



PACKAGE INSERT

FluoroPerm® 92 (paflucocon A)

Rigid Gas Permeable Contact Lenses for Daily and Extended Wear
Lentilles cornéennes rigides perméables aux gaz à port quotidien et prolongé

FluoroPerm® 60 (paflucocon B)

Rigid Gas Permeable Contact Lenses for Daily and Extended Wear
Lentilles cornéennes rigides perméables aux gaz à port quotidien et prolongé

FluoroPerm® 30 (paflucocon C)

Rigid Gas Permeable Contact Lenses for Daily Wear
Lentilles cornéennes rigides perméables aux gaz à port quotidien

FluoroPerm® 151 (paflucocon D)

Rigid Gas Permeable Contact Lenses for Daily and Extended Wear
Lentilles cornéennes rigides perméables aux gaz à port quotidien et prolongé

Shipped Dry; or Wet Shipped in Solution

IMPORTANT: Please read carefully and keep this information for future use.

IMPORTANT : veuillez lire attentivement ces renseignements et les conserver pour usage ultérieur.

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

AVERTISSEMENT : le spécialiste doit adresser cet avertissement au 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.

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

AVERTISSEMENT: 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.

LES PROBLÈMES LIÉS AUX LENTILLES CORNÉENNES ET AUX PRODUITS D'ENTRETIEN PEUVENT ENTRAÎNER DE GRAVES LÉSIONS OCULAIRES. Il est essentiel de suivre les consignes données par votre spécialiste des soins oculaires ainsi que toutes les instructions figurant sur les étiquettes afin d'utiliser correctement vos lentilles cornéennes et leurs produits d'entretien associés, y compris l'étui à lentilles.

Les patients doivent se conformer aux durées complètes de frottement et de rinçage figurant sur l'étiquetage du produit pour bien désinfecter leurs lentilles et réduire le risque de contamination des lentilles cornéennes. Leurs lentilles pourraient être mal nettoyées en cas de durées de frottement ou de rinçage réduites.

Les patients doivent remplir leur étui à lentilles de solution propre chaque fois qu'ils rangent leurs lentilles et ne jamais réutiliser la solution. Ils doivent jeter la solution immédiatement après avoir retiré leurs lentilles de leur étui. Ils ne doivent pas stocker leurs lentilles dans de l'eau du robinet, de l'eau en bouteille ou toute solution non stérile ni rincer leur étui à l'aide de ces liquides.

Les patients doivent nettoyer et rincer leur étui entre chaque utilisation comme le recommande leur spécialiste des soins oculaires.

DES PROBLÈMES OCULAIRES, Y COMPRIS DES ULCÈRES DE LA CORNÉE, PEUVENT SE DÉVELOPPER RAPIDEMENT ET ENTRAÎNER UNE PERTE DE VISION. SI VOUS RESSENTEZ UNE GÊNE OCULAIRE, UN LARMOIEMENT EXCESSIF, DES TROUBLES DE LA VISION, OU PRÉSENTEZ UNE ROUGEUR OCULAIRE OU D'AUTRES PROBLÈMES AUX YEUX, RETIREZ IMMÉDIATEMENT VOS LENTILLES ET CONSULTEZ IMMÉDIATEMENT VOTRE SPÉCIALISTE DES SOINS OCULAIRES.

FLUOROPERM® 92 (paflucocon A)

RIGID GAS PERMEABLE CONTACT LENSES FOR DAILY WEAR AND EXTENDED WEAR LENTILLES CORNÉENNES RIGIDES PERMÉABLES AUX GAZ À PORT QUOTIDIEN ET PROLONGÉ

Daily or Extended Wear Spherical, Aspheric contact lenses for:

Nearsightedness (myopia).
Farsightedness (hyperopia).

Daily Wear Bifocal, Toric contact lenses for:

Nearsightedness (myopia).
Farsightedness (hyperopia).

DESCRIPTION

FluoroPerm® 92 (paflucocon 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. FluoroPerm 92 rigid gas permeable contact lenses for extended wear are available as lathe cut or molded firm 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 rigid gas permeable contact lens material is a thermoset copolymer derived from fluorosilicone acrylate monomers.

FluoroPerm® 92 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 (paflucocon A)

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

⁺ 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 O₂) / (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
Powers Daily Wear	-20.00 to +12.00 Diopters
Powers 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

ACTION

FluoroPerm® 92 rigid gas permeable toric and bifocal contact lenses are intended for daily wear only. FluoroPerm® 92 spherical and aspheric contact lenses are intended for daily or extended wear.

When placed on the human cornea, the FluoroPerm® 92 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)

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 refractive ametropia in non-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.

INDICATIONS (USAGES)

Les lentilles cornéennes rigides perméables aux gaz sphériques ou asphériques FluoroPerm® 92 sont indiquées pour un port quotidien et prolongé entre un et sept jours entre les retraits pour nettoyage et désinfection, comme le recommande le spécialiste des soins oculaires. Les lentilles cornéennes rigides perméables aux gaz bifocales ou toriques FluoroPerm® 92 sont indiquées pour un port quotidien uniquement.

Les lentilles cornéennes rigides perméables aux gaz bifocales, asphériques et sphériques FluoroPerm® 92 sont indiquées pour la correction de l'amétropie de puissance chez les personnes non aphaques dont les yeux ne sont pas malades qui sont myopes, hypermétropes et peuvent présenter un astigmatisme cornéen jusqu'à 4,00 dioptries n'altérant pas l'acuité visuelle. Les lentilles cornéennes toriques FluoroPerm® 92 sont indiquées pour corriger l'astigmatisme jusqu'à 6,00 dioptries. Les lentilles bifocales FluoroPerm® 92 sont indiquées pour traiter la presbytie avec une puissance d'addition allant jusqu'à + 4,00 d.

Dans le cas d'un port quotidien, les lentilles cornéennes FluoroPerm® 92 sont indiquées pour la prise en charge des irrégularités pathologiques de la cornée telles que le kératocône, la dégénérescence pellucide marginale ou survenant à la suite d'une kératoplastie pénétrante, d'une kératotomie radiaire ou d'une chirurgie LASIK sur des yeux non malades par ailleurs.

CONTRAINDICATIONS (REASONS NOT TO USE)

FluoroPerm® 92 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.
- 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).
- For DAILY wear only: Any eye disease, injury or abnormality, other than keratoconus, pellucid marginal degeneration, penetrating keratoplasty, LASIK or radial keratotomy surgery, that affects the cornea, conjunctiva or eyelids.
- For EXTENDED wear only: Any disease which affects the cornea or conjunctiva.

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 also extremely important.

The maximum suggested wearing time for FluoroPerm® 92 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											

EXTENDED WEAR

Not every patient is able to wear the FluoroPerm® 92 rigid gas permeable contact lens on an extended wear basis, even if able to wear the lens for daily wear. An initial 14-day daily wear period is recommended prior to overnight wear. Regular check-ups, as determined by the eye care practitioner, are extremely important. The lens should be removed at least once every week (7 days) for cleaning and disinfection.

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

DAY	SUGGESTED HOURS	HOURS WORN
15 (and after)	24 hours	

WARNING

AVERTISSEMENT

The risk of ulcerative keratitis has been shown to be greater among wearers of extended wear lenses than among wearers of daily wear lenses. The risk among extended wear lens wearers increases with the number of consecutive days that lenses are worn between removals, beginning with the first overnight use. This risk can be reduced by carefully following directions for routine lens care, including cleaning of the lens storage case. Additionally, smoking increases the risk of ulcerative keratitis for contact lens wearers.

It is recommended that contact lens wearers see their eye care practitioners twice each year or, if directed, more frequently.

Le risque de kératite ulcéreuse s'est avéré plus important chez les porteurs de lentilles à port prolongé que chez les porteurs de lentilles à port quotidien. Le risque chez les porteurs de lentilles à port prolongé augmente avec le nombre de jours consécutifs de port des lentilles entre les retraits, en commençant par la

première utilisation nocturne. Ce risque peut être réduit en suivant scrupuleusement les consignes relatives à l'entretien courant des lentilles, y compris le nettoyage de leur étui de rangement. En outre, le tabagisme augmente le risque de kératite ulcéreuse chez les porteurs de lentilles cornéennes.

Il est recommandé aux porteurs de lentilles cornéennes de consulter leurs spécialistes des soins oculaires deux fois par an ou plus fréquemment si on le leur demande.

FLUOROPERM® 60 (paflucocon B)

RIGID GAS PERMEABLE CONTACT LENSES FOR DAILY WEAR AND EXTENDED WEAR
LENTILLES CORNÉENNES RIGIDES PERMÉABLES AUX GAZ À PORT QUOTIDIEN ET PROLONGÉ

Daily or Extended Wear Spherical, Aspheric contact lenses for:

Nearsightedness (myopia).
Farsightedness (hyperopia).

Daily Wear Bifocal, Toric contact lenses for:

Nearsightedness (myopia).
Farsightedness (hyperopia).

DESCRIPTION

FluoroPerm® 60 (paflucocon B) 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. FluoroPerm® 60 rigid gas permeable contact lenses for extended wear are available as lathe cut or molded firm 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® 60 rigid gas permeable contact lens material is a thermoset copolymer derived from fluorosilicone acrylate monomers.

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® 60 (paflucocon B)

Refractive Index	1.453 (n_d at 25° C)
Luminous Transmittance ⁺ (Clear)	99%
Luminous Transmittance (Crystal Blue)	98%
Luminous Transmittance (Blue)	95%
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 8599:1994

⁺⁺ 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

* (cm²/sec) (mL O₂) / (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
Powers Daily Wear	-20.00 to +12.00 Diopters
Powers 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

ACTION

FluoroPerm 60® rigid gas permeable toric and bifocal contact lenses are intended for daily wear only. FluoroPerm® 60 spherical and aspheric contact lenses are intended for daily or extended wear.

When placed on the human cornea, the FluoroPerm® 60 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)

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 refractive ametropia 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.

INDICATIONS (USAGES)

Les lentilles cornéennes rigides perméables aux gaz sphériques ou asphériques FluoroPerm® 60 sont indiquées pour un port quotidien et prolongé entre un et sept jours entre les retraits pour nettoyage et désinfection, comme le recommande le spécialiste des soins oculaires. Les lentilles cornéennes rigides perméables aux gaz bifocales ou toriques FluoroPerm® 60 sont indiquées pour un port quotidien uniquement.

Les lentilles cornéennes rigides perméables aux gaz bifocales, asphériques et sphériques FluoroPerm® 60 sont indiquées pour la correction de l'amétropie de puissance chez les personnes non aphaques dont les yeux ne sont pas malades qui sont myopes, hypermétropes et peuvent présenter un astigmatisme cornéen jusqu'à 4,00 dioptries n'altérant pas l'acuité visuelle. Les lentilles cornéennes toriques FluoroPerm® 60 sont indiquées pour corriger l'astigmatisme jusqu'à 6,00 dioptries. Les lentilles bifocales FluoroPerm® 60 sont indiquées pour traiter la presbytie avec une puissance d'addition allant jusqu'à + 4,00 d.

Dans le cas d'un port quotidien, les lentilles cornéennes FluoroPerm® 60 sont indiquées pour la prise en charge des irrégularités pathologiques de la cornée telles que le kératocône, la dégénérescence pellucide marginale ou survenant à la suite d'une kératoplastie pénétrante, d'une kératotomie radiaire ou d'une chirurgie LASIK sur des yeux non malades par ailleurs.

CONTRAINDICATIONS (REASONS NOT TO USE)

FluoroPerm® 60 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.
- 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).
- For DAILY wear only: Any eye disease, injury or abnormality, other than keratoconus, pellucid marginal degeneration, penetrating keratoplasty, LASIK or radial keratotomy surgery, that affects the cornea, conjunctiva or eyelids.
- For EXTENDED wear only: Any disease which affects the cornea or conjunctiva.

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 also extremely important.

The maximum suggested wearing time for FluoroPerm® 60 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											

EXTENDED WEAR

Not every patient is able to wear the FluoroPerm® 60 rigid gas permeable contact lens on an extended wear basis, even if able to wear the lens for daily wear. An initial 14-day daily wear period is recommended prior to overnight wear. Regular check-ups, as determined by the eye care practitioner, are extremely important. The lens should be removed at least once every week (7 days) for cleaning and disinfection.

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

DAY	SUGGESTED HOURS	HOURS WORN
15 (and after)	24 hours	

WARNING

AVERTISSEMENT

The risk of ulcerative keratitis has been shown to be greater among wearers of extended wear lenses than among wearers of daily wear lenses. The risk among extended wear lens wearers increases with the number of consecutive days that lenses are worn between removals, beginning with the first overnight use. This risk can be reduced by carefully following directions for routine lens care, including cleaning of the lens storage case. Additionally, smoking increases the risk of ulcerative keratitis for contact lens wearers.

It is recommended that contact lens wearers see their eye care practitioners twice each year or, if directed, more frequently.

Le risque de k ratite ulc reuse s'est av r  plus important chez les porteurs de lentilles   port prolong  que chez les porteurs de lentilles   port quotidien. Le risque chez les porteurs de lentilles   port prolong  augmente avec le nombre de jours cons cutifs de port des lentilles entre les retraits, en commen ant par la premi re utilisation nocturne. Ce risque peut  tre r duit en suivant scrupuleusement les consignes relatives   l'entretien courant des lentilles, y compris le nettoyage de leur  tui de rangement. En outre, le tabagisme augmente le risque de k ratite ulc reuse chez les porteurs de lentilles corn ennes.

Il est recommand  aux porteurs de lentilles corn ennes de consulter leurs sp cialistes des soins oculaires deux fois par an ou plus fr quemment si on le leur demande.

FLUOROPERM® 30

(paflucocon C)

RIGID GAS PERMEABLE CONTACT LENSES FOR DAILY WEAR
LENTILLES CORN ENNES RIGIDES PERM ABLES AUX GAZ   PORT QUOTIDIEN

Spherical, Aspheric, Bifocal, Toric contact lenses for:

Nearsightedness (myopia).
Farsightedness (hyperopia).

DESCRIPTION

FluoroPerm® 30 (paflucocon C) 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 FluoroPerm® 30 rigid gas permeable contact lens material is a thermoset copolymer derived from fluorosilicone acrylate monomers.

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 (paflucocon C)

Refractive Index	1.466 (n _d at 25° C)
Luminous Transmittance ⁺ (Clear)	99%
Luminous Transmittance (Crystal Blue)	98%
Luminous Transmittance (Green)	95%
Luminous Transmittance (Blue)	94%
Luminous Transmittance (Gray)	91%
Luminous Transmittance (Brown)	83%
Luminous Transmittance (Majestic Blue)	79%
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 8599:1994

⁺⁺ 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

* (cm²/sec) (mL O₂) / (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 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
Powers Daily Wear	-20.00 to +12.00 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

ACTION

FluoroPerm 30 rigid gas permeable spherical, aspheric, toric and bifocal contact lenses are intended for daily wear only.

When placed on the human cornea, the FluoroPerm 30 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)

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 refractive ametropia 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.

INDICATIONS (USAGES)

Les lentilles cornéennes rigides perméables aux gaz FluoroPerm® 30 sont indiquées pour un port quotidien comme le recommande le spécialiste des soins oculaires.

Les lentilles cornéennes rigides perméables aux gaz bifocales, asphériques et sphériques FluoroPerm® 30 sont indiquées pour la correction de l'amétropie de puissance chez les personnes non aphaques dont les yeux ne sont pas malades qui sont myopes, hypermétropes et peuvent présenter un astigmatisme cornéen jusqu'à 4,00 dioptries n'altérant pas l'acuité visuelle. Les lentilles cornéennes toriques FluoroPerm® 30 sont indiquées pour corriger l'astigmatisme jusqu'à 6,00 dioptries. Les lentilles bifocales FluoroPerm® 30 sont indiquées pour traiter la presbytie avec une puissance d'addition allant jusqu'à + 4,00 d.

Dans le cas d'un port quotidien, les lentilles cornéennes FluoroPerm® 30 sont indiquées pour la prise en charge des irrégularités pathologiques de la cornée telles que le kératocône, la dégénérescence pellucide marginale ou survenant à la suite d'une kératoplastie pénétrante, d'une kératotomie radiaire ou d'une chirurgie LASIK sur des yeux non malades par ailleurs.

CONTRAINDICATIONS (REASONS NOT TO USE)

FluoroPerm® 30 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.
- 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).
- For DAILY wear only: Any eye disease, injury or abnormality, other than keratoconus, pellucid marginal degeneration, penetrating keratoplasty, LASIK or radial keratotomy surgery, that affects the cornea, conjunctiva or eyelids.
- For EXTENDED wear only: Any disease which affects the cornea or conjunctiva.

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 also extremely important.

The maximum suggested wearing time for FluoroPerm® 30 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 FLUOROPERM 30 RIGID GAS PERMEABLE CONTACT LENS. Studies have not been completed to show that the FluoroPerm 30 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 above. Regular check-ups, as determined by the eye care practitioner, are extremely important.

NE PORTEZ PAS VOS LENTILLES CORNÉENNES RIGIDES PERMÉABLES AUX GAZ FLUOROPERM 30 EN DORMANT. Aucune étude ne prouve qu'il est sécuritaire de dormir avec les lentilles cornéennes rigides perméables aux gaz FluoroPerm 30. Au début, certains patients ont tendance à porter leurs lentilles trop longtemps. Il est important de respecter la durée maximale de port indiquée ci-dessus. Des contrôles réguliers, dont le calendrier est établi par le spécialiste des soins oculaires, sont extrêmement importants.

FLUOROPERM® 151 (pafluocon D)

RIGID GAS PERMEABLE CONTACT LENSES FOR DAILY WEAR AND EXTENDED WEAR LENTILLES CORNÉENNES RIGIDES PERMÉABLES AUX GAZ À PORT QUOTIDIEN ET PROLONGÉ

Spherical contact lenses for:
Nearsightedness (myopia).
Farsightedness (hyperopia).

DESCRIPTION

FluoroPerm® 151 (pafluocon D) rigid gas permeable contact lenses for daily wear and extended wear are available as lathe cut or molded firm contact lenses with spherical front and back surfaces in 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.

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 (pafluocon D)

Refractive Index	1.442 (n_d at 25° C)
Luminous Transmittance ⁺ (Crystal Blue)	98%
Luminous Transmittance (Blue)	93%
Wetting Angle (Receding Angle) ⁺⁺	42°
Wetting Angle (Contact Angle) ⁺⁺⁺	70°
Specific Gravity	1.10
Hardness (Shore D)	79
Water Content	<1%
Oxygen Permeability*	99×10^{-11} Dk at 35°C

⁺ 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

* (cm²/sec) (mL O₂) / (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
Powers Daily Wear	-20.00 to +12.00 Diopters
Powers 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

ACTION

FluoroPerm® 151 rigid gas permeable contact lenses are intended for daily wear or extended wear.

When placed on the human cornea, the FluoroPerm 151 rigid gas permeable contact lens acts as a refracting medium to focus light rays upon the retina.

INDICATIONS (USES)

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 refractive ametropia 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.

INDICATIONS (USAGES)

Les lentilles cornéennes rigides perméables aux gaz sphériques ou asphériques FluoroPerm® 151 sont indiquées pour un port quotidien et prolongé entre un et sept jours entre les retraits pour nettoyage et désinfection, comme le recommande le spécialiste des soins oculaires. Les lentilles cornéennes rigides perméables aux gaz bifocales ou toriques FluoroPerm® 151 sont indiquées pour un port quotidien uniquement.

Les lentilles cornéennes rigides perméables aux gaz bifocales, asphériques et sphériques FluoroPerm® 151 sont indiquées pour la correction de l'amétropie de puissance chez les personnes non aphaques dont les yeux ne sont pas malades qui sont myopes, hypermétropes et peuvent présenter un astigmatisme cornéen jusqu'à 4,00 dioptries n'altérant pas l'acuité visuelle. Les lentilles cornéennes toriques FluoroPerm® 151 sont indiquées pour corriger l'astigmatisme jusqu'à 6,00 dioptries. Les lentilles bifocales FluoroPerm® 151 sont indiquées pour traiter la presbytie avec une puissance d'addition allant jusqu'à + 4,00 d.

Dans le cas d'un port quotidien, les lentilles cornéennes FluoroPerm® 151 sont indiquées pour la prise en charge des irrégularités pathologiques de la cornée telles que le kératocône, la dégénérescence pellucide marginale ou survenant à la suite d'une kératoplastie pénétrante, d'une kératotomie radiaire ou d'une chirurgie LASIK sur des yeux non malades par ailleurs.

CONTRAINDICATIONS (REASONS NOT TO USE)

FluoroPerm® 151 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.
- 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).
- For DAILY wear only: Any eye disease, injury or abnormality, other than keratoconus, pellucid marginal degeneration, penetrating keratoplasty, LASIK or radial keratotomy surgery, that affects the cornea, conjunctiva or eyelids.
- For EXTENDED wear only: Any disease which affects the cornea or conjunctiva.

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 also extremely important.

The maximum suggested wearing time for FluoroPerm® 151 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											

EXTENDED WEAR

Not every patient is able to wear the FluoroPerm® 151 rigid gas permeable contact lens on an extended wear basis, even if able to wear the lens for daily wear. An initial 14-day daily wear period is recommended prior to overnight wear. Regular check-ups, as determined by the eye care practitioner, are extremely important. The lens should be removed at least once every week (7 days) for cleaning and disinfection.

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

DAY	SUGGESTED HOURS	HOURS WORN
15 (and after)	24 hours	

WARNING

AVERTISSEMENT

The risk of ulcerative keratitis has been shown to be greater among wearers of extended wear lenses than among wearers of daily wear lenses. The risk among extended wear lens wearers increases with the number of consecutive days that lenses are worn between removals, beginning with the first overnight use. This risk can be reduced by carefully following directions for routine lens care, including cleaning of the lens storage case. Additionally, smoking increases the risk of ulcerative keratitis for contact lens wearers.

It is recommended that contact lens wearers see their eye care practitioners twice each year or, if directed, more frequently.

Le risque de kératite ulcéreuse s'est avéré plus important chez les porteurs de lentilles à port prolongé que chez les porteurs de lentilles à port quotidien. Le risque chez les porteurs de lentilles à port prolongé augmente avec le nombre de jours consécutifs de port des lentilles entre les retraits, en commençant par la première utilisation nocturne. Ce risque peut être réduit en suivant scrupuleusement les consignes relatives à l'entretien courant des lentilles, y compris le nettoyage de leur étui de rangement. En outre, le tabagisme augmente le risque de kératite ulcéreuse chez les porteurs de lentilles cornéennes.

Il est recommandé aux porteurs de lentilles cornéennes de consulter leurs spécialistes des soins oculaires deux fois par an ou plus fréquemment si on le leur demande.

GENERAL INFORMATION

Convention: Reference to FluoroPerm® rigid gas permeable contact lenses indicates all four materials – FluoroPerm® 92 (paflucocon A), FluoroPerm® 60 (paflucocon B), FluoroPerm® 30 (paflucocon C), and FluoroPerm® 151 (paflucocon D).

TINTS

FluoroPerm rigid gas permeable contact lenses are available in untinted (clear) and tinted [blue, crystal blue, majestic blue, brown (daily wear only), gray, and green] versions with or without ultraviolet absorber. The tinted lenses contain one or more of the following color additives: D&D Green No. 6, D&C Red No. 17, D&C Violet No. 2 and Perox Yellow No. 9 (4-[(2,4-dimethylphenyl)azo]-2,4-dihydro-5-methyl-2-phenyl-3H-pyrazol-3-one). NOTE: Not all materials are available in all colors or with ultraviolet absorber.

UV ABSORBER

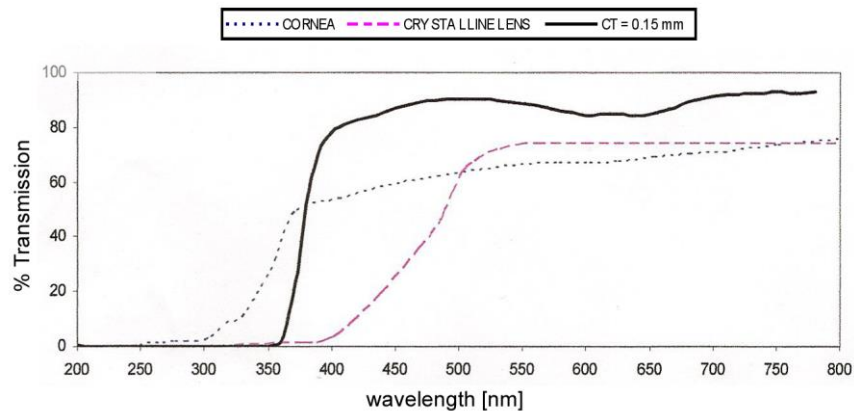
FluoroPerm® rigid gas permeable contact lenses are available with an ultraviolet absorber. The ultraviolet absorber, Acrymer™ 282, has been integrated as an additive within the FluoroPerm® 92, FluoroPerm® 60 and FluoroPerm® 30 polymer matrix and blocks up to 96% of light from 280 to 380 nm. Acrymer™ is 4-methacryloxy-2-hydroxybenzophenone. Uvinul™ D-49, has been integrated as an additive within the FluoroPerm® 151 polymer matrix blocking up to 97% of light below 380 nm. Uvinul D49 is 2,2'-dihydroxy-4,4'-dimethoxybenzophenone.

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.

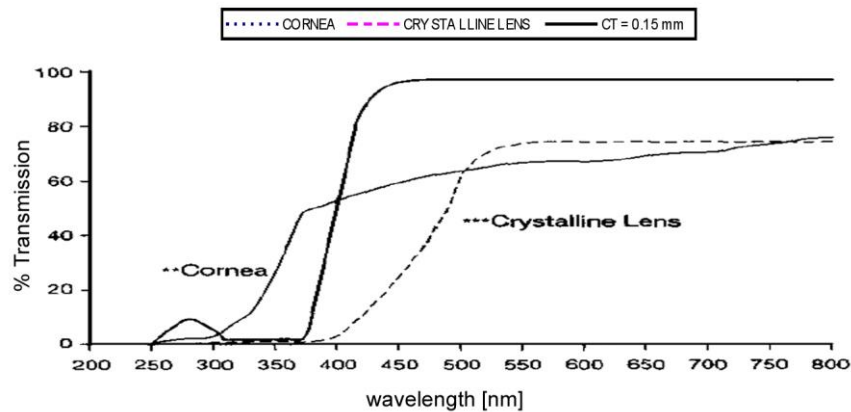
AVERTISSEMENT : les lentilles cornéennes à absorption UV ne remplacent pas des lunettes de protection à absorption UV telles que des lunettes de sécurité ou des lunettes de soleil à absorption UV. Ces personnes doivent continuer à porter leurs lunettes de protection à absorption UV comme indiqué.

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.

FluoroPerm® 92, FluoroPerm® 60 and FluoroPerm® 30 with Acrymer 282



FluoroPerm® 151 with Uvinul D54



**CORNEA - Human cornea from a 24-year old person as described in Lerman, S., Radiant Energy and the Eye, MacMillan, New York, 1980, p. 58, figure 2-21.

***CRYSTALLINE LENS - Human crystalline lens from a 25-year old person as described in Waxler, M., Hitchins, V.M., Optical Radiation and Visual Health, CRC Press, Boca Raton, Florida, 1986, p.19, figure 5.

WARNING: The practitioner should provide this warning to the patient.
AVERTISSEMENT : le spécialiste doit adresser cet avertissement au 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.

LES PROBLÈMES LIÉS AUX LENTILLES CORNÉENNES ET AUX PRODUITS D'ENTRETIEN PEUVENT ENTRAÎNER DE GRAVES LÉSIONS OCULAIRES. Il est essentiel de suivre les consignes données par votre spécialiste des soins oculaires ainsi que toutes les instructions figurant sur les étiquettes afin d'utiliser correctement vos lentilles cornéennes et leurs produits d'entretien associés, y compris l'étui à lentilles.

Les patients doivent se conformer aux durées complètes de frottage et de rinçage figurant sur l'étiquetage du produit pour bien désinfecter leurs lentilles et réduire le risque de contamination des lentilles cornéennes. Leurs lentilles pourraient être mal nettoyées en cas de durées de frottage ou de rinçage réduites.

Les patients doivent remplir leur étui à lentilles de solution propre chaque fois qu'ils rangent leurs lentilles et ne jamais réutiliser la solution. Ils doivent jeter la solution immédiatement après avoir retiré leurs lentilles de leur étui. Ils ne doivent pas stocker leurs lentilles dans de l'eau du robinet, de l'eau en bouteille ou toute solution non stérile ni rincer leur étui à l'aide de ces liquides.

Les patients doivent nettoyer et rincer leur étui entre chaque utilisation comme le recommande leur spécialiste des soins oculaires.

DES PROBLÈMES OCULAIRES, Y COMPRIS DES ULCÈRES DE LA CORNÉE, PEUVENT SE DÉVELOPPER RAPIDEMENT ET ENTRAÎNER UNE PERTE DE VISION. SI VOUS RESSENTEZ UNE GÊNE OCULAIRE, UN LARMOIEMENT EXCESSIF, DES TROUBLES DE LA VISION, OU PRÉSENTEZ UNE ROUGEUR OCULAIRE OU D'AUTRES PROBLÈMES AUX YEUX, RETIREZ IMMÉDIATEMENT VOS LENTILLES ET CONSULTEZ IMMÉDIATEMENT VOTRE SPÉCIALISTE DES SOINS OCULAIRES.

PRECAUTIONS - PRACTITIONER

Clinical studies have demonstrated that contact lenses manufactured from the FluoroPerm[®] 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. Extended wear lenses should not be used to correct keratoconus, pellucid marginal degeneration, or following penetrating keratoplasty, LASIK or radial keratotomy surgery.

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 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, hydroxyalkylphosphonate, boric acid, sodium borate, sodium chloride, hydroxypropylmethyl cellulose, Glucam and preserved with chlorhexidine gluconate (0.003%), polyaminopropyl biguanide (0.0005%). If the patient has experienced a prior history of allergy to any of these ingredients, remove the lens from the solution and soak the lens 24 hours in sterile unpreserved saline prior to cleaning, disinfecting and dispensing.

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

Never reuse the solution. You may store the lenses in the unopened container until ready to dispense, up to a maximum of thirty (30) days from the Fill Date (see container). When a lens has been stored for 30 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.

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 FLUOROPERM RIGID GAS PERMEABLE CONTACT LENSES WHILE SLEEPING UNLESS YOUR WEARING SCHEDULE IS INTENDED FOR EXTENDED WEAR.**
- 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 FluoroPerm 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.

PRÉCAUTIONS : PATIENT

Suivez les instructions ci-dessous pour éviter toute lésion au niveau de vos yeux ou de vos lentilles.

- Avant de quitter le cabinet de votre spécialiste, apprenez à enlever rapidement vos lentilles ou faites-en sorte que quelqu'un d'autre soit capable de le faire pour vous.
- **NE PORTEZ PAS VOS LENTILLES CORNÉENNES RIGIDES PERMÉABLES AUX GAZ FLUOROPERM EN DORMANT SAUF S'IL S'AGIT DE LENTILLES À PORT PROLONGÉ.**
- Lavez-vous toujours les mains avec un savon sans additif, rincez-les abondamment et séchez-les à l'aide d'une serviette non pelucheuse avant de manipuler vos lentilles. Vous pouvez souffrir d'une irritation oculaire si des produits de beauté, des lotions, des savons, des crèmes et des déodorants entrent en contact avec vos lentilles et si les lentilles sont contaminées par des débris infectieux ou non infectieux.
- Conformez-vous en permanence au système d'entretien recommandé pour vos lentilles FluoroPerm. Utilisez les solutions recommandées pour l'entretien de vos lentilles et conformez-vous scrupuleusement aux recommandations.
- Utilisez toujours des solutions de rinçage, de désinfection et de conservation PROPRES.
- **N'utilisez pas de salive, d'eau du robinet ou autre chose que les solutions recommandées pour humidifier vos lentilles.**
- Immergez toujours les lentilles intégralement dans la solution de conservation recommandée lorsque vous ne les portez pas.
- Évitez d'utiliser des aérosols, tels que des laques, lorsque vous portez vos lentilles. Si vous en utilisez, fermez les yeux jusqu'à ce que la laque soit fixée. Dans le cas contraire, vous pourriez endommager vos lentilles.
- Évitez toute vapeur ou fumée nocive ou irritante lorsque vous portez vos lentilles.
- Ne nagez pas avec vos lentilles.
- N'utilisez jamais de pince à épiler ou autres outils pour retirer vos lentilles de leur étui. Ne touchez pas vos lentilles avec vos ongles.
- Indiquez toujours à votre médecin (omnipraticien) que vous portez des lentilles cornéennes.
- Consultez toujours votre spécialiste des soins oculaires avant de vous mettre un médicament dans les yeux.
- Indiquez toujours à votre employeur que vous portez des lentilles cornéennes. Certains emplois peuvent exiger l'utilisation d'un équipement de protection oculaire ou peuvent exiger l'absence de port de lentilles cornéennes.
- Le port de toute lentille cornéenne entraîne la nécessité d'effectuer des visites de contrôle pour préserver votre santé. **PARLEZ-EN À VOTRE SPÉCIALISTE DES SOINS OCULAIRES.**
- Pour minimiser les déformations de la lentille au cours du nettoyage, nettoyez les lentilles dans la paume de la main, plutôt qu'entre le pouce et les doigts.
- Ne chauffez pas la solution de conditionnement ni les lentilles.
- L'innocuité de ces lentilles avec des médicaments ou des solutions pour lentilles cornéennes autres que celles recommandées n'a pas été démontrée.
- Si votre lentille colle à votre œil (n'est plus mobile), suivez les consignes relatives aux « Soins en cas de lentille collante ». La lentille doit se mouvoir librement sur l'œil pour préserver la santé de ce dernier. Si l'absence de mouvement persiste, consultez immédiatement votre spécialiste des soins oculaires.
- **MISE EN GARDE :** non stériles. Nettoyez et vérifiez l'état de vos lentilles avant utilisation.

EFFETS INDÉSIRABLES (PROBLÈMES ET COMMENT LES RÉSOUDRE)

Vous pouvez rencontrer les problèmes suivants :

- sensation de picotement, brûlure ou démangeaison oculaire (irritation);
- confort moindre par rapport à la pose initiale de la lentille sur l'œil;
- sensation d'avoir quelque chose dans l'œil (corps étranger, égratignure, abrasion);
- douleur excessive;
- larmoiement excessif;
- sécrétions oculaires inhabituelles;
- rougeur oculaire;
- netteté visuelle réduite (mauvaise acuité visuelle);
- vision floue, arcs-en-ciel ou halos autour des objets;
- sensibilité à la lumière (photophobie);
- yeux secs.

Si vous remarquez l'un de ces effets indésirables, **RETIREZ IMMÉDIATEMENT VOS LENTILLES.**

- Si la gêne ou le problème disparaît, inspectez attentivement la lentille.
- Si elle est abîmée, ne la remettez PAS dans votre œil. Placez la lentille dans son étui de rangement et appelez votre spécialiste des soins oculaires.
- Si la lentille est sale, si un cil ou un autre corps étranger s'est déposé dessus ou si le problème disparaît et que la lentille semble intacte, nettoyez, rincez et désinfectez correctement les lentilles avant de les remettre.
- Si le problème persiste, retirez IMMÉDIATEMENT vos lentilles cornéennes et consultez un spécialiste des soins oculaires.

Lorsqu'un des symptômes ci-dessus se manifeste, un problème grave peut se produire tel qu'une infection, un ulcère de la cornée, une néovascularisation, une iritis, un œdème stromal persistant ou une conjonctivite papillaire géante (CPG). Retirez immédiatement vos lentilles et demandez à un spécialiste d'identifier votre problème et de vous prescrire rapidement un traitement pour éviter des lésions oculaires graves, y compris une cicatrisation cornéenne, une opacification, la cécité ou la perte de l'œil.

FITTING

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

Paragon Vision Sciences, Inc	1-800-528-8279
2120 W. Guadalupe Rd.	1-480-892-7602
Gilbert, Arizona 85233-2810	1-480-926-7369 FAX

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

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.

FluoroPerm® 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 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. 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 solution 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.

FluoroPerm® 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 FluoroPerm® 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 non-movement of the lens continues, immediately consult your eye care practitioner.

CONSIGNES RELATIVES À L'ENTRETIEN DES LENTILLES

Lavez-vous toujours les mains avec un savon sans additif, rincez-les abondamment et séchez-les à l'aide d'une serviette non pelucheuse avant de manipuler vos lentilles.

N'utilisez jamais de pince à épiler ou autres outils pour retirer vos lentilles de leur étui. Mettez la lentille dans votre main.

Les lentilles cornéennes rigides perméables aux gaz FluoroPerm® doivent être nettoyées et désinfectées chaque fois que vous les enlevez. Une procédure ne remplace pas l'autre. Le nettoyage est nécessaire pour enlever mucus et film de la surface de la lentille. La désinfection est nécessaire pour détruire les germes nocifs. Laissez les lentilles cornéennes rigides perméables aux gaz FluoroPerm® dans une solution de conservation pendant au moins quatre heures ou conformez-vous aux indications figurant sur l'étiquette du produit. Pour minimiser les déformations de la lentille au cours du nettoyage, nettoyez les lentilles dans la paume de la main, plutôt qu'entre le pouce et les doigts. Les patients doivent se conformer aux durées complètes de frotage et de rinçage figurant sur l'étiquetage du produit pour bien désinfecter leurs lentilles et réduire le risque de contamination des lentilles cornéennes. Leurs lentilles pourraient être mal nettoyées en cas de durées de frotage ou de rinçage réduites.

Nettoyez tout d'abord une lentille. La méthode recommandée est de toujours nettoyer la même lentille en premier pour éviter les confusions. Rincez abondamment la lentille comme le recommande le fabricant du produit d'entretien pour lentilles afin d'enlever la solution de nettoyage. Placez la lentille dans le bon compartiment de rangement et remplissez le compartiment avec le système de désinfection recommandé comme indiqué par votre spécialiste des soins oculaires. Nettoyez et rincez l'autre lentille de la même manière et placez-la dans son compartiment.

Fermez hermétiquement le dessus de chaque compartiment de l'étui de rangement des lentilles.

Pour désinfecter vos lentilles, laissez-les dans la solution pendant au moins quatre heures ou conformez-vous aux indications figurant sur l'étiquette du produit.

Ne chauffez pas la solution de conditionnement ni les lentilles.

Laissez les lentilles dans l'étui de rangement fermé jusqu'à ce que vous soyez prêt à les mettre.

Les patients doivent remplir leur étui à lentilles de solution propre chaque fois qu'ils rangent leurs lentilles et ne jamais réutiliser la solution. Ils doivent jeter la solution immédiatement après avoir retiré leurs lentilles de leur étui. Ils ne doivent pas stocker leurs lentilles dans de l'eau du robinet, de l'eau en bouteille ou toute solution non stérile ni rincer leur étui à l'aide de ces liquides.

Les patients doivent nettoyer et rincer leur étui entre chaque utilisation comme le recommande leur spécialiste des soins oculaires.

Après avoir retiré vos lentilles de leur étui, videz et rincez votre étui de rangement des lentilles à l'aide d'eau du robinet propre et chaude, et laissez sécher à l'air libre. Lors de la prochaine utilisation de l'étui, remplissez-le à nouveau de solution de conservation propre.

Les lentilles cornéennes rigides perméables aux gaz FluoroPerm® doivent être désinfectées uniquement à l'aide d'un système de désinfection chimique (et non thermique).

Votre spécialiste des soins oculaires vous recommandera ses solutions d'entretien pour lentilles préférées approuvées par la FDA pour le nettoyage, la désinfection, la conservation et la lubrification de vos lentilles cornéennes rigides perméables aux gaz FluoroPerm®.

Suivez les instructions fournies avec chaque solution d'entretien pour lentilles. Le non-respect de ces procédures peut entraîner l'apparition de complications oculaires graves. Un patient ne doit pas changer de système d'entretien, sauf si son spécialiste des soins oculaires juge que cela est nécessaire. Ne mélangez pas ou n'alternez pas les systèmes de désinfection et de rangement sauf indication contraire sur l'étiquette du produit.

SOINS EN CAS DE LENTILLE COLLANTE

Si la lentille colle à votre œil (n'est plus mobile), appliquez quelques gouttes d'une solution lubrifiante. Attendez que la lentille commence à se mouvoir librement sur votre œil avant de la retirer. Si l'absence de mouvement persiste, consultez immédiatement votre spécialiste des soins oculaires.

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, hydroxyalkylphosphonate, boric acid, sodium borate, sodium chloride, hydroxypropylmethyl cellulose, Glucan and preserved with chlorhexidine gluconate (0.003%), polyaminopropyl biguanide (0.0005%). The case, packing slip, or invoice is marked with the base curve, 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 thirty (30) days from the Fill Date. When a lens has been stored for 30 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.

For information on material specifications contact:

**Paragon Vision Sciences, Inc.
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