June 20, 2023

# URGENT Field Safety Notice -MEDICAL DEVICE -CORRECTION

**Reference Number: 3011175548-02/25/2022-001-C**

**Atrium Advanta V12 Covered Stent System**

| | |
|---|---|
| **Product Code/Part Number- UPDATED:** | **Part numbers**<br>**85320 85321 85322 85323 85324 85325 85326 85327 85328 85329 85330 85331 85332 85333 85334 85335 85336 85337 85338 85339 85340 85341 85342 85343 85344 85345 85350 85351 85352 85353 85354 85355 85360 85361 85364 85365 85388 85389 85390 85391 85392 85394 85395 85396 85397 85398 85370 85371 85372 and 85379** |
| **Distributed Affected Lot Number:** | **All** |
| **Manufacturing Dates:** | **Updated: Affected product was manufactured after May 2, 2020**<br>Initial: Affected product was manufactured after November 11, 2016 |
| **Distribution Dates:** | **Updated: June 19, 2020 – May 2, 2023**<br>Initial: Affected product was distributed 3 years prior to Field Safety Notice initiation (March 14, 2022) |

Dear valued Customer

Atrium/Getinge is providing an update to our prior voluntary Urgent Field Safety Notification- Correction for the Advanta V12 Covered Stent System sent on February 17, 2022 due to reported complications, including a patient death, following separation of the balloon or catheter hub from the delivery catheter during delivery system withdrawal.

This notification is for user training with review of the instructions for use (IFU) segment below. No devices need to be returned as part of this Field Safety Notice.

**UPDATED Identification of the issue**:

Over a 4.5 year period, Atrium/Gentige received 86 complaints of the balloon or catheter hub separating from the delivery catheter due to difficulty withdrawing the catheter. Complications resulting from the malfunctions most commonly involved procedure delay, but instances of surgical intervention for component retrieval were also observed. Additionally, there was one event involving a patient death after myocardial infarction, which could not definitely be attributed to the separation of the balloon. Internal investigation identified that delivery system separations can occur if excessive force is used when removing the delivery catheter back through the sheath following stent deployment.

The need for excessive force during withdrawal was found to be the result of fluid remaining in the balloon during removal, i.e. the balloon was not fully deflated when withdrawal into a guide catheter or sheath was attempted.

The Advanta V12 Covered Stent System Instructions for Use (IFU) states to visually verify full balloon deflation via fluoroscopy before proceeding to the next step (withdrawal of the balloon catheter). Further, the IFU specifies not to force withdrawal of the delivery system if resistance is encountered, as this can lead to separation of the balloon or catheter hub from the delivery catheter. If unable to fully deflate the balloon or resistance is encountered, the IFU recommends to remove the delivery system and introducer sheath/guiding catheter as one unit.

**UPDATED Risk to Health:**

The most likely occurrence as a consequence of component separation is a procedural delay due to the necessity to either perform additional measures to deflate or retrieve the balloon. In high risk patients with renal insufficiency, if a balloon or catheter hub would separate, any use of additional anesthesia and contrast may cause increased concern if negatively impacting renal function. While infrequent, the potential does exist for occlusion or embolism and associated response, with specific 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.

**Actions to be taken by Customer in endovascular procedures:**

Our records indicate that you received one or more of the Advanta V12 covered stent system with a product code/lot number affected by this Urgent Field Safety Notification- Correction.

Maintaining patient safety is of upmost importance to Atrium/Getinge as such please ensure that all iCast covered stent users at your facility that may utilize this device for endovascular procedures are aware of this notice, then post a copy of the Urgent Medical Device notice (Page 4) in all inventory locations within your facility where the iCast covered stent products are stored.

**Product does not need to be returned.** You may continue to use the iCast covered stent, with consideration of the following when used for endovascular procedures:

**Deflation and Withdrawal Instructions:**

Deflate balloon by pulling vacuum on the inflation device to its maximum volume and allow sufficient time for full deflation.

NOTE: Deflation times may vary based on balloon size, catheter length, and inflation media used. Deflation may take longer with larger devices and higher concentrations of contrast.

IMPORTANT: Visually verify full deflation of the balloon using fluoroscopy before attempting to withdraw the delivery system.

CAUTION: Do not force withdrawal of the delivery system if resistance is encountered. Forcing withdrawal may result in damage to the delivery system, including separation of the balloon or catheter hub from the delivery catheter. If unable to fully deflate the balloon or resistance is encountered, remove the delivery system and introducer sheath as one unit.

Note: It is recommended that the guidewire remain across the lesion until the procedure is completed.

While maintaining guidewire position and negative pressure on the inflation device slowly withdraw

the delivery catheter.

Please complete the following actions:

1. Please forward this information to all current and potential iCast covered stent users within your hospital/facility and **ensure users are trained by reviewing the above deflation and withdrawal instructions.**

2. Post a copy of page 4 in all inventory locations where iCast covered stent products are stored.

Please complete and sign the attached URGENT: MEDICAL DEVICE - FIELD CORRECTION-RESPONSE FORM on page 5 to acknowledge that you have received this notification and trained users at your facility with review of the Instructions for Use. Return the completed form to Atrium/Getinge at chunsing.wee@getinge.com or by faxing the form to 62961937.

This Urgent Medical Device Correction only affects the product codes listed on page 1; no other products are affected.

We apologize for any inconvenience this recall may cause.

If you have any questions, please contact your Atrium/Getinge representative or call the Atrium/Getinge Customer Support at 62961992.

Sincerely,

Ye Da Tee

*Electronically signed by:*
*Ye Da Tee*
*Reason: I have reviewed this document.*
*Date: Jun 20, 2023 14:59 GMT+8*

Tee Ye Da

QRC Specialist

# URGENT MEDICAL DEVICE – Correction

## Advanta V12 Covered Stent System

**85320, 85321, 85322, 85323, 85324, 85325, 85326, 85327, 85328, 85329, 85330, 85331, 85332, 85333, 85334, 85335, 85336, 85337, 85338, 85339, 85340, 85341, 85342, 85343, 85344, 85345, 85350, 85351, 85352, 85353, 85354, 85355, 85360, 85361, 85364, 85365, 85388, 85389, 85390, 85391, 85392, 85394, 85395, 85396, 85397, 85398, 85370, 85371, 85372 and 85379**

**PLEASE POST THIS WARNING LABEL NEAR ALL PRODUCT INVENTORY**

**Atrium/Getinge is expanding the February 2022 voluntary Medical Device Field Correction for the Advanta V12 Covered Stent System due to reported complications following separation of the balloon or catheter hub from the delivery catheter during delivery system withdrawal. Additionally, there has been one event involving a patient death after myocardial infarction, which could not definitely be attributed to the separation of the balloon.**

**Review of the IFU and instructions below is required.**

**READ PRIOR TO USE OF DEVICE**

**Deflation and Withdrawal Instructions:**

**Deflate balloon by pulling vacuum on the inflation device to its maximum volume and allow sufficient time for full deflation.**

**NOTE: Deflation times may vary based on balloon size, catheter length, and inflation media used. Deflation may take longer with larger devices and higher concentrations of contrast.**

**IMPORTANT: Visually verify full deflation of the balloon via fluoroscopy before attempting to withdraw the delivery system.**

**CAUTION: Do not force withdrawal of the delivery system if resistance is encountered. Forcing withdrawal may result in damage to the delivery system, including separation of the balloon or catheter hub from the delivery catheter. If unable to fully deflate the balloon or resistance is encountered, remove the delivery system and introducer sheath/guiding catheter as one unit.**

**Note: It is recommended that the guidewire remain across the lesion until the procedure is completed.**

**While maintaining guidewire position and negative pressure on the inflation device slowly withdraw the delivery catheter.**

June 20, 2023

# URGENT: MEDICAL DEVICE – FIELD CORRECTION RESPONSE FORM
# Advanta V12 Covered Stent System

**Return the completed form by FAX to 62961937 or by EMAIL to chunsing.wee@getinge.com**

**DISTRIBUTION DATES: Please refer to the attached Consignee List**

**ADD ACCOUNT#**
**[FACILITY NAME**
**STREET ADDRESS**

**CITY, STATE, ZIP CODE]**

Please acknowledge that you have read and understand this Medical Device Field Correction Notice for the Advanta V12 Covered Stent System. Please ensure that all users of the Advanta V12 Covered Stent System at this facility are aware of this notice and **that all Users of the Advanta V12 Covered Stent System have been trained to the above deflation and withdrawl instruction (also included in the IFU).** Signature of the Facility Representative below represents confirmation of completion of training / re-training for all Advanta V12 Covered Stent System Users.

**No product is required to be returned as a result of this Field Notification.**

Facility Representative Information

Signature:_____ Date:_____

Name:_____ Phone:_____

Title:_____ Department:_____

Hospital Name:_____

Address, City and State:_____

**Return the completed form by FAX to** 62961937 **or by EMAIL to**
chunsing.wee@getinge.com