Urgent Field Safety Notice

Risk of Abnormally Short Device Lifetime in patients with a small subset of MICROPORT CRM pacemakers

Annex n°1 - List of affected devices distributed in Switzerland

Item Code	Commercial Name	Serial Number	Center
TPM015C	ENO SR	206CU70B	[redacted]
TPM016C	TEO DR	206CS3B1	
TPM016C	TEO DR	206CS56D	
TPM016C	TEO DR	206CS6D4	
TPM016C	TEO DR	207CS120	
TPM016C	TEO DR	209CS0B2	

February 27th , 2023

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FSCA identifier: CRM-SAL-2023-001

Affected devices: Subset of MicroPort CRM pacemakers ENO SR / ENO DR / TEO SR / TEO DR / OTO SR / OTO DR / KORA 250 SR / KORA 250 DR pacemakers.

FSN Type: New

Attention: Physicians, Healthcare professionals, Healthcare Centers

Dear Doctor,

MicroPort CRM is providing information related to **179** pacemakers potentially impacted by an anomaly during the manufacturing process.

As of February 23rd, 2023, MicroPort CRM has received six (6) confirmed complaints associated to abnormal battery impedance increase, out of approximately 305959 devices MicroPort CRM ENO SR / ENO DR / TEO SR / TEO DR / OTO SR / OTO DR / KORA 250 SR / KORA 250 DR pacemakers distributed worldwide.
The observed issue is an abnormal increase of the battery impedance during the first months following the pacemaker implantation that may indicate premature device depletion.

When can the issue occur?
If the issue occurs, it can be observed in the first months after pacemaker implantation.

How does this affect patients?
No bodily injury or death has been reported as a result of the confirmed malfunction. Nevertheless, the abnormal battery impedance increase could induce a premature replacement of the device.

Root cause investigation:
Initial investigations revealed that all complaints belong to one manufacturing batch that has undergone a common step (thermal cycling). This batch showed anomalies after in-depth process data review. No other anomalies have been identified on others manufacturing batches. Extensive analysis is currently ongoing.
In the meantime, the patient management recommendations below should be applied.

Patient management recommendations:
MicroPort CRM provides the following recommendations:

- For devices in stock: Do not implant any potentially impacted devices. Local MicroPort CRM representatives will replace the impacted devices in hospital inventory.

- **For patients implanted with potentially impacted pacemakers:**
1. For patients for whom the 4-6 month follow-up was already performed and no abnormality was observed (battery impedance below 0.5 kΩ), we advise continuing with the standard patient follow-up schedule.

2. For patients for whom the 4-6 month follow-up has not yet been performed, a follow-up within this range is recommended. According to the battery impedance measurement, a next follow-up or a device replacement should be considered depending on the patient's health conditions as follows:

- If the battery impedance is above or equivalent to 0.5 kΩ and the battery curve does not reach its inflection point, we advise performing a new in-clinic follow-up within 2-3 months. This 2-3 month follow-up should be repeated as long as the battery curve does not reach its inflection point.
- If the battery impedance is above or equivalent to 0.5 kΩ and/or the battery curve has already reached its inflection point, we recommend a pacemaker replacement as soon as possible.

3. For patients where the pacemaker is implanted for more than 6 months and no follow-up has already been performed, a prompt in-clinic follow-up is recommended. According to the device status, the recommendations noticed in the previous section (section 2) should be applied.

Transmission of this Field Safety Notice:

Please complete and return the Customer Reply Form as soon as possible to acknowledge that you have read and understood this Field Safety Notice. Returning the Customer Reply Form will also prevent repeated communication of this notice.

Please ensure that all personnel in your organization, involved in the management of patients implanted with potentially impacted pacemakers are promptly made aware of the information and guidelines outlined in this letter.

MicroPort CRM has communicated this information to the relevant Competent Authorities.

We regret any inconvenience caused to your patients and your organization. If you need further information, please contact your local CRM representative.

As always, MicroPort CRM is strongly committed to the safety of all patients.

Sincerely,

MicroPort CRM S.r.l.
Andrea VINCON
VP, Quality Assurance