- There may be excessive watering, unusual eye secretions or redness of the eye.
- Poor visual acuity, blurred vision, rainbows or halos around objects, photophobia, 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?
- Have I noticed a change in my vision?

If the patient reports any problems, he or she should be instructed to IMMEDIATELY REMOVE THE LENS. If the problem or discomfort stops, the patient should discard the lens and place a new fresh lens on the eye.

If after inserting the new lens, the problem continues, the patient should be directed to IMMEDIATELY REMOVE THE LENS AND CONTACT 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.

Vision Quality and Potential Symptoms:

Due to the intended optical design of these lenses for the purpose of reducing the patient's prescription change, under certain circumstances, some patients may experience visual symptoms.

- These lenses will provide vision correction while worn, but the vision quality may not be as clear as with conventional soft contact lenses.
  - Some patients may experience bothersome visual symptoms. For example, lights may appear streaked or smeared or have blur or fuzz around them; or things may appear to have a faint image overlapping them.
- Different patients may experience different levels of such visual symptoms, and some may find these visual symptoms bothersome and cause difficulties with some activities.
  - Patients should exercise extra care if performing potentially hazardous, vision demanding activities.
  - **If the patient is not comfortable with how well they can see with these lenses, remove the lenses and contact the Eye Care Professional.** The Eye Care Professional may modify the patient's prescription to help them see as well as possible. The Eye Care Professional may also decide to discontinue the patient from wearing these lenses.

GENERAL FITTING GUIDELINES

A. Patient Selection

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

- Motivation to wear lenses
- Ability to follow instructions regarding lens wear and care
- General health
- Ability to adequately handle and care for the lenses
- Ability to understand the risk and benefits of lens wear

Patients who do not meet the above criteria should not be provided with contact lenses.

B. Pre-fitting Examination

Initial evaluation of the patient should begin with a thorough case history to determine if there are any contraindications to contact lens wear. During the case history, the patient's visual needs and expectations should be determined as well as an assessment of their overall ocular, physical, and mental health.

Preceding the initial selection of trial contact lenses, a comprehensive ocular evaluation should be performed that includes, but is not limited to, refraction, best corrected visual acuity, binocular vision, slit lamp examination, keratometry, and axial length (when available).

Based on this evaluation, if it is determined that the patient is eligible to wear these lenses, the Eye Care Professional should proceed to the appropriate lens fitting instruction outlined below.

C. 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 ≥ ±4.00D.

D. Base Curve Selection (Trial Lens Fitting)

The following trial lenses should be selected for patients regardless of keratometry readings. However, corneal curvature measurements should be performed to establish the patient's baseline ocular status.

For the ACUVUE® Abiliti™ 1-Day Soft Therapeutic Lenses for Myopia Management, the intial lens should be selected from the currently available base curves.

The trial lens should be placed on each of the patient's eyes and evaluated after the patient has adjusted to the lenses.

1. Criteria of a Properly Fit Lens

   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.

2. Criteria of a Flat Fitting 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 the blink, and/or edge standoff. If the lens is judged to be flat fitting, it should not be dispensed to the patient.

3. Criteria of a Steep Fitting Lens

   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 lens is judged to be steep fitting, it should not be dispensed to the patient.

If the initial 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. The lens should move freely when manipulated digitally with lower lid, and then return to a 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.

E. 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 20/25 or better visual acuity with the correct lens power unless there is excessive residual astigmatism. To avoid over-minusing, positive over refraction is not acceptable, and up to -0.25D over-refraction may be acceptable if patients have at least 20/25 visual acuity. Adjust lens power in 0.25D steps as needed.

Example 1:	
Diagnostic lens:	-2.00D
Spherical over-refraction:	+0.25D
Final lens power:	-1.75D

Example 2:	
Diagnostic lens:	-2.00D, visual acuity ≥ 20/25 and patient confirms acceptance of vision
Spherical over-refraction:	-0.25D
Final lens power:	-2.00D

Example 3:	
Diagnostic lens:	-2.00D, visual acuity < 20/25
Spherical over-refraction:	-0.25D, improves visual acuity to ≥ 20/25 and patient confirms acceptance of vision
Final lens power:	-2.25D

If vision is acceptable, perform a slit lamp examination to assess adequate fit (centration and movement). If fit is acceptable, dispense the lenses instructing the patient to return in one week for reassessment (see dispensing and follow up information in **PATIENT MANAGEMENT**).

All patients should be supplied with a copy of the Patient Instruction Guide for these lenses. Copies are available for download from www.seeyourabiliti.com.

PATIENT MANAGEMENT

- **Follow the accepted standard of care in fitting and following up with your patient.**
- **Schedule the appropriate follow-up examination.**
- **Preferably, at the follow-up visits, lenses should have been worn for at least six hours.**
- **Provide the patient with a copy of the Patient Instruction Guide for these lenses, which can be found at www.seeyourabiliti.com. REVIEW THESE INSTRUCTIONS WITH THE PATIENT SO THAT HE OR SHE CLEARLY UNDERSTANDS THE PRESCRIBED WEARING AND REPLACEMENT SCHEDULE (DAILY DISPOSABLE).**

WEARING SCHEDULE

The wearing and replacement schedules should be determined by the Eye Care Professional. Regular checkups, as determined by the Eye Care Professional, are also extremely important.

Patients tend to over wear the lenses initially. The Eye Care Professional should emphasize the importance of adhering to the initial maximum wearing schedule. Maximum wearing time should be determined by the Eye Care Professional based upon the patient's physiological eye condition, because individual response to contact lenses varies.

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

REPLACEMENT SCHEDULE

These lenses are indicated for daily disposable wear and should be discarded upon removal.

LENS CARE DIRECTIONS

When lenses are dispensed, the Eye Care Professional should provide the patient with appropriate and adequate warnings and instructions for daily disposable lens wear.

The Eye Care Professional 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.

Basic Instructions:

- Always wash, rinse, and dry hands before handling contact lenses.
- Do not use saliva or anything other than the recommended solutions for lubricating or rewetting lenses. Do not put lenses in the mouth.
- Eye Care Professionals may recommend a lubricating/rewetting solution which can be used to wet (lubricate) lenses while they are being worn to make them more comfortable.

Care for a Sticking (Non-Moving) Lens

During removal, if the lens sticks to the eye, 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.

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.

REPORTING OF ADVERSE REACTIONS

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

Johnson & Johnson Vision Care, Inc.
7500 Centurion Parkway
Jacksonville, FL 32256
USA
Tel: 1-877-334-3937, Option 4
www.seeyourabiliti.com

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Revision number: AS-11-22-05
SAP Number: 20401260
TIN0401260

ACUVUE® Abiliti™ 1-Day Soft Therapeutic Lenses for Myopia Management are Trademarks of Johnson & Johnson Vision Care, Inc.

IMPORTANT: Please read carefully and keep this information for future use.

This Package Insert and Fitting Guide 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 appropriate instructions that pertain to the patient's prescribed lenses. Copies are available for download at www.seeyourabiliti.com.

ACUVUE® abiliti™
1-DAY SOFT THERAPEUTIC LENSES FOR MYOPIA MANAGEMENT

ACUVUE® Abiliti™ 1-Day Soft Therapeutic Lenses for Myopia Management senofilcon A Soft (hydrophilic) Contact Lenses

Visibility Tinted with UV Blocker for Daily Disposable Wear

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

SYMBOLS KEY

The following symbols may appear on the label or carton:

SYMBOL	DEFINITION
	Caution, Consult Instructions for Use
	Date of Manufacture
	Manufactured by or in
	Use By Date (expiration date)
	Batch Code
	Sterilized Using Steam or Dry Heat
	Do Not Re-Use (Single Use)
	Do Not Use if Package is Damaged
	Fee Paid for Waste Management
	Indicates a Single Sterile Barrier System
	CAUTION: US Federal law restricts this device to sale by or on the order of a licensed practitioner
UV BLOCKING	UV Blocking
DIA	Diameter
BC	Base Curve
D	Diopter (lens power)
	Lens Orientation Correct

SYMBOL	DEFINITION
	Lens Orientation Incorrect (Lens Inside Out)
	Contains Hazardous Substances
MD	Medical Device Symbol
EC REP	Authorized Representative in the European Community
A. B.	Package Opening Icon

Visit www.acuvue.com/guides for additional information about symbols.

DESCRIPTION

The ACUVUE® Abiliti™ 1-Day Soft Therapeutic Lenses for Myopia Management are soft (hydrophilic) contact lenses available as spherical lenses.

These lenses are made of a silicone hydrogel material (senofilcon A) containing an internal wetting agent, visibility tint, and ultraviolet (UV) absorbing monomer.

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

Lens Properties:

The physical/optical properties of the lens are:

- Specific Gravity (calculated): 0.98 – 1.12
- Refractive Index: 1.42
- Visible Light Transmittance: 89% minimum
- Surface Character: Hydrophilic
- Water Content: 38%
- Oxygen Permeability:

VALUE	METHOD
103 x 10^{-11} (cm^2/sec) ml O_2/ml x mm Hg) @ 35°C	Fatt (boundary corrected, edge corrected)

Lens Parameter Ranges:

- Diameter (DIA): 12.0 mm to 15.0 mm
- Center Thickness: varies with power
- Base Curve (BC): 7.85 mm to 10.00 mm
- Spherical Power (D): -20.00D to +20.00D

Each lens is supplied in a foil-sealed plastic package containing borate buffered saline solution with methyl ether cellulose.

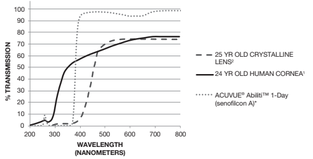
AVAILABLE LENS PARAMETERS

The ACUVUE® Abiliti™ 1-Day Soft Therapeutic Lenses for Myopia Management are hemispherical shells available in the following dimensions:

Diameter (DIA):	13.8 mm
Center Thickness:	0.085 mm to 0.097 mm (varies with power)
Base Curve (BC):	7.9 mm
Spherical Power (D):	-0.25D to -8.00D (in 0.25D increments)

TRANSMITTANCE CURVE

The ACUVUE® Abiliti™ 1-Day Soft Therapeutic Lenses for Myopia Management (senofilcon A) vs. 24 yr. old human cornea and 25 yr. old human crystalline lens.



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

*The data was obtained from measurements taken through the central 6 mm portion for the thinnest single vision lens (-8.00D lens, 0.085mm center thickness).

ACTIONS

In its hydrated state, the contact lens, when placed on the cornea, acts as a refracting medium to focus light rays on the retina.

These lenses contain a UV Blocker to help provide protection against transmission of harmful UV radiation to the cornea and into the eye. The light transmittance characteristics for these lenses are less than 1% in the UVB range of 280 nm to 315 nm and less than 10% in the UVA range of 315 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. The patient 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. The Eye Care Professional should be consulted for more information.

INDICATIONS (USES)

The ACUVUE® Abiliti™ 1-Day Soft Therapeutic Lenses for Myopia Management are intended for daily wear, worn on a daily disposable basis, for the correction of myopia (while the lenses are worn) and may slow myopia progression in children. The contact lenses are intended to be used by children who, at the initiation of treatment, are 7 to 12 years old, with myopia between -0.75D and -4.50D and 1.00D or less astigmatism, with non-diseased eyes and are symptomatic with regard to a need for distance vision correction.

Slowing axial elongation and myopia progression was demonstrated in a clinical study of children between 7 and 12 years of age with a required lens wear time of, at a minimum, 8 hours per day and 5 days per week. Longer-term myopia control effect of the lens as well as permanent myopia control after lens treatment is discontinued has not been established through clinical trials.

The lenses contain a UV Blocker to help protect against transmission of harmful UV radiation to the cornea and into the eye.

These lenses should be prescribed for daily disposable use only. Therefore, no cleaning or disinfection is required. Lenses should be discarded upon removal.

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE these lenses 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
- Any active corneal infection (bacterial, fungal, protozoal, or viral)
- If eyes become red or irritated
- Ocular irritation due to allergic reactions which may be caused by use of contact lens solutions (i.e., rewetting drops) that contain chemicals or preservatives (such as mercury or Thimerosal, etc.) to which some people may develop an allergic response

WARNINGS

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. IF THE PATIENT EXPERIENCES:

- **Eye Discomfort,**
- **Excessive Tearing,**
- **Vision Changes,**
- **Loss of Vision,**
- **Eye Redness, or**
- **Other Eye Problems,**

THE PATIENT SHOULD BE INSTRUCTED TO IMMEDIATELY REMOVE THE LENSES, AND PROMPTLY CONTACT THE EYE CARE PROFESSIONAL.

- When prescribed for daily wear, patients should be instructed not to wear their lenses while sleeping. Clinical studies have shown that the risk of serious adverse reactions is increased when lenses are worn overnight, and that the risk of ulcerative keratitis is greater for extended wear contact lens users than for daily wear users.[3]
- Studies have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than nonsmokers.
- 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 are essential for the safe use of these products.
- The overall risk of ulcerative keratitis may be reduced by carefully following directions for lens care.

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

Specific Instructions for Use and Warnings:

- **Water Activity**

  Instruction for Use

  Do not expose contact lenses to water while wearing them.

  WARNING:

  Water can harbor microorganisms that can lead to severe infection, vision loss, or blindness. If lenses have been submersed in water when participating in water sports or swimming in pools, hot tubs, lakes, or oceans, the patient should be instructed to discard them and replace them with a new pair. Ask the Eye Care Professional for recommendations about wearing lenses during any activity involving water.

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 and slowing myopia progression; therefore, the continuing ocular health of the patient and lens performance on the eye should be carefully monitored by the prescribing Eye Care Professional.

- Eye Care Professionals should instruct the patient to remove lenses immediately if the eyes become red or irritated.
- Eye Care Professionals should instruct the patient to always have a functional pair of spectacles with a current prescription available to use if the patient becomes unable to wear contact lenses, or in circumstances where contact lens wear is not advised.
- The patient's vision should be closely monitored by the Eye Care Professional to make sure their eyes and vision are performing properly.
  - If a young patient experiences blurred vision for a long enough period of time, this could theoretically cause a permanent reduction of their vision, even with the best prescription glasses, if it is not identified and treated promptly.[4]
  - If the patient is not comfortable with how well they can see with these lenses, remove the lenses and contact the Eye Care Professional. The Eye Care Professional may modify the patient's prescription to help them see as well as possible.
  - The Eye Care Professional may also decide to discontinue the patient from wearing these lenses if the patient's vision is reduced too much, to prevent any long-term risk of reduced visual acuity.
  - It is critical that the patient completes all scheduled follow-up visits with the Eye Care Professional on time to minimize the risk of these problems.

[4]No loss of best sphero-cylindrical corrected visual acuity (BSCVA) has been observed in JJVC myopia control clinical trials or reported in the literature for other optical interventions for myopia that introduce aberrations to the eye.

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

Handling Precautions:

- **DO NOT** use if the sterile blister package is opened or damaged.
- 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.
- Always wash, rinse, and dry hands before handling lenses. It is best to put on lenses before putting on makeup.
- Carefully follow the handling, insertion, removal, and wearing instructions in the "Patient Instruction Guide" for ACUVUE® Abiliti™ 1-Day Soft Therapeutic Lenses for Myopia Management and those prescribed by the Eye Care Professional.
- Never use tweezers or other tools to remove lenses from the lens container. Slide the lens up the side of the bowl until it is free of the container.

Lens Wearing Precautions:

- If the lens sticks (stops moving) on the eye, follow the recommended directions in *"Care for a Sticking (Non-Moving) 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.
- Never wear lenses beyond the period recommended by the Eye Care Professional.
- The patient should be advised to never allow anyone else to wear their lenses. Sharing lenses greatly increases the chance of eye infections.
- If aerosol products, such as hair spray, are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.
- Avoid all harmful or irritating vapors and fumes while wearing lenses.
- The patient should be advised to never rinse the lenses in water from the tap. Tap water contains many impurities that can contaminate or damage the lenses and may lead to eye infection or injury.

Lens Care Precautions:

- The patient should be informed that no cleaning or disinfection is needed when lenses are worn for daily disposable wear. Patients should always dispose of lenses when removed and have spare lenses or spectacles available.

Other Topics to Discuss with Patients:

- Always contact the Eye Care Professional before using any medicine in the eyes.
- 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.
- Do not change lens type (e.g. brand name, etc.) or parameters (e.g. diameter, base curve, lens power, etc.) without consulting the Eye Care Professional.
- Instruct patients to always confirm the lens parameters printed on the multi-pack and on the individual lens package match their prescription. If there is a mismatch the patient should not use the product.
- 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.

Who Should Know That the Patient is Wearing Contact Lenses?

- Patients should inform all doctors (Health Care Professionals) about being a contact lens wearer.
- Patients should always inform their teachers and coaches of being a contact lens wearer.

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 the potential for some temporary impairment due to peripheral infiltrates, peripheral corneal ulcers, or corneal erosion. There may be the potential for other physiological observations, such as local or generalized edema, corneal neovascularization, corneal staining, injection, tarsal abnormalities, iritis, and conjunctivitis; some of which are clinically acceptable in low amounts.