PROFESSIONAL FITTING GUIDE

FluoroPerm® 92 (paflufocon A)

Rigid Gas Permeable Contact Lenses for Daily and Extended Wear

FluoroPerm® 60 (paflufocon B)

Rigid Gas Permeable Contact Lenses for Daily and Extended Wear

FluoroPerm® 151 (paflufocon D)

Rigid Gas Permeable Contact Lenses for Daily and Extended Wear

FluoroPerm® 30 (paflufocon C)

Rigid Gas Permeable Contact Lenses for Daily Wear

CooperVision® Specialty EyeCare

Paragon

We Don't Just Change Vision, ***We Change Lives.***™

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

PRODUCT DESCRIPTIONS

FluoroPerm® 92 (paflufocon A) and FluoroPerm® 60 (paflufocon B) rigid gas permeable contact lenses for daily wear are available as lathe cut or molded contact lenses with spherical, aspheric, bifocal or toric anterior and/or posterior; or, bitoric surfaces in clear and tinted versions. FluoroPerm® 92 and FluoroPerm® 60 rigid gas permeable contact lenses for extended wear are available as lathe cut or molded contact lenses with spherical or aspheric anterior or posterior 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 FluoroPerm® 92 and FluoroPerm® 60 rigid gas permeable contact lens materials are both thermoset copolymers derived from fluorosilicone acrylate monomers.

The FluoroPerm® 92 and FluoroPerm® 60 rigid gas permeable tinted lenses offer a handling aid for locating the lens. These products may be plasma treated.

The lenses have the following attributes.

FLUOROPERM® 92 (paflufocon A)

Refractive Index	1.453 (Nd at 25°C)
Luminous Transmittance[+] (Clear)	99%
Luminous Transmittance (Blue)	93%
Luminous Transmittance (Green)	95%
Wetting Angle (Receding Angle)[++]	16°
Wetting Angle (Contact Angle)[+++]	64°
Specific Gravity	1.10
Hardness (Shore D)	81
Water Content	<1%
Oxygen Permeability*	64 x 10^{-11} Dk at 35°C

[+]Determination of the Spectral and Luminous Transmittance, ISO 8599
[++] 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

FLUOROPERM® 60 (paflufocon B)

Refractive Index	1.453 (Nd at 25°C)
Luminous Transmittance[+] (Clear)	99%
Luminous Transmittance (Blue)	95%
Luminous Transmittance (Crystal Blue)	98%
Luminous Transmittance (Green)	95%
Luminous Transmittance (Brown)	85%
Wetting Angle (Receding Angle)[++]	14.7°
Wetting Angle (Contact Angle)[+++]	62°
Specific Gravity	1.15
Hardness (Shore D)	83
Water Content	<1%
Oxygen Permeability[*]	43 x 10^{-11} Dk at 35°C

[+]Determination of the Spectral and Luminous Transmittance, ISO 8599
[++] 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

FluoroPerm® 151 (paflufocon D) rigid gas permeable contact lenses for daily wear and extended wear are available as lathe cut or molded contact lenses with spherical front and back 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 FluoroPerm® 151 rigid gas permeable contact lens material is a thermoset copolymer derived from fluorosilicone acrylate monomers.

The FluoroPerm® 151 rigid gas permeable tinted lenses offer a handling aid for locating the lens. These products may be plasma treated.

The lenses have the following attributes.

FLUOROPERM® 151 (paflufocon D)

Refractive Index	1.442 (Nd at 25°C)
Luminous Transmittance[+] (Blue)	93%
Luminous Transmittance (Crystal Blue)	98%
Wetting Angle (Receding Angle)[++]	42°
Wetting Angle (Contact Angle)[+++]	70°
Specific Gravity	1.10
Hardness (Shore D)	79
Water Content	<1%
Oxygen Permeability[*]	100 x 10^{-11} Dk at 35°C

[+]Determination of the Spectral and Luminous Transmittance, ISO 8599
[++] 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

Chord Diameter	7.0 to 21.0 mm

Lenses with diameters of 7.0 mm to 10.5 mm are available for extended wear.
Lenses with diameters of 7.0 mm to 21.0 mm are available for daily wear.

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 Power	+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

FluoroPerm® 30 (paflufocon C) rigid gas permeable contact lenses for daily wear are available as lathe cut or molded 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 FluoroPerm® 30 rigid gas permeable contact lens material is a thermoset copolymer derived from fluorosilicone acrylate monomers.

The FluoroPerm® 30 rigid gas permeable tinted lenses offer a handling aid for locating the lens. These products may be plasma treated.

The lenses have the following attributes.

FLUOROPERM® 30 (paflufocon C)

Refractive Index	1.466 (Nd at 25°C)
Luminous Transmittance[+] (Clear)	99%
Luminous Transmittance (Blue)	94%
Luminous Transmittance (Crystal Blue)	98%
Luminous Transmittance (Green)	95%
Luminous Transmittance (Gray)	91%
Wetting Angle (Receding Angle)[++]	12.8°
Wetting Angle (Contact Angle)[+++]	61°
Specific Gravity	1.14
Hardness (Shore D)	84
Water Content	<1%
Oxygen Permeability[*]	30 x 10^{-11} Dk at 35°C

[+]Determination of the Spectral and Luminous Transmittance, ISO 8599
[++] 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

Chord Diameter	7.0 to 21.0 mm

Lenses with diameters of 7.0 mm to 10.5 mm are available for extended wear.
Lenses with diameters of 7.0 mm to 21.0 mm are available for daily wear.

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
Bifocal Add Power	+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

TINTS (not all colors available in all materials)

FluoroPerm® rigid gas permeable contact lenses are available in nontinted (clear) and tinted (blue, crystal blue, gray, brown and green) versions. The tinted lenses contain one or more of the following color additives: D&C Green No. 6, Perox Yellow No. 9 (4-[(2,4-dimethylphenyl)azo]-2,4-dihydro-5-methyl-2-phenyl-3H-pyrazol-3-one), D&C Violet No. 2 and D&C Red No. 17.

UV ABSORBER (not available in all colors and materials)

FluoroPerm® rigid gas permeable contact lenses are available with an ultraviolet absorber. The ultraviolet absorber, Acrymer™ 282, has been integrated as an additive within the FluoroPerm® 92, FluoroPerm® 60 and FluoroPerm® 30 polymer matrix and blocks up to 96% of light from 280 to 380 nm. Acrymer™ is 4-methacryloxy-2-hydroxybenzophenone.

See Package Insert for light transmission comparison graphs.

WARNING: UV-absorbing contact lenses are not substitutes for protective UV-absorbing eyewear such as UV-absorbing goggles or sunglasses. Persons should continue to use their protective UV-absorbing eyewear as directed.

NOTE: Long-term exposure to UV radiation is one of the risk factors associated with cataracts. Exposure is based on a number of factors such as environmental conditions (altitude, geography, cloud cover) and personal factors (extent and nature of outdoor activities). UV

blocking contact lenses help provide protection against harmful UV radiation. However, clinical studies have not been done to demonstrate that wearing UV blocking contact lenses reduces the risk of developing cataracts or other eye disorders. Consult your eye care professional for more information.

ACTIONS

See Package Insert (Actions) for the actions of each product; FluoroPerm® 92 (paflufocon A), FluoroPerm® 60 (paflufocon B), FluoroPerm® 30 (paflufocon C) and FluoroPerm® 151 (paflufocon D).

INDICATIONS

Device Name: FluoroPerm® 30 (paflufocon C) rigid gas permeable contact lenses

FluoroPerm® 30 rigid gas permeable contact lenses are indicated for daily wear as recommended by the eye care practitioner.

FluoroPerm® 30 rigid gas permeable spherical, aspheric and bifocal contact lenses are indicated for the correction of visual acuity in not-aphakic persons with non-diseased eyes that are nearsighted (myopic), farsighted (hyperopic), and may exhibit corneal astigmatism up to 4.00 diopters that does not interfere with visual acuity. FluoroPerm® 30 toric contact lenses are indicated to correct astigmatism of up to 6.00 diopters. FluoroPerm® 30 bifocal lenses are indicated to treat presbyopia up to +4.00 D add power.

In daily wear use only, FluoroPerm® 30 contact lenses are indicated for management of irregular corneal conditions such as keratoconus, pellucid marginal degeneration, or following penetrating keratoplasty, radial keratotomy, or LASIK surgery, in otherwise non-diseased eyes.

Device Name: FluoroPerm® 60 (paflufocon B) rigid gas permeable contact lenses

FluoroPerm® 60 rigid gas permeable spherical or aspheric contact lenses are indicated for daily wear and extended wear from 1 to 7 days between removals for cleaning and disinfection as recommended by the eye care practitioner. FluoroPerm® 60 rigid gas permeable bifocal, or toric contact lenses are indicated for daily wear only.

FluoroPerm® 60 rigid gas permeable spherical, aspheric and bifocal contact lenses are indicated for the correction of visual acuity in not-aphakic persons with non-diseased eyes that are nearsighted (myopic), farsighted (hyperopic), and may exhibit corneal astigmatism up to 4.00 diopters that does not interfere with visual acuity. FluoroPerm® 60 toric contact lenses are indicated to correct astigmatism of up to 6.00 diopters. FluoroPerm® 60 bifocal lenses are indicated to treat presbyopia up to +4.00 D add power.

In daily wear use only, FluoroPerm® 60 contact lenses are indicated for management of irregular corneal conditions such as keratoconus, pellucid marginal degeneration, or following penetrating keratoplasty, radial keratotomy, or LASIK surgery, in otherwise non-diseased eyes.

Device Name: FluoroPerm® 92 (paflufocon A) rigid gas permeable contact lenses

FluoroPerm® 92 rigid gas permeable spherical or aspheric contact lenses are indicated for daily wear and extended wear from 1 to 7 days between removals for cleaning and disinfection as recommended by the eye care practitioner. FluoroPerm® 92 rigid gas permeable bifocal, or toric contact lenses are indicated for daily wear only.

FluoroPerm® 92 rigid gas permeable spherical, aspheric and bifocal contact lenses are indicated for the correction of visual acuity in not-aphakic persons with non-diseased eyes that are nearsighted (myopic), farsighted (hyperopic), and may exhibit corneal astigmatism up to 4.00 diopters that does not interfere with visual acuity. FluoroPerm® 92 toric contact lenses are indicated to correct astigmatism of up to 6.00 diopters. FluoroPerm® 92 bifocal lenses are indicated to treat presbyopia up to +4.00 D add power.

In daily wear use only, FluoroPerm® 92 contact lenses are indicated for management of irregular corneal conditions such as keratoconus, pellucid marginal degeneration, or following penetrating keratoplasty, radial keratotomy, or LASIK surgery, in otherwise non-diseased eyes.

Device Name: FluoroPerm® 151 (paflufocon D) rigid gas permeable contact lenses

FluoroPerm® 151 rigid gas permeable spherical or aspheric contact lenses are indicated for daily wear and extended wear from 1 to 7 days between removals for cleaning and disinfection as recommended by the eye care practitioner. FluoroPerm® 151 rigid gas permeable bifocal, or toric contact lenses are indicated for daily wear only.

FluoroPerm® 151 rigid gas permeable spherical, aspheric and bifocal contact lenses are indicated for the correction of visual acuity in not-aphakic persons with non-diseased eyes that are nearsighted (myopic), farsighted (hyperopic), and may exhibit corneal astigmatism up to 4.00 diopters that does not interfere with visual acuity. FluoroPerm® 151 toric contact lenses are indicated to correct astigmatism of up to 6.00 diopters. FluoroPerm® 151 bifocal lenses are indicated to treat presbyopia up to +4.00 D add power.

In daily wear use only, FluoroPerm® 151 contact lenses are indicated for management of irregular corneal conditions such as keratoconus, pellucid marginal degeneration, or following penetrating keratoplasty, radial keratotomy, or LASIK surgery, in otherwise non-diseased eyes.

CONTRAINDICATIONS, WARNINGS, PRECAUTIONS AND ADVERSE REACTIONS

See Package Insert [Contraindications (Reasons Not To Use)] and (Warning) for each product; FluoroPerm® 92 (paflufocon A), FluoroPerm® 60 (paflufocon B) and FluoroPerm® 151 (paflufocon D).

See Package Insert [Contraindications (Reasons Not To Use)] and (Wearing Schedule) for FluoroPerm® 30 (paflufocon C).

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

FluoroPerm® rigid gas permeable contact lenses must be both cleaned and disinfected each time they are removed from the eye. 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 FluoroPerm® 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.

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 not mix or alternate the disinfection and storage systems unless so indicated on the product label.

LENS FITTING

General Information

FluoroPerm® 92 (paflufocon A), FluoroPerm® 60 (paflufocon B) and FluoroPerm® 151 (paflufocon D) rigid gas permeable contact lenses may be fitted for daily wear or extended wear using the standard techniques for rigid contact lenses. A diagnostic lens fitting procedure is recommended, although not always required.

FluoroPerm® 30 (paflufocon C) 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 FluoroPerm® 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 fluorosilicone acrylate 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 weighed 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 general health, previous contact lens history, refraction, keratometry, and slit lamp examination. Patients 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, any disease or infection which will affect the eye or be exacerbated by the wearing of contact lenses, are not candidates for wearing these lenses.

FITTING PROCEDURE – SPHERICAL AND ASPHERIC

Patient Selection
Patients should be individuals who require a daily wear or extended wear lens, are not-aphakic, and have non-diseased 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

Fitting is recommended to 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 over refraction 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 over refraction. Only the spherical power needs to be determined in order to arrive at the final correction.

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

EXAMPLE:	Over refraction	-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 FluoroPerm® 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.

NOTE: Evaluation of fluorescein patterns for lenses manufactured in materials with the UV absorber is best accomplished using a slit lamp or Burton Lamp with a Wratten filter over the light source.

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 over refraction 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 over refraction. Only the spherical power needs to be determined in order to arrive at the final correction.

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

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

The selection of the FluoroPerm® 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 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.

NOTE: Evaluation of fluorescein patterns for lenses manufactured in materials with the UV absorber is best accomplished using a slit lamp or Burton Lamp with a Wratten filter over the light source.

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 over refraction 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 over refraction. 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 over refraction has been obtained, the correction should be added to the power of the diagnostic lens to arrive at the final prescription.

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

The selection of the FluoroPerm® 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 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.

NOTE: Evaluation of fluorescein patterns for lenses manufactured in materials with the UV absorber is best accomplished using a slit lamp or Burton Lamp with a Wratten filter over the light source.

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 over refraction 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 over refraction. 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 over refraction 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 over refraction has been obtained, the correction should be added to the power of the diagnostic lens to arrive at the final prescription.

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

The selection of the FluoroPerm® 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 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 8.0mm diameter. Hence, a lens design with an optic zone of 8.0mm or less is usually preferred.

NOTE: Evaluation of fluorescein patterns for lenses manufactured in materials with the UV absorber is best accomplished using a slit lamp or Burton Lamp with a Wratten filter over the light source.

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 that 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 over refractions.

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

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

The selection of the FluoroPerm® rigid gas permeable toric 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.

NOTE: Evaluation of fluorescein patterns for lenses manufactured in materials with the UV absorber is best accomplished using a slit lamp or Burton Lamp with a Wratten filter over the light source.

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.

FITTING PROCEDURE – IRREGULAR CORNEA

Patient Selection Criteria

FluoroPerm® 30, 60, 92 and 151 contact lenses are indicated for patients that require a rigid contact lens who have a demonstrated need for the management of irregular corneal conditions such as keratoconus, pellucid marginal degeneration, or following penetrating keratoplasty, radial keratotomy, or LASIK surgery, that desire a refractive correction with rigid gas permeable contact lenses and who do not have any of the contraindications for gas permeable contact lenses. Refer to CONTRAINDICATIONS (REASONS NOT TO USE).

Keratoconus is a non-inflammatory ocular condition in which the cornea progressively thins causing a cone-like bulge to develop. As the cornea steepens the anterior corneal surface (epithelium) becomes

irregular resulting in visual impairment. This irregularity cannot be completely corrected with spectacles – instead, a rigid gas permeable contact lens is used to become the new anterior refracting surface.

Pellucid marginal degeneration is characterized by non-inflammatory and progressive crescent-shaped corneal thinning inferiorly, often with against-the-rule astigmatism and a steepening topography pattern.

Special Fitting Considerations

FluoroPerm® 30, 60, 92 and 151 contact lenses for keratoconus, pellucid marginal degeneration, or after penetrating keratoplasty, radial keratotomy, or LASIK surgery are designed to be fitted so as to optically correct irregular astigmatism and thereby improve visual acuity. The lens designs and the manner in which the lens is fitted are intended to work together to accomplish this goal.

The keratoconus design utilizes smaller optic zone diameters, steeper base curves, spherical and/or aspherical periphery curves to closely approximate the unusual topography typical in patients with keratoconus. For example, keratoconus lens designs utilize small posterior optic zones and a series of peripheral curves to achieve this fitting relationship. These zone sizes may vary in lens diameters over 11.5 mm.

The pellucid marginal degeneration design utilizes larger lens diameter, larger optic zone diameters, flatter base curves, and spherical and/or aspherical periphery curves to closely approximate the unusual topography typical in patients with the condition.

FluoroPerm® 30, 60, 92 and 151 contact lenses for the management of irregular corneal conditions such as keratoconus, pellucid marginal degeneration, or following penetrating keratoplasty or refractive (e.g., LASIK) surgery, may be fitted using a modification of the standard techniques for rigid gas permeable contact lenses.

Extended wear lenses should not be used to correct keratoconus, pellucid marginal degeneration, or following penetrating keratoplasty, LASIK or radial keratotomy surgery.

Pre-fitting Examination

A complete refraction and visual health examination should be performed.

Pre-fitting patient history and examination are necessary to:

- Determine whether a patient is a suitable candidate for FluoroPerm® 30, 60, 92 and 151 contact lenses for pellucid marginal degeneration, or following penetrating keratoplasty post-refractive (e.g., LASIK) surgery.
- Collect and record baseline clinical information to which fitting examination results can be compared.

Initial Lens Power Selection

Standard procedures for determining power of rigid gas permeable contact lenses may be used, including compensation for vertex distance.

Initial Lens Diameter Selection

For keratoconus conditions, lens diameters between 7.0 and 21.0 mm FluoroPerm® 30, 60, 92 and 151 are chosen to maximize positioning on the cornea and to minimize lens movement.

For pellucid marginal degeneration, lens diameters are typically between 9.5 mm and 21.0 mm FluoroPerm® 30, 60, 92 and 151.

For post-surgical indications, a larger lens diameter between 9.0 mm and 21.0 mm FluoroPerm® 30, 60, 92 and 151 is chosen to avoid fitting on or near the graft (suture) line. Lens diameters outside of this range are occasionally used for some eyes.

This guide is only a general recommendation and the specification for an individual patient will depend on the eye care practitioner's judgment.

Lens diameter is primarily a function of the base curve but may be influenced by power (plus lenses require a larger diameter to compensate for weight) and anatomical considerations (small palpebral opening, excessively large pupil, etc.) and the patient's corneal topography.

NOTE: If the diameter chosen is larger than 16 mm, the practitioner should also refer to the section on large diameter lenses.

Initial Lens Base Curve Selection

For keratoconus, the base curve of the first lens fitted is generally equal to or slightly steeper than the flattest keratometry reading to achieve an apical clearance or apical alignment fitting relationship.

For pellucid marginal degeneration, the base curve chosen is generally flatter than the flattest "K" reading. It may be equal to the radius of curvature as measured 4 mm from the corneal apex by topography (which is usually flatter). If using "K" readings, the base curve chosen will be approximately 1.00 D flatter than the median "K" reading.

For post penetrating keratoplasty (corneal graft) fitting, initial base curve selection will depend on the shape and position of the graft.

The post-surgical cornea may be "prolate" where the graft is steeper than the surrounding peripheral "host" cornea. Typically, a slightly steeper-than-"K" or a reverse geometry lens may be required.

For post refractive surgical fitting (LASIK), the central cornea is much flatter than a "normal" (non-operated) cornea. Base curve choices are usually 0.50 to 1.00 D flatter than the pre-op flat "K" reading.

Initial Lens Evaluation

Movement:
Blink induced lens movement should show downward lens movement with the lid motion (average 1 mm) and then upward with the lid motion (average 1 mm) as with a standard gas permeable contact lens. During the interblink period the lens should have little or no motion (average less than 1 mm). Lens designs over 11.5 mm diameter may exhibit little or no movement.

Positioning:
The lens should position centrally or slightly inferiorly as it will tend to migrate to the steepest cornea area. Lens designs over 11.5 mm diameter will most always position centrally.

Characteristics of a Tight (too steep) Lens:

> A lens that is too tight will show reduced movement upon blinking. Bubbles may be detected behind the lens. For lens designs over 11.5 mm diameter the presence of bubbles may not indicate a poor fitting lens.

Characteristics of a Loose (too flat) Lens:

> 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.

Trial Lens Fitting

Trial Lens Fitting

Trial lens fitting is recommended whenever possible. Trial lens fitting allows a more accurate determination of lens specifications for the lens fit and power. Choose the first lens according to the base curve selection criteria for the specific lens design. Trial lenses are essential in fitting patients whose corneal topography is distorted.

Trial Lens Procedure

Select a trial lens and place the lens upon the eye. Evaluate the lens using white light for the following:

Centering
Lenses may not center well due to the unusual corneal topography in patients with keratoconus. Often the lens will position inferiorly over the steepest corneal area.

Movement
Lens movement should be equivalent to or slightly less than a standard RGP lens.

Evaluate the fluorescein pattern. The fluorescein pattern should show a lens with either mild apical clearance or "feather touch" (alignment) over the steepest conical area. In the periphery there should be another area of alignment and near the edge a thin band of pooling.

The fluorescein pattern provides the best method for monitoring the fit of the contact lens over time.

Special Follow-up Care

With lenses in place on the eyes, evaluate fitting performance to assure that the criteria of a well-fitted lens continue to be satisfied. The fluorescein pattern provides a guide to lens adaptation. If the lens demonstrates reduced movement consider exchanging for another of flatter base curve. Usually, a lens with a 0.50 diopters flatter base curve should be the next choice with variations from this based on the judgment of the eye care practitioner.

A lens with excessive movement should be replaced with another that is 0.50 diopters steeper base curve.

After lens removal, conduct a thorough biomicroscopy examination to detect the presence of unusual vertical corneal striae in the posterior central cornea and/or corneal neovascularization. Note: some vertical striae are typical in advanced stages of keratoconus. The presence of these conditions may be indicative of excessive corneal edema.

The recommended schedule for follow-up visits is the same as standard lenses. Reference: "Follow-up Patient Care", page 21.

NOTE: Practitioners should consult their finishing lab for available keratoconus, pellucid marginal degeneration, and post-surgical lens designs. The design parameters must meet the parameters specified in the product labeling.

FITTING PROCEDURE – LARGE DIAMETER LENS

Large diameter FluoroPerm® 30, 60, 92 and 151 lenses are typically fit utilizing the following principles:

1. Optic zone with base curve providing central alignment with feather touch or clearance,
2. Intermediate zone(s) providing moderate mid-peripheral and limbal clearance,
3. Periperal curve providing alignment along scleral surface,
4. Overall diameter – 1.0 to 2.0 mm of lens coverage beyond the HVID, and
5. Movement – 0.25 mm of movement.

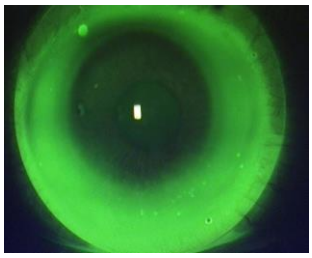
Large diameter FluoroPerm® 30, 60, 92 and 151 lenses are best fit utilizing diagnostic lenses supplied by your authorized manufacturing laboratory. If diagnostic lenses are not available, please contact your manufacturing laboratory's consultants for assistance. With diagnostic lenses, utilize the following guidelines to promote the most successful use of these lenses.

Diagnostic Fitting
Diagnostic sets frequently include a series of base curves associated with a standard peripheral curve having a proprietary standard relationship to the base curve. The lenses may also be available in a range of diameters and with alternate peripheral geometries.

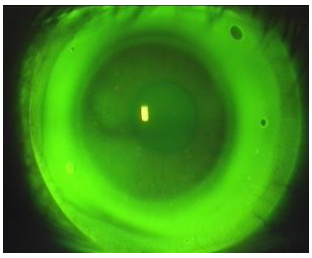
Base Curve Selection (BCR)
Select a base curve radius that provides alignment centrally, with mid-peripheral corneal and limbal clearance. The following table can be used to determine an initial diagnostic base curve in relation to corneal cylinder.

Corneal Cylinder	Base Curve
<1.00 D	on flat K
1.00 to 2.00 D	0.50 D steeper than flat K
> 2.25 D	1/3 corneal cylinder steeper than flat K

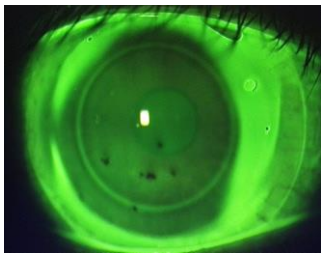
Example:
Keratometry: 44.00/45.25 @ 090 (1.25 D of corneal cylinder)
Initial BC: 44.00 + 0.50 = 44.50 D (7.58 mm)
Final BC: 7.58 mm



Base Curve 0.50 D Flat
44.00 D



Ideal Base Curve
44.50 D



Base Curve 0.50 D Steep
45.00 D

Lens Power Determination (PWR)
With the best fit (BC) diagnostic lens in place, perform an over-refraction to yield the final lens power.

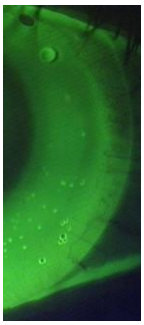
Example: Best BCR Diag. Lens: BCR 7.58 mm, Diam. 14.0, PWR -3.00 D, PC STD
Over refraction : -2.25 D
Final Lens Power: -2.25 + -3.00 = -5.25 D

Peripheral Curve Selection (PC)
Observe the fluorescein pattern in the periphery of the best fit base curve radius diagnostic lens to ensure alignment along the underlying sclera. If the lens appears to have too much edge lift (deviates rapidly from the conjunctiva) the PC is too flat. Select the next steepest diagnostic lens that provides PC alignment. If the lens appears to impinge into the conjunctiva, the PC is too steep. Select the next flattest diagnostic lens that provides PC alignment. Record the BC of the diagnostic lens giving the best fit in the periphery. In

diopters, subtract the BCR of the best fit BCR from the BCR of the lens giving the best fit in the periphery. Express the relationship as diopters flatter (result >0) or diopters steeper (result <0) than the best fit BCR.

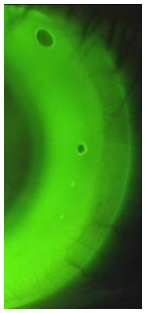
Specify the PC based upon the diopter change in base curve from the best fit BC to the best fit PC diagnostic lenses (e.g., S0.5, S1.0, S1.5, or F0.5, F1.0, F1.5, etc.).

PC 0.50 D Flat



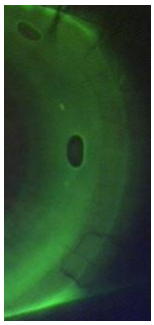
EX: PC STD

PC Ideal



EX: PC S0.50

PC 0.50 D Steep



EX: PC SI.00

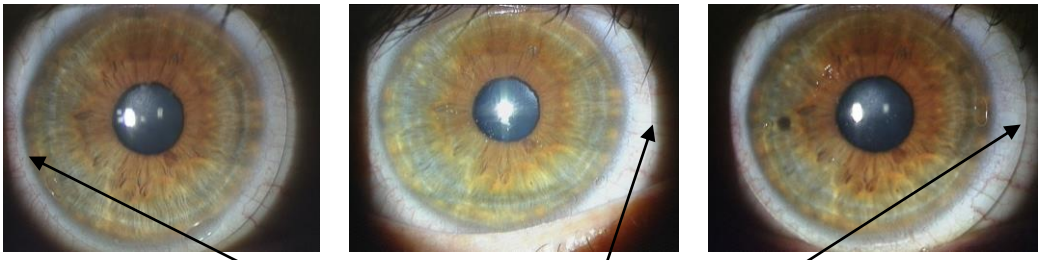
Example: Best Fit Diag. Lens: BC 7.58 mm, Diam. 14.0, PWR -3.00 D, PC STD
Best Fit PC Diag. Lens: BC 7.50
PC Determination: Best PC 7.50 (45.00) – Best BC 7.58 (44.50) = + 0.50
Final PC: S0.50

Note: Your laboratory may have an alternate system for determining the peripheral geometry of their design relative to the central base curve radius which provides proper central corneal alignment.

Overall Diameter Selection (OAD)
Corneo-scleral lenses are prescribed to have a diameter just larger than the cornea and most often demonstrate feather touch in the central area of the cornea along with contact just outside the limbus. Mini-scleral lenses have a diameter up to 16.0 mm and most often are free from any corneal contact.

The selection of OAD is a function of the fitting objectives. If feather touch is desired, the following table will provide a lens with an OAD that provides 1.0 to 1.25 mm of lens coverage beyond the limbus or Horizontal Visible Iris Diameter:

HVID	OAD
<11.5 mm	13.5 mm
11.5 to 12.00 mm	14.0 mm
>12.0 mm	14.5 mm



OAD 0.5 mm Too Small | OAD Ideal | OAD 0.5 mm Too Large

Note Lens Edge

Example: HVID: 11.8 mm
Final OAD: 14.0 mm

In the event the objective is a mini-scleral design with total corneal clearance, a lens diameter having 1.75 to 2.25 mm of coverage beyond the limbus is most often required. Mini-scleral lenses are most often 15.0 to 16.0 mm in diameter.

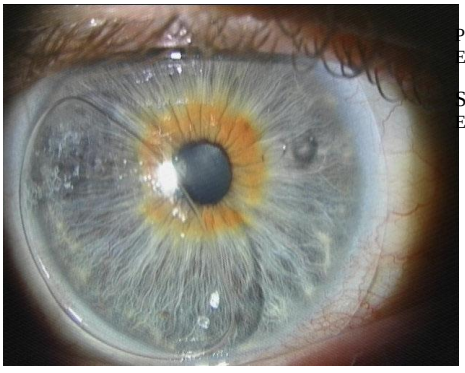
Clinical Example

Clinical Data:
Keratometry: 44.00/ 45.25 @ 090
Manifest Refraction: -5.00 -1.25 x 180
HVID: 11.8 mm

Final Lens Parameters: BCR 7.58, OAD 14.0, PWR -5.25, PC S0.50

Trouble-shooting

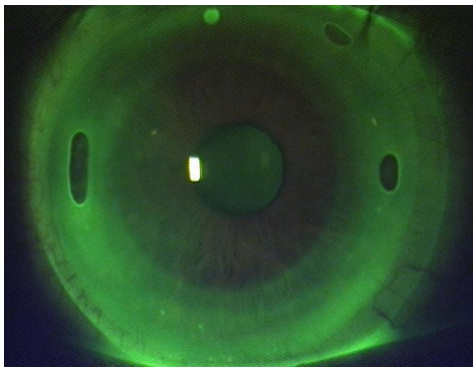
Finding	Cause	Solution
Central bubble	BCR too steep	Flatten BC
Mid-peripheralbubble	PC too steep	Flatten PC
Lens adherence	Steep fit	Flatten BCR and/or PC
Lens adherence	Coated lens surface	Surface/protein cleaning
Lens flexure	Steep fit	Flatten BCR or PC
Lens flexure	Thin profile	Increase CT (0.05 mm)



Problem - Steep BC
Ex: BC 45.00

Solution - Flatten BC
Ex: BC 44.00

Central Bubble — BCR Flattened to Resolve



Problem - Steep PC
Ex: PC Std

Solution - Flatten PC
Ex: PC F0.50

Mid-peripheral Bubble — PC Flattened to Resolve

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]

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.

[1] Mandell, R.G., Moore, C.F.: A Bitoric Lens Guide That Really Is Simple. Contact Lens Spectrum, November, 1988, 83-85.

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		XXXXXXXXXXXXX		XXXXXXXXXXXXX
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		XXXXXXXXXXXXX		XXXXXXXXXXXXX
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.

THE CLINICAL PICTURE

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. 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, 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.

<u>RECOMMENDED DAILY WEAR FOLLOW-UP SCHEDULE</u>

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

<u>RECOMMENDED EXTENDED WEAR FOLLOW-UP SCHEDULE</u>

First Follow-up Examination -	Immediately following the first overnight wearing of the lens
Second Follow-up Examination -	After 3 days of extended wear of the lens
Third Follow-up Examination -	After 1 week of extended wear of the lens
Fourth Follow-up Examination -	After 1 month of extended wear of the lens
Subsequent Follow-up Examinations -	After 3 and 6 months of extended wear of the lens; 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 directions.

CARE FOR A STICKING (nonmoving) LENS

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

HOW SUPPLIED

Each FluoroPerm® lens is supplied nonsterile in an individual plastic case. The lens is shipped dry; or wet shipped in Boston SIMPLUS® solution.* This solution contains poloxamine, hydroxyalklphosphonate, boric acid, sodium borate, sodium chloride, hydroxypropylmethyl cellulose, Glucam and preserved with chlorhexidine gluconate (0.003%), polyaminopropyl biguanide (0.0005%). The case, packing slip, or invoice is marked with the base curve radius, dioptric power, diameter, center thickness, inclusion of UV absorber, lot number, fill date, and the color of the lens.

*Boston SIMPLUS® is a registered trademark of Bausch & Lomb.

Never reuse the solution. You may store the lens in the unopened container until ready to dispense, up to a maximum of twenty-five (25) days from the Fill Date. When a lens has been stored for 25 days in its original packaging solution, it should be cleaned and disinfected with an FDA approved product and placed into inventory, as you presently do with any other RGP lens held in your office. Follow the directions on the selected disinfecting solution regarding prolonged storage.

REPORTING OF ADVERSE REACTIONS

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

Paragon Vision Sciences, Inc.
2120 W. Guadalupe Rd.
Gilbert, Arizona 85233-2810

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1-480-892-7602
1-480-926-7369 FAX

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