

EN INSTRUCTIONS FOR USE**Preparation of multipatient-use trial contact lenses****Name and address of manufacturer**

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

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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 General instructions

1.1 Hand washing



Wash your hands with disinfectant liquid soap before and after each appointment. Dry your hands with a new disposable paper towel. Drying the hands reduces the risk of spreading organisms found in water such as Acanthamoeba (see Section 6). Hand washing is also required prior to using gloves.

1.2 Shelf life and storage time



The contact lenses can only be worn / cleaned a maximum of 365 times or can only be used for seven years after the date of manufacture (YYYY-MM-DD), whichever occurs first.

1.3 Miscellaneous

- Contact lenses must be stored at an ambient temperature between 4°C and 25°C.
- The contact lenses are individually packaged.
- The only materials used in rigid contact lenses from Falco Linsen AG are materials made of copolymers of fluorine, silicone, and methyl methacrylate.

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 Precautionary measures in the case of infections

Dispose of any contact lenses that have been used by persons known to be infected with:

- Herpes simplex infection of the eyes
- Hepatitis
- Human immunodeficiency virus (HIV)
- Adenovirus

Use single-use, powder-free and latex-free gloves to remove the infected lenses from the patient's eyes. Also dispose of any containers and solutions that have been in contact with the infected lenses.

If it is necessary to dispose of lenses, containers or maintenance products due to infection (see list of precautionary measures in the case of infections), these objects must be treated as "biohazardous waste".



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 Procedure

1. Select the appropriate contact lens from the trial lenses box.
2. Clean the contact lens manually (clean for 30 seconds with Futuro Aqua detergent by Conil or Oté Clean by Oté), rinse with saline solution (0.9% sodium chloride) and check it for defects.
3. Put the contact lens on the client's eye, then examine and evaluate.
4. Take a note of changes / order.
5. Remove the contact lens from the eye and clean it manually (clean for 30 seconds with Futuro Aqua detergent by Conil or Oté Clean by Oté), rinse with saline solution (0.9% sodium chloride) and dry it with a lint-free drying cloth.
6. Cleaning (see Section 5.1)

7. Labelling (see Section 5.2)
8. Documentation (see Section 5.4)
9. Put the contact lenses back in the correct place in their storage box (trial lenses box).



Please note:

- If a contact lens has been on an infectious eye, the used contact lens must be disposed of immediately (disposable gloves must be used to remove it).
- If a contact lens is defective, it must be disposed of.

5.1 Cleaning

Clean and disinfect the contact lens after every use:

1. Put the contact lens in the appropriate container (the one recommended by the manufacturer of the cleaning solution) and fill with 3% hydrogen peroxide (in the case of a one-step container, remove the platinum catalyst).
2. Close the container and wait at least 3 hours.
3. Wash and disinfect hands or put on gloves.
4. Add a neutralising tablet and wait 6 hours / or empty the hydrogen peroxide and fill with saline solution (0.9% of sodium chloride).
5. Vigorously shake the container for 10 to 15 seconds.
6. Remove the contact lens from the container with tweezers and shake off the droplets.
7. Pat the contact lens dry with a lint-free paper tissue.
8. Put the cleaned, dried contact lens in the cleaned, disinfected and dried contact lens container.

5.2 Labelling

Note the following on the contact lens container to ensure that it can be identified:

- Parameters of the contact lens inside
- Lot or batch number
- Date of disinfection
- Lens identification (for follow-up later)

Add sufficient information to allow the individual lenses to be identified.

5.3 Container

- Use the enclosed Falco contact lens container to store the contact lenses.
- Any contact lens containers that are damaged must be replaced (infection risk).
- For cleaning, use the contact lens container recommended by the manufacturer of the cleaning solution.
- Replace the containers regularly.
- After each use, clean the contact lens containers with 3% hydrogen peroxide (fill the container, shake it for 10–15 seconds and then leave to stand for 3 hours, then empty the liquid, fill with saline solution (0.9% sodium chloride), shake for 10–15 seconds, empty the liquid and then pat the container dry with a new, lint-free drying cloth).

5.4 Documentation

In order to ensure traceability, record the following:

- How the contact lens was disinfected (chemical disinfection).
- The patient / client identifier of the person the contact lens was used on.
- Date of use
- Date of hygiene management
- Contact lens data
- The person who carried out the disinfection (may only be done by trained staff).

6 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 1)



Figure 1

7 Additional information

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