

Important Medical Device Information



November 2019

Dear Doctor,

Boston Scientific would like to inform you of important medical device information related to five (5) INOGEN™ implantable cardioverter defibrillators (ICDs) and cardiac resynchronization therapy defibrillators (CRT-Ds). You are receiving this letter because our records indicate that you are the physician who manages the care of a patient with an affected device.

Following a complete investigation, Boston Scientific has determined that a total of five (5) INOGEN ICD and CRT-D devices that were manufactured and subsequently implanted, included an additional laser marking that was not intended for the device. However, these devices are correctly marked with all required information, which includes model number, serial number and connection information.

Model	Serial
D140	243452
D141	202641
D142	552731
G146	381167
G148	201821

Each device with the additional laser marking/wording was manufactured and sterilized per relevant processes and met all required mechanical, electrical, sterility, and biocompatibility specifications. With the exception of the additional laser marking, these devices are no different than other commercial devices. Most importantly, there are no additional foreseeable adverse health consequences to patients implanted with one of these devices as a result of this observation. Boston Scientific has confirmed that there are no other similarly-affected devices available for implant.

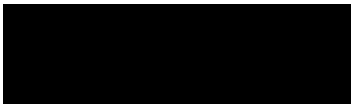
Recommendations

For affected devices that have been implanted, Boston Scientific recommends no change to the patient's follow-up care, as these devices are performing as anticipated.

Additional Information

Boston Scientific is committed to transparent communication with our physician customers to ensure you have timely, relevant information for managing your patients. If you have additional questions regarding this information, please contact your Boston Scientific sales representative.

Sincerely,



Renold Russie
Vice President, Quality Assurance