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Reference: FA2017-43

Balloon wall thickness of ATLAS® GOLD PTA Dilatation Catheter

Dear **Sherif Wady**

The balloon wall thickness of the ATLAS® GOLD PTA Dilatation Catheter (distributed by Bard Peripheral Vascular, Inc. (BPV), a wholly owned subsidiary of C.R. Bard) is potentially at the risk of being higher than the required specification. The issue is limited to the product code / lot number combinations in Attachment 1. All other product code / lot number combinations are not affected by this.

The clinical risk associated with this 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 one.

An additional effect might be an increase in the balloon's rigidity. This is a product of inflation pressure and unlikely to have a negative effect or incremental risk of harm during use.

Our records show that your facility has purchased one or more of the affected product code / lot number combinations. This letter is for informational purposes only. Please ensure it is passed to all in your facility and/or those whom the products have been further distributed to for awareness. **No further action required from you.** If you have any further product-related questions, however, please do not hesitate to contact your local Bard representative.

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

Yours faithfully,
For and on behalf of C. R. Bard, 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 |
| | 93XA0149 |
| | 93XA0131 |
| | 93YA0013 |
| | 93YA0037 |
| | 93PB0148 |
| ATG80182 | 93PB0272 |
| | 93YA0212 |
| ATG80184 | 93NB0040 |
| | 93YA0040 |
| ATG80186 | 93YA0084 |
| | 93YA0213 |
| ATG80202 | 93XA0174 |
| | 93XA0185 |
| | 93YA0094 |
| | 93ZA0169 |
| | 93ZA0193 |
| | 93QB0141 |

