

# PMMA (polymethylmethacrylate)

## Rigid Spherical, Aspherical, Toric, Multifocal and Toric Multifocal Contact Lenses for Daily Wear

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

### DESCRIPTION

PMMA (polymethylmethacrylate) rigid contact lenses are lathe cut hard (hydrophobic) contact lenses available as spherical, aspherical, astigmatic (toric), multifocal, and toric multifocal lenses. The posterior curves are selected so as to properly fit an individual eye and the anterior curves are selected to provide the necessary optical power to correct refractive error. A peripheral curve system on the posterior surface of each lens allows tear exchange between the lens and the cornea.

The PMMA lens material is poly(methyl methacrylate) polymer which may contain one or more of the following color additives: Phthalocyanine Blue, Phthalocyanine Green, D&C Green 6, D&C Violet 2; D&C Red 17 and/or Solvent Yellow 18.

PMMA (polymethylmethacrylate) lenses are hemispherical shells of the following characteristics:

### LENS PARAMETERS AVAILABLE:

Diameter	6.5 to 11.5 mm
Center Thickness	0.05 to 0.70 mm
Base Curve	6.50 to 9.00 mm
Powers	-20.00 to +20.00 Diopters
Aspheric Eccentricity	0 to 1.5 (oblate to prolate)
Peripheral curves	0.1 to 10 mm flatter than base
Toric Lens Axis	1° to 180° in 1° steps
Toric Cylinder Power	up to -4.00 Diopters
Add Powers	up to +4.00 Diopters

### PHYSICAL PROPERTIES:

Refractive Index	1.490
Light Transmittance*	greater than 90% T
Wetting Angle (CLMA)	18°
Specific Gravity	1.195 g/cc
Hardness (Shore D)	>90
Water Content	<1%
Oxygen Permeability*	0.5 (D <sub>k</sub> at 35 °C)

\* 380 to 780 nm

\* (cm<sup>2</sup>/sec)/(mL O<sub>2</sub>) / (mL x mm Hg) Revised Method of I. Fatt

### ACTIONS

When placed on the human cornea the PMMA rigid spherical, aspherical, toric, multifocal, and toric multifocal contact lenses act as refractive media to focus light rays on upon the retina. The toric lens provides a more even surface over the highly uneven astigmatic cornea and thus helps to focus light rays on the retina.

### INDICATIONS (USES)

PMMA (polymethylmethacrylate) rigid spherical, aspherical, toric, multifocal, and toric multifocal contact lenses are indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia and astigmatism) in not-aphakic persons with non-diseased eyes. The lens may be disinfected using a chemical disinfection system only.

### CONTRAINDICATIONS (REASONS NOT TO USE)

The PMMA (polymethylmethacrylate) contact lens is contraindicated by the presence of any of the following conditions.

- Acute and subacute inflammations of the anterior segment of the eye.
- Any eye disease which affects the cornea or conjunctiva.
- Insufficiency of lacrimal secretion.
- Corneal hypesthesia (reduced corneal sensitivity).
- Any systematic 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 the wearing of contact lenses and/or contact lens solutions.
- Any active corneal infection (bacterial, fungal or viral).

• Allergy to any ingredient, such as mercury or thimerosal, in a solution that is used to care for the PMMA (polymethylmethacrylate) rigid contact lens.

• If eyes become red or irritated.

### WARNINGS

WARNINGS: Patients should be advised of the following warnings pertaining to contact lens wear.

• Problems with contact lenses and contact lens care products could result in serious injury to the eye. It is essential that patients follow their eye care practitioner's directions and all labeling instructions for proper use of lenses and lens care products, including the lens case. Eye problems, including corneal ulcers, can develop rapidly and lead to loss of vision.

• Daily wear lenses are not indicated for overnight wear, and patients should be instructed not to wear lenses while sleeping. Clinical studies have shown that the risk of serious adverse reactions is increased when these lenses are worn overnight.

• Studies have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than nonsmokers.

• If a patient experiences eye discomfort, excessive tearing, vision changes, or redness of the eye, the patient should be instructed to immediately remove lenses and promptly contact his or her eye care practitioner.

ALL CONTACT LENS WEARERS MUST RETURN FOR PERIODIC CHECK-UP VISITS AS RECOMMENDED BY THEIR EYE CARE PRACTITIONER.

### PRECAUTIONS

CAUTION: Non-sterile. Clean and condition lenses prior to use.

#### Special Precautions for Eyecare Practitioners:

• Due to the small number of patients enrolled in clinical investigations of lenses, all refractive powers, design configurations, or lens parameters available in the lens materials are not evaluated in significant numbers. Consequently, when selecting an appropriate lens design and parameters, the eyecare practitioner should consider all characteristics of the lens that can affect lens performance and ocular health, including oxygen permeability, wettability, central and peripheral thickness, and optic zone diameter.

• The potential impact of these factors on the patient's ocular health should be carefully weighed against the patient's need for refractive correction; therefore, the continuing ocular health of the patient and lens performance on the eye should be carefully monitored by the prescribing eyecare practitioner.

• Fluorescein, a yellow dye may be used in the fitting of PMMA (polymethylmethacrylate) rigid spherical, aspherical, toric, multifocal, and toric multifocal contact lenses and for the evaluation of corneal integrity.

Eyecare practitioners should carefully instruct patients about the following care regimen and safety precautions:

• Different solutions cannot always be used together and not all solutions are safe for use with all lenses. Use only recommended solutions.

\* Do not heat the wetting/soaking solution and lenses. Keep lenses away from extreme heat.

\* Always use fresh unexpired lens care solution.

\* Always follow directions in the package inserts for the use of contact lens solutions.

• Use only a chemical lens care system. Use of a heat (thermal) care system can damage by warping the PMMA (polymethylmethacrylate) rigid gas permeable spherical, aspherical, toric, multifocal, and toric multifocal contact lenses manufactured by Unilens.

\* Sterile unpreserved solutions, when used, should be discarded after the time specified in the labeling directions.

\* Do not use saliva or anything other than the recommended solutions for lubricating or wetting lenses.

\* Always keep the lenses completely immersed in a recommended storage solution when the lenses are not being worn (stored). Prolonged periods of drying will reduce the ability of the lens surface to return to a wettable state. Follow the lens care directions for Care for a Dried Out Lens if the lens surface does become dried out.

• If the lens sticks (stops moving) on the eye, follow the recommended directions on "Care For a Sticking Lens". The lens should move freely on the eye for the continued health of the eye. If non-movement of the lens continues, the patient should be instructed to immediately consult his or her eye care practitioner.

• Always wash and rinse hands before handling lenses. Do not get cosmetics, lotions, soaps, creams and deodorants in the eyes or on the lenses. It is best to put on lenses before putting on makeup. Water-base cosmetics are less likely to damage lenses than oil-base products.

• Do not touch contact lenses with the fingers or hands if the hands are not free of foreign materials, as microscopic scratches of the lenses may occur, causing distorted vision and/or injury to the eye.

• Carefully follow the handling, insertion, removal, cleaning, disinfecting, storing and wearing instructions in the Patient Instructions for PMMA (polymethylmethacrylate) rigid spherical, aspherical, toric, multifocal, and toric multifocal contact lenses and those prescribed by the eyecare practitioner.

• Never wear lenses beyond the period recommended by the eyecare practitioner.

• If aerosol products such as hair spray are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.

• Always handle lenses carefully and avoid dropping them.

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

• Ask the eyecare practitioner about wearing lenses during sporting events.

• Inform the doctor (health care practitioner) about being a contact lens wearer.

• Never use tweezers or other tools to remove your lenses from the lens container unless specifically indicated for that use. Pour the lens into the hand.

• Do not touch the lens with fingernails.

• 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 use of eye protection equipment or may require that the patient not wear contact lenses.

• As with any contact lens, follow-up visits are necessary to assure continuing health of the patient's eyes. The patient should be instructed as to a recommended follow-up schedule.

### ADVERSE REACTIONS

The patient should be informed that the following problems may occur:

- Eyes sting, burn, itch (irritation) or other eye pain.
- Comfort is less than when lens was first placed on the eye.
- Feeling of something in the eye (foreign body, scratched area).
- Excessive watering (tearing) of the eye.
- 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 the patient notices any of the above, he or she should be instructed to:

- IMMEDIATELY REMOVE 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 the eye. Place the lens in the storage case and contact the 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 lens with recommended solutions, and then reinsert it.
- After reinsertion, if the problem continues, the patient should IMMEDIATELY remove the lens and consult the eye care practitioner.

When any of the above symptoms or problems occur, a serious condition such as infection, corneal ulcer, neovascularization, or iritis may be present. The patient should be instructed to keep the lens off the eye and seek immediate professional identification of the problem and prompt treatment to avoid serious eye damage.

#### FITTING

Conventional methods of fitting rigid contact lenses apply to the PMMA (polymethylmethacrylate) contact lens.

#### WEARING SCHEDULE

The PMMA (polymethylmethacrylate) rigid spherical, aspherical, toric, multifocal, and toric multifocal contact lenses are indicated for daily wear. The maximum suggested wearing time for the lenses is:

DAILY WEAR (less than 24 hours while awake)

Day	Hours	Day	Hours
1	5	5	9
2	6	6	10
3	7	7	15
4	8	8+	all waking hours

Studies have not been completed to show that PMMA (polymethylmethacrylate) lenses are safe to wear during sleep.

The wearing and replacement schedule should be determined by the eyecare practitioner. Patients tend to overwear their lenses initially. The eyecare practitioner should emphasize the importance of adhering to the initial maximum wearing schedule. Regular check-ups, as determined by the eye care practitioner, are also extremely important.

#### LENS CARE DIRECTIONS: (LENS HANDLING)

CAUTION: Non-sterile. Clean and condition lenses prior to use.

Eyecare practitioners should review with the patient lens care directions, including both basic lens care information and specific instructions on the lens care regimen recommended for the patient.

General Lens Care (To First Clean and Rinse, then Disinfect Lenses) Basic Instructions

- Always wash and rinse your hands before handling contact lenses.
- Always use fresh unexpired lens care solutions
- Use only a chemical system recommended for PMMA (polymethylmethacrylate) lenses for lens care. Different solutions cannot always be used together, and not all solutions are safe for all lenses. Do not alternate or mix lens care systems unless indicated on the solution labeling.
- Do not use saliva or anything other than the recommended solutions for lubricating or rewetting lenses. Do not put lenses in the mouth.
- Your lenses should be cleaned, rinsed and disinfected each time you remove them. CLEANING and RINSING are necessary to remove mucus and film from the lens surface. DISINFECTING is necessary to prevent growth of harmful germs.
- Always remove, clean, rinse, enzyme (as recommended by the eyecare practitioner) and disinfect lenses according to the schedule prescribed by the eyecare practitioner. The use of an enzyme or any cleaning solution does not substitute for disinfection.
- The following solutions are recommended for use with your PMMA (polymethylmethacrylate) contact lenses. Your eye care practitioner may recommend alternative lens care products that are appropriate for the patient's use with his or her lenses.

#### Contact Lens Care System

SYSTEM PROCESS	CHEMICAL (not heat) DISINFECTION SYSTEM
Cleaning	Unique-pH™ Multi-Purpose Solution, SupraClens®, Opti-Clean® II, Opti-Zyme®, Barnes-Hind® GP Daily Cleaner, LC-65®, Pro-Free/GP®, Lobob Optimum Extra Strength Cleaner
Rinsing	Preserved/Non-preserved Saline
Disinfection and Storage	Unique-pH™ Multi-Purpose Solution, Lobob Optimum Cleaning, Disinfecting and Storage Solution
Lubrication	Clerz® Plus, Opti-Tears®, Refresh Contacts™, Wet-N-Soak® Rewetting Drops, Lobob Wetting and Rewetting Drops
Enzyme	ProFree Enzymatic Cleaner

PRODUCT LIST: Unique-pH™ Multi-Purpose Solution, SupraClens®, Clerz® Plus, Opti-Clean® II, Opti-Zyme®, Opti-Tears® by Alcon Laboratories, Inc.; Barnes-Hind® GP Daily Cleaner, LC-65®, ProFree/GP®, n, Wet-N-Soak® Plus, Wet-N-Soak® Rewetting Drops by Allergan Pharmaceuticals

- Note: Some solutions may have more than one function, which will be indicated on the label. Read the label on the solution bottle, and follow instructions.
- Clean one lens first (always the same lens first to avoid mix-ups), rinse the lens thoroughly with recommended saline, tap water or disinfecting solution to remove the cleaning solution, mucus, and film from the lens surface, and put that lens into the correct chamber of the lens storage case. Then repeat the procedure for the second lens.
- After cleaning and rinsing, disinfect lenses using the system recommended by the manufacturer and/or eyecare practitioner.
- To store lenses, disinfect and leave them in the closed/unopened case until ready to wear. If the lenses are not to be used immediately following disinfection, the patient should be instructed to consult the package insert or the eyecare practitioner for information on storage of lenses.
- After removing the lenses from the lens case, empty and rinse the lens storage case with solution as recommended by the lens case manufacturer; then allow the case to air dry. When the case is used again, refill it with storage solution. Replace lens case at regular intervals as recommended by the lens case manufacturer or your eyecare practitioner.
- Eyecare practitioners may recommend a lubricating/rewetting solution which can be used to wet (lubricate) lenses while they are being worn to make them more comfortable.
- PMMA (polymethylmethacrylate) contact lenses cannot be heat (thermally) disinfected.

#### Chemical (Not Heat) Disinfection:

- Clean the contact lenses with a recommended cleaning solution and thoroughly rinse them with a recommended rinsing solution.
- After cleaning and rinsing, to disinfect, carefully follow the instructions accompanying the disinfecting solution in the care regimen recommended by the eyecare practitioner.
- When using hydrogen peroxide lens care systems (for office sterilization only), lenses must be neutralized before wearing. Follow the recommendations on the hydrogen peroxide system labeling.
- Thoroughly rinse lenses with a fresh solution recommended for rinsing before inserting and wearing, or follow the instructions on the disinfection solution labeling.
- Do not heat the disinfection solution and lenses.
- Leave the lenses in the unopened storage case until ready to put on the eye.

#### Lens Deposits and Use of Enzymatics Cleaning Procedure

Enzyme cleaning may be recommended by the eyecare practitioner. Enzyme cleaning removes protein deposits on the lens. These deposits cannot be removed with regular

cleaners. Removing protein deposits is important for the well-being of the patient's lenses and eyes. If these deposits are not removed, they can damage the lens and cause irritation.

Enzyme cleaning does NOT replace routine cleaning and disinfecting. For enzyme cleaning, the patient should carefully follow the instructions in the enzymatic cleaning labeling.

#### LENS CASE CLEANING AND MAINTENANCE:

Contact lens cases can be a source of bacterial growth. Lens cases should be emptied, cleaned, rinsed with solutions recommended by the lens case manufacturer, and allowed to air dry. Lens cases should be replaced at regular intervals as recommended by the lens case manufacturer or your eyecare practitioner.

#### CARE FOR A STICKING LENS

If the lens sticks (stops moving) on the eye, apply 2-3 drops of the recommended sterile rewetting or lubricating solution. Wait until the lens begins to move freely on the eye before removing it. If non-movement of the lens continues, immediately consult your eye care practitioner.

#### EMERGENCIES:

If chemicals of any kind (household products, gardening solutions, laboratory chemicals, etc.) are splashed onto the eyes, the patient should: FLUSH EYES IMMEDIATELY WITH TAP WATER and IMMEDIATELY CONTACT THE EYECARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.

#### HOW SUPPLIED

Each lens is supplied non-sterile in an individual plastic case. The case is marked with the base curve, dioptic power, diameter and lot number of the lens.

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

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