



URGENT FIELD SAFETY NOTICE

5 February 2016

NeoCoil Recall Ref # 0146
GE FMI reference: 60891

To: Hospital Administrators / Risk Managers
Radiology Department Managers
Radiologists

RE: 3.0T GEMflex Coil Potential Overheating

One of our customers, GE Healthcare, has recently become aware of a potential safety issue with the NeoCoil 3.0T GEMflex Coil manufactured by NeoCoil used with GE Healthcare 3.0T Scanners. **Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.**

Safety Issue Coil overheating can occur when the device is used. This may result in patient warming. There have been no injuries reported as a result of this issue.

Safety Instructions The issue is observed in various situations of coil setup and port connections. To prevent this issue: Follow the user instructions on using proper padding to avoid all direct contact of the patient with the cable. You may continue to use the device. Ensure that you use the following precautions as described in the 3.0T GEM Flex System Instructions for Use.

- Place the foam cover over the Interface.
- Do not allow the cable to touch the patient. Use a pad to keep the cable from touching the patient.
- Keep the length of the cable in the bore to a minimum.
- The system is indicated for adult use only.

Affected Product Details	3.0T GEM Flex Coil 16-L Array	5430008-2	NC040200
	3.0T GEM Flex Coil 16-M Array	5430008-3	NC033200
	3.0T GEM Flex Coil 16-S Array	5430008-4	NC034200
	3.0T GEM Flex Interface	5430008-5	NC032204

Product Correction NeoCoil will collaborate with GE Healthcare to correct all affected products at no cost to you. You will be contacted to arrange for the correction.

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



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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,

Michael Leigh
Quality & Regulatory Director
NeoCoil

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