

# The Truth About the **Treatment Gap** and **Drug-Resistant Epilepsy**

## About **Drug-Resistant Epilepsy** (D.R.E.)\*

\*Seizures that continue despite appropriate treatment with antiepileptic drugs

**3 Million people**  
in the United States have epilepsy



**1 in 3 people**  
with epilepsy  
have D.R.E.



If first two drugs don't result in seizure freedom, **there is a 95% chance** that no drug or combination of drugs will.

**Adding more medications**  
is not always the answer.

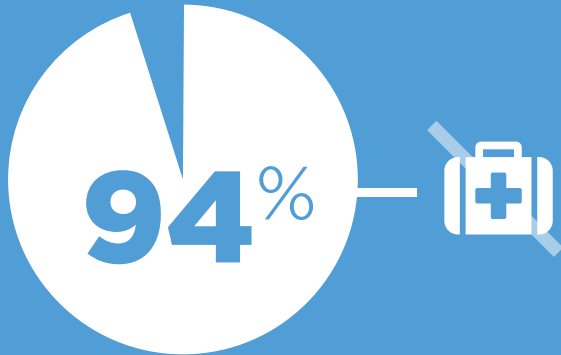


The rate of Drug-Resistant Epilepsy  
**has not been significantly reduced**  
over the last 20 years



# There is a Treatment Gap for People with Drug Resistant Epilepsy

**94% of people with D.R.E.**  
remain undertreated



That's more than  
**1 million people**  
in the U.S. alone



**Undertreated epilepsy** can lead to:



Seizure-related  
injury



Increased risk of Sudden  
Unexpected Death in  
Epilepsy (SUDEP)



Increased hospital  
and ER visits



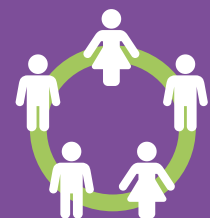
Depression, anxiety  
and developmental  
issues



Challenges with thinking  
and memory

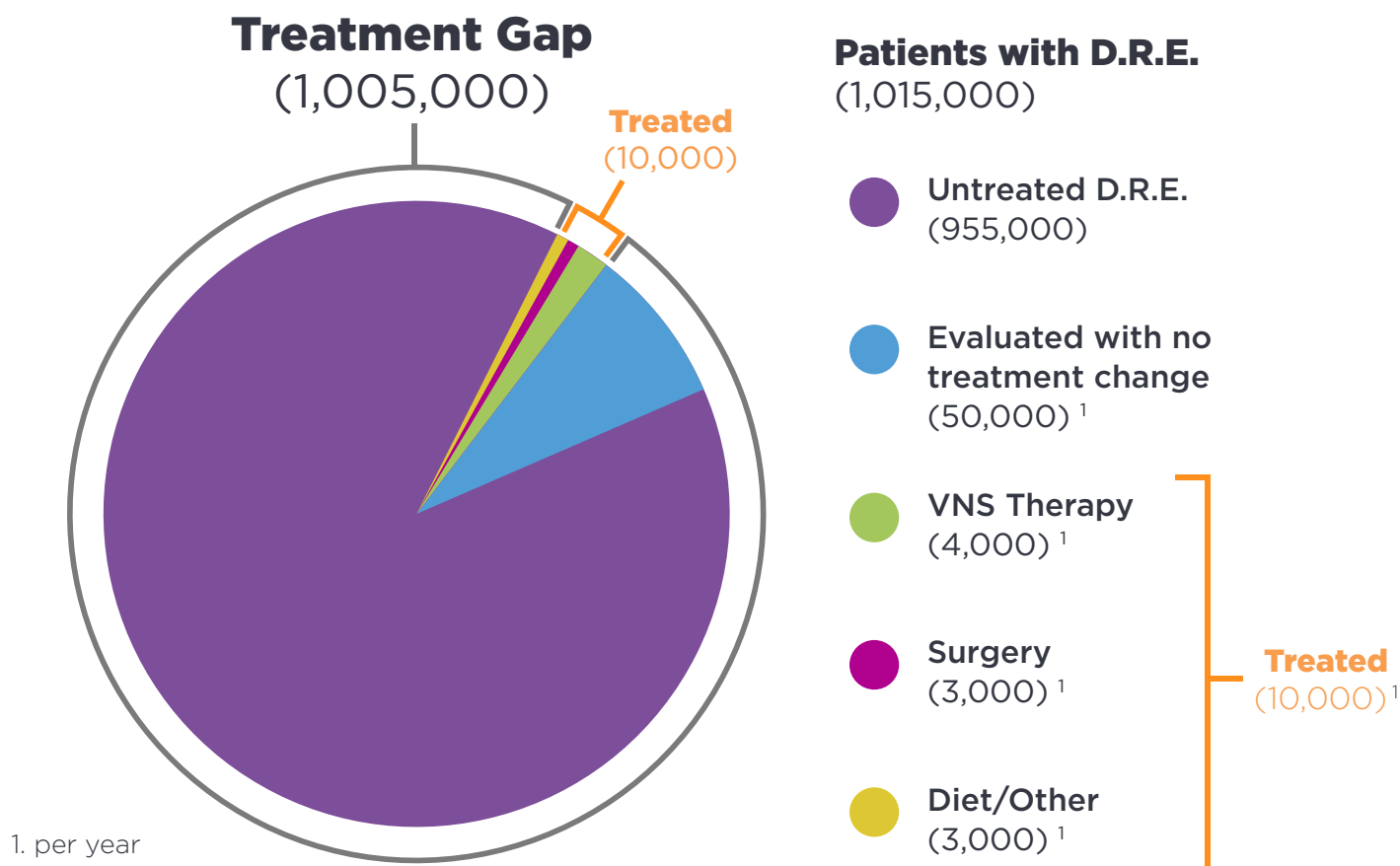


Adverse effects of long-term  
anti-epileptic drug use



Issues with social  
interactions

# The Truth About the Treatment Gap



**VNS Therapy** is a proven treatment option for D.R.E.

“Despite what we know about drug-resistant epilepsy, the treatment gap means over one million individuals in the U.S. continue to be undertreated. Clinical research proves the long-term positive effects of VNS Therapy, a therapy designed specifically for the treatment of drug-resistant epilepsy. Knowing lives could be improved is what drives our work at LivaNova and our desire to bring more attention to the treatment gap during Epilepsy Awareness Month.”

- Jason Richey, President of LivaNova's Neuromodulation division

Epilepsy Awareness Day  
**Everyday**  
#epilepsywellness



**To learn more**  
call **1-888-876-7846**  
or visit **VNSTherapy.com**

## INTENDED USE / INDICATIONS—UNITED STATES

Epilepsy—VNS Therapy is indicated for use as an adjunctive therapy in reducing the frequency of seizures in adults and adolescents over 12 years of age with partial onset seizures which are refractory to antiepileptic medications.

## CONTRAINDICATIONS

VNS Therapy cannot be used in patients after a bilateral or left cervical vagotomy. Do not use short-wave diathermy, microwave diathermy, or therapeutic ultrasound diathermy on patients implanted with the VNS Therapy system.

Diagnostic ultrasound is not included in this contraindication. Injury or damage can occur during diathermy treatment whether the VNS Therapy system is turned “ON” or “OFF.”

## WARNINGS

Physicians should inform patients about all potential risks and adverse events discussed in the VNS Therapy System Physician’s Manual, including information that VNS Therapy may not be a cure for epilepsy. Since seizures may occur unexpectedly, patients should consult with a physician before engaging in unsupervised activities, such as driving, swimming, and bathing, or in strenuous sports that could harm them or others. The safety and efficacy of VNS Therapy has not been established for uses outside of its approved indications. A malfunction of the VNS Therapy system could cause painful or direct current stimulation, which could result in nerve damage. Patients should use the magnet to stop stimulation if they suspect a malfunction, and contact their physician immediately for further evaluation. Removal or replacement of the VNS Therapy system requires an additional surgical procedure.

Patients who have pre-existing swallowing, cardiac, or respiratory difficulties (including, but not limited to, obstructive sleep apnea and chronic pulmonary disease) should discuss with their physicians whether VNS Therapy is appropriate for them since there is the possibility that stimulation might worsen their condition. VNS Therapy may also cause new onset sleep apnea in patients who have not previously been diagnosed with this disorder. MRI can be safely performed; however, special equipment and procedures must be used.

Postoperative bradycardia can occur among patients with certain underlying cardiac arrhythmias. (AspireSR® only) Inform your doctor if you have an existing heart condition or are being actively treated for a heart condition (such as beta adrenergic blocker medications). Your doctor will determine if the AutoStim feature is right for you.

## PRECAUTIONS

The safety and efficacy of VNS Therapy has not been established for use during pregnancy. Patients who smoke may have an increased risk of laryngeal irritation. There is a risk of infection with the implantation surgery that may require the use of antibiotics to treat or removal of the device. The VNS Therapy system may affect the operation of other implanted devices, such as cardiac pacemakers and implanted defibrillators. Possible effects include sensing problems and inappropriate device responses. If the patient requires concurrent implantable devices, careful programming of each system may be necessary to optimize the patient’s benefit from each device. (AspireSR® only) Use of the AutoStim Mode (also known as Detect & Respond Mode) will result in reduced battery life, which may require more frequent generator replacements.

## ADVERSE EVENTS

The most commonly reported side effects from stimulation include hoarseness (voice alteration), paresthesia (prickling feeling in the skin), dyspnea (shortness of breath), sore throat and increased coughing. Other adverse events reported during clinical studies as statistically significant are ataxia (loss of the ability to coordinate muscular movement); dyspepsia (indigestion); hypesthesia (impaired sense of touch); insomnia (inability to sleep); laryngismus (throat, larynx spasms); nausea; pain; pharyngitis (inflammation of the pharynx, throat); and vomiting. These typically occur only during stimulation, are well tolerated and noticed less as time goes on. The most commonly reported side effect from the implant procedure is infection.

\*THE INFORMATION CONTAINED IN THIS SUMMARY REPRESENTS PARTIAL EXCERPTS OF IMPORTANT PRESCRIBING INFORMATION TAKEN FROM THE PRODUCT LABELING. THE INFORMATION IS NOT INTENDED TO SERVE AS A SUBSTITUTE FOR A COMPLETE AND THOROUGH UNDERSTANDING OF THE VNS THERAPY SYSTEM NOR DOES THIS INFORMATION REPRESENT FULL DISCLOSURE OF ALL PERTINENT INFORMATION CONCERNING THE USE OF THIS PRODUCT. PATIENTS SHOULD DISCUSS THE RISKS AND BENEFITS OF VNS THERAPY WITH THEIR HEALTHCARE PROVIDER. PRESCRIPTION ONLY - DEVICE RESTRICTED TO USE BY OR ON THE ORDER OF A PHYSICIAN.

This brochure is not intended to be a complete source of information on VNS Therapy. Please contact your healthcare professional or visit [www.VNSTherapy.com](http://www.VNSTherapy.com) for more information.

CYBERONICS, INC.  
100 Cyberonics Boulevard  
Houston, Texas 77058  
Tel: +1.800.332.1375  
Fax: +1.281.218.9332  
[www.VNSTherapy.com](http://www.VNSTherapy.com)

LivaNova Belgium NV  
Ikaroslaan 83  
1930 Zaventem  
Belgium  
Tel: +32.2.720.95.93  
Fax: +32.2.720.60.53

©2016 Cyberonics, Inc, a wholly-owned subsidiary of LivaNova PLC. All rights reserved. Cyberonics® AspireSR® and VNS Therapy® are registered trademarks of Cyberonics, Inc.

**LivaNova**  
Health innovation that matters

EAMMNR2016U1