

From: [REDACTED]
Date: March 5, 2016 at 12:47:09 AM PST
To: [REDACTED]
Subject: RE: Boston Scientific Mesh News

Here is the latest response from our President Karen Prange about the allegation of this attorney over the resin.....

March 3, 2016

Dear Valued Customer:

Thank you for your inquiry concerning our mesh devices. We understand you may have questions about the recent, unfounded allegations made about the resin used in our mesh devices.

Boston Scientific's mesh devices are made from Marlex HGX 030-01, a particular polypropylene resin produced by Phillips Sumika in LaPorte, Texas. In 2011, Phillips Sumika, confirmed to Boston Scientific that it had discontinued production of that particular grade of Marlex due to low demand, and Boston Scientific's existing distributors could not guarantee a continuing supply over the next several years, so we located an alternative distributor with an available supply of the correct resin. Once we located that distributor, we ran samples of the resin it supplied to us through a thorough and rigorous battery of chemical tests, prior to its use, to ensure that it was the same grade of Phillips Sumika-produced, Marlex resin that we had previously used, and that it met material, design, and biocompatibility specifications for our mesh devices.

In particular, in addition to conducting multiple chemical tests, Boston Scientific had testing performed at each step of the mesh manufacturing process to confirm that the newly-sourced resin performed like previous lots of Marlex obtained from other distributors. This testing included extruding the resin and testing fibers for various properties, including tensile strength, elongation at break, and knot strength. The fibers extruded from the newly sourced resin as well as the mesh and finished products all met the standards set for previous lots of resin. The same was true of biocompatibility testing.

Boston Scientific is confident that the resin used in the manufacture of our mesh devices is neither counterfeit nor adulterated, and we have a robust quality system, which includes rigorous procedures and controls relating to the materials and components used in our products to ensure that remains the case. The Company has also discussed the allegations about the mesh resin with the FDA. As you may know, the FDA has posted the following reference to the allegations on its website:

The FDA is aware of allegations that Boston Scientific vaginal mesh devices may have contained counterfeit materials. We are examining those allegations to determine any necessary and appropriate next steps. We are currently not aware that the alleged contamination contributes to adverse events associated with these products.

Boston Scientific is dedicated to patient safety. We stand behind our products, the materials used in those products and our commitment to women's health.

Sincerely,

Karen Prange

Senior Vice President and President of Urology and Pelvic Health
Boston Scientific Corporation



JOE WILSON
Market Development Manager
Boston Scientific
Urology and Women's wilsonj7@bsci.com
C. 949-232-9457



From: [REDACTED]
Sent: Friday, March 04, 2016 6:59 PM
To: [REDACTED]
Subject: Fwd: Boston Scientific Mesh News

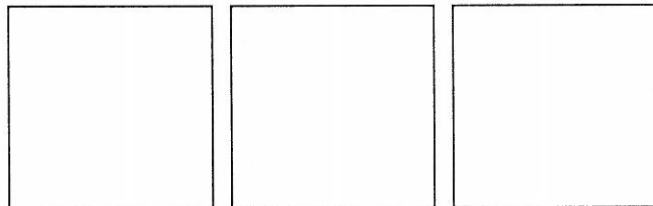
Any truth to the below?

Best regards,

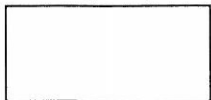
[REDACTED] MD
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St. Josephs Hospital, Orange, CA
Kern Medical Center, Bakersfield, CA
Clinical Professor OB/GYN
Keck/University of Southern California School of Medicine, Los Angeles, CA

Begin forwarded message:

From: "Boston Scientific Mesh News" <Boston_Scientific_Mesh_News@mail.vresp.com>
Date: March 4, 2016 at 5:06:02 PM PST
To: [REDACTED]
Subject: Boston Scientific Mesh News
Reply-To: "Boston Scientific Mesh News" <reply-7b85709cfe-4e3d9bf383-663b@u.cts.vresp.com>



January 15, 2016 By [Brad Perriello](#)



Boston Scientific smuggled counterfeit resin for pelvic mesh

A purported class-action racketeering lawsuit filed this week accused [Boston Scientific](#) (NYSE:BSX)

of illegally smuggling counterfeit resin made in China to make pelvic mesh, after its original supplier allegedly refused to continue providing the product because it's not supposed to be implanted in humans. Boston Scientific won 510(k) approval from the FDA in 2002 for the Advantage Mesh, Advantage Fit and Lynx mesh products, manufactured using the Marlex polypropylene resin made in Texas by a joint venture between Chevron and Phillips, the lawsuit alleged.

But by 2005, Phillips allegedly decided to stop supplying Marlex to Boston Scientific because it's not compatible with human tissue. By 2011, Boston was running out of Marlex and projected it would have none by the fall of 2012. At stake, according to the complaint, was the \$120 million worth of pelvic mesh products Boston Scientific sold each year.

“After failing to convince the manufacturer, Phillips, to sell it any more Marlex, BSX made the fateful decision to smuggle counterfeit Marlex out of China,” according to the complaint.

The company then allegedly bought 34,000 pounds of polypropylene resin from a Chinese firm, EMAI Plastic Raw Material Co. of Guandong, projecting that it would be enough to last until 2032. The companies allegedly conspired to put counterfeit labels, including fake lot numbers, designed to look like Phillips markings, on the Boston Scientific product and then allegedly “overbagged” the shipments with blank labels to get them past Chinese and U.S. customs.

The complaint charges Boston Scientific and co-defendants EMAI, Luxilon and Proxy with racketeering, mail fraud, wire fraud, intentional and negligent misrepresentation, unfair and deceptive acts and practices, fraud and unjust enrichment. Stevens asked Judge Joseph Goodwin for a jury trial, temporary and permanent injunctions barring the manufacture and sale of products using the allegedly fake Marlex, a warning to the public about it, punitive and consequential damages, legal costs, pre- and post-judgment interest and a temporary restraining order.

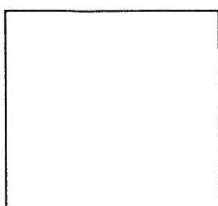
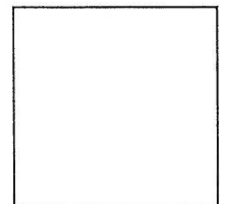
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January 25, 2016

Dear Valued Customer:

Thank you for your inquiry concerning our mesh devices. We understand you may have questions about the recent, unfounded allegations made about the resin used in our mesh devices.

Boston Scientific is confident that the resin used in the manufacture of our mesh devices is neither counterfeit nor adulterated. Boston Scientific has a robust quality system, which includes rigorous procedures and controls relating to the materials and components used in our products. The resin used in the manufacture of our devices has been appropriately tested to ensure that it matches, and is equivalent to, the resin that we have historically purchased from other distributors, that it meets material, design, and biocompatibility specifications for our mesh devices.

Boston Scientific is dedicated to patient safety. We stand behind our products, the materials used in those products and our commitment to women's health.

Sincerely,



Karen Prange
Senior Vice President and President of Urology and Pelvic Health
Boston Scientific Corporation