PACKAGE INSERT

Paragon Thin™ (paflufocon C)

Rigid Gas Permeable Contact Lenses for Daily Wear with Tangible™ Hydra-PEG

Paragon HDS® (paflufocon B)

Rigid Gas Permeable Contact Lenses for Daily Wear with Tangible™ Hydra-PEG

Paragon HDS® 100 (paflufocon D)

Rigid Gas Permeable Contact Lenses for Daily Wear with Tangible™ Hydra-PEG

Wet Shipped in Solution

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

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

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

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.

PARAGON Thin™

(paflufocon C)

RIGID GAS PERMEABLE CONTACT LENSES FOR DAILY WEAR WITH TANGIBLE™ HYDRA-PEG

Spherical, Aspheric, Bifocal and Toric contact lenses for:
Nearsightedness (myopia)
Farsightedness (hyperopia)

DESCRIPTION

Paragon Thin™ (paflufocon 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 Paragon Thin™ rigid gas permeable contact lens material is a thermoset copolymer derived from fluorosilicone acrylate monomers.

The Paragon Thin™ rigid gas permeable contact lenses may be treated to incorporate Tangible™ Hydra-PEG—which is a thin polyethylene glycol (PEG)-based polymer that is covalently bonded to the surface of the contact lens and is designed to enhance the surface properties of the contact lens while retaining the mechanical properties of the underlying material. When treated with Tangible™ Hydra-PEG, the underlying material is encapsulated in a thin layer of polymer that results in measurable improvement of wettability (sessile drop contact angle) compared to untreated lenses.

The Paragon Thin™ rigid gas permeable tinted lens offers a handling aid for locating the lens. These products may be plasma treated.

The lenses have the following attributes.

PARAGON Thin™ (paflufocon C)

Refractive Index	1.463 (n_d at 25° C)
Luminous Transmittance[+] (Clear)	99%
Luminous Transmittance (Sapphire Blue)	94%
Luminous Transmittance (Emerald Green)	95%
Wetting Angle (Receding Angle)[++]	12.8°
Wetting Angle (Contact Angle)[+++]	61°
Wetting Angle (with Tangible™ Hydra-PEG)	10°
Specific Gravity	1.15
Hardness (Shore D)	85
Water Content	< 1%
Oxygen Permeability*	23 x 10^{-11} Dk at 35° C

[+] Determination of the Spectral and Luminous Transmittance, ISO 8599
[++] Method adapted from article; A New Method for Wetting Angle Measurement; M. Madigan, B. Optom, B. Holden and D. Fong; 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
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

The Paragon Thin™ rigid gas permeable spherical, aspheric, bifocal and toric contact lenses are intended for daily wear only. When placed on the human cornea, the Paragon Thin™ 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 and near power prescriptions are provided in different areas of the lens.

INDICATIONS (USES)

Paragon Thin™ rigid gas permeable contact lenses with Tangible™ Hydra-PEG are indicated for daily wear as recommended by the eye care practitioner.

Paragon Thin™ rigid gas permeable spherical, aspheric and bifocal contact lenses with Tangible™ Hydra-PEG 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. Paragon Thin™ toric contact lenses are indicated to correct astigmatism of up to 6.00 diopters. Paragon Thin™ bifocal lenses are indicated to treat presbyopia up to +4.00 D add power.

In daily wear use only, Paragon Thin™ contact lenses with Tangible™ Hydra-PEG 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 (REASONS NOT TO USE)

The Paragon Thin™ 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).
- 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.

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 Paragon Thin™ 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 PARAGON Thin™ (paflufocon C) rigid gas permeable contact lens. Studies have not been performed to show that the Paragon Thin™ rigid gas permeable contact lens is safe to wear during sleep.

PARAGON HDS®
(paflufocon B)

RIGID GAS PERMEABLE CONTACT LENSES FOR DAILY WEAR WITH TANGIBLE™ HYDRA-PEG

Spherical, Aspheric, Bifocal and Toric contact lenses for:
Nearsightedness (myopia)
Farsightedness (hyperopia)

DESCRIPTION

Paragon HDS® (paflufocon 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 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 Paragon HDS® rigid gas permeable contact lens material is a thermoset copolymer derived from fluorosilicone acrylate monomers.

The Paragon HDS® rigid gas permeable contact lenses may be treated to incorporate Tangible™ Hydra-PEG—which is a thin polyethylene glycol (PEG)-based polymer that is covalently bonded to the surface of the contact lens and is designed to enhance the surface properties of the contact lens while retaining the mechanical properties of the underlying material. When treated with Tangible™ Hydra-PEG, the underlying material is encapsulated in a thin layer of polymer that results in measurable improvement of wettability (sessile drop contact angle) compared to untreated lenses.

The Paragon HDS® 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.

PARAGON HDS® (paflufocon B)

Refractive Index	1.449 (n_d at 25° C)
Luminous Transmittance+ (Crystal Blue)	98%
Luminous Transmittance (Violet)	97%
Luminous Transmittance (Sapphire Blue)	95%
Luminous Transmittance (Emerald Green)	95%
Luminous Transmittance (Forest Green)	90%
Wetting Angle (Receding Angle)++.....	14.7º
Wetting Angle (Contact Angle)+++	62°
Wetting Angle (with Tangible™ Hydra-PEG)	10°
Specific Gravity	1.16
Hardness (Shore D)	84
Water Content	< 1%
Oxygen Permeability*	40 x 10^{-11} Dk at 35º C

+Determination of the Spectral and Luminous Transmittance, ISO 8599
++ Method adapted from article; A New Method for Wetting Angle Measurement; M. Madigan, B. Optom, B. Holden and D. Fong; 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
Center Thickness	0.05 to 0.70 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 Paragon HDS® rigid gas permeable toric and bifocal contact lenses are intended for daily wear only.

When placed on the human cornea, the Paragon HDS® 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)

Paragon HDS® rigid gas permeable contact lenses with Tangible™ Hydra-PEG are indicated for daily wear as recommended by the eye care practitioner.

Paragon HDS® rigid gas permeable spherical, aspheric and bifocal contact lenses with Tangible™ Hydra-PEG 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. Paragon HDS® toric contact lenses are indicated to correct astigmatism of up to 6.00 diopters. Paragon HDS® bifocal lenses are indicated to treat presbyopia up to +4.00 D add power.
In daily wear use only, Paragon HDS® contact lenses with Tangible™ Hydra-PEG 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 (REASONS NOT TO USE)

The Paragon HDS® 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).
- 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.

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 Paragon HDS® 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 Paragon HDS® RIGID GAS PERMEABLE CONTACT LENS WITH TANGIBLE™ HYDRA-PEG. Studies have not been completed to show that the Paragon HDS® rigid gas permeable contact lens with Tangible™ Hydra-PEG 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.

PARAGON HDS® 100
(paflufocon D)

RIGID GAS PERMEABLE CONTACT LENSES FOR DAILY WEAR WITH TANGIBLE™ HYDRA-PEG

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

DESCRIPTION

Paragon HDS®100 (paflufocon D) rigid gas permeable contact lenses for daily 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 Paragon HDS®100 rigid gas permeable contact lens material is a thermoset copolymer derived from fluorosilicone acrylate monomers.

The Paragon HDS® 100 rigid gas permeable contact lenses may be treated to incorporate Tangible™ Hydra-PEG—which is a thin polyethylene glycol (PEG)-based polymer that is covalently bonded to the surface of the contact lens and is designed to enhance the surface properties of the contact lens while retaining the mechanical properties of the underlying material. When treated with Tangible™ Hydra-PEG, the underlying material is encapsulated in a thin layer of polymer that results in measurable improvement of wettability (sessile drop contact angle) compared to untreated lenses.

The Paragon HDS®100 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.

<u>PARAGON HDS® 100 (paflufocon D)</u>

Refractive Index	1.442 (n_d at 25° C)
Luminous Transmittance (Yellow)	99%
Luminous Transmittance (Emerald Green)	95%
Luminous Transmittance[+] (Sapphire Blue)	93%
Luminous Transmittance (Red)	89%
Wetting Angle (Receding Angle)[++]	42°
Wetting Angle (Contact Angle)[+++]	70°
Wetting Angle (with Tangible™ Hydra-PEG) [+++]	11°
Specific Gravity	1.10
Hardness (Shore D)	79
Water Content	<1%
Oxygen Permeability*	101 x 10^{-11} Dk at 35°C

[+] Determination of the Spectral and Luminous Transmittance, ISO 8599
[++] Method adapted from article; A New Method for Wetting Angle Measurement; M. Madigan, B. Optom, B. Holden and D. Fong; 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
Center Thickness	0.05 to 0.70 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 Paragon HDS®100 rigid gas permeable contact lenses are intended for daily wear.

When placed on the human cornea, the Paragon HDS®100 rigid gas permeable contact lens acts as a refracting medium to focus light rays upon the retina.

INDICATIONS (USES)

Paragon HDS®100 rigid gas permeable contact lenses with Tangible™ Hydra-PEG are indicated for daily wear as recommended by the eye care practitioner.

Paragon HDS®100 rigid gas permeable spherical, aspheric and bifocal contact lenses with Tangible™ Hydra-PEG 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. Paragon HDS®100 toric contact lenses are indicated to correct astigmatism of up to 6.00 diopters. Paragon HDS®100 bifocal lenses are indicated to treat presbyopia up to +4.00 D add power.
In daily wear use only, Paragon HDS® 100 contact lenses with Tangible™ Hydra-PEG 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 (REASONS NOT TO USE)

The Paragon HDS®100 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).
- 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.

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 Paragon HDS®100 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 Paragon HDS® 100 RIGID GAS PERMEABLE CONTACT LENS WITH TANGIBLE™ HYDRA-PEG. Studies have not been completed to show that the Paragon HDS® 100 rigid gas permeable contact lens with Tangible™ Hydra-PEG 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.

GENERAL INFORMATION

Convention: *Reference to Paragon HDS® rigid gas permeable contact lenses indicates all three materials – Paragon HDS® (paflufocon B), Paragon Thin™ (paflufocon C) and Paragon HDS®100 (paflufocon D).*

TINTS

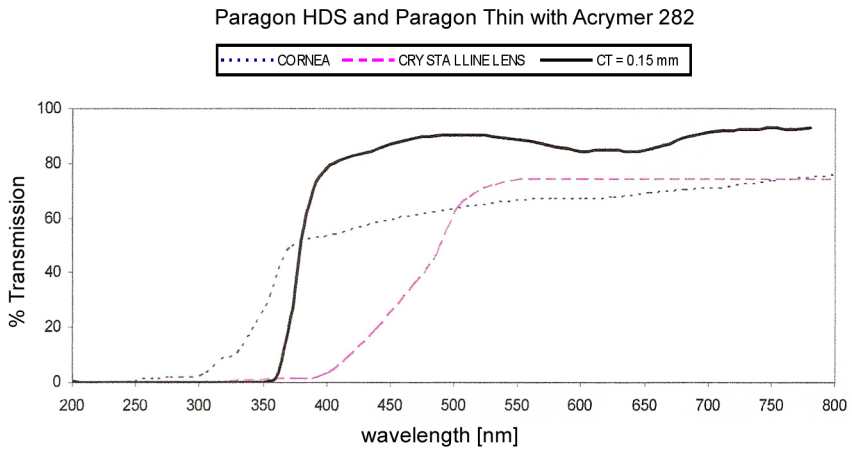
Paragon HDS® rigid gas permeable contact lenses are available in untinted (clear) and tinted (crystal blue, sapphire blue, emerald green, forest green, yellow and violet) versions with or without ultraviolet absorber. The tinted lenses contain one or more of the following color additives: D&D Green No. 6, D&C Yellow No. 10, D&C Violet No. 2, D&C Red No. 17, and Perox Yellow No. 9. (4-[(2,4-dimethylphenyl)azo]-2,4-dihydro-5-methyl-2-phenyl3H-pyrazol-3-one). NOTE: *Not all materials are available in all colors or with ultraviolet absorber.*

UV ABSORBER

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

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.



**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.

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 Paragon HDS® 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 Paragon HDS®, Paragon HDS® 100 or Paragon Thin™ lens is supplied nonsterile in an individual plastic case. The lens is 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%). 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 trade mark 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.

PRECAUTIONS - PATIENT

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

- Before you leave your eye care 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 PARAGON HDS® RIGID GAS PERMEABLE CONTACT LENSES WITH TANGIBLE™ HYDRA-PEG WHILE SLEEPING.
- Always wash your hands with an additive free soap, rinse thoroughly, and dry on a lint free towel before you handle your lenses. Eye irritation may result if cosmetics, lotions, soaps, creams and deodorants come in contact with your lenses and if the lenses are contaminated by infectious or non-infectious debris.
- Always follow the recommended lens care system for your Paragon HDS® 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. 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.
- 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 Paragon HDS® rigid gas permeable contact lens. For a description of fitting techniques, refer to the Fitting Guide for Paragon HDS® Rigid Gas Permeable Contact Lenses. Copies of which are available from:

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

LENS CARE DIRECTIONS

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

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

Paragon HDS® 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 Paragon HDS® 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.

Your eye care practitioner will recommend his/her preferred, FDA approved lens care solutions for the cleaning, disinfection, storage, and lubrication of your Paragon HDS® 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.

HOW SUPPLIED

Each Paragon HDS®, Paragon HDS®100 or Paragon Thin™ lens is supplied nonsterile in an individual plastic case. The lens is 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, dioptric power, diameter, center thickness, inclusion of UV absorber, lot number, fill date, and the color of the lens.

*Boston SIMPLUS® is a registered trade mark 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.

For information on material specifications contact:

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www.paragonvision.com