PROFESSIONAL FITTING GUIDE

Paraperm® O_2

Rigid Gas Permeable Contact Lenses for Daily Wear

CooperVision® Specialty EyeCare Paragon

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CAUTIONS: Federal (US) law restricts this device to sale by, or on the order of a licensed practitioner. Nonsterile. Clean and condition lenses prior to use.

PRODUCT DESCRIPTION

Paraperm® O_2 (pasifocon A) rigid gas permeable contact lenses for daily wear are available as a lathe cut or molded firm contact lenses with spherical, aspheric, bifocal or toric anterior and/or posterior; or, bitoric surfaces in clear and tinted versions. The posterior curve is selected so as to properly fit an individual eye and the anterior curve is selected to provide the necessary optical power to correct refractive error. A peripheral curve system on the posterior surface allows tear exchange between the lens and the cornea.

Paraperm® O_2 (pasifocon A) rigid gas permeable contact lens materials are thermoset copolymers derived from siloxane and methylmethacrylate.

These lens materials are available untinted (clear) and tinted (blue, electric blue, green and cool green) versions. The tinted lenses contain one or more of the following color additives; D&C Green No. 6, D&C Yellow No. 10 and Perox Yellow No. 9 (4-[(2,4-dimethylphenyl)azo]-2,4-dihydro-5-methyl-2-phenyl-3H-pyrazol-3-one).

The lenses have the following attributes.

Paraperm® O_2 (pasifocon A)

Refractive Index	1.473(Nd at 25ºC)
Luminous Transmittance[+] (Clear)	99%
Luminous Transmittance (Blue)	93%
Luminous Transmittance (Electric Blue)	81%
Luminous Transmittance (Green)	97%
Luminous Transmittance (Cool Green)	95%
Wetting Angle (Receding Angle)[++]	23°
Wetting Angle (Contact Angle)[+++]	64°
Specific Gravity	1.12
Hardness (Shore D)	86
Water Content	< 2%
Oxygen Permeability*	16 x 10^{-11} Dk at 35º

[+]Determination of the Spectral and Luminous Transmittance, ISO 8599:1994
[++]Adapted from: A New Method for Wetting Angle Measurement; Madigan, et. al., International Eyecare, 01/1998. vol. 2, no. 1, p. 45
[++]Sessile Drop Technique per ANSI Z80.20, 8.11
*(cm^2/sec) (mL O_2) / (mL x mm Hg) ISO/ANSI Method, ISO 9913-1

LENS PARAMETERS (not all available in all materials)

Chord Diameter	7.0 to 10.5 mm
Center Thickness	0.05 to 0.70 mm
Base Curve	6.50 to 9.00 mm
Power Daily Wear	-20.00 to + 12.00 diopters
Power Extended Wear	-20.00 to + 8.00 diopters
Bifocal Add Powers	+0.25 to + 4.00 diopters
Monocentric Bifocal Add Diameter	4.0 to 9.0 mm
Monocentric Bifocal Prism	1.0 to 2.5 diopters
Concentric Bifocal Add Diameter	2.0 to 4.0 mm

ACTIONS

The Paraperm® O_2 rigid gas permeable spherical, aspheric, toric and bifocal contact lenses are intended for daily wear only.

When placed on the human cornea, Paraperm® O_2 rigid gas permeable contact lenses act as a refracting medium to focus light rays upon the retina.

The toric lens provides for the individual meridional power requirements of the astigmatic eye. In the bifocal lens, the distance or near power prescription is provided in a small area with the near or distance prescription surrounding it.

INDICATIONS

The Paraperm® O_2 rigid gas permeable contact lenses are indicated for daily wear as recommended by the eye care practitioner.

Paraperm® O_2 rigid gas permeable spherical, aspheric, and bifocal contact lenses are indicated for the correction of refractive ametropia in not-aphakic persons with nondiseased eyes that are nearsighted (myopic), farsighted (hyperopic), and may exhibit corneal astigmatism up to 4.00 diopters. Paraperm® O_2 toric contact lenses are indicated to correct astigmatism of up to 6.00 diopters.

CONTRAINDICATIONS, WARNINGS, PRECAUTIONS AND ADVERSE REACTIONS

See Package Insert [Contraindications (Reasons Not To Use)] and (Warning) for Paraperm® O_2 (pasifocon A).

See Package Insert, General Information (Warnings), (Precautions) and [Adverse Effects (Problems And What To Do)] for all products.

LENS HANDLING

CAUTION: Nonsterile. Clean and condition lenses prior to use.

1. Prior to fitting, wash your hands and rinse them thoroughly to remove all traces of soap.
2. To condition (disinfect) your lenses, leave them in a recommended storage solution for at least 4 hours prior to usage or as indicated on the product label.
3. Remove the lens from the case and rinse it with wetting and soaking solution.
4. Place the lens on the tip of your index finger, concave side up.

LENS PLACEMENT

1. Retract the patient's lids with your index finger and thumb.
2. Direct the patient to look straight ahead and place the lens on the cornea.
3. Slowly release the lids and ask the patient to blink. This will center the lens.

LENS REMOVAL

1. Place your index fingers on the lid margins and direct the patient to look straight ahead.
2. Separate the lids, then push them together to remove the lens.

IN-OFFICE CLEANING, DISINFECTION AND STORAGE

Paraperm® O_2 rigid gas permeable contact lenses must be cleaned and disinfected each time they are removed from the eye. One procedure does no replace the other. Cleaning is necessary to remove mucus and film from the lens surface. Disinfecting is necessary to destroy harmful germs. Leave the Paraperm® O_2 rigid gas permeable contact lenses in a storage solution for a minimum of 4 hours or as indicated on the solution product label.

To minimize lens warpage during cleaning, the lenses should be cleaned in the palm of the hand rather than between the thumb and fingers.

The directions from any lens care systems used should be followed. Failure to adhere to these procedures may result in the development of serious ocular infections.

Do no mix or alternate the disinfection and storage systems unless so indicated on the product label.

LENS FITTING

<u>General Information</u>

Paraperm® O_2 (pasifocon A) rigid gas permeable contact lenses may be fitted for daily wear using the standard techniques for rigid contact lenses. A diagnostic lens fitting procedure is recommended, although not always required.

When placed on the human cornea, the Paraperm® O_2 rigid gas permeable contact lens acts as a refracting medium to focus light rays upon the retina.

Clinical studies have demonstrated that rigid gas permeable contact lenses manufactured from these contact lens materials are safe and effective for their intended use. However, the clinical studies may not have included all design configurations or lens parameters that are presently available in these materials. Consequently, when selecting an appropriate lens design and parameters, the eye care practitioner must consider all factors that affect lens performance and ocular health. The potential impact of these factors must be weighted against the patient's needs. Therefore, the continuing ocular health of the patient and lens performance on the eye should be carefully monitored.

Pretrial Examination

A complete contact lens examination should be carried out including health and previous contact lens history, refraction, keratometry and slit lamp examination. Patients should be eliminated who have evidence of any disease affecting the cornea or conjunctiva, acute or subacute inflammation of the anterior segment of the eye, insufficiency of the lacrimal secretion, corneal hypoesthesia or any disease or infection which will affect the eye or be exaggerated by the wearing of contact lenses.

FITTING PROCEDURE – SPHERICAL AND ASPHERIC

Selection of Patients
Patients should be individuals who require a daily wear or extended wear lens; are not-aphakic; and, have nondiseased eyes. Patients should have a refractive error which does not exceed 20.00 diopters of myopia and 12.00 diopters of hyperopia for daily wear, or 8.00 diopters of hyperopia for extended wear; and, who may exhibit corneal astigmatism up to 4.00 diopters. Patients predisposed to excessive edema or staining may not be suitable.

Diagnostic Lens Fitting Procedure
It is recommended that fitting be carried out with the aid of diagnostic lenses. Nearly every patient begins with a 9.2 mm trial lens. The exceptions would be patients who have keratometer readings below 41.00 D or above 45.00 D. If the corneal reading is below 41.00 D and the patient appears to have an exceptionally large cornea and palpebral fissure, begin with a 9.6 mm diameter lens. This is rare. Alternatively, if a patient has a keratometer reading which is greater than 45.00 D or has an unusually small palpebral aperture, begin the fitting with an 8.8 mm diameter lens.

The base curve of the lens may be found in Table 1. From the keratometer readings, find the flattest K and steepest K. Enter the table on the left with the corneal cylinder (ΔK) value and follow across to the first diagnostic lens base curve to be used.

TABLE 1

Corneal Cylinder (ΔK)	Lens Base Curve
Plano	0.25 D flatter to on flat K
0.25 – 0.75 D	on flat K to 0.25 D steeper
1.00 – 1.75 D	0.25 D steeper to 0.75 D steeper
>2.00 D	0.75 D steeper to 1.00 D steeper

Place the diagnostic lens on the patient's cornea. Wait approximately 10 minutes for tearing to subside. Check the lens for positioning and movement. Ideally, the lens will ride up with the blink and then quickly drop to a position that is near the center of the cornea. If the lens should drop to the lower limbus or position eccentrically, remove the lens and replace it with a lens that is 0.4 mm larger. If centering is still not achieved, use a diagnostic lens that is 0.25 D steeper.

The power for the final lens may be most accurately determined by an overrefraction with the diagnostic lens in place. This may be carried out with either a trial frame or refractor. Allow approximately 15 minutes for the lens to settle on the patient's eye before performing the overrefraction. Only the spherical power needs to be determined in order to arrive at the final correction.

When the optimum overrefraction has been obtained, the correction should be added to the power of the diagnostic lens to arrive at the final prescription.

EXAMPLE:	Overrefraction	-1.25 D
	Diagnostic Lens	(+) -3.00 D
	Lens Power Ordered	4.25 D

A patient's lens power requirement may be determined without diagnostic lenses by:

1. Converting the spectacle Rx to minus cylinder form.
2. Adjusting the spectacle Rx for vertex distance.
3. Using the sphere power only.

The selection of the Paraperm® O_2 rigid gas permeable contact lens may be aided by an examination of the fluorescein pattern. The ideal fluorescein pattern shows a definite green central area with some darkening near the periphery of the optic zone. The peripheral curve area should show a definite green band. The most important faulty lens fluorescein pattern to be detected is a corneal seal at the intermediate lens position. The fluorescein pattern shows a dark touch ring that runs completely around the contact lens in the intermediate zone. The larger the lens the greater is the tendency for this to happen. It also occurs most frequently when the optic zone of the contact lens is greater than an 8.0 mm diameter. Hence, a lens design with an optic zone of 8.0 mm or less is usually preferred.

A 9.6 mm (large) lens may be needed for patients who have a problem of flare with smaller diameter contact lenses. The flare may occur if the patient has either a very large pupil or if the smaller lens rides off the center of the cornea. Fortunately, flare is only an occasional problem with the 9.6 mm lens because the peripheral curve and edge are specifically designed to minimize the flare problem.

Some patients develop problems of staining, which are due to an optic zone that is too large. A 7.8 mm optic zone is large enough to avoid flare in nearly every contact lens patient. If the patient requires an even larger lens than the 9.2 mm diameter, choose the 9.6 mm diameter lens but keep the optic zone at 8.0 mm in all but the most unusual cases. In this way some tear pumping is achieved in nearly every case and avoids the corneal punctate staining that is due to inadequate lens pumping.

FITTING PROCEDURE – MONOCENTRIC BIFOCAL

Patient Selection
Patients should be selected who require a daily wear lens; are not-aphakic; and, have nondiseased eyes. Patients should have a refractive error which does not exceed 20.00 diopters of myopia and 12.00 diopters of hyperopia; and, who may exhibit corneal astigmatism up to 4.00 diopters and up to +4.00 diopters of add power. Patients predisposed to excessive edema or staining may not be suitable.

Power Compensation
Higher plus power spectacle prescriptions at distance require higher plus distance and add powers, while higher minus power spectacle prescriptions require less minus power and less add powers in bifocal contact lenses.

Prism
The purpose of the prism is to orient the lens, give a low reading position, and provide a supporting edge at the bottom to enable upward displacement by the lower lid.

DISTANT POWER	PRISM
>+8.00	1.00
+4.00	1.25
+2.00	1.50
Plano	1.75
-2.00	2.00
-4.00	2.25
-6.00	2.50
>-8.00	2.75

Seg Height
The average seg height is determined by the diagnostic lens selection and fitting evaluation.

Diagnostic Lens Fitting Procedure

Fitting is recommended to be carried out with the aid of diagnostic lenses. A suggested diagnostic lens set follows.

Base Curves	7.30 to 8.20 mm (.10 mm steps)
Size	9.2 mm
Optic Zone	7.8 mm
Power	- 3.00 diopters
Add	+ 2.00 diopters
Prism Ballast	1.50 diopters
Seg. Height	4.3 mm

The base curve of the lens may be found in Table 2. From the keratometer readings, find the flattest K and steepest K. Find the corneal cylinder (ΔK) value in the left column and follow across, this is the first diagnostic lens base curve to be used.

TABLE 2

Corneal Cylinder (ΔK)	Lens Base Curve
Plano	0.75 D flatter to 0.50 D flatter
0.25 - 0.75 D	0.50 D flatter to 0.25 D flatter
1.00 - 1.75 D	0.25 D flatter to on flat K
>2.00 D	Not more than 0.25 of difference steeper cylinder

Place the diagnostic lens on the patient's cornea. Wait approximately 10 minutes for tearing to subside and check the lens for positioning and movement. Ideally, the lens will ride up with the blink and then quickly drop to a position that is near the center of the cornea. If the lens should drop to the lower limbus or position eccentrically, remove the lens and replace it with a lens that is 0.4 mm larger. If centering is still not achieved use a diagnostic lens which is 0.50 D steeper.

The lens should translate up, with down gaze, so that the segment is within the visual axis for reading. The prism ballast should not rotate greater than 20 degrees nasally, and seg height, in primary gaze, should be even or slightly above lower pupillary margin. If the lens rotates excessively, a larger prism diopter ballast will be necessary.

The power for the final lens may be most accurately determined by an overrefraction with the diagnostic lens in place. This may be carried out with either a trial frame or refractor. Allow approximately 15 minutes for the lens to settle on the patient’s eye before performing the overrefraction. Only the spherical power needs to be determined in order to arrive at the final correction.

When the optimum overrefraction has been obtained, the correction should be added to the power of the diagnostic lens to arrive at the final prescription.

EXAMPLE:	Overrefraction	-1.25 D
	Diagnostic Lens	(+) - 3.00 D
	Lens Power Ordered	-4.25 D

The selection of the Paraperm® O_2 rigid gas permeable bifocal contact lens may be aided by an examination of the fluorescein pattern. The ideal fluorescein pattern shows a definite green central area with some darkening near the periphery of the optic zone. The peripheral curve area should show a definite green band. The most important faulty lens fluorescein pattern to be detected is a corneal seal at the intermedate lens position. The fluorescein pattern shows a dark touch ring that runs completely around the contact lens in the intermediate zone. The larger the lens the greater is the tendency for this to happen. It also occurs most frequently when the optic zone of the contact lens is greater than an 8.0 mm diameter. Hence, a lens design with an optic zone of 8.0 mm or less is usually preferred.

A larger lens may be needed for patients who have a problem of flare with smaller diameter contact lenses. The flare may occur if the patient has either a very large pupil or if the smaller lens rides off the center of the

cornea. Fortunately, flare is only an occasional problem with the 9.6 mm lens because the peripheral curve and edge are specifically designed to minimize the flare problem.

Some patients develop problems of staining, which are due to an optic zone that is too large. A 7.8 mm optic zone is large enough to avoid flare in nearly every contact lens patient. If the patient requires an even larger lens than the 9.2 mm diameter, choose the 9.6 mm diameter lens but keep the optic zone at 8.0 mm in all but the most unusual cases. In this way some tear pumping is achieved in nearly every case and avoids the corneal punctate staining that is due to inadequate lens pumping.

FITTING PROCEDURE – CONCENTRIC BIFOCAL

Patient Selection
Patients should be selected who require a daily wear lens; are not-aphakic; and, who have nondiseased eyes. Patients should have a refractive error which does not exceed 20.00 diopters of myopia and 12.00 diopters of hyperopia; and, who may exhibit corneal astigmatism up to 4.00 diopters and up to +4.00 diopters of add power. Patients predisposed to excessive edema or staining may not be suitable.

Power Compensation
Higher plus power spectacle prescriptions at distance require higher plus distance and add powers, while higher minus power spectacle prescriptions require less minus power and less add powers in bifocal contact lenses.

Seg Diameter
The average seg diameter is determined by the diagnostic lens selection and fitting evaluation.

Diagnostic Lens Fitting Procedure
Fitting is recommended to be carried out with the aid of diagnostic lenses. A suggested diagnostic lens set would be as follows.

Base Curves	7.30 to 8.20 mm (.10 mm steps)
Size	9.2 mm
Optic zone	7.8 mm
Power	-3.00 diopters
Add power	+2.00 diopters
Add diameter	2 to 4 mm

The base curve of the lens may be found in Table 3. From the keratometer readings, find the flattest K and steepest K. Find the corneal cylinder (ΔK) value in the left column and follow across, this is the first diagnostic lens base curve to be used.

TABLE 3

Corneal Cylinder (ΔK)	Lens Base Curve
PLANO	0.25 D flatter to on flat K
0.25 - 0.75 D	On flat K to 0.25 steeper
1.00 - 1.75 D	0.25 D steeper to 0.50 D steeper
2.00 - 2.75 D	0.50 D steeper to 0.75 D steeper
> 2.75 D	0.25 D steeper to 1.00 D steeper

Place the diagnostic lens on the patient's cornea. Wait approximately 10 minutes for tearing to subside and check the lens for positioning and movement. Ideally, the lens will ride up with the blink and then quickly drop to a position which is near the center of the cornea. If the lens should drop to the lower limbus or position eccentrically, remove the lens and replace it with a lens that is 0.4 mm larger. If centering is still not achieved use a diagnostic lens which is 0.25 D steeper.

The power for the final lens may be most accurately determined by an overrefraction with the diagnostic lens in place. This may be carried out with either a diagnostic frame or refractor. Allow approximately 15

minutes for the lens to settle on the patient's eye before performing the overrefraction. Only the spherical power needs to be determined in order to arrive at the final correction. Both distance and near acuity should be checked.

When the optimum overrefraction has been obtained, the correction should be added to the power of the diagnostic lens to arrive at the final prescription.

EXAMPLE:	Overrefraction	-1.25 D
	Diagnostic Lens	(+) -3.00 D
	Lens Power Ordered	-4.25 D

The selection of the Paraperm® O_2 rigid gas permeable bifocal contact lens may be aided by an examination of the fluorescein pattern. The ideal fluorescein pattern shows a definite green central area with some darkening near the periphery of the optic zone. The peripheral curve area should show a definite green band. The most important faulty lens fluorescein pattern to be detected is a corneal seal at the intermedate lens position. The fluorescein pattern shows a dark touch ring that runs completely around the contact lens in the intermediate zone. The larger the lens the greater is the tendency for this to happen. It also occurs most frequently when the optic zone of the contact lens is greater than an 8.0 mm diameter. Hence, a lens design with an optic zone of 8.0 mm or less is usually preferred.

A larger lens may be needed for patients who have a problem of flare with smaller diameter contact lenses. The flare may occur if the patient has either a very large pupil or if the smaller lens rides off the center of the cornea. Fortunately, flare is only an occasional problem with the 9.60 mm lens because the peripheral curve and edge are specifically designed to minimize the flare problem.

FITTING PROCEDURE – ASPHERIC BIFOCAL

Patient Selection
Patients should be selected who require a daily wear lens; are not-aphakic; and, have nondiseased eyes. Patients should have a refractive error which does not exceed 20.00 diopters of myopia and 12.00 diopters of hyperopia; and, who may exhibit corneal astigmatism up to 4.00 diopters and up to +4.00 diopters of add power. Patients predisposed to excessive edema or staining may not be suitable.

Diagnostic Lens Fitting Procedure
Fitting is recommended to be carried out with the aid of diagnostic lenses. A suggested diagnostic lens set follows.

Base Curves	7.30 to 8.20 mm (.10 mm steps)
Size	9.2 mm
Optic Cone	7.8 mm
Power	-3.00 diopters
Add	+2.00 diopters

The base curve of the diagnostic lens should be 2.75 diopters steeper than the flattest keratometer reading.

EXAMPLE:	K Reading	42.50 x 43.50
	+2.75 Steep	2.75
	Diagnostic Lens Base Curve	45.25 = 7.456 mm

Place the diagnostic lens on the patient's cornea. Wait approximately 10 minutes for tearing to subside and check the lens for positioning and movement. Ideally, the lens will ride up with the blink and then quickly drop to a position that is near the center of the cornea. If the lens should drop to the lower limbus or position eccentrically, remove the lens and replace it with a lens that is 0.4 mm larger. If centering is still not achieved, use a diagnostic lens that is 0.50 D steeper.

The power for the final lens may be most accurately determined by an overrefraction with the diagnostic lens in place. This may be carried out with either a diagnostic frame or refractor. Allow approximately 15 minutes for the lens to settle on the patient's eye before performing the overrefraction. Only the spherical

power needs to be determined in order to arrive at the final correction. Both distance and near acuity should be checked.

With the diagnostic lenses on the eyes, place the overrefraction in a diagnostic frame for both eyes. (The use of a phoropeter is not recommended for this test.)

- Add a +0.50 sphere to both sides of trial frame and ask the patient to read the near point card. Then ask the patient to read the 20/20 line on the distance chart (not how clearly he can read).
- Continue adding +0.25 at a time until the patient cannot read all of the 20/20 line.
- If the patient can read most of the 20/20 line, and at least J-3 on the near point card, the total power of the contact lens power and the power of diagnostic lenses from the trial frame should be ordered.

When the optimal overrefraction has been obtained, the correction should be added to the power of the diagnostic lens to arrive at the final prescription.

EXAMPLE:	Overrefraction	-1.25 D
	Diagnostic Lens	(+) -3.00 D
	Lens power ordered	-4.25 D

The selection of the Paraperm® O_2 rigid gas permeable bifocal contact lens may be aided by an examination of the fluorescein pattern. The ideal fluorescein pattern shows a definite green central area with some darkening near the periphery of the optic zone. The peripheral curve area should show a definite green band. The most important faulty lens fluorescein pattern to be detected is a corneal seal at the intermedate lens position. The fluorescein pattern shows a dark touch ring that runs completely around the contact lens in the intermediate zone. The larger the lens the greater is the tendency for this to happen. It also occurs most frequently when the optic zone of the contact lens is greater than an 8.0mm diameter. Hence, a lens design with an optic zone of 8.0mm or less is usually preferred.

A larger lens may be needed for patients who have a problem of flare with smaller diameter contact lenses. The flare may occur if the patient has either a very large pupil or if the smaller lens rides off the center of the cornea. Fortunately, flare is only an occasional problem with the 9.60 mm lens because the peripheral curve and edge are specifically designed to minimize the flare problem.

FITTING PROCEDURE – TORIC

Patient Selection
Patients should be selected who require a daily wear lens; are not-aphakic; and, who have nondiseased eyes. Patients should have a refractive error which does not exceed 20.00 diopters of myopia and 12.00 diopters of hyperopia; and, who may exhibit corneal astigmatism up to 6.00 diopters.

Diagnostic Lens Fitting Procedure
The base curve of the lens may be found in Table 4. From the keratometer readings, find the flattest K and steepest K. Find the corneal cylinder (ΔK) value in the left column and follow across, this is the first diagnostic set to be used.

TABLE 4

Corneal Cylinder (ΔK)	Diagnostic Set
1.00 - 2.50	2 Diopter Diagnostic Set
2.75 - 4.00	3 Diopter Diagnostic Set
4.25 – Up	4 Diopter Diagnostic Set

Place the diagnostic lens on the patient's cornea. Wait approximately 10 minutes for tearing to subside and check the lens for positioning and movement. Ideally, the lens will ride up with the blink and then quickly drop to a position that is near the center of the cornea. If the lens should drop to the lower limbus or position eccentrically, remove the lens and replace it with a lens that is 0.4 mm larger. If centering is still not achieved, use a diagnostic lens that is 0.50 D steeper.

Other Diagnostic Lens Procedure
Select a bitoric diagnostic lens that provides alignment bearing and positions the lens slightly beneath the upper lid.

Allow approximately 15 minutes for the lens to settle on the patient's eye before performing the overrefractions.

Perform a sphero-cylinder overrefraction, adding the sphere power from the overrefraction to the flattest meridian of the diagnostic lens.

EXAMPLE:	Diagnostic Lens	42.00	x 44.00
		-1.00	-2.00
	Overrefraction	-2.00	
	Order	-3.00	-2.00

If the cylinder finding is -0.50 or less, order cylinder power of diagnostic lens.

EXAMPLE:	Diagnostic Lens	42.00	x 44.00
		-1.00	-2.00
	Overrefraction	PL	-0.50
	Order	-1.00	-2.00

If cylinder finding is -0.75 or larger, and the axis is at or near the diagnostic lens axis, add the minus cylinder power to the steep meridian of the diagnostic lens.

EXAMPLE:	Diagnostic Lens	42.00	x 44.00
		-1.00	-2.00
	Overrefraction	PL	-1.00 x 180
	Order	-1.00	-3.00

The selection of a toric may be aided by an examination of the fluorescein pattern. The ideal fluorescein pattern shows a definite green central area with some darkening near the periphery of the optic zone. The peripheral curve area should show a definite green band.

A larger lens may be needed for patients who have a problem of flare with smaller diameter contact lenses. The flare may occur if the patient has either a very large pupil or if the smaller lens rides off the center of the cornea. Fortunately, flare is only an occasional problem.

MANDELL-MOORE BITORIC LENS GUIDE

Contact lens practitioners can now incorporate the FluoroPerm material advantages in lens designs for their astigmatic patients. The following fitting procedure and charts are derived from Mandell and Moore.[1]

[1] Mandell, R.G., Moore, C.F.: A Bitoric Lens Guide That Really Is Simple. Contact Lens Spectrum, November, 1988, 83-85.
As with spherical FluoroPerm lenses, you must first evaluate for contraindications to lens wear. Very precise keratometry and refraction will be necessary. You will need to determine the flat K and steep K readings and record the refraction in minus cylinder form.

The overall and optic zone diameters are chosen using the same criteria as with spherical lens designs. Generally, bitoric lens diameters are about 0.2 mm smaller than spherical lenses designed for intrapalpebral

fitting. It is important to avoid lid attachment since lid action may cause the lens to rotate from the intended axis.

There are two opposing considerations when selecting the toric posterior surface of a bitoric contact lens in order to achieve the optimum fit. The toric surface must conform close enough to the corneal contour to minimize rotation of the lens. However, some deviation from perfect lens-to-cornea conformation is needed to create pumping of the tear fluid.

The base curve in the flatter meridian should usually be made 0.25 D flatter than the cornea. The base curve in the steeper meridian should be 0.50 to 1.25 D flatter than the cornea depending on the amount of corneal astigmatism. This additional "fit factor" is summarized in the following table.

	FIT FACTOR	
CORNEAL CYL, D	FLAT MERIDIAN	STEEP MERIDIAN
2.00	ON K	.50 Flatter
2.50	.25 Flatter	.50 Flatter
3.00	.25 Flatter	.75 Flatter
3.50	.25 Flatter	.75 Flatter
4.00	.25 Flatter	1.00 Flatter
5.00	.25 Flatter	1.25 Flatter

The calculations of the toric lens powers are divided for the two principal meridians and treated as though they are two separate lenses.

The Mandell-Moore Bitoric Lens Guide presents the steps to be taken in a bitoric lens calculation and a simple form to be used in following these steps. This method follows exactly the same steps as are used to arrive at a spherical contact lens prescription.

Example Readings: OD 44.00 @ 180/47.25 @ 090
OS 42.00 @ 180/46.50 @ 090

Refraction: OD -3.50 -3.50 x 180
OS +12.50 -4.00 x 180

At the top of the form, enter K readings for flat and steep meridians and the spectacle Rx in minus cylinder form.

Line 1 Enter the flat K reading and the steep K reading where indicated.

Line 2 Enter the spherical power of the spectacle Rx. Then add the sphere and cylinder power algebraically and record this value in minus cylinder form where indicated.

Line 3 If either power value is greater than 4.00 D, convert the spectacle Rx to the corneal plane using the Vertex Distance Correction table on the form.

Line 4 Add the "fit factor." This adjustment promotes an alignment fit. First, enter the fit factor for the flat meridian, which will always be 0.25 D and have a minus sign. Next, enter the same value under sphere power, which will have a plus sign. Repeat the same process by finding the fit factor for the steeper meridian and enter the values.

Line 5 The base curve Rx is calculated by adding the values in line one and four. The power is determined by adding lines three and four.

As with spherical lenses, center thickness is a function of lens design. With bitoric lenses, the center thickness is based from the least minus or greatest plus power.

Intermediate and peripheral curves can be generated in either a spherical or toric design. Spherical peripheral curves will result in an oval optic zone. Review the spherical lens section for actual parameter determination.

Right Eye

KERATOMETRY: 44.00 @ 180 | 47.25 @ 90

SPECTACLE Rx (MINUS CYL FORM): -3.50 - 3.50 X 180

	FLATTEST K	SPHERE POWER	STEEPEST K	SPH +CYL POWER
1. ENTER K	44.00	XXXXXXXXXXXX	47.25	XXXXXXXXXXXX
2. ENTER SPECTACLE POWER		-3.50		-7.00
3. VERTEX CORRECTED		-3.50		-6.50
4. FIT FACTORS	(-) 0.25	(+) 0.25	(-) 0.75	(+) 0.75
ADD LINES	1&4	3&4	1&4	3&4
5. FINAL C.L. Rx	43.75	-3.25	46.50	-5.75
	BASECURVE	POWER	BASECURVE	POWER

Left Eye

KERATOMETRY: 42.00 @ 180 | 46.50 @ 90

SPECTACLE Rx (MINUS CYL FORM): +12.50 - 4.00 X 180

	FLATTEST K	SPHERE POWER	STEEPEST K	SPH +CYL POWER
1. ENTER K	42.00	XXXXXXXXXXXX	46.50	XXXXXXXXXXXX
2. ENTER SPECTACLE POWER		+12.50		8.50
3. VERTEX CORRECTED		+14.75		9.50
4. FIT FACTORS	(-) 0.25	(+) 0.25	(-) 1.00	(+) 1.00
ADD LINES	1&4	3&4	1&4	3&4
5. FINAL C.L. Rx	41.75	+15.00	45.50	+10.50
	BASECURVE	POWER	BASECURVE	POWER

VERTEX DISTANCE CORRECTION

4.00	3.75	8.00	7.25	12.00	10.50	16.00	13.25
4.25	4.00	8.25	7.50	12.25	10.75	16.25	13.50
4.50	4.25	8.50	7.75	12.50	10.75	16.50	13.75
4.75	4.50	8.75	8.00	12.75	11.00	16.75	13.75
5.00	4.75	9.00	8.00	13.00	11.25	17.00	14.00
5.25	5.00	9.25	8.25	13.25	11.25	17.25	14.00
5.50	5.25	9.50	8.50	13.50	11.50	17.50	14.25
5.75	5.50	9.75	8.75	13.75	11.75	17.75	14.50
6.00	5.50	10.00	9.00	14.00	12.00	18.00	14.50
6.25	5.75	10.25	9.00	14.25	12.00	18.25	14.75
6.50	6.00	10.50	9.25	14.50	12.25	18.50	15.00
6.75	6.25	10.75	9.50	14.75	12.50	18.75	15.00
7.00	6.50	11.00	9.75	15.00	12.50	19.00	15.25
7.25	6.75	11.25	10.00	15.25	12.75	19.25	15.50
7.50	7.00	11.50	10.00	15.50	13.00	19.75	15.75
7.75	7.00	11.75	10.25	15.75	13.00	20.00	16.00

CORNEAL CYL, D	FIT FACTOR	
	FLAT MERIDIAN	STEEP MERIDIAN
2.00	ON K	.50 FLATTER
2.50	.25 FLATTER	.50 "
3.00	.25 "	.75 "
3.50	.25 "	.75 "
4.00	.25 "	1.00 "
5.00	.25 "	1.25 "

If the spectacle lens power is less than 4.00 diopters then line 3 = line 2. Otherwise: For minus power spectacle lenses find the power in the left side of the column and convert to the power in the right side, but retain the minus sign. For plus power spectacle lenses find the power in the right side of the column and convert to the power in the left side, but retain the plus sign.

Right Eye

KERATOMETRY	@		@	
SPECTACLE Rx (MINUS CYL FORM)			X	

	FLATTEST K	SPHERE POWER	STEEPEST K	SPH +CYL POWER
1. ENTER K		XXXXXXXXXXXX		XXXXXXXXXXXX
2. ENTER SPECTACLE POWER				
3. VERTEX CORRECTED				
4. FIT FACTORS	(-)	(+)	(-)	(+)
ADD LINES	1 & 4	3 & 4	1 & 4	3 & 4
5. FINAL C.L. Rx				
	BASECURVE	POWER	BASECURVE	POWER

Left Eye

KERATOMETRY	@		@	
SPECTACLE Rx (MINUS CYL FORM)			X	

	FLATTEST K	SPHERE POWER	STEEPEST K	SPH +CYL POWER
1. ENTER K		XXXXXXXXXXXX		XXXXXXXXXXXX
2. ENTER SPECTACLE POWER				
3. VERTEX CORRECTED				
4. FIT FACTORS	(-)	(+)	(-)	(+)
ADD LINES	1 & 4	3 & 4	1 & 4	3 & 4
5. FINAL C.L. Rx				
	BASECURVE	POWER	BASECURVE	POWER

VERTEX DISTANCE CORRECTION

4.00	3.75	8.00	7.25	12.00	10.50	16.00	13.25
4.25	4.00	8.25	7.50	12.25	10.75	16.25	13.50
4.50	4.25	8.50	7.75	12.50	10.75	16.50	13.75
4.75	4.50	8.75	8.00	12.75	11.00	16.75	13.75
5.00	4.75	9.00	8.00	13.00	11.25	17.00	14.00
5.25	5.00	9.25	8.25	13.25	11.25	17.25	14.00
5.50	5.25	9.50	8.50	13.50	11.50	17.50	14.25
5.75	5.50	9.75	8.75	13.75	11.75	17.75	14.50
6.00	5.50	10.00	9.00	14.00	12.00	18.00	14.50
6.25	5.75	10.25	9.00	14.25	12.00	18.25	14.75
6.50	6.00	10.50	9.25	14.50	12.25	18.50	15.00
6.75	6.25	10.75	9.50	14.75	12.50	18.75	15.00
7.00	6.50	11.00	9.75	15.00	12.50	19.00	15.25
7.25	6.75	11.25	10.00	15.25	12.75	19.25	15.50
7.50	7.00	11.50	10.00	15.50	13.00	19.75	15.75
7.75	7.00	11.75	10.25	15.75	13.00	20.00	16.00

	FIT FACTOR	
CORNEAL CYL, D	FLAT MERIDIAN	STEEP MERIDIAN
2.00	ON K	.50 FLATTER
2.50	.25 FLATTER	.50 "
3.00	.25 "	.75 "
3.50	.25 "	.75 "
4.00	.25 "	1.00 "
5.00	.25 "	1.25 "

If the spectacle lens power is less than 4.00 diopters then line 3 = line 2. Otherwise: For minus power spectacle lenses find the power in the left side of the column and convert to the power in the right side, but retain the minus sign. For plus power spectacle lenses find the power in the right side of the column and convert to the power in the left side, but retain the plus sign.

With the ideal fit the lens should move freely with the lid during a blink and then drop quickly to a position near the center of the cornea. In some patients the lens will ride slightly high and this is most desirable. It is especially favorable if the lens rides slightly under the upper lid since that will reduce lens edge sensation and make the lens most comfortable. It is best to avoid having the lens ride exceptionally high so that excessive lid pressure is exerted on the superior lens margin. Over an extended wearing period, this inevitably leads to structural changes in the superior corneal epithelium. If the lens appears to center well and move adequately following the blink, proceed to determine the refractive correction.

A lens that is too tight will show reduced movement upon blinking. The lens usually occupies a centered corneal position and may not move far from this position. Bubbles may be detected in the post-lens space.

A lens that is too loose will move excessively on the cornea following each blink. The lens may ride in either a position that is too high or too low or in an eccentric position. A loose lens is usually uncomfortable for the patient.

FOLLOW-UP PATIENT CARE

Follow-up examination should include an evaluation of lens movement, centration, comfort, and fluorescein pattern. Lens movement will decrease as the tear volume is diminishing during adaptation. An assessment of vision and eye health, including inspection of the cornea for edema and/or staining, should be performed. Patient symptoms should also be assessed.

RECOMMENDED DAILY WEAR FOLLOW-UP SCHEDULE

First Follow-up Examination -	Immediately following 3 hours of lens wear on the 1st, 2nd, or 3rd day following dispensing
Second Follow-up Examination -	After 1 week of lens wear
Third Follow-up Examination -	After 3 weeks of lens wear
Subsequent Follow-up Examinations -	After 2 months of lens wear; then regular check-ups as determined by the eye care practitioner

NOTE: See Package Insert for additional safety information.

WEARING SCHEDULE

See Package Insert (Wearing Schedule) for the maximum suggested wearing time for each product.

PATIENT LENS CARE DIRECTIONS

See Package Insert (Lens Care Directions) for these instructions.

CARE FOR A STICKING (nonmoving) LENS

See Package Insert (Care For A Sticking Lens) for these instructions.

HOW SUPPLIED

Each Paraperm® O_2 lens is supplied nonsterile in an individual plastic case. The lens is shipped dry.

REPORT OF ADVERSE REACTIONS

All serious adverse experiences and adverse reaction observed in patients wearing or experienced with the lenses should be reported to the manufacturer.

Paragon Vision Sciences, Inc. 1-800-528-8279
947 E. Impala Avenue 1-480-892-7602
Mesa, Arizona 85204-6619 1-480-926-7369 FAX

PACKAGE INSERT

Paraperm® O_2 (pasifocon A)

Rigid Gas Permeable Contact Lenses for Daily Wear

Shipped Dry

IMPORTANT

Please read carefully and keep this information for future use.

CAUTION: Federal (US) law restricts this device to sale by, or on the order of a licensed practitioner.

WARNING: The practitioner should provide this warning to the patient.

PROBLEMS WITH CONTACT LENSES AND LENS CARE PRODUCTS COULD RESULT IN SERIOUS INJURY TO THE EYE. It is essential that you follow your eye care practitioner's directions and all labeling instructions for proper use of your contact lenses and lens care products, including the lens case.

Patients should follow the complete recommended lens rubbing and rinsing times in the product labeling to adequately disinfect their lenses and reduce the risk of contact lens contamination. Reduced rubbing or rinsing times may not adequately clean their lenses.

Patients should fill their lens case with fresh solution every time they store their lenses, and never re-use solution. They should discard their solution immediately after their lenses have been removed from the lens case. They should not store their lenses in or rinse their lens case with tap water, bottled water or any non-sterile solution.

Patients should clean and rinse their lens case between uses as recommended by their eye care practitioner.

EYE PROBLEMS, INCLUDING CORNEAL ULCERS, CAN DEVELOP RAPIDLY AND LEAD TO LOSS OF VISION; THEREFORE, IF YOU EXPERIENCE EYE DISCOMFORT, EXCESSIVE TEARING, VISION CHANGES, OR REDNESS OF THE EYE, OR OTHER PROBLEMS WITH YOUR EYES, IMMEDIATELY REMOVE YOUR LENSES, AND PROMPTLY CONTACT YOUR EYE CARE PRACTITIONER.

PARAPERM® O_2
(pasifocon A)

RIGID GAS PERMEABLE CONTACT LENSES
FOR DAILY WEAR

Daily Wear Spherical, Aspheric, Toric, Bitoric contact lenses for:

Nearsightedness (myopia).
Farsightedness (hyperopia).

DESCRIPTION

Paraperm® O_2 (pasifocon A) rigid gas permeable contact lenses for daily wear are available as lathe cut or molded firm contact lenses with spherical, aspheric, bifocal or toric anterior and/or posterior; or, bitoric surfaces in clear and tinted versions. The posterior curve is selected so as to properly fit an individual eye and the anterior curve is selected to provide the necessary optical power to correct refractive error. A peripheral curve system on the posterior surface allows tear exchange between the lens and the cornea.

The Paraperm O_2 rigid gas permeable contact lens material is a thermoset copolymer derived from siloxane and methylmethacrylate.

The Paraperm O_2 rigid gas permeable tinted lenses offer a handling aid for locating the lens.

The lenses have the following attributes.

Paraperm® O_2 (pasifocon A)

Refractive Index	1.473(Nd at 25ºC)
Luminous Transmittance[+] (Clear)	99%
Luminous Transmittance (Blue)	93%
Luminous Transmittance (Electric Blue)	81%
Luminous Transmittance (Green)	97%
Luminous Transmittance (Cool Green)	95%
Wetting Angle (Receding Angle)[++]	23°
Wetting Angle (Contact Angle)[+++]	64°
Specific Gravity	1.12
Hardness (Shore D)	86
Water Content	< 2%
Oxygen Permeability*	16 x 10^{-11} Dk at 35º

[+]Determination of the Spectral and Luminous Transmittance, ISO 8599:1994
[++]Adapted from: A New Method for Wetting Angle Measurement; Madigan, et. al., International Eyecare, 01/1998, vol. 2, no. 1, p.45
[+++]Sesslie Drop Technique per ANSI Z80.20, 8.11
*(cm^2/sec) (mL O_2) / (mL x mm Hg) ISO/ANSI Method, ISO 9913-1

Lens Parameters

Chord Diameter	7.0 to 10.5 mm
Center Thickness	0.05 to 0.70 mm
Base Curve	6.50 to 9.00 mm
Power	-20.00 to +20.00 Diopters
Bifocal Add Power	+.25 to +4.00 Diopters
Monocentric Bifocal Add Diameter	4.0 to 9.0 mm
Monocentric Bifocal Prism	1.0 to 2.5 Diopters
Concentric Bifocal Add Diameter	2.0 to 4.0 mm

ACTION

The Paraperm® O_2 rigid gas permeable spherical, aspheric, toric and bifocal contact lenses are intended for daily wear only.

When placed on the human cornea, the Paraperm® O_2 rigid gas permeable contact lens acts as a refracting medium to focus light rays upon the retina.

The toric lens provides for the individual meridional power requirements of the astigmatic eye. In the bifocal lens, the distance or near power prescription is provided in a small area with the near or distance prescription surrounding it.

INDICATIONS (USES)

The Paraperm® O_2 rigid gas permeable contact lenses are indicated for daily wear as recommended by the eye care practitioner.

The Paraperm® O_2 rigid gas permeable spherical, aspheric, and bifocal contact lenses are indicated for the correction of refractive ametropia in not-aphakic persons with nondiseased eyes that are nearsighted (myopic), farsighted (hyperopic), and may exhibit corneal astigmatism up to 4.00 diopters. Paraperm® O_2 toric contact lenses are indicated to correct astigmatism of up to 6.00 diopters.

CONTRAINDICATIONS (REASONS NOT TO USE)

The Paraperm® O_2 rigid gas permeable contact lenses are contraindicated by the presence of any of the following conditions:

- Acute or subacute inflammations of the anterior segment of the eye.
- Any disease which affects the cornea or conjunctiva.
- Insufficiency of lacrimal secretion (dry eyes).
- Corneal hypoesthesia (reduced corneal sensitivity).
- Any systemic disease, which may affect the eye or be exacerbated by wearing contact lenses.
- Allergic reactions of ocular surfaces or adnexa which may be induced or exaggerated by wearing contact lenses and/or using contact lens solutions.
- Any active corneal infection (bacterial, fungal or viral).

WEARING SCHEDULE

THE EYE CARE PRACTITIONER SHOULD DETERMINE THE WEARING SCHEDULE. Patients tend to over wear the lenses initially. It is important to adhere to the initial maximum wearing schedule. Regular checkups, as determined by the eye care practitioner, are extremely important.

The maximum suggested wearing time for Paraperm® O_2 rigid gas permeable contact lenses is:

DAILY WEAR (less than 24 hours while awake)

DAY	1	2	3	4	5	6	7	8	9	10 - 14	15 & after
SUGGESTED HOURS	3	4	5	6	7	8	9	10	11	12	All waking hours
HOURS WORN											

DO NOT SLEEP WHILE WEARING YOUR PARAPERM® O_2 RIGID GAS PERMEABLE CONTACT LENSES. Studies have not been completed to show that the Paraperm® O_2 rigid gas permeable contact lens is

safe to wear during sleep. There is a tendency for some patients to overwear the lenses initially. It is important to adhere to the maximum wearing schedule. Regular checkups, as determined by the eye care practitioner, are extremely important.

NOTES

GENERAL INFORMATION

TINTS

Paraperm® O_2 rigid gas permeable contact lenses are available in untinted (clear) and tinted (blue, electric blue, green, and cool green) versions. The tinted lenses contain one or more of the following color additives; D&D Green No. 6, D&C Yellow No. 10 and Perox Yellow No. 9 (4-[(2,4-dimethylphenyl)azo]-2,4-dihydro-5-methyl-2-phenyl-3H-pyrazol-3-one).

WARNING: The practitioner should provide this warning to the patient.

PROBLEMS WITH CONTACT LENSES AND LENS CARE PRODUCTS COULD RESULT IN SERIOUS INJURY TO THE EYE. It is essential that you follow your eye care practitioner's directions and all labeling instructions for proper use of your contact lenses and lens care products, including the lens case.

Patients should follow the complete recommended lens rubbing and rinsing times in the product labeling to adequately disinfect their lenses and reduce the risk of contact lens contamination. Reduced rubbing or rinsing times may not adequately clean their lenses.

Patients should fill their lens case with fresh solution every time they store their lenses, and never re-use solution. They should discard their solution immediately after their lenses have been removed from the lens case. They should not store their lenses in or rinse their lens case with tap water, bottled water or any non-sterile solution.

Patients should clean and rinse their lens case between uses as recommended by their eye care practitioner.

EYE PROBLEMS, INCLUDING CORNEAL ULCERS, CAN DEVELOP RAPIDLY AND LEAD TO LOSS OF VISION; THEREFORE, IF YOU EXPERIENCE EYE DISCOMFORT, EXCESSIVE TEARING, VISION CHANGES, OR REDNESS OF THE EYE, OR OTHER PROBLEMS WITH YOUR EYES, IMMEDIATELY REMOVE YOUR LENSES, AND PROMPTLY CONTACT YOUR EYE CARE PRACTITIONER.

PRECAUTIONS – PRACTIONER

Clinical studies have demonstrated that contact lenses manufactured from the Paraperm® O_2 rigid gas permeable contact lens material are safe and effective for their intended use. However, the clinical studies may not have included all design configurations or lens parameters that are presently available in the materials.

Consequently, when selecting an appropriate lens design and parameter, the eye care practitioner must consider all factors that affect lens performance and ocular health. The potential impact of these factors must be weighed against the patient's needs, therefore, the continuing ocular health of the patient and lens performance on the eye should be carefully monitored.

Each Paraperm® O_2 lens is supplied nonsterile in an individual plastic case. The lens is shipped dry.

PRECAUTIONS - PATIENT

Follow the instructions below to prevent damage to your eyes or to your lenses.

- Before you leave your practitioner's office be able to promptly remove your lens or have someone else be able to remove your lens for you.

- DO NOT WEAR YOUR PARAPERM® O_2 RIGID GAS PERMEABLE CONTACT LENSES WHILE SLEEPING

- Always wash your hands with an additive free soap, rinse thoroughly and dry on a lint free towel before you handle your lenses. Eye irritation may result if cosmetics, lotions, soaps, creams and deodorants come in contact with your lenses and if the lenses are contaminated by infectious or non-infectious debris.

- Always follow the recommended lens care system for your Paraperm® O_2 lenses. Use the recommended lens care solutions and carefully follow the recommended directions.

- Always use FRESH rinsing, disinfecting and storage solutions.

- Do not use saliva, tap water or anything other than the recommended solutions to wet your lenses.

- Always keep the lenses completely immersed in the recommended storage solution when the lenses are not being worn.

- Avoid using aerosol products such as hair spray while wearing your lenses. If hair sprays are used, keep your eyes closed until the spray has settled, otherwise, the lenses may be damaged.

- Avoid all harmful or irritating vapors and fumes while wearing your lenses.

- Do not swim with your lenses in place.

- Never use tweezers or other tools to remove your lens from the lens container. Do not touch the lens with your fingernails.

- Always inform your doctor (general health care practitioner) that you wear contact lenses.

- Always consult your eye care practitioner before using any medicine in your eyes.

- Always inform your employer that you wear contact lenses. Some jobs may require the use of protective eye equipment or may require that you not wear contact lenses.

- As with any contact lens, follow-up visits are necessary to assure continued health. CHECK WITH YOUR EYE CARE PRACTITIONER.

- To minimize lens warpage during cleaning, the lenses should be cleaned in the palm of the hand rather than between the thumb and fingers.

- Do not heat the conditioning solution and lenses.

- The safety of these lenses with medications or contact lens solutions other than those recommended has not been established.

- If your lens sticks (stops moving) on the eye, follow the recommended directions for "Care for a Sticking Lens". The lens must move freely on the eye for the continued health of the eye. If nonmovement of the lens continues, immediately consult your eye care practitioner.

CAUTION: Nonsterile. Clean and condition lenses prior to use.

ADVERSE EFFECTS (PROBLEMS AND WHAT TO DO)

The following problems may occur.

- Eyes sting, burn or itch (irritation)
- Comfort is less than when lens was first placed on eye
- Feeling of something in the eye (foreign body, scratched area, abrasion)
- Excessive pain
- Excessive watering (tearing) of the eyes
- Unusual eye secretions
- Redness of the eyes
- 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 these adverse effects, **IMMEDIATELY REMOVE YOUR LENSES.**

- If the discomfort or problem stops, then look closely at the 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 eye care practitioner.

- If the lens has dirt, an eyelash, or other foreign body on it, or the problem stops and the lens appears undamaged, thoroughly clean, rinse and disinfect the lenses; then reinsert it.

- If the problem continues, IMMEDIATELY remove your contact lens and consult your eye care practitioner.

When any of the above symptoms occur, a serious condition such as infection, corneal ulcer, neovascularization, iritis, persistent stromal edema or GPC (giant papillary conjunctivitis) may be present. Immediately remove your lenses and seek professional identification of the problem and prompt treatment to avoid serious eye damage, including corneal scarring, opacification, blindness or loss of eye.

FITTING

Conventional methods of fitting rigid contact lenses apply to the Paraperm® O_2 rigid gas permeable contact lens. For a description of fitting techniques, refer to the Fitting Guide for Paraperm® O_2 Rigid Gas Permeable Contact Lenses. Copies of which are available from:

Paragon Vision Sciences, Inc. 1-800-528-8279
947 E. Impala Avenue 1-480-892-7602
Mesa, Arizona 85204-6619 1-480-926-7369 FAX

LENS CARE DIRECTIONS

Always wash your hands with an additive-free soap, rinse thoroughly and dry on a lint-free towel before you handle your contact lenses.

Never use tweezers or other tools to remove your lens from the lens container. Pour the lens into your hand.

Paraperm® O_2 rigid gas permeable contact lenses must be both cleaned and disinfected each time you remove them. One procedure does not replace the other. Cleaning is necessary to remove mucus and film from the lens surface. Disinfecting is necessary to destroy harmful germs. Leave the Paraperm® O_2 rigid gas permeable contact lenses in a storage solution for a minimum of 4 hours or as indicated on the product label. To minimize lens warpage during cleaning, the lenses should be cleaned in the palm of the hand rather than between the thumb and fingers. Patients should follow the complete recommended lens rubbing and rinsing times in the product labeling to adequately disinfect their lenses and reduce the risk of contact lens contamination. Reduced rubbing or rinsing times may not adequately clean their lenses.

Clean one lens first. (The recommended procedure is to always clean the same lens first to avoid mix-ups). Rinse the lens thoroughly as recommended by your lens care product manufacturer to remove the cleaning solution. Place the lens into the correct storage chamber and fill the chamber with the recommended

disinfection system as recommended by your eye care practitioner. Clean and rinse the other lens in the same manner and place it in its chamber.

Tightly close the top of each chamber of the lens storage case.

To disinfect your lenses, leave them in the solution for at least 4 hours, or as indicated on the product label.

Do not heat the conditioning solution and lenses.

Leave the lenses in the unopened storage case until you are ready to put them on your eyes.

Patients should fill their lens case with fresh solution every time they store their lenses, and never re-use solution. They should discard their solution immediately after their lenses have been removed from the lens case. They should not store their lenses in or rinse their lens case with tap water, bottled water or any non-sterile solution.

Patients should clean and rinse their lens case between uses as recommended by their eye care practitioner.

After you remove your lens from the lens case, empty and rinse your lens storage case with fresh, hot running tap water and allow it to air dry. When you next use the case, refill it with fresh storage solution.

Paraperm® O_2 rigid gas permeable contact lenses should be disinfected using only a chemical (not heat) disinfection system.

Your eye care practitioner will recommend his/her preferred, FDA approved lens care solutions for the cleaning, disinfection, storage and lubrication of your Paraperm® O_2 rigid gas permeable contact lenses.

Follow the instructions provided with each lens care solution. Failure to adhere to these procedures may result in the development of serious ocular complications. A patient should not switch from one care system to another unless the eye care practitioner has determined that this is necessary. Do not mix or alternate the disinfection and storage systems unless so indicated on the product label.

CARE FOR A STICKING LENS

If the lens sticks (stops moving) on the eye, apply a few drops of a lubricating solution. Wait until the lens begins to move freely on your eye before removing it. If nonmovement of the lens continues, immediately consult your eye care practitioner.

HOW SUPPLIED

Each Paraperm® O_2 lens is supplied nonsterile in an individual plastic case. The lens is shipped dry.

For Information on material specifications contact:

Paragon Vision Sciences, Inc. 1-800-528-8279
947 E Impala Avenue 1-480-892-7602
Mesa, Arizona 85204-6619 1-480-926-7369 FAX