

Instruction For Use

IGEL

CUSTOM MADE SOFT CONTACT LENS

1	IGEL CD 38
2	IGEL CD 49
3	IGEL CD 55
4	IGEL CD 59
5	IGEL NUTORIC 38
6	IGEL NUTORIC 49
7	IGEL CD APHAKIC
8	IGEL CD APHAKIC RX
9	IGEL CD BIFOCAL
10	IGEL CD CHROMAX RED
11	IGEL CD CHROMAX GREEN
12	IGEL CD 38 PROSTHETIC

PATIENT PRODUCT INSTRUCTIONS FOR USE & SAFETY INFORMATION

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

DECLARATION

1	IGEL CD38 is manufactured in an ISO 13485 certified facility. This medical device is manufactured under strict GMP conditions and guarantees our customers total quality.
2	IGEL CD 49 is manufactured in an ISO 13485 certified facility. This medical device is manufactured under strict GMP conditions and guarantees our customers total quality.
3	IGEL CD 55 is manufactured in an ISO 13485 certified facility. This medical device is manufactured under strict GMP conditions and guarantees our customers total quality.
4	IGEL CD 59 is manufactured in an ISO 13485 certified facility. This medical device is manufactured under strict GMP conditions and guarantees our customers total quality.
5	IGEL NUTORIC 38 is manufactured in an ISO 13485 certified facility. This medical device is manufactured under strict GMP conditions and guarantees our customers total quality.
6	IGEL NUTORIC 49 is manufactured in an ISO 13485 certified facility. This medical device is manufactured under strict GMP conditions and guarantees our customers total quality.
7	IGEL CD APHAKIC is manufactured in an ISO 13485 certified facility. This medical device is manufactured under strict GMP conditions and guarantees our customers total quality.
8	IGEL CD APHAKIC RX is manufactured in an ISO 13485 certified facility. This medical device is manufactured under strict GMP conditions and guarantees our customers total quality.
9	IGEL CD BIFOCAL is manufactured in an ISO 13485 certified facility. This medical device is manufactured under strict GMP conditions and guarantees our customers total quality.
10	IGEL CD CHROMAX RED is manufactured in an ISO 13485 certified facility. This medical device is manufactured under strict GMP conditions and guarantees our customers total quality.
11	IGEL CD CHROMAX GREEN is manufactured in an ISO 13485 certified facility. This medical device is manufactured under strict GMP conditions and guarantees our customers total quality.
12	IGEL CD38 PROSTHETIC 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	IGEL CD 38 is a sterile soft hydrophilic contact lens for daily wear (material: 62% Polymacon, 38% Water) immersed in buffered saline solution. Base Curve: 8.00 mm – 9.00 mm, Centre Thickness: 0.09 mm, Diameter: 13.00 mm – 15.00 mm, Spherical Power: +22.00D to -22.00D
2	IGEL CD 49 is a sterile soft hydrophilic contact lens for daily wear (material: 51% Hioxifilcon B, 49% Water) immersed in buffered saline solution. Base Curve: 8.00 mm – 9.00 mm, Centre Thickness: 0.13 mm, Diameter: 13.00 mm – 15.00 mm, Spherical Power: +22.00D to -22.00D
3	IGEL CD 55 is a sterile soft hydrophilic contact lens for daily wear (material: 45% Polymacon, 55% Water) immersed in buffered saline solution. Base Curve: 8.00 mm – 9.00 mm, Centre Thickness: 0.09 mm, Diameter: 13.50 mm – 14.50 mm, Spherical Power: +22.00D to -22.00D
4	IGEL CD 59 is a sterile soft hydrophilic contact lens for daily wear (material: 41% Hioxifilcon B, 59% Water) immersed in buffered saline solution. Base Curve: 8.00 mm – 9.00 mm, Centre Thickness: 0.13 mm, Diameter: 13.50 mm – 14.50 mm, Spherical Power: +22.00D to -22.00D
5	IGEL NUTORIC 38 is a sterile soft hydrophilic contact lens for daily wear (material: 62% Polymacon, 38% Water) immersed in buffered saline solution. Base Curve: 8.00 mm – 9.00 mm,

	Centre Thickness: 0.09 mm, Diameter: 13.00 mm – 15.00 mm, Spherical Power: +22.00D to -22.00D, Cylinder Power: 0.00D to -6.00D, Axis: 0° to 180°
6	IGEL NUTORIC 49 is a sterile soft hydrophilic contact lens for daily wear (material: 51% Hioxifilcon B, 49% Water) immersed in buffered saline solution. Base Curve: 8.00 mm – 9.00 mm, Centre Thickness: 0.09 mm, Diameter: 13.00 mm – 15.00 mm, Spherical Power: +22.00D to -22.00D, Cylinder Power: 0.00D to -6.00D, Axis: 0° to 180°
7	IGEL CD APHAKIC is a sterile soft hydrophilic contact lens for daily wear (material: 62% Polymacon, 38% Water) immersed in buffered saline solution. Base Curve: 7.50 mm – 8.30 mm, Diameter: 11.50 mm – 13.50 mm, Spherical Power: +10.00D to +35.00D
8	IGEL CD APHAKIC RX is a sterile soft hydrophilic contact lens for daily wear (material: 62% Polymacon, 38% Water) immersed in buffered saline solution. Base Curve: 7.50 mm – 8.30 mm, Diameter: 11.50 mm – 13.50 mm, Spherical Power: +10.00D to +35.00D
9	IGEL CD BIFOCAL is a sterile soft hydrophilic contact lens for daily wear (material: 62% Polymacon, 38% Water) immersed in buffered saline solution. Base Curve: 8.60 mm, Centre Thickness: 0.09 mm, Diameter: 14.20 mm, Spherical Power: -1.00D to -12.00D, Add Power: +1.00D to +2.50D
10	IGEL CD CHROMAX RED is a sterile soft hydrophilic contact lens for daily wear (material: 62% Polymacon, 38% Water) immersed in buffered saline solution. Base Curve: 8.60 mm, Centre Thickness: 0.09 mm, Diameter: 14.00 mm, Spherical Power: -0.00D, Iris / Pupil Color: Red, Iris / Pupil Size: 7.00 mm
11	IGEL CD CHROMAX GREEN is a sterile soft hydrophilic contact lens for daily wear (material: 62% Polymacon, 38% Water) immersed in buffered saline solution. Base Curve: 8.60 mm, Centre Thickness: 0.09 mm, Diameter: 14.00 mm, Spherical Power: -0.00D, Iris / Pupil Color: Green, Iris / Pupil Size: 7.00 mm
12	IGEL CD PROSTHETIC is a sterile soft hydrophilic contact lens for daily wear (material: 62% Polymacon, 38% Water) immersed in buffered saline solution. Base Curve: 8.60 mm, Centre Thickness: 0.09 mm, Diameter: 14.00 mm, Spherical Power: -0.00D, Iris / Pupil Color: Dark Brown / Black, Medium Brown / Black, Light Brown / Black, Iris / Pupil Size: 11.00 mm / 4.00 mm

INDICATIONS	
1	IGEL CD 38 is a soft contact lens that is meant for daily wear use for the correction of visual acuity in aphakic or non-aphakic persons with non-diseased eyes that are myopic and may exhibit refractive astigmatism that does not interfere with visual acuity.
2	IGEL CD 49 is a soft contact lens that is meant for daily wear use for the correction of visual acuity in aphakic or non-aphakic persons with non-diseased eyes that are myopic and may exhibit refractive astigmatism that does not interfere with visual acuity.
3	IGEL CD 55 is a soft contact lens that is meant for daily wear use for the correction of visual acuity in aphakic or non-aphakic persons with non-diseased eyes that are myopic and may exhibit refractive astigmatism that does not interfere with visual acuity.
4	IGEL CD 59 is a soft contact lens that is meant for daily wear use for the correction of visual acuity in aphakic or non-aphakic persons with non-diseased eyes that are myopic and may exhibit refractive astigmatism that does not interfere with visual acuity.

5	IGEL NUTORIC 38 is a soft contact lens that is meant for daily wear use for the correction of visual acuity in aphakic or non-aphakic persons with non-diseased eyes that are myopic and may exhibit refractive astigmatism that does not interfere with visual acuity.
6	IGEL NUTORIC 49 is a soft contact lens that is meant for daily wear use for the correction of visual acuity in aphakic or non-aphakic persons with non-diseased eyes that are myopic and may exhibit refractive astigmatism that does not interfere with visual acuity.
7	IGEL CD APHAKIC is a soft contact lens that is meant for daily wear use for the correction of visual acuity in aphakic or non-aphakic persons with non-diseased eyes that are myopic and may exhibit refractive astigmatism that does not interfere with visual acuity.
8	IGEL CD APHAKIC RX is a soft contact lens that is meant for daily wear use for the correction of visual acuity in aphakic or non-aphakic persons with non-diseased eyes that are myopic and may exhibit refractive astigmatism that does not interfere with visual acuity.
9	IGEL CD BIFOCAL is a soft contact lens that is meant for daily wear use for the correction of visual acuity in aphakic or non-aphakic persons with non-diseased eyes that are myopic and may exhibit refractive astigmatism that does not interfere with visual acuity.
10	IGEL CHROMAX RED is a soft contact lens that is meant for daily wear use for the correction of visual acuity in aphakic or non-aphakic persons with non-diseased eyes that are myopic and may exhibit refractive astigmatism that does not interfere with visual acuity.
11	IGEL CHROMAX GREEN is a soft contact lens that is meant for daily wear use for the correction of visual acuity in aphakic or non-aphakic persons with non-diseased eyes that are myopic and may exhibit refractive astigmatism that does not interfere with visual acuity.
12	IGEL CD PROSTHETIC is a soft contact lens that is meant for daily wear use for the correction of visual acuity in aphakic or non-aphakic persons with non-diseased eyes that are myopic and may exhibit refractive astigmatism that does not interfere with visual acuity.

INTRODUCTION

All the above contact lenses are intended for daily wear, single patient use, or as recommended by your eye care practitioner. Each STERILE 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.

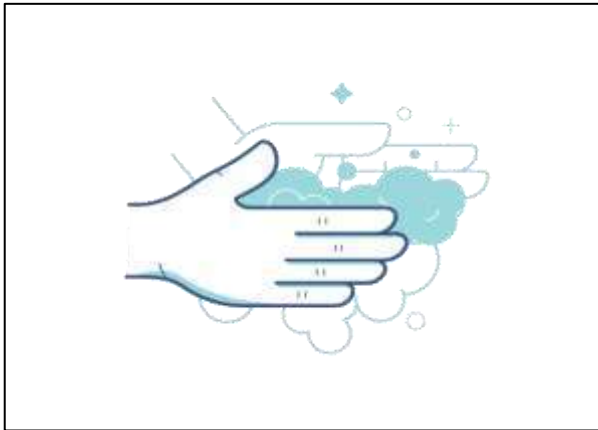


Figure 1 Washing Hands

- 2 Check packaging of new containers for signs of damage. Do not use if the original packaging is damaged or broken. Please return it immediately to your dispensing eye-care practitioner.

INSERTION

- 1 Remove lens from case with finger and place on fingertip and ensure lens is not inverted or inside out. (Figure 2)



Figure 2 Lens Inverted and Lens Not Inverted

- 2 *IF ABNORMAL DISCOMFORT IS FELT – remove lens and check it is not inverted.*

3 *IF DISCOMFORT PERSISTS – remove lens immediately and seek advice from your eye care practitioner.*

4 Pull down lower lid, lean forward, look into mirror with both eyes and then draw up upper lid and look downwards.



Figure 3 Lens Insertion

5 Press lens lightly onto the eye (Figure 3) and gently release the lids.

6 Repeat same procedure with the other lens.

LENS REMOVAL

1 Pull down lower lid; slide lens down to white of eye while looking up, gently pinch lens and remove.

2 Repeat same procedure with the other lens. (Figure 4)

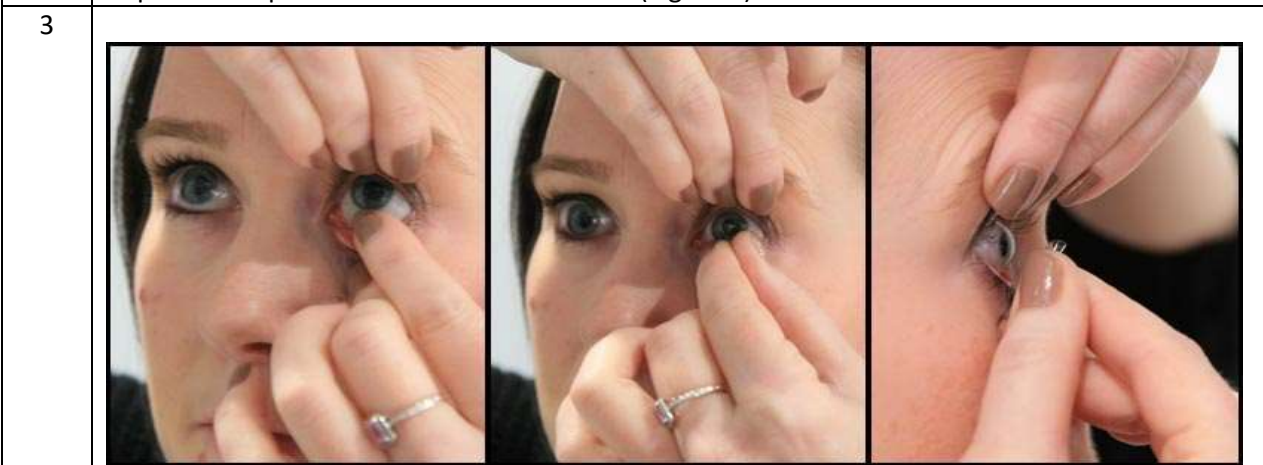


Figure 4 Lens Removal

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 soft contact lenses are indicated for daily wear. The maximum suggested wearing schedule for IGEL soft contact lenses is as follows:

Days	Continuous Hours	Days	Continuous Hours
1	3	8	8

	2	3	9	8
	3	4	10	10
	4	4	11	12
	5	6	12	14
	6	6	13	15
	7	8	14 and after	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 soft contact lenses takes very little time 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.
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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.
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CARE FOR A DRIED OUT (DEHYDRATED) DRY LENS

f	If for some reason, lens dried out completely, a minimum of handling is important, as they are very brittle in the dehydrated state. Carefully place them in rinsing or storage solution for a minimum of thirty minutes during which time they will become soft and flexible. The follow the cleaning, rinsing and disinfecting procedures – including soaking the lens in storage and disinfection solution for four hours before wearing.
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CARE FOR A STICKING (NON-MOVING) LENS

g	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.
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STORAGE

h	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.
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LENS DEPOSIT AND USE OF ENZYMATIC CLEANER

i	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.

Disinfecting Solution
Igel Clean, Moist & Refreshing Multipurpose Solution
Igel Plus Multipurpose Solution
Lens Lubricant/Rewetting Drops

Igel Refreshing Drops
Igel Comfort Drops

HOW SUPPLIED

Each custom-made soft contact lens is supplied sterile in a glass 7 cc vial containing buffered normal saline solution. The glass vial is labeled with lens parameters, unique identification number, and expiry date of the product.

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.





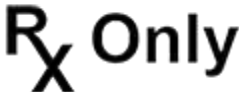
CONTACT LENS PATIENTS SHOULD FOLLOW INSTRUCTIONS GIVEN BY THEIR EYE CARE PRACTITIONER STRICTLY AND DISCARD THEIR CONTACT LENSES AFTER THE WEARING PERIOD (MODALITY) AS PRESCRIBED BY THE EYE CARE PRACTITIONER.

PRODUCT OWNER

IGEL SDN BHD

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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>