



**URGENT!
MEDICAL DEVICE
SAFETY ALERT**

Date: August 1, 2005

Dear Doctor:

Please familiarize yourself, your LADARVision4000® Excimer Laser System operators, staff, and any other system users with the information in this Safety Alert.

This Safety Alert applies to the use of the Measuring Mode (ruler tool) on all LADARVision4000® Excimer Laser Systems. Due to a software error, use of the Measuring Mode feature after alignment of the horizontal reference line will negate compensation for cyclotorsion on CustomCornea® procedures. Negation of cyclotorsion compensation may adversely affect clinical outcomes. Until this software error is corrected, you must discontinue using the Measuring Mode feature.

The software error is present only in CustomCornea® software and was not present in the prior versions of the software. A software modification is in-progress to correct this software error. Once released, a Field Service Engineer (FSE) will be visiting your facility to install the revised software. Once installed, you will be advised by the FSE that use of the Measuring Mode (ruler tool) may resume. As the Measuring Mode is a non-essential feature, you may continue to safely perform procedures without the use of the Measuring Mode feature.

We request that you complete and return (fill in appropriate instructions) the attached "Response to Safety Alert" form to confirm the Safety Alert has been received and understood.

If you have questions about this Safety Alert, please contact (*fill in appropriate affiliate name and number*). Thank you in advance for your cooperation.

Sincerely,

A handwritten signature in black ink that reads "Keith Bell". The signature is written in a cursive, flowing style.

Keith Bell
Vice President, Corporate Quality Assurance
Surgical Products