**PACKAGE INSERT**

For the IntelliWave2 (Hioxifilcon B) **SOFT CONTACT LENS FOR DAILY WEAR (clear and tinted)**

**CAUTION:** FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A LICENSED PRACTITIONER.

**IMPORTANT**
Please read and keep this information for future use. This package insert is intended for the eyecare practitioner, but should be made available to the patient upon request. The eyecare practitioner should provide the patient with the wearer's guide that pertains to the patients prescribed lens.

**DESCRIPTION**
The Hioxifilcon B Soft Daily Wear Contact Lens are fabricated from (Hioxifilcon B), which in the dry (unhydrated) state may be machined and polished. The hydrophilic nature of these materials allows the lens to become soft and pliable when immersed in an aqueous solution. The non-ionic lens material, Hioxifilcon B is a copolymer of 2-hydroxyethyl methacrylate (2-HEMA) and 2,3-Dihydroxypropyl methacrylate (2-DHPMA) with bis (trisulfosuccinimidyl)glycolate linked to ethylene glycol dimethacrylate (EGDMA). It consists of 5% Hioxifilcon B and 95% water by weight when measured in normal saline solution buffered with sodium tetaborate. The lens material is available clear and with a blue viability handling tint, phthalocyanato (2) - (copper).

**The Physical properties of the lens are:**
- Refractive Index 1.51 (dry/1.42 (hydrated)
- Base Curve: 7.60 - 10.00
- Power: +20.00 to -20.00
- Cylinder: ≤ -0.75D to ≤ -12.00
- Diameter: 13.0mm - 14.5mm
- Stiffness: 16.40 X 10^-2
- Oxygen Permeability (cm/sec: (n) O2/ml x hPa @ 35°C), (revised Fatt method).
- Water Content 49 %
- Specific Gravity 1.137 (Dried)
- Toric (Hioxifilcon B) Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in aphakic and anaphic persons with non-diseased eyes with myopia or hyperopia and/or possesses refractive astigmatism not exceeding 5 diopters and are presbyopic requiring add power of up to +4.00 diopters.
- Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in aphakic and anaphic persons with non-diseased eyes with myopia or hyperopia and/or possesses refractive astigmatism not exceeding 5 diopters and are presbyopic requiring add power of up to +4.00 diopters.

**INDICATIONS**
- The IntelliWave2, Soft Daily Wear Contact Lenses are indicated for the correction of visual acuity in aphakic and anaphic persons with non-diseased eyes with myopia or hyperopia and/or possesses refractive astigmatism not exceeding 5 diopters and are presbyopic requiring add power of up to +4.00 diopters.
- The IntelliWave2, Toric (Hioxifilcon B) Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in aphakic and anaphic persons with non-diseased eyes with myopia or hyperopia and/or possesses refractive astigmatism not exceeding 5 diopters and are presbyopic requiring add power of up to +4.00 diopters.

**CONTRAINdications (Reasons NOT to USE)**
DO NOT USE the lens if the patient:
- **PROBLEMS WITH CONTACT LENS AND LENS PRODUCTS COULD RESULT IN SEVERE INJURY TO THE EYE.** It is essential that patients follow their eyecare practitioner's demonstrated regimen to assure the continued health of the patient. A thorough patient evaluation must be done for each patient before use of lens and lens care products, including the lens care. EYE PROBLEMS, INCLUDING CORNEAL ULCERS, CAN DEVELOP RAPIDLY AND LEAD TO LOSS OF VISION; THEREFORE, IF YOU EXPERIENCE EYE DISCOMFORT, EXCESSIVE TEARING, VISION CHANGES, OR REDNESS OF THE EYE, IMMEDIATELY REMOVE YOUR LENS AND PROMPTLY CONTACT YOUR EYECARE PRACTITIONER.
- All contact lens wearers must see their eyecare practitioner as directed.
- Daily lens wear is not indicated for overnight wear, and patients should be instructed not to wear lens while sleeping. Clinical studies have shown that the risk of serious adverse reactions is increased when this lens is worn overnight.
- Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lens or use of contact lens solutions.
- Water-base cosmetics are less likely to damage lens than oil-base.
- Do not touch contact lens with the fingers or hands if the hands are not free of foreign materials, as microscope scratches of the lens may occur, causing distorted vision and/or injury to the eye.
- Avoid all harmful or irritating vapors and fumes while wearing lens.
- Any active corneal infection (bacterial, fungi, or viral)
- Any active corneal injury (bacterial, fungal, or viral)
- Never use tweezers or other tools to remove lens from the lens container unless specifically indicated for that use. Pour the lens into the hand.
- Place the lens in the storage case and
- The patient should be informed that the following problems may occur:
  - *Dry eyes.*
  - *Reduced sharpness of vision (poor visual acuity).*
  - *Redness of the eye.*
  - *Blurred vision, rainbows, or halos around objects.*
  - *Increased stinging or tearing of the eye.*
  - *Unusual and those
- Intermittent ocular irritation, possibly with prolonged instillation of solution, may occur.
-UIntmiten ocular irritation, possibly with prolonged instillation of solution, may occur.
- Whenever Fluorescein is used in eyes, the eyes should be flushed with a sterile saline solution that is recommended for in eye use. Wait at least one hour before replacing the lens. Too early replacement may allow the lens to absorb residual Fluorescein irreversibly.
- To check for corneal/ocular sensitivity, you should be able to promptly remove lens or should have secure availability of the instructions.
- Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lens or use of contact lens solutions.
- Active conjunctivitis.
- Avoid all harmful or irritating vapors and fumes while wearing lens.
- Do not touch contact lens with the fingers or hands if the hands are not free of foreign materials, as microscope scratches of the lens may occur, causing distorted vision and/or injury to the eye.
- Carefully follow the handling, insertion, removal, cleaning, disinfection, storing and wearing instructions in the patient instructions for the IntelliWave2, Soft Daily Wear Contact Lenses and those
- Do not touch lens with fingers or hands unless specifically indicated for that use. Pour the lens into the hand.
- Place the lens in the storage case and
- Avoid all harmful or irritating vapors and fumes while wearing lens.
- *Dry eyes.*
- *Reduced sharpness of vision (poor visual acuity).*
- *Redness of the eye.*
- *Blurred vision, rainbows, or halos around objects.*
- *Increased stinging or tearing of the eye.*
- *Unusual and those
SOLUTION LABELING

used to wet (lubricate) lens while they are being worn to make them more comfortable.

Different solutions cannot always be used together, and not all solutions are safe for use with all lens.

freely on the eye before removing it. If nonmovement of the lens continues after 15 minutes, the patient should

cleaning and disinfecting. For enzyme cleaning, the patient should carefully follow the instructions in the enzymatic cleaning labeling.

the lens case to air dry. When the case is used again, refill it with storage solution. Replace lens case at regular intervals as recommended by the lens case manufacture or your eyecare practitioner.

EMERGENCIES

Chemical (NOT HEAT) Lens Disinfection:

Lens cleaning, disinfection, and storage:

Care of contact lens takes very little time and involves THREE essential steps –

CARE OF YOUR CONTACT LENS

Art Optical recommends that the IntelliWave2, Soft Daily Wear Contact Lens be discarded and replaced with a new lens every six months. However, as the Eyecare practitioner, you are encouraged to determine an appropriate lens replacement schedule based upon the response of the patient.

LENS CARE DIRECTIONS

Eye Examinations

Lenses prescribed for frequent replacement: Art Optical recommends that the IntelliWave2, Soft Daily Wear Contact Lens be discarded and replaced with a new lens every six months. However, as the Eyecare practitioner, your are encouraged to determine an appropriate lens replacement schedule based upon the response of the patient.

Chemical (NOT HEAT) Lens Disinfection:

Rinse the lenses thoroughly with recommended rinsing or disinfecting solution to remove the cleaning solution, mucus, and film from the lens surface, and put lens into correct chamber of the lens storage case. Then repeat the procedure for the second lens. After cleaning, lens using the system recommended by the manufacturer and the eyecare practitioner. To store lens, disinfect and leave them in the closed/unopened case until ready to wear. If lens is not to be used immediately following disinfection, the patient should be instructed to consult the package insert or the eyecare practitioner for information on storage of lens.

Lens Case Cleaning and Maintenance:

Contact lens case can be a source of bacteria growth. After removing the lens from the case, empty and rinse the lens storage case with solution as recommended by the lens case manufacturer; then allow the lens case to air dry. When the case is used again, refill it with storage solution. Replace lens case at regular intervals as recommended by the lens case manufacture or your eyecare practitioner.

Care for a sticking (non-moving) lens:

If the lens sticks (cannot be removed), the patient should be instructed to apply 3 to 4 drops of the recommended lubricating or rewetting solution directly to the eye and wait until the lens begins to move freely on the eye before removing it. If no movement of the lens continues after 15 minutes, the patient should IMMEDIATELY consult the eyecare practitioners.

Storage:

The IntelliWave2, Soft Daily Wear Contact Lens must be stored only in the recommended solutions. If left exposed to the air, the lens will dehydrate. If lens dehydrates, refer above section on caring for dried out (dehydrated) dry lens.

Lens cleaning and disinfection:

Basic Instructions:

Care of contact lens takes very little time and involves THREE essential steps – CLEANSING, RINSING AND DISINFECTING. Each step in itself is important, and one step is not to be replaced by the other. Always wash, rinse and dry hands before handling contact lens. Always use FRESH, STERILE UNEXPOSED lens care solutions. Use the recommended chemical (not heat) lens care system. Different solutions cannot always be used together, and not all solutions are safe for use with all lens. DO NOT ALTERATE OR MIX LENS CARE SYSTEMS UNLESS INDICATED ON LABELING. Do not use saliva or anything other than the recommended solutions for lubricating or rewetting lens. Do not put lens in the mouth. Lenses should be cleaned, rinsed, and disinfected each time they are removed.

Cleansing:

To cleanse, carefully follow the lens care product directions. Each lens care product contains specific directions for use and importance.

Caution:

Storage:

LENS CARE DIRECTIONS

Basic Instructions:

Care of contact lens takes very little time and involves THREE essential steps – CLEANSING, RINSING AND DISINFECTING. Each step in itself is important, and one step is not to be replaced by the other. Always wash, rinse and dry hands before handling contact lens. Always use FRESH, STERILE UNEXPOSED lens care solutions. Use the recommended chemical (not heat) lens care system. Different solutions cannot always be used together, and not all solutions are safe for use with all lens. DO NOT ALTERATE OR MIX LENS CARE SYSTEMS UNLESS INDICATED ON LABELING. Do not use saliva or anything other than the recommended solutions for lubricating or rewetting lens. Do not put lens in the mouth. Lenses should be cleaned, rinsed, and disinfected each time they are removed.

Cleansing:

To cleanse, carefully follow the lens care product directions. Each lens care product contains specific directions for use and importance.

Caution:

Storage:

RECOMMENDED LENS CARE PRODUCTS

Art Optical recommends that a care system that is appropriate for the IntelliWave2, Soft Daily Wear Contact Lens. Each lens care product contains specific directions for use and important safety information, which should be read and carefully followed. The table below shows solutions that are recommended for use with the IntelliWave2, Soft Daily Wear Contact Lens.

EMERGENCIES

The patient should be informed that if chemicals of any kind (household products, gardening solutions, laboratory chemicals, etc.) are splashed into the eyes, the patient should

DISINFECTING

Lenses prescribed for frequent replacement: Art Optical recommends that the IntelliWave2, Soft Daily Wear Contact Lens be discarded and replaced with a new lens every six months. However, as the Eyecare practitioner, your are encouraged to determine an appropriate lens replacement schedule based upon the response of the patient.

Chemical (NOT HEAT) Lens Disinfection:

Rinse the lenses thoroughly with recommended rinsing or disinfecting solution to remove the cleaning solution, mucus, and film from the lens surface, and put lens into correct chamber of the lens storage case. Then repeat the procedure for the second lens. After cleaning, lens using the system recommended by the manufacturer and the eyecare practitioner. To store lens, disinfect and leave them in the closed/unopened case until ready to wear. If lens is not to be used immediately following disinfection, the patient should be instructed to consult the package insert or the eyecare practitioner for information on storage of lens.

Lens Case Cleaning and Maintenance:

Contact lens case can be a source of bacteria growth. After removing the lens from the case, empty and rinse the lens storage case with solution as recommended by the lens case manufacturer; then allow the lens case to air dry. When the case is used again, refill it with storage solution. Replace lens case at regular intervals as recommended by the lens case manufacture or your eyecare practitioner.

Care for a sticking (non-moving) lens:

If the lens sticks (cannot be removed), the patient should be instructed to apply 3 to 4 drops of the recommended lubricating or rewetting solution directly to the eye and wait until the lens begins to move freely on the eye before removing it. If no movement of the lens continues after 15 minutes, the patient should IMMEDIATELY consult the eyecare practitioners.

Storage:

The IntelliWave2, Soft Daily Wear Contact Lens must be stored only in the recommended solutions. If left exposed to the air, the lens will dehydrate. If lens dehydrates, refer above section on caring for dried out (dehydrated) dry lens.

CAUTION: FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A LICENSED PRACTITIONER.

PRINT DATE: 12/11 rev.2 ©Art Optical Contact Lens, Inc. 2017 s:b200:pi