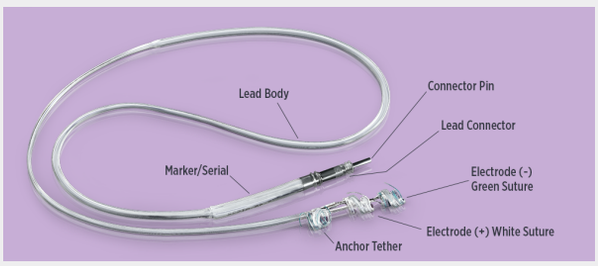
VNS Therapy®

PerenniaDURA® & PerenniaFLEX® Leads

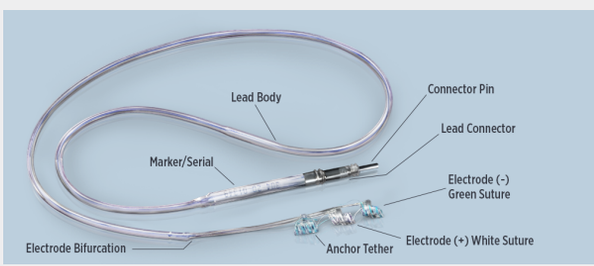
Perennia DURA® & Perennia FLEX® Leads

The Perennia® family of implantable leads is the latest generation of patient leads for the VNS Therapy system. The Perennia product portfolio is represented by the PerenniaDURA® and the PerenniaFLEX®. These leads illustrate the improved device longevity and system performance that define the Perennia family.

The PerenniaDURA (Model 303) o□ers greater lead reliability with 17-times greater durability over the previous LivaNova leads tested. Bench testing of the PerenniaDURA reflects a minimum of 1,000,000 cycles to failure before electrode bifurcation fatigue, and an average of 255,000 cycles to failure before conductor coil fatigue.[1]



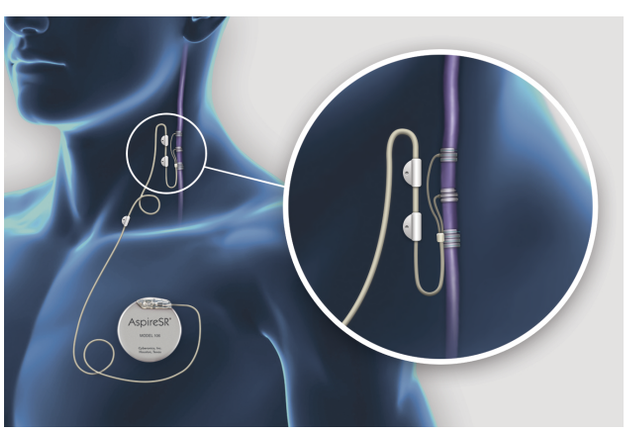
The PerenniaFLEX (Model 304) combines the flexible handling characteristics of early device models with 3.5-times greater durability over the previous LivaNova lead models. Bench testing of the PerenniaFLEX shows an average of 810,000 cycles to failure before electrode bifurcation fatigue, and an average of 76,000 cycles to failure before conductor coil fatigue.[1]



COMPATIBILITY

	PerenniaFLEX® Model 304	PerenniaDURA® Model 303	Model 302 Lead*	Model 300 Lead†
Pulse™ (102)	✓	✓	✓	
Pulse Duo™ (102R)				✓
Demipulse® (103)	✓	✓	✓	
Demipulse Duo® (104)				✓
AspireHC® (105)	✓	✓	✓	
AspireSR® (106)	✓	✓	✓	

*Not for sale in all markets. †No longer distributed.



The Perennia lead, which delivers the electrical signal from the implantable generator to the vagus nerve, is insulated with silicone. The lead is bifurcated at one end with two helical electrodes and an anchor tether, which are coiled around the vagus nerve. The opposite end of the lead has a single connector, which is tunneled subcutaneously from the vagus nerve and inserted into the generator. Perennia leads are available in multiple sizes (2.0 mm and 3.0 mm) to accommodate di□erent nerve sizes, ensuring the right lead for the right patient.

1. Data on File. LivaNova, Houston, TX

PerenniaDURA® Model 303

Conformance to Standards
American National Standards Institutes (ANSI) & Association for the Advancement of Medical Instrumentation (AAMI) NS15: Implantable peripheral nerve stimulators

EN 45502-1, Active implantable medical devices - Part 1: General requirements for safety, marking and information to be provided by the manufacturer

Lead Connector
Diameter: 3.2 mm (.127 in)
Material: Silicone*

Connector Pin
Diameter: 1.27 mm (.05 in)
Material: 300 series stainless steel

Connector Ring
Diameter: 2.67 mm (.105 in)
Material: 300 series stainless steel

Lead Body
Diameter: 2 mm (.08 in)
Insulation: Silicone*
Conductor coil construction: Helical, trifilar
Conductor material: MP-35N alloy
Overall length: 43 cm (17 in)
Lead resistance: 180 to 250 Ohms (connector pin/ring to electrode)

Electrodes and Anchor Tether
Helical material: Silicone elastomer*
Conductor material: Platinum/Iridium Alloy
Separation: 8 mm (.31 in) center to center
Suture material: Polyester

Inner Diameter of Helix
Model 303-20: 2 mm (.08 in) inner diameter
Model 303-30: 3 mm (.12 in) inner diameter

Tie-Downs
Dimensions: 5.7 mm x 7.7 mm (.22 in x .30 in)
Material: Radiopaque silicone*

Connector Assembly
One (1) lead connector

Connector Retention Strength
With VNS Therapy Pulse Generator: > 10 N

*Latex is not included in any component of the VNS Therapy® System.

PerenniaFLEX® Model 304

Conformance to Standards
American National Standards Institutes (ANSI) & Association for the Advancement of Medical Instrumentation (AAMI) NS15: Implantable peripheral nerve stimulators

EN 45502-1, Active implantable medical devices - Part 1: General requirements for safety, marking and information to be provided by the manufacturer

Lead Connector
Diameter: 3.2 mm (.127 in)
Material: Silicone*

Connector Pin
Diameter: 1.27 mm (.05 in)
Material: 300 series stainless steel

Connector Ring
Diameter: 2.67 mm (.105 in)
Material: 300 series stainless steel

Lead Body
Diameter: 2 mm (.08 in)
Insulation: Silicone*
Conductor coil construction: Helical, quadfilar
Conductor material: MP-35N alloy
Overall length: 43 cm (17 in)
Lead resistance: 120 to 180 Ohms (connector pin/ring to electrode)

Electrodes and Anchor Tether
Helical material: Silicone elastomer*
Conductor material: Platinum/Iridium Alloy
Separation: 8 mm (.31 in) center to center
Suture material: Polyester

Inner Diameter of Helix
Model 304-20: 2 mm (.08 in) inner diameter
Model 304-30: 3 mm (.12 in) inner diameter

Tie-Downs
Dimensions: 5.7 mm x 7.7 mm (.22 in x .30 in)
Material: Radiopaque silicone*

Connector Assembly
One (1) lead connector

Connector Retention Strength
With VNS Therapy Pulse Generator: > 10 N

*Latex is not included in any component of the VNS Therapy® System.

VNS Therapy Physician's Manuals. LivaNova; Houston, TX.
For full prescribing and important safety information, please visit www.VNSTherapy.com or ask your VNS Therapy representative.

VNS Therapy®

VNS THERAPY EUROPEAN INDICATION FOR USE

VNS Therapy is indicated for use as an adjunctive therapy in reducing the frequency of seizures in patients whose epileptic disorder is dominated by partial seizures (with or without secondary generalization) or generalized seizures that are refractory to seizure medications. The Model 106 AspireSR® (Seizure Response) features the Automatic Stimulation Mode, which is intended for patients who experience seizures that are associated with cardiac rhythm increases known as ictal tachycardia.

CONTRAINDICATIONS:
The VNS Therapy system 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. Cardiac arrhythmia (Model 106 only)—The AutoStim Mode feature should not be used in patients with clinically meaningful arrhythmias or who are using treatments that interfere with normal intrinsic heart rate responses.

WARNINGS:
Physicians should inform patients about all potential risks and adverse events discussed in the VNS Therapy Physician Manuals, 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.

A malfunction of the VNS Therapy system could cause painful or direct current stimulation, which could result in nerve damage. 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. Postoperative bradycardia can occur among patients with certain underlying cardiac arrhythmias. MRI can be safely performed; however, special equipment and procedures must be used.

ADVERSE EVENTS:
The most commonly reported side e□ects from stimulation include hoarseness (voice alteration), paresthesia (prickling feeling in the skin), dyspnea (shortness of breath), sore throat and increased coughing. The most commonly reported side e□ect from the implant procedure is infection.

*The information contained here represents partial excerpts of important prescribing information from the product labeling. Patients should discuss the risks and benefits of VNS Therapy with their healthcare provider. Visit www.VNSTherapy.com for more information.

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AspireSR® is CE mark approved and commercial distribution may vary by country.

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Health innovation that matters