**URGENT FIELD SAFETY NOTICE**
**Medical Device Recall**

Ref.: FCA-2020-02

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| **Date:** | 22nd June 2020 |
| **Product Name and Number:** | 4230-00 Neurosign V4 Intraoperative Nerve Monitor:<br>4444-00 Neurosign V4 Pre-Amplifier (affected components)<br>4440-00 Neurosign V4 Stimulator Pod (affected components) |
| **FCA Reference Number:** | FCA-2020-02 |
| **Type of Action:** | Preventive Action |
| **At the attention of:** | Distributor / Owner / User |

**Details on affected device:**
The products affected belong to the Neurosign V4 Intraoperative Nerve monitor family of devices. The Neurosign V4 Intraoperative Nerve Monitor serial numbers affected are S/N: 0001 – 0049, specifically the Pre-amplifier and Stimulator Pod cables for these systems.


*Figure 1: The Neurosign V4 Pre-amplifier and Stimulator Pod Cable*

**Description of the problem:**
Magstim are issuing a voluntary corrective action following reports that manipulation of the cable which connects the pre-amplifier to the nerve monitor, and the cable which connects the pre-amplifier to the stimulator pod, may cause damage to the internal construction of the cables. This may result in:

- Failure of the stimulator pod to be recognised by the system, in which case the user will be given a visual and audible warning;
- Or a partial failure of the pre-amplifier cable affecting the audible EMG audio; however, this does not affect the EMG waveform visible on the screen.

*Continued Overleaf*

**What you need to do:**

- Identify all affected products at your facility
- Raise awareness to all users of the device(s) within your organisation
- If you have forwarded any affected product to other organisations, please forward them a copy of this notice, and advise us accordingly on the acknowledgement form
- Complete and return the attached acknowledgement form, so we can contact you to arrange replacement of the cable.

- Users should continue to routinely inspect all devices for damage or signs of wear before use, as described in the operating manual.
- If damage is found or your device is exhibiting the failure modes described, contact the service department to arrange a repair or replacement.
- If damage is not found and the device is behaving as expected, the device can continue to be used whilst a replacement is arranged. Care should be taken to properly store the Pre-Amplifier and Stimulator Pod using the cable storage aids provided.

**What happens next?**

The affected cables have been re-designed to improve the longevity and cable performance. Using the details provided on the acknowledgement form, we will arrange for a replacement of affected cables at your facility to the updated design. It is important to return the acknowledgement form as soon as possible so that we can arrange for your cables to be replaced. In the meantime, you can continue to use your device(s).

Maintaining a high level of safety and quality is our highest priority. Please be assured that the relevant Regulatory Agencies have been informed of this issue. We appreciate your help in completing this action and apologize for any inconvenience this issue may have caused.

**Any questions?**

If you have any questions or concerns, please contact regulatory@magstim.com, your local representative, or call us on +44 (0) 1994 240798.

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**Please complete this form and return to:** regulatory@magstim.com

Due to current remote working conditions, please return all acknowledgement forms via email. If you do not have a scanner, a clear picture of the form taken with a camera or phone will suffice.

If you have any issues in completing or returning this form, please contact us ASAP to discuss.

**Once you have returned this form, we will arrange for replacement Pre-Amplifier and Stimulator Pod cable(s) to be sent to your facility or technical personnel. This will be accompanied by instructions on how to install the new parts. This is to limit transmission during the current Covid-19 pandemic.**

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## ACKNOWLEDGEMENT

I have read this Field Safety Notice, understand its content, and have followed the instructions as described.

**Please complete all sections**

Name: .....

Position: .....

Hospital/Institute: .....

Address: .....

Suite/Room no.: .....

City: .....

Post/Zip code: .....

State: .....

Country: .....

Telephone Number: .....

Email address: .....

Date: .....

Signature: .....

| **Device Serial Numbers*** | | | | |
|---|---|---|---|---|
| Nerve Monitor 4230-00 | Stimulator Pod 4440-00 | Pre-Amplifier 4444-00 | Mute Sensor 4225-00 | User Interface 4311-00 |
| SN | SN | SN | SN | SN |

**If required, please append a list or additional sheets.*