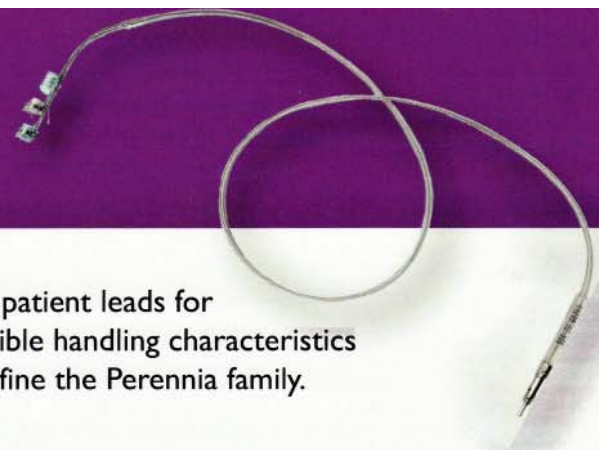
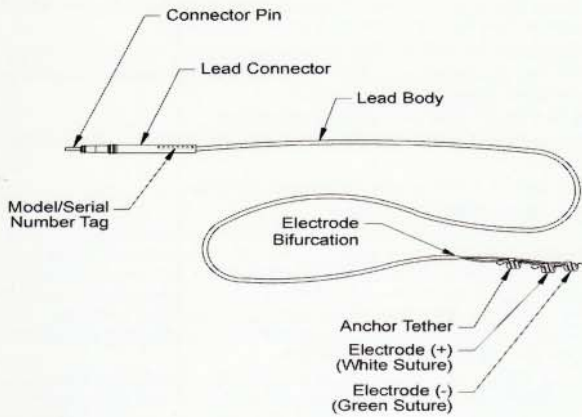


PerenniaFLEX™ Model 304 Lead



The Perennia™ line of products is the fourth generation of implantable patient leads for the VNS Therapy™ System. The PerenniaFLEX series combines the flexible handling characteristics of the previous generation with the lead durability and longevity that define the Perennia family.



GENERAL DESCRIPTION

Silicone insulated implantable patient lead, delivering the electrical signal from the Pulse™ or DemiPulse™ Generators to the vagus nerve. 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. The lead is available in multiple sizes to accommodate different nerve sizes.

PRODUCT SPECIFICATIONS

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 (.05in)
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

Generator Compatibility

Model 102 Pulse Generator
Model 103 DemiPulse Generator

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

Please refer to the Brief Summary for important prescribing and safety information.

M304PS09-31-1000-WW

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VAGUS NERVE STIMULATION

