Package Insert

It is important to read this leaflet before inserting your soft contact lens. The information summarises the important points about the contact lens, however if you have any further questions, please speak to your Eyecare Professional.

The soft contact lens is made from a Silicone Hyrdrogel material and is for daily wear.

Important

Please read carefully and keep this information for future use. This package insert is intended for the eyecare practitioner but should be made available to the patient upon request. The eyecare practitioner should provide the patient with the wearer's guide that pertains to the patient's prescribed lens.

Description

The soft Silicone Hydrogel Contact Lenses are manufactured using the Definitive 74 material which in the dry (un-hydrated) state may be machined and polished. The hydrophilic nature of this material allows the lens to become soft and pliable when immersed in an aqueous solution.

Definitive 74 oxygen permeabilities are the highest available to manufacturers of lathe cut hydrogel materials. It has an exclusive blend of fluorosilicone and hydrophilic monomers and a significantly higher DK than conventional hydrogels which therefore provides improved corneal health. The polymer compositions have been optimised to ensure that the Definitive 74 material can be machined in the same manner as any other hydrogel material. It is a material that can produce excellent optical performance and on eye comfort.

The material properties are: Refractive Index Wet: 1.375 Light Transmission: 99% Surface Character: Hydrophilic Water Content: 74%

Oxygen Permeability (ISO): 60

The hydrophilic characteristics allow aqueous solutions to enter the lens and in its fully hydrated state the lens is approximately 74% water by weight.

Chord Diameter: 12.00 - 16.5mm Centre Thickness: 0.07 - 0.5 Base Curve: 6.0 - 10.6

Sphere Power: +/-25.00 in 0.12 steps **Cylinder Power:** -0.25 – 10.00 in 0.25 steps

Axis: 0-180 in 1.0-degree step
Add: 0 - +4.00 in 0.12 steps
Base Prism: 0.12 – 4.0

Indications and Wearing Instructions

This contact lens is indicated for daily wear for the correction of Binocular Vision Dysfunction.

These lenses are supplied for single patient use and are intended for scheduled replacement as instructed by your eye care professional.

Contraindications

Do not use the contact lenses in any of the following conditions:

- Acute and subacute inflammation or infection of the anterior chamber of the eye

- Any disease, injury or abnormality that affects the cornea, the conjunctiva, or eyelids.
- Severe lacrimal secretion (dry eyes).
- Corneal hypoesthesia (reduced corneal sensitivity)
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses.
- Allergic reactions or ocular surfaces or adnexa (surrounding tissue) that may be induced or exaggerated by wearing contact lenses or uses of contact lens solution.
- Any active corneal infection (bacterial, fungal, or viral).
- If eyes become red or irritated.
- Use of any medication that is contraindicated or interferes with contact lens wear, including ocular medications.
- incomplete corneal healing following eye surgery.

Warnings

You should be advised of the following warnings relating to contact lens wear.

- If the vial is damaged, opened or the parameters cannot be read do not wear the contact lenses – contact your Eye Care Professional immediately.
- Parameters of your contact lens is not to be changed unless you have consulted with your Eye Care Professional.
- Tap water, distilled water, homemade saline solutions, or saliva should NOT be used at any time with contact lenses. The use of tap and distilled water has been associated with Acanthamoeba keratitis, a corneal infection that is resistant to treatment and cure.
- Problems relating to contact lens wear can result in serious injury to the eye. It is imperative that the patient listens to their Eye Care Professional's recommendations and labelling instructions for appropriate use of the contact lens.
- Eye problems, including corneal ulcers can develop rapidly and lead to loss of vision.
- If eye discomfort, excessive tearing, vision changes or eye redness is experienced, immediately remove the lenses and promptly call your Eye care professional.
- Contact lenses are not to be stored in the lens case with water or any nonsterile solution. Only use fresh soft contact lens solution so it does not contaminate the lenses or lens case. Use of non-sterile solution can lead to severe infection, vision loss or blindness.

Precautions

- Do not use saliva or anything other than the recommended solutions for lubricating or wetting lenses.
- Only use solutions recommended for soft contact lenses.
- Contact lenses should never be shared between users.
- Always wash and rinse hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, deodorants, aerosol products or hair sprays in the eyes or on the lenses. It is best to put on lenses before putting on make-up. Waterbased cosmetics are less likely to damage lenses than oil-based products.
- Seek advice from your Eye Care Professional if your lens is to be stored for extended periods.
- Avoid all harmful or irritating vapours and fumes while wearing contact lenses.

Adverse Reactions

If any of the following problems occur:

- Eye stinging, burning, itching or other eye pain.
- Continuous foreign body or scratching sensation.
- Excessive tearing, unusual eye secretions, redness, reduced visual acuity, blurred vision, halos, photophobia, or dry eyes

Immediately remove your contact lens(es) and inspect it carefully. If the lens is damaged, place the lens in your contact lens case and call your Eye Care Professional. Do not re-insert the lens. If the lens appears undamaged and appears dirty, has an eyelash or other foreign body on it, thoroughly clean the lens, rinse, and disinfect before reinserting it. If the problem continues to occur, remove the contact lens, and consult your Eyecare Professional. Serious conditions such as infection, corneal ulcer, corneal vascularization, or iritis may be present, and may progress rapidly. Less serious reactions such as abrasions, epithelial staining or bacterial conjunctivitis must be managed and

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treated carefully to avoid more serious eye damage.

Always wash, rinse, and dry your hands thoroughly before touching your lens.

Caring for your lens:

Opening the vial

Do not use the lens if the vial is damaged or the parameters on the label cannot be read.

To open an individual vial

- 1. Screw the lid on the vial where you will find one soft contact lens.
- 2. Remove the contact lens carefully and look at the lens following the handling instructions.

Handling the lens

It is recommended to always work with the same lens first to avoid any mixups.

Remove the lens from the case and examine to make sure the lens is not chipped or there are any foreign bodies.

Placing the lens on the eye

Your Eye Care Professional will discuss and provide you with a detailed process for lens insertion, but a suggested procedure is as follows:

- **1.** Place the lens on the tip of your forefinger on your dominant hand, concave side up.
- 2. Put lubricant drops or saline in the lens before insertion.
- **3.** Hold your top eyelid open with your middle finger on your non-dominant hand and then the lower lid your middle finger on the other hand.
- 4. Make sure your lids are wide apart.
- 5. Slowly bring the lens up to the eye while looking straight ahead and then gently place the lens on the cornea. Do not press the lens against your eye. Release the eyelids and gently blink.
- 6. Repeat this procedure with the other lens.

Note: If your vision is blurred after lens insertions, check the following

- The lens is decentered. Look into the mirror to locate the lens then gently manoeuvre the edge of the de-centered lens on the cornea while the eye is open. Use the pressure of your finger on the edge of the upper or lower lid until the lens is centered.
- If the lens is centered, you may remove the lens to see the following:
- The surface is dirty.
- The lens is in the wrong eye.

If any of the above occurs, clean the lens and rinse with saline before reinserting it into the eye. If your vision is still blurred, remove the lens, and see your Eye Care Professional.

Removing the lens

- It is recommended to always remove the same lens first
- wash hands and dry your hands thoroughly
- Place a towel in front of use as this will be used to catch the contact lens.
- Place the fingertip of one hand on your upper eyelid.
- Place a fingertip of your other hand on your lower eyelid.

- Press your eyelids inwards toward your nose and then bring your eyelids together.
- The lens should fall out onto the towel.
- Repeat the same procedure for the other lens.

Caring for your lens

It is important to follow the lens care regime recommended by your Eye Care Professional. You will be provided with a recommended cleaning and disinfecting regime. Heat disinfection is not recommended.

- Never use care products recommended only for soft lenses.
- Do not use tap water for cleaning and the maintenance of your contact lenses and contact lens case.
- Do not use saliva or anything other than the recommended care products for cleaning, rinsing, and disinfecting, lubricating, or wetting your lenses.
- Always store your contact lenses completely immersed in contact lens solution when the lens(es) are not being used.
- Contact Lens case should be emptied, cleaned, and rinsed with care products recommended by your Eye Care Professional and air dried between being used.