URGENT MEDICAL DEVICE CORRECTION

GE Healthcare
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<Date of Letter Deployment>

GEHC Ref# 76177

To: Chairman Medical Board and relevant Head of Departments
Hospital Administrators /Risk Manager
Biomedical Engineering
Head of Primary Care Ultrasound Department

RE: Use of Tristel Trio Wipes System with GE TEE probes

Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.

The Tristel Trio Wipes System has been validated for efficacy and residual toxicity for TEE probes that do not have visible signs of wear or damage, and when used with shorter procedure times such as cardiac scans. Note that the Tristel Trio Wipe System is not approved or available in all countries or regions.

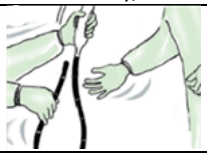
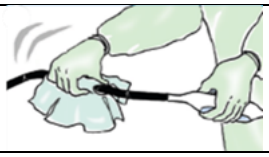
Safety Issue

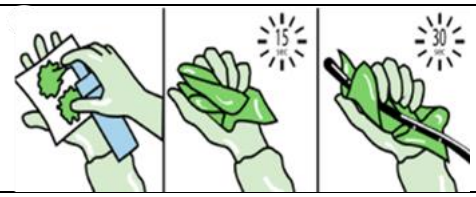
Further testing has identified a need for clarification of previously communicated disinfection guidance for GE TEE Probes.

Specifically, in-use experience and limited testing has revealed that the previously communicated disinfection methods may not always be effective when used in connection with procedures that have long TEE probe intubation times, such as cardiac surgeries, and/or with TEE probes with visible signs of wear or damage in areas to be disinfected, both of which may increase the bioburden on the probe. Under these conditions, GE recommends the use of a sterile sheath covering the TEE probe in addition to disinfection using the soak based disinfecting method or the Tristel Trio Wipes System as described below.

Safety Instructions

As part of each use of the probe when using the Tristel Trio Wipes System is appropriate (as per the guidance above), do the following:

	
STEP 1 of 4: Process the TEE probe immediately after extraction from the patient. Do not allow bodily fluids to dry on the probe.	**Step 2 of 4: Pre-Clean Wipe** Thoroughly wipe the surface until soil and organic matter have been visibly removed. Use at least two wipes. *Note: These instructions may differ from the manufacturer's guidance provided with the wipes, in that two pre-cleaning wipes must be used every time rather than one. This is to ensure an effective enzymatic cleaning, prior to disinfection.*

	
Step 3 of 4: Sporicidal Wipe Apply Tristel activator foam according to the instructions on the bottle and in the accompanying instruction leaflet from Tristel. Scrunch the wipe for 15 seconds. Ensure it is evenly covered with foam. Wipe the endoscope until it has been covered with Tristel. Wait for at least 30 seconds.	**Step 4 of 4: Rinse Wipe** Thoroughly wipe the surface that has been decontaminated.

Affected Product Details

The following TEE probe models: 6VT-D, 6Tc, 6Tc-RS, 6T, 6T-RS, 9T and 9T-RS.

Table 1: UDI marked probes shipped after July 2016

Probe type	Part number	GTIN
6VT-D	KN100120	00840682115650
6VT-D	KN100110	00840682115681
6Tc	KN100107	00840682115582
6Tc-RS	KN100106	00840682115735
9T	KN100121	00840682115636
9T-RS	KN100122	00840682115728

Table 2: Non-UDI marked probes shipped prior to July 2016

Probe type	Part number
6VT-D	KN100120
6VT-D	KN100110
6VT-D	KN100100
6Tc	KN100107
6Tc	KN100105
6Tc-RS	KN100104
6Tc-RS	KN100106
9T	KN100121
9T	KN100072
9T-RS	KN100122
9T-RS	KN100073
6T	KN100092
6T	KN100094
6T	KN100068
6T	KN100022
6T-RS	KN100093
6T-RS	KN100095
6T-RS	KN100062

The probe part numbers and types are printed on the rating plate of the probe connector.

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,

James W. Dennison
Vice President - Quality & Regulatory
GE Healthcare

Jeff Hersh, PhD MD
Chief Medical Officer – Medical Safety
GE Healthcare