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 users increases with the number of consecutive days that the lenses are worn between removals, beginning with the first overnight use. This risk can be reduced by careful lens care, including cleaning of the lenses case.

Studies have shown that contact lens wearers who have a history of exposure to extreme adverse reactions should follow a routine lens care, including cleaning of the lenses case.

If the patient experiences eye discomfort, excessive tearing, vision changes, or redness of the eye, the patient should be instructed to immediately remove the lenses and promptly contact their eye care practitioner.

PRECAUTIONS:

Special Considerations for Eye Care Practitioners:

- Due to the small numbers of patients enrolled in clinical investigation of lenses, all refractive powers, design configurations, or lens parameters available in the lens material are not evaluated in significant numbers. Consequently, when selecting an appropriate lens design and parameters, the eye care practitioner should consider all characteristics of the lens that can affect lens performance and 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 carefully weighed against the patient's need for refractive correction; therefore, the continous ocular health of the patient and lens performance on the patient should be carefully monitored by the prescribing eye care practitioner.

- Aromatic patients should not be fitted with any Frequency 55 lens unless the determination is made that the eye has healed completely.

- Fluorescein, a yellow dye, should not be used while the lenses are on the eyes. The lenses absorb the dye and become discolored. Whenever fluorescein is used in the eyes, the eyes should be flushed with a sterile saline solution that is recommended for in-eye use.

- The physical/optical properties of the lens are:
  - Refractive index: 1.41
  - Light Transmittance: >96%
  - Surface Character: Hydrophilic
  - Water Content: 55%
  - Oxygen Permeability: 19.7 x 10^(-11) (cm/sec) (mL O2/mL x mmHg) at 35°C (fatt method for determination of oxygen permeability)

- 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 users increases with the number of consecutive days that the lenses are worn between removals, beginning with the first overnight use. This risk can be reduced by careful lens care, including cleaning of the lenses case.

- Studies have shown that contact lens wearers who have a higher incidence of adverse reactions than nonsmokers.

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- Before leaving the eye care practitioner's office, the patient should be able to promptly remove the lenses or should have someone else available who can remove the lenses for him or her. Eye care practitioners should instruct the patient to remove the lenses immediately if the eye becomes red or irritated.

- Eye care practitioners should carefully instruct patients about the following care regimen and safety precautions:

- Different solutions cannot always be used together, and not all solutions are safe for use with all lenses. Use only recommended solutions.

- Never use solutions recommended for conventional hard lenses only.

- Use only chemical (not heat) disinfection with Frequency 55 lenses. Heat disinfection should NOT be used. Repeated heat disinfection will cause irreversible damage to any Frequency 55 lens.

- Always use fresh, unopened lens care solutions.

- Always follow directions in the package inserts for the use of contact lens solutions.

- Sterile unsupervised solutions, when used, should be discarded after the time specified in the labeling directions.

- Do not use saliva or anything other than the recommended solutions for lubricating or wetting lenses.

- Always keep the lenses completely immersed in the recommended storage solution when the lenses are not being worn (stored). Prolonged periods of drying may damage the lenses. Follow the lens care directions for Care for a Dried Out (Dehydrated) Lens if the lens surface does become dried out.

- If the lens sticks (stops moving) on the eye, follow the recommended directions on Care for a Sticking Lens. The lens should be moved freely on the eye for the continued health of the eye. If non-movement of the lens continues, the patient should be instructed to immediately remove the lenses and promptly contact their eye care practitioner.

- Always wash and rinse hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, or soaps, creams, or anything other than the recommended solutions for lubricating or wetting lenses.

- Do not touch the contact lenses with the finger or hands if the hands are not free of foreign materials, as lens damage may occur.

- Carefully follow the handling, insertion, removal, cleaning, disinfection, and care instructions, and wearing instructions in the Patient Instructions for Frequency 55 contact lenses and those prescribed by the eye care practitioner.

- Never wear lenses beyond the period recommended by the eye care practitioner.

- If aerosol products such as hair spray are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.

- Always handle lenses gently and avoid dropping them.

- Avoid all harmful or irritating vapors and fumes while wearing lenses.

- Ask the eye care practitioner about wearing the lenses during sporting activities.

- Inform the doctor (health care practitioner) about being a contact lens wearer.

- Never touch tweezers or other tools to remove lenses from the lens container unless specifically indicated for that use. Pour the lens into your hand.

- Do not touch the lens with fingernails.

- Always inform the employer of being a contact lens wearer. Some jobs may require use of eye protection equipment or may require that the patient not wear contact lenses.

- As with any contact lens, follow-up visits are necessary to assure the continuing health of the patient's eyes. The patient should be instructed as to a recommended follow-up schedule.

ADVERSE EFFECTS:

- The patient should be informed that the following problems may occur:

- Eyes stinging, burning, or itching (irritation), or other eye pain.

- Comfort is less than when the lens was first placed on the eye.

- Feeling that something is in the eye such as a foreign body or a scratch.

- Excessive watering (tearing) of the eyes.

- Unusual eye secretions.

- Redness of the eye.

- Reduced sharpness of vision (poor visual acuity).

- Blurred vision, rainbows, or halos around objects.

- Sensitivity to light (photophobia).

- Dry eyes.

- If the patient notices any of the above, he or she should be instructed to immediately remove the lenses.
- If the discomfort or the problem stops, then look closely at the lens. If the lens is in some way damaged, do not put the lens back on the eye. Place the lens in the storage case and contact the eye care practitioner. If the lens has dirt, an eyelash, or other foreign body on it, or the problem stops and the lens appears undamaged, the patient should thoroughly clean, rinse, and disinfect both lenses; then reinset them. After reinset, if the problem continues, the patient should immediately remove the lenses and consult the eye care practitioner.

When any of the above problems occur, a serious condition such as infection, corneal ulcer, neovascularization, or iris 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.

FITTING: Conventional methods of fitting contact lenses apply to all Frequency 55 contact lenses. For a detailed description of the fitting techniques, refer to the Frequency 55 or Frequency 55 Multifocal Professional Fitting and Information Guide, copies of which are available from CooperVision, Inc.

WEARING SCHEDULE: The wearing and replacement schedules should be determined by the eye care practitioner. Patients tend to over-wear the lenses initially. The eye care practitioner should emphasize the importance of adhering to the initial maximum wearing schedule. Regular checkups, as determined by the eye care practitioner are also extremely important.

CooperVision recommends that the all Frequency 55 lenses be discarded and replaced with a new lens on a frequent replacement basis. The eye care practitioner is encouraged to determine an appropriate lens replacement schedule based upon the response of the patient.

DAILY WEAR: (less than 24 hours, while awake). The maximum suggested wearing time is:

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EXTENDED WEAR: (greater than 24 hours, including while asleep) Frequency 55 lenses are suitable for extended wear. The wearing time should be determined by the eye care practitioner. First time wearers of contact lenses should begin following the DAILY WEAR SCHEDULE above, as directed by the eye care practitioner.

CAUTION: Not every patient is able to wear Frequency 55 lenses on an extended wear basis, even if they are able to wear the same lenses for daily wear. The eye care practitioner will determine, by history and physical exam, if each patient is a candidate for extended wear. The eye care practitioner will instruct the patient on the importance of good eye care and the necessity of replacing lenses as directed.

Note: Some solutions may have more than one function, which will be indicated on the label. Read the label on the solution bottle, and follow directions.

- Clean one lens first (always the same lens first to avoid mix-ups), rinse the lenses thoroughly with recommended saline or disinfection solution to remove cleaning solution, mucus, and film from the lens surface, and put lens into the correct chamber of the lens storage case. Then repeat the procedure for the second lens.

- After cleaning, and rinsing, disinfect lenses using the system recommended by the manufacturer and/or eye care practitioner.

- The solutions are available in a number of different products and systems, so you should choose the one that is recommended by your eye care practitioner.

- To store lenses, rinse and leave them in the closed/unopened case until ready to wear. If lenses are not to be used immediately following disinfection, the patient should be instructed to consult the package insert or the eye care practitioner for information on the storage of lenses.

- After removing the lenses from the lens 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 lens case is used again, refill it with storage solution. Replace the lens case at regular intervals as recommended by the lens case manufacturer or your eye care practitioner.

- Eye care practitioners may recommend a lubrication/rewetting solution, which can be used to wet (lubricate) the lenses while they are being worn to make them more comfortable.

- To rehydrate the lens:

- • Handle the lens carefully.

- • Place the lens in its storage case and soak the lens in a recommended rinsing and storage solution for at least one hour until it returns to a soft state.

- • Clean the lens first, then disinfect the rehydrated lens using a recommended lens care system.

- If after soaking, the lens does not become soft, if the surface remains dry, the lens should not be used unless it has been examined by the eye care practitioner.

CARE FOR A STICKING (NONMOVING) LENS:

If the lens sticks (stays moving or cannot be removed), the patient should be instructed to apply 2 to 3 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 non-movement of the lens continues, please contact your eye care practitioner.

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 immediately consult the eye care practitioner.

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- FLUSH THE EYES IMMEDIATELY WITH TAP WATER AND IMMEDIATELY CONTACT THE EYE CARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.

HOW SUPPLIED:

Each lens is supplied sterile in a blister pack containing buffered isotonic saline solution. The blister is labeled with the base curve, diameter, dioptric power, manufacturing lot number, and expiration date of the lens.

DO NOT USE IF THE BLISTER PACK IS BROKEN OR THE SEAL HAS BEEN DAMAGED

REPORTING OF ADVERSE REACTIONS:

All serious adverse experiences and adverse reactions observed in patients wearing any Frequency 55 contact lens or experienced with the lenses should be reported to CooperVision.

LENS CASE CLEANING AND MAINTENANCE:

Contact lens cases can be a source of bacterial growth. Lens cases should be emptied, cleaned, and rinsed with solution recommended by the lens case manufacturer, and allowed to dry completely. Lens cases should be replaced at regular intervals as recommended by the lens case manufacturer or the eye care practitioner.

CARING FOR A DRIED OUT (DEHYDRATED) LENS:

If any Frequency 55 lens is exposed to air while off the eye, it may become dry and brittle and need to be rehydrated. If the lens is adhering to a surface, apply sterile saline solution before handling.