June 2017

URGENT MEDICAL DEVICE FIELD SAFETY NOTICE Atrium Advanta V12 Balloon Expandable Covered Stent 7 mm x 22 mm x 120 cm Part Number 85355 Lot Number 240734 IMPROPER SIZE LABELNG ON DEVICE MANIFOLD IMMEDIATE ACTION REQUIRED	
Product Code/Part Number:	**85355**
Affected Lot Number:	**240734**
Manufacturing Dates:	**30 June 2016 – 12 July 2016**
Distribution Dates:	**6 September 2016 - 14 March 2017**

PLEASE FORWARD THIS INFORMATION TO ALL CURRENT AND POTENTIAL ATRIUM ADVANTA V12 BALLOON EXPANDABLE COVERED STENT USERS AND STAFF WITHIN YOUR HOSPITAL OR FACILITY.

Dear Risk Management Staff,

Getinge/Maquet is initiating a voluntary Field Safety Corrective Action (FSCA) involving the return of one lot number of Atrium Advanta V12 Balloon Expandable Covered Stent size 7 mm x 22 mm x 120 cm, listed above.

Reason for the FSCA:

This field notification addresses a labeling problem on devices listed above, in which the device manifold (or catheter hub) may state an incorrect size labeling. The product size printed on the manifold may not match the size on the internal and external packaging. However, the correct product size is listed on external box and internal sleeve package.

Identification of the issue:

The Advanta V12 product size is listed on the device manifold (or catheter hub). See **Figures 1 and 2** below.

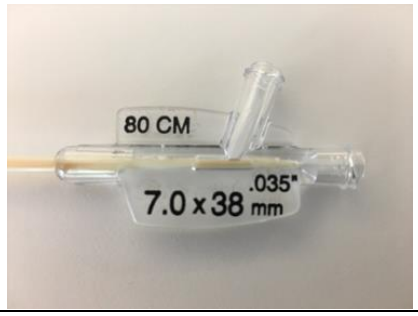

Figure 1 - Incorrect printing on manifold

Figure 2 - Correct printing on manifold

It has been discovered that a small quantity of devices may contain the incorrect size labeling on the device manifold (catheter hub). The product size is correctly noted on the box and internal product packaging.

Please Note: For the affected devices, the shelf box label matches the inside product, with the exception of the manifold printing. There is no physical difference between the labeled stent, delivery catheter and balloon to the actual product inside the box.

Risk to health:

Per the Getinge Health Hazard Analysis, if the stent dimensions on the catheter manifold are incorrect (compared to the actual size and correctly listed dimensions on the pouch/packaging), it could result in user inconvenience and increased procedural time.

The Advanta V12 Instructions for Use state: Carefully inspect this device prior to use to verify that it has not been damaged in shipment and the dimensions are suitable for the specific procedure. If the manifold label discrepancy was not detected by the clinician, there should be no additional risk to the patient as the stent, balloon, and delivery catheter match the shelf box (with the exception of the manifold printing).

To date, Getinge has not received any reports of patient injury related to the incorrect size labeling on the device manifold.

Action required:

Our records indicate that you have purchased the Advanta V12 Balloon Expandable Covered Stent 7mm x 22mm x 120cm having a lot number that is affected by this voluntary FSCA.

NOTE: The Advanta V12 Covered Stent lot number is listed on the product packaging label as the FIRST SIX (6) DIGITS of the serial number (SN). Please locate the serial number (SN) on the packaging label of Advanta V12 Covered Stent product code / part number 85355 in order to identify the lot number. A representative Advanta V12 Covered Stent packaging label, with lot number outlined as the first six digits of the serial number (SN), is provided in **Figure 3**, below.

Figure 3 – Advanta V12 Covered Stent part number 85355 with Location of Serial and Lot Number

Please examine your inventory to determine if you have any of the affected products listed on page 1. If so, please remove affected products, quarantine them, and place in a secure location.

If you have affected product, please contact Getinge Customer Service at +1-603-880-1433, Monday through Friday between 9:00 am to 5:00 pm U.S. Eastern Time Zone, for a Return Authorization (RA) and shipping instructions to return any affected prodct. Pack the product to be returned with the appropriate return documents, and using the shipping instructions provided, arrange for pick up with the designated delivery service provider.

Please complete and sign the enclosed Field Safety Notice Response Form on Page 4 of this letter to acknowledge receipt of this notification. Enter the quantity and RA number in the space provided, if you are returning products to Getinge.

Return the completed form to the following e-mail address: catheterhub.us@getinge.com or you may fax the form to +1-973-807-9207.

This FSCA only affects the products with lot numbers listed on page 1; no other products are affected by this FSCA.

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

This field action is being made in accordance with the supervision of the U.S. Food & Drug Administration.

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.

- **Online**: www.fda.gov/medwatch/report.htm
- **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 that this may cause. If you have any questions, please contact your Getinge/Maquet representative or call Maquet Customer Service at +1-603-880-1433, Monday through Friday between the hours of 9:00 am to 5:00 pm Eastern Time Zone.

Thank you for your cooperation and immediate assistance.

Sincerely,

Karen LeFevere

Karen LeFevere
Director Regulatory Affairs and Quality Compliance Field Actions,
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June 2017

URGENT FIELD SAFETY NOTICE – RESPONSE FORM
Atrium Advanta V12 Balloon Expandable Covered Stents 7mm x 22mm x 120mm
Product Code / Part Number: 85355
Lot Number: 240734
DISTRIBUTION DATES: 6-September-2016 through 14-March-2017

EMAIL TO: catheterhub.us@getinge.com or FAX TO: +1-973-807-9207

Account Number	**[INSERT SHIP-TO ACCOUNT NUMBER]**
Facility Name:	**[INSERT CUSOMER NAME]**
Facility Address	**[INSERT CUSTOMER ADDRESS]**

I acknowledge that I have read and understand the June 2017 Medical Device Field Safety Notification for the Advanta V12 Balloon Expandable Covered Stent. I confirm that all appropriate staff members at this facility that use and/or maintain Advanta V12 stents have been notified accordingly.

☐ Please check this box if you **do not have any affected product.** Please provide required information and signature. Return this form to Getinge, even if you do not have affected product.

☐ Please check this box if you **currently have affected Advanta V12 Stents.**

If you have affected product, please contact Getinge Customer Service at +1-603-880-1433, Monday through Friday between 9:00 am to 5:00 pm, U.S. Eastern Time Zone, for a Return Goods Authorization to return the product and receive credit.

Provide the quantity of product being returned:		
Enter Return Goods Authorization (RA) number:		
CUSTOMER ACKNOWLEDGEMENT:		
Print Name:		**Title:**
Signature:		**Date:**
Phone:		
Facility Name:		**Country:**
Facility Street Address:		
City:	**State:**	**Postal Code:**

EMAIL TO: catheterhub.us@getinge.com or FAX TO: +1-973-807-9207

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