Press release

Gothenburg, Sweden, on December 18, 2019

Getinge is announcing a voluntary recall of Reinforced Introducer Sets sold as an accessory for the 7 Fr., 7.5 Fr. and 8 Fr. Maquet Intra Aortic Balloon

Getinge is announcing a voluntary global medical device recall of Reinforced Introducer Sets sold as a standalong accessory for the 7 Fr., 7.5 Fr. and 8 Fr. Maquet Intra Aortic Balloon due to a potential breach in sterile packaging. To date, there are no known adverse events associated with illness or injuries related to the mentioned products. Getinge has reported to relevant authorities according to applicable regulations and the cost for the recall is not material.

Reinforced Introducer sets included as part of the Intra Aortic Balloon kits are not impacted by this recall. The issue was identified by the company during internal testing.

All concerned customers have received communication from Getinge. Should customers have any unused or unexpired affected Reinforced Introducer Sets they are to remove the affected products from areas of use and return it for credit.

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

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About Getinge

With a firm belief that every person and community should have access to the best possible care, Getinge provides hospitals and life science institutions with products and solutions that aim to improve clinical results and optimize workflows. The offering includes products and solutions for intensive care, cardiovascular procedures, operating rooms, sterile reprocessing and life science. Getinge employs over 10,000 people worldwide and the products are sold in more than 135 countries.