**PROFESSIONAL FITTING GUIDE**

For the

**Another Me Kristin Monthly, Sophisticated Kristin Monthly,**

**Sweet Tooth Kristin Monthly, Grrrr Kristin Monthly**

**DK Medivision Co., Ltd.**

**DK Medivision Color Contact lenses (Tinted, Color)**

***CAUTION: FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON***

***THE ORDER OF A LICENSED PRACTITIONER.***

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**DESCRIPTION OF LENS**

The **DK Medivision Color Contact lenses (Tinted, Color)** are manufactured using the cast

molding method. The hydrophilic characteristics allow aqueous solutions to enter the lens. The

lenses are fabricated from polymacon, which is a random copolymer of 2-hydroxyethyl

methacrylate (HEMA) crosslinked with ethylene glycol dimethacrylate (EGDMA). The co-

polymer consists of 62% polymacon and 38% water by weight when immersed in saline

solution. The polymacon name has been adopted by the United States Adopted Names Council

(USAN).

The **DK Medivision Color Contact lenses (Tinted, Color)** are available clear, tinted for

visibility, or tinted to enhance or alter the apparent color of the eye. The lenses are processed to

incorporate the ‘listed’ color additives and contain only the amount of the additive needed to

accomplish the intended coloring effect. The lenses contain one or a combination of one or more

of the following ‘listed’ color additives:

**Color Additive**

**Listing**

Iron Oxide

21 CFR § 73.3125

21 CFR § 73.3121

21 CFR § 73.3127

C.I. Reactive Blue No.4

Reactive Black 5

Titanium Dioxide

2

1 CFR § 73.3126

The **DK Medivision Color Contact lenses (Tinted, Color)** incorporate a UV absorbing

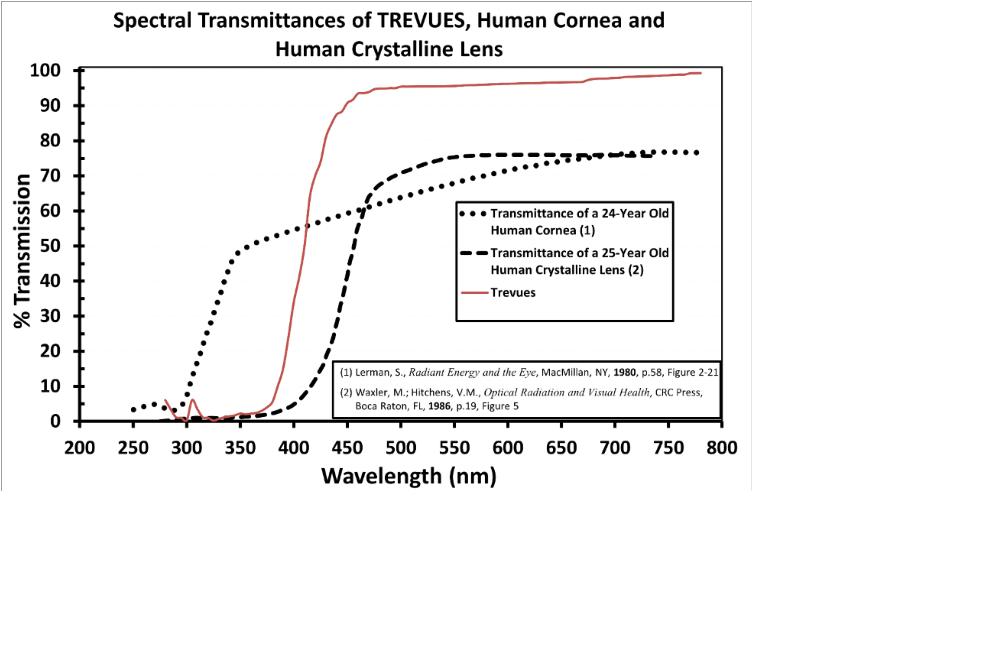
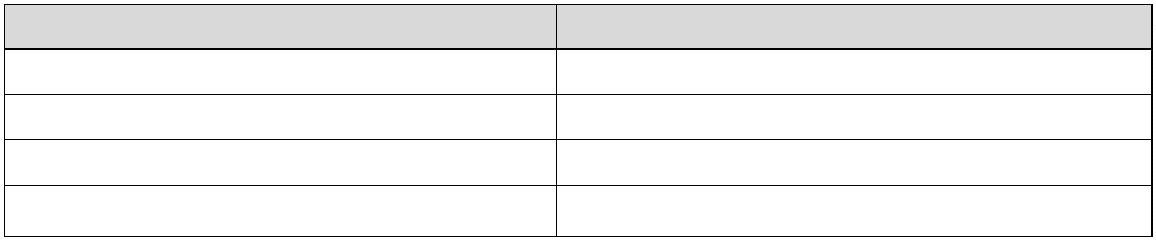
monomer. The lenses block >95% in the UVB range (280nm - 315nm), and >50% in the UVA

range (316nm - 380nm). The effectiveness of UV absorbing contacts in preventing disorders

caused by UV exposure have not been established, and UV blocking contacts are not a substitute

for UV absorbing eyewear. Refer to the following transmittance profile for the **DK Medivision**

**Color Contact lenses (Tinted, Color)**, as well as a human cornea and a human crystalline lens:



Note: the above % transmission data are based on measurements from -1.00 D, -3.00 D, -5.00 D and -10.00

D lenses. The data was obtained from measurements with a spectrophotometer taken through the central 3-

5

mm portion of the DK Medivision Color Contact lenses

The **DK Medivision Color Contact lenses (Tinted, Color)** are manufactured in an aspheric

design configuration. The material properties and available parameters of the finished lenses are

as follows:

**Parameter**

**Chord Diameter**

**Range**

**Tolerance\***

11.00 mm to 15.00 mm

±0.20 mm

When ≤ 0.10 mm → ±0.010 mm + 10%

When > 0.10 mm → ±0.015 mm + 5%

**Center Thickness**

0.05 mm to 0.15 mm

**Base Curve**

7.00 mm to 10.0 mm

±0.20 mm

-

0.50 D to -12.00D

When 0.00 < |F’v| ≤ 10.00 D → ±0.25 D

When 10.00 < |F’v| ≤ 20.00 D → ±0.50 D

**Back Vertex Power (F’v)**

(in 0.25D steps)

**Surface Appearance**

**Oxygen Permeability**

-

Lenses should be clear with no surface defect

**(x 10-11(cm2/sec)(mlO2)/(ml** 11.12

**x mmHg))**

±20%

±5%

**Light Transmission - Tinted**

**(@ 380-780nm)**

9

5%

**Ultraviolet Radiation**

**Transmittance**

< 5 % TUVB

< 50 % TUVA

TUVB (280 to 315 nm) < 0.05TV

TUVA (316 to 380 nm) < 0.50TV

**Water Content**

38%

±2%

**Refractive Index**

1.440 (hydrated)

±0.005

\*

ISO 18369-2:2017 Ophthalmic optics — Contact lenses — Part 2: Tolerances

**ACTIONS**

In its hydrated state, the **DK Medivision Color Contact lenses** , when placed on the cornea, acts

as a refracting medium to focus light rays on the retina. The lens may also be used to enhance or

alter the apparent color of the eye

**INDICATIONS**

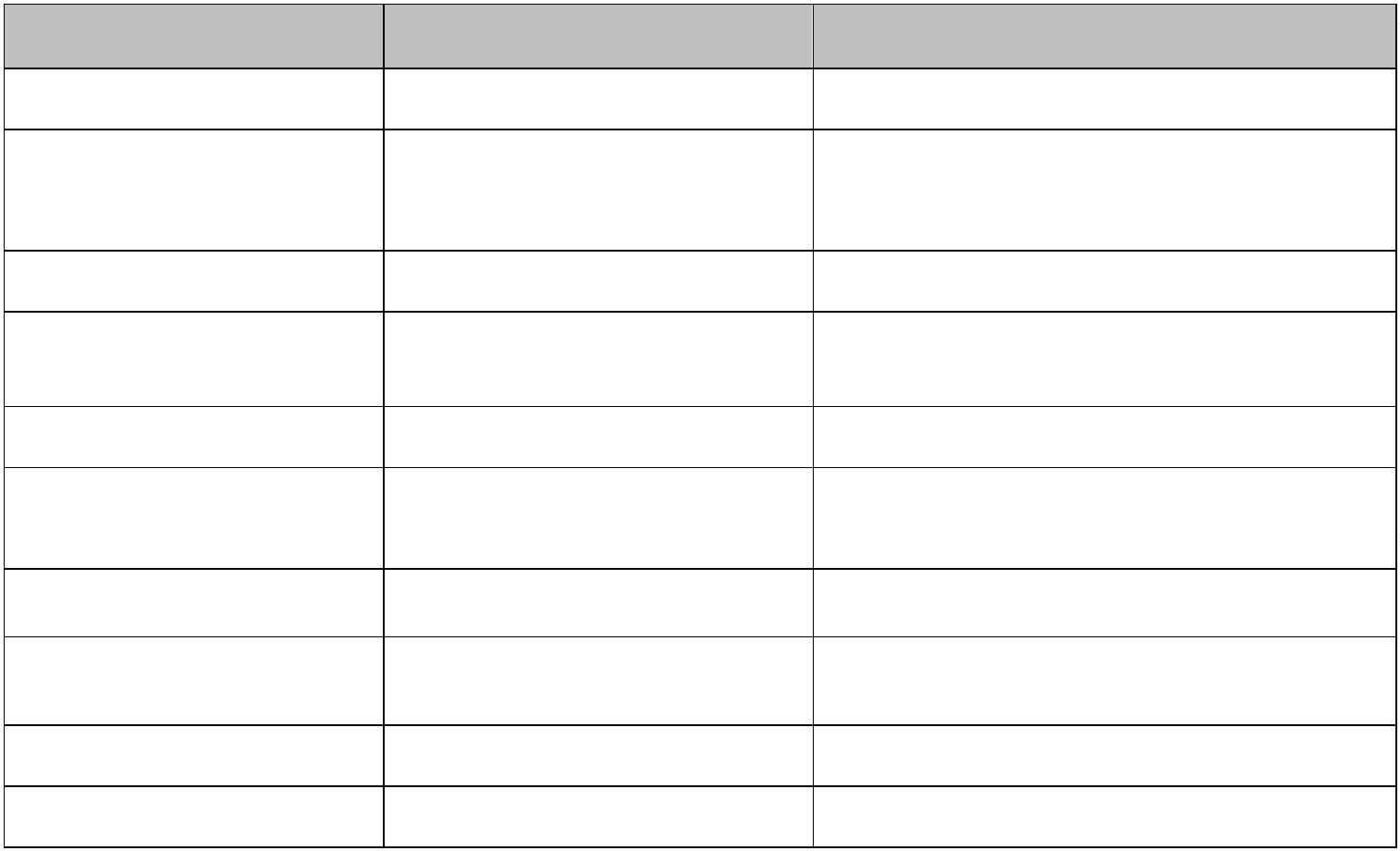
The **DK Medivision Color Contact lenses** are indicated for the correction of refractive

ametropia (myopia) in aphakic and not-aphakic persons with non-diseased eyes. The lenses may

be worn by persons who exhibit astigmatism of 2.00 diopters or less. where the astigmatism does

not interfere with visual acuity. The lens is available clear or tinted and may be used to enhance

or alter the apparent color of the eye.



The eye care professionals may prescribe the lens for single use daily disposable or daily wear in

a Frequent Replacement Program. As prescribed for planned replacement, the lens should be

disinfected using a chemical or hydrogen peroxide disinfecting system.

**Special Precautions for Eyecare Practitioner:**

Due to the small number of patients enrolled in clinical investigation of lens, all refractive

powers, design configurations, or lens parameters available in the lens material were not

evaluated in significant numbers. Consequently, when selecting an appropriate lens design and

parameters, the eyecare practitioner should consider all characteristics of the lens that can affect

lens performance and ocular health, including oxygen permeability, wettability, central and

peripheral thickness, and optic zone diameter. The potential impact of these factors on the

patient's ocular health must be carefully weighed against the patient's need for refractive

correction. Therefore, the continuing ocular health of the patient and lens performance on the eye

should be carefully monitored by the prescribing eyecare practitioner.

**CONTRAINDICATIONS (REASONS NOT TO USE)**

Please reference Contraindications (Reasons Not to Use) in the Package Insert included at the

end of this Fitting Guide.

**WARNINGS**

Please reference Warnings in the Package Insert included at the end of this Fitting Guide.

**PRECAUTIONS**

Please reference Precautions in the Package Insert included at the end of this Fitting Guide.

**ADVERSE REACTIONS**

Please reference Adverse Reactions in the Package Insert included at the end of this Fitting

Guide.

**PATIENT SELECTION**

Patient communication is vital. Patients who require visual correction but cannot adhere to the

recommended care of the **DK Medivision Color Contact lenses** should not be provided with

this lens. All necessary steps in lens care and all precautions and warnings should be discussed

and understood by the patient (*review Package Insert with patient*).



Fitting procedure for the **DK Medivision Color Contact lenses** :

**FITTING PROCEDURE**

1

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3

4

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. Pre-fitting Examination

. Initial lens power selection

. Initial lens diameter and base curve selection

. Initial lens evaluation

. Follow-up care

**1**

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**Pre-fitting Examination**

A pre-fitting patient history and examination are necessary to:

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determine whether a patient is a suitable candidate for daily wear contact lenses (refer

to contraindications)

collect and record baseline clinical information to which post-fitting examination

results can be compared

make ocular measurements for initial contact lens parameter selection

**2**

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**Initial Lens Power Selection**

a) Convert the spectacle Rx to minus cylinder forms

b) Compensate the spectacle Rx for vertex distance if the power is greater then + or –

4

.00 diopters

c) Drop the cylinder

d) Add + 0.25 diopter to compensate for minus tear lens

e) If refractive astigmatism exceeds 0.75 diopter, determine equivalent sphere and then

compensate for power by adding +0.25 diopter for minus tear lens

**1**

**2**

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**Initial Lens Diameter and Base Curve Selection**

The lens is currently offered in one diameter (14.00 mm) and one base curve (8.6)

**Initial Lens Evaluation**

a)

Check Lens Centration, Movement, and Size

The criteria for a well fit lens is one which centers easily after a blink, bridges the

limbus and extends onto the sclera about 1.5 millimeters, lags downward about 1

to 2 millimeters on upward gaze, and does not move excessively as a result of

blinking or exaggerated eye movements.

After the trial lens settled on the eye (5 – 10 minutes), manipulate the lens using

lid pressure and observe for indications of excessive tightness. The lens should

move freely and easily with the slightest pressure and return to the centered

position when released.

Movement of the lens on the eye is very important in assessing the fit and

performance of the lens. In primary gaze, slight vertical post-blinking lens

movement should occur. On upward gaze, the lens should sag approximately 1 –

2

millimeters.

b)

Refract Over the Lens and Determine Visual Acuity

Allow approximately 10 minutes for fluid equilibration and patient adaptation

prior to over refracting. Determine best visual acuity when final over refraction

has been achieved. If good visual acuity cannot be obtained through the lens with

spherocylindrical over refraction, re-evaluation of the physical fit should be

considered. Trial lens procedure should be repeated with lenses of different base

curves.

c)

Determine the Optical Power for the Lens Selected

When the proper physical fit has been determined, convert the over refraction

through the diagnostic lens to equivalent sphere and add this to the power of the

trail lens. This will provide the final power of the lens.

**3**

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**Follow-up Care**

a)

b)

Follow-up examinations, as recommended by the eyecare practitioner, are

necessary to ensure continued successful contact lens wear.

Prior to a follow-up examination, the contact lenses should be worn for at least

one continuous hour and the patient should be asked to identify any problems

which might be occurring related to contact lens wear.

c)

d)

With lenses in place on the eyes, evaluate fitting performance to assure that

CRITERIA OF A WELL FITTED LENS continues to be satisfied. Examine the

lenses closely for surface deposition and/or damage.

After the lens removal, conduct a thorough biomicroscopy examination.

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The presence of vertical corneal striae in the posterior central cornea

and/or cornea neovascularization is indicative of excessive corneal edema.

The presence of corneal staining and/or limbal-conjunctival hyperemia can

be indicative of an unclean lens, a reaction to solution preservatives,

excessive lens wear, and/or a poorly fitting lens.

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Papillary conjunctival changes may be indicative of an unclean and/or

damaged lens.

If any of the above observations are judged abnormal, various professional

judgments are necessary to alleviate the problem and restore the eye to optimal

conditions. If the CRITERIA OF A WELL FITTED LENS are not satisfied

during any follow-up examinations, the patient should be re-fitted with a more

appropriate lens.

**CLINICAL ASSESSMENT**

**1**

**. Criteria of a Well-Fitted Lens**

The criteria of a well fitted lens is one which centers easily after a blink, bridges

the limbus and extends onto the sclera about 1.5 millimeters, lags downward

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performance of the lens. In primary gaze, slight vertical post-blinking lens

movement should occur. On upward gaze, the lens should sag approximately 1 –

2

millimeters.

**2**

**3**

**. Characteristics of a Tight (Steep) Lens**

A tight (steep) lens does not move easily on the cornea with slight pressure

**. Characteristics of a Loose (Flat) Lens**

A loose (flat) lens sags more than 2.0 millimeters on upward gaze

**FOLLOW-UP EXAMINATIONS**

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Within one week of lens dispensing

After three weeks of lens wear

After seven weeks of lens wear

After each six month period of lens wear.

At the follow-up examinations, the patient should report good subjective quality of vision. Adaptation

to vision with **DK Medivision Color Contact lenses** should occur almost immediately and should

definitely be reported within the first (1 week) follow-up visit. At these follow-up visits the

practitioner should:

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. Check distance and near acuity with lens in place.

. Over-refract to verify lens prescription.

. Observe the position of the lens on the cornea. The lens should be centered and move on

upward gaze and with a blink.

4

. Evert the lids to examine the tarsal conjunctiva and check for incidence of giant papillary

conjunctivitis.

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. Remove the lens. Check corneal curvature. There should be no substantial changes in either

meridian.

. Perform a slit-lamp examination with and without Fluorescein. Check for corneal edema,

corneal abrasion, vascularization, corneal infiltrates, and perilimbal injection. Reinsert the

lens only after all residual Fluorescein has dissipated from the eye.

. For frequent/planned replacement lenses examine for deposits, foreign bodies or physical

imperfections of the lens surface.

7

**FREQUENT/PLANNED REPLACEMENT LENS HANDLING (in-office cleaning,**

**disinfection, and storage)**

This section does not apply to the Daily Disposable lenses, which are to be disposed of upon lens

removal.

Wash and rinse hands thoroughly, making certain all soap residues have been rinsed away before

drying with a lint-free towel. *It is suggested to wet the lens while in the eye using wetting drops*

*before removal.* Always start with the right lens first in order to avoid mixing the lens. In

removing the lens, try to avoid touching the inside (concave) surface of the lens. It is possible,

though not likely, that the lens might be inside out; therefore, check the lens by placing it on the

index finger and examine its profile. If the edges of the lens tend to point outward, the lens is

inside out. After removing the lens from its container assure that it is clean, clear and wet.

Each frequent/planned replacement **DK Medivision Color Contact lenses** received in the eye care

practitioner's office is received sterile in a sealed blister pack with sterile saline solution. Blister

packages are labeled as to the parameters of the contained lens. To assure sterility, the blister pack

should not be opened until ready for use.

To open the blister pack, pull back on the top where indicated. Upon removing the top cover of the

blister pack, the lens may be removed and is ready for use.

Prior to reusing in a diagnostic procedure or before dispensing to a patient, the lens should be surfaced

cleaned and disinfected.

-

**Cleaning:**

A surfactant cleaner must be used with the frequent/planned replacement **DK Medivision Color**

**Contact lenses** to ensure a clean lens surface. The manufacturer’s instruction for Opti-Free

Daily Contact lens cleaner is as follows:

**Directions for use:**

1

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. Place lens in the palm of your hand.

. Apply 1 or 2 drops of cleaner to each lens surface and gently rub with the forefinger

of the opposite hand.

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. Clean for about 15-20 seconds

. Rinse the lens thoroughly with sterile saline solution. DO NOT use water to rinse

your lenses.

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. After rinsing, place the lens in a storage case.

. Repeat the process with the other lens.

. Disinfect lenses as per manufacturer’s instructions.

-

**Rinsing:**

Thoroughly rinse both surfaces of the lens with a steady stream of fresh, sterile rinsing or

multipurpose solution.

**Chemical (Not-Heat) Lens Care System:**

A sterile rinsing, storing and disinfecting multipurpose solution should be used to rinse and

chemically disinfect frequent/planned replacement **DK Medivision Color Contact lenses** .

After cleaning the lens, rinse with a liberal amount of fresh multipurpose solution to remove

loosened debris and traces of cleaner. The lens should then be placed in the plastic container

supplied in a multi-purpose solution kit and filled with enough fresh disinfecting solution to

completely submerge the lens. To ensure disinfecting, the lens must remain in the disinfecting

solution for the recommended period of time as written on the multipurpose solution bottle.

Before reinsertion, lens should be rinsed with fresh sterile rinsing solution.

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**Storage:**

The frequent/planned replacement **DK Medivision Color Contact lenses** must be stored in the

recommended solutions. If exposed to the air, the lens will dehydrate. If a lens dehydrates, it

should be soaked ONLY in a soft contact lens storage solution until it returns to a soft, supple

state. It should not be put on an eye until it has been put through a complete disinfection cycle.

**LENS CARE DIRECTIONS**

Please reference LENS CARE DIRECTIONS in the Package Insert included at the end of this

Professional Fitting Guide.

**RECOMMENDED WEARING SCHEDULE**

The maximum suggested wearing schedule for the **DK Medivision Color Contact lenses** should

be determined by the practitioner. Close professional supervision is recommended to ensure safe

and successful contact lens wear. If the patient complains of discomfort, decreased vision,

ocular injection or corneal edema, the lens should be removed and the patient scheduled for

examination. The problem may be relieved by putting the patient on a different wearing

schedule or possibly by refitting the lens. Patients tend to overwear the lens initially. It is

important not to exceed the initial wearing schedule. Regular check-ups, as determined by the

eyecare practitioner, are also extremely important.

**STUDIES HAVE NOT BEEN COMPLETED TO SHOW THAT THE DK MEDIVISION**

**COLOR CONTACT LENSES IS SAFE TO WEAR DURING SLEEP.**

**MONOVISION FITTING GUIDELINES**

1

. Patient Selection

A. Monovision Needs Assessment

For a good prognosis the patient should have adequately corrected distance and

near visual acuity in each eye. The amblyopic patient or the patient with

significant astigmatism (greater than 1.50 diopter) in one eye may not be a good

candidate for monovision with the **DK Medivision Color Contact lenses .**

Occupational and environmental visual demands should be considered. If the

patient requires critical vision (visual acuity and stereopsis) it should be

determined by trial whether this patient can function adequately with monovision.

Monovision contact lens wear may not be optimal for such activities as:

(1) Visually demanding situations such as operating potentially

dangerous machinery or performing other potentially hazardous

activities; and

(2) Driving automobiles (e.g., driving at night). Patients who cannot

pass their state driver’s license requirements with monovision

correction should be advised to not drive with this correction, OR

may require that additional over-correction be prescribed.

B. Patient Education

All patients do not function equally well with monovision correction. Patients

may not perform as well for certain tasks with this correction as they have with

bifocal reading glasses. Each patient should understand that monovision, as well

as other presbyopic contact lenses, or other alternative, can create vision

compromise that may reduce visual acuity and depth perception for distance and

near tasks. During the fitting process it is necessary for the patient to realize the

disadvantages as well as the advantages of clear near vision in straight ahead and

upward gaze that monovision contact lenses provide.

2

. Eye Selection

Generally, the non-dominant eye is corrected for near vision. The following test for eye

dominance can be used.

A. Ocular Preference Determination Methods

Method 1—determine which eye is the “sight eye”. Have the patient point to and

object at the far end of the room. Cover one eye. If the patient is still pointing

directly at the object, the eye being used is the dominant (sighting) eye.

Method 2—Determine which eye will accept the added power with the latest

reduction in vision. Place a trial spectacle near add lens in front of one eye and

then the other while the distance refractive error correction is in place for both

eyes. Determine whether the patient functions best with the near add lens over

the right or left eye.

B. Refractive Error Method

For anisometropic corrections, it is generally best to fit the more hyperopic (less

myopic) eye for distance and the more myopic (less hyperopic) eye for near.

C. Visual Demands Method

Consider the patient's occupation during the eye selection process to determine

the critical vision requirements. If a patient's gaze for near tasks is usually in one

direction correct the eye on that side for near.

Example: A secretary who places copy to the left side of the desk will usually

function best with the near lens on the left eye.

3

. Special Fitting Considerations

Unilateral Lens Correction

There are circumstances where only one contact lens is required. As an example, an

emmetropic patient would only require a near lens while a bilateral myope may require

only a distance lens.

Example:

A presbyopic emmetropic patient who requires a +1.75 diopter add would have a +1.75

lens on the near eye and the other eye left with a lens.

A presbyopic patient requiring a +1.50 diopter add who is -2.50 diopters myopic in the

right eye and -1.50 diopters myopic in the left eye may have the right eye corrected for

distance and the left uncorrected for near.

4

. Near Add Determination

Always prescribe the lens power for the near eye that provides optimal near acuity at the

midpoint of the patient's habitual reading distance. However, when more than one power

provides optimal reading performance, prescribe the least plus (most minus) of the

powers.

5

. Trial Lens Fitting

A trial fitting is performed in the office to allow the patient to experience monovision

correction. Lenses are fit according to the directions in the general fitting guidelines and

base curve selection described earlier in the guide.

Case history and standard clinical evaluation procedure should be used to determine the

prognosis. Determine which eye is to be corrected for distance and which eye is to be

corrected for near. Next determine the near add. With trial lenses of the proper power in

place observe the reaction to this mode of correction.

Immediately after the correct power lenses are in place, walk across the room and have

the patient look at you. Assess the patient's reaction to distance vision under these

circumstances. Then have the patient look at familiar near objects such as a watch face or

fingernails. Again assess the reaction. As the patient continues to look around the room at

both near and distance objects, observe the reactions. Only after these vision tasks are

completed should the patient be asked to read print. Evaluate the patient's reaction to

large print (e.g. typewritten copy) at first and then graduate to news print and finally

smaller type sizes.

After the patient's performance under the above conditions are completed, tests of visual

acuity and reading ability under conditions of moderately dim illumination should be

attempted.

An initial unfavorable response in the office, while indicative of a guarded prognosis,

should not immediately rule out a more extensive trial under the usual conditions in

which a patient functions.

6

. Adaptation

Visually demanding situations should be avoided during the initial wearing period. A

patient may at first experience some mild blurred vision, dizziness, headaches, and a

feeling of slight imbalance. You should explain the adaptation symptoms to the patient.

These symptoms may last for a brief minute or for several weeks. the longer these

symptoms persist, the poorer the prognosis for successful adaptation.

To help in the adaptation process the patient can be advised to first use the lenses in a

comfortable familiar environment such as in the home.

Some patients feel that automobile driving performance may not be optimal during the

adaptation process. This is particularly true when driving at night. Before driving a motor

vehicle, it may be recommended that the patient be a passenger first to make sure that

their vision is satisfactory for operating an automobile. During the first several weeks of

wear (when adaptation is occurring), it may be advisable for the patient to only drive

during optimal driving conditions. After adaptation and success with these activities, the

patient should be able to drive under other conditions with caution.

7

. Other Suggestions

The success of the monovision technique may be further improved by having your patient

follow the suggestions below.

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Having a third contact lens (distance power) to use when critical distance

viewing is needed.

Having a third contact lens (near power) to use when critical near viewing is

needed.

Having supplemental spectacles to wear over the monovision contact lenses for

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specific visual tasks may improve the success of monovision correction. this is

particularly applicable for those patients who cannot meet state licensing

requirements with a monovision correction.

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Make use of proper illumination when carrying out visual tasks.

Success in fitting monovision can be improved by the following suggestions:

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Reverse the distance and near eyes if a patient is having trouble adapting.

Refine the lens powers if there is trouble with adaptation. Accurate lens power is

critical for presbyopic patients.

Emphasize the benefits of the clear near vision in straight ahead and upward

gaze with monovision.

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The decision to fit a patient with a monovision correction is most appropriately

left to the eyecare practitioner in conjunction with the patient after carefully

considering the patient's needs.

All patients should be supplied with a copy of the **DK Medivision Color**

**Contact lenses** Patient Instruction / Wearer’s Guide.

**RECOMMENDED FREQUENT/PLANNED REPLACEMENT LENS CARE PRODUCTS**

The eyecare practitioner should recommend a care system indicated for soft contact lenses that is

appropriate for the frequent/planned replacement **DK Medivision Color Contact lenses** . Each

lens care product contains specific directions for use and important safety information, which

should be read and carefully followed.

**EMERGENCIES**

The patient should be informed that if chemicals of any kind (household products, gardening

solutions, laboratory chemicals, etc.) are splashed into the eyes, the patient should: FLUSH

EYES IMMEDIATELY WITH TAP WATER AND IMMEDIATELY CONTACT THE

EYECARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT

DELAY.

**REPORTING OF ADVERSE REACTIONS**

Practitioners should report any adverse reactions to **DK Medivision Color Contact lenses**

within 5 days to DK Medivision Co., Ltd. Additional Fitting Guides, Package Inserts and Patient

Guides are available from:

**DK Medivision Co., Ltd.**

2

3 Busong 1-gil, jiksan-eup,

Seobuk-gu Cheonan-si, Chungcheongnam-do,

KOREA

Toll Free: [To be included when available]

**HOW SUPPLIED**

The **DK Medivision Color Contact lenses** are sterile in sealed blister packages containing a

buffered saline solution. The base of the package is made from polypropylene, which is covered

with an aluminum foil seal on top. The blister packages are marked with the base curve,

diameter, dioptric power, lens color, manufacturing lot number, and expiration date of the lens.

Print Date: YYYY-MM-DD

**PACKAGE INSERT FOLLOWS ON THE NEXT PAGE**

**PACKAGE INSERT**

**for the**

**DK Medivision Co., Ltd.**

Refer to the following website for a current list of lens models for which this packge insert

Applies: http://hapakristin.us/pages/fda-vision

***CAUTION: FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON***

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**IMPORTANT**

Please read carefully and keep this information for future use. This package insert is

intended for the eyecare practitioner but should be made available to the patient upon

request. The eyecare practitioner should provide the patient with the wearer’s guide that

pertains to the patients prescribed lens.

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2

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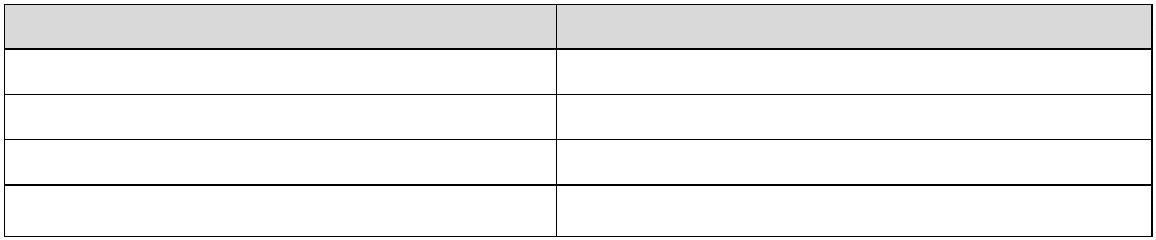
3

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absorbing eyewear. Refer to the following transmittance profile for the **DK Medivision Color**

**Contact lenses** as well as a human cornea and a human crystalline lens:



Note: the above % transmission data are based on measurements from -1.00 D, -3.00 D, -5.00 D and -10.00

D lenses. The data was obtained from measurements with a spectrophotometer taken through the central 3-

5

mm portion of the DK Medivision Color Contact lenses .

The **DK Medivision Color Contact lenses** are manufactured in an aspheric design

configuration. The material properties and available parameters of the finished lenses are as

follows:

**Parameter**

**Chord Diameter**

**Range**

**Tolerance\***

11.00 mm to 15.00 mm

±0.20 mm

When ≤ 0.10 mm → ±0.010 mm + 10%

When > 0.10 mm → ±0.015 mm + 5%

**Center Thickness**

0.05 mm to 0.15 mm

**Base Curve**

7.00 mm to 10.0 mm

±0.20 mm

-

0.50 D to -12.00D

When 0.00 < |F’v| ≤ 10.00 D → ±0.25 D

When 10.00 < |F’v| ≤ 20.00 D → ±0.50 D

**Back Vertex Power (F’v)**

**Surface Appearance**

(in 0.25D steps)

-

Lenses should be clear with no surface defect

**Oxygen Permeability**

**(x 10-11(cm2/sec)(mlO2)/(ml x**

**mmHg))**

**Light Transmission - Tinted**

**(@ 380-780nm)**

1

9

1.12

5%

±20%

±5%

**Ultraviolet Radiation**

**Transmittance**

< 5 % TUVB

< 50 % TUVA

TUVB (280 to 315 nm) < 0.05TV

TUVA (316 to 380 nm) < 0.50TV

**Water Content**

38%

±2%

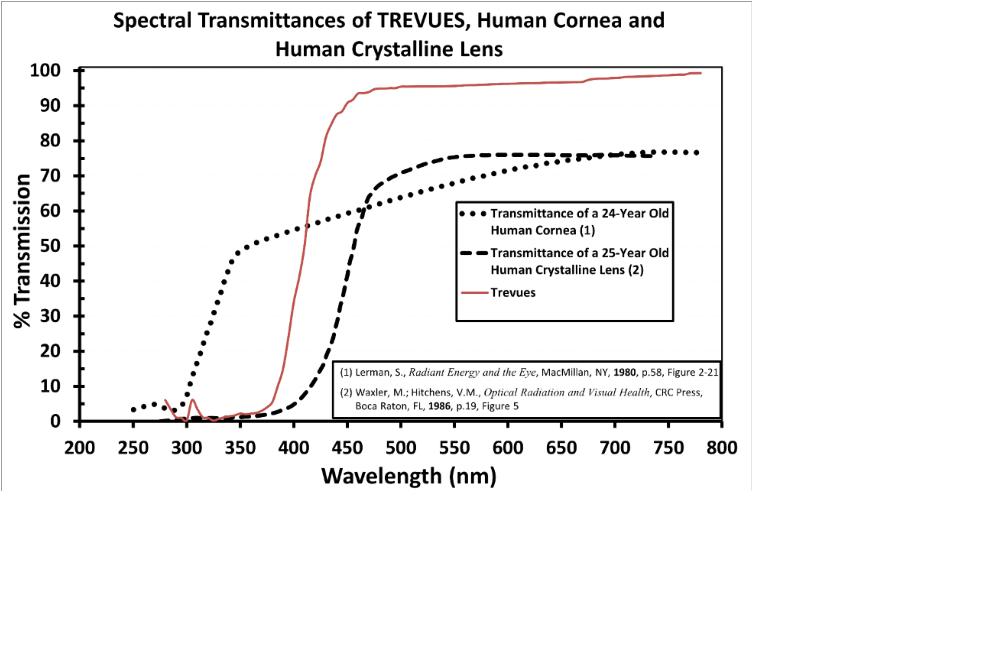
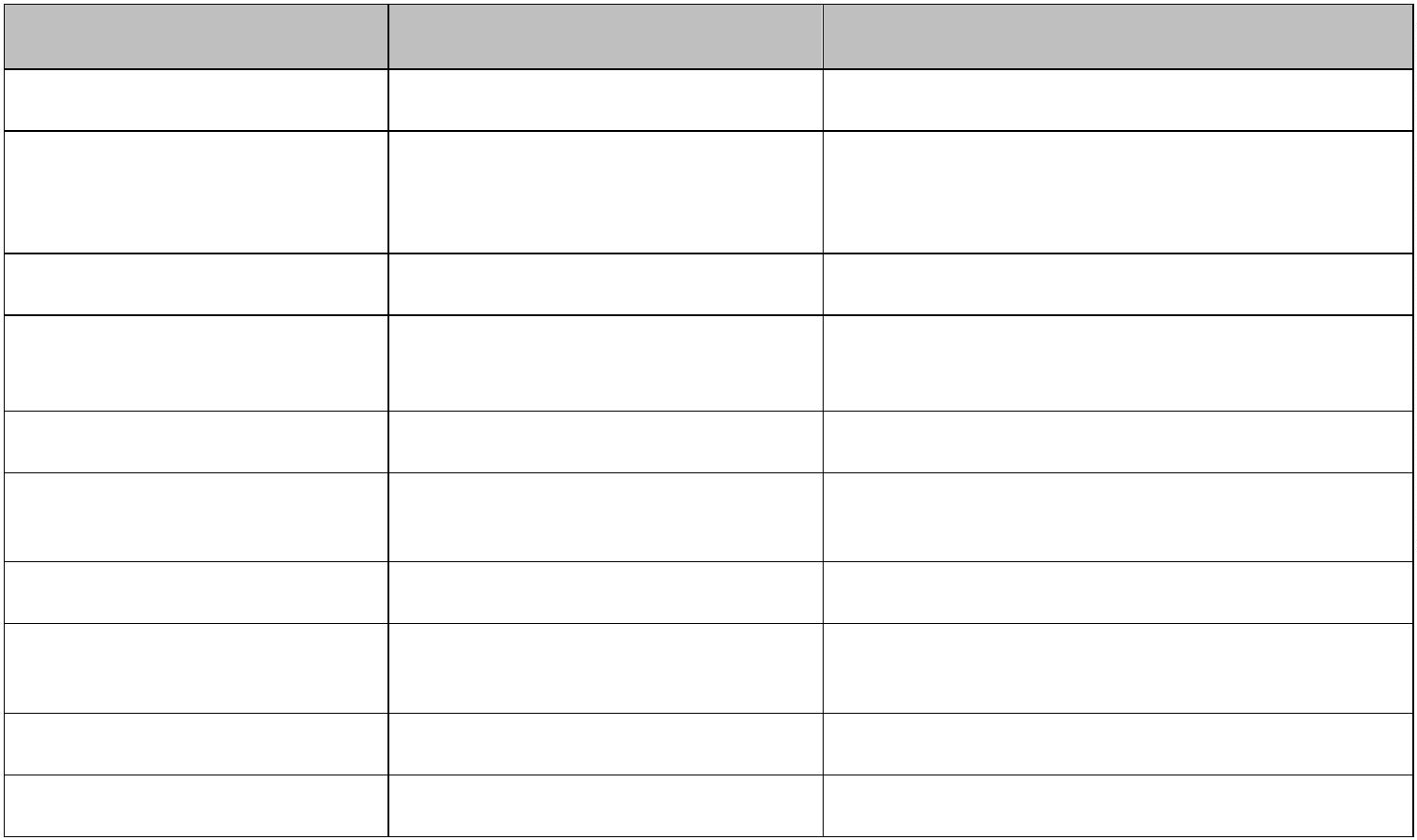
**Refractive Index**

1.440 (hydrated)

±0.005

\*

ISO 18369-2:2017 Ophthalmic optics — Contact lenses — Part 2: Tolerances



**ACTIONS**

In its hydrated state, the **DK Medivision Color Contact lenses** when placed on the

cornea, acts as a refracting medium to focus light rays on the retina. The lens may also

be used to enhance or alter the apparent color of the eye

**INDICATIONS**

The **DK Medivision Color Contact lenses** are indicated for the correction of refractive

ametropia (myopia) in aphakic and not-aphakic persons with non-diseased eyes. The

lenses may be worn by persons who exhibit astigmatism of 2.00 diopters or less. where

the astigmatism does not interfere with visual acuity. The lens is available clear or tinted

and may be used to enhance or alter the apparent color of the eye.

The eye care professionals may prescribe the lens for single use daily disposable or daily

wear in a Frequent Replacement Program. As prescribed for planned replacement, the

lens should be disinfected using a chemical or hydrogen peroxide disinfecting system.

**CONTRAINDICATIONS (REASONS NOT TO USE)**

DO NOT USE the **DK Medivision Color Contact lenses** when any of the following

conditions are present:

\*

\*

Acute and subacute inflammation or infection of the anterior chamber of the eye.

Any eye disease, injury, or abnormality that affects the cornea, conjunctiva, or

eyelids.

\*

\*

\*

Severe insufficiency of lacrimal secretion (dry eyes).

Corneal hypoesthesia (reduced corneal sensitivity), if not-aphakic.

Any systemic disease that may affect the eye or be exaggerated by wearing

contact lens.

\*

\*

Allergic reactions of ocular surfaces or adnexa that may be induced or

exaggerated by wearing contact lens or use of contact lens solutions.

Allergy to any ingredient, such as mercury or thimerosal, in a solution which is to

be used to care for the **DK Medivision Color Contact lenses**

Any active corneal infection (bacterial, fungi, or viral)

If eyes become red or irritated.

Patients unable to follow lens care regimen or unable to obtain assistance to do so.

\*

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\*

**WARNINGS**

-

-

PROBLEMS WITH CONTACT LENSES AND LENS CARE PRODUCTS COULD

RESULT IN SERIOUS INJURY TO THE EYE.

Patients wearing lenses on a frequent/planned replacement schedule should not reuse or

“top off” old solution left in the lens case since solution reuse reduces effective lens

disinfection and could lead to severe infection, vision loss or blindness. “Topping-Off” is

the addition of fresh solution to solution that has been sitting the case.

-

When disinfecting frequent/planned replacement lenses the patient should rub and rinse

the lenses for the recommended amount of time to help prevent serious eye infections

(see the frequent/planned replacement wearer’s instruction guide for detailed

instructions).

-

-

The patient should never use water, saline solution, or rewetting drops to disinfect the

lenses. These solutions will not disinfect the lenses. Not using the recommended

disinfectant can lead to severe infection, vision loss or blindness.

Patients should not store their lenses or rinse their lens case with water or any non-sterile

solution. Patients wearing frequent/planned replacement lenses must only use fresh multi-

purpose solution (or sterile saline solution) so their lenses or lens case are not

contaminated. Use of non-sterile solution can lead to severe infection, vision loss or

blindness.

-

Water can harbor microorganisms that can lead to severe infection, vision loss or

blindness. If the patient’s lenses have been submersed in water such as when swimming

in pools, lakes, or oceans the patient should discard them and replace them with a new

pair. Patients should be instructed to ask their eye care practitioner (professional) for

recommendations about wearing their lenses during any activity involving water.

Using the multi-purpose solution beyond the discard date could result in contamination of

the solution and can lead to severe infection, vision loss or blindness. Multi-purpose

solution is not to be used with daily disposable lenses at any time.

-

-

EYE PROBLEMS, INCLUDING CORNEAL ULCERS, CAN DEVELOP RAPIDLY

AND LEAD TO LOSS OF VISION IF THE PATIENT EXPERIENCES:

•

•

•

•

•

•

Eye Discomfort,

Excessive Tearing,

Vision Changes,

Loss of Vision,

Eye Redness

Or Other Eye Problems

THE PATIENT SHOULD IMMEDIATELY REMOVE THE LENSES, AND

PROMPTLY CONTACT THEIR EYE CARE PRACTITIONER.

-

Daily wear lenses are not indicated for overnight wear, and patients should be instructed

not to wear lenses while sleeping. Clinical studies have shown that the risk of serious

adverse reactions is increased when these lenses are worn overnight.

Studies have shown that contact lens wearers who are smokers have a higher incidence of

adverse reactions than nonsmokers.

-

-

All contact lens wearers must see their eyecare practitioner as directed.

**PRECAUTIONS**

**Special Precautions for the Eyecare Practitioner:**

\*

Clinical studies have demonstrated that contact lenses manufactured from

(polymacon) are safe and effective for their intended use. However, due to

the small number of patients enrolled in clinical investigation of lens, all

refractive powers, design configurations, or lens parameters available in the

lens material are not evaluated in significant numbers. Consequently, when

selecting an appropriate lens design and parameters, the eyecare practitioner

should consider all characteristics of the lens that can affect lens performance

and ocular health, including oxygen permeability, wettability, central and

peripheral thickness, and optic zone diameter. The potential impact of these

factors on the patient's ocular health should be carefully weighed against the

patient's need for refractive correction. Therefore, the continuing ocular

health of the patient and lens performance on the eye should be carefully

monitored by the prescribing eyecare practitioner.

\*

\*

Fluorescein, a yellow dye, should not be used while the lens is on the eye.

The lens absorbs this dye and become discolored. Whenever Fluorescein is

used in eyes, the eyes should be flushed with a sterile saline solution that is

recommended for in eye use. Wait at least one hour before replacing the lens.

Too early replacement may allow the lens to absorb residual Fluorescein

irreversibly.

Before leaving the eyecare practitioner's office, the patient should be able to

promptly remove lens or should have someone else available who can remove

the lens for him or her.

\*

\*

Eyecare practitioners should instruct the patient to remove the lens

immediately if the eye becomes red or irritated.

The patient should be instructed to always discard disposable lenses and

lenses worn on a frequent/planned replacement schedule after the

recommended wearing schedule prescribed by the eye care professional.

**PRECAUTIONS FOR DAILY DISPOSABLE WEAR**

\*

\*

If the lenses are prescribed for disposable wear. They are to be disposed of

once they are removed from the patient’s eye. It is important that patients be

instructed to always have available a pair of replacement lenses. In the event

that a lens must be removed from the eye because of dust, a foreign body or

other contaminant gets on the lens or the lens becomes dehydrated, the lens

should be removed and replaced with a replacement lens.

Carefully follow the handling, insertion, removal, emergency care instructions

in the daily disposable patient instructions for the **DK Medivision Color**

**Contact lenses** and those prescribed by the eyecare practitioner.

**PRECAUTIONS FOR FREQUENT/PLANNED REPLACEMENT WEAR**

\*

Different solutions cannot always be used together, and not all solutions are safe for

use with all lens. Use only recommended solutions that are fresh and sterile. Never

use solutions recommended for conventional hard contact lens only. Chemical

disinfection solutions should not be used with heat unless specifically indicated on

product labeling for use in both heat and chemical disinfection. Always use **FRESH,**

**STERILE UNEXPIRED** lens care solutions. Always follow directions in the

package inserts for the use of contact lens solutions. Sterile unpreserved solutions,

when used, should be discarded after the time specified in the labeling directions. Do

not use saliva or anything other than the recommended solution for lubricating or

rewetting lens. Always keep the lens completely immersed in the recommended

storage solution when the lens is not being worn (stored). Prolonged periods of

drying will damage the lens. Follow the lens care directions for (Care for a Dried Out

Dehydrated Dry Lens) if the lens surface does become dried out.

\*

Carefully follow the handling, insertion, removal, cleaning, disinfection, storing and

wearing instructions in the frequent/planned replacement patient instructions for the

**DK Medivision Color Contact lenses** and those prescribed by the eyecare

practitioner.

**PRECAUTIONS FOR FREQUENT/PLANNED REPLACEMENT AND DISPOSABLE**

**WEAR**

\*

\*

\*

If the lens sticks (stops moving) on the eye, follow the recommended directions on

(care for sticking non-moving lens). The lens should move freely on the eye for the

continued health of the eye. If nonmovement of the lens continues, the patient should

be instructed to **IMMEDIATELY** consult his or her eyecare practitioner.

Always wash and rinse hands before handling lens. Do not get cosmetics, lotions,

soaps, creams, deodorants, or sprays in the eyes or on the lens. It is best to put on

lens before putting on makeup. Water-base cosmetics are less likely to damage lens

than oil-base.

Do not touch contact lens with the fingers or hands if the hands are not free of foreign

materials, as microscope scratches of the lens may occur, causing distorted vision

and/or injury to the eye.

\*

\*

Never wear lens beyond the period recommended by the eyecare practitioner.

Water activity: The Patient should not expose their contact lenses to water while

wearing them.

\*

If aerosol products such as hair spray are used while wearing lens, exercise caution

and keep eyes closed until the spray has settled.

\*

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\*

Always handle lens carefully and avoid dropping them.

Avoid all harmful or irritating vapors and fumes while wearing lens.

Ask the eyecare practitioner about wearing lens during sporting activities.

Inform the doctor (health care practitioner) about being a contact lens wearer.

Never use tweezers or other tools to remove lens from the lens container unless

specifically indicated for that use. Pour the lens into the hand.

Do not touch the lens with fingernails.

\*

\*

Always contact the eyecare practitioner before using any medicine or medications in

the eyes.

\*

\*

Always inform the employer of being a contact lens wearer. Some jobs may require

use of eye protection equipment or may require that the patient not wear contact lens.

As with any contact lens, follow-up visits are necessary to assure the continuing

health of the patient's eyes. The patient should be instructed as to a recommended

follow-up schedule.

**ADVERSE REACTIONS**

The patient should be informed that the following problems may occur:

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Eyes stinging, burning, itching (irritation), or other eye pain.

Comfort is less than when lens was first placed on eye.

Feeling that something is in the eye such as a foreign body or scratched area.

Excessive watering (tearing) of the eye.

Unusual eye secretions.

Redness of the eye.

Reduced sharpness of vision (poor visual acuity).

Blurred vision, rainbows, or halos around objects.

Sensitivity to light (photophobia).

Dry eyes.

If the patient notices any of the above, he or she should be instructed to:

\*

**IMMEDIATELY REMOVE LENS**.

Discard lens if wearing daily disposable. For frequent/planned replacement

wearers: if discomfort or problem(s) stops, then look closely at the lens. If the

lens is in any damage, **DO NOT PUT THE LENS BACK ON THE EYE.**

Place the lens in the storage case and contact the eyecare practitioner. If the

lens has dirt, an eyelash, or other foreign body on it, or the problem stops and

the lens appears undamaged, the patient should thoroughly clean, rinse, and

disinfect the lens then reinsert them. After reinsertion, if the problem

continues, the patient should **IMMEDIATELY REMOVE THE LENS**

**AND CONSULT THE EYECARE PRACTITIONER.**

When any of the above problems occur, a serious condition such as infection,

corneal ulcer, neovascularization, or iritis may be present. The patient should

be instructed to **KEEP LENS OFF THE EYE AND SEEK IMMEDIATE**

**PROFESSIONAL IDENTIFICATION** of the problem and prompt

treatment to avoid serious eye damage.

**FITTING**

For a detailed description of the fitting techniques, refer to **DK Medivision Color Contact**

**lenses** Professional Fitting and Information Guide, copies of which are available from:

**DK Medivision Co., Ltd.**

3 Busong 1-gil, jiksan-eup,

2

Seobuk-gu Cheonan-si, Chungcheongnam-do,

KOREA

Tell: +82 41 581 0100

**WEARING SCHEDULE**

**THE WEARING AND REPLACEMENT SCHEDULES SHOULD BE DETERMINED**

**BY THE EYECARE PRACTITIONER**. The **DK Medivision Color Contact lenses** are

indicated for daily wear. Patients tend to over wear the lens initially. The eyecare

practitioner should emphasize the importance of adhering to the initial maximum wearing

schedule.

**STUDIES HAVE NOT BEEN COMPLETED TO SHOW THAT DK Medivision Color**

**Contact lenses ARE SAFE TO WEAR DURING SLEEP.**

**LENS CARE DIRECTIONS**

When lenses are dispensed, the patient should be provided with appropriate and adequate

instructions and warnings for lens care handling. The eye care professional should

recommend procedures and products for each individual patient in accordance with their

particular lens wearing schedule and care system selected by the practitioner, the specific

instructions for such products and the particular characteristics of the patient.

**Disposable Wear:** This section, LENS CARE DIRECTIONS, is not applicable to daily

disposable lenses. For complete information and instruction concerning Daily Disposable

lenses refer to **DK Medivision Color Contact lenses** Daily Disposable Patient

Instruction/Wearer’s Guide.

**Frequent/Planned Replacement:** Eyecare practitioners should review with the patient

lens care directions, including both basic lens care information and specific instructions

on the lens care regimen recommended for the patient:

**\***

**Basic Instructions:**

-

Care of contact lens takes very little time and involves THREE essential steps –

**CLEANING, RINSING AND DISINFECTING**. Each step in itself is

important, and one step is not to be replaced by the other.

-

-

-

Always wash, rinse and dry hands before handling contact lens.

Always use **FRESH, STERILE UNEXPIRED** lens care solutions.

Use the recommended chemical (not heat) lens care system. Different solutions

cannot always be used together, and not all solutions are safe for use with all

lenses.

-

**DO NOT ALTERNATE OR MIX LENS CARE SYSTEMS UNLESS**



**INDICATED ON SOLUTION LABELING**.

-

Do not use saliva or anything other than the recommended solutions for

lubricating or rewetting lens. Do not put lens in the mouth.

Lens should be **cleaned, rinsed, and disinfected** each time they are removed.

**Cleaning and rinsing** are necessary to remove mucus and film from the lens

surface.

-

-

-

**Disinfecting** is necessary to destroy harmful germs.

The lens case must be emptied and refilled with fresh, sterile recommended

storage and disinfection solution prior to disinfecting the lens. Eyecare

practitioners may recommend a lubricating/rewetting solution, which can be used

to wet (lubricate) lens while they are being worn to make them more comfortable.

**Note:** Some solutions may have more than one function, which will be indicated

on the label. Read the label on the solution bottle and follow instructions.

**\***

**Specific Instructions for Use and Warnings:**

**Soaking and Storing the Lenses**

**Instruction for Use:**

***a.***

•

Use only fresh multi-purpose (contact lens disinfecting) solution each time

the lenses are soaked (stored).

**WARNING***:*

•

Do not reuse or “top off” old solution left in the lens case since solution

reuse reduces effective lens disinfection and could lead to severe infection,

vision loss or blindness.

•

“Topping-Off” is the addition of fresh solution to solution that has been

sitting the case.

***b.***

**Rub and Rinse Time**

**Instruction for Use:**

•

Rub and rinse the lenses according to the recommended lens rubbing and

rinsing times in the labeling of the multi-purpose solution to adequately

disinfect the lenses.

**WARNING:**

•

Rub and rinse the lenses for the recommended amount of time to help

prevent serious eye infections.



•

Never use water, saline solution, or rewetting drops to disinfect the lenses.

These solutions will not disinfect the lenses. Not using the recommended

disinfectant can lead to severe infection, vision loss or blindness.

***c.***

**Lens Case Care**

**Instruction for Use:**

•

Empty and clean contact lens cases with digital rubbing using fresh, sterile

disinfecting solutions/contact lens cleaner. Never use water. Cleaning

should be followed by rinsing with fresh, sterile disinfecting solutions

(never use water) and wiping the lens cases with fresh, clean tissue is

recommended. Never air-dry or recap the lens case lids after use without

any additional cleaning methods. If air drying, be sure that no residual

solution remains in the case before allowing it to air dry.

•

•

Replace the lens case according to the directions given by the eye care

professional or the labeling that came with the case.

Contact lens cases can be a source of bacterial growth.

**WARNING:**

•

Do not store the lenses or rinse the lens case with water or any non-sterile

solution. Only use fresh multi-purpose solution to prevent contaminating

the lenses or lens case. Use of non-sterile solution can lead to severe

infection, vision loss or blindness.

***d.***

**Water Activity**

**Instruction for Use:**

•

Do not expose the contact lenses to water while wearing them.

**WARNING:**

•

Water can harbor microorganisms that can lead to severe infection, vision

loss or blindness. If the lenses have been submersed in water when

swimming in pools, lakes or oceans, the patient should discard them and

replace them with a new pair. The patient should ask the eye care

practitioner (professional) for recommendations about wearing the lenses

during any activity involving water.

***e.***

**Discard Date on Multipurpose Solution Bottle**

**Instruction for Use:**

•

Discard any remaining solution after the recommended time period

indicated on the bottle of multipurpose solution used for disinfecting and

soaking the contact lenses.

•

The Discard date refers to the time the patient can safely use contact lens

care product after the bottle has been opened. It is not the same as the

expiration date, which is the last date that the product is still effective

before it is opened.

**WARNING:**

•

Using the multi-purpose solution beyond the discard date could result in

contamination of the solution and can lead to severe infection, vision loss

or blindness.

•

•

To avoid contamination, DO NOT touch tip of container to any surface.

Replace cap after using.

To avoid contaminating the solution, DO NOT transfer to other bottles or

containers.

**\***

**Lens cleaning, disinfection, and storage:**

**Clean** one lens first (always the same lens first to avoid mix-ups), rinse the lens

thoroughly with recommended rinsing or disinfecting solution to remove the

cleaning solution, mucus, and film from the lens surface, and put lens into correct

chamber of the lens storage case. Then repeat the procedure for the second lens.

After cleaning, **disinfect** lens using the system recommended by the manufacture

and/or the eyecare practitioner. To store lens, disinfect and leave them in the

closed/unopened case until ready to wear. If lens is not to be used immediately

following disinfection, the patient should be instructed to consult the package

insert or the eyecare practitioner for information on storage of lens.

\*

**Rinsing**

Thoroughly rinse both surfaces of the lens with a steady stream of fresh, sterile

rinsing or multipurpose solution.

**\***

**Lens Care Regimen:**

Patients must adhere to the lens care regimen recommended by their eyecare

practitioner. Failure to follow this procedure may result in development of

serious ocular infections

**\***

**Care for a dried out (dehydrated) dry lens:**

If for some reason, your lenses dry out completely a minimum of handling is

important, as they are very brittle in the dehydrated state. Carefully place them in

rinsing or storage solution for a minimum of thirty minutes during which time

they will become soft and flexible. Then follow the cleaning, rinsing, and

disinfecting procedures - including soaking the lens in storage and disinfection

solution for four hours before wearing again.

**\***

**Care for a sticking (non-moving) lens:**

If the lens sticks (cannot be removed), the patient should be instructed to apply 3

to 4 drops of the recommended lubricating or rewetting solution directly to the

eye and wait until the lens begins to move freely on the eye before removing it. If

nonmovement of the lens continues after 15 minutes, the patient should

**IMMEDIATELY** consult the eyecare practitioner.

**\***

**\***

**Lenses prescribed for frequent replacement:**

It is recommended that the **DK Medivision Color Contact lenses** be discarded

and replaced with a new lens every one (1) month. However, as the Eyecare

practitioner, you are encouraged to determine an appropriate lens replacement

schedule based upon the response of the patient.

**Chemical (NOT HEAT) Lens Disinfection:**

1

2

. Wash and rinse hands thoroughly BEFORE HANDLING LENS.

. After removal of lens, CLEAN the lens by applying three drops of cleaner to each

surface. Rub and rinse the lenses for 15-20 seconds or more and then repeat with

the second side for a total of 2 times 30 seconds or more. Follow the complete

recommended lens rubbing and rinsing times in the labeling to adequately

disinfect the lenses and reduce the risk of contact lens infection.

. AFTER CLEANING, thoroughly rinse both surfaces of the lens with a steady

stream of fresh, sterile rinsing solution for approximately 10 seconds.

. Fill contact lens carrying case with the recommended disinfection and storage

solution and place lens in the proper cells and soak as recommend in solution

labeling.

3

4

Note:

DO NOT HEAT THE DISINFECTION SOLUTION AND LENS.

Caution: Lenses that are chemically disinfected may absorb ingredients from the

disinfecting solution which may be irritating to the eyes. A thorough rinse

in fresh, sterile rinsing solution prior to placement on the eye should reduce

the potential for irritation.

-

When using hydrogen peroxide lens care systems, **the patient must use ONLY**

**the lens case provided with the hydrogen peroxide care system. This case is**

**specially designed to neutralize the solution.** Failure to use the specialized case

will result in severe stinging, burning, and injury to the eye. Follow the

recommendations on the hydrogen peroxide system labeling

exclusively. Following disinfection with a peroxide system, the lenses should be

rinsed with sterile saline.

For additional information concerning the care, cleaning and disinfecting of contact

lenses refer to the **DK Medivision Color Contact lenses** Patient Instruction/Wearer’s

Instruction Guide.

**LENS DEPOSITS AND USE OF ENZYMATIC CLEANER**

Enzyme cleaning may be recommended by the eyecare practitioner. Enzyme cleaning

removes protein deposits on the lens. These deposits cannot be removed with regular

cleaners. Removing protein deposits is important for the wellbeing of the patient's lens

and eyes. If these deposits are not removed, they can damage the lens and cause

irritation.

Enzyme cleaning does NOT replace routine daily cleaning and disinfecting. For enzyme

cleaning, the patient should carefully follow the instructions in the enzymatic cleaning

labeling.

**HOW SUPPLIED:**

The **DK Medivision Color Contact lenses** are sterile in sealed blister packages

containing a buffered saline solution. The base of the package is made from

polypropylene, which is covered with an aluminum foil seal on top. The blister packages

are marked with the base curve, diameter, dioptric power, lens color, manufacturing lot

number, and expiration date of the lens.

**REPORTING OF ADVERSE REACTIONS:**

All serious adverse experiences and adverse reactions observed in patients wearing **DK**

**Medivision Color Contact lenses** or experienced with the lens should be reported to:

**DK Medivision Co., Ltd.**

2

3 Busong 1-gil, jiksan-eup,

Seobuk-gu Cheonan-si, Chungcheongnam-do,

KOREA

Tel: +82-41-581-0100

PRINT DATE: 2025-04-15

**\***

**SYMBOL GLOSSARY**

**Graphic**

**Title**

**Description**

**Graphic**

**Title**

**Description**

Indicates a medical

device that has been

sterilized using steam or

dry heat

Indicates the temperature

limits to which the

medical device can be

Serilized using

steam or dry

heat

Temperature

limit

safely exposed(1~30℃)

Indicates that caution in

necessary when

operating the device or

control close to where

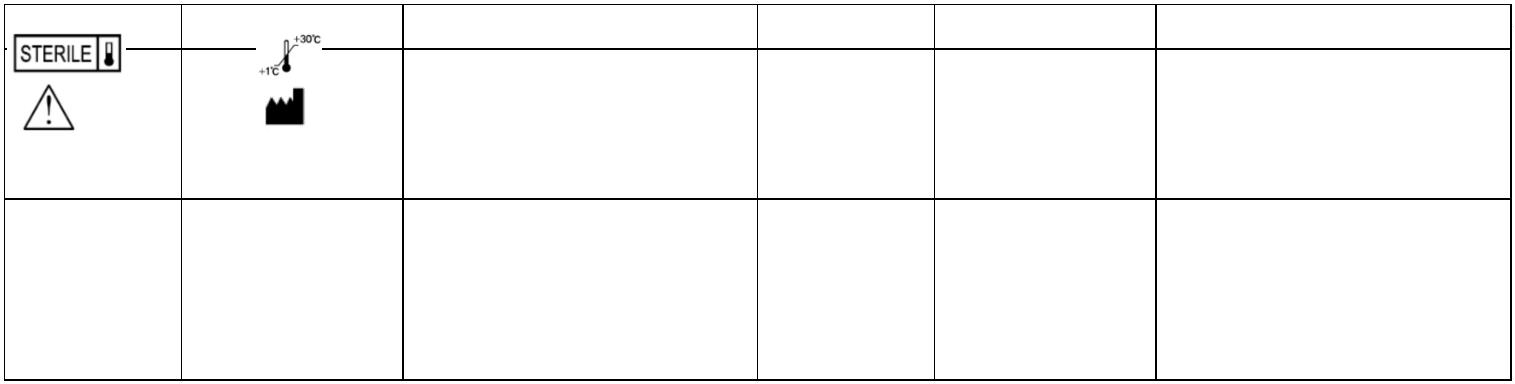
the symbol is placed, or

Indicates the medical

device manufacturer

Caution

Manufacturer



that the current situation

needs operator awareness

or operator action in

order to avoid

undesirable

consequences

Indicates that a medical

device that should not be

used if the package has

been damaged or opened

and that the user should

consult the instructions

for use for additional

information

Do not use if

package is

damaged and

consult

instructions

for use

Indicates the date after

which the medical device

is not to be used

Use-by date

Batch code

Indicates the

manufacturer’s batch

code so that the batch or

lot can be identified

Indicates a medical

device that has been

sterilized using steam or

dry heat & Indicates a

single sterile barrier

system

Indicates that the box

(and contents) should be

kept dry.

Keep dry

Indicates that a product

is a prescription-only

medical device and can

only be obtained with a

medical prescription.

Serilized using

steam or dry

heat & Single

sterile barrier

system

Prescription

only

Consult

instruction for

use or consult

electronic

instructions

for use

Indicates the need for the

user to consult the

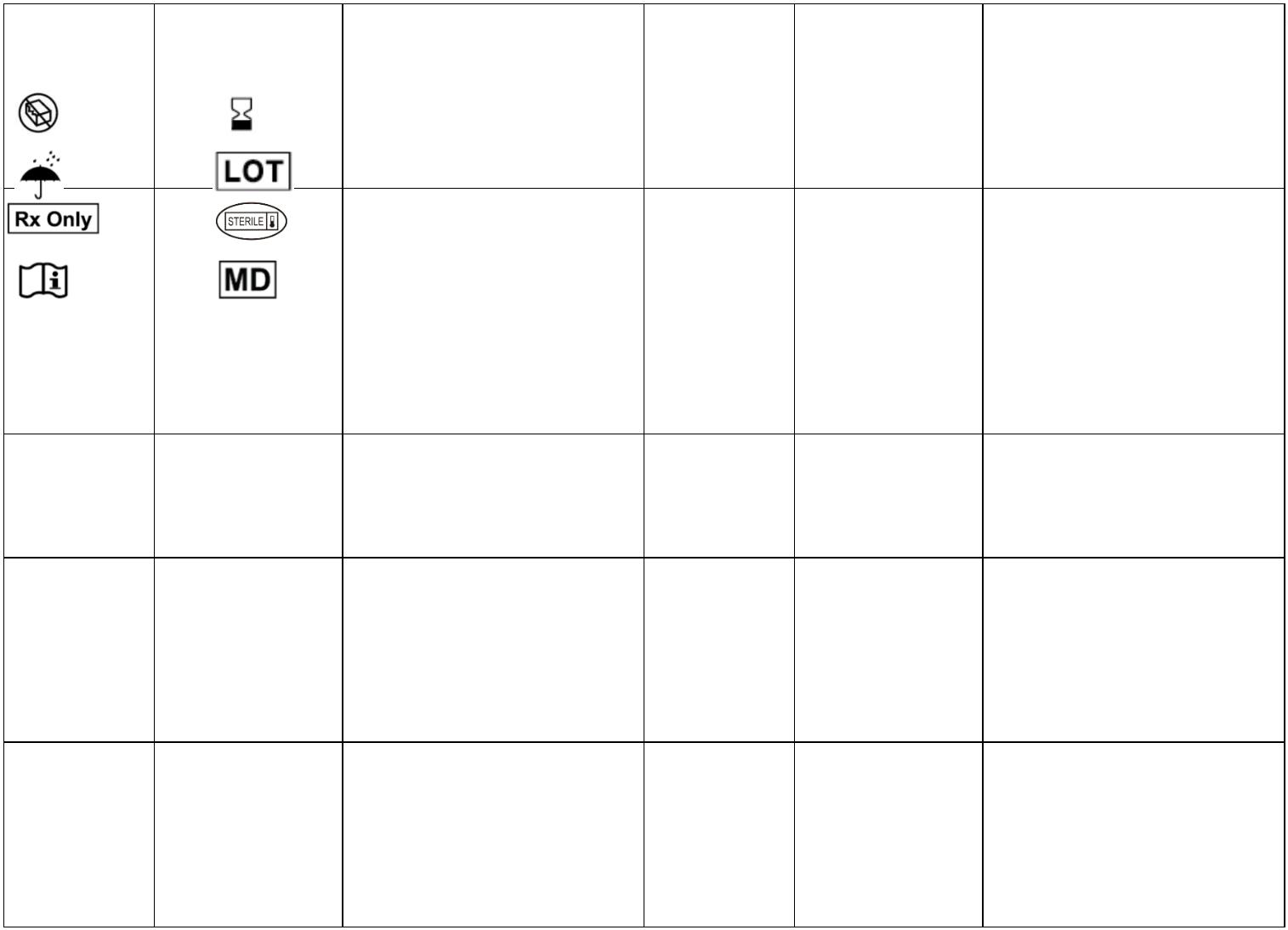
Medical

device

Indicates the item is a

medical device

instructions for use



**FREQUENT/PLANNED REPLACEMENT PATIENT**

**INSTRUCTION / WEARER'S GUIDE**

For the

**DK Medivision Co., Ltd.**

**DK Medivision Color Contact lenses (Tinted, Color)**

***CAUTION: FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON***

***THE ORDER OF A LICENSED PRACTITIONER.***

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Wearing Schedule

Appointment Schedule



You have just received your new frequent/planned replacement (e.g. 2-week, monthly) **DK**

**Medivision Color Contact lenses (Tinted, Color)**. This booklet has been prepared to help you

care for it. Please read it carefully and follow the instructions so that you receive full satisfaction

from your lens.

PRACTITIONER:

ADDRESS:

TELEPHONE:

**Daily Cleaner:**

**Rinsing Solution:**

**Disinfecting Solution:**

**Lubricant/Rewetting Drops:**

**Rewetting Solution:**

**Hydrogen Peroxide System:**

**INTRODUCTION:**

Read this Wearer's Guide carefully. It contains the information you need to know to wear,

handle, and care for your frequent/planned replacement **DK Medivision Color Contact lenses**

**(Tinted, Color)**.

**WEARING RESTRICTIONS and INDICATIONS:**

The DK Medivision Color Contact lenses (Tinted, Color) are indicated for the correction of

refractive ametropia (myopia) in aphakic and not-aphakic persons with non-diseased eyes. The

lenses may be worn by persons who exhibit astigmatism of 2.00 diopters or less where the

astigmatism does not interfere with visual acuity. The lens is available clear or tinted and may be

used to enhance or alter the apparent color of the eye.



As prescribed for planned replacement, the lens should be disinfected using a chemical or

hydrogen peroxide disinfecting system.

**DO NOT WEAR YOUR DK MEDIVISION COLOR CONTACT LENSES (TINTED,**

**COLOR) WHILE SLEEPING.**

**CONTRAINDICATIONS (REASONS NOT TO USE):**

DO NOT USE the frequent/planned replacement **DK Medivision Color Contact lenses** when

any of the following conditions exist:

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Acute and subacute inflammation or infection of the anterior chamber of the eye.

Any eye disease, injury, or abnormality that affects the cornea, conjunctiva, or

eyelids.

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Severe insufficiency of lacrimal secretion (dry eyes).

Corneal hypoesthesia (reduced corneal sensitivity), if not-aphakic.

Any systemic disease that may affect the eye or be exaggerated by wearing contact

lens.

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Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by

wearing contact lens or use of contact lens solutions.

Allergy to any ingredient, such as mercury or thimerosal, in a solution which is to be

used to care for your frequent/planned replacement **DK Medivision Color Contact**

**lenses** .

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Any active corneal infection (bacterial, fungi, or viral)

If eyes become red or irritated.

Patients unable to follow lens care regimen or unable to obtain assistance to do so.

**WARNINGS:**

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PROBLEMS WITH CONTACT LENSES AND LENS CARE PRODUCTS COULD

RESULT IN SERIOUS INJURY TO THE EYE.

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You should not reuse or “top off” old solution left in your lens case since solution

reuse reduces effective lens disinfection and could lead to severe infection, vision loss

or blindness. “Topping-Off” is the addition of fresh solution to solution that has been

sitting the case.

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When disinfecting your lenses, you should rub and rinse the lenses for the

recommended amount of time to help prevent serious eye infections (see CARING

FOR YOUR LENS for specific instructions).

You should never use water, saline solution, or rewetting drops to disinfect the lenses.

These solutions will not disinfect the lenses. Not using the recommended disinfectant

can lead to severe infection, vision loss or blindness.

You should not store your lenses or rinse your lens case with water or any non-sterile

solution. You must only use fresh multi-purpose solution (or sterile saline solution) so

your lenses or lens case are not contaminated. Use of non-sterile solution can lead to

severe infection, vision loss or blindness.

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Water can harbor microorganisms that can lead to severe infection, vision loss or

blindness. If your lenses have been submersed in water such as when swimming in

pools, lakes, or oceans; then you should discard them and replace them with a new

pair. You should ask your eye care practitioner (professional) for recommendations

about wearing their lenses during any activity involving water.

Using the multi-purpose solution beyond the discard date could result in

contamination of the solution and can lead to severe infection, vision loss or

blindness.

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EYE PROBLEMS, INCLUDING CORNEAL ULCERS, CAN DEVELOP

RAPIDLY AND LEAD TO LOSS OF VISION IF YOU EXPERIENCE:

o Eye Discomfort,

o Excessive Tearing,

o Vision Changes,

o Loss of Vision,

o Eye Redness

o Or Other Eye Problems

YOU SHOULD IMMEDIATELY REMOVE THE LENSES, AND PROMPTLY

CONTACT YOUR EYE CARE PRACTITIONER.

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Daily wear lenses are not indicated for overnight wear; therefore, you are instructed

not to wear lenses while sleeping. Clinical studies have shown that the risk of serious

adverse reactions is increased when these lenses are worn overnight.

Studies have shown that contact lens wearers who are smokers have a higher

incidence of adverse reactions than nonsmokers.

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You must see your eyecare practitioner as directed.

**PRECAUTIONS**

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If the lens sticks (stops moving) on the eye, follow the recommended directions on

(care for sticking non-moving lens). The lens should move freely on the eye for the

continued health of the eye. If non-movement of the lens continues, you should

**IMMEDIATELY** consult your eyecare practitioner.

Always wash and rinse hands before handling lens. Do not get cosmetics, lotions,

soaps, creams, deodorants, or sprays in the eyes or on the lens. It is best to put on

lens before putting on makeup. Water-base cosmetics are less likely to damage lens

than oil-base.

Do not touch contact lens with the fingers or hands if the hands are not free of foreign

materials, as microscope scratches of the lens may occur, causing distorted vision

and/or injury to the eye.

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Never wear lens beyond the period recommended by the eyecare practitioner.

If aerosol products such as hair spray are used while wearing lens, exercise caution

and keep eyes closed until the spray has settled.

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Always handle lens carefully and avoid dropping them.

Do not expose your contact lenses to water while you are wearing them.

Avoid all harmful or irritating vapors and fumes while wearing lens.

Ask your eyecare practitioner about wearing your lens during sporting activities.

Inform the doctor (health care practitioner) about you being a contact lens wearer.

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Never use tweezers or other tools to remove lens from your lens container unless

specifically indicated for that use. Pour the lens into your hand.

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Do not touch the lens with your fingernails.

Always contact your eyecare practitioner before using any medicine or medications in

your eyes.

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Always inform your employer of being a contact lens wearer. Some jobs may require

use of eye protection equipment or may require that you not wear contact lens.

As with any contact lens, follow-up visits are necessary to assure the continuing

health of your eyes. You should be instructed as to a recommended follow-up

schedule.

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Different solutions cannot always be used together, and not all solutions are safe for

use with all lens. Use only recommended solutions that are fresh and sterile. Never

use solutions recommended for conventional hard contact lens only. Chemical

disinfection solutions should not be used with heat unless specifically indicated on

product labeling for use in both heat and chemical disinfection. Always use **FRESH,**

**STERILE UNEXPIRED** lens care solutions. Always follow directions in the

package inserts for the use of contact lens solutions. Sterile unpreserved solutions,

when used, should be discarded after the time specified in the labeling directions.

Do not use saliva or anything other than the recommended solution for lubricating or

rewetting lens. Always keep the lens completely immersed in the recommended

storage solution when the lens is not being worn (stored). Prolonged periods of

drying will damage the lens. Follow the lens care directions for (Care for a Dried Out

Dehydrated Dry Lens) if the lens surface does become dried out.

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Carefully follow the handling, insertion, removal, cleaning, disinfection, storing and

wearing instructions in your instructions for the **DK Medivision Color Contact**

**lenses (Tinted, Color)** and those prescribed by the eyecare practitioner.

Always discard your lenses after the recommended wearing schedule prescribed by

your eyecare practitioner.

**ADVERSE REACTIONS**

The following problems may occur:

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Eyes stinging, burning, itching (irritation), or other eye pain.

Comfort is less than when lens was first placed on eye.

Feeling that something is in the eye such as a foreign body or scratched area.

Excessive watering (tearing) of the eye.

Unusual eye secretions.

Redness of the eye.

Reduced sharpness of vision (poor visual acuity).

Blurred vision, rainbows, or halos around objects.

Sensitivity to light (photophobia).

Dry eyes.

If you notice any of the above, **IMMEDIATELY REMOVE YOUR LENS**.

\*

If discomfort or problems stop following lens removal, then look closely at your lens.

If the lens is in any way damaged, **DO NOT PUT THE LENS BACK ON YOUR**

**EYE.** Place the lens in the storage case and contact your eyecare practitioner. If the

lens has dirt, an eyelash, or other foreign body on it, or the problem stops and the lens

appears undamaged, you should thoroughly clean, rinse, and disinfect the lens then

reinsert them. After reinsertion, if the problem continues, you should

**IMMEDIATELY REMOVE THE LENS AND CONSULT YOUR EYECARE**

**PRACTITIONER.**

When any of the above problems occur, a serious condition such as infection, corneal

ulcer, neovascularization, or iritis may be present. The patient should be instructed to

**KEEP LENS OFF YOUR EYE AND SEEK IMMEDIATE PROFESSIONAL**

**IDENTIFICATION** of the problem and prompt treatment to avoid serious eye

damage.

**PERSONAL CLEANLINESS and LENS HANDLING**

Before Handling Your Lens:

*Cleanliness is the first and most important aspect of proper contact lens care.*

Before handling your lens, always wash and rinse your hands thoroughly and dry them

with a lint-free towel. Do not use soaps, lotions, cold creams, or perfumes which leave a

residue on your hands. Avoid using medications, creams, deodorants, make-up, after

shave lotions, or similar items prior to touching your lens. When hair spray is used, the

eye must be kept closed until the spray has settled. Take care in handling your lens.

Always avoid touching your lens with your fingernails or other sharp objects. NEVER

WORK DIRECTLY OVER A SINK WITH THE DRAIN OPEN, AS THE LENS MAY

BE LOST.

Handling and Placing the Lens on the Eye:

i. To avoid the possibility of lens mix-ups, always start with the same lens first.

ii. Remove the lens from its storage case and examine it to be sure that it is moist, clean,

clear, and free of any nicks or tears.

iii. Before inserting the lens, rinse well with fresh, sterile rinsing solution. Then place

the lens on the tip of the index finger of your dominant hand.

iv.

While positioned on your index finger, check to ensure the lens has not turned inside

out. To check this, look at the profile of the lens against a light background. If the

edge profile appears convex and bowl-shaped, then it is correct. If the lens is

inverted, it will flare out at the edge. If the lens is inverted, simply reverse it by using

light fingertip pressure. Be sure to avoid damaging the lens with your fingernails.

v. Look straight ahead and raise the upper lid with your other index finger.

vi.

Then look down, keep both eyes open and place the lens on the upper white part of

the eye.

vii.

Slowly release upper lid, and gently close your eye.



viii. The lens should center automatically, or it can be moved on center by gentle fingertip

pressure through the lids.

ix.

Repeat the above procedure for the second lens.

x. If the lens appears to be stuck on your eye, apply a few drops of a recommended

lubricating or rewetting solution to the eye and blink a few times. If the lens does not

move freely on your eye, contact your eyecare practitioner for further instructions.

There is no single "right way" of putting on lens. If you find this method of lens

placement difficult, your eyecare practitioner will suggest another method or provide

additional information.

Centering the Lens:

Very rarely, a lens that is on the cornea will be displaced onto the white part of the eye

during lens wear. This can also occur during placement and removal of the lenses if the

correct techniques are not performed properly. To center a lens on the eye, follow the

procedure below.

Using your index finger, gently apply pressure to the lens and slide it back into the cornea. If

the lens gets under the upper lid, gently massage the upper lid while looking down and move

the lens toward the cornea.

Removing the Lens:

Preparation:

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) Wash and rinse your hands thoroughly.

) Dry hands with a lint-free towel.

) Check that the lens is centered on the cornea before attempting to remove the lens.

Check your vision by covering one eye. If vision is blurry, the lens is off-center. Re-

center the lens before attempting to remove it.

Removal:

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) To avoid the possibility of lens mix-ups, always begin with the same lens.

) Look up and keep both eyes open.

) Using the middle finger of your dominant hand, gently pull down the lower lid of the

first eye. Using the tip of your index finger of the same hand, touch the lens and slide

it onto the white of the eye.

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) Gently "pinch" the lens between the index finger and the thumb and remove.

) Repeat the procedure for the second eye.

) If the lens cannot be easily moved, apply a few drops of lubricating or rewetting

solution to the eye, blink a few times, and when the lens moves freely on the eye,

remove in the manner described above. If the lens still cannot be moved, contact

your eyecare practitioner for further instruction.

7

) Upon removal, clean each lens with a contact lens cleaner per the procedures

described under the heading, CARING FOR YOUR LENS. Rinse well with rinsing

solution and place in the lens storage case filled with fresh storage solution.

IMPORTANT: Always avoid touching your lens with your fingernails. Use only your

fingertips.

If you find this method difficult, your eyecare practitioner will suggest another method or

provide additional instruction.

If the lens is chipped or torn, do not put the lens back on your eye. Return the lens to the storage

case with fresh solution and contact your eyecare practitioner.

**CARING FOR YOUR LENS**

Basic Instructions:

-

For continued safe and comfortable wearing of your lens, it is important that you

first clean and rinse, then disinfect your lens after each removal, using the care

regimen recommended by your eyecare practitioner. Cleaning and rinsing are

necessary to remove mucus, secretions, films, or deposits, which may have

accumulated after removing them. Disinfecting is necessary to destroy harmful

germs.

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You should adhere to a recommended care regimen. Failure to follow the

regimen may result in development of serious ocular complications as discussed

in the warning section above.

If you require only vision correction, but will not or cannot adhere to a

recommended care regimen for your lens, or are unable to place and remove your

lens or have someone available to place and remove them, you should not attempt

to get and wear contact lens.

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When you first get your lens, be sure you are able to put the lens on and remove

them while you are in your eyecare practitioner's office. At that time you will be

provided with a recommended cleaning and disinfection regimen and instructions

and warnings for lens care, handling, cleaning, and disinfection.

Your eyecare practitioner should instruct you about appropriate and adequate

procedures and products for your use, and provide you with a copy of the

Frequent/Planned Replacement Patient Instruction/Wearer's Guide for the **DK**

**Medivision Color Contact lenses (Tinted, Color)**.

For safe contact lens wear, you should know and always practice your lens care routine:

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Always wash, rinse, and dry hands before handling contact lens.

Always use fresh, sterile unexpired lens care solutions.

Use recommended system of lens care and carefully follow instructions on solution

labeling.

\*

Different solutions cannot always be used together, and not all solutions are safe for

use with all lens. DO NOT ALTERNATE OR MIX LENS CARE SYSTEMS

UNLESS INDICATED ON SOLUTION LABELING.

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Do not use saliva or anything other than the recommended solutions for lubricating or

rewetting lens. Do not put lens in the mouth.

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Never rinse your lens in water from the tap. There are two reasons for this:

a. Tap water contains many impurities that can contaminate or damage your lens and

may lead to eye infection or injury.

b. You might lose the lens down the drain.

Your eyecare practitioner should recommend a care system that is appropriate for the

frequent/planned replacement **DK Medivision Color Contact lenses (Tinted,**

**Color)**. Each lens care product contains specific directions for use and important

safety information, which should be read and carefully followed.

Clean one lens first (always the same lens first to avoid mix-ups), rinse the lens

thoroughly with recommended rinsing or disinfecting solution to remove the cleaning

solution, mucus, and film from the lens surface, and put lens into correct chamber of

the lens storage case. Then repeat the procedure for the second lens.

After cleaning, disinfect lens using the system recommended by the manufacture

and/or your eyecare practitioner.

To store lens, use only fresh multi-purpose (contact lens disinfecting) solution each

time you soak (store) your lenses. Disinfect and leave them in the closed/unopened

case until ready to wear. If lens are not to be used immediately following

disinfection, you should consult the package insert or your eyecare practitioner for

information on storage of lens.

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Always keep your lens completely immersed in a recommended

disinfecting/conditioning solution when the lens are not being worn. If you

discontinue wearing your lens, but plan to begin wearing them after a few weeks, ask

your eyecare practitioner for a recommendation on how to store your lens.

Frequent/Planned Replacement **DK Medivision Color Contact lenses (Tinted,**

**Color)** can be disinfected using a chemical (NOT HEAT) disinfecting system.

Contact lens cases can be a source of bacteria growth. After removing the lens from

the case, empty and rinse the lens storage case with solution as recommended by the

lens case manufacture; then allow the lens case to air dry. When the case is used

again, refill it with storage solution. Replace lens case at regular intervals as

recommended by the lens case manufacture or your eyecare practitioner.

Your eyecare practitioner may recommend a lubricating/rewetting solution for your

use. Lubricating/Rewetting solutions can be used to wet (lubricate) your lens while

you are wearing them to make them more comfortable.

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Lenses prescribed for frequent/planned replacement should be thrown away after the

recommended wearing period prescribed by your eyecare practitioner.

**Specific Instructions for Use and Warnings:**

***a.***

**Soaking and Storing Your Lenses**

**Instruction for Use:**

•

Use only fresh multi-purpose (contact lens disinfecting) solution each time

you soak (store) your lenses.

**WARNING***:*

•

Do not reuse or “top off” old solution left in your lens case since solution

reuse reduces effective lens disinfection and could lead to severe infection,

vision loss or blindness.

•

“Topping-Off” is the addition of fresh solution to solution that has been

sitting your case.

***b.***

**Rub and Rinse Time**

**Instruction for Use:**

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Rub and rinse your lenses according to the recommended lens rubbing and

rinsing times in the labeling of your multi-purpose solution to adequately

disinfect your lenses.

**WARNING:**

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Rub and rinse your lenses for the recommended amount of time to help

prevent serious eye infections.

Never use water, saline solution, or rewetting drops to disinfect your

lenses. These solutions will not disinfect your lenses. Not using the

recommended disinfectant can lead to severe infection, vision loss or

blindness.

***c.***

**Lens Case Care**

**Instruction for Use:**

•

Empty and clean contact lens cases with digital rubbing using fresh, sterile

disinfecting solutions/contact lens cleaner. Never use water. Cleaning

should be followed by rinsing with fresh, sterile disinfecting solutions

(never use water) and wiping the lens cases with fresh, clean tissue is

recommended. Never air-dry or recap the lens case lids after use without

any additional cleaning methods. If air drying, be sure that no residual

solution remains in the case before allowing it to air dry.

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Replace your lens case according to the directions given you by your eye

care professional or the labeling that came with your case.

Contact lens cases can be a source of bacterial growth.

**WARNING:**

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Do not store your lenses or rinse your lens case with water or any non-

sterile solution. Only use fresh multi-purpose solution so you do not

contaminate your lenses or lens case. Use of non-sterile solution can lead

to severe infection, vision loss or blindness.

***d.***

**Water Activity**

**Instruction for Use:**

•

Do not expose your contact lenses to water while you are wearing them.

**WARNING:**

•

Water can harbor microorganisms that can lead to severe infection, vision

loss or blindness. If your lenses have been submersed in water when

swimming in pools, lakes or oceans, you should discard them and replace

them with a new pair. Ask your eye care practitioner (professional) for

recommendations about wearing your lenses during any activity involving

water.

***e.***

**Discard Date on Multipurpose Solution Bottle**

**Instruction for Use:**

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Discard any remaining solution after the recommended time period

indicated on the bottle of multipurpose solution used for disinfecting and

soaking your contact lenses.

The Discard date refers to the time you can safely use contact lens care

product after the bottle has been opened. It is not the same as the

expiration date, which is the last date that the product is still effective

before it is opened.

**WARNING:**

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Using your multi-purpose solution beyond the discard date could result in

contamination of the solution and can lead to severe infection, vision loss

or blindness.

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To avoid contamination, DO NOT touch tip of container to any surface.

Replace cap after using.

To avoid contaminating your solution, DO NOT transfer to other bottles or

containers.

**LENS DEPOSITS AND USE OF ENZYMATIC CLEANER:**

Enzyme cleaning may be recommended by your eyecare practitioner. Enzyme cleaning

removes protein deposits on the lens. These deposits cannot be removed with regular

cleaners. Removing protein deposits is important for the well-being of your lens and

eyes. If these deposits are not removed, they can damage the lens and cause irritation.

Enzyme cleaning does NOT replace routine cleaning and disinfecting. For enzyme

cleaning, you should carefully follow the instructions in the enzymatic cleaning labeling.

**CARE FOR A STICKING (NON-MOVING) LENS:**

If the lens sticks (cannot be removed), you should apply 3 to 4 drops of the recommended

lubricating or rewetting solution directly to the eye and wait until the lens begins to move

freely on the eye before removing it. If non-movement of the lens continues after 15

minutes, you should IMMEDIATELY consult your eyecare practitioner.

**CARE FOR A DRIED OUT (DEHYDRATED) DRY LENS:**

If for some reason your lens dry out completely: a minimum of handling is important as

they are very brittle in the dehydrated state. Carefully place them in rinsing or storage

solution for a minimum of thirty minutes during which time they will become soft and

flexible. Then follow the cleaning, rinsing, and disinfecting procedures, including

soaking the lens in storage and disinfection solution for four hours before wearing again.

**CHEMICAL (NOT HEAT) DISINFECTION:**

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. Wash and rinse your hands thoroughly BEFORE HANDLING LENS.

. After removal of lens, CLEAN the lens by applying three drops of cleaner to each

surface. You should rub and rinse the lenses for 15-20 seconds or more and then

repeat with the second side for a total of 2 times 30 seconds or more. Follow the

complete recommended lens rubbing and rinsing times in the labeling to

adequately disinfect the lenses and reduce the risk of contact lens infection.

. AFTER CLEANING, thoroughly rinse both surfaces of the lens with a steady

stream of fresh, sterile rinsing solution for approximately 10 seconds.

. Fill contact lens carrying case with the recommended disinfection and storage

solution and place lens in the proper cells and soak as recommend in solution

labeling.

3

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Note:

DO NOT HEAT THE DISINFECTION SOLUTION AND LENS.

Caution: Lenses that are chemically disinfected may absorb ingredients from the

disinfecting solution which may be irritating to the eyes. A thorough rinse

in fresh, sterile rinsing solution prior to placement on the eye should reduce

the potential for irritation.

-

When using hydrogen peroxide lens care systems, **use ONLY the lens case**

**provided with the hydrogen peroxide care system. This case is specially**

**designed to neutralize the solution.** Failure to use the specialized case will

result in severe stinging, burning, and injury to the eye. Follow the

recommendations on the hydrogen peroxide system labeling

exclusively. Following disinfection with a peroxide system, the lenses should be

rinsed with sterile saline.

**EMERGENCIES:**

If any chemicals of any kind (household products, gardening solutions, laboratory

chemicals, etc.) are splashed into the eyes, you should:

**FLUSH EYES IMMEDIATELY WITH TAP WATER AND IMMEDIATELY**

**CONTACT YOUR EYECARE PRACTITIONER OR VISIT A HOSPITAL**

**EMERGENCY ROOM WITHOUT DELAY.**

**WHEN TO CALL YOUR PRACTITIONER?**

Certain symptoms may be early indicators of potentially serious problems. A careful

examination of your lens, and professional examination of your eyes, may be required.

Remove the lens following the instructions outlined in this guide, and call your eyecare

practitioner if:

1

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3

) Your eye becomes red and feels irritated or "gritty".

) You notice a change in your vision or see rainbows or halos around objects.

) You experience discomfort and/or sensitivity to lights.

*A good general policy is:*

IF IN DOUBT ... TAKE THE LENS OUT” and contact your eyecare practitioner.

Learn and Use Proper lens Care Habits:

“

1

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) Follow Instructions.

) Handle Lens Properly.

) Learn How to Put On and Take Off Your Lens.

) Keep Your Lens Clean.

) Disinfection is a Necessary Security

**INSTRUCTIONS FOR MONOVISION WEARERS**

•

You should be aware that as with any type of lens correction, there are advantages

and compromises to monovision contact lens therapy. The benefit of clear near

vision in straight ahead and upward gaze that available with monovision may be

accompanied by a vision compromise that may reduce your visual acuity and depth

perception for distance and near tasks. Some patients have experienced difficulty

adapting to it. Symptoms, such as mild blurred vision, dizziness, headaches and a

feeling of slight imbalance, may last for a brief minute or for several weeks as

adaptation takes place. The longer these symptoms persist, the poorer your prognosis

for successful adaptation. You should avoid visually demanding situations during the

initial adaptation period. It is recommended that you first wear these contact lenses in

familiar situations, which are not visually demanding. For example, it might be better

to be a passenger rather than a driver of an automobile during the first few days of

lens wear. It is recommended that you only drive with monovision if you pass your

state driver’s license requirements with the correction.

•

Some monovision patients will never be fully comfortable functioning under low

levels of illumination, such as driving at night. If this happens, you may want to

discuss with your eyecare practitioner having additional contact lenses prescribed so

that both eyes are corrected for distance when sharp distance binocular vision is

required.

If you require very sharp near vision during prolonged close work, you may want to

have additional contact lenses prescribed so that both eyes are corrected for near

when sharp near binocular vision is required.

•

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Some monovision patients require supplemental spectacles to wear over the

monovision to provide the clearest vision for critical tasks. You should discuss this

with your eyecare practitioner.

It is important that you follow your eyecare practitioner’s suggestions for adaptation

to monovision contact lens therapy. You should discuss any concerns that you may

have during and after the adaptation period.

The decision to be fit with monovision correction is most appropriately left to the

eyecare practitioner in conjunction with you, after carefully considering and

discussing your needs.

**RECOMMENDED LENS CARE PRODUCTS**

The eyecare practitioner should recommend a care system indicated for use with soft

contact lenses and appropriate for the frequent/planned replacement **DK Medivision Color**

**Contact lenses (Tinted, Color).** Each lens care product contains specific directions for use

and important safety information, which should be read and carefully followed.

**WEARING SCHEDULE:**

THE WEARING AND REPLACEMENT SCHEDULES SHOULD BE DETERMINED BY

YOUR EYECARE PRACTITIONER. The **DK Medivision Color Contact lenses (Tinted,**

**Color)** are indicated for daily wear.

APPOINTMENT SCHEDULE:

Your appointments are on:

Month

Year

Time

Day



IMPORTANT:

In the event that you experience any difficulty wearing your lens or you do not understand

the instructions given you, DO NOT WAIT for your next appointment. TELEPHONE

YOUR EYECARE PRACTITIONER IMMEDIATELY.

Manufactured and Distributed by:

**DK Medivision Co., Ltd.**

2

3 Busong 1-gil, jiksan-eup,

Seobuk-gu Cheonan-si, Chungcheongnam-do,

KOREA

Toll Free: [To be included when available]

PRINT DATE: YYYY-MM-DD

**DAILY DISPOSABLE PATIENT INSTRUCTION /**

**WEARER'S GUIDE**

For the

**DK Medivision Co., Ltd.**

**DK Medivision Color Contact lenses (Tinted, Color)**

***CAUTION: FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON***

***THE ORDER OF A LICENSED PRACTITIONER.***

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Appointment Schedule



You have just received your new daily disposable **DK Medivision Color Contact lenses**

**(Tinted, Color)**. This booklet has been prepared to help you care for it. Please read it carefully

and follow the instructions so that you receive full satisfaction from your lens.

PRACTITIONER:

ADDRESS:

TELEPHONE:

**INTRODUCTION:**

Read this Wearer's Guide carefully. It contains the important information for wearing

and handling your Daily Disposable **DK Medivision Color Contact lenses (Tinted,**

**Color)**. If you are in doubt about any instructions, request clarification from your

eyecare practitioner.

**WEARING RESTRICTIONS and INDICATIONS:**

The DK Medivision Color Contact lenses (Tinted, Color) are indicated for the correction of

refractive ametropia (myopia) in aphakic and not-aphakic persons with non-diseased eyes. The

lenses may be worn by persons who exhibit astigmatism of 2.00 diopters or less where the

astigmatism does not interfere with visual acuity. The lens is available clear or tinted and may be

used to enhance or alter the apparent color of the eye.

**DO NOT WEAR YOUR DK MEDIVISION COLOR CONTACT LENSES**

**(TINTED, COLOR) WHILE SLEEPING.**

**CONTRAINDICATIONS (REASONS NOT TO USE):**

DO NOT USE the **DK Medivision Color Contact lenses (Tinted, Color)** when any of the

following conditions exist:

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Acute and subacute inflammation or infection of the anterior chamber of the eye.

Any eye disease, injury, or abnormality that affects the cornea, conjunctiva, or

eyelids.

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Severe insufficiency of lacrimal secretion (dry eyes).

Corneal hypoesthesia (reduced corneal sensitivity), if not-aphakic.

Any systemic disease that may affect the eye or be exaggerated by wearing contact

lens.

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Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by

wearing contact lens or use of contact lens solutions.

Any active corneal infection (bacterial, fungi, or viral)

If eyes become red or irritated.

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**WARNINGS:**

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PROBLEMS WITH CONTACT LENSES COULD RESULT IN SERIOUS INJURY

TO THE EYE.

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EYE PROBLEMS, INCLUDING CORNEAL ULCERS, CAN DEVELOP

RAPIDLY AND LEAD TO LOSS OF VISION; IF YOU EXPERIENCE:

o Eye Discomfort,

o Excessive Tearing,

o Vision Changes,

o Loss of Vision,

o Eye Redness

o Or Other Eye Problems

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YOU SHOULD IMMEDIATELY REMOVE THE LENSES, AND PROMPTLY

CONTACT YOUR EYE CARE PRACTITIONER.

Water can harbor microorganisms that can lead to severe infection, vision loss or

blindness. If your lenses have been submersed in water such as when swimming

in pools, lakes, or oceans; then you should discard them and replace them with a

new pair. You should ask your eye care practitioner (professional) for

recommendations about wearing their lenses during any activity involving water.

Daily wear lenses are not indicated for overnight wear, therefore, you are

instructed not to wear lenses while sleeping. Clinical studies have shown that the

risk of serious adverse reactions is increased when these lenses are worn

overnight.

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You must see your eyecare practitioner as directed. Strict compliance with your

wearing restrictions, wearing schedule, and follow-up visit schedule should be

followed.

Studies have shown that contact lens wearers who are smokers have a higher

incidence of adverse reactions than nonsmokers.

**PRECAUTIONS:**

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Daily disposable lenses are to be disposed of once they are removed from the

patient’s eye. It is important that patients be instructed to always have available a

pair of replacement lenses. In the event that a lens must be removed from the eye

because of dust, a foreign body or other contaminant gets on the lens or the lens

becomes dehydrated, the lens should be removed and replaced with a replacement

lens.

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Carefully follow the handling and wearing instructions in your Daily Disposable

Patient Instruction/Wearer’s Guide for the **DK Medivision Color Contact lenses**

**(Tinted, Color)** and those prescribed by the eyecare practitioner.

Always wash and rinse hands before handling lens. Do not get cosmetics, lotions,

soaps, creams, deodorants, or sprays in the eyes or on the lens. It is best to put on

lens before putting on makeup. Water-base cosmetics are less likely to damage lens

than oil-base.

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Do not touch contact lens with the fingers or hands if the hands are not free of foreign

materials, as microscope scratches of the lens may occur, causing distorted vision

and/or injury to the eye.

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Never wear lens beyond the period recommended by the eyecare practitioner.

If aerosol products such as hair spray are used while wearing lens, exercise caution

and keep eyes closed until the spray has settled.

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Always handle lens carefully and avoid dropping them.

Do not expose your contact lenses to water while you are wearing them.

Avoid all harmful or irritating vapors and fumes while wearing lens.

Ask your eyecare practitioner about wearing your lens during sporting activities.

Inform the doctor (health care practitioner) about you being a contact lens wearer.

Never use tweezers or other tools to remove lens from your lens container unless

specifically indicated for that use. Pour the lens into your hand.

Do not touch the lens with your fingernails.

If the lens sticks (stops moving) on the eye, follow the recommended directions on

(care for sticking non-moving lens). The lens should move freely on the eye for the

continued health of the eye. If non-movement of the lens continues, you should

**IMMEDIATELY** consult your eyecare practitioner.

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Always contact your eyecare practitioner before using any medicine or medications in

your eyes.

Always inform your employer of being a contact lens wearer. Some jobs may require

use of eye protection equipment or may require that you not wear contact lens.

As with any contact lens, follow-up visits are necessary to assure the continuing

health of your eyes. You should be instructed as to a recommended follow-up

schedule.

**ADVERSE REACTIONS:**

The following problems may occur:

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Eyes stinging, burning, itching (irritation), or other eye pain.

Comfort is less than when lens was first placed on eye.

Feeling that something is in the eye such as a foreign body or scratched area.

Excessive watering (tearing) of the eye.

Unusual eye secretions.

Redness of the eye.

Reduced sharpness of vision (poor visual acuity).

Blurred vision, rainbows, or halos around objects.

Sensitivity to light (photophobia).

Dry eyes.

If you notice any of the above, **IMMEDIATELY REMOVE AND DISCARD YOUR**

**LENS**.

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DO NOT put the lens back on the eye

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After inserting a new lens, if the problem continues you should **KEEP THE**

**LENS OFF YOUR EYE AND CONSULT YOUR EYECARE**

**PRACTITIONER.**

When any of the above problems occur, a serious condition such as infection,

corneal ulcer, neovascularization, or iritis may be present. You should be

instructed to **KEEP LENS OFF THE EYE AND SEEK IMMEDIATE**

**PROFESSIONAL IDENTIFICATION** of the problem and prompt

treatment to avoid serious eye damage.

**PERSONAL CLEANLINESS and LENS HANDLING**

Before Handling Your Daily Disposable Lens:

*Cleanliness is the first and most important aspect of proper contact lens care.*

Before handling your lens, always wash and rinse your hands thoroughly and dry them

with a lint-free towel. Do not use soaps, lotions, cold creams, or perfumes which leave a

residue on your hands. Avoid using medications, creams, deodorants, make-up, after

shave lotions, or similar items prior to touching your lens. When hair spray is used, the

eye must be kept closed until the spray has settled. Take care in handling your lens.

Always avoid touching your lens with your fingernails or other sharp objects. NEVER

WORK DIRECTLY OVER A SINK WITH THE DRAIN OPEN, AS THE LENS MAY

BE LOST.

Handling and Placing the Daily Disposable Lens on the Eye:

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) Remove the lens from its packaging and examine it to be sure that it is moist, clean,

clear, and free of any nicks or tears.

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) Place the lens on the tip of the index finger of your dominant hand.

) While positioned on your index finger, check to ensure the lens has not turned inside

out. To check this, look at the profile of the lens against a light background. If the

edge profile appears convex and bowl-shaped, then it is correct. If the lens is

inverted, it will flare out at the edge. If the lens is inverted, simply reverse it by using

light fingertip pressure. Be sure to avoid damaging the lens with your fingernails.

) Look straight ahead and raise the upper lid with your other index finger.

) Then look down, keep both eyes open and place the lens on the upper white part of

the eye.

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) Slowly release upper lid, and gently close your eye.

) The lens should center automatically, or it can be moved on center by gentle fingertip

pressure through the lids.

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) Repeat the above procedure for the second lens.

) If the lens appears to be stuck on your eye, apply a few drops of a recommended

lubricating or rewetting solution to the eye and blink a few times. If the lens does not

move freely on your eye, contact your eyecare practitioner for further instructions.



There is no single "right way" of putting on lens. If you find this method of lens

placement difficult, your eyecare practitioner will suggest another method or provide

additional information.

Centering the Daily Disposable Lens:

Very rarely, a lens that is on the cornea will be displaced onto the white part of the eye

during lens wear. This can also occur during placement and removal of the lenses if the

correct techniques are not performed properly. To center a lens on the eye, follow the

procedure below.

Using your index finger, gently apply pressure to the lens and slide it back into the cornea. If

the lens gets under the upper lid, gently massage the upper lid while looking down and move

the lens toward the cornea.

Removing the Daily Disposable Lens:

Preparation:

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) Wash and rinse your hands thoroughly.

) Dry hands with a lint-free towel.

) Check that the lens is centered on the cornea before attempting to remove the lens.

Check your vision by covering one eye. If vision is blurry, the lens is off-center. Re-

center the lens before attempting to remove it.

Removal:

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) To avoid the possibility of lens mix-ups, always begin with the same lens.

) Look up and keep both eyes open.

) Using the middle finger of your dominant hand, gently pull down the lower lid of the

first eye. Using the tip of your index finger of the same hand, touch the lens and slide

it onto the white of the eye.

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) Gently "pinch" the lens between the index finger and the thumb and remove.

) Repeat the procedure for the second eye.

) If the lens cannot be easily moved, apply a few drops of lubricating or rewetting

solution to the eye, blink a few times, and when the lens moves freely on the eye,

remove in the manner described above. If the lens still cannot be moved, contact

your eyecare practitioner for further instruction.

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) Upon removal always discard your Daily Disposable lens. Never reuse your Daily

Disposable lens.

IMPORTANT: Always avoid touching your lens with your fingernails. Use only your

fingertips.

If you find this method difficult, your eyecare practitioner will suggest another method or

provide additional instruction.

**Water Activity**

**Instruction for Use:**

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Do not expose the contact lenses to water while wearing them.

**WARNING:**

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Water can harbor microorganisms that can lead to severe infection, vision loss or

blindness. If the lenses have been submersed in water when swimming in pools, lakes or

oceans, the patient should discard them and replace them with a new pair. The patient

should ask the eye care practitioner (professional) for recommendations about wearing

the lenses during any activity involving water.

**CARE FOR A STICKING (NON-MOVING) LENS:**

If the lens sticks (cannot be removed), you should apply 3 to 4 drops of the recommended

lubricating or rewetting solution directly to the eye and wait until the lens begins to move

freely on the eye before removing it. If non-movement of the lens continues after 15

minutes, you should IMMEDIATELY consult your eyecare practitioner.

**EMERGENCIES:**

If any chemicals of any kind (household products, gardening solutions, laboratory

chemicals, etc.) are splashed into the eyes, you should:

**FLUSH EYES IMMEDIATELY WITH TAP WATER AND IMMEDIATELY**

**CONTACT YOUR EYECARE PRACTITIONER OR VISIT A HOSPITAL**

**EMERGENCY ROOM WITHOUT DELAY.**

**WHEN TO CALL YOUR PRACTITIONER?**

Certain symptoms may be early indicators of potentially serious problems. A careful

examination of your lens, and professional examination of your eyes, may be required.

Remove the lens following the instructions outlined in this guide, and call your eyecare

practitioner if:

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) Your eye becomes red and feels irritated or "gritty".

) You notice a change in your vision or see rainbows or halos around objects.

) You experience discomfort and/or sensitivity to lights.

*A good general policy is:*

IF IN DOUBT ... TAKE THE LENS OUT” and contact your eyecare practitioner.

Learn and Use Proper lens Care Habits:

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) Follow Instructions.

) Handle Lens Properly.

) Keep Your Lens Clean.

**INSTRUCTIONS FOR MONOVISION WEARERS**

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You should be aware that as with any type of lens correction, there are advantages

and compromises to monovision contact lens therapy. The benefit of clear near

vision in straight ahead and upward gaze that available with monovision may be

accompanied by a vision compromise that may reduce your visual acuity and depth

perception for distance and near tasks. Some patients have experienced difficulty

adapting to it. Symptoms, such as mild blurred vision, dizziness, headaches and a

feeling of slight imbalance, may last for a brief minute or for several weeks as

adaptation takes place. The longer these symptoms persist, the poorer your prognosis

for successful adaptation. You should avoid visually demanding situations during the

initial adaptation period. It is recommended that you first wear these contact lenses in

familiar situations, which are not visually demanding. For example, it might be better

to be a passenger rather than a driver of an automobile during the first few days of

lens wear. It is recommended that you only drive with monovision if you pass your

state driver’s license requirements with the correction.

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Some monovision patients will never be fully comfortable functioning under low

levels of illumination, such as driving at night. If this happens, you may want to

discuss with your eyecare practitioner having additional contact lenses prescribed so

that both eyes are corrected for distance when sharp distance binocular vision is

required.

If you require very sharp near vision during prolonged close work, you may want to

have additional contact lenses prescribed so that both eyes are corrected for near

when sharp near binocular vision is required.

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Some monovision patients require supplemental spectacles to wear over the

monovision to provide the clearest vision for critical tasks. You should discuss this

with your eyecare practitioner.

It is important that you follow your eyecare practitioner’s suggestions for adaptation

to monovision contact lens therapy. You should discuss any concerns that you may

have during and after the adaptation period.

The decision to be fit with monovision correction is most appropriately left to the

eyecare practitioner in conjunction with you, after carefully considering and

discussing your needs.

**WEARING SCHEDULE:**

THE WEARING AND REPLACEMENT SCHEDULES SHOULD BE DETERMINED BY

YOUR EYECARE PRACTITIONER. The **DK Medivision Color Contact lenses (Tinted,**

**Color)** are indicated for daily wear.

APPOINTMENT SCHEDULE:

Your appointments are on:

Month

Year

Time

Day

IMPORTANT:

In the event that you experience any difficulty wearing your lens or you do not understand

the instructions given you, DO NOT WAIT for your next appointment. TELEPHONE

YOUR EYECARE PRACTITIONER IMMEDIATELY.

Manufactured and Distributed by:

**DK Medivision Co., Ltd.**

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KOREA

Toll Free: [To be included when available]

PRINT DATE: YYYY-MM-DD

