PACKAGE INSERT

IMPORTANT: 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 the patient instructions that pertain to the patient's prescribed lens.

VISTAKON® (senofilcon A) Contact Lenses (Spherical)
VISTAKON® (senofilcon A) Contact Lenses (Multifocal)
VISTAKON® (senofilcon A) Contact Lenses (Toric)
VISTAKON® (senofilcon A) Contact Lenses (Multifocal-Toric)

Clear and Visibility Tint with UV Blocker
For Daily and Extended Wear

VISTAKON®
DIVISION OF
Johnson & Johnson
Vision Care, Inc.

VISTAKON® (senofilcon A) Contact Lenses (Spherical); VISTAKON® (senofilcon A) Multifocal Contact Lenses; VISTAKON® (senofilcon A) Toric Contact Lenses VISTAKON® (senofilcon A) Multifocal-Toric Contact Lenses; Soft (hydrophilic) Contact Lenses- Clear and Visibility Tinted with UV Blocker for Daily and Extended Wear.

SYMBOLS KEY

The following symbols may appear on the label or carton:

SYMBOL	DEFINITION
	See Instruction Leaflet
	Use By Date (expiration date)
LOT	Batch Code
STERILE	Sterile Using Steam or Dry Heat
DIA	Diameter
BC	Base Curve
D	Diopter (lens power)
CE 0086	Quality System Certification Symbol
	UV Blocking
	Fee Paid for Waste Management
	Peel Back Foil
Rx Only	Caution: Federal law restricts this device to sale by or on the order of a licensed practitioner
C.T.	Center Thickness

	Visibility Tinted Lens Orientation Correct
	Visibility Tinted Lens Inside Out

CYL	Cylinder Power
AXIS	Axis

Spherical Lenses For:
Myopia, Hyperopia, Phakic or Aphakic

Multifocal Lenses For:
Presbyopia, Phakic or Aphakic

Toric Lenses For:
Myopic Astigmatism, Hyperopic Astigmatism, Mixed Astigmatism, Phakic or Aphakic

Multifocal-Toric Lenses For:
Presbyopic Astigmatism , Phakic or Aphakic

CAUTION: Federal U.S.A law restricts this device to sale by or on the order of a licensed practitioner.

DESCRIPTION

The VISTAKON® (senofilcon A) Soft (hydrophilic) Contact Lenses are available as a spherical, Multifocal, Toric or a Multifocal-Toric lens. The lenses are made of a silicone hydrogel material containing an internal wetting agent with or without visibility tinted UV absorbing monomer. The VISTAKON® (senofilcon A) Contact Lens Visibility Tint with UV Blocker is tinted blue using Reactive Blue Dye #4 to make the lenses more visible for handling. A benzotriazole UV absorbing monomer is used to block UV radiation. The transmittance characteristics are less than 1% in the UVB range of 280 nm to 315 nm and less than 10% in the UVA range of 316 nm to 380 nm for the entire power range.

The physical/optical properties of the lens are:

- Specific Gravity (calculated): 0.98 – 1.12
- Refractive Index: 1.42
- Light Transmittance: 85% minimum
- Surface Character: Hydrophilic
- Water Content: 38%
- Oxygen Permeability:

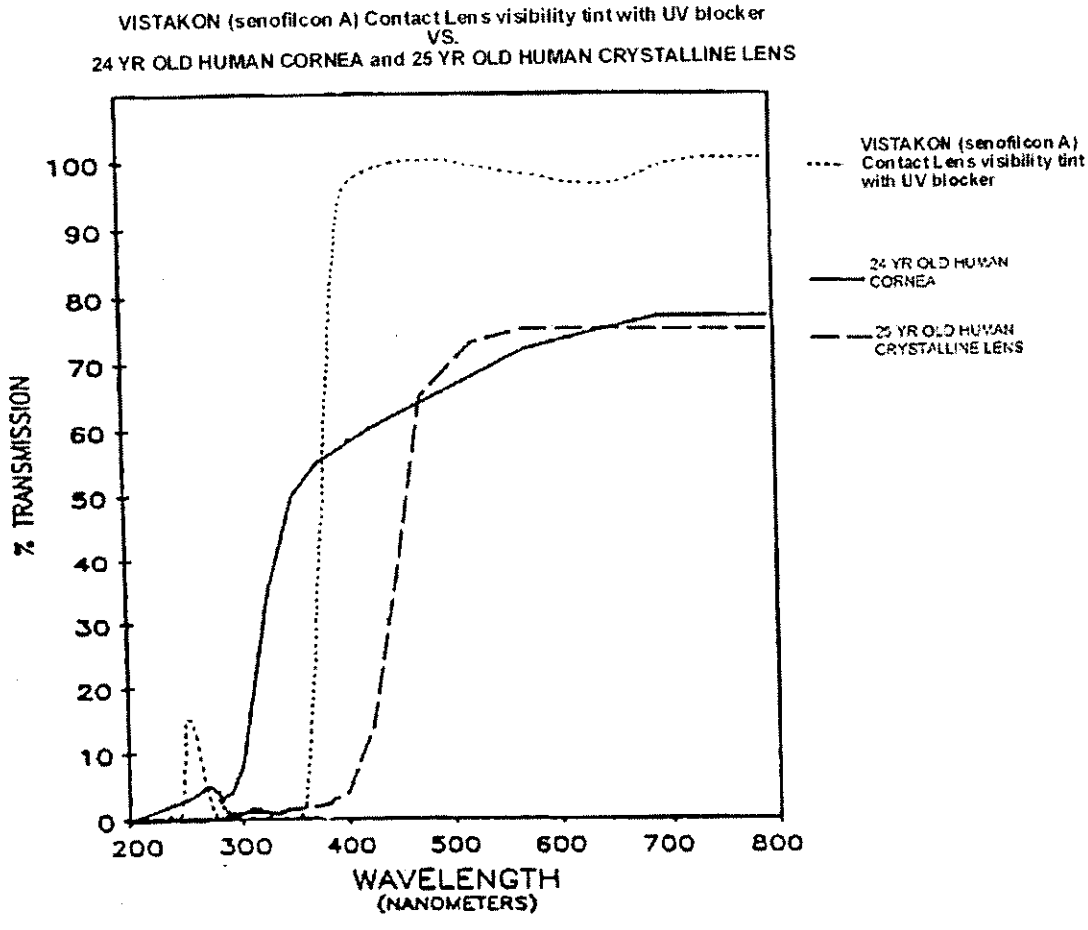
VALUE	METHOD
103×10^{-11} (cm^2/sec) (ml O2/ml x mm Hg) at 35°C	Fatt (boundary corrected, edge corrected)
122×10^{-11} (cm^2/sec) (ml O2/ml x mm Hg) at 35°C	Fatt (boundary corrected, non-edge corrected)

The VISTAKON® (senofilcon A) Contact Lenses are a hemispherical or hemitoric shell of the following dimensions:

Diameter Range:	12.0mm to 15.0mm		
Center Thickness:	Low minus lens – varies with power (e.g., -4.00D: 0.070mm) Plus lens – varies with power (e.g., +4.00D: 0.170mm)		
Base Curve Range:	7.85mm to 10.00mm		
Power Range:	Spherical Power:	Daily Wear	-20.00D to +20.00D
		Extended Wear	-20.00D to +14.00D
	Multifocal ADD Powers:	+0.25D to +4.00D Labeled power = Measured Distance Power +0. 25D	
	Multifocal-Toric ADD Powers:	+0.25D to +4.00D Labeled power = Measured ADD Power -0.50D	
	Cylinder Power:	-0.25D to -10.00D	
	Axis:	2.5 ° to 180 °	

Transmittance Curves

VISTAKON® (senofilcon A) Contact Lens visibility tinted with UV blocker, 24 yr. old human cornea and 25 yr. old human crystalline lens



* The data was obtained from measurements taken through the central 3-5mm portion for the thinnest marketed lens (-1.00D lens, 0.070mm center thickness).

1. Lerman, S., Radiant Energy and the eye, MacMillan, New York, 1980, p.58, figure 2-21
2. Waxler, M. Hitchins, V.M., Optical Radiation and Visual Health, CRC Press, Boca Raton, Florida, 1986, p.10, figure 5

WARNING: UV absorbing contact lenses are NOT substitutes for protective UV absorbing eyewear such as UV absorbing goggles or sunglasses because they do not completely cover the eye and surrounding area. You should continue to use UV absorbing eyewear as directed.

ACTIONS

In its hydrated state, the VISTAKON® (senofilcon A) Contact Lens, when placed on the cornea, acts as a refracting medium to focus light rays on the retina.

The toric lens provides a more even surface over the highly uneven astigmatic cornea and thus helps to focus light rays on the retina.

The transmittance characteristics are less than 1% in the UVB range of 280nm to 315nm and less than 10% in the UVA range of 316nm to 380nm for the entire power range.

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

INDICATIONS (USES)

The VISTAKON® (senofilcon A) Soft Contact Lens (spherical) is indicated for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who have 1.00D or less of astigmatism.

The VISTAKON® (senofilcon A) Multifocal Soft Contact Lens is indicated for the optical correction of distance and near vision in presbyopic, phakic or aphakic persons with non-diseased eyes who may have 0.75D of astigmatism of less.

The VISTAKON® (senofilcon A) Toric Soft Contact Lens is indicated for the optical correction of visual acuity in phakic or aphakic persons with non-diseased eyes that are hyperopic or myopic and may have 10.00D of astigmatism of less.

The VISTAKON® (senofilcon A) Multifocal-Toric Soft Contact Lens is indicated for the optical correction of distance and near in presbyopic phakic or aphakic persons with non-diseased eyes who may have 10.00D of astigmatism of less.

VISTAKON® (senofilcon A) UV Blocking Contact Lenses help protect against transmission of harmful UV radiation to the cornea and into the eye.

Eye Care Professionals may prescribe the lenses either for single-use disposable wear or frequent/planned replacement wear with cleaning, disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lenses may be cleaned and disinfected using a chemical disinfection system only.

VISTAKON® (senofilcon A) Contact Lenses may be prescribed for daily and extended wear for up to 6 nights/7 days of continuous wear. It is recommended that the contact lens wearer first be evaluated on a daily wear schedule. If successful, then a gradual introduction of extended wear can be followed as determined by the prescribing Eye Care Professional.

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE the VISTAKON® (senofilcon A) Contact Lens when any of the following conditions exist:

- Acute or subacute inflammation or infection of the anterior chamber of the eye
- Any eye disease, injury or abnormality that affects the cornea, conjunctiva or eyelids
- Severe insufficiency of lacrimal secretion (dry eye)
- Corneal hypoesthesia (reduced corneal sensitivity
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses
- Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lenses or use of contact lens solutions
- Allergy to any ingredient, such as mercury or Thimerosal, in a solution which is to be used to care for the VISTAKON® Contact Lenses
- Any active corneal infection (bacterial, fungal, protozoal or viral)
- If eyes become red or irritated

WARNINGS

Problems with contact lenses or lens care products could result in serious injury to the eye. Patients should be cautioned that proper use and care of contact lenses and lens care products, including lens cases, are essential for the safe use of these products. Patients should be advised of the following warnings pertaining to contact lens wear:

Eye problems, including corneal ulcers, can develop rapidly and lead to loss of vision. The results of a study[1] indicate the following:

- The overall annual incidence of ulcerative keratitis in daily wear contact lens users is estimated to be about 4.1 per 10,000 persons and about 20.9 per 10,000 persons in extended wear contact lens users.

- The risk of ulcerative keratitis is 4 to 5 times greater for extended wear contact lens users than for daily wear users. When daily wear users who wear their lenses overnight and extended wear users who wear their lenses on a daily basis are excluded from the comparison, the risk among extended wear users is 10 to 15 times greater than among daily wear users.

- When daily wear users wear their lenses overnight (outside the approved indication), the risk of ulcerative keratitis is 9 times greater than among those who do not wear them overnight.

- The overall risk of ulcerative keratitis may be reduced by carefully following directions for lens care, including cleaning the lens case.

- The risk of ulcerative keratitis among contact lens users who smoke is estimated to be 3 to 8 times greater than among non-smokers.

If patients experience eye discomfort, excessive tearing, vision changes, redness of the eye or other problems, they should be instructed to immediately remove their lenses and promptly contact their Eye Care Professional. It is recommended that contact lens wearers see their Eye Care Professional routinely as directed.

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

PRECAUTIONS

Special Precautions for Eye Care Professionals

- Due to the small number of patients enrolled in clinical investigation of lenses, all refractive powers, design configurations or lens parameters available in the lens material are not evaluated in significant numbers. Consequently, when selecting an appropriate lens design and parameters, the Eye Care Professional should consider all characteristics of the lens that can affect lens performance and ocular health, including oxygen permeability, wettability, central and peripheral thickness and optic zone diameter.

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

- **DO NOT** use if the sterile blister package is opened or damaged.

- Patients who wear the VISTAKON® (senofilcon A) Contact Lenses to correct presbyopia using Monovision or patients who use the VISTAKON® Multifocal Contact Lenses or the VISTAKON® Multifocal-Toric 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.

- 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.

- Before leaving the Eye Care Professional's office, the patient should be able to promptly remove lenses or should have someone else available who can remove the lenses for him or her.

- Eye Care Professionals should instruct the patient to remove the lenses immediately if the eyes become red or irritated.

Eye Care Professionals should carefully instruct frequent replacement lens wear patients about the following care regimen and safety precautions:

- Different solutions cannot always be used together and not all solutions are safe for use with all lenses. Use only recommended solutions.
- Never use solutions recommended for conventional hard contact lenses only.
- - Always use fresh, unexpired lens care solutions and lenses.
- Always follow directions in the package inserts for the use of contact lens solutions.
- Use only a chemical (not heat) lens care system. Use of a heat (thermal) care system can damage the VISTAKON® (senofilcon A) Contact Lens.
- Sterile unpreserved solutions, when used, should be discarded after the time specified in the labeling directions.
- Do not use saliva or anything other than the recommended solutions for lubricating or wetting lenses.
- Always keep the lenses completely immersed in the recommended storage solution when the lenses are not being worn (stored). Prolonged periods of drying will reduce the ability of the lens surface to return to a wettable state. Follow the lens care directions in "Care For A Dried Out (Dehydrated) Lens" if lens surface does become dried out.

- If the lens sticks (stops moving) on the eye, follow the recommended directions in "Care for a Sticking Lens". The lens should move freely on the eye for the continued health of the eye. If

non-movement of the lens continues, the patient should be instructed to immediately consult his or her Eye Care Professional.

- Always wash and rinse hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, deodorants or sprays in the eyes or on the lenses. It is best to put on lenses before putting on makeup. Water-based cosmetics are less likely to damage lenses than oil-based products.

- Do not touch contact lenses with the fingers or hands if the hands are not free of foreign materials, as microscopic scratches of the lenses may occur, causing distorted vision and/or injury to the eye.

- Carefully follow the handling, insertion, removal, cleaning, disinfecting, storing and wearing instructions in the "Patient Instruction Guide" for the VISTAKON® Contact Lens and those prescribed by the Eye Care Professional.

- Never wear lenses beyond the period recommended by the Eye Care Professional.

- If aerosol products, such as hair spray, are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.

- Always handle lenses carefully and avoid dropping them.

- Avoid all harmful or irritating vapors and fumes while wearing lenses.

- Ask the Eye Care Professional about wearing lenses during sporting activities, especially swimming and other water sports. Exposing contact lenses to water during swimming or while in a hot tub may increase the risk of eye infection from microorganisms.

- Inform the doctor (Health Care Professional) about being a contact lens wearer.

- Never use tweezers or other tools to remove lenses from the lens container unless specifically indicated for that use. Pour the lens and the packing solution into the hand.

- Do not touch the lens with fingernails.

- Always discard lenses worn on a disposable or frequent replacement schedule after the recommended wearing schedule prescribed by the Eye Care Professional.

- Always contact the Eye Care Professional before using any medicine in the eyes.

- Always inform the employer of being a contact lens wearer. Some jobs may require use of eye protection equipment or may require that the patient not wear contact lenses.

- Certain medications, such as antihistamines, decongestants, diuretics, muscle relaxants, tranquilizers and those for motion sickness, may cause dryness of the eye, increased lens awareness or blurred vision. Should such conditions exist, proper remedial measures should be prescribed. Depending on the severity, this could include the use of lubricating drops that are indicated for use with soft contact lenses or the temporary discontinuance of contact lens wear while such medication is being used.

- Oral contraceptive users could develop visual changes or changes in lens tolerance when using contact lenses. Patients should be cautioned accordingly.

- As with any contact lens, follow-up visits are necessary to assure the continuing health of the patient's eyes. The patient should be instructed as to a recommended follow-up schedule.

ADVERSE REACTIONS

- The patient should be informed that the following problems may occur when wearing contact lenses:

- The eye may burn, sting and/or itch.
- There may be less comfort than when the lens was first placed on the eye.
- There may be a feeling of something in the eye (foreign body, scratched area).
- There may be excessive watering, unusual eye secretions, or redness of the eye.
- Poor visual acuity, blurred vision, rainbows or halos around objects, photo-phobia, or dry eyes may also occur if the lenses are worn continuously or for too long a time.

The patient should be instructed to conduct a simple 3-part self-examination at least once a day. They should ask themselves:

- How do the lenses feel on my eyes?
- How do my eyes look?
- Do I continue to see well?

If the patient reports any problems, he or she should be instructed to IMMEDIATELY REMOVE THE LENS.

If the discomfort or problem stops, the patient should then look closely at the lens.

If the lens is in any way damaged, the patient SHOULD NOT put the lens back on the eye. The patient should discard the lens and apply a new fresh lens on the eye.

If the lens has dirt, an eyelash, or foreign body on it, or the problem stops and the lens appears undamaged, he or she should be instructed to dispose of the lens and apply a new fresh lens.

If the problem continues, the patient SHOULD NOT put the lens back on the eye but IMMEDIATELY CONSULT HIS OR HER EYE CARE PROFESSIONAL.

The patient should be advised that when any of the above symptoms occur, a serious condition such as infection, corneal ulcer, neovascularization or iritis may be present. He or she should be instructed to seek immediate professional identification of the problem and prompt treatment to avoid serious eye damage.

/20.

FITTING

Conventional methods of fitting contact lenses apply to the VISTAKON® (senofilcon A) Contact Lenses. For a detailed description of the fitting techniques, refer to the "VISTAKON® Contact Lenses Fitting and Patient Management Guide", copies of which are available from:

VISTAKON®, Johnson & Johnson Vision Care, Inc.
P.O. Box 10157
Jacksonville, FL 32247-0157
1-800-843-2020

WEARING SCHEDULE

The wearing and replacement schedules should be determined by the Eye Care Professional. Patients tend to over wear the lenses initially. The Eye Care Professional should emphasize the importance of adhering to the initial maximum wearing schedule. Regular checkups, as determined by the Eye Care Professional, are also extremely important.

DAILY WEAR

For Daily Wear, VISTAKON® recommends that the VISTAKON® (senofilcon A) Contact Lenses prescribed for frequent replacement wear be discarded and replaced with a new lens every 2 weeks. However, the Eye Care Professional is encouraged to determine an appropriate lens replacement schedule based upon the response of the patient. When prescribed for disposable wear, the VISTAKON® (senofilcon A) Contact Lens should be discarded upon removal.

The maximum suggested wearing time for these lenses is:

Day	Hours
1	6-8
2	8-10
3	10-12
4	12-14
5 and after	all waking hours

EXTENDED WEAR

The Eye Care Professional should determine the wearing and replacement schedule, based upon the patient's history and their ocular examination, as well as the practitioner's experience and clinical judgment.

VISTAKON® (senofilcon A) Contact Lenses may be prescribed for daily wear and extended wear for up to 6 nights/ 7 days of continuous wear. Not all patients can achieve the maximum wear time. It is recommended that the contact lens wearer first be evaluated on a daily wear schedule. If successful, then a gradual introduction of extended wear can be followed as determined by the prescribing Eye Care Professional.

Once removed, it is recommended that the lens remain out of the eye for a period of rest overnight or longer and discarded in accordance with the prescribed wearing schedule. The Eye Care Professional should examine the patient during the early stages of extended wear.

Lens Care Directions

For VISTAKON® (senofilcon A) Contact Lenses prescribed for disposable wear: The Eye Care Professionals should review with patients that no cleaning or disinfection is needed with disposable lenses. Patients should always dispose of lenses when they are removed and have replacement lenses or spectacles available.

For VISTAKON® (senofilcon A) Contact Lenses prescribed for frequent replacement wear: Eye Care Professionals should review with the patient, lens care directions, including both basic lens care information and specific instructions on the lens care regimen recommended for the patient.

General Lens Care (To First Clean and Rinse, Then Disinfect Lenses)

Basic Instructions

- Always wash, rinse and dry hands before handling contact lenses.
- Always use fresh, **unexpired** lens care solutions.
- Use the recommended system of lens care, chemical (not heat), and carefully follow instructions on solution labeling. Different solutions cannot always be used together and not all solutions are safe for use with all lenses. **Do not alternate or mix lens care systems unless indicated on solution labeling.**
- Do not use saliva or anything other than the recommended solutions for lubricating or rewetting lenses. Do not put lenses in the mouth.
- Lenses should be **cleaned**, **rinsed** and **disinfected** each time they are removed. **Cleaning** and **rinsing** are necessary to remove mucus and film from the lens surface. **Disinfecting** is necessary to destroy harmful germs.
- Always remove, clean, rinse, and disinfect lenses according to the schedule prescribed by the Eye Care Professional. Enzyme as frequently as recommended by the Eye Care Professional. The use of an enzyme or any cleaning solution does not substitute for disinfection.
- Clinical studies were conducted with ReNu® Multi-Plus cleaning and disinfection system.

- Since the lens material contains silicone, the wettability may differ when different lens care products are used. The Eye Care Professional should recommend a care system that is appropriate for the VISTAKON® (senofilcon A) Contact Lenses. Each lens care product contains specific directions for use and important safety information, which should be read and carefully followed.

  Note: Some solutions may have more than one function, which will be indicated on the label. Read the label on the solution bottle, and follow instructions.

- **Clean** one lens first (always the same lens first to avoid mix-ups), rinse the lens thoroughly with recommended saline or disinfecting solution to remove the cleaning solution, mucus and film from the lens surface, and put that lens into the correct chamber of the lens storage case. Repeat the procedure for the second lens.

- After cleaning, **disinfect** lenses using the system recommended by the manufacturer and/or the Eye Care Professional.

- To store lenses disinfect and leave them in the closed/unopened case until ready to wear. If lenses are not to be used immediately following disinfection, the patient should be instructed to consult the package insert or the Eye Care Professional for information on storage of lenses.

- After removing the lenses from the lens case, empty and rinse the lens storage case with solution as recommended by the lens case manufacturer; then allow the lens case to air dry. When the case is used again, refill it with storage solution. Replace lens case at regular intervals as recommended by the lens case manufacturer or your Eye Care Professional.

- Eye Care Professionals may recommend a lubricating/rewetting solution which can be used to wet (lubricate) lenses while they are being worn.

CHEMICAL (NOT HEAT) DISINFECTION OF LENSES WORN ON A FREQUENT REPLACEMENT SCHEDULE

- **Clean** the contact lenses with a recommended cleaning solution and thoroughly rinse them with a recommended rinsing solution.

- **After cleaning,** to disinfect, carefully follow the instructions accompanying the disinfecting solution in the care regimen recommended by the lens manufacturer or the Eye Care Professional.

- When using hydrogen peroxide lens care systems, lenses **must be neutralized before wearing**. Follow the recommendations on the hydrogen peroxide system labeling.

- Thoroughly rinse lenses with a fresh solution recommended for rinsing before applying and wearing, or follow the instructions on the disinfection solution labeling.

- Do not heat the disinfection solution and lenses.

- Leave the lenses in the unopened storage case until ready to put on the eyes.

Caution: Lenses that are chemically disinfected may absorb ingredients from the disinfecting solution which may be irritating to the eyes. A thorough rinse in fresh sterile saline solution prior to placement on the eye should reduce the potential for irritation.

LENS CASE CLEANING AND MAINTENANCE
(Frequent Replacement Lens Wearers Only)

Contact lens cases can be a source of bacteria growth. Lens cases should be emptied, cleaned, rinsed with solutions recommended by the lens case manufacturer and allowed to air dry. Lens cases should be replaced at regular intervals, as recommended by the lens case manufacturer or your Eye Care Professional.

CARE FOR A DRIED OUT (DEHYDRATED) LENS

If the frequent replacement lens is off the eye and exposed to air from 30 minutes to 1 hour or more, its surface will become dry and gradually become non-wetting. If this should occur, discard the lens and use a new one.

CARE FOR A STICKING (NON-MOVING) LENS

If the lens sticks (stops moving), the patient should be instructed to apply a few drops of the recommended lubricating or rewetting solution directly to the eye and wait until the lens begins to move freely on the eye before removing it. If non-movement of the lens continues after a few minutes, the patient should immediately consult the Eye Care Professional.

IN OFFICE USE OF TRIAL LENSES

For fitting and diagnostic purposes, the lenses should be discarded 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 AND IMMEDIATELY CONTACT THE EYE CARE PROFESSIONAL OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.

HOW SUPPLIED

Each sterile lens is supplied in a foil-sealed plastic package containing buffered saline solution with 0.005% methyl ether cellulose. The plastic package is marked with base curve, diopter power, diameter, color (visibility tint noted on visibility tinted product only), lot number and expiration date. [ADD power, cylinder and axis will be included as appropriate].

REPORTING OF ADVERSE REACTIONS

All serious adverse experiences and adverse reactions observed in patients wearing VISTAKON® Contact Lenses or experienced with the lenses should be reported to:

VISTAKON®, Johnson & Johnson Vision Care, Inc.
P.O. Box 10157
Jacksonville, FL 32247-0157
1-800-843-2020
acuvue.com

Revision date xx/xx
Revision number:xx-xx-xx-xx

PATIENT INSTRUCTION GUIDE

DISPOSABLE & FREQUENT REPLACEMENT

VISTAKON® (senofilcon A) Contact Lenses (Spherical)
VISTAKON® (senofilcon A) Contact Lenses (Multifocal)
VISTAKON® (senofilcon A) Contact Lenses (Toric)
VISTAKON® (senofilcon A) Contact Lenses (Multifocal-Toric)

Clear and Visibility Tinted with UV Blocker
For Daily and Extended Wear

VISTAKON®
Division of
Johnson & Johnson
Vision Care, Inc.

PATIENT INSTRUCTION GUIDE
DISPOSABLE & FREQUENT REPLACEMENT

VISTAKON® (senofilcon A) Contact Lenses (Spherical); VISTAKON® (senofilcon A) Multifocal Contact Lenses; VISTAKON® (senofilcon A) Toric Contact Lenses; VISTAKON® (senofilcon A) Multifocal-Toric Contact Lenses; Soft (hydrophilic) Contact Lenses- Clear and Visibility Tinted with UV Blocker for Daily and Extended Wear.

SYMBOLS KEY

The following symbols may appear on the label or carton:

SYMBOL	DEFINITION
	See Instruction Leaflet
	Use By Date (expiration date)
LOT	Batch Code
STERILE	Sterile Using Steam or Dry Heat
DIA	Diameter
BC	Base Curve
D	Diopter (lens power)
CE 0086	Quality System Certification Symbol
	UV Blocking
	Fee Paid for Waste Management
	Peel Back Foil
Rx Only	Caution: Federal law restricts this device to sale by or on the order of a licensed practitioner
C.T.	Center Thickness

O.K.	Visibility Tinted Lens Orientation Correct
	Visibility Tinted Lens Inside Out

CYL	Cylinder Power
AXIS	Axis

Spherical Lenses For:
nearsightedness (myopia) or farsightedness (hyperopia), Phakic or aphakic

Multifocal Lenses For:
Presbyopia, Phakic or aphakic

Toric Lenses For:
Nearsightedness with astigmatism (myopic astigmatism), farsightedness with astigmatism (hyperopic astigmatism) or mixed astigmatism, phakic or aphakic

Multifocal-Toric Lenses For:
Presbyopic Astigmatism , Phakic or aphakic

TABLE OF CONTENTS

CAUTION: Federal U.S.A law restricts this device to sale by or on the order of a licensed practitioner.

INTRODUCTION

In the VISTAKON (senofilcon A) Contact Lenses Clear and with Visibility Tinted and UV Blocker, a UV absorbing monomer is used to block UV radiation. When your prescribed replacement period is over, you simply throw the used lens away and replace it with a new sterile one. By replacing your VISTAKON Contact Lens on a regular basis, lens deposits, which can affect vision and cause irritation and discomfort to the eye, have little chance to build up over time as with conventional lens wear. When you discard the lens, you dispose of potential deposit build-up problems.

The VISTAKON Contact Lenses are soft spherical, aspherical or toric lenses. They are made from a "water-loving" (hydrophilic) material that has the ability to absorb water, making the lens soft and flexible. They differ from other lenses available because of the way they are manufactured. Simply put, the multi-patented manufacturing process that took years to perfect, makes disposable or frequent replacement possible. Since the lenses are produced identically one after another, you will experience the same excellent comfort and vision, lens after lens after lens.

The information and instructions contained in this booklet apply only to the VISTAKON (senofilcon A) Contact Lenses. The VISTAKON (senofilcon A) Contact Lenses are intended to be used for daily and extended wear within the VISTAKON® planned lens replacement system. For your eye health, it is important that the VISTAKON Contact Lenses be worn only as prescribed by your Eye Care Professional. Your Eye Care Professional should be kept fully aware of your medical history. Your Eye Care Professional will tailor a total program of care based on your specific needs. He or she will review with you all instructions for lens handling and care, including how to safely and easily open the packaging. You will also be instructed on how to properly insert and remove lenses. This booklet will reinforce those instructions. After the accumulated wearing period prescribed by your Eye Care Professional, VISTAKON Contact Lenses should be discarded and replaced with a new sterile pair. If you have any questions, always ask your Eye Care Professional.

WEARING RESTRICTIONS AND INDICATIONS

The VISTAKON® (senofilcon A) Soft Contact Lens (spherical) is indicated for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who have 1.00D or less of astigmatism.

The VISTAKON® (senofilcon A) Multifocal Soft Contact Lens is indicated for the optical correction of distance and near vision in presbyopic, phakic or aphakic persons with non-diseased eyes who may have 0.75D of astigmatism of less.

The VISTAKON® (senofilcon A) Toric Soft Contact Lens is indicated for the optical correction of visual acuity in phakic or aphakic persons with non-diseased eyes that are hyperopic or myopic and may have 10.00D of astigmatism of less.

The VISTAKON® (senofilcon A) Multifocal-Toric Soft Contact Lens is indicated for the optical correction of distance and near in presbyopic phakic or aphakic persons with non-diseased eyes who may have 10.00D of astigmatism of less.

VISTAKON® (senofilcon A) UV Blocking Contact Lenses help protect against transmission of harmful UV radiation to the cornea and into the eye.

Your Eye Care Professional may prescribe the lenses either for single-use disposable wear or frequent/planned replacement wear with cleaning, disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, you may clean and disinfect the lenses using a chemical disinfection system only.

VISTAKON® (senofilcon A) Contact Lenses may be prescribed for daily and extended wear for up to 6 nights/ 7 days of continuous wear. . It is recommended that you first be evaluated on a daily wear schedule. If successful, then a gradual introduction of extended wear can be followed as determined by your Eye Care Professional.

***WARNING: UV absorbing contact lenses are not substitutes for protective UV absorbing eyewear such as UV absorbing goggles or sunglasses because they do not completely cover the eye and surrounding area. You should continue to use UV absorbing eyewear as directed.**

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

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE the VISTAKON (senofilcon A) Contact Lens when any of the following conditions exist:

- Inflammation or infection in or around the eye or eyelids
- Any eye disease, injury or abnormality that affects the cornea, conjunctiva or eyelids
- Any previously diagnosed condition that makes contact lens wear uncomfortable.
- Reduced corneal sensitivity (corneal hypoesthesia)
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses
- Allergic reactions of ocular surfaces or surrounding tissues (adnexa) that may be induced or exaggerated by wearing contact lenses or use of contact lens solutions
- Allergy to any ingredient, such as mercury or Thimerosal, in a solution which is to be used to care for the VISTAKON (senofilcon A) Contact Lenses
- Any active corneal infection (bacterial, fungal, protozoal or viral)
- If eyes become red or irritated

WARNINGS

What you should know about Contact Lens Wear

Problems with contact lenses or lens care products could result in serious injury to the eye. Proper use and care of your contact lenses and lens care products, including lens cases, are essential for the safe use of these products. You should be aware of the following **warnings** pertaining to contact lens wear:

Eye problems, including a sore or lesion on the cornea (corneal ulcers)can develop rapidly and lead to loss of vision. The results of a study[1] indicate the following:

> The overall annual incidence of infected corneal ulcers (ulcerative keratitis) in daily wear contact lens users is estimated to be about 4.1 per 10,000 persons and about 20.9 per 10,000 persons in extended wear contact lens users.

- The risk of ulcerative keratitis is 4 to 5 times greater for extended wear contact lens users than for daily wear users. When daily wear users who wear their lenses overnight and extended wear users who wear their lenses on a daily basis are excluded from the comparison, the risk among extended wear users is 10 to 15 times greater than among daily wear users.

- When daily wear users wear their lenses overnight (outside the approved indication), the risk of ulcerative keratitis is 9 times greater than among those who do not wear them overnight.

- The overall risk of ulcerative keratitis may be reduced by carefully following directions for lens care, including cleaning the lens case.

- The risk of ulcerative keratitis among contact lens users who smoke is estimated to be 3 to 8 times greater than among non-smokers.

If you experience eye discomfort, excessive tearing, vision changes, redness of the eye or other problems, you should immediately remove your lenses and promptly contact your Eye Care Professional. It is recommended that you see your Eye Care Professional routinely as directed.

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

PRECAUTIONS

- **DO NOT** use if the sterile blister package is opened or damaged.

- If you wear the VISTAKON® (senofilcon A) Contact Lenses to correct presbyopia using Monovision or if you use the VISTAKON® Multifocal Contact Lenses or the VISTAKON® Multifocal-Toric Contact Lenses to correct presbyopia you **may not** achieve the best corrected visual acuity for either far or near vision. Visual requirements vary with the individual and should be considered by your eye care professional in conjunction with you when selecting the most appropriate type of lens for you.

- Before leaving the Eye Care Professional's office, you should be able to promptly remove the lenses or should have someone else available who can remove the lenses for you.

- You should remove your lenses immediately if your eyes become red or irritated.

- Different solutions cannot always be used together, and not all solutions are safe for use with all lenses. Use only recommended solutions.

  - **NEVER** use solutions recommended for conventional hard contact lenses only.
  - **Always** use fresh, unexpired lens care solutions and lenses.
  - **Always** follow directions in the package inserts for the use of contact lens solutions.
  - Use **only** a chemical (not heat) lens care system. Use of heat (thermal) care systems can damage the VISTAKON® Contact Lens.
  - Sterile unpreserved solutions, when used, **should be** discarded after the time specified in the labeling directions.
  - **DO NOT** use saliva or anything other than the recommended solutions for lubricating or wetting lenses.
  - **Always** keep your lenses completely immersed in the recommended storage solution when the lenses are not being worn (stored). Prolonged periods of drying will reduce the ability of the lens surface to return to a wettable state. Follow the lens care directions for "Care For A Dried Out (Dehydrated) Lens" if lens surface does become dried out. If the lens sticks (stops moving) on your eye, follow the recommended directions in "Care for a Sticking Lens". The lens should move freely on your eye for the continued health of your eye. If non-movement of the lens continues, you should immediately consult your Eye Care Professional.

- **Always wash and rinse your hands before handling lenses**. Do not get cosmetics, lotions, soaps, creams, deodorants or sprays in your eyes or on your lenses. It is best to put on your lenses before putting on makeup. Water-based cosmetics are less likely to damage lenses than oil-based products.

- **DO NOT** touch your contact lenses with your fingers or hands if they are not free of foreign materials, as microscopic scratches of the lenses may occur, causing distorted vision and/or injury to your eye.

- **Carefully** follow the handling, insertion, removal and wearing instructions in this booklet and those prescribed by the Eye Care Professional.

- **Never** wear your lenses beyond the period recommended by your Eye Care Professional.
- If aerosol products, such as hair spray, are used while wearing lenses, exercise caution and **keep your eyes closed** until the spray has settled.
- **Always** handle lenses carefully and avoid dropping them.
- **Avoid** all harmful or irritating vapors and fumes while wearing lenses.
- **Ask** your Eye Care Professional about wearing contact lenses during sporting activities, especially swimming and other water sports. Exposing contact lenses to water during swimming or while in a hot tub **may increase the risk of eye infection** from microorganisms.
- **Inform** your doctor (Health Care Professional) about being a contact lens wearer.
- **Never** use tweezers or other tools to remove your lenses from the lens container unless specifically indicated for that use. Pour the lens and the packing solution into the hand.
- **Do not** touch the lens with your fingernails.
- **Always** discard lenses worn as prescribed by your Eye Care Professional.
- **Always** contact your Eye Care Professional before using any medicine in your eyes.
- **Always** inform your employer of being a contact lens wearer. Some jobs may require use of eye protection equipment or may require that you not wear contact lenses.
- **Be aware** that certain medications, such as antihistamines, decongestants, diuretics, muscle relaxants, tranquilizers and those for motion sickness may cause dryness of the eye, increased lens awareness or blurred vision. Always inform your eye care professional if you experience any problems with your lenses while taking such medications. Depending on the severity, your eye care professional may prescribe the use of lubricating drops that are indicated for use with soft contact lenses or the temporary discontinuance of contact lens wear while such medication is being used.
- **Be aware** that if you use oral contraceptives, you could develop visual changes or changes in lens tolerance when using contact lenses.
- As with any contact lens, follow-up visits are <u>necessary</u> to assure the continuing health of your eyes.

ADVERSE REACTIONS (PROBLEMS AND WHAT TO DO)

Be aware that the following problems may occur when wearing contact lenses:

- Your eyes may burn, sting and/or itch.
- There may be less comfort than when the lens was first placed on your eye.
- There may be a feeling of something in your eye (foreign body, scratched area).
- There may be excessive watering, unusual eye secretions or redness of your eye.
- Poor visual acuity, blurred vision, rainbows or halos around objects, sensitivity to light (photophobia) or dry eyes may also occur if your lenses are worn continuously or for too long a time.

You should conduct a simple 3-part self-examination at least once a day.

Ask yourself:
- How do the lenses feel on my eyes?
- How do my eyes look?
- Do I continue to see well?

If you report any problems, you should IMMEDIATELY REMOVE YOUR LENS.

If the discomfort or problem stops, you should look closely at the lens.

If the lens is in any way damaged, you SHOULD NOT put the lens back on your eye. You should discard the lens and insert a new fresh lens on your eye.

If your lens has dirt, an eyelash, or foreign body on it, or the problem stops and the lens appears undamaged, you should dispose of the lens and insert a new fresh lens.

If the problem continues, you SHOULD NOT put the lens back on your eye but IMMEDIATELY CONSULT YOUR EYE CARE PROFESSIONAL.

When any of the above symptoms occur, a serious condition such as infection, corneal ulcer, neovascularization or iritis may be present. **Seek immediate** professional identification of the problem and prompt treatment to avoid serious eye damage.

PERSONAL CLEANLINESS FOR LENS HANDLING AND INSERTION

1. Prepare the Lens for Wearing

It is essential that you learn and use good hygienic methods in the care and handling of your new lenses. Cleanliness is the first and most important aspect of proper contact lens care. In particular, your hands should be clean and free of any foreign substances when you handle your lenses. The procedures are:

- Always wash your hands thoroughly with a mild soap, rinse completely and dry with a lint-free towel before touching your lenses.
- Avoid the use of soaps containing cold cream, lotion, or oily cosmetics before handling your lenses, since these substances may come into contact with the lenses and interfere with successful wearing.
- Handle your lenses with your fingertips, and be careful to avoid contact with fingernails. It is helpful to keep your fingernails short and smooth.

Start off correctly by getting into the habit of always using proper hygienic procedures so that they become automatic.

2. Opening the Multipack and Lens Package

Multipack

Each multipack contains individually packaged lenses. Each lens comes in its own lens package designed specifically to maintain sterility. You may choose to keep your lenses inside the multipack for storage until you are ready to use them.

Lens Package

To open an individual lens package, follow these simple steps:

1. Shake the lens package and check to see that the lens is floating in the solution.
2. Peel back the foil closure to reveal the lens. By stabilizing the lens package on the table-top, you will minimize the possibility of a sudden splash.

Occasionally, a lens may adhere to the inside surface of the foil when opened, or to the plastic package itself. This will not affect the sterility of the lens. It is still perfectly safe to use. Carefully remove and inspect the lens following the handling instructions.

3. Handling the Lenses

- Develop the habit of always working with the same lens first to avoid mix-ups.
- Remove the lens from its storage case and examine it to be sure that it is moist, clean, clear, and free of any nicks or tears. If the lens appears damaged, do not use it. Use the next lens in the multipack.

Verify that the lens is not turned inside out by placing it on your forefinger and checking its profile. The lens should assume a natural, curved, bowl-like shape. If the lens edges tend to point outward, the lens is inside out. Another method is to gently squeeze the lens between the thumb and forefinger. The edges should turn inward. If the lens is inside out, the edges will turn slightly outward.

OR

Place the lens on your forefinger and, looking up at the lens, locate the numbers 123. 1-2-3 indicates correct orientation while a reverse of 1-2-3 indicates the lens is inside out. If the lens is inside out (reverse 1-2-3), invert the lens and locate the numbers again to confirm correct lens orientation.

4. Placing the Lens on the Eye

Remember, start with your right eye.

Once you have opened the lens package, removed and examined the lens, follow these steps to apply the lens to your eye:

1. Place the lens on the tip of your forefinger. BE SURE LENS IS CORRECTLY ORIENTED (see "Handling the Lenses").
2. Place the middle finger of the same hand close to your lower eyelashes and pull down the lower lid.
3. Use the forefinger or middle finger of the other hand to lift the upper lid.
4. Place the lens on the eye.
5. Gently release the lids and blink. The lens will center automatically.
6. Use the same technique when inserting the lens for your left eye.

There are other methods of lens placement. If the above method is difficult for you, your Eye Care Professional will provide you with an alternate method.

Note: If after placement of the lens, your vision is blurred, check for the following:

- The lens is not centered on the eye (see "Centering the Lens", next in this booklet).

- If the lens is centered, remove the lens (see "Removing the Lens" section) and check for the following:

  a. Cosmetics or oils on the lens. Dispose of the lens and insert a new fresh lens.
  b. The lens is on the wrong eye.
  c. The lens is inside out (it would also not be as comfortable as normal).

If you find that your vision is still blurred after checking the above possibilities, remove both lenses and consult your Eye Care Professional.

If a lens becomes less comfortable than when it was first inserted or if it is markedly uncomfortable upon insertion, remove the lens immediately and contact your Eye Care Professional.

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

- How do the lenses feel on my eyes?
- How do my eyes look?
- Do I see well?

If your examination shows any problems, IMMEDIATELY REMOVE YOUR LENSES AND CONTACT YOUR EYE CARE PROFESSIONAL.

5. Centering the Lens

A lens, which is on the cornea, will very rarely be displaced onto the white part of the eye during wear. This, however, can occur if insertion and removal procedures are not performed properly. To center a lens, follow either of these procedures:

a. Close your eyelids and gently massage the lens into place through the closed lids.

OR

b. Gently manipulate the off-centered lens onto the cornea while the eye is opened using finger pressure on the edge of the upper lid or lower lid.

6. Removing the Lens

Always remove the same lens first.

a. Wash, rinse and dry your hands thoroughly.

CAUTION: Always be sure the lens is on the cornea before attempting to remove it. Determine this by covering the other eye. If vision is blurred, the lens is either on the white part of the eye or it is not on the eye at all. To locate the lens, inspect the upper area of the eye by looking down into a mirror while pulling the upper lid up. Then inspect the lower area by pulling the lower lid down.

b. There are two recommended methods of lens removal: the Pinch Method and the Forefinger and Thumb Method. You should follow the method that is recommended by your Eye Care Professional.

Pinch Method:

1. Look up, slide the lens to the lower part of the eye using the forefinger.

2. Gently pinch the lens between the thumb and forefinger.

3. Remove the lens.

Forefinger and Thumb Method:

1. Place your hand or towel under your eye to catch the lens.

2. Place your forefinger on the center of the upper lid and your thumb on the center of the lower lid.

3. Press in and force a blink. The lens should fall onto your hand or the towel.

Once the lens is removed, simply follow the lens care directions recommended by your Eye Care Professional.

Note: The lens may come out, but remain on the eyelid, finger or thumb.

4. Remove the other lens by following the same procedure.

5. Follow the required lens care procedures described under the heading, "Caring For Your Lenses (Cleaning, Rinsing, Disinfecting, Storage and Rewetting/Lubricating)".

Note: If these methods of removing your lens are difficult for you, your Eye Care Professional will provide you with an alternate method.

CARING FOR YOUR LENSES

For Disposable Wear:

Remember, there is no cleaning or disinfection needed with VISTAKON® Contact Lenses prescribed for disposable wear. Always dispose of lenses when they are removed and have replacement lenses or spectacles available.

Your Eye Care Professional may recommend a lubricating/rewetting solution for your use. Lubricating/Rewetting solutions can be used to wet (lubricate) your lenses while you are wearing them.

For Frequent Replacement Wear:

1. Basic Instructions

For continued safe and comfortable wearing of your lenses, it is important that you first clean and rinse, then disinfect [and neutralize (for hydrogen peroxide systems)] your lenses after each

removal, using the care regimen recommended by your Eye Care Professional. Cleaning and rinsing are necessary to remove mucus, secretions, films or deposits that may have accumulated during wearing. The ideal time to clean your lenses is immediately after removing them. Disinfecting is necessary to destroy harmful germs.

You should adhere to a recommended care regimen. Failure to follow the regimen may result in development of serious ocular complications, as discussed in the "Warnings" section.

If you require only vision correction, but will not or cannot adhere to a recommended care regimen for your lenses, or are unable to place and remove lenses or have someone available to place and remove them, you should not attempt to get and wear contact lenses.

When you first get your lenses, be sure to put the lenses on and remove them while you are in your Eye Care Professional's office. At that time you will be provided with a recommended cleaning and disinfection regimen and instructions and warnings for lens care, handling, cleaning and disinfection. Your Eye Care Professional should instruct you about appropriate and adequate procedures and products for your use.

For safe contact lens wear, you should know and always practice your lens care routine:

- Always wash, rinse and dry hands before handling contact lenses.
- Always use fresh unexpired lens care solution.
- Use the recommended system of lens care, chemical (not heat), and carefully follow instructions on solution labeling. Different solutions cannot always be used together, and not all solutions are safe for use with all lenses. **Do not alternate or mix lens care systems unless indicated on solution labeling.**
- Always remove, clean, rinse and disinfect your lenses according to the schedule prescribed by your Eye Care Professional. The use of any cleaning solution does not substitute for disinfection.
- Do not use saliva or anything other than the recommended solutions for lubricating or rewetting your lenses. Do not put lenses in your mouth.
- Lenses prescribed on the frequent replacement program should be thrown away after the recommended wearing period prescribed by your Eye Care Professional.
- Never rinse your lenses in water from the tap. There are two reasons for this:
    a. Tap water contains many impurities that can contaminate or damage your lenses and may lead to eye infection or injury.
    b. You might lose your lens down the drain.
- Clinical studies were conducted with ReNu® Multi-Plus cleaning and disinfection system.

- Since the lens material contains silicone, the wettability may differ when different lens care products are used. The Eye Care Professional should recommend a care system that is appropriate for the VISTAKON (senofilcon A) Contact Lenses. Each lens care product contains specific directions for use and important safety information, which should be read and carefully followed.

  Note: Some solutions may have more than one function, which will be indicated on the label. Read the label on the solution bottle and follow instructions.

- Clean one lens first (always the same lens first to avoid mix-ups), rinse the lens thoroughly with recommended saline or disinfecting solution to remove the cleaning solution, mucus and film from the lens surface. Follow the instructions provided in the cleaning solution labeling. Put that lens into the correct chamber of the lens storage case. Then repeat the procedure for the second lens.

- After cleaning, **disinfect** lenses using the system recommended by your Eye Care Professional and/or the lens manufacturer. Follow the instructions provided in the disinfection solution labeling.

- To store lenses, disinfect and leave them in the closed/unopened case until ready to wear. If lenses are not to be used immediately following disinfection, you should consult the Package Insert or your Eye Care Professional for information on storage of your lenses.

- Always keep your lenses completely immersed in a recommended disinfecting solution when the lenses are not being worn. If you discontinue wearing your lenses, but plan to begin wearing them again after a few weeks, ask your Eye Care Professional for a recommendation on how to store your lenses.

- VISTAKON Contact Lenses cannot be heat (thermally) disinfected.

- After removing your lenses from the lens case, empty and rinse the lens storage case with solution(s) recommended by the lens case manufacturer; then allow the lens case to air dry. When the case is used again, refill it with fresh storage solution. Replace lens case at regular intervals.

- Your Eye Care Professional may recommend a lubricating/rewetting solution for your use. **Lubricating/rewetting** solutions can be used to wet (lubricate) your lenses while you are wearing them.

2. Care For A Sticking (Non-moving) Lens

If a lens sticks (stops moving) on your eye, apply a few drops of the recommended lubricating solution. You should wait until the lens begins to move freely on the eye before removing it. If non-movement of the lens continues, you should immediately consult your Eye Care Professional.

3. Chemical (Not Heat) Disinfection

- **Clean** the contact lenses with a recommended cleaning solution and thoroughly rinse them with a recommended rinsing solution.

- **After cleaning**, to disinfect, carefully follow the instructions accompanying the disinfecting solution in the care regimen recommended by the lens manufacturer or the Eye Care Professional.
- When using hydrogen peroxide lens care systems, lenses **must be neutralized before wearing.** Follow the recommendations on the hydrogen peroxide system labeling.
- Thoroughly rinse lenses with a fresh solution recommended for rinsing before inserting and wearing, or follow the instructions on the disinfection solution labeling.
- **Do not heat the disinfection solution and lenses.**
- Leave the lenses in the unopened storage case until ready to put on the eyes.

Caution: Lenses that are chemically disinfected may absorb ingredients from the disinfecting solution that may be irritating to the eyes.

A thorough rinse in fresh sterile saline solution prior to placement on the eye should reduce the potential for irritation.

4. Lens Case Cleaning and Maintenance

Contact lens cases can be a source of bacteria growth. Lens cases should be emptied, cleaned, rinsed with solutions recommended by the lens case manufacturer and allowed to air dry. Lens cases should be replaced at regular intervals, as recommended by the lens case manufacturer or your Eye Care Professional.

5. Care For A Dehydrated Lens

If a soft, hydrophilic contact lens is exposed to air while off the eye, it may become dry and brittle. If this happens, dispose of the lens and use a new fresh one.

6. Emergencies

If chemicals of any kind (household products, gardening solutions, laboratory chemicals, etc.) are splashed into your eyes: Flush eyes immediately with tap water and immediately contact your Eye Care Professional or visit a hospital emergency room without delay.

INSTRUCTIONS FOR THE PRESBYOPIC PATIENT (MONOVISION & MULTIFOCAL)

- You should be aware that, as with any type of lens correction, there are advantages and compromises to presbyopic contact lens correction. The benefit of clear near vision in straight ahead and upward gaze that is available with VISTAKON Contact Lenses for Monovision and multifocal correction may be accompanied by a vision compromise that may reduce your visual acuity and depth perception for distance and near tasks. Some patients have experienced difficulty adapting to this. Symptoms, such as mild blurred vision and

variable vision, may last for a brief period or for several weeks as adaptation takes place. The longer these symptoms persist, the poorer your chances 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 that are not visually demanding. For example, it might be better to be a passenger rather than a driver of an automobile during the first days of lens wear. It is recommended that you only drive with Monovision correction if you pass your state drivers license requirements with Monovision correction.

- Some presbyopic patients require supplemental spectacles to wear over the VISTAKON Contact Lenses for Monovision or multifocal correction to provide the clearest vision for critical tasks. You should discuss this with your Eye Care Professional.

- Some presbyopic patients will never be fully comfortable functioning under low levels of lighting, 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.

  For monovision patients, if you require very sharp near vision during prolonged close work, you may want to have additional contact lenses prescribed so that both eyes are corrected for near when sharp near binocular vision is required. It is important that you follow your Eye Care Professional's suggestions for adaptation to presbyopic contact lens correction. You should discuss any concerns that you may have during and after the adaptation period.

- The decision to be fit with Monovision or multifocal correction is most appropriately left to the Eye Care Professional, in conjunction with you, after carefully considering and discussing your needs.

WEARING AND APPOINTMENT SCHEDULE

Prescribed Wearing Schedule

Day	Wearing Time (Hours)
1	
2	
3	
4	
5	
6	
7	
8	
9	
10	
11	
12	
13	
14	

Appointment Schedule

Your appointments are on:

Minimum number of hours lenses to be worn at time of appointment:

Month: Year:

Time: Day:

PATIENT/EYE CARE PROFESSIONAL INFORMATION

Next Appointment:

Date:

Dr:

Address:

Phone:

Day	Date	Hours Worn	Day	Date	Hours Worn
1			1		
2			2		
3			3		
4			4		
5			5		
6			6		
7			7		

IMPORTANT: In the event that you experience any difficulty wearing your lenses or you do not understand the instructions given you, DO NOT WAIT for your next appointment. TELEPHONE YOUR EYE CARE PROFESSIONAL IMMEDIATELY.

NOTES

Glossary of Technical Terms

Term	Definition
Adnexa	Tissues surrounding the eyeball
Ametropia	Abnormal vision requiring correction for proper focus
Anterior chamber	Internal portion of the eye, between the cornea and iris
Aphakic	An eye that lacks a crystalline lens
Astigmatism	Optical defect in which refractive power is not uniform in all directions.
Conjunctiva	Membrane that lines the eyelids and the white part of the eye
Cornea	Transparent front part of the eye that covers the iris, pupil and anterior chamber and provides most of an eye's optical power.
Corneal ulcer	A sore or lesion on the cornea
Edema	Swelling of tissue from excess fluid accumulation
Hyperopia	Farsighted
Infiltrate	Abnormal accumulation of cells and fluid
Iritis	Inflammation of the colored part of the eye (iris)
Myopia	Nearsighted
Neovascularization	Blood vessels growing into the cornea
Phakic	An eye that possesses its natural lens
Presbyopia	Condition in which as the lenses in the eyes lose some of their elasticity, as occurs with aging, they lose some of their ability to change focus for different distances. Usually becomes significant after age 45.
Ulcerative keratitis	An infected corneal ulcer

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FITTING AND PATIENT MANAGEMENT GUIDE

VISTAKON (senofilcon A) Contact Lens (Spherical)
VISTAKON (senofilcon A) Contact Lens (Multifocal)
VISTAKON (senofilcon A) Contact Lens (Toric)
VISTAKON (senofilcon A) Contact Lens (Multifocal-Toric)
Clear and Visibility Tint with UV Blocker
for Daily and Extended Wear

VISTAKON®
DIVISION OF
Johnson & Johnson
Vision Care, Inc.

TABLE OF CONTENTS

CAUTION: Federal Law Restricts This Device To Sale By Or On The Order Of A Licensed Practitioner.

INTRODUCTION

VISTAKON (senofilcon A) Soft (hydrophilic) Contact Lenses are made from senofilcon A with a water content of 38% by weight. For a complete listing of available lens parameters, please refer to "Available Lens Parameters".

PRODUCT DESCRIPTION

The VISTAKON (senofilcon A) Soft (hydrophilic) Contact Lens is available as a spherical lens, a multifocal lens, a toric lens and a multifocal-toric lens. The lenses are made of a silicone hydrogel material containing an internal wetting agent with or without visibility tinted UV absorbing monomer. The VISTAKON (senofilcon A) Contact Lens Visibility Tint with UV Blocker is tinted blue using Reactive Blue Dye #4 to make the lens more visible for handling. A benzotriazole UV-absorbing monomer is used to block UV radiation. The transmittance characteristics are less than 1% in the UVB range of 280 nm to 315 nm and less than 10% in the UVA range of 316 nm to 380 nm for the entire power range.

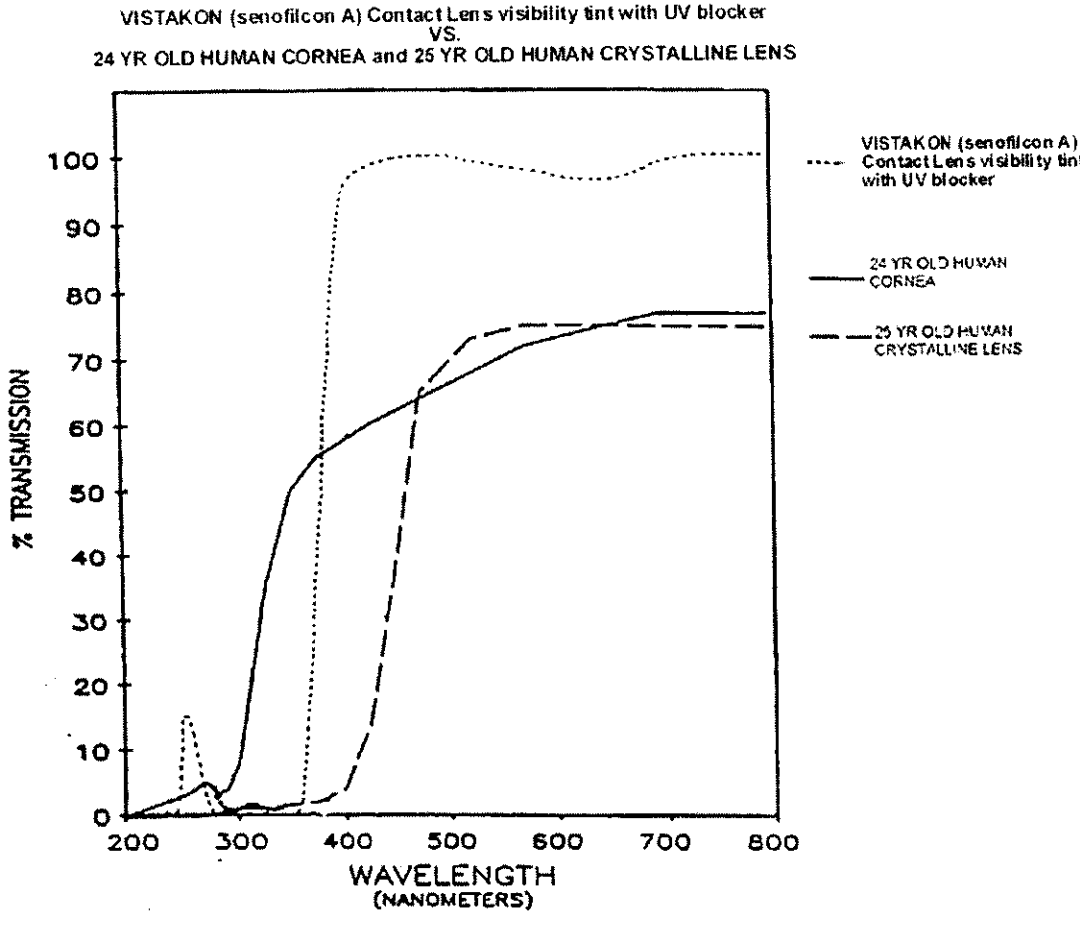
WARNING: UV-absorbing contact lenses are NOT substitutes for protective UV-absorbing eyewear, such as UV-absorbing goggles or sunglasses because they do not completely cover the eye and surrounding area. You should continue to use UV-absorbing eyewear as directed.

AVAILABLE LENS PARAMETERS

Diameter:	12.0mm to 15.0mm		
Center Thickness:	Low minus lens – varies with power (e.g., -4.00D: 0.070mm)		
	Plus lens – varies with power (e.g., +4.00D: 0.170mm)		
Base Curve:	7.85mm to 10.00mm		
Power Range:			
	Spherical Power:	Daily Wear	-20.00D to +20.00D
		Extended Wear	-20.00D to +14.00D
	Multifocal ADD Powers:		+0.25D to +4.00D
			Labeled power = Measured Distance Power +0. 25D
	Multifocal-Toric ADD Powers:		+0.25D to +4.00D
			Labeled power = Measured ADD Power -0.50D
	Cylinder Power:		-0.25D to -10.00D
	Axis:		2.5 ° to 180 °

TRANSMITTANCE CURVES:

VISTAKON (senofilcon A) Contact Lens visibility tint with UV blocker, 24 yr. old human cornea and 25 yr. old human crystalline lens



* The data was obtained from measurements taken through the central 3-5mm portion for the thinnest marketed lens (-1.00D lens, 0.07mm center thickness).

1. Lerman, S., Radiant Energy and the eye, MacMillan, New York, 1980, p.58, figure 2-21
2. Waxler, M. Hitchins, V.M., Optical Radiation and Visual Health, CRC Press, Boca Raton, Florida, 1986, p.10, figure 5

WEARING RESTRICTIONS AND INDICATIONS

ACTIONS

See Package Insert for "Actions".

INDICATIONS (USES)

The VISTAKON® (senofilcon A) Soft Contact Lens (spherical) is indicated for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who have 1.00D or less of astigmatism.

The VISTAKON® (senofilcon A) Multifocal Soft Contact Lens is indicated for the optical correction of distance and near vision in presbyopic, phakic or aphakic persons with non-diseased eyes who may have 0.75D of astigmatism of less.

The VISTAKON® (senofilcon A) Toric Soft Contact Lens is indicated for the optical correction of visual acuity in phakic or aphakic persons with non-diseased eyes that are hyperopic or myopic and may have 10.00D of astigmatism of less.

The VISTAKON® (senofilcon A) Multifocal-Toric Soft Contact Lens is indicated for the optical correction of distance and near in presbyopic phakic or aphakic persons with non-diseased eyes who may have 10.00D of astigmatism of less.

VISTAKON® (senofilcon A) UV Blocking Contact Lenses help protect against transmission of harmful UV radiation to the cornea and into the eye.

Eye Care Professionals may prescribe the lenses either for single-use disposable wear or frequent/planned replacement wear with cleaning, disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lenses may be cleaned and disinfected using a chemical disinfection system only.

VISTAKON® (senofilcon A) Contact Lenses may be prescribed for daily and extended wear for up to 6 nights/ 7 days of continuous wear. It is recommended that the contact lens wearer first be evaluated on a daily wear schedule. If successful, then a gradual introduction of extended wear can be followed as determined by the prescribing Eye Care Professional.

Note: Long-term exposure to UV radiation is one of the risk factors associated with cataracts. Exposure is based on a number of factors such as environmental conditions (altitude, geography, cloud cover) and personal factors (extent and nature of outdoor activities). UV-blocking contact lenses help provide protection against harmful UV radiation. However, clinical studies have not been done to demonstrate that wearing UV-blocking contact lenses reduces the risk of developing cataracts or other eye disorders.

CONTRAINDICATIONS, WARNINGS, PRECAUTIONS AND ADVERSE REACTIONS

See Package Insert for "Contraindications", "Warnings", "Precautions" and "Adverse Reactions".

GENERAL FITTING GUIDELINES

(Spherical, Multifocal, Toric, Multifocal-Toric)

PATIENT SELECTION

You should first assess the patient's needs and ensure that the patient is an appropriate candidate for the VISTAKON (senofilcon A) Contact Lens. The VISTAKON (senofilcon A) Contact Lens, like other soft contact lenses, will require the appropriate and usual physiological and diagnostic assessments necessary to ensure proper patient selection. Refer to the Package Insert for additional information on patient selection.

Pre-fitting Examination

A pre-fitting patient history and examination are necessary to:

- Determine whether a patient is a suitable candidate for daily wear contact lenses (consider patient hygiene and mental and physical state), and
- Take ocular measurements for the initial contact lens parameter selection, and
- Collect and record baseline clinical information to which post-fitting examination results can be compared.

A. VISTAKON® (senofilcon A) Spherical &Toric Contact Lenses

A pre-fitting examination may include a determination of optimal distance and near spectacle correction and corneal curvature measurements. The near correction should be determined at the midpoint of the patient's habitual reading distance. When more than one power provides optimal reading performance, prescribe the least plus (most minus) of the powers. Prescribe the least plus (most minus) of the powers that meet the patient's near requirements.

B. VISTAKON® (senofilcon A) Multifocal & Multifocal-Toric Contact Lenses

Clinical information should be collected and utilized to determine the initial VISTAKON (senofilcon A) Multifocal Contact Lens and/or Multifocal-Toric Contact Lens parameters and to establish a baseline to which post-fitting examination results can be compared. The pre-fitting clinical examination should include: a determination of optimal distance and near spectacle correction, corneal curvature measurements and the status of ocular physiology. The near correction should be determined at the patient's preferred reading distance.

LENS SELECTION (Spherical)

A. Initial Power Determination

A spectacle refraction should be performed to establish the patient's baseline refractive status and to guide in the selection of the appropriate lens power. Remember to compensate for vertex distance if the refraction is greater than ±4.00 D.

B. Base Curve Selection (Trial Lens Fitting)

The VISTAKON (senofilcon A) 8.4mm/14.0mm Contact Lens should be selected for myopic patients regardless of keratometry readings. However, corneal curvature measurements should be performed to establish the patient's baseline ocular status.

A VISTAKON (senofilcon A) trial lens should be placed on each of the patient's eyes and evaluated after the patient has adjusted to the lenses. A properly fit lens will center and completely cover the cornea (i.e., no limbal exposure), have sufficient movement to provide tear exchange under the contact lens with the blink and be comfortable. The lens should move freely when manipulated digitally with the lower lid, and then return to its properly centered position when released. If resistance is encountered when pushing the lens up, the lens is fitting tightly and should not be dispensed to the patient.

A flat fitting lens may exhibit one or more of the following characteristics: decentration, incomplete corneal coverage (i.e., limbal exposure), excessive movement with the blink and/or edge standoff. If the VISTAKON (senofilcon A) Contact Lens is judged to be flat fitting, it should not be dispensed to the patient.

A steep fitting lens may exhibit one or more of the following characteristics: insufficient movement with the blink, conjunctival indentation and resistance when pushing the lens up digitally with the lower lid. If the VISTAKON (senofilcon A) Contact Lens is judged to be steep fitting, it should not be dispensed to the patient.

If the initial VISTAKON (senofilcon A) base curve is judged to be flat or steep fitting, the alternate base curve, if available, should be trial fit and evaluated after the patient has adjusted to the lens.

C. Final Lens Power

A spherical over-refraction should be performed to determine the final lens power after the lens fit is judged acceptable. The spherical over-refraction should be combined with the trial lens power to determine the final lens prescription. The patient should experience good visual acuity with the correct lens power unless there is excessive residual astigmatism.

Example 1:		
Diagnostic lens:		-2.00 D
	Spherical over-refraction	-0.25 D
	Final lens power:	-2.25 D

Example 2:		
Diagnostic lens:		-2.00 D
	Spherical over-refraction	+0.25 D
	Final lens power:	-1.75 D

MONOVISION SPHERE & TORIC FITTING GUIDELINES

PATIENT SELECTION

A. Monovision Needs Assessment

For a good prognosis the patient should have adequately corrected distance and near visual acuity in each eye. The amblyopic patient or the patient with significant astigmatism (greater than 1.00 D) in one eye may not be a good candidate for monovision correction with the VISTAKON (senofilcon A) Contact Lens.

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

(a) visually demanding situations such as operating potentially dangerous machinery or performing other potentially hazardous activities; and

(b) driving automobiles (e.g., driving at night). Patients who cannot pass their state drivers license requirements with monovision correction should be advised to not drive with this correction, OR may require that additional over-correction be prescribed.

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 should understand that Monovision, as well as other presbyopic 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 and straight ahead and upward gaze that monovision contact lenses provide.

EYE SELECTION

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

A. Ocular Preference Determination Methods

Method 1: Determine which eye is the "sighting 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 with the least reduction in vision. Place a hand-held trial lens equal to the spectacle near ADD 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.

Other methods include the refractive error method and the visual demands method.

B. Refractive Error Method

For anisometropic correction, 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 secretary who places copy to the left side of the desk will function best with the near lens on the left eye.

SPECIAL FITTING CHARACTERISTICS

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 only require a distance lens.

Example:
A presbyopic emmetropic patient who requires a +1.75D ADD would have a +1.75D lens on the near eye and the other eye left without a lens.

A presbyopic patient requiring a +1.50D ADD who is –2.50D myopic in the right eye and –1.50D myopic in the left eye may have the right eye corrected for distance and the left uncorrected for near.

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 fitting is performed in the office to allow the patient to experience monovision correction. Lenses are fit according to the General Fitting Guidelines for base curve selection described in this guide.

Case history and standard clinical evaluation procedure should be used to determine the prognosis. Determine the distance correction and the near correction. Next determine the near ADD. With trial lenses of the proper power in place, observe the reaction to this mode of correction.

Allow the lenses to settle for about 20 minutes with the correct power lenses 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 roommate both near and distance objects, observe the reactions. Only after these vision tests 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 the patient's performance under the above conditions are completed, 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 guarded 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 a feeling of slight imbalance. You should explain the adaptational symptoms to the patient. These symptoms may last for a brief minute or for several weeks. The longer these symptoms persist, the poorer the prognosis 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 performances may not be optimal during the adaptation process. This is particularly true when driving at night. Before driving a motor vehicle, it may be recommended that the patient 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 during 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.
- Having supplemental spectacles to wear over the monovision contact lenses for specific visual tasks may improve the success of monovision correction. This is particularly applicable for those patients who cannot meet state 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 clear near vision and 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 "VISTAKON (senofilcon A) Patient Instruction Guide".

LENS SELECTION (Multifocal)

A. Presbyopic Needs Assessment

For a good prognosis, the patient should have adequately corrected distance and near visual acuity in each eye. The amblyopic patient or the patient with significant astigmatism (greater than 0.75D) in one or both eyes, may not be a good candidate for presbyopic correction with the VISTAKON (senofilcon A) Multifocal Contact Lens.

Occupational and environmental visual demands should be considered. If the patient requires critical visual acuity and stereopsis, it should be determined by trial whether this patient can function adequately with the VISTAKON (senofilcon A) Multifocal Contact Lens. VISTAKON (senofilcon A) Multifocal Contact Lens wear may not be optimal for such activities as:

(a) visually demanding situations such as operating potentially dangerous machinery or performing other potentially hazardous activities; and

(b) driving automobiles (e.g., driving at night). Patients who cannot pass their state drivers license requirements with the VISTAKON (senofilcon A) Multifocal Contact Lens should be advised to not drive with this correction, OR may require that additional over-correction be prescribed.

B. Patient Education

All patients do not function equally well with presbyopic correction. Patients may not perform as well for certain tasks with this correction as they have with spectacles that correct for presbyopia. Each patient should understand that multifocal contact lenses, as well as other presbyopic 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 of multifocal contact lenses as well as the advantages of clear near vision in straight ahead and upward gaze that multifocal contact lenses provide.

VISTAKON (senofilcon A) Multifocal Contact Lens Parameter Selection (Trial lens fitting)

A trial fitting is performed in the office to allow the patient to experience presbyopic correction with the VISTAKON (senofilcon A) Multifocal Contact Lens and to determine the proper lens fit of the contact lenses (see CRITERIA OF A PROPERLY FIT LENS). Since lens centration is important for multifocal lens performance, insert the trial lens with the steepest sagittal depth available.

VISTAKON Multifocal Power Selection

A. Initial Distance Power Selection

1. It is very important to determine an accurate distance spectacle Rx; this should be the least minus/most plus power that provides the best corrected binocular and monocular visual acuity.

2. Convert the spherocylindrical distance spectacle Rx to a spherical equivalent Rx or conduct a spherical refraction. If the spherical equivalent power is greater than ±4.00D, a correction for vertex distance will be necessary.

3. For patients with spectacle ADDs ranging from +0.75D to +2.00D, insert a VISTAKON (senofilcon A) Multifocal Contact Lens equal to the patient's spherical equivalent distance Rx (vertex adjustment) determined for each eye.

Note: If the spherical equivalent Rx is calculated to a 0.125D increment, this should be rounded to the more minus/least plus 0.25D contact lens distance power (e.g., if –3.87D, fit –4.00D; if +3.87D, fit +3.75D).

4. For patients with a spectacle ADD of +2..25D or +2.50D, insert a lens with more minus power (e.g., -0.50D) than the spherical equivalent distance Rx (vertex adjusted) of the dominant eye (see EYE SELECTION). For the non-dominant eye, insert a VISTAKON (senofilcon A) Multifocal Contact Lens equal to the spherical equivalent Rx (vertex adjusted).

Initial Near (ADD) Power Selection

Choose the initial VISTAKON (senofilcon A) Multifocal Contact Lens ADD equal to the patient's spectacle ADD determined for the preferred reading distance (if between available multifocal lens ADDs, round up to the next highest ADD).

Spectacle ADD	VISTAKON (senofilcon A) Multifocal ADD
+0.75D to +1.00D	+1.00D
+1.25D to +1.50D	+1.50D
+1.75D to +2.00D	+2.00D
+2.25D to +2.50D	+2.50D

Example 1 (for patients with spectacle ADDs up to +2.00D):

A. Initial Distance Power Selection
A patient with a spectacle Rx: (O.D.) = -3.00 –0.50 x 180, +1.50D ADD
(O.S.) = -2.25D –0.50 x 170, +1.50D ADD
The distance spherical equivalent Rx: (O.D.) = -3.25D
(O.S.) = -2.50D
Initial VISTAKON (senofilcon A) Multifocal lens distance power selection
(O.D.) = -3.25D
(O.S.) = -2.50D

B. Initial Near (ADD) Power Selection
The patient's near spectacle ADD = +1.50D
Initial VISTAKON (senofilcon A) Multifocal lens ADD power selection = +1.50D

Example 2 (for patients with spectacle ADDs of +2.25 or +2.50D):

A. Initial Distance Power Selection

A patient with a spectacle Rx: (O.D.) = -3.00 –0.50 x 180, +2.25D ADD
(O.S.) = -2.25D –0.50 x 170, +2.25D ADD

The patient is determined to be right eye dominant.

The distance spherical equivalent Rx: (O.D.) = -3.25D
(O.S.) = -2.50D

Add more minus power (e.g., -0.50D) to the distance spherical equivalent Rx of the dominant eye.

Initial VISTAKON (senofilcon A) Multifocal lens distance power selection
(O.D./dominant eye) = -3.75D
(O.S./non-dominant eye) = -2.50D

B. Initial Near (ADD) Power Selection

The patient's near spectacle ADD = +2.25D Since the near ADD power selection is between two available VISTAKON (senofilcon A) Multifocal lens ADDs, round up to the next highest ADD.

Therefore, the initial VISTAKON (senofilcon A) Multifocal lens ADD power selection = +2.50D

Initial Clinical Assessment

1. Insert the VISTAKON (senofilcon A) Multifocal Contact Lenses properly (i.e., ensure that the lenses are not inside out).

2. Evaluate the lens fit ensuring that it is acceptable (see CRITERIA OF A PROPERLY FIT LENS).

3. Allow at least 20 minutes for the patient to adapt to the lenses before evaluating vision.

4. After 20 minutes, ask the patients to binocularly assess their distance vision, near vision and position of best focus for near. **NOTE**: For a more accurate assessment, try to simulate the patient's own environment and visual demands (e.g., lighting, print size most typically read, etc.).

5. Measure the binocular and monocular distance VA and near VA at the patient's preferred reading distance.

If the lens fit is acceptable (see CRITERIA OF A PROPERLY FIT LENS), and the patient obtains acceptable visual performance, the trial lenses should be dispensed for up to one week of wear (see follow up examinations in PATIENT MANAGEMENT).

If the patient does not obtain acceptable visual performance, please see the TROUBLESHOOTING section.

Troubleshooting (Unacceptable visual performance)

1. Ensure that the lenses have been inserted properly. Some patients will exhibit poor vision from a lens that is inside out, but still report good comfort and the lens will exhibit good fit characteristics. If a lens is inside out, remove the lens and insert it properly. Allow the patient to adapt to the lens again before evaluating vision.

2. If lenses were inserted properly, conduct a distance over-refraction to ensure the patient has the least minus/most plus distance correction (i.e., ensure that the patient is not over-minused at distance). If the patient does not have the least minus/most plus distance correction, adjust the prescription and reassess the visual performance.

3. If the patient does have the least minus/most plus distance correction (i.e., is not over-minused at distance) but has unacceptable visual performance, please follow the flow chart according to the patient's complaint.

NOTES:

1. The use of hand-held trial lenses allows for a quick assessment of distance and near vision prior to any lens changes.

2. After a lens change, minor adjustments in distance power may again be required to optimize the visual performance of an individual patient.

POOR NEAR VISION	POOR DISTANCE & NEAR VISION	POOR DISTANCE VISION
1. Present +0.50D hand-held trial lens to the non-dominant eye. 2. Assess distance and near vision. If acceptable, change the contact lens 3. If performance is still unacceptable, increase the ADD on the non-dominant eye or on both eyes by changing the contact lenses.	1. Present hand-held trial lenses in –0.25D steps to the dominant eye along with +0.25D steps to the non-dominant eye. 2. Assess distance and near vision. If acceptable, change the contact lenses. 3. If performance is still unacceptable, decrease the ADD on the dominant eye and/or increase the ADD on the non-dominant eye by changing the contact lenses.	1. Present hand-held trial lenses on –0.25D steps to one (dominant) eye or both eyes. 2. Assess distance and near vision. If acceptable, change the contact lens or lenses. 3. If performance is still unacceptable, decrease the ADD on the dominant eye by changing the contact lenses.

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4. After inserting the lens(es) with optimal powers, allow 20 minutes for the patient to adapt to the lens(es).
5. Assess performance
6. If good performance, dispense. If poor performance, discard both lenses, and then go to ALTERNATIVE FITTING APPROACHES

↓

ALTERNATIVE FITTING APPROACHES
1. Fit a single vision lens (e.g., VISTAKON) on the dominant eye and a VISTAKON (senofilcon A) Multifocal Contact Lens on the non-dominant eye (see ALTERNATIVE FITTING APPROACHES).
2. Fit VISTAKON (senofilcon A) Multifocal Contact Lenses on a monovision basis.

Alternative Fitting Approaches

Prior to attempting the alternative fitting approach, remove the multifocal lenses from both eyes and then follow the initial lens selection for the alternative fitting approach.

The alternative fitting approach involves placing a single vision lens on the dominant eye and a multifocal on the non-dominant eye.

A. Single Vision Lens (distance lens) Power Selection

1. Select a single vision contact lens (e.g., VISTAKON) with a distance power equal to the vertex adjusted spherical equivalent distance Rx of the dominant eye.

B. Multifocal Lens (near lens) Power Selection for the non-dominant eye

1. Distance power selection

   For patients with a spectacle ADD of +1.50D or less, add +0.50D to the distance spherical equivalent Rx. For patients with spectacle ADDs of +1.75 or greater, add +0.75D to the distance spherical equivalent Rx.

2. Near power selection

   Select the VISTAKON (senofilcon A) Multifocal Contact Lens ADD using the spectacle ADD for the preferred reading distance as indicated below:

Spectacle ADD		VISTAKON MULTIFOCAL ADD
+0.75D to +1.50D	=	+1.00D
+1.75D to +2.00D	=	+1.50D
+2.25D to +2.50D	=	+2.00D (or +2.50D, if necessary)

Example:

A. Initial Distance Power Selection

A patient with a spectacle Rx: (O.D.) = +2.00 –0.50 x 180, +2.00D ADD
(O.S.) = +2.25 –0.50 x 170, +2.00D ADD

The patient is determined to be left eye dominant.
The distance spherical equivalent Rx: (O.D.) = +1.75D
(O.S.) = +2.00D

The dominant eye is fit with a single vision VISTAKON lens equal to the distance spherical equivalent Rx.

Therefore, the initial VISTAKON single vision lens power selection for this patient's dominant eye (left) = +2.00D

The non-dominant eye is fit with the VISTAKON (senofilcon A) Multifocal lens. For this patient (with a =2.00D spectacle ADD), an additional +0.75D is added to the spherical equivalent distance Rx.

Therefore, the initial VISTAKON (senofilcon A) Multifocal distance power selection for this patient's non-dominant eye (right) = +2.50D.

B. Initial Near (ADD) Power Selection

The initial VISTAKON (senofilcon A) Multifocal Contact Lens ADD power selection is equal to this patient's spectacle ADD = +2.00D.

Initial Clinical Assessment

1. Insert the single vision VISTAKON lens and the VISTAKON (senofilcon A) Multifocal Contact Lens lens properly (i.e., ensure that the lenses are not inside out).

2. Evaluate the lens fit ensuring that the lens fit is acceptable (see CRITERIA OF A PROPERLY FITTING LENS).

3. Allow at least 20 minutes for the patient to adapt to the lenses before evaluating vision.

4. After 20 minutes, ask the patient to binocularly assess their distance vision, near vision and position of best focus for near. **NOTE:** For a more accurate assessment, try to simulate the patient's own environment and visual demands (e.g., lighting, print size most typically read, etc.).

5. Measure the binocular and monocular distance VA and near VA at the patient's preferred reading distance.

If the lens fit is acceptable (see CRITERIA OF A PROPERLY FIT LENS) and the patient obtains acceptable visual performance, the trial lenses should be dispensed for up to one week of wear (see follow-up examinations in PATIENT MANAGEMENT).

If the patient reports visual difficulties, ensure that the lenses have been properly inserted and then use hand-held trial lenses to adjust the distance power in one or both eyes until an acceptable balance between distance and near is achieved. Insert new lenses and confirm performance. If the patient's vision is still not acceptable, consider monovision.

EYE SELECTION

The Eye Selection assessment previously described in the Monovision Fitting Section apply to the Multifocal Contact Lens.

CRITERIA OF A PROPERLY FIT LENS

A properly fit lens will center well and completely cover the cornea (i.e., no limbal exposure), have sufficient movement to provide tear exchange under the contact lens with the blink and be comfortable. The lens should move freely when manipulated digitally with the lower lid and then return to its properly centered position when released. If significant resistance is encountered when pushing the lens up, the lens is fitting tightly and should not be dispensed to the patient.

Characteristics of a steep (tight) lens

A steep fitting lens may exhibit one of more of the following characteristics: insufficient movement with a blink, conjunctival indentation and/or significant resistance when pushing the lens up digitally with the lower lid. If the VISTAKON (senofilcon A) Multifocal Contact Lens is judged to be steep fitting, choose an alternate base curve, if available.

Characteristics of a flat (loose) lens

A flat fitting lens may exhibit one or more of the following characteristics: decentration, incomplete corneal coverage, (i.e., limbal exposure), excessive movement with blink and edge standoff. If the VISTAKON (senofilcon A) Multifocal Contact Lens is judged to be flat fitting, choose an alternate base curve, if available.

The lens fit for the VISTAKON (senofilcon A) Multifocal Contact Lens should meet the CRITERIA OF A PROPERLY FIT LENS to ensure optimal lens performance.

Adaptation

The adaptation previously described in the Monovision Fitting Section apply to the Multifocal Contact Lens.

LENS SELECTION (Toric)

The only new steps you must follow in prescribing the VISTAKON® (senofilcon A) Toric Contact Lenses are that you must determine the stability, repeatability and drift angle of the lens axis so that you can prescribe the correct lens axis for your patient.

A. Initial Power Determination

A spectacle refraction should be performed to establish the patient's baseline refractive status and to guide in the selection of the appropriate lens power. Remember to compensate for vertex distance in both the sphere meridian and cylinder meridian if the refraction is greater than ±4.00 D.

All patients should be supplied with a copy of the VISTAKON® (senofilcon A) Toric Contact Lens Patient Instruction Guide.

B. Base Curve Selection (Trial Lens Fitting)

Use the same base curve selection criteria used to fit the VISTAKON® (senofilcon A) Contact Lens (spherical) may be applied to the VISTAKON® (senofilcon A) Toric Contact Lens.

Determination of Cylinder Power and Axis – VISTAKON (senofilcon A) Toric Contact Lenses

Although most aspects of the fitting procedure are identical for all types of soft contact lenses, including torics, there are some additional steps and/or rules to follow to assure the proper fit of toric lenses.

How to Determine Lens Cylinder and Axis Orientation for VISTAKON Toric Lenses

1. Locate the Orientation Marks

To help determine the proper orientation of the toric lens, locate the orientation marks. You'll find three marks about 1mm from the edge of the lens, on opposite edges of the lens. The marks are about 1mm in length. You'll need a biomicroscope and a 1mm or a 2mm parallelepiped to highlight the marks when the lens is fitted to the eye.

There are a number of techniques you can use to improve the visibility of the mark.

With your parallelepiped and medium magnification (10X or 15X), slowly pan across the nasal and temporal portions of the lens, looking just to the side of the direct illumination at the retroilluminated area. Backlighting the marks this way should make them more visible. Sometimes manipulating the lower lid against the lens will make the marks move and, therefore, easier to see.

2. Observe Lens Rotation and Stability

Using these and other techniques, observe the position and stability of the marks. The 3 o'clock and 9 o'clock (180 °) positions are not a "must," however, the absolute requirement is that the axis position be stable and repeatable.

The marks may stabilize somewhat above or below the horizontal meridian (vertical could be the reference point) at an angle and still enable you to fit a toric lens for that eye as long as it always returns to the same position after movement (drift axis). The deviation can be compensated for in the final prescription. Your objective is to ensure that whatever position the lens assumes near the 3 & 9 o'clock positions, the "drift" position must be stable and repeatable. With full eye movement or heavy blink you may see the marks swing away, but they return quickly to the original stable position. If this does not occur, you may need to select a different lens.

The marks usually stabilize in the 180 ° position – precisely at 3 and 9 o'clock. If they do, calculation of the lens power will be straight forward.

If the Marks Stabilize to Either Above or Below the 180 ° Position:

Sometimes the marks will stabilize somewhat above or below the 180 ° position (90 ° position). Because the final lens will orientate on the eye with the same deviation, this "drift" of the axis must be added or subtracted from the refractive axis. You can use an axis reticule in the slit lamp or use a line-scribed lens in a spectacle trial frame to measure or estimate the "drift angle" of the cylinder axis.

Imagine the eye as a clock dial and every hour represents 30 °; 4 o'clock would be 30 ° below the 3 o'clock base-line position; 2 o'clock would be 30 ° above. You can interpolate between these positions.

If the stable mark is above or below the 180 ° position, measure or estimate it, translate it into rounded off 5 ° increments, and add or subtract it from the refractive axis to determine the correct cylinder axis.

How to determine the Final Lens Power for VISTAKON (senofilcon A) Toric Contact Lens

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

In fitting soft contact lenses, it is customary to prescribe the full power in the sphere. In the cylinder, however, any lens rotation is visually disturbing to the patient, so it's more practical to prescribe as weak a cylinder as possible. A great deal of experience with patients has shown that is possible to under-prescribe minus cylinders near 180 ° ("with the rule") by as much as 30% and to under-prescribe minus cylinders near 90 ° ("against the rule") by as much as 20%. So here is how to determine final lens power:

For the Sphere:

If Rx > ±4.00, compensate for vertex distance.

If Rx < ±4.00, vertex distance compensation is not necessary.

For the Cylinder:

If the sphere + cylinder > ±4.00, compensate for vertex distance Adjust the axis by the drift angle.

Choose a cylinder which is ±0.50D from the refractive cylinder. (If between powers, choose the lowest minus power.)

Case Examples

Here are two examples of fitting VISTAKON (senofilcon A) Toric Contact Lens.

Example 1:

Manifest Refraction:

O.D. –2.50 –1.25 x 180 20/20
O.S. –2.25 –1.00 x 180 20/20

Choose a diagnostic lens for each eye with an axis as close to 180 ° as possible. Place the lens on each eye and allow sufficient time for it to equilibrate, based on the patient's initial response to the lens.

Check the orientation of the axis marks. If the axis marks are in the three and nine o'clock positions on both eyes, choose the appropriate cylinder as listed previously.

Here is the Rx chosen:

O.D. –2.50–1.25 x 180
O.S. –2.25 –0.75 x 180

Example 2:

Manifest Refraction:

O.D. –2.75 –1.00 x 90 20/20
O.S. –4.50 –2.25 x 90 20/20

Choose diagnostic lenses of –2.75 –0.75 x 90 for the right eye and –4.25 –1.75 x 90 for the left eye, the nearest lenses available to the spherical power and axis needed. Allow enough time for each lens to equilibrate. The markings on the right lens indicate that the lens axis rotates clockwise by 5 °. The Fitting Indicates the Following:

Right Eye

Compensate the axis 5 ° by adding it to the manifest refraction axis.

Here is the Rx prescribed:

O.D. –2.75 –0.75 x 95

The lens on the left eye shows good centration movement and consistent tendency for the marks to drift counter clockwise by 10 positions following a forced blink.

Left eye

Since the manifest refraction called for a power of –4.50, reduce the sphere 0.25D for vertex distance. As the sphere + cylinder is ±4.00, compensate for vertex and prescribe the –1.75D cylinder.

Compensate the axis 10 ° by subtracting it from the manifest refraction axis.

Here is the Rx prescribed:

O.S. –4.25 –1.75 x 80

LENS SELECTION (Multifocal-Toric)

A. Presbyopic Needs Assessment

For a good prognosis the patient should have adequately corrected distance and near visual acuity in each eye. The amblyopic patient or the patient with less than 0.75D of astigmatism in one or both eyes, may not be a good candidate for presbyopic correction with the VISTAKON (senofilcon A) Multifocal-Toric Contact Lens.

Occupational and environmental visual demands should be considered. If the patient requires critical (visual acuity and stereopsis), it should be determined by trial whether this patient can function adequately with the VISTAKON (senofilcon A) Multifocal-Toric Contact Lens. VISTAKON (senofilcon A) Multifocal-Toric Contact Lens wear may not be optimal for such activities as:

(a). visually demanding situations such as operating potentially dangerous machinery or performing other potentially hazardous activities; and

(b). driving automobiles (e.g., driving at night). Patients who cannot pass their state drivers license requirements with the VISTAKON (senofilcon A) Multifocal-Toric Contact Lens should be advised to not drive with this correction, OR may require that additional over-correction be prescribed.

B. Patient Education

All patients do not function equally well with presbyopic correction. Patients may not perform as well for certain tasks with this correction as they have with spectacles that correct for presbyopia. Each patient should understand that multifocal contact lenses, well as other presbyopic 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 of multifocal contact lenses as well as the advantages of clear near vision in straight ahead and upward gaze that multifocal contact lenses provide.

VISTAKON (senofilcon A) Multifocal-Toric Contact Lens Parameter Selection (Trial lens fitting)

A trial fitting is performed in the office to allow the patient to experience presbyopic correction with the VISTAKON (senofilcon A) Multifocal-Toric Contact Lens and to determine the proper lens fit of the contact lenses (see CRITERIA OF A PROPERLY FIT LENS). Since lens centration is important for multifocal toric lens performance, insert the trial lens with the steepest sagittal depth available.

VISTAKON (senofilcon A) MULTIFOCAL-TORIC CONTACT LENS SELECTION

In is important when prescribing the VISTAKON (senofilcon A) Multifocal-Toric Contact Lens that you determine the stability, repeatability and drift angle of the lens axis so that you can prescribe the correct lens axis for your patient.

A. Initial Distance Power Selection

1. It is very important to determine an accurate distance spectacle Rx; this should be the least minus/most plus power that provides the best corrected binocular and monocular visual acuity. If the distance spectacle Rx is greater than ±4.00D, a correction for vertex distance will be necessary.

2. The spherical power selected should be equal to the vertex adjusted spherical power of the best corrected spectacle Rx.

   Note: For patients with higher spectacle ADDs of +2.25D or +2.50D, additional minus power (e.g., -0.50D) may be required over the vertex adjusted spherical component of the best corrected spectacle Rx on the dominant eye (see EYE SELECTION) to provide acceptable distance vision.

3. The cylinder power selected should be equal to the vertex adjusted cylinder power of the best corrected spectacle Rx.

   Note: Any lens rotation is visually disturbing to the patient, so it's more practical to prescribe as weak a cylinder power as possible. A great deal of experience with patients has shown that it is possible to under-prescribe the minus cylinders near 180 ° ("with the rule") by as much as 30% and to under-prescribe minus cylinders near 90 ° ("against the rule") by as much as 20%. Therefore, if the cylinder correction is in between two available cylinder powers, choose the less minus power.

B. Initial Near (ADD) Power Selection

Choose the initial VISTAKON (senofilcon A) Multifocal-Toric ADD lens equal to the patient's spectacle ADD determined for the preferred reading distance (if between available bifocal lens ADDs, round up to the next highest ADD).

Spectacle ADD	VISTAKON (senofilcon A) Multifocal-Toric ADD
+0.75D to +1.00D	+1.00D
+1.25D to +1.50D	+1.50D
+1.75D to +2.00D	+2.00D
+2.25D to +2.50D	+2.50D

Example 1 (for patients with spectacle ADDs up to +2.00D):

A. Initial Distance Power Selection

A patient with a spectacle Rx:

(O.D.) = -3.00D –1.50D x 180, +1.50D ADD
(O.S.) = -2.25D –1.50D x 170, +1.50D ADD

Initial VISTAKON (senofilcon A) Multifocal-Toric Contact Lens distance power selection:

(O.D.) = -3.00D –1.25D x 180
(O.S.) = -2.50D –1.25D x 170

Note:

1. Since the spectacle cylinder power is between two available VISTAKON (senofilcon A) Multifocal-Toric Contact Lens cylinder powers, choose the less minus contact lens cylinder power.
   Therefore, the initial VISTAKON (senofilcon A) Multifocal-Toric Contact Lens cylinder power selection = +1.25D

2. Choose the diagnostic lens with an axis closest to the patient's spectacle cylinder axis.

B. Initial Near (ADD) Power Selection

The patient's near spectacle ADD = +1.50D
Initial VISTAKON (senofilcon A) Multifocal-Toric Contact Lens ADD power selection =
+1.50D

Example 2 (for patients with spectacle ADDs of +2.25 or +2.50D):

A. Initial Distance Power Selection

A patient with a spectacle Rx:
(O.D.) = -3.00D –1.50D x 180, +2.25D ADD
(O.S.) = -2.25D –1.50D x 170, +2.25D ADD

The patient is determined to be right eye dominant.
Add more minus power (e.g., -0.50D) to the distance spherical power of the dominant eye.

Initial VISTAKON (senofilcon A) Multifocal-Toric Contact Lens distance power
selection
O.D. (dominant eye) = -3.50D –1.25D x 180
O.S. (dominant eye) = -2.25D –1.25D x 170

B. Initial Near (ADD) Power Selection

The patient's near spectacle ADD = +2.25D

Since the near ADD power selection is between two available VISTAKON (senofilcon A) Multifocal-Toric Contact Lens ADDs, round up to the next highest ADD.
Therefore, the initial VISTAKON (senofilcon A) Multifocal-Toric Contact Lens ADD power selection = +2.50D

Initial Clinical Assessment

1. Insert the VISTAKON (senofilcon A) Multifocal-Toric Contact Lenses properly (i.e., ensure that the lenses are not inside out).

2. Evaluate the lens fit ensuring that it is acceptable (see CRITERIA OF A PROPERLY FIT LENS).

3. Allow at least 20 minutes for the patient to adapt to the lenses before evaluating lens orientation and vision.

4. After 20 minutes, determine lens cylinder and axis orientation by locating the orientation marks and ask the patients to binocularly assess their distance vision, near vision and position of best focus for hear. **NOTE**: For a more accurate assessment, try to simulate the patient's own environment and visual demands (e.g., lighting, print size most typically read, etc.). Also, measure the binocular and monocular distance VA and near VA at the patient's preferred reading distance.

A. Locate the Orientation Marks

To help determine the proper orientation of the VISTAKON (senofilcon A) Multifocal-Toric Contact Lens, you'll find three marks about 1mm from the edge of the lens, on opposite edges of the lens. The marks are about 1mm in length. You'll need a biomicroscope and a 1mm or a 2mm parallelepiped to highlight the marks when the lens is fitted to the eye.

There are a number of techniques you can use to improve the visibility of the mark.

With you parallelepiped and medium magnification (10X or 15X), slowly pan across the nasal and temporal portions of the lens, looking just to the side of the direct illumination at the retro-illuminated area. Back-lighting the marks this way should make them more visible. Sometimes manipulating the lower lid against the lens will make the marks move and easier to see.

B. Observe Lens Rotation and Stability

Using these and other techniques, observe the position and stability of the marks. The 3 o'clock and 9 o'clock (180 °) positions are not a "must", however, the absolute requirement is that the axis position be stable and repeatable.

The marks may stabilize somewhat above or below the horizontal meridian at an angle and still enable you to fit a Multifocal-Toric lens for that eye as long as it always returns to the same position after movement (drift axis). The deviation can be compensated for in the final prescription. Your objective is to ensure that whatever position the lens assumes near the 3 & 9 o'clock positions, the "drift" position must be stable and repeatable. With full eye movement or heavy blink, you may see the marks swing away, but they return quickly to the original stable position. If this does not occur, you may need to select a different lens. The marks usually stabilize in the 180 ° position – precisely at 3 and 9 o'clock. If they do, calculation of the lens power will be straight forward.

If the Marks Stabilize to above or below the 180 ° Position:

Sometimes the marks will stabilize somewhat above or below the 180 ° position. Because the final lens will orient on the eye with the same deviation, this "drift" of the axis must be added or subtracted from the refractive axis. You can use an axis reticule in the slit lamp or use a line-scribed lens in a spectacle trial frame to measure or estimate the "drift angle" of the cylinder axis.

Imagine the eye as a clock dial and every hour represents 30 °; 4 o'clock would be 30 ° below the 3 o'clock base-line position; 2 o'clock would be 30 ° above. You can interpolate between these positions.

5. If the stable mark is above or below the 180 ° position, measure or estimate it, translate it into rounded off 5 ° increments, and add or subtract it from the refractive axis to determine the correct cylinder axis. Adjust the cylinder axis in the following manner,

   Example:

   Manifest Refraction:
   O.D. –2. 50D – 1.25D x 180/+2.00D
   O.S. –2.25D – 1.00D x 180/+2.00D

   Initial Power Selection:
   O.D. –2. 50D – 1.25D x 180/+2.00D
   O.S. –2.25D – 0.75D x 180/+2.00D

   After 20 minutes of settling, the markings on the right lens indicate that the lens axis rotates 10 ° counter clockwise or nasal, while the markings on the left lens rotated 10 ° degrees clockwise or nasal and the patient is experiencing decreased vision.

   For the right eye, compensate the axis 10 ° by subtracting it from the manifest refraction axis. The new trial lens would be:

   O.D. –2.75D – 1.25D x 170/+2.00D.

   For the left eye, compensate the axis 10 ° by adding it to the manifest refraction axis. The new trial lens would be:

   O.S. –2.25D – 0.75D x 010/+2.00D

6. Once the cylinder axis orientation is adjusted, re-assess vision after allowing the lenses to settle approximately 20 minutes.

7. If no adjustment was required and lens fit (see CRITERIA OF A PROPERLY FIT LENS), axis orientation and rotational stability are acceptable, and the patient obtains acceptable visual performance, the trial lenses should be dispensed for up to one week of wear (see follow up examinations in PATIENT MANAGEMENT).

8. If the patient does not obtain acceptable visual performance, please see the TROUBLESHOOTING section.

Troubleshooting

Ensure that the lenses have been inserted properly. Some patients will exhibit poor vision from a lens that is inside out, but still report good comfort and the lens will exhibit good fit characteristics. If a lens is inside out, remove the lens and insert it properly. Allow the patient to adapt to the lens again before evaluating vision.

If lenses were inserted properly, ensure that axis orientation and rotational stability is acceptable. If the axis is not located at the 3 and 9 o'clock position, adjust the axis as previously mentioned in Step 4. If the axis is oriented properly and the rotational stability is acceptable but the patient has unacceptable vision, conduct a distance over-refraction to ensure the patient has the least minus/most plus distance correction (i.e., ensure that the patient is not over-minused at distance). If the patient does not have the least minus/most plus distance correction, adjust the prescription and reassess the visual performance.

If the patient does have the least minus/most plus distance correction (i.e., is not over-minused at distance) but has unacceptable visual performance, please follow the flow chart according to the patient's complaint.

Notes:

The use of hand-held trial lenses allows for a quick assessment of distance and near vision prior to any lens changes.
After a lens change, minor adjustments in distance power may again be required to optimize the visual performance of an individual patient.

POOR NEAR VISION	POOR DISTANCE & NEAR VISION	POOR DISTANCE VISION
1. Present +0.50D hand-held trial lens to the non-dominant eye. 2. Assess distance and near vision. If acceptable, change the contact lens 3. If performance is still unacceptable, increase the ADD on the non-dominant eye or on both eyes by changing the contact lenses.	1. Present hand-held trial lenses in –0.25D steps to the dominant eye along with +0.25D steps to the non-dominant eye. 2. Assess distance and near vision. If acceptable, change the contact lenses. 3. If performance is still unacceptable, decrease the ADD on the dominant eye and/or increase the ADD on the non-dominant eye by changing the contact lenses.	1. Present hand-held trial lenses on –0.25D steps to one (dominant) eye or both eyes. 2. Assess distance and near vision. If acceptable, change the contact lens or lenses. 3. If performance is still unacceptable, decrease the ADD on the dominant eye by changing the contact lenses.

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7. After inserting the lens(es) with optimal powers, allow 20 minutes for the patient to adapt to the lens(es).
8. Assess performance
9. If good performance, dispense. If poor performance, discard both lenses, and then go to ALTERNATIVE FITTING APPROACHES

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ALTERNATIVE FITTING APPROACHES
1. Fit a single vision lens (e.g., VISTAKON) on the dominant eye and a VISTAKON (senofilcon A) Multifocal-Toric Contact Lens on the non-dominant eye (see ALTERNATIVE FITTING APPROACHES). 2. Fit VISTAKON (senofilcon A) Multifocal-Toric Contact Lenses on a monovision basis. 3. Consider a non-toric lens as appropriate.

Alternative Fitting Approaches

Prior to attempting the alternative fitting approach, remove the multifocal lenses from both eyes and then follow the initial lens selection for the alternative fitting approach.

The alternative fitting approach involves placing a toric single vision lens on the dominant eye and a toric multifocal on the non-dominant eye.

A. Toric Single Vision Lens (distance lens) Power Selection

1. Select a Toric single vision lens (e.g., VISTAKON) with a distance power equal to the vertex adjusted sphero-cylindrical distance Rx of the dominant eye.

B. Multifocal-Toric Lens (near lens) Power Selection for the non-dominant eye

1. Distance power selection
   For patients with a spectacle ADD of +1.50D or less, add +0.50D to the distance spherical power of the sphero-cylindrical distance Rx. For patients with spectacle ADDs of +1.75 or greater, add +0.75D to the distance sphero-cylindrical Rx.

2. Near power selection
   Select the VISTAKON (senofilcon A) Multifocal-Toric Contact Lens ADD using the spectacle ADD for the preferred reading distance as indicated below:

Spectacle ADD		VISTAKON (senofilcon A) Multifocal-Toric ADD
+0.75D to +1.50D	=	+1.00D
+1.75D to +2.00D	=	+1.50D
+2.25D to +2.50D	=	+2.00D (or +2.50D, if necessary)

Example:

A. Initial Distance Power Selection

A patient with a spectacle Rx: (O.D.) = +2.00 –1.50 x 180, +2.00D ADD
(O.S.) = +2.25 –1.50 x 170, +2.00D ADD
The patient's left eye is determined to be the dominant eye.
The dominant eye is fit with a toric single vision VISTAKON lens equal to the distance Rx.

Therefore, the initial VISTAKON toric single vision lens power selection for this patient's dominant eye (left) = +2.25D –1.25D x 170

The non-dominant eye is fit with the VISTAKON (senofilcon A) Multifocal-Toric Contact Lens. For this patient (with a +2.00D spectacle ADD), an additional +0.75D is added to the spherical power of the distance Rx.

Therefore, the initial VISTAKON (senofilcon A) Multifocal-Toric Contact Lens distance power selection for this patient's non-dominant eye (right) = +2.75D – 1.25D x 180.

B. Initial Near (ADD) Power Selection

The Patient's spectacle ADD is = +2.00D therefore, the initial VISTAKON (senofilcon A) Multifocal-Toric Contact Lens ADD power selection is +1.50D.

Initial Clinical Assessment

Follow the same Initial clinical assessments as previously described in the fitting section on Multifocal-Toric.

Eye Selection

Follow the same Eye Selection process as previously described in the fitting section on Multifocal.

CRITERIA OF A PROPERLY FIT LENS

Follow the same Lens Fit assessment as previously described in the fitting section on Multifocal.

PATIENT MANAGEMENT

Dispensing Visit

Each sterile lens is supplied in a foil-sealed plastic package containing buffered saline solution with 0.005% methyl ether cellulose. In removing the lens from the container, peel back the foil seal, place a finger on the lens and slide the lens up the side of bowl of the lens package until it is free of the container.

- Evaluate the physical fit and visual acuity of the lens on each eye.
- Teach the patient how to insert and remove his or her lenses.
- Explain the daily wear regimen and schedule a follow-up examination.
- PROVIDE THE PATIENT WITH A COPY OF THE APPROPRIATE VISTAKON PATIENT INSTRUCTIONS (DISPOSABLE OR FREQUENT REPLACEMENT). REVIEW THESE INSTRUCTIONS WITH THE PATIENT SO THAT HE OR SHE CLEARLY UNDERSTANDS THE PRESCRIBED WEARING AND REPLACEMENT SCHEDULE.
- Recommend an appropriate cleaning and disinfecting system and provide the patient with instructions regarding proper lens care (see Package Insert). Chemical or hydrogen peroxide disinfection is recommended.
- Review the Package Insert for the VISTAKON (senofilcon A) Contact Lens, the VISTAKON (senofilcon A) Multifocal Contact Lens, the VISTAKON (senofilcon A) Toric Contact Lens and the VISTAKON (senofilcon A) Multifocal-Toric Contact Lens and

provide the patient with all of the relevant information and precautions on the proper use of VISTAKON (senofilcon A) Contact Lenses.

FOLLOW-UP EXAMINATIONS

Follow-up care (necessary to ensure continued successful contact lens wear) should include routine periodic progress examinations, management of specific problems, if any, and a review with the patient of the wear schedule, lens replacement schedule and proper lens care and handling procedures.

Recommended Follow-up Examination Schedule for VISTAKON Contact Lenses (complications and specific problems should be managed on an individual patient basis):

1. One week from the initial lens dispensing to patient
2. One month post-dispensing
3. Every three to six months thereafter

(NOTE: preferably, at the follow-up visits, lenses should be worn for at least six hours.)

Recommended Procedures for Follow-up visits:

1. Solicit and record patient's symptoms, if any.

2. Measure visual acuity monocularly and binocularly at distance and near with the contact lenses.

3. Perform an over-refraction at distance and near to check for residual refractive error.

4. With the biomicroscope, judge the lens fitting characteristics (as described in the General Fitting Guidelines) and evaluate the lens surface for deposits and damage.

5. Following lens removal, examine the cornea and conjunctiva with the biomicroscope and fluorescein.
   - The presence of vertical corneal striae in the posterior central cornea and/or corneal neovascularization is indicative of excessive corneal edema.
   - The presence of corneal staining and/or limbal-conjunctival hyperemia can be indicative of an unclean lens, a reaction to solution preservatives, excessive lens wear and/or a poorly fitting lens.
   - Papillary conjunctival changes may be indicative of an unclean and/or damaged lens.
6. Periodically perform keratometry and spectacle refractions. The values should be recorded and compared to the baseline measurements.

If any observations are abnormal, use professional judgement to alleviate the problem and restore the eye to optimal conditions. If the criteria for successful fit are not satisfied during any follow-up examinations, repeat the patient's trial fitting procedure and refit the patient.

RECOMMENDED WEARING SCHEDULE

See Package Insert.

PATIENT LENS CARE DIRECTIONS

See Package Insert for "Lens Care Directions" for lenses worn on a frequent replacement schedule.

CHEMICAL (NOT HEAT) DISINFECTION

See Package Insert for "Chemical Lens Disinfection" of lenses worn on a frequent replacement schedule.

CARE FOR A DRIED OUT (DEHYDRATED) LENS

See Package Insert for "Care For A Dehydrated Lens" when lenses are worn on a frequent replacement schedule.

CARE FOR A STICKING (NON-MOVING) LENS

See Package Insert for "Care For A Sticking Lens".

IN OFFICE USE OF TRIAL LENSES

For fitting and diagnostic purposes, the lenses should be discarded after a single use and not be re-used from patient to patient.

REPORTING OF ADVERSE REACTIONS

All serious adverse experiences and adverse reactions observed in patients wearing VISTAKON (senofilcon A) Contact Lenses or experienced with the lenses should be reported to:

VISTAKON™
Division Of
Johnson & Johnson
Vision Care, Inc.

VISTAKON®, Division of Johnson & Johnson Vision Care, Inc.
P. O. Box 10157
Jacksonville, FL 32247-0157
1-800-843-2020

HOW SUPPLIED

Each sterile lens is supplied in a foil-sealed plastic package containing buffered saline solution with 0.005% methyl ether cellulose. The plastic package is marked with base curve, diameter, color (visibility tint noted on visibility tinted product only), lot number and expiration date. [Diopter power, ADD power, cylinder and axis will be included as appropriate].

PACKAGE INSERT INCLUDED HERE