	URGENT FIELD SAFETY NOTICE	Reference: FSCA-23001
		Date: 06 Jun 2023

Product: **directSTIM DBS System Patient Programmer Charger**

Product Number: **PN-12300-DE**

Aleva Reference: FSCA-23001

Aleva SRN: CH-MF-000015804

Date: 06 Jun 2023

Dear Health Care Professional,

The purpose of this letter is to inform you of a potential situation where the Patient Programmer Charger (PPC) internal battery could not be charged due to a failure of the Micro-USB connector of the PPC.

To address that potential situation, the Micro-USB connector of the PPC was reinforced. PPCs featuring this improvement will be provided to existing patients as a replacement.

Issue Overview:

Connecting the Power Cord cable to the Micro-USB port of the PPC to charge its internal battery may result, due to mechanical stress, in the micro-USB connector breaking inside the PPC. In such event, the user will not be able to charge the PPC and, when the PPC battery is empty, the user will not be able to recharge, program or control the implanted neurostimulator (IPG). When the battery of the IPG cannot be recharged, the battery will eventually reach a level at which stimulation will stop. No stimulation delivered would result in the return of symptoms, potentially requiring medical intervention until stimulation is restored. A broken Micro-USB connector requires the replacement of the PPC.

From June 2021 to May 2023, Aleva has received 3 complaints associated with a broken Micro-USB connector, of which there have been no reports of patient injury attributed to this issue. In all cases the patient was provided a replacement PPC by an Aleva field representative.

A PPC exchange program is launched:

- PPCs made available on the market with serial numbers lower than SN# 200079 will be exchanged. The list of devices is in appendix 1 of this letter
- The exchange of a PPC is achieved by pairing the new PPC to the patient's neurostimulator. This does not require to modify or reload the stimulation programs that are in the patient's neurostimulator.
- An Aleva field representative will contact you to determine the best way to perform this exchange, e.g. at the hospital or directly with the patient.
- The exchange program is expected to be completed by end August 2023

Additional Information:


- Aleva has notified the Competent Authority of your country of this action.
- This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.
- Please maintain awareness on this notice and resulting action to ensure effectiveness of the PPC exchange program.

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We regret any inconvenience that this issue may have caused. We are committed to patient safety and appreciate your prompt attention to this matter. If you have questions or would like assistance, please contact your Aleva Representative.

Contact person in Germany:
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Yours sincerely,


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Appendix 1:

List of PPC serial numbers below SN#200079, either used by patients or distributed in clinical sites.

SN	UDI
200003	01076401837600511119121221200003
200004	01076401837600511119121221200004
200006	01076401837600511119121221200006
200011	01076401837600511119121221200011
200012	01076401837600511119121221200012
200018	01076401837600511119121221200018
200022	01076401837600511119121221200022
200026	01076401837600511119121221200026
200028	01076401837600511119121221200028
200030	01076401837600511119121221200030
200031	01076401837600511119121221200031
200032	01076401837600511119121221200032
200038	01076401837600511119121221200038
200039	01076401837600511119121221200039
200040	01076401837600511119121221200040
200043	01076401837600511119121221200043
200045	01076401837600511119121221200045
200046	01076401837600511119121221200046
200050	01076401837600511119121221200050

SN	UDI
200002	01076401837600511119121221200002
200005	01076401837600511119121221200005
200010	01076401837600511119121221200010
200014	01076401837600511119121221200014
200017	01076401837600511119121221200017
200020	01076401837600511119121221200020
200021	01076401837600511119121221200021
200029	01076401837600511119121221200029
200034	01076401837600511119121221200034
200036	01076401837600511119121221200036
200048	01076401837600511119121221200048
200074	01076401837600511119121221200074