

# IMPLANT PROFILE

## IDENTIFIER

### **Read all instructions, warnings and cautions carefully.**

Failure to do so may damage the SetPoint System,  
cause it to malfunction or perform poorly, and could result in injury.

If you have any questions about the information contained in the **SetPoint System  
Implant Profile Identifier**, please **contact SetPoint Medical**.

All SetPoint System Instructions for Use (IFUs) are available on the SetPoint Medical website.

If you experience any incident or problem related to the SetPoint System  
that may pose a safety risk, report it to SetPoint Medical immediately.

### **Contact**



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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.

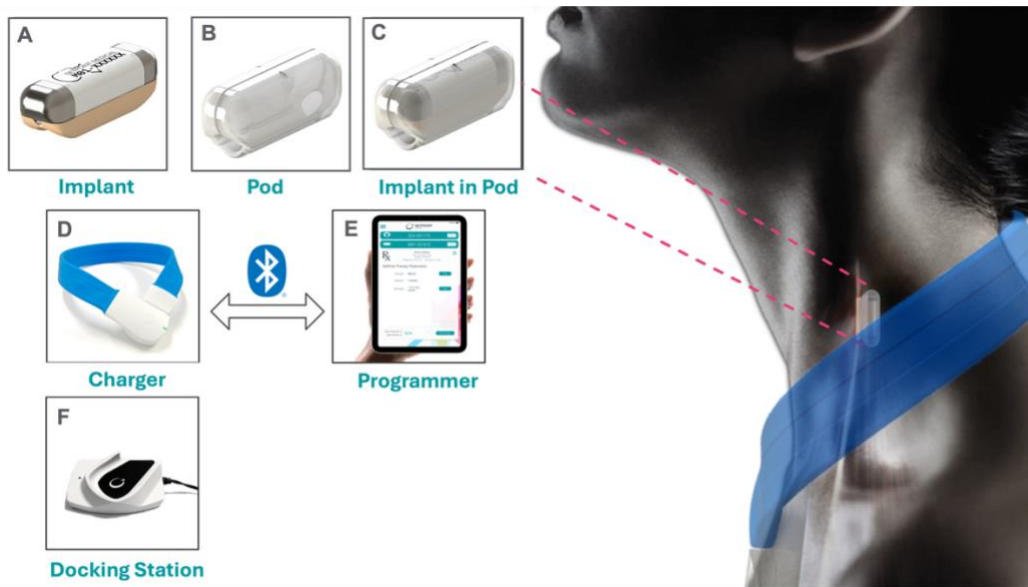
Device Name	Model Number
Implant	M01
Charger	E04
Docking Station	C01

*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)



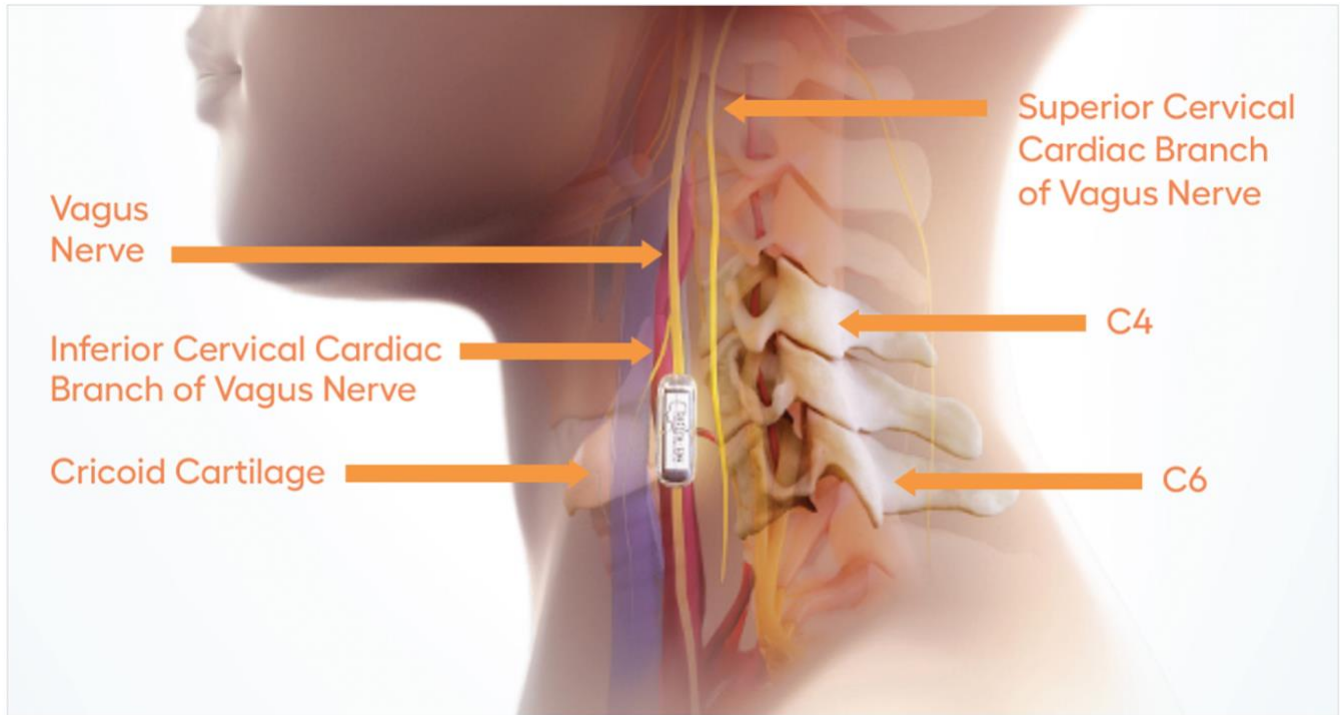
*Figure 1 – SetPoint System and Components*

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

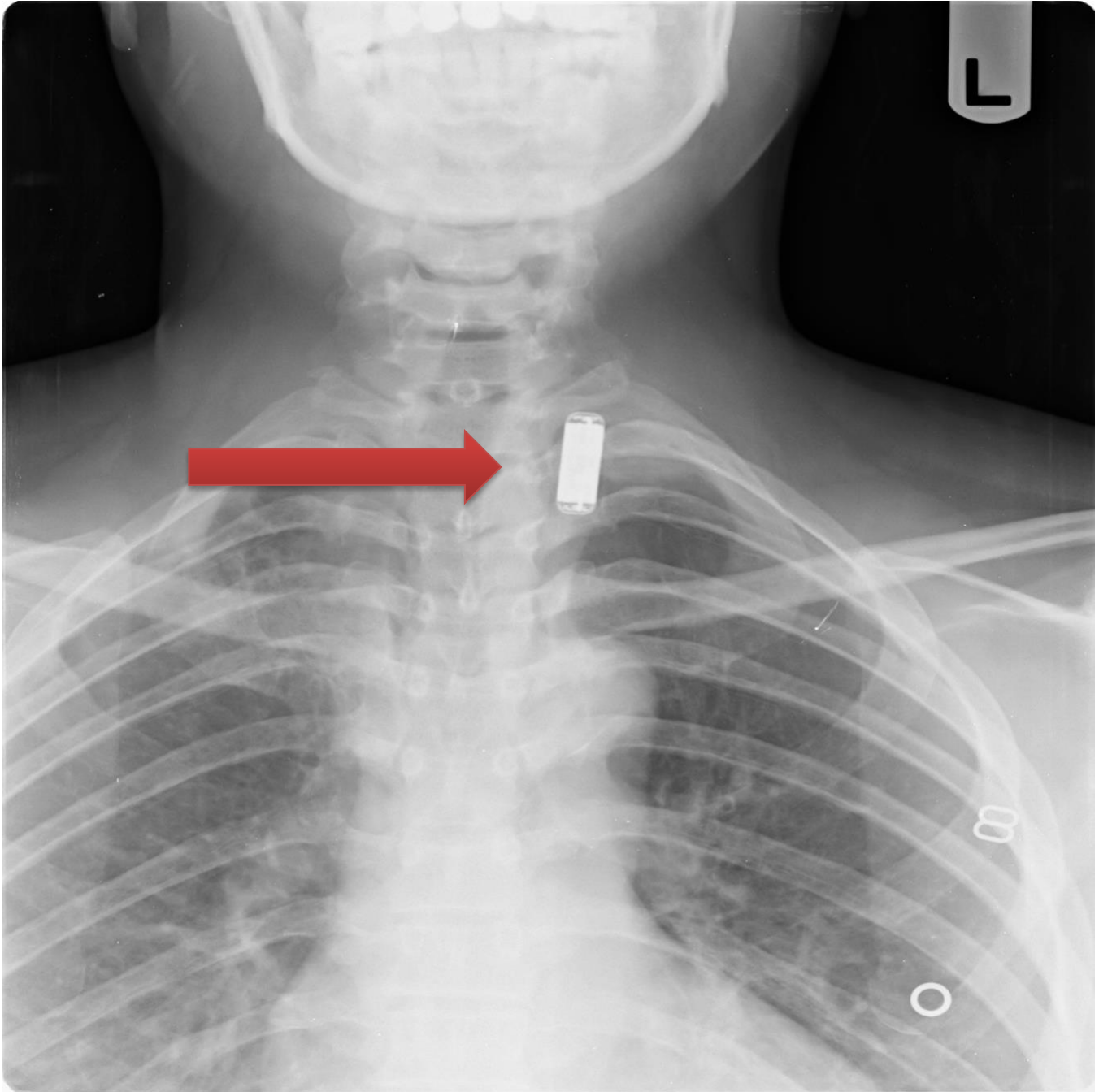
The Implant is placed on a segment of the vagus nerve that is at least 1.2 in (3 cm) long and free from any branches. A suitable segment is typically half-way up between the clavicle and the mastoid process and below both the inferior and superior cervical cardiac branches.

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.

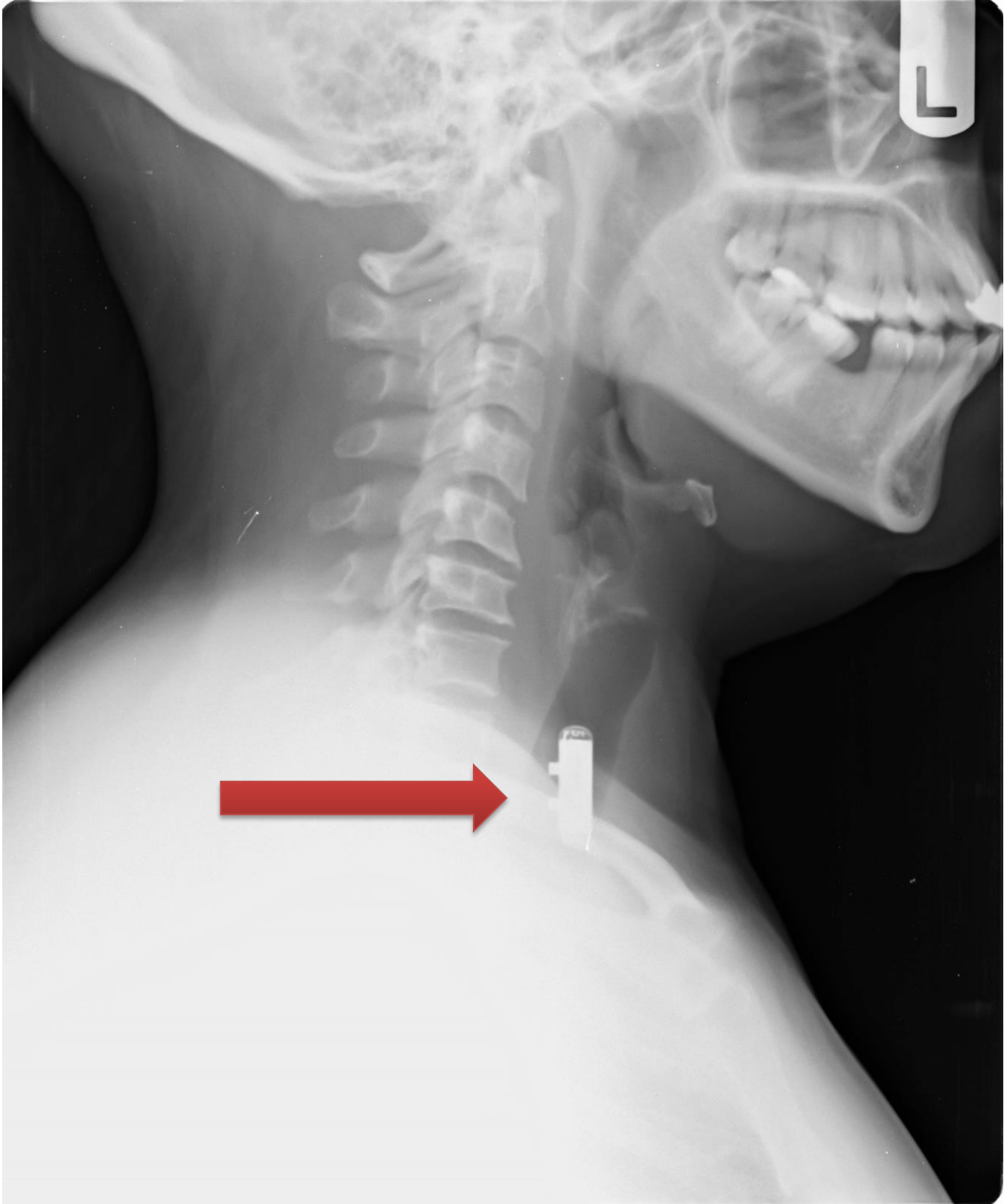


*Figure 2 - Relationship Between Implant Implantation Location and Vagus Nerve Branches*

## 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.