PACKAGE INSERT

ACUVUE® Abiliti™ Overnight Therapeutic Lenses for Myopia Management

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.

All information in this package insert is equally applicable to the ACUVUE® Abiliti™ Overnight Therapeutic Lenses as for ACUVUE® Abiliti™ Overnight Therapeutic Lenses with Astigmatism.

CAUTION:

- Federal law restricts this device to sale by, or on the order of a licensed practitioner.
- 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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DESCRIPTION

ACUVUE® Abiliti™ Overnight Therapeutic Lenses for Myopia Management are lathe cut contact lenses for orthokeratology. The lenses are designed to have three zones which are a central spherical optic zone, a midperipheral reverse zone and a linear peripheral landing zone. Using a double reverse geometry design, the lenses have a smooth connection between the central curve and the landing zone.

ACUVUE® Abiliti™ Overnight are manufactured from Menicon Z (tisilfocon A). The lens material (tisilfocon A) is a thermoset copolymer derived from fluoro-methacrylate and siloxanylstyrene, bound by crosslinking agents. The lens is available in a light blue tint, for the left eye, D&C Green No. 6 or in a red tint for the right eye, D&C Red No.17. Also, a UV absorber (Benzotriazol) is added as an additive during the manufacturing process.

LENS PARAMETERS AVAILABLE

ACUVUE® Abiliti™ Overnight lenses for myopia management – Finished Lens Specifications	
	Specification
Diameter (mm)	10.20, 10.60, 11.00
Center thickness (mm)	0.24
Base curve (mm)	7.50 – 10.00 (0.05 steps)
Tangential angle (°)	50 – 65 (1 steps)
Height (mm)	0.95 – 1.45 (0.01 steps)
Vertex power (D)	0.00 - +2.00 (0.25 steps)
Fenestration	3 holes
Diameter of hole (mm)	0.25

ACUVUE® Abiliti™ Overnight lenses for myopia management with astigmatism – Finished Lens Specifications	
	Specification
Diameter (mm)	10.20, 10.60, 11.00
Center thickness (mm)	0.24
Base curve (mm)	7.50 – 10.00 (0.05 steps)
Tangential angle flat (°)	50 – 65 (1 steps)
Tangential angle steep (°)	46 – 63 (1 steps)
Height flat (mm)	0.95 – 1.45 (0.01 steps)
Height steep (mm)	0.97 – 1.54 (0.01 steps)

Vertex power (D)	0.00 - +2.00 (0.25 steps)
Fenestration	3 holes
Diameter of hole (mm)	0.25

PHYSICAL PROPERTIES

The physical properties of tisilfocon A are:

- Specific Gravity: 1.20
- Refractive Index: $n^{20}e$ 1.439±0.002
- Surface Character: Hydrophobic
- Wetting Angle: 51 degrees (after soaking)
- Light Transmittance: (sample thickness 0.2mm)
  - Visible region ≧80% (380 nm – 780 nm)
  - Ultraviolet region ≤5% (210 nm – 380 nm)
- Water Absorption: Less than 0.5% by weight
- Oxygen Permeability:
  - $163x10^{-11}$ (cm^2/sec)(mL O_2/(mL × mmHg)) Dk
- "Hardness(Shore D): 83

ACTIONS

The ACUVUE® Abiliti™ Overnight produce a temporary reduction of myopia by changing the shape (flattening) of the cornea, which is elastic in nature. Flattening the cornea reduces the focusing power of the eye, and if the amount of corneal flattening is properly controlled, it is possible to bring the eye into correct focus and completely compensate for myopia.

The posterior surface of regular contact lenses generally aligns with the central cornea and rests directly on the corneal tear layer. Regular contact lenses are designed to cause little or no effect on the cornea but ACUVUE® Abiliti™ Overnight are designed to purposely flatten the shape of the cornea by applying slight pressure to the center of the cornea when the patient is asleep.

After the lens is removed, the cornea retains its altered shape for all or part of the remainder of the day. The lenses are designed to be worn overnight with removal during the following day. The ACUVUE® Abiliti™ Overnight must be worn at night on a regular schedule to maintain the orthokeratology effect, or the myopia will revert to the pre-treatment level.

INDICATIONS

ACUVUE® Abiliti™ Overnight are indicated for use in the control of myopia in non-diseased eyes when prescribed and managed by a qualified eye care professional. ACUVUE® Abiliti™ Overnight Therapeutic Lenses for Myopia Management are available in powers from 0 D to + 2.0 D and are intended for correction and control of myopia between -0.5 and -4.0 D. ACUVUE® Abiliti™ Overnight Therapeutic Lenses for Myopia Management with Astigmatism are available in powers from 0 D to +2.0 D and are intended for correction and control of myopia between between -0.5 and -5.0 D with between -1.25 and -3.50 D of with-the-rule astigmatism. The lenses may only be disinfected using a chemical disinfection system.

Note: To maintain the Orthokeratology effect of myopia control, overnight lens wear must be continued on a prescribed schedule. Failure to do so can affect daily activities (e.g., night driving), cause visual fluctuations, and changes in intended correction.

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE the ACUVUE® Abiliti™ Overnight when any of the following conditions exist:

- Acute and sub-acute inflammations 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 tears (dry eyes)
- Corneal hypoesthesia (reduced corneal sensitivity).
- Any systemic disease which may affect the eye or be exacerbated by wearing contact lenses.
- Allergic reactions of ocular surfaces or adnexa which 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 your ACUVUE® Abiliti™ Overnight.
- Any active corneal infection (bacterial, fungal or viral).
- If eyes are red or irritated

WARNINGS

The practitioner should provide this warning to the patient.

PROBLEMS WITH CONTACT LENSES AND LENS CARE PRODUCTS COULD RESULT IN SERIOUS INJURY TO THE EYE.

Incorrect use of contact lenses and lens care products can result in serious injury to the eye. It is essential that the patient follows the directions of the eye care professional and all labelling instructions for proper use of contact lenses and lens care products.

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,
- Redness of The Eye,
- Or Other Problems with their Eyes,

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

All contact lens wearers must see their eye care professional according to the schedule given to them. ACUVUE® Abiliti™ Overnight lenses are to be worn overnight with removal during all or part of each following day. Wearing the lenses continuously (extended wear) presents increased risk, which increases with the number of consecutive days that the lenses are worn between removals. Although ACUVUE® Abiliti™ Overnight lenses are prescribed only for overnight wear with removal during the waking hours, and although the safety risks of intermittent overnight wear may not be as great as with sustained overnight wear; there is still increased risk beginning with the first overnight period.

The risk of ulcerative keratitis has been shown to be greater among wearers of extended wear lenses than among wearers of daily wear lenses. The risk among extended wear lens wearers increases with the number of consecutive days that lenses are worn between removals, beginning with the first overnight use. This risk can be reduced by carefully following directions for routine lens care, including cleaning of the lens storage case. Additionally, smoking increases the risk of ulcerative keratitis for contact lens wearers. Studies have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than non-smokers.

It is recommended that contact lens wearers see their eye care practitioner twice each year or, if directed, more frequently.

To avoid serious eye infections, vision loss or blindness, please be aware of the following warnings…

- Inadequate rubbing, rinsing, and disinfecting of your lenses may cause serious eye infections, vision loss or blindness.
- Do not reuse or "top off" old solution left in your lens case since solution reuse reduces effective lens disinfection and could lead to severe infection, vision loss or blindness. "Topping-Off" is adding fresh solution to solution that has been sitting in your case.
- Never use water, saline solution, or rewetting drops to disinfect your lenses. These solutions will not disinfect your lenses. Not using the recommended disinfectant can lead to severe infection, vision loss or blindness.
- Do not expose your contact lenses to water while you are wearing them.
- Do not use your multi-purpose solution beyond the expiration and/or discard date because it could result in contamination of the solution and can lead to severe infection, vision loss or blindness.
- Do not store your lenses or rinse your lens case with water or any non-sterile solution. Only use fresh multi-purpose solution (or sterile saline solution) so you do not contaminate your lenses or lens case.

PRECAUTIONS

Eye care professional

Clinical studies have demonstrated that ACUVUE® Abiliti™ Overnight 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 corneal irregularity and ocular high-order aberrations, and reduce the eye's contrast sensitivity function 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 labelling 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).

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 eyecare practitioner.
- 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.
- For use in pediatrics, parents should supervise lens care regimen to reduce the chance of complications such as infection.

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 the "Instructions for Wearers" 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 vapours 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.
- What should be done if vision is inadequate during the day.

ADVERSE EFFECTS (PROBLEMS AND WHAT TO DO)

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 Section of this 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 infection, corneal ulcer, neovascularization, iritis, persistent stromal edema 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.

CLINICAL STUDY DATA

A total of 300 eyes (150 patients) were enrolled in the clinical study with 274 eyes (137 patients) completing a minimum of 12 months of contact lens wear. Data on 252 eyes were analysed after 12 months of wear. A total of 251 eyes showed some reduction in myopic refractive error. The average reduction was -2.48 diopters with a range from -0.25 to -4.00 diopters.

The average amount of myopia that can be expected to be corrected is shown in the following table. These values are only averages and some patients can be expected to achieve more or less than these averages.

AVERAGE REDUCTION IN MYOPIA

Initial Myopia	Mean Reduction	Mean Residual
0.00 to -1.00 D (N=16)	-0.73 D	-0.16 D
-1.25 to -2.00 D (N=47)	-1.55 D	-0.10 D
-2.25 to -3.00 D (N=104)	-2.50 D	-0.19 D
-3.25 to -4.00 D (N=85)	-3.29 D	-0.35 D

The amount of myopia reduced varied between patients and could not be predicted prior to treatment. The ACUVUE® Abiliti™ Overnight provided a temporary full reduction in some patients with up to -4.00 diopters of myopia. The percentage of patients that can be expected to achieve full or partial temporary refractive reduction is shown in the following table.

Initial Myopia	Full Reduction	Up to 0.5 D Under Full Reduction	Up to 1.0 D Under Full Reduction	Final V.A. 20/20 or Better	Final V.A. 20/40 or Better
0.00 to -1.00 D (N=16)	81%	81%	100%	81%	100%
-1.25 to -2.00 D (N=47)	81%	94%	100%	83%	100%
-2.25 to -3.00 D (N=104)	71%	93%	96%	75%	96%
-3.25 to -4.00 D (N=85)	53%	80%	91%	65%	93%

The percentage of eyes that achieved uncorrected visual acuity of 20/20 or better and 20/40 or better in relation to the initial myopia is given in the above table. A total of 185 (73%) eyes achieved a visual acuity of 20/20 or better and 242 (96%) eyes achieved 20/40 or better. For the 252 eyes analysed after 12 months of wear, 55% had no change in or improved BSCVA, while 38% had a loss of 1 line in BSCVA compared to baseline. Four eyes (2 patients) showed a constant reduction of ≥ 2 lines of BSCVA from initial visit to 12-month visit. Reasons of the vision loss were not accurately determined in these cases, but no significant ocular abnormalities were observed in these eyes at the time of study exit.

EFFECTS ON ASTIGMATISM

Either increases or decreases in astigmatism may occur following orthokeratology. Of the 252 eyes with initial cylinder power ranging from 0 to 1.50 diopters, changes in astigmatism after 12 months of wear were as follows:

Astigmatism Change	Number of eyes (%)
No Change	81 (32%)

Decrease from 0.25 to 0.50 D	85 (34%)
Decrease from 0.75 to 1.00 D	71 (28%)
Decrease ≥ 1.25 D	14 (6%)
Increase	1 (0%)

WEARING TIME

The average wearing time required for patients who wore the ACUVUE® Abiliti™ Overnight for various time periods was as follows:

Wearing Time		1 W	2 W	1 M	3 M	6 M	9 M	12 M
Day(s) per Week	**0**	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
	1 to 3	1.4%	0.0%	0.0%	0.8%	0.0%	0.0%	0.0%
	4 to 5	3.5%	3.6%	5.8%	8.4%	10.9%	4.9%	8.7%
	6 to 7	95.1%	96.4%	94.2%	90.8%	89.1%	95.1%	91.3%

There was considerable variability, however, as many patients required several hours more or less than the averages as shown for the 12-month time period as follows:

Wearing Time		1 W	2 W	1 M	3 M	6 M	9 M	12 M
Hours per Day	**<4**	0.0%	0.0%	0.7%	0.0%	0.0%	0.0%	0.0%
	≥4; <6	1.4%	2.2%	0.7%	0.8%	0.0%	0.0%	1.6%
	≥6; <8	14.8%	15.9%	15.8%	21.4%	20.3%	26.2%	35.7%
	≥8	83.8%	81.9%	82.7%	77.9%	79.7%	73.8%	62.7%

FITTING

Caution: ACUVUE® Abiliti™ Overnight should be fitted only by a contact lens fitter trained at a workshop and certified in the fitting of reverse geometry rigid gas permeable contact lenses.

Conventional methods of fitting rigid contact lenses for orthokeratology DO NOT APPLY to the ACUVUE® Abiliti™ Overnight . For a description of fitting techniques, refer to the **Fitting Guide for ACUVUE® Abiliti™ Overnight Therapeutic Lenses for Myopia Management**, copies of the Fitting guide are available from:

JOHNSON & JOHNSON VISION CARE, INC.
7500 Centurion Parkway
JACKSONVILLE , FL 32256

RECOMMENDED WEARING SCHEDULE

Although many practitioners have developed their own initial wearing schedules, the following schedule is recommended as a guideline. Patients should be advised to follow their eye care professional's recommended wearing schedule regardless of how comfortable the lenses feel.

Wearing Schedule: On the first night of lens wear, lenses should be inserted at a time early enough to 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 good centration with the eye closed. The patient should place the lens(es) on their eye 15 to 20 minutes before going to sleep. Try to limit the time the lenses are own with the eyes open as the effects of lid interaction from blinking and gravity may result in lens and treatment decentration.

Be aware that "when in doubt, take it out". It is important that the new wearer not sleep in a lens 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: The patient should report for a follow-up evaluation the morning after the first overnight wear. The visit is best scheduled within a few hours of awakening. Lenses should be removed in the morning and brought to the appointment. This visit provides an excellent opportunity to evaluate lens centration and potential lens adherence issues.

In the absence of clinical signs and complications, the patient will be instructed to continue overnight wear of the lenses until the next scheduled follow-up visit.

An alternate daytime wear schedule may be offered at the practitioner's discretion.

LENS CARE INSTRUCTIONS

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

Chemical Lens Care System

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

The directions found in the package inserts from these products should be followed. Failure to follow or adhere to these procedures may result in the development of serious ocular complications. A patient should not switch from one care system to another unless it has been determined by the eye care professional that this is necessary. Do not mix or alternate the disinfection and storage systems unless so indicated on the product label.

Inform the patient of the following lens care suggestions:

- Always wash, rinse and dry your hands before handling your contact lenses
- ACUVUE® Abiliti™ Overnight must be both cleaned and disinfected each time you remove them. One procedure does not replace the other. Cleaning is necessary to remove mucus and film from the lens surface. Disinfecting is necessary to destroy harmful germs. To minimize lens warpage during cleaning, the lenses should be cleaned in the palm of the hand rather than between the thumb and fingers.
- Clean one lens at a time. The recommended procedure is to always clean the same lens first to avoid mixing up the lenses. Rinse the lens thoroughly to remove the cleaning solution. Place the lens into the correct storage chamber of the lens case and fill the chamber with the recommended disinfecting solution as recommended by your eye care professional. Clean and rinse the other lens in the same manner and place it in its chamber.
- Tightly close the top of each chamber of the lens storage case.
- To disinfect your lenses, leave them in the solution during the day.
- Leave the lenses in the closed storage case until you are ready to put them on your eye.
- Water should NOT be used for lens cleaning, rinsing, wetting and/or storage.
- For use in pediatrics, parents should supervise lens care regimen to reduce the chance of complications such as infection.

LENS CASE CLEANING AND MAINTENANCE

Contact lens cases are a common source of bacterial contamination. Lens cases should be emptied, cleaned, and rinsed daily with solutions recommended by the lens case manufacturer. Lens cases should be replaced at regular intervals as recommended by the eye care professional.

INTENSIVE CLEANING

For intensive cleaning, a dedicated intensive cleaner for gas permeable lenses should be used on a (bi-) weekly basis or as advised by the eye care professional.

EMERGENCIES

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 then remove lenses promptly. The patient should **CONTACT THE EYE CARE PROFESSIONAL OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.**

HOW SUPPLIED

Each lens is supplied non-sterile in an individual plastic case. The case, packing slip or invoice is marked with the base curve, power in diopters, diameter, center thickness, sagittal depth, tangential angle, color, patient name or reference id, and Lot #.

REPORTING OF ADVERSE REACTIONS

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

Manufactured by:

Menicon B.V.
Waanderweg 6, 7812 HZ, Emmen,
The Netherlands
TEL: +31 (0) 591610640
QARA@menicon.nl

Manufacturer:

Menicon Co., Ltd.
3-21-19, Aoi, Naka-ku, Nagoya,
460-0006 Japan
TEL: +81 -52-935-1515
https://www.menicon.com/

Manufactured for:

JOHNSON & JOHNSON VISION CARE, INC.
7500 Centurion Parkway
JACKSONVILLE , FL 32256
United States of America

Printed: September 2022

PROFESSIONAL FITTING
AND
INFORMATION GUIDE

ACUVUE® Abiliti™
Overnight Therapeutic Lenses
for Myopia Management

CAUTION:

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

Note:

All information in this document is equally applicable to the ACUVUE® Abiliti™ Overnight Therapeutic Lenses as for ACUVUE® Abiliti™ Overnight Therapeutic Lenses with Astigmatism.

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INTRODUCTION

ACUVUE® Abiliti™ Overnight Therapeutic Lenses for Myopia Management produce a temporary reduction of myopia by reversibly altering the curvature of the cornea. A slight reduction of the curvature of the cornea can reduce the excessive focusing power of the myopic eye. If the amount of corneal reshaping is precisely controlled as is the objective of the ACUVUE® Abiliti™ Overnight lens design, it is possible to bring the eye into correct focus and completely compensate for myopia. The lens is designed to be worn overnight with removal during the following day. The ACUVUE® Abiliti™ Overnight lenses must be worn at night on a regular schedule to maintain the corneal reshaping, or the pre-treatment myopia will return.

DESCRIPTION

ACUVUE® Abiliti™ Overnight are lathe cut contact lenses for orthokeratology. The lenses are designed to have three zones which are a central spherical optic zone, a midperipheral reverse zone and a linear peripheral landing zone. Using a reverse geometry design, the lenses have a smooth connection between the central curve and the landing zone.

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Vertex power (D)	0.00 - +2.00 (0.25 steps)
Fenestration	3 holes
Diameter of hole (mm)	0.25

ACUVUE® Abiliti™ Overnight lenses for myopia management with astigmatism – Finished Lens Specifications	
	Specification
Diameter (mm)	10.20, 10.60, 11.00
Center thickness (mm)	0.24

Base curve (mm)	7.50 – 10.00 (0.05 steps)
Tangential angle flat (°)	50 – 65 (1 steps)
Tangential angle steep (°)	46 – 63 (1 steps)
Height flat (mm)	0.95 – 1.45 (0.01 steps)
Height steep (mm)	0.97 – 1.54 (0.01 steps)
Vertex power (D)	0.00 - +2.00 (0.25 steps)
Fenestration	3 holes
Diameter of hole (mm)	0.25

PHYSICAL PROPERTIES

Physical properties of Tisilfocon A	
Specific Gravity	1.20
Refractive Index	$n^{20}e$ 1.439±0.002
Surface Character	Hydrophobic
Wetting Angle	51 degrees (after soaking)
Light Transmittance (sample thickness 0.2mm)	Visible region ≧80% (380 nm – 780 nm)
	Ultraviolet region ≤5% (210 nm – 380 nm)
Water Absorption	Less than 0.5% by weight
Oxigen Permeability	$163x10^{-11}$ (cm^2/sec)(mL O_2/(mL × mmHg)) Dk
Hardness (Shore D)	83

ACTIONS

The ACUVUE® Abiliti™ Overnight produce a temporary reduction of myopia by changing the shape (flattening) of the cornea, which is elastic in nature. Flattening the cornea reduces the focusing power of the eye, and if the amount of corneal flattening is properly controlled, it is possible to bring the eye into correct focus and completely compensate for myopia.

The posterior surface of regular contact lenses generally aligns with the central cornea and rests directly on the corneal tear layer. Regular contact lenses are designed to cause little or no effect on the cornea but ACUVUE® Abiliti™ Overnight are designed to purposely flatten the shape of the cornea by applying slight pressure to the center of the cornea when the patient is asleep.

After the lens is removed, the cornea retains its altered shape for all or part of the remainder of the day. The lenses are designed to be worn overnight with removal during the following day. The ACUVUE® Abiliti™ Overnight must be worn at night on a regular schedule to maintain the orthokeratology effect, or the myopia will revert to the pre-treatment level.

INDICATIONS

ACUVUE® Abiliti™ Overnight are indicated for use in the control of myopia in non-diseased eyes when prescribed and managed by a qualified eye care professional. ACUVUE® Abiliti™ Overnight Therapeutic Lenses for Myopia Management are available in powers from 0 D to + 2.0 D and are intended for correction and control of myopia between -0.5 and -4.0 D. ACUVUE® Abiliti™ Overnight Therapeutic Lenses for Myopia Management with Astigmatism are available in powers from 0 D to +2.0 D and are intended for correction and control of myopia between

between -0.5 and -5.0 D with between -1.25 and -3.50 D of with-the-rule astigmatism. The lenses may only be disinfected using a chemical disinfection system.

Note: To maintain the Orthokeratology effect of myopia control, overnight lens wear must be continued on a prescribed schedule. Failure to do so can affect daily activities (e.g., night driving), cause visual fluctuations, and changes in intended correction.

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE the ACUVUE® Abiliti™ Overnight when any of the following conditions exist:

- Acute and sub-acute inflammations 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 tears (dry eyes)
- Corneal hypoesthesia (reduced corneal sensitivity).
- Any systemic disease which may affect the eye or be exacerbated by wearing contact lenses.
- Allergic reactions of ocular surfaces or adnexa which 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 your ACUVUE® Abiliti™ Overnight.
- Any active corneal infection (bacterial, fungal or viral).
- If eyes are red or irritated

WARNINGS

The practitioner should provide this warning to the patient.

PROBLEMS WITH CONTACT LENSES AND LENS CARE PRODUCTS COULD RESULT IN SERIOUS INJURY TO THE EYE.

Incorrect use of contact lenses and lens care products can result in serious injury to the eye. It is essential that the patient follows the directions of the eye care professional and all labelling instructions for proper use of contact lenses and lens care products.

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,
- Redness of The Eye,
- Or Other Problems with their Eyes,

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

All contact lens wearers must see their eye care professional according to the schedule given to them. ACUVUE® Abiliti™ Overnight lenses are to be worn overnight with removal during all or part of each following day. Wearing the lenses continuously (extended wear) presents increased risk, which increases with the number of consecutive days that the lenses are worn between removals. Although ACUVUE® Abiliti™ Overnight lenses are prescribed only for overnight wear with removal during the waking hours, and although the safety risks of intermittent overnight wear

may not be as great as with sustained overnight wear; there is still increased risk beginning with the first overnight period.

The risk of ulcerative keratitis has been shown to be greater among wearers of extended wear lenses than among wearers of daily wear lenses. The risk among extended wear lens wearers increases with the number of consecutive days that lenses are worn between removals, beginning with the first overnight use. This risk can be reduced by carefully following directions for routine lens care, including cleaning of the lens storage case. Additionally, smoking increases the risk of ulcerative keratitis for contact lens wearers. Studies have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than non-smokers.

It is recommended that contact lens wearers see their eye care practitioner twice each year or, if directed, more frequently.

To avoid serious eye infections, vision loss or blindness, please make the patient aware of the following warnings…

- Inadequate rubbing, rinsing, and disinfecting of the lenses may cause serious eye infections, vision loss or blindness.
- Do not reuse or "top off" old solution left in the lens case since solution reuse reduces effective lens disinfection and could lead to severe infection, vision loss or blindness. "Topping-Off" is adding fresh solution to solution that has been sitting in the case.
- Never use water, saline solution, or rewetting drops to disinfect the lenses. These solutions will not disinfect the lenses. Not using the recommended disinfectant can lead to severe infection, vision loss or blindness.
- Do not expose the contact lenses to water while wearing them.
- Do not use the multi-purpose solution beyond the expiration and/or discard date because it could result in contamination of the solution and can lead to severe infection, vision loss or blindness.
- Do not store the lenses or rinse the lens case with water or any non-sterile solution. Only use fresh multi-purpose solution (or sterile saline solution) to avoid lens and lens case contamination.

PRECAUTIONS

Eye care professional

Clinical studies have demonstrated that ACUVUE® Abiliti™ Overnight 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 corneal irregularity and ocular high-order aberrations, and reduce the eye's contrast sensitivity function 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 labelling 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).

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-base cosmetics are less likely to damage lenses than oil-base 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.
- 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.
- For use in pediatrics, parents should supervise lens care regimen to reduce the chance of complications such as infection.

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 the "Instructions for Wearers" 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 vapours 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 Section of this 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 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.

PATIENT SELECTION

Patients are selected who have a demonstrated need and desire for a refractive reduction by orthokeratology with rigid gas permeable contact lenses and who do not have any of the contraindications for contact lenses described above.

ACUVUE® Abiliti™ Overnight are indicated for myopic patients who desire to have time periods during the day in which they do not need to wear their contact lenses, but still need to see clearly.

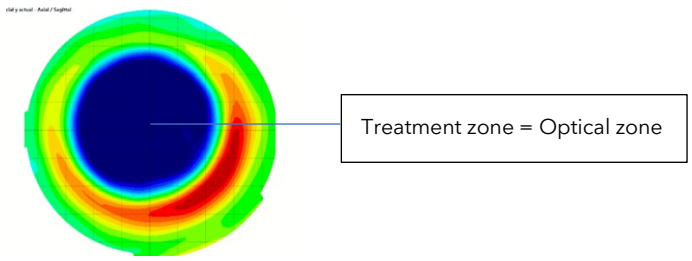
ACUVUE® Abiliti™ Overnight are primarily intended for patients who are within the following parameters.

Refractive error:	-0.50 to -4.00 diopters or -0.50 to -5.00 diopters with between -1.25 and -3.50D of WTR astigmatism
Keratometry:	40.00 to 46.00 diopters

FITTING CONCEPT

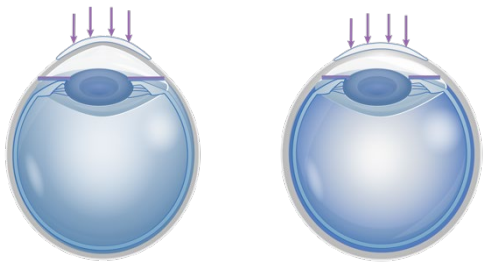
GENERAL INFORMATION

The aim of orthokeratology is to alter the corneal curvature of the original correction and thus avoid the need for glasses or contact lenses during the day. Theoretically this is easily achieved, however in practice more factors need to be taken into consideration before the end user is satisfied. One of these many factors is the size of the treatment area.



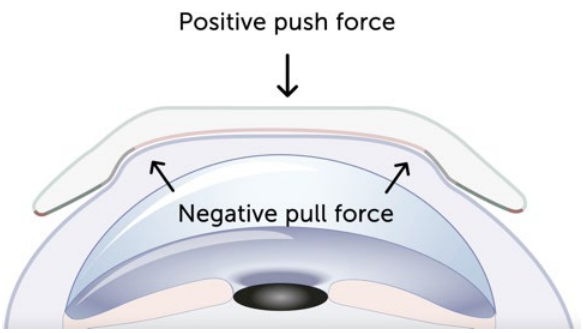
The axial/sagittal differential map of the sagittal map clearly shows the treated area. It is important to keep this as large as possible to prevent people suffering from glare and halo effects in the evening.

Defining the treatment area



For successful orthokeratology, the treatment area should be located in the centre and should be as large as possible but also as smooth and even as possible. This means that there should be as little variation as possible in the power of the correction. This occurs by smoothing the central curve of the front of the cornea. This is what ACUVUE® Abiliti™ Overnight lens does.

By using a flatter central radius in the optical zone of the contact lens and a steeper radius in the midperiphery (reverse curve) it is possible to create a difference in pressure.



The minimal clearance centrally between the cornea and the back of the ACUVUE® Abiliti™ lens creates a positive pressure resulting in a local push force on the central cornea. The space between the lens and the cornea in the mid-periphery (reverse curve) creates a negative pressure resulting in a local pull force. These combined forces result in a cornea that is flatter in the center and steeper in the mid-periphery.

To create this difference in pressure, the orthokeratology lens is designed in such a way that the central distance is less than 10 microns between the back of the lens and the front of the cornea. This creates the optimum pressure difference to achieve the best and fastest effect. Centrally there is also no direct contact between the contact lens and the cornea, which prevents staining.

Each contact lens actually rests on the periphery of the cornea. Controlling the fit in the peripheral area automatically allows more control over the distance between the lens and the center of the cornea. This is extremely important for an orthokeratology lens as it creates the optimal difference in pressure and guarantees that there is no contact with the center of the cornea.

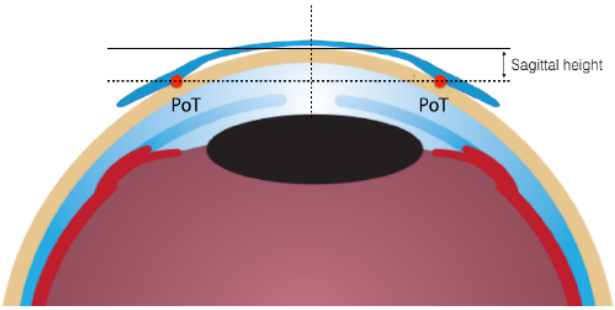
There is limited value in using fluorescein to assess the central fit of an orthokeratology lens. Fluorescein is only visible to the human eye at thicknesses of over 20 microns. As we aim for a central thickness of less than 10 microns, this will not be visible with fluorescein. Fluorescein can however, be used to quickly verify that the overall pattern looks appropriate for a myopic orthokeratology fitting.

Fitting in the peripheral area

By using the periphery as a basis for the fit, it is no longer necessary to rely on the eye's central K values. In order to trace the periphery of the cornea, some other parameters are required. In order to determine the correct values, we use the *point of touch* as the basis for attaining the correct peripheral fit.

Point of touch

A good lens fit is all about the *point of touch*. The point of touch (PoT) is the part of the contact lens that actually rests on the cornea. This is the part where the actual fit takes place. Controlling the PoT allows for maximum control over the centration of the lens. Proper centration of an orthokeratology lens provides immediate maximum control over the appropriate distance between the back of the lens and the front of the cornea.



This image clearly shows that the Point of Touch, and therefore a peripheral fit, is essential to gain maximum control of the distance to the central cornea.

Sagittal height

Throughout the development of the ACUVUE® Abiliti™ Overnight lens, one of the key considerations was the fact that the lens is fitted on the periphery. As such, the PoT is one of the factors that is considered throughout the duration of the fit. When evaluating the lens, this is taken as the starting point for the lens fit. The sagittal height is one of the parameters used to ensure that the PoT is maintained. Correctly selecting the sagittal height ensures that the central part of the lens will not make contact with the cornea and thus prevent staining.

ACUVUE® Abiliti™ Overnight lens fitting philosophy

Controlling the point of touch is therefore key when fitting the ACUVUE® Abiliti™ Overnight lens. This means that there are also minimum requirements for adapting an ACUVUE® Abiliti™ Overnight lens. For instance, using corneal topography is essential, as it enables the periphery of the cornea to be measured. It should be noted that a simple keratometer is not suitable for fitting and monitoring orthokeratology treatments correctly and safely.

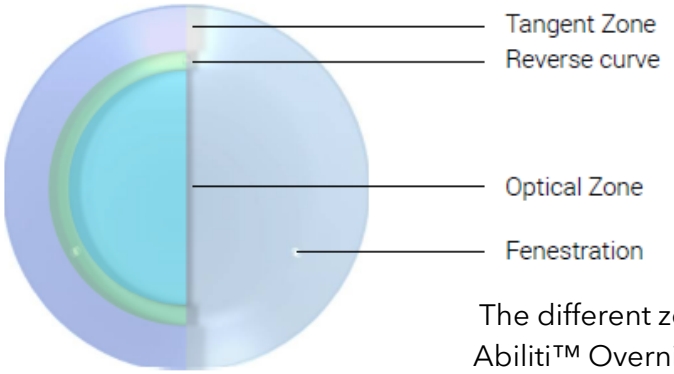
Thorough, basic knowledge of orthokeratology is also a requirement for successful use of the ACUVUE® Abiliti™ Overnight lens. Experience has shown that this basic knowledge contributes, in general, to proper and safe orthokeratology treatment.

ACUVUE® ABLITI™ OVERNIGHT THERAPEUTIC LENS DESIGN

The design of the ACUVUE® Abiliti™ Overnight lens is characterized in the structure of the lens providing maximum control of the point of touch. Having more understanding of the structure allows for better comprehension of terms such as height and tangent. This is important as these terms are frequently encountered when checking an ACUVUE® Abiliti™ Overnight.

General structure

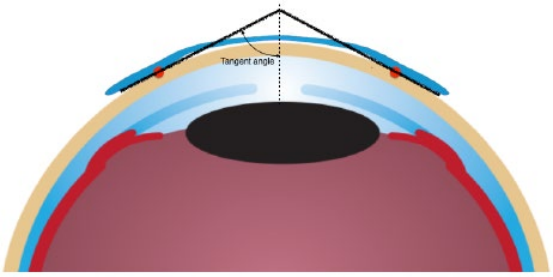
The ACUVUE® Abiliti™ Overnight lens consists of various zones. From the outside edge towards the center, these are the tangent zone, the reverse zone and the optical zone. All these are calculated separately for each individual, so they can differ from person to person. However, to achieve the best result, all zones need to cooperate directly.



The different zones of an ACUVUE® Abiliti™ Overnight Therapeutic lens

Tangent zone

The tangent zone is on the periphery of an ACUVUE® Abiliti™ Overnight lens. The tangent zone provides more control of the point of touch to improve centration. A tangent zone is in fact nothing more than a straight line on a certain angle. This angle is calculated separately for each individual and depends on the peripheral cornea and the chosen diameter of the ACUVUE® Abiliti™ Overnight lens.



The tangent angle is determined near the point of touch.

Reverse zone

The reverse zone is essential for proper orthokeratology treatment. Together with the optical zone, it creates a difference in pressure which modifies the distribution of the epithelial layer of the cornea in a controlled manner. The reverse curve is the zone where the back of the lens is furthest away from the cornea and it is responsible for creating negative pressure in this area.

Optical zone

The optical zone is the area that is largely responsible for the refractive correction effect. Together with the reverse zone, it creates a difference in pressure which modifies the distribution of the epithelial layer of the cornea in a controlled manner. The optical zone is the area where positive overpressure is created, but never allowing the lens to be in direct touch with the cornea.

PREDICTING LENS RESULTS

Various methods have been proposed for predicting the amount of corneal flattening that may be achieved for a given patient by orthokeratology however, further research is needed to clarify this. It is not possible at this time to predict which patients will achieve the greatest corneal flattening with various orthokeratology designs.

The clinical study results for the ACUVUE® Abiliti™ Overnight show that the lens design is effective and predictable for correcting myopia between the range of –0.50 to –4.00 diopters.

The ACUVUE® Abiliti™ Overnight will produce a temporary reduction of all or part of a patient's myopia. The amount of reduction will depend on many factors including the amount of myopia, the elastic characteristics of the eye and the way that the contact lenses are fit. Average amounts of reduction have been established by clinical studies but the reduction for each individual patient may vary from those averages.

FITTING PROCEDURES

PRE-FITTING EXAMINATION

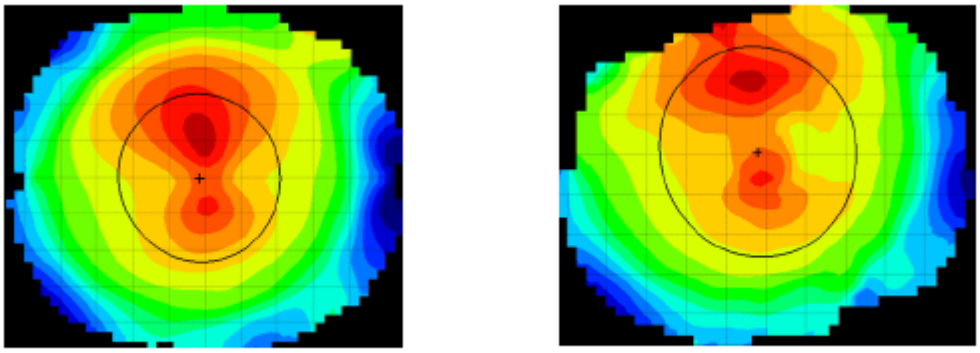
ACUVUE® Abiliti™ Overnight lens is an orthokeratology lens that is fitted on the periphery and not on the central curvatures of the eye. This provides many advantages such as increased predictability and a high success rate.

As the ACUVUE® Abiliti™ Overnight lens uses the periphery as its starting point, it must be fitted with the aid of corneal topography. Unlike a keratometer, corneal topography measures the shape of the eye including the periphery and thus provides the necessary information to accurately fit an ACUVUE® Abiliti™ Overnight lens. The quality of the topographic images influences the fitting of the ACUVUE® Abiliti™ Overnight lens and therefore also the result of the treatment. Below are some tips to help achieve correct and effective topographic scans and thus a higher fitting success rate.

Measure the tear film

A frequent error in Placido disk-based corneal topography is to assume that the cornea is what is being measured. This kind of topographer uses the reflections that are received to generate the measurements. However, the cornea itself is a non-reflective surface. So instead, the reflective tear film is used on the presumption that it has the same shape as the cornea.

Given the fact that it is the tear film that is measured, the conclusion can be drawn that the quality of the topographic image relies quite heavily on the quality of the tear film.



Stable tear film | Instable tear film

The right image above clearly shows that the topographic image is very irregular in the case of an unstable tear film. This is unlike the stable tear film on the left, where we see a smooth, nicely sloping pattern.

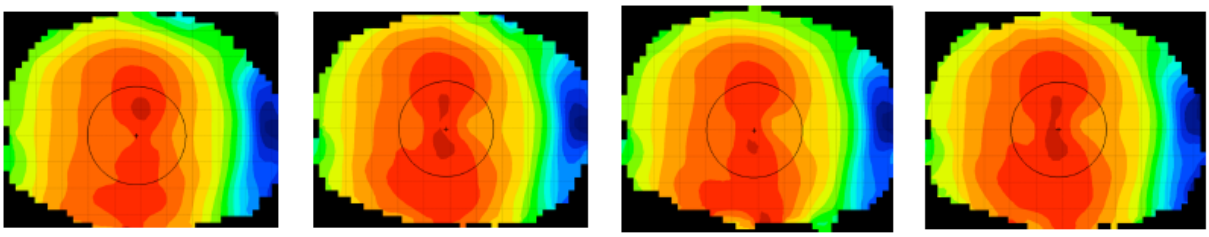
Ensure the tear film is stable

It is essential to focus on the tear film when taking topography scans. If tear film is unstable, this will directly influence the quality of the measurement and the eventual result. The patient should remember to blink normally throughout the process. Often, anxiety will cause the patient to blink less frequently which can lead to an unstable tear film.

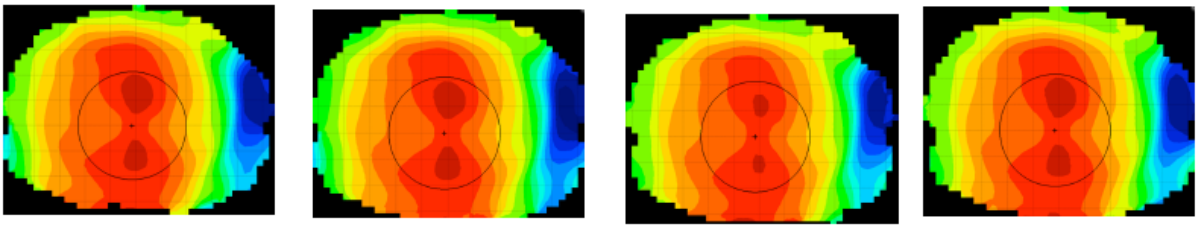
Create/generate several topographic images

A good way to check the stability of the tear film is to take several scans and compare them. If all images are alike, then the tear film is likely stable. If not, it is probably worth repeating the measurement with the addition of artificial tears.

Using artificial tears during topography is becoming more common as it provides a temporarily stable tear film and therefore more reliable measurements. Experience has shown that creating topographic images right after the use of artificial tears is not always effective; it is often best to wait a few minutes before proceeding, although this does depend on the viscosity of the tears used.



Four measurements without artificial tears



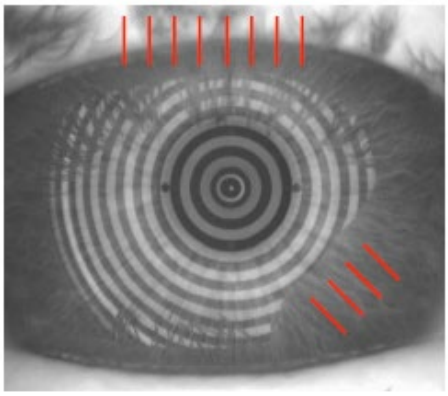
Four measurements with artificial tears

The above images clearly show that the four measurements without artificial tears are very different. This indicates that the quality of the topographic scans is insufficient. If artificial tears are used, the measurements look more similar. This improves the reliability of the measurements and gives a better indication of whether or not the images should be used.

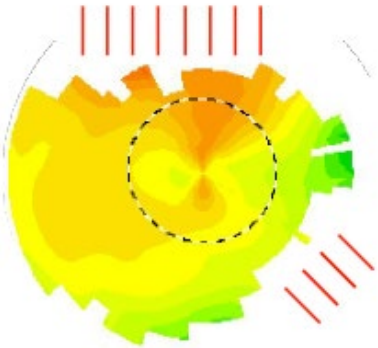
Measure the periphery

The ACUVUE® Abiliti™ Overnight lens is fitted around the periphery, which is why the peripheral measurements are so important. Corneal topography is indispensable when it comes to assessing this area. Ensure that a sufficient peripheral area is measured: reflections of the eyelids and/or the nose can result in the omission of essential information. If an insufficient area is measured it can result in a poor fit which in turn can have a negative effect on the success of the treatment.

A good way to ensure sufficient coverage is to check where the Placido disc rings meet the eye and where they don't. Slightly adjusting the patient's head position can solve this problem fairly easily. This is common issue with wide cone topographer devices. The best way to resolve this is to turn the head so that the nose or eyelids no longer obstruct the Placido disc rings. It is also a good idea to frequently remind the patient to open the eyes as wide as possible to enable maximum peripheral measurement. It's also worth considering the use of artificial tears: often, when eyes are opened wide on purpose, the tear film becomes more unstable.



Projected Placido disc rings



Topographic image result

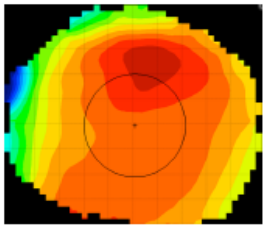
The image on the left shows that a large part of the projected Placido disc rings is missing and the topographic image on the right reflects this. Too much information is missing to calculate a good fit for the ACUVUE® Abiliti™ Overnight lens. A different head position behind the topographer enables easier measurement of the periphery.

Make sure other lenses have been discontinued for a sufficient amount of time

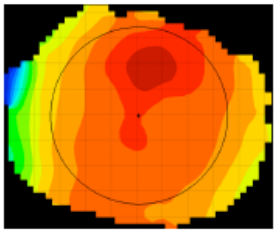
If other lenses have been worn prior to starting the ACUVUE® Abiliti™ Overnight lenses, it is important that they are discontinued for a sufficient period of time to eliminate any residual corneal changes that may be present from those lenses. As a general rule:

- Soft lenses: At least three days
- Hard lenses: At least three weeks

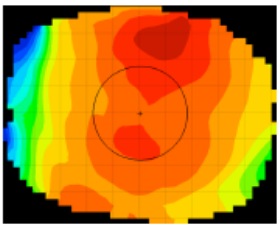
Please note that this is only a guideline. The topographic images can be used to determine if the discontinuation period was long enough by comparing the most recent images with older ones. If a difference is no longer discernible, then a suitable starting point has been reached. If treatment is started too early then it can negatively affect the fit of the lens. This is applicable to any kind of lens fitting.



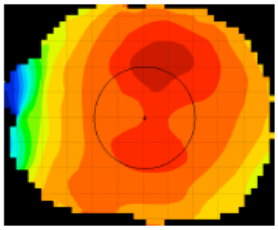
After one night



After three nights



After one week

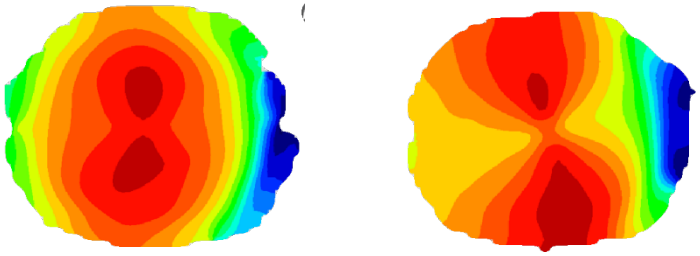


After three weeks

Peripheral cornea

The advent of topography has led to greater insight into the peripheral cornea shape. Corneal topography has shown that central corneal astigmatism is not always the same as peripheral astigmatism. This is important as the lens is fitted on the periphery.

In general, a distinction can be made between a central astigmatism and a limbus-to-limbus astigmatism. In central astigmatism, the corneal astigmatism in the periphery is usually equal to or less than the central astigmatism. In limbus-to-limbus astigmatism, the peripheral astigmatism is usually greater than the central astigmatism. These differences each require a different lens fit.



Central Astigmatism

The corneal astigmatism in the centre is more than in the periphery.

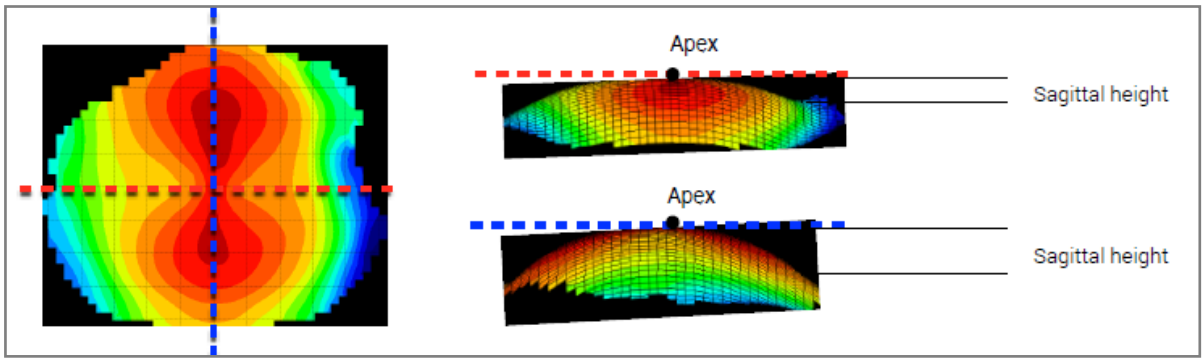
Limbus-to-Limbus

Astigmatism The corneal astigmatism in the periphery is even more than in the centre.

Limbus-to-limbus astigmatism can affect the lens centration. As explained below, the Easyfit software used to calculate the lenses is able to interpret a huge quantity of information when the topography scans are imported to it. It also assesses the astigmatism and considers whether to use an ACUVUE® Abiliti™ Overnight or an ACUVUE® Abiliti™ Overnight with Astigmatism lens, to avoid lens decentration in corneas with higher peripheral corneal astigmatism.

Peripheral height difference

Although we talk about peripheral corneal astigmatism, the periphery for a lens fit is better defined in height. Therefore, the discussion should actually be about peripheral height difference.



This image clearly shows that in the vertical direction (blue dotted line) there is more difference in height in the periphery than in the horizontal direction (red dotted line).

The image reveals peripheral corneal astigmatism, in terms of topography. If, however, the focus is on the horizontal (red line) and vertical (blue line) meridians, a difference in height can be clearly seen. The horizontal is flatter than the vertical when measured against the apex of the cornea, so the height difference is less.

CALCULATE INITIAL LENS PARAMETERS WITH FITABILITI™

FitAbiliti™ empirical fitting software is used to calculate the correct ACUVUE® Abiliti™ Overnight lens. It enables the accurate determination of peripheral parameters that result in higher accuracy of the fit and a high success rate. However, FitAbiliti™ requires two key things to calculate an ACUVUE® Abiliti™ Overnight lens: refraction and accurate topographic images. It is the practitioner's responsibility to ensure proper refraction measurements and good quality topographic scans are used.
Fitabiliti™ can be accessed at https://fitabiliti.bigpicturemedical.com/

Once good quality scans are available, they should be imported into FitAbiliti™.

Base Curve Radius

A flatter base curve (in relation to the flat K from central keratometry) of the optical zone is required to correct myopia.

This rule of thumb is as follows: 0.05 mm flatter BCR = 0.25 D correction

In addition, Jessen Factor is considered to slightly over-correct the refraction and avoid regression during the day.

Please note that this is a guideline only, but does still apply in the majority of cases. It may be different due to rounding off. Base curve will be a non-modifiable value in FitAbiliti™. Manually modifying the base curve would potentially alter the results of the treatment.

Power

The power of the ACUVUE® Abiliti™ Overnight lens is 0.00 D. However, they do provide an extremely sharp image when they are worn on eye.

Diameter

Choosing the correct diameter for the ACUVUE® Abiliti™ Overnight lens is very important for its success.

If the wrong diameter is selected, the lens may be in the correct location on the eye or not be centering well. This means that correction may occur in the wrong area or that there is an insufficient degree of correction.

ACUVUE® Abiliti™ Overnight lenses are often selected in quite large sizes. If there is any uncertainty about the diameter, the lens can be checked on the eye before it is delivered. Ideally, the lens should cover approximately 90% to 95% of the corneal surface, but never exceed the limbus.

Lens diameter is automatically suggested by FitAbiliti™ after Horizontal Visible Iris Diameter (HVID) is entered. Although HVID is a measurement that many topographers provide automatically, it is strongly recommended to measure it manually on the topography scan to obtain the most accurate measurement possible.

Tangent & Height

Both values are directly related to the control over the point of touch and thus, the correct centration.

Good quality topography scans will provide accurate values for tangent and height.

Tangent and height will be non-modifiable values in FitAbiliti™. Modifying them would potentially alter the results of the treatment.

Residual astigmatism

Residual astigmatism is the cylinder that will remain after ACUVUE® Abiliti™ Overnight lens correction. Refractive cylinder can be considered as the "total" cylinder of the eye. If corneal and refractive cylinder are not equal, this means that there is some other astigmatism (from the internal optics of the eye).

As a rule of thumb, the closer the corneal astigmatism and refraction astigmatism values are, the less residual astigmatism can be expected.

If residual astigmatism is expected, making a spherical equivalent can be a solution. This means that the residual astigmatism can be divided by two and the outcome of this can be added to the spherical value.

This can work fine as long as the residual astigmatism is not too high. As example, if anyone requires a power of S-2.50 dpt. and the residual astigmatism is C-1.00 dpt. then it is recommended to correct to a spherical strength of S-3.00.

Once again: residual astigmatism cannot be corrected with the ACUVUE® Abiliti™ Overnight lens. This is important to manage patients' expectations.

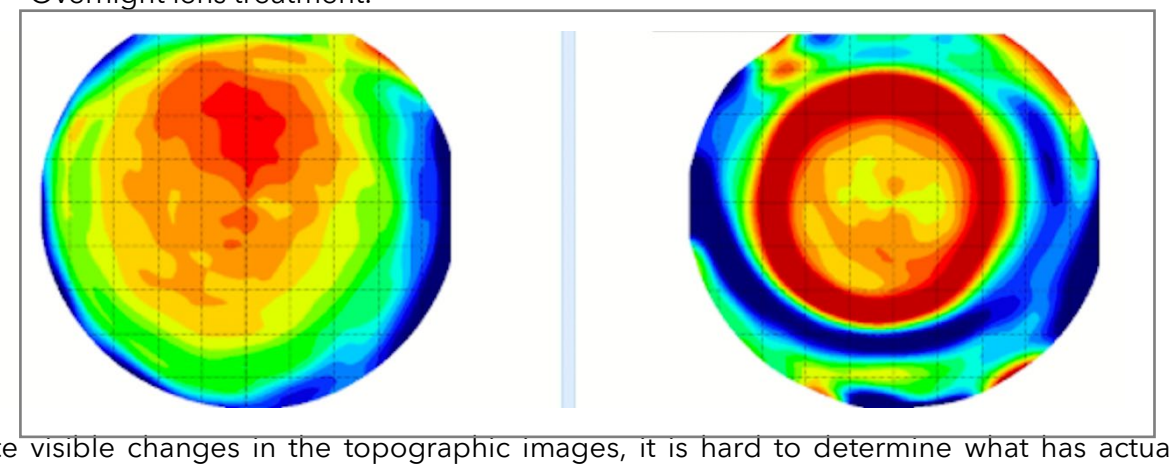
LENS PERFORMANCE EVALUATION

Good initial topographic images are important for properly calculating the ACUVUE® Abiliti™ Overnight lens, but also for the subsequent followups. Poor topographic images will result in an incorrect lens fit and the orthokeratology treatment will not have the desired effect. During orthokeratology the aim is to create a treatment area that is as large and as centered as possible over the pupil. If this is not the case, the patient may suffer visual complaints that are more annoying than under-correction. This is why it is important that the topographic images are created and reviewed critically.

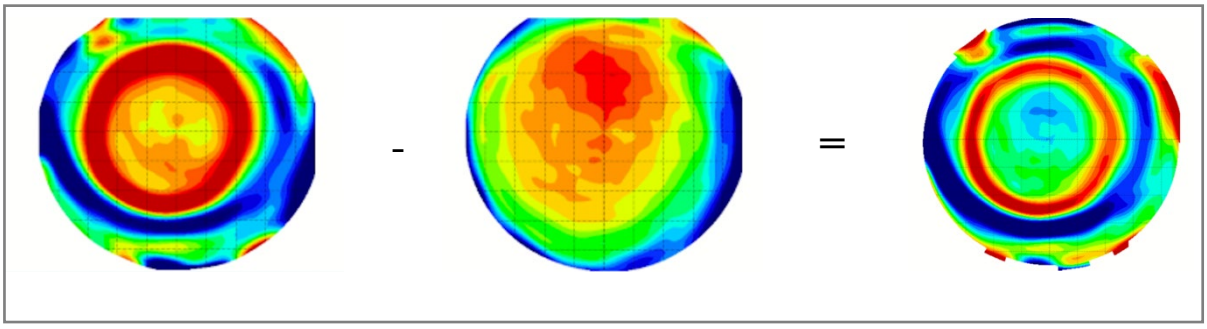
Differential Image Patterns

During each visit the current state of the treatment zone is checked. This is done with topographic images to provide insight into how the ACUVUE® Abiliti™ Overnight lens was positioned at night.

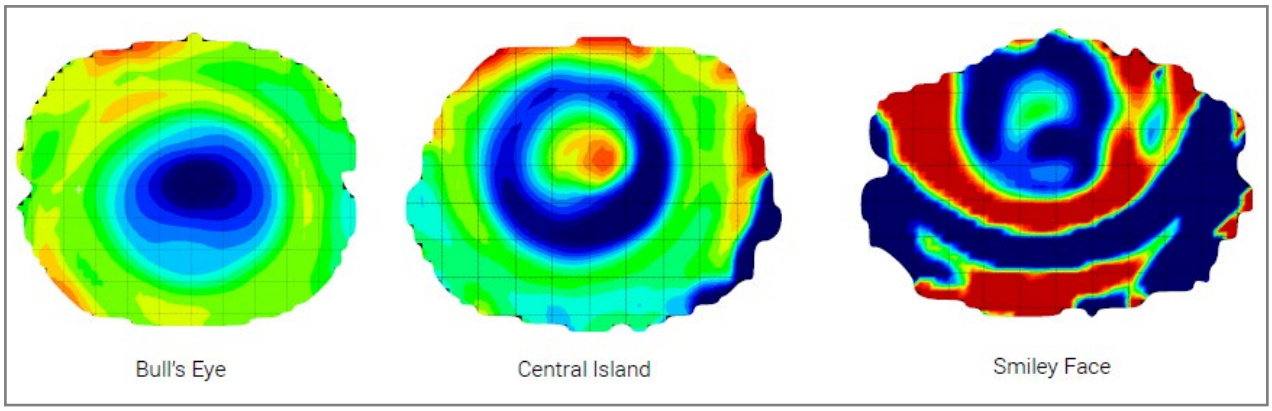
As previously mentioned, the corneal changes are caused by the difference in pressure created by the lens. Once a patient wears an ACUVUE® Abiliti™ Overnight lens, the central cornea becomes flatter (see image below). This change can be seen thanks to corneal topography. Corneal topography is therefore essential for the fitting and subsequent checks of the ACUVUE® Abiliti™ Overnight lens treatment.



Despite visible changes in the topographic images, it is hard to determine what has actually changed. FitAbiliti™ software will automatically generate differential maps when current topographies are imported. In these differential images the values of each topographic scan are deducted from each other and only the differences between the two are visible. This gives more insight into the actual change that has taken place.



Differential images are essential for checking the effect of ACUVUE® Abiliti™ Overnight lenses, and for orthokeratology in general. The changes in the epithelium that occur during the night can be made visible with differential images. In general, these can be subdivided into three patterns to decide whether we should change the lens specifications.



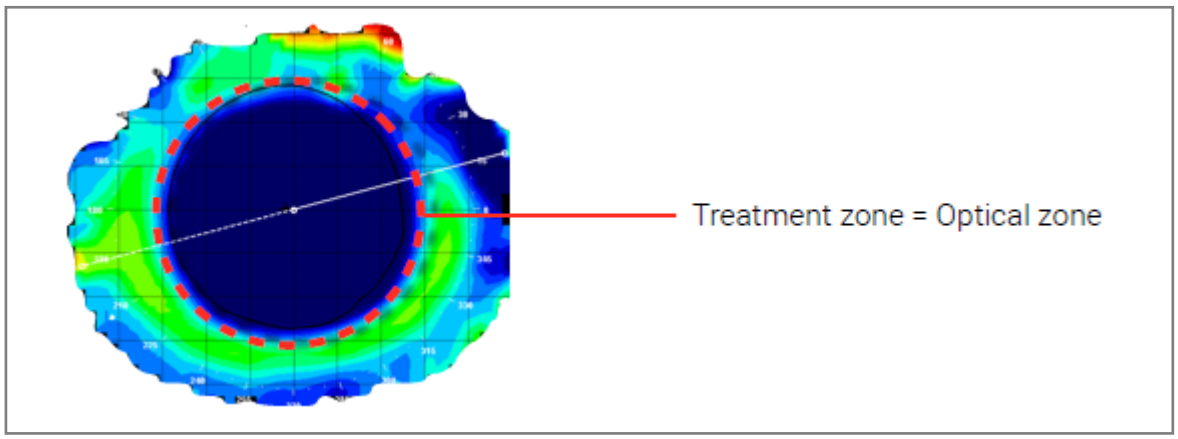
How To Recognize Patterns

Before categorizing the actual patterns, it is necessary to look at the differential images using two different topography map displays. Please note that decisions about the lens performance must only be done after 3 weeks of continuous overnight wear, and not before. Once the most recent topography scans are imported and the best one selected for evaluation, FitAbiliti™ will automatically calculate the difference maps by comparing it to the originally chosen baseline topography maps. It will then guide the ECP through their analysis at the 3-week Efficacy Assessment.

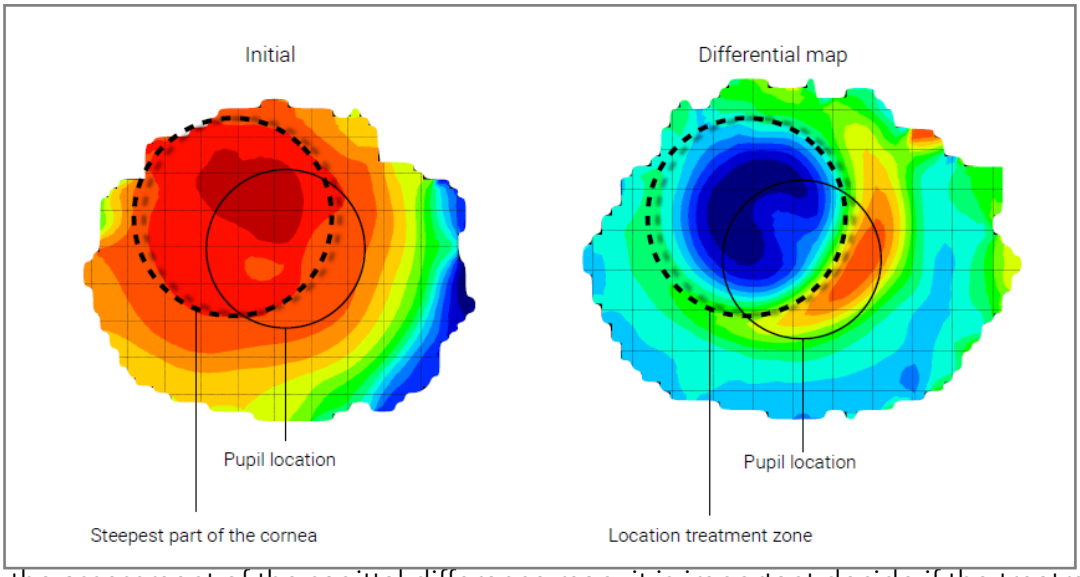
To properly assess the fit of the ACUVUE® Abiliti™ Overnight lens, the two key differential maps to evaluate are the sagittal/axial map and the tangential map. The sagittal map is used to evaluate the size and quality of the treated area and the tangential map is used to evaluate the centration of the lens. If both are satisfactory, then the fit is correct and this is referred to as a Bull's Eye.

Axial/Sagittal Map

Axial difference maps provide information about the treatment area, also called the "optical zone". The objective here is to have a large, smooth and even area. The size of the treated area in relation to the pupil diameter determines if the patient's pupil will be fully "covered" by the corrected area or if he/she will have halos due to the reverse curve area invading the pupil zone. An important rule of thumb to remember is: the higher the myopia to be corrected, the smaller the area to be treated can be expected.



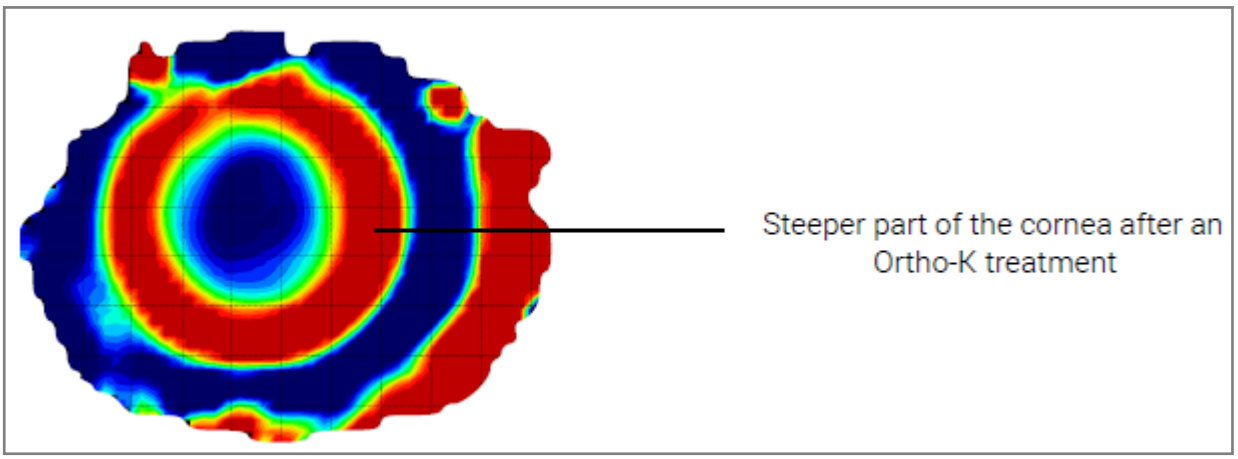
It is not only the size of the treated area that determines the success of orthokeratology but the location in relation to the pupil is also significant. The goal is to be as central to the pupil as possible, although this is not always an option. Thankfully this can be easily predicted in advance because in general, the location of the optical zone will be located where the cornea is initially the steepest.



During the assessment of the sagittal difference map, it is important decide if the treatment area is as expected with regard to size and location, smoothness and evenness. FitAbiliti™ will ask this question after displaying the axial difference map in the software.

Tangential Map

The tangential map is used to evaluate the centration of the ACUVUE® Abiliti™ Overnight lens. The assessment of the tangential difference map focuses on the steepened area adjacent to the central flattened treatment zone and will be identified as a red ring. This red ring will correspond with the location of the reverse zone of the ACUVUE® Abiliti™ Overnight lens. The goal and expectation is to have this ring centered on the eye as much as possible. After displaying the tangential map, FitAbiliti™ will ask whether the centration is according to expectations.



The image above helps to identify the steeper part (red ring) of the cornea after orthokeratology. The centration is correct when the red ring is in the mid-periphery of the cornea, which corresponds to the reverse zone of the lens.

Both axial and tangential difference maps must be assessed separately. Unfortunately, this is something that occasionally goes wrong in practice. Due to time pressure or perceived experience, the temptation is to analyse just one map which will lead to making the wrong assessment. This is why FitAbiliti™ was designed guide the ECP through the correct analysis of the topography maps.

To summarize, the treatment zone must always be assessed with the axial difference map and the treatment centration must always be assessed with the tangential difference map.

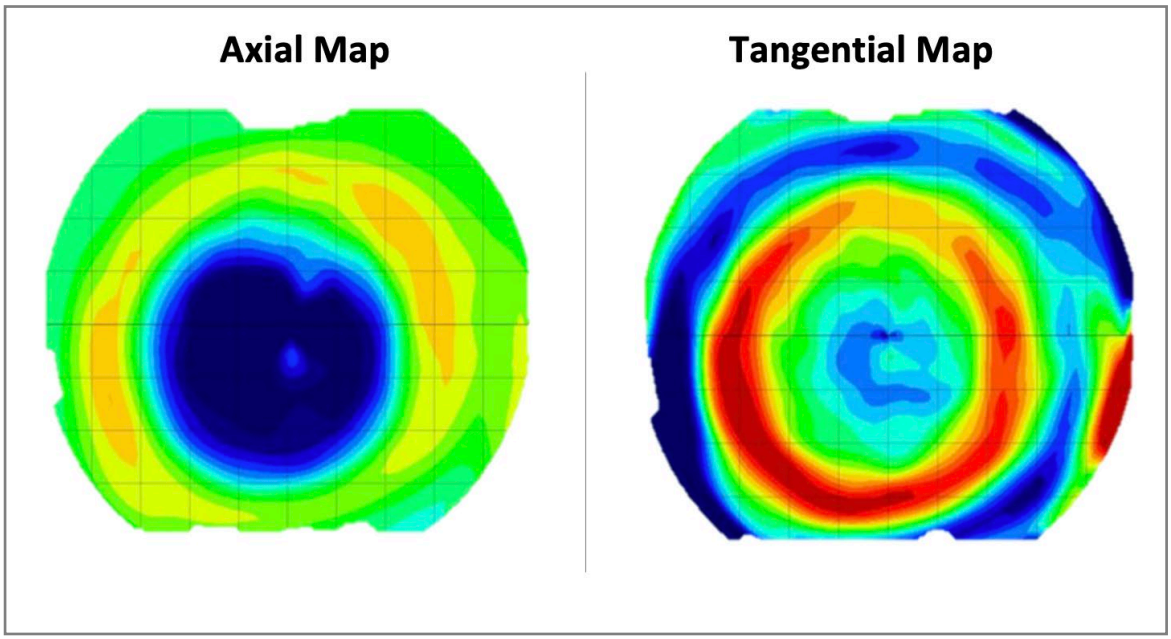
Topographic patterns

Bull's Eye

A Bull's Eye is the desired and expected pattern from an orthokeratology treatment. This pattern will be achieved in about 90% of all first lens fits with FitAbiliti™ if a good baseline topography scan is used. This high percentage should be motivation to invest the time to capture good quality initial topographic images.

The term Bull's Eye comes from the idea that we have hit the target, which means we have an optimum fit. Below are the questions that FitAbiliti™ will ask during the axial and tangential difference map analyses as well as the expected answers in the case of a Bull's Eye result.

- Axial map: Is the treated area according to expectations? YES
- Tangential map: Is the centration according to expectations? YES



The treatment area on the axial map is mostly smooth and even.

The red ring on the tangential map is centered on the eye.

With regards to vision correction, the desired result is to correct the patient's full refractive error so they can see clearly in the distance. Sometimes the centration and treatment zones look correct, but a slight over-refraction is found. This can be solved by flattening the base curve and FitAbiliti™ will assist with this lens adjustment.

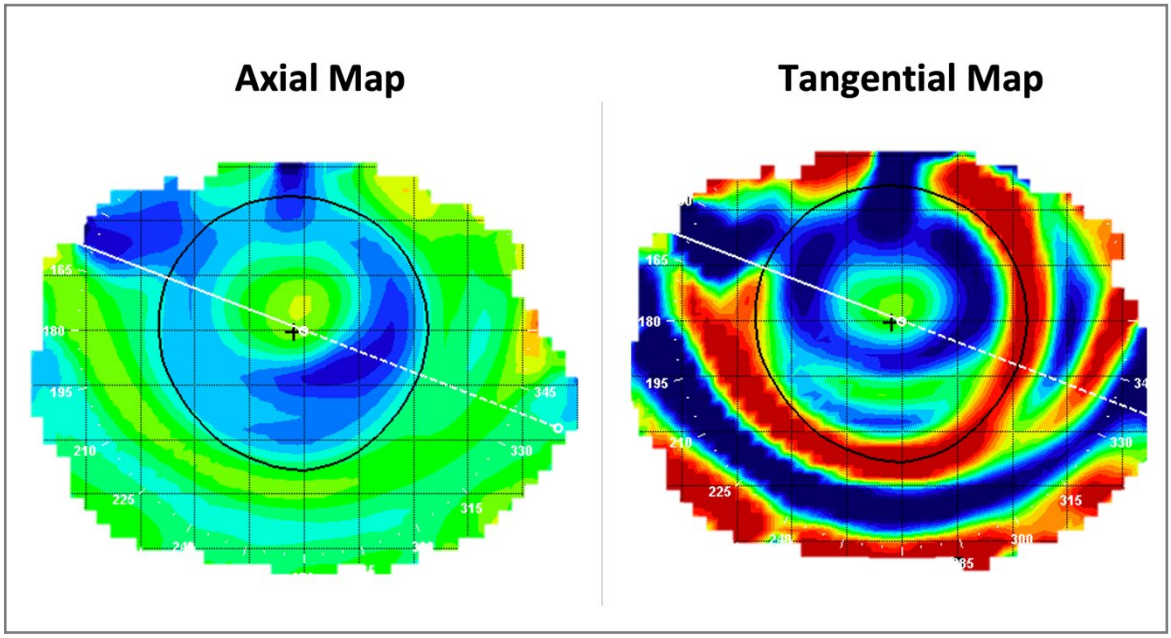
In case of a Bull's Eye, we can state the following about the lens parameters:

Height	Correct
Tangent	Correct
Base Curve Radius	Correct or small residual power

Central Island

A Central Island pattern refers to a steeper central area inside the flattened treatment zone seen on the differential maps. This is unlike a Bull's Eye, where the central treatment zone is smooth and evenly flattened in the center.
The centration with a Central Island pattern is good when assessing the tangential difference map; it is the axial difference map that is anomalous in a Central Island pattern.
The answers to the questions posed by FitAbiliti™ will be as follows:

- Axial map: Is the treated area according to expectations? NO
- Tangential map: Is the centration according to expectations? YES



The axial difference map clearly shows that the treatment area is abnormal. In a correct fitting, we see the dark blue color (flattest part) in the middle of the treated area. With a central island, the pattern is opposite with the darker blue color located towards the edge of the treated area, surrounding a green "island". The tangential map indicates that good centration is present.

The reason for the central island pattern is that the height of the lens was not chosen correctly: there is 'too much' space between the back of the ACUVUE® Abiliti™ Overnight lens and the front of the central cornea. This results in an insufficient pressure differential between the center and mid-periphery, thus affecting the treatment and resulting in insufficient correction.

This can manifest as a negative over-refraction or as no VA improvement with any over-refraction.

In a Central Island we can state the following about the lens parameters:

Height	Incorrect (too high)
Tangent	Correct
Base Curve Radius	Correct or small residual power

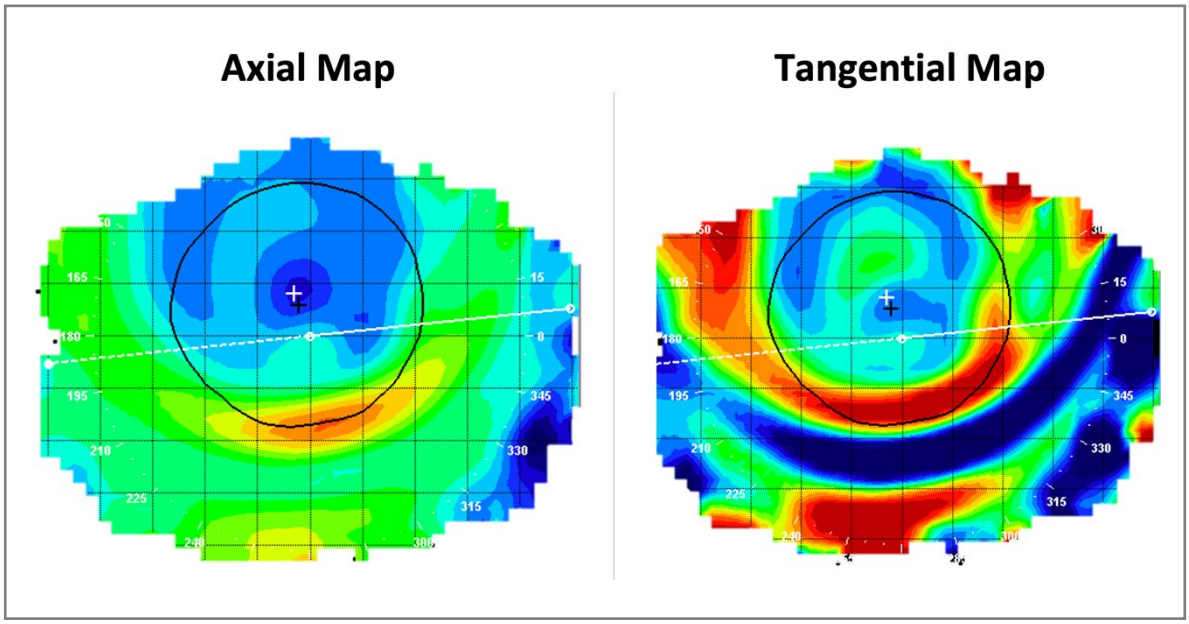
Smiley Face

The Smiley Face pattern is primarily identified in the tangential difference map and means that the centration of the lens is not correct.

A decentered ACUVUE® Abiliti™ Overnight lens indicates that the chosen tangent is incorrect. This is often the result of inaccurate or poor topographic scans. With an incorrect tangent, there is no longer control of the point of touch and therefore no control of the fit or correction. Even the treatment zone (axial map) can show an anomalous pattern resulting in an anomalous over-refraction (e.g., residual astigmatism). It is therefore important to carefully analyse the tangential map in case of unexpected over-refractions.

The answer to the questions posed by FitAbiliti™ will be as follows:

- Axial map: Is the treated area according to expectations? YES/NO
- Tangential map: Is the centration according to expectations? NO



With Smiley Face topography pattern, we can state the following about the lens parameters:

Height	Correct
Tangent	Incorrect (too flat)
Base Curve Radius	Correct

ORTHO-K PROBLEM SOLVING

Once the fit of the ACUVUE® Abiliti™ Overnight lens has been assessed with the guidance of FitAbiliti™, the software will provide a new lens calculation if necessary and the order will be submitted through the system.

Three weeks of overnight lens wear is needed to ensure that the maximum results with the lenses are achieved. At this time point, any necessary changes in lens parameters are revealed through an over-refraction and analysis of the differential maps. When the difference maps show a Bull's Eye pattern and the patient is satisfied with their vision, no further action is required and the patient can continue to wear the lenses.

If an exchange is needed, FitAbiliti™ will automatically calculate the new ACUVUE® Abiliti™ Overnight lens after receiving the information from the questions asked in the system.

Depending on the responses given, FitAbiliti™ will change a specific parameter of the ACUVUE® Abiliti™ Overnight lens.

PATTERN	SOLUTION
Bull's Eye	Flatten BC if neccessary
Central Island	Decrease Height Flatten BC if neccessary
Smiley Face	Decrease Tangent

FOLLOW-UP CARE

GENERAL INFORMATION

Correcting myopia through orthokeratology gives the patient a sense of freedom and is a good solution for people who complain about dry eyes with other types of lenses. Many advantages can be listed for choosing this correction method. It is true, however, that the effect of orthokeratology is a process that takes a few days before the desired myopia is actually corrected. It is important that the consumer realizes this.

In practice, we have noted that lesser amounts of myopia is often corrected faster than greater amounts of myopia, but in general a three-week period is required to achieve the desired effect. Does this mean that the patient can't see for three weeks? No, absolutely not. Even patients with a greater degree of myopia often notice an improvement within a few days.

The treatment zone will be relatively small for the first few days and will get bigger as time progresses. This, in relation to large and small pupils in dark or light situations, can result in variable visual acuity in the first few days. This is why it is important to properly inform the patient about the potential for this. Fortunately, the majority of patients actually do not experience this and are happy that they can see increasingly better without wearing lenses or glasses during the day.

If a patient still experiences problems such as halos and glare, there is no benefit to making alterations too soon as corneal changes are still occurring. A more stable treatment effect can be expected after a period of three weeks. Once again, the patient is generally extremely satisfied.

Below is the recommended monitoring schedule for the ACUVUE® Abiliti™ Overnight lens. It explains what to look out for during these followup visits.

Important:

- Schedule the 1-night and 1-week follow-up visits in the morning. This is important as it allows for proper comparison of the topography scans between visits while the treatment is being established.
- The 3-week follow up visit should be scheduled in the afternoon/evening. This will provide insights on the visual results after potential regression during the day has occurred and thus will help guide any lens changes to improve visual performance.
- The follow ups are carried out without the lenses worn on the eye. The patient can simply remove the lenses in the morning as usual. Lenses should be brought to all follow up visits so they can be inspected or checked.

FOLLOW UP TIME AND EVALUATION

One of the keys to success in orthokeratology is good communication and proper management of expectations. For instance, it is important to explain that there is a build-up phase with orthokeratology treatment so the patient will not expect to be fully corrected after one night.

A patient should also know from the start of the treatment that there will be a number of follow up visits they must attend. This means that the full and proper course of treatment should be explained clearly.

It is also important that the practitioner does not make changes to the lens too soon. Changes should only be made after three weeks of treatment with the ACUVUE® Abiliti™ Overnight lens have been completed.

Remember that some patients may find it stressful to wear lenses overnight in the beginning so make sure that patients have ample opportunity to address any concerns or ask any questions they may have.

1st Night Follow up

We are unable to comment on the orthokeratology effect of ACUVUE® Abiliti™ Overnight lens after just one night. This follow up is mainly for checking the health of the eye and creating a sense of safety and confidence in the patient.

To do:

- Refraction
  - Expect about 25% refractive correction to be achieved but this may be higher.
- Slit lamp exam
  - Check for corneal staining and the presence of infiltrates. Apart from some potential central micropunctate staining, the eye should look healthy.
- Topography
  - A change in the corneal shape will be visible.

Important: If refraction is lower than expected, do not be discouraged, it may be because the corneal changes take place more slowly in that particular patient.

1 Week Follow up

After one week of wear we expect more changes to have occurred and the patient should be largely satisfied with the result so far.

To do:

- Refraction
  - Expect about 75% refractive correction.
- Slit lamp exam
  - The eyes should look healthy. No central staining should be visible.
- Topography
  - There needs to be a clear indication of the corneal changes taking place.

3 Week Efficacy Assessment

We do not expect any more corneal changes after three weeks. Now is the right time to consider any lens adjustments.

To do:

- Refraction
  - The full 100% refractive correction is expected.
- Slit lamp exam
  - The eye should look healthy. No central staining should be visible.
- Topography
  - There should be a clear indication of the full corneal changes.

3 & 6 month of wear

If the ACUVUE® Abiliti™ Overnight lenses have been worn to the wearer's satisfaction, it is important to check the eye and contact lenses every three or six months. The eye should appear healthy and the contact lenses and lens holder should be clean. A follow up every six months should be sufficient, but parents of younger patients will generally feel more at ease with a follow up after three months. Lenses should be replaced every six months.

To do:

- Refraction
  - The full 100% refractive correction is expected.
- Slit lamp exam
  - The eyes should look healthy.
- Topography
  - The topography scans should show the desired results (see INITIAL LENS EVALUATION)

If the treatment fails to provide the expected result, action is required. (See *INITIAL LENS EVALUATION* and *ORTHO-K PROBLEM SOLVING*)

RECOMMENDED WEARING SCHEDULE

Although many practitioners have developed their own initial wearing schedules, the following schedule is recommended as a guideline. Patients should be advised to follow the their eye care professional's recommended wearing schedule regardless of how comfortable the lenses feel.

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 on any given night. A well fit lens provides for good centration with the eye closed. The patient should place the lens on the 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.
different wear schedule may be offered at the practitioner's discretion. The cornea normally changes within five to eight hours of wear. The practitioner should modulate the wearing time to determine the MINIMUM wear time required for myopic reduction and the patient should attempt to maintain wearing time at this minimal level.

Be aware that "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: The patient should report for a follow up evaluation the morning after the first overnight wear. The visit is best scheduled within a few hours of awakening. Lenses should be removed in the morning and brought to the appointment. This visit provides an excellent opportunity to look at lens centration and potential lens adherence.

Assuming the absence of clinical signs and complications, the patient will be instructed to continue overnight wear of the lenses until the next scheduled follow up visit.

LENS CARE INSTRUCTIONS

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

CHEMICAL LENS CARE SYSTEM

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

The directions found in the package inserts from these products should be followed. Failure to follow or adhere to these procedures may result in the development of serious ocular complications. A patient should not switch from one care system to another unless it has been determined by the eye care professional that this is necessary. Do not mix or alternate the disinfection and storage systems unless so indicated on the product label.

Z material has a plasma treatment that can be damaged by some lens care products that contain silica. Avoid these products and/or contact your ACUVUE® Abiliti™ supplier for further information.

Inform the patient of the following lens care suggestions:

- Always wash, rinse and dry your hands before handling your contact lenses
- ACUVUE® Abiliti™ Overnight must be both cleaned and disinfected each time you remove them. One procedure does not replace the other. Cleaning is necessary to remove mucus and film from the lens surface. Disinfecting is necessary to destroy harmful germs. To minimize lens warpage during cleaning, the lenses should be cleaned in the palm of the hand rather than between the thumb and fingers.
- Clean one lens at a time. The recommended procedure is to always clean the same lens first to avoid mixing up the lenses. Rinse the lens thoroughly to remove the cleaning solution. Place the lens into the correct storage chamber of the lens case and fill the chamber with the recommended disinfecting solution as recommended by your eye care professional. Clean and rinse the other lens in the same manner and place it in its chamber.
- Tightly close the top of each chamber of the lens storage case.
- To disinfect your lenses, leave them in the solution during the day.
- Leave the lenses in the closed storage case until you are ready to put them on your eye.
- Water should NOT be used for lens cleaning, rinsing, wetting and/or storage.
- For use in pediatrics, parents should supervise lens care regimen to reduce the chance of complications such as infection.

INTENSIVE CLEANING

For intensive cleaning, a dedicated intensive cleaner for gas permeable lenses should be used on a (bi-) weekly basis or as advised by the eye care professional.

LENS CASE CLEANING AND MAINTENANCE

Contact lens cases are a common source of bacterial contamination. Lens cases should be emptied, cleaned and rinsed daily with solutions recommended by the lens case manufacturer. Lens cases should be replaced at regular intervals as recommended by the eye care professional.

CLINICAL STUDY DATA

Reference the ***"Clinical Study Data"*** found in the enclosed Package Insert.

RISK ANALYSIS

There is a small risk of experiencing an adverse event when any contact lens is worn. It is not expected that the ACUVUE® Abiliti™ Overnight will provide a significantly greater risk than other overnight wear of rigid gas permeable contact lenses. Additionally, orthokeratology patients in general may experience episodes of blurry distance vision or visual flare and/or ghosting.

The two most common side effects that occur in rigid contact lens wearers are corneal oedema and corneal staining. It is anticipated that these two side effects will also occur in some wearers of ACUVUE® Abiliti™ Overnight. Other side effects, which sometimes occur in all hard lens wearers, are pain, redness, tearing, irritation, discharge, and abrasion of the eye or distortion of vision. These are usually temporary conditions if the contact lenses are removed promptly and professional care is obtained. When overnight orthokeratology lenses mislocate during sleep, transient distorted vision may occur the following morning after removal of the lenses. This distortion may not be immediately corrected with spectacle lenses. The duration of the distorted vision would rarely be greater than the duration of the daily visual improvement normally achieved with the lenses.

In rare instances, there may be permanent corneal scarring and a resulting permanent decrease in vision may occur. In general, the risk of serious problems (such as corneal ulcers and vision loss) is greater when lenses are worn overnight. In addition, studies have shown that smoking increases the risk of corneal ulcers, for those who wear lenses overnight. The benefits and risks of overnight lens wear should be carefully discussed with your patient. Your patient should be instructed to remove the contact lenses if any abnormal signs are present.

HOW SUPPLIED

Each lens is supplied non-sterile in an individual plastic case. The label and packing slip are marked with the base curve, power in diopters, diameter, centre thickness, sagittal depth, tangential angle, colour, patient name or reference id, and Lot #.

REPORTING OF ADVERSE REACTIONS

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

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