



The Benefits of Frangible Seals in Diagnostic Point-of-Care Testing

Frangible seals enable the controlled release of reagents, eliminating the need for complex fluid handling systems while lowering costs and enhancing the performance of POC test devices.

October 8, 2014

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Changes in healthcare economics are clearly having an impact on point-of-care (POC) diagnostic testing. Market demand for remote testing is driving companies to develop easy-to-use platforms versus the moderately complex in vitro (IVD) tests that have historically been available. This shift will challenge IVD manufacturers to respond with cost-effective, accurate, precise, and rapid POC testing platforms in an expanding test menu that includes infectious disease, coagulation, cardiac disease, pregnancy and fertility, coagulation, and other critical-care markers. Among the technologies that will facilitate this transition are frangible seals.

In many near-patient testing environments, frangible seals can be used for reagent delivery, simplifying IVD platforms and testing processes for the user and manufacturer. This article examines the use and application of frangible seals in POC testing applications and explains how they meet the broadening and evolving needs of clinicians and patients.

Healthcare Delivery and Diagnostic Testing Trends

The continuing growth of POC IVD testing has been supported by technology improvements and the recognition that rapid test results offer economic and patient outcome benefits. At the same time, global and domestic changes in healthcare delivery are expanding opportunities for less complex testing devices and protocols in the areas of primary and preventive care. While the Affordable Care Act seeks to improve patient outcomes and lower costs, the expansion of urgent care centers, regional intermediate care facilities, and telemedicine are creating new demands that can be fulfilled by the development of innovative POC tests for screening patients and performing preventive medicine.

IVD blister card. (All photos courtesy of J-Pac Medical LLC)

POC testing offers a host of benefits. It eliminates the need to send test samples to a central facility, significantly reducing turnaround times and costs for both the patient and the healthcare provider. It can also simplify test processes, making them less complex, expanding their use to larger numbers of trained personnel, and increasing the accessibility and availability of tests to more patients. Moreover, POC testing enables the delivery of the right care to the right patient at the right time. As a result, it allows healthcare providers to operate more efficiently, reduces costs and risks, and increases patient satisfaction.

Frangible Seal Reservoirs

Frangible seal technology enables the controlled release of testing reagents, eliminating the need for complex fluid handling systems. Frangible sealed reservoirs use differential weld strengths that are designed to fail under specific pressures, allowing for a unit-of-use measure to be precisely delivered to a target well or reaction zone. The availability of many different materials enables manufacturers to develop custom form factors for a host of media, including powders; latex and magnetic beads; and aqueous, alcohol-based, and organic liquids. The resulting packaging is extremely stable and can be easily integrated into a variety of test platforms.

Because frangible seal reservoirs, or blisters, can lower costs while enhancing the performance and ease of use of POC test devices, they offer a range of benefits to manufacturers and patients alike.

Frangible seal reservoirs come in a variety of sizes and formats, enabling integration into existing form factors.

- The blisters can be easily customized to integrate into existing form factors as single blister units or multiple blister cards containing multiplex reagents. This capability reduces the number and cost of separate reagent bottles and applicators, lowering filling, packaging, and labeling costs.
- The reagents can be lot-matched on the device, eliminating potential confusion and reducing misuse by users of multiple lots.
- The reservoirs deliver the precise unit-of-use volume needed for the reaction, reducing waste and the risk of incorrect dispensing.
- The blisters can be designed to manually or automatically release reagents while eliminating partial or incomplete outcomes.
- Designed to control the release of reagents to a required location, blisters eliminate the risk of benchtop contamination and also enable device miniaturization.

- Featuring an environmentally friendly footprint, blister technology eliminates the need for companion reagent plastic bottles and can be disposed of as integrated units.
- The liquid volume of single-dose reagents in blister reservoirs can range from 30 to 5000 µl.
- Because blister reservoir materials prevent gas exchange, in contrast to onboard plastic bottles or messy drop applicators, they offer optimal protection and long-term stability.

Frangible seals are suitable for several IVD applications, including lateral-flow POC diagnostic formats, lab-on-a-chip and microfluidic platforms, and microbiology and molecular diagnostic applications.

Lateral Flow Formats. In lateral-flow devices, frangible seals can result in workflow improvements and faster test results. The reservoirs can be integrated into the card device, delivering exact unit-of-measure reagents precisely and accurately to the target area. This method is much easier than using bottled reagents. Furthermore, the ability to match onboard reagent lots reduces the total amount of packaging required, leading to more cost-effective, reproducible, and less complex devices.

Lab-on-a-Chip and Microfluidic Formats. Lab-on-a-chip and microfluidic devices can be easily integrated with single and multiple blister packs, providing precise and accurate delivery to small targets, chambers, and wells. Powders and beads, mixed reagents, aqueous buffers, organic solvents, and alcohols can be incorporated into blister technology.

Microbiology and Molecular Diagnostic Applications. Because of its aseptic fill process, blister packaging is finding increasing use in microbiology and molecular diagnostic applications. It also provides a low-evaporation, sterile barrier that increases stability and accessibility. Moreover, because it can control directional flow, this packaging reduces the likelihood of contamination, and the high-quality materials used to form the reservoirs support long-term storage and stability.

Improving POC Testing

Frangible seal technology has the potential to significantly impact the near-patient diagnostics market, enabling faster and more reliable test results for a variety of applications. Ultimately, it holds the promise of eliminating many costs associated with lab testing. Because reagent reservoirs in frangible form factors can be customized to affordably interface with many different diagnostic test platforms, diagnostics manufacturers can create new offerings without drastically changing their testing platforms. Burst pressure and pinpoint release of the reagent from the blister reservoirs can be designed into the blister shape for either manual or mechanical actuation. Accurate filling and dispensing by design—in single or multiplex formats—results in consistent and reproducible tests.

With healthcare delivery poised for rapid change, IVD companies have an opportunity to scrutinize their product portfolios and position themselves by developing innovative POC technologies. Among those technologies are frangible seals. Using frangible seals, POC platforms can provide accurate test results and help to eliminate the multistep lab process in which human error and instrument contamination are most likely to occur.

Example of a blister pack for use in POC diagnostic testing.



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Manufacturing processes are critical to part outcome and getting to market faster. It is important to consider key factors that will assist in improving upon your overall efficiency and production timing.

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