

ATTENTION: RISK MANAGER/MATERIALS MANAGER

NON-SAFETY RELATED MEDICAL DEVICE NOTIFICATION

ATLAS[®] GOLD PTA Dilatation Catheter

September 29, 2017

Dear Customer,

This letter is to provide information to you about the ATLAS[®] GOLD PTA Dilatation Catheter, distributed by Bard Peripheral Vascular, Inc. (BPV), a wholly owned subsidiary of C.R. Bard, Inc. Specific product code / lot number combinations of ATLAS[®] GOLD PTA Dilatation Catheters are affected as outlined in Attachment 1. Our records show that your facility has purchased one or more of the affected product code / lot number combinations.

All other product code / lot number combinations are not affected by this notification.

Reason for Notification:

Bard Peripheral Vascular (BPV) has confirmed that the product code / lot number combinations listed in Attachment 1 may be at risk for having a balloon wall thickness that is higher than the required specification.

Clinical Risk Statement:

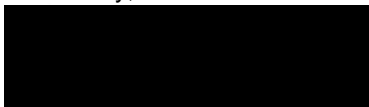
It is reasonable to suggest that there could be a slight increase in the force required to advance the balloon through the sheath and/or withdraw the balloon after inflation and deflation. This could potentially lead to a slight prolongation of the procedure if the physician needs to completely withdraw the device and replace it with another.

Another potential effect of a change in balloon wall thickness might be an increase in the balloon's non-compliance or rigidity. This is a product of inflation pressure and unlikely to have a negative effect or incremental risk of harm during use.

Instructions to Customer:

No further action is necessary. If the unit does not meet your needs, please contact Customer Service (1-800-321-4254 Option #2) for a Return Authorization Number and to place a new order. We sincerely regret any inconvenience this may cause you and your facility. If you have any questions, please do not hesitate to contact your Bard representative.

Sincerely,



Garth Conrad
Vice President, Quality Assurance
Bard Peripheral Vascular, Inc.

Attachment 1 – List of Affected Product Code / Lot Number Combinations

Product Code	Lot Number
ATG120146	93YA0080
ATG120162	93XA0135
ATG120164	93PB0163
	93NB0051
	93NB0052
ATG120182	93YA0039
	93YA0093
ATG120184	93YA0071
	93YA0085
ATG120186	93QB0125
ATG120202	93YA0086
ATG120204	93QB0070
ATG120242	93YA0036
ATG80146	93YA0091
ATG80162	93XA0134
ATG80164	93XA0149
	93XA0131
	93YA0013
	93YA0037
	93PB0148
	93PB0272
ATG80182	93YA0212
	93NB0040
ATG80184	93YA0040
	93YA0084
ATG80186	93YA0213
	93XA0174
ATG80202	93XA0185
	93YA0094
	93ZA0169
	93ZA0193
	93QB0141