[month DD, 2023]

URGENT Field Safety Notice -MEDICAL DEVICE REMOVAL
3011175548-09/13/2023-001-R
Advanta V12 Covered Stent

Pn/Reference-No.	Product / Trade Name	UDI-DI
85361	Advanta V12 Covered Stent, 10mm x 59mm x 80cm	00650862853612
Distributed Affected Lot Number(s):	464909 464910	
Manufacturing Dates:	September 30, 2020	
Distribution Dates:	December 28, 2020 – June 10, 2021	

Dear Risk Manager,

Atrium/Getinge is initiating a voluntary Medical Device recall/removal for the Advanta V12 covered stent system due to an identified manufacturing deficiency that may cause a loss of balloon pressure or inability to hold balloon pressure during Advanta V12 balloon-expandable covered stent deployment.

Affected Devices in Your Inventory Must Be Returned as part of this Removal Notice.

Identification of the issue:
There has been 1 (one) confirmed complaint reported to Atrium/Getinge over a 3 year period, involving a leak in the area where the balloon is welded to the catheter shaft of the delivery system. This resulted in a loss in balloon pressure during deployment of the stent and release of saline and contrast mixture from the balloon into the kidney, but without reported patient harm. The stent was able to be successfully deployed, however a loss of or inability to hold balloon pressure during stent deployment due to a leak may result in unsuccessful deployment of a stent under other circumstances.

The leak has been attributed to a deficiency in the balloon welding process, as well as a lack of adequate inspection processes that allowed this defect to go undetected in the manufacturing process. Corrective actions have been implemented; however, it is possible that additional devices in your inventory that were manufactured prior to these corrections may exhibit this defect.

There are no expected adverse events related to the defect if the product has already been used and successfully deployed. Additionally, product manufactured after September 30, 2020 is not affected.

Risk to Health:
While the user may not always be able to detect that the weld defect is present, the most likely result of the defect being present is that there will be a loss in pressure or inability to maintain pressure during stent deployment. The user may observe a pressure drop while attempting to apply or maintain positive pressure to the inflation device. The most likely impact of the defect is that there will be difficulty fully deploying the stent or deflating/removing the balloon catheter once the stent has been deployed. Stent embolization could occur. In both scenarios, the need for an additional procedure to retrieve the stent or separated balloon may arise. Any use of additional anesthesia and contrast may cause increased concern if negatively impacting renal function. While infrequent, the potential does exist for outcomes such as amputation, embolism, loss of organ

function, organ infarction, or tissue infarction. Further, additional surgical stress caused by prolonged interventional surgery has the potential to lead to myocardial infarction or death. While this is more likely in the at-risk population, it may also be possible in the general population.

The use of fluoroscopy to confirm proper deployment of the stent and full deflation of the balloon can mitigate the impact. If a balloon leak prohibits any stent deployment, the Instructions for Use (IFU) includes instructions on removal of an unexpanded stent.

Actions to be taken by Customer:

Our records indicate that you received one or more of the Advanta V12 covered stent systems with a product code/lot number affected by this Medical Device Recall Notice.

- Please examine your inventory immediately to determine if you have any of the Advanta V12 covered stent product listed above. Should you have any affected product, please remove from area(s) of use.
- If you have affected product, you are entitled to a replacement at no cost to your facility or credit. You will receive a replacement/credit upon your acknowledgement that you have affected product for return.
- 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 Atrium/Getinge Customer Service department to request a return authorization (RMA) and shipping instructions to return any affected product.
- Whether or not you have affected product(s) with a LOT number listed in this notice, please complete and sign the attached MEDICAL DEVICE- REMOVAL RESPONSE FORM (page 3) to acknowledge that you have received this notification. Return the completed form to Atrium/Getinge by [INSERT LOCAL SSU CONTACT INFO HERE]

Type of Action by Getinge:

Atrium/Getinge has identified the cause of the issue and has implemented corrective measures to resolve the noted manufacturing deficiency in the welding process, as well as additional detection measures implemented to detect balloon weld defects. These corrective actions were implemented September 09, 2020. Product Manufactured through the welding process after September 09, 2020 is not affected by this recall. If you have affected product, you will receive a replacement at no cost to your facility, or credit.

This voluntary recall only affects the products listed on pages 1 and 4; 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. [INSERT SSU CONTACT INFO]

Sincerely,
LOCAL SSU CONTACT INFO

[Month DD, YYYY]

URGENT Field Safety Notice – MEDICAL DEVICE REMOVAL RESPONSE FORM
3011175548 -09/13/2023-001-R
Advanta V12 Covered Stent

DISTRIBUTION DATES: Dec 28, 2020 – Jun,10, 2021

Insert Local Customer Info here

I acknowledge that I have read and understand this Medical Device Removal Notice for the Atrium Advanta V12 covered stent system.

I ensure that all users of the Getinge Atrium Advanta V12 covered stent at this facility have been notified accordingly.

If you have no affected product at your facility check here: ☐

If you have affected product please report it below after calling Customer Support for your RMA:

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

Facility Representative Information:

Signature:_____ **Date:**_____

Name:_____ **Phone:**_____

Title:_____ **Department:**_____

Hospital Name:_____

Address, City and State:_____

Return the completed form TO [INSERT LOCAL SSU CONTACT INFO HERE]