[Month DD, YYYY]

URGENT FIELD SAFETY NOTICE
URGENT MEDICAL DEVICE – Removal

Ultima Activator II Reusable Drive Mechanism

Product Code/REF Number:	**UA-5001**
UDI Code:	**00607567700901**
Distributed Affected Lot Numbers (device package only):	**25153700, 25157489, 25158616**
Distributed Affected Device Component Lot Number (etched on device components):	**200501**
Manufacturing Dates:	**September 18, 2020 to June 03, 2021**
Distribution Dates:	**Country Specific – SSUs to fill in**

Dear Hospital Contact,

Maquet Cardiovascular, LLC/Getinge is initiating a voluntary Medical Device Removal for the Ultima Activator II Reusable Drive Mechanism due to potential corrosion on the pins that may result in an unreasonable risk of harm to the patient.

The Ultima Activator II Drive Mechanism, Product Code/REF Number UA-5001, is a reusable device designed for use with the AccessRail Platforms (AccessRail Platforms are sold separately). The AccessRail Platforms along with the Ultima Activator II Drive Mechanism are designed to create surgical access to, and direct visualization of, the thoracic cavity through a sternotomy incision. This is accomplished by spreading the sternum following creation of the sternotomy incision.

Identification of the issue:
Maquet Cardiovascular, LLC /Getinge has received 9 complaints for the lot numbers listed above regarding corrosion / rust observed on the device. Investigation of the reported devices returned on complaint confirmed the observed issue. There have been no adverse events reported resulting in serious illness or injuries caused by this Ultima Activator II Reusable Drive Mechanism issue.

Risk to Health:
Potential harms may include allergic reaction, metal toxicity, and other delayed responses that in the high risk patient population could lead to very serious consequences.

Actions to be taken by the Customer:
Our records indicate that you have received the Ultima Activator II Reusable Drive Mechanism(s) from lots affected by this recall. Please note that Distributed Affected Lot Number (25153700, 25157489, 25158616) appears on the device package only. If the packaging has been discarded, the affected devices can be identified by Device Component Lot number (200501), which is etched onto all 3 device components as shown in Figure 1 below.

Please examine your inventory immediately to determine if you have any of the Ultima Activator II Reusable Drive Mechanism(s) with the product code/lot numbers listed in this notice.

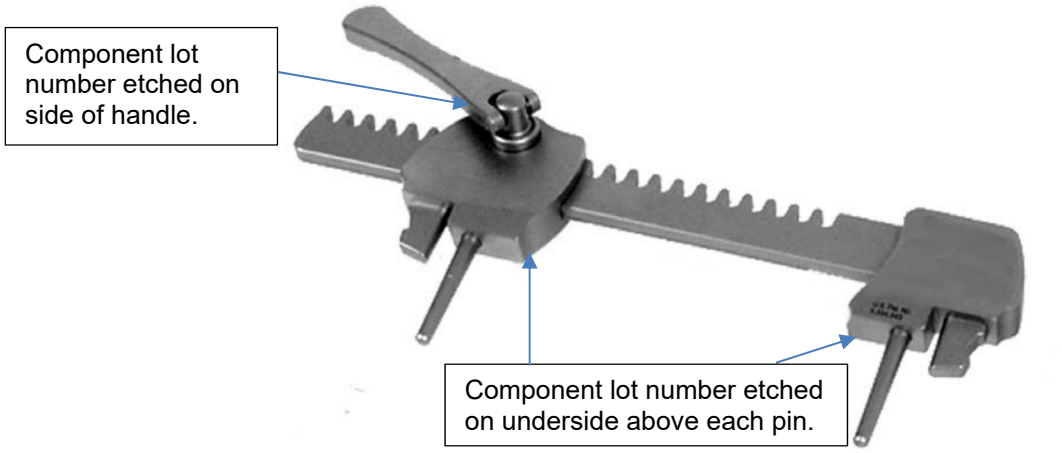

Figure 1: Ultima Activator II Reusable Drive Mechanism: location of component lot number on each of the three (3) device components.

- Should you have any affected product lots as listed in this notification, please stop using and remove the complete device (all 3 components) from areas of use. Distributed Affected Lot Number (25153700, 25157489, 25158616) can be found on the device package if available. Distributed Affected Device Component Lot Number (200501) can be found etched on the device itself (all 3 components), as pictured in Figure 1 above.
- If you have affected product, you are entitled to a replacement at no cost to your facility. Please note you must return the entire device (all 3 components) as pictured in figure 1 above. You will receive replacement upon your acknowledgement that you have affected product for return.
- Please forward this information to all current and potential Ultima Activator II Reusable Drive Mechanism 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.
- Please contact your local Getinge Customer Service department to request a return authorization (RMA) and shipping instructions to return any affected product. A biohazard box will be shipped to you in order to return the affected product. Pack the product to be returned with the appropriate return documents and, using the shipping instructions provided, arrange for pickup with the designated delivery service provider.
- Whether you have affected product or not, please complete and sign the attached MEDICAL DEVICE Removal - RESPONSE FORM (page 4) to acknowledge that you have received this notification. Return the completed form to Maquet Cardiovascular, LLC /Getinge by e-mailing a scanned copy to insert SSU email or by faxing the form to insert SSU fax.

Type of Action by the Getinge:
Maquet Cardiovascular, LLC /Getinge has identified the cause of the issue and is currently working with their supplier who has already implemented corrective measures.

If you have affected product, you will receive a replacement at no cost to your facility.

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

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax using the following:

- **Online**: www.accessdata.fda.gov/scripts/medwatch/
- **Regular Mail**: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form
- **Fax**: 1-800-FDA-0178

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

This recall is being made with the knowledge of the U.S. Food and Drug Administration.

Sincerely,

[redacted]

[Month DD, YYYY]

URGENT FIELD SAFETY NOTICE - Removal RESPONSE FORM

Ultima Activator II Reusable Drive Mechanism

FAX BACK TO: insert SSU fax or EMAIL TO: insert SSU email

DISTRIBUTION DATES: November 03, 2020 to August 23, 2021

ADD ACCOUNT#
[FACILITY NAME
STREET ADDRESS
CITY, STATE, ZIP CODE]

I acknowledge that I have reviewed and understand this Urgent Medical Device Removal Letter for the affected Ultima Activator II Reusable Drive Mechanism(s) at this facility.

I confirm that all users of the Ultima Activator II Reusable Drive Mechanism(s) at this facility have been notified accordingly.

If you have any affected product for return, please indicate the information required in the table below. Please contact your local Getinge Customer Service Department to request return authorization, packaging and shipping instructions.

Affected Lot Number:	Quantity Being Returned:	Getinge Returned RMA #:

Please provide the required information and signature below.

Facility Representative Information:

Signature:_____ **Date:**_____

Name:_____ **Phone:**_____

E-Mail Address:_____

Title:_____ **Department:**_____

Hospital Name:_____

Address, City and State: _____

We have scrapped/discarded our Ultima Activator II Reusable Drive Mechanism(s):
Circle one **YES** **NO**
We have sold/moved our Ultima Activator II Reusable Drive Mechanism(s) to another facility:
Circle one **YES** **NO**
If you answered YES above: please provide new facility information below.

New Facility Name:_____

New Facility Address:_____

New Facility Contact Name:_____ **New Facility Phone #:** _____

Return the completed form by FAX to insert SSU fax or by EMAIL to isert SSU email