Important Safety Alert – 3rd Notice

VNS Therapy™ Lead Model 302
VNS Therapy Perennia™ Lead Model 303

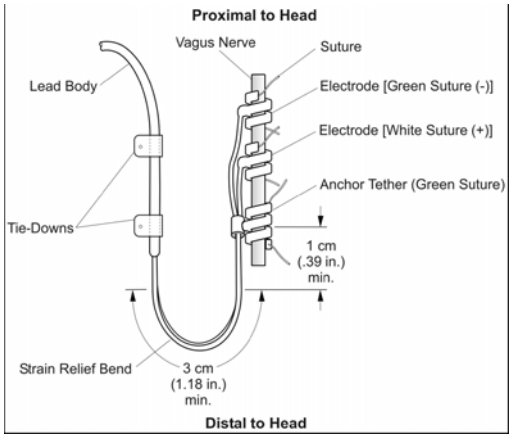
Cyberonics, Inc. is making a third attempt to notify all VNS Therapy practitioners of a labeling change made for the VNS Therapy Lead Model 302 and Model 303. This labeling change is based on a review of field reports and lead x-rays reviewed by Cyberonics. The results of this review indicate that some leads were implanted with sub-optimal strain relief bend configurations.

The labeling change is intended to emphasize the need for adequate strain relief, as well as provide clarification on the proper techniques for forming the strain relief of the lead. Following these techniques is critical to the long-term success of the implant and to minimize the potential for lead breaks.

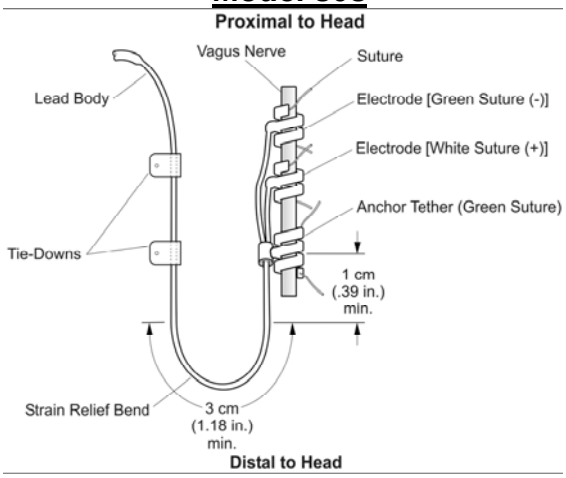
To maximize system performance and minimize possible mechanical damage to the nerve or lead, **pay careful attention to the helical placement and lead routing.** Adequate exposure of the vagus nerve (>3 cm) facilitates placement of the helices on the nerve. Stretching the nerve or allowing it to dry during implantation may result in temporary swelling of the nerve. Constriction of the nerve or other nerve damage may result in vocal cord dysfunction.

The illustrations in the product labeling have been updated to better demonstrate the recommended strain relief.

Model 302



Model 303



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Proper techniques include the following:

1) Route at least 1 cm of the lead parallel to the nerve.
2) Provide at least 3 cm of strain relief bend.
3) Place the first tie-down laterally to the anchor tether.

By following these 3 techniques, mechanical stress to the lead body should be reduced. Also, by following these techniques, nerve manipulation may be decreased. Excessive nerve manipulation may result in the patient experiencing potential vocal cord dysfunction such as vocal cord paralysis or paresis. For complete instructions, see the *Implantation Procedure* section of the Physician's Manual at www.VNSTherapy.com. This section of the manual also discusses the other areas of importance for proper lead placement.

Cyberonics, Inc. is sending this third notice to emphasize its importance. **Please complete and return the enclosed receipt card as soon as possible.** By returning this Effectiveness Check Card, you are acknowledging receipt and understanding of this Safety Alert regarding updated labeling addressing the proper strain relief technique. Returning the Effectiveness Check Card also will prevent repeat notifications of this Safety Alert.

If you need further information, please contact us at the following numbers:

United States customers may contact Clinical Technical Support at 866-882-8804 or via email at clinicaltechnicalservices@cyberonics.com.

International customers may contact Clinical Technical Support at +32 – 2 – 720 95 93 or via email at europeclintechservices@cyberonics.com.

This Safety Alert is being made with the knowledge of the US Food and Drug Administration.

We appreciate your assistance in this matter.

Sincerely,

Richard L. Rudolph, MD
Special Safety Advisor