

Cosmetic Contact Lenses: Potential Threat to Vision Health

This statement applies to anyone who may consider getting contact lenses without a proper prescription and/or without proper contact lens care.

Summary:

Patients using cosmetic lenses dispensed by stores or websites without eye care professionals or prescriptions have experienced adverse events and complications, including vision loss and serious infections. Doctors, patients, and consumers should be aware that there is a federal statute stating that a contact lens seller cannot provide contact lenses to its customer without a valid prescription.¹ Stores or websites selling any contact lenses without requiring a prescription are engaging in illegal business activities that are subject to federal law enforcement—and the contact lenses may be counterfeit and not FDA-approved.

When contact lenses are initially prescribed and dispensed, patients should be trained and supervised in contact lens insertion and removal. Patients should be aware that all contact lenses, even decorative and costume contact lenses, are medical devices and require an eye doctor's prescription and supervision.²

Background:

The peer-reviewed literature includes reports of patients receiving cosmetic contact lenses from unauthorized vendors with eye pain and infections causing vision loss, including two patients requiring corneal transplantation.³⁻⁵ Another study showed that the relative risk of microbial keratitis related to contact lenses is significantly increased in patients wearing cosmetic contact lenses.⁶ In addition, these studies have noted that patients who acquire these cosmetic contact lenses are less likely to be educated on appropriate use and care.^{3,6} FDA evaluated over 300 cosmetic contact lenses and found that 60% of the counterfeit contact lenses and 27% of the unapproved contact lenses were found to have microbial contamination, and were a threat to consumer health and safety.⁷

The FDA and CDC have made recommendations for contact lens wearers regarding proper lens care practices, which are incorporated into the recommendations below:^{8,9}

- Wash hands with soap and water, and dry (lint-free method) before handling contact lenses every time.
- Do not sleep in your contact lenses unless instructed by your eye doctor.
- Never store your contact lenses in tap water, well water, or distilled water.
- Keep water away from your contact lenses. Take contact lenses out before showering, swimming, or using a hot tub.

- Rub and rinse contact lenses in disinfecting solution each time you remove them.
- Rub and rinse the case with contact lens solution, dry it with a clean tissue, and store it upside down with the caps off after each use.
- Do not top off solution. Use only fresh contact lens disinfecting solution in your case—never mix old and new solutions.
- Wear and replace contact lenses according to the schedule prescribed by your doctor.
- Follow the specific contact lens cleaning and storage guidelines from your doctor and the solution manufacturer.
- Keep the contact lens case clean and replace it every 3 months.
- Remove the contact lenses and consult your doctor immediately if you experience symptoms such as redness, pain, tearing, increased light sensitivity, blurry vision, discharge, or swelling.
- See your eye doctor yearly or as often as he or she recommends for contact lens examination.

These recommendations apply to contact lenses prescribed for refractive error and for contact lenses that alter the appearance of the eye.¹⁰⁻¹²

Recommendations:

The American Academy of Ophthalmology and the American Academy of Optometry encourage consumers to understand the risks of using unprescribed costume contact lenses. The risks include adverse events, such as corneal abrasions, corneal ulcers and infections, including even potentially vision-threatening infections. Contact lenses, including colored contact lenses, Halloween-inspired designs and other holiday designs, require a prescription and supervision by an eye care professional and should never be shared, just like regular contact lenses.

References:

1. Federal Trade Commission. Contact Lens Rule. 2016. www.ftc.gov/enforcement/rules/rulemaking-regulatory-reform-proceedings/contact-lens-rule. Accessed October 5, 2018.
2. U.S. Food and Drug Administration. Consumer Products. Decorative Contact Lenses. 2018. <https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM071578.pdf> Accessed October 5, 2018.
3. Steinemann TI, Pinninti U, Szczotka LB et al. Ocular complications associated with the use of cosmetic contact lenses from unlicensed vendors. *Eye Contact Lens* 2003; 29:196-200.
4. Steinemann TL, Fletcher M, Bonny AE et al. Over-the-counter decorative contact lenses: Cosmetic or Medical Devices? A case series. *Eye Contact Lens* 2005; 31:194-200.
5. Gagnon MR, Walter KA. A case of acanthamoeba keratitis as a result of a cosmetic contact lens. *Eye Contact Lens*. 2006; 32:37-8.

6. Sauer A, Bourcier T, French Study Group for Contact Lenses Related Microbial Keratitis. Microbial keratitis as a foreseeable complication of cosmetic contact lenses: a prospective study. *Acta Ophthalmol* 2011; 89:e439-42.
7. Land AD, Penno KL, Brzezinski JL. Identification of microorganisms isolated from counterfeit and unapproved decorative contact lenses. *J Forensic Sci* 2018; 63:635-9.
8. U.S. Food and Drug Administration. Consumer Health Information. Ensuring safe use of contact lens solution; 2009.
www.fda.gov/ForConsumers/ConsumerUpdates/ucm164197.htm. Accessed October 5, 2018.
9. Centers for Disease Control and Prevention. Healthy contact lens wear. 2016.
www.cdc.gov/features/healthy-contact-lens/. Accessed October 5, 2018.
10. U.S. Food and Drug Administration. Guidance for Industry, FDA Staff, Eye Care Professionals, and Consumers. Decorative, non-corrective contact lenses. November 24, 2006.
<https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM071578.pdf> Accessed October 5, 2018.
11. American Academy of Ophthalmology. Eye Health. Colored contact lenses; 2015.
www.aao.org/eye-health/glasses-contacts/colored-lenses. Accessed October 5, 2018
12. American Academy of Ophthalmology. Consult an Eye care professional if your Halloween costume includes scary eyes. 2018. <https://www.aao.org/newsroom/news-releases/detail/consult-eye-care-professional-if-your-halloween-co>
Accessed October 5, 2018

October 2018: Approved by the American Academy of Ophthalmology Secretary, Quality of Care and the American Academy of Optometry