

Johnson & Johnson Vision Care, Inc. – Educational Materials

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The Path to Better Vision

Over 44 million Americans choose contact lenses to correct their vision. Contact lenses are complex, federally-regulated medical devices that require a prescription. **That is why a contact lens patient's journey begins in their eye doctor's office.**

1 SCHEDULING A COMPREHENSIVE EXAM

An eye exam diagnoses the need for glasses or contact lenses and can be an early detector of certain diseases – which is why regular eye exams are so important.

DID YOU KNOW THAT OF THE 87% OF CONTACT LENS WEARERS WHO HAD AN EYE EXAM LAST YEAR, 94% REPORTED A CHANGE IN THEIR PRESCRIPTION SINCE THEIR LAST VISIT?¹

3 FINDING THE RIGHT LENSES

The doctor identifies the best contact lens brands for the patient and provides free trial lenses to ensure that the lens brand ultimately prescribed suits the patient's physiological features, wearing habits, and price preferences.

DID YOU KNOW THAT WITH OVER 160 CONTACT LENS BRANDS TO CHOOSE FROM, 85% OF CONSUMERS SAY IT'S EASY TO FIND A BRAND THAT WORKS FOR THEIR EYES?²

5 CHOOSING WHERE TO PURCHASE

Patients can choose to purchase lenses directly from their eye doctor or from a variety of retail options, like an optical retail chain or an online retailer.

DID YOU KNOW THAT 96% OF CONTACT LENS WEARERS ARE SATISFIED WITH THEIR OPTIONS WHEN PURCHASING CONTACT LENSES?³

2 EVALUATING EYE HEALTH

During the contact lens exam, the doctor measures features like cornea curvature and diameter, and checks for signs of lens-related complications.

DID YOU KNOW THAT YOUR EYE DOCTOR EVALUATES OVER 10 DIFFERENT FACTORS AND MEASUREMENTS WHEN DETERMINING THE RIGHT CONTACT LENS FOR PATIENTS?

4 RECEIVING YOUR PRESCRIPTION

The eye doctor then provides the patient with a written prescription for their lenses.

DID YOU KNOW THAT YOUR EYE CARE PROFESSIONAL IS REQUIRED BY LAW TO PROVIDE YOU WITH A COPY OF YOUR PRESCRIPTION AFTER YOUR CONTACT LENS FITTING?

Rx for Jane Doe

- ✓ Expiration Date
- ✓ Lens Power
- ✓ Lens Brand (Material)

6 VERIFYING YOUR PRESCRIPTION

By law, contact lens sellers must verify patient prescriptions with the prescribing doctor—either by fax, email, or phone—to guarantee that the lenses being sold are the same as those identified to address the patient's vision and physiological needs.

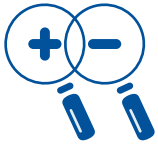
DID YOU KNOW THAT ONCE A REQUEST IS RECEIVED A PRESCRIBER ONLY HAS EIGHT HOURS TO VERIFY THE PRESCRIPTION OR ADDRESS INACCURACIES, OTHERWISE THE SALE IS AUTOMATICALLY AUTHORIZED?

^{1,2,3} From July 27 – August 16, 2015, APCO Insight conducted a telephone survey among adult contact lens consumers 18 years and older on behalf of Johnson & Johnson Vision Care, Inc. A total of 867 decision-makers who have purchased contacts in the last year participated in the survey. Data have been weighted according to a 2014 Gallup Study of the U.S. Consumer Contact Lens Market to reflect representation on key demographic measures.

The Contact Lens Prescription

WHY ONE CONTACT LENS DOES NOT FIT ALL

A contact lens fitting involves more than what it takes to sharpen vision to 20/20. It also includes an assessment of the contact lens after several days to weeks of wear to determine how the contact lens may change on the eye, how the patient's eyes may react to contact lens wear, and how the lens fits over time.¹ **As concluded by a recent literature review by The Ohio State University**, other aspects of a contact lens prescription – like the shape of the lens and the material used in each brand – are important factors of an eye doctor's judgement in protecting patient eye health.



REFRACTIVE POWER

The refractive power indicates the amount of correction each contact lens must provide to sharpen a patient's vision to 20/20, and often, is not the same as the patient's glasses prescription.



EXPIRATION DATE

Because a patient's vision may change over time and wearing contact lenses can alter eye health, contact lens prescriptions typically expire after a year to encourage regular vision care.

DID YOU KNOW THAT BEFORE WRITING A PRESCRIPTION, THE EYE DOCTOR ASSESSES OVER 10 STRUCTURAL AND BIOLOGICAL FEATURES UNIQUE TO THE PATIENT'S EYES? THIS COMPREHENSIVE EVALUATION ENABLES THE DOCTOR TO IDENTIFY THE CONTACT LENS BRAND THAT WILL BEST AND MOST SAFELY MEET A PATIENT'S NEEDS.

Rx

Prescribed by: Joe Jacobsen, M.D.
Prescription for: Jane Smith
Prescription expires 1 year from issue.

	OD	OS
PWR	-2.75	-3.50
BC	8.6	8.6
DIA	14.5	14.5
AXIS	90	90
CYL	+2.50	+1.50
BRAND	ACUVUE OASYS® FOR ASTIGMATISM*	ACUVUE OASYS® FOR ASTIGMATISM*

*Brand substitution is federally prohibited

BASE CURVE & DIAMETER

The base curve and diameter of contact lenses are measured to mimic a patient's unique eye shape for the best fit and comfort. Additional factors not included in the prescription, such as material stiffness and wettability also impact the fit of the lens.



LENS BRAND

Each contact lens brand's proprietary material can cause different patient reactions,² which is why the eye doctor may have a patient try on several brands to determine which material is best for the patient's eyes.



DID YOU KNOW THAT CONTACT LENSES WITH THE SAME BASE CURVE AND DIAMETER CAUSED DIFFERENT PHYSIOLOGICAL REACTIONS AMONG PATIENTS IN A RECENT STUDY,³ BASED ON THE VARYING BRAND OF LENSES WORN?

*"Contact lenses are not merely pieces of plastic that inertly rest on the front of the eye. Several crossover studies...showed that the **physiological reactions and the contact lens parameters differed, based on the brand of contact lens used.**"*

– Dr. Jeffrey J. Walline, OD, PhD, Associate Dean for Research, The Ohio State University

^{1,2,3}Walline J, Morrison A, Smith M, Widmer D. "Are Contact Lenses Interchangeable"—The Ohio State University Technical Report, 2015 on behalf of Johnson & Johnson Vision Care.

Bringing Healthy Vision to Everyone, Every Day

ACCESS, QUALITY, & COMPETITION—FCLCA & REGULATORY ACTIVITY

In the fall of 2015, the **Federal Trade Commission (FTC)** solicited public comments as part of its 10 year review of the **Fairness to Contact Lens Consumers Act's (FCLCA)** implementing rule. This review offers an opportunity for manufacturers, vision care providers, sellers, and patients to provide valuable input on ways to preserve patient access to a range of retail options, while strengthening existing health and safety protections.

BACKGROUND

In December 2003, Congress enacted the FCLCA to improve consumers' ability to access quality contact lenses. This legislation authorized FTC to develop and enforce the FCLCA legislative requirements which resulted in the FTC's July 2004 Contact Lens Rule.

FCLCA AND THE CONTACT LENS RULE

Enactment of FCLCA and the Contact Lens Rule marked a key milestone for consumers in how they are able to access quality contact lenses, including:

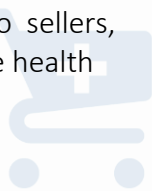
- Prescribers must **provide consumers with a copy of the contact lens prescription** following a contact lens fitting with an eye care professional.
- Sellers are required to **verify the prescription** with an eye care professional before providing lenses to consumers.

These changes encouraged competition by allowing consumers to purchase contact lenses from an eye care professional or other seller while underscoring the importance of routine vision care from eye care professionals.

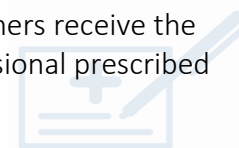
OPPORTUNITIES FOR IMPROVEMENT

Johnson & Johnson Vision Care, Inc. (JJVCI) has been preparing since early June to address a range of vision care concerns—as well as, share our continued support of certain provisions in the existing FCLCA and FTC rule—during this open comment, including:

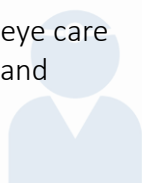
Encouraging open competition in the vision care market by **preserving consumer access** to sellers, with the option to purchase from an eye health professional or via a third party seller.



Maintaining the brand name on the contact lens prescription; ensuring consumers receive the product their eye care professional prescribed during the eye exam.



Ensuring patients continue to see their eye care professionals for their **annual check-up** and prescription renewal.



Strengthening the prescription verification process between third-party sellers and eye care professionals in order to preserve market competition, while better protecting consumer health.



THE INTENT

The Fairness to Contact Lens Consumers Act (FCLCA) and the Federal Trade Commission's (FTC) subsequent Contact Lens Rule were enacted over a decade ago to enhance consumer choice and encourage competition in the contact lens retail market by:



Requiring doctors to **provide patients with a copy of their prescription**, ensuring access to a variety of retail options when shopping for contact lenses.



Assuring consumers that **regardless of where they purchase their lenses**, they should receive the **exact lenses prescribed** by their eye doctor.



Protecting consumers from potential adverse events from **wearing different lenses than those prescribed** by their eye doctor or purchased **beyond the life** of their prescription.



THE REALITY

The ability for prescriptions to be verified automatically, without confirmation from the prescribing doctor, coupled with the tendency of sellers to schedule verification robo-calls straight to doctors' voicemail systems or outside of the 8-business hour window, means it is possible to:



Purchase lenses with an expired prescription.



Make-up or falsify prescription details.



Buy more lenses than medically recommended, particularly in the absence of quantity limits.



Purchase lenses from nondomestic sellers without a prescription.

The reality is these loopholes are not only counter to Congress' intent, but can put patients' eye health and safety at risk.

Bringing Healthy Vision to Everyone, Every Day

CONTACT LENSES & MEDICAL DEVICES – FDA CLASSIFICATION

Contact lenses have been recognized by the U.S. Food and Drug Administration (FDA) as **Class II and Class III medical devices** since 1976.

While regular-wear contact lenses pose a moderate risk to patient health and are classified as Class II medical devices, lenses that can be worn overnight or on an extended-wear schedule are Class III devices because they pose a higher risk to patient health when worn without appropriate physician oversight.

By law, consumers are required to have a valid prescription from an eye care professional to purchase lenses.

DEVELOPING MEDICAL DEVICE STANDARDS TO KEEP PATIENTS SAFE

Congress passed the *Medical Device Amendments (MDA) of 1976* to address the growing need for a review process for medical devices, including contact lenses.

Enactment of MDA was a landmark development in fulfilling FDA's mission to ensure the safety and effectiveness of drugs and devices available to patients.

MDA established a number of minimum requirements and directed FDA to classify all medical devices into one of three classes based on patient risk.

SUPPORTING THE SAFETY & EFFECTIVENESS OF CONTACT LENSES

As JJVCI continues to research and innovate new ways to promote the vision health of patients across the country, maintaining contact lenses' current medical device classification will help support the safety and effectiveness of contact lenses.

MEDICAL DEVICE CLASSIFICATIONS

CLASS I DEVICES

- Pose the lowest risk of injury to patients
- Require a minimum level of FDA regulation to provide reasonable assurance of safety and effectiveness

Class I devices include elastic bandages, examination gloves, and visual acuity charts.



CLASS II DEVICES

- Pose a moderate risk to patients
- Require additional regulation to provide reasonable assurance of safety and effectiveness, such as labeling and post-market surveillance

Class II devices include infusion pumps, hearing aids, and daily wear contact lenses.



CLASS III DEVICES

- Life-supporting or life-sustaining devices
- Pose a higher risk of illness or injury
- Subject to premarket approval and increased regulation aimed at ensuring their safety and effectiveness

Class III devices include certain dental implants, heart valves, and extended-wear contact lenses.



Competition in the Contact Lens Marketplace

HIGH LEVEL OF CONSUMER CHOICE AND SATISFACTION

Today's contact lens marketplace is rich with competition at the manufacturer, prescriber, and retailer levels. As a result, eye care professionals have better options when prescribing lenses to suit their patient's ocular needs, and consumers have more choices when deciding where to have their eyes examined and where to purchase contact lenses. The result – according to a recent consumer survey¹ – is not only **high satisfaction with the lens technological advancements offered today (83%), but overwhelming support for the current options for purchasing lenses (96%).**

HIGH CONSUMER SATISFACTION

Contact lens wearers are satisfied with the quality of lenses available and rely on their eye care professional to find the best fit.

83% agree that **contacts have improved** in recent years.²



97% say that their eye care professional has been helpful in finding contacts they liked.³



MANY RETAIL OPTIONS

Consumers have a variety of choices of where to buy their lenses.

96% are satisfied with the different ways they can buy contacts.⁴



78% say that it is important to be able to purchase contacts through their eye care professional.⁵

CHOICE IN LENSES

Today's market offers more than 160 different brands of contact lenses, giving consumers and eye care professionals access to a greater variety of contact lens brands. Competition among the contact lens manufacturers benefits consumers wholly because it drives manufacturers to bring meaningful, innovative, and advanced contact lenses to the market.

85% say it is easy to find a contact lens brand they like.⁶



^{1,2,3,4,5,6} From July 27 – August 16, 2015, APCO Insight conducted a telephone survey among adult contact lens consumers 18 years and older on behalf of Johnson & Johnson Vision Care, Inc. A total of 867 decision-makers who have purchased contacts in the last year participated in the survey. Data have been weighted according to a 2014 Gallup Study of the U.S. Consumer Contact Lens Market to reflect representation on key demographic measures.

The contact lens retail marketplace has changed significantly since the enactment of the Fairness to Contact Lens Consumers Act (FCLCA) and Contact Lens Rule over ten years ago. Unfortunately, loopholes in today's marketplace have resulted in a system that often side-steps the physician oversight of these FDA-regulated medical devices. According to a recent survey of online contact lens consumers¹, **here is the reality of today's contact lens marketplace:**

Consumers believe it's important to receive the exact lenses they order and rely on the FCLCA's existing safeguards to ensure they receive the lenses prescribed by their eye doctor.

94% say it's important they receive the **exact brand of contact lenses they order.**



65% think online retailers **should be required to verify** consumer prescriptions with their eye doctor prior to completing a sale.



Unfortunately, some online retailers send patients lenses that don't match their prescription or advise them to substitute another brand, without notifying the prescribing doctor.

1 in 4

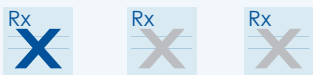
consumers reported **receiving a different brand** of contact lenses than they had ordered **without any advance warning.**

1 in 3

reported their online retailer had advised them to **substitute non-prescribed lenses** due to supply issues.

In fact, some online retailers not only complete sales based on expired or nearly-expired prescriptions, but encourage this practice, despite the health and safety risks.

1 in 3



consumers were able to purchase lenses using an **already expired prescription.**

6 in 10



say they have **received a reminder** from their retailer that their prescription was near-expiration.

86%



of those who received a reminder **ordered more contact lenses as a result.**

It's time to modernize, strengthen, and enforce the FCLCA and Contact Lens Rule's existing safeguards in order to better protect patients' vision health and safety and maintain consumer access to retail options in today's marketplace.

¹ From September 24-October 2, 2015 APCO Insight conducted an online quantitative survey among 500 U.S. consumers who have purchased contacts online in the last six months, on behalf of Johnson & Johnson Vision Care.

An Overview of Contact Lens Technology

THE STRUCTURAL & CHEMICAL COMPONENTS OF A CONTACT LENS

Contact lens manufacturers design lenses based on diverse combinations of material formulas, as well as over 10 structural and chemical features. These combinations create lenses that are unique and proprietary to each manufacturer's brand and designed to suit a different set of corresponding needs.

Today, doctors have over 160 brands of contact lenses to choose from when navigating the unique needs of their patients. As highlighted by a recent literature review from The Ohio State University College of Optometry, **contact lenses are not freely interchangeable because every brand can elicit different reactions based on patients varying eye shapes, vision abilities, and physiological needs.**¹

Importantly – because the U.S. Food and Drug Administration (FDA) classifies contact lenses as Class II/III medical devices – consumers can be confident that regulations ensure their lenses will continue to be safe and effective as even more combinations are discovered.

SEE SOME OF THE FEATURES CONTACT LENS MANUFACTURERS CONSIDER WHEN DEVELOPING UNIQUE COMBINATIONS FOR THEIR BRANDS:

LIPID DEPOSITION

impacts optical performance, wettability, and comfort



DIAMETER

determines how the device sits on eye

IONICITY

affects lens surface sensitivity to changes in pH and to what degree it attracts protein deposits



WATER CONTENT

can affect the oxygen transmissibility, fragility, rigidity, and thickness of the lens

THICKNESS

impacts wearer comfort and affects oxygen transmissibility of lens

SILICONE AND FLUORIDE CONTENT

influences the flexibility, oxygen permeability, and lipid/protein deposition

OXYGEN TRANSMISSIBILITY

determines the rate at which oxygen flows through the lens



RIGIDITY/MODULUS

aids in determining the flexibility of each lens



BASE CURVE

curvature of the back surface of the lens which affects fit and comfort

MODALITY

refers to the length of time a contact can be worn prior to requiring replacement



WETTABILITY/WETTING AGENT

Affects the moisture retention of the lens



An Overview of Contact Lens Technology

THE STRUCTURAL & CHEMICAL COMPONENTS OF A CONTACT LENS



OXYGEN TRANSMISSIBILITY: The oxygen transmissibility of a contact lens is critical in avoiding oxygen deprivation of the cornea and subsequent corneal damage. As transmissibility is determined by the thickness and material type of the lens, manufacturers continue to seek new material compositions to enhance transmissibility and better enable doctors to fine tune prescriptions to the physiological needs of their patients.



SILICONE AND FLUORINE CONTENT: Lens polymers can include a combination of both silicone and fluorine, neither, or an alternative material altogether. Some lens polymers contain hydrophilic (water-loving) silicones, while others contain hydrophobic (water-hating) silicones. How these polymers are integrated into the contact lens material is critical to the success of the device on the patient's eye.



WATER CONTENT: In addition to determining classification, FDA regulates soft lenses based on water content. High water hydrogel content lenses provide increased oxygen flow, while lower water content hydrogel lenses provide limited oxygen flow, but are more durable. As such, prescribers have options when identifying the lenses that balance the physiological response, durability preference and vision performance of their patients.



LIPID DEPOSITION: While most silicone-based lenses are prone to the appearance of fatty deposits in the lens, the degree of lipid deposition is dependent on each patient's biological response. Adding greater complexity, there are 'good' lipids and 'bad' lipids that can deposit on lenses, similar to 'good' and 'bad' cholesterol in the blood. That's why eye care professionals offer different contact lens materials based on individuals' tear film composition.



IONICITY: Ionic lenses are classified by FDA as group III and group IV lenses, while non-ionic contact lenses are FDA groups I and II. Ionicity (or the charge) of the lens material affects the tendency of protein from the patient's tear film to be attracted to the lens. Therefore, a patient's tear film can help determine the type of lens that will perform best with their eyes.



DIAMETER: Appropriate coverage of the cornea is important because a soft contact with too large or too small a diameter for the patient's cornea can move excessively, cause tearing or discomfort, may dislodge, or may not move compatibly with the patients' eyes.



RIGIDITY OR MODULUS: Rigidity refers to the stiff or flexible structure of the lens, and modulus affects how the lens sits on the patient's eye and how it handles upon insertion. Both aspects can vary widely across brands and are determinants of patient comfort. Some brands offer more rigid lenses while others more flexible options, each serving a different patient preference.



BASE CURVE: Proper base curve selection is critical to ensuring proper alignment with the ocular surface. An appropriately aligned lens provides an optimal environment for tear exchange behind the lens, enables the provision of nutrients to the cornea and the removal of toxins. An ill-fitted lens, however, may slide up under the lid, fall out during wear, or adversely affect patient vision and comfort.



WETTABILITY/WETTING AGENT: Contact lens manufacturers have developed a range of proprietary, specially-formulated wetting agents that continually improve the patients' wearing experience by interacting more seamlessly with the tear film and ocular surface. These advances provide options that allow doctors to meet the needs of their patients in changing environments where variations in humidity, temperature and airflow can impact a patient's success with contact lenses.



MODALITY: Modality is a decision made based on eye health and lifestyle. For example, patients with very busy and active lifestyles may be better suited to daily disposable lenses than reusable lenses. Patients who sleep in their lenses require lenses that have undergone rigorous safety testing and FDA approval to determine that the lens can be worn safely on an extended wear replacement schedule.



THICKNESS: Contact lens thickness can affect oxygen transmissibility, comfort, and lens centration over the cornea. Poor oxygen transmission can reduce wearing time and inflict potentially irreversible corneal damage. Poor centration can cause redness, irritation and general discomfort.

Patients physiological reactions to contact lens brands vary significantly due to chemical features, structural features, and varying combinations of the two.² That is why it's so important that eye doctors have a wide variety of lenses from which to choose when identifying the best brand for their patients needs. Thankfully, contact lens manufacturers have innovated, and continue to innovate, to bring these options to the 44 million contact lens wearers in the U.S. today.

1,2 Walline J, Morrison A, Smith M, Widmer D. "Are Contact Lenses Interchangeable"—The Ohio State University Technical Report, 2015 on behalf of Johnson & Johnson Vision Care.

HOW MANUFACTURERS HAVE CHANGED THE WAY WE SEE

While the first contact lens dates back over 500 years, the modern lenses worn today by nearly 44 million Americans only came into existence in the 1950s. Since that time, contact lenses have seen dramatic improvements over the last seven decades. Manufacturers continue to research and develop innovative technologies aimed at tackling challenging vision conditions and improving the quality of life for the millions of contact lens consumers across the country.

Contact lenses are made with plastic for the first time—a dramatic improvement from the original rigid, blown-glass lenses.

Manufacturers redesign lenses to cover only the cornea of the eye—improving comfort and oxygen permeability—and develop the first hydrogel-based lenses, which better drape the eye's surface.

Lens manufacturers introduce contacts that can be replaced after daily, weekly or monthly wear—increasing patient choice and making lenses safer than ever before.

1988



ACUVUE® introduces the brand's first disposable contact lenses.

1940s

1950s

1980s

2007



ACUVUE® Brand introduces its first silicone hydrogel lenses with BLINK STABILIZED™ design to realign naturally after the blink to help keep vision stable.

2000s

Manufacturers develop the first contact lenses made of silicone hydrogel – the most oxygen permeable lenses to date.

1993



ACUVUE® launches the very first daily disposable contact lenses.

1990s

Contact lens accessibility surges as lenses become safer and more user-friendly.

2008



The world's first daily disposable lenses made of silicone hydrogel are introduced by ACUVUE®.

2014

Contact lenses come in a variety of thicknesses – some up to 65% thinner than the contact lenses of the 1950's.

TODAY



ACUVUE OASYS® Lenses now address 98% of patients' spherical and astigmatism needs.

Today, there are over 160 contact lens brands, designed to address a range of vision health needs: from lenses that reshape the wearer's cornea during sleep, to bifocal and UV blocking lenses, to lenses that can partially correct color blindness.

THE FUTURE

By 2024, it is estimated that there will be more than 46 million U.S. contact lens wearers.

Thanks to the continued innovation of contact lens manufacturers, we can hope to see lenses in the future that better-suit the unique ocular features of lens wearers, and that seek to address currently unmet vision and eye health needs. For example:



Even thinner contact lenses that maximize oxygen transmissibility and wearer comfort,



Scleral lenses that could correct severe corneal injuries without surgery,



Zoom capable lenses that would be controlled by the wearer's blink,



Smart contact lenses that would monitor the glucose levels of diabetic patients.