BAUSCH+ Health

INSERT SPEC DIMENSIONS: Flat: 8.5"x11"

DESCRIPTION: Bausch + Lomb PIC Instructions IFU / Australia / CLW

PART No.: 4167602 **SPEC No.** N/A

SPECIAL INSTRUCTIONS: N/A

PRINT SUPPLIERS: Please refer to Bausch Health's *Print Supplier Guidelines*

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BAUSCH + LOMB

For Patients In Australia: Patient Implant Identification Card Instructions

The Patient Implant Identification Card (PIC) is provided to record the details of the intraocular lens (IOL) and surgery. The PIC contains 2 parts, one for the hospital performing the surgery to fill out and return to Bausch + Lomb and a second one to provide to the patient to keep for their records with all the information about the IOL (including Name of the Device, Serial Number, the link to the Warnings and Precautions online and other relevant information). The table below is a guide for the professional to fill out the Patient Identification and Health Care Centre or Doctor. Each number is a field to fill out.

INFORMATION ON CARD

	Patient Identification
(1)	Patient's first name
(2)	Patient's last name
(3)	Patient's date of birth
(4)	Patient's gender
(5)	Patient's age
	Health Care Centre or Doctor
(6)	Name of the hospital
(7)	Street address of the hospital
(8)	City of the hospital
(9)	Country of the hospital
(10)	Billing PO# (USA only)
(11)	Surgeon's name
	Date of implantation
(13)	Eye affected
OS	Left eye
OD	Right eye
Bausch & Lomb Incorporated Attn: Customer Service 3375 Tree Court Industrial Blvd St. Louis, MO 63122 USA	Please send the card back to the manufacturer using the provided address.
	The link provided is for the patient to get to the Warnings, Precautions, and other important information related to the implanted IOL.

SAMPLE

Patient Identification

(1) John
(2) Doe
(3) January 10, 1956
(4) Male
(5) 64

Health Care Centre or Doctor

(6) University Hospital
(7) 123 Main Street
Springfield, NY 12345
(8) Springfield, NY
(9) USA
(10) 123456-123456
(11) Dr. Sarah Smith
November 10, 2020
(13) OS ☐ / OD ☐

BAUSCH + LOMB IOLs:

Name Of Device	Model
Akreos™ advanced optics aspheric lens	ADAPT-AO
Akreos™ AO microincision lens	MI60
enVista™ IOL	MX60
enVista™ enhanced IOL	MX60E
enVista™ toric IOL	MX60T
enVista™ enhanced toric IOL	MX60ET
enVista™ preloaded IOL	MX60PL
enVista™ toric preloaded IOL	MX60PT
SofPort™ AO	LI61AO
PMMA IOL	L122UV

Intended Purpose

The IOL is designed to replace the natural crystalline lens of the eye in adults following cataract surgery.

Warnings / Precautions / Additional Measures To Be Taken

Cataract surgery is not completely risk-free. Complications may occur as a result of the removal of your cataract whether or not an IOL is implanted. Complications of cataract surgery range from minor, usually temporary side effects, to sight-threatening complications. Significant sight-threatening complications are extremely rare and include, but are not limited to, infection, bleeding, swelling, and retinal detachment. People with existing medical conditions such as diabetes and chronic eye infections are at a higher risk of developing complications. This IOL is compatible with Magnetic Resonance Imaging (MRI) scans.

After Cataract Surgery

- Be sure to attend all follow-up visits so that your eye doctor can monitor healing.
- Expect your vision to begin improving within a few days. Your vision may be blurry at first as your eye heals and adjusts.
- It is normal to feel itching and mild discomfort for a couple of days after surgery. Avoid rubbing or pushing on your eye.
- Avoid most exercise or heavy lifting. Your doctor will tell you when you can do those activities again.
- Your doctor may ask you to wear a protective shield for a few days after surgery. This is especially important during sleep.
- Your doctor may prescribe eye drops or other medication to prevent infection, reduce inflammation, and control eye pressure.
- After a couple of days, most of the discomfort should disappear. Often, complete healing occurs within eight (8) weeks.
- Contact your doctor immediately if you experience any of the following:
  - Vision loss
  - Persistent or severe pain
  - Increased eye redness
  - Light flashes or multiple new spots (floaters) in front of your eye

Expected Lifetime Of The Device And/Or Follow-Up Information

IOLs are made out of polymers, so they are expected to have a long lifetime. The long-term safety and effectiveness of this lens have not been proven. The safety of the IOL has not been substantiated in patients with preexisting conditions.

Qualitative And Quantitative Information For The Materials And Substances Used In The Product

IOLs are individually packaged in a sterile vial containing saline solution or in a stand-alone sterile container.

Note: Please discuss any questions with your eye doctor. Always follow your doctor's instructions after cataract surgery.

Any serious event that you experience in relation to the device, you can report to the manufacturer or the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems

Sponsor Information

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