



URGENT FIELD SAFETY NOTICE

GE Healthcare

3000 N. Grandview Blvd. - W440
Waukesha, WI 53188, USA

<Date of Letter Deployment>

GEHC Ref# 60952

To: Director of Clinical/Radiology
Risk Manager/Hospital Administrator
Director of Biomedical Engineering

RE: AIR Anterior Array coil outer seam separation

This document contains important information for your product. Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions. Please retain this document for your records.

Safety Issue

The outer seam of the coil, closest to the system cable, may separate and expose the porous material internal to the coil. This could result in user and/or patient contact with infectious agents since the internal porous material cannot be disinfected. No injury has been reported to GE as a result of this issue.

Safety Instructions

You can continue to use the coil by following the existing Operator Manual Safety Information. This safety information includes:

WARNING: Use only coils, cables and accessories that are in good condition. Before using the coil, visually check each coil component, cable and accessory to ensure that there is no external damage. Visually check the coil for tears or damage to make sure no internal conductors are exposed. If any coil component, cable or accessory is suspected of not being in good condition, discontinue use and contact a GE Service Engineer.

Figure 1 example of separated seam



**Affected
Product
Details**

AIR Anterior Array – Table 1 below lists the potentially impacted serial numbers.

Table 1. Potentially Impacted Serial Numbers

301	307	321	324	328	337	339
303	320	322	326	335	338	

**Product
Correction**

GE Healthcare will correct all affected products at no cost to you. A GE Healthcare representative will contact you to arrange for the correction.

**Contact
Information**

If you have any questions or concerns regarding this notification, please contact GE Healthcare Service or your local Service Representative.

Please be assured that maintaining a high level of safety and quality is our highest priority. If you have any questions, please contact us immediately per the contact information above.

Sincerely,

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