August 20, 2012

URGENT FIELD SAFETY NOTICE/ DEVICE RECALL

COMMERCIAL NAME: Armada 35 and Armada 35 LL Percutaneous Transluminal Angioplasty (PTA) Catheter

Dear Valued Abbott Vascular Customer:

Abbott Vascular has initiated a voluntary field action for the Armada 35 and Armada 35 LL PTA Catheters.

Abbott Vascular has discovered that some devices may exhibit difficulty inflating and/or deflating. To date, the frequency of worldwide reported events for difficulties inflating and/or deflating the balloon has reached 0.1%. Potential risks associated with this event include prolonged procedure times, additional physician intervention including minor surgery and possible thrombus. There have been no long term or irreversible patient effects reported.

This action does not affect patients having successfully undergone endovascular PTA procedures.

What you should do:
Our records indicate Armada 35 or Armada 35 LL devices have been shipped to your account. Please reference the attached list of part numbers and lot numbers range. The use of these devices should cease immediately. Please review your inventory, complete the attached Field Action Reconciliation / Effectiveness Check Form and return it with all unused devices to Abbott Vascular.

What Abbott Vascular is doing:
Abbott Vascular has already implemented corrective actions to ensure ongoing product performance. Abbott Vascular will work with you to replace returned units with similar product, pending availability. The appropriate regulatory agencies have been notified of this action.

We regret any inconvenience this may have caused you and appreciate your patience. Abbott Vascular is committed to providing high quality products and ensuring customer satisfaction. If you have any questions, please do not hesitate to contact your Abbott Vascular Representative or Abbott Vascular regulatory contact at +420 267 292 255.

Sincerely,

GM/Country Manager

Attachments: Armada 35 / Armada 35 LL part number list
Armada 35 / Armada 35 LL Reconciliation / Effectiveness Check Form

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Lot Numbers to be returned: All lots up to and including Lot Number 783705
Part Numbers Affected Part Numbers:

Balloon Diameter (mm)	Catheter Length (cm)	Armada 35 Balloon Length (mm)						Armada 35 LL Balloon Length (mm)		
		20	40	60	80	100	120	150	200	250
3	80	B1030-020	B1030-040							
	135	B2030-020	B2030-040							
4	80	B1040-020	B1040-040	B1040-060	B1040-080	B1040-100	B1040-120	B1040-150	B1040-200	B1040-250
	135	B2040-020	B2040-040	B2040-060	B2040-080	B2040-100	B2040-120	B2040-150	B2040-200	B2040-250
5	80	B1050-020	B1050-040	B1050-060	B1050-080	B1050-100	B1050-120	B1050-150	B1050-200	B1050-250
	135	B2050-020	B2050-040	B2050-060	B2050-080	B2050-100	B2050-120	B2050-150	B2050-200	B2050-250
6	80	B1060-020	B1060-040	B1060-060	B1060-080	B1060-100	B1060-120	B1060-150	B1060-200	B1060-250
	135	B2060-020	B2060-040	B2060-060	B2060-080	B2060-100	B2060-120	B2060-150	B2060-200	B2060-250
7	80	B1070-020	B1070-040	B1070-060	B1070-080	B1070-100	B1070-120	B1070-150	B1070-200	
	135	B2070-020	B2070-040	B2070-060	B2070-080	B2070-100	B2070-120	B2070-150	B2070-200	
8	80	B1080-020	B1080-040	B1080-060	B1080-080					
	135	B2080-020	B2080-040	B2080-060	B2080-080					
9	80	B1090-020	B1090-040	B1090-060	B1090-080					
	135	B2090-020	B2090-040	B2090-060	B2090-080					
10	80	B1100-020	B1100-040	B1100-060	B1100-080					
	135	B2100-020	B2100-040	B2100-060	B2100-080					
12	80	B1120-020	B1120-040	B1120-060	B1120-080					
	135	B2120-020	B2120-040	B2120-060	B2120-080					
14	80	B1140-020	B1140-040	B1140-060	B1140-080					
	135	B2140-020	B2140-040	B2140-060	B2140-080					

Please reference the list of affected part numbers and lot number range above. The use of these devices should cease immediately. Please review your inventory, complete the attached Field Action Reconciliation / Effectiveness Check Form and return all unused devices to Abbott Vascular.

Abbott
A Promise for Life

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Armada 35 / Armada 35 LL Reconciliation / Effectiveness Check Form

Distributor/Customer # _____

Distributor Name _____

Address _____

_____

Phone _____

(information required for regulatory effectiveness checks)

After reviewing your inventory of Armada 35 and Armada 35 LL lot numbers up to and including Lot Number 783705, please check one box in the section below. If affected inventory was identified, indicate the number of devices being returned. After signing this form, please return the form and any identified products to Abbott Vascular.

☐ A thorough search for all affected products has been completed and none remain in inventory.

No devices will be returned.

☐ Affected Armada 35 or Armada 35 LL have been identified and are being returned.

Quantity: _____ RGA Number: _____

_____ _____ _____

Distributor's Authorized Person Name/ Title (print) ***Signature*** ***Date***

This form is to be returned to Abbott Vascular.

- If returning product, contact eva.boruvkova@av.abbott.com and alena.silova@av.abbott.com to receive RGA#
- Fax this completed form to **+420 292 267 227**
- Return a copy of this completed form with the returned product.