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October 10, 2014

Urgent: Medical Device Recall Notification

**Elite XPL (Pulsed Light) Handpiece for the Cynosure Elite MPX Laser System
All Serial Numbers**

Dear Customer:

Cynosure, Inc. ("Cynosure") is conducting a proactive, voluntary recall of the **Elite XPL (Pulsed Light) Handpiece used with the Elite MPX Laser System**. We are contacting you because our records indicate that this device was supplied to you.

Issue

Cynosure has identified a potential situation where the user of the device could receive an electrical shock under certain conditions. If the laser system is turned on and the user adjusts, installs or removes the XPL pulsed light handpiece, there is a potential risk of an electrical shock.

There have been NO reported incidents of this event occurring and no injuries have been reported due to an electrical shock.

The health risk associated with this matter if an electrical shock were to occur could lead to a serious life threatening injury. However, the probability of such an incident is remote.

Actions To Be Taken

- **Do not remove the XPL pulsed light handpiece from the laser system even if it is turned off.**
- If your XPL pulsed light handpiece is currently attached to the laser system, please immediately turn off the laser system and cease using the laser system until you are contacted by a Cynosure representative.

- You will be contacted by a Cynosure representative who will schedule a Field Service Engineer to come to your site, remove the XPL pulsed light handpiece from the laser system and put your system in a safe mode.
- After the Field Service Engineer has put your system in a safe mode, your laser system will be safe to use without the XPL pulsed light handpiece.
- If your XPL pulsed light handpiece is not attached to the laser system you are safe to use your laser system without the XPL pulsed light handpiece.
- If your XPL pulsed light handpiece is not attached to the laser system please call your local Cynosure customer service to arrange for the handpiece to be returned and repaired.

Your XPL pulsed light handpiece will be repaired by Cynosure and returned to you. There will be no charge to you for the repair and return of the XPL pulsed light handpiece.

We sincerely apologize for any inconvenience this may have caused. If additional information is required, please contact [REDACTED] from CRS Medical at 49 (0) [REDACTED] or via email at [REDACTED]@mps-gmbh.eu. Thank you for your cooperation.

Sincerely,

A large black rectangular redaction box covering the signature of the sender.

SVP of Regulatory Affairs and Quality Systems