# Biomedics 55 Asphere (ocufilcon D) HYDROPHILIC CONTACT LENSES

# In Scheduled Replacement Program Patient Information Booklet

Important: This Patient Information Booklet contains important information and instructions. Please read carefully and keep this information for future use.

Before you read on, the following information is very important to you.

Practit	ioner		
	Name:		
	Address:		
	Telephone:	-	

#### INTRODUCTION TO YOUR NEW LENSES

Your new lens is especially designed for comfort, ease of handling and excellent optical qualities. You lenses are precisely made by a patented molding system. Made of soft supple, water loving (hydrophilic) material, your new lenses are designed to give you comfort and easy handling.

Of course, one of the nicest benefits of your new scheduled replacement lens system is convenience – when your replacement period has elapsed just throw the used lens away.

We again welcome you to the ocufilcon D UV asphere Soft (Hydrophilic) Contact Lenses for use in a scheduled replacement program. Remember, to be successful you do need to listen to and continue to visit your eye care provider.

Therefore, please read on.

Cleanliness is an important aspect of contact lens care.

Before handling your lenses, always wash and rinse your hands thoroughly and dry them with a lint-free towel. Do not use soaps, lotions, cold creams or perfumes which leave residues on your hands. Avoid using medication creams, deodorants, make-up, after-shave lotions, or similar items prior to touching your lenses. When hair spray is used, the eyes must be kept closed until the spray has

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settled. Take care in handling your lenses. Always avoid touching your lenses with your fingernails or other sharp objects.

Soft contact lenses including ocufilcon D UV asphere Soft (Hydrophilic) Contact Lenses are made of a type of plastic that absorbs liquids and vapors. As such they may collect both extraneous and naturally occurring deposits.

Therefore, if the lens needs to be removed before the prescribed wearing time has elapsed, you must follow the sections in the booklet entitled, "Lens Care and Lens Handling" as well as the written instructions on the recommended care products. Damaged lenses can lead to serious eye infections and discomfort.

If any problems do occur, remove your lenses and visit you eye care practitioner.

Ocufilcon D UV asphere Soft (Hydrophilic) Contact Lenses in a scheduled replacement program were designed to provide comfortable vision. Proper care and adherence to instructions should enable you to feel good and see clearly.

The ocufilcon D UV asphere Soft (Hydrophilic) Contact Lenses are indicated for the correction of visual acuity in persons with not-aphakic, non-diseased eyes which manifest myopia (nearsightedness), hyperopia (farsightedness) and astigmatism lower than -2.00 diopters that does not interfere with visual acuity.

The ocufilcon D UV asphere Soft (Hydrophilic) Contact Lenses may be prescribed for daily wear or extended wear. The eye care practitioner may prescribe the ocufilcon D UV asphere Soft (Hydrophilic) Contact Lenses for single use disposable wear or for scheduled replacement wear, with cleaning, disinfection, and scheduled replacement (see Patient Information Booklet for the Scheduled Replacement Program). When prescribed for scheduled replacements the lens may be disinfected using a chemical (no heat) or hydrogen peroxide disinfecting systems.

The ocufilcon D UV asphere Soft (Hydrophilic) Contact Lenses help protect against transmission of harmful UV radiation to the cornea and into the eye.

#### WARNINGS AND ADVERSE EFFECTS

#### **WARNINGS**

Prior to purchasing contact lenses, you should discuss fully with your practitioner the effect of contact lenses on your eyes, and all risks associated with contact lens wear, in addition to receiving a thorough eye examination. While the great majority of people successfully wear contact lenses without problems, a small percentage of wearers have experienced adverse effects with contact lens wear and usage of lens care solutions, resulting in serious eye problems such as infections, ulcers, and other damage to the cornea (the front layer of the eye). In some cases, these problems can lead to serious eye injury and loss of vision, particularly if prompt and effective medical treatment is not obtained. Additionally, smoking increases the risk of ulcerative keratitis for contact lens users.

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The ocufilcon D UV asphere Soft (Hydrophilic) Contact Lenses in a scheduled replacement program should be regularly removed on the schedule prescribed by your eye care practitioner. The risk of ulcerative keratitis has been shown to be greater among users of extended wear lenses than among users of daily wear lenses. The risk among extended wear lens users increase with the number of consecutive days that the lenses are worn between removals, beginning with the first overnight use. As a result, eye care practitioners have differing views concerning the maximum wearing time of lenses. Some eye care practitioners do not prescribe extended wear at all, while others prescribe flexible wearing times of occasional overnight wear and still others prescribe wearing times from 1 to 7 days/6 nights for certain patients.

Many practitioners are prescribing specified intervals of no lens wear for overnight or longer between wearing periods, in order to allow the eyes to "rest" and receive more oxygen. Some practitioners also recommend scheduled replacement of lenses. Other practitioners may prescribe disposable contact lens wear, where lenses are disposed of at each removal. The ocufilcon D UV asphere Soft (Hydrophilic) Contact Lenses are for use in scheduled replacement program. Your practitioner will determine the appropriate lens wearing time, follow-up visit and replacement schedules for you. Therefore, be sure to discuss these important topics with your practitioner at your initial visit and at each follow-up visit.

To minimize the risks of contact lens wear, it is essential that you follow your eye care practitioner's directions and all instructions in this booklet for proper care and handling of our lenses, use of solutions and other lens care products, wearing restrictions and schedule, lens replacement and check-up visits.

If a problem should occur, you may require immediate medical attention because some eye problems, such as infections and corneal ulcers can develop rapidly and unexpectedly lead to loss of vision. Prompt professional attention to these problems is essential. If you have any pain, eye discomfort, tearing, sensitivity to light, vision changes, redness of the eye or any other symptom or unusual feeling in your eye, follow the steps in the "Adverse Effects" section.

### **ADVERSE EFFECTS**

#### (Problems and what to do)

The following problems may occur

- Eye discomfort
- Eye pain
- Eyes sting, burn, or itch (irritation)
- Comfort is less than when lens was first placed on eye
- Feeling something in the eye (foreign body, scratched area)
- Watering (tearing) of the eyes
- Eye secretions or discharge of matter
- Redness of the eyes
- Reduced sharpness or decrease in vision
- Blurred vision, rainbows or halos around objects

Sensitivity to light

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• Feeling of dryness

If any of the above symptoms occur:

- Immediately remove your lenses.
- If the discomfort or problem stops, then look closely at the lens.
- If the lens is in any way damaged, has dirt, an eyelash or foreign body in it, or the problem stops, discards the lens and replace it with a new ocufilcon D UV asphere Soft (Hydrophilic) Contact Lens from your container, as directed by your eye care practitioner.
- If the above symptoms continue after removal of the lens or upon insertion of a new lens, the lens should be removed immediately and you should immediately contact your eye care practitioner or physician, who will determine the need for examination, treatment or referral without delay.

Problems with contact lenses may lead to a medical emergency, because a serious condition, such as infection, corneal ulcer, neovascularization (small blood vessels growing into the cornea), or iritis (inflammation in the eye) may be present, and may progress rapidly and lead to loss of vision unless treated promptly. When you go for treatment, bring your lenses, lens case, and care products. The doctor may want to examine, test, or analyze these items to help your treatment. If your eye care practitioner or physician is not available, go to the nearest emergency room.

#### **Chemical in Eyes**

If chemicals of any kind (household products, gardening solutions, or laboratory chemicals) are splashed onto the eyes, do the following:

- Immediately remove your lenses and flush your eyes with water.
- If unable to remove lenses, immediately flush your eyes with water.
- Seek immediate medical eye care treatment.

The safe wear of contact lenses requires you to observe certain precautions and wearing restrictions designed to reduce the possibility of problems and eye injuries. Your eye care practitioner may prescribe additional precautions and restrictions for you to follow, and you should ask your eye care practitioner to explain anything that you do not understand.

#### At your Initial Visit to Your Eye Care Practitioner:

- Be sure that you read and understand the full context of this booklet, and discuss it with your eye care practitioner.
- Give your eye care practitioner a complete history of your eye health, including any eye injuries, diseases, conditions, or other problems you have had with your eyes, even if they seem unimportant to you.
- Also, tell your eye care practitioner about your general health, any medicines you are taking, current treatment by a physician, any disease you had or now have, and any prior surgery.
- Before leaving your eye care practitioner's office, make sure that you are able to place and promptly remove your lenses.

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#### **Lens Handling:**

Ocufilcon D UV asphere Soft (Hydrophilic) Contact Lenses for Scheduled Replacement Wear are intended to be disposed of at the end of the prescribed period (1 week, 2 weeks, 1 month, etc.) Therefore, it is important to always have a pair of replacement lenses available.

- In the event that a lens must be removed from your eye because of dust, a foreign body or other contaminant gets on the lens or the lens becomes dehydrated (dry), the lens should be removed, cleaned and disinfected in the recommended manner. Refer to the section of this booklet entitled "Lens Care."
- If the lens becomes dehydrated, which may occur if the lens is dislodged from your eye while sleeping, discard the lens.
- Do not touch your eyes or contact lenses until after you have washed and rinsed your hands thoroughly. Failure to wash your hands before handling may result in eye infections.
- Do not allow any cosmetics, lotion, soaps, creams, or deodorants to come into contact with lenses, which also can cause eye infections or irritations.
- Do not touch the lenses with your finger nail, which can cause contamination or damage of the les. If the lens becomes nicked or torn, do not wear it, because damaged lenses can cause injury.
- Before placing lenses on your eyes, examine the lenses to assure they are moist, clean, clear, and free of any nicks or tears.
- Do not place a dry or brittle lens on your eye.
- Do not use saliva, tap water, distilled water or anything other than a recommended sterile solution labeled for the care of your soft lenses.
- Do not use tweezers or other tools to remove your lens from the lens package. Pour the lens into your hand.
- Soft contact lenses occasionally fold on the eye and do not remain on the cornea (front portion). This is not cause for alarm. Although the contact lens can never be lost behind the eye, it may become lodged under the eyelids without irritation (usually the upper lid). IN this case, the lens should be located and removed by yourself, or if you cannot find it, by your eye care practitioner. Once removed, dispose of the lens and replaced it with a new lens.
- It is important to the health of your eyes that your contact lenses move freely. If the lens sticks (stops moving), put a few drops of the lubricating or rewetting solution or drops recommended by your eye care practitioner into your eye. In this case, do not use plain water or anything other than the recommended solutions. Do not attempt to remove a lens that is sticking, which could damage your eye. If the lens does not begin to move when you blink after several applications of the solutions or drops, contact your eye care practitioner immediately.
- If you are on a daily wear schedule, do not sleep with the lenses on. If you forget, however, check to see, immediately upon awakening, if the lenses will move on the eyes. If they do not move readily, do not attempt to remove them. Place several drops of recommended lubricating or rewetting solution in the eyes and try moving them again. If, after several applications of solution the lenses still do not move, contact your eye care practitioner immediately.

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#### **Wearing Restrictions:**

- Always keep a pair or replacement lenses with you when you wear your lenses, in case you have to remove the lenses immediately upon the appearance of a problem or symptom.
- Always keep your recommended lens care products with you to have available if and when you have to clean and disinfect your lenses.
- Do not use aerosol products, such as hair spray, while wearing your lenses. The lenses may absorb the spray, resulting in injury to the eye and damage to the lens.
- Avoid wearing the lenses around fumes, irritation vapors, or smoky or dusty conditions. The lenses may absorb the chemicals or particles, resulting in injury to the eye.
- Void rubbing your eyes with the lenses in, which can irritate the eye or dislodge the lens.
- Keep your eyes closed tightly when washing or showering to keep water and soaps out of the eyes, which can cause loss of the lenses, contamination or injury to the eye.
- Do not wear your lenses while in a hot tub or steam room or while swimming.
- If you get something in your eye, remove the lens immediately and dispose of the lens. Do not replace the lens with a replacement lens until your eye feels normal.
- Tell your employer that you wear contact lenses. Some jobs may require use of eye protection equipment or that you not wear contact lenses.
- Tell your regular physician and every other doctor that you visit that you wear contact lenses and the type of lenses that you wear. If you are admitted to a hospital, also tell your nurses that you wear contact lenses.
- Do not use any eye drops, ointments or medicines in your eye unless they are specifically
  approved by your eye care practitioner or physician. Some drops, ointments or medicines
  will cause injury to the eye if used by a contact lens wearer.

### On Check-Up Visits to Your Eye Care Practitioner:

- When you return for check-up visits, be sure to tell your eye care practitioner if your eyes
  have felt dry, irritated or anything other than completely comfortable while wearing your
  contact lenses.
- If there is any question in your mind about your wearing schedule and restrictions, lens handling procedures, lens replacement program, the condition of your lenses, your follow-up visit schedule, cleaning and disinfection procedures or anything else about contact lens wear, be sure to discuss the subject with your eye care practitioner, who is there to help you use your contact lenses safely and properly.
- If your eye care practitioner puts dye or drops in your eye during the examination, ask when you may insert your cleaned and disinfected lenses. The use of most dyes or drops will require a waiting period before lenses may be reinserted.

The procedures in this booklet are recommended for the care of ocufilcon D UV asphere Soft (Hydrophilic) Contact Lenses for Scheduled replacement Wear. Lens care products are provided with instructions and warnings for its use, which must be read and followed.

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Your eye care practitioner may recommend alternative products and procedures for lens care which must be followed. Ask your practitioner for specific information on all recommended products.

Your contact lenses schedule is preserved by your eye care practitioner. At the end of the prescribed wearing time, each lens is to be removed, cleaned and disinfected in the recommended manner prior to reinsertion.

# **Basic Precautions for Cleaning and Disinfecting:**

- Wash and rinse your hands before handling your contact lenses.
- Do not use hard contact lens solutions not indicated for use with soft lenses in any care system for soft contact lenses. Serious injury to the eye can result from wearing a soft contact lens that has been soaked in a hard contact lens solution.

It is recommended that you use the lens care system recommended by your eye care practitioner, either heat (thermal) or chemical (not heat). Chemical includes hydrogen peroxide solutions specifically indicated for use with soft (hydrophilic) lenses. Unless specifically indicated in the labeling, do not alternate, mix or change lens care systems for the same pair of lenses. Changing, or mixing the two systems can damage the lenses and injure your eyes. Use the solutions and other care products specifically recommended by your eye care practitioner.

#### LENS HANDLING

#### **Rewetting Your Lenses**

Soft contact lens wearers may occasionally experience period of slight discomfort or blurred vision caused by wearing lenses that have been partially dehydrated. Lens wearers on an extended wear schedule may upon awakening experience eye secretions or hazy vision. These conditions can usually be remedied by using a rewetting drop. You can apply rewetting solutions while the lenses are on the eye.

Just place drop of rewetting solution on each lens and blink 2 to 3 times. Use 3-4 times daily or as needed.

CAUTION: Anything other than a very slight symptom that goes away within a few minutes may indicate a problem, and the need for immediate medical attention, as stated in the WARNINGS Sections. Be sure to follow the steps provided in the section entitled, "Adverse Effects."

#### **General Tips**

- Hands must be washed, rinsed thoroughly and dried with a lent free towel before handling the lenses.
- Cosmetics, lotions, soaps and creams must not come in contact with the lenses since eye irritation or infection may result. Do not use aerosol or pump products, such as hair spray, while the lenses are being worn since liquids and vapors may damage the lens.

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## **THE PACKAGING**

Your new ocufilcon D UV asphere Soft (Hydrophilic) Contact Lenses are individually packaged in a sterile saline solution. The unique tamper-evident mini vials are made from recyclable glass and the blister pack containers are made of plastic. In order to help our environment please recycle all used mini vials with your glass products.

To remove the fresh lens from the mini-vial, grasp the polished aluminum tab and pull straight bank and down. Remove the broken ring. Remove the rubber-like stopper. Shake the vial and pour the fluid AND the lens into your cleaned palm of your hand. To remove the fresh lens from a blister pack, peel the aluminum foil back. Remove the lens from the plastic tub by pouring the lens into your cleaned palm of your hand.

After you remove the lens from the container:

- Examine it to be sure that it is moist, clean, clear and free of any nicks or tears.
- Make sure the lens is not turned inside out. Simply inspect the lens to see if the edges turn out. If they do, the lens is inside out. Should you accidently place an inside-out lens on your eye, one of the following signs should signal you to remove it and replace it correctly:
- Less than usual comfort
- The lens may fold on the eye
- Excessive lens movement on blink
- Blurred vision
- If the lens folds and stickers together: Place the lens in the palm of your hand and wet thoroughly with a recommended rinsing or storing solution. Then GENTLY rub the lens between your index finger and palm in a gentle back and forth motion. If this gentle rubbing does not work, dispose of the lens and replace it with a replacement lens.

# PLACING YOUR LENSES ON YOUR EYE

- To avoid the possibility of lens mix-ups, always start with the same lens.
- Before inserting the lens, rinse well with fresh recommended rinsing solution. Then place it on the tip of the index finger of your dominant hand.
- While position on your index finger, check to ensure the lens has not turned inside out. To check this, look at the profile of the lens against a light background. If the edge profile appears convex and bowl-shaped, then it is correct. If the lens is inverted, it will flare out at the edge. If the lens is inverted, simply reverse it by using light fingertip pressure. Be sure to avoid damaging the lens with your fingernails.
- Look straight ahead and raise the upper lid with your other index finger.
- While looking down, and keeping both eyes open, place the lens on the upper white part of the eye.
- Slowly release the upper lid and gently close your eye.
- The lens should center automatically, or it can be moved on center by gentle fingertip pressure through the lids.
- Repeat the above procedure for the second lens.
- If a lens appears to be stuck on your eye, apply one or two drops of a recommended lubricating solution to the eye and blink a few times. If the lens does not move freely on your

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eye, contact your eye care practitioner for further instructions. There is no single "right way" of putting on lenses. If you find this method of lens placement difficult, your eye care practitioner will suggest another method of provide additional instruction.

#### **Removing Your Lenses**

#### Preparation:

- Wash and rinse hands thoroughly.
- Dry hands with a lint-free towel.
- Check that the lens is centered on the cornea before attempting to remove the lens. Check your vision by covering one eye. If vision is blurry, the lens may be off-center. Re-center the lens before attempting to remove it.

#### Removal:

- Always begin with the same eye.
- Look up and keep both eyes open.
- Using the middle finger of your dominant hand, gently pull down the lower lid of the first eye. Using the tip of your index finger of the same hand, touch the lens and slide it onto the white of the eye.
- Gently "pinch" the lens between the index finger and the thumb and remove.
- Repeat the procedure for the second eye.
- If the lens cannot be easily moved, apply a few drops of a lubricating solution to the eye, blink a few times, and when the lens moves freely on the eye, remove in the manner described above. If the lens still cannot be easily moved, contact your eye care practitioner for further instruction.

**IMPORTANT**: Always avoid touching your lens with your finger nails. Use only your fingertips. If you find this method of removal difficult, your eye care practitioner will suggest another method or provide additional instruction.

#### MORE IMPORTANT INFORMATION

Contact lenses are medical devices and must always be treated with your great respect.

Certain symptoms may be early indicators of potentially serious problems. A careful examination of your lens, and professional examination of your eyes, may be required. Remove the lens following the instructions outlined in this guide, and call your eye care practitioner if:

- Your eye becomes red and/or feels irritated or "gritty".
- You notice a change in your vision or see rainbows or halos around objects.
- You experience discomfort and/or sensitivity to lights. A good general policy is "IF IN DOUBT, TAKE THE LENS OUT!" and immediately contact your eye care practitioner.

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# **Learn and Use Proper Lens Care Habits**

- Follow instructions.
- Handle lens properly.
- Learn how to apply and remove your lenses.

#### **FURTHER CONSIDERATIONS**

#### CHECK-UP EXAMINATION SCHEDULE

Regulatory check-ups examinations by your eye care practitioner are an important part of wearing your new contact lenses when prescribed in a Scheduled Replacement Program. Keep all appointments for check-up visits. If you move to a new city, ask your present eye care practitioner to refer you to a contact lens practitioner in your new location.

VISIT SCHEDULE:		
1.	(DATE)	(TIME)
2.	(DATE)	(TIME)
3.	(DATE)	(TIME)
4.	(DATE)	(TIME)
5	(DATE)	(TIME)
6.	(DATE)	(TIME)
7.	(DATE)	(TIME)
8.	(DATE)	(TIME)
9.	(DATE)	(TIME)
10.	(DATE)	(TIME)

#### REPLACING YOUR SCHEDULED REPLACEMENT LENSES

Clean and fresh lenses are more comfortable, are less likely to irritate gentle tissues around your eyes. Your eye care practitioner will recommend an appropriate lens replacement schedule for you. He or she will design the schedule for you. It is imperative that you follow the direction of your eye care provider.

# REMEMBER: ALWAYS RETURN TO YOUR PRACTITIONER FOR REPLACEMENT LENSES AND ONGOING CARE.

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