⟨382⟩ Elastomeric Component Functional Suitability in Parenteral Product Packaging/Delivery Systems

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Expert Committee	Packaging and Distribution Expert Committee

In accordance with the Rules and Procedures of the Council of Experts, the General Chapters–Packaging and Distribution Expert Committee (PDEC) has revised *<382> Elastomeric Component Functional Suitability in Parenteral Product Packaging/Delivery Systems*. The purpose of this revision is to address the safety concerns raised by the FDA and to ensure alignment with regulatory expectations while allowing time for thorough data collection and analysis.

Background
On June 1, 2020, USP published the new general chapter *<382> Elastomeric Component Functional Suitability in Parenteral Product Packaging/Delivery Systems*. This chapter is scheduled to become official on December 1, 2025. In alignment with the scope of this new chapter the Expert Committee also recently proposed a revision to general chapter *<381> Elastomeric Components in Injectable Pharmaceutical Product Packaging/Delivery Systems* in *PF* 50(4) [Jul.–Aug. 2024] to remove section *4.3 Functionality Tests*, which includes information on fragmentation tests, as this topic is now covered as part of the scope of the new general chapter *<382>* under section *5.1 Fragmentation*.

Comments from the FDA
USP received public comments from the FDA on *<382>* and the proposed revisions to *<381>* indicating concerns with the impact of differences in the fragmentation test in *<382>* from the fragmentation test in *<381>*. The FDA also submitted letters to USP dated June 14 and July 30, 2024, in which they expressed specific concerns with section *5.1 Fragmentation* in *<382>*. These concerns are related to the increase in the particle size threshold for fragmentation detection in *<382>* (from 50 µm in *<381>* to 150 µm in *<382>*); a lack of sufficient supporting safety data was cited as the basis for this concern. Additionally, the FDA opposed broadening the acceptance criteria beyond NMT 5 for specific applications, stressing the need to maintain the 50-µm detection limit and to introduce microscopic examination along with an acceptance criterion of NMT 5 to ensure patient safety.

Revisions to <382>
In response to the recent FDA letters, the PDEC, which includes government liaisons from the FDA, has engaged in an extensive review of all the comments received on *<382>* and *<381>*. As an outcome of these deliberations, the Expert Committee revised the current to be official text of *<382>* to remove section *5.1 Fragmentation* from the general chapter before it becomes official on December 1, 2025. Removal of the test will provide additional time for USP to engage with industry stakeholders and elastomer suppliers to gather data and establish more appropriate particle detection limits and acceptance criteria.

Correspondingly, the Expert Committee did not adopt the proposed revision to remove section *4.3 Functionality Test* from *<381>*, which was published for comment in *PF* 50(4) [Jul.–Aug. 2024]. The revision to chapter *<381>* will become official on December 1, 2025, and will retain the fragmentation test but omit the penetrability and self-sealing capacity tests, which can be found in *<382>*.

Should you have any questions, please contact Desmond G. Hunt, Scientific Liaison to the General Chapters–Packaging and Distribution Expert Committee (301-816-8341 or dgh@usp.org).