Limited Warranty

Rx ONLY
CAUTION: Federal law restricts this device to sale, distribution and use by or on the order of a physician.
Boston Scientific Neurostimulation System
Limited Warranty

Rechargeable Implantable Pulse Generator (IPG)

Boston Scientific Corporation warrants to the patient who receives an implantable rechargeable pulse generator (referred to as the Rechargeable IPG) that the Rechargeable IPG will be free from defects in workmanship and materials for a period of five (5) years from the date of surgical implant of the Rechargeable IPG. This warranty applies only to the patient who has the Rechargeable IPG implanted and no other person or entity. This warranty does not apply to the leads, extensions, or surgical accessories used with the Rechargeable IPG.

A Rechargeable IPG that fails to function within normal ranges within five (5) years after the date it is implanted is covered under this Limited Warranty. The liability of Boston Scientific under this warranty shall be limited to: (a) replacement of the Rechargeable IPG with a functionally equivalent Rechargeable IPG made by Boston Scientific; or (b) credit applied towards the purchase of a new IPG. The warranty amount is calculated using least expensive device price (original vs. replacement). No other relief whatsoever is available under this limited warranty. This limited warranty for a replacement Rechargeable IPG will last only for five years from the date of surgical implant of the original Rechargeable IPG.

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 Rechargeable IPG must be purchased after January 1, 2005 and implanted before the “Use By” date.
3. Failure of the Rechargeable IPG must be confirmed by Boston Scientific.
4. The Rechargeable IPG must be returned to Boston Scientific (or a Boston Scientific authorized agent) within 30 days after it fails to function within normal ranges. That Rechargeable IPG will be the property of Boston Scientific.
5. Accidental damage to the Rechargeable IPG occurring during a medical procedure is covered by this limited warranty.
6. The 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 Rechargeable IPG in accordance with manufacturer’s instructions;
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(c). Unauthorized attempts to repair, maintain, or modify the Rechargeable IPG for the patient or any unauthorized third party.

This limited warranty is the only warranty that applies to the Rechargeable IPG, 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 Rechargeable IPG with a functionally equivalent Rechargeable IPG made by Boston Scientific and will not be liable for any damages (whether direct, indirect, consequential, or incidental) caused by the Rechargeable IPG, 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.**

**Non-Rechargeable Implantable Pulse Generator (IPG)**

Boston Scientific Corporation warrants to the patient who receives an implantable non-rechargeable pulse generator (referred to as the Non-Rechargeable IPG) that the Non-Rechargeable IPG will be free from defects in workmanship and materials for a period of two (2) years from the date of surgical implant of the Non-Rechargeable IPG. This warranty applies only to the patient who has the Non-Rechargeable IPG implanted and no other person or entity. This warranty does not apply to the leads, extensions, or surgical accessories used with the Non-Rechargeable IPG.

A Non-Rechargeable IPG that fails to function within normal ranges within two (2) years after the date it is implanted is covered under this Limited Warranty. The liability of Boston Scientific under this warranty shall be limited to: (a) replacement of the Non-Rechargeable IPG with a functionally equivalent Non-Rechargeable IPG made by Boston Scientific; or (b) credit applied towards the purchase of a new IPG. The warranty amount is calculated using least expensive device price (original vs. replacement). No other relief whatsoever is available under this limited warranty. This limited warranty for a replacement Non-Rechargeable IPG will last only for two years from the date of surgical implant of the original Non-Rechargeable IPG.

Note: Battery life of a Non-rechargeable IPG may vary due to a variety of factors. Therefore, this warranty shall not extend to battery depletion of a Non-rechargeable IPG unless such depletion is caused by a defect in workmanship or material.

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 Non-Rechargeable IPG must be implanted before the “Use By” date.
3. Failure of the Non-Rechargeable IPG must be confirmed by Boston Scientific.

4. The Non-Rechargeable IPG must be returned to Boston Scientific (or a Boston Scientific authorized agent) within 30 days after it fails to function within normal ranges. That Non-Rechargeable IPG will be the property of Boston Scientific.

5. Accidental damage to the Non-Rechargeable IPG occurring during a medical procedure is covered by this limited warranty.

6. The 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 Non-Rechargeable IPG in accordance with manufacturer’s instructions;
   (c). Unauthorized attempts to repair, maintain, or modify the Non-Rechargeable IPG for the patient or any unauthorized third party

This limited warranty is the only warranty that applies to the Non-Rechargeable IPG, 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 Non-Rechargeable IPG with a functionally equivalent Non-Rechargeable IPG made by Boston Scientific and will not be liable for any damages (whether direct, indirect, consequential, or incidental) caused by the Non-Rechargeable IPG, 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.**

**Limited Warranty - Leads, Extensions, Splitters, and Connectors**

Boston Scientific Corporation warrants to the patient that the Linear™ Lead Models, Infinion™ Lead, Lead Extensions, Lead Splitters, Artisan™ Surgical Paddle Leads, CoverEdge™ Surgical Leads, Splitters, and Lead Connectors are free from defects in workmanship and materials for a period of one (1) year from the date of implantation.

A Lead, Extension, Splitter, or Connector 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, Splitter, or Connector; or (b) full credit equal to the original purchase price to be applied towards the purchase of a new Lead, Extension, Splitter, or Connector. 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, Splitter, or Connector must be returned to Boston Scientific (or authorized agent) within 30 days of malfunction or discovery of defect, and shall be the property of Boston Scientific.

3. The Lead, Extension, Splitter, or Connector must be implanted prior to the “Use By” date.

4. Failure of the Lead, Extension, Splitter, or Connector 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 or Extension 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 Linear™ Lead or Extension, or the Surgical Lead or Extension.

5. The decision as to product replacement or credit shall be made solely at the discretion of Boston Scientific. For a replacement Lead, Extension, Splitter, or Connector, the warranty will run only to the end of the warranty period for the original Lead or Extension 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.

**Limited Warranty - 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 (or Boston Scientific’s authorized agent) 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.