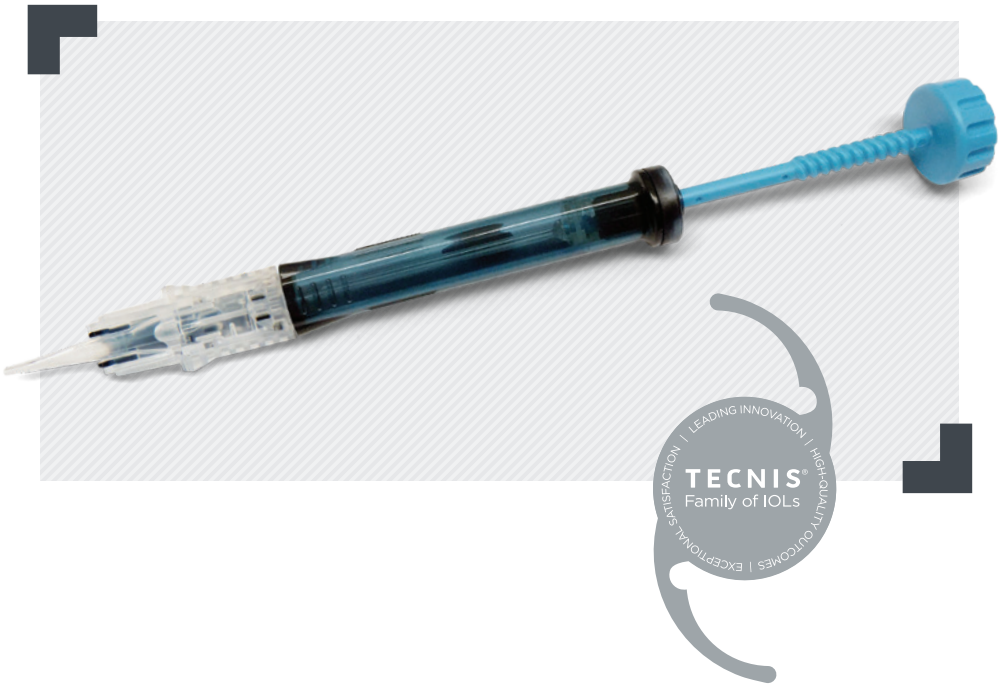
TECNIS Simplicity™ — The Next-Generation TECNIS® IOL Disposable Delivery System

Simplifying delivery of the IOL you prefer.



BENEFITS:

- Easy 3-step process - hydrate, advance, deliver
- Advanced design for a smooth and controlled IOL delivery
- Flexibility to use BSS or OVD for hydration

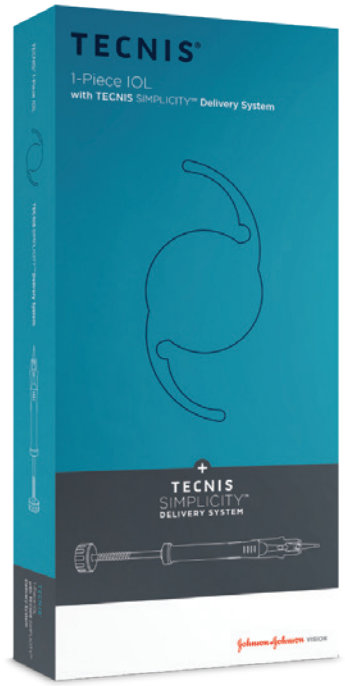
For more information on TECNIS Simplicity™ Delivery System, please contact your Johnson & Johnson Vision Representative or visit surgical.jnjvision.com

TECNIS SIMPLICITY™ DELIVERY SYSTEM

Johnson & Johnson VISION

The Next-Generation TECNIS® IOL Disposable Delivery System

TECNIS® 1



Product Code:	DCB00	
OPTIC CHARACTERISTICS		
Power Range:	+5.0 D to +34.0 D in 0.5 diopter increments	
Diameter:	6.0 mm	
Shape:	Biconvex, anterior aspheric surface	
Material:	UV-blocking hydrophobic acrylic	
Refractive Index:	1.47 at 35ºC	
Edge Design:	ProTEC 360° Edge; frosted edge design; continuous uninterrupted posterior square edge	
OPTICAL BIOMETRY/ APPLANATION ULTRASOUND BIOMETRY		
A-constant:	119.3*	118.8†
Theoretical AC Depth:	5.7 mm	5.4 mm
Surgeon Factor[1]:	1.96 mm	1.68 mm
HAPTIC CHARACTERISTICS		
Lens Overall Diameter:	13.0 mm	
Style:	C	
Design:	Tri-Fix, haptics offset from optics, 1-piece lens	
Incision size:	2.2 mm – 2.4 mm	

*Derived from clinical evaluation results of the 1-Piece IOL Platform for optical biometry.
† A-Constant theoretically derived for ultrasound biometry.

Reference: 1. Holladay JT. International Intraocular Lens & Implant Registry 2003. J Cataract Refract Surg. 2003; 29:176-197. ReF2016CT0151.

INDICATIONS AND IMPORTANT SAFETY INFORMATION for the TECNIS® 1-Piece IOL with the TECNIS SIMPLICITY™ Delivery System

Rx Only

ATTENTION
Reference the Directions for Use labeling for a complete listing of indications and important safety information.

INDICATIONS
TECNIS 1-piece lenses are indicated for the visual correction of aphakia in adult patients in whom a cataractous lens has been removed by extracapsular cataract extraction. These devices are intended to be placed in the capsular bag.

PRECAUTIONS
Do not resterilize the lens or the TECNIS SIMPLICITY™ Delivery System. Most sterilizers are not equipped to sterilize the soft acrylic material and the preloaded inserter material without producing undesirable side effects. Do not store the device in direct sunlight or at a temperature under 5°C (41°F) or over 35°C (95°F). Do not autoclave the device. Do not advance the lens unless ready for lens implantation. The contents are sterile unless the package is opened or damaged. The recommended temperature for implanting the lens is at least 17°C. The combination of low operating room temperatures and high IOL diopter powers may require slower delivery. The use of balance salt solutions (BSS) and/or viscoelastics is required when using the TECNIS SIMPLICITY™ Delivery System. For optimal performance when using an OVD, use the HEALON® family of viscoelastics. Do not use if the TECNIS SIMPLICITY™ Delivery System has been dropped or if any part was inadvertently struck while outside the shipping case.

WARNINGS
Physicians considering lens implantation under any of the following circumstances should weigh the potential risk/benefit ratio: Patients with recurrent severe anterior or posterior segment inflammation or uveitis; patients in whom the intraocular lens may affect the ability to observe, diagnose or treat posterior segment diseases; surgical difficulties at the time of cataract extraction, which may increase the potential for complications (e.g., persistent bleeding, significant iris damage, uncontrolled positive pressure or significant vitreous prolapse or loss); a compromised eye due to previous trauma or developmental defect in which appropriate support of the IOL is not possible; circumstances that would result in damage to the endothelium during implantation; suspected microbial infection; patients in whom neither the posterior capsule nor the zonules are intact enough to provide support for the IOL; children under the age of 2 years are not suitable candidates for intraocular lenses. Do not attempt to disassemble, modify or alter this device or any of its components, as this can significantly affect the function and/or structural integrity of the design. Use of methylcellulose viscoelastics is not recommended as they have not been validated for use with the TECNIS SIMPLICITY™ Delivery System. Do not implant the lens if the rod tip does not advance the lens or if it is jammed in the cartridge. Do not push the plunger forward to fully advance the lens until ready for lens implantation. Discard the device if the lens has been folded within the cartridge for more than 10 minutes. Single-use medical devices are labeled with instructions for use and handling to minimize exposure to conditions which may compromise the product, patient, or the user. When used according to the directions for use, the TECNIS SIMPLICITY™ Delivery System minimizes the risk of infection and/or inflammation associated with contamination. The reuse/resterilization/reprocessing of single-use devices may result in physical damage to the medical device, failure of the medical device to perform as intended, and patient illness or injury due to infection, inflammation, and/or illness due to product contamination, transmission of infection, and lack of product sterility. The TECNIS® 1-piece IOL should be placed entirely in the capsular bag. Do not place the lens in the ciliary sulcus.

ADVERSE EVENTS
The most frequently reported adverse event that occurred during the clinical trial of the 1-Piece IOL was cystoid macular edema, which occurred at a rate of 3.3%. Other reported events occurring in less than 1% of patients were secondary surgical intervention (0.8%, vitrectomy) and lens exchange (0.8%, due to torn lens haptic).

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