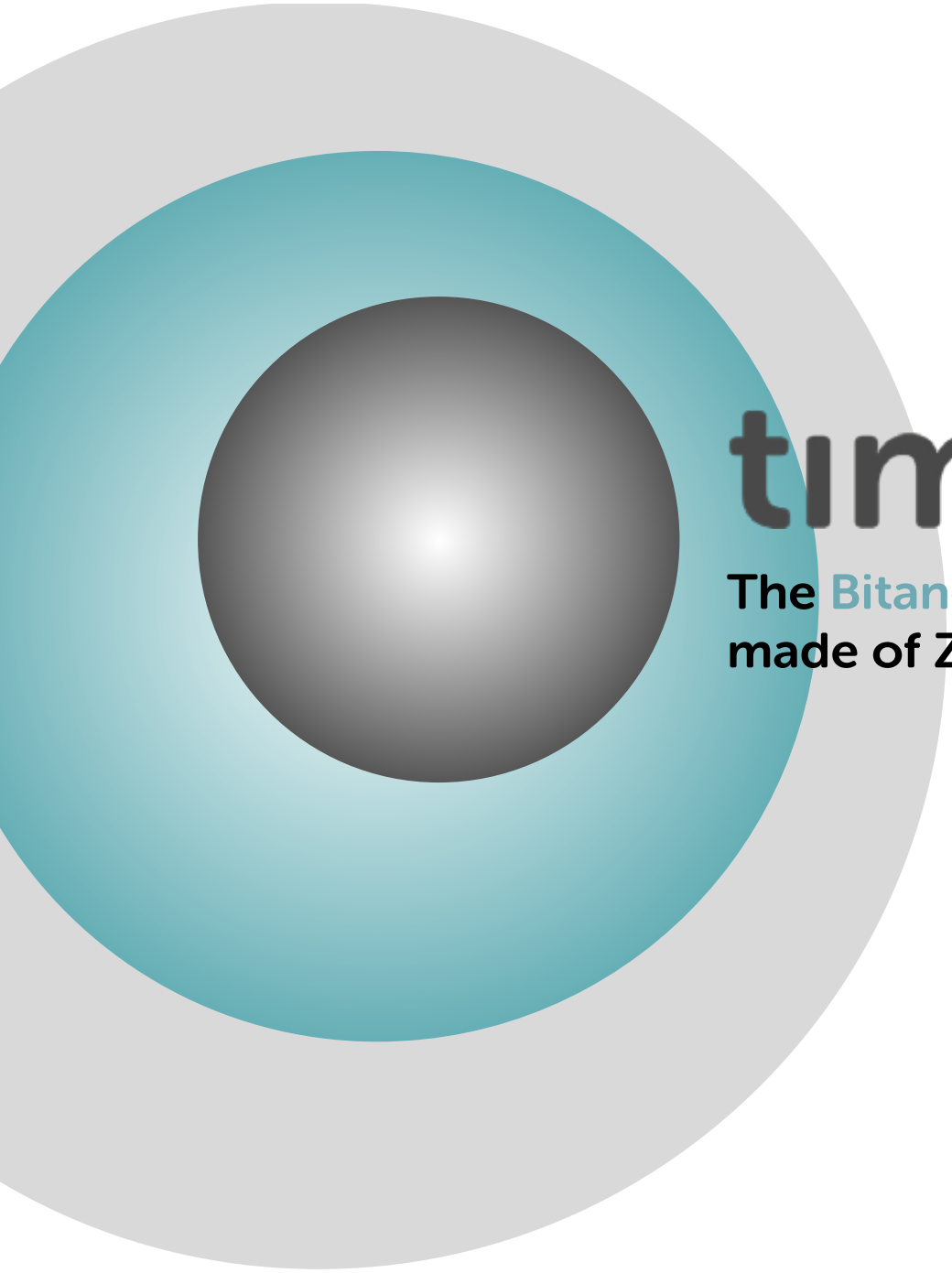
Menicon



# timeXL

The Bitangential scleral lens made of Z material

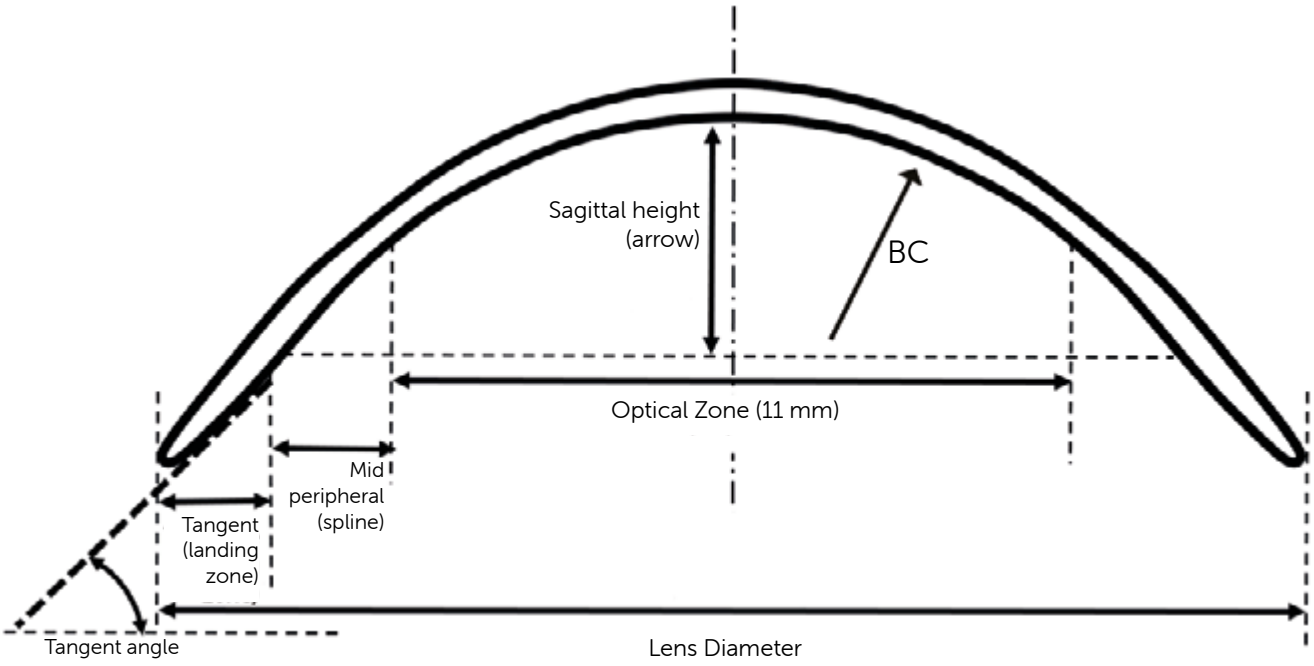
timeXL
The Bitangential scleral lens made of Z material

# Introduction

Menicon brings to you Time XL, the first scleral lens with a **bitangential** periphery. Time XL is designed to fit the anatomy of human eyes. Typically the shape of the limbus and the sclera is linear and not curved[1] ; in 95% of cases the surface of sclera is toric and not spherical. The bitangential design of TimeXL optimizes the pressure distribution of the lens on the conjunctiva, therefore the patient's tolerance is higher and the daily wearing time is longer.[2,3]

# Design

Two important innovations are combined for maximum comfort and optimum performance of TimeXL. The periphery is produced linearly and torically (bitangential). The toric periphery of the lens can be precisely controlled in both flat and steep meridians and the sclera is outlined for a simple fit and stability. This allows the cornea to be optimally bridged.[3] The toricity is limited to just the periphery of the lens: the back surface geometry of the optical zone is spherical. If necessary, the front of the TimeXL's optical zone can be fitted with a corrective cylinder.




1. Van der Worp E, Graf T, Caroline PJ. Exploring beyond the corneal borders. Contact Lens Spectrum 2010; 25 (6):26–32.
2. Van der Worp E. A Guide to Scleral Lens Fitting (monography online). Pacific University Common Knowledge: Books and Monographs. 2010. Available at: http://commons.pacificu.edu/cgi/viewcontent.cgi?article=1003&context=mono. Consulted on 13 June 2013.
3. Visser, Medical Applications and Outcomes of Bi-tangential Scleral Lenses. Optometry and Vision Science VOL. 90. No.10, October 2013.

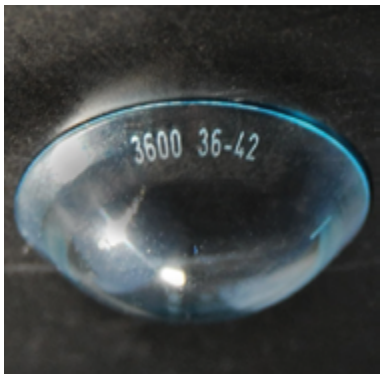
timeXL
The Bitangential scleral lens made of Z material

# Fitting philosophy

## Objective

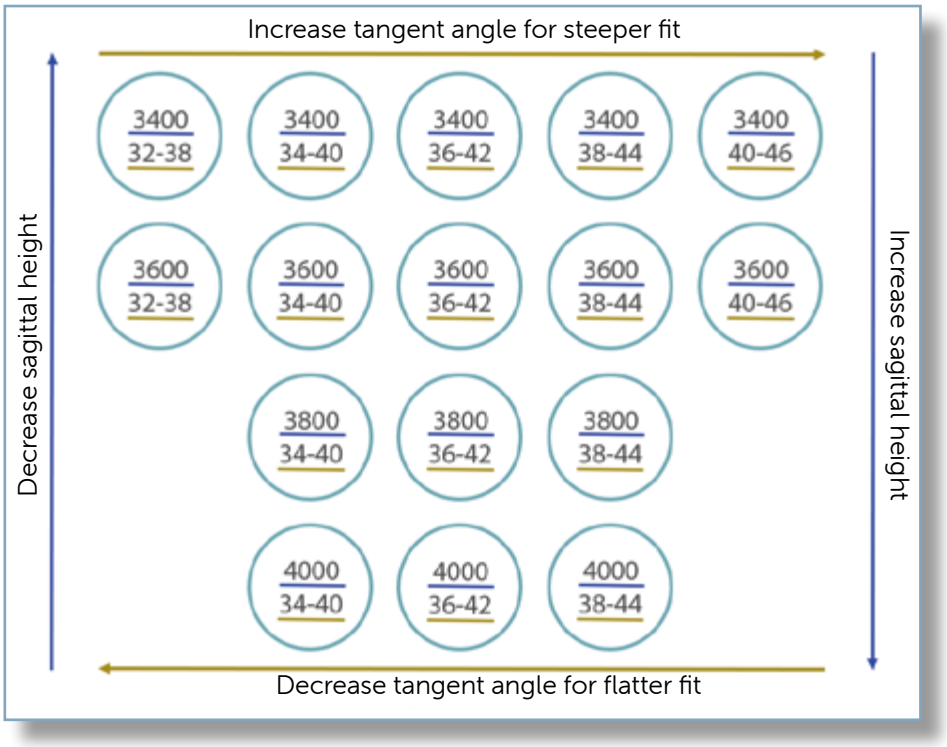
The TimeXL is designed to fully bridge the cornea and the limbus and to rest on the sclera. An optimal fitting is achieved when following characters are observed after 30 minutes of wearing:

- Pressure is distributed equally, no visible blanching
- Central corneal clearance of approximately 200 µm
- Limbal clearance of approximately 100 µm, with a minimum of 50 µm




## Setup of diagnostic set

TimeXL diagnostic set has 16 diagnostic lenses of BC 8.40 mm, diameter 16.00 mm and power of 0. All lenses feature a toric periphery and the toricity is expressed in tangent angles. The toricity difference between flat meridian and steep meridian is of 6° for all diagnostic lenses. 4 different sagittal heights (in µm) are available: 3400, 3600, 3800 and 4000.

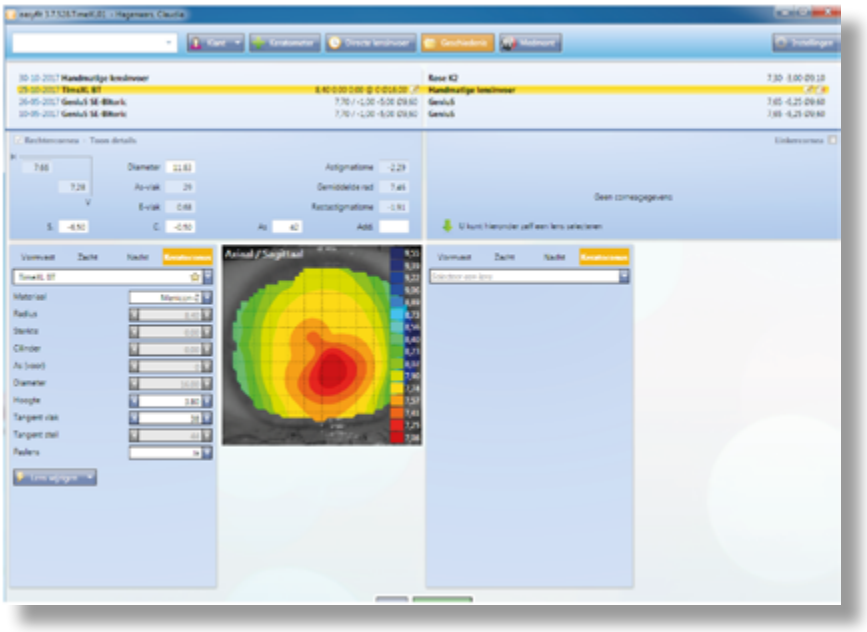



**Example : 3600 36-42**
3600 = sagittal height
36° = tangent of flat meridian
42° = tangent of steep meridian

# Choose a diagnostic lens

## 1. With easyfit

Import the topography into easyfit. The program estimates sagittal height and tangent and recommends the diagnostic lens accordingly.



## 2. Empirically, without easyfit

The most common sagittal height is **3600** µm. Like other scleral lenses, sagittal height varies from eye to eye. A patient with keratoconous may have a deeper corneal profile and require a more significant increase in sagittal height when compared to a normal eye. For patients who have undergone a corneal transplant or refraction operation, a lower height may be required. The corneal scleral profile can be assessed eye by eye. If uncertain or inexperienced, start with a lens of sagittal height 3600 and tangents 36/42 for keratoconus and transplant, and a sagittal height 3400 tangents 36/42 for regular cornea.

| Cornea profil | Sagittal height | % of lens used |
|---|---|---|
| Shallow | 3000 - 3300 µm | 10% |
| Normal | 3400 - 3800 µm | 75% |
| Deep | 3900 - 4100 µm | 10% |
| Very deep | 4200 - 4400 µm | 5% |

| Scleral profil | Flat meridian | % of lens used |
|---|---|---|
| Flat | 28-32 | 8% |
| Normal | 34-38 | 80% |
| Steep | 40-50 | 12% |

# Assess the fitting

## Diameter

The diameter of diagnostic lens is 16.0 mm, it suits most patients of average to small cornea. The lens must cover about 1.5 to 2.5 mm larger than limbus, or 3.0 to 5.0 mm larger than horizontal visible iris diameter (HVID). The lens is available of diameter from 14.0 to 17.5 mm in 0.5 mm steps. If a patient needs a diameter other than 16.0 mm, enter the diameter needed at the moment of ordering. Take into account that the diameter is no longer 16.0 mm in further assessment for this patient.

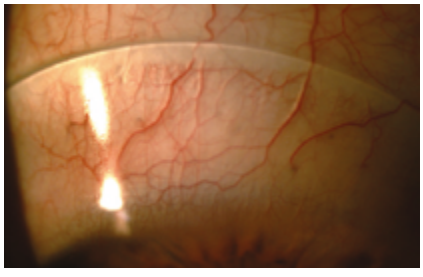
## Tangents

First, assess the lens in primary gaze. Keep the eyelids at a distance to assess the periphery. Then ask the patient to look in all directions to assess the lens movement and potential bonding. Extreme viewing direction may lead to incorrect result. Check the tangent against the outline with the sclera by looking for blanching or edge lift. Reduce the tangent angle (flatter) to the corresponding meridian in case of blanching. Increase the tangent angle (steeper) to the corresponding meridian in the event of too much edge lift.

### Fitting and tangents

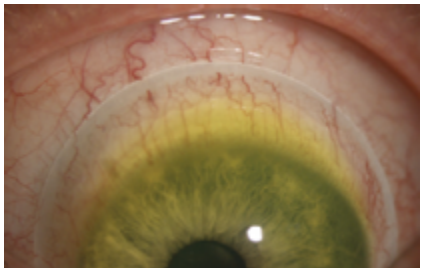
Tight tangent (too steep) → reduce the angle (flatten)
Loose tangent (too flat) → increase the angle (steepen)

**In case of tangent too steep → decrease angle (flatten)**



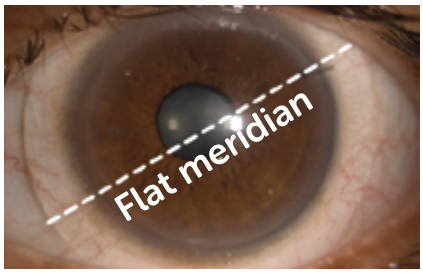
Lens edge is too steep. Blanching of the capillaries. Decrease the tangent by 2°.

Lens too tight. Blanching (the capillaries close). Decrease the tangent by 4°.

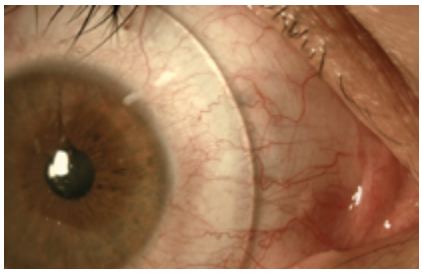


Extreme edge tightness around the entire lens. Decrease the tangent by 6°.

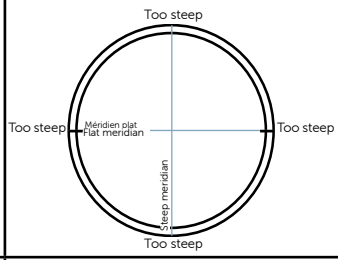
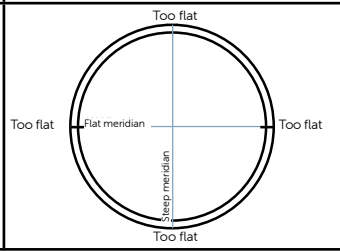
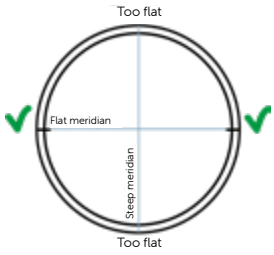
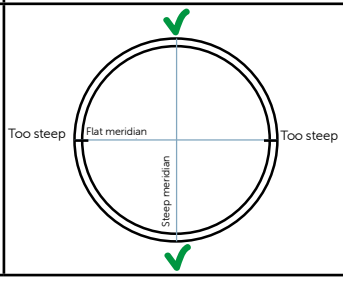
## In case of tangent too flat → increase angle (steepen)




Excessive edge lift on the flat meridian. Increase the tangent by 2° on the flat meridian.



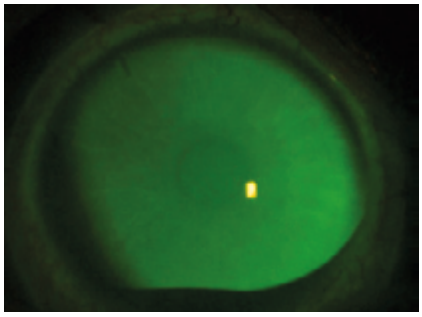
Excessive edge lift on both meridians. Increase the tangent in both meridians.

| Observation | | Solution |
|---|---|---|
| **Blanching**:<br>The lens is too steep on both meridians (too tight). |  | Decrease the tangent on the flat meridian by 4° and decrease the tangent on the steep meridian by 4°.<br>**Example** :<br>On the flat meridian: from 36° to 32°.<br>On the steep meridian: from 42° to 38°. |
| **Edge lift**:<br>The lens is too flat on both meridians(too loose). |  | Increase the tangents by 4° on both meridians.<br>**Example** :<br>On the flat meridian: from 38° to 42°.<br>On the steep meridian: from 44° to 48°. |
| **Edge lift:**<br>The lens is too flat (too loose) on the steep meridian and OK on the flat meridian. |  | Increase the tangent by 4° (steepen) ONLY on steep meridian. Do not change tangent on flat meridian.<br>**Example :**<br>On the flat meridian: tangent remains 36°.<br>On the steep meridian: from 42° to 46°. |
| **Blanching** :<br>The lens is too steep (too tight) on the flat meridian and OK on the steep meridian. |  | Increase the tangent by 4° (steepen) ONLY on steep meridian. Do not change tangent on flat meridian.<br>**Example :**<br>On the flat meridian: from 38° to 34 °.<br>On the steep meridian: tangent remains 44°. |

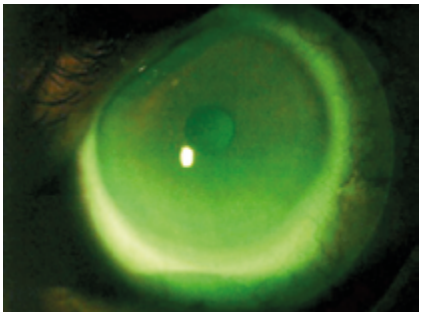
# Assessing limbal clearance

Use fluorescein and a yellow filter, as shown in the photos below. White light or an OCT can also be used. It is important that the lens does not make contact with the limbus. The ideal limbal clearance is around 100 µm, small variation is acceptable. When the tangent and the sagittal height are correct, the limbal clearance can be modified by changing the base curve or diameter. In case of pressure or clearance < 50 µm, re-assess the landing zone. A smaller limbal clearance will be observed if the tangent is flat. Increasing tangent should lead to ideal limbal clearance.

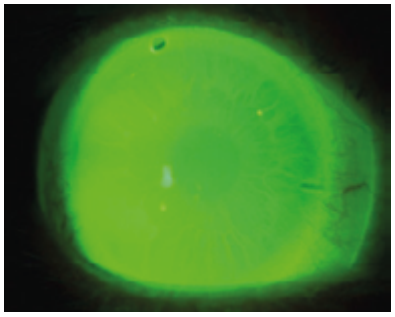
**Check the landing zone before you change the base curve. Increase the tangent by 2° in the edge bends upward.**



Pressure on the limbal area.
Flatten BC or increase Ø.



Too much fluo on limbus.
Steepen BC or decrease Ø.



Ideal limbal clearance.
Do not change BC or Ø.

## TIPS

If BC is changed, the power should be changed too.

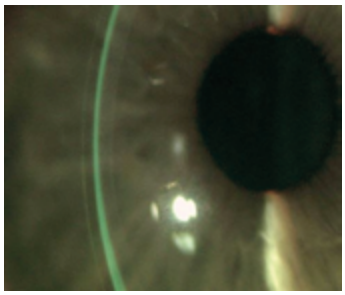
# Assessing central clearance

Assess the clearance at the highest point of the cornea using an optical section with fluorescein and white light or an OCT of the anterior segment.
The ideal central clearance is approximately 200 µm. The thickness of diagnostic lens is 350 µm.The central clearance can be changed by increasing or decreasing the sagittal height of the lens. Increase the sagittal height in case of too little central clearance.

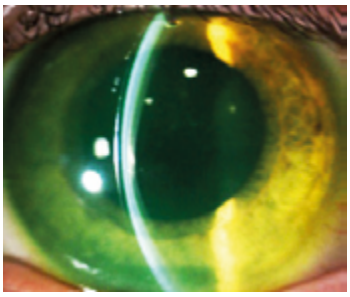
## TIPS

The central clearance can be estimated by comparing the thickness of the lens (350 µm at 0 dpt) with the tear reservoir below the lens: move a small amount of light using a slit lamp from limbus to limbus at an angle of 45°. If the clearance is too high, it is more difficult to insert the lenses without air bubbles. If a patient tends to dirty the lenses, a lower sagittal height must be selected. Greater sagittal height may be necessary for eyes that are sensitive to progressive ectasia.

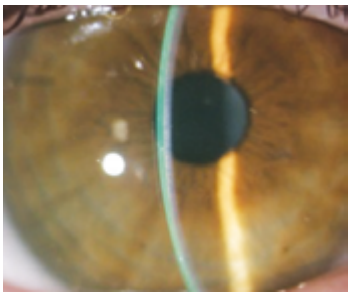
Too little clearance



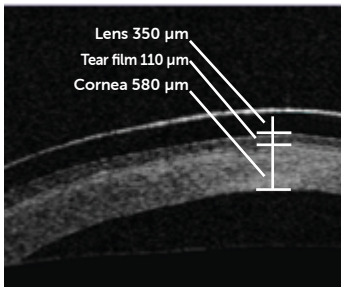
Too much clearance



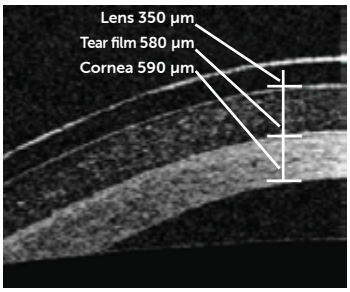
Ideal clearance



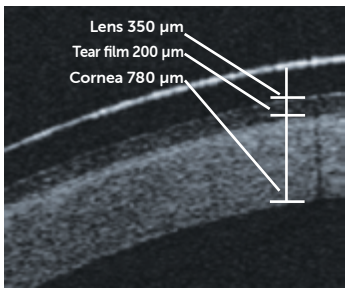
Increase sagittal height




Decrease sagittal height




Do not change height

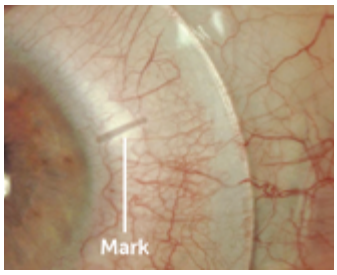


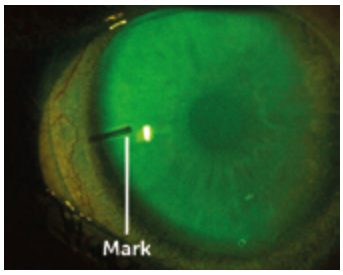

### TIPS

When one or both of the tangent angles are changed, there will be an effect on the distribution of pressure under the lens. It will also have consequences for the central clearance.

## Determining lens power

Conduct an over refraction test after the eye has adjusted to the optimum diagnostic lens. The power of the diagnostic lens is 0 dpt. The TimeXL is a non-rotational symmetrical lens that aligns with the flat meridian on the marks for cylinder availability on any given axis.




### TIPS

All diagnostic lenses and toric lenses have marks. They align the flat meridian.

Determine the position of the marks who should be aligned with the flat meridian. If the lens has the correct shape, the marks will be stable and maintain their position. Make sure to note where the marks of diagnostic lens are and order a lens accordingly with the cylinder axis to compensate the rotation. Use the over refraction feature of easyfit.

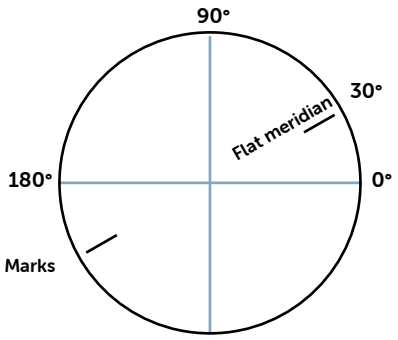
Without easyfit: Determine cylinder axis according to over refraction and mark position (with respect to the meridian axis 0°-180°).

| | | |
|---|---|---|
| X° conter-clockwise | → | order axis – X° |
| X° clockwise | → | order axis + X° |

**Example :**
Marker stabilises at 30°

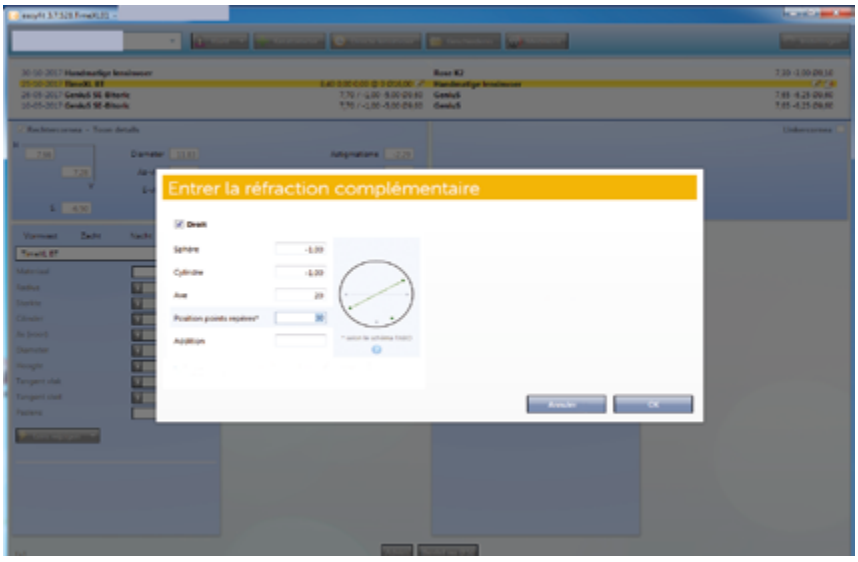
To compensate the rotation :

- Mark at 30°
- Over refraction : -1.00 (-1.00)140°
- 140°-30°=110°
- Order : -1.00 (-1.00)110°




**TIPS**

Easyfit can also determine the lens by using axis of marks and axis of over refraction.



## Problem shooting

| Observation | Solution |
|---|---|
| Steep fit:<br>blanching, compression on either flat or steep meridian | Mild : decrease the tangent on the concerned meridian by 2° (60 µm)<br>Moderate : decrease the tangent by 4° (120 µm)<br>Note : by changing a tangent, the tangent on the opposite side of the lens is also changed in the trial lens. |
| Flat fit:<br>too much edge lift (too much slceral standoff ), or too mobile | Mild : increase the tangent on the concerned meridian by 2° (60 µm)<br>Moderate : increase the tangent on the concerned meridian by 4° (120 µm)<br>Note : by changing a tangent, the tangent on the opposite side of the lens is also changed in the trial lens. |
| Too much mobility | Increase the diameter if tangents are correct. |
| Too much central clearance | Decrease the sagittal height to reach 200-250 µm after at least 30 min of wearing. |
| Too little central clearance | Increase the sagittal height to reach 200-250 µm after at least 30 min of wearing. |
| Too little or too much limbal clearance | Make sure that tangents are correct. Too low limbal clearance : increase BC; too high limbal clearance : decrease BC. |
| Cylinder over refraction | Determine the position of marks, order a front toric lens. |
| Visual fluctuations | Check the quality of the surface (for wettability and deposits).<br>Decrease the sagittal height, increase the diameter, check the lens stability. |
| Lens surface deposits | Use suitable cleaning solutions (MENICARE PURE & PROGENT). Check and treat ocular causes (GPC, MGD). Replace the material if the cleaning system is not effective. |
| Blurry vision | Conduct an over refraction test to identify any remaining astigmatism. Order a front toric lens. Record the lens stability in degrees during follow-up visits in order to keep track of the lens stability over time. |
| Deposits in tear | Remove the lens, clean and rinse it if vision is blurry. Improve the tangent in order to prevent deposit under the lens. Check and treat ocular causes (GPC, MGD). Choose proper solution. Rinse the eye with saline or another solution before inserting lenses. Decrease the sagittal height. |
| Inferior decentering | Light decentering is acceptable. First, check the vertical scleral fit and the tangent. Next, increase the diameter. |
| Air bubbles under the lens | Insert again the lens to remove “insertion bubbles”. Constant central air bubbles may signify excessive sagittal lens height that should be decreased. Constant air bubbles in the limbal zone may signify a BC that’s too flat and should be steepened. The appearance of air bubbles after proper placement may signify a tangent that is too flat and should be increased. |
| Discomfort due to the lens | The first lens should be felt, but should not feel uncomfortable. Check edge lift. Increase the tangent on the meridian concerned. Check central clearance, and increase it if it’s insuffisant. |

timeXL
The Bitangential scleral lens made of Z material

# Instruction for use of diagnostic set

**General information**

- Always wash hands before handling diagnostic set
- Always use a lint-free cloth when cleaning the lenses.

**Before insertion**

- Make sure the lens is not damaged.
- Check the code engraved on the lens correspond with the label.
- Clean the lens with Spray & Clean then with MENICARE PURE
- Rinse the lens with preservative-free saline solution.
- Fill the lens fully with preservative-free saline solution and place the lens onto the eye.

**After removal**

- Clean the lens with MeniLab during 5 minutes.
- Then rinse the lens with perservative-free saline solution
- Dry the lens and put it back in the lens case if it needs dry conservation .
- Or conserve the lens in MENICARE PURE


# Set up of diagnostic set

| | | | | |
|---|---|---|---|---|
| **3400** 32-38 | **3400** 34-40 | **3400** 36-42 | **3400** 38-44 | **3400** 40-46 |
| **3600** 32-38 | **3600** 34-40 | **3600** 36-42 | **3600** 38-44 | **3600** 40-46 |
| | **3800** 34-40 | **3800** 36-42 | **3800** 38-44 | |
| | **4000** 34-40 | **4000** 36-42 | **4000** 38-44 | |

**Example : 3600 32-38**
3600 : sagittal height
32° : tangent of flat meridian
38° : tangent of steep meridian

| | |
|---|---|
| BC | 8.4 mm |
| Diameter | 16.0 mm |
| Power | Plano |
| Material | Dk 125 (blue) |
| Marking | Marks on the flat meridian |
| Length of markers | 1.0 mm and 1.5 mm near edge |
| Graving | Code / Material / N° of order |

timeXL
The Bitangential scleral lens made of Z material

# Parameters

| | |
|---|---|
| **Sagittal height** | 3000 µm to 4600 µm per 100µm |
| **Tangents of flat meridian to steep meridian** | Both meridians are available from 28° to 50° per 2° |
| **Base curve** | 7.40 mm tp 9.20 mm in per 0.20 mm |
| **Diameter** | 14.00 mm to 17.50 mm per 0.50 mm |
| **Power** | -25.00 to +25.00 D per 0.25 D |
| **Material*** | Menicon Z - Dk 163 x $10^{-11}$ (ISO) |
| **Handling tint** | Clear |
| **Wearing type** | Daily wear |
| **Replacement recommended** | Yearly |

*Available in Dk 125

| Parameters of TimeXL BT (front toric lenses) : | |
|---|---|
| **Axes** | **Cylinder** |
| From 0° to 180° per 1° | -0.75 D to -3.00 D per 0.25 D |


**Technical Assistance**
+33 (0) 1 85 73 13 12
atechnique@menicon.fr

**Campus Menicon**
campus@menicon.fr
www.campusmenicon.fr

**Customer Service**
+33 (0)1 85 73 13 11
serviceclients@menicon.fr


TimeXL and TimeXL BT contact lenses are class IIa medical device certified by CE 0344.
Read instructions for use.

Menicon

www.e-menicon.fr www.menicon.com www.campusmenicon.fr