FDA: Complications increased with surgical mesh used in breast reconstruction

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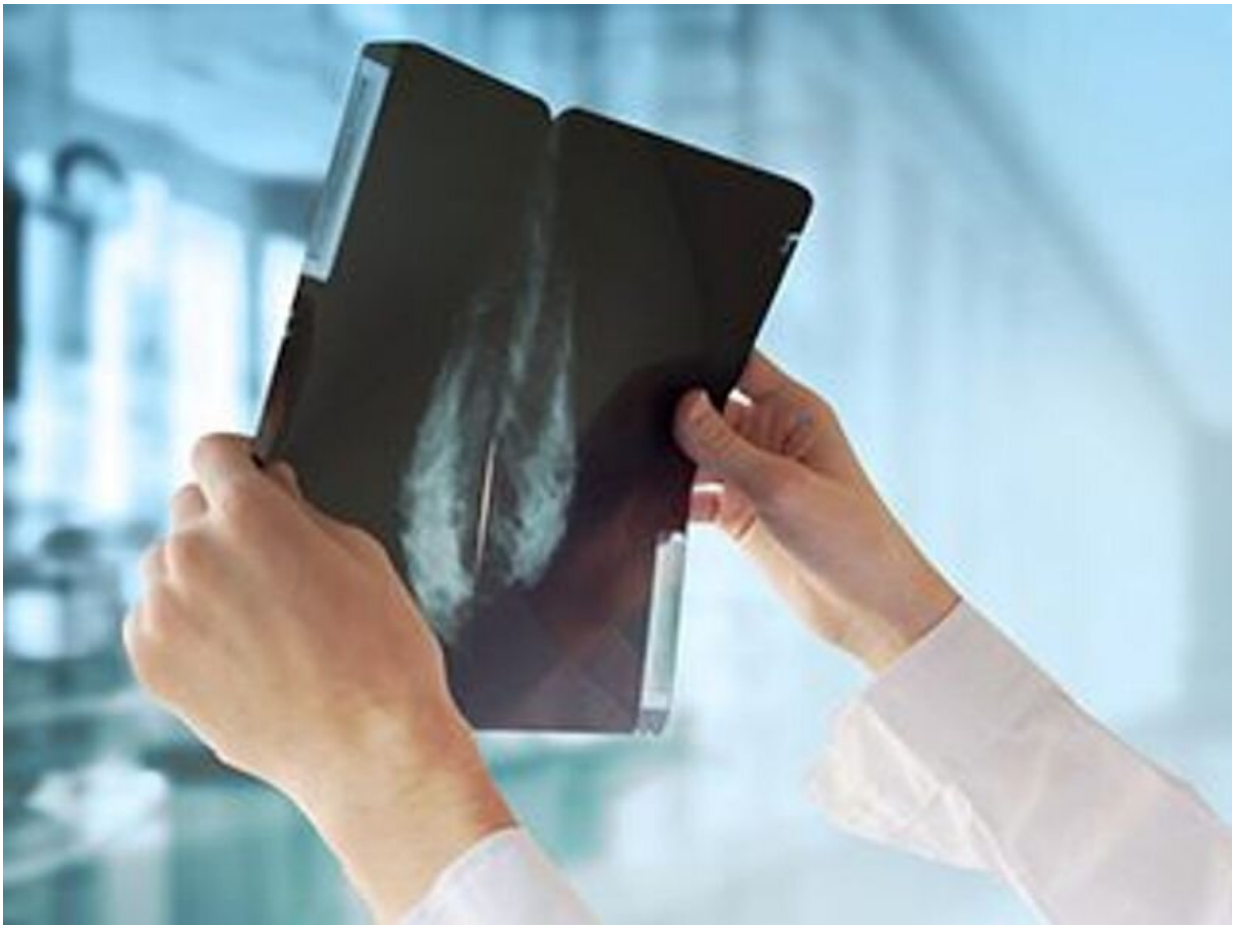

FlexHD and AlloMax brands of acellular surgical mesh products used in

breast implant reconstruction may pose a higher risk for complications and problems than other brands, the U.S. Food and Drug Administration said Wednesday.

The surgical mesh is developed from human or animal skin, where the cells are removed and the support structure is left in place.

An analysis of data from a study of outcomes in patients who had breast implant reconstruction after mastectomy revealed that those who received FlexHD and AlloMax brands had significantly higher rates of implant removal, reoperations, and infection within two years than those who received SurgiMend or AlloDerm brands or no surgical mesh, the FDA said in a safety communication.

"Over the past several years, the use of ADM [acellular dermal matrix] has increased and is now commonly used off-label in implant-based breast reconstruction," Binita Ashar, M.D., director of the Office of Surgical and Infection Control Devices at the FDA Center for Devices and Radiological Health, said in an agency news release. "We strongly encourage patients to discuss all the possible benefits and risks related to breast reconstruction procedures with their surgeon, including the pros and cons of the use of different brands of ADM."

More information: More Information