

LIMITED WARRANTY

Subject to the limitations and exclusions set forth below, Aleva Neurotherapeutics SA (Aleva) warrants that its directSTIM™ DBS System, which is used in accordance with the instructions, will be free from defects in material and workmanship appearing under normal service and use (as specified below) for the following periods of time from the date of implantation (for the implanted components) or the date of purchase (for the externals):

Five Years: ● PN-12000 directSTIM 24-channel Implantable Pulse Generator kit
● PN-12050 Port Plug
● PN-12700 Magnet

One Year: ● PN-11500 directSTIM 12-electrode lead kit
● PN-12100 12-connector extension kit
● PN-12200 directSTIM Clinician Programmer
● PN-12300 directSTIM Patient Programmer Charger kit
● PN-12310 Charging Paddle
● PN-12320 directSTIM Adjustable Harness kit
● PN-12340 Power Cord
● PN-12400 directSTIM External Pulse Generator

Single Use: ● PN-12500 Trial Cable
● PN-12600 Tunneling tool

Aleva does not warrant that failure or cessation of function of any component or the system will not occur or that medical complications will not develop.

If a directSTIM DBS System product fails to function within normal ranges due to a defect in material or workmanship within the applicable warranty period above, Aleva as the sole and exclusive remedy under this Limited Warranty will replace the product or defective component thereof with a functionally equivalent product or component (Replacement Product). Each Replacement Product is warranted hereunder for the remainder of the applicable original warranty period of the product it replaced.

Claims under this Limited Warranty are subject to the following additional conditions and limitations:

1. The product registration form must be completed and returned to Aleva within 60 days if an initial patient implant.
2. Aleva must confirm the product or component failure.
3. The product or component must be returned to Aleva, or other party designated by Aleva, within 30 days after it fails to function within normal ranges. The product or component will be Aleva property upon replacement.
4. This Limited Warranty does not include damage or any failure to function within normal ranges caused by:
 - a. Water damage, fire, accident, lightning, or other natural disasters
 - b. Misuse, neglect, abuse, or use contrary to Aleva's instructions for use
 - c. Unauthorized repair or modifications by an individual or other party
 - d. Additions of equipment or materials to the directSTIM DBS System not supplied or authorized by Aleva

EXCEPT FOR THE LIMITED WARRANTY PROVIDED ABOVE, ALEVA MAKES NO WARRANTY, EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, WHETHER ARISING FROM STATUTE, COMMON LAW, OR OTHERWISE. THIS LIMITED WARRANTY SHALL BE THE EXCLUSIVE REMEDY AVAILABLE TO ANY PERSON. ALEVA IS NOT LIABLE FOR DIRECT OR INDIRECT, SPECIAL, INCIDENTAL, OR CONSEQUENTIAL DAMAGES (INCLUDING BUT NOT LIMITED TO LOSS OF PROFITS OR BUSINESS OR MEDICAL OR HOSPITAL EXPENSES) WHETHER BASED ON CONTRACT, TORT, OR ANY OTHER LEGAL THEORY.

Any legal action arising from the purchase or use of Aleva products shall be commenced within one year from the accrual of the cause of action, or be barred forever. In no event shall Aleva liability under this warranty or otherwise exceed the purchase price of the product giving rise to the cause of action.

The above limitations of liability apply to all warranty claims. No waiver or amendment of this Limited Warranty shall be valid unless in writing signed by Aleva. Some states, and some countries, do not allow the exclusion or limitation of incidental or consequential damages, so the above limitations may not apply to you. This Limited Warranty gives the patient specific legal rights, and he/she may have additional rights which vary from state to state.

(2019-08)