

After Your
ACUVUE® Abiliti™
Overnight Therapeutic Lenses
for Myopia Management
Have Been Fitted

Instructions for Wearers of ACUVUE® Abiliti™ Overnight

CAUTION:

- Federal law restricts this device to sale by, or on the order of a licensed professional.
- ACUVUE® Abiliti™ Overnight should be fitted only by a contact lens eye care professional trained at the workshop and certified in the fitting of reverse geometry rigid gas permeable contact lenses.
- Non-sterile. Clean and condition lenses prior to use.

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PRECAUTIONS

Eye care professional

Clinical studies have demonstrated that ACUVUE® Abiliti™ Overnight Therapeutic Lenses for Myopia Management are safe and effective for their intended use. However, the clinical studies may not have included all design configurations or lens parameters that are presently available in the material. Consequently, when selecting an appropriate lens design and parameters, the eye care professional should consider all factors that affect lens performance and the patient's 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 weighed against the patient's need for refractive reduction; therefore, the continuing ocular health of the patient, and lens performance on the eye should be carefully monitored by the prescribing eye care professional.

Overnight orthokeratology lenses in adults have been shown to induce optical aberrations, increase irregularity of the surface of the eye, and reduce the eye's ability to detect subtle differences in shading and patterns (contrast sensitivity) to a degree correlated with myopic correction achieved, even in clinically successful orthokeratology cases. This may cause bothersome symptoms in vision (i.e.: double vision, glare, halos, blurring, and night vision problems).

ACUVUE® Abiliti™ Overnight are supplied non-sterile in an individual plastic case. The lens is shipped wet and must be cleaned and conditioned prior to use.

Patient

Patients should be informed of the following precautions.

Solution Precautions

- Different solutions cannot always be used together, and not all solutions are safe for use with all lenses. Use only recommended solutions with the contact lenses.
- Do not heat the wetting/soaking solution and lenses.
- Always use fresh unexpired lens care solutions.
- Always follow directions in the package inserts of the contact lens solutions used.
- Use only a chemical lens care system. Use of a heat (thermal) lens care system can cause damage by warping the lenses.
- 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).
- Do not use lens care products that contain an abrasive component (i.e., silica) to prevent wearing away wettable plasma-treated surface which in turn can improve the comfort of the lens and reduce fogging problems.

Handling Precautions

- Always wash, rinse and dry 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.

- Be certain that fingers or hands are free of foreign material before touching the contact lenses. 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 this booklet and those prescribed by the eye care professional.
- Always handle the lenses carefully and avoid dropping them.
- Never use tweezers or other tools to remove lenses from the lens container unless specifically indicated for that use.
- Do not touch the lens with fingernails.
- To minimize lens warpage during cleaning, the lenses should be cleaned in the palm of the hand rather than between the thumb and fingers.

Lens Wearing Precautions

- **CAUTION:** Non-sterile. Clean and condition lenses prior to use.
- If the lens sticks (stops moving) on the eye, follow the recommended directions on Care for a Sticking Lens in this booklet. The lens should move freely on the eye for the continued health of the eye. If non-movement of the lens continues, patients should immediately consult with the eye care professional.
- Lens should be mobile before taking out. A lens (in the morning) that sticks to the eye should be made mobile by following the instructions before removal.
- Never wear contact lenses beyond the period recommended by the eye care professional.
- Avoid, if possible, all harmful or irritating vapors and fumes when wearing lenses.
- If aerosol products such as sprays are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.

Lens Case Precautions

Contact lens cases can be a source of bacterial growth. To prevent contamination and to help avoid serious eye injury, always empty, clean, and rinse the lens case with fresh, sterile rinsing solution and allow to air dry. Do not use tap water.

- Lens cases should be replaced at regular intervals as recommended by the lens case manufacturer or eye care professional.

Discuss these topics with each patient

- Use of any medication in the eye.
- Importance of adhering to the recommended follow-up schedule to assure the continuing health of the eyes.
- Informing health care practitioner about being a contact lens wearer.
- Informing employers of being a contact lens wearer. Some jobs may require the use of eye protection equipment or may require that contact lenses not be worn during work hours.
- What should be done if vision is inadequate during the day.

ADVERSE EFFECTS

Patients should be informed that the following problems might occur:

- Eyes stinging, burning, itching (irritation), or other eye pains.
- Comfort is less than when lens was first placed on eye.

- Feeling of something in the eye, such as a foreign body or scratched area.
- Excessive watering (tearing) of the eyes.
- Unusual eye secretions.
- Redness of the eyes.
- Reduced sharpness of vision (poor visual acuity).
- Blurred vision, rainbows, or halos around objects.
- Sensitivity to light (photophobia).
- Dry eyes.

Please refer to the Clinical Study Data Section of the Package Insert for adverse effects observed during the study.

If the patient notices any of these conditions, the patient should be instructed to **IMMEDIATELY REMOVE THE LENSES**.

The patient should be advised to follow these instructions:

- If the discomfort or problem stops, then look closely at the lens.
- If the lens is in any way damaged, **DO NOT** put the lens back on the eye. Place the lens in the storage case and contact the eye care professional.
- If the lens has dirt, an eyelash, or other foreign objects on it, or the problem stops and the lens appears undamaged, thoroughly clean, rinse and disinfect the lens; then reinsert it.
- If the problem continues, **IMMEDIATELY** remove the contact lenses and consult the eye care professional.

When any of the above problems occur, a serious condition such as Acanthamoeba Keratitis, infection, corneal ulcer, neovascularization, iritis, persistent stromal oedema or GPC (giant papillary conjunctivitis) may be present. The patient should be instructed to keep the lens off the eye and seek immediate professional identification of the problem and prompt treatment to avoid serious eye damage including corneal scarring, opacification, blindness or loss of eye.

PERSONAL CLEANLINESS FOR LENS HANDLING

Preparing 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 substance 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.
- To avoid damaging your lenses, handle them with your fingertips, and be careful to avoid contact with your 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.

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 and tears.

Placing the Lens on the Eye

- Work over a table, upon which is placed a clean towel.
- Do not place lenses on the eye while working over a sink.

For the RIGHT EYE

- Wet the forefinger of the right hand with a drop of conditioning solution and place the right (Red) contact lens on the forefinger of the right hand.
- Place the second finger of the left hand on the middle of the upper lid and press upward firmly.
- Place the second finger of the right hand on the lower lid and press downward firmly.
- Stare into a mirror as though looking through the forefinger holding the contact lens. You will later learn to do this without a mirror.
- Slowly move the hand to advance the forefinger with the contact lens towards the cornea until the lens touches the cornea and release the lids.
- Release the lid and close the eye for a few seconds.

For the LEFT EYE

- Wet the forefinger of the left hand with a drop of conditioning solution and place the left (bLue) contact lens on the forefinger of the left hand.
- Repeat the instruction like for the right 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 section in this booklet). If the lens is centered, remove the lens (see "Removing the Lens" section) and check for the following:

- Cosmetics, eye lash or oils on the lens. Clean, rinse, disinfect, and place on the eye again.
- The lens is on the wrong eye.

If you find that your vision is still blurred after checking the above possibilities remove both lenses and consult your eye care professional.

Centering the Lens

Very rarely, a lens that is on the cornea will be displaced onto the white part of the eye during lens wear. This can also occur during placement and removal of the lenses if the correct techniques are not performed properly. To center a lens, follow the procedure below.

- First, locate the lens by pulling away the lids.
- After the lens is found gently press on the lid over the lens while looking away from the direction of the lens.
- Next, look back towards the lens. The lens should center on the cornea.

Removing the Lens

- Always remove the same lens first.
- Wash, rinse, and dry your hands thoroughly.

- Work over a table with a clean towel. Do not remove lenses over a sink unless you have first placed a clean towel over the drain.
- Place the right index finger of the right hand at the outer corner of the eye.
- Place the left hand cupped below the eye.
- Open the eyes wide as if to stare.
- Continue to keep the eyes open and pull the lids sideways away from nose.
- Blink quickly and firmly.
- Remove the other lens by following the same procedure.
- Follow the required lens care procedures described under the heading: CARING FOR YOUR LENSES

Note: If this method of removing your lens is difficult for you, your eye care professional will provide you with an alternate method.

CARING FOR YOUR LENSES

Basic Instructions

For continued safe and comfortable wearing of your lenses, it is important that you clean and rinse, then disinfect 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, rinse, and disinfect your lenses is immediately after wearing them. Disinfecting is necessary to destroy harmful germs.

- You should comply with to a recommended care regimen.
- Failure to follow the regimen may result in development of serious ocular complications as discussed in the WARNINGS section above.
- When you first receive your lenses, practice how to put the lenses on and removing 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 solutions.
- Use the recommended system of lens care, which is 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 cleaning solution does not substitute for disinfection.
- To avoid contamination, do not use saliva or anything other than the recommended solutions for lubricating or rewetting your lenses. Do not put lenses in your mouth.

The lens care products listed below are recommended by the manufacturer for use with your ACUVUE® Abiliti™ Overnight.

Chemical Lens Care System

For daily use, a multipurpose lens care solution approved for rigid gas permeable contact lenses is recommended for Cleaning, Conditioning, Disinfect and Rinsing lenses prior to lens insertion.

Avoid lens care products that contain an abrasive component (e.g., silica) and/or contact your ACUVUE® Abiliti™ supplier for further information.

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.

In order to provide appropriate care for your lenses the following steps must be completed each time you remove your lenses. Do not skip any step.

Cleaning

Rub both sides of the lenses carefully with 2 to 4 drops of approved cleaning solution or multipurpose solution of rigid gas permeable solution. Be sure to clean each side of the lens.

Rinsing

Thoroughly rinse with an approved rinsing solution for rigid gas permeable solution or another rinsing solution recommended by your eye care professional.

Conditioning and Storage

Place each lens in the correct side of the lens storage case, then fill each chamber with fresh approved for rigid gas permeable storing solution completely covering the lenses. Close the case tightly. Store the lenses in storing solution for at least four hours prior to wearing your lenses.

Care of Your Lens Case

Contact lens cases can be a source of bacterial growth. To prevent contamination and to help avoid serious eye injury, always empty, clean, and rinse the lens case with fresh, sterile rinsing solution and allow to air dry. Do not use water. When the case is used again, refill it with fresh disinfecting solution. Lens cases should be replaced at regular intervals as recommended by the lens case manufacturer or your eye care professional.

Lubricating / Re-wetting

Your eye care professional will recommend a lubricating / re-wetting solution for your use. Lubricating / Re-wetting solutions can be used to re-wet (lubricate) your lenses while you are wearing them to make them more comfortable.

Intensive Cleaning Procedure

For intensive cleaning a dedicated intensive cleaner for gas permeable lenses is advise on a (bi-) weekly base advised by the eye care professional.

Intensive cleaning or protein deposit cleaning does not replace routine cleaning and disinfecting. The patient should carefully follow the instructions in the package inserts of the intensive cleaner.

Care for a Sticking (Non-Moving) Lens

If the lens is stuck (stops moving) or cannot be removed, you should apply 5 drops of the recommended lubricating or re-wetting solution directly to the eye. Wait until the lens begins to move freely on the eye before removing it.

If it still won't move, proceed as follows:

- Add a few more artificial tears to the eye.
- Look up and push the lower eyelid a few times against the eyeball with your forefinger, just below the lens.
- Look down and push the upper eyelid a few times against the eyeball with your forefinger, just above the lens.
- Look straight ahead and blink a few times.
- Repeat these steps until the lens moves. Only remove the lens if it moves.
- If in doubt, contact your eye care professional.

EMERGENCIES

If chemicals of any kind (household products, gardening solutions, laboratory chemicals, etc.) are splashed into your eyes, you should:

- FLUSH EYES IMMEDIATELY WITH TAP WATER
- REMOVE YOUR LENSES
- IMMEDIATELY CONTACT YOUR EYE CARE PROFESSIONAL OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.

WEARING AND APPOINTMENT SCHEDULE

Wearing Schedule: On the first night of lens wear, lenses should be inserted to ideally achieve 8 to 10 hours of closed eye wearing time (sleep). A minimum of 6 hours of sleep is recommended for any given night. A well fit lens provides for centration with the eye closed. You should place the lens(s) on your eye 15 to 20 minutes before going to sleep. Try to limit the time the lenses are worn with the eyes open as the effects of lid interaction from blinking and gravity may result in lens and treatment decentration. Your eye care professional will advise you if the wearing schedule needs to be changed. Be aware "when in doubt, take it out". It is important that the new wearer does not sleep in a lens that causes a significant foreign body sensation. If this occurs, the lenses must be removed, cleaned and re-wetted; only after these steps lenses can be worn again. If the sensation continues, lenses must be removed, and an appointment should be scheduled.

Appointment Schedule: Your eye care professional will schedule a follow-up evaluation after the first overnight wear. The visit is best scheduled within a few hours of awakening, and you should report with your lenses in place. This visit provides an excellent opportunity to look at lens centration and potential lens adherence.

Assuming the absence of clinical signs and complications, you will be instructed to continue overnight wear of the lenses until the next scheduled follow-up visit. Keeping these appointments is important to maintain good eye health.

Appointment Dates

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