August 14, 2018

Dear Valued Customer:

In June 2018, Embolx received 510(k) clearance from the United States Food and Drug Administration (FDA) for its next generation family of Sniper® Balloon Occlusion Microcatheters, an innovative system for pressure-directed arterial embolization therapy. To support physician inquiries, Embolx conducted additional testing on Sniper to ensure its compatibility with chemicals to which exposure during clinical procedures is common.

Tested with dimethyl sulfoxide (DMSO) and Lipiodol®, Sniper passed all tests regarding the material integrity of the microcatheter. Parameters used to assess these results included: hub bond and tubing tensile strength; freedom from liquid leakage; rated infusion pressure and burst pressure after chemical exposure; balloon performance under chemical exposure. Chemicals were used in a non-diluted state in excess of exposure periods seen under clinical conditions. Test data and results are on file at Embolx.

Testing with n-Butyl cyanoacrylate (n-bCA) was conducted to confirm functional use and compatibility with Sniper. N-bCA was tested in both non-diluted and diluted with 50% Lipiodol states and in excess to exposure seen under clinical conditions. Timing for polymerization was taken into consideration. Sniper passed all tests when exposed to n-bCA. Test data and results are on file at Embolx.

This letter is being provided for informational purposes and to describe the results confirming chemicals compatible with the Sniper Balloon Occlusion Microcatheter. Embolx does not make any claims as to the clinical use of chemicals noted in this letter.

If you have any further questions, please contact your local Embolx sales representative.

Yours Sincerely,

John Layton
Director of Marketing

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