A Randomized, Active-Controlled, Double-Masked, Crossover Study to Evaluate the Clinical Performance of Deseyne (vifilcon C) Daily Disposable Soft Contact Lens for Presbyopia Extended Depth of Focus (EDOF)

Protocol 23001-2

24JAN2026

TITLE PAGE

A Randomized, Active-Controlled, Double-Masked, Crossover Study to Evaluate the Clinical Performance of Deseyne (vifilcon C) Daily Disposable Soft Contact Lens for Presbyopia Extended Depth of Focus (EDOF)

PROTOCOL 23001-2

Sponsor: Bruno Vision Care, LLC

This clinical investigation is being conducted in accordance with 21 Code of Federal Regulations (CFR) Parts 11, 50, 54, 56, and 812. The protocol was developed with consideration of the provisions in: International Organization for Standardization (ISO) 14155-1:2011 Clinical investigation of medical devices for human subjects – Part 1: General requirements; 14155-2:2011 Part 2: Clinical investigation of medical devices for human subjects – Part 2: Clinical investigational plan; ISO 11980:2012 Ophthalmic Optics – Contact lenses and contact lens care products – Guidance for clinical investigations; International Council for Harmonisation Good Clinical Practice, and applicable local regulations. The Sponsor intends to register this clinical trial with the public database https://ClinicalTrials.gov.

Revision Chronology:

Original	1.0	11 Jun 2024
Amendment 1	2.0	17 Jul 2024
Amendment 2	3.0	30 Sep 2024

SPONSOR APPROVAL PAGE

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PROTOCOL 23001-2

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INVESTIGATOR STATEMENT OF APPROVAL

A Randomized, Active-Controlled, Double-Masked, Crossover Study to Evaluate the Clinical Performance of Deseyne (vifilcon C) Daily Disposable Soft Contact Lens for Presbyopia Extended Depth of Focus (EDOF)

PROTOCOL 23001-2

I have read the attached document, concur that it contains all information necessary to conduct the study, and agree to abide by all provisions set forth therein.

I agree to conduct this study in accordance with 21 Code of Federal Regulations (CFR) Parts 11, 50, 54, 56, and 812. The protocol was developed with consideration of the provisions in: International Organization for Standardization (ISO) 14155-1:2011 Clinical investigation of medical devices for human subjects – Part 1: General requirements; 14155-2:2011 Part 2: Clinical investigation of medical devices for human subjects – Part 2: Clinical investigational plan; ISO 11980:2012 Ophthalmic Optics – Contact lenses and contact lens care products – Guidance for clinical investigations, International Council for Harmonisation Good Clinical Practice, and applicable local regulations. I will not initiate the study until I have obtained written approval by the appropriate Institutional Review Board (IRB)/Ethics Committee (EC) and have complied with all financial and administrative requirements of the governing body of the clinical institution and the Sponsor. I will obtain written informed consent from each study subject prior to performing any study specific procedures.

I understand that my signature on a case report form indicates that the data therein has been reviewed and accepted by me.

I understand that this document and related information is subject to confidentiality terms found in my signed Confidentiality or Clinical Services Agreement. I agree to protect the confidentiality of my patients when allowing the Sponsor of this clinical investigation, and/or relevant regulatory authorities and IRB/ECs, direct access to my medical records for study subjects.

_____

Principal Investigator, Printed Name

_____ _____

Principal Investigator, Signature Date

1. SYNOPSIS

Title:	A Randomized, Active-Controlled, Double-Masked, Crossover Study to Evaluate the Clinical Performance of Deseyne (vifilcon C) Daily Disposable Soft Contact Lens for Presbyopia Extended Depth of Focus (EDOF)
Sponsor:	Bruno Vision Care, LLC
Phase of study:	Effectiveness
Study number:	23001-2
Number of study centers and subjects:	Approximately 75 subjects will be treated at approximately 3 investigational (non-institutional) sites in the United States.
Objective:	To evaluate improvements in near vision and EDOF with the Deseyne (vifilcon C) Daily Disposable Soft Contact Lens for Presbyopia EDOF
Study design:	A multicenter, randomized, active-controlled, double-masked, crossover study design will be used to compare the clinical performance of the Deseyne (vifilcon C) for Presbyopia EDOF soft contact lens (test) to the 1-Day Acuvue Moist (etafilcon A) soft contact lens for Single Vision (control). This is a 1-day crossover study and will consist of approximately 75 subjects (75 study eyes [all study eyes will be right eyes]) randomly assigned in-office to wear the test or the control lens first. A 30-minute washout period will be scheduled between the crossover. Subjects must be otherwise healthy, with spectacle refraction between -6.00 and +4.00 D and astigmatism ≤1.00 D that does not interfere with visual acuity (VA). The Screening and Lens Fitting Visit (Visit 1) will determine eligibility for inclusion in the study, and subjects will be fitted with the test and control devices in both eyes. To maintain subject masking, each time study lenses are to be inserted (at Visit 1 and Visit 2), an unmasked technician will remove the foil labels from the assigned contact lens blister packs before giving the opened blister packs to the subject, who will insert both lenses. The Testing Visit (Visit 2) will be conducted in the manner described to assess vision with either the test or control lens followed by a 30-minute washout period (after the first set of lenses is removed) followed by crossover to the second set of lenses. To maintain Investigator masking, the subject (not the Investigator) will

	remove study lenses and immediately dispose of them. With this approach, the Investigator will not see the lenses either through the slit lamp or out of the subject's eye. Subjects will wear their assigned lenses bilaterally only for the period required for testing. Lenses will not be dispensed to subjects for wear beyond the visit. This is a non-dispensing study.
Subject selection:	*Inclusion Criteria:* 1. Age 45 to 70 years 2. Presence of clear corneas 3. Correction between -6.00 and +4.00 D in the spectacle plane 4. Phakic and/or pseudophakic subjects 5. Monocular best-corrected distance visual acuity (BCDVA) of 0.1 logMAR or better in the right eye 6. Be an adapted soft contact lens wearer in each eye 7. Able and willing to attend all scheduled sessions 8. Able to read, understand, and provide written informed consent *Exclusion Criteria:* 1. Anisometropia (spherical equivalent >2.00 D) in either eye 2. Ocular astigmatism >1.00 D in either eye 3. Monocular BCDVA worse than 0.3 logMAR in either eye 4. Any corneal infiltrates in either eye 5. Grade ≥2 slit lamp findings during Screening in either eye 6. Any scar or neovascularization within the central 4 mm of the cornea during Screening in either eye 7. History of ocular disease (eg, dry eye disease, blepharitis, conjunctivitis, ocular herpes simplex or herpes zoster, etc.) within 30 days prior to Screening in either eye 8. History of gas-permeable lens wear within 30 days prior to Screening in either eye or history of "hard" contact lens wear within 3 months of Screening in either eye 9. History of any corneal surgery, including refractive or laser surgery, in either eye 10. Implantation or removal of absorbable punctal plug within 6 months of Screening in either eye or permanent punctal occlusion in 1 or more puncta or nasolacrimal duct obstruction in either eye

	11. Use of any prescription ocular medication or any over-the-counter eyedrops within 1 week of Screening in either eye or during the period of study participation 12. Participation in any drug or device clinical investigation within 2 weeks prior to Screening or during the period of study participation 13. Women of childbearing potential (those who are not surgically sterilized or postmenopausal) who are currently pregnant or breastfeeding 14. Systemic disease or use of any systemic medications that may, in the opinion of the Investigator, interfere with normal lens wear
Planned study period and duration of treatment:	Total duration of study participation is 2 visits (separated by no more than 1 month): 1. Screening and Lens Fitting 2. Testing The duration of lens wear is limited to the Testing Visit, during which vision testing will be performed in clinic.
Test lens:	The Deseyne (vifilcon C) Daily Disposable Soft Contact Lens for Presbyopia EDOF is proposed to be indicated for the optical correction of refractive ametropia (myopia and hyperopia) in non-diseased presbyopic eyes with ≤1.00 D of astigmatism that does not interfere with VA. • Sphere power: -6.00 to +4.00 D • Diameter: 14.1 mm • Base curve: 8.6 mm • Material: vifilcon C
Control lens:	1-Day Acuvue Moist (etafilcon A) daily disposable soft contact lens for Single Vision (Vistakon): • Sphere power: -6.00 to +4.00 D • Diameter: 14.2 mm • Base curve: 9.0 mm • Material: etafilcon A
Schedule of study visits:	Visits and visit windows: 1. Screening and Lens Fitting Visit: 14 to 2 days prior to the Testing Visit 2. Testing Visit

Primary effectiveness endpoints:	The primary effectiveness endpoint for the study is monocular (study [right] eye only) photopic negative lens-induced distance-corrected depth of focus (DOF) at the 0.2 logMAR VA threshold. The statistical hypothesis is stated in terms of 1-sided hypotheses to reflect the superiority claims. H_0: The monocular photopic negative lens-induced distance-corrected DOF with the test lens is smaller than 0.5 D compared with the control lens. H_1: The monocular photopic negative lens-induced distance-corrected DOF with the test lens is greater than or equal to 0.5 D compared with the control lens. The study eye will be used to evaluate this hypothesis.
Secondary effectiveness endpoints:	• Mean monocular (study eye only) photopic distance-corrected intermediate visual acuity (DCIVA) at 66 cm The statistical hypothesis is stated in terms of 1-sided hypotheses to reflect the superiority claims. H_0: The monocular photopic DCIVA with the test lens is less than or equal to the monocular photopic DCIVA with the control lens. H_1: The monocular photopic DCIVA with the test lens is greater than the monocular photopic DCIVA with the control lens. • Mean monocular (study eye only) photopic distance-corrected near visual acuity (DCNVA) at 40 cm The secondary effectiveness endpoints will be summarized descriptively over all visits by treatment group and eye for the ITT and PP populations. Comparisons between treatment groups will use the same analysis of covariance as for the primary effectiveness endpoint, but inferential results for the secondary effectiveness endpoints will be considered exploratory. No formal hypothesis will be tested for these endpoints.
Additional analyses:	• Defocus curves (study eye only) • Binocular contrast sensitivity (mesopic conditions with and without glare) • Age stratification into 2 age groups (<60 and ≥60 years) to identify the effect of EDOF as age increases • Pupil diameter (study eye) stratification into 3 tertiles • DCNVA stratification into 3 tertiles based on monocular (study eye) near VA with the control lens

Statistical plan:	All analyses will compare values between the test and control lenses. A full declaration of planned statistical analyses will be documented in a formal Statistical Analysis Plan.
Sample size:	The primary effectiveness endpoint is the monocular photopic negative lens-induced distance-corrected DOF. To test the hypothesis that the difference between test and control means is less than 0.5 D at alpha=0.025 using a 2×2 crossover design, 75 subjects (75 study eyes) are required to achieve 90% power, assuming a standard deviation of the paired differences = 1.06 D and an observed difference of at least 0.90 D.