

EN INSTRUCTIONS FOR USE

— Scleral contact lenses

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IMPORTANT: Please read through these instructions for use completely before using any of the products.

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General instructions

Please read through these instructions for use carefully and if you have any questions, please ask your practitioner (qualified optician, optometrist, or ophthalmologist). Please keep these instructions for future reference.

These contact lenses may only be fitted by a qualified practitioner (qualified optician, optometrist, or ophthalmologist).

The contact lenses are individually packaged in the Futuro GP storage solution. (Composition: Polysorbate 80, hypromellose, preservative: PHMB (polyhexanide) 0.0002%).



The contact lenses are not sterile.



If the contact lenses are used for the first time any later than 7 days after the date of manufacture (YYYY-MM-DD) the lens must first undergo the cleaning process (see Section 7.3).

Abbreviations:

Abbreviated form:	Explanation:
CE	Communauté Européenne
∅	Diameter
Lot	Production number
R	Right contact lens
L	Left contact lens
i.e.	that is

Symbols used in this document:

Symbol:	Explanation:
	Symbol for "Consult instructions for use"
	Symbol for "Batch code"
	Symbol for "Non-sterile" products
	Symbol for "Date of manufacture (YYYY-MM-DD)"
	Symbol for "Manufacturer and manufacturer's address"
	Symbol for "Do not use if packaging (contact lens container) is damaged"
	Symbol for "Caution"

The symbols are taken from EN ISO 15223-1:2017.

1 Description and applications

1.1 Categorisation of rigid scleral contact lenses

These instructions for use are for rigid contact lenses from Falco Linsen AG (see Table 1). The scleral contact lenses are categorised into two diameter sizes (∅14.80 / ∅16.00), which in turn are divided into two geometries (rotationally symmetrical, toric peripheral) with regard to the back surface of the contact lenses.

Trade names organised by product types and geometries:

	Ø 14.80	Ø 16.00
Rotationally symmetrical	miniV	SKV / SMV
Toric peripheral	miniT	SKT / SMT
Keratoconus	miniV / miniT	SKV / SMV / SKT / SMT
Keratoplasty	miniV / miniT	SKV / SMV / SKT / SMT
Lasik	miniV / miniT	SKV / SMV / SKT / SMT

Table 1

Keratoconus lenses are used: in the case of progressive thinning and conical deformation of the cornea of the eye.

Keratoplasty lenses are used: after a corneal transplant. In this case, the wearing of contact lenses must be authorised by an ophthalmologist.

Lasik lenses are used: when vision needs correcting after LASIK surgery (laser eye surgery to correct optical vision defects).

All contact lens geometries can be provided with an iris print if required.

All contact lens geometries are available with an additional presbyopia system.

The presbyopia systems for scleral contact lenses are categorised into two types: “Simultaneous bifocal, Simultaneous trifocal”.

Trade names organised by presbyopia systems:

	Designation	E. g. SKV
Simultaneous bifocal	B	SKVB
Simultaneous trifocal	D	SKVD

Table 2

1.2 Rigid, gas permeable contact lenses – intended purpose

Rigid, gas permeable scleral contact lenses are used to treat, alleviate, or compensate for poor vision and to optimise the eye’s visual capacity.

Indications:

Pathological and optical indications:

- Facilitating or improving binocular vision
- High astigmatism
- Unilateral aphakia
- Anisometropia

Normalisation of refractive media, resulting in better vision:

- Keratoconus
- Irregular corneal astigmatism (following injury or inflammation, or following a surgical procedure)

Improvement of the optical situation:

- Moderate to high myopia
- High hyperopia

- Regular astigmatism of more than 3.00 dpt
- Bilateral aphakia

Cosmetic indications:

- Rejection of glasses for cosmetic or psychological reasons

Professional indications:

- Professions that involve working with water or dust (baker, farmer, joiner, etc.)

The only materials used in scleral contact lenses from Falco Linsen AG are materials made of copolymers of fluorine, silicone, and methyl methacrylate.

Some advantages of rigid contact lenses (rigid gas permeable) over soft lenses:

Good, stable visual acuity, fewer infections, only option for treatment of irregular corneal geometries.

The contact lenses can be adapted to all corneal geometries. The qualified practitioner (qualified optician, optometrist, or ophthalmologist) will determine which contact lens geometry is appropriate.



The contact lenses are designed for daily use. They are reusable and are only worn during the day / while awake. Afterwards, the contact lens is taken out, cleaned and disinfected (at least 6 hours). The next day, the contact lens can be put back in. (See Section 7/8).



We recommend regular check-ups with a qualified practitioner (qualified optician, optometrist, or ophthalmologist) during the adaption period – at least every 10 days. After the adaption period, you should have check-ups at least every 6 months. The practitioner (qualified optician, optometrist, or ophthalmologist) will decide when the adaption period is over.

In the case of children or persons who, due to the severity of their disability, are unable to use the product correctly in accordance with these instructions for use, a parent or guardian must ensure correct handling.

The mode of wearing (wearing times) will be determined by your practitioner (qualified optician, optometrist, or ophthalmologist). (max. 16 hours).



The contact lens can be used for a maximum of 1 year after the date of manufacture.

The contact lens must be disposed of in the household waste.

2 Contraindication

The contact lenses must not be used in the following cases:

- Acute or subacute inflammation or infection of the anterior chamber of the eye (bacterial, fungal or viral).
- Any eye disease, injury or abnormality affecting the cornea, conjunctiva or eyelids.
- Severe insufficiency of tear secretion (dry eye)
- Corneal hypoesthesia (reduced corneal sensitivity)
- Any systemic disease that affects the eye or is aggravated by wearing contact lenses (e.g. leukaemia, rheumatism)
- Allergic reactions on the ocular surface, conjunctiva or eyelids and surrounding tissue that can be induced or aggravated by wearing contact lenses or by using contact lens solutions.

3 Side effects

Generally, contact lenses are tolerated well, but the following side effects cannot be ruled out:

- Increased foreign body sensation
- Formation of a secretion in the eye
- Pain, burning, stinging
- Redness of the eyes or eyelids
- Sensitivity to light
- Poorer vision
- Blurred vision
- Tearing eyes
- Dry eyes

If these or any similar symptoms occur, you must stop wearing the contact lenses. Inform your practitioner (qualified optician, optometrist, or ophthalmologist) immediately and discuss the further course of action with them.



4 Warning

The contact lenses must not be used if:

- The eyes are red or irritated.
- The contact lens has any defect.
- The contact lens is dirty or contaminated with a fungus.
- The contact lens container is defective or contaminated.



5 Safety precautions for use

- Direct exposure of the contact lenses to non-sterile water (e.g. tap water, hot tub, swimming, participation in water sports) increases the risk of a microbial infection. Please wear watertight protective goggles / diving goggles to help protect against this.
- Using non-sterile water (e.g. tap water) when handling the contact lenses and contact lens containers increases the risk of a severe microbial infection.
- Replace the contact lens containers regularly, according to the product manufacturer's instructions, or if the contact lens container is contaminated or defective.
- Do not use the same storage solution in your contact lens container twice (risk of infection).
- Please note the stated product life of the contact lenses. The contact lenses can be used for a maximum of 1 year after the date of manufacture.
- The contact lenses must not be used while sleeping.
- Please only use the **cleaning** and storage product that we recommend (**Oté Clean** and **Oté Fine** by Oté Optics; in Switzerland: **Futuro Lens Aqua Reiniger** and **Futuro GP** by Conil), which are suitable for rigid Falco contact lenses.
- Do not change contact lens care systems without consulting your practitioner (qualified optician, optometrist, or ophthalmologist).
- Do not exceed the wearing time recommended by your practitioner (qualified optician, optometrist, or ophthalmologist).
- Certain medications (such as birth control pills, antibiotics, anti-allergics, antihypertensives, etc.) may affect your ability to wear contact lenses. Inform your

practitioner (qualified optician, optometrist, or ophthalmologist) about any new medications you are taking or changes in your medication.

- Wearing contact lenses after an eye operation requires prior authorisation from an ophthalmologist.
- In the case of redness of the eye, excessive tearing, pain or blurred vision that is not due to contaminated contact lens surfaces, remove the contact lenses from the eyes and contact your practitioner (qualified optician, optometrist, or ophthalmologist) as soon as possible.
- If you use make up, put the contact lenses in before applying it. Remove your contact lenses before removing your make up. Wherever possible, use fibre-free mascara and oil-free products (suitable for contact lens wearers).
- Do not expose the contact lenses to any hair spray, cosmetics, or aerosol sprays (e.g. deodorant).
- Contact lenses should be removed immediately in the case of contact with irritant vapours, such as chemicals or hazardous substances, or exposure to hazardous environments that can affect the eyes.
- The contact lenses must not be shared with other people.
- Inform all your doctors and your employer that you wear contact lenses. There are situations in which wearing contact lenses is prohibited.
- If the contact lens is in defective primary packaging (contact lens container) or if the liquid in the primary packaging has dried out, the contact lens must not be put in. Inform your practitioner (qualified optician, optometrist, or ophthalmologist).
- The UV filters contained within the contact lens material do not protect your eye from UV radiation completely. Therefore, you should still wear sunglasses.



6 Ambient conditions

Contact lenses must be stored at an ambient temperature between 4°C and 25°C. If the contact lens has not been worn for one day or longer, then the cleaning process should be repeated before wearing the lens again.

If the contact lens is not to be worn for a week or longer, then the contact lens must be cleaned again and stored dry at an temperature between 4°C to 25°C in a clean, dry contact lens container.

7 Applications of scleral contact lenses

7.1 Insertion of the contact lenses

1. Wash and dry your hands before taking the contact lens out of the contact lens container (see Section 8). Taking care to maintain personal hand hygiene is very important.
2. Take the contact lens out of the container and check it for defects.
3. After removing the contact lens from the packaging and before placing it on the eye, rinse the contact lens thoroughly with an isotonic saline solution (0.9% sodium chloride).
4. Place the contact lens between the thumb, middle and index fingers and fill the contact lens completely with unpreserved isotonic saline solution (0.9% sodium chloride in vial form).
5. Put a mirror on the table. Look at your nose or your eye in the mirror image. Use the index finger of the hand on the same side of the body to pull the lower lid downwards and use the index finger of the other hand to pull the upper lid upwards.
6. Now slowly move the contact lens towards the eye. Place the contact lens in the centre of the eye, on the pupil (see figure 1).

7. Slowly release the upper and lower eyelids.
8. Check the positioning of the contact lens. There should be no air bubble underneath the contact lens.

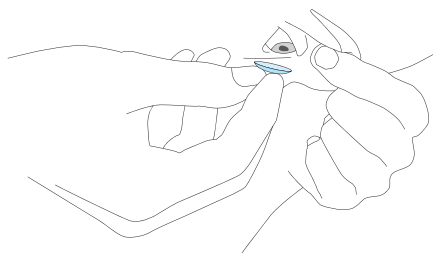


Figure 1

Note If the contact lens falls down, it is essential to clean it thoroughly with isotonic saline solution (0.9% sodium chloride) before attempting to put it in again. When you pick up the contact lens, take care not to cause any defects on the edges. (Do not drag the contact lens over the surface of the table or mirror).

Note If the contact lens is irritating you, if your eye begins to tear, or if your vision is poor, take the contact lens out again. Check that the correct contact lens has been placed in the correct eye. Rinse the contact lens and put it back in. (However, if the contact lens is defective, you must not put it in again.) If the contact lens is contaminated, repeat the cleaning process. If the problem persists, you must not put the lens on your eye. Inform your practitioner (qualified optician, optometrist, or ophthalmologist).

7.2 Removing the contact lenses

1. Wash and dry your hands before touching the contact lens (see Section 8). Taking care to maintain personal hand hygiene is very important.
2. Put the middle finger of one hand on the upper lid, as close as possible to the edge of the lid. Put the middle finger of the other hand on the lower lid, as close as possible to the edge of the lid. Now pull the eyelids open until they are outside the edge of the contact lens (see figure 2).
3. Now push the eyelid edges together again using a light pressure. This will release the contact lens from the eye (see figure 3).

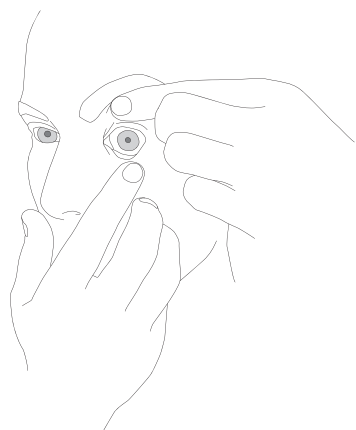


Figure 2

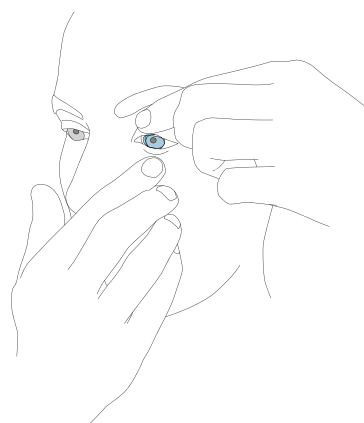


Figure 3

Note If the contact lens gets stuck in place: Put a few drops of isotonic saline solution (0.9% sodium chloride) on the eye and wait a few minutes. The contact lens can also be nudged slightly by the lower lid at the edge of the contact lens. Now try to take the contact lens out again.

Inform your practitioner (qualified optician, optometrist, or ophthalmologist) about this event.

The practitioner (qualified optician, optometrist, or ophthalmologist) will practice putting the contact lens in and taking it out with the customer/patient until they are able to do it independently.

7.3 Cleaning / contact lens care

1. The contact lens must be cleaned every time it is taken out.
2. Put the contact lens in your palm and drop a few drops of the cleaning fluid on it (Oté Clean by Oté Optics; in Switzerland: Futuro Lens Aqua Reiniger by Conil) and rub it in using a finger from the other hand for 30 seconds on both sides.
3. Rinse the contact lens well with isotonic saline solution (0.9% sodium chloride) and then put the contact lens in the contact lens container.
4. Add a few drops of the storage solution (Oté Fine by Oté Optics; in Switzerland: Futuro GP by Conil) until the contact lens is completely covered with the fluid.
5. When closing the contact lens container, please make sure that the contact lens does not get jammed in the thread of the closing mechanism.

Note If the contact lens is not worn one day or longer, the cleaning process must be repeated once more.

Note If the contact lens is not be worn for a week or longer, the contact lens must be cleaned again and stored dry at a temperature between 4°C to 25°C in a clean, dry contact lens container.

The practitioner (qualified optician, optometrist, or ophthalmologist) shall practices cleaning with the customer/patient until they are able to do it independently.

8 Hygienic hand washing

Please wash your hands thoroughly every time before your hands come into contact with the contact lenses in order to prevent infections and contamination.

0. Put your hands under running water and wet them completely.
1. Put soap on the inner surface of the hands.
2. Rub your palms across each other.
3. Put your right palm on the back of your left hand and interlock your fingers, then move back and forth. Do the same thing with the left palm on top of the back of the right hand.
4. Put your palms together and interlock your fingers. Move your hands up and down.
5. Place the backs of the fingers of each hand inside the palm of the other hand and clasp hands together. Move back and forth.
6. Grasp the left thumb using the right hand and twist around. Do the same with the right thumb.
7. Circle the tips of the fingers of the right hand in the palm of the left hand. Do the same thing with the tips of the fingers of the left hand on the palm of the right hand.
8. Rinse off the soap.

9. Dry your hands using a lint-free disposable towel.
10. Use the towel to close the tap, then dispose of it.
11. End of hygienic hand washing.

(see figure 4)



Figure 4



9 Information for the practitioner

- These instructions for use must be issued to the customer/patient.
- The contact lenses must be replaced 1 year after the date of manufacture.
- Please note the check-up intervals and wearing time.
- These contact lenses may only be fitted by a qualified practitioner (qualified optician, optometrist, or ophthalmologist) who has attended our scleral lenses seminar.
- Inform your customers/patients about the risks, contraindications, side effects and safety precautions.
- The practitioner (qualified optician, optometrist, or ophthalmologist) must practice cleaning and handling with the customer/patient until they are able to carry out the procedures independently.
- New customers will receive relevant information and a product catalogue in paper and/or electronic form upon registration. You will receive any updates and additional information automatically.

10 Additional information

For further information, go to www.falco-linsen.com. For a larger print, we recommend the digital version of this document which can be found on our website.

Document version: 2020-02-15, version 4