## TABLE OF CONTENTS

- 1.0 Indications for Use
  - 1.1 Purpose
    - 1.1.1 Single use
    - 1.1.2 Prescription use only
    - 1.1.3 Where used
  - 1.2 Intended Use 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

Diameter

Center thickness

Base curve

Power range

- **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

Ocular preference determination methods

Refractive error method

Visual demands method

Unilateral vision correction requirement

Near ADD determination

### 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

# 14.0 Contact and Reporting Information

## 15.0 Date of Latest Revision