

## Test Summary

The patent-pending QUICKSEAL™ aseptic tube separation system was designed to make aseptic sealing of thermoplastic and elastomeric tubing quick, reliable and safe. Key to its performance, the QUICKSEAL™ must prevent unwanted organisms from contaminating the fluids or space inside the sealed tubing.

This report concludes that that The QUICKSEAL™ aseptic tube separation system maintains an aseptic barrier preventing contamination from external organisms.

## Introduction

Pharmaceutical and biopharmaceutical manufacturers follow procedures and select equipment to ensure safety and purity. After a tube is used for fluid transfer, sampling or other processes, it often needs to be aseptically disconnected or isolated.

Aseptic technique is practiced to eliminate contamination events. Equipment used in the manufacturing process is relied upon to promote good aseptic technique.

This paper summarizes a study conducted at Harrisburg Area Community College confirming the aseptic sealing properties of the patent-pending QUICKSEAL™ aseptic tube separation system. This white paper should be reviewed by pharmaceutical and biopharmaceutical professionals working in development, pilot and commercial manufacturing; including Process Engineering, Process Technology, Quality Assurance, Quality Control and others.

## Product Overview

In pursuit of efficient operations, manufacturing professionals seek a balance between reliability, low cost and ease of use when selecting aseptic tube separation or disconnection techniques. The QUICKSEAL™ aseptic tube separation system is this ideal balance.

The QUICKSEAL™ collar is molded to the thermoplastic or elastomeric tubes (C-Flex® or platinum-cured silicone). These materials, or their close relatives, represent almost the entire flexible tubing market, making QUICKSEAL™ applicable to nearly every application.



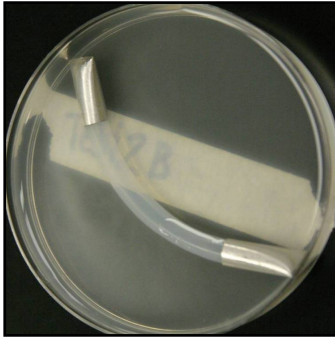
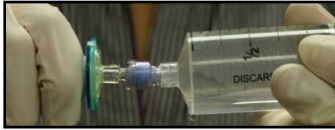
Using the simple and robust QUICKSEAL™ cutter, operators simply cut the collar to make the aseptic tube separation. The cutting action compresses the collar and squeezes the tube shut, creating a seal. Burst tests conclude this seal is stronger than the tubing itself. QUICKSEAL™ yields successful cuts if the tube is filled with either air or liquid.



Molding the metallic QUICKSEAL™ collar to the tubing is unique and proprietary to AllPure Technologies. If not molded to the tubing, the collar would need to be otherwise secured, usually by crimping, so that a cut collar does not pull off.

## Study Overview

The study tests if bacteria migrate across a cut collar.

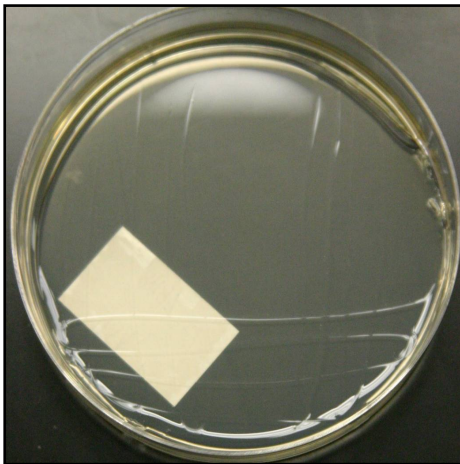


Immersed tubing after incubation

- Tube sections with two QUICKSEAL™ collars and sterilizing-grade filters installed on ends were built per AllPure Technologies standard operating procedures.
- The units were gamma-irradiated.
- Nutrient-rich broth was sterile filtered into the tubing sections and the collars were cut, creating a short length of tubing filled with the broth.
- The tubing lengths were then immersed in a bacterial solution (*Brevundimonas diminuta*) and incubated for 24 to 48 hours at 30°C to 32°C.
- The liquid in the tubes were plated on tryptic soy agar plates, incubated for 24-48 hours at 30°C to 32°C and observed for growth.

## Study Results

- All tryptic soy agar plates plated with liquid from the tubing assembly showed no bacterial growth. (image below)



### ***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.

## Study Conclusion

No bacterial growth on the plates with liquid from the tubing assembly concludes that bacteria do not travel across the cut collar. These results confirm that the cut QUICKSEAL™ collar maintains an aseptic barrier.

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