When selling medical products, the adapter, hereinafter referred to as the optician, is obliged to inform the end user, hereinafter referred to as the spectacle wearer, about restrictions of use, preferably in writing.
Convince with your professional competence by pointing out relevant restrictions of use to your customer 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

- Myopia management lenses are spectacle lenses for children and teenager 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.

- Myopia management lenses are designed for permanent use in spectacles.

- Myopia management lenses are used for distance correction. Since children and teenagers usually have a sufficiently large accommodation capacity, they can see sharply at all distances up to near with myopia management lenses for distance by using their accommodation.

1.2 Design of myopia management lenses

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

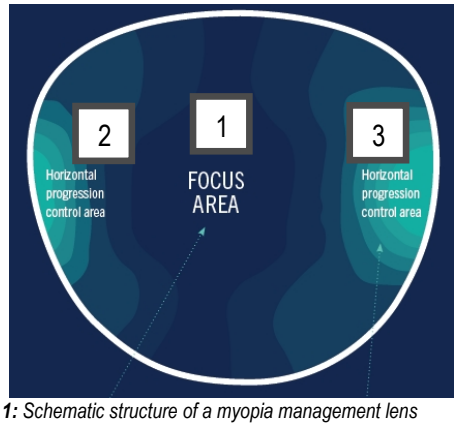

Figure 1: *Schematic structure of a myopia management lens*

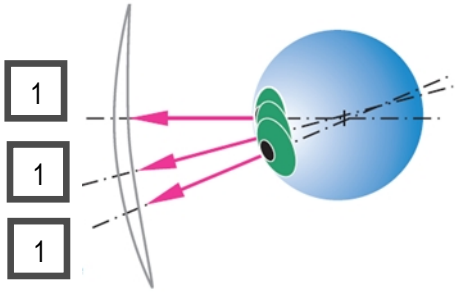

Figure 2*: Vertical gaze deflection when looking through a myopia management lens*

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 Myopia management lenses is the distance refraction.
- Myopia Management lenses “MyCon” are calculated for a fixed tilt situation and “centred alignment“.
- Myopia Management lenses “MyCon 2” are optimised for a variable tilt situation depending on the base curve, frame, and individual parameters.
  - Possible ranges for the individual wearing situation: Corneal vertex distance: 5 – 30 mm, interpupillary distance: 20 – 40 mm, face form angle: -5° – 15°, pantoscopic tilt: -5° - 20°
- 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 retina[1], causing peripheral hyperopia[2]. 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 Myopia management 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 myopia management 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 myopia management 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 myopia management 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 myopia management 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 Myopia management! 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.

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

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2 Restrictions of use & foreseeable misuse

- Myopia management 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.
- Myopia management lenses offer the spectacle wearer large visual areas. 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.
- Myopia management lenses are not recommended for highly curved prescription frames with severely tilted lenses.
- Myopia management 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 use".

3 Correct use

- To fully utilise the optical performance of myopia management lenses and ensure that the lenses are correctly centred on the child's face, it is essential that the spectacle frame is anatomically fitted to the wearer's face.
- The individual parameters of the wearing situation (Corneal vertex distance, interpupillary distance, face form angle and pantoscopic tilt) should be measured and the appropriate singe vision lens selected based on this data. To ensure that the full optical performance of the lens is maintained, the wearing situation cannot be changed afterwards by the optician or spectacle wearer.

Figure 4: *Individual parameters of the wearing situation*

- The frame should at least fulfil the following criteria in terms of size and centring:

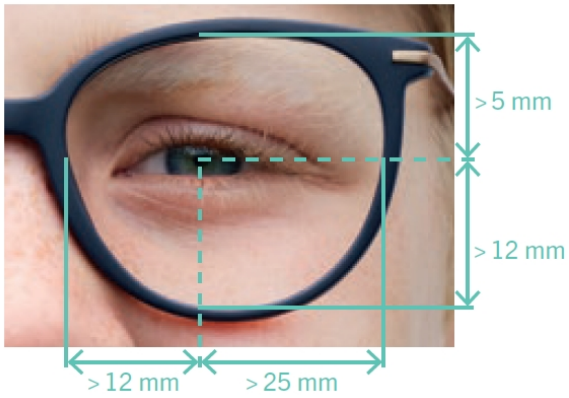

Figure 5: Recommended minimum frame dimensions and centre point position

For “MyCon” myopia management lenses, the maximum corneal vertex distance should be 14 mm. In case of “MyCon 2”, an individual corneal vertex distance can be ordered.

- The fitted frame should not be changed afterwards by the optician or spectacle wearer.
- The myopia management lenses “MyCon” must be centred in such a way that the centring point coincides with the centre of the wearer´s pupil  when the frame is vertical, and the wearer is looking straight ahead (centre of eye rotation requirement).

Figure 6: *Head posture with fitting according to centre of eye rotation requirement*

- The myopia management lenses “MyCon 2” must be centred in the habitual head and body position and zero gaze direction. The centring point should coincide with the centre of the pupil (reference point requirement). 

Figure 7: *Head posture with adaptation to zero gaze direction in habitual head and body posture*

4 Risks & side effects

The time it takes to get used to the myopia management lenses 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 regarding 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 myopia management 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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