The Realities of Hydrogen Peroxide Lens Care
Use & Misuse in Today's Marketplace

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CLEAR CARE® Hydrogen Peroxide System:

- Contact lens disinfecting systems use a 3% Hydrogen Peroxide solution
- Hydrogen peroxide systems have been marketed for over 30yrs in the US
- Contact lens case is provided with every box of CLEAR CARE®/CLEAR CARE® PLUS
  - Platinum disc neutralizes the peroxide into a gentle saline solution
  - Directions for Use advise to dispose of lens case with each new purchase
Residual Peroxide Levels - Literature Review

• 1988- Chalmers & McNally reported that human subjects reported **mild discomfort at peroxide levels of >250 ppm** when used in conjunction with contact lenses

• 2011- Konyenbelt et al reported that at levels of 0.01% (100 ppm) none of their clinical evaluations of their in-vitro model detected significant peroxide damage, and that **at levels of 0.02% (200 ppm) some patients reported mild stinging upon insertion. Only at levels of 0.04% (400ppm) and higher was there conjunctival hyperemia observed, and that the damage was transient and reversible.**

• 2015- Chen et al reported that the range of residual peroxide with CLEAR CARE, from 1 to 100 cycles at 6hrs of neutralization was between 5 and 20ppm

H$_2$O$_2$ Share Of Lens Care Ounces Sold Has Grown 50% Since 2009

Source: Nielsen xAOC 2009-2016 Last 4 wk period by year
Total CLEAR CARE® Represents 84% of Total H$_2$O$_2$ Ounces Sold

Chemical Disinfectant Ounce Share (Last 4 Week Period by Year)

Source: Nielsen xAOC 2009-2016 Last 4 wk period by year
Examples of Peroxide Brands Recently Marketed in the US

• Alcon CLEAR CARE®/CLEAR CARE® PLUS
• AMO Oxysept
• Examples of Private Label Brands
  – Up & Up
  – Equate
  – CVS
• Alcon does not manufacture Private Label Brands
Peroxide provides unique benefits

• Unsurpassed cleaning and disinfection
  – Standard Organisms & Clinical Isolates [Gabriel BCLA 2015; Mowrey-McKee ECL 2007]
  – *Acanthamoeba* [Johnston *J Clinical Microbiology* 2009; Hughes *Antimicrobial Agents & Chemotherapy* 2001; Gabriel BCLA 2015]
  – Biofilms [Szczotka-Flynn *Cornea* 2009; Szczotka-Flynn OVS 2010]

• Preservative free
  – Important for sensitive patients [Lievens OVS 2016; Maissa BCLA 2013]
    • No corneal staining
    • No loss of biocidal activity
Additional Benefits of CLEAR CARE®

• In a survey of over 9000 contact lens wearers, CLEAR CARE® users reported better overall lens care compliance when compared with MPS users¹
  – 4x less likely to top off solution
  – 7x more likely to replace lens case
  – Return more often for routine exams

• CLEAR CARE® has a higher level of repurchase loyalty and satisfaction than any other lens care brand²,³

Why do Eye Care Practitioners Like CLEAR CARE® Cleaning & Disinfecting Solutions?

- No preservatives
- Powerful cleaning
- One-step process
- Indicated for use with SCL and GP lenses
- Recommended by eye care professionals for over 10 years\(^1,2\)
- Promotes patient compliance\(^3\)
- Most loyal patients of any lens care brand\(^3\)

Alcon CLEAR CARE®: Patient Education Tools

In ECP Offices
• Instructions for use
• Warnings

Contact Lens Fitting Education Table Mat

Consumer Brochure
Alcon CLEAR CARE®: Consumer Education Tools

CLEARCARE.com
- Instructions for use
- Warnings

Consumer Videos On How To Use CLEAR CARE® and To Educate On Differences from MPS

Examples of Social Media Posts
CLEAR CARE® Peroxide Labeling & Packaging Evolution

Warnings with increasing prominence added through the years
CURRENT CLEAR CARE® PLUS BOTTLE
CURRENT CLEAR CARE® PLUS BOTTLE LABEL AND BOTTLE
IMPORTANT: MISUSE WILL RESULT IN BURNING AND STINGING
• USE ONLY LENS CASE PROVIDED • NEVER RINSE LENS WITH PRODUCT PRIOR TO INSERTION
• RED SNAP CAP MEANS PRODUCT IS NOT FOR DIRECT USE ON EYE
CURRENT CLEAR CARE® PLUS BOTTLE LABEL

WARNINGS
NOT FOR DIRECT USE ON EYE

If non-neutralized CLEAR CARE® PLUS gets into your eyes it will cause burning and stinging. Remove your contact lenses immediately and flush eyes with a large amount of water or sterile saline. Seek immediate assistance from an eye care professional.

- Never put non-neutralized CLEAR CARE® PLUS directly into your eye.
- Never rinse your contact lenses with CLEAR CARE® PLUS before you put them in your eyes. If you want to rinse your lenses, use sterile saline.
- Do not use a flat lens case. Only use CLEAR CARE® PLUS with the special lens case provided.
- Do not remove lenses from the lens case for at least 6 hours. The solution needs time to neutralize.
CURRENT CLEAR CARE® PLUS BOTTLE LABEL

ESSENTIAL STEPS FOR CLEANING AND DISINFECTION:
To ensure proper cleaning and disinfection of your lenses, you must follow the instructions completely. Do not skip any steps. Always wash, rinse and dry your hands before handling your lenses.

1. Remove and place each lens into the appropriately marked L/R domed lens holder. Thoroughly rinse with CLEAR CARE® PLUS for 5 seconds.
2. Fill the CLEAR CARE® PLUS lens cup to the fill line with CLEAR CARE® PLUS and place the lens holder in the lens cup. DO NOT UNDERFILL OR OVERFILL.
3. Tighten the cap on the CLEAR CARE® PLUS lens cup and store lenses for at least 6 hours. DO NOT SHAKE THE CASE.

YOUR LENSES ARE READY TO WEAR AFTER SOAKING FOR AT LEAST 6 HOURS.
ALWAYS USE THE NEW LENS CASE PROVIDED WITH EACH NEW PURCHASE OF CLEAR CARE® PLUS AND THEN DISPOSE OF YOUR OLD LENS CASE.
CURRENT CLEAR CARE® PLUS BOX LABELING

FOR FULL PRODUCT USE AND SAFETY INFORMATION IT IS ESSENTIAL TO READ THE ENCLOSED INSTRUCTIONS FOR USE. ALWAYS FOLLOW THE ENCLOSED INSTRUCTIONS. ONLY USE THE PROVIDED LENS CASE. DO NOT USE ANY OTHER LENS CASE. See bottom of carton for LOT NUMBER AND EXPIRATION DATE. TAMPER EVIDENT: Do not use if safety seal around the bottle cap is broken or missing or if the bottle or lens case is damaged.
DO NOT USE FLAT LENS CASE. USE ONLY THE CLEAR CARE® PLUS LENS CASE PROVIDED.
CURRENT CLEAR CARE® PLUS BOX LABELING

ESSENTIAL STEPS FOR CLEANING AND DISINFECTION:
To ensure proper cleaning and disinfection of your lenses you must follow the instructions completely. Do not skip any steps. Always wash, rinse and dry your hands before handling your lenses.

1. Remove and place each lens into the appropriately marked L/R domed lens holder. Thoroughly rinse with CLEAR CARE® PLUS for 5 seconds.

2. Fill the CLEAR CARE® PLUS lens cup to the fill line with CLEAR CARE® PLUS and place the lens holder in the lens cup. DO NOT UNDERFILL OR OVERFILL.

3. Tighten the cap on the CLEAR CARE® PLUS lens cup and store lenses for at least 6 hours. DO NOT SHAKE THE CASE.

YOUR LENSES ARE READY TO WEAR AFTER SOAKING FOR AT LEAST 6 HOURS.
ALWAYS USE THE NEW LENS CASE PROVIDED WITH EACH NEW PURCHASE OF CLEAR CARE® PLUS. DISPOSE OF YOUR OLD LENS CASE.

Always follow your eye care professional’s instructions. Please refer to the package insert printed on the inside of this carton for detailed directions and important safety information. Keep CLEAR CARE® PLUS out of reach of children. Store at room temperature. Once bottle is opened, discard any remaining solution after 3 months of first opening.

WARNINGS
NOT FOR DIRECT USE ON EYE
If non-neutralized CLEAR CARE® PLUS gets into your eyes it will cause burning and stinging. Remove your contact lenses immediately and flush eyes with a large amount of water or sterile saline. Seek immediate assistance from an eye care professional.

- Never put non-neutralized CLEAR CARE® PLUS directly into your eye.
- Never rinse your contact lenses with CLEAR CARE® PLUS before you put them in your eyes. If you want to rinse your lenses, use sterile saline.
- Do not use a flat lens case. Only use CLEAR CARE® PLUS with the special lens case provided.
- Do not remove lenses from the lens case for at least 6 hours. The solution needs time to neutralize.
• Important instructions highlighted in red
DIRECTIONS FOR USE:

Never put CLEAR CARE® PLUS on your lenses and insert directly into the eye. Otherwise, burning and stinging will result. If spillage occurs, clean up immediately with a paper towel. Wash, rinse and dry your hands before handling your lenses or touching your eyes.
The red snap cap and dropper tip means that this product is NOT FOR DIRECT USE ON EYE.

DO NOT PUT CLEAR CARE® PLUS THAT HAS NOT BEEN NEUTRALIZED IN YOUR EYE OR USE TO RINSE LENSES. Lenses must be soaked in the provided lens case for at least 6 hours (neutralization process) prior to insertion. OTHERWISE, BURNING AND STINGING WILL RESULT.
DO NOT REUSE OR “TOP OFF” CLEAR CARE® PLUS IN YOUR LENS CASE. Use only fresh solution to clean and disinfect contact lenses on every cleaning occasion.

DO NOT USE A FLAT LENS CASE. Only use the provided lens case with CLEAR CARE® PLUS for disinfection and neutralization.

NEVER clean or rinse your contact lenses in your hands with CLEAR CARE® PLUS. A mild, temporary skin discoloration (bleaching) of the fingers or hands may result from contact with non-neutralized solution. Always wash and rinse your hands after exposure.
If the discomfort or problem stops and the lenses appear to be undamaged, repeat the cleaning, disinfection and neutralization process and reinsert the lenses. Do not put non-neutralized solution in your eyes or burning and stinging will result.
If the lens is not damaged but has dirt, an eyelash, or other foreign body on it, repeat the cleaning, disinfection and neutralization process and reinsert the lens. Do not put non-neutralized solution in your eyes or burning and stinging will result.
Alcon US Complaint Rate (CPM): All CLEAR CARE® Burning/Stinging with Misuse Error
2016 MAUDE Summary: All Peroxide Associated Complaints

- 444 complaints related to any hydrogen peroxide use registered in MAUDE in 2016
- 73% (n=325) of complaints were associated with a single H₂O₂ product recently recalled with 9% H₂O₂ market share*
- Alcon CLEAR CARE® had 16% (n=74) of complaints with 76% H₂O₂ market share*

* Nielsen xAOC June 2016
Complaint rates are low for Alcon CLEAR CARE®
Summary

• Alcon remains committed to evaluating labeling changes that have the potential to improve consumer safety
  – Alcon would like to explore reducing text and using more graphics to make important information easily understandable

• Alcon will carefully consider recommendations from the Advisory Panel

• Alcon is committed to the safety and effectiveness of CLEAR CARE®