

ULTRAHEALTH™

The Healthy Vision Choice for Irregular Corneas

2014 Fitting Guide

SynergEyes

www.synergeyes.com

UltraHealth Lens Design

The **UltraHealth™** lens is the most advanced hybrid contact lens and is ideal for patients with irregular corneas. The lens performs well on patients with keratoconus, ectasias, post-surgical, post corneal cross-linking, intacs and other corneal irregularities.

The lens design incorporates a proprietary reverse geometry, aspheric GP lens that vaults corneal irregularities and provides twice the lift of previous hybrid designs enabling you to fit patients with a broader range of corneal irregularities.

One of the major benefits of the UltraHealth lens is the emphasis on eye health. This lens has extremely high oxygen transmission from a hyper-Dk GP and a high-DK silicone hydrogel skirt. The lens design allows for enhanced tear exchange allowing patients to enjoy all-day wear without having to remove the lenses part-way through the day.

As a patient's need for more vault increases, the vault design of UltraHealth hybrid contact lens shifts from a fixed vault system (figure A) to a variable vault system (figure B). The more aggressive reverse geometry lift allows the lens to clear the majority of ectasias.

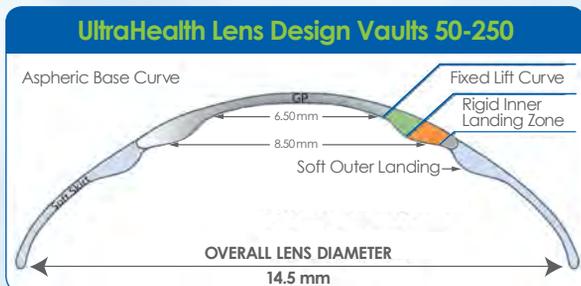


FIGURE A

NOTE: Drawings not to scale

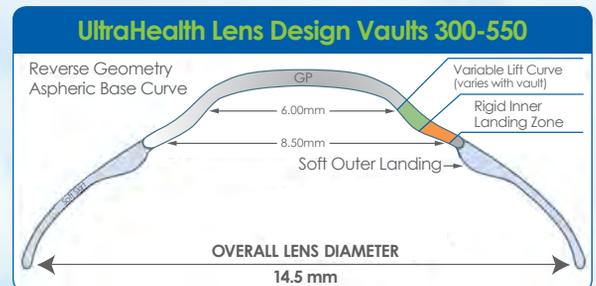


FIGURE B

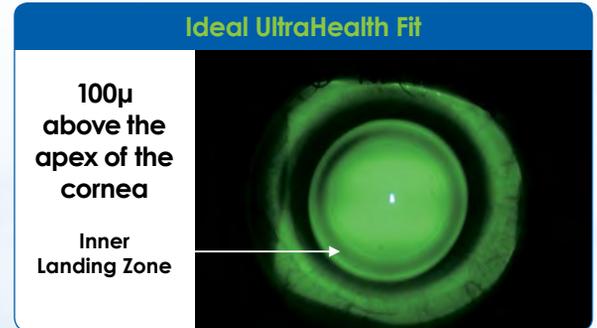
NOTE: Drawings not to scale



IDEAL FIT

The UltraHealth lens should clear the apex of the cornea between 100 μ and 150 μ at initial fit. The lens is expected to settle between 30 μ -60 μ with wear. After wear, the final lens is expected to vault the cornea by about 50 μ .

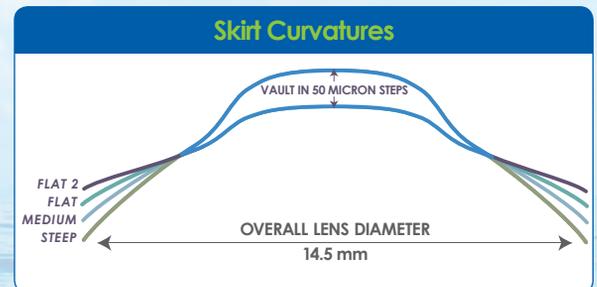
The soft silicone hydrogel skirt helps center the GP lens and there should be a thin bearing ring at the inner landing zone. Expect movement on blink at initial fit, but movement after a few hours of wear or at follow up may not be perceptible, although there is still tear exchange.



CHARACTERISTICS:

1. The UltraHealth hybrid lens provides excellent oxygen transmission to the cornea through the high Dk materials and all-day tear exchange.
2. The silicone hydrogel (soft) skirt facilitates consistent GP centration as well as edge lens comfort.
3. Unlike previous SynergEyes lens designs, the new silicone hydrogel skirt does not suspend the GP or provide sustainable vertical lift. The skirt may initially appear to be holding up the GP lens, but, during wear, the skirt relaxes and the GP settles down.
4. The skirt is designed to create a tear pump unique to hybrid lenses, allowing for an all-day flow of tears.
5. The idea is to select the skirt that conforms to the shape of the eye and provides optimum edge lens comfort and centration.
6. The most successful skirt curve is an 8.4 flat.

The purpose of the soft skirt is to help center the lens and to provide edge lens comfort.



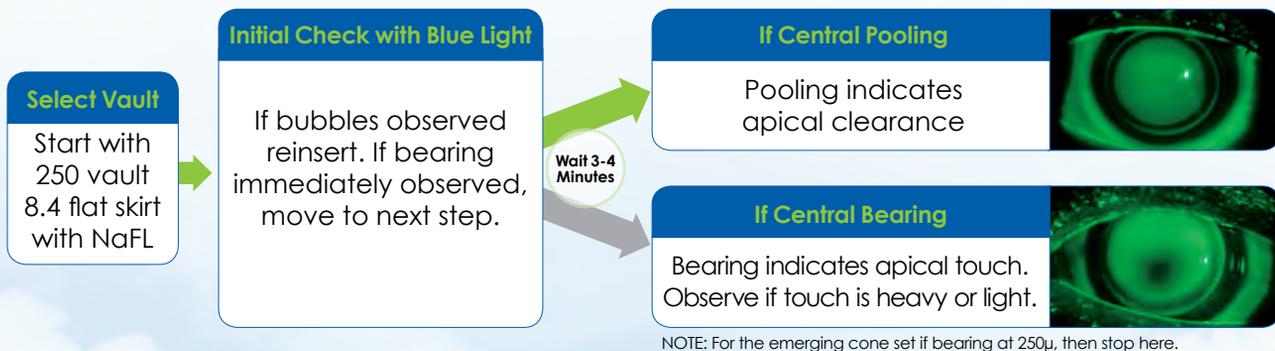
ULTRAHEALTH™

IDEAL FIT

100-150 μ apical clearance during initial fit.
Expect lens to settle 30-60 μ .
50+ μ of apical clearance after lens settles.

Diagnostic

Step 1: GP Vault Determination



Step 2: Skirt Determination



Technical Consultation

USA & Canada

Monday-Friday:
9:00AM to 8:00PM (EST)

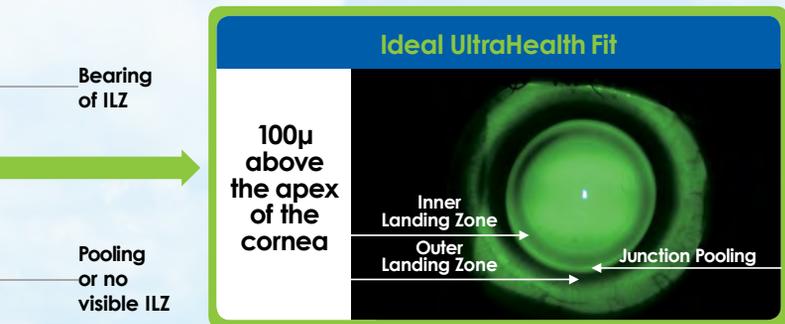
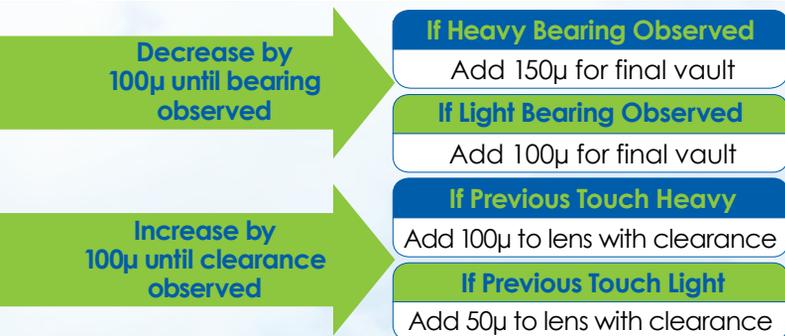
Technical Consultation

Tel: 877.733.2012, option 2
E-Mail: consultation@synergeyes.com

Place Orders & Customer Care

Tel: 877.733.2012, option 1
Fax: 877.329.2012
E-Mail: orders@synergeyes.com
Online: www.synergeyes.com

Fitting Approach



Outside USA & Canada

To locate an International Distributor visit www.synergieyes.com/international.

To contact Customer Care in USA call +1 760.476.9410, option 1, or to place an order email: intorders@synergieyes.com.

Power Determination

Lens power can be determined at the same time that either the vault or skirt is determined.

Over-refraction

Over-refract once. Add over-refraction to the Rx of the final diagnostic lens.

Vault Power Chart

Vault (μ)	Rx (D)
050	Plano
100	-2.00
150	-4.00
200	-6.50
250*	-9.00
300	-6.50
350	-8.00
400	-9.00
450	-10.50
500	-12.00
550	-14.00

*Lens thickness 210 μ

NOTE: Diagnostic lens power calculated so over-refraction the same for all vaults

Examples of -2.00 over-refraction

150 μ Lens Dx Power = -4.00
Over-refraction = -2.00
Power to Order = -6.00

250 μ Lens Dx Power = -9.00
Over-refraction = -2.00
Power to Order = -11.00

300 μ Lens Dx Power = -6.50
Over-refraction = -2.00
Power to Order = -8.50

Step 1: Vault Determination

The ideal diagnostic lens is 100 to 150 μ above the apex of the cornea.

Since the skirt is expected to settle between 30-60 μ during wear, the final lens will be around 50 μ above apical touch.

Central Pooling



Central Bearing



- Lens selection is determined by an examination of fluorescein patterns to evaluate apical touch versus apical clearance. Once apical touch is identified, select a lens that provides 100 μ of apical clearance.
- Begin with a **250 vault** lens with an **8.4 flat skirt** using fluorescein. Check for bubbles under the lens with the blue pen light and reinsert if you see bubbles. Use the Wratten filter in the set to improve clarity of the fluorescein pattern.
- If you observe central pooling which indicates that the lens is clearing the apex, decrease the vault in 100 μ increments until central bearing is observed.
 - Once you observe central bearing, if heavy central bearing, add 150 μ for final vault. If light bearing is observed, add 100 μ for final vault.
- In the other situation, if you put on a 250 μ lens and see central bearing this indicates that there is apical touch with the initial 250 lens.
 - If apical touch is observed, note whether the touch is heavy or light and increase vault by 100 μ until pooling is observed. If last touch was heavy, then add 100 μ to last pooling lens. If last touch was light, then add 50 μ to last pooling lens.

Optic Section & OCT Methods of Vault Determination

- Use an optic section from a lens that has clearance. The average lens thickness is approximately 210 μ . Clearance over the corneal apex should be approximately half the lens thickness at initial fit, or approximately 100 μ . At follow-up, the apical clearance should be $\frac{1}{4}$ to $\frac{1}{2}$ the thickness of the lens, or 50-100 μ . Corneal thickness measurements may also be used.
- If fitting using an anterior segment OCT, clearance at initial fit should be between 100 and 150 μ or approximately half the lens thickness (see figure 1). At follow-up, expect apical clearance to be approximately 50-100 μ .

OCT Image at Dispense

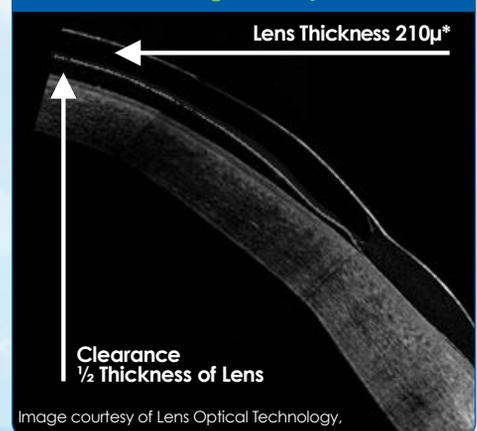


Image courtesy of Lens Optical Technology.

FIGURE 1

*250 μ Diagnostic lens with -9.00 power. Thickness ranges from 300 μ at plano power to 180 μ at -14.00 power.

Step 2: Skirt Determination

Ideal Fit

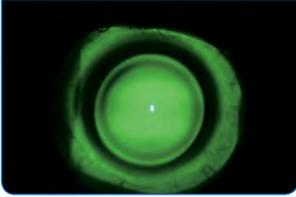


FIGURE A

Light thinning on the ILZ after 4 minutes indicates that this skirt is correct

- To determine the correct skirt, evaluate the fluorescein pattern of the 8.4 flat skirt using a lens vault that has some apical clearance. This may be the initial 250 μ vault lens. This eliminates the need to put the final vault lens back on after the vault is determined. The proper skirt should only be determined using a lens vault that does not exhibit central bearing.
- Examine the corneal clearance of the inner landing zone (ILZ) 3-4 minutes after insertion. A thin layer of fluorescein indicating light touch, with a little bearing indicates an ideal skirt fit (see figure A).
- If there is no defined inner landing zone (see figure B), then this indicates that the skirt may be too steep. Try on or order a lens with a flatter skirt.
- If there is heavy bearing at the inner landing zone (see figure C), this indicates that the skirt is too flat. Try on or order a lens with a steeper skirt. Excessive movement on blink or a skirt that is fluting are signs of a skirt that is too flat.

Skirt Too Steep

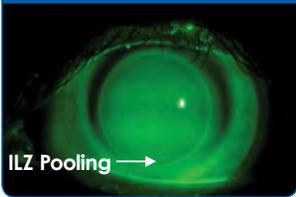


FIGURE B

Pooling or no visible ILZ indicates that flatter skirt is needed

Fitting Notes

- There should be movement on blink during fitting.
- Movement on blink after a few hours of wear is not mandatory because of the high Dk of the lens and the pumping action from the hybrid design.
- Approximately fifteen percent of the weight of the lens will rest on the inner landing zone, while the remaining eighty five percent is distributed to the soft skirt.
- Bearing of the inner landing zone may leave a temporary impression ring observed at follow up. This light bearing is normal and not pathologic.

Skirt Too Flat

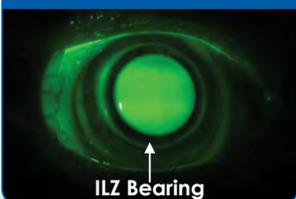


FIGURE C

Bearing on the ILZ indicates that steeper skirt is needed

Power Determination

Lens power may be selected once the vault or the skirt is determined by a single over-refraction. Simply add the spherical over-refraction to the diagnostic lens power to determine the power to prescribe. Only one over-refraction is needed during the entire fitting process to determine the final lens power to order.

EXAMPLE FIT WITH A -2.00 OVER-REFRACTION

Examples of -2.00 over-refraction		
150μ Lens	Dx Power	= -4.00
	Over-refraction	= -2.00
	Power to Order	= -6.00
250μ Lens	Dx Power	= -9.00
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*Lens thickness 210 μ

NOTE: Diagnostic lens power calculated so over-refraction the same for all vaults

Diagnostic Lens Identification

All diagnostic lenses are laser marked:

UltraHealth Lens Type: H

Vault: "05" = 50 vault, "10" = 100 vault, "15" = 150 vault

Skirt Curve: Y = 8.7 Flat 2, F = 8.4 Flat,

M = 8.1 Medium, S = 7.9 Steep

Example: (H 25 Y) UltraHealth 250 Vault Flat 2 Skirt



1. Instruct patient with proper insertion and removal techniques. See suggestions on pages 13 and 14 or refer to Patient Lens Handling & Care brochure. Patient lens handling videos are available at synergeyes.com.

2. Assess Visual Acuity

- If a bubble is observed, remove lens and re-insert.
- If there is discomfort, remove the lens, rinse and reinsert.

3. Assess Lens Movement

- Confirm lens movement of up to 1mm (at straight ahead and upward gaze).

NOTE: After a few hours of wear, movement may be minimal and is not mandatory for an adequate level of oxygen transmission due to the high Dk and pumping action of the hybrid design.

- Confirm no fluting or wrinkling at the skirt edge.

4. Assess Patient Comfort

- Early lens awareness is acceptable.

5. Dispense

- As long as fit and vision are acceptable, refrain from making changes at dispense.
- Patient may experience a period of adaptation to the feel and vision of the lenses.
- Recommend a scheduled increase in wear time.

Follow-Up Visit

If you are comfortable with the fit and the patient did well on dispense day, a two-week follow-up may be appropriate. However, if the patient is coming out of a GP lens, a one week follow-up visit may be necessary, since rebounding of the cornea may necessitate a lens change.

FOLLOW-UP VISIT GUIDELINES

- Have patient return having worn the lens for 4-6 hours.
- Check visual acuities and over-refract if necessary.
- Observe at lens with white light on slit lamp.
- Check for movement.
 - Lens may move with blink or with push-up test.
 - If no movement is observed, instill fluorescein and verify tear exchange.
- If patient has no complaints and eye is white and quiet, order the second lens to complete the annual supply. A lack of movement is acceptable due to tear exchange and high DK of the lens.
- If patient has complaints or you can see any corneal issues, follow the steps on the next page.



IF PATIENT IS COMPLAINING ABOUT COMFORT OR HAS CORNEAL ISSUES

- Conduct initial follow-up evaluation.
- Remove lens, instill fluorescein in the eye and check for epithelial disruption.
- Re-insert lens with fluorescein and evaluate the pattern.
 - If pattern looks ideal, review insertion again with patient. Confirm that the patient is filling the bowl completely with saline and that they are not inserting lens with too much force.
 - If a small amount of apical touch is observed (feather touch) increase the vault by 50 μ . Insert the adjusted lens with fluorescein in the flat skirt and re-evaluate.
 - If larger amount of apical touch is observed (heavy bearing), increase the vault by 100 μ and re-evaluate. Insert the adjusted lens with the flat skirt and re-evaluate.
 - If clearance is observed in the vault, then decrease the vault by 100 μ increments until touch is observed. Once touch is achieved, if feather touch, add 50 μ , if heavy touch add 100 μ .
 - Once the vault is achieved using the flat skirt, evaluate the inner landing zone for bearing. If hard bearing appears in the ILZ, steepen the skirt to allow for better clearance in the ILZ. If bearing persists, increase the vault by 50 μ .
 - If no improvement is seen and bearing still persists in the ILZ with any of these changes, then the UltraHealth design may not work for this patient. Call your Irregular Cornea Specialist or the SynergEyes Consultation Department.
- Once desired fit is obtained and patient is comfortable - order new parameters with Rx adjustment for vault change.

LENS MOVEMENT

- If the lens does not move after it has settled, verify tear exchange by instilling fluorescein in the cul-de-sac. Vertical movement in the UltraHealth lens is not necessary at the follow up visit due to the active tear pump created by the design of the hybrid lens.
- If the lens moves too much, this is a sign that the skirt may be too flat. This will most likely be uncomfortable and the patient will feel the excessive movement.

IMPRESSION RING

- An impression ring is not uncommon at the follow up visit. As long as there is no sign of epithelial disruption or other negative symptoms, the ring is acceptable.
- If there is an impression ring with epithelial disruption, then re-evaluate the fit of the skirt. If the skirt is too steep, then the lens may be dropping down on the cornea after a few hours of wear.

VISION ISSUES

- Vision is usually not an issue and can be addressed by an over-refraction and a subsequent change in power.
- Check for residual astigmatism. Conduct an over-refraction and k-readings over the lenses to confirm whether the residual astigmatism is due to lenticular cylinder or lens flexure. The UltraHealth lens does not correct for lenticular astigmatism. Lens flexure may be caused by the location of the corneal irregularity in relation to the skirt.

BUBBLES

- A bubble under the lens may cause discomfort and distorted vision. Confirm that the patient is filling the bowl of the lens completely with saline prior to insertion and that his/her head is down and parallel with the table top. Try to have the patient avoid pushing the lens onto the eye or rubbing the eye after insertion.
- If you see bubbles being sucked under the lens, this is indicative of a skirt that is too flat. Insert a lens with the same vault and a steeper skirt and confirm that the issue goes away. Sometimes if the landing area of the skirt is uneven, due to a corneal irregularity, this may result in part of the skirt lifting up and bubbles being pumped under the lens.

Check for Bubbles with Blue Light



COMFORT

- The most common issue at the follow up visit is lens discomfort which may be indicative of a tight lens or a lens that is bearing on the cornea. If patient complains that wear time is decreasing, then it may be a symptom of a lens that needs an adjustment.

Symptom	Possible Cause	Solution
Initial Lens Awareness	Lens awareness may occur when the patient initially starts to wear the lens, especially patients that are coming out of a lens that has very little movement.	This awareness should go away and wear time should increase by the follow up visit.
Central Lens Awareness or Peripheral Lens Awareness	Central lens awareness may be caused by apical touch of the GP. Peripheral lens awareness may be an awareness of the skirt.	Determine if the lens awareness is central or at the periphery. If lens awareness is central, confirm that there is apical clearance and adjust vault if necessary. If lens awareness is in the periphery, a skirt change may be necessary.
Increased discomfort and gradual decrease in wear time	Discomfort may result from apical touch that wasn't initially present due to rebounding of the cornea from previous lens.	Reinsert lens with fluorescein and reconfirm apical touch. Ideally, the lens should be approximately 100 μ above apical touch.
Increased discomfort and gradual decrease in wear time	Discomfort may result if the skirt is too steep. If the skirt is fit too steep, the lens may tighten up after the skirt settles down. If the skirt is too steep (no visible inner landing zone), the weight of the lens is no longer resting on the outer landing zone. The lens may initially feel fine, but after wear, skirt will drop and seal off the GP portion of the lens.	Flatten skirt to engage the OLZ.
Discomfort with occasional "glare"	GP has too much Vault	Re-confirm apical touch using a flat skirt. When a small amount of apical touch is observed (feather touch) increase the vault by 50 μ . If a larger amount of central touch is observed (heavy bearing), increase the vault by 100 μ .
Discomfort upon insertion or within a few hours. Lens may feel "tight"; patient experiences photophobia.	GP Bearing or ILZ bearing of skirt	Reinsert the lens with fluorescein and evaluate pattern. If you see central bearing increase vault. If light central bearing increase vault 50 μ . If heavy bearing increase vault 100 μ . If there is no central bearing, evaluate the pattern of the skirt. Check to see if there is bearing in the ILZ. If so, steepen the skirt. If you are sure that the lens is vaulted properly and the steeper skirt curve does not provide a thinning of fluorescein in the ILZ then you may have to change to a different lens design. Call your Irregular Cornea Specialist or Consultation.

Lens Insertion Tips

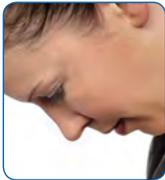
Practice insertion and removal prior to your first patient dispense.

UltraHealth lenses are in vials. The easiest way to remove them is to shake the lens over the sink into the palm of your hand. Lenses then may be stored in a flat pack for easy access.

INSERTION TIPS



- Use lens inserter to make insertion quick and easy.
- Fill the bowl of the lens with non-preserved saline before insertion.
- Add one drop of fluorescein, or use a fluorescein strip to the solution (high molecular fluorescein not required).



1. Have patient lean forward with chin tucked to their chest.



2. Have patient hold lower lid, you hold upper lid.



3. With upper and lower lid retracted, use inserter to gently place lens on the eye.

Lens Removal Tips

Make sure your patient is comfortable with removal prior to leaving the office. The following tips will help a patient successfully wear the UltraHealth lens.

REMOVAL TIPS



1. **Clean dry fingers are the key.**
Have patient look straight ahead.



2. With dry fingers, pinch bottom of soft skirt at the 5 o'clock & 7 o'clock position—similar to removing a piece of lint.



3. Lift the lens away from the eye.

Recommended Solutions

Cleaning Solutions

- Sof/Pro® and Sof/Pro2® by Lobob®
- Walgreen's Extra Strength Daily Soft Lens Cleaner
- CVS® Extra Strength Daily Cleaner for Soft Lenses
- Opti-Clean® II by Alcon®

Disinfection Systems

- ClearCare* by Alcon (Recommended)
- Biotrue by Bausch & Lomb (Recommended)
- Complete® by AMO (Approved)
- ReNu MultiPlus® by Bausch & Lomb (Approved)

Rewetting Drops

- Blink Contacts by AMO
- Blink Tears by AMO
- Refresh Contacts® by Allergan
- Refresh Optive® by Allergan

The use of a contact lens daily cleaner and digitally rubbing the lenses each day is absolutely recommended.



*In some patients, the tear chemistry may react with the peroxide to cause a permanent white ring at the junction of the rigid center and soft skirt. This ring does not affect vision or comfort.



- If patient is tearing up significantly, or is having trouble removing the lenses, training tips (finger cots) may be used to help grasp the lenses during removal.

Lens Materials

- **130 DK** rigid gas permeable center
- **84 DK** silicone hydrogel soft skirt
- Class II UV blocker: >80% of UVA and >95% of UVB radiation

Diameter

14.5mm

Skirt Curves

8.7 Flat 2, 8.4 Flat, 8.1 Medium, 7.9 Steep

Lens Powers

+10.00 to -20.00D

+10.00 to +2.50 in 0.50D steps

+2.00 to -8.00 in 0.25D steps

-8.50 to -20.00 in -0.50D steps

Vault Values

50, 100, 150, 200, 250, 300, 350, 400, 450, 500, 550

Wear & Replacement

Daily Wear. Replace at 6 months.

- Vertical movement at follow up is not mandatory due to tear exchange created by the pumping action of the soft skirt.
- If patient complains of discomfort at follow-up, remove the lens and check for corneal staining. If moderate or advanced staining is observed, then re-examine the lens fit.
- If the patient is coming out of a GP lens, it is possible that the cornea may rebound after the initial fit and a different lens vault may be necessary.
- A lens that is fit with a skirt that is too steep may look good at initial dispense, but may exhibit a tight fit at follow up. Remember, the purpose of the SiHy skirt is to center the GP, not lift the GP.
- An impression ring at follow-up is common and acceptable as long as the patient is asymptomatic and the corneal epithelium is not disrupted.
- Some patients moving from ClearKone to UltraHealth occasionally experience initial lens sensation. This awareness should go away after wearing a properly fit UltraHealth lens for a few days.