

CLI

Contact Lens Institute

Alcon

CIBA Vision

AMO

CooperVision

Bausch & Lomb

Johnson & Johnson

Contact Lens Institute

- **Current CLI Efforts**
- **Acanthamoeba Testing**
- **SiHy Material Groupings**
- **Product Labeling**
- **Postmarket Surveillance**

Ongoing CLI Efforts

- **AEEMC Disinfection Efficacy Test Method**
 - Assess Solution/Lens/Lens Case System
 - New Parameters
- **Other ISO/ANSI Standard Activities**
 - Update Current Disinfection Efficacy Standard ISO 14729
 - Cytotoxicity Test Sample Preparation
 - Kinetics of Preservative Uptake and Release by Lens
 - Contact Lens Storage Cases

Acanthamoeba Testing

- **Appropriate Addition to the Evaluation of Safety and Efficacy of These Products**
- **Recommend Reprioritizing Work Items Within the ANSI and ISO Working Groups**
- **Develop Standard Test Method**
 - **Testing Procedure**
 - **Specific Organisms**
 - **Evaluation Criteria**
- **Revised Labeling**
 - **Eliminated Tap Water from Lens Care Regimens**
 - **Practitioner Advice for Water Related Activities**

Silicone Hydrogel Materials

- **Acknowledge SiHy Materials are Different**
- **Data Collection Phase**
- **Interim 4 Groups Based on Manufacturing Technology**

Silicone Hydrogel Materials

Group i

- CIBA Vision NIGHT & DAY (lotrafilcon A)
- CIBA Vision O₂Optix (lotrafilcon B)

Group ii

- Bausch & Lomb PureVision (balafilcon A)

Group iii

- J&J ACUVUE ADVANCE (galyfilcon A)
- J&J ACUVUE OASYS (senofilcon A)

Group iv

- CooperVision Biofinity (comfilcon A)
- CooperVision Avaira (enfilcon A)

Product Labeling

- **Recommend Adding a Standard Caution to Reinforce Importance of Compliance**
 - **Topping Off/Reuse of Solution**
 - **No Tap Water**
- **Class Labeling – Directions for Use**
 - **Could Mandate Steps Not Necessary for Safe and Effective Use**
 - **Impede Innovation**
- **Labeling Statements and Claims Based on Sound Science**

Postmarket Surveillance & Responsiveness

- **Sightnet**
- **Medical Device Reporting**
- **Adverse Event Reporting for Clinical Trials**