

Urgent Field Safety Notice

NIM Eclipse® System

Single Use Direct Nerve Probes

Information for Use Modification

December 2018

Medtronic reference: FA796 phase II

Dear Customer/Distributor,

In follow-up to our Field Safety Notice FA796 from December 2017 Medtronic is informing you of availability of class III stimulation probes used for speech mapping and Motor Modalities offered by Spes Medica S.R.L. The NIM Eclipse® system and Direct Nerve probes listed in Appendix A are affected by this Field Safety Notice.

Issue Description:

Single Use Direct Nerve Probes (BNP2001 and BNP2002) are classified as a MDD Class IIa device, intended to be used with the monitoring system NIM Eclipse to locate, identify and monitor cranial motor nerves, peripheral nerves and spinal nerve roots during surgery.

In the NIM Eclipse E4 SD IFU, speech and motor mapping modalities are included. These modalities require stimulation in direct contact with the central nervous system (brain), it would require the use of MDD Class III stimulation probes, which are currently not offered by Medtronic. However, class III stimulation probes may be acquired from Spes Medica S.R.L. to be used with the NIM Eclipse® system.

Action:

Therefore, we are providing the following guidance:

If your organization is using the NIM Eclipse® system for speech mapping and Motor Modalities, Class III stimulation probes may be acquired from Spes Medica S.R.L. For additional information please refer to the enclosed NIM Eclipse insert card M986136A001DOC1.

Read this Field Safety Notice carefully and share the communication with the other users and concerned parties in your facility.

The Competent Authority of your country has been notified of this action.

Medtronic regrets any inconvenience this matter may cause; and respectfully ask for your cooperation in helping us with the communication of this issue. Please do not hesitate to contact your Medtronic representative at <XXXX> if you have any questions regarding the content of this letter.

Sincerely,

Country/BU manager



Appendix A: Model numbers of NIM-ECLIPSE® System and NIM-ECLIPSE® System Disposable Stimulator Probes which are not approved for Speech Mapping and Motor Mapping Modalities in the European Economic Area, Switzerland and Turkey.

Product	Model Number	Description
NIM-ECLIPSE® System	NWCPUE4	COMPUTER NWCPUE4 DESKTOP E4 EN ROHS
	NCCPUE4	COMPUTER NCCPUE4 NOTEBOOK E4 EN ROHS
	NCCPU	COMPUTER NCCPU NOTEBOOK
	NWCPU	COMPUTER NWCPU NOTEBOOK
NIM-ECLIPSE® System Single-use Stimulator Probes	BNP2001	PROBE BNP2001 10PK 100MM BIPOLAR ROHS
	BNP2002	PROBE BNP2002 100MM BIPOLAR ROHS
	CNP2001	PROBE CNP2001 100MM CONCENTRIC ROHS
	CNP2002	PROBE 945CNP2002 100MM CONCENTRIC ROHS
	FTP1001	PROBE FTP1001 100MM FLUSH TIP ROHS
	MNP1001	PROBE MNP1001 100MM DIR NERVE ROHS
	PSP1000	PROBE PSP1000 100MM PEDI SCREW ROHS
	PSP1001	PROBE PSP1000 175MM PEDI SCREW ROHS
	PSP1002	PROBE PSP1002 230MM BALL TIP ROHS
	FTP2001	PROBE FTP2001 100MM FLUSH TIP ROHS
	MNP2001	PROBE MNP2001 100MM DIRECT NERVE ROHS
	PSP2000	PROBE PSP2000 100MM BALL TIP ROHS
	PSP2001	PROBE PSP2001 175MM BALL TIP ROHS
	PSP2002	PROBE PSP2002 230MM BENT BALL TIP ROHS