Cardiovascular
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May 22, 2023

Dr. Filip Banovac
Medstar Georgetown University Hospital
3800 Reservoir Rd. NW
Washington, DC 20007

Reference:
Product Name: TheraSphere™ Administration Set
Product Number: Not Reported
Serial/Lot Number: Not Reported
Procedure Date: January 11, 2023

Dear Dr. Banovac:

Thank you for notifying Boston Scientific of your experience related to the performance of the above-referenced product and returning it to us for analysis. The purpose of this letter is to provide a summary of our investigation, including quality assurance laboratory analysis results.

Reported Clinical Observations
It is our understanding that during a TheraSphere procedure, misadministration occurred (68% delivery of a 3.0 GBq vial).

Investigation Summary
Upon receipt, this product was thoroughly analyzed in our Quality Assurance laboratory. The investigation included visual inspection, radiation measurement, digital microscopy, and pressure/flow tests of returned components.

Visual inspection revealed that the Administration Set was returned with all components, a microcatheter, and a guide catheter. The dose vial was not returned. The returned microcatheter was a Terumo Progreat 2.4 microcatheter. Visual inspection of the Administration Set revealed that the injector needles were bent at a 90-degree angle. We cannot confirm product changes to the Administration Set that may have occurred post-treatment but prior to our inspection. There was also a kink in the outlet tubing at the pinch clamp. Microspheres were present in the outlet tubing and microcatheter hub. Radiation measurements confirmed this.

Flow testing of the Administration Set was not performed because the needles were too bent, and the dose vial was not returned. Flow testing was performed on the microcatheter, and a sufficient

flow rate was observed. Microspheres and blood clots were observed in the waste collection vial following flushing of the microcatheter.

Further Discussion
The cause of the low delivery event appears to be a low flow rate (below the recommended 20 cc/min). Microspheres will fall out of suspension and settle within the outlet tubing at flow rates below the recommended 20 cc/min. The cause of the low flow rate is unknown based on the available information; however, a low flow rate could result from giving less than the recommended 20cc/min, slowing or stopping flow, or a partial or full obstruction caused by torturous anatomy or kinking of the microcatheter.

Additional Information
It is important to note that we monitor and trend product experience data as part of our quality system and the information you provided will be included in this process.

We value your feedback about your experience with our product, and we thank you again for reporting it to us. If you have any additional information or questions/concerns, please contact your local representative, Stephen Seaman, or the applicable department listed below:

Complaint Management Center
ICardioQAComplaints@bsci.com

Sincerely,

Kaylee Dugan
CV Division, Post Market Surveillance
Boston Scientific

cc: Stephen Seaman, TheraSphere Consultant, Boston Scientific

Internal Reference: 16118533