

Attention: Risk Manager/Materials Manager

July 9, 2015

NOTIFICATION OF MISLABELING OF RIVAL® PTA CATHETERS

Dear Customer,

This letter is to inform you of a mislabeling on a specific lot of Rival® PTA Dilatation Catheters manufactured by Bard Peripheral Vascular, a wholly owned subsidiary of C.R. Bard, Inc. This mislabeling is related to the following product code and lot only:

Table 1: AFFECTED PRODUCT CODES

Part Number	Lot Number
RV135610	GFYG3726

DESCRIPTION OF THE PROBLEM:

A portion of the affected lot contains units with an incorrect compliance card affixed to the catheter hoop inside the product pouch. **The labeling on the outer product carton, inside pouch and catheter hub is correct.** The image shown in Figure 1 illustrates the incorrect compliance card (it has been removed from the catheter hoop and positioned next to the pouch label for visual clarity).

Specifically, the incorrect **7mm** compliance card contains the incorrect balloon diameter, lengths, diameter growth (compliance), and rated burst pressure (RBP) information.

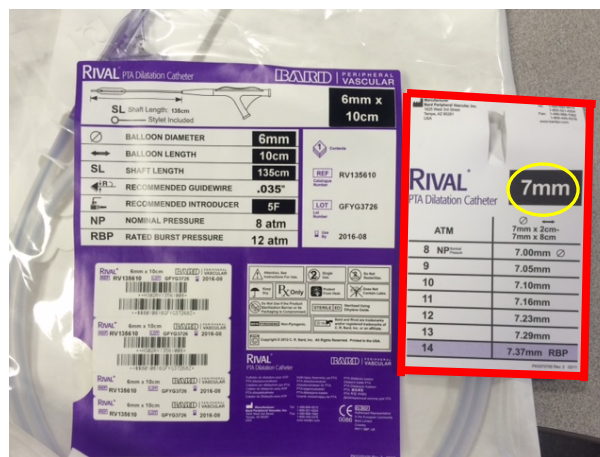


Figure 1 – Label Image of Incorrect Label

The correct **6mm** compliance card should have stated the following pressure vs. outer diameter information:

PRESSURE (ATM)	BALLOON OUTER DIAMETER
8 NP (Nominal Pressure)	6.00mm Ø
9	6.07mm
10	6.14mm
11	6.20mm
12	6.26mm RBP

DEPTH OF MISLABELING:

This mislabeling is specific to product code **RV135610**, lot # **GFYG3726** only, and is limited to the compliance card. All other labelling information (balloon size, rated burst pressure, expiry dates, etc.) are correctly stated on the carton and pouch product labels, as well as on the catheter hub.

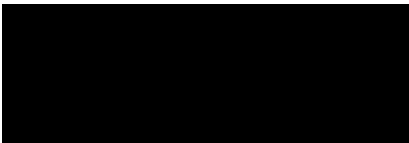
INSTRUCTIONS TO CUSTOMER:

The mislabeling does not impact the product use. **No action is required on your part.** If the unit does not meet your needs, we will provide you with a replacement unit.

We sincerely regret any inconvenience this may cause you or your facility.

If you have any questions please do not hesitate to contact us at 1-800-321-4254.

Sincerely yours,



Chad Modra
Vice President, Quality Assurance
Bard Peripheral Vascular