Self-Sealing Polymer Technology:

Parker’s TechSeal Division offers extruded self-sealing septa which exhibit the ability to reseal themselves after multiple punctures by a medical syringe or needle.

These septa are manufactured from two of TechSeal’s materials with resealing properties: silicone S7577-45 and thermoplastic elastomer (TPE) JA571-45. These materials have passed the USP <381> functionality guidelines and are FDA white listed and USP Class VI, making them ideal for medical applications.

TechSeal’s septa made from S7577-45 and JA571-45 are easily penetrable by medical needles, highly resistant to coring or fragmentation, as well as resealable after several punctures. This sealing solution ensures leak free vials and eliminates concerns about sample contamination.

Product Features:

- FDA “white listed” materials
- USP Class VI certified compounds
- Resealability after several punctures
- No flash and parting lines
- Various compound durometers offered for easy piercing
- Custom engineered to fit each application design
- High volume supply capability
- Wide size range available
- Size adjustments with no tooling required
- Color matching available

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USP <381> Functionality Guidelines

USP <381> functionality guidelines - Elastomeric Closures for Injections - provides guidelines for testing the functionality of elastomeric septa in terms of penetrability, fragmentation, and self-sealing capacity.

Penetrability

Penetrability testing measures the amount of force required to puncture the septum with a needle. To pass the USP <381> guidelines, the force for piercing cannot exceed ten newtons (10N) for each closure.

The chart below represents the force required to puncture each of ten silicone septa during the test procedure.

![Penetrability Testing Results](chart)

<table>
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<th>Vial Number</th>
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<th>During puncture</th>
<th>After puncture</th>
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Fragmentation and Resealability

Fragmentation testing gauges the likelihood of the septum to break into small particles as a result of being penetrated. USP <381> requires that no more than five (5) fragments are visible after four injections.

Self-sealing capacity testing measures a septum’s ability to reseal itself after being punctured by a needle. The USP test requires a septum to be punctured ten (10) times without sample leakage.

The illustrations below exhibit the high resistance to coring as well as the self-sealing property of the septum.