



MedMarket

D I L I G E N C E

Products, Technologies, Markets and
Opportunities in Ophthalmology Surgical,
Device and Drug Markets Worldwide, 2007

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A tiny opening, less than 2 mm, is made near the upper edge of the cornea beneath the eyelid. Intacs are inserted through this opening so that they rest between the layers of tissue in the cornea, outside the central optical zone. This procedure usually takes about 15 minutes and is performed on an outpatient basis.

The procedure to implant ICRs/ICRSs costs the patient between \$2,000 and \$2,500 per eye.

3.1.5 Refractive Surgery

Refractive surgery is a generic term that is used to describe any surgical technique that is employed to change the shape of the cornea to improve the eyes' refractive error. An overview of the various approaches to refractive surgery follows.

3.1.5.1 LASIK

LASIK or "laser *in situ* keratomileusis," permanently changes the shape of the cornea, and is performed for varying degrees of nearsightedness, farsightedness, and astigmatism. A surgical knife, called a microkeratome, or alternatively a high-frequency laser is used to cut a flap in the cornea, leaving a hinge at one end of the flap. The flap is then folded back to reveal the middle layer of the cornea, called the stroma. Pulses from a computer-controlled excimer laser vaporize a portion of the stroma and the flap is then replaced. By removing this tissue, the shape of the central cornea is changed, and the refractive error is reduced.

Exhibit 3-3: LASIK Products and Manufacturers

Manufacturer	Brands	Product	Status
Alcon	LadarWave™ Custom Cornea Wavefront System	Excimer laser system with custom corneal shaping can measure even the highest refractive errors instantaneously.	510(k) approved by FDA for USA distribution in October 2002. Now available worldwide
Alcon	LadarVision® platform	Includes Ladar4000 Excimer Laser System and LadarWave CustomCornea Wavefront system.	PMA approved October 2002 for USA distribution. Now available worldwide.
AMO	Star S4 IR®	Excimer Laser - Integrating data collected by the WaveScan WaveFront System, the STAR S4 utilizes these exclusive VISX technologies to deliver precision custom ablations	Performs LASIK by removing layers of the corneal stroma.
AMO	Wavescan WaveFront®	An ophthalmic diagnostic instrument that measures the refractive error and wavefront aberrations of the human eye using a Hartmann-Shack wavefront sensor. The measurements can be used to determine regular (spherocylindrical) refractive errors and irregularities (aberrations) that cause decreased or blurry vision in the human eye. WaveScan software uses the information to create a custom tailored correction map for the unique characteristics of each individual eye.	Diagnostic for assessment of corneal aberrations used to guide custom LASIK.
AMO		Presbyopic LASIK Custom Vue monofocal	Currentl in Phase III anticipated release Q3 2007
AMO		Presbyopic LASIK multi-focal	Early Phase III, Expect release 2008
AMO, Advanced Medical Optics	Amadeus II®	The Amadeus II is a computer-driven microkeratome used to cut a flap in the outer layer of the cornea to expose the softer tissue underneath.	Used to cut a flap in the outer layer of the cornea before LASIK is performed.
Bausch & Lomb	Zyoptix	Upgrade to treat hyperopia and monovision presbyopia	Targeted launch mid 2007
Bausch & Lomb	Technolas® 217z Excimer Laser system	LASIK system	May 2002 Approval. Now available worldwide.
Bausch & Lomb	Hansatome® Microkeratome	Corneal resection instrument that features automated pivoting motion and resistance-free travel and a superior-positioned hinge.	FDA approved in January 2001. Now available worldwide.

Manufacturer	Brands	Product	Status
Bausch & Lomb	PlanoScan 2000 Software	Software used in Technolas® 217 excimer laser to correct myopia from -1.0 to -12.0 diopters.	Available in Europe.
Bausch & Lomb	Dynamic Iris	Registration upgrade for Zyoptix	Targeted US launch mid 2007
Carl Zeiss-Meditec	MEL 80 Excimer Laser System	for use in the LASIK treatments of patients with near-sightedness ≤ -7.0 D with or without refractive astigmatism ≤ 3.0 D	FDA Approved August 2006 for sale in the USA, also available throughout Europe.
IntraLase	Intralase F2S	Femtosecond laser for use in LASIK to cut flaps or for use in posterior/anterior lamellar keratoplasty	Approved for LASIK
Nidek	EC 5000	Excimer laser system for LASIK procedures also approved for the reduction and elimination of myopia in the low, moderate and high ranges from -0.75 to -13.00 diopters (D) and moderate myopia with astigmatism ranging in severity from -1.00 to -8.00 D, with a refractive astigmatism from -0.50 to -4.00 D cylinder by manifest refraction, using PRK (Photorefractive Keratectomy).	Approved April 2000 for US distribution.
Norwood Eyecare	Norwood Eyecare Epikeratome	A specialized tool used in Epi-LASIK for lifting a flap without surgical blade or laser dissection of the corneal surface.	FDA approved in October 2003.
Perfect Vision 20/10 (Heidelberg, Germany)	Femtec	Femtosecond laser for penetrating keratoplasty and flap cutting during LASIK	FDA approval received February 2004 for the FemTec™ Laser Microkeratome. Also available in the EU.
Schwind eye-tech solutions	ESIRIS	ESIRIS is an excimer laser system that integrates the entire Schwind technology into a single system. It includes an eye tracker, custom ablation algorithm software and the optional Optical coherence pachymetry (OCP).	As of June 2006 Schwind products are available in over 60 countries in Europe, Asia, Latin and South America.
Schwind eye-tech solutions	Corneal Wavefront Analyzer	A topographic device for the analysis of corneal wavefront data, which provides a precise diagnosis of corneal aberrations.	As of June 2006 Schwind products are available in over 60 countries in Europe, Asia, Latin and South America.
Schwind eye-tech solutions	Carriazo-Pendular	Pendulum movement microkeratome	Approved for US distribution January 2006.

Manufacturer	Brands	Product	Status
WaveLight	Allegretto Wave™ Excimer Laser System	Excimer Laser system for use in LASIK procedures	FDA clearance for treatment of hyperopic refractive errors received October 2003
WaveLight	200 Hz Allegretto Wave excimer laser system	Excimer laser system for correction of up to 7D of myopia or myopia with up to 3D of astigmatism.	FDA clearance for treatment of myopic refractive errors received August 2006
WaveLight	400 Hz Allegretto Wave excimer laser system	Excimer laser system for correction of up to 12D of myopia or myopia with up to -6D of astigmatism and 6D hyperopia with up to +5D astigmatism.	Approved to treat mixed astigmatism in May 2006. FDA clearance for treatment of myopic refractive errors received July 2006

Source: MedMarket Diligence, LLC

3.1.5.2 Custom LASIK (Wavefront-Guided Laser Surgery)

As light rays from distant objects pass through the individual optical components of the eye, they may be distorted by the imperfections found in the cornea or the crystalline lens. The majority of these distortions or "aberrations" create common refractive errors, such as nearsightedness, farsightedness and astigmatism, which can be treated by optical devices, like glasses and contact lenses, or by Laser Vision Correction, using the conventional methods of LASIK, PRK or LASEK. The remaining optical aberrations create images which are altered by chromatic aberration, spherical aberration, diffraction, curvature of field, coma, trefoils and quadri-foils – collectively known as "higher order aberrations". These higher order aberrations are visually significant in 10% to 15% of the general population. When they do occur, they are unique to a particular patient much like a fingerprint. For these patients, the use of a wavefront-guided laser technique to create a customized reshaping of the corneal surface may be the best treatment option.

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4.1.3 Europe

4.1.3.1 Vision Disorders: Europe

Exhibit 4-3: Europe, Prevalence of Vision Disorders

Country/Region	Myopia Prevalence	Hyperopia Prevalence	Presbyopia Prevalence	Population Estimated Used ¹²
Europe (Extrapolated Statistics)				
Austria	2,103,800	1,831,146	735,728	8,174,762
Belgium	2,663,159	2,318,013	931,344	10,348,276 ²
Denmark	1,393,152	1,212,600	487,205	5,413,392
France	15,550,349	13,535,023	5,438,180	60,424,213
Germany	21,212,215	18,463,112	7,418,215	82,424,609
Greece	2,740,172	2,385,046	958,277	10,647,529
Hungary	2,581,861	2,247,251	902,913	10,032,375
Netherlands	4,200,000	3,655,276	1,468,637	16,318,199
Italy	14,941,262	13,004,874	5,225,172	58,057,477
Poland	9,940,604	8,652,302	3,476,371	38,626,349
Portugal	2,708,419	2,357,408	947,173	10,524,145
Romania	5,753,266	5,007,643	2,012,000	22,355,551
Spain	10,366,377	9,022,894	3,625,270	40,280,780
Sweden	2,312,676	2,012,953	808,776	8,986,400
Switzerland	1,917,502	1,688,994	670,578	7,450,867
United Kingdom	15,510,844	13,500,638	5,424,363	60,270,708

Source: MedMarket Diligence, LLC

¹² US Census Bureau, International Data Base 2004

4.1.3.2 Keratoconus: Europe

Exhibit 4-4: Europe, Prevalence of Keratoconus, by Country

Country/Region	Extrapolated Prevalence of Keratoconus	Population Estimated Used ¹³
Keratoconus in Europe (Extrapolated Statistics)		
Austria	4,087	8,174,762
Belgium	5,174	10,348,276 ²
Denmark	2,706	5,413,392
France	30,212	60,424,213
Germany	41,212	82,424,609
Greece	5,323	10,647,529
Hungary	5,016	10,032,375
Italy	29,028	58,057,477
Netherlands	8,159	16,318,199
Poland	19,313	38,626,349
Portugal	5,262	10,524,145
Romania	11,177	22,355,551
Russia	71,987	143,974,059
Spain	20,140	40,280,780
Sweden	4,493	8,986,400
Switzerland	3,725	7,450,867
Ukraine	23,866	47,732,079
United Kingdom	30,135	60,270,708

Source: MedMarket Diligence, LLC

¹³ US Census Bureau, International Data Base 2004

4.1.4 Asia/Pacific

4.1.4.1 Vision Disorders: Asia/Pacific

Exhibit 4-5: Asia-Pacific, Prevalence of Vision Disorders

Country/Region	Myopia Prevalence	Hyperopia Prevalence	Presbyopia Prevalence	Population Estimated Used ¹⁴
Australia	5,124,706	4,460,544	1,792,182	19,913,144
Bangladesh	36,374,387	31,660,266	12,720,642	141,340,476
China	334,262,259	290,941,862	116,896,286	1,298,847,624
Hong Kong	1,764,186	1,535,547	616,961	6,855,125
India	274,099,055	238,575,811	95,856,354	1,065,070,607
Indonesia	61,366,569	53,413,460	21,460,765	238,452,952
Japan	32,769,522	28,522,591	11,459,970	127,333,002
Malaysia	6,053,579	5,269,035	2,117,023	23,522,482
New Zealand	1,027,820	894,614	359,443	3,993,817
North Korea	5,841,282	5,084,251	2,042,780	22,697,553
Pakistan	40,969,645	35,659,978	14,327,670	159,196,336
Philippines	22,194,554	19,318,139	7,761,752	86,241,697
Russia	37,052,147	32,250,188	12,957,665	143,974,059
Singapore	1,120,487	975,272	391,850	4,353,893
South Korea	12,413,100	10,804,362	4,341,038	48,233,760
Taiwan	5,854,737	5,095,963	2,047,485	22,749,838
Thailand	16,693,333	14,529,876	5,837,897	64,865,523
Turkey	17,730,052	15,432,237	6,200,452	68,893,918
Ukraine	12,283,991	10,691,985	4,295,887	47,732,079
Vietnam	21,273,514	18,516,466	7,439,652	82,662,800

Source: MedMarket Diligence, LLC

¹⁴ US Census Bureau, International Data Base 2004

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5.4.2.3 GERMANY: Cataract Surgery Market

Exhibit 5-40: Germany Cataract Surgery Market, 2004-2012

GERMANY	2004	2005	2006	2007	2008	2009	2010	2011	2012
Prevalence (thousands)									
Cataracts	1,667	1,672	1,676	1,681	1,686	1,690	1,695	1,700	1,705
% Candidates for IOL Implants	80.0%	82.0%	82.5%	83.8%	84.0%	85.0%	86.0%	86.1%	86.2%
# Cataract Surgery Candidate Eyes	1,334	1,371	1,383	1,409	1,416	1,437	1,458	1,464	1,469
# Cataract Surgery Procedures	667	721	733	761	793	833	889	937	999
% Market Penetration	50.0%	52.6%	53.0%	54.0%	56.0%	58.0%	61.0%	64.0%	68.0%
Cost per Procedure*	\$160	\$170	\$180	\$210	\$255	\$300	\$325	\$370	\$400
Total Cataract Surgery Market (\$000s)	\$106,688	\$122,574	\$131,937	\$159,748	\$202,209	\$250,020	\$289,024	\$346,594	\$399,693

*Cost per procedure includes implantables and associated surgical equipment, not surgeon or facility fees.

Source: MedMarket Diligence, LLC

5.4.2.4 GERMANY: Cataract Surgery Market Share (%) by Company

Exhibit 5-41: Germany, Cataract Surgery Market Share by Company

	<u>2004</u>	<u>2005</u>	<u>2006</u>	<u>2007</u>	<u>2008</u>	<u>2009</u>	<u>2010</u>	<u>2011</u>	<u>2012</u>
Alcon	42.0%	40.8%	38.0%	37.2%	37.0%	35.0%	34.0%	32.0%	30.0%
AMO	20.0%	23.0%	23.2%	24.0%	24.0%	24.0%	22.0%	20.4%	19.9%
Bausch&Lomb	22.0%	18.8%	14.0%	13.0%	12.2%	11.0%	10.2%	9.6%	8.0%
STAAR	9.3%	10.0%	16.0%	15.5%	15.0%	14.8%	14.0%	13.2%	12.0%
Eyeonics	0.0%	0.0%	2.0%	3.5%	4.0%	5.0%	6.6%	7.2%	7.3%
CarlZeiss/IOLTech	0.0%	1.5%	3.0%	3.3%	4.3%	4.3%	4.4%	4.5%	4.6%
Calhoun	0.0%	0.0%	1.0%	1.6%	3.3%	5.3%	7.8%	9.0%	11.0%
Other	6.7%	5.9%	2.8%	1.9%	0.2%	0.6%	1.0%	4.1%	7.2%
TOTAL	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

Source: MedMarket Diligence, LLC

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6.1.2 Alcon Laboratories, Inc.

6.1.2.1 Overview

Alcon, Inc. is the world's leading eye care company with products in each of the major ophthalmic product categories and sales approaching \$5 billion. Alcon has a broad product portfolio with its most significant product offering in cataract and refractive surgery – including a strong intraocular lens business and associated surgical instruments in phacoemulsification. The company boasts a dominant market share in the hospital setting for its IOL products and a major share in ambulatory surgical centers (ASCs). In addition, Alcon's pharmaceutical franchise is strong with products in each of the major product categories with the exception of retina, which is a major area of focus for the company given the recent R&D investment in this segment. The smallest of its business segments is its consumer eye care business. Each of the business segments does business around the world with the United States being its largest market, accounting for approximately 50% of sales in each category.

6.1.2.2 Products

Alcon is the current market leader in the new class of IOLs that are used to treat presbyopia. Its ReSTOR lens has captured significant share. The company claims that ReSTOR is the preferred lens for bilateral implants with more than 70% of its use being in patients that receive two ReSTOR lenses.

Alcon is well positioned to penetrate the Toric IOL market with the AcrySof Toric lens. Today the company estimates that approximately 13% of cataract surgery surgeons are implanting Toric lenses – the number of surgeons implanting TIOLs is expected to grow five-fold in the next five years.

Exhibit 6-5: Alcon Pharmaceutical & Surgical Products

	Cataract Surgery	Refractive Surgery	Pharmaceuticals
Implantables	Monofocal IOLs: AcrySof AcrySof Natural, AcrySof Toric Multifocal IOL: ReSTOR		
Equipment	Infiniti Phaco system	LADARVision System OZil hand piece CustomCornea Wavefront LadarWave aberrometer	
Consumables	DisCoVisc		Allergy: Patanol, Naphcon-A Glaucoma: Travatan, Betoptic S, Azopt, Iopidine TobraDex, Vigamox, Ciloxan Dry Eye: Systane Inflammation: Nevanac, TobraDex, Vexol

Source: Alcon

Pipeline

In keeping with the importance of pharmaceutical products in the Alcon pipeline, Alcon will invest in additional products to treat glaucoma, allergy and dry eye with additional emphasis on retina and back of eye disorders. Much of its intended growth will come from adding to its product pipeline in international markets including;

Exhibit 6-6: Alcon Product Launches Adding to International Pipeline

Product	Category	Target Market
DuoTrav	Pharmaceutical	Europe
Opti-Free RepleniSH	Contact Lens Care	USA
AcrySof Natural	IOL	Japan
AcrySert	IOL	Japan
AcrySof Toric	IOL	USA
Systane Liquid Gel	Pharmaceutical – Dry Eye	USA
LADAR6000	Refractive Surgery	USA
OZil	Cataract Surgery Phaco instrument	USA/Europe
Vegamox	Pharmaceutical	Japan
Patanol	Pharmaceutical	Japan
Travatan BAC Free	Pharmaceutical – Glaucoma	USA
Retaane	Pharmaceutical – Wet AMD	USA
AcrySof ReSTOR	IOL	USA
AcrySof phakic lens	Refractive IOL	USA
Next Gen. Vitreoretinal Sys.	Surgery: Vitreoretinal	USA

Source: Alcon

More than 70% of Alcon's R&D investments in 2005 were for products that will treat age-related eye diseases – this includes conditions such as macular degeneration, macular edema, diabetic retinopathy and dry eye. In July 2006, Alcon announced a long-term agreement with Eli Lilly whereby Alcon will promote the use of a diabetic retinopathy drug, Arxxant, an investigational oral drug, to eye specialists. If approved by the FDA, Alcon will make milestone payments to Lilly and Alcon will be compensated based on product sales.

Financials

Exhibit 6-7: Alcon Revenue (Millions), 2003-2006

	2003	2004	2005	2006
Revenues	\$3,407	\$3,914	\$4,369	\$4,952 E

Source: Alcon

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APPENDIX A: Worldwide Prevalence of Vision Disorders

Country/Region	Myopia Prevalence	Hyperopia Prevalence	Presbyopia Prevalence	Population Estimated Used ⁴⁹
North America (Extrapolated Statistics)				
USA ⁵⁰	75,573,082	65,778,809	26,428,986	293,655,405
Canada	8,365,997	7,281,763	2,925,708	32,507,874
Mexico	27,011,660	23,510,948	9,446,363	104,959,594
South America (Extrapolated Statistics)				
Brazil	47,378,962	21,238,647	16,569,100	184,101,109
Chile	4,072,341	3,544,566	1,424,156	15,823,957
Colombia	10,882,802	9,477,613	3,807,970	42,310,775
Peru	7,088,607	6,169,924	2,478,990	27,544,305
Venezuela	6,438,298	5,603,894	2,251,564	25,017,387
Europe (Extrapolated Statistics)				
Austria	2,103,800	1,831,146	735,728	8,174,762
Belgium	2,663,159	2,318,013	931,344	10,348,276 ²
Denmark	1,393,152	1,212,600	487,205	5,413,392
France	15,550,349	13,535,023	5,438,180	60,424,213
Germany	21,212,215	18,463,112	7,418,215	82,424,609
Greece	2,740,172	2,385,046	958,277	10,647,529
Hungary	2,581,861	2,247,251	902,913	10,032,375
Netherlands	4,200,000	3,655,276	1,468,637	16,318,199
Italy	14,941,262	13,004,874	5,225,172	58,057,477
Poland	9,940,604	8,652,302	3,476,371	38,626,349
Portugal	2,708,419	2,357,408	947,173	10,524,145
Romania	5,753,266	5,007,643	2,012,000	22,355,551
Spain	10,366,377	9,022,894	3,625,270	40,280,780
Sweden	2,312,676	2,012,953	808,776	8,986,400
Switzerland	1,917,502	1,688,994	670,578	7,450,867
United Kingdom	15,510,844	13,500,638	5,424,363	60,270,708
Asia (Extrapolated Statistics)				
Australia	5,124,706	4,460,544	1,792,182	19,913,144
Bangladesh	36,374,387	31,660,266	12,720,642	141,340,476
China	334,262,259	290,941,862	116,896,286	1,298,847,624
Hong Kong s.a.r.	1,764,186	1,535,547	616,961	6,855,125
India	274,099,055	238,575,811	95,856,354	1,065,070,607
Indonesia	61,366,569	53,413,460	21,460,765	238,452,952
Japan	32,769,522	28,522,591	11,459,970	127,333,002
Malaysia	6,053,579	5,269,035	2,117,023	23,522,482
New Zealand	1,027,820	894,614	359,443	3,993,817
North Korea	5,841,282	5,084,251	2,042,780	22,697,553
Pakistan	40,969,645	35,659,978	14,327,670	159,196,336
Philippines	22,194,554	19,318,139	7,761,752	86,241,697
Russia	37,052,147	32,250,188	12,957,665	143,974,059
Singapore	1,120,487	975,272	391,850	4,353,893
South Korea	12,413,100	10,804,362	4,341,038	48,233,760

49 US Census Bureau, International Data Base 2004

50 US Census Bureau, Population Estimates 2004