American Latex Allergy Association

FDA Clears Glove Made from New Type of Latex

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The U.S. Food and Drug Administration has cleared for marketing the first device made from a new form of natural rubber latex, guayule latex. The product, the Yulex Patient Examination Glove, is derived from the guayule bush, a desert plant native to the Southwestern United States.

Traditional latex gloves are made from the milky sap of a rubber tree, Hevea braziliensis. The sap contains a protein that may trigger allergic reactions, especially after prolonged and repeated contact. Sensitized people may experience mild reactions such as skin redness, rash, hives, or itching. More severe reactions may include respiratory symptoms such as difficulty breathing, coughing spells and wheezing. Rarely, shock may occur.

Estimates vary, but anywhere from 3 percent to 22 percent of all health care workers are sensitized to traditional latex. Available data on the new guayule latex show that even people who are highly allergic to traditional latex do not react on first exposure to guayule latex proteins.

?This approval has the potential to make a significant difference to both the general public and the medical community at large,? said Daniel Schultz, M.D., director of FDA?s Center for Devices and Radiological Health. ?Gloves made from guayule latex may prove to be a safer alternative for some people with sensitivity to traditional latex. And yet they will not sacrifice the desirable properties of traditional latex such as flexibility and strength.?

Health care workers first began using traditional latex gloves in the 1890s. But concerns about allergic reactions increased in the late 1980s after modifications in glove materials made them more sensitizing just as glove use was soaring in response to the HIV epidemic. Some health care institutions have since responded by shifting to alternative glove materials for their workers.

FDA has taken numerous steps to address the glove allergy problem including working with industry to develop a consensus standard that identifies maximum protein and powder levels for medical gloves. A 1998 rule requires that all medical devices containing latex carry a statement on the label warning about the risk of allergic reactions. Because there is no data on people?s long-term experience with the Yulex glove, the product will carry a warning for now about the potential for allergic reactions.

The Yulex glove is made by the Yulex Corporation of Maricopa, Ariz.

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