

## SOFT CONTACT LENS INSTRUCTIONS FOR USE

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English



### IMPORTANT

Lenses should not be worn unless prescribed by a registered eye care professional. The patient of the device **MUST** read these instructions BEFORE use – important information is inside.

### Description

All soft contact lenses manufactured by Cantor Barnard Ltd are covered under this instruction for use document.

### Intended Use

Sterile Soft Lenses are to be worn on the front of the eye to correct vision conditions and to alleviate visual symptoms that can co-occur with academic skills disorders.

### Indications for use and Clinical Benefits

Trade name	Clinical indication
Hydrolens	Treatment of Myopia, Hyperopia, Astigmatism, Presbyopia, Masking of Cosmetic Defects of the Eye, Colour Deficiency, and Academic Skills Disorders
Cantor Prosthetic	
Cantor Cosmetic	
X-Chrom	
ChromaGen	
Nissel Custom	
PV Series	
OmniFlex	
Hydrolit	
30 Days	
Hydrocyl	
Meridian Toric	
Nissel KII Toric Soft	
Zero 6	
Pastel Tints	

### Instructions for Use

These lenses are conventional daily wear soft contact lenses. The lenses wear time will be suggested by your eye care professional. Your eye care professional will recommend lens wearing, cleaning regime, and replacement regime. Do not vary these. If in doubt seek the advice of your eye care professional.

#### Instructions on Handling Lenses & Contact Lens Solutions

- Keep your finger nails short and smooth to avoid scratching your eyes or your lenses.
- Always wash your hands with warm water and soap and dry thoroughly before handling your lenses. Lenses may become contaminated if you do not wash your hands properly.
- Always handle your lenses somewhere that is well-lit, clean and sterile.
- Your contact lenses may become damaged if mis-handled.

The risk of infection is higher without proper care for your contact lenses and cleaning solutions

#### Checking the lenses and packaging

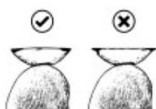
- Check which lenses are for the right eye and which lenses are for the left eye. (if applicable)
- Check if there is anything wrong with the lenses, glass packaging, or tamper evident seal. If there is anything wrong, for example, if there is any damage or leakage, do not open or use and contact the point of purchase.

#### Removing the lenses from the sterile glass packaging

- Hold the package and use one hand to pull upwards against the tamper evident seal of the packaging.
- Remove the metal seal from the top of the vial and then remove the stopper.
- Remove the lens with either soft tip tweezers or carefully pour the lens from the vial with the saline.

#### Checking the lenses – Figure 1

- Hold the edges of the lens from the side and gently move it up and down to remove the liquid.
- Put the convex surface on the index finger of your dominant hand and check the lens
- Ensure that the lens is not inside out (fig 1)
- Check if there is anything wrong with the lens, for example, if the lens is deformed, discoloured, contains foreign matter, is damaged, is scratched or is dirty. Do not wear the lens if you notice any abnormalities.



CE	CE Marking of conformity to Regulation (EU) 2017/745 on medical devices.
UKCA	UKCA Marking of conformity to UK Medical Device Regulations 2002.
MD	Medical Device
Importer	Importer
Manufacturer	Manufacturer
EC REP	European Authorized Representative EC Rep (Emergo Europe) Emergo Europe Westervoortsedijk 60, 6827 AT Arnhem The Netherlands
CH REP	Swiss Representative CH Rep (Decomplex AG) Decomplex AG Freiburgstrasse 3 3010 Bern Switzerland
LOT	Batch Code
UDI	Unique Device Identifier
Date of Manufacture	Date of Manufacture
Use-by-date	Use-by-date
STERILE	Sterilized using steam.
Fragile, handle with care.	Fragile, handle with care.
Back (central) optic zone radius	Back (central) optic zone radius
Paraxial back vertex power	Paraxial back vertex power
Total diameter	Total diameter
Axis	Axis
Cylinder Power	Cylinder Power
Water Content	Water Content
Do not use if packaging is damaged and consult instructions for use.	Do not use if packaging is damaged and consult instructions for use.
Single Patient Multiple Use	Single Patient Multiple Use
Consult Instructions for Use or Consult Electronic Instructions for Use	Consult Instructions for Use or Consult Electronic Instructions for Use



Figure 2 & 3

#### Inserting Lenses - Figure 2

- Put the lens onto your finger, and with your middle finger of the same hand, pull down your lower eyelid. With your index finger of your other hand, pull up your top eyelid. If you put your finger on your eyelash line, you can open your eye wide.
- Look in the mirror so that your cornea is located centrally. Slowly bring the lens close to your eye and put it gently in place whilst still looking in the mirror. If you glance upwards when doing this, the lens will not be properly centred on your cornea. (Figure 2)
- When you have placed the lens properly on the cornea, slowly remove your index finger and then release your eyelids, starting with the bottom lid first and then the top lid. If you remove your fingers too quickly or blink too quickly, the lens may change position or fall out.
- Check in the mirror that the lens is on top of your cornea and covering the opposite eye with your hand, check your sight in both eyes. Follow the same procedure to fit the lens in your other eye.
- Infants and young children should have their lenses fitted by a responsible adult who is familiar with fitting contact lenses, and who follows the recommendations of the eyecare professional.

#### Removing the lenses – Figure 3

- Check the position of the lens in the mirror.
- Looking straight in the mirror, tilt your head slightly down whilst still looking in the mirror.
- Using both index fingers place them on both upper and lower lids.
- In this position, use your fingers and lids to very carefully prize the lens from the surface of your cornea.

#### Contact Lens & Contact Lens Case Care

- Since proteins and lipids in your tears will become attached to the surface of your contact lenses as you wear them, it is important to follow the correct lens care regime for washing, rinsing, disinfecting and storing your lenses.
- Failure to follow the lens care regime can cause lenses to become dirty and may result in a serious eye disorder or eye infection.
- Use lens care products according to their accompanying booklet or instructions.
- The extent to which lenses become dirty varies from person to person. If your lenses tend to become dirty, try rubbing your lenses with a cleaning solution or using a protein removal liquid. Dispose of the lenses if you are unable to clean them sufficiently.
- Replace your lens case roughly every one or two months. Prolonged use will result in a proliferation of bacteria due to the build-up of dirt, rendering disinfection inadequate and potentially leading to eye infection.
- If your contact lenses have not been worn for a length of time you must re-sanitize your contact lenses for the full contact time of the solution used and use a new contact lens storage case.

#### Compatible contact lens cleaning solutions:

- Ote Twins Active
- Avizor Unica Sensitive

#### Contact Lens Storage and Transportation

- Your contact lenses will remain sterilised until you break the tamper evident seal. If the lenses are not worn directly after doing this, your lenses must be stored straight away in an appropriate contact lens case with contact lens solution.
- Contact lenses which have been removed from their packaging should be transported in an adequate contact lens case to ensure that they stay sanitized and to prevent the ingress of dirt and bacteria.

#### Contraindications

##### Medical Conditions

- Acute and sub-acute inflammation of the anterior eye, eye infection, uveitis, reduced corneal sensitivity, dry eye or lacrimal apparatus disease to an extent that poses a problem for wearing lenses, eyelid disorders, or allergy to an extent that affects the wearing of lenses, and other diseases which would complicate the use of contact lenses.

##### Environmental Conditions

- Anyone living or working in dry environments. Anyone living or working in an environment where dust or chemicals are likely to enter the eye.
- Use with non-compatible cleaning solutions is contraindicated.

##### Personal Qualities

- Anyone who cannot follow the recommendations of their eye care professional, anyone who cannot use contact lenses properly, anyone who fails to attend regular check-ups, anyone who cannot follow the hygiene routine required to wear contact lenses.

Lenses may be damaged or become damaged. If you have inadvertently worn a lens which is damaged or otherwise faulty, or if a lens become damaged while you are wearing it, remove the lens immediately and consult your eye care professional.

#### Precautions

Be sure to read this booklet carefully before using your contact lenses, and if you are in any doubt about the terms or information contained herein, please consult your eye care professional for clarification before using the medical device.

Please retain this document for future reference.

- Do not wear contact lenses that are damaged.
- Do not wear contact lenses for longer than the recommended wearing period.
- Do use contact lenses properly in accordance with recommended methods for handling contact lenses.
- Always attend regular contact lens check-ups.
- If you experience any problems at all, consult your eye care professional immediately.
- Always insert lenses promptly after opening, as lenses can become easily contaminated. If you do not use them straight away, store them according to the instructions of the lens care products used.
- Avoid rubbing your eyes while wearing lenses, as this may result in scratches to the surface of your cornea or lens displacement.
- Do not mix up right and left lenses, as doing so may result in impairment of vision and discomfort.
- Make sure you have appropriate glasses to use in case you are unable to wear your contact lenses due to a condition of your eyes or for other reasons, or after you have worn your lenses longer than the recommended wearing period stated by the eye care professional. Continuing to wear your contact lenses regardless may cause eye disorders or other problems.
- Follow the instructions of your eye care professional if using eye drops while wearing contact lenses.
- Do not allow cosmetics, pharmaceuticals or other substances to come into contact with your lenses. If cosmetics (eyeliner, cleansing products, etc.) contaminate your lenses this could result in discolouration, irritation and/or deterioration of the quality of the contact lens.
- When your eyes and contact lenses are exposed to strong wind (such as riding a bicycle, skiing, or direct wind etc.) always use some kind of protection against the wind such as sunglasses or goggles. Failure to do so may result in uncomfortably dry lenses and/or potential displacement of lens.
- If solvents such as household detergents or cleaning products get in your eyes, remove and dispose of your lenses immediately, and consult your eye care professional.
- Never wear someone else's contact lenses or give your lenses to someone else to wear, as this could result in possible infection and serious eye disorders.
- Users who find it difficult to insert lenses, such as the elderly, young children or severely vision impaired should first consult an eye care professional for guidance.
- Some pregnant women may find that lenses (which were once comfortable) may become uncomfortable and experience a temporary deterioration of vision. Guidance on further lens wear should be consulted with an eye care professional.
- People who suffer from allergies may be more prone to diseases of the eye and skin than other wearers of contact lenses. Guidance should be received from an eye care professional before wearing of contact lenses.
- Use of contact lenses may be affected by illness, pregnancy, childbirth, use of medications, physical conditions, eye conditions and living environment. The conditions in which you wear contact lenses may also change after you have started wearing contact lenses.
- Consult your eye care professional before using filtered lenses in low light conditions, particularly when driving and using machinery.

#### Warnings

To wear your contact lenses safely, be sure to read this booklet carefully and to follow the instructions of your eye care professional and the proper methods for handling contact lenses.

If you experience any pain or continued discomfort, discontinue wear and consult an eye care professional immediately. Wearing contact lenses and the direct exposure of contact lenses to non-sterile water sources (e.g. tap water, bathing, showering, swimming, participating in waters sports etc.) severely increases the risk of microbial infection and permanent eye damage.

The use of non-sterile water (tap water, etc) in the handling of contact lenses and contact lens cases severely increases the risk of microbial infection and permanent eye damage.

Do not change contact lens care systems, lens types or parameters without first consulting an eye care professional. Improper handling and use of contact lens solutions can result in serious infection. Follow all instructions given by the manufacturer of the contact lens solution, making sure to disinfect lenses for the full contact time stated by the solution used.

#### Disposal of Contact Lenses

Contact lenses can be disposed of in standard waste. Contact lenses should NOT be flushed down the toilet, or disposed of down the sink. The preferred method of disposing of contact lenses is through a dedicated contact lens recycling program.

#### Side Effects

Examples of uncommon eye disorders that can be caused by Soft contact lenses

- Corneal oedema
- Corneal ulcer
- Keratitis (including infectious keratitis & acanthamoeba keratitis)
- Conjunctivitis
- Corneal Haemorrhaging
- Corneal Abrasion
- Corneal Neovascularization

#### Patient Target Group and Intended Users

Sterile Soft Lenses are prescribed by an eye care professional for your individual use.

Sterile Soft Lenses are intended to be used from ages 0 to 70+

#### Performance Characteristics of the Device

Performance Characteristics of the Device will be provided on the label.

#### Characteristics required of the Contact Lens Cleaning Solution, Protein Removal Substances and Contact Lens Case to be Suitable for use with the Lenses

Multi-purpose solution is recommended for Contact Lens Cleaning Solution.

- Compatible contact lens cleaning solutions:
- Ote Twins Active
- Avizor Unica Sensitive
- Any Protein Removal substances required will be advised by the Eye Care Professional along with recommended storage containers.

#### Serious Incident Statement

Any serious incident that has occurred in relation to the product should be reported to the manufacturer and applicable competent authority.



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