INTRODUCTION
UltraHealth® FC (Flat Cornea) SiH (petrafocon A hem-larafilcon A) Hybrid Contact Lenses for Post Surgical Patients should be instructed that using their multi-purpose solution beyond the discard date could result in Refractive Error and Trauma.

INDICATIONS (USES)
UltraHealth® FC (Flat Cornea) SiH (petrafocon A hem-larafilcon A) Hybrid Contact Lenses are indicated for use in the correction of eye deficiencies excluding trauma resulting from corneal surgery or trauma including hyperopia (<0.50 D) or myopia (<0.50 D) related to the pre-existing corneal curvature, with or without presbyopia. The lenses are indicated for the correction of up to -20.00 D and -20.00 D in eyes with astigmatism or corneal conditions that prevent their use with other contact lenses. The lenses are recommended for people with presbyopia +1.00 and +4.00 D. The lenses may be prescribed for daily wear with removal for cleaning and disinfection (chemically, not heat) prior to use.

CONTRAINDICATIONS (REASONS NOT TO USE)
DO NOT USE UltraHealth FC Contact Lenses for any of the following conditions:
- Acute and subacute infections or infections of the anterior chamber of the eye.
- Any eye disease or abnormality that affects the cornea, conjunctiva or eyelids except corneal trauma deemed to benefit from the device (active corneal infection, bacterial, viral) or fungal.
- Severe insufficiency of tear (Dry eye) or if eyes become red or irritated.
- Corneal hypothermia (reduced corneal sensitivity).
- Any condition that may affect the eye or be exacerbated by wearing contact lenses.
- Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lenses or use of contact lens solutions or allergy to any ingredient, e.g., such as a preservative or Thimerosal, in a solution that is to be used for contact care.

WARNINGS, PROBLEMS WITH CONTACT LENSES AND LENS CARE PRODUCTS COULD RESULT IN INSEDFICTION TO THE EYE. It is essential that the patient follow the directions of the eyecare practitioner and all labeling instructions for proper use of contact lenses and care products, including the lens case. Patients should be advised of the following instructions for use and warnings pertaining to contact lens wear:
- Patients should be instructed to use only fresh multi-purpose (contact lens disinfecting) solution each time they soak their lenses. WARNING: Patients should be instructed not to reuse or "top off" old solution left in their lens case. New solution should be added to the lens case after the recommended time period indicated on the bottle. "Topping-off" is the addition of fresh solution to solution that has been sitting the case.
- Patients should be instructed to use contact lens solutions recommended by the lens care products, including the lens case. As with rigid gas permeable lenses there may be residual astigmatism uncorrected by the lenses. The amount of residual astigmatism may be estimated by comparison of the corneal and refractive astigmatism. Eyes with near equal corneal and refractive astigmatism are not expected to demonstrate residual astigmatism. The amount of residual astigmatism may be estimated by comparison of the corneal and refractive astigmatism. Eyes with near equal corneal and refractive astigmatism are not expected to demonstrate residual astigmatism. Eyes with near equal corneal and refractive astigmatism are not expected to demonstrate residual astigmatism.
- Patients should be instructed to discard any remaining solution after the recommended time period indicated on the bottle of multi-purpose solution used for disinfecting and soaking their contact lenses.
- Patients should be instructed to not expose their contact lenses to water before wearing them. WARNING: Water can harbor microorganisms that can lead to severe infection, vision loss or blindness. Patients should be instructed that if their lenses have been submerged in water when swimming in pools, lakes or oceans, they should discard them and replace them with a new pair. Patients should be instructed to ask the eyecare practitioner about solutions containing chlorine to help prevent bacterial growth.
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- Patients should be instructed to immediately remove the lenses and promptly contact their eyecare practitioner.

PRECAUTIONS
- Patients with contact lenses and lens care products could result in serious injury to the eye. It is essential that the patient follow the directions of the eyecare practitioner and all labeling instructions for proper use of their lenses and lens care products, including the lens case. Eye problems, including corneal ulcers, can develop rapidly and lead to loss of vision.

- Do not touch contact lenses with fingers or hands if hands are not free of foreign materials, as microscopic debris or contamination of the lens can occur.
- Carefully handle insertion, removal, cleaning, disinfecting, storing and wearing instructions in the Patient Instruction Booklets for UltraHealth FC Contact Lenses and those prescribed by the eyecare practitioner.

- Never wear glasses with bubbles, nor beyond the recommended time by the eyecare practitioner.
- If removed for cleaning, disinfection, or wearing a contact lens case, exercise caution and keep eyes closed until the spray has settled.

WARNING: Patients should be instructed that using their multi-purpose solution beyond the discard date could result in infection of the solution and can lead to severe infection, vision loss or blindness.
- To avoid contamination, patients should be instructed to NOT touch the tip of the container to any surface. Replace cap after using.
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Basic Instructions

**Day 1:** wear not to exceed 6 hours total

**Day 2:** 6 hours

**Day 3:** 6-8 hours

The lens-only may be worn daily for use and for a period of up to six (6) months or as recommended by the eyecare practitioner.

A well fit lens provides for centration and minimal movement. The effects of lid interaction on blinking and gravity provides an excellent opportunity to evaluate lens fit, comfort and vision.

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ADVERSE REACTIONS (PROBLEMS AND WHAT TO DO)

Patients should be informed that the following problems may occur:

- Allergic reactions to contact lens solution, base curves, or irregular surfaces of the lens;
- Sensitivity to light (photophobia);
- Inflammation, redness or swelling of the eye;
- Sensitivity to contact lenses which require wear of extended wear lenses (greater than 7 days) or lenses worn continuously without removal during the day; and
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