Boston Scientific Statement on Attorney’s Petition to FDA Regarding Mesh Products

Boston Scientific does not use “counterfeit” or “adulterated” materials in our medical devices. The company rejects the allegations in the petition to the Food and Drug Administration filed by a Texas-based law firm on March 31, 2016. Boston Scientific has a robust quality system and dedication to patient safety. We stand behind our products, the materials used in those products and our commitment to women’s health.

Boston Scientific mesh products provide relief to thousands of patients for painful and progressive medical conditions. These mesh devices are made with Marlex HGX-030-01, a polypropylene resin. Polypropylene resins like Marlex have been part of implantable medical devices for more than 50 years.

Large scale manufacturers of raw materials like resin sell products directly and through diverse networks of distributors. Changing suppliers of raw materials is not unusual for medical device companies, and when Boston Scientific makes such a change, we follow the processes required by our quality system.

In 2011, we located a new supplier of Marlex resin. Upon doing so, we put samples of the resin through a rigorous battery of tests to demonstrate equivalency. In addition, we conducted extensive mechanical tests to ensure that our mesh products manufactured with the newly sourced material met product specifications.

We have the highest confidence in the safety of our mesh devices. We have shared our test data with the Food and Drug Administration (FDA), and are fully cooperating with the agency’s requests for information as part of our ongoing discussions. Additionally, we have offered to conduct further biocompatibility and chemical characterization testing to complement the results from existing tests. This entire process is expected to take several months, depending on the individual tests.

In the interim, we encourage physicians to continue to have confidence in our products and make the best, informed decisions with their patients.

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