

PACKAGE INSERT
TYRO™-97 (hococon A) Rigid Gas Permeable Spherical, Aspheric, Toric and Bifocal Contact Lenses

IMPORTANT: PLEASE READ CAREFULLY AND RETAIN FOR FUTURE USE

This package insert is intended for the eyecare practitioner, but should be made available to patients upon request. The eyecare practitioner should provide the patient with the patient instructions that pertain to the patient's prescribed lens.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a licensed practitioner.

This Package Insert applies to all TYRO-97 (hococon A) Rigid Gas Permeable Spherical, Aspheric, Toric and Bifocal Contact Lenses.

DESCRIPTION: TYRO™-97 (hococon A) Rigid Gas Permeable Spherical, Aspheric, Toric and Bifocal Contact Lenses are available in spherical designs in the clear untinted or blue, green, blue-violet (onzure) and gray tinted varieties, and blue with UV-blocker. Each is a shell of the following dimensions.

Spherical Contact Lens:

Horizontal Lens Size: 6.5 mm to 11.50mm
 Base Curve: 6.50mm to 9.50mm
 Distance Powers: +12.00D to -20.00D
 Center Thickness: for low minus 0.05mm to 0.30mm
 for plus 0.10mm to 0.70mm

Aspheric Lens

Eccentricity 0 to 1.5
 Peripheral Curves 0.1 to 1.0mm

Toric Lens

Axis 1 to 180 degrees in 1 degree steps
 Cylinder power 0.50 to 4.00D

Translating Bifocal Contact Lens:

Horizontal Lens Size: 8.00mm to 10.50mm
 Base Curve: 6.50mm to 8.50mm
 Distance Power: +12.00D to -20.00D
 Add Power 1.00 to 4.00D

The lens material, hococon A, is a fluorosilicone acrylate copolymer with additional hydrophilic and crosslinking monomers. The blue tinted lenses contain D&C Green No. 6; the green lenses contain D&C Green No 6 and CI Solvent Yellow 18; the gray lenses contain D&C Green No 6, D&C Violet No. 2, and CI Solvent Yellow 18; the blue-UV lenses contain D&C Green No 6 and a UV absorber. The colorants are used in quantities approved for use in contact lenses and proportions required to obtain the desired color.

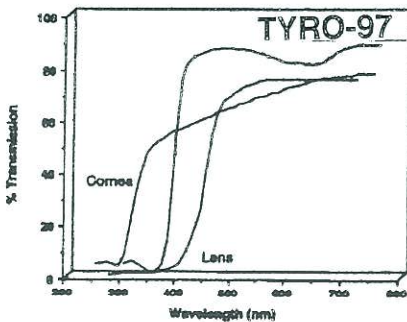
The physical properties of the lenses are as follows:

<u>Typical Property</u>	<u>Test Value</u>
Hardness	D/82(Shore Hardness Units)
Water Content	<0.2%
Wetting Angle	23.3.° (sessile drop method)
Oxygen Permeability	97 ANSI units
Dimensional Stability	Stable
Refractive Index	1.440
Specific Gravity	1.087
Light Transmission	Clear >95%T
	Blue >70%T*
	Green >70%T*
	Gray >70%T*
	Blue-UV >70%T* 400-780nm, 0% T 200-380nm

Mechanical(flexural strength) 3952 psi

*The wearer may experience a reduction in visibility while wearing the lens in conditions of low illumination.

The following graph compares the UV transmittance curve of the TYRO™-97 (hococon A) Rigid Gas Permeable Spherical, Aspheric, Toric and Bifocal Contact Lens, Blue-UV, 0.12mm thick) to that of the human cornea of a 24 year old person as described in Lerman, S., Radiant Energy and the Eye, MacMillan, New York, 1980, p.58, fig 2-21, and that of the human crystalline lens from a 25 year old, as described in Waxler, M., Hitchins, V.M., Optical Radiation and Visual Health, CRC Press, Boca Raton, Florida, 1986, p.19, fig 5.



Note: Long term exposure to 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-absorbing contact lenses help provide protection against harmful UV radiation. However, clinical studies have not been done to demonstrate that wearing UV-absorbing contact lenses reduces the risk of developing cataracts or other eye disorders. Consult your eye care practitioner for more information.

Warning: UV-absorbing contact lenses are **NOT** substitutes for protective UV-absorbing eyewear such as UV-absorbing sunglasses. Persons should continue to use their protective UV-absorbing eyewear as directed.

ACTIONS: The TYRO™-97 (hococon A) Rigid Gas Permeable Spherical, Aspheric, Toric and Bifocal Contact Lenses each, when placed on the cornea, acts as a refracting medium to focus light rays onto the retina.

INDICATIONS: The TYRO-97 (hococon A) Rigid Gas Permeable Spherical, Aspheric, Toric and Bifocal Contact Lens is indicated for daily wear for the correction of visual acuity in not-aphakic persons with non-diseased eyes that are myopic, hyperopic or presbyopic and which may exhibit corneal astigmatism. The lenses may be disinfected by using chemical disinfection only.

CONTRAINDICATIONS: **DO NOT USE** the TYRO™-97 (hococon A) Rigid Gas Permeable Spherical, Aspheric, Toric and Bifocal Contact Lens when any of the following conditions exist:

- * Acute or subacute inflammation of the cornea, the iris or the anterior chamber of the eye.
- * Any eye disease, injury, or abnormality that affects the cornea, conjunctiva or eyelids.
- * Insufficiency of lacrimal secretion (dry eyes).
- * Corneal hypesthesia (reduced corneal sensitivity)
- * Any systemic disease which 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 or use of contact lens solutions.
- * Allergy to any ingredient, such as mercury or thimerosal, in a solution which must be used to care for the TYRO™-97 (hococon A) lenses.
- * Any active corneal infection: bacterial, fungal or viral.
- * If eyes become red or irritated.

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

Problems with contact lenses and contact lens care products could result in serious injury to the eye. It is essential that patients follow their eye care practitioner's directions and all labeling instructions for proper use of lenses and lens care products. Eye problems, including corneal ulcers, can develop rapidly and lead to loss of vision.

Daily wear lenses are not indicated for overnight wear, and patients should be instructed not to wear lenses while sleeping. Clinical studies have shown that the risk of serious adverse reactions is increased when these lenses are worn overnight.

Studies have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than nonsmokers.

If a patient experiences eye discomfort, excessive tearing, vision changes, or redness of the eye, the patient should be instructed to immediately remove lenses and promptly contact his or her eye care practitioner.

ALL CONTACT LENS WEARERS MUST RETURN FOR PERIODIC CHECK-UP VISITS AS RECOMMENDED BY THEIR EYE CARE PRACTITIONER.

PRECAUTIONS: CAUTION: Non-sterile. Clean and condition lenses prior to use.

Special Precautions for Eyecare Practitioners:

* Due to the small number of patients enrolled in clinical investigations of lenses, all refractive powers, design configurations, or lens parameters available in the lens materials are not evaluated in significant numbers. Consequently, when selecting an appropriate lens design and parameters, the eyecare practitioner should consider all characteristics of the lens that can affect lens performance and ocular health, including oxygen permeability, wettability, central and peripheral thickness, and optic zone diameter.

The potential impact of these factors on the patient's ocular health should be carefully weighed against the patient's need for refractive correction; therefore, the continuing ocular health of the patient and lens performance on the eye should be carefully monitored by the prescribing eyecare practitioner.

Patients who wear aspheric contact lenses to correct presbyopia may not achieve the best corrected visual acuity for either far or near vision. Visual requirements vary with the individual and should be considered when selecting the most appropriate type of lens for each patient.

Before leaving the eyecare practitioner's office, the patient should be able to promptly remove lenses or should have someone else available who can remove the lenses for him or her.

Eyecare practitioners should carefully instruct patients about the following care regimen and safety precautions:

* Different solutions cannot always be used together and not all solutions are safe for use with all lenses. Use only recommended solutions.

- Do not heat the wetting/soaking solution and lenses. Keep away from extreme heat.
- Do not use heat or thermal lens care systems. Heat disinfection will damage the lens.
 - always use **fresh unexpired** lens care solution.

* **Always use a lens care system for your TYRO™-97 (hococon A) Rigid Gas Permeable Spherical, Aspheric, Toric and Bifocal Contact Lens which has been recommended for use with fluorosilicone acrylate contact lenses.**

- **CONVENTIONAL HARD CONTACT LENS SOLUTIONS ARE NOT INDICATED FOR USE WITH THE TYRO™-97 (hococon A) RIGID GAS PERMEABLE SPHERICAL, ASPHERIC, TORIC AND BIFOCAL CONTACT LENS**
- Always use **FRESH** rinsing and storage solutions.
 - Always follow directions in the package insert for the use of each contact lens solution.
- Sterile unpreserved solutions, when used, should be discarded after the time specified in the labeling directions.
 - Do not use saliva or anything other than the recommended solutions for lubricating or wetting lenses.
- Always keep the lenses completely immersed in a recommended storage solution when the lenses are not being worn (stored). Prolonged periods of drying will reduce the ability of the lens surface to return to a wettable state. Follow the lens care directions for Care for a Dried Out (Dehydrated) Lens if the lens surface does become dried out.

* If the lens sticks (stops moving) on the eye, follow the recommended directions on "Care For a Sticking Lens". The lens should move freely on the eye for the continued health of the eye. If non-movement of the lens continues, the patient should be instructed to immediately consult his or her eye care practitioner.

* Always wash and rinse hands before handling lenses. Do not get cosmetics, lotions, soaps, creams and deodorants in the eyes or on the lenses. It is best to put on lenses before putting on makeup. Water-base cosmetics are less likely to damage lenses than oil-base products.

* Do not touch contact lenses with the fingers or hands if the hands are not free of foreign materials, as microscopic scratches of the lenses may occur, causing distorted vision and/or injury to the eye.

* Carefully follow the handling, insertion, removal, cleaning, disinfecting, storing and wearing instructions in the Patient Instructions for the TYRO™-97 (hococon A) Rigid Gas Permeable Spherical, Aspheric, Toric and Bifocal Contact Lens and those prescribed by the eyecare practitioner.

* Never wear lenses beyond the period recommended by the eyecare practitioner.

* If aerosol products such as hair spray are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.

* Always handle lenses carefully and avoid dropping them.

* Avoid all harmful or irritating vapors and fumes while wearing your lenses.

* Ask the eyecare practitioner about wearing lenses during sporting events.