



Urgent Field Safety Notice
FOR A SUBSET OF ASSURITY™ AND ENDURITY™ PACEMAKERS
MODELS PM2152, PM2162, PM2172, PM2272

July 2022

Dear Physician or Healthcare Professional:

Abbott is committed to ensuring our customers receive the most current information available to provide optimal care for patients. To that end, our records indicate that your institution received Assurity™ and/or Endurity™ pacemaker(s) impacted by a manufacturing issue. While we continue to investigate this issue, the pacemaker(s) should not be implanted and will need to be returned.

As background, the issue is connected to a manufacturing laser roughening process, unique to a single assembly site production line, which may not have properly prepared the device's metal housing potentially leading to an abnormal bond adhesion. This in turn may allow moisture ingress into the pulse generator header. This specific manufacturing process is no longer in use. To date, one hundred twenty-eight (128) complaints have been received related to this issue (0.15% of the affected population) where the reported clinical impact has included loss of pacing, reduced battery longevity, devices reverting to back up-mode, and/or loss of telemetry / communication.

Further communication with additional details about this action, inclusive of patient management recommendations for any devices that may have been implanted, will be forthcoming in the near future.

Your Abbott representative will assist you in removing these pacemakers from your account and will facilitate replacing them. We are requesting your support on the removal and return of these pacemakers. Abbott will notify all applicable regulatory agencies about this matter.

In the meantime, if you or your physicians have any questions, please contact your local Abbott Representative.

We sincerely apologize for any difficulties or inconvenience that this may cause. Please know that Abbott is committed to providing the highest quality products and support, and we thank you for assisting us with this process.

Sincerely,

A handwritten signature in black ink that reads 'Robert Blunt'.

Robert Blunt
Divisional Vice President, Quality
Abbott Cardiac Rhythm Management