24 Hour Summary
General and Plastic Surgery Devices Panel
Advisory Committee Meeting
August 13, 2025

Introduction:

A virtual meeting of the General and Plastic Surgery Devices Panel of the Medical Device Advisory Committee was convened to discuss a new indication for use for dermal filler devices in the décolletage area and make recommendations regarding risks associated with new indications for use such as in the décolletage area, the potential impact of filler material on imaging studies and clinical exams (e.g., breast cancer screening), premarket and post-market study assessments for benefit and risk, removal of dermal filler implant material, and patient preference.

Device Description:

Dermal fillers are soft, moldable products, either synthetic or sourced from bacteria or animals, that are injected into tissue with the intent to create a smoother or fuller appearance in, or adjacent to, the injected area. The dermal filler products discussed in this Advisory Committee meeting are Class III medical devices identified with product code LMH (implant, dermal, for aesthetic use) or PKY (implant, dermal, for aesthetic use in the hands). These products may consist of material components (e.g., collagen, poly-L-lactic acid (PLLA), polymethylmethacrylate beads, calcium hydroxylapatite, and/or cross-linked hyaluronic acid) or may be combination products with an added drug constituent (e.g., lidocaine or mepivacaine).

Presentations:

The committee heard presentations from FDA regarding clinical and regulatory background on dermal fillers, benefits and risks of the use of dermal fillers in the décolletage area and incorporating patient preference information into benefit-risk determinations. Representatives of professional societies, including the American Academy of Dermatology Association, the American Society of Plastic Surgeons, the Aesthetic Society, and the American Society for Dermatologic Surgery Association were invited to present current perspectives on dermal filler risks and benefits with an emphasis on the décolletage area, removal of filler material, and patient preference information. In addition to these presentations, two device manufacturers of dermal filler devices presented their perspective on the use of dermal filler devices in the décolletage area. During the Open Public Hearing, the panel heard presentations from practicing physicians, a medical device manufacturer, and an advocacy

group. Topics covered included communication of risks to patients, approaches to preventing intravascular injection of dermal fillers, and clinical experience with dermal fillers in the décolletage area.

FDA Questions/Panel Deliberations:

Question 1: Patient-Specific Risk Factors and Subpopulations

The panel discussed recommendations for additional risks to be considered and specific subpopulations to be studied or excluded for décolletage injections.

Panel Recommendations:

The panel recommended the following subpopulations be excluded: women who are breastfeeding or pregnant, or individuals undergoing active cancer treatment. In addition, the panel recommended people who have had radiation in the chest area should be studied with appropriate precautions, as the impact of radiotherapy can vary for different patients. The panel also emphasized the need for a better definition of the décolletage anatomical area and recommended that injection into breast tissue should be excluded.

Question 2: Risk Mitigation Strategies

The panel discussed proposed mitigation strategies for risks unique to the décolletage anatomical location.

Panel Recommendations:

The panel agreed that requesting imaging in premarket studies is appropriate. If patients are at an age where breast cancer screening is recommended, they should have a mammogram or appropriate imaging before injection. The panel saw limited benefit to including representative images in labeling because factors such as timeframe of injection, volume of injection, and other considerations can impact the appearance of the material under imaging. Panel opinions on patient device cards were mixed. Device cards may provide some benefit; however, they may not impact the standard of care. Some panel members recommended post-approval studies for assessment of certain long-term adverse events. Additionally, if any study subject becomes pregnant during a clinical study, the panel recommended that follow-up data should be collected.

Question 3: Removal Options and Communication

The panel addressed how to evaluate benefit-risk profiles considering current removal options and how to communicate these to patients.

Panel Recommendations:

The panel noted that this issue is not specific to the décolletage and the considerations are not substantially different from those for other anatomical regions. The panel recommended that the labeling should clearly communicate that there are no FDA-approved products for dermal filler removal in language that is easy for patients to understand. They recommended

including reference to what strategies have been used to address adverse events associated with dermal fillers.

Question 4: Patient Preference Study Considerations

The panel discussed which key risks should be incorporated into patient preference studies.

Panel Recommendations:

The panel recommended that the most important risks to include are those related to screening for breast cancer. They also noted other risks to be considered, including: potential increases in associated financial costs and anxiety related to additional diagnostic or imaging procedures, lymphadenopathy, loss of bone density if dermal filler is injected adjacent to the periosteum, potential risks for pregnant and breastfeeding patients, and theoretical risks for malignancy. Finally, they emphasized the importance of representing risks and benefits in a fair and balanced manner in any potential future patient preference information (PPI) study.

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Transcripts:

Transcripts may be downloaded from the link below when they become available:
UPDATED MEETING TIME AND PUBLIC PARTICIPATION INFORMATION: August 13, 2025 General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee Meeting Announcement - 08/13/2025 | FDA

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