

PATIENT INSTRUCTION GUIDE

Daily Wear Frequent Replacement

FRAICHE™ Monthly Disposable Contact Lenses

CAUTION: Certain country law restricts this device to sale by or on the order of a licensed practitioner.

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1. INTRODUCTION

The information and instructions in this guide apply to **FRAICHE™ Monthly Disposable Contact Lens (Hioxifilcon A)**. Your contact lens is prescribed for daily wear, frequent replacement within the Aquilus planned lens replacement regimen. By replacing your contact lenses on a daily basis, the build-up of deposits on the lenses, which affects vision and causes irritation and discomfort to the eyes, is restricted. It is essential that you read and understand the contents in this guide and have your eye care professional answer any questions, both before and after you have been prescribed the lenses.

A majority of people successfully wear contact lenses without problems. However, before you decide whether or not to begin or to continue wearing contact lenses for daily wear, you should discuss with your eye care professional the effects of contact lenses on your eyes and the risks associated with wearing them.

Contact lenses are different from wearing eye glasses as they are worn directly on your eyes, they affect the way in which your eyes function. These effects tend to increase with the length of time that the lenses remain on your eyes between removals. Therefore, it is important **NOT** to wear your lenses longer than recommended by your eye care professional as doing so increases the risk of adverse effects.

Do remember that soft contact lenses are made of hydrophilic material that absorbs vapours, liquids and soft particles. Hence, you should strictly adhere to the instructions in this guide entitled “Personal Cleanliness and Lens Handling” and seek clarifications with your eye care professional if you have any doubts, including any additional restrictions which may be advised to you by your eye care professional.

Last but not the least, adhering to your prescribed wearing schedule, adopting good hygiene practice and going for regular examinations with your eye care professional is necessary for the proper and safe use of contact lenses, which in turn allows you to feel and look good with crisp and clear vision.

Please refer to the Glossary of Medical Terminology for the definitions of medical/technical terms used in this guide.

2. INDICATIONS (USES) AND WEARING RESTRICTIONS

The device is designed for daily wear for myopic and hypermetropic visual correction in non-aphakic person with non-diseased eyes with corrective power within the limits of the device power specification.

The product is for single patient use. The monthly frequent replacement lens is intended for daily wear and the lens is to be cleaned, rinsed and disinfected each time it is removed from the eye and replaced every month. However, the qualified Eye Care Professional is strongly encouraged to prescribe the appropriate device replacement schedule based on the ocular response of the patient.

*** DO NOT Wear Your FRAICHE™ Monthly Disposable Contact Lens While Sleeping.**

3. CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE the FRAICHE™ Monthly Disposable Contact Lens when any of the following conditions exist:

- a) Acute and sub-acute inflammation or infection of the anterior chamber of the eye.
- b) Any eye disease, injury or abnormality that affects the cornea, conjunctiva or eyelids.
- c) Any previously diagnosed condition that makes contact lens wear uncomfortable.
- d) Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses.
- e) Any active corneal infection (bacterial, fungi or viral).
- f) Allergic reactions of ocular surfaces or adnexa (surrounding tissue) that may be induced or exaggerated by wearing contact lenses or use of contact lens solutions.
- g) Allergic reactions to any ingredient, such as mercury or Thimerosal in contact lens solutions.
- h) Corneal hypoesthesia (reduced corneal sensitivity), if non-aphakic.
- i) If eyes become red or irritated.
- j) Severe insufficiency of lacrimal secretion (dry eyes).
- k) You are unable to follow prescribed lens wearing schedule or unable to obtain assistance to do so.

4. WARNINGS

- a) Problems with contact lenses or lens care product, including the lens case could result in serious injury to the eye. It is essential that you follow your eye care professional's direction and all labeling instructions for proper use of lens and lens care products, including the lens case. Eye problems, including a sore or lesion on the cornea (corneal ulcers) can develop rapidly and lead to loss of vision.
- b) Daily wear lenses are not indicated for overnight wear and you should not wear the FRAICHE™ Monthly Disposable Contact Lens while sleeping. Clinical studies have shown that the risk of an infected sore or lesion on the cornea (ulcerative keratitis) and other serious adverse reactions is greater when these lenses are worn overnight.
- c) Studies have shown that contact lens wearers who smoke have a higher occurrence of adverse reactions than non-smokers and possibility of ulcerative keratitis.
- d) Strict adherence to your wearing restrictions, wearing schedule and regular follow-up visits will reduce the risks of adverse effects associated with your eye.
- e) Should you experience eye discomfort, excessive tearing, vision changes, redness of the eye or other problems, you should **immediately remove** your lenses and promptly contact your eye care professional.

5. PRECAUTIONS

Handling Precautions:

- i) Do not use if sterile blister pack is damaged or broken.
- ii) Before leaving your eye care professional's office, be sure that you are able to remove your lenses promptly or have someone else available who can remove the lenses for you.
- iii) Always wash and rinse hands before handling your lenses. Do not get cosmetics, lotions, soaps, creams, deodorants or sprays in your 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.
- iv) Ensure that your fingers or hands are free of foreign materials prior to touching your lenses, as microscopic scratches of the lenses may occur, resulting in distorted vision and/or injury to your eye.
- v) Always handle your lenses carefully and avoid dropping them.
- vi) Do not touch the lens with your fingernails.
- vii) Never use tweezers or other tools to remove your lenses from the lens container unless specifically indicated for that use. Pour the lens into your hands.

- viii) Carefully follow the handling, insertion, removal, cleaning and wearing instructions in this guide for FRAICHE™ Monthly Disposable Contact Lens and those prescribed by your eye care professional.

Lens Wearing Precautions:

- i) Never wear lenses beyond the period recommended by your eye care professional. You should remove your lenses immediately if your eyes become red or irritated.
- ii) If aerosol products, such as hair spray are used while wearing lenses, exercise caution and keep your eyes closed until the spray has settled.
- iii) Avoid all harmful or irritating vapours and fumes while wearing lenses.
- iv) Ask your eye care professional about wearing contact lenses during sporting and water related activities.
- v) Always discard lenses following the recommended wearing schedule prescribed by your eye care professional.

Solutions Precautions:

- i) Different solutions cannot always be used together and not all solutions are safe for use with all lenses. Use only recommended solutions.
- ii) Refrain from using solutions recommended for conventional hard lenses only.
- iii) Always use fresh unexpired lens care solutions.
- iv) Always adhere to the directions in the package inserts for the use of contact lens solutions.
- v) Use only a chemical (not heat) lens care system. Use of heat care systems can damage your contact lens.
- vi) Sterile unpreserved solutions when used, should be discarded after the time specified in the labeling directions.
- vii) Do not use saliva or anything other than the recommended solutions for lubricating or rewetting the lenses. Do not put lenses in the mouth.
- viii) Always keep the lens completely immersed in the recommended storage solution when the lenses are not being worn (stored). Prolonged periods of drying will damage the lenses. When this happens, damaged lenses must be discarded.
- ix) If the lens sticks (stops moving) on the eye, follow the recommended directions on “Care for a Sticking (Non-moving) Lens”. The lens should move freely on the eye for the continued health of the eye. If non-movement of the lens continues, you should immediately consult your eye care professional.

Lens Case Precautions:

- i) Bacteria can cultivate in contact lens cases. Therefore, it is important that you properly use, clean and replace your cases at regular intervals as recommended by the lens care manufacturer or your eye care professional.
- a) Inform your family doctor (health care professional) that you are a contact lens wearer.
- b) Certain medications such as antihistamines, decongestants, diuretics, muscle relaxants, tranquilizers and those for motion sickness may cause dryness in the eye, increased lens awareness or blurred vision. Always inform your eye care professional if you experience any problems with your lenses while taking such medications. Depending on the severity, your eye care professional may prescribe the use of lubricating drops that are indicated for use with soft contact lenses or the temporary discontinuance of contact lens wear while such medication is being used.
- c) If you are an oral contraceptive user, you could develop visual changes or changes in lens tolerance when using contact lenses.
- d) Always consult your eye care professional before applying any medication in your eyes.
- e) Always inform your employer of being a contact lens wearer. Some profession may require use of eye protection equipment or may require that you not wear contact lenses.
- f) As with any contact lens, follow-up visits are necessary to ensure the continuing health of your eyes. You should be instructed as to a recommended follow-up schedule.

6. POTENTIAL ADVERSE REACTIONS/EFFECTS (PROBLEMS AND WHAT TO DO)

- a) You should be aware of the following problems that may occur when wearing contact lenses:
 - i) Your eyes may sting, burn and/or itch.
 - ii) There may be:
 - less comfort than when the lens was first placed on your eye.
 - a feeling of something in your eye (scratched area, foreign body).
 - the potential for some temporary impairment due to peripheral infiltrates, peripheral corneal ulcers and corneal erosion.
 - the potential for other physiological observations, such as local or generalized edema, corneal neovascularization, corneal staining, injection, tarsal abnormalities, iritis and conjunctivitis, some of which are clinically acceptable in low amounts.
 - excessive watering, unusual eye secretions or redness of your eye.

- iii) Poor visual acuity, blurred vision, rainbows or halos around objects, photophobia (sensitivity to light) or dry eyes may also occur if your lenses are worn for too long a period.
- iv) If you experience or notice any of the above, you should **immediately remove your lens**.
- v) If the discomfort or problem stops, look closely at the lens. If the lens is in any way damaged, you should not put the lens back on your eye. You should discard the lens and insert a fresh new lens on the eye. If the problem persists with the fresh new lenses, you **should immediately remove the lenses and consult your eye care professional**.
- vi) When any of the above signs occur, a serious condition such as infection, corneal ulcer, neovascularization or iritis may be present. **Keep the lens off your eye and seek immediate professional identification of the problem and prompt treatment to avoid serious eye damage.**

7. PERSONAL CLEANLINESS AND LENS HANDLING

✓ **Always adopt good hygienic methods in the care and handling of your new lenses.**

✓ **Cleanliness is the first and most important aspect of proper contact lens care.**

a) Preparing the Lens for Wearing

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

b) Lens Package

- i) To open an individual lens package, shake the lens package and check to see that the lens is floating in the solution.
- ii) Peel open the back of the foil slowly and carefully. You will minimize the possibility of sudden splash by stabilizing the lens package on a table-top.

c) Handling and Placing the Lens on the Eye

- i) Always develop the habit of working with the same lens first to avoid mix-ups.
- ii) Remove the lens from its blister, position it on your index finger and examine it to ensure that it is moist, clean and free of any nicks or tears. If the lens appears damaged, do not use it.
- iii) Once you have opened the blister, removed and examined the lens, follow these steps to apply the lens to your eye:
 - Check and make sure that the lens is not inside out by placing the lens on the tip of your index finger and checking its profile against the light. The lens should assume a natural, convex and bowl-like shape. If the lens edges point outwards, this implies that it is inside out. Another way is to invert it by gently squeezing the lens between the thumb and index finger. Do not allow your fingernails to come in contact with the lens.
 - With the lens on your index finger, use the middle finger of the placement hand to pull down the lower lid. Use the index or middle finger of the other hand to lift the upper lid against the brow. Place the lens on your cornea. While holding this position, look upwards to position the lens properly. Gently release the lids and blink. The lens will center automatically.
 - Repeat the same technique when inserting the lens for your other eye.
- iv) There are other techniques of lens placement besides the above. If the above technique is difficult for you, your eye care professional will provide you with an alternative technique.

Note:

N¹) If after placement of your lens, your vision is blurred, check for the following:

- If the lens is not centered on the eye (refer to the section on “*Centering the Lens*”)
- If the lens is centered, remove the lens (refer to the section on “*Removing the Lens*”) and check for the following:
 - Cosmetics or oils on the lens. Discard the lens and insert a new fresh lens.
 - The lens is on the wrong eye.
 - The lens is placed inside out (it would not be as comfortable as normal).

N²) If you find your vision still blurred after checking the above possibilities, remove both lenses and consult your eye care professional.

d) Centering the Lens

- i) A lens that is on the cornea will rarely be displaced onto the white part of the eye during wear. However, this can occur if the insertion and removal techniques are not properly performed. To center the lens, follow one of the steps below:

- Close your eyelids and gently massage the lens into place through the closed lids, **or**
- Hold the upper and lower eyelids open with your fingers. Then while looking in a mirror, gently place a finger on the lens and slide it towards the center of the eye, **or**
- Gently direct the off-centered lens onto the cornea while the eye is opened using fingertip pressure on the edge of the upper or lower lid.

e) Removing the Lens

- i) Always remove the same lens first.
- ii) Wash, rinse and dry your hands thoroughly with a lint free towel.
- iii) Always ensure that the lens is on the cornea before you try to remove it. You can check this closing the other eye. If your vision is blurred, the lens is either on the white part of your eye or it is not on the eye at all. To detect the lens, check the upper eye area by looking into the mirror while pulling the upper lid up, followed by checking the lower eye area by pulling the lower lid down.
- iv) To remove your lens, look up and slowly pull down your lower lid with the middle of your removal hand and place your index finger on the lower edge of the lens. Gently pinch the lens between the thumb and index finger and remove it. Repeat the same step for the removal of the other lens. *If this technique of lens removal is difficult for you, you should follow the technique recommended by your eye care professional.*
- v) Once the lenses are removed, follow the required lens care procedures described under “Caring for Your Lenses”.

8. CARING FOR YOUR LENS

a) Basic Lens Care Directions

- i) If you require only vision correction, but will not or cannot follow the recommended care schedule for your lenses, or are unable to put on and remove your lens or have someone available to place and remove them, you should not try to get and wear contact lenses.
- ii) When you first get your lenses, be sure that you are able to put on and remove your lenses while you are in your eye care professional’s premises.
- iii) Always wash, rinse and dry your hands before handling your contact lenses. Do not touch the lenses with your finger nails.
- iv) Do not use saliva or anything apart from the recommended solutions for lubricating or rewetting the lenses. Do not put the lenses in the mouth.

- v) Never rinse your lenses in water from the tap as tap water may contain impurities that can damage or contaminate your lenses and may lead to eye infection or injury. The other likelihood is losing your lens down the pipe.
- vi) Upon prescription of your lenses, you will be given a recommended cleaning and disinfecting procedures, instructions and warnings for lens care, handling, cleaning and disinfecting. Your eye care professional should guide you on the applicable procedures and products for your use. Always rinse your lenses with a contact lens solution recommended by your eye care professional before lens insertion.
- vii) The ideal time to clean your lenses is immediately after each removal. For continued safe and comfortable wearing of your lenses, it is important that you first clean and rinse, then disinfect your lenses after each removal, using the lens care regimen recommended by your eye care professional. Cleaning and rinsing are necessary to eliminate mucus, secretions, films or deposits that may have accumulated on your lenses during wearing; whilst disinfecting is essential to destroy harmful bacteria.
- viii) You should always follow the recommended care regimen determined by your eye care professional, and pay attention to any restrictions highlighted. Failure to follow may result in the development of serious ocular complications as discussed in the “Warnings” section.
- ix) For safe contact lens wear, you must be aware and always practice your lens care routine by:
 - Using fresh and unexpired lens care solution at all times.
 - Using the recommended system of lens care, chemical (not heat) and carefully following instructions on solution labeling. Different solutions cannot always be used together and not all solutions are safe for use with all lenses. **Hence, do not mix or alternate the lens care systems unless specified on the solution labeling.**
 - Removing, cleaning, rinsing and disinfecting your lenses according to the schedule prescribed by your eye care professional. The use of any cleaning solution does not substitute for disinfection.
 - Discarding the lenses after the recommended wearing period prescribed by your eye care professional.

Note:

Some solutions may have more than one function specified on the label. Read the label on the solution bottle and follow the instructions.

b) Cleaning

- i) Always clean the same lens first to avoid mix-ups.
- ii) Strictly follow the instructions provided in the cleaning solution labeling.
- iii) Upon cleaning, rinse the lens thoroughly with a recommended rinsing solution to remove the cleaning solution, mucus, secretions, film and deposits from the lens surface.
- iv) Place the lens into the correct chamber of the lens storage case.

c) Disinfecting (Chemical - Not Heat)

- i) Do not disinfect your lenses using heat.
- ii) Upon cleaning, disinfect lenses using the system recommended by your eye care professional.
- iii) Strictly follow the instructions provided in the disinfecting solution labeling or recommendations by your eye care professional.
- iv) If disinfection is by using hydrogen peroxide lens care system, **the lenses must be neutralized before wearing**. Strictly follow the recommendations on the hydrogen peroxide system labeling.

Caution: Chemically disinfected lenses may absorb ingredients from the disinfecting solution that may cause irritation to the eyes. A thorough rinse in fresh sterile saline (or another recommended solution) prior to insertion may reduce the potential for irritation.

d) Rinsing

- i) Rinse the disinfected lenses thoroughly with fresh solution recommended for rinsing before inserting and wearing lenses or follow the instructions on the disinfection solution labeling.

e) Storage

- i) To store your lenses, disinfect and leave them in the closed/unopened case until ready to wear.
- ii) Always keep your lenses completely immersed in a recommended disinfecting solution when the lenses are not being worn.

iii) If the lenses are not worn immediately following disinfection, you should refer to the instructions in the solution package insert or consult your eye care professional for information about storing your lenses.

f) Lens Case Cleaning and Maintenance

i) Contact lens cases can be a source of bacteria growth. Upon removal of lenses from the lens case, you should empty, clean and rinse the lens case with solutions recommended by the lens case manufacturer or your eye care professional, then allow it to air dry.

ii) When reusing the lens case, always refill it with fresh solution. Lens case should also be replaced at regular intervals as recommended by the lens case manufacturer or your eye care professional.

g) Lubricating/Re-wetting

Your eye care professional may recommend a lubricating/re-wetting solution for your use. These solutions can be used to wet (lubricate) your lenses while you are wearing them.

h) Care for Sticking (Non-moving) Lens

i) If your lens sticks (i.e. stops moving) on your eye, apply a few drops of the lubricating or rewetting solution recommended by your eye care professional.

ii) Do not attempt to use plain water or anything besides the recommended solution nor try to remove a sticking lens.

iii) After applying the recommended lubricating or rewetting solution, you should wait until the lens begins to move freely before removing it. If the lens does not move, you should immediately consult your eye care professional.

i) Care for a Dehydrated (Dried Out) Lens

If the FRAICHE™ Monthly Disposable Contact Lens is off the eye and exposed to air for a while, it will become brittle and dry. When this occurs, you should discard your lens and use a fresh new one.

j) Emergencies

If chemicals of any kind (household products, gardening solutions, laboratory chemicals, etc.) are splashed into the eyes, you should: **flush eyes immediately with tap water and immediately contact your eye care professional or visit a hospital emergency room without delay.**

9. INSTRUCTIONS FOR THE MONOVISION (PRESBYOPIC) WEARER

- a) You should be aware that as with any type of lens correction, there are advantages and limitations to monovision contact lens therapy. The benefit of clear near vision in straight ahead and upward gaze that is available with monovision may be accompanied by a vision compromise that may reduce your visual acuity and depth perception for distance and near tasks. Some patients have experienced difficulty adapting to this. Symptoms, such as mild blurred vision, dizziness, headaches and a feeling of slight imbalance, may last for a brief minute or for several weeks as adaptation takes place. The longer these symptoms persist, the poorer your chances for successful adaptation. You should avoid visually demanding situations during the initial adaptation period. It is recommended that you first wear these contact lenses in familiar situations, which are not visually demanding. For example, it might be better to be a passenger rather than a driver of an automobile during the first few days of lens wear. It is recommended that you only drive with monovision correction if you pass your state drivers license requirements with monovision correction.
- b) Some monovision patients will never be fully comfortable functioning under low levels of illumination, such as driving at night. If this happens, you may want to discuss with your eye care professional having additional contact lenses prescribed so that both eyes are corrected for distance when sharp distance binocular vision is required.
- c) If you require very sharp near vision during prolonged close work, you may want to have additional contact lenses prescribed so that both eyes are corrected for near when sharp near binocular vision is required.
- d) Some monovision patients require supplemental spectacles to wear over the monovision correction to provide the clearest vision for critical tasks. You should discuss this alternative with your eye care professional.
- e) It is important that you follow your eye care professional's suggestions for adaptation to monovision contact lens therapy. You should discuss any concerns that you may have during and after the adaptation period.
- f) The decision to be fit with monovision correction is most appropriately left to the eye care professional in conjunction with you, after carefully considering and discussing your needs.

10. WEARING SCHEDULE

- a) You will be prescribed your own lens wearing and replacement schedules by your eye care professional. The space below is for you to note down your schedule and wearing record.

Day	Date	Hours To Wear	Hours Worn
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			
13			
14			

11. APPOINTMENT SCHEDULE

- a) Regular check-up examinations by your eye care professional is an important part of wearing contact lenses. It is highly recommended that you follow your eye care professional’s directions. The space below is for you to keep a record of all your appointments.

Appointment	Date	Time
1.		
2.		
3.		
4.		
5.		
6.		
7.		
8.		
9.		
10.		

12. EYE CARE PROFESSIONAL INFORMATION

Name of Eye Care Professional:	
Address:	Telephone:







IMPORTANT: In the event that you experience any difficulty wearing your lenses or you do not understand the instructions given to you, **DO NOT WAIT FOR YOUR NEXT APPOINTMENT. CONTACT YOUR EYE CARE PROFESSIONAL IMMEDIATELY**

GLOSSARY OF MEDICAL TERMINOLOGY

Term	Definition
Adnexa	Tissues surrounding the eyeball
Ametropia	Abnormal vision requiring correction for proper focus
Anterior chamber	Internal portion of the eye, between the cornea and iris
Aphakic	An eye that does not have its natural lens (e.g. after cataract surgery)
Astigmatism	A vision condition that causes blurred vision due either to the irregular shape of the cornea or sometimes the curvature of the lens inside the eye
Conjunctiva	Membrane that lines the eyelids and the white part of the eye
Conjunctivitis	Inflammation of the conjunctiva
Cornea	Clear front part of the eye that covers the iris, pupil and anterior chamber
Corneal erosion	Wearing away of the surface of the cornea
Corneal staining	When a dye is put onto the eye and shows problems with the corneal surface
Corneal ulcer	A sore or lesion on the cornea, which left untreated could lead to a permanent vision loss
Disinfection	A process that kills germs (harmful microorganisms) which can cause eye infections
Edema	Swelling of tissue from excess fluid accumulation
Hydrophilic material	Water absorbing substance
Hyperopia	Farsighted/Long-sighted
Iritis	Internal inflammation of the coloured part of the eye (iris)
Inflammation	Swelling, pain and redness
Monovision	A correction method for presbyopia (loss of reading vision) with the use of contact lenses where one eye is fitted for distant vision and the other for near vision
Myopia	Nearsighted/Short-sighted
Neovascularization	Small blood vessels growing into the cornea
Non- Aphakic	An eye that has its natural lens
Presbyopia	A vision condition in which the crystalline lens of your eye loses its flexibility with age and loses the ability to change focus for different distances (loss of reading vision)
Tarsal abnormalities	Problems with the eyelids
Ulcerative keratitis	An infected corneal ulcer

The following symbols may appear on the label or carton.

SYMBOLS KEY

Symbol	Definition
	Caution: Certain country law restricts this device to sale by or on the order of a licensed practitioner
BC	Base Curve
DIA	Diameter
D	Diopter (Lens Power)
	Lot Number or Batch Number
	Use By (Expiration Date), expressed in YYYY/MM
	Caution or Attention: See Instructions for Use
	Sterilized Using Moist Heat
	Product packaging is recyclable

Name and Address of Manufacturer

Aquilus Lens International Pte Ltd
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 Singapore 368358