4130301

BAUSCH+LOMB

enVista®

Hydrophobic Acrylic Intraocular Lens

FOLDABLE HYDROPHOBIC ACRYLIC UV ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS

DEVICE DESCRIPTION

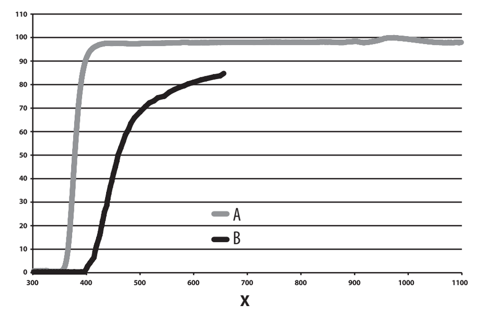
The enVista® intraocular lens (IOL) is a single-piece ultra-violet absorbing posterior chamber intraocular lens developed to replace the natural crystalline lens in adult patients in whom the cataractous lens has been removed.

The enVista IOL has an aspheric optic and is designed to be free of spherical aberration. Clinical studies have not been conducted with the enVista IOL to assess the effect of the aspheric surface on spherical aberration, visual acuity, or contrast sensitivity.

PHYSICAL CHARACTERISTICS OF ENVISTA® MODEL MX60E

Lens / Haptic Material	Hydrophobic acrylic (hydroxyethyl methacrylate (HEMA)-polyethylene glycol phenyl ether acrylate (poly(EG)PEA)-styrene copolymer, crosslinked with ethylene glycol dimethacrylate)
Material Characteristics	Index Of Refraction: 1.53 @ 35°C ; Specific Gravity: 1.19 g/ml
Optic Type / Powers	Aspheric / 0.0 to +34.0 Diopters (0.0 to +9.0 in 1.0 Diopter increments, +10.0 to +30.0 in 0.5 Diopter increments, and +31.0 to +34.0 in 1.0 Diopter increments)
Dimensions	Body Diameter: 6.0 mm; Overall Diameter: 12.5 mm; Haptic Angle: 0°
Spectral Transmittance	**UV(364):** 10% transmittance for +20.0 diopter IOL See figure **1** with chart's **X** value = Wavelength (nm) and **Y** value = % Transmittance; chart compares the transmittance curve of an enVista MX60 Lens to a 53 Year Old Human Lens. **A** = + 20 Diopter enVista MX60 Lens and **B** = 53 Year Old Human Lens. **NOTE:** Light transmittance values for an IOL material may vary slightly depending on the method of measurement. **Reference:** 53 year old human lens data from Boettner, E.A. and Wolter, J. R., "Transmission of the Ocular Media," Investigative Ophthalmology, 1:776-783, 1962.

1



INDICATIONS

Indicated for primary implantation for the visual correction of aphakia in adult patients in whom the cataractous lens has been removed. The lens is intended for placement in the capsular bag.

WARNINGS

Physicians considering lens implantation under any of the following circumstances should weigh the potential risk/benefit ratio:

1. Recurrent severe anterior or posterior segment inflammation or uveitis.
2. Patients in whom the intraocular lens may affect the ability to observe, diagnose, or treat posterior segment diseases.
3. Surgical difficulties at the time of cataract extraction, which might increase the potential for complications (e.g., persistent bleeding, significant iris damage, uncontrolled positive pressure, or significant vitreous prolapse or loss).
4. A distorted eye due to previous trauma or developmental defect in which appropriate support of the IOL is not possible.
5. Circumstances that would result in damage to the endothelium during implantation.
6. Suspected microbial infection.
7. Children under the age of 2 years are not suitable candidates for intraocular lenses.
8. Patients in whom neither the posterior capsule nor zonules are intact enough to provide support.

PRECAUTIONS

1. Do not attempt to resterilize the lens as this can produce undesirable side effects.
2. Do not use if product sterility or quality is thought to be compromised due to damaged packaging or signs of leakage (such as the loss of saline storage solution, or the presence of salt crystallization).
3. Do not soak or rinse the intraocular lens with any solution other than sterile balanced salt solution or sterile normal saline.
4. Do not store the lens at a temperature greater than 43°C (109°F) or lower than 0°C (32°F). Do not autoclave the intraocular lens.
5. Do not re-use the lens. It is intended for permanent implantation. If explanted, sterility and proper function cannot be assured.
6. The safety and effectiveness of the enVista IOL have not been substantiated in patients with pre-existing ocular conditions and intraoperative complications (see below). Careful preoperative evaluation and sound clinical judgment should be used by the surgeon to decide the benefit/risk ratio before implanting a lens in a patient with one or more of these conditions. Physicians considering lens implantation in such patients should explore the use of alternative methods of aphakic correction and consider lens implantation only if alternatives are deemed unsatisfactory in meeting the needs of the patient.

Before Surgery

- Retinal conditions or predisposition to retinal conditions, previous history of, or a predisposition to, retinal detachment or proliferative diabetic retinopathy, in which future treatment may be compromised by implanting this lens.
- Amblyopia
- Clinically severe corneal dystrophy (e.g., Fuchs')
- Rubella, congenital, traumatic or complicated cataracts
- Extremely shallow anterior chamber, not due to swollen cataract
- Recurrent anterior or posterior segment inflammation of unknown etiology, or any disease producing an inflammatory reaction in the eye (e.g. iritis or uveitis).
- Aniridia
- Iris neovascularization
- Glaucoma (uncontrolled or controlled with medication)
- Microphthalmos or macrophthalmos
- Optic nerve atrophy
- Previous corneal transplant
- Pre-existing ocular conditions which may negatively impact stability of the implant.

During Surgery

- Mechanical or surgical manipulation required to enlarge the pupil
- Vitreous loss (significant)
- Anterior chamber bleeding (significant)
- Uncontrollable positive intraocular pressure
- Complications in which the IOL stability could be compromised

7. Patients with preoperative problems such as corneal endothelial disease, abnormal cornea, macular degeneration, retinal degeneration, glaucoma, and chronic drug miosis may not achieve the visual acuity of patients without such problems. The physician must determine the benefits to be derived from lens implantation when such conditions exist.
8. A high level of surgical skill is required for intraocular lens implantation. The surgeon should have observed and/or assisted in numerous implantations and successfully completed one or more courses on intraocular lens implantation before attempting to implant intraocular lenses.
9. As with any surgical procedure, there is risk involved. Potential complications accompanying cataract or implant surgery may include, but are not limited to the following: corneal endothelial damage, infection (endophthalmitis), retinal detachment, vitritis, cystoid macular edema, corneal edema, pupillary block, cyclitic membrane, iris prolapse, hypopyon, transient or persistent glaucoma, and secondary surgical intervention. Secondary surgical interventions include, but are not limited to: lens repositioning, lens replacement, vitreous aspiration or iridectomy for pupillary block, wound leak repair, and retinal detachment repair.
10. Care should be taken to remove viscoelastic from the eye at the close of surgery.

CALCULATION OF LENS POWER

The recommended A-constant listed on the lens carton is intended for use with axial length measurements obtained by optical biometry. Use of axial length measurements by other techniques (e.g. Applanation A-scan) will normally require a different lens constant. This number is a guideline only and is based on an evaluation of clinical data obtained using the IOL Master.

The physician should determine preoperatively the power of the lens to be implanted. Lens power calculation methods are described in the following references:

- Hoffer K J. The Hoffer Q formula: a comparison of theoretic and regression formulas, Journal of Cataract and Refractive Surgery Vol. 19, pp. 700-712, 1993; ERRATA, Vol. 20, pp. 677, 1994.
- Holladay JT, Musgrove KH, Prager TC, Lewis JW, Chandler TY, Ruiz RS. A three-part system for refining intraocular lens power calculations. Journal of Cataract and Refractive Surgery, Vol. 14, pp. 17-24, 1988.
- Norrby NES. Unfortunate Discrepancies, Letter to the Editor and Reply by Holladay JT. Journal of Cataract and Refractive Surgery, Vol. 24, pp. 433-434, 1998.
- Olsen T, Olesen H, Thim K, and Corydon L. Prediction of pseudophakic anterior chamber depth with the newer IOL calculation formulas. Journal of Cataract and Refractive Surgery, Vol. 18, pp. 280-285, 1992.
- Retzlaff JA, Sanders DR, Kraff MC. Development of the SRK/T intraocular lens implant power calculation formula. Journal of Cataract and Refractive Surgery, Vol. 16, pp. 333-340, 1990; ERRATA, Vol. 16, pp. 528, 1990.
- Haigis W: The Haigis Formula. In: Intraocular lens power calculations. H. John Shammas (eds), Slack Incorporated, Thorofare, NJ, USA, pp. 39-57, 2004.

DIRECTIONS FOR USE

1. Prior to implanting, examine the lens package for type, power, and proper configuration.
2. Open the peel pouch and remove the vial in a sterile environment.
3. Remove the lid from the vial.
4. With a pair of smooth forceps, remove the lens from the vial by gently grasping the lens haptic.
5. Rinse the entire lens with sterile balanced salt solution or sterile normal saline.
6. Examine the lens thoroughly to ensure particles have not become attached to it, and examine the lens optical surfaces for other defects.
7. The lens may be soaked in sterile balanced salt solution until ready for implantation.
8. *Amvisc*®, *Amvisc® Plus*, or *OcuCoat*® viscoelastic should be used for lubrication of the delivery system when inserting the lens.
9. Bausch + Lomb recommends using a Bausch + Lomb approved delivery system, which includes, but is not limited to the Medicel ACCUJECT 2.2-1P, the Medicel ACCUJECT 2.6-1P, or other injector sets that specifically identify the enVista MX60 lens in their cleared labeling. Please refer to the Directions For Use of the insertion instrument for additional information.
10. There are various surgical procedures that can be utilized, and the surgeon should select a procedure that is appropriate for the patient. Surgeons should verify that appropriate instrumentation is available prior to surgery.

OVERVIEW OF CLINICAL STUDIES

Clinical studies have been conducted on the enVista single-piece IOL (model MX60) and the parent xact X-60 three-piece IOL (model X-60)*. The results of these studies are described herein.

* The AVS xact X-60 Intraocular Lens is not licensed for sale in Canada.

1. Summary of Clinical Study for enVista Model MX60

A clinical study of the enVista Hydrophobic Acrylic Intraocular Lens, Model MX60, began in the United States on October 19, 2010. This prospective, single arm, open label study included a total of 122 subjects (122 eyes) at 6 clinical sites. Postoperatively, subjects underwent complete ophthalmic evaluations at regularly scheduled intervals through Form 4 (Postoperative Days 120-180).

Table 1 displays demographic information of subjects enrolled in the clinical trial. Table 2 displays BCVA results for best case subjects (those without clinically significant preoperative pathologies or macular degeneration at any time during the study) for 3 visits. At the Form 4 visit, 118 subjects (100%) achieved BCVA of 20/40 or better, which exceeds the FDA grid of 96.7%.

The key safety outcomes for this study are presented in Table 3. The rates of FDA defined potentially sight-threatening adverse events that occurred in the clinical trial at Form 4 were found to be less than the "FDA Grid" of Historical Controls. Two cumulative adverse events (2/122; 1.6%) of cystoid macular edema were reported through the Form 4 visit. One persistent adverse event (1/121; 0.8%) of cystoid macular edema was reported at the Form 4 visit. No serious ocular adverse events occurred during this study. One serious non-ocular adverse event of advanced leukemia with an outcome of death was reported during this study. The adverse event was determined by the study investigator to be unrelated to the investigational device, Model MX60 IOL.

The results of clinical investigations provide reasonable assurance that the Model MX60 IOL is safe and effective for the visual correction of aphakia following cataract extraction.

CLINICAL TABLES

TABLE 1: SUBJECT DEMOGRAPHICS

	n	%
Number of Subjects	122	100.0
Gender		
Male	53	43.44
Female	69	56.56
Race		
African-American	1	0.82
Caucasian	119	97.54
Hispanic	2	1.64
Age		
< 60	13	10.66
60 to < 70	50	40.98
70 to < 80	54	44.26
≥ 80	5	4.10
Mean ± SD	69.0 (8.0)	
Range (Min, Max)	46, 93	

TABLE 2: BEST CORRECTED VISUAL ACUITY BY POSTOPERATIVE VISIT (BEST CASE ANALYSIS SET)

Visual Acuity	Form 2		Form 3		Form 4	
	n	%	n	%	n	%
20/20 or better	82	69.5	93	78.2	99	83.9
20/25 or better	108	91.5	113	95.0	110	93.2
20/32 or better	117	99.2	117	98.3	117	99.2
20/40 or better	118	100	118	99.2	118	100
Exact 95% CI for 20/40 or better[1]	96.9%, 100%		95.4%, 100%		96.9%, 100%	
Binomial Test p-value for comparing % of 20/40 or better, using FDA recommended p=0.967	1.0000					
20/41 to 20/63[2]	0	0.0	1	0.8	0	0.0
20/64 to 20/100	0	0.0	0	0.0	0	0.0
20/101 to 20/200	0	0.0	0	0.0	0	0.0
Worse than 20/200	0	0.0	0	0.0	0	0.0
N[3]	118		119		118	
N missing[4]	1		0		1	
Total N[5]	119		119		119	

[1]Exact 95% confidence interval for the true percent from the study.
[2]Subject No. 04-027 experienced an AE of cystoid macular edema at Form 3; however, this AE was not persistent, and the subject achieved a BCVA of 20/20 at the Form 4 visit.
[3]Number of available best case subjects, plus best case subjects who missed scheduled visit but were seen later, and with VA measurement for the corresponding group [% = (n ÷ N) x 100%].
[4]Number of subjects with missing VA measurement for the corresponding group.
[5]Total N: N + N-missing subjects for the corresponding group.

TABLE 3: ISO DEFINED CUMULATIVE AND PERSISTENT ADVERSE EVENTS THROUGH FORM 4 (SAFETY ANALYSIS SET)

Adverse Event	n/N[6]	%	ISO Grid (%)	90% CI[7]	p-value[8]
Cumulative Safety Events[9]					
Endophthalmitis	0/122	0.0	0.1	0.00, 2.43	1.0000
Hyphema	0/122	0.0	2.2	0.00, 2.43	1.0000
Hypopyon	0/122	0.0	0.3	0.00, 2.43	1.0000
IOL Dislocation	0/122	0.0	0.1	0.00, 2.43	1.0000
Cystoid Macular Edema	2/122	1.6	3.0	0.29, 5.07	0.8839
Pupillary Block	0/122	0.0	0.1	0.00, 2.43	1.0000
Retinal Detachment	0/122	0.0	0.3	0.00, 2.43	1.0000
Secondary Surgical Intervention	0/122	0.0	0.8	0.00, 2.43	1.0000
Persistent Safety Events[10]					
Corneal Edema	0/121	0.0	0.3	0.00, 2.45	1.0000
Iritis	0/121	0.0	0.3	0.00, 2.45	1.0000
Cystoid Macular Edema	1/121	0.8	0.5	0.04, 3.86	0.4548
Raised IOP Requiring Treatment	0/121	0.0	0.4	0.00, 2.45	1.0000

[6] n: number of eyes reported with corresponding event. For cumulative event, N: number of implanted eyes. For persistent event, N: number of eyes returned for the Form 4 examination with non-missing response for the corresponding adverse event. A subject could be reported with more than one AE.
[7] Based on binomial distribution.
[8] Binomial test for the null hypothesis H_0: Percent from study ≤Percent from ISO Grid [per ISO 11979-7:2006 (E)].
[9] Occurring at any time during the study.
[10] Present at Form 4.

Other Clinical Findings

All subjects in the safety analysis set were evaluated for IOL glistenings at Form 3 and Form 4 visits. IOL glistenings were evaluated via retroillumination slit lamp examination utilizing a photographic grading scale provided in the protocol. The grading scale consisted of (in order of severity), "none, grade 0 (trace), grade 1, 2, 3, or 4." No glistenings of any grade were reported for any subject at any visit in the clinical study.

2. Summary of Clinical Study for xact Model X-60 (Three-Piece IOL)

A clinical study of the xact Model X-60 IOL began in the United States on May 8th, 2002 and was conducted by Advanced Vision Science. A total of 383 subjects were enrolled, and 367 subjects were available for examination at one year, 312 were available at two years, and 281 were available at three years.

Table 4 displays demographic information of subjects enrolled in the clinical trial. Table 5 summarizes the best-corrected distance visual acuity (BCVA) results for best case subjects (those without clinically significant preoperative pathologies or macular degeneration at any time during the clinical trial).

Potentially sight threatening adverse events are listed in Table 6, along with the rate of occurrence in the clinical trial of the X-60 IOL, and are compared to the FDA Grid of Historical Controls. The number of patients included in the analysis of both cumulative and persistent adverse events in some cases was less than the number of patients who returned for examination and were available for analysis as a result of missing information in certain fields on the case report forms.

The results of clinical investigations provide reasonable assurance that the X-60 IOL is safe and effective for the visual correction of aphakia following cataract extraction.

CLINICAL TABLES

TABLE 4: SUBJECT DEMOGRAPHICS

	n	%
Number of Subjects	383	100.0
Gender		
Male	152	39.7
Female	231	60.3
Race		
Black	8	2.1
Caucasian	373	97.4
Hispanic	2	0.5
Age		
< 60	43	11.2
60 to < 70	105	27.2
70 to < 80	177	46.2
≥ 80	58	15.4
Mean ± SD	71.0 (9.11)	
Range (Min, Max)	45, 93	

TABLE 5: VISUAL ACUITY IN BEST CASE POPULATION

Visual Acuity	1 Year		2 Years		3 Years	
	n	%	n	%	n	%
20/20 or better	209	65.3	163	60.8	167	72.2
20/25 or better	275	85.9	215	80.2	203	86.3
20/30 or better	307	95.9	239	89.2	221	92.7
20/40 or better	317	99.1	253	94.4	229	95.1
FDA Grid for % of 20/40 or better	96.7%		N/A		N/A	
N	320		268		242	

TABLE 6: CUMULATIVE AND PERSISTENT ADVERSE EVENTS

Adverse Events	1 Year		FDA Grid 1 Year	2 Years		3 Years	
Cumulative Safety Events **Number of Eyes with Postop Visits = 382**	n/N	%	%	n/N	%	n/N	%
Endophthalmitis	0/382	0.0	0.1	0/382	0.0	0/382	0.0
Hyphema	0/382	0.0	2.2	0/382	0.0	0/382	0.0
Hypopyon	0/382	0.0	0.3	0/382	0.0	0/382	0.0
IOL Dislocation	0/382	0.0	0.1	0/382	0.0	0/382	0.0
Cystoid Macular Edema	3/376	0.8	3.0	3/377	0.8	3/377	0.8
Pupillary Block	0/382	0.0	0.1	0/382	0.0	0/382	0.0
Retinal Detachment	3/376	0.8	0.3	4/377	1.1	4/377	1.1
Secondary Surgical Intervention	1/382[11]	0.3	0.8	1/382	0.3	3/382[12,13]	0.8
Persistent Safety Events	**n/N**	**%**	**%**	**n/N**	**%**	**n/N**	**%**
Number of Eyes Available at the Visit	367		N/A	312		281	
Corneal Edema	0/366	0.0	0.3	0/312	0.0	0/281	0.0
Iritis	1/366	0.3	0.3	0/312	0.0	0/281	0.0
Cystoid Macular Edema	0/364	0.0	0.5	0/309	0.0	0/280	0.0
Raised IOP Requiring Treatment	0/366	0.0	0.4	0/312	0.0	0/281	0.0

[11]IOL was exchanged due to patient complaint of blurred vision, despite good BCVA. Investigator suspected glistenings might be related, however only modest improvement of vision was achieved after IOL exchange.
[12]IOL with glistenings was exchanged during retinal surgery to improve fundus visualization by the surgeon. Loss of vision was the result of retinal pathology and was not associated with the IOL.
[13]IOL was exchanged due to patient complaint of blurred vision. Investigator suspected glistenings might be related, however vision did not improve after IOL exchange. Since vision did improve after subsequent Nd:Yag capsulotomy, the complaint of blurred vision was not associated with the IOL.

OTHER CLINICAL FINDINGS

In the IDE clinical trial, "glistenings" were observed in some cases. Glistenings, known to sometimes occur in some other hydrophobic acrylic IOLs, are microscopic vacuoles within the optic of the IOL that are visible through the slit lamp as multiple small refractile specks. Analysis of the clinical data confirmed no effect of glistenings on visual outcomes.

Testing established that glistenings were eliminated by a change in the IOL hydration solution from 10.0% saline to 0.9% saline. This was confirmed in an additional clinical trial conducted outside of the United States. In this study, 172 eyes of 142 patients were examined at least once between 1 and 6 months, and 123 eyes of 101 patients were examined at least once between 6 months and 2 years. No glistenings were observed at any time.

HOW SUPPLIED

The lens is individually packaged in a sterile vial (containing a 0.9% saline solution), within a peel pouch, and should only be opened under sterile conditions. A patient card and self-adhesive labels are supplied to provide traceability of the lens. The package is sterilized by gamma irradiation.

EXPIRATION DATE

Sterility is guaranteed unless the pouch is damaged or opened. The expiration date on the lens package is the sterility expiration date. This lens should not be implanted after the indicated sterility expiration date.

ADVERSE EVENT REPORTING

Adverse events and/or potentially sight threatening complications that may be regarded as lens related and that were not previously expected in nature, severity or degree of incidence should be reported within five (5) days to Bausch & Lomb Incorporated. This information is being requested from all surgeons in order to document potential long-term effects of intraocular lens implantation.

Physicians are encouraged to report these events in order to aid in identifying emerging or potential problems with intraocular lenses. These problems may be related to a specific lot of lenses or may be indicative of long-term effects associated with these lenses or with IOLs in general. If you wish to report a problem, please call Bausch + Lomb at 1-800-338-2020.

PATIENT REGISTRATION INSTRUCTIONS AND REPORTING REGISTRATION

Each patient who receives an enVista IOL must be registered with Bausch + Lomb at the time of lens implantation. Registration is accomplished by completing the Implant Registration Card that is enclosed in the lens package and mailing it to Bausch + Lomb. Patient registration is essential and will assist Bausch + Lomb in responding to adverse reaction reports and/or potentially sight-threatening complications. An implant identification card is supplied in the lens package and must be given to the patient.

RETURNED GOODS POLICY

All lenses being returned must be accompanied by a returned goods authorization number issued by Bausch + Lomb Customer Service. Call 1-800-338-2020 for return authorization and full policy information.

WARRANTY

Bausch & Lomb Incorporated warrants that the intraocular lens, when delivered, will conform to all applicable laws and the manufacturer's then current version of the published specifications for such intraocular lens in all material respects and will be free from defects in material and workmanship.

BAUSCH & LOMB INCORPORATED DISCLAIMS ALL OTHER WARRANTIES, EXPRESS, IMPLIED OR BY OPERATION OF LAW, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. BAUSCH & LOMB INCORPORATED SHALL NOT BE LIABLE FOR ANY INCIDENTAL, CONSEQUENTIAL, INDIRECT OR EXEMPLARY DAMAGES OF ANY KIND, DIRECTLY OR INDIRECTLY ARISING FROM THE PURCHASE OR USE OF THIS PRODUCT EVEN IF BAUSCH & LOMB INCORPORATED HAD BEEN ADVISED OF THE POSSIBILITY OF SUCH LOSS, DAMAGE OR EXPENSE.

SYMBOLS USED ON LABELING

Symbol	Description	Symbol	Description
IOL	Intraocular Lens	STERILE R	Sterilized Using Irradiation
PC	Posterior Chamber	Rx ONLY	Prescription Only (USA)
PCL	Posterior Chamber Lens	⚠	Caution
UV	Ultraviolet		Temperature Limit
D	Diopter		Do Not Resterilize
$Ø_B$	Body Diameter (Optic Diameter)		Meets EU Packaging Directive
$Ø_T$	Overall Diameter (Overall Length)		Do Not Use if Package is Damaged
SN	Serial Number		Manufacturer
	Do Not Re-use		eIFU Indicator
	Use-By Date		

MANUFACTURER
Bausch & Lomb Incorporated
1400 North Goodman Street
Rochester, NY 14609 USA

Manufactured by:
Bausch & Lomb Incorporated
21 Park Place Blvd. North, Clearwater, FL 33759 USA

U.S. Patent Numbers: 6,281,319 and 6,635,731

Rev. 2018-03

Rx ONLY — PRESCRIPTION ONLY (USA)
STERILE R — STERILIZED USING IRRADIATION
DO NOT RE-USE
DO NOT RESTERILIZE
MEETS EU PACKAGING DIRECTIVE
0°C 32°F 43°C 109°F — TEMPERATURE LIMIT

VALEANT

1400 North Goodman Street Rochester, NY 14609, USA

DESCRIPTION: enVista MX60E_DFU_U.S._Clearwater

PART No.: 4130301 **SPEC No. or SPEC DIMENSIONS:** 45104 / C-68754

SPECIAL INSTRUCTIONS: n/a

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

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