ICL/TICL Calculation/IOD Software

FOR USE WITH STAAR IMPLANTABLE COLLAMER® LENS (ICL AND TICL)

DIRECTIONS FOR USE

PRODUCT INFORMATION

Please review this product information completely before performing your initial clinical procedure. All physicians must complete the STAAR Surgical ICL Physician Certification Program.

DEVICE DESCRIPTION

ICL/TICL Calculation/IOD Software

The ICL/TICL Calculation/IOD Software consists of both ICL/TICL Calculation Software (Calculator) and Toric ICL Implantation Orientation Diagram Software (IOD Software). The Calculation and IOD Software resides on STAAR AG's e-commerce website in the Online Calculation and Ordering System (OCOS) https://ocos.staarag.ch/. Prior to implantation of the Implantable Collamer® Lens (ICL) physicians use the Online Calculation Software as an aid in the calculation of the size and diopter power (with residual refraction) for physician selection of the lens. For Toric ICLs, an Implantation Orientation Diagram (IOD) is also generated to provide the physician with pictorial representation of axis rotation and alignment.

Intended Purpose

The ICL/TICL Calculation/IOD Software is designed to automate the calculation of the ICL/TICL lens power and size based on specific patient biometrics.

Intended Patient Population

The ICL/TICL Calculation/IOD Software does not directly interact with patients but is a tool for ophthalmic physicians and staff to calculate ICL/TICL lens power and size based on specific patient biometrics and calculate lens rotation in the eye.

Intended Use Environment

The Calculation/IOD software is a web-based program located on secure STAAR servers. The software is available to physicians and may be accessed on a Personal Computer (PC) with Windows XP or higher with internet access and a secure browser. It is recommended that the user maintain an up-to-date operating system and a secure browser with up to date anti-virus software. The calculator may not function properly if used outside of the intended use environment.

Use of the ICL/TICL Calculation/IOD Software is restricted to ICL certified ophthalmic physicians, other refractive practice staff, and authorized intermediaries who have been trained to use the software. Each user of the software is granted access, authorized, and authenticated by STAAR Surgical using a unique ID and password as login credentials.

The STAAR authorized user (surgeon or other healthcare personnel) is responsible of proper management of the ID and password. The authorized user is also responsible for maintenance of PC security. Report any ID, password, or PC security breaches to STAAR Surgical immediately via the phone numbers provided in the reporting section. If there is a problem during data entry or calculation, the user can close the browser and exit the website and all information will be deleted. The user should reload the website and enter the biometric data again to begin calculations.

Software Version

ICL/TICL Calculation Software: Version 5.00

Toric ICL implantation Orientation Diagram Software: Version 4.0

INDICATIONS FOR USE

The ICL/TICL Calculation Software is designed as an aid in the calculation of the size and diopter power (with residual refraction) for physician selection of the lens. For Toric ICLs, an Implantation Orientation Diagram (IOD) is also produced to provide the physician with pictorial representation of the axis of rotation and alignment.

CONTRAINDICATIONS

The use of ICL/TICL Calculation/IOD Software for any other phakic intraocular implants has not been tested or approved for use by STAAR Surgical Company.

OPERATION

Accessibility

The ICL/TICL Calculation/IOD Software resides on STAAR Surgical's e-commerce website in the Online Calculation and Ordering System (OCOS) https://ocos.staarag.ch/. Use of the ICL/TICL Calculation/IOD Software is restricted to ICL certified ophthalmic physicians and other refractive practice staff and intermediaries who have been authorized to use the software and have been granted access by STAAR Surgical.

New Calculations

The calculator is accessed in the **CALCULATOR** tab.

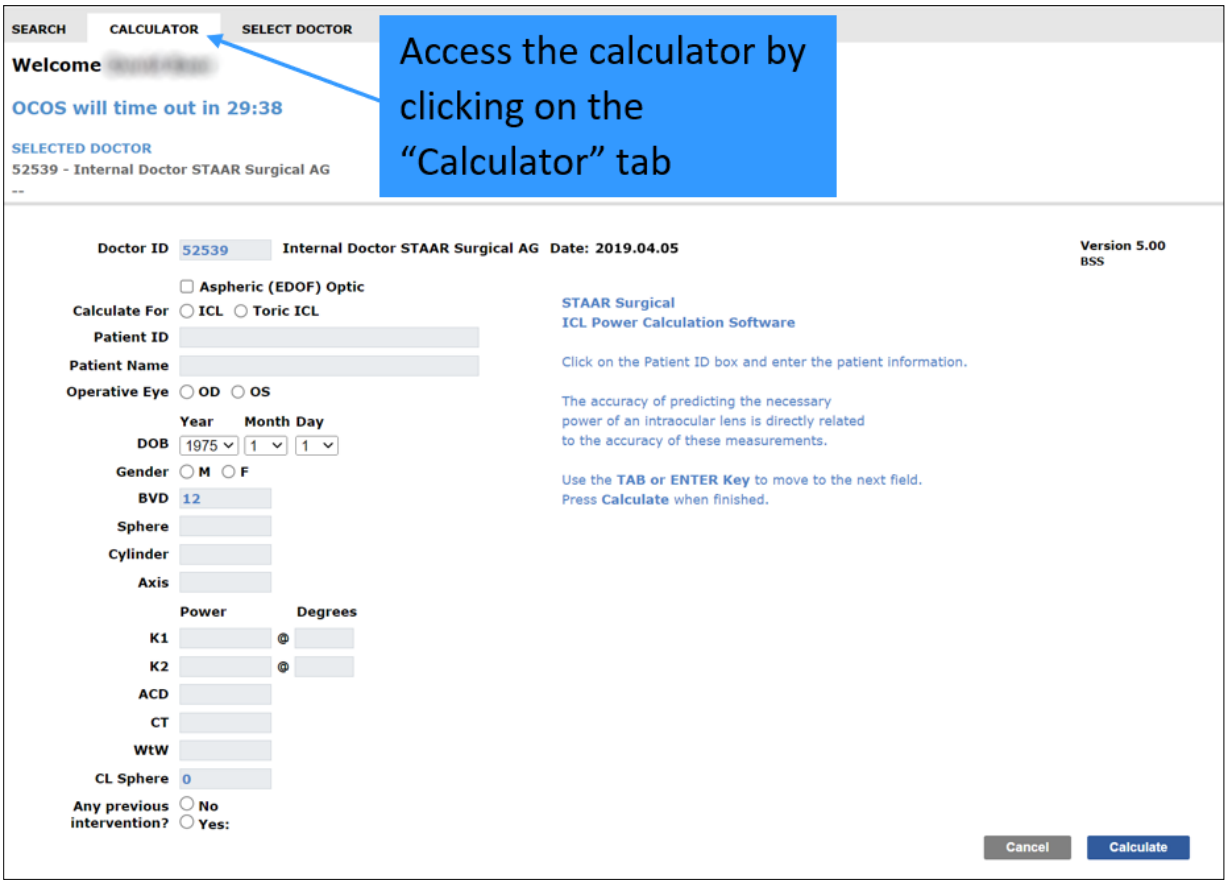

Figure 1: Accessing the ICL/TICL Calculation Software in OCOS

The user must choose to calculate for an **ICL** or a **Toric ICL**. If **ICL** is selected, EDOF certified users can also select for an **EDOF ICL**. The user then enters the Patient ID, Patient Name, Date of Birth, operative eye (OD or OS), gender, and pre-operative data. After entering the pre-operative data, the user should select the **Calculate** button to calculate the residual refraction.

Error messages will appear in red if no value has been entered in a required field, or if the value entered is invalid/outside the required range. The calculation cannot proceed if the errors are not corrected.

Popup messages notifying the user of unexpected values will appear for the following reasons:

- The patient data entered does not or may not meet the age or anterior chamber depth indications for the country.
- STAAR Surgical does not manufacture a lens that would treat the refractive error for the patient information entered.
- The data entered includes a cylindrical power, but the user selected the calculation for a lens without cylindrical power.
- The refractive cylinder values and corneal cylinder values do not agree.

Please ensure that the input data is correct.

The user will be presented with a list of lens powers and the expected residual refraction for the patient for each of those lenses based upon the data entered.

Alternative Lens Length Selection

Users have the ability to select an alternative length from the length recommended by the software at the time of calculation. The user should enter the pre-operative data, select the lens that will achieve the desired outcome and then click on the **DIFFERENT LENGTH REQUESTED** box to access the drop down list of available lengths and click on the radio dial corresponding to the length desired. Click **Submit** to continue. Alternative lengths should be chosen only after careful consideration by the surgeon.

Saving and Printing Calculations

The calculation results will be saved to the STAAR server and can be printed by the user by selecting **PRINT**. The calculation can also be saved to the STAAR server by selecting **SUBMIT**. For users with lens ordering/reserving authority, selecting submit will also facilitate lens ordering or reservations. After a Toric lens has been ordered/reserved, an Implantation Orientation Diagram can be generated. See IOD section below.

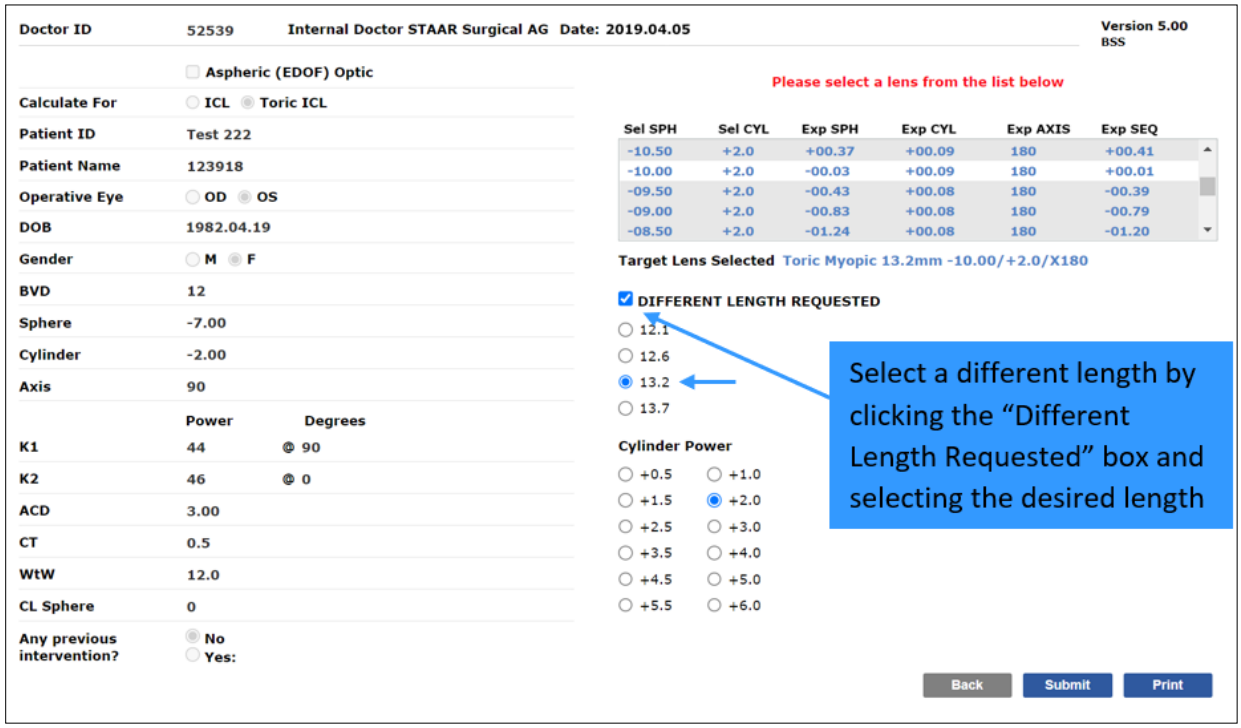

Figure 2: Selecting Lens Length

Fellow Eye Calculation

For convenience, the calculation of a fellow eye can be performed at various steps in the calculation or ordering process. This will eliminate the need to re-enter patient information. Users can request a fellow eye calculation:

1. After a lens has been reserved
2. After saving a calculation
3. After a lens has been added to the shopping cart (for users with purchasing rights)

A pop-up will appear to remind the user to verify that the prepopulated information imported from the fellow eye is correct.

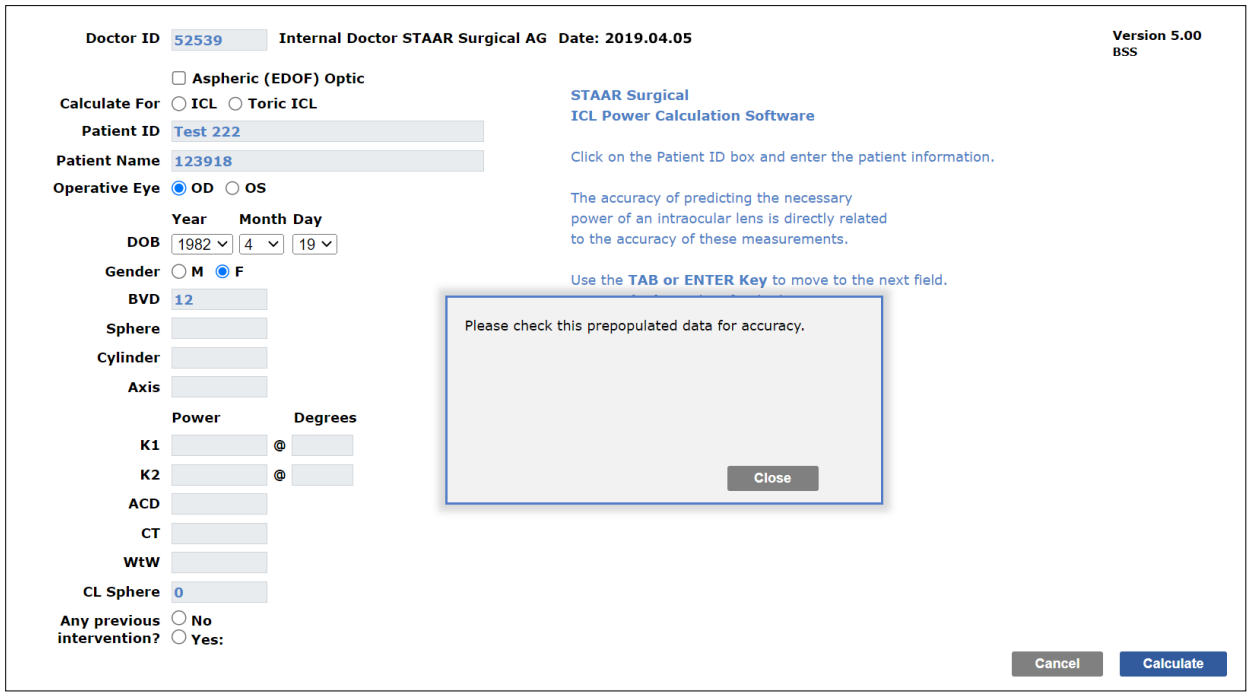

Figure 3: Starting A Fellow Eye Calculation

IOD (Implantation Orientation Diagram) – For Toric Lenses Only

Once a Toric lens has been ordered or reserved, the user can generate an IOD. The user can search for the calculation in the **SEARCH** tab by either the patient ID or the date of the calculation. Then the user should select the IOD icon appearing to the right of the name of the person who entered the calculation.

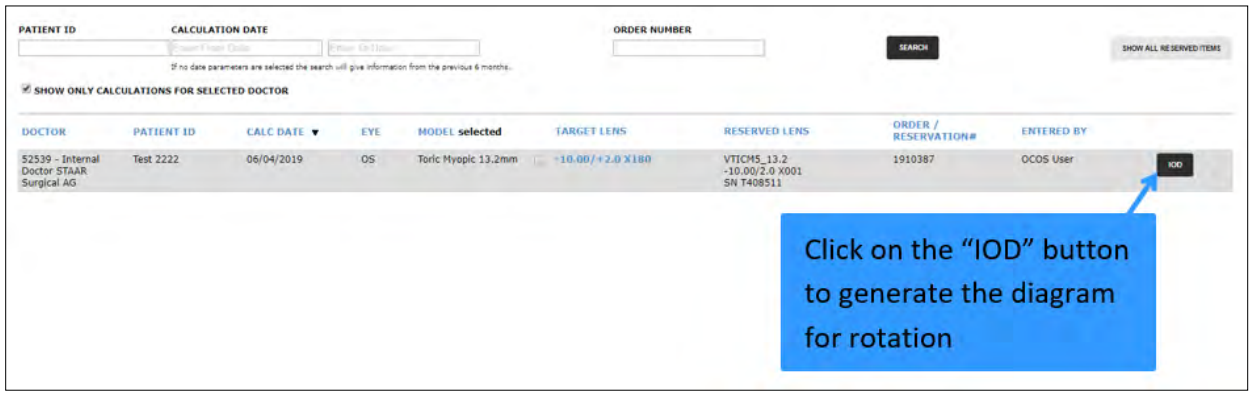

Figure 4: Accessing Implantation Orientation Diagram (IOD)

The user may print the diagram by clicking the **Print** button.

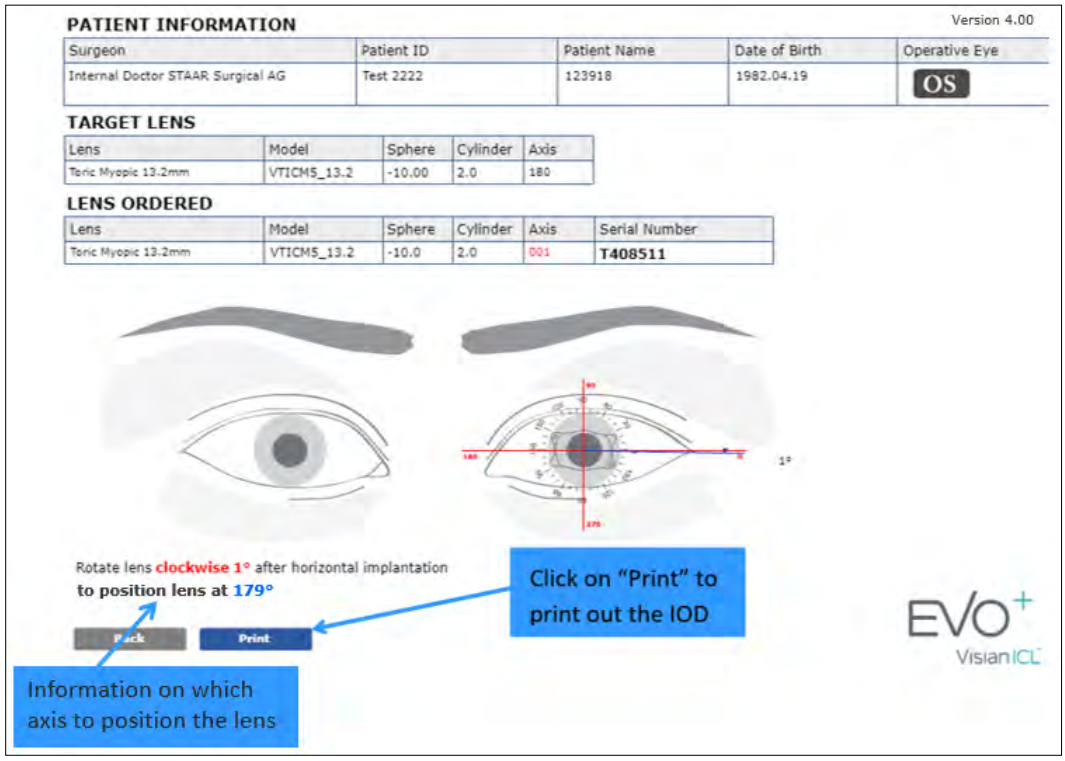

Figure 5: Generating the IOD

REPORTING

Adverse events and/or potentially sight-threatening complications that may reasonably be regarded as ICL/TICL Calculation/IOD Software related and that were not previously expected in nature, severity and degree of incidence should be reported to STAAR Surgical. For surgeons/patient located in the EU, the competent authority should also be notified in the EU member state where the surgeon/patient is established.

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SYMBOL GLOSSARY

MD	Medical device
EC REP	Authorized representative in the European Community
CE	CE conformity marking per European Council Directive 93/42/EEC or European Council Regulation (EU) 2017/745
	Manufacturer
edfu.staar.com +1-800-352-7842 +41 32 332 8888	Consult electronic instructions for use