreign body on it, thoroughly clean, rinse, and disinfect prior to reinsertion.
- **If the discomfort or problem continues after removing lens(es) or upon reinsertion, IMMEDIATELY remove the lens(es) and contact the eye care professional for identification of the problem and prompt treatment to avoid serious eye damage.**
- The patient should be instructed NOT to use a new lens as self-treatment for the problem.
- **The patient should be informed that a serious condition such as corneal ulcer, infection, corneal vascularization, or iritis may be present, and may progress rapidly. Less serious reactions such as abrasions, infiltrates, and bacterial conjunctivitis must be managed and treated carefully to avoid more serious complications.**
- Additionally, contact lens wear may be associated with ocular changes that require consideration of discontinuation or restriction of wear. These include but are not limited to local or generalized corneal edema, epithelial microcysts, epithelial staining, infiltrates, neovascularization, endothelial polymegathism, tarsal papillary changes, conjunctival injection or iritis.

ADVERSE EFFECT REPORTING

If a patient experiences any serious adverse effects associated with the use of Focus® NIGHT & DAY™ (Iotrafilcon A) contact lenses, please notify: CIBA Vision Corporation, Technical Consultation, in the USA at 1-800-241-7629.

CLINICAL STUDY RESULTS

Study Description:

A total of 1395 subjects (697 Focus NIGHT & DAY subjects and 698 Control subjects) were enrolled in a pre-market clinical trial at 59 investigative sites throughout the United States. This clinical trial was a prospective, randomized, controlled, open label clinical trial lasting one year. An equal number of subjects were randomized to the Focus NIGHT & DAY and

Control groups at each site. Subjects wore either the Focus NIGHT & DAY or control lenses bilaterally for the duration of the trial.

Focus NIGHT & DAY lenses were worn on an extended wear schedule for up to 30 nights of continuous wear. Control lenses were worn on an extended wear schedule for up to 6 nights of continuous wear. Focus NIGHT & DAY subjects replaced lenses every month. Control subjects replaced lenses every week.

483 Focus NIGHT & DAY subjects (966 eyes) and 579 Control subjects (1158 eyes) completed the study. The Focus NIGHT & DAY group had 175 subjects (350 eyes) discontinued whereas the Control group had 102 subjects (204 eyes) discontinued.

Patient Assessments

Whenever possible, subjects were evaluated toward the end of the lens replacement cycle. Subjects were allowed to use their Focus NIGHT & DAY lenses for up to 35 days before replacement to assure that this was possible. Follow-up visits were scheduled for 24 hours, 1 week, and 1, 3, 6, 9, and 12 months after starting extended wear.

Demographic Data

The Focus NIGHT & DAY and Control groups were comparable with regard to age, lens power, and type of habitual correction at the start of the study. In each group the age ranged from 18 to 70 years with a Focus NIGHT & DAY group mean of 34.5 years and a Control group mean of 34.8 years. Lens power ranged from +6.00 D to -6.00 D for the Focus NIGHT & DAY group and +4.50 to -6.50 for the Control group. There were 78 (11.9%) lens wear neophytes in the dispensed Focus NIGHT & DAY group and 93 (13.7%) lens wear neophytes in the dispensed Control group. Previously successful DW subjects accounted for 47.4% of the Focus NIGHT & DAY group and 47.1% of the Control group. Previously successful EW subjects accounted for 39.7% of the Focus NIGHT & DAY group and 38.5% of the Control group. A small number of RGP wearers and previously unsuccessful soft lens wearers were enrolled in each group.

Gender distribution was the same in each group, 70% female and 30% male. The study population showed no differences in distribution of ethnicity. Smokers comprised 15.7% of the Focus NIGHT & DAY group and 14.0% of the Control group.

DATA ANALYSIS AND RESULTS:

The primary safety endpoint analysis was based on the proportion of subjects in each group who developed corneal infiltrates \geq Grade 3 or infiltrates with overlying fluorescein staining. In order to estimate an annualized rate for these endpoint infiltrates, life-table (survival) analysis was used to compensate for potential exposure time differences caused by differing dropout rates for each group. For statistical analysis of the life-table rate, a non-inferiority statistical design was employed. The equivalence margin was set at 5%.

The percentages of subjects able to successfully maintain the extended wearing schedule and of eyes maintaining Snellen contact lens visual acuity within 2 lines of dispensing were the efficacy endpoints analyzed. Completion was defined as wearing the test or control lenses for 12 months after initiation of extended wear and the subject had the required evaluations performed.

Primary Safety Endpoint

A total of 33 (5.0%) of the Focus NIGHT & DAY subjects and 21 (3.1%) of the Control subjects experienced one or more of the endpoint infiltrates during the trial. These incidence rates are not statistically different ($p = 0.073$, chi-square). There were a total of 44 endpoint infiltrates reported for the Focus NIGHT & DAY group and 25 reported for the Control group. According to the life table analysis, the estimated annualized rate for subjects experiencing

one or more of these infiltrates was 6.1% per person-year for the Focus NIGHT & DAY group (95% CI = 4.1% to 8.2%), and 3.3% per person-year for the Control group (95% CI = 1.9% to 4.7%). The Focus NIGHT & DAY group was found to be non-inferior by the equivalence margin.

Primary Effectiveness Endpoints

Visual Acuity

Eighty-three percent (83.0% or 909/1095) of the Focus NIGHT & DAY eyes and 83.6% (1046/1252) of the Control eyes had Snellen acuity of 20/20 or better as measured with contact lenses at the final visit.

Ninety-eight and one-tenths percent (98.1% or 1074/1095) of the Focus NIGHT & DAY eyes and 97.9% (1226/1252) of the Control eyes were within two lines of baseline BSCVA as measured with contact lenses at the final visit. Three percent (3.0% or 33/1095) of the Focus NIGHT & DAY eyes and 1.0% (12/1252) of the Control eyes demonstrated an improvement of more than one Snellen line of acuity with lenses worn at the final visit.

Reasons for the reduction in acuity with the Control lenses included changes in refractive status, deposits, and optical defects. The reasons for the reduction in acuity with Focus NIGHT & DAY lenses included lens deposits, change in refractive status, and defective lenses.

Wearing Schedules

The average wearing schedule achieved for subjects who completed the clinical study is presented below:

**Average Achieved Wearing Schedule
 (n = 966 eyes, one year)**

Consecutive Nights	
0 - 2	1.5%
3 - 4	1.0%
5 - 7	2.0%
8 - 14	6.9%
15 - 21	14.0%
22 - 31	67.2%
Not Reported	7.3%

Adverse Device Effects

Adverse device effects were reported at the following annual rates during the clinical study.

Eyes With At Least One Adverse Device Effect

Eyes Dispensed: Focus Night & Day = 1316 Control = 1362	Focus Night & Day %	Control %
Conjunctivitis	3.57%	3.89%
Moderate Infiltrative Keratitis	2.58%	1.54%
CLPU, non-infectious peripheral ulcer	0.84%	0.37%
Severe Infiltrative Keratitis	0.53%	0.37%
Other*	0.23%	0.37%
Asymptomatic Infiltrates	0.68%	0.37%
Hordeolum / Chalazion	0.30%	1.10%
Temporary Refractive change > 1.00 D	0.15%	0.00%
Infiltrative Keratitis & anterior chamber reaction	0.00%	0.15%

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Superior Epithelial Arcuate Lesion (SEAL)	0.15%	0.00%
Optical axis (4mm) scar with anterior chamber reaction	0.08%	0.00%
Moderate or mild uveitis	0.08%	0.00%
CLPU & ant. chamber reaction	0.08%	0.00%
Severe staining, edema, microcysts, injection	0.08%	0.00%
Central ulcer	0.00%	0.07%
Optic neuritis	0.00%	0.07%

TOTAL EVENTS WITHIN 30 NIGHT EXTENDED WEAR: 0.22% (2/91)

*Thygeson's keratitis, recurrent erosion in Focus NIGHT & DAY and subconjunctival hemorrhage, blepharokeratoconjunctivitis, intraepithelial keratitis in the Control group.

There were no reports of microbial keratitis, neovascularization or loss of best corrected visual acuity greater than 2 lines.

Discontinued Subjects

There were 58 Focus NIGHT & DAY subjects discontinued for discomfort, 33 (57%) within the first week of dispensing and the remainder within the first month. These discontinuations were attributed to fitting problems. Sixteen (16) Focus NIGHT & DAY and 3 Control subjects were discontinued for positive biomicroscopy. Of these, 5 Focus NIGHT & DAY and 1 Control were due to infiltrates. Four (4) of the Focus NIGHT & DAY subjects were discontinued for contact lens induced papillary conjunctivitis. One (1) additional Control subject was discontinued for reasons categorized as "Other-Ulcer."

Other Important Study Results

- Fourteen (42.4%) Focus NIGHT & DAY subjects experiencing infiltrates did so in the first month of extended wear compared to 5 (23.8%) of the Control subjects.
- For Focus NIGHT & DAY subjects experiencing more than one endpoint, 70% (7/10) experienced the endpoint in the first month.
- For both groups, if a subject experienced an infiltrate event in one eye the risk of a second event in the same or fellow eye was 6 times more likely as compared to having a first event.
- Papillary conjunctivitis occurred in 30 (4.6%) Focus NIGHT & DAY and 8 (1.2%) Control subjects. Subjects in both groups with a prior history of papillary conjunctivitis were more likely to develop it again in this investigation.
- Fewer Focus NIGHT & DAY subjects (19.8%) reported symptoms of dryness compared to the Control (24.2%) This finding of less dryness was noted in the case history, study questionnaire and subject diary.

FITTING GUIDE AND PATIENT INFORMATION

- The lens must move adequately on the eye for a proper fit and continued health of the eye. When prescribing the Focus® NIGHT & DAY™ lens for extended wear, it is important to reevaluate the lens fit for adequate movement at various times after the patient sleeps while wearing lenses. This reevaluation should include a follow-up visit as soon as possible after the patient awakens, as well as at other times of the day. If the fit is judged to be too tight or steep, the patient must be refit into a lens that provides the criteria of a well-fitted lens.
- Refer to the *Patient Instruction Booklet* or *Practitioner Fitting Guide* for more information.

LENS WEARING SCHEDULES

The wearing schedule should be determined by the eye care professional. Not all patients can achieve the maximum wear time of up to 30 nights of continuous wear. Patients should be monitored closely during the first month of 30-night continuous wear. If problems occur during this first month, the patient may not be suitable for the full 30-night wearing schedule. The maximum suggested wearing time should be determined by the eye care professional based upon the patient's physiological eye condition because individual responses to contact lenses vary.

- **DAILY WEAR** (less than 24 hours, while awake):
 - To avoid any tendency for the daily wear patient to over wear the lenses initially, stress the importance of adhering to a proper, initial daily wearing schedule. Normal daily wear of lenses assumes a minimum of 6 hours of non lens wear per 24 hour period.
 - It may be advisable for patients who have never worn contact lenses previously to be given a wearing schedule that gradually increases wearing time over a few days. This allows more gradual adaptation of the ocular tissues to contact lens wear.
- **EXTENDED WEAR** (greater than 24 hours, including while asleep):
 - The eye care professional should establish an extended wear period up to 30 continuous nights that is appropriate for each patient. Once the lens is removed, the patient's eyes should have a rest period with no lens wear of overnight or longer, as recommended by the eye care professional.
 - **It is suggested that the new contact lens wearers first be evaluated on a daily wear schedule. If the patient is judged to be an acceptable extended wear candidate, the eye care professional may determine an extended wear schedule based upon the response of the patient.**
 - See **Warnings** for information about the relationship between wearing schedule and corneal complications and **Clinical Results** for important information about average wear times and other study findings.

LENS REPLACEMENT

Lenses should be replaced every month, as recommended by the eye care professional. Longer replacement periods have not been studied and are not recommended by CIBA Vision. When removed between replacements times lenses must be cleaned and disinfected prior to reinsertion or be discarded and replaced with a fresh new lens.

LENS CARE DIRECTIONS

Disposable Wear:

- No lens care is indicated, as lenses are discarded upon removal from the eye.
- Lenses should only be cleaned, rinsed and disinfected on an emergency basis when replacement lenses are not available.

Replacement Wear:

- When removed between replacement periods lenses must be cleaned and disinfected prior to reinsertion or be discarded and replaced with a fresh lens.

Basic Instructions for Lens Cleaning and Disinfection:

When lenses are dispensed, the eye care professional should recommend an appropriate system of lens care and provide the patient with instructions according to the package labeling.

Failure to follow the complete regimen in accordance with manufacturer's package inserts may contribute to problems (see **ADVERSE EFFECTS**) and/or result in the development of serious ocular complications as discussed in **WARNINGS**.

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The eye care professional should review the following instructions with the patient:

- **Lenses must be cleaned, rinsed, and disinfected each time they are removed, for any reason.** If removed while the patient is away from the lens care products, the lenses may not be reinserted, but should be stored in a lens case filled with the recommended storage solution until they can be cleaned, rinsed, and disinfected. If a proper lens storage container is not available, discard lenses upon removal.
- **Cleaning** is necessary to remove mucus, film, and contamination from the lens surface. **Rinsing** removes all traces of the cleaner and loosened debris. **Disinfecting** is necessary to destroy remaining microorganisms.
- CIBA Vision recommends a chemical method of disinfection, including AOSEPT®, Quick CARE® or SOLO-care®.
- Enzyme cleaners have not been tested and are not recommended. Deposited lenses should be discarded and replaced with a fresh new lens.
- Lens compatibility with an abrasive type cleaner such as Opticlean I or II has not been tested and is not recommended.
- Heat disinfection has not been tested and is not recommended.
- **To help avoid serious eye injury from contamination:**
 - Always wash, rinse and dry hands before handling the lenses.
 - Use only fresh sterile solutions recommended for use with soft (hydrophilic) contact lenses. When opened, sterile non-preserved solutions must be discarded after the time specified in the label directions.
 - Do not use saliva, tap water, homemade saline solution, distilled water, or anything other than a recommended sterile solution indicated for the care of soft lenses.
 - Do not reuse solutions.
 - Use only fresh solutions for each lens care step. Never add fresh solution to old solution in the lens case.
 - Always empty and rinse the lens case with fresh sterile rinsing or disinfecting solution and allow to air dry. At the next use of the lens case, fill with fresh sterile solution.
- Never use a hard (rigid) lens solution unless it is also indicated for use with soft contact lenses. Corneal injury may result if hard (rigid) lens solutions not indicated for use with soft lenses are used in the soft lens care regimen.
- Always keep the lenses completely immersed in the recommended storage solution when the lenses are not being worn to avoid lens dehydration.
- Unless specifically indicated in the labeling, do not alternate, change, or mix lens care systems or solutions for any one pair of lenses. If in doubt as to solution suitability, consult the eye care professional.

CARE FOR A STICKING LENS

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

IN OFFICE USE OF TRIAL LENSES

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

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

EMERGENCIES

The patient should be informed that if chemicals of any kind (household products, gardening solutions, laboratory chemicals, etc.) are splashed into the eyes, the patient should: **flush eyes immediately with tap water or fresh saline solution, remove the lenses and place them in the recommended storage solution, and call or visit the eye care professional or a hospital emergency room immediately.**

HOW SUPPLIED

Each lens is packaged in a foil-sealed plastic container containing isotonic phosphate buffered saline solution and is steam sterilized. The package is marked with the base curve, diameter, dioptric power, manufacturing lot number and expiration date.

CIBA Vision Corporation
11460 Johns Creek Parkway
Duluth, Georgia USA 30097



Print Date: *(insert month, year)*

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Focus® NIGHT & DAY™ (lotrafilcon A) Soft Contact Lenses for Extended Wear

IMPORTANT:

The following basic information about contact lens wear and Focus NIGHT & DAY lenses is provided for you by CIBA Vision.

If you are interested in Focus NIGHT & DAY lenses, please see a licensed eye care professional. Based on your individual needs, your eye care professional will determine if Focus NIGHT & DAY lenses are right for you and how many days and nights you can wear them.

What are Focus NIGHT & DAY Soft Contact Lenses?

Focus NIGHT & DAY are soft contact lenses made of lotrafilcon A, a fluoro-silicone material that contains about 24% water. This new lens material provides a high level of oxygen to your eyes and has been surface treated to wet with your tears.

How are Focus NIGHT & DAY Soft Contact Lenses used?

The lenses are worn on the cornea (front part of the eye) and used to correct vision by refocusing light rays onto the retina (back part of the eye).

The lenses may be used to correct nearsightedness (myopia) or farsightedness (hyperopia). They may be prescribed for:

- ◆ Daily wear use – worn only while you are awake
- ◆ Extended wear use – worn while you are awake and asleep
 - They may be worn for up to 30 nights (one month) of continuous wear based on how your eyes respond to lens wear and your eye care professional's recommendation.

Can everyone wear Focus NIGHT & DAY Soft Contact Lenses for 30 nights of continuous wear?

Not everyone can reach the maximum wear time of 30 continuous nights. During the U.S. clinical study, 1000 of the 1300 eyes dispensed completed the full year of lens wear, with 67% wearing the lens between 22 to 30 days.

Your eye care professional may recommend a shorter wearing time depending on your individual needs, and you should always adhere to his or her recommendations. Once lenses are removed, your eyes should have a rest without lens wear for at least one overnight.

Who should not wear contact lenses?

You should not wear contacts if you:

- ◆ Have an eye infection or inflammation (redness & swelling).
- ◆ Have an eye disease, eye injury or dryness that interferes with contact lens wear.
- ◆ Have a systemic disease that may be affected by or impact lens wear.
- ◆ Have certain types of allergic conditions.
- ◆ Are using certain medications, such as some eye medications.

What are the risks of wearing contact lenses for extended wear?

While there are many benefits of wearing contacts, sometimes problems can occur and the risk of serious problems is greater when lenses are worn for extended wear. You should carefully discuss the benefits and risks of extended wear lenses with your eye care professional.

There is an increased risk of developing a serious ocular infection, such as a corneal ulcer. A corneal ulcer may develop rapidly and cause eye pain, redness or blurry vision as it progresses. If left untreated, a scar, and in rare cases loss of vision, may result.

In addition, studies have shown that smoking increases the risk of corneal ulcers for those who wear lenses overnight.

What are other possible side effects of extended wear contact lenses?

An inflammation of the cornea called infiltrative keratitis is another potential side effect. During the one-year U.S. study about 5% of the 1300 eyes experienced this type of side effect. Other less serious side effects were conjunctivitis and lid irritation or discomfort while wearing the lenses, including dryness of the eye and mild burning or stinging.

Are there times when you should not wear contact lenses?

Your eye care professional can tell you about situations or environmental conditions that may be inappropriate for contact lens wear. Some examples are:

- ◆ Exposing contact lenses to water during swimming or while in a hot tub may increase the risk of eye infection from microorganisms.
- ◆ Fumes, smoke or vapors should be avoided to reduce the chance of lens contamination.

How often do I replace the lenses and how do I care for them?

Lenses should be replaced every month, as recommended by the eye care professional. When removed from your eyes in between replacement times, they should be cleaned and disinfected with a chemical disinfection system (not heat), if not replaced with a new lens. The lenses are sold in multi-packs so replacements are at hand.

What are some important things to remember?

- ◆ While wearing contacts your eyes should look well, feel comfortable and vision should be clear.
 - If you have a problem, immediately remove your lenses and contact your eye care professional.
- ◆ Carefully follow your eye care professional's instructions for lens wear, care and replacement.
 - Never wear your lenses for longer periods than prescribed for you.
- ◆ See your eye care professional for follow-up care and periodic checkups.

What if I have other questions about Focus NIGHT & DAY Soft Contact Lenses?

It is essential to see and talk with your eye care professional about your eye health and to obtain complete information about Focus NIGHT & DAY lenses. If you have questions, discuss them with your eye care professional.

If you want to read more about Focus NIGHT & DAY Soft Contact Lenses, ask your eye care professional for the patient instruction booklet available from CIBA Vision or the package insert written for the eye care professional.

For more information call 1-800-875-3001 or visit our website at www.cibavision.com

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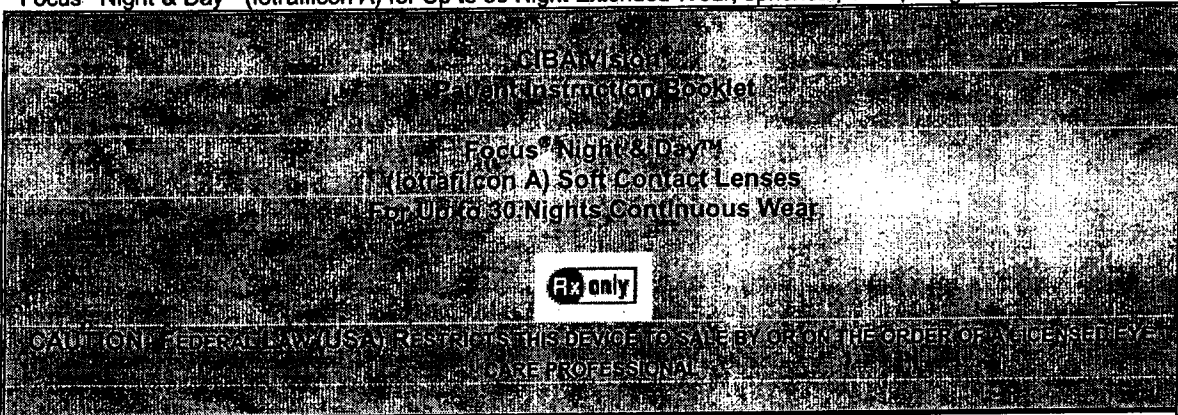


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Commonly Used Terms

- Cornea** The clear "window" of the eye, permitting light to enter, located in front of the iris and pupil
- Iris - The colored part of the eye which controls the size of the pupil
 - Pupil - The black round opening surrounded by the iris
- Astigmatism** A common vision condition where the cornea is not equally curved in all parts of its surface. It is somewhat oval in shape causing the visual image to be out of focus (blurred)
- Presbyopia** The gradual loss of the eye's ability to change focus from distance to near resulting in a need for additional correction for near tasks such as reading. The effects of presbyopia are generally first noticed after age 40.
- Disinfect** A process which kills harmful microorganisms (germs) which can cause serious eye infections
- Lens Deposits** Particles such as cosmetics, lotions, protein from the tear film, environmental pollutants, etc., which collect on the lens surface
- Extended Wear** Wearing lenses for 24 hours a day, including while sleeping.
- 30 Night Continuous Wear** Extended wear for up to 30 nights in a row.

INTRODUCTION

Welcome!

Focus® Night & Day™ lenses are a breakthrough in soft contact lenses and represent a new option for contact lens convenience and comfort. This booklet explains how to safely use your Focus® Night & Day lenses. Read it carefully and keep it in a safe place for future reference.

About Your Contact Lenses

Focus® Night & Day™ lenses may be prescribed for daily wear or extended wear for up to 30 nights of continuous wear, with removal for disposal, or cleaning and disinfection prior to reinsertion, as recommended by your eye care professional. This is possible because Night & Day contact lenses are made of a lens material that provides a high level of oxygen to your eyes and has been surface treated to wet with your tears.

Your eye care professional may recommend daily wear, or a shorter extended wearing time depending on your individual needs, and you should always adhere to his or her recommendations. Not everyone can reach the maximum wear time of 30 continuous nights.

For daily wear, lenses are worn for part of a day and not worn while sleeping. For extended wear, once the lenses are removed, your eyes should have a rest without lens wear for at least one overnight, as recommended by your eye care professional. Your eye care professional will tell you how long to rest your eyes in between wearing periods and will also recommend a replacement period and appropriate lens care products that are right for you.

For your eye health, it is important that you follow the wearing and replacement schedule as prescribed by your eye care professional. If you wear your lenses too long, you can harm your eyes.

Focus NIGHT & DAY lenses are available in various lens designs that are used for different kinds of vision correction.

- Spherical lenses are used to correct nearsightedness (myopia) or farsightedness (hyperopia).
- Toric lenses are used to correct astigmatism.
- Progressives lenses are used to correct presbyopia.

In addition, each of the lens designs comes in a range of prescriptive powers. Your eye care professional will prescribe the appropriate lens design and prescriptive power (Rx) that's needed to correct vision in your right and left eye.

About This Booklet

Read this booklet carefully and follow all of the instructions.

This booklet explains how to wear and care for your new lenses. If you have questions after reading this booklet, call or visit your eye care professional. Also, you may call CIBA Vision Consumer Relations toll free in the USA at 1-800-875-3001.

Focus® Night & Day™ (lotrafilcon A) for Up to 30 Night Extended Wear, spherical, Toric, Progressives
Successful, safe contact lens wear depends on following the recommendations of your eye care professional and practicing good lens care habits. If you do not, you may:

- increase the chances of serious eye infection and injury
- cause damage to your contact lenses

WARNINGS AND PRECAUTIONS

What You Should Know About Contact Lens Wear

Warning

Serious injury to the eye, scarring of the cornea, and loss of vision may result from problems associated with wearing contact lenses and using lens care products.

Eye problems, including corneal ulcers, can develop rapidly and lead to loss of vision. Immediately call or visit your eye care professional for persistent symptoms of any eye discomfort, watering, vision change, or redness.

Extended Wear

Overnight wear of contact lenses has been shown to increase the risk of certain serious contact lens related complications. **Do not wear your Focus Night & Day™ contact lenses for extended wear (24 hours a day including during sleep) unless directed by your eye care professional.**

Smoking

Smoking increases the risk of serious problems with contact lens wear, especially when lenses are worn overnight^{1, 1}. If you smoke, be sure to inform your eye care professional.

Following Directions

Be sure to follow exactly the instructions of your eye care professional and manufacturers' labeled lens care instructions for the proper use and care of your contact lenses and lens care products, including lens cases. Failure to do so may put you at significant risk of developing a serious eye infection.

Use Proper Lens Care Solutions

Do not use saliva, tap water, distilled water, or homemade saline solution for any purpose in caring for your lenses. The use of these solutions has been associated with serious eye infections including Acanthamoeba keratitis, a corneal infection which is resistant to treatment and cure.

Adverse Effects (Possible Problems)

It is possible that problems can occur and may be accompanied by one or more of the following conditions:

- Moderate to severe eye pain not relieved by removing the lens
- Feeling of something in the eye
- Unusual eye secretions
- Eye redness
- Sensitivity to light (photophobia)
- Eyes burn, sting or itch
- Eyes water
- Reduced sharpness of vision
- Rainbows or halos around objects
- Uncomfortable lens
- Feeling of dryness

A serious condition such as corneal ulcer or eye infection may be present and may progress rapidly. Even less serious reactions such as a scratched cornea must be treated promptly to avoid more serious complications.

What To Do if a Problem Occurs

If you experience any of the above signs or symptoms, immediately remove your lens(es). Identification of the problem and prompt treatment may help avoid serious eye damage.

IMMEDIATELY remove the lens(es),

1. **If the discomfort stops, then look closely at the lens(es).**
 - **If the lens(es) are damaged in any way, DO NOT put the lens(es) back on your eye. Place the lens(es) in the storage case, or discard and contact the eye care professional.**
 - **If the lenses have dirt, an eyelash or other foreign body on them, and the lens(es) appear undamaged, thoroughly clean, rinse and disinfect the lenses, then reinsert. After reinsertion, if the problem continues, remove the lens(es) immediately and contact the eye care professional.**
2. **If discomfort continues after you have removed your lenses,**
 - **IMMEDIATELY contact the eye care professional.**
 - **Do not insert a new or spare lens onto an eye that is red, irritated, or painful. A new lens may hide symptoms and delay treatment.**

WHEN LENSES SHOULD NOT BE WORN

Contact lenses should not be worn under certain general health and eye conditions. Only your eye care professional can determine if continued contact lens wear is right for you. These include the following:

- Inflammation or infection in or around the eye or eyelids.
- Excessive dryness of the eyes that makes contact lens wear uncomfortable.
- Any condition which reduces corneal sensitivity.
- Systemic diseases that may be affected by or impact lens wear.

- Allergic conditions, reactions or ocular irritation caused or exaggerated by lens wear or certain preservatives in lens care products.
- The use of any medication, including some eye medications, that shouldn't be used with, or interferes with contact lens wear.
- If eyes become red or irritated.

CLINICAL STUDY

A one-year US pre-marketing clinical study of Focus NIGHT & DAY lenses showed that the product is safe and effective for vision correction for up to 30 nights of continuous wear.

A total of 1395 subjects (697 Focus NIGHT & DAY Test Subjects and 698 Control Subjects) were enrolled in the clinical trial at 59 investigative sites throughout the United States. Of these, 483 subjects wearing the Focus NIGHT & DAY lens and 579 subjects wearing the Control lens completed the study. The Focus NIGHT & DAY lens was worn for up to 30 days and nights of continuous wear and replaced monthly, and the Control lens was worn for up to 6 days and nights of continuous wear and replaced weekly.

Overall Findings:

Safety: There were no serious adverse events such as a corneal ulcer observed during this trial. However, out of the 1394 eyes (697 subjects) that started the trial wearing Focus NIGHT & DAY, about 5% experienced at least one episode of infiltrative keratitis, a localized inflammation of the cornea. Other less serious problems were conjunctivitis and lid irritation or discomfort while wearing the lenses, including dryness of the eye and mild burning or stinging.

Effectiveness: Wearing Schedule – Not everyone reached and maintained the maximum extended wear time of 30 continuous nights for the entire one-year period. About 67% achieved an average wearing schedule of 22 to 31 days. **Visual Acuity** – Approximately 93% of all subjects completing the Focus NIGHT & DAY trial achieved at least 20/25 vision.

RISK ANALYSIS

While there are many benefits of wearing contact lenses, sometimes problems occur. You should carefully discuss the benefits and risks of extended wear lenses with your eye care professional.

With overnight contact lens wear there is an increased risk of developing a serious eye infection, such as a corneal ulcer. A corneal ulcer may develop rapidly and cause eye pain, redness or blurry vision as it progresses. If left untreated, a corneal scar, and in rare cases, loss of vision may result.

In addition, studies have shown that smoking increases the risk of corneal ulcers for contact lens users who wear lenses overnight.

GENERAL GUIDELINES FOR SAFE CONTACT LENS WEAR

While wearing your Night & Day lenses, your eyes should look well, feel comfortable and your vision should be clear.

- Your lenses are provided to you in a foil sealed plastic container. Never use a lens if the container seal is broken, as damage or contamination may have occurred.
- **Don't wear your lenses longer than recommended by your eye care professional, no matter how comfortable the lenses feel. Doing so increases the risk of adverse effects.**

- Don't excessively rub your eyes while the lenses are in. You may harm your eyes or damage the lens.
- Don't get water, soap, or shampoo into your eyes during a bath or shower. These substances could get on your lenses and irritate your eyes.
- Be aware that hot and windy conditions may dry out your lenses. For example, air from a hair dryer, ceiling fan, or open car window may dry out your lenses and irritate your eyes.
- Always inform your eye care professional, physician and employer that you wear contact lenses. Contact lenses may not be used with certain medications or medical procedures, may not be suitable for certain occupations, or may require eye protection equipment.
- Exposure to water while wearing contact lenses in activities such as swimming, water skiing and hot tubs may increase the risk of:
 - eye infection, including but not limited to Acanthamoeba keratitis
 - damage to the lenses by chemicals in the water
 - loss of the lenses

Storing Your Lenses

- Store your lenses in the recommended solution when not being worn. Soft lenses are made of special materials that must be kept wet at all times to avoid damage from drying out.
- Always use fresh solution when storing your lenses. Previously used solutions can become contaminated and increase the risk of infection.
- Always follow the manufacturer's instructions for the lens care system your eye care professional has prescribed.

When to Remove Your Lenses

- Remove your lenses for sleeping unless your eye care professional has prescribed overnight wear for you. Not all people can wear lenses while sleeping. Sleeping with lenses on increases the risk of eye infection.
- Remove your lenses immediately if they become uncomfortable. Discomfort can be an early warning sign of a more serious problem. If the discomfort continues after lens removal, contact your eye care professional. Early treatment can help avoid more serious complications.
- Remove your lenses if you will be in the presence of irritating liquids, gases, chemicals, or smoke. Your lenses can become damaged by absorbing these substances and irritate or injure your eyes. If exposed to these substances while wearing your lenses, see the section titled "Emergencies" in the back of this booklet.
- **Note: Lenses removed from your eye must be cleaned, rinsed, and disinfected prior to reinsertion.**

Cosmetic Products and Your Lenses

- Lens damage, eye irritation or infection may result if cosmetics, lotion, soap, cream, hair spray, deodorant, perfume, or aerosol products come in contact with your lenses. If sprays are used, close your eyes until the spray has settled.
- Apply eye make-up only after you have inserted the lenses. Otherwise, make-up can become trapped under the lens and irritate or injure your eyes.
- Do not use nail polish remover while wearing your lenses. The fumes can damage the lenses.

Other Eye Care Products and Medications

- Do not use eye drops, solutions, or medications in your eyes unless directed by your eye care professional. These solutions may damage your lenses or irritate your eyes. You may use lens rewetting drops while lenses are worn.
- Certain medications may cause blurred vision, lens dryness, or lens discomfort. These include antihistamines, decongestants, diuretics, muscle relaxants, oral contraceptives, tranquilizers, and motion sickness medications. Always inform your eye care professional if you experience any problems with your lenses while taking such medications.
- Do not use solutions made only for hard contact lenses. They can damage your soft lenses, which may result in serious eye complications.

LENS PLACEMENT ON THE EYE

Introduction

Cleanliness is one of the most important aspects of handling and caring for your contact lenses. Starting with clean hands helps to reduce the chance of eye infections and irritation.

Step 1 – Wash, Rinse, and Dry Hands

- **Wash your hands thoroughly** with soap that does not have any oils, lotions, or perfumes.
 - Thorough hand washing will remove dirt, germs, and oils that could get on the lenses and cause irritation or infection. Using the proper soap prevents chemical residues from getting on the lenses.

Always wash your hands before handling your lenses. This will remove dirt and oils that could get on the lenses. Proper hand washing also helps prevent eye infections.

- **Rinse your hands thoroughly after washing.**

- This removes all traces of soap and dirt.

- **Dry your hands with a lint-free towel.**

- This helps keep lint and dust from getting on your lenses and irritating your eyes.

- Long fingernails can make lens placement, removal and cleaning more difficult. Sharp, rough fingernails can damage the lenses.



Photograph of proper hand washing technique

Step 2 – Open the Multipack Carton and Lens Container

Focus Night & Day™ contact lenses are supplied sterile in multipack cartons with individual foil sealed plastic containers. Locate the opening flap on the multipack carton and pull up to break the seal.

Each multipack carton and lens container is marked with the lens power (your vision prescription). Lens powers may not be the same for both eyes, so multipack cartons have a check box for your eye care professional to mark indicating which lens is for your left and right eye. Be sure to open and use the correct lens for each eye.

The Lens Package

- Each *Focus Night & Day™* soft contact lens is supplied in a foil sealed plastic container designed to maintain sterility of the lens and saline solution. To open an individual container, follow these simple steps:
 1. Shake the lens package gently, and peel back lid.
 2. Carefully remove the lens from package.
 - With a clean finger, gently slide the lens out of the lens container or pour the lens onto the palm of your clean hand.
 - Do not use tweezers or other tools to remove the lens from container. This could damage the lens.

Step 3 – Inspect the Lens for Damage or Foreign Matter

- Thoroughly rinse the lens with the recommended sterile saline solution according to the manufacturer's instructions. This will remove any possible traces of dust, lint or other particles from the lens. Foreign material could get trapped under the lens and cause eye discomfort.

- Examine the lens to be sure it is clean and moist and does not have any nicks, tears, or particles sticking to it.

- Place the lens on the tip of your index finger and hold it up against a bright light.

- If the lens appears damaged or dried out, do not use it. Discard it and use the next lens in the multipack.

Never handle your lenses over a sink with an open drain. Shut the drain or place a clean paper towel over the opening to keep from losing your lenses.

Step 4 – Make Sure the Lens Is Right Side Out

Check to see that your lens is right side out. A lens that is placed on the eye inside out may not feel comfortable or provide good vision.

Method 1

One way to do this is to place the lens between your thumb and index finger and squeeze the edges together gently.

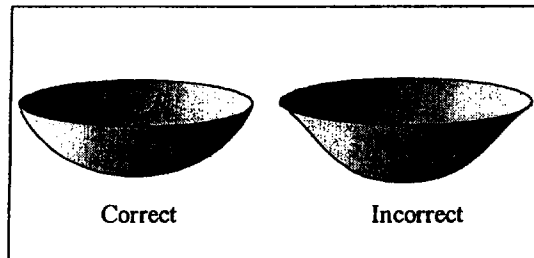
- If the edges come together, the lens is right side out.
- If the edges turn outward, the lens is wrong side out. Carefully reverse it with your fingers.

Photographs or line drawings of
Method 1
(right side vs wrong side out)

Method 2

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

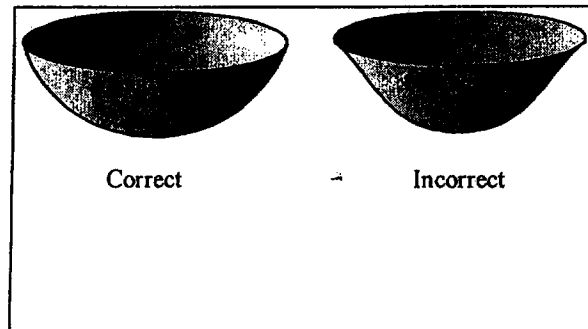
- If the edge appear bowl-shaped, it is right side out.
- If the edge has a lip or flares outward, it is wrong side out and must be reversed.



Method 3

A third way to tell if the lens is right side out is to look at the lens engravings at the edge of the lens.

- Place the lens on the tip of your index finger and hold it up against a light source.
- If the lens is right side out, you should be able to read "CIBA" at the edge of the lens. If the lens is inside out, the engravings will be reversed. Carefully turn the lens right side out with your fingers.



Step 5 - Place Lens on Eye

After you have thoroughly washed, rinsed, and dried your hands, rinsed and inspected the lens, and made sure it is right side out, you are ready to place the lens on your eye.

Remember to start with the same lens first (right or left), then the other lens. This helps avoid getting the lenses mixed up.

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1. Place the lens on the tip of your right index finger (left index finger if you are left-handed and this is easier for you). Make sure your finger is completely dry, or the lens will stick to your finger and be difficult to transfer to your eye.

2. Place the middle finger of the same hand close to your lower eyelashes and pull down the lower eyelid.

Photograph of lens placement technique, depicting proper positioning of fingers, eyelids, and lens.

3. Use the fingers of the other hand to lift the upper right eyelid.

4. Place the lens directly on the eye (cornea) by gently rolling it off the index finger.

5. Look down and slowly remove your right hand, releasing the lower lid.

Photograph of lens placement technique, depicting proper positioning of fingers, eyelids, and lens.

6. Look straight ahead and slowly remove your left hand, releasing the upper lid.

7. Blink gently. The lens should center automatically.

8. Repeat steps 1-7 above for the other lens.

Your eye care professional may suggest alternate methods for insertion of the lens onto the eye.

If your vision is blurred or the lens is uncomfortable on your eye, check for the following:

- The lens is not centered on the eye (see **Centering the Lens**, next section)
- The lens is centered. Remove the lens (see **Lens Removal** section) and check for the following:
 - Cosmetics, oils, or particles on the lens. Clean and rinse the lens and place on the eye again.
 - The lens is on the wrong eye.
 - The lens is wrong side out.
 - The lens may be torn or damaged. If so, do not place the lens back on your eye. Discard the lens and replace it with a new lens.

If your vision is still blurred or the lens is uncomfortable after checking the above, remove both lenses and contact your eye care professional.

After you have successfully inserted your lenses, you should ask yourself:

- Do the lenses **feel good**? (There should be no discomfort.)
- Do my eyes **look good**? (Your eyes should not be red or swollen or have any discharge.)
- Is my **vision good**? (You should be able to see clearly out of each eye individually and together.)

If the answer to any of these questions is no, immediately remove your lenses and contact your eye care professional.

Centering the Lens

Occasionally a lens will be displaced onto the white part of the eye during lens placement or during lens wear. To center a lens, follow one of the methods below:

Method 1. Look in the direction of the displaced lens. Blink gently. The lens should automatically move toward the center of the eye and into the correct position.

Method 2. Close your eyelids and gently massage the lens into place through the closed eyelid.

Photograph of lens centering technique, method 2.

Method 3. Gently push the off-centered lens onto the cornea with the eye open, using gentle finger pressure on the edge of the upper or lower eyelid.

LENS REMOVAL

Remember to remove the same lens first (right or left), then the other lens. This helps avoid getting the lenses mixed up.

It may be easier to remove your contact lenses if you use rewetting drops (approved for use with soft lenses) recommended by your eye care professional 10 to 15 minutes before lens removal. This will also help prevent lens tearing during the removal process.

Step 1 - Wash, Rinse, and Dry Hands

- **Wash your hands thoroughly** with soap that does not have any oils, lotions, or perfumes.

Refer to the section, "Lens Placement on the Eye" for important additional information.

Step 2 - Make Sure Lens is on the Eye

Make sure the lens is centered on your eye before trying to remove it. Cover the other eye; if your vision is blurred, the lens is either off center or not on the eye at all. Locate the lens with a mirror and re-center it using one of the methods described in the section, ***Centering the Lens***.

Step 3 - Pull Down Lower Eyelid

Look upward, keeping your head level. Pull down the lower lid of your eye with your middle finger.

Photograph of Step 3

Step 4 - Slide Lens Down

While looking up, place the tip of your index finger on the lower edge of the lens and slide it down onto the lower white part of your eye.

Photograph of Step 4

Step 5 - Pull Lens Off Eye

Still looking up, squeeze the lens gently between your thumb and index finger. Gently remove the lens from the eye.

Repeat Steps 2-5 for the other lens

Photograph of Step 5

REPLACING YOUR LENSES

Replace your lenses with a new pair as often as recommended by your eye care professional. Old lenses can cause discomfort, decreased vision and may adversely affect your eye health. CIBA Vision recommends lenses be replaced every one month, or as recommended by the eye care professional.

FOLLOW-UP CARE

Do not skip visits with your eye care professional just because your lenses feel comfortable. Routine follow-up visits help prevent problems. Only a thorough examination by your eye care professional can determine how your eyes are responding to contact lenses. Early signs of a problem can be detected and treated before they can be felt by you.

LENS CARE

Your eye care professional may either recommend using lenses for disposable wear or for replacement wear.

For Disposable Wear:

- No lens care is indicated, as lenses are discarded upon removal from the eye.
- Lenses should only be cleaned, rinsed and disinfected on an emergency basis when replacement lenses are not available.

For Replacement Wear:

- When removed between replacement periods lenses must be cleaned and disinfected prior to reinsertion or be discarded and replaced with a fresh new lens.

Focus® Night & Day™ lenses should be cleaned, rinsed, and disinfected each time they are removed from the eye prior to re-insertion.

General Guidelines for Lens Care

- **Follow the complete lens care regimen exactly as directed in the specific labeling instructions which accompany the solutions recommended by your eye care professional. Failure to do so may contribute to problems.**
- Lenses removed from your eyes must be cleaned, rinsed, and disinfected after each wearing before reinsertion.
 - **Cleaning** loosens and removes accumulations of film, deposits, and debris that can cause irritation, and prepares lenses for disinfection.
Rinsing removes cleaning and disinfection solutions and helps make your lenses feel more comfortable.
Disinfecting kills germs that can cause eye infections.
 - Failure to clean and rinse prior to disinfection may result in incomplete lens disinfection.
 - Saline solutions are used to rinse, **NOT** to clean or disinfect.

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- CIBA Vision recommends a chemical method of disinfection, such as AOSEPT[®], Quick CARE[®] or SOLO-care[®] for use with *Focus NIGHT & DAY[™]* contact lenses.
- Heat disinfection has not been tested and is not recommended.
- Use of an enzymatic cleaner has not been tested and is not recommended. Worn lenses with protein deposits should be discarded and replaced with a new lens.

- Lens compatibility with an abrasive type cleaner such as Opticlean I or II has not been tested and is not recommended.
- Never use a hard (rigid) lens solution unless it is also indicated for use with soft contact lenses, as corneal injury could result.
- Do not alternate, change, or mix lens care systems or solutions for any one pair of lenses unless specifically indicated in the product labeling. Different solutions cannot always be used together, and not all solutions are safe for use with all lenses. If in doubt, consult your eye care professional.
- If you remove your lenses and do not have access to your lens care products, do not reinsert the lenses. Store your lenses in the lens case until they can be cleaned, rinsed, and disinfected.
- Use only fresh, unexpired, sterile lens care solutions recommended for use with soft contact lenses according to the manufacturer's instructions provided with the specific products.
- **When opened, sterile, non-preserved, non-aerosol solutions must be discarded after the time specified in the label directions.**

Step 1 - Cleaning

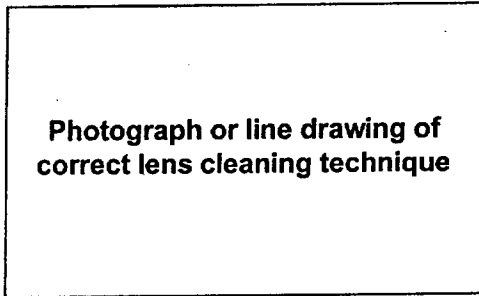
Cleaning loosens and removes accumulations of film, deposits, and debris that can cause irritation, and prepares lenses for disinfection.

Wash, Rinse, and Dry Hands

Remove and Clean One Lens at a Time

Clean Lens

- **Place the lens in the palm of one hand and add cleaner according to the manufacturer's instructions for use.**
 - Rub the lens with firm but gentle pressure, in a back and forth (not circular) motion. A circular motion may cause the lens to split or tear.
 - The rubbing action of your finger against the lens removes mucus, dirt, and other material from the lens surface. These substances may not be visible even though they are present on your lenses.

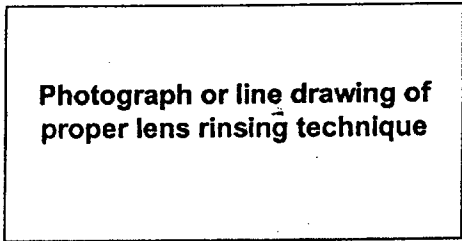


Photograph or line drawing of correct lens cleaning technique

Step 2 - Rinsing

Rinsing removes cleaning and disinfecting solutions and helps make your lenses feel more comfortable.

- Thoroughly rinse the lens with fresh sterile saline solution according to the manufacturer's instructions for use.
- Make sure all of the cleaning solution has been rinsed off. Any remaining cleaner can irritate the eye and may interfere with the disinfection process.



Photograph or line drawing of proper lens rinsing technique

Step 3 - Disinfection

Disinfecting kills germs that can cause eye infection.

- Follow the manufacturer's instructions that come with the chemical disinfection system recommended by your eye care professional. In most cases, you will:
 1. Always fill the lens case with **fresh** disinfection solution.
 2. **Close tightly.** The lenses must be fully covered by the disinfection solution to ensure proper disinfection and to keep from drying out.
 3. **Allow lenses to remain in case for the length of time specified in the instructions.** This will help keep harmful germs from growing on your lenses.

Care of the Lens Case

Contact lens cases can be a source of growth for harmful organisms. These germs may be present even when the case looks clean. Putting clean lenses in a dirty or contaminated case makes the lenses unsafe to wear.

Rinse lens case

To prevent contamination and help avoid serious eye infection:

- Always empty the lens case after putting the lenses on your eyes
 - Rinse the case with either sterile saline solution or disinfecting solution recommended by your eye care professional
 - Allow the case to air dry.

Replace lens case regularly

Regular replacement will help prevent case contamination by germs which can be harmful to your eyes.

- Replace the lens case at regular intervals according to the manufacturer's instruction for use.
- If there are not instructions for how often to replace the case, follow the recommendations of your eye care professional.
- **Fresh solution should be used each time the lens is placed in the lens case. Never add fresh solution to old solution since this can increase the risk of lens and lens case contamination and eye infection.**

OTHER IMPORTANT INFORMATION

Using Wetting Drops (Lens Lubricant)

- If wetting drops are recommended by your eye care professional (such as CIBA Vision Focus® Lens Drops), follow the directions for use provided by the manufacturer. Not all lens lubricants can be used with soft contact lenses.

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If a Lens Dries Out

- If a lens is exposed to air while off the eye it may become dry, brittle, and permanently damaged. If this should occur, discard the lens and use a new one to avoid possible irritation or injury to the eye.

Care for a Sticking Lens

- If a lens sticks (stops moving) or begins to dry on the eye, apply a lubricating solution recommended for soft lenses according to the manufacturer's instruction for use.
- Wait until the lens begins to move freely on the eye before trying to remove it. If the lens continues to stick, IMMEDIATELY consult your eye care professional.

Emergencies

- If chemicals of any kind (household cleaners, gardening solutions, laboratory chemicals, pesticides, etc.) are splashed into the eyes:
 - **Flush eyes immediately with tap water or fresh saline solution.**
 - **Remove the lenses and place them in the recommended storage solution.**
 - **Call or visit your eye care professional or a hospital emergency room immediately.**

INSTRUCTIONS FOR THE MONOVISION WEARER (SPHERICAL OR TORIC)

- You should be aware that as with any type of lens correction, there are advantages and compromises to monovision contact lens therapy. The benefit of clear near vision in straight ahead and upward gaze that is available with monovision may be accompanied by a vision compromise that may reduce your distance visual acuity and depth perception for distance and near tasks. Some patients have experienced difficulty adapting to it. Symptoms, such as mild blurred vision, dizziness, headaches and a feeling of slight imbalance, may last for a brief minute or for several weeks as adaptation takes place. The longer these symptoms persist, the poorer your prognosis for successful adaptation. You should avoid visually demanding situations during the initial adaptation period. It is recommended that you first wear these contact lenses in familiar situations, which are not visually demanding. For example, it might be better to be a passenger, rather than a driver of an automobile, during the first few days of lens wear. It is recommended that you drive with monovision correction only if you pass the driver's license requirements with your monovision correction.
- Some monovision patients will never be fully comfortable functioning under low levels of illumination, such as driving at night. If this happens, you may want to discuss with your eye care professional having additional contact lenses prescribed so that both eyes are corrected for distance when sharp distance binocular vision is required.
- If you require very sharp near vision during prolonged close work, you may want to have additional lenses prescribed so that both eyes are corrected for near when sharp near vision binocular vision is required.
- Some monovision patients require supplemental spectacles to wear over the monovision contact lens correction to provide the clearest vision for critical tasks. You should discuss this with your eye care professional.
- It is important that you follow your eye care professional's suggestions for adaptation to monovision contact lens therapy. You should discuss any concerns that you may have during and after the adaptation period.
- The decision to be fit with a monovision correction is most appropriately left to the eye care professional in conjunction with you, after carefully considering and discussing your needs.

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INSTRUCTIONS FOR THE PRESBYOPIC PATIENT (multifocal or monovision)

Two common methods of using contact lenses for presbyopic vision correction include multifocal or bifocal lenses, and monovision. Like bifocal, trifocal, or progressive addition spectacles, multifocal contact lenses have separate powers for distance and near vision in each lens. This allows the wearer to use both eyes for seeing at all distances. Monovision correction entails the use of standard single vision lenses with a distance powered lens being worn on one eye and a near powered lens on the other eye.

As with any type of lens correction, there are advantages and compromises with multifocal or monovision correction. The benefit of clear near vision in straight ahead and upward gaze that is available may be accompanied by reduced vision at certain distances or under certain lighting conditions. Some individuals, particularly those wearing monovision lenses may experience reduced depth perception. Some patients experience difficulty adapting to this. Symptoms such as mild blurring, dizziness, headaches and a feeling of slight imbalance, may last briefly or for several weeks as adaptation takes place. The longer these symptoms persist, the poorer your prognosis for successful adaptation.

During the adaptation period it is recommended that you wear these contact lenses only in familiar situations which are not visually demanding. For example, you should avoid driving an automobile until you are comfortable that your eyes have adjusted. It is recommended that you drive with multifocal or monovision correction only if you can pass the driver's license requirements with your lenses.

- Some patients will never be fully comfortable functioning in low light, such as driving at night. If this happens, you may want to discuss with your eye care professional having additional contact lenses prescribed so that both eyes are corrected for distance when sharp distance vision is required.
- If you perform prolonged close work requiring very sharp near vision you may need to wear spectacles over your lenses or have additional lenses prescribed specifically for this task. You should discuss your specific visual needs with your eye care professional.
- It is important that you follow your eye care professional's advice regarding adaptation to presbyopic vision correction. During the adaptation period you should make careful note of any specific situation where you feel unable to function effectively and safely, and discuss these concerns with your eye care professional.
- The decision to be fit with multifocal lenses or a monovision correction should be made in conjunction with your eye care professional only after carefully considering and discussing your needs.

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LENS CARE PRODUCT CHART FOR SOFT CONTACT LENSES, AVAILABLE IN THE U.S.A.

AOSEPT® Lens Care System

AOSEPT® Disinfectant

AOSEPT® Lens Cup

AODISC® Neutralizer

Softwear® Saline

Miraflo® Extra Strength Daily Cleaner

Disinfecting solution

Lens case for AOSEPT Disinfectant and

AODISC Neutralizer

Neutralizes AOSEPT into a gentle buffered saline solution

Rinsing and storage

Cleaner

Pure Eyes®

Disinfection System

Pure Eyes® Disinfectant/Soaking Solution

Pure Eyes® Cleaner/Rinse

Pure Eyes® Lens Case/built-in neutralizer

Disinfecting solution

Cleaning and rinsing solution

Neutralizes Pure Eyes Disinfectant into a gentle buffered saline solution

Quick CARE® Care System

Quick CARE® Starting Solution

Quick CARE® Finishing Solution

The Quick CARE System cleans, disinfects, rinses, and soaks in about 5 minutes

SOLO-CARE® brand

Multi-purpose Solution

Multipurpose solution for cleaning, rinsing, disinfecting, storing, & protein removal

Other CIBA Vision® Lens Care Products

CIBA Vision® Cleaner

CIBA Vision® Saline

CIBA Vision® Lens Drops

Focus® Lens Drops

Cleaning

Rinsing

Lubricating

Lubricating

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WEARER INFORMATION

Eye Care Professional:		Contact Lens Information:	
Name:		Lens Brand/Type:	
Street:		Prescription/Date:	
City/State/Zip:			
Phone:			

Wear & Replacement Schedules:

The wearing and replacement schedules should be determined by your eye care professional. Patients tend to overwear the lenses initially. It is very important to adhere to the initial maximum wearing schedule. Regular checkups, as determined by your eye care professional, are also extremely important.

CIBA Vision Corporation recommends that the lens be discarded and replaced with a new lens every month. However, your eye care professional is encouraged to determine a lens replacement schedule based upon the response of the patient.

Daily Wear Only (less than one day, while awake):

Extended Wear (Maximum 30 nights continuous wear): How many nights you can safely wear the lenses overnight will be established during the follow-up visits.

Initial Wearing Schedule:

DAY	DATE (Month/Day)	Wearing Time (# Hours)	DAY	DATE (Month/Day)	Wearing Time (# Hours)
1	_____	_____	6	_____	_____
2	_____	_____	7	_____	_____
3	_____	_____	8	_____	_____
4	_____	_____	9	_____	_____
5	_____	_____	10	_____	_____

REPLACEMENT SCHEDULE:

Replace lenses every _____ days or every ___ / ___ weeks

LENS CARE SUPPLIES (Product Name or Manufacturer):

Saline Solution:		Lens Wetting Drops:	
Daily Cleaning Solution:			
Disinfecting Solution:			

Appointment Schedule:

Date:	_____	Time:	_____	Date:	_____	Time:	_____
Date:	_____	Time:	_____	Date:	_____	Time:	_____

Important: In the event that you experience difficulty wearing your lenses or do not understand the instructions given you, DO NOT WAIT for your next appointment. Phone your eye care professional immediately.

CIBA Vision Corporation
 11460 Johns Creek Parkway
 Duluth, GA USA 30097
 Part # [insert part number]

Printed in [insert USA or Canada]



A Novartis Company
 Print Date: [insert month, year]

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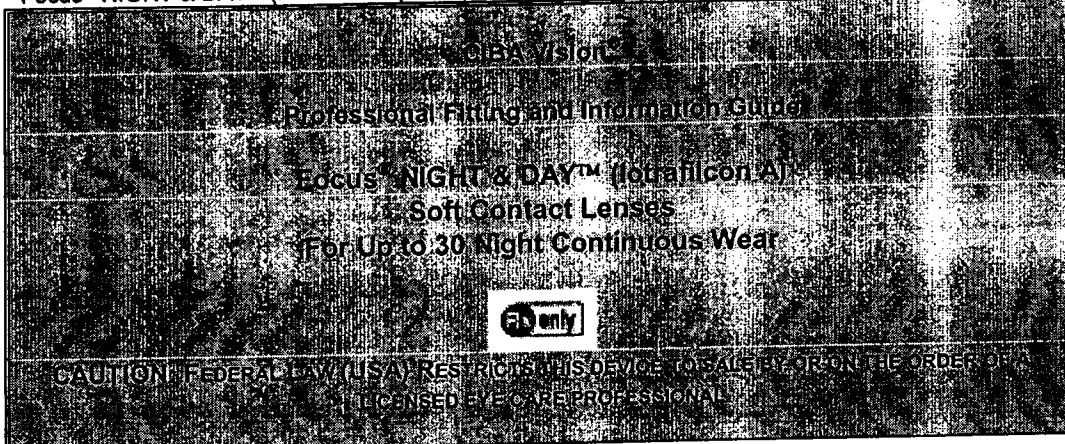


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INTRODUCTION

Thank you for prescribing Focus® NIGHT & DAY™ (lotrafilcon A) soft contact lenses. Focus NIGHT & DAY lenses allow you, the eye care professional, to offer your patients the comfort and convenience of extended wear lenses that can be worn for up to 30 nights of continuous wear.

Fitting Focus® NIGHT & DAY™ contact lenses is easy and predictable. This guide contains important information regarding fitting procedures and aftercare of the NIGHT & DAY™ patient.

Focus® NIGHT & DAY™ (lotrafilcon A) Soft Contact Lenses are available in spherical, toric and multifocal lens designs. The lens material is approximately 24% water and 76% lotrafilcon A, a fluoro-silicone containing hydrogel. This breakthrough lens material provides a high level of oxygen to the eyes and has been surface treated to wet with the tears.

Focus® is a registered trademark of CIBA Vision®, a Novartis Company.

• Lens Properties

- Specific Gravity: 1.08
- Refractive Index (hydrated): 1.43
- Light Transmittance: $\geq 99\%$
- Oxygen Permeability (Dk): 140×10^{-11} (cm²/sec)(ml O₂/ml x mm Hg), measured at 35° C (intrinsic Dk - Coulometric method)
- Water Content: 24% by weight in normal saline

• Available Lens Parameters

Focus® NIGHT & DAY™ (spherical)

- Chord Diameter Available: 13.8 mm
- Center Thickness: 0.080 mm @ -3.00D (varies with power)
- Base Curve Available: 8.4mm, 8.6 mm
- Powers Available: [-0.25D to -8.00D (0.25D steps); -8.50D to -10.00D (0.50D steps); +0.25D to +6.00D (0.25D steps)]

Focus® NIGHT & DAY™ TORIC

- Chord Diameter Available: 14.2 mm
- Center Thickness: 0.080 mm @ -3.00D (varies with power)
- Base Curve Available: 8.8 mm
- Powers Available: -0.25D to -8.00D (0.25D steps); -8.50D to -10.00D (0.50D steps); +0.25D to +6.00D (0.25D steps)
-1.00, -1.75, -2.50 cylinder, Full circle (10° steps)

Focus® NIGHT & DAY™ PROGRESSIVES

- Chord Diameter Available: 13.8 mm
- Center Thickness: 0.080 mm @ -3.00D (varies with power)
- Base Curve Available: 8.6 mm, 8.9 mm
- Powers Available: -0.25D to -9.00D (0.25D steps)
+0.25D to +8.00D (0.25D steps)
Single progressive add. Effective range up to 3.00D

NOTE: Hereafter, Focus® NIGHT & DAY™, Focus® NIGHT & DAY™ TORIC, and Focus® NIGHT & DAY™ PROGRESSIVES will be referred to as Focus® NIGHT & DAY™ unless product distinction is necessary.

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- **Actions**

When hydrated and placed on the cornea, Focus® NIGHT & DAY™ (Itrafilcon A) contact lenses act as a refracting medium to focus light rays on the retina.

INDICATIONS (USES)

- Focus® NIGHT & DAY™ (Itrafilcon A) soft contact lenses are indicated for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes with up to approximately 1.50 diopters of astigmatism.
- Focus® NIGHT & DAY™ TORIC (Itrafilcon A) soft contact lenses are indicated for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes with 6.00 diopters (D) or less of astigmatism.
- Focus® NIGHT & DAY™ PROGRESSIVES (Itrafilcon A) soft contact lenses are indicated for the optical correction of refractive ametropia (myopia and hyperopia) and/or presbyopia in phakic or aphakic persons with non-diseased eyes who may require a reading addition of +3.00 diopters (D) or less and who may have up to approximately 1.50 diopters of astigmatism.
- The lenses may be prescribed for daily wear or extended wear for up to 30 nights of continuous wear, with removal for disposal, or cleaning and disinfection prior to reinsertion, as recommended by the eye care professional.

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

CONTRAINDICATIONS, WARNINGS, PRECAUTIONS & ADVERSE REACTIONS

For additional important prescribing and safety information, refer to the Package Insert that is printed in the back of this guide. The package insert includes a summary of results of the U.S. Safety and Effectiveness Clinical Study.

ADVERSE EFFECT REPORTING

If a patient experiences any serious adverse effects associated with the use of NIGHT & DAY™ (Itrafilcon A) contact lenses, please notify CIBA Vision Corporation, **Technical Consultation in the USA at 1-800-241-7468.**

FITTING GUIDELINES

Please see the appropriate sections of this booklet that contain fitting guidelines for spherical, toric and multifocal lenses:

- Spherical Fitting Guidelines
- Toric Fitting Guidelines
- Progressives Fitting Guidelines
- Monovision Fitting Guidelines

Spherical Fitting Guidelines

1. Patient Selection

The patient characteristics necessary to achieve success with NIGHT & DAY™ lenses are similar to those for other spherical soft contact lenses. A thorough pre-fitting examination should be conducted to ensure the patient is a suitable candidate for soft contact lens wear.

While NIGHT & DAY™ lenses are indicated for up to 30 nights of continuous wear, your patients should be told to follow some basic safety precautions. Patients should check their eyes every day to make sure they are comfortable and free of redness or irritation, and that their vision is clear. The *Patient Instruction Booklet* contains a list of problem symptoms and patients should be instructed to contact you if a problem persists.

The following procedures should be followed when fitting Focus® NIGHT & DAY™ lenses. For additional tips on fitting the monovision patient refer to the section *Monovision Fitting Guidelines*.

2. Pre-fitting Examination

A pre-fitting examination is necessary to:

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

A pre-fitting examination should include:

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

3. Trial Lens Evaluation

A. Lens Base Curve Selection:

A well-fitted lens provided good movement, centration and comfort. This can be achieved for the majority of patients with the 8.6 mm base curve.

B. Initial Lens Power Selection

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

Spherical Equivalent Calculation

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

$$\text{Spherical Equivalent} = \text{Sphere power} + 1/2 (\text{Cylinder Power})$$

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

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Vertex Distance Conversion

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

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

C. Lens Fit Assessment

Allow the lenses to settle on the eyes for approximately **15 minutes**. This allows time for the patient to adapt to the lenses and time for the lens to equilibrate.

Evaluate the fit and movement of the lenses on the eye. The **Push-Up Test**, as described below, is an important part of the lens evaluation. The following guidelines will be helpful in fit evaluation:

Characteristics of a Well-Fitted Lens

A well-fitted NIGHT & DAY™ (lotrafilcon A) contact lens satisfies the following criteria:

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

Characteristics of a Tight (Steep) Lens Fit

A tight or steep fit should not be dispensed. If a lens fit is judged to be too steep a flatter lens (larger base curve), if available, should be evaluated. A tight or steep lens fit would display some or all of the following characteristics:

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

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Characteristics of a Loose (Flat) Lens Fit

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

1. **Lens edge standoff.** Even minor lifting of the edge indicates a loose fitting lens.

Focus® NIGHT & DAY™ (lotrafilcon A) for Up to 30 Night Extended Wear, spherical, Toric, Progressives

2. Reduced comfort. This finding is often the only signal of a loose fitting lens. If initial comfort doesn't improve quickly, try a steeper base curve, if available.
3. Excessive lens movement during the blink in primary or upgaze.
A loose fitting lens will move very easily, well beyond the limbus and possibly encroaching upon or going beyond the pupil. It will then return very quickly to its original position and often times return lower than its original position.
4. Poor centration with limbal exposure on exaggerated eye movement.
5. Vision may be blurred after the blink.

General Fitting Tips

- Trial fitting of the individual eye is strongly recommended.
- A well fitting lens will show movement of 0.1 to 0.5 mm.
- When prescribing Focus® NIGHT & DAY™ lenses for **extended wear**, it is important to **reevaluate** the lens fit for adequate movement at various times after the patient sleeps while wearing lenses. This reevaluation should include a follow-up visit as soon as possible after the patient awakens from sleeping, as well as at other times of the day. If the fit is judged to be too tight or steep, the patient must be refit into a lens that provides the criteria of a well-fitted lens.

D. Final Lens Power Determination

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

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

TORIC Fitting Guidelines

The Focus NIGHT & DAY Toric lens is similar to the thin zone design used for CIBA Vision's Torisoft (tefilcon) lenses. This double slab-off design uses a toric geometry on one surface of the lens and spherical on the opposite. Stabilization is achieved by thin zones at the top and bottom of the lens (double slab-off) on the front surface (dynamic stabilization) and with power parameters on the back surface. Each zone is a half-moon shaped segment, one with its center at the 12 o'clock position, the other at the 6 o'clock position.

To aid the fitting process, Focus NIGHT & DAY Toric lenses feature scribe lines on the front lens surface to enable assessment of the lens orientation. These lines are at the 3 o'clock, 6 o'clock and 9 o'clock positions approximately 1.0mm in from the lens edge. The lens orientation findings are then used for calculation of axis compensations.

1. Patient Selection

The patient characteristics necessary to achieve success with NIGHT & DAY™ TORIC lenses are similar to those for spherical lenses. A thorough pre-fitting examination should be conducted to ensure the patient is a suitable candidate for soft contact lens wear.

While NIGHT & DAY™ lenses are indicated for up to 30 nights of continuous wear, your patients should be told to follow some basic safety precautions. Patients should check their eyes every day to make sure they are comfortable and free of redness or irritation, and that their vision is clear. The *Patient Instruction Booklet* contains a list of problem symptoms and patients should be instructed to contact you if a problem persists.

The following procedures should be followed when fitting Focus® NIGHT & DAY™ TORIC lenses. For additional tips on fitting the monovision patient refer to the section *Monovision Fitting Guidelines*.

2. Pre-fitting Examination

A pre-fitting examination is necessary to:

- determine whether a patient is a suitable candidate for contact lenses in general (see package insert, **Indications and Contraindications**).
- determine whether a patient is astigmatic to a degree requiring a toric visual correction
- make ocular measurements for initial contact lens parameter selection
- collect baseline clinical information to which post-fitting examination results can be compared

A pre-fitting examination should include:

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

3. Fitting Methods

The following method is recommended for fitting Focus NIGHT & DAY Toric lenses to maximize success. This method allows for an extended trial period outside the office which will help the eye care professional to minimize chair time, reduce trial lens usage and

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Focus® NIGHT & DAY™ (Iotraficon A) for Up to 30 Night Extended Wear, spherical, Toric, Progressives inventories, as well as increase the accuracy of final lens orientation and the final multipack prescription.

Trial Period Method

- a) Make initial base curve selection.
- b) Determine the appropriate sphere and cylinder power.
- c) Select cylinder axis based on spectacle prescription - assume no rotation.
- d) Place trial lens on the eye. Order trial lens if it is not in office inventory - having the correct lens allows the patient to experience good vision during the trial period.
- e) Evaluate fit, vision, and lens orientation.
- f) Dispense lens if characteristics of a **Well-Fitted Lens** are satisfied.
- g) Reevaluate fit, vision, and lens orientation at the end of the trial period (typically a few days to a week).**
- h) Order multipack after fitting adjustments, if any, are made to satisfy the characteristics of a **Well-Fitted Lens**.

The following alternatives are offered to describe the more traditional methods of fitting lenses. While these methods are adequate to use, they can lead to an increase in chair time, trial lens usage, and multipack purchases as the fit and vision of the lens are refined.

Empirical Method

- a) Make initial base curve selection.
- b) Determine the appropriate sphere and cylinder.
- c) Select the cylinder axis assuming zero rotation.
- d) Order multipack.
- e) Evaluate fit, vision, and lens orientation.
- f) Dispense lens if characteristics of a **Well-Fitted Lens** are satisfied.
- g) Reorder multipacks if adjustments are made.

In Office Trial Lens Fitting Method

- a) Make base curve selection.
- b) Select diagnostic lens with similar sphere, cylinder power and axis as spectacle Rx.
- c) Evaluate fit, vision, over-refraction, and lens orientation.
- d) Order multipack if characteristics of a **Well-Fitted Lens** are satisfied.
- e) Reorder multipack if further adjustments are necessary.

NOTE: For information on fitting the monovision wearer with toric lenses, please refer to the monovision fitting guidelines.

4. Initial Base Curve Selection

- A **Well-Fitted Lens** provides **good movement, centration, and comfort**. This can be achieved for the majority of patients by beginning with the Focus® NIGHT & DAY Toric 8.8 mm base curve.
- If keratometry readings indicate that the central cornea is unusually flat, the eye care professional may wish to exercise clinical judgment and start with a flatter base curve, if available.

5. Initial Lens Power Selection

Spherical Lens Power:

- To determine the initial lens spherical power, use the spherical component of the spectacle Rx in minus cylinder form.
- If this spherical component is greater than $\pm 4.00D$, a vertex distance correction is necessary. This will determine the spherical lens power required at the corneal plane.

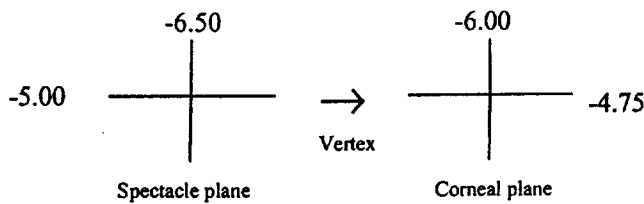
Cylinder Lens Power:

Three cylinder powers are available for Focus NIGHT & DAY Toric contact lenses. These three powers will normally allow correction of -0.75 to -3.00 diopters of astigmatism.

Select Focus NIGHT & DAY Toric cylinder power according to the chart below:

Refraction Cylinder Power	Focus NIGHT & DAY Toric Cylinder Power
-0.75	-1.00
-1.00	-1.00
-1.25	-1.00
-1.50	-1.00 or -1.75
-1.75	-1.75
-2.00	-1.75
-2.25	-1.75
-2.50	-2.50
-2.75	-2.50
-3.00	-2.50

- Note:** If the combination of sphere power and cylinder power is greater than $+4.00D$, vertex distance compensation must be performed for each power meridian.



Example: Spectacle Rx: $-5.00D - 1.50 \times 180$ (vertex distance = 12 mm)
 Corneal Plane Rx: $-4.75 - 1.25 \times 180$
 Focus Toric Rx: $-4.75 - 1.00 \times 180$ (assuming no rotation)

- When the difference between the cylinder correction at the corneal plane and the selected cylinder to fit the patient differs by $0.50D$ or more, it is necessary to make a compensation to the spherical component using the following formula:

$$\frac{\text{Corneal plane cylinder} - \text{Selected cylinder}}{2} = \text{Spherical Compensation}$$

Example: Spectacle Rx: $-4.50 - 2.50 \times 180$
 Corneal Plane Rx: $-4.25 - 2.25 \times 180$
 Selected cylinder power: $-1.75D$
 Spherical equivalent = $-4.25 - (-1.75) / 2 = -1.25$
 Focus Toric: $-4.50 - 1.75 \times 180$ (assuming no rotation)

6. Lens Fit Evaluation

- Allow the lenses to settle on the eyes for approximately **30 minutes**. This allows time for the patient to adapt to the lenses and time for the lens to equilibrate with the patient's tears, replacing the buffered, isotonic saline which was in the foil pack.
- Evaluate the fit of the lenses on the eye. Focus NIGHT & DAY Toric, like other relatively thin, high water content lenses, drape over the cornea more and exhibit less movement

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Focus® NIGHT & DAY™ (lotrafilcon A) for Up to 30 Night Extended Wear, spherical, Toric, Progressives compared to thicker, low water lenses. Therefore, the **Push-Up Test**, as described below is an important part of the lens evaluation. The following guidelines will be helpful in fit evaluation:

Characteristics of a Well-Fitted Lens

A well-fitted Focus NIGHT & DAY Toric (vifilcon A) contact lens satisfies the following criteria:

1. Full corneal coverage and good centration (no limbal exposure).
2. Sufficient lens movement to allow tear exchange under the lens during blink in primary or upgaze

Push-Up Test:

- This test is a reliable indicator of a good fit. With the patient looking straight ahead, place your index finger on the patient's lower lid and nudge the edge of the lens upward while observing lens movement. Then pull the lid back down and observe the return of the lens.
 - A well fitted lens will move freely upward, stopping shortly after passing the limbus and then return freely to its original position.
3. Good comfort.
 4. Acceptable visual acuity with over-refraction.

Characteristics of a Tight (Steep) Lens Fit

A tight or steep fit should not be dispensed. If a lens fit is judged to be too steep a flatter lens (larger base curve), if available, should be evaluated. A tight or steep lens fit would display some or all of the following characteristics:

1. Good centration.
2. Insufficient or no lens movement during a blink in primary or upgaze.

Push-Up Test:

- A tight fitting lens will resist movement. If successfully nudged upward, the lens may remain decentered or return slowly to its original position.
3. Good comfort.
 4. Blurred vision between blinks.

Characteristics of a Loose (Flat) Lens Fit

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

1. Decentration.
2. Excessive lens movement during a blink in primary or upgaze.

Push-Up Test:

- A loose fitting lens will move very easily, well beyond the limbus and possibly encroaching upon or going beyond the pupil. It will then return very quickly to its original position and often times return lower than its original position.
3. Reduced comfort.
 4. Lens edge standoff.
 5. Blurred vision immediately after the blink.
- If you are prescribing Focus NIGHT & DAY Toric for **extended wear**, it is important to **reevaluate** the lens fit for adequate movement at various times after the patient sleeps while wearing lenses. This reevaluation should include a follow-up visit as soon as possible after the patient awakens from sleeping, as well as at other times of the day. If the fit is

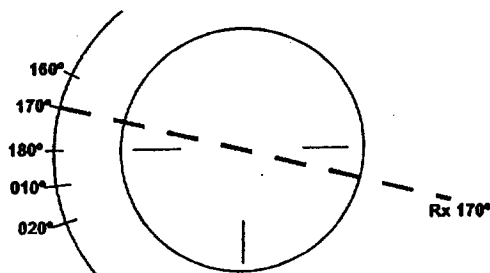
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Focus® NIGHT & DAY™ (Iotraficon A) for Up to 30 Night Extended Wear, spherical, Toric, Progressives
 judged to be too tight or steep, the patient must be refit into a lens that meets the criteria of a well-fitted lens.

5. Initial Lens Orientation Evaluation

A. No Rotation

When the scribe lines orient horizontally, the cylinder axis of the lens that is dispensed or ordered should be the same as the spectacle refractive axis - not the trial lens axis.



Contact lens cylinder axis = Spectacle refractive axis

B. Clockwise Rotation

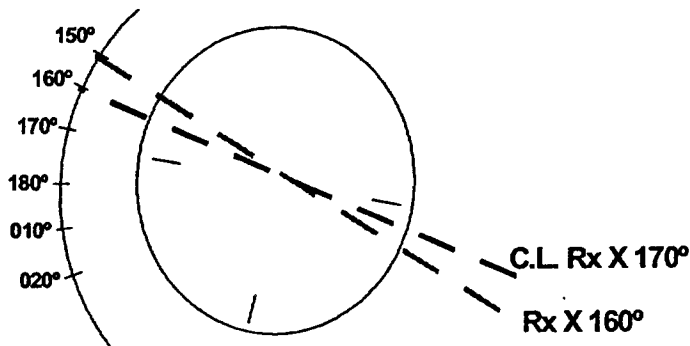
When the scribe lines rotate clockwise as observed looking at the patient, (i.e., temporally for the right eye, nasally for the left eye), add the degree of rotation to the spectacle refractive axis - not the trial lens axis.

Example:

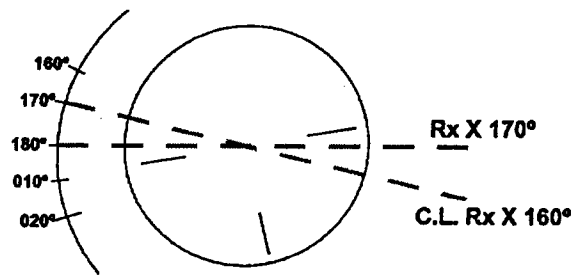
Spectacle Rx:	-2.50 -1.75 x 160
Diagnostic lens:	-2.00 -1.75 x 170
Over-refraction:	-0.50 sphere
Orientation:	10 degrees clockwise (add) (160 + 10)
Final Power to order:	-2.50 -1.75 x 170

C. Counterclockwise Rotation

When the scribe lines rotate counterclockwise, subtract the degree of rotation from the spectacle refractive axis - not the trial lens axis.



Spectacle refractive axis + Trial lens rotation = Axis to order



Spectacle refractive axis - Trial lens rotation = Axis of lens to order

- Example:**
 Spectacle Rx: +2.75 -1.00 x 170
 Diagnostic lens: +2.00 -1.00 x 180
 Over-refraction: +0.75 sphere
 Orientation: 10 degrees counterclockwise (subtract)
 Final Power to Order: +2.75 -1.00 x 160

NOTE: Occasionally when a cylinder axis compensation is made for orientation, the result may fall outside the traditional range of 0 - 180 degrees. In this case, the axis in accepted notation will be the difference between the absolute value determined and 180 degrees.

Example 1:

Spectacle Rx cylinder: x 170
 Orientation: 20 degrees clockwise
 Axis calculation: $170 + 20 = 190$
 (The 190 degrees is outside the traditional axis range)
 Difference: $190 - 180 = 10$
 Axis to order: x 010

Example 2:

Spectacle Rx: x 020
 Orientation: 30 degrees counterclockwise
 Axis calculation: $20 - 30 = -10$
 (The -10 degrees is outside the traditional axis range)
 Difference: $180 - 10 = 170$
 Axis to order: x 170

- NOTE:** Scribe marks on dispensed lenses must be at the same orientation as the trial lenses. Record rotation compensation as part of the final Rx.

D. Scribe Lines

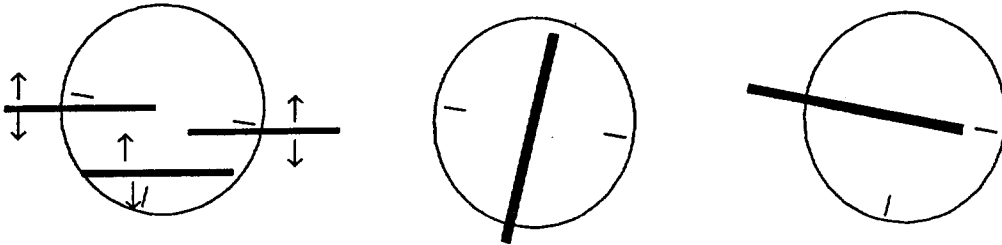
To view the scribe lines, the following tips may be helpful:

- The first step is to narrow the slit lamp beam to approximately 0.5 mm in a horizontal orientation. Focus the beam on the lens surface at the 6:00 position.
- Slowly move the beam in an up and down fashion. As the beam passes near and through the scribe mark it will be easy to see in retro illumination.

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- Once the scribe line is located, rotate the light beam so it is parallel to the scribe mark and measure the amount of lens rotation.
- Depending on the diameter of the cornea the 6 o'clock scribe mark may be in the limbal area, in which case the 3 or 9 o'clock position may be easier to view.
- If the 3 or 9 o'clock scribe mark is used, follow the same procedure of rotating the light beam so that it is parallel to the scribe mark, and measure the degree of lens rotation.



6. Initial Visual Evaluation

The visual result is evaluated by first performing a spherical over-refraction and then measuring visual acuity. If visual acuity is acceptable, the determination of lens power required after the over-refraction will be uncomplicated.

Example:

Diagnostic Lens: -2.00 -1.75 x 180
Over-refraction: -0.50 sphere
Final Power to Order: -2.50 -1.75 x _____*

If the spherical over-refraction does not yield acceptable vision proceed to perform a spherocylindrical over-refraction. For the resultant lens power to order from this over-refraction call Technical Consultation in the U.S.A. at 1-800-241-7468, or in Canada at 1-800-268-3968.

*Determination of final cylinder axis to order will be made after compensation for lens orientation.

PROGRESSIVES Fitting Guidelines

The Focus NIGHT & DAY PROGRESSIVES (Iotrafilcon A) soft contact lens is a progressive aspheric simultaneous vision soft contact lens. In designing Progressives, CIBA Vision has incorporated a constant near power profile into each lens across the full range of distance powers. This has greatly simplified the fitting procedure by eliminating add powers as a separate variable. For each lens the near and intermediate powers are concentrated primarily in the central portion of the optical zone while the surrounding portion is weighted towards distance. The continuous changes in power across the surface of the lens allow patients requiring a reading addition of up to + 3.00 D to see clearly at far, intermediate, and near distances.

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

1. Pre-fitting Examination

A pre-fitting examination is necessary to:

- determine whether a patient is a suitable candidate for Focus Progressives contact lenses
- make ocular measurements for initial contact lens parameter selection
- collect baseline clinical information to which post-fitting examination results can be compared

A pre-fitting examination should include:

- a thorough case history
- detailed assessment of patient's individual visual demands
- understanding of patient's objectives for lens wear and expectations
- a distance spherocylindrical refraction, near add determination and measurement of pupil diameter
- keratometry
- tear assessment
- biomicroscopy

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

2. Patient Selection

Several factors should be weighed by the practitioner when considering patient selection for a Focus NIGHT & DAY Progressives (Iotrafilcon A) soft contact lens fitting. When fitting a lens intended to correct for presbyopia, it is especially important to evaluate the particular visual needs, objectives, lifestyle and expectations of the individual patient. Prospective candidates may include current contact lens wearers, former wearers, and persons with no previous wear history. For former wearers it is important to determine the cause for discontinuation. Good success has been achieved with Focus NIGHT & DAY Progressives in all three wearing groups.

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

While candidates with greater than 1.00 diopter of refractive error have often been thought of as better candidates than those with low error or emmetropia, this is a generalization that often does not hold true for a given individual. Success is influenced by many factors and the eye care professional

Focus® NIGHT & DAY™ (Iotraficon A) for Up to 30 Night Extended Wear, spherical, Toric, Progressives is encouraged to offer Focus NIGHT & DAY Progressives to all interested presbyopic patients who satisfy the standard requirements for soft contact lens wear.

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

Ideal Candidates

- Refractive cylinder ≤ 1.00 D.
- Near add $> +0.75$ D.
- Attainable visual demands that do not depend upon resolving very fine (smaller than 20/20 letters) details at *both* distance and near for extended periods.
- Emphasis on tasks where it is advantageous to have objects simultaneously in focus over a large range of viewing distances.
- Expectations consistent with actual everyday visual demands.
- Motivated to wear lenses and understands that vision may not *always* be as sharp as with spectacles for some distances or lighting conditions.
- Unable to adapt to monovision correction.

Less than Ideal Candidates

- Critical or very fine visual demands at both distance and near.
- Emerging presbyope with plano or very low distance powers.
- Refractive cylinder ≥ 1.50 D (any axis) in one or both eyes or against-the-rule refractive cylinder > 1.00 D 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 (< -1.50 D) and has not been habitually corrected.
- Pupil size larger than norm for presbyopic population (> 4 mm) under natural illumination conditions.
- Abnormal binocular sensory function (e.g., amblyopia or strabismus).
- Expectation to discard and never use spectacles again, even for special tasks or viewing conditions.
- Highly satisfied monovision wearers.
- Any other contraindications to successful contact lens wear such as tear abnormality or lid margin disease.

3. Initial Lens Selection

a. Initial Base Curve Selection

Because a stable fit and good centration are important it is best to begin with an 8.6mm base curve in all cases unless keratometry readings indicate that the central cornea is unusually flat. In this case the eye care professional may wish to exercise clinical judgment and start with the flatter base curve (8.9mm).

b. Initial Lens Power Selection

Note: A careful maximum plus spherocylindrical refraction and nearpoint add determination should be conducted prior to selecting a Focus Progressives trial lens. Autorefractometer findings should be refined manually to rule out effects of instrument myopia and ensure proper control of residual accommodation.

The Focus NIGHT & DAY Progressives lens design makes selecting the initial lens power easy. You need only manipulate the distance power. **The optimum starting point is with a power that is more plus or less minus than the vertex corrected spherical equivalent spectacle refraction.** Using the Power Selection Table provided on the following pages will simplify the process of initial lens selection.

Step 1: Convert the spectacle Rx to a spherical equivalent.

$$\text{Spherical Equivalent} = \text{Sphere power} + \frac{1}{2} (\text{Cylinder Power})$$

Step 2: In the Power Selection Table locate the spherical equivalent from step 1 on the vertical axis.

Step 3: Locate the spectacle add power on the horizontal axis.

Step 4: The intersection of these 2 boxes is the initial trial lens power.

Example 1:	Spectacle Rx:	-6.00 -1.00 x 090	Add +1.75
	Spherical equivalent:	-6.50 D	
	Initial trial lens:	-5.00 D	

Focus® NIGHT & DAY Progressives Power Selection Table*

Select the initial power from the table by matching the spherical equivalent spectacle refraction on the vertical scale with the add requirement on the horizontal scale.

* Table values compensated for vertex distance. No vertex conversion necessary.

		ADD			
		1.00 to 1.25	1.50	1.75 to 2.25	2.50 to 3.00
Equivalent Sphere Spectacle Refraction*	0.00	+0.50	+0.75	+1.00	+1.25
	+0.25	+0.75	+1.00	+1.25	+1.50
	+0.50	+1.00	+1.25	+1.50	+1.75
	+0.75	+1.25	+1.50	+1.75	+2.00
	+1.00	+1.50	+1.75	+2.00	+2.25
	+1.25	+1.75	+2.00	+2.25	+2.50
	+1.50	+2.00	+2.25	+2.50	+2.75
	+1.75	+2.25	+2.50	+2.75	+3.00
	+2.00	+2.50	+2.75	+3.00	+3.25
	+2.25	+2.75	+3.00	+3.25	+3.50
	+2.50	+3.00	+3.25	+3.50	+3.75
	+2.75	+3.25	+3.50	+3.75	+4.00
	+3.00	+3.50	+3.75	+4.00	+4.25
	+3.25	+3.75	+4.00	+4.25	+4.50
	+3.50	+4.00	+4.25	+4.50	+4.75
	+3.75	+4.25	+4.50	+4.75	+5.00
	+4.00	+4.75	+5.00	+5.25	+5.50
	+4.25	+5.00	+5.25	+5.50	+5.75
	+4.50	+5.25	+5.50	+5.75	+6.00
	+4.75	+5.50	+5.75	+6.00	+6.25
	+5.00	+5.75	+6.00	+6.25	+6.50
	+5.25	+6.00	+6.25	+6.50	+6.75
	+5.50	+6.25	+6.50	+6.75	+7.00
	+5.75	+6.50	+6.75	+7.00	+7.25
	+6.00	+7.00	+7.25	+7.50	+7.75
	+6.25	+7.25	+7.50	+7.75	+8.00
	+6.50	+7.50	+7.75	+8.00	+8.00
	+6.75	+7.75	+8.00	+8.00	+8.00
+7.00	+8.00	+8.00	+8.00	+8.00	

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* Table values compensated for vertex distance. No vertex conversion necessary.

ADD

	1.00 to 1.25	1.50	1.75 to 2.25	2.50 to 3.00
0.00	+0.50	+0.75	+1.00	+1.25
-0.25	+0.25	+0.50	+0.75	+1.00
-0.50	0.00	+0.25	+0.50	+0.75
-0.75	-0.25	0.00	+0.25	+0.50
-1.00	-0.50	-0.25	0.00	+0.25
-1.25	-0.75	-0.50	-0.25	0.00
-1.50	-1.00	-0.75	-0.50	-0.25
-1.75	-1.25	-1.00	-0.75	-0.50
-2.00	-1.50	-1.25	-1.00	-0.75
-2.25	-1.75	-1.50	-1.25	-1.00
-2.50	-2.00	-1.75	-1.50	-1.25
-2.75	-2.25	-2.00	-1.75	-1.50
-3.00	-2.50	-2.25	-2.00	-1.75
-3.25	-2.75	-2.50	-2.25	-2.00
-3.50	-3.00	-2.75	-2.50	-2.25
-3.75	-3.25	-3.00	-2.75	-2.50
-4.00	-3.50	-3.25	-3.00	-2.75
-4.25	-3.50	-3.25	-3.00	-2.75
-4.50	-3.75	-3.50	-3.25	-3.00
-4.75	-4.00	-3.75	-3.50	-3.25
-5.00	-4.25	-4.00	-3.75	-3.50
-5.25	-4.50	-4.25	-4.00	-3.75
-5.50	-4.75	-4.50	-4.25	-4.00
-5.75	-5.00	-4.75	-4.50	-4.25
-6.00	-5.25	-5.00	-4.75	-4.50
-6.25	-5.25	-5.00	-4.75	-4.50
-6.50	-5.50	-5.25	-5.00	-4.75
-6.75	-5.75	-5.50	-5.25	-5.00
-7.00	-6.00	-5.75	-5.50	-5.25
-7.25	-6.25	-6.00	-5.75	-5.50
-7.50	-6.50	-6.25	-6.00	-5.75
-7.75	-6.75	-6.50	-6.25	-6.00
-8.00	-7.00	-6.75	-6.50	-6.25
-8.25	-7.25	-7.00	-6.75	-6.50
-8.50	-7.25	-7.00	-6.75	-6.50
-8.75	-7.50	-7.25	-7.00	-6.75
-9.00	-7.75	-7.50	-7.25	-7.00
-9.25	-8.00	-7.75	-7.50	-7.25
-9.50	-8.25	-8.00	-7.75	-7.50
-9.75	-8.25	-8.00	-7.75	-7.50
-10.00	-8.50	-8.25	-8.00	-7.75
-10.25	-8.75	-8.50	-8.25	-8.00
-10.50	-8.75	-8.50	-8.25	-8.00
-10.75	-9.00	-8.75	-8.50	-8.25
-11.00	-9.00	-9.00	-8.75	-8.50

Equivalent Sphere Spectacle Refraction*

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As an alternative to the Table, the following simple calculations can be made:

$$\text{Initial Lens Power} = \text{Vertex corrected spherical equivalent} + \frac{1}{2} (\text{Spectacle Add Power})$$

Note: If either plane of the spherocylindrical spectacle Rx is greater than $\pm 4.00\text{D}$, a vertex distance correction is necessary to determine the lens distance power required at the corneal plane (see *Vertex Distance Conversion Chart* in the back of this booklet).

Example 1:

Spectacle Rx:	+4.50 -0.50 x 90 Add +1.50
Spherical equivalent:	+4.25 D
Vertex corrected Rx:	+4.50 D
Initial trial lens:	$+4.50 + \frac{(1.50)}{2} = +5.25 \text{ D}$

Example 2:

Spectacle Rx:	-6.00 -1.00 x 090 Add +2.00
Spherical equivalent:	-6.50D
Vertex corrected Rx:	-6.00D
Initial trial lens:	$-6.00 + \frac{(2.00)}{2} = -5.00 \text{ D}$

NOTE: This is not equivalent to over-correcting the hyperope or under-correcting the myope. The greater plus derives from the unique optical power profile whereby the power changes in a progressive fashion from the center outwards. Failure to follow this guideline is a primary cause of an unsatisfactory visual response.

Initial Lens Fitting Evaluation

- Insert the lenses selected in Step 3. If the exact power is not available, choose the next closest lens power in your trial set.
- Allow the lenses to settle on the eyes for approximately **10 minutes**. This allows time for the patient to adapt to the lenses and time for the lens to equilibrate with the patient's tears.
- Evaluate the fit of the lenses on the eye. Focus (vifilcon A) lenses, like other relatively thin, high water content lenses, drape over the cornea more and exhibit less movement as compared to thicker, low water lenses. Therefore the **Push-Up Test** as described below is an important part of the lens evaluation. The following guidelines will be helpful in evaluating the physical fit of the lens:

Characteristics of a Well-Fitted Lens

A well-fitted Focus NIGHT & DAY Progressives (Iotrafilcon A) contact lens satisfies the following criteria:

1. Full corneal coverage and good centration (no limbal exposure). A lens that is decentered > 1mm, regardless of the direction, is less likely to give adequate vision.
2. Lens movement of 0.3 mm or less should be present to allow tear exchange under the lens during a blink in primary gaze or up-gaze.

Push-Up Test:

- This test is a reliable indicator of a good fit. With the patient looking straight ahead, place your index finger on the patient's lower lid and nudge the edge of the lens upward while observing lens movement. Then pull the lid back down and observe the return of the lens.
 - A well fitted lens will move freely upward, stopping shortly after passing the limbus and then return freely to its original position.
3. Good comfort.
 4. Acceptable visual acuity with over-refraction.

Characteristics of a Tight (Steep) Lens Fit

A tight or steep fit should not be dispensed. If a lens fit is judged to be too steep a flatter lens (larger base curve), if available, should be evaluated. A tight or steep lens fit would display some or all of the following characteristics:

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

Push-Up Test:

- A tight fitting lens will resist movement. If successfully nudged upward, the lens may remain decentered or return slowly to its original position.
4. Good comfort.
 5. Blurred vision between blinks.

Characteristics of a Loose (Flat) Lens Fit

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

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

Push-Up Test:

- A loose fitting lens will move very easily, well beyond the limbus and possibly encroaching upon or going beyond the pupil. It will then return very quickly to its original position and often times return lower than its original position.
3. Reduced comfort.
 4. Lens edge standoff.
 5. Blurred vision immediately after the blink.

When prescribing Focus NIGHT & DAY Progressives lenses for **extended wear**, it is important to **reevaluate** the lens fit for adequate movement at various times after the patient sleeps while wearing lenses. This reevaluation should include a follow-up visit as soon as possible after the patient awakens from sleeping, as well as at other times of the day. If the fit is judged to be too tight or steep, the patient must be refit into a lens that provides the criteria of a well-fitted lens.

5. **Initial Lens Visual Evaluation**

Once an acceptable fit has been achieved, the visual performance of the lenses may be evaluated. Visual acuity is tested first at distance. A spherical over-refraction should be performed using a trial frame or hand held lenses rather than a phoropter. This technique is essential when fitting multifocal lenses because it allows the patient to maintain the head posture and direction of gaze (relationship between eye and head) that he or she would naturally use during everyday tasks. This ensures that the visual performance of the lens is being assessed under conditions where the on-eye positioning matches that which will occur when the lens is being used, for example, for near work activities. In addition, pupil size will not be artificially decreased by the reduction in light associated with looking through the aperture of the phoropter cells, or by proximal cues associated with the nearness of the instrument.

6. **Fitting Procedures**

Step 1. After the trial lenses have settled for 10 minutes, measure distance acuity while the patient is viewing the chart binocularly (i.e., simultaneously with both eyes). Using hand-held trial lenses, add +0.25 D simultaneously to each eye or alternatively one at a time to achieve best distance vision. Note whether or not this reduces the measured binocular distance acuity. If it does not, then there will be some extra tolerance for increasing the amount of plus for one or both eyes in the event that near vision is less than optimal.

Step 2. Evaluate the patient's subjective impression of the near vision when trying to read typical everyday material (e.g., a newspaper, magazine, numbers on a watch). Lighting and reading distance should be what is normal for the patient.

Step 3. Allowing the patient to assume a natural reading position, measure binocular acuity at 40 cm (16 in) under good lighting conditions.

Step 4. The results of steps 2 and 3 will determine whether the patient requires an increment in plus power for nearwork activities. If the subjective quality of near vision is less than optimal, then use hand-held trial lenses to determine whether additional plus power will improve performance at near. Binocular viewing must be maintained throughout this assessment.

Improved vision at near may be achieved by adding plus power to one or both eyes. If the testing performed in Step 1 indicated some tolerance for plus, determine whether the additional plus power for each eye will produce the necessary improvement in near vision.

If the patient cannot tolerate additional plus power for each eye when viewing at distance, or if this does not produce the required improvement in near vision, then try adding plus power to just one eye. Determine which eye will accept the added power for near with the least reduction in distance vision. Important Note: ± 0.25 D may have a significant impact on visual acuity.

Place a plus power hand-held trial lens in front of one eye, and then the other, while the distance refractive error correction is in place for both eyes. Determine whether the patient functions best at *both* distance and near with the extra plus power for the right eye or for the left eye. Although as much as +0.75 D may be added to one eye, visual performance and patient satisfaction with the lenses are more likely to be optimal if the amount of plus power added to one eye is +0.50 D or less.

There are some patients for whom adding a small amount of plus power to improve vision at near will significantly disrupt distance vision. In such cases, success may be achieved with a unioocular (one eye only) Focus NIGHT & DAY Progressive lens (see "Special Fitting Considerations" in the next section).

Step 5: With the final over-refraction in place, evaluate the patient's subjective range of clear vision for tasks requiring near and intermediate viewing distances. Using a near vision acuity chart, ask the patient to find the lowest line he or she can read comfortably (i.e., without a great deal of extra effort). Then direct the patient's attention to letters in the row two lines up (i.e., larger) than the one previously selected. Have the patient slowly move the card closer until the first detectable but definite blur is experienced for these letters. Repeat, this time moving the card slowly further away.

This range of subjectively clear vision should be fairly well balanced about the specific patient's habitual near viewing distance that the patient uses for nearwork tasks in everyday life. If, for example, the patient's typical working distance falls near the extreme of the range of subjectively clear vision, try adding a small amount (i.e., 0.25 to 0.50D) of plus or minus to one or both eyes.

7. Alternate Lens Selection

If an initially fitted lens is too steep, change to the flatter base curve and repeat the power optimization procedure described above.

There are some patients for whom adding a small amount of plus power to improve vision at near will significantly disrupt distance vision. In such cases, success may be achieved with a unioocular (one eye only) Focus NIGHT & DAY Progressives lens (see "Special Fitting Considerations" in the next section).

Special Fitting Considerations

There are circumstances where optimal performance will be achieved by using only *one* Focus NIGHT & DAY Progressives contact lens. Some examples where a unioocular Focus NIGHT & DAY Progressives lens might be recommended are indicated below.

- A patient for whom the standard fitting procedures described above do not result in acceptable vision at *both* distance and near. This might occur with an individual who has very critical (very fine) visual demands at both distance and near, or with an emmetropic patient who is entering presbyopia but has never worn any form of visual correction at either distance or near. Fitting one eye with a Focus NIGHT & DAY Progressives lens and the other eye with a single vision lens (or possibly, no lens) maintains a greater degree of binocular function than would be the case when using two single vision lenses in a monovision format (one eye biased for distance and one eye biased for near).

• Unilateral astigmat:

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

Spectacle Rx

O.D. Plano

O.S. -1.00 -1.00 x 090

Add: +1.50 D

Potential Contact Lens Rx

+0.75 Focus NIGHT & DAY Progressives lens

-1.00 -1.00 x 090 Focus Toric lens

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

Spectacle Rx

O.D. -1.50

O.S. -2.00 -1.75 x 090

Add: +2.00 D

Potential Contact Lens Rx

-0.50 D Focus NIGHT & DAY Progressives lens

-2.00 -1.75 x 090 Focus Toric lens

It is important to understand that in any case where a Focus NIGHT & DAY Progressives lens is worn on only one eye, best results will be obtained where careful assessment and optimization of the fit is carried out.

- a) If the patient is *not* a unilateral astigmat, a choice must be made regarding on which of the two eyes the Focus NIGHT & DAY Progressives lens will be worn. The best way to determine this is to allow the patient to walk around for several minutes while wearing the multifocal lens, for example, on the right eye, and simultaneously on the left eye, the single vision lens (if any) normally predicted from the distance spectacle Rx. Print and various objects should be observed at a variety of distances. After a few minutes, reverse the assignment of lenses to eyes so that the left eye receives the multifocal lens while the right eye receives the single vision lens (if any) that would be normally predicted from the spectacle Rx. If the patient indicates that one of the two trials seemed to result in vision being acceptable over a greater range, or vision that seemed "more natural", then lenses should be assigned to eyes accordingly.

- b) When the particular eye that will wear the Focus NIGHT & DAY Progressives lens has been determined (either from the patient's spectacle Rx if a unilateral astigmat, or from the trials performed above in part a), then additional testing to optimize the power of the lens (if any) selected for each eye should still be performed. Follow Steps 5 through 7 from the procedures detailed previously for optimizing the Focus Progressives lens. It is common that the final lens powers selected may be slightly different (more plus or less minus) for the eye wearing the multifocal lens and/or for the eye wearing the spherical or toric lens than would be predicted from the patient's spectacle Rx.

Dispensing Visit

NIGHT & DAY lenses are supplied in multipack cartons with individual foil-sealed lens containers. Locate the opening flap on the multipack carton and pull up to break the seal.

The lenses are supplied in an easy-to-open foil container designed to maintain sterility of the lens and saline storage solution. To open an individual lens container peel back the lid and carefully remove the lens from its container. (Do not use tweezers or other tools to remove the lens from the package. This could damage the lens.)

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

1. Evaluation of Lens Fit

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

2. Lens Placement and Removal Directions

Instruct the patient on proper lens placement and removal procedures. Patients who are unable to place and remove lenses should not be provided with them.

3. Specific Instructions for Presbyopic Patients

Specific instructions, explanations and demonstrations are important for optimizing patient success with multifocal contact lenses. The following information and instructions have proven useful in advising patients who wear Focus NIGHT & DAY Progressives soft contact lenses.

- a. A contact lens that contains different powers for distance and near involves greater technological and optical complexity than does a bifocal or multifocal spectacle lens. This is because the contact lens moves *with the eye*, rather than having the eye move up and down while the lens remains suspended in a frame. While the contact lens therefore gives an unobstructed field of view and greater freedom regarding *where* to look, these advantages *may* mean that the sharpness of vision *may* not always be exactly the same as what would be experienced with spectacles.
- b. Although many individuals use Focus NIGHT & DAY Progressives contact lenses for full-time wear, it is not unusual to find that there may be some activities where one prefers to wear spectacles, or where the disadvantages associated with spectacles are outweighed by other issues. This is an entirely normal and natural response to the challenges presented by presbyopia.
- c. Situations where vision with multifocal contact lenses may be less sharp or otherwise "different" than what is experienced with spectacles often involve low illumination (e.g., a semi-dark room), reduced visibility (e.g., outdoor conditions of fog or heavy rain), or isolated sources of very bright light (e.g., headlights of an oncoming vehicle on a narrow country road).
- d. Patients should be aware that it might be advisable to refrain from wearing their lenses while driving, flying an airplane or operating heavy machinery under these conditions until they gain some experience with the lenses in a similar visual environment.
- e. Small changes in lens power can often make an enormous difference in the quality of the vision experienced with multifocal contact lenses. Such changes can be best tailored to individual needs only after the lenses have been worn during the tasks and environmental conditions that the patient will personally encounter on a day-to-day basis. Confidence and assurance that such refinements, if needed, can be achieved is important for patient motivation during the initial period of lens wear.

FOLLOW-UP EXAMINATION PROCEDURES

- Prior to a follow-up examination, the contact lenses should be worn for at least four continuous hours.
- Record patient's symptoms, if any. Particular attention should be paid to addressing any specific situations noted by the patient where further improvement of vision performance is desired.
- Measure visual acuity at distance and near with the contact lenses in place.
- Perform an over-refraction as described in the procedures for initial fitting.
- With a biomicroscope, evaluate lens-fitting characteristics and examine the lens surface for deposits.
- Remove the lenses and conduct a thorough biomicroscopic examination with fluorescein.
- Periodically perform keratometry and spectacle refractions. These results should be recorded to compare to the initial measurements.
- If any observations are abnormal, use professional judgment to manage the problem and restore the eye to optimal conditions. If visual requirements or the **Characteristics of a Well-Fitted Lens** are not satisfied during any follow-up examination, the patient should be re-fitted with a more appropriate lens.

SUMMARY OF FITTING PROCEDURE

1. Carefully assess patient's needs and expectations
2. Assess ocular health including adequacy of the lacrimal system
3. Perform a maximum plus spherocylindrical spectacle refraction and determine the spectacle add
4. Select 8.6mm base curve trial lens unless patient has flat corneas or habitually wears a flat base curve in another contact lens
5. Select trial lens power from the Power Selection Table or the vertex corrected "spherical equivalent plus ½ the Add" rule
6. Over-refract to full plus that allows good distance acuity using hand held lenses and trial frame
7. Assess near vision binocularly
8. Fine tune power as necessary
9. Verify physical fit and dispense lenses
10. Explain lens handling and care procedures
11. Perform first follow-up at 3-5 days following dispensing; modify power if necessary based on patient's real-world experience

Patient Selection

A. Monovision Needs Assessment

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

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

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

B. Patient Education

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

Eye Selection

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

A) Ocular Preference Determination Methods

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

B) Refractive Error Method

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

C) Visual Demands Method

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

Example:

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

Special Fitting Considerations

Unilateral Lens Correction

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

Examples:

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

a) Emmetropic in one eye, astigmatic in the other

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

b) Myopic in one eye, astigmatic in the other

	<u>Spectacle Rx</u>	<u>Potential Monovision Rx</u>
O.D.	-1.50	Uncorrected for near
O.S.	-2.00 -1.75 x 090	-2.00 -1.75 x 090 for distance

Amblyopia

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

Astigmatism

Patients with less than 1.50 diopters of astigmatism might be successfully fit in NIGHT & DAY™ spherical lenses.

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

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

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Near Add Determination

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

Trial Lens Fitting

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

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

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

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

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

Adaptation

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

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

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

Other Suggestions

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

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

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

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

The decision to fit a patient with a monovision correction is most appropriately left to the eye care professional in conjunction with the patient after carefully considering the patient's needs. All patients should be supplied with a copy of the **Patient Instruction Booklet**, which contains important instructions for the monovision wearer. You can obtain copies of the instruction book by contacting a customer service representative, in the USA at **(800) 241- 5999**.

LENS DISPENSING EXAMINATION

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

Focus® NIGHT & DAY™ lenses are supplied in sterile in foil sealed blister pack containers. Open the foil pack by peeling back the foil lidding material and gently slide the lens out of the container with your finger.

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

A. Verification Lens Fit

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

B. Hygiene and Lens Handling Instructions

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

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

Prescribe and explain the patient's wearing and replacement schedules.

D. Lens Care Directions (see Package Insert)

Recommend an appropriate cleaning, rinsing, and disinfecting system, and provide the patient with instructions for proper lens care, including the case.

E. Additional Instructions

Review the Package Insert

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

Provide the Patient Instruction Booklet for Night and Day Lenses.

Give the patient a copy of CIBA Vision's **Patient Instruction Booklet** for Focus® NIGHT & DAY™ contact lenses. Review the contents so the patient clearly understands the prescribed lens wear, care, and replacement schedule. You can obtain copies of the instruction book by contacting a customer service representative, in the USA at (800) 241-5999.

FOLLOW-UP EXAMINATIONS

Follow-up care is extremely important for continued successful contact lens wear and for monitoring the patient's ocular response to lens wear. Follow-up care should include:

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

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NOTE: If you have prescribed an **extended wear** schedule, more frequent or additional visits may be necessary to monitor corneal health and to see that the characteristics of a **Well-Fitted Lens** are maintained.

Follow-Up Examination Procedures

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

LENS HANDLING HINTS

Lens Placement

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

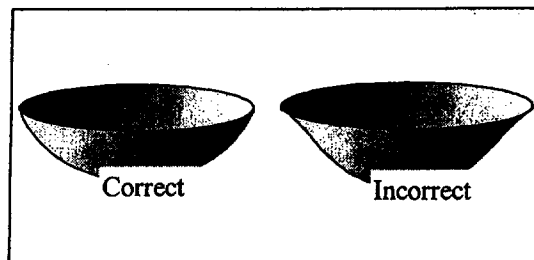
One way to do this is to place the lens between your thumb and index finger and squeeze the edges together gently.

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

Photographs or line drawings of
Method 1
(right side vs wrong side out)

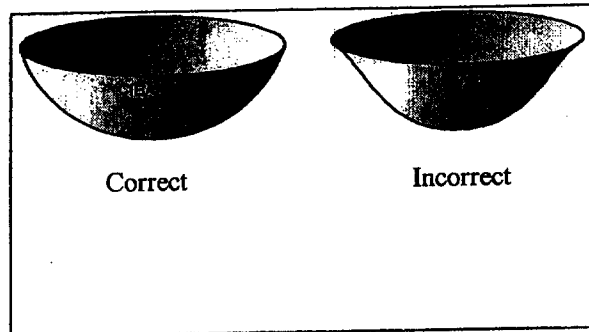
Another way is to place the lens on the tip of your index finger and check its shape.

- If the edge appear bowl-shaped, it is right side out.
- If the edge has a lip or flares outward, it is wrong side out and must be reversed.



A third way to tell if the lens is right side out is to look at the lens engravings at the edge of the lens.

- Place the lens on the tip of your index finger and hold it up against a light source.
- If the lens is right side out, you should be able to read "CIBA" at the edge of the lens. If the lens is inside out, the engravings will be reversed. Carefully turn the lens right side out with your fingers.



- Place the lens directly onto the cornea (placing it on the lower sclera can lead to the lens folding after a blink). While continuing to hold both lids in place, the patient should look down to seat the lens. The lids may then be released.

Lens Removal

- To remove the lens from the cornea, assure that the fingers are clean and dry.
- Slide the lens off the cornea (down or to the side) onto the sclera. This produces a fold in the lens, which assists in removal. With the index finger and thumb, gently pinch the lens off the eye.
- Remember to remove the same lens first (right or left), then the other lens. This helps avoid getting the lenses mixed up.
- It may be easier to remove your contact lenses if you use rewetting drops (approved for use with soft lenses) recommended by your eye care professional 10 to 15 minutes before lens removal. This will also help prevent lens tearing during the removal process.

Care for a Sticking Lens

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

IN OFFICE CARE OF TRIAL LENSES:

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

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

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ADDITIONAL INFORMATION

CIBA Vision is pleased to assist with fitting or clinical questions regarding Focus® NIGHT & DAY™ contact lenses. Eye care professionals having questions or problems should contact the CIBA Vision Technical Consultation department, in the USA at (800) -241-7468. To order Focus®NIGHT & DAY™ contact lenses contact your CIBA Vision sales representative or call Customer Service, in the USA at (800) 241-5999.

Vertex Distance Conversion Chart

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

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

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Focus® NIGHT & DAY™ (lotrafilcon A) for Up to 30 Night Extended Wear, spherical, Toric, Progressives
[Insert Package Insert Here]

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LENS CARE PRODUCT CHART FOR SOFT CONTACT LENSES, AVAILABLE IN THE U.S.A

AOSEPT® Lens Care System

AOSEPT® Disinfectant

Disinfecting solution

AOSEPT® Lens Cup

Lens case for AOSEPT Disinfectant and
AODISC Neutralizer

AODISC® Neutralizer

Neutralizes AOSEPT into a gentle buffered
saline solution

Softwear® Saline

Rinsing and storage

Miraflo® Extra Strength Daily Cleaner

Cleaner

Pure Eyes® Disinfection System

Pure Eyes® Disinfectant/Soaking Solution

Disinfecting solution

Pure Eyes® Cleaner/Rinse

Cleaning and rinsing solution

Pure Eyes® Lens Case/built-in neutralizer

Neutralizes Pure Eyes Disinfectant into a
gentle buffered saline solution

Quick CARE® Care System

Quick CARE® Starting Solution

The Quick CARE System cleans, disinfects,
rinses, and soaks in about 5 minutes

Quick CARE® Finishing Solution

**SOLO-care® brand
Multi-purpose Solution**

Multipurpose solution for cleaning, rinsing,
disinfecting, storing, & protein removal

Other CIBA Vision® Lens Care Products

CIBA Vision® Cleaner

Cleaning

CIBA Vision® Saline

Rinsing

CIBA Vision® Lens Drops

Lubricating

Focus® Lens Drops

Lubricating

CIBA Vision Corporation
11460 Johns Creek Parkway
Duluth, Georgia USA 30097
Part #: [insert part number]

Date: [insert month, year]

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