QUICKSEAL® Aseptic Tube Sealing Container Closure Study/ Bacterial Immersion – Freeze/Thaw

AllPure® Technologies, Inc.

Test Report Summary

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. placed in a freezer at -60°C to -100°C
4. thawed
5. immersed in bacterial solution
6. 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 after freeze/thaw cycle preventing contamination from external organisms.

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

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 after the system has been frozen and thawed. 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. After cutting the QUICKSEAL® collar the tubes were placed in a freezer at -60°C to -100°C for 48 hours. 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 performed at ambient conditions. Sealed tubes are frozen and thawed. The silicone & C-Flex® tubes have outer diameters of 1/4" and 5/8".

You've been heard

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Study Results

Description	Observation
C-Flex® 1/4″ OD	*No growth observed*
C-Flex® 5/8″ OD	*No growth observed*
Silicone 1/4″ OD	*No growth observed*
Silicone 5/8″ OD	*No growth observed*

Study Conclusion

The QUICKSEAL® aseptic tube sealing system maintains an aseptic seal after freezing to -100C and thawing."

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.

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C-Flex® is a registered trademark of Saint-Gobain.