Company Reg.: 2003/001618/07

Unit 102, Tannery Industrial Park, 309 Derdepoort Road, Silverton, Pretoria, South Africa, 0184
Tel +27 12 743 5959| Fax:+27 86 547 0026 | e-mail: support@xavant.com | www.xavant.com

Urgent Field Safety Notice

PRODUCT AFFECTED	**STIMPOD NMS410 / NMS450 Nerve Stimulator**
MANUFACTURER	Xavant Technology (Pty) Ltd
PRODUCT CODE	XT-41000, XT-41000-NA, XT-41001, XT-41001-NA, XT-45011, XT-45011-NA, XT-45001, XT-45001-NA
DATE OF NOTICE	7 July 2016
TYPE OF ACTION	Advisory notice (Update in the instruction for use)
FSN REFERENCE:	**FSN450-15001**

Attention: Distributors, Product Specialists, Anesthesiologists, Ward Managers, Sisters

Details on affected devices:

STIMPOD NMS410 / NMS450 Neuromuscular Stimulator manufactured by Xavant Technology. The unit is supplied in a black carry case with the Xavant Technology logo. It contains a unit, relevant cables and an instruction for use (IFU).
The product code is XT-41000, XT-41000-NA, XT-41001, XT-41001-NA, XT-45011, XT-45011-NA, XT-45001, XT-45001-NA, indicated on the label affixed to the front left of the lid of the carry case.

Description of the problem:

The potential risks that may result from the medical device have not changed. There are no changes or modification to the medical device; the FSN concerns an update of the instruction for use (IFU), which includes changes to the sections warnings, and introduces instruction to the user to aid in the safe and precise use of the medical device.

1. Inspect all parts for any damage or manipulation. Never use any damaged or manipulated part!
2. If an electrically conductive surface of the Stimpod device or its cables is exposed, such electrically conductive surface may shock a person handling it. Do not use such a device or accessory, please contact the manufacturer for repair.
3. The refractory period delay is set at a default value to prevent the user from repeating stimulation while the nerve synapse is recovering from effects of the previous stimulation as per example: a refractory period of less than 12 seconds in TOF mode is not advisable as measurements might not represent the effect of blocking agents on the neuromuscular junction.

Advice on action to be taken by the user:

Read this FSN and the updated IFU. Implement the IFU additional actions when the medical device is, or would be in use. Sign and return the customer reply form to the contact reference person listed below.

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The IFU is available in English and French on the Xavant webpage, the links are indicated below.

http://www.xavant.com/downloads/XM400-21A04-06.pdf

http://www.xavant.com/downloads/XM400-21B04-06.pdf

Transmission of this Field Safety Notice:

This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

Please transfer this notice to other organisations on which this action has an impact.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

[redacted]

The undersigned confirms that this notice has been notified to the appropriate regulatory agency.

[redacted]

7 July 2016
Date

07 July 2016
Date

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FIELD SAFETY NOTICE – CUSTOMER REPLY FORM

Immediate action required – PLEASE complete form and return to Xavant Technology as soon as possible to the listed contact person.

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PRODUCT CODE	XT-41000, XT-41000-NA, XT-41001, XT-41001-NA, XT-45011, XT-45011-NA, XT-45001, XT-45001-NA
DATE OF NOTICE	7 July 2016
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FSN REFERENCE:	**FSN450-15001**

This receipt provides Xavant Technology (Pty) Ltd and subsequently the MHRA, with the means to monitor the progress of Field Safety Notices.

It is important that this acknowledgement form is returned for our records and to enable us to meet our obligations to notify the MHRA of non-responders

By signing this receipt of notice, it is acknowledged that the receiver has received, read, understood and carried out the respective actions as recommended in the FSN.

Acknowledgement of Receipt

Name:		**Date:**	
Signature		**Telephone:**	
Designation:		**Email:**	
Company:		**Address:**	