

March 23, 2026

URGENT: MEDICAL DEVICE FIELD ACTION M ZN-AIR BATTERY PAK (CI-5501)
Non-Tamperproof Battery Door

Dear Valued Customer,

The purpose of this letter is to advise you that Advanced Bionics is voluntarily initiating a field action on the non-tamperproof battery door from the packaged configuration for all M Zn-Air Battery Pak (CI-5501). The M Zn-Air Battery Pak includes a battery cartridge, a non-tamperproof battery door, and a tamperproof battery door.



As part of our ongoing commitment to product safety and regulatory compliance, we have identified that the non-tamperproof battery door does not require the use of a tool to replace the button batteries and therefore could allow unintended access to the button cell batteries within the battery compartment.

Button cell batteries and other small parts may be swallowed, breathed into the airway, or inserted into the nose or ears. These events can result in:

- **Choking or blocked airway.**
- **Serious internal injury** if breathed into the airway or ingested.
- **Burns or other injury** if inserted into the nose or ears.

Keep batteries and small parts away from children and individuals at risk of accidental ingestion or insertion.
If ingestion or insertion is suspected, seek immediate medical attention.

The battery cartridge and tamperproof battery door included in the packaged configuration for the M Zn-Air Battery Pak meet current safety and compliance requirements and may continue to be used normally.

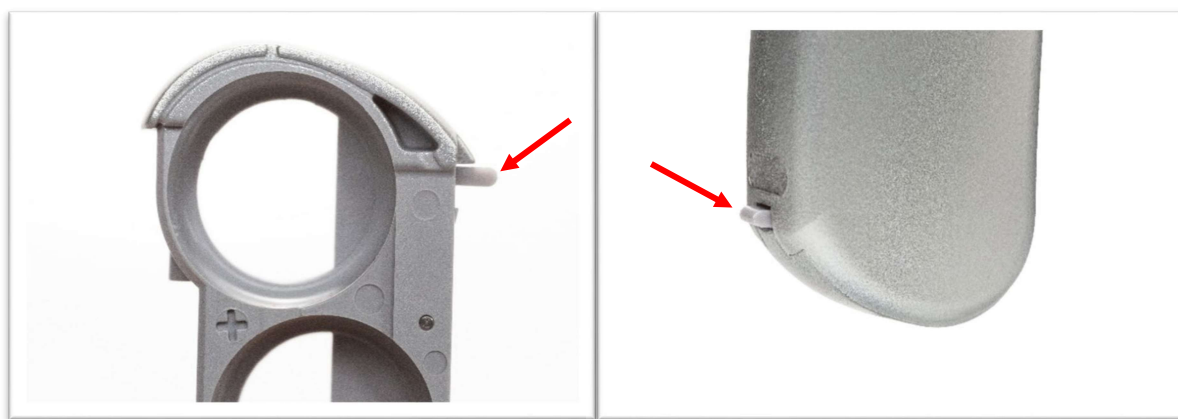
Required Actions for Users

Please take the following actions immediately:

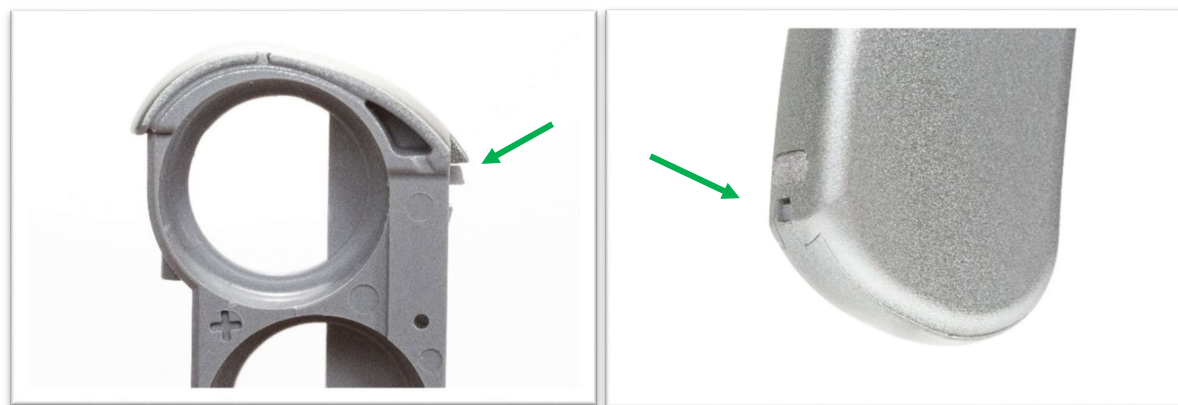
1. Identify the Non-Tamperproof Battery Door

Two battery doors were included with your product. They are similar in appearance, but the non-tamperproof door has a locking tab that extends slightly farther.

Non-tamperproof battery door



Tamperproof battery door



You can confirm which door is installed by performing the following check:

- When inserted into the battery cartridge, the non-tamperproof door can be removed without using a tool.
- The tamperproof battery door requires a tool for removal once installed.

If you must use a tool to remove the door, you have the tamperproof door installed.

2. Remove and Dispose of the Non-Tamperproof Battery Door

Once identified, ensure the non-tamperproof battery door is removed from the battery cartridge. **Do not reinstall or use this component.**

Dispose of the non-tamperproof battery door in accordance with your local waste or recycling guidelines. Local requirements may vary so please follow the disposal practices applicable in your region.

Ensure that the tamperproof battery door is installed for all future use of this product.

3. Complete the Acknowledgement & Disposal Form (required)

After disposing of the non-tamperproof battery door, please confirm that the component has been removed from service and disposed of appropriately by completing the Acknowledgement & Disposal Form provided.

Replacement Information

If you have lost or misplaced your tamperproof battery door, please contact your local Advanced Bionics representative. One (1) replacement will be provided at no cost.

Reporting Adverse Events

Healthcare professionals and patients are encouraged to report adverse events or quality problems experienced with the use of your product(s) to their local Advanced Bionics representative.

Additionally, healthcare professionals and patients may choose to report adverse events or quality problems to their local competent authority.

We Are Here to Support You

We apologize for any inconvenience this may have caused you and appreciate your prompt attention to this matter.

Sincerely,



Alistair Simpson
President/GVP Cochlear Implants
Advanced Bionics LLC



ACKNOWLEDGEMENT & DISPOSAL FORM
M Zn-Air Battery Pak (CI-5501)
RESPONSE REQUIRED

The purpose of this form is to confirm that you received and understood the field action notice and completed the necessary disposal steps.

A. Your Information

Name: _____

Phone or Email: _____

B. Receipt & Understanding

1. I have read the field action notice about the nontamperproof battery door.
☐ Yes ☐ No
2. I understand that the tamperproof battery door is safe, and the non-tamperproof door must not be used.
☐ Yes ☐ No (If No, please contact us.)

C. Identification & Action Taken

3. Were you able to locate all non-tamperproof battery door(s) within your possession?
☐ Yes – I have the product in my possession.
☐ No — I cannot locate the product. It is not available for disposal.
4. Disposal details (complete only if you answered “Yes”)
Quantity: _____
Date of disposal: ____ / ____ / ____

D. Optional Replacement

If you have lost or misplaced your tamperproof battery door and want a replacement, please contact your local Advanced Bionics representative. One (1) replacement will be provided at no cost.

E. Certification

I certify the information above is accurate to the best of my knowledge.

Signature: _____ Date: ____ / ____ / ____

Please email completed form to: [insert email address]