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**Johnson & Johnson Vision Announces FDA Approval of ACUVUE® Abiliti™ Overnight
Therapeutic Lenses for Myopia Management**

- *First and only FDA-approved orthokeratology contact lens for myopia management.*
- *Available in sphere and toric designs to correct various levels of corneal shapes and refractions.*

JACKSONVILLE, FL – May 12, 2021 – Johnson & Johnson Vision*, a global leader in eye health and part of the Johnson & Johnson Medical Devices Companies†, today announced that the U.S. Food and Drug Administration (FDA) has approved [ACUVUE® Abiliti™](#) Overnight Therapeutic Lenses. This is the first and only FDA approved orthokeratology (ortho-k) contact lens for the management of myopia.

Click to Tweet: #BREAKINGNEWS @JNVision announces ACUVUE® Abiliti™ Overnight Therapeutic Lenses – the first and only @US_FDA approved ortho-k lens for the management of myopia. [\[LINK TO RELEASE\]](#)

“The FDA approval of Abiliti™ Overnight marks an important milestone in our commitment to help change the trajectory of eye health and reshape the future of myopia in children,” said Xiao-Yu Song, MD, PhD, Global Head of Research & Development, Johnson & Johnson Vision‡. “We look forward to supporting parents and eye care professionals in their care of children by providing comprehensive resources, starting with Abiliti™ Overnight Therapeutic Lenses, and continuing with additional products and services to address the progression of myopia.”

*Johnson & Johnson Vision represents the products and services of Johnson & Johnson Surgical Vision, Inc., Johnson & Johnson Vision Care, Inc., and the affiliates of both.

†The Johnson & Johnson Medical Devices Companies comprise the surgery, orthopedics, vision, and interventional solutions businesses within Johnson & Johnson’s Medical Devices segment.

‡Dr. Xiao-Yu Song, MD, PhD is an employee of Johnson & Johnson Vision Care, Inc., with oversight of Research and Development for both the Surgical Vision and Vision Care organizations.

Myopia is sometimes called ‘nearsightedness’ but it is much more. It is a chronic and progressive disease that poses the biggest eye health threat of the 21st Century¹. Young children that are less than 12 years of age and become myopic are the most vulnerable to develop high myopia and can be at increased risk of sight-threatening eye diseases later in life². Additionally, half of the world’s population is projected to be myopic by 2050 with nearly one billion people expected to have high myopia³.

Clinical studies have demonstrated that ortho-k lenses can be a safe and effective treatment option to manage myopia⁴. Abiliti™ Overnight ortho-k contact lenses are specifically designed and fitted to improve a patient’s vision by reshaping the cornea and will be available in two different contact lens designs: Abiliti™ Overnight Therapeutic Lenses, and Abiliti™ Overnight Therapeutic Lenses Toric.

Abiliti™ Overnight contact lenses are optimized by the use of corneal topography connected to leading-edge Abiliti™ Easyfit software. Abiliti™ Easyfit software is a sophisticated, user-friendly tool that provides a precise measure of the corneal shape, and accurately guides the eye care professional through the fitting process for consistent and successful fit rates of approximately 90%⁵.

“The prevalence of myopia in children is increasing, and as optometrists we are on the front lines of this epidemic that may threaten the vision of future generations,” said Moshe Mendelson, OD, FIAO^{**}. “For too long we have relied on increasing the prescription of glasses for children, while having few resources to address the underlying disease and help change this worrying trajectory of eye health. The FDA approval of Abiliti™ Overnight will provide eye care professionals and parents with more options to manage myopia.”

Johnson & Johnson Vision is collaboratively advancing the next generation of science, research and development with the potential to transform standards of care in myopia. Earlier this year, the company announced the development of a first-of-its-kind [myopia management guide](#) with recommendations for eye care professionals to assess, monitor and treat myopia in children. This approval from the FDA stems from the collaboration [Johnson & Johnson Vision created with Menicon](#) to bring forward therapeutic contact lenses for the treatment of myopia under the Abiliti™ – a [new brand for future products and services to help parents and eye care professionals address the progression of myopia in children](#). Each annual purchase of an Abiliti™ product will provide a free comprehensive eye health exam to a child in need through [Sight for Kids](#) – a joint program from Johnson & Johnson Vision and the not-for-profit program from the Lions Clubs International Foundation (LCIF). Sight for Kids is one of the largest-known, school-based eye health programs that mobilizes Lions and eye care professionals to provide comprehensive eye health services in low-income schools around the world.

Abiliti™ Overnight contact lenses are expected to be available in the U.S. by the end of 2021. Parents and eye care providers who want more information can visit www.seeyourabiliti.com.

⁵Final lens fit is determined by the ECP – software is a decision support only.

^{**}Dr. Moshe Mendelson is a paid consultant of Johnson & Johnson Vision, Inc.

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About ACUVUE® Abiliti™ Overnight Therapeutic Lenses

ACUVUE® Abiliti™ Overnight Therapeutic Lenses are the first and only orthokeratology lenses approved by the U.S. Food and Drug Administration (FDA) for myopia management. Abiliti™ Overnight lenses can reduce the axial elongation of the eye in myopic children by 0.28mm, on average, over a 2-year period, accounting for a treatment effect of approximately 1.00 diopter of myopia^{5,6,7}.

About Johnson & Johnson Vision*

At Johnson & Johnson Vision, part of Johnson & Johnson Medical Devices Companies, we have a bold ambition: to change the trajectory of eye health around the world. Through our operating companies, we deliver innovation that enables eye care professionals to create better outcomes for patients throughout their lives, with products and technologies that address unmet needs including refractive error, cataracts and dry eye. In communities with greatest need, we work in collaboration to expand access to quality eye care, and we are committed to helping people see better, connect better and live better. Visit us at www.jjvision.com. Follow [@JNJVision](#) on Twitter and [Johnson & Johnson Vision](#) on LinkedIn.

About Johnson & Johnson Medical Devices Companies[†]

At Johnson & Johnson Medical Devices Companies, we are helping people live their best lives. Building on more than a century of expertise, we tackle pressing healthcare challenges, and take bold steps that lead to new standards of care while improving people's healthcare experiences. In surgery, orthopedics, vision and interventional solutions, we are helping to save lives and paving the way to a healthier future for everyone, everywhere.

Important Safety Information for Contact Lens Wearers

ACUVUE® Abiliti™ Overnight Therapeutic Lenses are approved in the U.S. for the temporary reduction of myopia up to 4.00 diopters and with eyes having astigmatism up to 1.50 diopters. The lenses may only be disinfected using a chemical disinfection system. To maintain the Orthokeratology effect of myopia management, overnight lens wear must be continued on a prescribed schedule. Failure to do so can affect daily activities, cause visual fluctuations, and changes in intended correction.

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†The Johnson & Johnson Medical Devices Companies comprise the surgery, orthopedics, vision, and interventional solutions businesses within Johnson & Johnson's Medical Devices segment.

¹ JJV data on file 2021.

² Hu Y, Ding X, Guo X, Chen Y, Zhang J, He M. Association of Age at Myopia Onset with Risk of High Myopia in Adulthood in a 12-Year Follow-up of a Chinese Cohort. *Jama Ophthalmol.* 2020;138(11):1129-1134. doi:10.1001/jamaophthalmol.2020.3451.

³ Holden BA, Fricke TR, Wilson DA, Jong M, Naidoo K, et al. Global Prevalence of Myopia and High Myopia and Temporal Trends from 2000 to 2050. *Ophthalmol.* 2016;123(5):1036-1042. doi: 10.1016/j.ophtha.2016.01.006.

- ⁴ Liu, YM, Peiying, X. The Safety of Orthokeratology—A Systematic Review. *Eye Contact Lens*. 2016;42(1):35-42. doi: 10.1097/ICL.0000000000000219.
- ⁵ Cho P, Cheung SW. Retardation of Myopia in Orthokeratology (ROMIO) Study: a 2-year Randomized Clinical Trial. *Invest Ophthalmol Vis Sci*. 2012;53(11):7077–85. doi: 10.1167/iops.12-10565.
- ⁶ Santodomingo-Rubido J, Villa-Collar C, Gilmartin B, Gutiérrez-Ortega R. Myopia Control with Orthokeratology Contact Lenses in Spain: Refractive and Biometric Changes. *Investig Ophthalmol Vis Sci*. 2012;53(8).5060-5. doi: 10.1167/iops.11-8005.
- ⁷ Chen C, Cheung SW, Cho P. Myopia Control Using Toric Orthokeratology (TO-SEE study). *Invest Ophthalmol Vis Sci*. 2013;54(10):6510–7. doi: 10.1167/iops.13-12527.