

Complex Diagnostic Fitting Set Instruction For Use



These instructions for use acknowledge that risk factors for possible transmission of specific disease by use of trial contact lenses on multiple patients can vary by country or other political or geographical barriers. Legal requirements involving national practices or regulations take precedence over these instructions.

The diagnostic fitting lenses in this set are designed to be used by a practitioner or fitter for the purpose of selecting the appropriate contact lens parameters for the intended wearer. The preference for the lenses in this fitting set is for single use, after which the lens is discarded. If single use cannot be followed disinfection of the lenses used is to be carried out by use of a 3% hydrogen peroxide solution (see Disinfection Process).

Single use must be applied to patients identified as potential carriers of infectious diseases such as CJD (No reported cases of transmission of CJD exist at the time of writing these instructions), Herpes Simplex, Hepatitis, Human Immunodeficiency Virus (HIV), or Adenovirus. If any country's regulations require other infectious diseases to be added, these apply in the country/area concerned.

Handling Precautions

- Contact lenses used for fitting patients admitting to CJD, Herpes Simplex, Hepatitis, HIV AIDS, or Adenovirus need to be disposed of after use. Any lens known to be infected needs to be discarded immediately in order to minimize contamination in practice. The use of disposable gloves is recommended. – *Local regulations governing the disposal of bio-hazardous waste can apply.*
- Wash and dry your hands in accordance with the eye care professionals recommendations. For countries without eye care professionals recommendations, wash and dry your hands before and after each patient fitting with a surgical scrub or a liquid soap. Dry your hands on a new paper towel. Use of an alcohol hand rub may be used after washing, make sure your hands are dry and free from the rub before touching the contact lens, because a lens contaminated with alcohol will cause ocular tissue irritation.
- Clean and rinse the contact lens before and after use according to the instructions of the manufacturer of the cleaning solution. A recommended solution for use with our contact lenses is Quattro Multifunctional Solution.

Disinfection Process

- Chemical management is achieved by soaking the lens. In the case of a 3% hydrogen peroxide contact lens solution, the soaking period is for a minimum of 3 hours prior to neutralization of the hydrogen peroxide. Following neutralization of the hydrogen peroxide, the lens should be stored in a preserved solution.
- Lenses should be disinfected using the case and holder provided by the contact lens solution manufacturer, duly labelled so that the lens can be identified as to its parameters, manufacturers lot number and date/time of treatment.
- Fill the case to the upper line with disinfection solution.
- Place a lens in the lens holder and close the case securely.
- After a minimum soak of 3 hours, remove the holder, shake off the residual drops and discard the solution in the case.
- Refill the case to the lower line with neutralizing solution and re-insert the contact lens holder. Securely tighten the cap and shake vigorously for 10 to 15 seconds.
- Undo the cap, remove the lens holder, shake off the residual drops and discard the neutralising solution.
- Fill the case to the upper line with more neutralizing solution, re-insert the lens holder, secure the cap and leave for a minimum of 1 hour.
- Undo the cap remove the lens holder, shake off the residual drops and discard the neutralizing solution. Fill the original fitting set mailer with soaking/storage solution and insert the contact lens, making sure it is in the correct mailer with regards to parameters, noting the date and time of treatment (an example form is attached in the diagnostic set) – *If an RGP lens is to be stored dry, after discarding the neutralizing solution, dry the lens with a clean tissue and store in the original mailer noting the date and time of treatment.*
- For lenses stored in soaking solution, repeat the procedures above if the contact lens has not been used for 28 days.

Number of re-uses or times in use

- If the lens is damaged or its physical appearance has changed, the lens should be discarded.
- All lenses stored in a soaking solution or in a dry condition should be discarded after 12 times of use or after 12 months from time of first use, whichever comes first.

Records

- It is the practitioners responsibility to log the patients reference, date of use the date of hygienic management and the contact lens details after each use, see example enclosed (multi use only)

The process for disinfection above is to be used as a guide only. Please refer to the specific user instructions for the hydrogen peroxide solution used.

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It is recommended to use one sheet per lens. This will allow for easy reference to times used and discard date.

Date of first use: _____ Discard Date: _____

Lens Parameters: Diam: _____ BC: _____ Power: _____

Manufacturers Lot No: _____

Disinfection Solution used: _____

Storage Solution used: _____

	Date	Patient	Disinfection Date	Storage Date	Initials
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					