

ClearKone[®]

Restoring vision. Changing lives.[™]



FITTING GUIDE & TIPS FOR ACHIEVING SUCCESS

synergeyes[®]
see. change. enjoy vision.[™]



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Contents

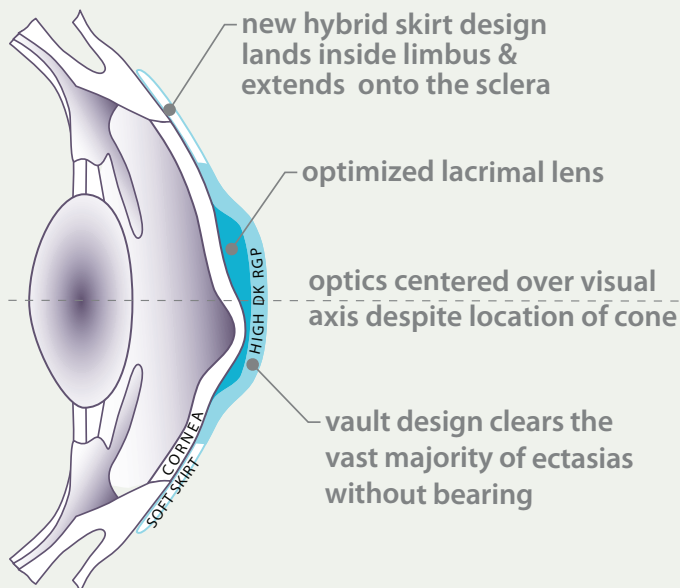
Advanced Lens Design	2
Patient Candidates	3
Design Features	3
Key Fitting Principles	4
Ideal <i>ClearKone</i> [®] Fit	5
Vault and Skirt Curvature	6
Diagnostic Set	7
Fitting Flow Chart	8-9
Bubbles	10
Proper Insertion Process	10-11
Determining Proper Vault	12-13
Determining Proper Skirt Curvature	14-15
Available Parameters	16
Contact Information	16

Advanced Lens Design

The *ClearKone*[®] patent-pending vault design and the reverse geometry landing system are optimized to clear the predominant irregularities of the keratoconic cornea, thus effectively restoring vision to a vast majority of irregular cornea patients without compromising comfort or eye health, even in the most challenging cases. The excellent centration and stability of the hybrid platform keep the optics centered over the visual axis, regardless of the location of the cone, to successfully decrease aberrations resulting in superior visual acuity.

ClearKone[®]

hybrid contact lens for keratoconus



Patient Candidates

- Oval and Nipple Keratoconus
- Central and Decentered Cones
- RK, PRK and LASIK Induced Ectasia
- Globus (depending on the specifics of the case)
- Pellucid Marginal Degeneration (depending on the specifics of the case)
- Most Irregular Corneas (depending on the specifics of the case)

Design Features

1. Exclusive vault design optimizes lacrimal lens to fit a vast majority of ectasias
2. *ClearKone*[®] design centers the optics independent of the location of the cone, decreasing aberrations, resulting in superior visual acuity
3. Design allows for much of the power to come from the lacrimal lens, which substantially lowers lens powers to further enhance optical quality
4. *ClearKone*[®] incorporates a new hybrid skirt curve design which promotes all-day tear flow and movement, providing comfortable lens wear, corneal health and simplified lens removal
5. *ClearKone*[®] utilizes a linear vault fitting system which simplifies the fitting process and minimizes chair time

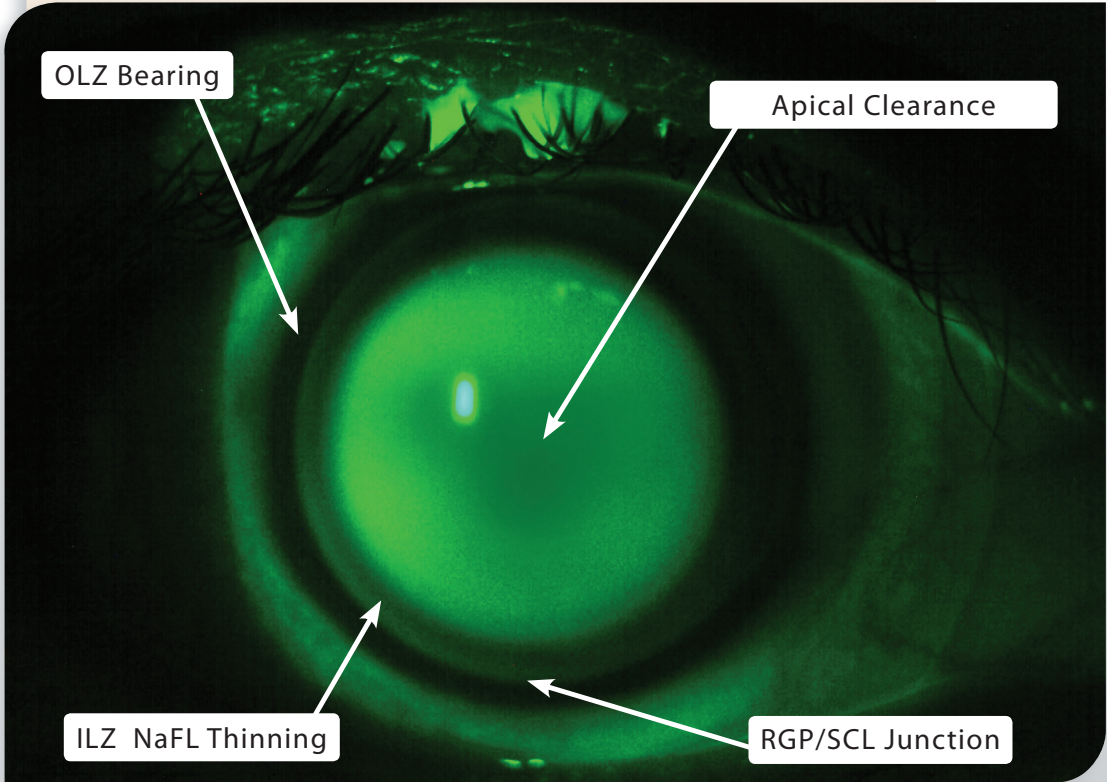
Key Fitting Principles

The fitting philosophy of the *ClearKone*® lens is based on the concept of fitting on overall sagittal depth instead of varying the base curve in relation to the irregular cornea. The fit of the *ClearKone*® depends upon the depth of the lens clearing the elevation of the cone, rather than a match in curvature. The fitting process involves first determining the minimal vault needed to clear the cone and then determining the skirt curvature that properly lands inside the limbus and extends onto the sclera.

The **vault** value describes the overall relative depth of the lens. The goal is to determine the appropriate vault that provides complete apical clearance to clear the cone.

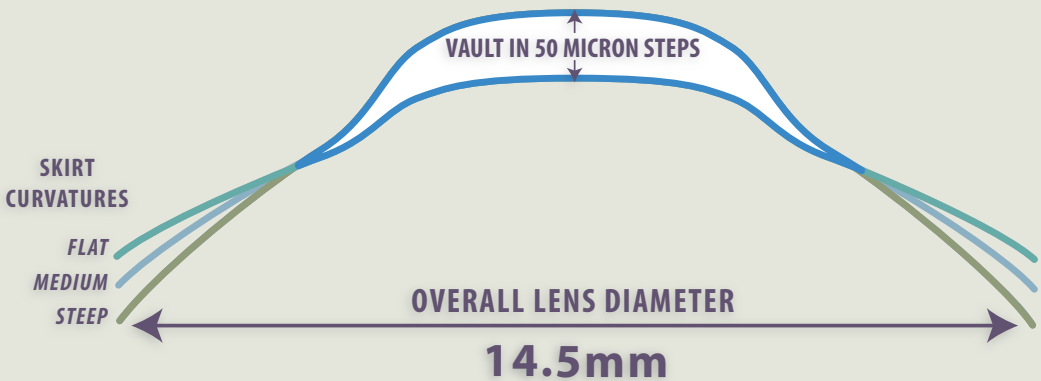
The lens lands on both the soft (defined as **Outer Landing Zone [OLZ]**) and rigid (defined as **Inner Landing Zone [ILZ]**) materials. The landing area is divided by the junction of the hybrid lens.

Ideal *ClearKone*[®] Fit



Vault and Skirt Curvature

ClearKone[®] is available in 11 different vaults of which each can be ordered in 3 different skirt curvatures, flat, medium, and steep, to properly fit a vast majority of irregular cornea patients. The fit of the vault is independent of the fit of the skirt curvature – each should be fit separately.



ClearKone[®] is available in 11 vault values. Each vault can be ordered in 3 different skirt curves.

Diagnostic Set

To enable practitioners to properly fit *ClearKone*[®], SynergEyes offers a 22 lens diagnostic set that is critical and required to achieve success with this product. **The diagnostic set contains 11 vaults ranging from 100 – 600 μ in 50 μ steps. Each vault within the diagnostic set is available in two different skirt curve options, medium and steep.** A flat skirt can be ordered for the patients for whom it may be needed. Each diagnostic lens has laser markings that indicate its lens type, vault and skirt curvature.

Linear Vault Fitting System

ClearKone[®] utilizes a linear vault fitting system, which simplifies the fitting process and minimizes chair time. The power of the diagnostic lenses is calibrated to change at the same rate as the vault value. Therefore, any two lenses within the fitting set will require the same over-refraction. Once the over-refraction of a diagnostic lens has been determined, every other lens in the set should take the same over-refraction.

Fitting Flow Chart

DETERMINE VAULT

Begin with the 250 μ vault value

If central bearing is seen:

Increase the vault in 100 μ increments, until apical clearance is achieved

Proper Vault Determined - Patient

DETERMINE SKIRT

Evaluate landing area at 3 and 9 o'clock positions with the
GOAL: On most patients, best fit landing area
is observed in ILZ area

If bearing observed under **BOTH** the ILZ and the OLZ
- Change to the STEEP skirt curve

If pooling observed under the OLZ and ILZ is bearing
- Change to the STEEP skirt curve

Proper Skirt Determined - Patient

Over-refract to determine final lens power

Value in the Medium Skirt Curve

If **central pooling** is seen:

Decrease the vault in 100 μ increments,
until bearing is observed

Then increase the vault 100 μ

It Determined

the slit beam perpendicular to the area being observed.
ing area achieved when NaFL thinning
and bearing in the OLZ.

If pooling observed under the
ILZ and OLZ is bearing
– Order the **FLAT** skirt curve

If pooling observed under
both the ILZ and OLZ
– Order the FLAT skirt curve

comfort will greatly validate final fit.

for the selected vault/skirt combination

Bubbles

There are areas within the optic zone that could result in trapped air bubbles if the lens is not inserted properly. **Because air bubbles can affect the appearance of the NaFL pattern, it is critical to eliminate them prior to evaluating the fit.**

- **Bubbles are ALWAYS representative of an insertion error – NOT a fitting error. Do not attempt to displace bubbles by decreasing vault.**
- You must remove the lens and re-insert – making certain that the bowl of the lens is filled to the TOP with solution.
- **Bubbles cannot be displaced by lens manipulation.**
- Bubbles are less likely to occur if patient maintains fixated gaze (straight to the floor) throughout the insertion process.

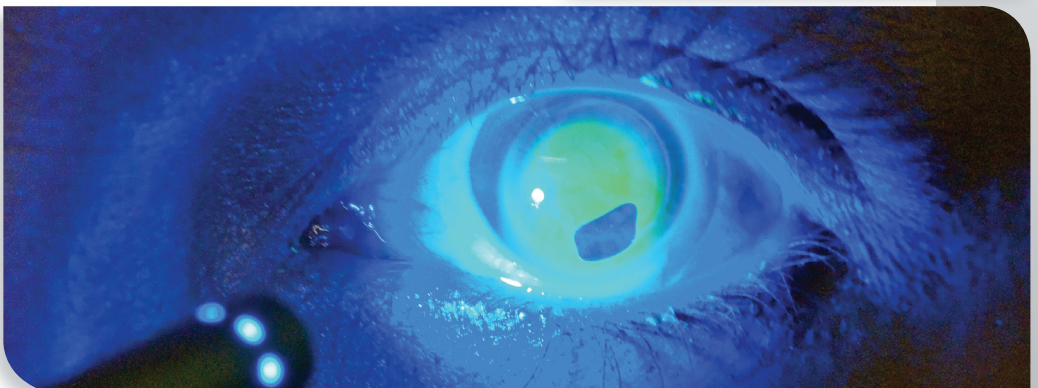
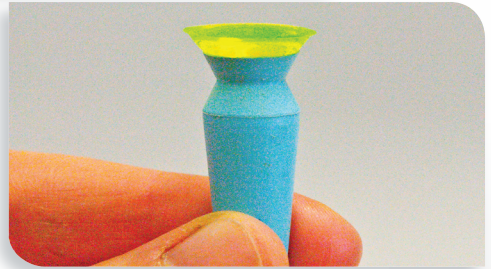
Proper Insertion Process



- High molecular-weight fluorescein (FluoreSoft®) is necessary for fit evaluation, both central (vault) and peripheral (landing zone/skirt curve).
- To increase the comfort of the fluorescein and to minimize insertion bubbles, fill the bowl of the lens with 1 drop of fluorescein and fill the remainder of the bowl completely to the top with non-preserved saline.

Proper Insertion Process *cont'd*

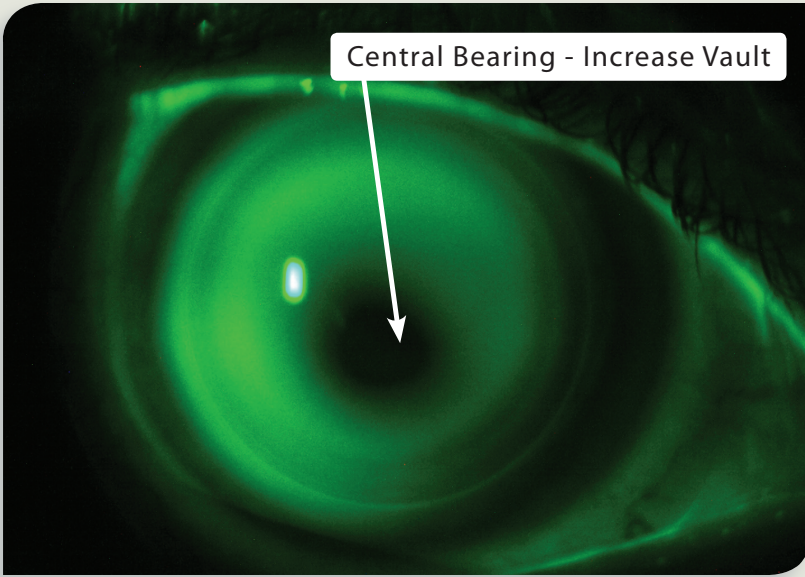
- Fill the lens while holding it horizontally on the DMV scleral cup (included in the diagnostic set) OR by stabilizing the lens between the index and middle finger.
- Have the patient lean forward and tuck their chin to chest. Nose should be perpendicular to the floor.
- Retract the upper and lower lids and elevate the lens onto the center of the cornea, displacing the saline. **Be careful not to push the lens too forcefully upon insertion.**



Check for bubbles under the lens with NaFL illuminating cobalt penlight (included in the diagnostic set).

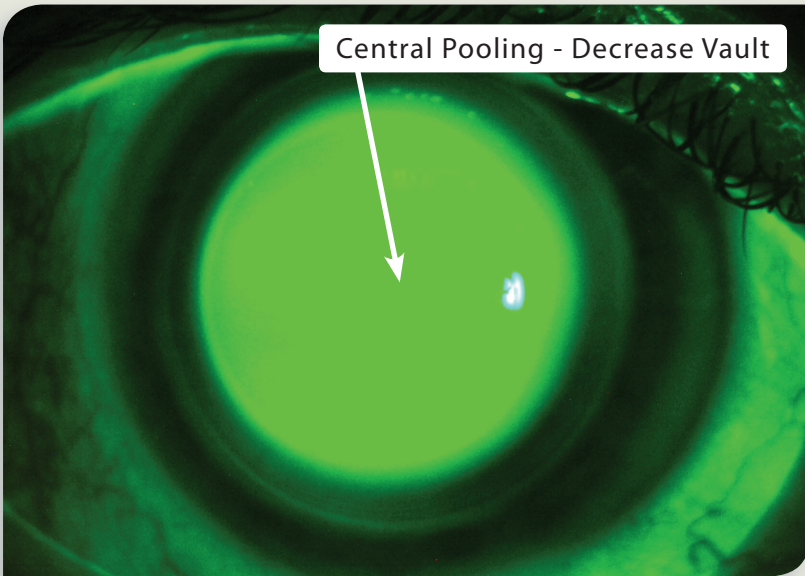
Determining Proper Vault

- It is critical to eliminate any central touch when fitting. Even the lightest touch or "feather touch" will cause patient discomfort.
- For patients who are being re-fit from RGPs, *SynergEyes*® *KC*, or *SynergEyes*® *A*, the cornea will most likely return to its natural shape once the pressure of the predicate lens is removed. You may need to re-order deeper *ClearKone*® lenses after the cornea has re-normalized.
- It is important to evaluate the fit within 3-5 minutes after insertion, because the tear flow will thin the NaFL and can give a false evaluation.
- After a few minutes of wear, the patient will tell you if you have apical touch because the lens will not be comfortable.
- Topography can be very misleading when fitting *ClearKone*®. You may not always find a correlation between K values and vault values.



Central Bearing - Increase Vault

Vault too shallow

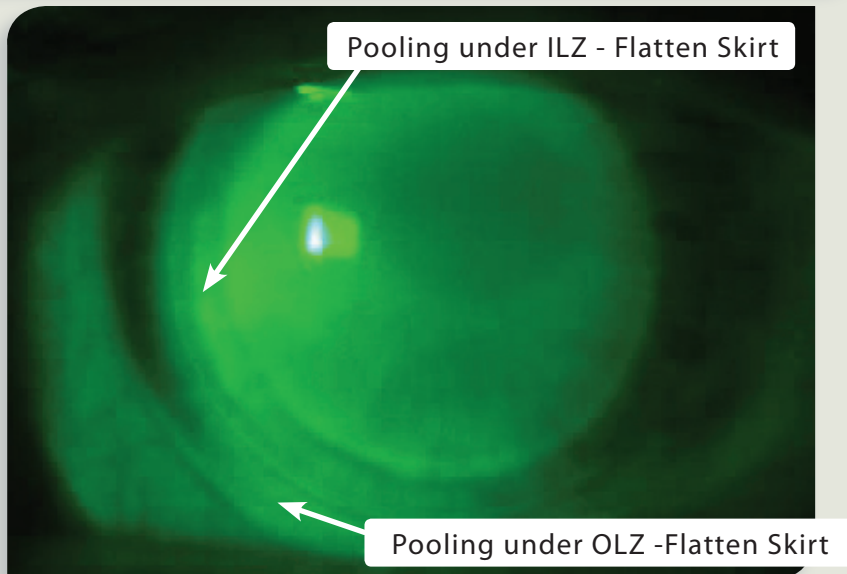


Central Pooling - Decrease Vault

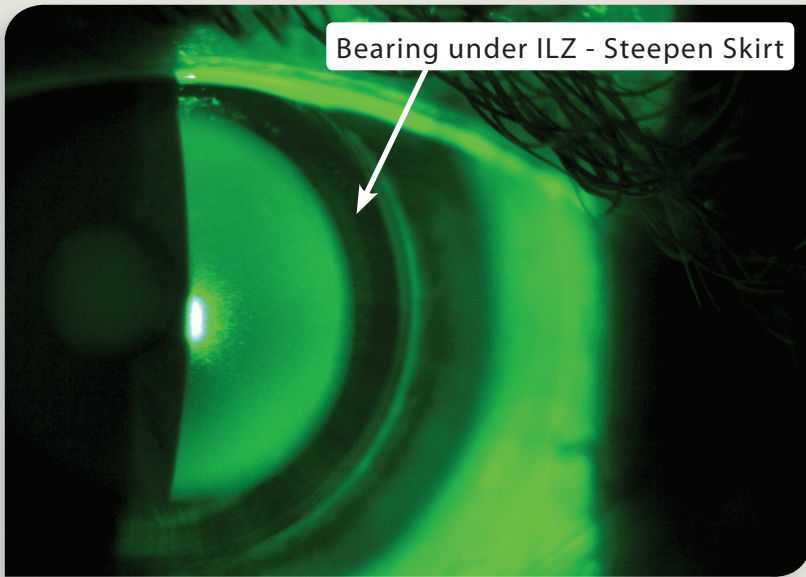
Vault too deep

Determining Proper Skirt Curvature

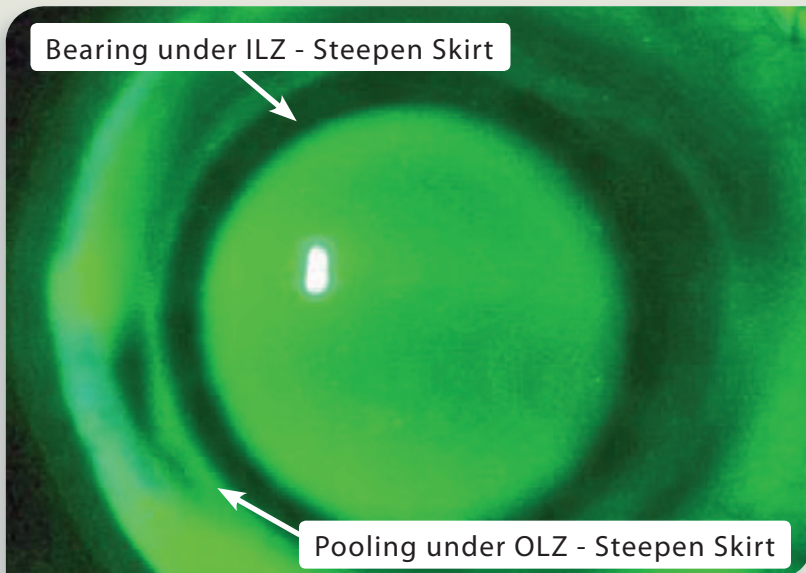
- Evaluate skirt curve only after the proper vault has been determined and is on the eye.
- It is critical to use a Wratten filter (provided in the diagnostic set) to enhance the NaFL contrast. This makes fine tuning the skirt curve much easier and will save chair time.
- The ideal fit will exhibit NaFL thinning in the Inner Landing Zone (ILZ) and bearing in the Outer Landing Zone (OLZ).
- The lens will exhibit movement very similar to a standard soft lens.
- The patient's comfort/discomfort comparison will confirm whether you have the correct/incorrect skirt curve.



Skirt curve is too steep

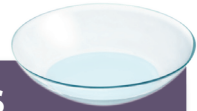


Skirt Curve is too flat



Skirt Curve is too flat

ClearKone® Available Parameters



Material	Paflucocon D center (hemiberfilcon A skirt)
Dk	100
Water Content	27% (soft skirt)
Diameter	14.5mm
Vault	100 – 600 in 50 μ steps
Skirt Curvature	Steep, Medium, Flat
Sphere Power	+2.00 to -8.00 in 0.25D steps -8.50 to -20.00 in 0.50D steps +2.50 to +5.00 in 0.50D steps
Wear Indications	Daily Wear
Recommended Replacement	6 Months
Lens Care	Hydrogen Peroxide
Delivery	1-2 Weeks



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