

Qualis (Linofilcon A) Silicone Hydrogel Soft Contact Lens



sterile using steam / 38% water and 62% Linofilcon A

DESCRIPTION OF LENS

The Qualis (Linofilcon A) Silicone Hydrogel Soft Contact Lens is a hemispherical shell with a molded spherical base curve and a molded front surface. The hydrophilic characteristics allow aqueous solutions to enter the lens. The lenses are fabricated from Linofilcon A, which is a random co-polymer of silicone containing monomers and hydrophilic monomers. The lens consists of 62.0% Linofilcon A and 38.0% water by weight when immersed in saline solution. The Linofilcon A name has been adopted by the United States Adopted Names Council (USAN).

The Qualis (Linofilcon A) Silicone Hydrogel Soft Contact Lens contains C.I. Reactive Blue No. 19 for visibility and handling. The Qualis (Linofilcon A) Silicone Hydrogel Soft Contact Lens incorporates a benzotriazole UV blocking monomer to help protect against transmission of harmful UV radiation*. The lens blocks >95% in the UVB range (280nm - 315nm), and >50% in the UVA range (316nm - 380nm).

Qualis Lens parameter Available		Range
Diameter		13.5~15.0 mm
Base curve		8.0~9.5 mm
Power Range (D) Spherical Lens		+6.00D ~ +4.50D in 0.50D per step +4.00D ~ -6.00D in 0.25D per step -6.50D ~ -12.00D in 0.50D per step
Center Thickness		0.080 mm ~ 0.250 mm
Lens Physical/Optical Properties		
Water Content		38.0 %
Oxygen permeability (DK) ($\times 10^{-11}(\text{cm}^2/\text{sec})(\text{mlO}_2)/(\text{ml} \times \text{mmHg})$)		100
Refractive Index		1.415
Transmittance	Visible (380nm~780nm)	95%
	UVA(316nm~380nm)	Avg. < 50%
	UVB(280nm~315nm)	Avg. < 5%

Note: Long-term exposure to ultraviolet (UV) radiation is one of the risk factors associated with cataracts. Exposure is based on a number of factors such as environmental conditions (altitude, geography, cloud cover) and personal factors (extent and nature of outdoor activities). UV-blocking contact lenses help provide protection against harmful UV radiation. However, clinical studies have not been done to demonstrate that wearing UV-blocking contact lenses reduce the risk of developing cataracts or other eye disorders. Consult your eye care practitioner for more information.

INTENDED USE

Indicated for the correction of ametropia (myopia, hyperopia) in aphakic and/or non-aphakic persons with non-diseased eyes and 1.00 diopters (D) or less of astigmatism and aged over 18 years old.

THE EXPECTED CLINICAL BENEFITS AND PERFORMANCE CHARACTERISTICS

Contact lenses can help users achieve better and clearer vision with full field of view.

WARNINGS

Patients should be advised of the following warnings pertaining to contact lens wear:

- Store the lens at ambient temperature and away from direct sunlight.
- Do not use if the sterile blister package is opened or damaged.
- All contact lens wearers must see their eye care professional as directed. Adequate follow-up by an eye care professional is essential for the safe use of contact lenses.
- The safety of contact lenses depends upon proper use.
- Daily wear lenses are not indicated for overnight wear, and lenses should not be worn while sleeping. Clinical studies have shown that the risk of serious adverse reactions such as infection or permanent damage to vision is increased when these lenses are worn overnight.
- If any of eye discomfort, excessive tearing, blurred vision or vision changes, or redness of the eye are experienced, immediately remove the lenses and contact an eye care professional prior to resuming use.
- If the contact lens is a cosmetically tinted contact lens, visibility could be reduced in low light conditions. (only for colored lenses.)
- Strictly follow recommended DIRECTIONS FOR USE and lens care procedures as failure to do so can result in infection with possible permanent damage to vision.
- Do not allow tap water, home made solution or other non-sterile solutions (pool water) from what has been suggested for storing the lenses to come into contact with your lenses.
- **An eye care professional should be consulted prior to use in certain atmospheric or environmental conditions that can cause irritation to the eye.**
- Never wear your lenses when you're going to be around irritating vapors.
- If reusing daily contact lens that will be infected by microorganisms or blind.
- **An eye care professional should be consulted prior to wear lenses during sporting and water-related activities.**
- Exposure to water while wearing contact lenses in sporting activities, such as swimming, water skiing, and other water sports may increase the risk of eye infection from microorganisms. It is recommended that swimming goggles may prevent the contact lenses from coming into contact with water.
- Cleaning silicone lenses with a solution that was not designed specifically for this material may shorten the life and comfort of the lenses.
- When wearing contact lens keep away the chemical substance or after exposing to chemicals, remove the contact lens, rinse your eye and immediately seek a doctor.
- Inform your eye care professional on any changed or new use of medications. And you should consult the eye care professional before starting wearing contact lens again after disuse.

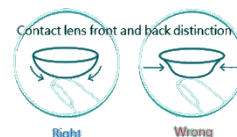
INSTRUCTION

1. Please remove and dispose of the lenses every day and use a fresh replacement contact lenses each day.
2. After using the contact lens, please put it into the trash can, do not throw it into the toilet or sink.

INSERTION AND REMOVAL TIPS

General tips:

- Hands should be washed and thoroughly rinsed before handling lenses.
- A soap which is free of oils, lotions or perfumes is recommended.
- Hands should be dried with a lint-free towel.
- Use finger tips to handle lens (avoid finger nails and sharp objects).
- Check lens is clean, wet and damage-free.
- The lens should appear as a bowl (Right). If the edge flares out, the lens is inverted (Wrong).



HOW TO INSERT YOUR LENSES

1. Place the wet, clean "right" lens on the tip of the index or middle finger of your dominant hand (if you're right-handed this would be your right hand) and pull down the lower lid with the middle or ring finger of the same hand. Use your other hand to hold the upper lid firmly open.

2. Look directly at the lens or look directly into a mirror and place the lens directly on the cornea (the large colored circle in the center of your eye).
3. Slowly release your hold on the lid. If there are any air bubbles beneath the lens, close your eye, and with the eye closed, roll the eye gently. Another way of getting rid of air bubbles is to massage the lids very lightly. Under no condition, however, should you rub your eyes.

REMOVING THE LENS

Look up. With middle finger, hold down lower lid. Use forefinger to slide lens to lower part of eye. Pinch lens with thumb and forefinger and remove without excessively folding the lens. Make sure that fingers are dry when removing the lens.

Attention: If the patient reports any problem, she or he should be instructed to IMMEDIATELY remove the lens. Then the patient should look closely at the lens and check it is damaged or not. If the problem continues, the patient should IMMEDIATELY consult her or his eye care professional.

MAINTENANCE

Always dispose of lenses when they are removed and have replacement lenses or eyeglasses available.

CONTRAINDICATIONS

Do not use UNICON lenses when any of the following conditions exist:

- Acute and sub-acute inflammation or infection of the anterior chamber of the eye.
- Any eye disease, injury, or abnormality that affects the cornea, conjunctiva, or eyelids.
- Severe insufficiency of 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 of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lenses.
- Any active corneal infection (bacterial, fungal, or viral)
- If eyes become red or irritated.
- The patient is unable to follow lens care regimen or unable to obtain assistance to do so.

WEARING SCHEDULE

For the first time user, please wear not to exceed 6 hours total and thereafter add 1~2 hour each day. Based on health considerations, the maximum suggested daily wearing time for the lenses is:

Day	Hours
1	4~6
2	6~8
3	8~10
4	10~12
5 and after	All waking hours

- Daily wear contact lenses are made to be worn during the day only and lenses should not be worn while sleeping.
- As with any contact lens, follow-up visits are necessary to assure the continuing health of the patient's eyes. The patient should be instructed as to a recommended follow-up schedule.

NOTE

- **Daily disposable** products are restricted for **single use**.
Daily lenses are not intended to be cleaned or disinfected for material and production-related reasons. An improper, repeated usage of daily contact lenses may result in severe, negative consequences for your eye health.
- After insertion of the lens, if your vision is blurred or changed, please check for the following:

1. Lens is not centered on the eye.
2. The lens is on the wrong eye.
3. The lens is inside-out.
4. The surface of lens is unclean.
5. Please dispose of the lens and apply a fresh lens every time.

EMERGENCIES

If chemicals of any kind (e.g. household products, gardening solutions, laboratory chemicals, etc.) are splashed into the eyes, patients should: **FLUSH EYES IMMEDIATELY WITH TAP WATER, THEN REMOVE LENSES PROMPTLY, IF POSSIBLE, AND IMMEDIATELY CONTACT THE EYE CARE PROFESSIONAL OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.**

REPORTING OF ADVERSE REACTIONS

All serious adverse experiences and adverse reactions observed in patients wearing Qualis (Linofilcon A) Silicone Hydrogel Soft Contact Lens or experienced with the lens should be reported to the competent authority of the Member State and/or following establishments:

EC REP Emergo Europe: Westervoortsedijk 60, 6827 AT Arnhem, The Netherlands.



EU IMPORTER: To be assigned.



No.16, Gongye E.9th Rd., Hsinchu Science Park,
Baoshan Township, Hsinchu County 30075, Taiwan
(R.O.C.).

CE₂₇₉₇

SYMBOLS KEY

The following symbols may appear on the label or carton.

SYMBOL	DEFINITION	SYMBOL	DEFINITION	SYMBOL	DEFINITION
	USE BY DATE (EXPIRATION DATE)		DO NOT USE IF PACKAGE IS DAMAGED		MANUFACTURER
	DO NOT REUSE		STERILE USING STEAM		UV BLOCKING
	BATCH CODE		CONSULT INSTRUCTIONS FOR USE	BC	BASE CURVE
	CAUTION	EC REP	AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY	DIA	CONTACT LENS DIAMETER
PWR	POWER IN DIOPTRIS		KEEP AWAY FROM SUNLIGHT	CE ₂₇₉₇	CE IDENTIFICATION NUMBER OF BSI
MD	MEDICAL DEVICE	UDI	UNIQUE DEVICE IDENTIFIER		SINGLE <i>STERILE</i> BARRIER SYSTEM
	IMPORTER	MFD	MANUFACTURE DATE		

Issue Date: **31 Jan, 2023 (revised)**