BIOTRONIK SE & Co. KG · Postfach 470255 · 12311 Berlin

Urgent Field Safety Notice

Ilivia, Inlexa, Intica, Intica Neo ICD and CRT-D Devices

Berlin, 20. November 2020

Dear Physician or Healthcare Professional,

BIOTRONIK has identified a rare but potentially serious issue with the battery in 24 devices. The affected models are Ilivia, Inlexa, Intica and Intica Neo ICD and CRT-D. If you are receiving this letter it is because we believe your patient or patients may be impacted.

As of today, no device failure and no patient injury has been observed; however, this issue could potentially lead to rapid battery depletion at any time over the service time of an affected device. The possible clinical consequence could be sudden inability of the ICD or CRT-D device to deliver therapies, without triggering an alert.

A defect in the battery's inner assembly was identified in a small number of the total manufactured devices. The underlying cause has been identified and the issue is limited to 24 devices recently distributed.

Attached to this letter, please find a list of the serial numbers of affected devices that were distributed in your country. Please check this against devices that you have in stock or that have been implanted.

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Patient management recommendations

BIOTRONIK takes this observation very seriously. Following a consultation with our medical advisors, BIOTRONIK recommends the following:

- **Do not implant affected devices**. Local BIOTRONIK representatives will replace affected devices in your hospital inventory.
- For those devices that are implanted, your medical judgement in the case of each individual patient is crucial. Based on our clinical assessment, the risk of a device malfunction outweighs the risk of an elective device replacement. **Therefore, we recommend replacing devices that have already been implanted.**

Additional information

- If you have any questions or concerns, please contact your local BIOTRONIK representative or the Technical Service (technical.services@biotronik.de or +49 (0) 30 68905 2200).
- Please find a list of affected devices attached to this notification.
- Please ensure that all users of the above products and other persons in your organization who need to be informed are aware of this urgent safety information
- Please be informed that your local health authority has been informed about this field safety corrective action.

Patient safety remains our highest priority at BIOTRONIK. Please accept our sincere apologies for any additional strain this puts on you or your patients.

Yours sincerely,

Stephan Schwerzel
Senior Director Quality Assurance
Medical Device Safety Officer

Roman Borkowski
Senior Vice President Quality Management & Regulatory Affairs CRM