

Advanced Technology IOLs (ATIOLs) Coding and Reimbursement Fact Sheet

What is an ATIOL?

Like conventional intraocular lenses (IOLs), ATIOLs provide the correction of aphakia post-cataract extraction, but they also provide an additional refractive treatment that may reduce the need for glasses after cataract surgery. This additional refractive property of the ATIOL is considered elective, not medically necessary, and therefore, the patient is responsible for the physician and facility charges related to the refractive component. Alcon’s AcrySof® IQ ReSTOR® and AcrySof® IQ Toric are considered advanced technology IOLs. Please see back page for Important Safety Information.

What are the special billing and reimbursement considerations for ATIOLs?

In 2005 and 2007, The Centers for Medicare and Medicaid Services (CMS) issued landmark Rulings that provide Medicare beneficiaries a choice between cataract surgery with a conventional IOL (a covered service and supply), or cataract surgery with an ATIOL (a partially covered service and partially covered supply). These Rulings established what is commonly referred to as the “two-aspect payment model” that allows the patient to pay out-of-pocket for the non-covered component of cataract surgery with the implantation of an ATIOL.

Summary of the CMS Rulings for presbyopia- and astigmatism-correcting intraocular lenses:

CMS Ruling	Date	Purpose
CMS 05-01 ¹	May 3, 2005	Set forth the CMS policy regarding the covered and non-covered aspect of presbyopia-correcting lenses and outlined the Medicare beneficiary’s responsibility for the non-covered item/services.
CMS 1536-R ²	January 22, 2007	Set forth the CMS policy regarding the covered and non-covered aspect of astigmatism-correcting lenses and outlined the Medicare beneficiary’s responsibility for the non-covered item/services.

What models are covered by the Medicare Rulings?

Alcon’s AcrySof® IQ ReSTOR® and AcrySof® IQ Toric intraocular lenses are included in the Medicare Rulings. Medicare publishes a list of CMS Recognized PC-IOLs (presbyopia-correcting intraocular lenses) and A-C IOLs (astigmatism-correcting intraocular lenses) on their website.³

Do we need to provide the patient with an Advanced Beneficiary Notice (ABN)?

Although an ABN is not required for services that are non-covered, the use of an ABN or NEMB (Notice of Exclusion from Health Plan Benefits for commercial payers) is strongly encouraged. Sample ABNs with language specific to Alcon’s ATIOLs are available on the Alcon Reimbursement Services website.

Do commercial plans provide coverage for ATIOLs, or do they allow the non-covered amount to be collected from the patient?

While many commercial plans mirror the Medicare Rulings, commercial plans vary and are subject to provider/payer agreements. It is crucial that providers consult with the specific plan for guidance.

1. Centers for Medicare and Medicaid Services, Ruling 05-01: <https://www.cms.gov/Rulings/downloads/CMSR0501.pdf>
 2. Centers for Medicare and Medicaid Services, Ruling CMS 1536-R: <https://www.cms.gov/Rulings/downloads/CMS1536R.pdf>
 3. <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/downloads/PCIOL-ACIOL.pdf>

What is the patient's responsibility for the implantation of the ATIOL?

As per the Medicare Rulings, the patient is responsible for the physician and facility charges for the services and supplies that exceed the charges for implantation of a conventional IOL following cataract surgery.

	COVERED	NON-COVERED	PATIENT'S RESPONSIBILITY
Physician	Surgery for treatment of cataract	Physician's services attributable to the non-covered functionality of the ATIOL (astigmatism and presbyopia correction). Additional physician work and resources required for insertion, fitting, and vision acuity testing.	Payment of charges for the physician services that exceed the physician charge for insertion of a conventional IOL.
Facility	Surgery for treatment of cataract	Astigmatism- or presbyopia correcting function of an IOL and any additional resources required for insertion, fitting, and vision acuity testing.	Payment of charges for the facility item / service that exceed the facility charge for insertion of a conventional IOL.

How do we determine the charges for the non-covered component of the ATIOL?

When determining the patient's responsibility for the non-covered aspect of the ATIOL, it is important to recognize that the service/item is partially covered. The patient should only be charged for the additional services provided by the physician that are clearly identifiable and solely related to the refractive component. And, the facility should only bill the patient for the portion of the IOL that is not covered by Medicare. For additional details on determining the patient's responsibility, please see Alcon Reimbursement Services Reimbursement Guide for ATIOLs.

What codes are associated with billing for ATIOLs?

CPT® Codes	Description	Notes
66982	Cataract surgery, complex	Facility reimbursement includes a payment for a conventional intraocular lens
66984	Cataract surgery with IOL, one stage	Facility reimbursement includes a payment for a conventional intraocular lens
HCPCS Codes	Description	Notes
V2787	Astigmatism-correcting function of an IOL (Use with AcrySof® IQ Toric.)	Used by physicians and facilities on Medicare claims to report the non-covered physician and facility charges for astigmatism-correcting IOLs like the AcrySof® IQ Toric
V2788	Presbyopia-correcting function of an IOL (Use with AcrySof® IQ ReSTOR)	Used by physicians and facilities on Medicare claims to report the non-covered physician and facility charges for presbyopia-correcting IOLs like the AcrySof® IQ ReSTOR®
V2632	Posterior chamber IOL	Hospitals may use to account for the covered component of the ATIOL
A9270	Noncovered item or service	Codes for billing non-covered services/items to commercial payers vary. It is important to consult with each payer for guidance.
S9986	Not medically necessary service (patient is aware that service not medically necessary)	
Diagnosis Codes		Notes
ICD-9-CM	ICD-10-CM	
367.2_	H52.2__	Astigmatism (Use with AcrySof® IQ Toric)
367.4	H52.4	Presbyopia (Use with AcrySof® IQ ReSTOR®)

Sample claim forms for each setting of care are included to illustrate billing options.

Physician Office

Sample CMS - 1500 Paper Claim Form

Alcon Reimbursement Services
(866)457-0277

ATIOL
SAMPLE CLAIM FORM

Use for billing physician services

HEALTH INSURANCE CLAIM FORM
APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

1. MEDICARE <input checked="" type="checkbox"/> MEDICAID <input type="checkbox"/> TRICARE <input type="checkbox"/> CHAMPVA <input type="checkbox"/> GROUP HEALTH PLAN <input type="checkbox"/> FECA BLK LUNG <input type="checkbox"/> OTHER <input type="checkbox"/>		1a. INSURED'S ID. NUMBER (For Program In Item 1) 123-45-6789							
2. PATIENT'S NAME (Last Name, First Name, Middle Initial) Smith, Jane N		4. INSURED'S NAME (Last Name, First Name, Middle Initial) Smith, Jane N							
3. PATIENT'S BIRTH DATE MM DD YY XX 09 15 99 XX		7. INSURED'S ADDRESS (No., Street) 123 Main Street							
5. PATIENT'S ADDRESS (No., Street) 123 Main Street		8. RESERVED FOR NUCC USE							
6. PATIENT RELATIONSHIP TO INSURED Self <input checked="" type="checkbox"/> Spouse <input type="checkbox"/> Child <input type="checkbox"/> Other <input type="checkbox"/>		11. INSURED'S POLICY GROUP OR FECA NUMBER							
CITY Anytown STATE USA		CITY Anytown STATE USA							
ZIP CODE 12345 TELEPHONE (Include Area Code) (203) 555-1234		ZIP CODE 12345 TELEPHONE (Include Area Code) (203) 555-1234							
9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)		10. IS PATIENT'S CONDITION RELATED TO:							
a. OTHER INSURED'S POLICY OR GROUP NUMBER		a. EMPLOYMENT? (Current or Previous) <input type="checkbox"/> YES <input type="checkbox"/> No							
b. RESERVED FOR NUCC USE		b. AUTO ACCIDENT? <input type="checkbox"/> YES <input type="checkbox"/> No PLACE (State)							
c. RESERVED FOR NUCC USE		a. EMPLOYMENT? (Current or Previous) <input type="checkbox"/> YES <input type="checkbox"/> No							
d. INSURANCE PLAN NAME OR PROGRAM NAME		10d. CLAIM CODES (Designated by NUCC)							
12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment below.									
13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below.									
14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) 01 01 2014		15. OTHER DATE QUAL MM DD YY							
17. NAME OF REFERRING PROVIDER OR OTHER SOURCE		17a. CURRENT SERVICES MM DD YY							
19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)		17b. CHARGES MM DD YY							
21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD-10d									
A. 366.xx B. XXX.XX									
24. A. DATE(S) OF SERVICE B. PLACE OF SERVICE C. D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) E. DIAGNOSIS POINTER F. CHARGES G. DAYS OR UNITS H. ICD-10 I.D. QUAL. J. RENDERING PROVIDER I.D.#									
1	07 31 14	07 31 14	66984 RT	A	XXX.XX				
2	07 31 14	07 31 14	V2787 GY	B	XX.XX				
3	07 31 14	07 31 14	or V2788 G	B	XX.XX				
4									
5									
6									
25. FEDERAL TAX ID NUMBER SSN EIN		26. PATIENT SIGNATURE		28. TO WHOM SERVICE IS TO BE RENDERED		29. BILLING PROVIDER INFO & PH#		30. BILLING PROVIDER I.D.#	
31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREE OR CREDENTIALS		32. SERVICE FACILITY LOCATION INFORMATION		33. BILLING PROVIDER INFO & PH#		34. BILLING PROVIDER I.D.#		35. BILLING PROVIDER I.D.#	

AcrySof®
IQ Toric®

V2787 (Astigmatism correcting function of intraocular lens)

Include appropriate secondary diagnosis code to describe refractive condition. For example, 367.4, presbyopia, or 367.2, astigmatism.

AcrySof®
IQ ReSTOR®

V2788 (Presbyopia correcting function of intraocular lens)

Modifier GY - (Item or service statutorily excluded or does not meet the definition of any Medicare benefit)

Customary charges for non-covered services equals patient payment.

Note regarding commercial payors: Some payors may not recognize code V2788 and may require another code for reporting non-covered services (eg; A9270, non-covered item or service)

¹www.cms.hhs.gov/MLNMattersArticles/downloads/MM5527.pdf

Gray: required
Blue: if requested by the patient

Information contained in this document is provided as a reference for providers in obtaining appropriate and accurate reimbursement. Content within the document is for information purposes only. Alcon does not guarantee that the use of the recommended codes will result in reimbursement. Providers may always contact the payer directly in regards to any reimbursement or billing questions.



(866) 457-0277 | ARS.SupportUS@alcon.com

NOTE: CMS does not require non-covered services to be listed on the claim form. The code recommended above should be used if a patient requests a denial and/or for facility tracking of non-covered charges.¹

Ambulatory Surgery Center

Sample CMS - 1500 Paper Claim Form

Alcon Reimbursement Services
(866)457-0277

ATIOL
SAMPLE CLAIM FORM

Use for billing in ASC setting

HEALTH INSURANCE CLAIM FORM

APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

1. MEDICARE <input checked="" type="checkbox"/> MEDICAID <input type="checkbox"/> TRICARE <input type="checkbox"/> CHAMPVA <input type="checkbox"/> GROUP HEALTH PLAN <input type="checkbox"/> FECA/BLK LUNG <input type="checkbox"/> OTHER <input type="checkbox"/>		1a. INSURED'S I.D. NUMBER (For Program In Item 1) 123-45-6789	
2. PATIENT'S NAME (Last Name, First Name, Middle Initial) Smith, Jane N		3. PATIENT'S BIRTH DATE MM DD YY XX M F <input checked="" type="checkbox"/>	
4. INSURED'S NAME (Last Name, First Name, Middle Initial) Smith, Jane N		5. INSURED'S BIRTH DATE MM DD YY XX M F <input type="checkbox"/>	
5. PATIENT'S ADDRESS (No. Street) 123 Main Street		6. PATIENT RELATIONSHIP TO INSURED Self <input checked="" type="checkbox"/> Spouse <input type="checkbox"/> Child <input type="checkbox"/> Other <input type="checkbox"/>	
7. INSURED'S ADDRESS (No. Street) 123 Main Street		8. RESERVED FOR NUCC USE	
CITY Anytown		CITY Anytown	
STATE USA		STATE USA	
ZIP CODE 12345		ZIP CODE 12345	
TELEPHONE (Include Area Code) (203) 555-1234		TELEPHONE (Include Area Code) (203) 555-1234	
9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)		10. IS PATIENT'S CONDITION RELATED TO:	
a. OTHER INSURED'S POLICY OR GROUP NUMBER		a. EMPLOYMENT? (Current or Previous) <input type="checkbox"/> YES <input type="checkbox"/> No	
b. RESERVED FOR NUCC USE		b. AUTO ACCIDENT? <input type="checkbox"/> YES <input type="checkbox"/> No PLACE (State)	
c. RESERVED FOR NUCC USE		c. EMPLOYMENT? (Current or Previous) <input type="checkbox"/> YES <input type="checkbox"/> No	
d. INSURANCE PLAN NAME OR PROGRAM NAME		10d. CLAIM CODES (Designated by NUCC)	
11. INSURED'S POLICY GROUP OR FECA NUMBER		11. INSURED'S DATE OF BIRTH MM DD YY XX M F <input type="checkbox"/>	
a. INSURED'S DATE OF BIRTH		SEX M <input type="checkbox"/> F <input type="checkbox"/>	
b. OTHER CLAIM ID (Designated by NUCC)		c. INSURANCE PLAN NAME OR PROGRAM NAME	
d. IS THERE ANOTHER HEALTH BENEFIT PLAN? <input type="checkbox"/> YES <input type="checkbox"/> No If yes, complete items 9, 9a, and 9d.		13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below.	
12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment below.			
SIGNED _____ DATE _____		SIGNED _____ DATE _____	
14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) 01 01 2014		15. OTHER DATE QUAL MM DD YY	
17. NAME OF REFERRING PROVIDER OR OTHER SOURCE		16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION FROM MM DD YY TO MM DD YY	
19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)		CURRENT SERVICES MM DD YY	
21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD-10		CHARGES	
A. 366.XX B. V2787		REF. NO.	
E. F. G. H. I. J. K. L.			
24. A. DATES(S) OF SERVICE		D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances)	
B. PLACE OF SERVICE		E. DIAGNOSIS POINTER	
C. EMG		F. CHARGES	
		G. DAYS OR UNITS	
		H. EPST PLAN	
		I. I.D. QUAL	
		J. RENDERING PROVIDER I.D.#	
1 07 31 14 07 31 14		66984 RT A XXXXX	
2 07 31 14 07 31 14		V2787 GY B XXXX	
3 07 31 14 07 31 14		or V2788 G B XXXX	
4			
5			
6			
25. FEDERAL TAX IDENTIFICATION NUMBER SSN EIN		26. PATIENT'S SIGNATURE	
27. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREE OR CREDENTIALS		28. T. UCC Usa	
31. SIGNATURE OF PHYSICIAN OR SUPPLIER		32. SERVICE FACILITY LOCATION INFORMATION	
SIGNED _____ DATE _____		a. b. c. d. e. f. g. h. i. j. k. l. m. n. o. p. q. r. s. t. u. v. w. x. y. z.	

AcrySof®
IQ Toric®

V2787 (Astigmatism correcting function of intraocular lens)

Include appropriate secondary diagnosis code to describe refractive condition. For example, 367.4, presbyopia, or 367.2, astigmatism.

AcrySof®
IQ ReSTOR®

V2788 (Presbyopia correcting function of intraocular lens)

Modifier GY - (Item or service statutorily excluded or does not meet the definition of any Medicare benefit)

Non-covered charges - Facility charge for surgery with ATIOL MINUS facility charge for surgery with conventional IOL EQUALS patient payment.

Note regarding commercial payors: Some payors may not recognize code V2788 and may require another code for reporting non-covered services (eg: A9270, non-covered item or service)

¹www.cms.hhs.gov/MLN MattersArticles/downloads/MM5527.pdf

Gray: required
Blue: if requested by the patient

Information contained in this document is provided as a reference for providers in obtaining appropriate and accurate reimbursement. Content within the document is for information purposes only. Alcon does not guarantee that the use of the recommended codes will result in reimbursement. Providers may always contact the payer directly in regards to any reimbursement or billing questions.



(866) 457-0277 | ARS.SupportUS@alcon.com

NOTE: CMS does not require non-covered services to be listed on the claim form. The code recommended above should be used if a patient requests a denial and/or for facility tracking of non-covered charges.¹

Hospital Outpatient Fact Sheet

Sample UB-04 Paper Claim Form

Alcon Reimbursement Services
(866)457-0277

ATIOL SAMPLE CLAIM FORM
Use for billing in hospital setting

AcrySof®
IQ Toric®

V2787 (Astigmatism correcting function of intraocular lens)

AcrySof®
IQ ReSTOR®

V2788 (Presbyopia correcting function of intraocular lens)

List charge for cataract surgery (which includes STANDARD monofocal IOL).

Non-covered charges - Facility charge for surgery with Toric IOL MINUS facility charge for surgery with conventional IOL EQUALS patient payment.

Include appropriate secondary diagnosis code to describe refractive condition. For example, 367.4, presbyopia, or 367.2, astigmatism.

42 REV CD	43 DESCRIPTION	44 HCPCS / RATE / HPPS CODE	45 SERV DATE	46 SERV UNITS	47 TOTAL CHARGES	48 UNDISCOUNTED CHARGES	49
0363	Surgery	66984RT/LT	01-01-12	1	X,XXX .XX		
025X	Pharmacy		01-01-12	1	XXX .XX		
0276	IOL	V2632	01-01-12	1	001 .00		
037X	Anesthesia	00142	01-01-12	1	XXX .XX		
027X	Supplies		01-01-12	1	XXX .XX		
0276	Astigmatism or Presbyopia correcting function	V2787 or V2788	01-01-12	1		XXX .XX	

50 PAYER NAME	51 HEALTH PLAN ID	52 BILL INFO	53 PMS BIN	54 PRIOR PAYMENTS	55 EST AMOUNT DUE	56 NPI
						57 OTHER PRIV ID
58 INSURED'S NAME	61 GROUP NAME	62 INSURANCE GROUP NO.				
63 TREATMENT AUTHORIZATION CODES	65 EMPLOYER NAME					
66 DK	67 A B C D E F G H	68				
69 ADMIT DX	70 PATIENT REASON DX	71 PPS CODE	72 EC	73		
	366.xx XXX.XX					
74 PRINCIPAL PROCEDURE CODE	75 OTHER PROCEDURE CODE	76 ATTENDING NPI	77 OPERATING NPI	78 OTHER NPI	79 OTHER NPI	
80 REMARKS	81 CC a b c d					

The items listed on this claim form are not intended to be comprehensive of all services and supplies provided.

AcrySof® IQ ReSTOR® IOL (Models SN6AD3 and SN6AD1)

Patient Brief Statement

09.23.11

CAUTION:

Restricted by law to sale by or on the order of a physician.

DESCRIPTION:

The AcrySof® IQ ReSTOR® Intraocular Lenses (IOLs) are artificial lenses implanted in the eye of adult patients following cataract surgery. These lenses are designed to allow for clear distance, intermediate, and near vision with the potential to be more independent of the need to use glasses for daily tasks.

WARNINGS / PRECAUTIONS:

You may experience and need to contact your eye doctor immediately if you have any of the following symptoms while using the antibiotic eye drops prescribed by your doctor: itching, redness, watering of your eye, sensitivity to light. The safety and effectiveness of the AcrySof® IQ ReSTOR® IOL has not been established in patients with eye conditions, such as an increase in eye pressure (glaucoma) or complications of diabetes in the eye (diabetic retinopathy). As with any surgical procedure, there are risks involved. These risks may include but are not limited to infection, damage to the lining of the cornea, the retinal layer which lines the inside back wall of your eye may become separated from the tissue next to it (retinal detachment), inflammation or swelling inside or outside the eye, damage to the iris (the colored diaphragm around the pupil), an increase in eye pressure that cannot be controlled by medicine and secondary surgical procedure. With this IOL, there may be a loss of sharpness of your vision that may become worse in dim light or in foggy conditions. There is also a possibility that you may have some visual effects such as rings or circles around lights at night. You may also have trouble seeing street signs due to bright lights or glare from oncoming headlights.

ATTENTION:

As with any surgical procedure, there are risks involved. Prior to surgery, ask your eye doctor to provide you with an AcrySof® IQ ReSTOR® IOL Patient Information Brochure, which will inform you of the risks and benefits associated with this IOL. Discuss any questions about possible risks and benefits with your eye doctor.

AcrySof® IQ Toric IOL (Models SN6AT3-T9)

Patient Brief Statement

08.25.11

CAUTION:

Restricted by law to sale by or on the order of a physician.

DESCRIPTION:

The AcrySof® IQ Toric Intraocular Lenses (IOLs) are artificial lenses implanted in the eye of adult patients following cataract surgery. These lenses are designed to correct pre-existing corneal astigmatism, which is the inability of the eye to focus clearly at any distance because of difference curvatures on the cornea, and provide distance vision.

WARNINGS / PRECAUTIONS:

You may experience and need to contact your eye doctor immediately if you have any of the following symptoms while using the antibiotic eye drops prescribed by your doctor: itching, redness, watering of your eye, sensitivity to light. The safety and effectiveness of the AcrySof® IQ Toric IOL has not been established in patients with eye conditions, such as an increase in eye pressure (glaucoma) or complications of diabetes in the eye (diabetic retinopathy). As with any surgical procedure, there are risks involved. These risks may include but are not limited to infection, damage to the lining of the cornea, the retinal layer which lines the inside back wall of your eye may become separated from the tissue next to it (retinal detachment), inflammation or swelling inside or outside the eye, damage to the iris (the colored diaphragm around the pupil), an increase in eye pressure that cannot be controlled by medicine and secondary surgical procedure. A toric IOL corrects astigmatism only when it is placed in the correct position in the eye. There is a possibility that the toric IOL could be placed incorrectly or could move within the eye. This may result in less improvement or a reduction in vision because your astigmatism has not been fully corrected, or it may cause visual symptoms.

ATTENTION:

As with any surgical procedure, there are risks involved. Prior to surgery, ask your eye doctor to provide you with an AcrySof® IQ Toric Patient Information Brochure, which will inform you of the risks and benefits associated with this IOL. Discuss any questions about possible risks and benefits with your eye doctor.

AcrySof® IQ ReSTOR® Intraocular Lenses Physician Brief Statement

CAUTION:

Restricted by law to sale by or on the order of a physician.

DESCRIPTION: The AcrySof® IQ ReSTOR® Intraocular Lenses (IOLs) are artificial lenses implanted in the eye of adult patients following cataract surgery. These lenses are designed to allow for clear distance, intermediate, and near vision with the potential to be more independent of the need to use glasses for daily tasks.

WARNINGS / PRECAUTIONS:

You may experience and need to contact your eye doctor immediately if you have any of the following symptoms while using the antibiotic eye drops prescribed by your doctor: itching, redness, watering of your eye, sensitivity to light. The safety and effectiveness of the AcrySof® IQ ReSTOR® IOL has not been established in patients with eye conditions, such as an increase in eye pressure (glaucoma) or complications of diabetes in the eye (diabetic retinopathy). As with any surgical procedure, there are risks involved. These risks may include but are not limited to infection, damage to the lining of the cornea, the retinal layer which lines the inside back wall of your eye may become separated from the tissue next to it (retinal detachment), inflammation or swelling inside or outside the eye, damage to the iris (the colored diaphragm around the pupil), an increase in eye pressure that cannot be controlled by medicine and secondary surgical procedure. With this IOL, there may be a loss of sharpness of your vision that may become worse in dim light or in foggy conditions. There is also a possibility that you may have some visual effects such as rings or circles around lights at night. You may also have trouble seeing street signs due to bright lights or glare from oncoming headlights.

ATTENTION:

As with any surgical procedure, there are risks involved. Prior to surgery, ask your eye doctor to provide you with an AcrySof® IQ ReSTOR® IOL Patient Information Brochure, which will inform you of the risks and benefits associated with this IOL. Discuss any questions about possible risks and benefits with your eye doctor.

AcrySof® IQ Toric Intraocular Lenses Physician Brief Statement

CAUTION:

Federal (USA) law restricts this device to the sale by or on the order of a physician.

DESCRIPTION:

The AcrySof® IQ Toric posterior chamber intraocular lenses are intended for primary implantation in the capsular bag of the eye for visual correction of aphakia and pre-existing corneal astigmatism secondary to removal of a cataractous lens in adult patients with or without presbyopia, who desire improved uncorrected distance vision, reduction of residual refractive cylinder and increased spectacle independence for distance vision.

WARNINGS / PRECAUTIONS:

Careful preoperative evaluation and sound clinical judgment should be used by the surgeon to decide the risk/benefit ratio before implanting a lens in a patient with any of the conditions described in the Directions for Use labeling. Toric IOLs should not be implanted if the posterior capsule is ruptured, if the zonules are damaged, or if a primary posterior capsulotomy is planned. Rotation can reduce astigmatic correction; if necessary lens repositioning should occur as early as possible prior to lens encapsulation. All viscoelastics should be removed from both the anterior and posterior sides of the lens; residual viscoelastics may allow the lens to rotate.

Optical theory suggests that high astigmatic patients (i.e. > 2.5 D) may experience spatial distortions. Possible toric IOL related factors may include residual cylindrical error or axis misalignments. Prior to surgery, physicians should provide prospective patients with a copy of the Patient Information Brochure available from Alcon for this product informing them of possible risks and benefits associated with the AcrySof® IQ Toric Cylinder Power IOLs.

Studies have shown that color vision discrimination is not adversely affected in individuals with the AcrySof® Natural IOL and normal color vision. The effect on vision of the AcrySof® Natural IOL in subjects with hereditary color vision defects and acquired color vision defects secondary to ocular disease (e.g., glaucoma, diabetic retinopathy, chronic uveitis, and other retinal or optic nerve diseases) has not been studied. Do not resterilize; do not store over 45° C; use only sterile irrigating solutions such as BSS® or BSS PLUS® Sterile Intraocular Irrigating Solutions.

ATTENTION:

Reference the Directions for Use labeling for a complete listing of indications, warnings and precautions.



(866) 457-0277 | ARS.SupportUS@alcon.com

<http://ars.alcon.com>

© 2014 Novartis 12/14 IOL14029RM

Alcon[®]
a Novartis company