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## **Urgent Field Safety Notice**

**Commercial name of the affected product – GentleLase Pro**

**FSCA-identifier – November 2013**

**Type of action – Voluntary Medical Device Field Correction Notification**

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Date: November 19, 2013

Attention: Pro Series Customers

### **Details on affected devices:**

Candela Corporation has initiated a voluntary field corrective action for the GentleLase Pro laser system.

### **Description of the problem:**

The release of an unintended single pulse of laser energy can occur when there is a failure of the beam shutter blade. The shutter prevents the energy from being emitted from the unit, dissipating it safely inside the device. The failure of the beam shutter is detected by software, but when a failure of beam shutter blade occurs, the system fails to detect it and fails to prevent laser operation.

Under worst case conditions, which are situations where (1) the handpiece is not in the calibration port (calport) when the pulse occurs, (2) the handpiece is directed at the patient or user's eye when the pulse occurs, and (3) the patient and/or user are not wearing the proper safety eyewear, the possible risk associated with unintended laser emissions is the potential for eye injury. There is a remote likelihood of serious injury, since the system operator, the patient, and any other person within the treatment area normally will be wearing wavelength appropriate protective eyewear, as instructed by the user manual and the training, thereby mitigating the potential for eye injury. This failure has been determined to be unlikely to cause adverse health consequences due to the remote likelihood of serious injury to occur. When appropriate user instructions are followed, there is negligible risk of serious injury. User error or lack of proper adherence to instructions in actual practice raises this risk index to low. Therefore, this failure is considered a negligible risk.

**Note:** To date, there have been no reported patient or user injuries due to this issue.

### **Advise on action to be taken by the user:**

Until your software can be upgraded, Candela recommends that you make sure that the handpiece is seated in the calibration port (calport) when transitioning from the "Standby" to "Ready" state. This step will ensure that, if an unintended pulse is emitted, it is contained within the calport. Following this step will not prevent the release of energy, but if it does occur, the pulse will be contained in a safe manner.

Candela is releasing a software upgrade to safely detect and disable the system in the event that an unintended single pulse may be released. A Candela Technical Service representative will be in contact with you to schedule a time to install the software upgrade at no cost to you within the next several days.

We apologize for any inconvenience that this field action creates for both you and your customers; however we want to make every effort to ensure we are providing users the safest laser operation possible.

**Contact reference person:**

Samuel D Wade  
Vice President, Regulatory Affairs and Quality Assurance  
Candela Corporation  
530 Boston Post Road  
Wayland, MA 01778 USA

The undersign confirms that this notice has been notified the appropriate Regulatory Agency.

A handwritten signature in black ink, appearing to read 'SD Wade', is positioned below the confirmation text.

Samuel D Wade  
Vice President, Regulatory Affairs and Quality Assurance