

Limited Warranty

I. GENERAL WARNING

A. The following limited warranty terms and conditions apply only to the Abbott Medical Liberta RC™ Deep Brain Stimulation (DBS) System. The Abbott Medical Liberta RC™ DBS System is comprised of the Liberta RC™ implantable pulse generator (IPG), charging system, leads, extensions, accessories, clinician programmer, patient controller, and other items in the kits (collectively, the “Liberta RC™ DBS System”). Upon being implanted, the implantable components must withstand exposure to an extremely hostile and unpredictable environment in the human body. The implanted components may fail during or following implantation into the body for any one or a number of reasons, including, but not limited to, medical complications; body rejection phenomena; lead breakage; improper handling, implantation, or use; and insulation breach.

B. Abbott Medical makes no representations or warranties that failure or cessation of function of any component, or the Liberta RC™ DBS System, will not occur; that the body will not react adversely to implantation; or that medical complications will not develop.

C. In addition to the general limited warranty terms in this Section and Section VI, additional specific warranty terms apply to the different components of the Liberta RC™ DBS System. Please refer to the titles of each section for information about specific warranty terms applicable to the different components that comprise the Liberta RC™ DBS System.

II. LIMITED WARRANTY: LIBERTA RC™ IMPLANTABLE PULSE GENERATOR

A. Subject to the other conditions set forth in this limited warranty (including but not limited to Sections I and VI), a limited warranty is available for a credit for the replacement of the Abbott Medical Liberta RC™ implantable pulse generator (the “Device”), if the Device fails to function within operating specifications due to defects in materials or workmanship within ten (10) years from the date of implantation (the “Warranty Period”) and as further specified in the rest of this Section.

B. If the Device fails to function within operating specifications due to defects in materials or workmanship during the Warranty Period when used as intended under normal surgical conditions and in conformance with the instructions for its use and maintenance, subject to the other terms and conditions contained in this limited warranty, Abbott Medical will issue a full replacement credit as described in this limited warranty for up to five (5) years from the date of implantation, and at a prorated cost between five (5) and ten (10) years from the date of implantation.

C. In addition, for replacements made and covered under this limited warranty, Abbott Medical will reimburse the patient up to US \$1,250 for reasonable, unreimbursed out-of-pocket medical expenses associated with the replacement procedure. In such cases, the Abbott Medical Warranty Department will contact the patient or the patient’s authorized representative. To qualify for this reimbursement, the patient or an authorized representative must submit any additional documentation reasonably requested by Abbott Medical in connection with the out-of-pocket expenses for review and approval.

D. The following additional conditions apply to coverage under this limited warranty:

1. The Device must be implanted prior to the expiration date indicated on the Device’s packaging.
2. A completed Implant/Patient Registration Form must be returned to Abbott Medical within 45 days of implant of the Device.
3. The physician, hospital, or surgical center must return the Device (mail or ship the Device together with a return number obtained from Abbott Medical Technical Support (+1-855-478-5833) to Abbott Medical, 6901 Preston Road, Plano, TX 75024, USA) within 45 days after removal from the patient.
4. Abbott Medical will analyze the Device and determine whether it qualifies for warranty coverage.
5. Upon receipt of the Device by Abbott Medical, the returned Device shall become the exclusive property of Abbott Medical.
6. The credit may only be used toward the purchase of an equivalent or functionally equivalent Abbott Medical neurostimulation pulse generator in the original patient.
7. In no event shall the amount of the replacement credit exceed the lesser of the net invoiced price of the original Device or the replacement Abbott Medical device.
8. See Sections I and VI for additional terms applicable to this limited warranty.

III. LIMITED WARRANTY: ABBOTT MEDICAL CHARGER USED WITH THE LIBERTA RC™ DBS IPG

A. Subject to the other conditions set forth in this limited warranty (including but not limited to Sections I and VI), a limited warranty is available for a credit for the replacement of the Abbott Medical Charger used with the Liberta RC™ DBS System (the “Charger”), if the Charger fails to function within operating specifications due to defects in materials or workmanship within five (5) years from the date of Charger invoice, when used as intended under normal conditions and in conformance with the instructions for its use and maintenance.

B. For a replacement credit under this limited warranty:

1. The Charger must be invoiced prior to the expiration date indicated on the Charger's packaging.
2. A completed Implant/Patient Registration Form must be returned to Abbott Medical within 45 days of implant of the Device.
3. The patient, or his or her authorized representative, must, at his or her own expense, mail or ship the Charger together with a return number obtained from Abbott Medical Technical Support (+1-855-478-5833) to Abbott Medical, 6901 Preston Road, Plano, TX 75024, USA, within 45 days. Appropriate identification details such as the serial number or lot number must be provided to Abbott Medical Technical Support within 45 days after discovery of the failure or malfunction along with relevant additional data indicating the failure or malfunction.
4. Abbott Medical will analyze the Charger and determine whether it qualifies for warranty coverage.
5. Upon receipt of the Charger by Abbott Medical, the returned Charger shall become the exclusive property of Abbott Medical.
6. The credit may only be used toward the purchase of an equivalent or functionally equivalent Abbott Medical Charger.
7. In no event shall the amount of the replacement credit exceed the lesser of the net invoiced price of the original Charger or the replacement Abbott Medical Charger.
8. See Sections I and VI for additional terms applicable to this limited warranty.

IV. LIMITED WARRANTY: ABBOTT MEDICAL LEADS AND EXTENSIONS USED WITH THE LIBERTA RC™ DBS IPG

A. Subject to the other conditions set forth in this limited warranty (including but not limited to Sections I and VI), a limited warranty is available for a credit for the replacement of Abbott Medical implantable neurostimulation lead or leads used with the Liberta RC™ DBS System (the “Lead”) and Abbott Medical implantable neurostimulation extension or extensions used with the Liberta RC™ DBS System (the “Extension”), if the Lead or Extension fails to function within operating specifications due to defects in materials or workmanship within one (1) year from the date of implantation, when used as intended under normal conditions and in conformance with the instructions for its use and maintenance.

B. For a replacement credit under this limited warranty:

1. The Lead or Extension must be implanted prior to the expiration date indicated on the Lead's packaging.
2. A completed Implant/Patient Registration Form must be returned to Abbott Medical within 45 days of implant of the Lead or Extension.
3. The patient, or his or her authorized representative, must, at his or her own expense, mail or ship the Lead or Extension together with a return number obtained from Abbott Medical Technical Support (+1-855-478-5833) to Abbott Medical, 6901 Preston Road, Plano, TX 75024, USA, within 45 days after removal from the patient. If removal is not feasible, appropriate identification details such as the serial number or lot number must be provided to Abbott Medical Technical Support within 45 days after discovery of the failure or malfunction along with relevant additional data, such as X rays, indicating the failure or malfunction.
4. Abbott Medical will analyze the Lead or Extension and determine whether it qualifies for warranty coverage.
5. Upon receipt of the Lead by Abbott Medical, the returned Lead or Extension shall become the exclusive property of Abbott Medical.
6. The credit may only be used toward the purchase of an equivalent or functionally equivalent Abbott Medical neurostimulation Lead or Extension in the original patient.

7. In no event shall the amount of the replacement credit exceed the lesser of the net invoiced price of the original Lead or Extension or the replacement Abbott Medical Lead or Extension.
8. See Sections I and VI for additional terms applicable to this limited warranty.

V. LIMITED WARRANTY: ABBOTT MEDICAL EXTERNAL COMPONENTS USED WITH THE LIBERTA RC™ DBS SYSTEM

A. Subject to the other conditions set forth in this limited warranty (including but not limited to Sections I and VI), a limited warranty is available for (at Abbott Medical sole option) replacement, a credit for the replacement, or the repair of any of the following components used in connection with the Abbott Medical Liberta RC™ DBS System: charger power adapter, charging cable, reusable apparel, travel case, patient magnet, and patient controller (each, a "Related Component"), if the Related Component fails to function when used in accordance with the labeling and instructions for use provided with the Related Component and is returned to Abbott Medical within one (1) year of the date of invoice.

B. To qualify for repair or replacement under this limited warranty:

1. The patient, or his or her authorized representative, must, at his or her own expense, mail or ship the Related Component together with a return number obtained from Abbott Medical Technical Support (+1-855-478-5833) to Abbott Medical, 6901 Preston Road, Plano, TX 75024, USA, within 45 days after discovery of the failure.
2. If the Related Component qualifies for coverage, Abbott Medical will (at its sole option) either repair or replace the returned Related Component with an equivalent or functionally equivalent item (which may include a repaired or refurbished item) or issue a replacement credit for the benefit of the patient limited as set forth in the rest of this Section.
3. Upon receipt of the Related Component by Abbott Medical, the returned Related Component shall become the exclusive property of Abbott Medical.
4. If any replacement credit is offered by Abbott Medical under this limited warranty, it is for the benefit of the patient and will not exceed the lesser of the net invoice price of the original Related Component or the replacement Abbott Medical component.
5. See Section I and VI for additional terms applicable to this limited warranty.

VI. IMPORTANT LIMITATIONS AND OTHER LIMITED WARRANTY TERMS

A. THIS LIMITED WRITTEN WARRANTY CONTAINS THE FINAL, COMPLETE, AND EXCLUSIVE STATEMENT OF WARRANTY TERMS FOR THE ABBOTT MEDICAL LIBERTA RC™ DBS SYSTEM. THIS WARRANTY IS IN LIEU OF, AND ABBOTT MEDICAL HEREBY DISCLAIMS AND EXCLUDES, ALL OTHER WARRANTIES, REPRESENTATIONS, OR CONDITIONS, WHETHER EXPRESS OR IMPLIED BY OPERATION OF LAW OR OTHERWISE, INCLUDING BUT NOT LIMITED TO, ANY IMPLIED WARRANTIES OF MERCHANTABILITY, NON-INFRINGEMENT, COURSE OF DEALING, QUIET ENJOYMENT, OR FITNESS FOR A PARTICULAR PURPOSE. NO PERSON IS AUTHORIZED TO MAKE ANY OTHER GUARANTEES, WARRANTIES, OR REPRESENTATIONS ON BEHALF OF ABBOTT MEDICAL. Descriptions of specifications or other statements or claims appearing in Abbott Medical literature are meant solely as general descriptions of the LIBERTA RC™ DBS System and are hereby expressly disclaimed. THE DISCLAIMERS AND LIMITATIONS CONTAINED IN THIS SECTION SHALL BE CONSTRUED TO COMPLY WITH APPLICABLE LAW, AND THIS LIMITED WARRANTY SHALL BE REFORMED ACCORDINGLY AS NECESSARY TO COMPLY WITH APPLICABLE LAW.

B. THIS LIMITED WARRANTY FOR THE LIBERTA RC™ DEEP BRAIN STIMULATION SYSTEM DOES NOT APPLY TO:

1. Any damage caused by misuse, neglect, accident, modification, improper application, or from other than normal and ordinary use.
2. Any damage caused by any repair or attempted repair by one other than an authorized Abbott Medical-trained technician.
3. Any damage resulting from failure to maintain, clean, or use in accordance with the user's guide and/or clinician's manual furnished by Abbott Medical.

C. THE REMEDIES SET FORTH IN THIS WARRANTY WILL BE THE ONLY REMEDIES AVAILABLE TO ANY PERSON.

D. ABBOTT MEDICAL WILL NOT BE RESPONSIBLE FOR ANY INDIRECT, SPECIAL, COVER, PUNITIVE, CONSEQUENTIAL, INCIDENTAL, OR OTHER DAMAGES DIRECTLY OR INDIRECTLY ARISING FROM THE USE OF OR RELATED TO THE LIBERTA RC™ DBS SYSTEM OR ANY OF ITS COMPONENTS, WHETHER SUCH CLAIM IS BASED ON CONTRACT, TORT, WARRANTY, OR OTHERWISE. THE SOLE LIABILITY OF ABBOTT MEDICAL AND YOUR SOLE REMEDY RELATED TO THE SYSTEM OR ANY OF ITS COMPONENTS IS THE REPAIR, REPLACEMENT OR

REPLACEMENT CREDIT DESCRIBED IN THIS LIMITED WARRANTY. IN NO EVENT SHALL ABBOTT MEDICAL BE LIABLE TO YOU OR ANY THIRD PARTY FOR ANY CLAIM OR DAMAGES, HOWEVER ARISING, IN AN AMOUNT THAT EXCEEDS THE PRICE THE ORIGINAL PURCHASER PAID FOR THE APPLICABLE LIBERTA RC™ DBS SYSTEM COMPONENT.

VII. OTHER TERMS AND CONDITIONS

A. The purchaser must inspect all components of the Abbott Medical Liberta RC™ DBS System upon receipt. If any component is received in damaged condition, Abbott Medical will replace it at no charge to the purchaser if the damage is reported to Abbott Medical within 15 days of receipt of the component and it is promptly returned to Abbott Medical.

B. This limited warranty is expressly limited to products sold in the United States and its territories.



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