TECNIS™ Toric Calculator

User Tutorial

Welcome to the TECNIS™ Toric Calculator.

The TECNIS™ Toric Calculator has been specifically designed to make calculating the TECNIS™ Acrylic 1-Piece Toric Intraocular Lenses (IOLs) accurate, intuitive, and easy.

With the TECNIS™ Toric Calculator you can:

- Input prompted data in order to determine the TECNIS™ Toric IOL model that will provide an optimized surgical outcome.

- Get calculated TECNIS™ Toric IOL results for your surgical needs.

- Print a report of patient information and results for surgeons' reference during cataract surgery.

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Overview

Johnson & Johnson Surgical Vision, Inc. (Johnson & Johnson Vision) has developed the Toric Intraocular Lens (IOL) models with patients undergoing cataract surgery in mind. The goal is to deliver a lens which will reduce residual refractive astigmatism based on a personalized level of data entry. The TECNIS™ Toric Calculator considers preoperative corneal astigmatism, as well as any anticipated surgically induced astigmatism in determining the optimal Toric IOL power for the correction of postoperative corneal astigmatism. The TECNIS™ Toric Calculator also provides the option of including an algorithm to account for posterior corneal astigmatism. The practice that will afford appropriate results requires that accurate keratometry measurements are used to determine preoperative corneal astigmatism. While the desired surgical procedure strives towards astigmatic neutrality, even minor incisions during cataract surgery can induce corneal astigmatism. This may affect the amount of postoperative corneal astigmatism as well as the respective axis. As a result, Johnson & Johnson Vision recommends that based upon individual surgical technique and past results, surgeons should customize their surgically induced corneal astigmatism value.

The TECNIS™ Toric Calculator is a tool, designed to help further integrate toric lenses into your practice. It is a software application that helps you select an appropriate TECNIS™ IOL for your patient. In the TECNIS™ Toric Calculator, the spherical equivalent IOL power is introduced as an input for each patient. Surgeons are able to use their spherical equivalent IOL power calculation method of choice. The TECNIS™ Toric Calculator calculates different cylinder IOL power options for you, as well as the orientation in which the IOL should be implanted. In addition, predicted postoperative residual astigmatism is calculated for each cylinder IOL power suggested and, placed in the indicated orientation in the patient's eye in order to facilitate the surgeon's lens selection.

In the TECNIS™ Toric Calculator, the toricity and residual astigmatism are calculated for each particular eye in a customized fashion, using the Holladay 1 formula instead of using a fixed ratio based on average ocular physiology. The TECNIS™ Toric Calculator allows for the input of personalized surgically induced astigmatism and/or IOL A-constants, as well as different options for keratometry input, to fit the needs of your practice.

Although the tool has been tested to a large range of possible situations, it is the user's responsibility to decide the usefulness of the calculated information.

Intended Use / Purpose

The TECNIS™ Toric Calculator is a software application that informs the selection of an appropriate TECNIS™ IOL.

Indications for Use

The TECNIS™ Toric Calculator is a software application that informs the selection of an appropriate TECNIS™ Toric IOL that is indicated to correct aphakia following removal of the natural crystalline lens and treatment of preexisting astigmatism.

Intended Users

The intended users for the TECNIS™ Toric Calculator are clinicians, ophthalmologists, and/or eye surgeons.

Contraindications

None.

Expected Clinical Benefits

The TECNIS™ Toric Calculator assists surgeons in selecting the appropriate TECNIS™ IOL Model to fit patient needs.

TECNIS™ Toric Calculator

Prerequisites

To use the TECNIS™ Toric Calculator, you will need: An Apple® computer (Mac OS® 14) or PC (Windows® 10 operating system).

- A working Internet connection
- Safari®, Google Chrome™ or Microsoft Edge® browser

Documentation Prerequisites

- Adobe® Reader® Software (Download it here.)

Note: This manual is applicable for all approved TECNIS™ Toric IOLs and their corresponding non-Toric IOLs; TECNIS™ IOL is listed for example throughout this manual.

Performance Characteristics

The performance and safety of the TECNIS™ Toric Calculator has been established through pre-clinical testing and clinical use and represents state-of-the-art medical software. The TECNIS™ Toric Calculator performs as intended for the function as a software application that helps to calculate and select the appropriate TECNIS™ IOL for postoperative corneal astigmatism correction based on user inputs when used according to the instructions for use and labeling.

Warnings & Precautions

None.

Note: Warnings and precautions for the specific intraocular lenses are described in their respective instructions for use.

Screen images shown below are for illustration purposes only.

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Quick Setup Guide
Read this page if this is your first time using the TECNIS™ Toric Calculator.

Within this guide, you will find the recommended first steps for getting your TECNIS™ Toric Calculator configured and ready to perform calculations.

After accessing the TECNIS™ Toric Calculator for the first time, a Registration page, similar to the one shown highlighted to the right, is displayed.

Once you are on the Registration page:

1. Select your location and language from the drop-down lists.

2. Review and Accept the TECNIS™ Toric Calculator Terms of Service.

Once the Terms of Service are accepted the Calculator page is displayed, and the TECNIS™ Toric Calculator is ready for use.

Registration Page

TECNIS™
Family of IOLs

TECNIS™ Toric Calculator

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Registration

| Europe - Middle East - Africa | English | I have read and agree to the terms below. |
| | | Accept |

TECNIS™ intraocular lenses are currently available for sale in select markets. This application is therefore intended only for residents of those markets in which the respective TECNIS™ intraocular lens(es) are available, and this application may only be used for those TECNIS™ intraocular lens(es) that are approved for use in your market. Using this mobile application and clicking the "Accept" button constitutes your acknowledgement of these restrictions, and your acknowledgement that you selected your proper location of residence.

TECNIS™ TORIC CALCULATOR LICENSE AGREEMENT, TERMS OF USE AND PRIVACY POLICY

PLEASE READ THIS USE AND LICENSE AGREEMENT ("AGREEMENT") IN FULL

TERMS OF SERVICE   LRI CALCULATOR

The product-specific application is intended for the residents of a particular country or countries. As a result, the application may contain information on pharmaceuticals, medical devices and other products or uses of those products that are not approved in other countries or regions. If you are a resident of a country other than those to which the application lists, please return to surgical.jnjvision.com or contact your local Johnson & Johnson Vision affiliate to obtain the appropriate product information for your country of residence.

This application is intended for use in connection with Johnson & Johnson Vision IOLs only and should not be used in connection with any other IOLs.

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Lens Selection

If there are more than one type of TECNIS™ Toric IOL available for the selected location, the TECNIS™ Family of IOLs logo is displayed in the upper-left corner until a lens is selected. If there is only a single TECNIS™ Toric IOL available for the selected location, the lens will be automatically selected and the logo for the lens is displayed in the upper-left corner.

To select from more than one TECNIS™ Toric IOL, the "SELECT LENS" button displays the available lenses for the current location. Simply select the lens of choice from the list of lenses displayed.

The logo for the newly selected lens will be displayed in the upper-left corner, and the "SELECT LENS" button is now labeled "CHANGE LENS" but functions the same.

Calculator Page – Lens Selection

This is a representative image of lens selection and not all lens options are available worldwide.

Calculation Results

Data entry fields, shown highlighted to the right, are on the left side of the page. However, the Eye Selection can also be made by selecting the appropriate eye on the Patient Face on the right side of the page.

Select any of the Section Headers with the circled information symbols to display definition and data input range information for each field within that section.

Note: Make sure to always input anterior corneal astigmatism measurements, regardless of "Include Posterior Corneal Astigmatism" checkbox selection. To ensure accurate calculation results, total corneal astigmatism values should never be used.

Note: A predetermined value for posterior corneal astigmatism can be included in the calculation by checking the box labeled "*Include Posterior Corneal Astigmatism*". The option to include the predetermined value of posterior corneal astigmatism is based on an algorithm that combines published literature[1] with a retrospective analysis of existing clinical data.

Note: Personalized constants for the corresponding non-Toric model (i.e., Model ZCB00) are valid starting points for Toric model calculations. Note that the formula used for cylinder power calculation is the Holladay-1.

Once the data entry is complete, select the "Calculate Results" button to calculate the results.

Calculator Page – Data Entry

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[1] Koch DD et al. Contribution of posterior corneal astigmatism to total corneal astigmatism. J Cataract Refract Surg. 2012 Dec;38(12):2080-7

Calculation results, shown highlighted to the right, are displayed on the right side of the page.

The postoperative corneal astigmatism orientation (orange / red: steep axis) and incision location (blue) are displayed on the diagram of the eye located in the graphical area on the right side of the page, as well as the recommended IOL orientation. Identification of Temporal and Nasal are displayed, relative to the choice of eye (OD or OS).

The Final Results table contains different Toric IOL cylinder power suggestions for this eye with their respective orientations and predicted residual astigmatism, in the convention chosen by the Calculation Preferences section.

Select the Final Results section header for more information.

Once an IOL Model is selected from the Final Results, the "Print Results" button is enabled to allow printing of the results.

Calculator Page – Calculation Results

Note: User-entered data and calculated results are not stored when the user exits the TECNIS™ Toric Calculator.

In order to keep a record of the TECNIS™ Toric Calculator output for the patient's file and for surgeon reference during the procedure:

1. Select an IOL Model from the Final Results table on the Calculator page.

2. Select the "Print Results" button at the bottom of the Calculator page.

3. Verify the input and results and proceed according to the confirmation message displayed.

4. When the Print dialog is displayed, select the printer of choice, and select the "OK" button to print and display the Results page.

5. Select the "Return to Calculator" button to leave the Results page and return to the Calculator page.
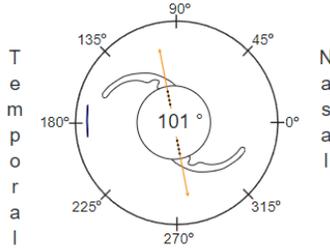
Print Results Page

TECNIS Eyhance™ with TECNIS SIMPLICITY™   DIU   Return to Calculator   Johnson&Johnson VISION

Surgeon Name	Patient Information	Date	Patient Age
Surgeon	XYZ-123-ABC	2/6/2024	65

OD (Right)

101°

(Incision Location) 180°
Calculated Orientation

IOL Details		Residual Refraction	
IOL Model	**Orientation**	**Cylinder**	**Axis**
DIU300	101 °	+0.33 D	101 °

Calculation Details

SE IOL Power	K Index	Refractive Cylinder Convention	
+20.0	1.3375	Plus	

Keratometry and Biometry

Flat K1 @ Meridian	Steep K2	SIA @ Meridian	AxL Length	Biometry Method	A-constant	PCA
41.25@12°	43.34@102°	0.30@180°	24.11	Optical or Immersion	119.30	No

IOL Details		Residual Astigmatism	
IOL Model	**Orientation**	**Cylinder**	**Axis**
DIU300	101 °	+0.33 D	101 °
DIU375	101 °	+0.16 D	11 °
DIU450	101 °	+0.65 D	11 °

Notes

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Clearing Data Input and Calculation Results

If you would like to initiate a new calculation, select the "Clear Entries" button to clear all previously entered data and calculation results. A prompt to confirm your choice, shown highlighted to the right, is displayed.

Note: Changing the Patient Information or Patient Age without clearing previous data and results will display a similar prompt to confirm whether you want to clear all the data entries or not.

Note: Changing the selected Lens Type without clearing previous data and results will also display a similar prompt to confirm whether you want to clear all the data entries or not.

It is good practice to choose to clear all data and results when entering information for a new patient.

Calculator Page – Clear Entries

Preferences are accessed by selecting the "Preferences & Support" button. The Preferences & Support page has two sections. The upper section, shown highlighted to the right, is for setting the user preferences.

The Preferences are separated into settings for the Display and for the Calculation.

The Display preferences allow the user to change the default location and language. In addition, the K Notation can be set to default to either "mm" for millimeters or "D" for diopters and the Decimal format can be set to default to "0.00" or "0,00" for numeric entries.

The Calculation preferences allow the user to change the default settings for the Refractive Cylinder Convention, the K Index and whether to Include Posterior Corneal Astigmatism. In addition, the default Biometry Method can be selected. If a personalized constant is selected for the Biometry Method the corresponding value field allows the user to enter their personalized A-Constant, Surgeon Factor or Anterior Chamber Depth accordingly.

Select the "Apply Preferences" button, on the right side of the Preferences header, to save any changes made to the preferences.

Select the "Reset to Defaults" button, on the right side of the Preferences header, to reset all of the preferences, except Location and Language, to the system defaults.

Preferences and Support – Preferences Page

Preferences and Support - Support

Support documents are accessed by selecting the "Preferences & Support" button. The Preferences & Support page has two sections. The lower section, shown highlighted to the right, is for accessing the support documents, and indicating compliance information along with the version number of the application.

There are three linked documents in the Support section. Please refer to the Documentation Prerequisites shown previously for a link to install the required Adobe® Reader® software if it is not already installed.

Note: The Version Number uniquely identifies the software on the site and is displayed for reference in the lower-right corner of the Support section. The date shown below the manufacturer address in the upper-right corner of the Support section corresponds to the date the software version was built.

Preferences and Support – Support Page

Serious Incidents Reporting

For a patient/user/third party in the European Union and in countries with identical regulatory regime; if, during the use of this software or as a result of its use, a serious incident has occurred, please report it to Johnson & Johnson Surgical Vision, Inc. and/or its authorized representative and to your national authority.

Symbol/Title (explanation):

SYMBOL	TITLE (EXPLANATION)
	Manufacturer. The date below the manufacturer name and address is the Date of manufacture (YYYY-MM-DD: year-month-day).
EC | REP	Authorized representative in the European Community/European Union
CH | REP	Authorized representative in Switzerland
	Consult instructions for use or consult electronic instructions for use
MD	Medical Device
UDI	Unique Device Identifier
	Importer
EC	European Community/European Union
CH	Switzerland

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