

Instructions for use Rodenstock MyCon lenses For opticians

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Instructions for use Rodenstock MyCon lenses

For opticians

When selling medical devices, the fitter, hereinafter referred to as optician, is obliged to inform the end user, hereinafter referred to as spectacle wearer, about restrictions of use - preferably in writing. Convince your customers with your professional competence by also pointing out relevant usage restrictions during your individual and personal consultation.

You can find important information about Rodenstock lenses at any time at <https://www.rodenstock.de/de/de/instructions-for-use.html>.

1 Intended use

1.1 Intended use & target group

- MyCon lenses are spectacle lenses for children and adolescents from 6 to 14 years of age. They are used to correct short-sightedness (myopia) and/or to prevent myopia. Correction in combination with astigmatism as well as eye position errors is possible.
- MyCon lenses are designed for permanent use in spectacles.
- MyCon lenses are used for distance correction. Since children and adolescents usually have a sufficiently large accommodation capacity, they can see sharply at all distances up to near with MyCon glasses for distance by using their accommodation.

1.2 Design of MyCon lenses

- 1 Central visual area**
Sharp vision in the central distance area.

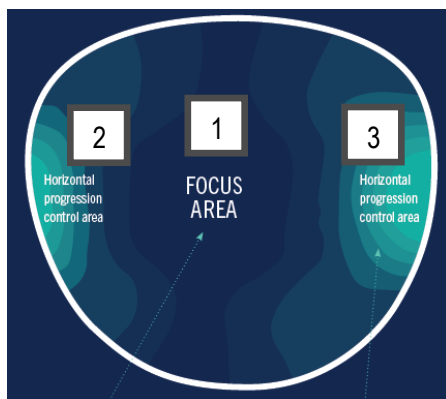


Figure 1: Schematic structure of a MyCon lens

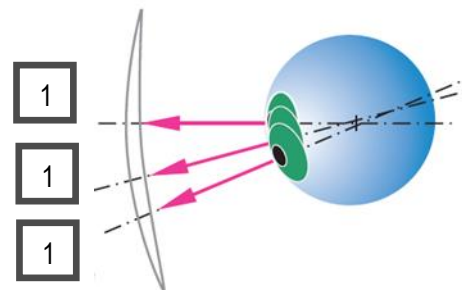


Figure 2: Vertical gaze deflection when looking through a MyCon lens

- 2 Nasal lens area with peripheral defocusing**
The defocus induced in the spectacle lens in the horizontal meridian is asymmetrical on the nasal and temporal sides: the nasal defocus is approx. 2.00 D.

- 3 Temporal lens area with peripheral defocusing**
The defocus on the temporal side is greater and reaches a value of about 2.50 D.

1.3 Further information

- The basis for the calculation of the MyCon lenses is the distance refraction.
- Normal single vision lenses correct myopia and provide central sharp vision. However, they are not designed to control the growth of the eye or the progression of myopia. They produce light in the periphery of the retina that theoretically strikes behind the retina¹, causing peripheral hyperopia². Some eyes try to adapt to the growth stimulus caused by peripheral blurring and grow more than desired, causing myopia to progress.

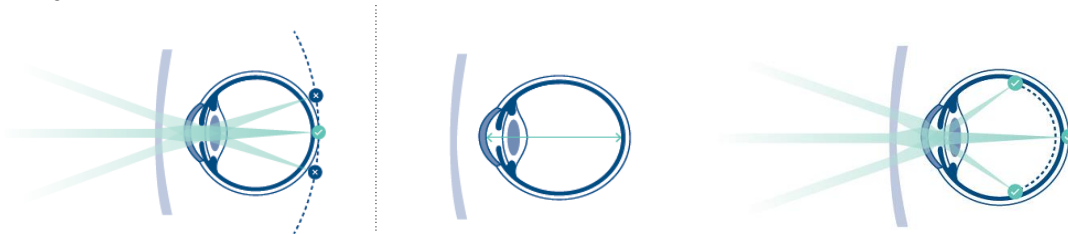


Figure 3: Vision with conventional single vision lenses (left). Peripheral blurring can trigger a growth stimulus to which some eyes try to adapt by growing longer (centre). With MyCon lenses, the light is refracted in the periphery of the lens so that it hits in front of the retina, which slows down eye growth (right).

- During the development of the MyCon lenses, various studies were consulted, which led to the following conclusions:
 - There is a link between prolonged near work and the development of myopia.^{3, 4, 5, 6}
 - Peripheral refraction and eye length vary in different parts of the retina.^{7, 8, 9, 10, 11}
 - Differences in the asymmetry of the peripheral refraction and the corresponding peripheral eye shape were demonstrated for different refraction groups as well as progressive and non-progressive myopes.^{12, 13, 14}
 - The hypothesis that the risk of developing myopia is greater when peripheral focus is behind the retina both when looking far^{8, 10} and near suggests the idea to "start early with a treatment to reduce or completely avoid myopia, maybe by introducing peripheral myopia."¹⁵

This is why MyCon lenses offer an asymmetrical distribution of optical power to favourably influence peripheral focus and thus slow down myopia progression.

- Efficiency and benefits: An independent 5-year clinical study on 7-14 year old Caucasian children has shown that myopia management lenses - comparable to the principle of the MyCon lens - can effectively reduce the progression of myopia by up to 40%. In addition, the axial length of the eye could be reduced by up to 56% after 2 years and by up to 35% after 4 to 5 years.¹⁶
The results of the eye length measurements show an efficacy in slowing myopia progression of up to 56% after 2 years.
The reduction in myopia progression is still present after 4 to 5 years with spectacle lenses based on the MyCon principle. The effect is about 35 % for eye length and 40 % in terms of refraction.
- The asymmetrical distribution of the horizontal defocus optimises the effect and reduces the areas of blurred vision.
- It is recommended that regular follow-up appointments are made to check the fit of the spectacles, refraction data and progression of myopia.
- Myopia management - optional recommendations:
A comprehensive assessment of the child's eye health and visual habits is recommended at the first visit to identify risk factors for myopia.

Anamnesis

It is advised to take the patient's anamnesis. This information must be recorded in an orderly manner, having regard to the following fundamental details:

- Patient's full name and surname
- Age
- Gender
- Ethnicity
- Systemic diseases
- Family history (parental ametropia, glaucoma, maculopathies, etc.)

History

- Age of onset of ametropia (if applicable)
- Optical correction used (if applicable)
- Date of last check-up

Lifestyle

- Time spent outside
- Time spent inside / with near distance tasks

Testing

Comprehensive eye exam

Rodenstock recommends carrying out a comprehensive eye exam during the first visit, including:

- Subjective refraction (with cycloplegia if possible)
- Measuring monocular and binocular visual acuity with and without correction.

Axial length (optional)

- The measurement of axial length is becoming a higher priority for myopia management, thanks to the objective and highly accurate data it provides.
- (Not mandatory for fitting MyCon! Only for further tracking of the axial length!)

Ocular health examination

The optician should recommend children with refractive errors for regular visits to the eye care practitioner (ophthalmologist, optometrist) for checking ocular health in general.

- MyCon lenses meet the criteria for roadworthiness prescribed by EN ISO 14889 and 8980-3:2013.
- The satisfaction guarantee for MyCon lenses is only valid for the described intended use and with proper application.

Sources

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2 Restrictions of use & foreseeable misuse

- MyCon lenses are specifically designed to slow the progression of myopia in children. Nevertheless, despite the studies that have been carried out, it is not possible to guarantee maximum slowing of myopia, which is partly due to the influence of genetic and environmental factors.
- According to the International Myopia Institute (IMI) guidelines, the best practice for myopia management includes fully correction of myopic refractive errors, education on and treatment of risk factors, as well as visual health.
- MyCon lenses offer the spectacle wearer large visual ranges. However, due to the peripheral progressive and asymmetrical defocusing in the horizontal meridian, there may be smaller usable visual areas compared to conventional single vision lenses.
- MyCon lenses are not recommended for highly curved prescription frames with severely tilted lenses.
- MyCon tinted lenses are intended for use in very bright light and outdoors. Indoor use of tinted lenses to reduce the light entering the eyes should be avoided because it is known that the strength and composition of natural light has a preventive effect on the development of myopia.
- The points mentioned for restrictions of use and foreseeable misuse are only examples and do not claim to be complete. Reference is made to the contents of the chapter "Intended use" and "Correct application".

3 Correct use

- In order to fully exploit the optical performance of the MyCon lenses and to ensure correct centring of the lenses in the child's face, an anatomical fit of the spectacle frame to the face of the spectacle wearer is absolutely essential.
- The spectacle frame should at least meet the following criteria regarding size and centring:

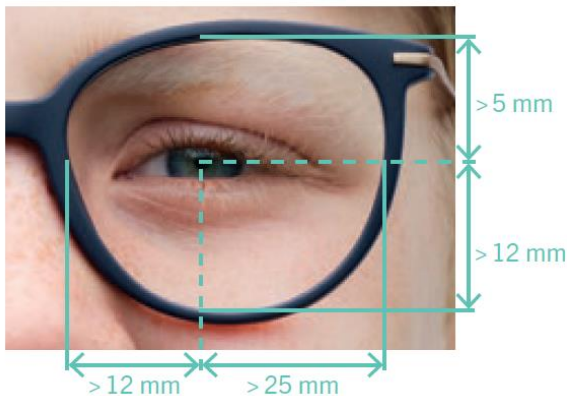


Figure 4: Recommended minimum mounting dimensions and centring point position

- The corneal vertex distance (CVD) should not exceed 14 mm.
- The fitted spectacle frame should not be changed afterwards by the optician or spectacle wearer.
- MyCon lenses are like all spherical and aspherical Standard single vision lenses to be centred following the eye's centre of rotation requirement, e.g. that the centring point of the lens coincides in vertical plane of the frame with the pupil centres of the spectacle wearer in zero gaze direction.



Figure 5: Head posture during fitting according to eye's centre of rotation requirement

- The lenses must be fitted according to the given centring specifications and the resulting spectacles must correspond to the transmitted order parameters so that the respective calculations are optimally effective.
- MyCon lenses are calculated like all spherical and aspherical Standard single vision lenses which are fitted according to the eye's centre of rotation requirement.
- MyCon lenses are checked for tolerance in the reference point in accordance with ISO 8980-1 before delivery to the optician. If the measured values of the lens at the distance reference point correspond to the order values on the lens bag, taking into account the tolerance, the MyCon lens is fully corrective in the situation of use.
- With MyCon lenses, a stamp is used to mark the right or left lens, the centring point and the lens horizontal.
- MyCon lenses are provided with permanent markings (engravings). These serve to identify the manufacturer and the lens type as well as to reconstruct the distance reference point. The engravings are usually only visible when the lens is held against the light at a light/dark edge.
- Single and repeat orders of MyCon lenses are possible.
For single lens orders, it is recommended to know the values of the counter lens and to include them in the order so that they can be taken into account in the calculation.
- To achieve the desired preventive effect and slow the progression of myopia, MyCon lenses must not be paired with other lenses in a pair of spectacles.
- Further information on MyCon lenses can be found in the current Rodenstock product catalogue, in the white paper "MyCon by Rodenstock" and in the Rodenstock consulting programme.

4 Risks & side effects



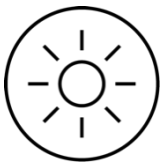
The time it takes to get used to the MyCon glasses can vary from child to child (usually one to two weeks).



Initially, due to the horizontal defocusing, swim effects and distortions can be perceived in the peripheral areas of the lens combined with an altered perception of space.

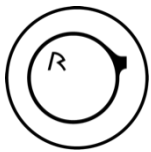
During the acclimatisation phase, the following activities should therefore be carried out carefully:

- Intensive sports activities and school sports
- Cycling and other means of transport



The best effects with regard to myopia prevention are achieved if the following recommendations are also observed:

- spend at least two hours outdoors,
- regular breaks for prolonged near work and
- ensure good lighting and sufficiently large working distances



Rodenstock recommends regular monitoring of the progress of the treatment.

- of the seat of the MyCon glasses,
- the refraction data and
- the progression of myopia

For further information on Rodenstock spectacle lenses, please refer to the "Rodenstock General Instructions for Use".

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