



SetPoint System Implant Profile Identifier

Read all instructions, warnings and cautions carefully. Failure to follow them could lead to misidentification of an active implantable medical device (AIMD).

Contact SetPoint Medical with any questions about the information contained in the SetPoint System Implant Profile Identifier. Copies of all SetPoint System Instructions for Use (IFUs) are available on the SetPoint Medical website. Any SetPoint System-related incident or problem, which is believed to represent a safety issue, should be reported to SetPoint Medical, Inc. immediately.

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Caution: Federal law restricts this device to sale by or on the order of a physician.

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Introduction

While the manufacturer and model number of an active implantable medical device (AIMD) is typically identified using radio-opaque symbols embedded within the device, the SetPoint Implant is too small for symbols of this type to be readable utilizing an X-Ray image. Instead, this Implant Profile Identifier provides implantation location information along with sample X-Ray images to aid with the identification of the AIMD through use of the radiographic silhouette of the Implant.

The table below shows the SetPoint System model numbers for the parts of the system that are described in this manual.

Device Name	Model Number
Implant	M01
Charger	E04
Docking Station	C01

Table 1 - Device Names and Model Numbers

SetPoint System Description

The SetPoint System includes:

- The Implant (A) which is placed within a Pod (B) and implanted on the left vagus nerve in the neck (C)
- A Charger (D) with a Docking Station (F)
- A Programmer (E)

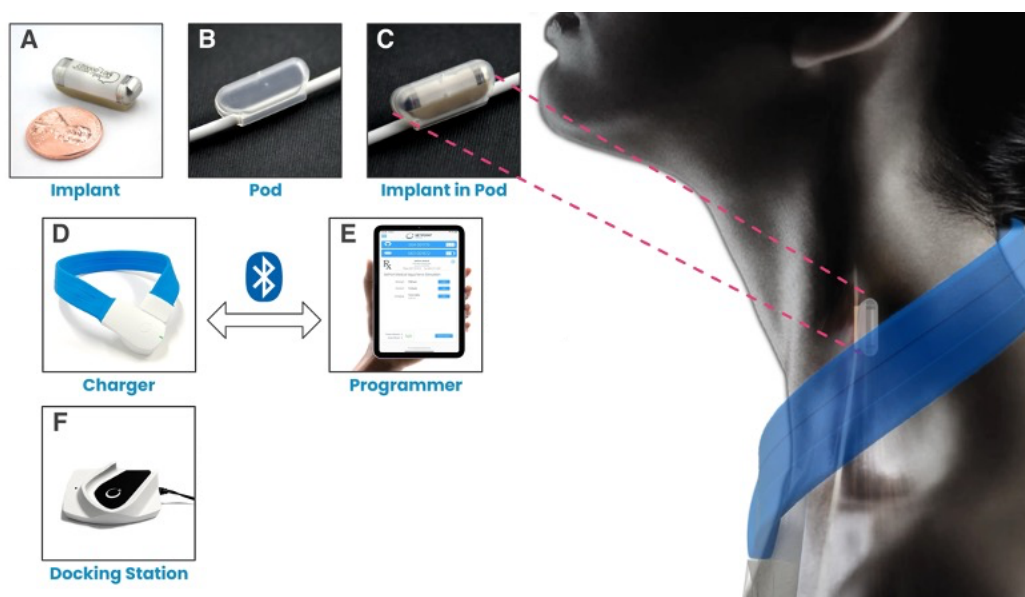


Figure 1 – SetPoint System and Components

The Implant is an integrated neurostimulation device. It is used to electrically stimulate the vagus nerve for 1 minute, every day. It is about 1 in (2.5 cm) long and weighs about 0.1 oz (3 g). Both the Charger and Docking Station are intended to be used at home for Implant charging. The Programmer is a software application on an Apple® iPad that is used to program the stimulation parameters of the Implant. The Programmer is intended to be used in the clinic.



Implantation Location

The Implant is placed on a segment of the vagus nerve that is at least 1.2 in (3 cm) long and free from any branches. A suitable segment is typically half-way up between the clavicle and the mastoid process and below both the inferior and superior cervical cardiac branches.

Ideal placement for the Implant to optimize communication with the Charger is between the C4 and C6 cervical vertebrae. The Implant should never be placed below the C7 cervical vertebra. An example placement is illustrated below.

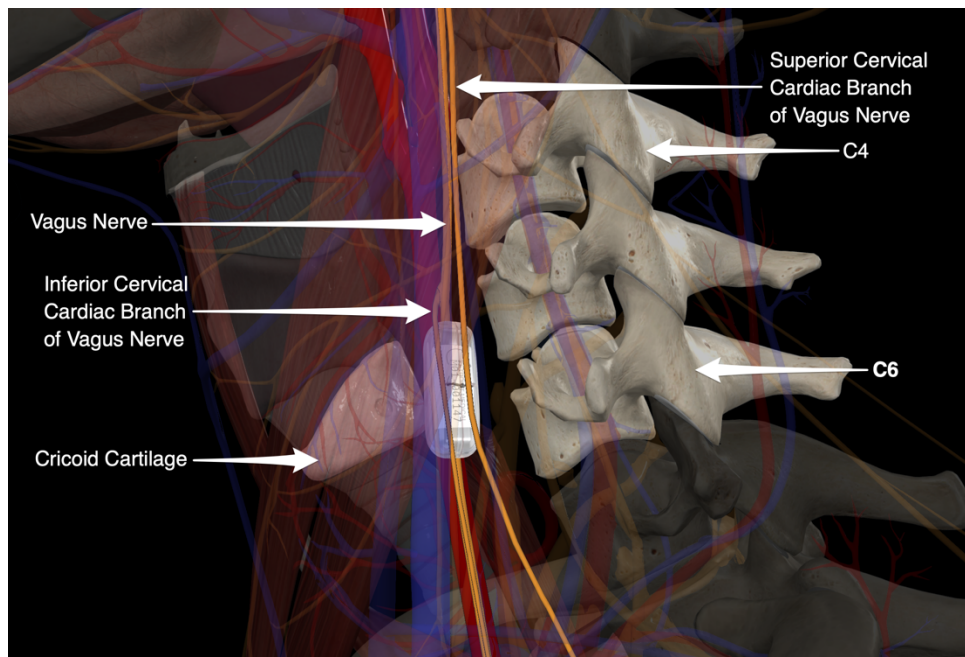


Figure 2 - Relationship Between Implant Implantation Location and Vagus Nerve Branches



Radiographic Silhouette

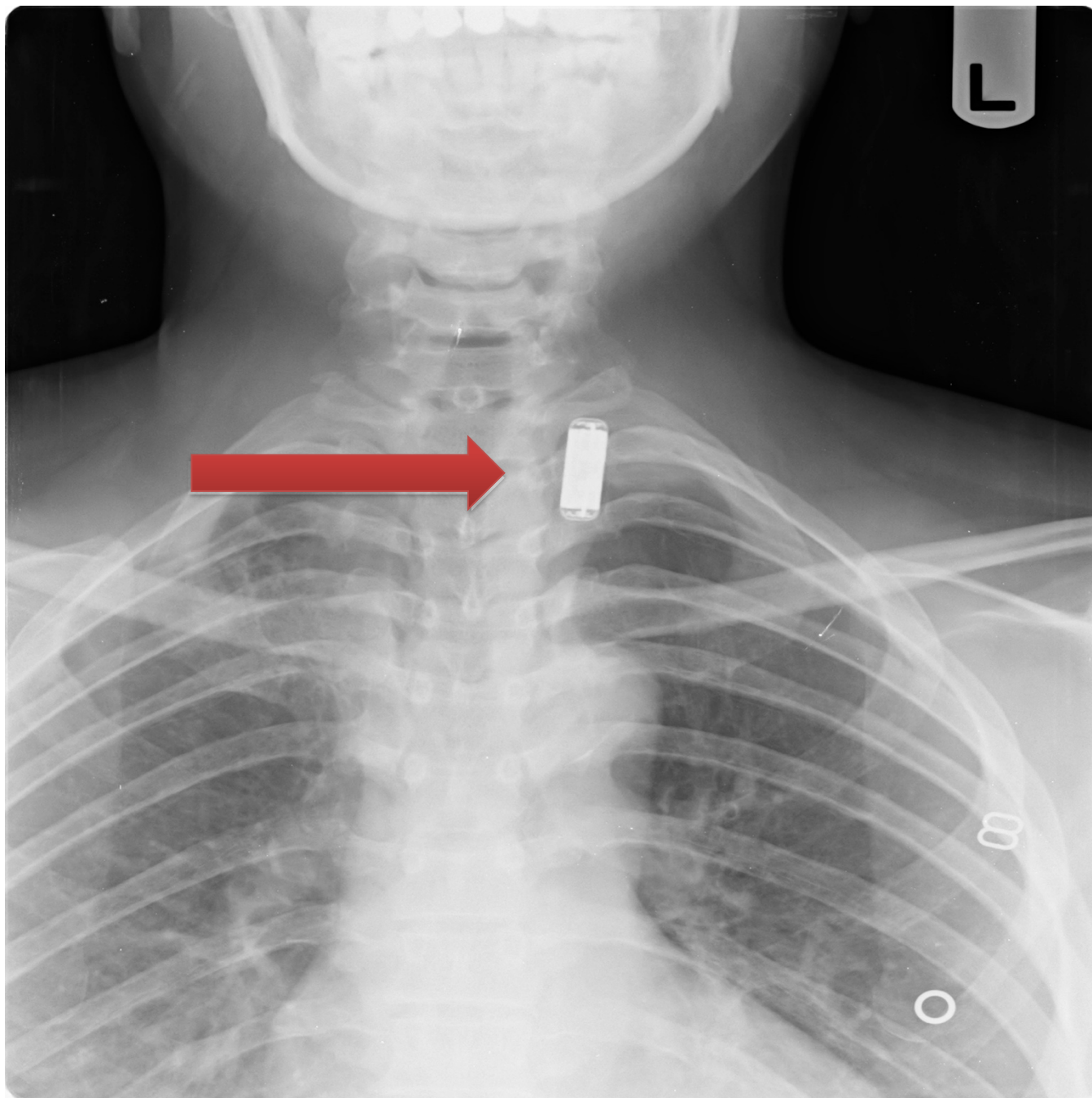


Figure 3 – Anteroposterior (AP) Cervical X-Ray

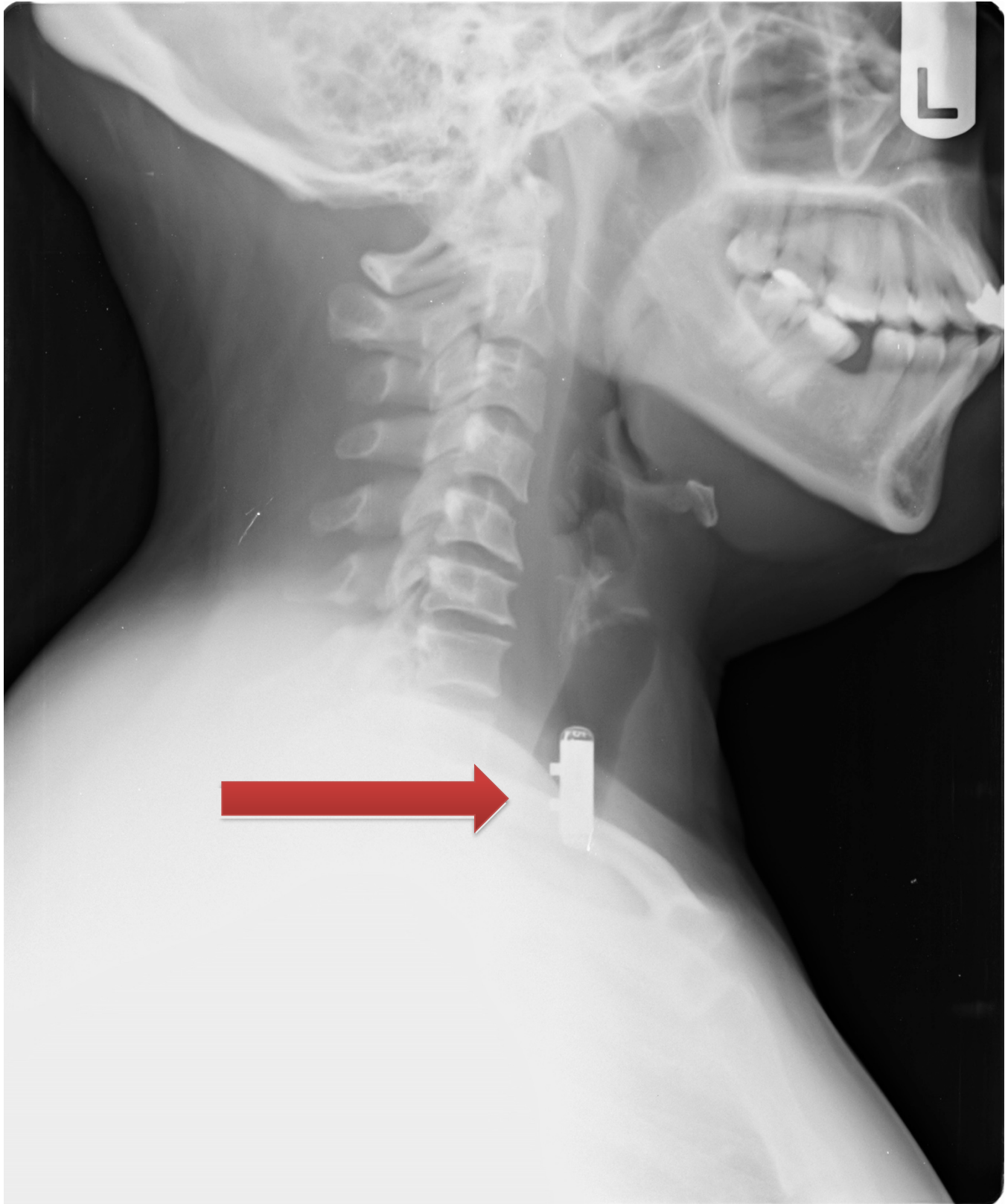


Figure 4 – Lateral Cervical X-Ray



Device Interrogation

The Programmer and Charger can be used to interrogate the Implant. Using telemetry, the Implant can transmit its serial number and other information to positively identify itself. If the radiographic silhouette of the AIMD is consistent with that of the Implant, you can contact SetPoint Medical to arrange support for a device interrogation.