

Focusing on Contact Lens Safety



PhotoDisc

FDA regulates contact lenses through the Federal Food, Drug, and Cosmetic Act.

More than 30 million Americans use contact lenses, according to the Contact Lens Council. In addition to offering flexibility, convenience, and a “no-glasses” appearance, “contacts” help correct a variety of vision disorders, including nearsightedness, farsightedness, astigmatism, and poor focusing with reading material.

But contact lenses also present potential risks. “Because they are worn directly on the eye, they can lead to conditions such as eye infections and corneal ulcers,” says James Saviola, M.D. He is the Ophthalmic and Ear, Nose and Throat Devices Network Leader in the U.S. Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH). “These conditions can develop very quickly and can be very serious. In rare cases, they can lead to blindness.”

Best strategies for reducing your risk of infection involve proper hygiene, following recommended wearing schedules, using proper lens care practices for cleaning, disinfecting and storing your lenses, and having routine eye exams.

FDA regulates contact lenses through the Federal Food, Drug, and Cosmetic Act. The agency also regulates contact lenses—including those intended for vision correction and for decorative purposes—as prescription devices, and has jurisdiction over contact lens solution.

The Federal Trade Commission (FTC) regulates device advertising and marketing practices that cause or are likely to cause substantial consumer injury.

Types of Contact Lenses

General categories

- **Soft Contact Lenses** are comfortable and made of flexible plastics that allow oxygen to pass through to the cornea. Users get accustomed to wearing

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them within several days. Most soft-contact wearers are prescribed some type of frequent replacement schedule. An example of this is a schedule that calls for the lenses to be replaced with new ones after two weeks of use.

- **Rigid Gas Permeable (RGP) Lenses** are durable, resist deposit buildup, and generally allow for clear, crisp vision. They last longer than soft contacts, and also are easier to handle and less likely to tear. However, they may take a few weeks of getting used to.

Other types

- **Extended Wear Contacts** are good for overnight or continuous wear ranging from one to six nights, or up to 30 days. It's important for the eyes to have a rest without lenses for at least one night following each scheduled removal.
- **Disposable (Replacement Schedule) Contacts.** To FDA, "disposable" means "to be used once and discarded." However, some soft contacts referred to as "disposable" by sellers are actually worn on a frequent replacement schedule—for two weeks, for example—that calls for them to be disinfected between uses.
- **Lenses Designed for "Ortho-K."** Orthokeratology (Ortho-K) is a lens-fitting procedure that uses specially designed RGP contact lenses to change the curvature of the cornea to temporarily improve the eye's ability to focus. It's primarily used for the correction of nearsightedness. The most common type is overnight Ortho-K, and FDA requires that eye care professionals be trained and certified before using them in their practices.
- **Decorative (Plano) Contacts.** FDA

has often warned people about the risks associated with wearing these lenses without appropriate professional involvement. They don't correct vision and are intended solely to change the appearance of the eye.

Getting a Prescription

When you get an eye exam, you have the right to get a copy of your prescription. You can then use it at another vendor or to order contact lenses on the Internet, over the phone, or by mail.

As per FTC regulations, a prescription should contain sufficient information for a seller to completely and accurately fill the prescription: examination date, date you received the prescription after a contact lens fitting, expiration date, and the name, address, phone and fax number of the prescribing professional.

The prescription should also offer information about material and/or manufacturer, base curve or appropriate designation, and diameter (when appropriate) of the prescribed contact lens.

Tips for Buying

With a valid prescription, it is possible to purchase contact lenses from stores, the Internet, over the phone or by mail. But be extremely cautious when buying contacts from someone other than your eye care professional.

Contact lenses are NOT over-the-counter devices. Companies that sell them as such are misbranding the device and violating FTC regulations by selling you contact lenses without having your prescription.

Avoiding problems

- Make sure your prescription is current. Don't order with an expired prescription, and don't stock up on lenses

right before the prescription is about to expire. If you haven't had your eyes checked within the last year or two, you may have eye problems that you are not aware of, or your lenses may not correct your vision well.

- Order from a supplier that you are familiar with and know is reliable.
- Request the manufacturer's written patient information for your contact lenses. It will give you important risk/benefit information and instructions for use.
- Beware of attempts to substitute a different brand than you presently have. There are differences in the water content and shape among the brands. The correct choice of which lens is right for you should be based only on an examination by your eye care professional.
- Make sure that you get the exact brand, lens name, power, sphere, cylinder (if any), axis (if any), diameter, base curve, and peripheral curves (if any) noted on the prescription. If you think you've received an incorrect lens, check with your eye care professional. Don't accept a substitution unless your eye care professional approves it.

Proper Care Required

Contact lens users run the risk of infections such as pink eye (conjunctivitis), corneal abrasions, and eye irritation. A common result of eye infection is corneal ulcers, which are open sores in the outer layer of the cornea. Many of these complications can be avoided through everyday care of the eye and contact lenses.

To reduce your chances of infection

- Replace your contact lens storage case every 3-6 months.
- Clean and disinfect your lenses properly.

- Remove your contact lenses before swimming.
- Never reuse any lens solution. Always discard all of the used solution after each use, and add fresh solution to your lens case.
- Avoid using non-sterile water (distilled water, tap water and homemade saline) on your lenses. It can be a source of microorganisms that may cause serious eye infections.
- Never use homemade saline solution, as tap and distilled water are not sterile.
- Never transfer contact lens solutions into smaller travel size containers. This can affect sterility and may also leave you open to accidentally applying a harmful liquid to your eyes.
- Never put your lenses in your mouth; saliva is not sterile.

“Also, any lenses worn overnight increase your risk of infection,” says Saviola.

“This is because contact lenses stress the cornea by reducing the amount of oxygen to the eye. They can also cause microscopic damage to the surface of the cornea, making it more susceptible to infection.”

Never ignore symptoms of eye irritation or infection that may be associated with wearing contact lenses. The symptoms include discomfort, excess tearing or other discharge, unusual sensitivity to light, itching, burning, gritty feelings, unusual redness, blurred vision, swelling and pain.

If you experience any of these symptoms

- Remove your lenses immediately and keep them off.
- Get in touch with your eye care professional immediately.
- Keep the lenses. They may help your eye care professional determine the cause of your symptoms.
- Report serious eye problems associated with your lenses

to FDA’s MedWatch reporting program.

Decorative Contact Lenses

Every year, the approach of Halloween heightens fears at FDA that consumers will harm their eyes with unapproved decorative contact lenses. These are lenses that some people use to temporarily change their eye color or to make their eyes look weird—perhaps giving them an “eye-of-the-tiger” look.

“Although unauthorized use of decorative contact lenses is a concern year-round, Halloween is the time when people may be inclined to use them, perhaps as costume accessories,” says Saviola.

The problem is not that people use decorative, non-corrective lenses. It’s that many go about it the wrong way, which is dangerous.

Prescription required

Just like their corrective counterparts, decorative contacts—sometimes called plano, zero-powered or non-corrective lenses—are regulated by FDA.

“What troubles us is when they are bought and used without a valid prescription, without the involvement of a qualified eye care professional, or without appropriate follow-up care,” says Saviola. “This can lead to significant risks of eye injuries, including blindness.”

FDA is aware that consumers without valid prescriptions have bought decorative contact lenses from beauty salons, record stores, video stores, flea markets, convenience stores, beach shops and the Internet.

Recent legislation has made it illegal to market decorative contact lenses as over-the-counter products.

Unauthorized contact lenses of all types present risks to the eye that include corneal ulcers, corneal abrasion, vision impairment, and blindness.


If you want decorative contacts

- Get an eye exam from a licensed eye care professional, even if you

feel your vision is perfect.

- Get a valid prescription that includes the brand and lens dimensions.
- Buy the lenses from an eye care professional or from a vendor who requires that you provide prescription information for the lenses.
- Follow directions for cleaning, disinfecting, and wearing the lenses, and visit your eye care professional for follow-up eye exams.

How to Report Problems

- If you find a Web site you think is illegally selling contact lenses over the Web, you should report it to FDA .
- If you don’t get the exact lenses you ordered, report the problem directly to the company that supplied them.
- To file a complaint about prescribing practices to FTC, use the FTC Consumer Complaint Form .
- Consumers should report any problems with decorative contact lenses to their local FDA office. Any adverse reactions experienced with the use of these products, and/or quality problems should also be reported to FDA’s MedWatch Program at www.fda.gov/medwatch. 

This article appears on FDA’s Consumer Health Information Web page (www.fda.gov/consumer), which features the latest updates on FDA-regulated products. Sign up for free e-mail subscriptions at www.fda.gov/consumer/consumerenews.html.

For More Information

Everyday Eyecare Tips
www.fda.gov/cdrh/contactlenses/eyecare.html

CDRH’s Contact Lenses Web Site
www.fda.gov/cdrh/contactlenses/index.html