

# Healthcare Common Procedure Coding System (HCPCS)



HCPCS Code		IOL Model		CMS Payment Category
<b>V2632</b> Posterior chamber intraocular lens	SN60AT MN60AC MA30AC MA60AC MA50BM	MN60MA MA60MA AU00T0 SA60AT SA60WF	SN60WF CCA0T0 CNA0T0 CZ70BD ACU0T0 SY60WF	Packaged service / item; no separate payment made
<b>V2630</b> Anterior chamber intraocular lens	MTA3U0	MTA4U0	MTA5U0	Packaged service / item; no separate payment made
V2787 Astigmatism-correcting function of intraocular lens (covered conventional IOL component may be reported as V2632)	SA6AT3 SA6AT4 SA6AT5 SA6AT6 SA6AT7 SA6AT8 SA6AT9 CNA0T3 CNA0T4 CNA0T5	CNAOT6 CNAOT7 CNAOT8 CNAOT9 SN6AT3 SN6AT4 SN6AT5 SN6AT6 SN6AT7	SN6AT8 SN6AT9 CNW0T3 CNW0T4 CNW0T5 CNW0T6 CNW0T7 CNW0T8 CNW0T9	Two-aspect reimbursement; see CMS Ruling 1536-R regarding patient responsibility for astigmatism-correcting IOLs
V2788 Presbyopia-correcting function of intraocular lens (covered conventional IOL component may be reported as V2632)	SN6AD1 MN6AD1 SND1T3 SND1T4 SND1T5 SND1T6 SV25T0 SV25T3 SV25T4 SV25T5 SV25T6 SA25T0 SA25T3 SA25T4 SA25T5 SA25T6 SA25T6 SA6AD1 TFNT00 TFNT30	TFNT50 TFNT60 TFAT00 TFAT30 TFAT40 TFAT50 TFAT60 DFT015 DAT015 DFT315 DFT415 DFT515 DFT515 DAT315 DAT415 DAT515 DAT615 CNWTT0 CCWTT0	CNATTO CNWTT3 CNWTT4 CNWTT5 CNWTT6 CNATT3 CNATT4 CNATT5 CNATT6 CCWET0 CCWET3 CCWET4 CCWET5 CCWET6 CNWET5 CNWET6 CNWET5 CNWET5 CNWET6 CNWET5 CNWET6	Two-aspect reimbursement; see CMS Ruling 05-01 regarding patient responsibility for presbyopia-correcting IOLs



# Clareon® Aspheric Hydrophobic Acrylic IOL with the AutonoMe® Automated Pre-loaded Delivery System Important Product Information

## Caution

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

### Indications

The Clareon® Aspheric Hydrophobic Acrylic Intraocular Lens (IOL) is indicated for primary implantation in the capsular bag in the posterior chamber of the eye for the visual correction of aphakia in adult patients in whom a cataractous lens has been removed.

## 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 The Clareon® IOL is intended for implantation in the capsular bag only. Physicians considering lens implantation under any of the following circumstances should weigh the potential risk / benefit ratio: Patients in whom the posterior capsule is ruptured, zonules are damaged, or primary posterior capsulotomy is planned.

DO NOT re-sterilize the Clareon® IOL or the AutonoMe® Delivery System by any method. DO NOT implant the IOL if the sterility has been compromised or if the sterile package has been unintentionally opened before use. DO NOT reuse the Clareon® IOL or AutonoMe® Delivery System. The device is for single use only.

The safety and effectiveness of the Clareon® IOL has not been substantiated in clinical trials in patients with certain pre-existing conditions and / or intraoperative conditions (listed in Tables 4 and 5 of the Directions for Use).

As with any surgical procedure, there is risk involved. Potential complications accompanying cataract and / or IOL implantation surgery may include, but are not limited to, the following: lens epithelial cell ongrowth, corneal endothelial cell damage, infection (endophthalmitis), toxic anterior segment syndrome (TASS), retinal detachment, vitritis, cystoid macular edema, corneal edema, pupillary block, cyclitic membrane, iris prolapse, hypopyon, anterior uveitis, hyphema, pigment dispersion, posterior capsule opacification, transient or persistent glaucoma, and secondary surgical interventions. 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. 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**

Refer to the Directions for Use labeling for a complete list of indications, warnings, and precautions.



## AcrySof® IQ ReSTOR® Family of Multifocal IOLs Important Product Information

## Caution

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

## **Indications**

The AcrySof® IQ ReSTOR® Posterior Chamber Intraocular Multifocal IOLs include AcrySof® IQ ReSTOR® and AcrySof® ReSTOR® Toric and are intended for primary implantation for the visual correction of aphakia secondary to removal of a cataractous lens in adult patients with and without presbyopia, who desire near, intermediate and distance vision with increased spectacle independence. In addition, the AcrySof® IQ ReSTOR® Toric IOL is intended to correct pre-existing astigmatism. The lenses are intended to be placed in the capsular bag.

## **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 for each IOL. Physicians should target emmetropia, and ensure that IOL centration is achieved. Care should be taken to remove viscoelastic from the eye at the close of surgery.

The ReSTOR® Toric IOL 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.

Some patients may experience visual disturbances and / or discomfort due to multifocality, especially under dim light conditions. A reduction in contrast sensitivity may occur in low light conditions. Visual symptoms may be significant enough that the patient will request explant of the multifocal IOL. Spectacle independence rates vary; some patients may need glasses when reading small print or looking at small objects.

Posterior capsule opacification (PCO), when present, may develop earlier into clinically significant PCO with multifocal IOLs. Prior to surgery, physicians should provide prospective patients with a copy of the Patient Information Brochure available from Alcon informing them of possible risks and benefits associated with the AcrySof® IQ ReSTOR® IOLs.

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 each IOL for a complete listing of indications, warnings, and precautions.





## UltraSert® Pre-loaded IOL Delivery System with the AcrySof® IQ Aspheric IOL **Important Product Information**

## **Caution**

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

## **Indications**

The AcrySof® IQ Aspheric Intraocular Lens ("AcrySof® IQ") is intended for the replacement of the human lens to achieve visual correction of aphakia in adult patients following cataract surgery. This lens is intended for placement in the capsular bag.

Use the UltraSert® Pre-loaded Delivery System ("UltraSert®") at temperatures between 18°C (64°F) and 23°C (73°F). Use only Alcon viscoelastics qualified for this device. Do not use the UltraSert® if the nozzle appears damaged or deformed. Follow the Directions for Use for correct order and sequence of steps to avoid damage to the IOL or the UltraSert®.

Careful preoperative evaluation and sound clinical judgement 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. Caution should be used prior to lens encapsulation to avoid lens decentrations or dislocations. Studies have shown that color vision discrimination is not adversely affected in the 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.

Reference the Directions for Use for Model AU00T0 for a complete listing of indications, warnings and precautions.



# AcrySof® IQ PanOptix® Family of Trifocal IOLs **Important Product Information**

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

The AcrySof® IQ PanOptix® Trifocal IOL is a type of multifocal IOL used to focus images clearly onto the back of your eye (retina) to allow clear vision after the cataract removal. In addition, the center of the AcrySof® IQ PanOptix® Trifocal IOL allows for better near (reading) vision and intermediate (computer work) vision versus what a monofocal lens would provide.

There is a chance that you still may need glasses for distance, intermediate, and / or near vision. You will get the full benefit of the AcrySof® IQ PanOptix® Trifocal IOL when it is placed in both eyes. Please discuss with your eye doctor whether this is the right IOL for you.

## Warning / Precaution

Due to the design of multifocal IOLs, there are some side effects that can be associated with the AcrySof® IQ PanOptix® Trifocal IOL models. These may be worse than with a monofocal IOL, including visual disturbances such as glare, rings around lights, starbursts (rays around light sources), and reduced contrast sensitivity (decrease in ability to distinguish objects from their background, especially in dim lighting). These side effects may make it more difficult to see while driving at night or completing tasks in low lighting conditions, such as at night or in fog or in a dimly lit room, after surgery as compared to before surgery.

Further, 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. If the toric lens is not positioned correctly following surgery, the change in your astigmatism correction by the IOL, along with any necessary correction with glasses, may cause visual distortions. If the lens rotates in your eye, you may need additional surgery to reposition or replace the IOL.

As with any surgical procedure, there are risks involved. Prior to surgery, ask your eye doctor to provide you with the Patient Information Brochure for the proposed AcrySof® IQ PanOptix® Trifocal IOL to be implanted. This document will further inform you of the risks and benefits associated with this IOL. Discuss any questions about possible risks and benefits with your eye doctor, as well as your medical condition and any eye disease you may have.



## **AcrySof® IQ Vivity™ Family of Extended Vision IOLs Important Product Information**

## Caution

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

## **Indications**

The AcrySof® IQ Vivity™ Extended Vision IOLs include AcrySof® IQ Vivity™ and AcrySof® IQ Vivity™ Toric IOLs and are indicated for primary implantation for the visual correction of aphakia in adult patients with < 1.00 D of preoperative corneal astigmatism, in whom a cataractous lens has been removed by extracapsular cataract extraction. The lens mitigates the effects of presbyopia by providing an extended depth of focus. Compared to an aspheric monofocal IOL, the lens provides improved intermediate and near visual acuity, while maintaining comparable distance visual acuity. The AcrySof® IQ Vivity™ IOL is intended for capsular bag placement only. In addition, the AcrySof® IQ Vivity™ Toric IOL is indicated for the reduction of residual refractive astigmatism in adult patients with pre-existing corneal astigmatism.

## **Warning / Precaution**

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.

This lens 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.

Most patients implanted with the AcrySof® IQ Vivity™ IOL are likely to experience significant loss of contrast sensitivity as compared to a monofocal IOL. Therefore, it is essential that prospective patients be fully informed of this risk before giving their consent for implantation of the AcrySof® IQ Vivity™ IOL. In addition, patients should be warned that they will need to exercise caution when engaging in activities that require good vision in dimly lit environments, such as driving at night or in poor visibility conditions, especially in the presence of oncoming traffic.

It is possible to experience very bothersome visual disturbances, significant enough that the patient could request explant of the IOL. In the AcrySof® IQ Vivity™ IOL clinical study, 1% to 2% of AcrySof® IQ Vivity™ IOL patients reported very bothersome starbursts, halos, blurred vision, or dark area visual disturbances; however, no explants were reported.

Prior to surgery, physicians should provide prospective patients with a copy of the Patient Information Brochure available from Alcon informing them of possible risks and benefits associated with the AcrySof® IQ Vivity™ IOLs.

### Attention

As with any surgical procedure, there are risks involved. Prior to surgery, ask your eye doctor to provide you with the Patient Information Brochure for the proposed AcrySof® IQ PanOptix® Trifocal IOL to be implanted. This document will further inform you of the risks and benefits associated with this IOL. Discuss any questions about possible risks and benefits with your eye doctor, as well as your medical condition and any eye disease you may have.



# Clareon® Family of IOLs Important Product Information

## Caution

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

## **Indications**

The family of Clareon® intraocular lenses (IOLs) includes the Clareon® Aspheric Hydrophobic Acrylic and Clareon® Aspheric Toric IOLs, the Clareon® PanOptix® Trifocal Hydrophobic IOL, Clareon® PanOptix® Toric, Clareon® Vivity™ Extended Vision Hydrophobic Posterior Chamber IOL and Clareon® Vivity™ Toric IOLs. Each of these IOLs is indicated for visual correction of aphakia in adult patients following cataract surgery. In addition, the Clareon® Toric IOLs are indicated to correct pre-existing corneal astigmatism at the time of cataract surgery. The Clareon® PanOptix® lens mitigates the effects of presbyopia by providing improved intermediate and near visual acuity, while maintaining comparable distance visual acuity with a reduced need for eyeglasses, compared to a monofocal IOL. The Clareon® Vivity™ lens mitigates the effects of presbyopia by providing an extended depth of focus. Compared to an aspheric monofocal IOL, the lens provides improved intermediate and near visual acuity, while maintaining comparable distance visual acuity. All of these IOLs are intended for placement in the capsular bag.

## **Warnings / Precautions**

## General cautions for all Clareon® IOLs:

Careful preoperative evaluation and sound clinical judgment should be used by the surgeon to decide the risk / benefit ratio before implanting any IOL in a patient with any of the conditions described in the Directions for Use that accompany each IOL. Physicians should target emmetropia, and ensure that IOL centration is achieved.

For the Clareon® Aspheric Toric, PanOptix® Toric and Vivity™ Toric IOLs, the lens 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.

For the Clareon® PanOptix® IOL, some visual effects may be expected due to the superposition of focused and unfocused multiple images. These may include some perceptions of halos or starbursts, as well as other visual symptoms. As with other multifocal IOLs, there is a possibility that visual symptoms may be significant enough that the patient will request explant of the multifocal IOL. A reduction in contrast sensitivity as compared to a monofocal IOL may be experienced by some patients and may be more prevalent in low lighting conditions. Therefore, patients implanted with multifocal IOLs should exercise caution when driving at night or in poor visibility conditions. Patients should be advised that unexpected outcomes could lead to continued spectacle dependence or the need for secondary surgical intervention (e.g., intraocular lens replacement or repositioning). As with other multifocal IOLs, patients may need glasses when reading small print or looking at small objects. Posterior capsule opacification (PCO), may significantly affect the vision of patients with multifocal IOLs sooner in its progression than patients with monofocal IOLs.

For the Clareon® Vivity™ IOL, most patients implanted with the Vivity™ IOL are likely to experience significant loss of contrast sensitivity as compared to a monofocal IOL. Therefore, it is essential that prospective patients be fully informed of this risk before giving their consent for implantation of the Clareon® Vivity™ IOL. In addition, patients should be warned that they will need to exercise caution when engaging in activities that require good vision in dimly lit environments, such as driving at night or in poor visibility conditions, especially in the presence of oncoming traffic. It is possible to experience very bothersome visual disturbances, significant enough that the patient could request explant of the IOL. In the parent AcrySof® IQ Vivity™ IOL clinical study, 1% to 2% of AcrySof® IQ Vivity™ IOL patients reported very bothersome starbursts, halos, blurred vision, or dark area visual disturbances; however, no explants were reported.

Prior to surgery, physicians should provide prospective patients with a copy of the Patient Information Brochure available from Alcon informing them of possible risks and benefits associated with these IOLs.

## **Attention**

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

