

Press release

Gothenburg, Sweden, April 8, 2020

Getinge is announcing a voluntary medical device recall for specific lots of Hemashield Vascular Grafts

Getinge is announcing a voluntary global medical device recall for specific lots of branched or axillo-bifemoral Hemashield Vascular Grafts due to potential small holes at the seam lines of the Hemashield aortic arch branches. 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.

The affected products are the Axillo-Bifemoral Hemashield Gold Knitted Microvel Double Velour Vascular Graft and the branched Hemashield Platinum Woven Double Velour Vascular Graft. Five initial complaints have been reported. The complaints state that small holes have been detected near the seam line of the branches of Hemashield aortic arches. In all five cases, a medical or surgical intervention was needed but all five grafts were successfully implanted. The recall is only applicable for specifically identified HEMASHIELD grafts that have not been implanted. There is no concern about late complications occurring as the structural integrity of the graft is not impacted.

All concerned customers have received communication from Getinge and have been advised to return un-used products to Getinge.

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.