



**THIS IS AN IMPORTANT SAFETY NOTICE! PLEASE  
READ IT CAREFULLY  
IMMEDIATE RESPONSE REQUESTED  
5<sup>th</sup> Notice**

**VNS Therapy™ System Leads  
Models 300, 302, and 303  
Lead Breaks and Dissolution**

As part of our ongoing commitment to quality, Cyberonics diligently evaluates data collected from field reports. Cyberonics also requests return of all explanted VNS Therapy System components. Once returned, Cyberonics performs thorough evaluations of these components. Recent tests show that lead dissolution (or corrosion) of the VNS Therapy Leads can occur in the presence of a lead break if stimulation of the VNS Therapy System is allowed to continue. Consequently, we are providing a field notification to inform our customers of labeling corrections.

***What is lead dissolution?***

Lead dissolution or corrosion of the lead can occur over time in the presence of a lead break while stimulation continues. Lead dissolution can potentially cause localized inflammation, pain, and vocal cord dysfunction.

***How does one identify when a lead break is present?***

Performing routine System Diagnostics during patient visits identifies potential lead breaks or discontinuities. For all models of generators, a System Diagnostics result showing the following may indicate a lead break or discontinuity condition:

- “Output Current – LIMIT”
- “Lead Impedance – HIGH”
- “DCDC – 7”
- “Impedance Value -  $\geq 7000$  Ohms”

Usually, an X-ray will confirm that the results received were actually due to a lead break or discontinuity.

***How do I minimize the risks to my patients?***

The Introduction to the VNS Therapy System – Indications, Contraindications, Warnings, and Precautions section of the Physician’s Manual has been updated to inform physicians of the following possibility:

**Potential effects of lead breaks**—Lead fractures of the VNS Therapy System may prevent patients from receiving therapy. If a lead fracture is suspected, perform diagnostic testing to evaluate continuity within the system. If diagnostics suggest that a fracture is present, consider turning the VNS Pulse Generator to zero milliamps (0 mA) of output current. Continuing stimulation with a fractured lead may result in dissolution of the conductor material resulting in adverse events, such as pain, inflammation, and vocal cord dysfunction. The benefits and risks of leaving the Pulse Generator ON (actively stimulating) when a lead fracture is present should be evaluated and monitored by the medical professional treating the patient.

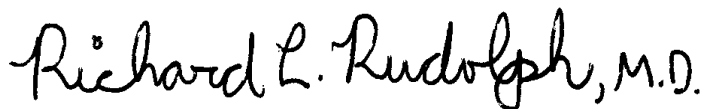
Introduction to the VNS Therapy System—Indications, Contraindications, Warnings, and Precautions can be found in the manuals section at [www.VNSTherapy.com](http://www.VNSTherapy.com).

**This notice is an additional attempt by Cyberonics to obtain an effectiveness card from physicians who have not previously returned a card acknowledging that they have received and understood this Safety Alert letter. As part of Cyberonics’ commitment to the quality of its products and to patient safety, it is important that you sign and return the effectiveness card included in this mailing.**

If you need any further assistance with this matter please feel free to contact our Clinical Technical Support group at 1-866-882-8804 or via email at [clinicaltechnicalservices@cyberonics.com](mailto:clinicaltechnicalservices@cyberonics.com).

**This field notification is being made with the knowledge of the US Food and Drug Administration.**

**We appreciate your assistance in this matter.**



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Special Safety Advisor