Getinge is Announcing Recall Related to Sevoflurane Vaporizers for Flow Family Anesthesia Systems

Getinge is announcing a global medical device recall related to specific Sevoflurane vaporizers for Flow Family Anesthesia systems. To date, no patient or operator adverse events have been reported. Getinge has reported to relevant authorities according to applicable regulations and is now informing affected customer about the issue through a field safety notice/recall. The cost for the field action is not material.

The vaporizer is the unit containing anaesthetic agent and is available for the anaesthetic agents Sevoflurane, Desflurane and Isoflurane. This issue is only applicable for specific Vaporizers used for certain types of Sevoflurane, which is used as an inhalational anesthetic for induction and maintenance of general anesthesia.

Getinge has received eight complaints describing the presence of a yellow substance in the vaporizer. This issue has only been observed when using certain types of Sevoflurane. No patient or operator adverse events have been reported in any of these complaints.

Getinge will continue to investigate and will provide an update once the root cause and/or corrective actions are identified. Customers are requested to follow the instructions in the field safety notice/ field correction notice until further communication from Getinge.

This information is released in order to inform users of mentioned Getinge products, according to standard procedure recommended by regulatory authorities.

Source & Image Credit: Getinge

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