Supplement to CRST Cataract & Refractive Surgery Today

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MILLENNIALEYE

IS PRESBYOPIA FINALLY TAKING CENTER STAGE?

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Vuity™
(pilocarpine HCl ophthalmic solution) 1.25%

THE WAIT IS OVER

A revolutionary new way to treat presbyopia[1]

The first and only

FDA-approved eye drop specifically designed for presbyopia in adults.[1,2]

AVAILABLE NATIONWIDE

INDICATION
VUITY™ (pilocarpine hydrochloride ophthalmic solution) 1.25% is indicated for the treatment of presbyopia in adults.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS
VUITY is contraindicated in patients with known hypersensitivity to any ingredient in the formulation.

WARNINGS AND PRECAUTIONS
Patients should be advised to exercise caution in night driving and other hazardous occupations in poor illumination. In addition, miotics may cause accommodative spasm. Patients should be advised not to drive or use machinery if vision is not clear.

Rare cases of retinal detachment have been reported with other miotics when used in susceptible patients and those with pre-existing retinal disease. Patients should be advised to seek immediate medical care with sudden onset of vision loss.

VUITY is not recommended to be used when iritis is present because adhesions (synechiae) may form between the iris and lens.

Contact lens wearers should be advised to remove their lenses prior to the instillation of VUITY and to wait 10 minutes after dosing before reinserting their contact lenses.

To prevent eye injury or contamination, care should be taken to avoid touching the dispensing bottle to the eye or to any other surface.

ADVERSE REACTIONS
The most common adverse reactions (>5%) reported in clinical trials were headache and conjunctival hyperemia.

Please see Brief Summary of full Prescribing Information on the following page.

Allergan
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References: 1. VUITY Prescribing Information. **2.** Price FW, et al. Ophthalmol Sci. 2021; doi: https://doi.org/10.1016/j.xops.2021.100065

Learn more about the drop everyone's talking about at VuityPro.com.

VUITY™ (pilocarpine hydrochloride ophthalmic solution) 1.25%, for topical ophthalmic use

PROFESSIONAL BRIEF SUMMARY
CONSULT PACKAGE INSERT FOR FULL PRESCRIBING INFORMATION

INDICATIONS AND USAGE

VUITY is indicated for the treatment of presbyopia in adults.

CONTRAINDICATIONS

VUITY is contraindicated in patients with known hypersensitivity to the active ingredient or to any of the excipients.

WARNINGS AND PRECAUTIONS

Poor Illumination

Patients should be advised to exercise caution in night driving and other hazardous occupations in poor illumination. In addition, miotics may cause accommodative spasm. Patients should be advised not to drive or use machinery if vision is not clear.

Risk of Retinal Detachment

Rare cases of retinal detachment have been reported with other miotics when used in susceptible individuals and those with pre-existing retinal disease. Patients should be advised to seek immediate medical care with sudden onset of vision loss.

Iritis

VUITY is not recommended to be used when iritis is present because adhesions (synechiae) may form between the iris and the lens.

Use with Contact Lenses

Contact lens wearers should be advised to remove their lenses prior to the instillation of VUITY and to wait 10 minutes after dosing before reinserting their contact lenses.

Potential for Eye Injury or Contamination

To prevent eye injury or contamination, care should be taken to avoid touching the dispensing bottle to the eye or to any other surface.

ADVERSE REACTIONS

The following clinically significant adverse reactions are described elsewhere in labeling:

- Hypersensitivity *[see Contraindications]*

Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

VUITY was evaluated in 375 patients with presbyopia in two randomized, double-masked, vehicle-controlled studies (GEMINI 1 and GEMINI 2) of 30 days duration. The most common adverse reactions reported in >5% of patients were headache and conjunctival hyperemia. Ocular adverse reactions reported in 1-5% of patients were blurred vision, eye pain, visual impairment, eye irritation, and increased lacrimation.

USE IN SPECIFIC POPULATIONS

Pregnancy

Risk Summary

There are no adequate and well-controlled studies of VUITY administration in pregnant women to inform a drug-associated risk. Oral administration of pilocarpine to pregnant rats throughout organogenesis and lactation did not produce adverse effects at clinically relevant doses.

Data

Human Data

No adequate and well-controlled trials of VUITY have been conducted in pregnant women. In a retrospective case series of 15 women with glaucoma, 4 patients used ophthalmic pilocarpine either pre-pregnancy, during pregnancy or postpartum. There were no adverse effects observed in patients or in their infants.

Animal Data

In embryofetal development studies, oral administration of pilocarpine to pregnant rats throughout organogenesis produced maternal toxicity, skeletal anomalies and reduction in fetal body weight at 90 mg/kg/day (approximately 970-fold higher than the maximum recommended human ophthalmic dose [MRHOD] of 0.015 mg/kg/day, on a mg/m^2 basis).

In a peri-/postnatal study in rats, oral administration of pilocarpine during late gestation through lactation increased stillbirths at a dose of 36 mg/kg/day (approximately 390-fold higher than the MRHOD). Decreased neonatal survival and reduced mean body weight of pups were observed at ≥18 mg/kg/day (approximately 200 times the recommended human daily dose of VUITY).

Lactation

Risk Summary

There is no information regarding the presence of pilocarpine in human milk, the effects on the breastfed infants, or the effects on milk production to inform risk of VUITY to an infant during lactation.

Pilocarpine and/or its metabolites are excreted in the milk of lactating rats. Systemic levels of pilocarpine following topical ocular administration are low, and it is not known whether measurable levels of pilocarpine would be present in maternal milk following topical ocular administration.

The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for VUITY and any potential adverse effects on the breastfed child from VUITY.

Data

Animal Data

Following a single oral administration of ^{14}C-pilocarpine to lactating rats, the radioactivity concentrations in milk were similar to those in plasma.

Pediatric Use

Presbyopia does not occur in the pediatric population.

Geriatric Use

Clinical studies of VUITY did not include subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience with ophthalmic pilocarpine solutions have not identified overall differences in safety between elderly and younger patients.

OVERDOSAGE

Systemic toxicity following topical ocular administration of pilocarpine is rare, but occasionally patients who are sensitive may develop sweating and gastrointestinal overactivity. Accidental ingestion can produce sweating, salivation, nausea, tremors and slowing of the pulse and a decrease in blood pressure. In moderate overdosage, spontaneous recovery is to be expected and is aided by intravenous fluids to compensate for dehydration. For patients demonstrating severe poisoning, atropine, the pharmacologic antagonist to pilocarpine, should be used.

NONCLINICAL TOXICOLOGY

Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis

Pilocarpine did not induce tumors in mice at any dosage level studied (up to 30 mg/kg/day; approximately 160-times the MRHOD). In rats, an oral dose of 18 mg/kg/day (approximately 200 times the MRHOD), resulted in a statistically significant increase in the incidence of benign pheochromocytomas in both male and female rats, and a statistically significant increase in the incidence of hepatocellular adenomas in female rats.

Mutagenesis

Pilocarpine did not show any potential to cause genetic toxicity in a series of studies that included: 1) bacterial assays (Salmonella and E. coli) for reverse gene mutations; 2) an in vitro chromosome aberration assay in a Chinese hamster ovary cell line; 3) an in vivo chromosome aberration assay (micronucleus test) in mice; and 4) a primary DNA damage assay (unscheduled DNA synthesis) in rat hepatocyte primary cultures.

Impairment of Fertility

Pilocarpine oral administration to male and female rats at a dosage of 18 mg/kg/day (200 times the recommended human daily dose) resulted in impaired reproductive function, including reduced fertility, decreased sperm motility, and morphologic evidence of abnormal sperm. It is unclear whether the reduction in fertility was due to effects on males, females, or both. In dogs, exposure to pilocarpine at a dosage of 3 mg/kg/day for 6 months resulted in evidence of impaired spermatogenesis (approximately 110 times the recommended human daily dose).

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IS PRESBYOPIA FINALLY TAKING CENTER STAGE?

Presbyopia is the eye condition that will impact 100% of patients at some point. It has long been said that a solution for presbyopia is the "holy grail" of eye care. While there is not yet a cure for presbyopia, there are more tools than ever before to help patients have functional near and intermediate vision while maintaining distance vision. Recently, George O. Waring IV, MD, FACS, moderated a discussion with Steven J. Dell, MD; Rex Hamilton, MD, MS, FACS; and Cathleen M. McCabe, MD, on the profound need for eye care providers to provide more presbyopia solutions to their patients and how they are doing that.

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PRESBYOPIA: UNDERSTANDING THE OPPORTUNITY

George O. Waring IV, MD, FACS: We know there are currently more than 1.8 billion presbyopes worldwide,[1] and that a survey of patients ages 40-55 revealed that 96% of respondents are at least 'somewhat affected' by the symptoms, while nearly one-half find the impact of presbyopia in their daily activities to be 'extreme.'[2] This is probably the first time we are all treating a condition that we are also experiencing. How does this impact how you treat your patients?

Cathleen M. McCabe, MD: I am a presbyope and would definitely describe the impact as severe. Even as a myope, it is extremely frustrating to have difficulty at near. I can empathize with my patients in a way I never did as a younger practitioner. The sooner we talk to our patients about what is coming, sympathize, and offer treatment options, the better we serve them and the more likely we are to retain them in our practice. I have optometrists integrated in my practice, so most of our presbyopes first come to our practice to see these primary care providers. But as they move through severity of disease, working together we can offer them a continuum of treatment over time.

Steven J. Dell, MD: As the technology for treating presbyopia has improved, our practice has adapted to be more willing to intervene in earlier stages because we feel confident that we can help our patients.

Rex Hamilton, MD, MS, FACS: I have a multifocal contact in one eye, and I am unable to function without it. It is such a pain to be presbyopic! The eye care community often doesn't consider presbyopia a true problem. The mentality is not there to look at the loss of near vision as truly disabling, and we need to change that. In our practice, we establish a continuum of care as early as possible. I use the patient education software by Rendia to show every patient how their eye is changing and how the lens will change, and then I explain to them the solutions

available for the different stages of the aging eye. They know we will be with them at each stage.

Dr. McCabe: I'm always so disappointed when a previously very happy LASIK patient comes back in their 40s thinking I did something wrong, causing their LASIK to wear off. Explaining to them the process of the aging eye when they are young really prepares them for the unavoidable changes that are coming. Early in my career, I convinced a patient who was pre-presbyopic to under-correct one eye during LASIK to retain some near vision. It didn't go well, as the patient could not immediately appreciate the tradeoff in distance vision for better near when they would become presbyopic in the future. Now, I hesitate to do that in patients who are under 40, preferring to educate them so they know presbyopia will come and that we have options when it does.

Dr. Waring: I tell patients that we typically utilize LASIK to fix focus problems we are born with, and we perform lens procedures for problems that are age-related. Once they hit presbyopia, they have taken a step off the vision cliff, and they are going to keep falling with readers, bifocals, and then cataracts. Patients understand this. We let them know it's okay because we can help them with each of these stages. Do you see presbyopia correction becoming a pillar of your practice in the near or mid-term?

Dr. Dell: For me, it already is. Correcting presbyopia with refractive lens exchange (RLE) is a significant percentage of my weekly surgical volume. For those patients who seek to reduce or eliminate glasses with a lens procedure, my typical recommendation, whether cataract or RLE, is to offer presbyopia-correcting technology of some variety. We now have technologies that are applicable to virtually every type of patient who comes in the door, whether that's a bit of monovision, a light adjustable lens, an extended depth-of-focus IOL, or a bifocal, trifocal, or multifocal IOL. Soon we will add a small aperture IOL to this list with the approval of the AcuFocus IC-8. There is a treatment applicable to the overwhelming majority of our patients, barring other ocular pathologies. Thus, a presbyopia-correcting option is my standard offering, and everything else is a downgrade.

Dr. McCabe: For me, it is becoming as common as astigmatism correction. There is no eye care practitioner that would ignore astigmatism when maximizing distance correction, no matter the age of the patient. We have so many options now that we can offer the vast majority of patients a range of vision. Instead of assessing whether a patient is a good candidate for presbyopia correction, we should be considering if this patient is the rare exception that cannot have a presbyopia-correcting solution. Patients are not going to have one focal point for the rest of their lives, and a lens procedure really is a lifelong choice for the patient.

Dr. Hamilton: I have reached the point that, when I fail to convince a patient of the value of a presbyopia-correcting option, it really bothers me because I've just relegated them to being very dependent on glasses for the rest of their life. I look for reasons to not put in a presbyopia-correcting lens, and they are few and far between.

Dr. Waring: We have reached a point where we don't talk about astigmatism or presbyopia. We explain to patients that we are going to fix the vision problems they have while we have the opportunity, given they are an appropriate candidate. Our RLE patients are some of our most satisfied patients from Day 1. Realizing that, our lens replacement program has grown significantly, and this continues to be a group of patients with very high satisfaction. Now, we have built a practice around that.

NEW SOLUTIONS FOR PRESBYOPIA

Dr. Waring: We are all aware that in November of 2021 the FDA approved the first prescription eyedrop for presbyopia, Vuity (pilocarpine 1.25%; AbbVie/Allergan). There has been a lot of interest and excitement around this drop. Personally, I look forward to the educational opportunities surrounding age-related blurry near vision. Have you taken any concrete operational steps to prepare for the potential influx?

Dr. Dell: While we need to gain more clinical experience with this drop, it has the potential to bring in an entire new segment of the population that has been outside our realm previously. We are embracing these patients because, although they are currently in their initial discovery phase, that will ultimately lead to surgical intervention in a large percentage of patients. We are educating our intake personnel on the new Vuity drop and then setting appointments with our optometrist to meet with them and start educating them on the aging eye and what their options are at various stages.

Dr. Hamilton: It's great to finally have an option for those presbyopia patients who want to improve their near vision without glasses. Even though we know it is not a permanent solution, we are excited to access these patients and let them know we will be with them down the road as well. It's a great opportunity to establish a relationship with the patient.

Dr. McCabe: Frequently we see a patient for cataract surgery, and when we talk to them about the IOL options, they say they have been using glasses for so long that they no longer mind. Vuity will allow patients to function at near without glasses and foster the desire to continue to do so once they have cataract surgery. This will help them appreciate the presbyopia-correcting IOL options we can offer them.

Dr. Dell: There is also a segment of the population that is not getting LASIK because they are worried about what will happen when they get presbyopia.

Knowing there may be a pharmaceutical to help them see up close, I believe, will entice many more of them to get LASIK for their current vision concerns. This could dramatically increase our LASIK numbers.

Dr. Waring: The opportunity to use Vuity following LASIK surgery has palpably streamlined our LASIK consultation. One of the most difficult and time-consuming conversations we have is with the myopic patient in their early 40s who wants LASIK; it's challenging trying to address their current concerns while also looking ahead to when they develop presbyopia. Vuity just brings that full circle. We are talking about blended vision less with those patients. Has it changed how you approach your myopic patients?

Dr. McCabe: I have some staff members who had multifocal contact lenses but weren't really happy with their distance vision. They have switched to a monofocal lens for distance and are using Vuity for their near vision. My thoughts on LASIK and EDOF technology are changing, in that we have another tool to get patients the range of vision that they want and meet their expectations.

Dr. Hamilton: The fact that you can instill these drops and they work so quickly allows us to try them out in the office. Then if a patient has a positive result, we can assess the options.

APPROACHING DIFFERENT PATIENT GROUPS

Dr. Waring: We've talked a bit about how our treatment of presbyopia has changed over time. We are moving toward lens-based procedures earlier, and we are considering presbyopia drops as adjunctive or standalone treatment early. Let's talk about some specific patient groups, starting with your hyperopic and myopic patients who now have presbyopia.

Dr. Dell: How I approach patients with hyperopia changes with their degree of hyperopia. If I see a patient still in their late twenties but with a +7.0 D prescription, I tend to think about RLE much earlier because I know we can provide a dramatic improvement in function. For the fully presbyopic hyperope, it's an easy discussion. I know I am going to treat them with RLE. We had to educate an entire generation of cataract patients that surgery with the goal of spectacle independence is not free, and that it can also improve their near vision. Now we have an entire cohort of presbyopic hyperopes who had RLE and are telling their friends how successful it was, and now we have patients that come in asking for RLE.

Dr. Hamilton: The myopic patient in the early years of presbyopia is more challenging because we worry about retinal pathology and increasing the risk of retinal tears with a lens procedure. However, vitrectomy has become so routine and low risk that we may start to think of vitrectomy as routinely paired with RLE in myopic patients.

Dr. McCabe: I certainly see that, when I am trying to get to the level of great image quality for a lifetime for my patients, the quality of the vitreous is a real factor. I think we are moving toward addressing the vitreous, and this does increase my comfort in operating on younger patients with myopia. There are a lot of patients that, if we are not willing to perform vitrectomy, they will never get the quality of vision they want or be fully satisfied.

Dr. Waring: Now I'd like to review a few cases and see how each of you would treat these patients.

CASE 1: 45-YEAR-OLD -4.0 D MYOPE WHO IS A GREAT CANDIDATE FOR LASIK WITH AN AXIAL LENGTH OF 25.5

Dr. Hamilton: I would probably start them with a distance vision contact lens plus a miotic drop, and, if that works well for them, I would go forward with LASIK for distance vision and the drop. Now that we have a miotic drop that works, I'm moving more away from monovision when performing laser vision correction or RLE, particularly with the patient who does not use monovision habitually with contact lenses.

Dr. Dell: It depends on whether they are currently using contact lenses. If they are using contact lenses all day and using readers on top of that, I would go for LASIK for distance vision, maybe with occasional use of a miotic. I do like the idea of a monovision contact lens trial in this patient, if you can get them to do it. It's too early for me to say whether miotics will be widely accepted in these patients, but I'm certain we will learn more.

CASE 2: 50-YEAR-OLD PLANO PRESBYOPE

Dr. Dell: I think it's important to learn who you are talking to. I love Malcolm Gladwell's 'Talking to Strangers' concept, which states that we make assumptions about who is sitting across from us that may be incorrect. We need to learn what this person's visual demands are like and what they have been doing to cope with them. If we are dealing with a detail-oriented computer programmer, then that is a whole different situation than a person who can't imagine being seen with glasses at a cocktail party. Maybe we put a multifocal in their non-dominant eye and see how they do. Maybe we do nothing and tell them to come back when their distance vision starts to decline.

Dr. Hamilton: I couldn't agree more with Dr. Dell. This is a wide-open frontier. If this is a true plano presbyope that still has really great distance vision, then a miotic drop is a great bridging tool because they are not yet ready for an RLE. I still have some hesitancy with the true plano presbyope with 20/20 or better uncorrected distance vision and their ability to tolerate the night vision aberrations from RLE with multifocal IOLs. The cosmetically oriented patient will usually tolerate it, but the detail-oriented patient may not. I also think there are a lot of 'plano presbyopes' that are actually latent hyperopes, and that is a different scenario.

Dr. McCabe: It really is essential to figure out the daily demands of this particular patient. However, we now have something very simple and completely

reversible that they can try in the office. I would definitely start with a miotic drop here, and if they like it, great. If they don't like it, we can move on to other solutions.

Dr. Dell: It is also worth pointing out that this is the type of patient that has never needed glasses before and didn't have a clue that eventually they would lose their vision. This is a patient that really needs a continuum of care and will be a surgical candidate in 1 to 5 years.

Dr. Waring: Excellent analysis here. Treatment depends on whether there is any hyperopia, including latent hyperopia, or myopia, as well as the patient's uncorrected reading vision. If we have a 50-year-old J3 plano presbyope, miotic drops are a great solution. If we have a 50-year-old J10 plano presbyope, then we lean more toward lens replacement.

PRESBYOPIA THERAPEUTICS IN THE PIPELINE

Dr. Waring: What are some other presbyopia drops or technologies in the innovation pipeline that you are excited about?

Dr. Dell: I am consulting for Lenz Therapeutics, which has completed its phase 2 trials for a drug based on aceclidine, which also results in miosis. It's a bit farther from coming to market, but it does have some differences to pilocarpine. Aceclidine creates a smaller pupil without ciliary spasm, and its duration of action is significantly longer than pilocarpine. It will be interesting to see how that plays out clinically.

Dr. Hamilton: I think the next new option we are going to see is the AcuFocus IC-8 IOL. This is a small aperture IOL that will not just be helpful for presbyopia in an otherwise normal eye, but may open the door for more aberrated corneas, post-refractive keratotomy patients for example, and others that are not optically ideal. The IC-8 is a really exciting and potentially expansive technology that may open up a presbyopia solution for eyes that we might otherwise be hesitant to offer a surgical solution.

Dr. Dell: That's a great point. We're really on the cusp of a whole revolution in small aperture optics, which will really open up options for aberrated corneas, people who have dysphotopsias with existing IOLs, and maybe even monofocal pseudophakic patients.

Dr. McCabe: I totally agree with the potential for the small aperture optics. I am also excited for technology that adjusts postoperatively, like the light adjustable lens, or the modular IOLs that allow us to choose what is best for the eye health today but then maybe change it in the future in a way that is less risky for the patient. Finally, I'm looking forward to a truly accommodative IOL. There are designs out there that look promising, and our ability to provide presbyopia correction for patients is just going to improve. In addition, I see another big focus on image quality. The IC-8 IOL allows us to really think about image quality with pinhole optics, and our previous discussion about potentially combining vitrectomies goes along with this. We are thinking more and more about the quality of the image.

Dr. Waring: That's a great snapshot of some of the excitement and technologies being investigated. To round it out, there are also scleral procedures with laser scleral microporation, which seem to be working quite well in a minimally invasive fashion. There are a lot of exciting developments.

LOOKING TO THE FUTURE

Dr. Waring: As comprehensive refractive surgeons, we look to help our patients through the various stages of ocular maturity through their lifetime. What kind of impact do you see these new presbyopia therapies having on our profession, particularly for refractive surgeons?

Dr. McCabe: We are in an era of redefining refractive results. In the past, the focus was on getting our patients to see their best at distance. Over the last decade, we have seen a big shift to really considering near vision. Now that we have more tools that are reliable for patients, they really can have both distance and near vision independent from glasses. The definition of a refractive surgeon now is one that provides a complete range of vision. It is a complete mind shift in how we look at what our goals are and what is an optimal result. I think we are going to see more and more focus on creating a comprehensive refractive visual solution for patients.

Dr. Dell: It will become increasingly evident to our colleagues that ignoring presbyopia, which is what we have done surgically for a long time, is not an option anymore. Correction of presbyopia is an essential component of refractive surgery, and it is the standard of care to which we hold ourselves.

Dr. Hamilton: We have a whole generation of refractive surgeons who are going to become the patients very soon, and we now have the tools to really help them. I think that is going to be a driving force in educating both our colleagues and the consumers.

Dr. Waring: Talking to this group, it is extraordinary that only around 10% of IOLs used in cataract surgery are presbyopia correcting. As we evolve and embrace the correction of presbyopia early on with drops, then with blended vision LASIK and eventually with lens replacement, I imagine we will see the emergence of presbyopia correction as a core component of refractive surgery. It will become better understood, it will be taught during fellowship training, and it will be incorporated professionally early in a surgeon's career. The public will also begin to have the expectation that if their distance vision can be corrected, their near vision should be as well. I am excited to see this. ■

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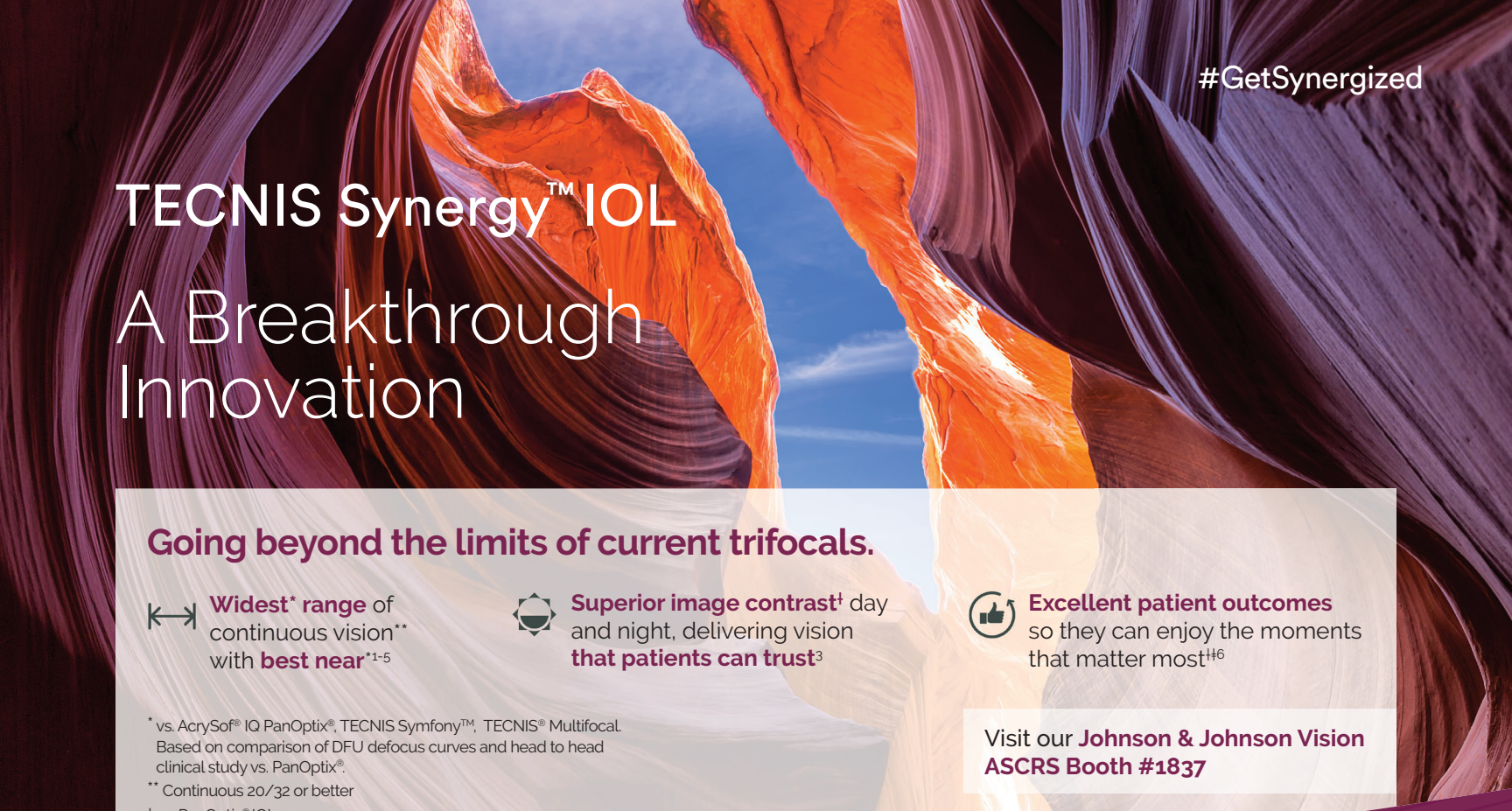

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INDICATIONS and IMPORTANT SAFETY INFORMATION FOR TECNIS Synergy™ IOL with TECNIS Simplicity® Delivery System, Model DFR00V and TECNIS Synergy™ Toric II IOL with TECNIS Simplicity® Delivery System, Models DFW150, DFW225, DFW300, DFW375

Rx Only

INDICATIONS: The TECNIS Simplicity® Delivery System is used to fold and assist in inserting the TECNIS Synergy™ IOL which is indicated for primary implantation for the visual correction of aphakia in adult patients, with less than 1 diopter of pre-existing corneal astigmatism, in whom a cataractous lens has been removed. The TECNIS Simplicity® Delivery System is used to fold and assist in inserting the TECNIS Synergy™ Toric II IOLs that are indicated for primary implantation for the visual correction of aphakia and for reduction of refractive astigmatism in adult patients with greater than or equal to 1 diopter of preoperative corneal astigmatism, in whom a cataractous lens has been removed. Compared to an aspheric monofocal lens, the TECNIS Synergy™ IOLs mitigate the effects of presbyopia by providing improved visual acuity at intermediate and near distances to reduce eyeglass wear, while maintaining comparable distance visual acuity. The lens is intended for capsular bag placement only. WARNINGS: Intraocular lenses may exacerbate an existing condition, may interfere with diagnosis or treatment of a condition or may pose an unreasonable risk to the eyesight of patients. Patients should have well-defined visual needs and be informed of possible visual effects (such as a perception of halo, starburst or glare around lights), which may be expected in nighttime or poor visibility conditions. Patients may perceive these visual effects as bothersome, which, on rare occasions, may be significant enough for the patient to request removal of the IOL. The physician should carefully weigh the potential risks and benefits for each patient. Patients with a predicted postoperative residual astigmatism greater than 1.0 diopter, with or without a toric lens, may not fully benefit in terms of reducing spectacle wear. Rotation of the TECNIS Synergy™ Toric II IOL from its intended axis can reduce its astigmatic correction. Misalignment greater than 30° may increase postoperative refractive cylinder. If necessary, lens repositioning should occur as early as possible, prior to lens encapsulation. The lens and delivery system should be discarded if the lens has been folded within the cartridge for more than 10 minutes. Not doing so may result in the lens being stuck in the cartridge. Do not attempt to disassemble, modify, or alter the delivery system or any of its components, as this can significantly affect the function and/or structural integrity of the design. PRECAUTIONS: Interpret results with caution when using autorefractors or wavefront aberrometers that utilize infrared light, or when performing a duochrome test. Confirmation of refraction with maximum plus manifest refraction technique is strongly recommended. The ability to perform some eye treatments (e.g., retinal photocoagulation) may be affected by the IOL optical design. The surgeon should target emmetropia, as this lens is designed for optimum visual performance when emmetropia is achieved. The TECNIS Synergy™ IOLs should not be placed in the ciliary sulcus. Carefully remove all viscoelastic and do not over-inflate the capsular bag at the end of the case. Residual viscoelastic and/or over-inflation of the capsular bag may allow the lens to rotate, causing misalignment of the TECNIS Synergy™ Toric II IOL. All preoperative surgical parameters are important when choosing a TECNIS Synergy™ Toric II IOL for implantation, including preoperative keratometric cylinder (magnitude and axis), incision location, the surgeon's estimated surgically induced astigmatism (SIA) and biometry. Variability in any of the preoperative measurements can influence patient outcomes and the effectiveness of treating eyes with lower amounts of preoperative corneal astigmatism. The effectiveness of TECNIS Synergy™ Toric II IOLs in reducing postoperative residual astigmatism in patients with preoperative corneal astigmatism < 1.0 diopter has not been demonstrated. Patients with a predicted postoperative astigmatism greater than 1.0 D may not be suitable candidates for implantation with the TECNIS Synergy™ and TECNIS Synergy™ Toric II IOLs, as they may not obtain the benefits of reduced spectacle wear or improved intermediate and near vision seen in patients with lower predicted postoperative astigmatism. ATTENTION: Reference the Directions for Use for a complete listing of Indications and Important Safety Information.

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