Nevro Corp. • 1800 Bridge Parkway, Redwood City, CA 94065 USA • 650-251-0005

Urgent Field Safety Notice
M8 and S8 Adaptors

April 30th, 2021

Dear Nevro Physician,

Background:

Nevro has recently become aware that a relatively small number of patients who have been implanted with a Nevro Senza SCS System and received an S8 Lead Adaptor SADP2008-xx(B) or M8 Lead Adaptor MADP2008-xx(B) received implant cards (patient ID cards) at the time of their implant that incorrectly indicate the system is "MR Conditional" when in fact they should be identified as "MR Unsafe". The M8 and S8 Lead Adapters of the implanted Senza system are not MR Conditional.

These Lead Adapters are correctly listed as MR Unsafe in the MRI Manual (10095) that Patients receive at the time of their implant and that MRI Technicians are required to adhere to while preparing for an MRI procedure.

This action is being taken by Nevro proactively as there have been no reports of serious harm to patients because of the incorrect MRI compatibility information stated on the implant card.

Our records indicate you are implanting physician involved in the care of, one or more patients implanted with one of these devices (see enclosed Patient List).

Next steps

Nevro recognizes that patient safety is important and having accurate information is essential. Nevro is providing the below guidelines that must be followed to address this issue:

Patient follow up and Actions:

1. Enclosed patient list identifies the impacted patients by this safety notice.
2. We will soon mail you a "MR Unsafe" Implant card to be provided to the impacted patient(s). Your Nevro representative will work with you to retrieve their current implant card and replace with the new implant card and explanatory information.
3. Please communicate to the patient in their native language, as appropriate. Our goal in taking this action is to correct this situation as quickly as possible.
4. Please contact Nevro or your Nevro representative immediately if you are no longer the treating physician.
5. Please complete the attached Customer Notification by emailing a completed, signed copy of this Acknowledgement Form to fieldsafetynotice@nevro.com by 31 May 2021.

Inventory follow up and Actions:

1. Review your inventory and immediately quarantine products listed on the safety notice.
2. Contact your Nevro representative immediately if you have inventory of product listed on this safety notice. Your Nevro representative will work with you to provide the new implant card. Do not use the product until the new implant card is made available.
3. Do not use the product until the new implant card is made available.
4. Your Nevro representative can assist with identifying the impacted products by this safety notice.
5. Please complete the attached Customer Notification by emailing a completed, signed copy of this Acknowledgement Form to fieldsafetynotice@nevro.com by 31 May 2021.

Should you have any questions about this notice, please contact Nevro Technical Product Support at 1-888-895-8105 (U.S.). Please work with your Nevro Representative if you need further information or assistance.

We sincerely apologize for any difficulties or inconvenience that this may cause. Nevro is committed to keeping customers informed about important product information and ensuring that we deliver the highest quality user experience.

We thank you for assisting us with this process.

Sincerely,

Donald A. Middlebrook
Vice President, Clinical, Regulatory and Quality
Nevro Corp.

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Field Safety Notice (FSN) information	
FSN Reference number	FAR-000002
FSN Date	April 30, 2021
Product/ Device name	M8 Lead Adaptor (MADP2008-xx(B)) S8 Lead Adaptors (SADP2008-xx(B))

Customer Information:

Name	
Healthcare facility	
Address	
Telephone no.	
Email address.	

Customer action undertaken on behalf of Healthcare Organisation:

☐	I confirm receipt of the Field Safety Notice and that I read and understood its content.	*Customer to complete or enter N/A*
☐	I performed all actions requested by the FSN.	*Customer to complete or enter N/A*
☐	The information and required actions have been brought to the attention of all relevant users and executed.	*Customer to complete or enter N/A*

Number of Impacted patients:	*Customer to complete or enter N/A*	Number of impacted implant card corrected/destroyed (as applicable to this safety notice):	*Customer to complete or enter N/A*
If number of implant card corrected/destroyedis different to the number issued, please account for the difference: *Customer to complete or enter N/A*			

Number of products impacted and quarantined:	*Customer to complete or enter N/A*	Number of products corrected (as applicable to this safety notice):	*Customer to complete or enter N/A*
If number of products corrected is different to the number issued, please account for the difference with explanation: *Customer to complete or enter N/A*			

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Customer Signature and Date

Return acknowledgement to sender

Email	fieldsafetyaction@nevro.com
Customer Helpline	1-888-895-8105 (U.S.)
Postal Address (If mailing in)	1800 Bridge Parkway, Redwood City, CA 94065 USA
Deadline for returning the customer reply form*	May 31, 2021

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.
Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.