



August 2016

Dear Partners,

We have become aware that after-market manufacturers and retailers are selling unbranded Cardiac Science replacement batteries and electrode pads for use with Cardiac Science automated external defibrillators (“AEDs”). Use of these after-market products will void the Cardiac Science AED warranty. Use of these after-market products will also nullify the provisions of Cardiac Science’s industry-leading indemnification policy for owners and users of Cardiac Science AEDs.

Many of these after-market manufacturers and retailers claim that use of their unauthorized replacement parts does not allow Cardiac Science to void its warranties. This statement is simply wrong. The inability to void warranties for use of after-market replacement parts applies only to consumer products. Class III medical devices, like AEDs, are exempt from such laws. Thus, if customers use after-market replacement parts, their warranties will be voided.

This is equally true for remanufactured after-market products that modify original Cardiac Science products. Such remanufactured products can diminish the efficacy and safety of our AEDs, resulting in product malfunction or even patient death. This is because these products fail to maintain the high quality and exacting tolerances necessary for Cardiac Science AEDs to operate properly. Additionally, some of these products include instructions for use that are incompatible with proper operation of the AED.

Finally, the claim by some that their products are “equivalent to OEM” because they have received a 510(k) clearance is also misleading and inaccurate. A 510(k) clearance indicates only that the cleared device has the same intended use and technological characteristics of the legally marketed device. It does not mean the cleared device is equivalent to a Cardiac Science device. And we do not believe the after-market products are suitable.

We thank you in advance for your attention and cooperation in addressing these problems. We trust that, like Cardiac Science, you prioritize the well-being of our customers and patients. Should you have any questions or concerns about these or other matters, please feel free to contact me.

Sincerely,

A handwritten signature in blue ink that reads 'Bev Magrane'.

Bev Magrane  
Vice President, Quality Assurance & Regulatory Affairs

