**FDA Standard Content Version**

**Define 1-Day ACUVUE Brand Contact Lenses**

**Generated from J&J Labeling (August 2014)**

“Cover” page includes the following:

Define 1-Day ACUVUE Brand Contact Lenses with Lacreon

etafilcon A Soft (hydrophilic) Contact lenses Cosmetically Tinted

with UV Blocker for Daily Disposable Wear

August, 2014

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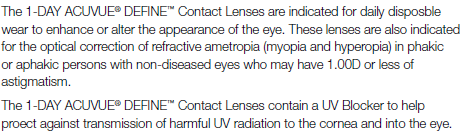
Transmittance curves

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1.0 Indications for Use



1.1 Purpose

1.1.1 Single use

1.1.2 Prescription use only



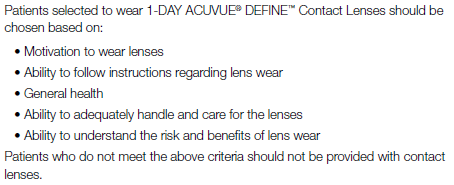
1.1.3 Where used

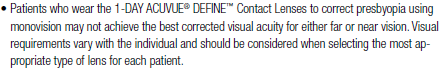
Indicated for use in any clinical or non-clinical environment.

1.2 Intended Use Population

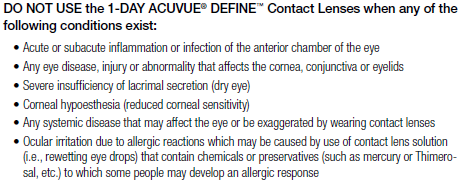
Indicated for use in the general population.

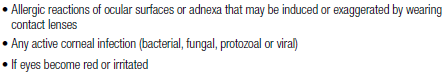
2.0 Individual Patient Selection Considerations





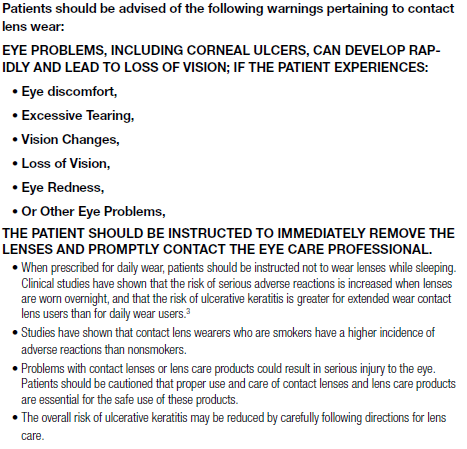
3.0 Contraindications





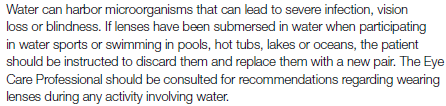
4.0 General Warnings and Precautions

4.1 Eye Problems leading to Vision Loss



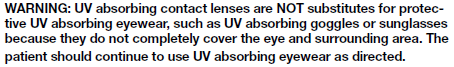
4.2 Specific Instructions for Use and Warnings about Water

Activity

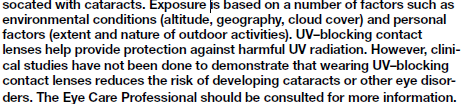




4.3 UV Absorption and Radiation Exposure

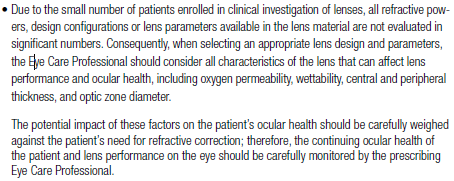






4.4 Special Precautions for Eye Care Professionals



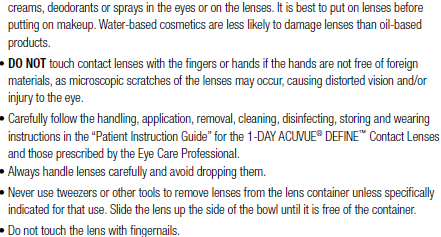


4.5 Instructions for Patients

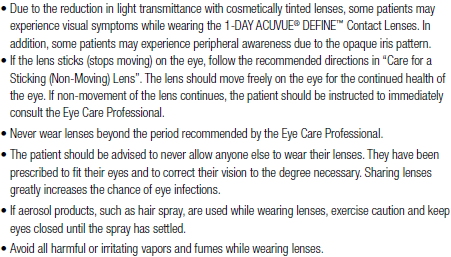


4.5.1 Handling precautions





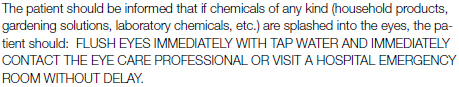
4.5.2 Lens wearing precautions



4.5.3 Lens care precautions

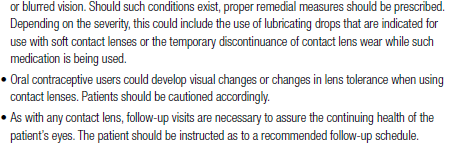


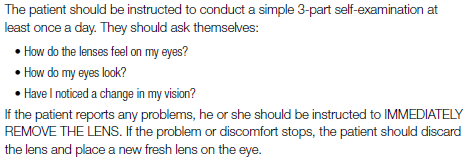
4.5.4 Emergencies

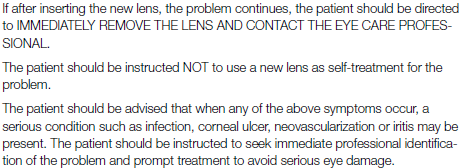


4.5.5 Other topics to discuss with patients









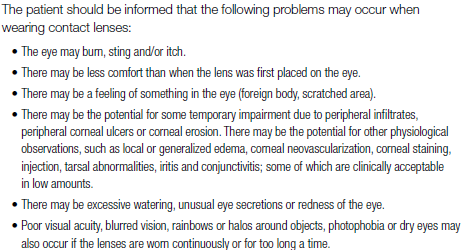
4.5.6 Who should know that the patient is wearing

contact lenses?

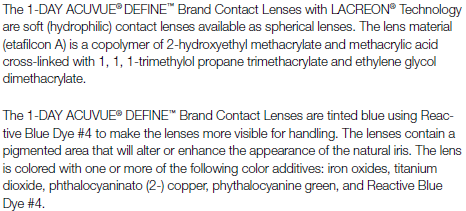


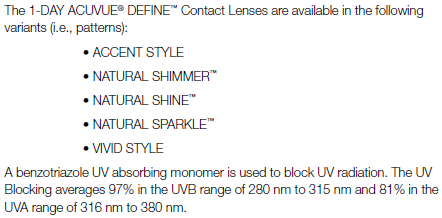
5.0 Adverse Events



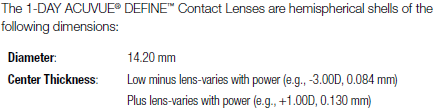


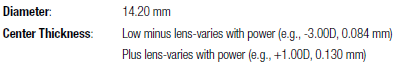
6.0 Device Description

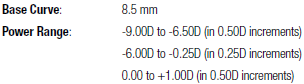




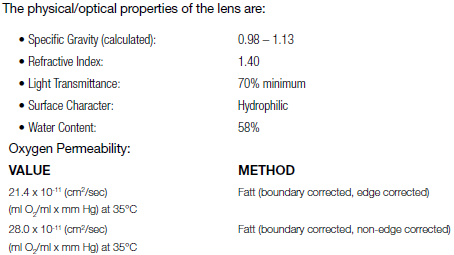
6.1 Available Lens Parameters







6.2 Lens Properties



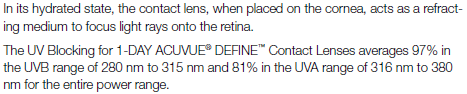
6.3 Oxygen Permeability



6.4 How Supplied



6.5 Theory of Operation

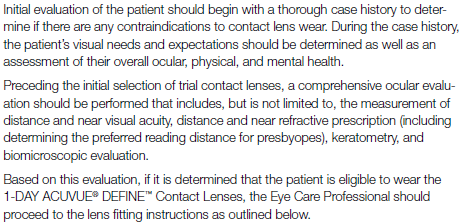


7.0 Instructions for Use

7.2 Preparation

7.2.1 General fitting guidelines

Pre-fitting examination

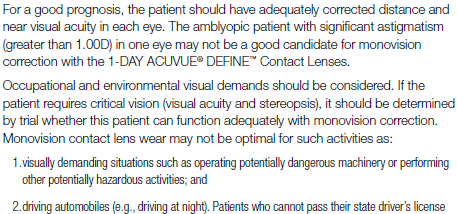


Initial Power Determination



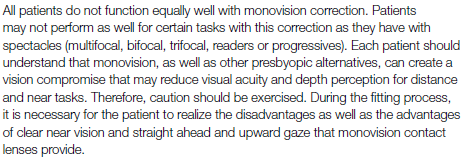
7.2.2 Monovision fitting guidelines

Monovision needs assessment

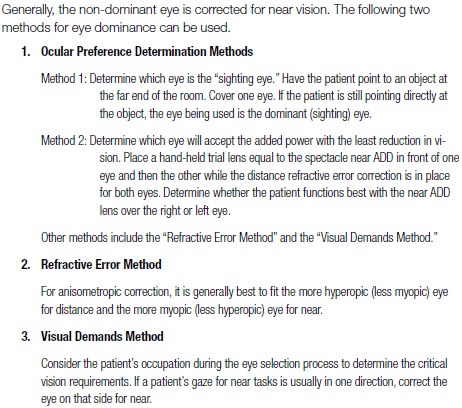




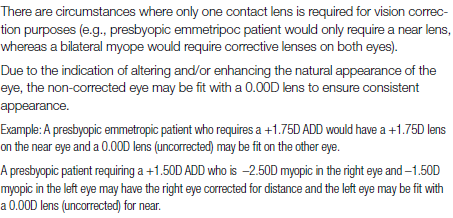
Patient education



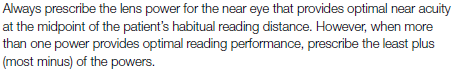
Eye selection



Unilateral vision correction requirement

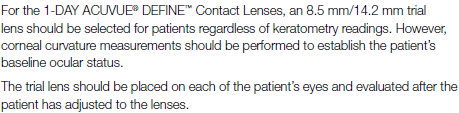


Near ADD determination

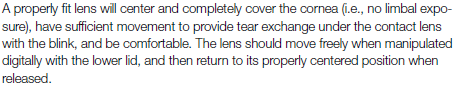


7.3 Use

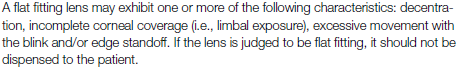
7.3.1 Base curve selection (trial lens fitting)



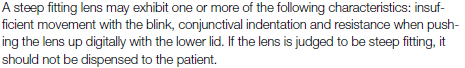
Criteria of a properly fit lens



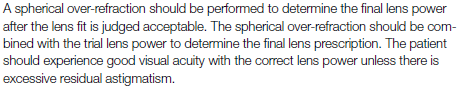
Criteria of a flat fitting lens

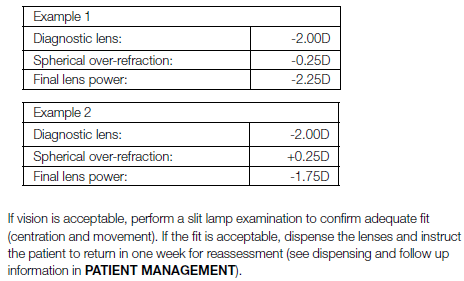


Criteria of a steep fitting lens

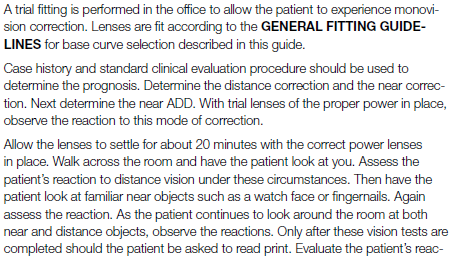
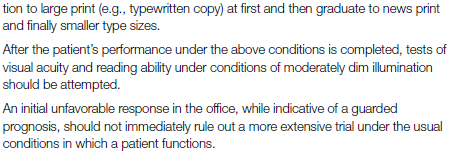


7.3.2 Final lens power

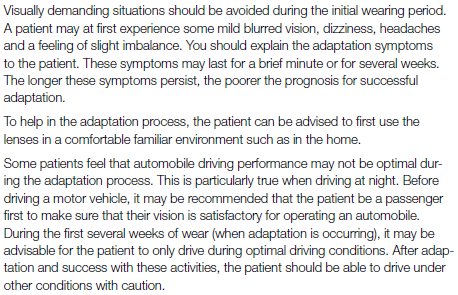




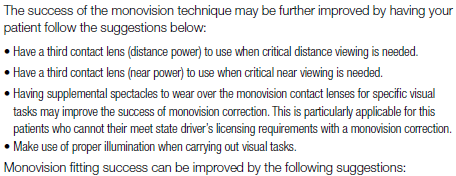
7.3.3 Trial lens fitting – monovision

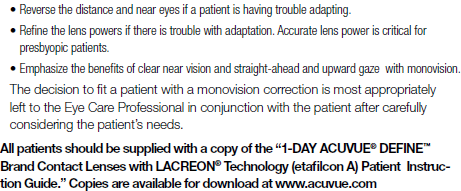
 

Adaptation



Other suggestions

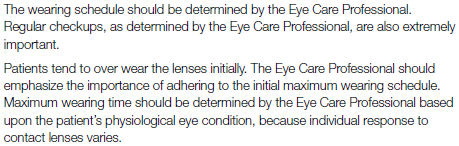


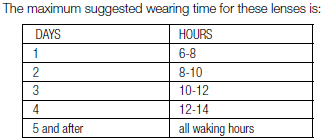




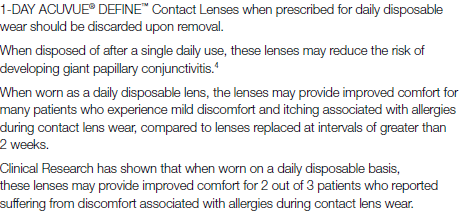
7.4 After Use

7.4.1 Wearing schedule

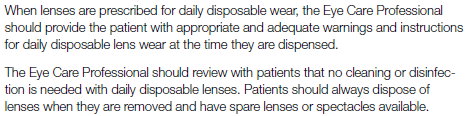




7.4.2 Replacement schedule



7.4.3 Lens care directions

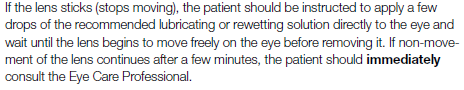


Basic instructions



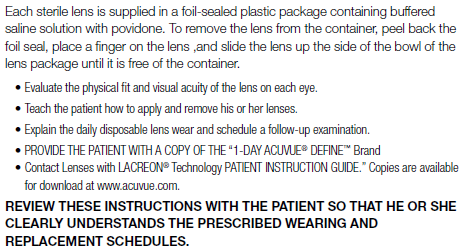


Care for a sticking (non-moving) lens

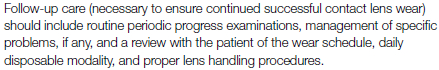


7.4.4 Patient management

Dispensing visit



Follow-up examinations



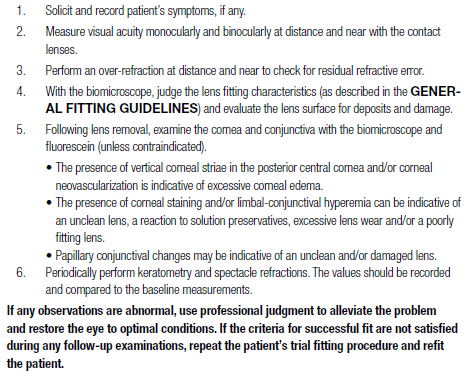
Recommended follow-up examination





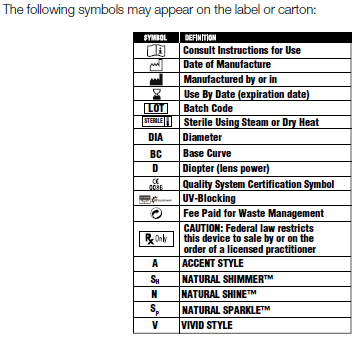


Recommended procedures for follow-up visits



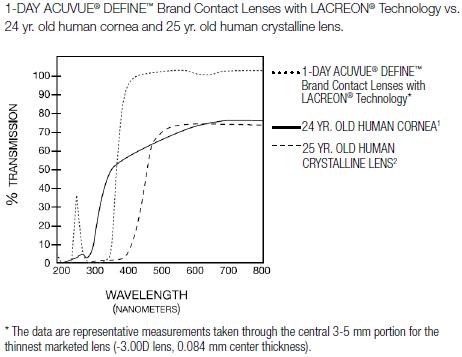
12.0 Glossary

12.1 Symbols Key



13.0 Resources

Transmittance curves



Citations

1. Lerman, S., Radient Energy and the Eye, MacMillan, New York, 1980, p.58 figure 2-21
2. Waxler, M. Hitchins, V.M., Optical Radiation and Visual Health, CRC Press, Boca Raton, Florida, 1987, p.19, figure 5
3. New England Journal of Medicine, September 21, 1989, 321 (12), pp. 773-783
4. The CLAO Journal, July 1999, Volume 25, Number 3

14.0 Contact and Reporting Information



15.0 Date of Latest Revision

