Discussion Questions

General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee

Dermal Filler General Issues

August 13, 2025

Décolletage refers to the area of the chest or cleavage between the breasts up to the collarbone. Beyond the anticipated adverse events of filler injections, dermal filler injection into the décolletage area include the following unique risks which are specific for this anatomic area:

a) Potential for dermal fillers to cause interference or other findings on breast cancer screening studies
b) Potential for positive findings during clinical examination
c) Proximity to breast tissue which may impact breast feeding and the lymphatic drainage system of the breast.

Panel Question 1:

The benefit risk profile of dermal filler devices for the décolletage indication may vary based on patient specific factors such as their risk for breast cancer, risk for scarring, or their age and potential to receive larger cumulative volumes over their lifetime.

a. Does the panel recommend additional risks to be considered for injection into the décolletage area?
b. Does the panel have recommendations about specific subpopulations to be studied or to be excluded because the benefits may never outweigh the risks?

Panel Question 2:

Given the risks unique to this anatomic location, FDA proposes the following additional criteria to be incorporated in the premarket and/or post-market mitigation strategies for the patient subpopulation that may be candidate for injection into the décolletage area:

a. To mitigate the risk of interference or other findings on breast cancer screening studies:
   - Collection of baseline imaging (e.g., mammogram, ultrasound, or MRI), preferably within 2 years prior to injection and post-injection imaging
   - Evaluation of imaging by committee with experience and expertise
   - Post-approval study if imaging evaluation was not included in premarket study
   - Inclusion of radiographic images of the implanted device in labeling
b. To mitigate the risk of potential positive findings during clinical examination:
   - Recommend device cards be provided to patients and included in patient records
   - Post-approval study to assess late-onset adverse events and their effects on clinical diagnosis
c. To mitigate the risk that proximity to breast tissue may impact breast feeding and the lymphatic drainage system of the breast:
   - Premarket follow-up until quiescence of inflammatory response
   - Post-approval study to evaluate effects on lactation and lymphatic system

Does the panel agree with the proposed strategies for risk mitigation?

Based on the risks discussed, does the panel recommend additional assessments or mitigations that should be considered and included?
Does the panel recommend this data be provided in the premarket study before approval to inform the patient in the labeling?
Does the panel have recommendations on assessment of long-term adverse events or the duration of follow-up of the patients?

Panel Question 3:
Currently, there are several approaches reported for treatment of adverse events after dermal filler injections such as aspiration/drainage, extrusion, excision, or enzymatic degradation. FDA has not approved any product indicated for enzymatic degradation or removal of dermal fillers. Does the panel have recommendations for how the benefit-risk profile for dermal fillers injected into the décolletage should be evaluated considering the current removal options? How should the available removal options for a specific device be communicated to patients in the labeling and other patient materials?

Panel Question 4:
A patient preference study may help inform FDA's benefit risk assessment as part of the premarket review of devices for this new indication. Considering the risks identified in the prior questions, which key risks would the panel recommend for incorporating into a patient preference study to estimate the maximum risk that patients would be willing to accept? In other words, are there specific risks that the panel is most concerned about given the potential benefit for this new indication?