

# LIMITED WARRANTY

## IMPLANTED PULSE GENERATOR

Boston Scientific Corporation (referred to as Boston Scientific) warrants to the patient who receives a Vercise Genus™ R16 Implant Pulse Generator and Vercise Genus R32 Implant Pulse Generator (referred to as the Stimulator) that the Stimulator will be free from defects in workmanship and materials for a period of fifteen (15) years from the date of surgical implant of the Stimulator. This warranty applies only to the patient who has the Stimulator implanted and no other person or entity. This warranty does not apply to the leads, extensions, or surgical accessories used with the Stimulator.

Boston Scientific will replace the Stimulator with a functionally equivalent Stimulator made by Boston Scientific if the following events occur:

1. The Stimulator fails to function within normal ranges within fifteen (15) years after the date it is implanted.
2. The patient has attempted to charge the Stimulator for six (6) months and is unsuccessful due to medical condition within one (1) year after the date it is implanted.

Prior to acceptance of a warranty claim regarding event 2, a medical necessity must exist. Medical necessity is defined as healthcare services or supplies needed to prevent, diagnose, or treat an illness, injury, condition, disease, or its symptoms and that meet accepted standards of medicine.

In the event that the IPG is used with the Vercise™ M8 Adapter, Boston Scientific will provide a one (1)-year limited warranty on previously implanted leads and extensions. This warranty provides for the replacement of previously implanted leads and /or extensions with new leads or extensions; provided that such previously implanted leads or extensions were in good operating condition at the time of connection.

No other relief whatsoever is available under this limited warranty. The limited warranty for a replacement Stimulator will last only for the number of years specified in events 1 and 2 from the date of surgical implant of the original Stimulator. Claims under this limited warranty are subject to the following additional conditions and limitations:

1. The product registration card must be completed and returned to Boston Scientific within 30 days of surgery.
2. The Stimulator must be purchased after January 1, 2005 and implanted before the "Use By" date.
3. Failure of the Stimulator must be confirmed by Boston Scientific.
4. The Stimulator must be returned to Boston Scientific within 30 days after it fails to function within normal ranges. That Stimulator will be Boston Scientific's property.
5. Accidental damage to the Rechargeable Stimulator occurring during a medical procedure is covered by this limited warranty.
6. This limited warranty does not include failures to function within normal ranges caused by:
  - a) Fire, floods, lightning, natural disasters, water damage, and other calamities commonly defined as "Acts of God";
  - b) Misuse, abuse, or the customer's failure to operate the Stimulator in accordance with manufacturer's instructions; or
  - c) Unauthorized attempts to repair, maintain, or modify the Stimulator by the patient or any unauthorized third party.

This limited warranty is the only warranty that applies to the Stimulator, and Boston Scientific expressly disclaims any other warranty, express or implied, including any warranty of merchantability or fitness for a particular purpose.

Under this limited warranty, Boston Scientific will be responsible only for replacement of the Stimulator with a Stimulator made by Boston Scientific available at the time of replacement and will not be liable for any damages (whether direct, indirect, consequential, or incidental) caused by the Stimulator, whether the claim is based on warranty, contract, tort, or any other theory.

Boston Scientific assumes no liability with respect to instruments reused, reprocessed or resterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments.

## LEADS

Boston Scientific Corporation (referred to as Boston Scientific) warrants to the patient that the Deep Brain Stimulation (DBS) Leads, Lead Extensions, and Lead Boots are free from defects in workmanship and materials for a period of one (1) year from the date of implantation.

A Lead, Extension, or Boot that fails to function within normal tolerances within (1) year from the date of surgery is covered under this Limited Warranty. The liability of Boston Scientific under this warranty shall be limited to: (a) replacement with a functionally equivalent Lead, Extension, or Boot; or (b) full credit equal to the original purchase price to be applied towards the purchase of a new Lead, Extension, or Boot. Product claims under Boston Scientific Limited Warranty are subject to the following conditions and limitations:

1. The product registration card must be completed and returned to Boston Scientific within 30 days of surgery in order to obtain warranty rights.
2. The Lead, Extension, or Boot must be returned to Boston Scientific within 30 days of malfunction or discovery of defect, and shall be the property of Boston Scientific.
3. The Lead, Extension, or Boot must be implanted prior to the “use by” date.
4. Failure of the Lead, Extension, or Boot must be confirmed by Boston Scientific. This warranty specifically excludes defects or malfunctions caused by: (a) fire, floods, lightning, natural disasters, water damage, and other calamities commonly defined as “Acts of God”; (b) accident, misuse, abuse, negligence, or the customer’s failure to operate the Lead, Extension, and Boot in accordance with manufacturer’s instructions; (c) unauthorized attempts to repair, maintain, or modify the equipment by the customer or any unauthorized third party; or (d) attachment of any equipment not supplied by Boston Scientific without prior approval.

a) This warranty does not include surgical accessories used with the Lead, Extension, or Boot.

5. The decision as to product replacement or credit shall be made solely at the discretion of Boston Scientific.

For a replacement Lead, Extension, or Boot, the warranty will run only to the end of the warranty period for the original Lead, Extension, or Boot that was replaced. This warranty is in lieu of any other warranty, expressed or implied, including any warranty of merchantability or fitness for intended use. Except as expressly provided by this Limited Warranty, Boston Scientific shall not be responsible or liable for any direct, consequential or incidental damages caused by device malfunction, failure or defect, whether the claim is based on warranty, contract, tort, or otherwise.

Boston Scientific assumes no liability with respect to instruments reused, reprocessed or resterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments.

## EXTERNALS

Boston Scientific Corporation (referred to as Boston Scientific) warrants to the patient that the Remote Control device and Charging System (Charger and/or Charger Base Station) are free from defects in workmanship and materials for a period of one (1) year from the date of purchase.

If a Remote Control Device or Charging System component fails to function within normal ranges within one year after the date of purchase, Boston Scientific will replace the device or component with a functionally equivalent device or component made by Boston Scientific. No other relief whatsoever is available under this limited warranty. The limited warranty for a replacement device or component will last only for one year after the date of purchase. Claims under this limited warranty are subject to the following additional conditions and limitations:

1. The product registration card must be completed and returned to Boston Scientific within 30 days of purchase.
2. Boston Scientific must confirm the device or component failure.
3. The device or component must be returned to Boston Scientific within 30 days after it fails to function within normal ranges. That device or component will be Boston Scientific’s property.
4. This limited warranty does not include failures to function within normal ranges caused by:
  - a) Fire, floods, lightning, natural disasters, water damage, and other calamities commonly defined as “Acts of God”;
  - b) Accident, misuse, abuse, negligence, or the customer’s failure to operate the device or component in accordance with manufacturer’s instructions;
  - c) Unauthorized attempts to repair, maintain, or modify the device or component by the patient or any unauthorized third party; or
  - d) Attaching equipment to the device or component that is not supplied or expressly authorized by Boston Scientific.

This limited warranty is the only warranty that applies to the device or component, and Boston Scientific expressly disclaims any other warranty, express or implied, including any warranty of merchantability or fitness for a particular purpose.

Under this limited warranty, Boston Scientific will be responsible only for replacement of the device or component with a functionally equivalent device or component made by Boston Scientific and will not be liable for any damages (whether direct, indirect, consequential, or incidental) caused by the device or component, whether the claim is based on warranty, contract, tort, or any other theory.

Indications for Use: The Boston Scientific Deep Brain Stimulation Systems are indicated for use in:

-Bilateral stimulation of the subthalamic nucleus (STN) as an adjunctive therapy in reducing some of the symptoms of moderate to advanced levodopa responsive Parkinson’s disease (PD) that are not adequately controlled with medication.

-Bilateral stimulation of the internal globus pallidus (GPi) as an adjunctive therapy in reducing some of the symptoms of advanced levodopa responsive Parkinson’s disease (PD) that are not adequately controlled with medication.

Contraindications: The Boston Scientific Deep Brain Stimulation Systems are not recommended for patients who will be exposed to the following procedures: Diathermy as either a treatment for a medical condition or as part of a surgical procedure, Electroconvulsive Therapy (ECT) and Transcranial Magnetic Stimulation (TMS). The safety of these therapies in patients implanted with the Vercise DBS System has not been established. Patients implanted with Boston Scientific Deep Brain Stimulation Systems without ImageReady™ MRI Technology should not be exposed to Magnetic Resonance Imaging (MRI). Patients implanted with the Vercise Gevia™ or Vercise Genus™ or Vercise DBS Lead-only system (before Stimulator is implanted) with ImageReady MRI Technology are Full Body MR Conditional only when exposed to the MRI environment under the specific conditions defined in ImageReady MRI Guidelines for Boston Scientific Deep Brain Stimulation Systems. Boston Scientific Deep Brain Stimulation Systems are not recommended for patients who are unable to operate the system or are poor surgical candidates or who experience unsuccessful test stimulation.

Warnings: Unauthorized modification to the medical devices is prohibited. You should not be exposed to high stimulation levels. High level of stimulation may damage brain tissue. Patients implanted with the Vercise DBS System may be at risk for intracranial hemorrhages (bleeding in the brain) during DBS lead placement. Strong electromagnetic fields, such as power generators, security screeners or theft detection systems, can potentially turn the stimulator off, or cause unpredictable changes in stimulation. The system should not be charged while sleeping. If you notice new onset or worsening depression, changes in mood or behavior or impulse control, or have thoughts of suicide contact your physician or emergency services immediately. Chemical burns may result if the Vercise Stimulator housing is ruptured or pierced. The Deep Brain Stimulation System may interfere with the operation of implanted stimulation devices, such as cardiac pacemakers, implanted cardioverter defibrillators, or medication delivery pumps. Patients should operate motorized vehicles or potentially dangerous machinery with caution. It is unknown if the device may hurt an unborn baby. Your doctor may be able to provide additional information on the Boston Scientific Vercise DBS System. For complete indications for use, contraindications, warnings, precautions, and side effects see DBSandME.com or call 833-DBS-INFO or 833-327-4636.

Caution: U.S. Federal law restricts this device to sale by or on the order of a physician.

**Boston  
Scientific**  
Advancing science for life™

25155 Rye Canyon Loop  
Valencia, CA 91355 USA

Copyright ©2021 by  
Boston Scientific Corporation  
or its affiliates. All rights reserved.

NM-917712-AB