



Health innovation that matters

Neuromodulation Returned Product Form (RPF) – Anonymous

Before you begin, please read the **Returned Product Kit Instructions** on the back of this form.

For a returned product authorization number call: **+32.2.790.27.73**

Note: The returned product authorization number must be clearly marked on the outside of the package. **If the material is biohazardous, the package must be marked and treated as such.** All returned products shall become the property of LivaNova USA, Inc..

Authorization Number:

This form must accompany the returned product(s). Send all returned product(s) to the following address:

**Sorin Group Italia
Via Statale 12 Nord, 86
41037 Mirandola (MO)
Italy**

A. Facility Information

Hospital:		Date (DD/MM/YYYY):
City:	State/Province:	Country:
Form completed by (<i>Print name clearly</i>):		Phone or E-mail:

B. Products to Return—

VNS: Pulse Generator, Lead, Programming Wand/Computer, Software, Tunneling Tool, Accessory Pack

OSA: Pulse Generator, Lead, Charging Antenna (CA), Remote Control Charger (RCC), Remote Control Charger (RCC) Battery

Returned Item/Model Number	Serial or Other ID #	Returned Item/Model Number	Serial or Other ID #
1.	#	4.	#
2.	#	5.	#
3.	#	6.	#

C. Reason for Product Return

<input type="checkbox"/> Sterilization break (<i>product opened but unused</i>)	<input type="checkbox"/> Other— <i>Describe:</i>
<input type="checkbox"/> Explant— <i>Please complete sections D, E, and F below.</i>	

D. Treating Physician Information

If not applicable, please check box.

Referring physician's name:

E. Reason for Explant

If not applicable, please check box.

<input type="checkbox"/> Battery depletion— <i>For VNS Therapy (only), please choose one below.</i> <input type="checkbox"/> Near EOS/NEOS = Yes <input type="checkbox"/> EOS (Device disabled) <input type="checkbox"/> Unable to interrogate due to battery depletion	<input type="checkbox"/> Prophylactic (elective) generator replacement— <i>For VNS Therapy (only), please choose one below:</i> <input type="checkbox"/> Near EOS/NEOS = No <input type="checkbox"/> IFI = Yes
<input type="checkbox"/> Lead discontinuity	<input type="checkbox"/> Lack of efficacy
<input type="checkbox"/> Adverse event— <i>If so, please describe:</i>	<input type="checkbox"/> Other— <i>If so, please describe:</i>

F. Explant Information

If not applicable, please check box.

Explant physician:	Date of explant (DD/MM/YYYY):
Physician's address:	Physician's phone number or e-mail:
	Was a replacement unit implanted? <input type="checkbox"/> Yes <input type="checkbox"/> No
	New Generator Model: _____ Serial #: _____
	New Lead Model: _____ Serial #: _____

G. LivaNova Use Only

Received by:	Date:
--------------	-------

RETURNED PRODUCT KIT INSTRUCTIONS

Please Read Complete Instructions

STEP 1

- Disinfect all biohazardous components being shipped back to LivaNova/Sorin Group Italy srl. Use your facility's approved disinfectant procedure for handling biohazard materials. Examples of products that may be included for disinfecting biohazard materials are Cidex® or Betadine®. If disinfection is not possible, place the device in the supplied bio-hazard bags.
- Please call LivaNova's Neuromodulation Technical Support (+32 2 790 27 73) for the Return Authorization Number before shipping any products back to LivaNova or by contacting your local LivaNova sales representative.
 - VNS Therapy – Call +32 2 790 27 73, or e-mail cservices@livanova.com
 - THN (OSA) Sleep Therapy –E-mail (preferred) SleepApnea.Support@Livanova.com, or call +32 2 790 27 73

STEP 2

- Place all biohazardous products (e.g. lead, generator, screwdriver, setscrew, tunneling tool), as applicable, inside the biohazard bag (provided by LivaNova) and seal the bag.
- Place the bag inside another biohazard bag (also provided) and seal the outer bag. Both bags **must** be fully sealed.

STEP 3

- Place the double-bagged biohazardous material and all other materials to be returned between the foam inserts in the box.
- Place the **completed** Returned Product Form inside the envelope provided.
- Fold the envelope in half and place it on top of the foam inserts in the box.
- Close the box by using the enclosed biohazard sticker for all biohazard products (e.g. lead, generator, screwdriver, setscrew, tunneling tool).
- Close the box with normal tape for all other non-explanted/non-used/non-biohazardous devices.

STEP 4

- Obtain the transport documentation that is provided by your local courier company.
- Fully complete the transport documentation that is provided by your local courier company and then insert back into the pouch at the top of the Returned Product Kit.
- Write the Return Authorization Number on the outside of the box.

STEP 5

- Close the box.
- Tape the box shut.
- For all biohazardous products (e.g. lead, generator, screwdriver, setscrew, tunneling tool), Sorin Group Italy personnel will apply the UN3373 label on an external side of the box prior to return shipment to USA.

STEP 6

- Deliver box to shipping company or shipping company pickup point.