Electronic Supplementary Material (ESI) for Analytical Methods

Supplemental Information

A Test Method to Evaluate Chronic Particulate Generation from Durable Polymer Stent Coatings: A Case Study of CYPHER® Sirolimus-eluting Coronary Stents

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Experimental

Samples:

5 stents each of CYPHER® (2.5 x 18) and Competitor A (3 x 20 mm) and 3 stents of Competitor B (3.0 x 18 mm) were selected for analysis.

Simulated Acute Testing

During testing the stent is delivered through a tortuous track designed per ASTM F2394 followed by deployment at rated burst pressure (RBP) in a mock artery with an approximate 15 mm radius bend. After removal of the delivery catheter, the entire delivery path is flushed with a flow of 0.1% sodium dodecyl sulfate (SDS) in water and captured into a pre-cleaned particle collection vial. The contents of the vial are then subjected to light obscuration analysis to size and quantify particulates generated during deployment.

Results

Figure S1 compares the average amount of particulates observed for the three stent products. The USP 788 guideline amount (<6000) is shown for reference. Competitor A had significantly more particles than CYPHER® and competitor B and was above the USP 788 limit for particles greater than 10 μm. For particles greater than 25 μm, Competitor B< CYPHER®<Competitor A and all three products displayed levels well below USP788 limits.

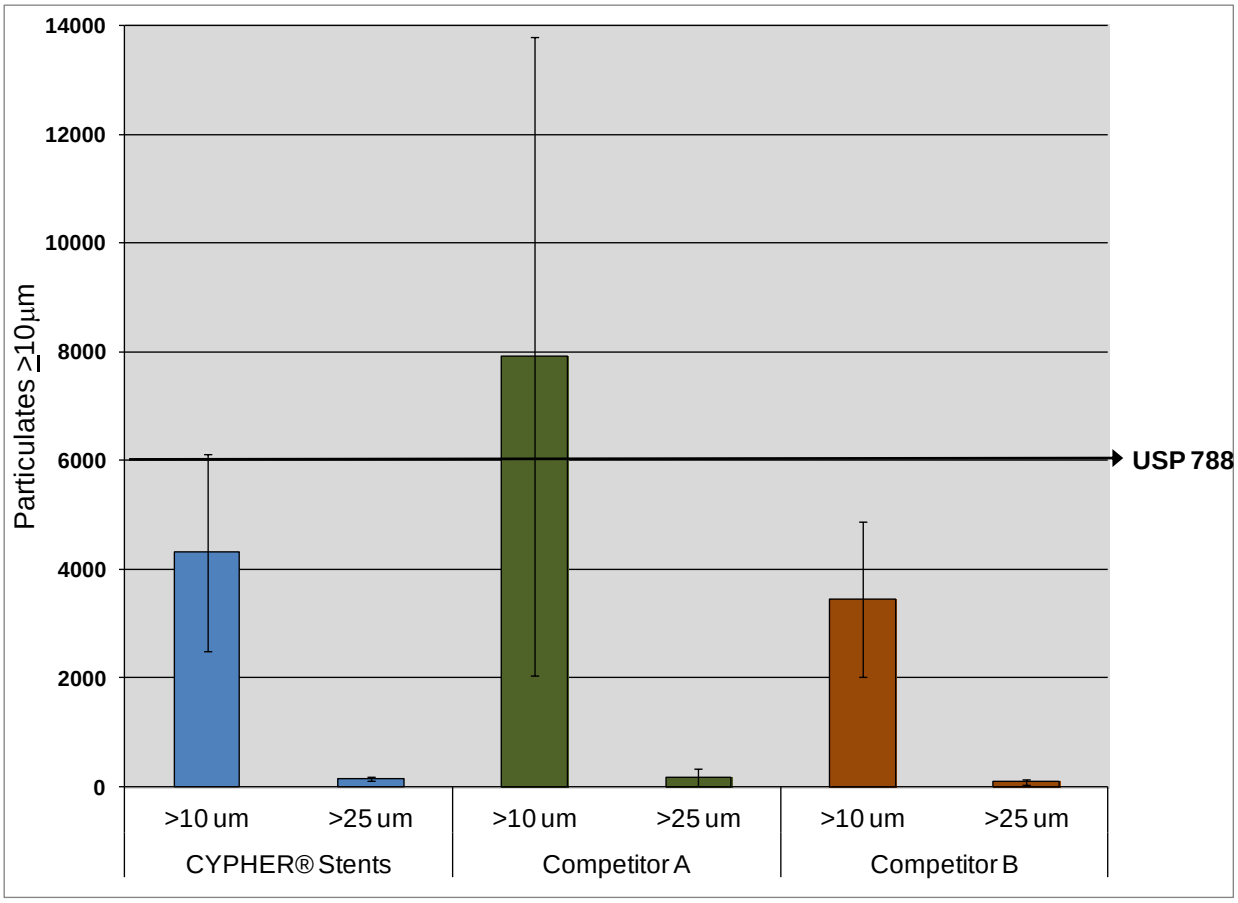

Figure S1. A comparison of acute particulate data for three different DES products for particles >10 μm and > 25 μm.