Innovative Technologies Designed to Meet the Needs of Surgeons and their Patients

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Unlocking the potential of the supraciliary space

By Nathan Radcliffe, MD

Over the past 4 years or so, many cataract surgeons have become familiar with the ab interno approach to minimally invasive glaucoma surgery (MIGS). For many of us, this has been achieved by implanting trabecular microbypass stents. In the more recent years, we have had alternative approaches to addressing glaucoma through the angle, such as ab interno goniotomy and ab interno viscocanalostomy. As a result, we are becoming familiar and comfortable with the algorithm of treating glaucoma in the angle at the time of cataract surgery.

The ciliary body represents a large, easily visualized, and easily treatable target that can be comfortably approached using intraoperative gonioscopy at the time of cataract surgery. Unlike the trabecular meshwork, which varies in pigmentation, appearance, and microanatomy, the ciliary body can be reliably found at the iris root. The CyPass Micro-Stent is placed into the supraciliary space under gonioscopic visualization after cataract extraction and intraocular lens implantation.

My experience has been that the ciliary body is the easiest landmark to identify gonioscopically, and the tissue has also been the most intuitive target to hit with the supraciliary stent. When we target the trabecular meshwork, we know there is a floor in terms of how low we can get the intraocular pressure because we will have additional resistance to the remainder of Schlemm’s canal, the collector channels, and the episcleral venous system. Episcleral venous pressures can typically be around 12 mm Hg, so with the added resistance, trabecular bypass can often result in pressures higher than that.

The ciliary space presents a unique opportunity to achieve significant pressure reduction in a safe and minimally invasive manner. The design of the CyPass Micro-Stent provides a level of resistance to aqueous outflow, and the supraciliary space provides access to the uveoscleral outflow pathway, whereby the intraocular pressure will not be limited by episcleral venous pressure. Significant pressure reduction can occur, and, because the tip of the CyPass Micro-Stent remains in the angle and free of obstruction, iris adhesions and other forms of scar formation are less likely to influence pressure reduction. Because we are accessing a space with so much pressure-lowering potential and using a microstent that is designed to protect against clinically significant hypotony, we are maximizing the potential of the supraciliary space without compromising on safety as compared to cataract surgery alone. Therefore, it makes so much sense to approach the supraciliary space using a MIGS implant—so that we can control the flow.

Glaucoma is a progressive and blinding disease, and medications themselves carry risk of ocular surface disease and are often difficult for patients to comply with. We cannot call topical therapy risk-free. Cataract surgery provides us the opportunity to lower the pressure. Often, the pressure reduction from cataract surgery alone is insufficient to meet our patients’ needs.

The 2-year COMPASS trial showed significant additive intraocular pressure lowering as well as significant reduction in the requirements for topical medications with a safety signature that was similar to cataract extraction by itself.1 These data, which carry out to 2 years without a degradation in the procedure’s value, show us that the risk-to-benefit ratio of performing supraciliary micro-stenting in combination with cataract surgery in patients with mild to moderate open-angle glaucoma is indeed favorable.

It is always important for patients to understand the procedure they are having and the risks and benefits. My patients have been excited at the prospect of getting better glaucoma control and reducing their eyedrop burden along with the burden of the side effects from drops. In my discussion with patients, I have found that they are open to the idea of internally draining the fluid and using a micro-stent to do so. Typically, patients will have concerns with drains that are external to the eye because they know that they can be seen and felt. I have been impressed with patient acceptance and excitement about this approach.


Please see page 8 for Important Product Information.
CyPass Micro-Stent is a successful treatment for cataract patients with mild to moderate glaucoma

By Quang H. Nguyen, MD

CyPass Micro-Stent is a novel approach for treating patients with mild to moderate glaucoma in conjunction with cataract surgery, and may possibly reduce the burden of topical glaucoma medication.

CyPass Micro-Stent creates a controlled cyclodialysis and maintains a permanent cleft due to the “tenting” effect of the implant. It improves uveoscleral outflow similar to a mechanism of action of prostaglandin analog, which contributes greatly to pressure reduction. An attribute of CyPass Micro-Stent is the intuitive nature and the fact that it bypasses Schlemm’s canal and collector channels that may be atrophic in glaucoma patients.

The COMPASS trial, a pivotal clinical trial of 2 years’ duration, demonstrated the effectiveness CyPass Micro-Stent for lowering IOP with an excellent safety profile.* The COMPASS trial recruited 505 patients with randomization of 3:1 (3 patients with phacoemulsification + CyPass Micro-Stent (374 patients) to every 1 patient who underwent phacoemulsification alone (131 patients). This is the largest MIGS trial to date. Moreover, the COMPASS trial has washout IOP measurements at 1 and 2 years to truly demonstrate the effectiveness of CyPass Micro-Stent compared to phacoemulsification alone. Patients in both groups had similar baseline mean IOPs: 24.5±3.0 mmHg in the control group and 24.4±2.8 mmHg in the CyPass Micro-Stent group. The study found early and sustained pressure reduction, with 72.5% of CyPass Micro-Stent patients compared with 58% of controls achieving 20% or more unmedicated IOP lowering compared with baseline at 24 months (Fig. 1). Mean IOP reduction was 7.0 mmHg in the CyPass Micro-Stent group compared with 5.3 mmHg in the control group, a 32% increase in reduction of IOP with the CyPass Micro-Stent (p<0.0001). Patients’ mean 24-month medication use was 20.6% lower in the CyPass Micro-Stent patients, and 72.4% of patients in the control group and 93.0% of CyPass Micro-Stent patients were medication-free at the end of 2 years (Fig. 2). No sight-threatening adverse events occurred in the CyPass Micro-Stent group. Visual acuity was high in both...

* Primary outcome measure was unmedicated diurnal IOP reduction at 24 months versus cataract surgery alone at baseline. Secondary outcomes measures included mean change in 24 month DIO from baseline and 24 month unmedicated mean IOP (between 6 mmHg to 18 mmHg) versus cataract surgery alone. Medication use at 24 months was also analyzed. The primary and secondary effectiveness analyses were performed using intent to treat (ITT) population.

Case highlight

In my practice, a 68-year-old Caucasian woman underwent CyPass Micro-Stent in conjunction with uncomplicated phacoemulsification and posterior chamber IOL implantation. The right eye was operated on first, and the left eye underwent surgery a few weeks later.

Preoperatively, best-corrected visual acuity was 20/100 in the left eye and 20/80 in the right eye. The patient had moderate glaucoma that was treated with a prostaglandin analog and fixed-dose combination therapy. Intraocular pressure was 18 mm Hg in the right eye and 17 mm Hg in the left eye.

Postoperatively, best-corrected visual acuity was 20/20 in both eyes. Intraocular pressure in the immediate postoperative period was stable with no IOP spikes or hypotony. Intraocular pressure remained at 10 mm Hg in the right eye and 11 mm Hg in the left eye. The patient discontinued the fixed-dose combination within a week of surgery. IOP was still stable in the low teens, and the plan is to discontinue the prostaglandin analog in the coming weeks.

• 32% increase in reduction of IOP with the CyPass Micro-Stent

• 93% of CyPass Micro-Stent responders were medication-free at the end of 2 years

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groups through 24 months, with more than 98% of patients achieving 20/40 or better best-corrected visual acuity.\(^1\)

The 1-year results of an ongoing open-label, interventional, multicenter study provide additional information on the use of the CyPass Micro-Stent for the surgical treatment of open-angle glaucoma when implanted in conjunction with cataract surgery. The study included 167 eyes of 142 patients with open-angle glaucoma who underwent combined phacoemulsification with intracocular lens insertion and Micro-Stent implantation into the supraciliary space. Patients were divided into two groups: those with a baseline IOP of 21 mmHg or higher (65 patients) and those with a medicated baseline IOP of less than 21 mmHg (102 patients). Glaucoma medications were discontinued or tapered at surgery. Patients’ mean follow-up was 294±121 days, and no major intraoperative or postoperative complications occurred. Patients’ mean preoperative baseline IOP was 20.2±6.0 mmHg, and their mean number of IOP-lowering medications was 2.0±1.1. Patients with a medicated baseline IOP of 21 mmHg or higher demonstrated a 35% decrease in mean IOP and a 49% reduction in mean glaucoma medication usage. Those with a medicated baseline IOP of less than 21 mmHg had a 75% reduction in mean medication usage while maintaining a mean IOP of less than 21 mmHg. Mean IOP at 12 months was 15.9±3.1 mmHg in all eyes, which was a reduction from baseline of 14%.\(^2\)

In summary, the CyPass Micro-Stent, in conjunction with phacoemulsification, effectively demonstrated sustained unmedicated IOP lowering along with an excellent safety profile as demonstrated in the COMPASS trial. This is truly a special time for ophthalmologists to treat glaucoma in patients undergoing cataract surgery. Surgeons now have another MIGS option for their patients to control IOP at the time of cataract surgery with the high potential of reducing the glaucoma medication burden.

References

Please see page 8 for Important Product Information.
Q&A: How three surgeons go the distance with ACTIVEFOCUS

What patient characteristics lead you to conclude that a patient is an appropriate candidate for AcrySof IQ ReSTOR +2.5 with ACTIVEFOCUS Optical Design IOL?

**Steve Scoper, MD:** The best candidate for this multifocal option for cataract surgery is a patient who desires an extended range of vision and reduced glasses use. Most of my patients understand that they will likely need to wear reading glasses—particularly in dim lighting—but most want uncompromised distance vision without resorting to glasses or contacts.

**Matt Hammond, MD:** These lenses are ideal for someone who is interested in excellent distance vision, or potentially does a lot of intermediate work such as computer work. These lenses are great for patients who really want crystal clear distance vision. Anatomically, we look for the same things we would consider with any multifocal lens: a normal cornea, low astigmatism (less than 1.0 D) or at least a plan to address the astigmatism, and low coma or other aberrations that would prevent them from being a good candidate for any multifocal.

**Tony Weaver, MD:** I tell patients that I want to give them great distance vision without glasses. With ACTIVEFOCUS, I can give them pretty much uncompromised distance vision—similar to a standard monofocal IOL. There are some reports of more visual disturbances like halos and starbursts, but with my patients, these have been minimal due to the ACTIVEFOCUS design. I have had a lot of experience with multifocals during the past 10 years or so. I implanted some of the first multifocals in our area. Initially, my main desire was to give patients good uncorrected near vision. I have learned over the years that patients really want—but that they don’t know to ask for—good distance vision. That knowledge has changed my way of thinking. Now, rather than concentrating on just good near vision, I concentrate on good distance vision. I believe that patients’ second priority is good arm’s length or intermediate vision. I tell patients that I can give them really good distance vision without glasses and that I can extend that distance vision into a range to help them manage most of their important daily activities that are done at arm’s length, such as seeing the dashboard of your car or seeing the food on your plate. Patients also have some near vision. My patients report that they sometimes need a pair of reading glasses for regular-sized or small print, or if they read for long periods of time.

What do you tell your patients about ACTIVEFOCUS to set expectations?

**Dr. Scoper:** I tell patients right up front that they should expect really good, nice, sharp, clear distance vision and good computer vision. They will need to wear a pair of low-power readers. For the most part, they should have great distance vision and really good computer vision.

**Dr. Weaver:** The main goal of surgery is to remove the cataract, and my secondary goal is to decrease or eliminate glasses. There is never a guarantee that a patient will be spectacle-free, so we need to set that expectation correctly. With ORA, there is a 98% chance that I hit my refractive target, which decreases my patients’ need for glasses. There is now objective data on surgeons and their postoperative results. As far as expectations, my favorite implant is ReSTOR +2.5 with ACTIVEFOCUS. It is the only implant that I have used that has a central portion 100% dedicated towards distance. It is a unique hybrid-design IOL. Other premium implants compromise that center area, and the advantage of the ACTIVEFOCUS optic is that it has that “wow” factor by providing uncompromised distance vision. However, I think it’s important to set clear expectations with this implant. I tell patients to anticipate that they will need a +1.25 D reader if they want to see close up, but otherwise, from arm’s length through infinity, my patients have reported that they see very well without needing glasses or contacts. Another option I use for the patient who wants a little more near is to undercorrect the non-dominant eye by 0.50 D.

**Dr. Hammond:** The key to success with any lens choice is setting patient expectations. I tell patients right up front that they should expect really good, nice, sharp, clear distance vision and good computer vision. They will need to wear a pair of low-power readers. For the most part, they should have great distance vision and really good computer vision.

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Drs. Hammond, Scoper, and Weaver are consultants for Alcon and received compensation for their contributions to this supplement.
What is your approach for implanting the AcrySof IQ ReSTOR +2.5 D with ACTIVEFOCUS? Do you have any pearls?

**Dr. Scoper:** It is very straightforward to implant, just like any of the other multifocals. I want a good, consistent capsulorhexis, and I want the lens to be well-centered on the light reflex of the operating microscope. With the AcrySof material, it’s sticky to the capsule, so once I put that lens in and it well-centered, I tap it down so it is sticking to the posterior capsule and there can be no viscoelastic behind it. Once this is done, that lens just doesn’t move. It doesn’t slip and slide around like some other materials. We absolutely must correct even low levels of corneal astigmatism (1.0 D and less) with a multifocal IOL, and I do this with gimbal relaxing incisions (LRIs) with a femtosecond laser very successfully. If we can’t correct all of the astigmatism with the LRIs, I will definitely wait until ACTIVEFOCUS toric is commercially available. I am very excited about that option because of the exceptional stability with the AcrySof IQ Toric platform.

**Dr. Hammond:** The most important thing is tracking your outcomes, so you know when you put a lens in that you will get the result you expect. It is the same technique as any other multifocal lens—while the ACTIVEFOCUS optic is very forgiving, it does need to be aligned with the optical axis.

**Discuss the hybrid monofocal/multifocal design of the lens.**

**Dr. Hammond:** With a typical multifocal IOL, a certain percentage of the lens is dedicated to distance vision and a certain percentage of the lens is dedicated to near vision. The nice thing about the ACTIVEFOCUS design is that the very central part of the multifocal is 100% dedicated to distance vision. So, it acts similarly to a monofocal as far as the very central aspect of the lens goes, meaning that it provides really nice, crystal clear, distance vision. The unique ACTIVEFOCUS optical was designed specifically to minimize visual disturbances like halo and glare that have been so highly reported in the past with multifocal IOLs.

**Dr. Weaver:** It’s a multifocal, but the center part acts like a monofocal. That’s the hybrid designed lens. The outside of the lens has 7 diffractive rings to provide intermediate and near vision. It has fewer rings than the ReSTOR 3.0 D, so I have not had any patients who have reported significant haloing in their vision. It’s a very forgiving implant from that standpoint.

**Dr. Scoper:** This aspect of the lens has really made a big difference. When the ACTIVEFOCUS design launched, I thought it was just another model of the ReSTOR multifocal or just another low-add lens. I have learned that it is not just another multifocal, because the central portion of the lens is 100% dedicated to distance. I would describe it as a hybrid lens and not just another low power. The central portion is dedicated to 100% distance vision—my patients report wonderful uncorrected distance vision. That has been a game-changer for me, and I have been implanting this lens with confidence that I’m providing patients with uncompromised distance vision. With all of the other multifocals that I have implanted, the central portion is a blend for intermediate vision, so patients see well at distance, but they don’t see as well at distance as with ACTIVEFOCUS. It is very similar to a monofocal lens when it comes to the quality of distance vision.

**What has been your patients’ response to the ACTIVEFOCUS optic?**

**Dr. Weaver:** “Wow!” is a routine response, because patients have such sharp distance vision. It has become my go-to implant in terms of today’s patients, who are very different from the patients we’ve seen before. Today’s patients have greater expectations and with the ACTIVEFOCUS design I’m able to deliver on those expectations.

**Dr. Hammond:** It’s been great! This is my favorite lens so far because the patients are so happy. If I have been able to appropriately set the expectations, deal with astigmatism, and hit my target, these are the happiest patients I’ve ever had. Before ReSTOR +2.5 with ACTIVEFOCUS, I have never had a multifocal lens 20/15 distance vision patient. Many of my patients who are 20/15 at distance can read the computer very easily without glasses.

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**ACTIVEFOCUS™: Optical design**

- **Central portion 100% dedicated to distance**
  - Optimized to offer your patients monofocal-like distance vision

- **Contrast sensitivity comparable to the AcrySof IQ IOL**
  - +2 D add power at the spectacle plane (when targeting plano)
  - Provides an extended range of visual disturbances
  - Further decreases visual disturbances
  - 7-step apodized diffractive design for more efficient light management
  - +2 D add power at the spectacle plane (when targeting plano)
During the past 1.5 years that I have been implanting with AcrySof IQ ReSTOR +2.5 D with ACTIVEFOCUS, I have made it a point to see all of my patients personally postoperatively and ask them how they are doing. I have been just amazed at how well almost all of the patients are seeing postoperatively. If I also correct their astigmatism and hit their spherical equivalent correctly, they are going to have great uncorrected distance vision and be very happy with that vision. I have very few patients who are not totally pleased with their vision at distance and intermediate with ACTIVEFOCUS design.

What role does your staff play in your IOL recommendation?  
Dr. Scoper: Our staff plays a major role, and patients receive all of their education about cataract surgery, femtosecond lasers, and different IOL options before they see the doctor. I’m a big believer that the doctor should do what only a doctor can do. I do not want to spend time explaining to patients what cataract surgery is, what an IOL is, and what astigmatism is. All of those things are explained to them before they get to me. As the patient is being worked up by the staff, the technician will write a note to one of our counselors saying that he or she appears to be a very good candidate for an ACTIVEFOCUS lens. The patient then sees the counselor before he or she sees me. They first see videos about different IOLs and cataract surgery choices to educate them about options to help them reach their best visual outcomes. Then, the counselor explains what cataract surgery is, what astigmatism is, and how ACTIVEFOCUS multifocal design works. They also discuss what vision and outcome the patient can reasonably expect. The counselor also discusses price and will even get approved for care credit if the patient is interested. I then examine the patient and make a recommendation.

Dr. Hammond: In my practice, I select the lens with the patient. I sit down and go through the entire exam and if there is astigmatism or corneal aberrations, we talk about those, and we talk about what patients want from cataract surgery, their hobbies, and their occupation. Then, I will make a recommendation for the lens based on what the patient wants and what he or she expects from cataract surgery. My staff takes it from there and discusses cost with the patient. They are crucial in closing the deal and making sure that everything is well understood. So, they reinforce what I do, but I do the actual lens recommendation and discussion with the patient.

Where does an IOL with the ACTIVEFOCUS optic fit in your armamentarium?  
Dr. Weaver: I offer it to everyone who is a candidate, which is a large part of my practice. The biggest deciding factor, at least in Tallahassee, is cost. Tallahassee is a very middle-class community, so I must explain to patients the value of what they are getting. I wish I could implant a lens with ACTIVEFOCUS in one eye and another lens in the other eye, and let patients choose. I believe they would all choose a lens with ACTIVEFOCUS.

Dr. Scoper: If patients have a healthy ocular exam and have a desire to be free of glasses at a distance, I ask if they would like to pull that distance vision into intermediate. I look at all of my multifocal patients who want good uncorrected distance vision, and I offer them the addition of intermediate vision. You really don’t have to give up anything. The only thing I tell them is that they will see rings around lights and have a little glare and halos at nighttime with this lens. If they are willing to accept that at night, then they can have uncompromised distance vision with an extended range of vision with ACTIVEFOCUS.

What would you say to other eye surgeons about ACTIVEFOCUS?  
Dr. Weaver: Surgeons need to try this lens if they haven’t already. Having an ORA will help as well. It allows you to be dead-on accurate in the sphere calculation, which is critical when you are doing premium implants, but even more so when you are aligning the axis of astigmatism. I recommend using ORA whenever implanting ACTIVEFOCUS toric or ACTIVEFOCUS for patients without astigmatism because it helps me to hit the refractive target.

Dr. Scoper: If you have tried multifocals in the past and have stopped using multifocals for whatever reason, give ACTIVEFOCUS optic a try because it is not just another multifocal. This hybrid design is a totally different lens, so I would encourage everyone to give it a try. My patients have never been happier.

References

Please see page 8 for Important Product Information.
CyPass Micro-Stent
Important Product Information

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

Indication: The CyPass Micro-Stent is indicated for use in conjunction with cataract surgery for the reduction of intraocular pressure (IOP) in adult patients with mild to moderate primary open-angle glaucoma (POAG).

Contraindications: Use of the CyPass Micro-Stent is contraindicated in the following circumstances or conditions: (1) in eyes with angle closure glaucoma; and (2) in eyes with traumatic, malignant, uveitic or neovascular glaucoma or discernible congenital anomalies of the anterior chamber angle.

MRI Information: The CyPass Micro-Stent is magnetic resonance (MR) Safe: the implant is constructed of polyimide material, a non-conducting, non-metallic, non-magnetic polymer that poses no known hazards in all magnetic resonance imaging environments.

Warnings: Gonioscopy should be performed prior to surgery to exclude peripheral anterior synchiae (PAS), rubeculae, and other angle abnormalities or conditions that would prohibit adequate visualization of the angle that could lead to improper placement of the stent and pose a hazard.

Precautions: The surgeon should monitor the patient postoperatively for proper maintenance of intraocular pressure. The safety and effectiveness of the CyPass Micro-Stent has not been established as an alternative to the primary treatment of glaucoma with medications, in patients 21 years or younger, in eyes with significant prior trauma, chronic inflammation, eyes with an abnormal anterior segment, eyes with chronic inflammation, eyes with glaucoma associated with vascular disorders, pseudophakic eyes with glaucoma, eyes with uveitic glaucoma, eyes with pseudo-exfoliative or pigmentary glaucoma, eyes with other secondary open angle glaucomas, eyes that have undergone prior incisional glaucoma surgery or cilioablatative procedures, eyes with laser trabeculoplasty performed ≤ 3 months prior to the surgical screening visit, eyes with unmedicated IOP less than 21 mmHg or greater than 33 mmHg, eyes with medicated IOP greater than 25 mmHg, in the setting of corneal edema 30 or more days after surgery, more days after surgery (4.3% vs. 2.3%); and corneal edema 30 or more days after surgery, or severe in nature (3.5% vs. 1.5%).

Attention: Please refer to the Product Instructions for a complete list of contraindications, warnings, precautions and adverse events.

AcrySof IQ ReSTOR Family of 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 Lens (IOL) is intended for primary implantation for the correction of aphakia secondary to removal of a cataractous lens in adult patients with and without presbyopia, who desire near, intermediate and distance vision discrimination is not adversely affected in individuals with the AcrySof Natural IOL and visual disturbances and/or discomfort due to multifocality, especially under dim light conditions. As with other multifocal IOLs, visual symptoms may be significant enough that the patient will request explant of the multifocal IOL.

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

Experience unique video case studies and a moderated discussion on the most advanced multifocal technology.

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CyPass Micro-Stent
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Warnings: Gonioscopy should be performed prior to surgery to exclude peripheral anterior synchiae (PAS), rubeculae, and other angle abnormalities or conditions that would prohibit adequate visualization of the angle that could lead to improper placement of the stent and pose a hazard.

Precautions: The surgeon should monitor the patient postoperatively for proper maintenance of intraocular pressure. The safety and effectiveness of the CyPass Micro-Stent has not been established as an alternative to the primary treatment of glaucoma with medications, in patients 21 years or younger, in eyes with significant prior trauma, chronic inflammation, eyes with an abnormal anterior segment, eyes with chronic inflammation, eyes with glaucoma associated with vascular disorders, pseudophakic eyes with glaucoma, eyes with uveitic glaucoma, eyes with pseudo-exfoliative or pigmentary glaucoma, eyes with other secondary open angle glaucomas, eyes that have undergone prior incisional glaucoma surgery or cilioablatative procedures, eyes with laser trabeculoplasty performed ≤ 3 months prior to the surgical screening visit, eyes with unmedicated IOP less than 21 mmHg or greater than 33 mmHg, eyes with medicated IOP greater than 25 mmHg, in the setting of corneal edema 30 or more days after surgery, more days after surgery (4.3% vs. 2.3%); and corneal edema 30 or more days after surgery, or severe in nature (3.5% vs. 1.5%).

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Important Product Information

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Indications: The AcrySof IQ ReSTOR Posterior Chamber Intraocular Lens (IOL) is intended for primary implantation for the correction of aphakia secondary to removal of a cataractous lens in adult patients with and without presbyopia, who desire near, intermediate and distance vision. Clinical studies with the AcrySof ReSTOR lens indicated that posterior capsule opacification (PCO), when present, developed earlier into clinically significant PCO. 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 ReSTOR 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.