

## Test Summary

The TAKEONE™ Aseptic Sampling System is designed for quick, reliable and safe aseptic sampling. High-quality aseptic sampling equipment should prevent unwanted contamination.

This report concludes that the TAKEONE™ Aseptic Sampling System maintains an aseptic barrier before, during and after sampling. TAKEONE™ prevents contamination from external organisms.

## Introduction

Pharmaceutical and biopharmaceutical drug manufacturers use routine sampling to assure that a drug product is safe, has the identity, strength, quality and purity characteristics it purports or is represented to possess. Equipment supporting good aseptic technique is used for sampling to reduce or eliminate the chance of contamination.



Information contained in the paper is important for upstream and downstream sampling and should prove useful to pharmaceutical and biopharmaceutical professionals working in development, pilot and commercial manufacturing — including Process Engineering, Process Technology, Quality Assurance, Quality Control and others.

This paper summarizes a study conducted at Harrisburg Area Community College confirming the aseptic properties of the patent-pending TAKEONE™ aseptic sampling system.

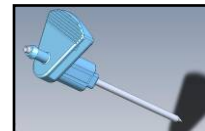
## Product Overview

TAKEONE™ is factory-assembled and gamma-irradiated. Each independent sampling mechanism resides inside a closed chamber of the TAKEONE™ body. Each chamber is sealed against a platinum-cured septum which is molded into the electropolished 316L stainless steel mount.



The device is installed on plant equipment via the mount. Internal surfaces and the fluid pathways of TAKEONE™ are sealed to remain free of external contaminants. Clean-in-place and steam-in-place procedures sterilize the mount.

The TAKEONE™ aseptic sampling system transfers fluid when one of the 2mm cannula is actuated, piercing the platinum-cured silicone septum. The fluid being sampled is communicated through the hole at the tip of the cannula for the length of the fully-contained sampling pathway (from needle, through tubing, to collection vessel).

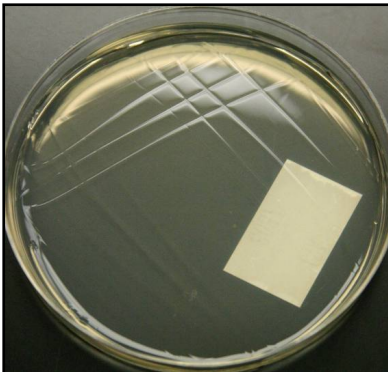
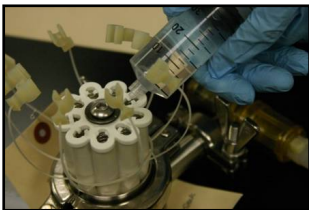


## Study Overview

The study questions if bacteria migrate across the pierced septa.

- TAKEONE™ units were built per AllPure Technologies standard operating procedures and gamma irradiated
- The units installed steamable piping assembly and steamed in place for 1 hour at 120°C and allowed to cool to ambient temperature.





Cultured plate from pipe assembly  
(no growth observed)

- c. The piping assembly was filled with sterile, nutrient-rich broth.
- d. All nine sampling lines were actuated, so each cannula pierced its septa.
- e. The actuator tabs were removed and a bacterial solution (*Brevundimonas diminuta*) was filled into each chamber of the TAKEONE™ body.
- f. The entire system was then incubated for 24 to 48 hours at 30°C to 32°C.
- g. Liquid from the chambers of the TAKEONE™ body and the piping assembly was plated on tryptic soy agar plates, incubated for 24-48 hours at 30°C to 32°C and observed for growth.

## Study Results

1. A control of bacterial solution plated on the tryptic soy agar plates showed bacterial growth.
2. All tryptic soy agar plates plated with liquid from the piping assembly showed no bacterial growth. (image below)

## Study Conclusion

No bacterial growth on the plates with liquid from the piping assembly concludes that bacteria do not travel across the pierced septa. These results confirm that the platinum-cured silicone septa maintain an aseptic barrier before, during and after actuation of the TAKEONE™ aseptic sampling system.

The TAKEONE™ aseptic sampling system should be considered acceptable for use in aseptic processes where establishing and maintaining a contaminant-free system is desired.

### **About AllPure**

AllPure Technologies, Inc. designs, manufactures and markets cutting-edge products for biopharmaceutical and pharmaceutical drug developers and manufacturers. AllPure operates in compliance with cGMP guidelines, where applicable. **You've Been Heard** is the company philosophy and is elemental to our products and services. You've Been Heard means engaging with our customers and partners to understand their challenges and helping them realize practical solutions. From enhancing operating efficiencies and perfecting process reliability to improving operator safety, AllPure launches sensible products.