

Date: 2022-07-29

## **Urgent Field Safety Notice**

### **NeuRx Diaphragm Pacing System External Pulse Generator (EPG)**

**For the Attention of:** Healthcare Providers

<b>Contact details of local representative:</b>
Moustapha Diop Synapse Biomedical - Europe 7 Rue de la Liberation 95880 Enghien Les Bains, France France and other Countries Tel: +33 (0) 1 34 16 49 11 Fax: +33 (0) 1 74 18 08 19 Email: mdiop@synapsebiomedical.com

## 1. Information on Affected Devices

### 1.1. Device Description

The External Pulse Generator (EPG) provides repetitive electrical stimulation to the implanted electrodes of the NeuRx DPS to cause the patient's diaphragm to contract and cause the patient to inhale in a manner similar to natural breathing.

The EPG is programmed so that it produces the right stimulation patterns. If the stimulation is uncomfortable, the EPG settings can be adjusted by the clinician to reduce or eliminate the discomfort.

The user simply connects the device to the implanted electrodes and turns it on for use; no other controls are available or necessary for operation.



### 1.2. Commercial Name

NeuRx Diaphragm Pacing System (NeuRx DPS) External Pulse Generator (EPG)

### 1.3. Unique Device Identifier (UDI-DI)

00852184003212

### 1.4. Primary Clinical Purpose of Device

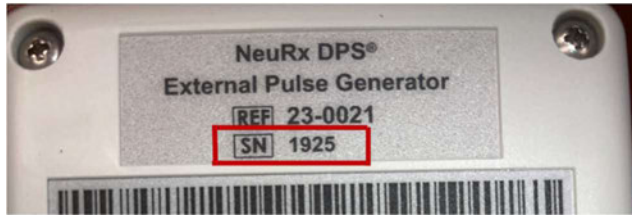
The NeuRx Diaphragm Pacing System (NeuRx DPS®) provides ventilatory support in patients with diaphragm dysfunction of neuromuscular origin who require chronic ventilatory support because of diaphragm paralysis. The device is indicated in patients with high-level spinal cord injury, whose remaining phrenic nerve, lung and diaphragm muscle function are sufficient to accommodate electrical stimulation.

### 1.5. Device Part Number

23-0021

### 1.6. Affected Serial Number Range

The devices are labeled on the back of the device with REF 23-0021. Affected serial numbers (SN) include: 1900 through 2017.



## 2. Reason for Field Safety Corrective Action (FSCA)

### 2.1. Description of the product problem

Due to a defect identified on the EPG controller printed circuit board assembly, device performance may degrade over time.

### 2.2. Hazard giving rise to the FSCA

Refer to section 2.4

### 2.3. Probability of problem arising

Because of the nature of the defect, it is difficult to estimate the likelihood of a problem occurring. However, because of the serious nature of some of the potential adverse events, immediate action is recommended.

### 2.4. Predicted risk to patients/users

Depending on the particular failure mode, the following adverse events could occur:

- Stimulation from 1 or 2 channels may exceed programmed values causing pain if the patient has sensation
- Stimulation from 1 or 2 channels may exceed programmed values causing muscle fatigue and decreased breathing effectiveness
- Stimulation from 1 or 2 channels may exceed programmed values causing cardiac rhythm interference (arrhythmia or cardiac arrest)
- A clinician may not be able to program the device
- The device display may not be readable
- The device may indicate that a battery is low when it is not
- A battery may become depleted without warning causing the device to stop unexpectedly

### 2.5. Further information to help characterise the problem None

**2.6. Background on issue**

One adverse event has been reported while using an affected device. A patient with sensation reported intense pain when stimulation with the device was initiated. Degraded device performance initially manifested with improper selection of output channels on the device. The electrical stimulation pulses from two of the four output channels were incorrectly sent out to the remaining two channels. The stimulation on those two channels could exceed the maximum stimulation programmed for that channel potentially causing adverse health effects.

**2.7. Other information relevant to the FSCA**

The defect has been found to exist in a total of 118 devices. 101 of the affected devices have been distributed and are the subject of the FSCA.

The devices were distributed as follows: 95 US 4 EU 2 Other

The affected devices were distributed between 2021-07-13 – 2021-11-29.

The affected devices cannot be repaired and the manufacturer requests that these devices be returned to Synapse Biomedical, Inc. (the manufacturer) as soon as possible to remove any risk that they will be inadvertently used in the future.

**3. Type of action to mitigate the risk**

**3.1. Action to be taken by the user**

**Do not stop using the device without consulting with your healthcare provider.**

Contact the health care provider that either implanted your NeuRx Diaphragm Pacing System, or that is currently helping you with the device, to discuss your options.

- Identify Device   
  Quarantine Device   
  Return Device   
  Destroy Device  
 On-site device modification/inspection  
 Follow patient management recommendations  
 Take note of amendment/reinforcement of Instructions For Use (IFU)  
 Other                       None

**3.2. By when should the action be completed**

As soon as possible

**3.3. Particular considerations for:**

Implantable device

**3.4. Is a customer reply required?**

Yes - Contact the healthcare provider to arrange replacement of affected devices

<p><b>3.5. Action taken by the manufacturer</b></p> <p><input checked="" type="checkbox"/> Product Removal      <input type="checkbox"/> On-site device modification/inspection</p> <p><input type="checkbox"/> Software upgrade      <input type="checkbox"/> IFU or labelling change</p> <p><input type="checkbox"/> Other      <input type="checkbox"/> None</p>
<p><b>3.6. By when should the action be completed:</b></p> <p>As soon as possible</p>
<p><b>3.7. Is the FSN required to be communicated to the patient/lay user?</b></p> <p>Yes</p>
<p><b>3.8. If yes, has the manufacturer provided additional information suitable for the patient/lay user in a patient/lay user information letter/sheet?</b></p> <p>No      Not appended to this FSN</p>

<b>4. General Information</b>	
<b>4.1. FSN type</b>	New
<b>4.2. For an updated FSN, reference the number and date of the previous FSN</b>	N/A
<b>4.3. For an updated FSN, key new information is as follows:</b>	N/A
<b>4.4. Is further advice or information already expected in a follow-up FSN?</b>	No
<b>4.5. If a follow-up FSN is expected, what is the further advice expected to relate to:</b>	N/A
<b>4.6. Anticipated timescale for follow-up FSN:</b>	N/A
<b>4.7. Manufacturer information:</b>	
a. Company Name	Synapse Biomedical, Inc.
b. Address	300 Artino Street Oberlin, OH 44074 USA
c. Website address	www.synapsebiomedical.com

<b>4.8. The Competent Authority of your country has been informed about this communication to customers</b>	
<b>4.9. List of attachments/appendices:</b> None	
<b>4.10. Name/Signature</b>	Moustapha Diop, COO/Managing Director of Europe

<b>Transmission of this Field Safety Notice</b>
<p>This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate)</p> <p>Please transfer this notice to other organisations on which this action has an impact. (As appropriate)</p> <p>Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.</p> <p>Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.</p>