[Month DD, YYYY]

URGENT MEDICAL DEVICE – REMOVAL
FSCA 2242352-09/06/2023-004-R
Acrobat-i Vacuum Stabilizer System

Product Description	Product Code/ Part Number	UDI Code
Acrobat-i Vacuum Stabilizer System	OM-10000Z	00607567100008

Distributed Affected Lot Number:	**3000188485, 3000193165, 3000193670, 3000195673, 3000198652, 3000199944, 3000201253, 3000204442**
Manufacturing Dates for All:	**August 05, 2021 to November 11, 2021**
Distribution Dates for All:	**November 4, 2021 – January 10, 2023**

Dear Risk Manager,

Our records indicate that you have received the Acrobat-i Stabilizer System having one or more of the lot numbers that are affected by this recall.

Maquet/Getinge is initiating a voluntary Medical Device Removal for the Acrobat-i Vacuum Stabilizer System due to a risk of the Housing Mount Jaw of these devices breaking during normal use. This issue may result in injury to the epicardial tissue or vasculature, or a coronary artery or previously placed bypass graft, or could result in procedural delay and/or conversion. The affected devices, as specified above, will be removed from the field.

The company received complaints that the Mount Jaw may fracture when the Acrobat -i Vacuum Stabilizer System is being fastened to the AccessRail Platform, during surgical set-up for the Stabilizer system.

The potential risk if the issue is identified during the pre-surgery device assembly inspection step is procedural delay or conversion.

No adverse events have been reported in association with this issue.

The Acrobat -i Vacuum Stabilizer System is designed to provide surgical access to and exposure of coronary arteries for off-pump bypass surgery.

The AccessRail Platform (Standard Blades or Deep Blades) attaches onto a reusable MAQUET Activator Drive Mechanism. The AccessRail Platform, along with an Activator Drive Mechanism, is designed to create surgical access to, and direct visualization of, the thoracic cavity through a sternotomy incision. The AccessRail Platform accommodates the Acrobat-i Stabilizer. The Acrobat -i Stabilizer consists of the

FLEXLINK Arm (Arm) with Swivel, an articulating and malleable Stabilizer Foot at the distal end of the Arm, and a mounting system that attaches the Stabilizer to the AccessRail Platform, Activator Drive Mechanism and/or a sternal retractor. A locking system tightens the FLEXLINK Arm to its desired position. The Stabilizer Foot provides local immobilization of an anastomotic site.

Identification of the issue:

Maquet/Getinge has received fifteen (15) complaints between 24-June-2021 and 30-August-2023 reporting that the Mount Jaw fractured when attempting to fasten it to the AccessRail Platform.

Risk To Health:

The potential intraoperative risk is that the Mount Jaw could fracture while the Stabilizer Mount is being locked into place on the sternal retractor after positioning the Stabilizer Foot onto the heart at the area of the planned distal coronary artery anastomosis and vacuum suction has been applied. At this point, the Stabilizer Foot is directly in contact with the epicardial tissue of a beating heart at the location the surgeon is planning to create the distal anastomosis. A Stabilizer Mount Jaw fracture and detachment at this point has the risk of causing cardiac tissue injury, coronary artery injury, and potential bleeding of the epicardial on a beating heart.

No new product distributed after August 10, 2023 is expected to exhibit this issue.

Actions to be taken by the customer:

Please examine your inventory immediately to determine if you have any of the Acrobat-i Stabilizer System with the product codes/lot numbers listed in this notice.

If you have unused/unexpired affected product that you will be returning from your inventory, please contact your local Getinge Customer Service. Insert Local SSU Information here)
If you have affected product, you are entitled to a credit. You will receive credit upon your acknowledgement that you have affected product for return.
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Please complete and sign the attached MEDICAL DEVICE Removal - RESPONSE FORM (page 4) to acknowledge that you have received this notification, include any RMA number provided by Customer Service. Return the completed form to Maquet/ Getinge by e- mailing a scanned copy to [INSERT LOCAL SSU EMAIL HERE or by faxing the form to [INSERT LOCAL SSU FAX NUMBER HERE.

Please forward this information to all current and potential Acrobat-i Stabilizer System users within your hospital / facility.

If you are a distributor who has shipped any affected products to customers, please forward this document to their attention for appropriate action.

Actions to be taken by Getinge:

The root cause was identified to be a mold temperature control issue at Getinge's supplier. The supplier has implemented Corrective Actions which have corrected this issue in the molding process that produces the Mount Jaw components.

This voluntary removal only affects the products listed on page 1; no other products are affected by this voluntary recall.

We apologize for any inconvenience this recall may cause. If you have any questions, please contact your Maquet Cardiovascular, LLC /Getinge representative or office.

Sincerely,

Specialist, Regulatory Affairs and Field Action Compliance Maquet/Getinge

[Month DD, YYYY]

URGENT: Field Safety Notice MEDICAL DEVICE REMOVAL RESPONSE FORM

FSCA 2242352-09/06/2023-004-R

Acrobat-i Vacuum Stabilizer System

DISTRIBUTION DATES: November 4, 2021 – January 10, 2023

INDEX NUMBER - ACCOUNT#
FACILITY NAME
STREET ADDRESS

CITY, STATE, ZIP CODE

Please acknowledge that you have read and understand this Medical Device Recall Notice for the Maquet/Getinge Acrobat-i Vacuum Stabilizer System from page 1 affected by this recall. Please ensure that all users of the Maquet/Getinge Acrobat-i Vacuum Stabilizer System at this facility have been notified accordingly and complete the entire form where applicable whether or not you have product to return.

Facility Representative Information:	
Name	Title:
Department:	Phone:
Signature	Date:
Hospital Name-If different from above	
Address, City and State-if different from above	

I **DO NOT HAVE** ANY AFFECTED PRODUCT: ☐ I **HAVE AFFECTED** PRODUCT: ☐

If you have affected product lot(s) to return, please complete the table below:

Enter Lot and Part Number	**Quantity**	**RMA#**

Return the completed form by FAX to (Insert local Fax)

or by EMAIL To (Insert local EMAIL)