

Test Summary

The patent-pending QUICKSEAL[®] aseptic tube separation system makes aseptic sealing of thermoplastic and elastomeric tubing quick, reliable and safe. Aseptic disconnects shall maintain a sterile barrier after disconnect.

The devices evaluated were:

1. filled with sterile broth
2. sealed with QUICKSEAL[®]
3. immersed in bacterial solution
4. fluid was plated, incubated & observed for growth

The acceptance criteria is **no growth observed** after plating on nutrient media and incubation.

This study concludes that the QUICKSEAL[®] aseptic tube separation system maintains an aseptic barrier preventing contamination from external organisms.

Product Overview

QUICKSEAL[®] aseptic tube sealing balances reliability, low cost and ease of use. QUICKSEAL[®] makes aseptic seals in seconds on ranging tube sizes and materials.

The QUICKSEAL[®] collar is molded to thermoplastic or elastomeric tubes (C-Flex[®] or platinum-cured silicone, for example).

The QUICKSEAL[®] cutter compresses the collar and tubing to create a sterile seal. Seals can be made on wet or dry tubes.

AllPure's proprietary molding of the metallic QUICKSEAL[®] collar to the tubing bypasses the need for secondary or simultaneous crimping operations. The result is a simply executed and unambiguous aseptic seal.



Study Overview

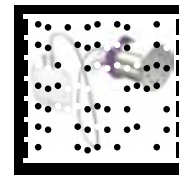
The purpose of this protocol is to evaluate the adequacy of a cut QUICKSEAL[®] collar in maintaining a sterile barrier. Integrity is tested by immersing tubes with sealed QUICKSEAL[®] collars into a bacterial solution (*Brevundimonas diminuta*). The tubes were filled with sterile medium supportive of bacterial growth. During immersion the system is cycled between positive 15psig and negative 10psig.

Fluid from the sealed tubing is plated, in triplicate, on soybean casein digest agar (SCDA), incubated for 7 days and observed for growth of organisms as indicated by colony forming units (CFU).

The scope of this test is limited seals at ambient conditions on silicone & C-Flex[®] tubing. Tubes have outer diameters of 1/4" and 5/8".

What's this?

Scan the image
with your **smartphone**
to see this report animated!



get the free app at
<http://gettag.mobi>
or visit

www.youtube.com/user/allpure01

You've been heard

AllPure Technologies Inc.

80 Progress Ave New Oxford PA 17350

t 717.624.3241 f 717.624.3051

www.AllPureInc.com

Study Results

Description	Observation
C-Flex® 1/4" OD	<i>No growth observed</i>
C-Flex® 5/8" OD	<i>No growth observed</i>
Silicone 1/4" OD	<i>No growth observed</i>
Silicone 5/8" OD	<i>No growth observed</i>



Study Conclusion

The **QUICKSEAL** aseptic tube sealing system creates an aseptic seal on elastomeric tubing.

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.