



# **Ophthalmic Medical Devices and Risk Communications Joint Panel Meeting: Peroxide-based Contact Lens Care Products**

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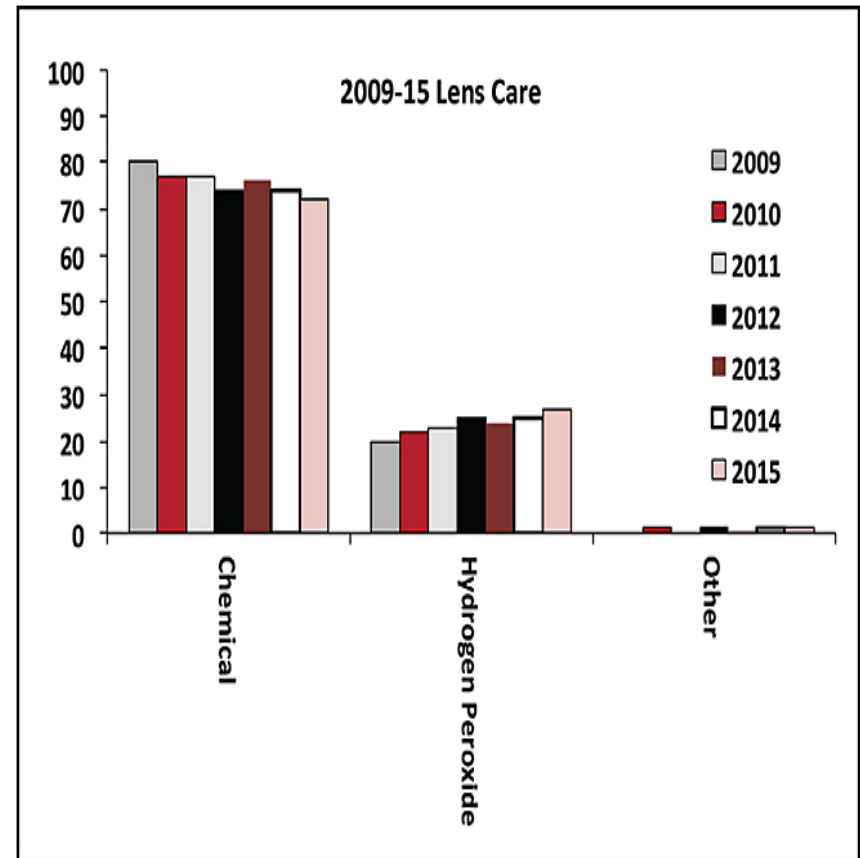
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# Hydrogen Peroxide Contact Lens Care Product History

- **Original approval was obtained by American Optical Corporation in 1983 under PMA P820040**
  - for the SEPTICON" Disinfection System for use in disinfecting the SOFTCON' (vifilcon A) Contact Lens,
  - SEPTICON" Disinfection System consists of:
    - LENSEPT® Sterile Disinfection Solution (3% H<sub>2</sub>O<sub>2</sub>),
    - the SEPTICON' Disc,
    - the SEPTICON' Cups
- **Since the first peroxide based contact lens care product entered the market these products were down classified to Class II in 1997 and other peroxide care products were introduced into the marketplace**

# Lens Care Trends<sup>1</sup>

- **Approximately 41 million US CL wearers<sup>2</sup>**
- **72% of contact lens wearers use a multipurpose chemical system for cleaning and disinfection.<sup>1</sup>**
- **27% of contact lens wearers use hydrogen peroxide based systems for cleaning and disinfection.<sup>1</sup>**



1. Jason J. Nichols, OD, MPH, PhD, FAAO. Contact Lenses 2015 Strong growth in some segments and a few surprises highlight a year of modest gains overall. Contact Lens Spectrum. January, 2016.

2. Cope JR, Collier SA, Rao MM, et al. Contact lens wearer demographics and risk behaviors for contact lens-related eye infections—United States, 2014. MMWR Morb Mortal Wkly Rep 2015;64:865–70. <http://dx.doi.org/10.15585/mmwr.mm6432a2>

# Characteristics of Hydrogen Peroxide Contact Lens Solutions

- **Contact lens care products are formulated to clean and disinfect contact lenses by breaking up and removing trapped debris, protein, and lipid deposits**
- **Multipurpose solutions (MPS) include both a rub-and-rinse step prior to placing the contact lenses in the case containing the MPS for a disinfection cycle**
- **Peroxide care products do not include a rub-and-rinse step because the 3% hydrogen peroxide solution is adequate for loosening debris**
- **Preservative-free – useful for individuals allergic or sensitive to preservatives found in multipurpose solutions**

# Contact Lens Consumer Behaviors

- **80% of complications are due to deficient compliance with wear/maintenance care<sup>1</sup>**
- **Wearer's perception of own behavior is essential to minimizing and/or preventing complications**
- **Noncompliance ranges from 50% to 79%<sup>2,3</sup>**

<sup>1</sup> Ky W., Scherick K., Stenson S.: Clinical survey of lens care in contact lens patients. *CLAO* 1998; 24: 4: 216-219

<sup>2</sup>De Oliveira PR, Temporini-Nastari ER, Ruiz Alves M, Kara-Jose N. Self-evaluation of contact lens wearing and care by college students and health care workers. *Eye Contact Lens*. 2003 July;29(3):164-7.

<sup>3</sup>Davidson, Si, Akingbehin T. Compliance in Ophthalmology. *Trans Ophthalmol soc UK* 1980;100:286-290.

# Factors Affecting Contact Lens Compliance<sup>1</sup>

- **Complexity of treatment**
- **Frequency and duration**
- **Cost of regimen/treatment**
- **Nature of the Condition**
  - There is a higher incidence of noncompliance in conditions that are asymptomatic, prophylactic, or suppressive in nature

<sup>1</sup>Donshik PC, Ehlers WH, Anderson LD, Suchecki JK. Strategies to better engage, educate, and empower patient Compliance and safe lens wear: compliance: what we know, what we do not know, and what we need to know. Eye Contact Lens. 2007 Nov;33(6 Pt 2): 430-3; discussion 434.

# Contact Lens Compliance Study

## Findings

- **54% considered themselves poor wearers<sup>1</sup>**
  - inadequate cleaning of lenses or case (44%)
  - noncompliance with medical orientation (15%)
- **Contact lens care procedures<sup>1</sup>**
  - 79% failing in implementation of procedures
  - 30% poorly prepared for cleaning and maintenance awareness
- **91% of patients failed in following at least one procedure regarding the use of a multipurpose solution, despite the ease of use<sup>2</sup>**

<sup>1</sup>De Oliveira PR, Temporini-Nastari ER, Ruiz Alves M, Kara-Jose N. Self-evaluation of contact lens wearing and care by college students and health care workers. *Eye Contact Lens*.2003;29(3):164-7.

<sup>2</sup>Turner FD, Stein JM, Sager DP, et al. A new method to assess contact lens care compliance. *CLAO J* 1993;19:108-113

# Compliance Critical for Peroxide Care Products

- **A special case to allow neutralization**
  - Equipped with an attached metallic neutralization disc, is provided with each bottle of peroxide based contact lens cleaning and disinfecting solution
  - Or, a neutralization tablet must be added to the case
- **Cannot be used to rinse lenses prior to insertion**
  - Direct exposure of the eye to peroxide can be toxic to the corneal epithelium and even more so to a slightly compromised corneal epithelium after contact lens wear



# Hydrogen Peroxide Disinfecting Process

- **Either a one-step or two-step process**
  - One-step process - neutralizes lenses during the disinfecting stage
    - storage cases have a neutralizing metallic disc built into the case
  - Two-step process - a neutralizing tablet must be added
- **Some of these products include the option of a final rinse with saline at the completion of the disinfection cycle**

# Sample Directions for Use

## One Step Process

- Place lenses in the baskets in the special case provided.
- Rinse (squirt) each lens for several seconds with the Brand X over a sink or basin.
- Fill the lens case up to the line with Brand X. Do not invert or shake case.
- Let the lenses soak in the case for 4/6 hours depending on brand.
- Remove lenses and use.

## Two Step Process

- Place lenses in the baskets in the special case provided.
- Fill the lens case up to the line with Brand X.
- Place one neutralizing tablet into the solution and immediately place the lens holder containing the lenses into the case. Tighten the cap.
- Turn the case upside down/right side up 3 times. Brand X neutralizing tablet will color the solution.
- Soak lenses for a minimum of 6 hours
- Turn case upside down to verify neutralization has occurred (no bubbles)
- Rinse lenses with saline & wear

## Safe Use & Misuse

- **Safety and effectiveness of peroxide-based contact lens care products when used as directed have been well established for over 30 years**
- **The number of adverse event reports related to misuse of these products has been increasing**

# FDA & Industry Actions

- **Signal raised in 2009 ISMP (Institute for Safe Medical Practice)**
- **Addressed by an internal working group in conjunction with industry**
- **2010, FDA recommended modified labeling, assessment of consumer responses to the labeling changes through structured focus groups**
- **The first modified labeling began entering the market in Summer of 2011**

# Misuse = Adverse Events

- **3 most common sources of misuse of hydrogen peroxide based contact lens care products:**
  - **Accidental Use**
    - While at a friend/relatives home
    - Mistaking bottles on the bathroom sink as saline
  - **Failure to follow the specific directions on the box & bottle for neutralization**
    - Assuming that peroxide care solutions are the same as multipurpose solutions (MPS)
  - **Erroneous purchase**
    - Cartons are indistinguishable from MPSs



# FDA's Strategies to Enhance Safe Use of Peroxide Care Products

- **Labeling**
  - Carton
  - Bottle
- **Education**
  - Patient
    - Publications
    - Website

# Carton Labeling Strategies





Brand X

Contents: -----

Directions: -----



Warnings:

-  Do not use a flat lens case. only works with the special lens case provided.
-  Do not remove lenses from case until at least 6 hours later. The solution needs time to neutralize.
-  Do not rinse lenses with prior to inserting lenses into your eyes. If you want to rinse lenses, use a sterile saline.
-  Do not squirt directly into your eyes.

Exp. date

**\*Important. Warnings**

Brand X

Contents: -----

Directions: -----




Warnings:


-  Do not use a flat lens case. only works with the special lens case provided.
-  Do not remove lenses from case until at least 6 hours later. The solution needs time to neutralize.
-  Do not rinse lenses with prior to inserting lenses into your eyes. If you want to rinse lenses, use a sterile saline.
-  Do not squirt directly into your eyes.


Exp. date


# Carton Labeling Strategies (enlarged view)

**WARNINGS:**

- 

Do not use a flat lens case.  
This solution only works with the special lens case provided.
- 

Do not remove lenses from case until at least 6 hours later. The solution needs time to neutralize.
- 

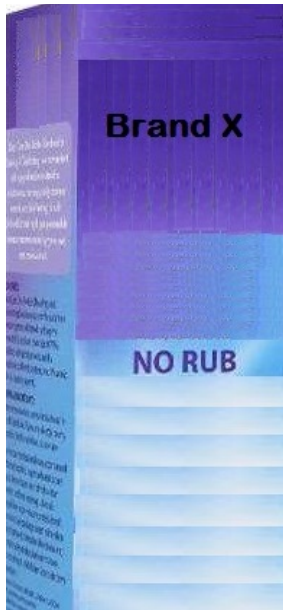
Do not rinse lenses with **this solution** prior to inserting lenses into your eyes. If you want to rinse lenses, use a sterile saline.
- 

Do not squirt **solution** directly into your eyes.



# Carton Labeling Strategies

Old Carton



New Carton



The phrase "NO RUB" has been removed so that it would not be confused with other products portraying the "No Rub" label.

# Bottle Labeling Strategies

## Prior Warnings on Collar

- Misuse will result in burning and stinging
- Use only Lens Case Provided
- Red tip means do not put this solution directly in your eye
- Do not rinse lens with this solution prior to insertion in your eye

## Collar Warnings Ring Top of bottle



# Bottle Strategies

- The bottle already had a red tip to identify it as different from other care products.
- The cap was subsequently changed to bright red.



# Carton & Bottle Summary Changes

- “No Rub” was removed from the Carton Labeling
- Use only the lens case provided
- Only use the special Lens case for disinfection and neutralization
- DO NOT use flat lens case
- Brand X only works with the special lens case provided
- Specific safety instructions in bold font and red boxes

# Education: Publication

## Contact Lens Solutions With Hydrogen Peroxide: To Avoid Injury, Follow All Instructions (FDA Consumer: April, 2016)

- Provides the following summary points



### Checklist for Solutions With Hydrogen Peroxide

- ✓ Talk to your eye-care provider before deciding on the best cleaning and disinfecting method for your contact lenses. Never change your lens-care system before consulting your provider.
- ✓ Before you use a new solution, read all instructions on the box and bottle and follow them carefully. If you have questions, stop and contact your eye-care provider.
- ✓ Never share solution that contains hydrogen peroxide. Other people might confuse your solution with multipurpose solution and not follow instructions. This could result in damage to their eyes.
- ✓ Always use the special contact lens case that comes with each new bottle of solution. Never use a case other than the one that comes with each new bottle. (An old case would not neutralize the peroxide, which would cause burning, stinging and irritation when you put contacts in your eyes.)
- ✓ Leave contacts in the solution for at least 6 hours to allow the neutralizing process to finish.
- ✓ Never rinse your contact lenses with hydrogen peroxide solutions or put these solutions in your eyes.
- ✓ Report any eye problems with your contacts or solution to the FDA's MedWatch (<https://www.accessdata.fda.gov/scripts/medwatch/>) voluntary reporting program.

# Education: Website

- <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/HomeHealthandConsumer/ConsumerProducts/ContactLenses/ucm482480.htm>

The screenshot shows the FDA website's page for Hydrogen Peroxide Solution. The header includes the FDA logo and navigation links. The main content area is titled "Hydrogen Peroxide Solution" and includes a "Print this page" button. The text explains that hydrogen peroxide and multipurpose solutions both disinfect contact lenses by breaking up and removing trapped debris, protein, and fatty deposits (lipids). Unlike multipurpose solutions, hydrogen peroxide solutions are preservative-free, which makes them a suitable option for those who are allergic or sensitive to the preservatives found in multipurpose solutions. They are not risk-free, however, and should be used with appropriate cautions.

**How to use Hydrogen Peroxide correctly**

Hydrogen peroxide placed directly into the eyes or on your contact lenses can cause stinging, burning, and temporary corneal damage. When using hydrogen peroxide you must follow the disinfecting process with a neutralizer. The neutralizer turns the peroxide into water and oxygen, making it safe to put your lenses back into your eyes.

Neutralization can be either a one-step or two-step process. The one-step process neutralizes your lenses during the disinfecting stage, while the two-step process neutralizes your lenses after the disinfecting stage.

The image shows a contact lens case with a "Neutralization Disc" and a "Lens" being placed into it.



Always consult your eye-care provider before deciding on the best cleaning and disinfecting method for your lenses. Never change your lens-care system before consulting your eye care provider.

## Tips for Using Hydrogen Peroxide Contact Lens Solutions Safely

- Before you use a new contact lens solution, **READ ALL THE INSTRUCTIONS LISTED ON THE BOX AND BOTTLE AND FOLLOW THEM CAREFULLY.**
- Be sure to use the special contact lens case that comes with your hydrogen peroxide contact lens solution. **NEVER** use any case other than the one that comes with every new bottle. Do **NOT** use the old case when you get a new bottle of peroxide based contact lens solution. If you do, it will not neutralize the peroxide and it will cause burning, stinging and irritation when you put your contacts in your eyes.
- Be sure to leave your contacts in the solution for **at least 6 hours** to allow the neutralizing process to finish.
- The red tip on the solution bottle is a reminder that these products require special handling. **NEVER** rinse your lenses with hydrogen peroxide solutions or put hydrogen peroxide solutions in your eyes. You will experience burning, stinging and irritation.
- **DO NOT** allow friends and house guests to use your hydrogen peroxide solution because they may confuse this with multipurpose solution and not use it according to the specific instructions for hydrogen peroxide solution. This could result in stinging, burning and even damage to their eyes.

# Summary Statements

- Consumers have reported numerous adverse events – burning and stinging to FDA
- Consumers believe that the packaging is too similar to other contact lens care products resulting mistaken purchases and/or misuse of the product
- Consumers do not notice the warnings related to the directions for use on the carton and/or the bottle
- Despite updated and enhanced labeling instructions, use errors resulting in adverse events continue



# Objectives of Today's Panel Meeting

- To engage FDA, industry, and consumers to assess the adequacy of existing labeling instructions and packaging for peroxide based contact lens care solutions
  - Allowing industry to hear about the problems experienced by the consumers and hear their recommendations for making the packaging and labeling more user friendly
- To obtain panel recommendations regarding the labeling and packaging of peroxide-based contact lens care products





*Thank you for your attention!*