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In-line Fluid Sampling Without Contamination

TO ACHIEVE AND MAINTAIN THE OPTIMAL PERFORMANCE LEVELS ESSENtial in today's competitive market place, food processors must have intimate knowledge of their processes and a solid set of empirical data. Process sensors can obtain some of these data. However, data on sensory quality, nutritional composition or specific microbial contaminants usually require direct in-line sampling. Since any direct sampling method crosses the protective barrier of the process equipment, risk of contaminating the product stream with microorganisms exists. Direct in-line fluid sampling minimizes the risk of introducing microbial contaminants; the technology is equally suitable for adding small quantities of desired fluids to the process line.

Rigorous quality control requires routine process monitoring according to a sampling plan that places sample ports at critical control points after a cooling or pasteurization unit, or on storage tanks. If monitoring identifies bacterial contamination, quickly pinpointing the source minimizes disruption of the production process and revenue loss. Direct sampling at several locations within the process can significantly accelerate the search. Therefore, sampling ports that can be easily inserted into the existing piping system prove helpful.

The QMI Aseptic Sampler is available in clear silicone (left), or Black EPDM with seven (front) or 12 injection ports

For liquid materials, sampling cocks are currently the easiest way to collect samples. They're relatively cheap and easy to operate. However, the simple design impedes effective sanitizing, increases risk of microbial contamination of the sample or the process itself. More complex sampling valves are on the market that can be steam-sterilized between samples. These units are usually quite expensive and require a hard-plumed steam connection that prevents them from being moved easily to different locations within the process.

A cheaper, more flexible sampling alternative is to insert a disposable hypodermic needle with a syringe into a stainless steel-nipple covered by a septum. In its simplest form, the septum is a flat disk made of rubber-like materials. Unfortunately, flat septa can provide entry points for contamination, especially if the process lines to be sampled are operated under positive pressure. The positive pressure leads to septum bulging, which can leave needle holes open even after the needle has been retracted. This problem is exacerbated by the lack of needle guides, which often results in repeated piercing of the same area. Under these conditions, the content of the process line can leak onto the surface of the septum, where it provides a breeding ground for airborne, microbial contaminants. Eventually, colonies of these organisms can either grow through the open hole or contaminate a clean needle during subsequent sampling.

SAFE-SEPTUM DESIGN

Safe-Septum® technology is based on a radically different design intended to prevent the problems associated with the flat septum. The Safe-Septum system consists of three components: boot, needle guide and fitting. The plug-shaped Safe-Septum boot, made of Ethylene Propylene Diene Monomer (EPDM) or silicone, is non-coring and provides a completely aseptic barrier for needle insertion and withdrawal. The boot is free of the metal screens often used with flat septa to reduce bulging. They can break. The Safe-Septum—also known as QMI Aseptic Sampler—is available with seven or twelve injection ports (Fig. 1). A plastic or nylon needle guide covering the boot contains a series of holes corresponding to injection ports. The puncture created by a needle inserted through one of these holes will be completely separate and physically isolated from the others. The holes in the needle are covered by a thin plastic membrane that clearly indicates when an injection port has been used. Boot, needle guide, and membrane cover make up the Safe-Septum cartridge. They are shipped in pre-sterilized packages and inserted directly into the stainless-steel Safe-Septum fitting and are easily replaced. The fitting can be clamped, threaded or welded in place at the desired location. A very flexible solution for process lines is a Safe-Septum fitting welded to a triclamp (Fig. 2). Compression with a stainless steel screw collar secures the cartridge within the fitting and provides the force that seals needle penetration holes after the needle is retracted.

VALIDATION STUDY

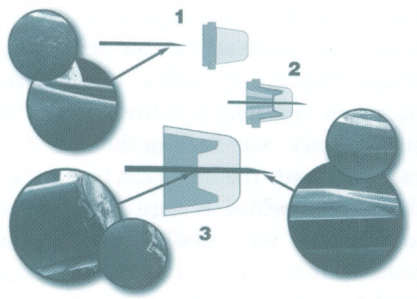
The effectiveness of the Safe-Septum technology was validated by the Biotechnology Institute of the University of Minnesota in St. Paul. The study tested the performance of an EPDM-made Safe-Septum under sub-optimal sampling conditions. For this purpose, the material transfer process across the Safe-Septum was challenged with unusually high levels of *Bacillus stearothermophilus*, which is widely accepted as a test organism for microbial contamination studies.

Safe-Septum was tested under four different operating conditions to reflect possible failure scenarios. First, the SOP described by the manufacturer served as the control condition. The septum surface was sanitized with dilute hypochlorite solution before collecting or injecting liquid with a sterile needle through the septum. Second, the septum surface, instead of being sani-

Table 1: Validation Study Results

Key:
S=Sterile
C=Contaminated

	TREATMENTS Septum	Needle	Media	RESULTS Replicate# 1 2 3
Safe-Septum®				
Condition 1 (Control, SOP)	Sanitized Sanitized	Sterile Sterile	Injected Withdrawn	S S S S S S
Condition 2 (Sanitation Failure)	Contaminated Contaminated	Sterile Sterile	Injected Withdrawn	S S S S S S
Condition 3 (Needle Failure)	Sanitized Sanitized	Sterile, then C Sterile, then C	Injected Withdrawn	S S S S S S
Condition 4 (Full Failure)	Contaminated Contaminated	Sterile, then C Sterile, then C	Injected Withdrawn	S S S S S S
Conventional Septum				
Condition 1 (Control, SOP)	Sanitized Sanitized	Sterile Sterile	Injected Withdrawn	S S S S S S
Condition 4 (Full Failure)	Contaminated Contaminated	Sterile, then C Sterile, then C	Injected Withdrawn	C C C S C S

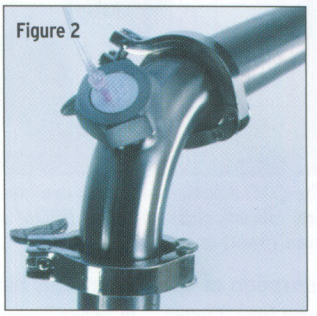


Pictures of a contaminated needle taken before and after penetrating a Safe-Septum show the bacteria are wiped off the needle completely (Figure 3).

tized, was swabbed with a suspension of *B. stearothermophilus* prior to mass transfer operations with a sterile needle (sanitation failure). Third, septum surface was sanitized according to SOP, but the needle was swabbed with the bacterial suspension (needle failure). Fourth, bothseptum surface and needle were contaminated with bacteria (full failure). As an additional comparison, the control condition and the full failure condition were also conducted with a conventional flat disk septum.

For each of the tests, Safe-Septa or conventional septa were affixed to the opening of six 1-liter stainless steel canisters, each filled with 200mL bacterial growth media (nutrient broth). Each unit was sterilized at 121°C for 35 minutes. Three of the canisters were injected with 5mL of sterile growth media and from the other three 5mL of media was withdrawn using a syringe with an 18-gauge needle. After the media transfer, the canisters were incubated in a shaker for three days at 60°C. Samples of the growth media from each canister were plated out on petri dishes with nutrient agar to determine if any of the canisters had become contaminated with *B. stearothermophilus.*

Figure 2



Of the eight conditions tested for the Safe-Septum, not one showed any contamination on the inside of the canister (see Table 1). In contrast, the conventional septum performed satisfactorily under SOP conditions, but, when challenged by full-failure conditions, showed contamination in all three injection canisters and in one of three withdrawal canisters. Under adverse sampling conditions, the Safe-Septum reliably protects the process content.

The Safe-Septum technology has been used in the dairy processing industry for aseptic sampling and material transfer such as the injection of starter cultures for more than 20 years. Used by dairy farms, juice producers, and mayonnaise manufacturers, the technology is appropriate for any fluid that can be transferred through a 14-gauge needle. The Safe-Septum is gaining popularity in research laboratories and the biopharmaceutical industry, where contamination avoidance has the highest priority. In all these applications, the Safe-Septum technology has proven to be an important tool for improving product quality and process performance.

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