

PACKAGE INSERT

Paraperm[®] EW (pasifocon C)

Rigid Gas Permeable Contact Lenses for Daily and Extended Wear

Paraperm[®] O₂ (pasifocon A)

Rigid Gas Permeable Contact Lenses for Daily Wear

Shipped Dry

IMPORTANT

Please read carefully and keep this information for future use.

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

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

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

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

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

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

PARAPERM® EW
(pasifocon C)

**RIGID GAS PERMEABLE CONTACT LENSES FOR
DAILY WEAR AND EXTENDED WEAR**

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

Paraperm® EW (pasifocon 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. Paraperm® EW 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 Paraperm® EW rigid gas permeable contact lens material is a thermoset copolymer derived from siloxane and methylmethacrylate.

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

The lenses have the following attributes.

Paraperm® EW (pasifocon C)

Refractive Index	1.467 (n_d at 25° C)
Luminous Transmittance ⁺ (Clear)	99%
Luminous Transmittance (Blue)	95%
Luminous Transmittance (Green)	96%
Wetting Angle (Receding Angle) ⁺⁺	26°
Wetting Angle (Contact Angle) ⁺⁺⁺	61°
Specific Gravity	1.07
Hardness (Shore D)	82
Water Content	< 1%
Oxygen Permeability*	50×10^{-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, 9913-1

Lens Parameters

Chord Diameter	7.0 to 10.5 mm
Center Thickness	0.05 to 0.40 mm
Base Curve	6.50 to 9.00 mm
Powers	-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

The Paraperm[®] EW rigid gas permeable toric and bifocal contact lenses are intended for daily wear only. The Paraperm[®] EW spherical and aspheric contact lenses are intended for daily or extended wear.

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

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

INDICATIONS (USES)

The Paraperm[®] EW 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. The Paraperm[®] EW rigid gas permeable bifocal or toric contact lenses are indicated for daily wear only.

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

CONTRAINDICATIONS (REASONS NOT TO USE)

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

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

WEARING SCHEDULE

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

The maximum suggested wearing time for Paraperm® EW 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 Paraperm® EW 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.

DAY	SUGGESTED HOURS	HOURS WORN
15 and after	24 hours	

WARNING

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.

NOTES

PARAPERM[®] O₂
(pasifocon A)

**RIGID GAS PERMEABLE CONTACT LENSES
FOR DAILY WEAR**

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

Nearsightedness (myopia).
Farsightedness (hyperopia).

DESCRIPTION

Paraperm[®] O₂ (pasifocon A) rigid gas permeable contact lenses for daily wear are available as lathe cut or molded firm contact lenses with spherical, aspheric, bifocal or toric anterior and/or posterior; or, bitoric surfaces in clear and tinted versions. The posterior curve is selected so as to properly fit an individual eye and the anterior curve is selected to provide the necessary optical power to correct refractive error. A peripheral curve system on the posterior surface allows tear exchange between the lens and the cornea.

The Paraperm[®] O₂ rigid gas permeable contact lens material is a thermoset copolymer derived from siloxane and methacrylate.

The Paraperm[®] O₂ rigid gas permeable tinted lenses offer a handling aid for locating the lens.

The lenses have the following attributes.

Paraperm[®] O₂ (pasifocon A)

Refractive Index	1.473 (n _d at 25° C)
Luminous Transmittance ⁺ (Clear)	99%
Luminous Transmittance (Blue)	93%
Luminous Transmittance (Electric Blue)	81%
Luminous Transmittance (Green)	97%
Luminous Transmittance (Cool Green)	95%
Wetting Angle (Receding Angle) ⁺⁺	23°
Wetting Angle (Contact Angle) ⁺⁺⁺	64°
Specific Gravity	1.12
Hardness (Shore D)	86
Water Content	< 1%
Oxygen Permeability*	16 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 10.5 mm
Center Thickness	0.05 to 0.70 mm
Base Curve	6.50 to 9.00 mm
Power	-20.00 to +20.00 Diopters
Bifocal Add Power	+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

The Paraperm[®] O₂ rigid gas permeable spherical, aspheric, toric and bifocal contact lenses are intended for daily wear only.

When placed on the human cornea, the Paraperm[®] O₂ rigid gas permeable contact lens acts as a refracting medium to focus light rays upon the retina.

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

INDICATIONS (USES)

The Paraperm[®] O₂ rigid gas permeable contact lenses are indicated for daily wear as recommended by the eye care practitioner.

The Paraperm[®] O₂ rigid gas permeable spherical, aspheric, and bifocal contact lenses are indicated for the correction of refractive ametropia in not-aphakic persons with nondiseased eyes that are nearsighted (myopic), farsighted (hyperopic), and may exhibit corneal astigmatism up to 4.00 diopters. Paraperm[®] O₂ toric contact lenses are indicated to correct astigmatism of up to 6.00 diopters.

CONTRAINDICATIONS (REASONS NOT TO USE)

The Paraperm[®] O₂ rigid gas permeable contact lenses are contraindicated by the presence of any of the following conditions:

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

WEARING SCHEDULE

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

The maximum suggested wearing time for Paraperm[®] O₂ rigid gas permeable contact lenses is:

DAILY WEAR (less than 24 hours while awake)

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

DO NOT SLEEP WHILE WEARING YOUR PARAPERM[®] O₂ RIGID GAS PERMEABLE CONTACT LENSES. Studies have not been completed to show that the Paraperm[®] O₂ rigid gas permeable contact lens is safe to wear during sleep. There is a tendency for some patients to overwear the lenses initially. It is important to adhere to the maximum wearing schedule. Regular checkups, as determined by the eye care practitioner, are extremely important.

NOTES

GENERAL INFORMATION

Convention: Reference to Paraperm[®] rigid gas permeable contact lenses indicates both materials – Paraperm[®] EW (pasifocon C) and Paraperm[®] O₂ (pasifocon A).

TINTS

Paraperm[®] rigid gas permeable contact lenses are available in untinted (clear) and tinted (blue, electric blue, green, and cool green) versions. The tinted lenses contain one or more of the following color additives; D&D Green No. 6, D&C Yellow No. 10 and Perox Yellow No. 9. NOTE: *Both materials are not available in all colors.*

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

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

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

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

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

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

PRECAUTIONS – PRACTITIONER

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

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

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

PRECAUTIONS - PATIENT

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

- Before you leave your practitioner's office be able to promptly remove your lens or have someone else be able to remove your lens for you.
- **DO NOT WEAR YOUR PARAPERM[®] 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 Paraperm[®] lenses. Use the recommended lens care solutions and carefully follow the recommended directions.
- Always use FRESH rinsing, disinfecting and storage solutions.
- Do not use saliva, tap water or anything other than the recommended solutions to wet your lenses.
- Always keep the lenses completely immersed in the recommended storage solution when the lenses are not being worn.
- Avoid using aerosol products such as hair spray while wearing your lenses. If hair sprays are used, keep your eyes closed until the spray has settled, otherwise, the lenses may be damaged.
- Avoid all harmful or irritating vapors and fumes while wearing your lenses.
- Do not swim with your lenses in place.
- Never use tweezers or other tools to remove your lens from the lens container. Do not touch the lens with your fingernails.
- Always inform your doctor (general health care practitioner) that you wear contact lenses.
- Always consult your eye care practitioner before using any medicine in your eyes.
- Always inform your employer that you wear contact lenses. Some jobs may require the use of protective eye equipment or may require that you not wear contact lenses.

- As with any contact lens, follow-up visits are necessary to assure continued health. **CHECK WITH YOUR EYE CARE PRACTITIONER.**
- To minimize lens warpage during cleaning, the lenses should be cleaned in the palm of the hand rather than between the thumb and fingers.
- Do not heat the conditioning solution and lenses.
- The safety of these lenses with medications or contact lens solutions other than those recommended has not been established.
- If your lens sticks (stops moving) on the eye, follow the recommended directions for "Care for a Sticking Lens". The lens must move freely on the eye for the continued health of the eye. If nonmovement of the lens continues, immediately consult your eye care practitioner.

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

ADVERSE EFFECTS (PROBLEMS AND WHAT TO DO)

The following problems may occur.

- Eyes sting, burn or itch (irritation)
- Comfort is less than when lens was first placed on eye
- Feeling of something in the eye (foreign body, scratched area, abrasion)
- Excessive pain
- Excessive watering (tearing) of the eyes
- Unusual eye secretions
- Redness of the eyes
- Reduced sharpness of vision (poor visual acuity)
- Blurred vision, rainbows, or halos around objects
- Sensitivity to light (photophobia)
- Dry eyes

If you notice any of these adverse effects, **IMMEDIATELY REMOVE YOUR LENSES.**

- If the discomfort or problem stops, then look closely at the lens.
- If the lens is in any way damaged, **DO NOT** put the lens back on your eye. Place the lens in the storage case and contact your eye care practitioner.
- If the lens has dirt, an eyelash, or other foreign body on it, or the problem stops and the lens appears undamaged, thoroughly clean, rinse and disinfect the lenses; then reinsert it.
- If the problem continues, **IMMEDIATELY** remove your contact lens and consult your eye care practitioner.

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

FITTING

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

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

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.

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

Clean one lens first. (The recommended procedure is to always clean the same lens first to avoid mix-ups). Rinse the lens thoroughly as recommended by your lens care product manufacturer to remove the cleaning solution. Place the lens into the correct storage chamber and fill the chamber with the recommended disinfection system as recommended by your eye care practitioner. Clean and rinse the other lens in the same manner and place it in its chamber.

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

To disinfect your lenses, leave them in the solution for at least 4 hours, or as indicated on the product label. Paraperm[®] rigid gas permeable contact lenses should be disinfected using only a chemical (not heat) disinfection system.

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.

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

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

CARE FOR A STICKING LENS

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

HOW SUPPLIED

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

For information on material specifications contact:

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

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