

Instruction For Use

IGEL

CUSTOM MADE RGP & HARD CONTACT LENS

1	GP NORMAL DESIGN
2	GP BITORIC
3	ELENS
4	ELENS PRO
5	EE CONUS
6	ESEE LENS
7	CE PRECISION

PATIENT PRODUCT INSTRUCTIONS FOR USE & SAFETY INFORMATION

PLEASE READ THE FOLLOWING INFORMATION CAREFULLY AND KEEP IT FOR REFERENCE.

DECLARATION

1	GP NORMAL DESIGN is manufactured in an ISO 13485 certified facility. This medical device is manufactured under strict GMP conditions and guarantees our customers total quality.
2	GP BITORIC is manufactured in an ISO 13485 certified facility. This medical device is manufactured under strict GMP conditions and guarantees our customers total quality.
3	ELENS is manufactured in an ISO 13485 certified facility. This medical device is manufactured under strict GMP conditions and guarantees our customers total quality.
4	ELENS PRO is manufactured in an ISO 13485 certified facility. This medical device is manufactured under strict GMP conditions and guarantees our customers total quality.
5	EE CONUS is manufactured in an ISO 13485 certified facility. This medical device is manufactured under strict GMP conditions and guarantees our customers total quality.
6	ESEE LENS is manufactured in an ISO 13485 certified facility. This medical device is manufactured under strict GMP conditions and guarantees our customers total quality.
7	CE PRECISION is manufactured in an ISO 13485 certified facility. This medical device is manufactured under strict GMP conditions and guarantees our customers total quality.

PRODUCT DESCRIPTION

1	GP NORMAL DESIGN is a gas permeable or hard contact lens for daily wear (Material: Refer to Material Description). Base Curve: 7.00 mm – 8.30 mm, Diameter: 8.50 mm – 10.00 mm, Spherical Power: +22.00D to -22.00D
2	GP BITORIC is a gas permeable or hard contact lens for daily wear (Material: Refer to Material Description). Base Curve: 7.00 mm – 8.30 mm, Diameter: 8.50 mm – 10.00 mm, Spherical Power: +22.00D to -22.00D, Cylinder Power: +8.00D to -8.00D
3	ELENS is a gas permeable or hard contact lens for daily wear (Material: Boston XO, Boston XO2). Flat K: 40.00D – 44.00D, Diameter: 10.20 mm & 10.60 mm, Spherical Power: -1.00D to -4.75D
4	ELENS PRO is a gas permeable or hard contact lens for daily wear (Material: Boston XO, Boston XO2). Flat K: 40.00D – 44.00D, Diameter: 10.20 mm – 10.60 mm, Spherical Power: -5.00D to -8.00D
5	EE CONUS is a gas permeable or hard contact lens for daily wear (Material: Refer to Material Description). Base Curve: 5.50 mm – 7.50 mm, Diameter: 8.00 mm – 9.60 mm, Spherical Power: +22.00D to -22.00D
6	ESEE LENS is a gas permeable or hard contact lens for daily wear (Material: Boston XO). Base Curve: 5.50 mm – 7.50 mm, Diameter: 14.40 mm, Spherical Power: +22.00D to -22.00D
7	CE PRECISION is a gas permeable or hard contact lens for daily wear (Material: Refer to Material Description). Base Curve: 7.00 mm – 8.30 mm, Diameter: 8.50 mm – 10.00 mm, Spherical Power: +22.00D to -22.00D, Add Power: +1.50D to +2.50D

MATERIAL DESCRIPTION

Boston ES	Boston EO	Boston XO
Boston XO2	Paragon FP30	Paragon FP60
Paragon FP92	Paragon FP151	Paragon HDS
Paragon HDS100	Paragon THIN	PMMA

INDICATIONS

1	GP NORMAL DESIGN is a gas permeable or hard contact lens that is meant for daily wear use for the correction of visual acuity (myopia, hyperopia, astigmatism and presbyopia) in aphakic or non-aphakic persons with non-diseased eyes. Also, the lens may be prescribed in otherwise non-diseased eyes that require a gas permeable contact lens for the management of irregular cornea conditions such as keratoconus, pellucid marginal degeneration or following penetrating keratoplasty or refractive (e.g. LASIK) surgery.
2	GP BITORIC is a gas permeable or hard contact lens that is meant for daily wear use for the correction of visual acuity (myopia, hyperopia, astigmatism and presbyopia) in aphakic or non-aphakic persons with non-diseased eyes. Also, the lens may be prescribed in otherwise non-diseased eyes that require a gas permeable contact lens for the management of irregular cornea conditions such as keratoconus, pellucid marginal degeneration or following penetrating keratoplasty or refractive (e.g. LASIK) surgery.
3	ELENS is a gas permeable or hard contact lens that is meant for daily wear use for the correction of visual acuity (myopia, hyperopia, astigmatism and presbyopia) in aphakic or non-aphakic persons with non-diseased eyes. Also, the lens may be prescribed in otherwise non-diseased eyes that require a gas permeable contact lens for the management of irregular cornea conditions such as keratoconus, pellucid marginal degeneration or following penetrating keratoplasty or refractive (e.g. LASIK) surgery.
4	ELENS PRO is a gas permeable or hard contact lens that is meant for daily wear use for the correction of visual acuity (myopia, hyperopia, astigmatism and presbyopia) in aphakic or non-aphakic persons with non-diseased eyes. Also, the lens may be prescribed in otherwise non-diseased eyes that require a gas permeable contact lens for the management of irregular cornea conditions such as keratoconus, pellucid marginal degeneration or following penetrating keratoplasty or refractive (e.g. LASIK) surgery.
5	EE CONUS is a gas permeable or hard contact lens that is meant for daily wear use for the correction of visual acuity (myopia, hyperopia, astigmatism and presbyopia) in aphakic or non-aphakic persons with non-diseased eyes. Also, the lens may be prescribed in otherwise non-diseased eyes that require a gas permeable contact lens for the management of irregular cornea conditions such as keratoconus, pellucid marginal degeneration or following penetrating keratoplasty or refractive (e.g. LASIK) surgery.
6	ESEE LENS is a gas permeable or hard contact lens that is meant for daily wear use for the correction of visual acuity (myopia, hyperopia, astigmatism and presbyopia) in aphakic or non-aphakic persons with non-diseased eyes. Also, the lens may be prescribed in otherwise non-diseased eyes that require a gas permeable contact lens for the management of irregular cornea conditions such as keratoconus, pellucid marginal degeneration or following penetrating keratoplasty or refractive (e.g. LASIK) surgery.
7	CE PRECISION is a gas permeable or hard contact lens that is meant for daily wear use for the correction of visual acuity (myopia, hyperopia, astigmatism and presbyopia) in aphakic or non-aphakic persons with non-diseased eyes. Also, the lens may be prescribed in otherwise non-diseased eyes that require a gas permeable contact lens for the management of irregular cornea conditions such as keratoconus, pellucid marginal degeneration or following penetrating keratoplasty or refractive (e.g. LASIK) surgery.

INTRODUCTION

All the above contact lenses are intended for daily wear, single patient use, or as recommended by your eye care practitioner. Each contact lens is supplied in a sealed container and no special storage conditions are required before opening. However, normal room temperature storage is recommended to maintain the overall condition of the lenses.

CONTRAINDICATIONS

	DO NOT USE the contact lenses when any of the following conditions (as below) exists:
a	Acute and sub-acute inflammation or infection of the anterior chamber of the eye
b	Any eye disease, injury or abnormality that affects the cornea, conjunctiva or eyelids
c	Severe insufficiency of lacrimal secretion (dry eyes syndrome)
d	Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses
e	Allergic reactions of ocular surfaces
f	Any active corneal infection (bacterial, fungal, protozoal or viral)
g	If eyes become red or irritated

CAUTION

To be dispensed and sold by a **qualified and licensed eye-care practitioner** only.

WARNINGS

DO

1	Use recommended soft contact lens care products and follow the manufacturers' instructions for use.
2	Remove lenses and seek advice if any of the following occur: pain, red eyes, blur vision, excessive tears and sensitivity to light.
3	Visit your eye care practitioner regularly for check-ups.

DON'T

1	Do not use any unusual fluids with your lenses or lens case e.g. tap water, mineral water and solutions formulated for lenses other than soft contact lenses.
2	Do not neglect hygiene for lenses and storage cases. (Poor hygiene during use and care of lenses introduce the risk of eye infections)
3	Do not swim with contact lenses unless watertight goggles are worn.
4	Do not use any new eye care products without consulting your eye care practitioner or doctor.
5	Do not expose the lenses to hairsprays, cosmetics, eye drops and aerosol sprays.
6	Do not wear lenses during sleep (unless otherwise advised by eye care practitioner).
7	Do not use saliva to wet your lenses. It is teeming with potentially harmful bacteria. (It is not true, that your own bacteria are safe)
8	Do not wear lenses in the presence of noxious or irritating fumes.

PRECAUTIONS

1	Some medical conditions may affect the ability to wear lenses successfully.
2	Lenses can be associated with clinical conditions e.g. corneal anoxia, allergic response, trauma and bacterial infection.
3	Keep lenses and lens care products out of reach of children.
4	If the lenses dry out, put them in the case with some storage solution and leave them for 1 to 2 hours. Clean, disinfect and check them carefully for damage.
5	Do wear make-up if you wish, but insert lenses first. Remove lenses before removing make-up.
6	If the lens sticks (stop moving), the patient should be instructed to apply a few drops of the recommended lubricating or rewetting solution directly to the eye and wait until the lens begins to move freely on the eye before removing it. If non movement of the lens continues, the patient should immediately consult the eye care practitioner.
7	Eyecare professionals should instruct the patient to remove lenses immediately if the eyes become red or irritated.

SPECIAL NOTE

IN AN EMERGENCY SITUATION OR IF YOU ARE IN DOUBT WITH THE INFORMATION ON THIS LEAFLET, PLEASE CONSULT YOUR EYE CARE PRACTITIONER OR EYE DOCTOR FOR ADDITIONAL ADVICE.

FITTING GUIDELINES

PREPARATION

1	Always wash and dry your hands before handling lenses so as not to contaminate them.
INSERTION	
1	Remove lens from case with finger and place on fingertip and ensure lens is in good order.
2	Rinse the lens with Igel Conditioning & Cleaning Multipurpose Disinfecting Solution.
3	Rub several drops of the solution over the lens surface.
4	Place the lens on the top of the index finger of your hand. Place the middle finger of the same hand close to the lower eye lash and hold down the lower eyelid.
5	Use the forefinger or middle finger of your other hand to lift the upper eyelid and then place the lens on the eye. It is not necessary to press the lens against the eye. (Figure 1)
6	Gently release the lid and blink. The lens will center automatically. Always verify its proper position by checking your vision immediately after insertion.
7	If your vision is blurred after placement of the lens, it could be due to the lens is not centered. If the lens is centered and yet blurred vision exists, lens need to be removed and check whether if there are presence of dirt, cosmetic or oil on the lens. If yes, then the lens needs to be cleaned, rinsed, disinfected and place on the eye again. Or the blur vision is due to lens on the wrong eye. If none of the above reasons exist, then remove the lens and consult the eyecare practitioner.
8	IF DISCOMFORT – remove lens immediately and seek advice from your eye care practitioner.


9	 <p style="text-align: center;">Figure 1 Lens Insertion</p>
10	Repeat same procedure with the other lens.
11	There are other methods of lens placement. Please consult eyecare practitioner for alternative method.
LENS REMOVAL	
1	Before removing the lenses, it is recommended to have the following items available: 1. RGP lens case, 2. Lens care solution, 3. Clean towel
2	Always remove the same lens first.
3	Always wash, rinse and dry hands thoroughly.
4	There are two common methods for lens removal.
BLINKING METHOD	
5	Place the middle finger in the outer corner of the eyelid.
6	Look straight ahead. Gently but firmly pull straight back, pulling the edges of your eyelid tightly against your eye.
7	Blink hard and the lens will pop out. Catch the lens with one of the hand, or let it fall onto a flat surface covered with a clean towel
FINGER METHOD	
8	Place a towel under your eyes to catch your lens.
9	Place the tip of forefinger of one hand on the middle of the upper eyelid margin and the forefinger of the other hand on the middle of the lower eyelid margin.
10	Press the eyelid margin inward and then together. The lens should be wedged out of your eye onto the hand or towel.
11	Lens may come out but remain on the eyelid or hand or be decentered onto the white part of the eye. If the latter occurs, recenter the lens onto your cornea before repeating the removal procedure.
12	Repeat same procedure with the other lens.
LENS SUCTION HOLDER METHOD	
13	Another method of lens removal by using the RGP suction holder.
14	This makes it much easier to remove the lenses but please remember to carry it along, whereas for blink method, one will always have their fingers around.
15	Moisten the cup of the RGP suction holder with Igel conditioning solution and gently touch it squarely on the contact lens . The contact lens will adhere to the soft suction cup and will come off the eye easily. After the lens is removed from the eye, gently slide it from the suction cup .
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Figure 3 Lens removal by suction holder

- 17 There are also other methods of lens removal. Please consult eyecare practitioner for alternative method.

WEARING SCHEDULE

- 1 The eyecare practitioner should determine the wearing and replacement schedule.
- 2 Patients tend to over-wear the lenses initially. It is important not to exceed the initial wearing schedule.
- 3 Regular check-ups, as determined by the eyecare practitioner, are extremely important.
- 4 The eye care practitioner is encouraged to determine an appropriate lens wearing schedule based upon the response of the patient.
- 5 IGEL custom-made RGP & Hard contact lenses are indicated for daily wear. The maximum suggested wearing schedule for IGEL custom-made RGP & Hard contact lenses is as follows:

Days	Continuous Hours
1	4
2	6
3	8
4	10
5	12
6	All waking hours
7	All waking hours

LENS CARE DIRECTIONS

- a Use the lens care system recommended by eyecare practitioner. Always rinse your hands before handling contact lenses.

BASIC INSTRUCTIONS

- b Care of custom-made RGP & hard contact lenses is necessary and involves **THREE** essential steps – **CLEANING, RINSING AND DISINFECTING**. Each step on itself is important, and one step is not to be replaced by the other. Always wash, rinse and dry hands before handling contact lenses. Always use **FRESH, STERILE, UNEXPIRED** lens care solutions. Use the recommended lens care system, either chemical (no heat) or heat (thermal). Different solutions cannot always be used together, and not all solutions are safe for use, with all lenses. **DO NOT ALTERNATE OR**

MIX LENS CARE SYSTEMS UNLESS INDICATED ON SOLUTION LABELING. Do not use saliva or anything other than the recommended solutions for lubricating or rewetting lenses. Do not put lenses in your mouth. Lenses should be **cleaned, rinsed and disinfected** each time they are removed. Cleaning and rinsing are necessary to remove mucus and film from the lens surface. Disinfecting is necessary to destroy harmful germs. The lens case must be emptied and refilled with fresh, sterile recommended storage and disinfecting solution prior to disinfecting the lens. Eyecare practitioners may recommend a lubricating / rewetting solution, which can be used to wet (lubricate) the lenses while they are being worn to make them more comfortable.

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.

LENS CLEANING, DISINFECTION AND STORAGE

c **Clean** one lens first (always the same lens first to avoid mix-ups), **rinse** the lens thoroughly with recommended rinsing or disinfecting solution to remove the cleaning solutions, mucus, and film from the lens surface, and put lens into correct chamber of the lens storage case. Then repeat the procedure for the second lens. After cleaning, **disinfect** lens using the system recommended by the manufacturer and/or the eyecare practitioner. To store lenses, disinfect and leave them in the close/unopened case until ready to wear. Lenses must be stored fully submerged in a clean lens case using fresh solutions every day. If lenses are not to be used immediately following disinfection or the lenses are only worn occasionally, the patient should be instructed to consult the package insert or the eyecare practitioner for information on storage of the lenses.

LENS CASE CLEANING AND MAINTENANCE

d Contact lens cases be a source of bacteria growth. After removing the lens from the case, empty and rinse the lens storage case with solution as recommended by the lens case manufacturer; then allow the lens 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 eyecare practitioner.

LENS CARE REGIMEN

e Patients must adhere to the lens care regimen recommended by eyecare practitioner for the custom-made soft contact lenses. Failure to follow this procedure may result in development of serious ocular infections.

CARE FOR A STICKING (NON-MOVING) LENS

F If the lens sticks (cannot be removed), the patient should be instructed to apply 3 to 4 drops of the recommended lubricating or rewetting solution directly to the eye and wait until the lens begins to move freely on the eye before removing it. If non-movement of the lens continues after 15 minutes, the patient should **IMMEDIATELY** consult eyecare practitioner.

STORAGE

G Custom made soft contact lenses must be stored only in recommended solutions. If left exposed to the air, the lens will dehydrate. If lens dehydrate, reference above section on caring for dried out (dehydrated) dry lenses.

LENS DEPOSIT AND USE OF ENZYMATIC CLEANER

h	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 lenses and cause irritation. Enzymatic cleaning does NOT replace daily cleaning and disinfecting. For enzyme cleaning, the patient should carefully follow the instructions on the enzymatic cleaning label.
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RECOMMENDED LENS CARE PRODUCTS

Each lens care product contains specific directions for use and important safety information, which should be read and carefully followed. The table below are some recommended solutions that can be used for cleaning and disinfecting custom made soft contact lenses.

Conditioning & Cleaning Disinfecting Solution
Igel Conditioning & Cleaning Multipurpose Disinfecting Solution
Lens Lubricant/Rewetting Drops
Igel Refreshing Drops
Igel Comfort Drops

HOW SUPPLIED

Each custom-made RGP & Hard contact lens is supplied non-sterile in an individual plastic case. The lens is shipped dry. The plastic case is marked with base curve radius, dioptric power, diameter, material, Lot number and color of lens.

IN CASE OF COMPLAINT

Please contact your eye-care practitioner with details of your concern. Give details of batch references to assist with prompt processing of concerns.






CONTACT LENS PATIENTS SHOULD FOLLOW INSTRUCTIONS GIVEN BY THEIR EYE CARE PRACTITIONER STRICTLY AND DISCARD THEIR CONTACT LENSES AFTER THE WEARING PERIOD (MODALITY) AS PRESCRIBED BY THE EYE CARE PRACTITIONER.

PRODUCT OWNER

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	<p>Manufacturer Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.</p>
	<p>Batch Code or Lot Number Indicates the manufacturer's batch code so that the batch or lot can be identified.</p>
	<p>Caution (See product information) Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself</p>
	<p>Non-Sterile Indicates a medical device that has not been subjected to a sterilization process.</p>
	<p>Prescription Device Indicates that the product is a medical device as defined in Malaysian Medical Device Act 737 and Medical Device Regulations 2012 restricts this device to sale by or on the order of a licensed eyecare practitioner.</p>