

Important Medical Device Information

Patient Management of the Axium® Neurostimulator System (MN2045-50, MN20450-90)

Xx May 2014

Dear Healthcare Professional:

Spinal Modulation is committed to providing our customers with the highest quality of products and support. We are distributing this notice to clarify the steps necessary to ensure safe lead removal after permanent implantation. These methods are described in the “Physician Implant Manual” associated with the products below.

MN20450-50	KIT IMPLANT LEAD 50CM
MN20450-90	KIT IMPLANT LEAD 90CM

Over 2000 DRG leads have been implanted in patients worldwide. At this time, there have been 10 reports of lead breakage during attempted lead removal, resulting in lead fragments. To date, there has not been any reported complications or long-term sequelae surrounding these events. As a result, we are providing a clarification to the Physician Implant Manual instructions. During lead removal of a permanently implanted lead, the Spinal Modulation implant instructions and warnings must be followed to help prevent lead breakage. Medical advisors to the company and our experience suggest the following:

- When removing the lead, place the patient in a flexed position. Put the patient in the prone position by bolstering with pillows or bend the table into an inverted “V”. This will put the patient in flexion and may help release tension on the lead.
- When removing the lead, use live fluoroscopy to monitor the position of the lead during extraction.
- Note the following precaution and warning from the Physician Implant Manual:
 - PRECAUTION: If resistance is met while removing leads from the epidural space, do not use excessive force to extract. Always perform removal with the patient conscious and able to give feedback.
 - WARNING: Do not remove a lead quickly, as this may result in lead breakage and unintentional lead fragments being left in the patient.
- If the lead cannot be easily removed, seek surgical advice regarding lead removal.

Please pass this notice to others in your risk management organizations that need to be made aware of this information. Please also note that the relevant National Competent Authorities have been advised of this notice.

The Company continues to monitor the occurrence of this issue. If you have any questions or require additional information or clarification, please contact myself through the information provided below.

Sincerely,

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