sartorius stedim biotech

# Validation Guide
# QUICKSEAL® Aseptic Disconnections

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# Table of Contents


| | | |
|---|---|---|
| **1.** | **Introduction** | **4** |
| 1.1 | Product Description | 4 |
| 1.2 | Scope Statement | 5 |
| 1.3 | Security of Supply | 5 |
| 1.4 | Manufacturing Resources | 5 |
| 1.5 | cGMP Quality Assurance | 5 |
| 1.6 | Gamma Irradiation | 5 |
| 1.7 | Validation Test Summary | 6 |
| **2.** | **Production and Quality** | **8** |
| 2.1 | Personnel | 8 |
| 2.2 | Facilities | 8 |
| 2.3. | Supply Chain | 8 |
| 2.3.1 | Supplier Evaluation & Qualification | 8 |
| 2.3.2 | Component & Raw Material Qualification | 8 |
| 2.3.3 | Incoming Quality Controls | 8 |
| **3.** | **Production** | **9** |
| 3.1 | Equipment Qualification | 9 |
| 3.2 | Production Environment | 9 |
| 3.2.1 | Viable Organism Control and Monitoring | 9 |
| 3.2.2 | Non-viable Control and Monitoring | 9 |
| 3.3 | Material Receipt | 9 |
| 3.4 | Traceability & Batch Control | 10 |
| 3.5 | In-Process & Product Release Controls | 10 |
| **4.** | **QUICKSEAL® Product Properties** | **11** |
| 4.1 | QUICKSEAL® Structure | 11 |
| 4.1.1 | Silicone QUICKSEAL® | 11 |
| 4.1.2 | TPE QUICKSEAL® | 11 |
| 4.2 | QUICKSEAL® Shelf-Life | 12 |
| 4.2.1 | QUICKSEAL® on Thermoplastic Elastomer Tubing | 12 |
| 4.2.2 | QUICKSEAL® on Platinum-Cured Silicone Tubing | 12 |
| 4.3 | QUICKSEAL® Product Sizes | 13 |
| 4.4 | Collar Dimensions | 13 |
| 4.5 | Properties | 13 |
| 4.5.1 | Disconnection Qualification | 13 |
| 4.5.2 | Push-Pull Test | 14 |
| 4.5.3 | Burst Testing | 15 |
| 4.5.4 | Tensile Strength Test | 16 |
| 4.5.5 | Bacterial Challenge Testing\|Container Closure | 17 |
| 4.5.6 | Low Temperature Bacterial Challenge Testing\|Container Closure | 18 |
| **5.** | **Leachables & Extractables** | **19** |
| **6.** | **QUICKSEAL® Cutting Tools** | **20** |
| 6.1 | Large Diameter QUICKSEAL® Cutting Tool | 20 |
| 6.2 | Small Diameter QUICKSEAL® Cutting Tool | 20 |
| **7.** | **QUICKSEAL® Protective Caps** | **21** |
| 7.1 | Installation | 21 |

# 1. Introduction

QUICKSEAL® aseptic disconnect is a component of an assembly that may be used in a variety of process areas for and in support of the discovery, development and clinical or commercial production of drug products such as vaccines, recombinant proteins and monoclonal antibodies.

QUICKSEAL® aseptic disconnect components are qualified, manufactured and released under a Quality Control system which is compliant to the key principles of cGMP.

Validation, as used in these guidelines, comprises the systematic testing of essential production steps and production equipment including testing and inspection of final products with the goal of ensuring that the finished products can be reliably and reproducibly manufactured in respect with the established production and quality control procedures.

We have compiled this validation guide so that users of QUICKSEAL® aseptic disconnect can plan, implement and document their own validation procedures.

## 1.1 Product Description

QUICKSEAL® reduces operating time and improves reliability for biopharmaceutical and other high-purity fluid handling industries.

The QUICKSEAL® aseptic disconnect are used after fluid transfer to disconnect single-use transfer lines and bag assemblies used in biopharmaceutical applications. QUICKSEAL® aseptic disconnect provide aseptic disconnection in non-classified and classified environments while maintaining product sterility.

QUICKSEAL® can be included as a component on single-use tube, bag or bottle assemblies, sampling manifolds, single-use bioreactors and more.

QUICKSEAL® can be installed on a variety of tube materials across a range of tube sizes. The tubing runs continuously through the collar for an uninterrupted fluid path.

## 1.2 Scope Statement

The validation contained in this guide applies, unless otherwise noted to the following tubing materials:

**Platinum-cured Silicone**

| | |
|---|---|
| Watson-Marlow | Pumpsil® |
| Dow Corning | Dow Pharma-50 |
| St. Gobain | STHT®-C |
| AdvantaPure | AdvantaSil™ |

**Thermoplastic Elastomer**

| | |
|---|---|
| St. Gobain | C-Flex® |
| AdvantaPure | AdvantaFlex® |
| St. Gobain | Pharmed® |
| Watson-Marlow | Bioprene® |

Please contact us for an evaluation or confirmation of alternative tubings.

This Validation Guide is applicable for both QUICKSEAL® aseptic disconnect sold as a standalone product and pre-assembled on Sartorius Stedim fluid management systems.

Wherever possible, Sartorius refers to our supplier's product validation documentation. Supplier documentation is available upon request or by contacting the supplier directly.

## 1.3 Security of Supply

Assurance and security of supply is a significant market requirement for QUICKSEAL® aseptic disconnect. The robustness of our supply chain relies on effective supplier management, multiple manufacturing sites with consistent industrial and quality processes, process automation, application of lean manufacturing practices, expertise for designing fluid management systems, close collaborative relationships with customers and senior management's strong commitment to continuous and dynamic improvement.

## 1.4 Manufacturing Resources

Sartorius Stedim Biotech's manufacturing resources for QUICKSEAL® aseptic disconnect operate under strictly controlled manufacturing procedures and quality system.

New Oxford, Pennsylvania –
United States of America
80 Progress Avenue
New Oxford, PA 19460

**Total Facility Size:**

- 17,000 $ft^2$
- ISO 7 Manufacturing & Raw Materials: 3,100 $ft^2$

**Manufacturing Competencies**

- QUICKSEAL® Manufacturing
- Subcomponent assembly
- Final assembly
- Packaging & Labelling

## 1.5 cGMP Quality Assurance

Our documented quality system is consistent with industry-recognized quality standards including the following:

The FDA current Good Manufacturing Practices (cGMPs)

**Note:**
Sartorius is not a manufacturer of finished pharmaceuticals or finished medical devices, yet we have chosen to align our quality system clauses of 21 CFR Parts 210, 211 and 820 that apply to our processes and products.

These quality system processes direct and inform our entire quality system and all the procedures, work instructions, forms, etc. contained therein:

- Management Responsibility & Review
- Document Control
- Records Control & Retention
- Corrective & Preventive Action
- Internal Auditing
- Personnel Training & Competency
- Customer Notification & Recall

## 1.6 Gamma Irradiation

QUICKSEAL® aseptic disconnect is suitable for gamma irradiation up to 50 kGy.

QUICKSEAL® aseptic disconnect is a component included on multi-component assemblies which have been validated to Sterility Assurance Level (SAL) $10^{-6}$ per ISO11137.

## 1.7 Validation Test Summary

### Qualification Tests

- Disconnection (0 – 2 bar)
- Push-Pull Test (after disconnect)
- Burst Test (after disconnect)
- Tensile Pull Test (after disconnect)
- Microbial Ingress (after disconnect)

Material Tests
(tubing dependent)
- USP 87
- USP 88
- USP 85
- USP 661
- USP 381
- USP 788
- 21CFR177.2600
- TSE|BSE risk
- REACH
- Melamine
- Bisphenol A

### Monitoring Tests

- Particulate control
  - ISO 14644-1: Cleanrooms and associated controlled environments
  - Classification of air cleanliness by particle concentration
- Bioburden & Sterility
  - ISO 14698: Cleanrooms and associated controlled environments – Biocontamination control

### Lot Release Tests

- 100% Visual inspection
  - Visible particulate
  - Component defects
- Compliance to technical drawing|specification
- Packaging and labeling

QUICKSEAL® aseptic disconnect does not introduce a new fluid contact surface so many validation properties are carried-over from validation testing performed on the tubing by the tubing manufacturer. Some material validation information from our tubing suppliers is confidential – Sartorius suggests contacting the tubing supplier directly for tubing material information.

| Tubing Supplier | Tubing Brand | USP 87 | USP 88 | USP 85 | USP 661 | USP 381 | 21CFR177.2600 | USP 788 |
|---|---|---|---|---|---|---|---|---|
| Watson-Marlow | Pumpsil® | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| Dow Corning | Dow Pharma-50 | Yes | Yes | - | Yes | Yes | Yes | Yes |
| St. Gobain | STHT-C® | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| AdvantaPure | AdvantaSil™ | Yes | Yes | Yes | Yes | Yes | Yes | - |

| Tubing Supplier | Tubing Brand | USP 87 | USP 88 | USP 85 | USP 661 | USP 381 | 21CFR177.2600 |
|---|---|---|---|---|---|---|---|
| St. Gobain | C-Flex® | Yes | Yes | Yes | Yes | Yes | Yes |
| AdvantaPure | AdvantaFlex® | Yes | Yes | Yes | Yes | Yes | Yes |
| St. Gobain | Pharmed® | - | Yes | Yes | - | Yes | Yes |
| Watson-Marlow | Bioprene® | Yes | Yes | Yes | Yes | Yes | Yes |

# 2. Production and Quality

**2.1 Personnel**

Sartorius Stedim Biotech recognizes that human resources and personnel competency are of utmost importance and have therefore established a comprehensive human resources management program. Stringent selection, motivation, initial and continuous training and qualification of personnel at all levels of the company assure that every employee is at his or her best at all times for each step of the manufacturing and control processes. Comprehensive training records are kept for all employees.

**2.2 Facilities**

The buildings, equipment and work environment at Sartorius Stedim Biotech have been designed to maximize employee comfort and safety while complying with the key principles of GMP for the manufacture of QUICKSEAL® aseptic disconnect destined to the pharmaceutical industry. All infrastructure (equipment, utilities, etc.) that has an impact on the product quality is inventoried and undergoes an appropriate qualification, calibration and maintenance.

**2.3. Supply Chain**

**2.3.1 Supplier Evaluation & Qualification**

Suppliers are carefully selected according to internal standards and applicable regulations. Typical requirements for suppliers are the following (not exhaustive list):

- Quality Control System
- Quality Assurance System
- Facility & Cleanroom Controls
- Product|Component Lot Traceability System
- Change Notification Procedures

Suppliers are evaluated and approved according to internal standards.

**2.3.2 Component & Raw Material Qualification**

Each raw material and|or component is qualified. This qualification includes a list of required statements from the supplier that is dependent on the final use of the component and|or raw material. Typical requirements for components that are in contact with the product flow are the following (not exhaustive list):

- USP Class VI and|or ISO10993 conformity
- TSE|BSE statement
- EP conformity (if applicable)
- Change notification statement
- REACH Compliance
- Bisphenol A free

Beyond these requirements, Sartorius Stedim Biotech may perform qualification of the proposed component and|or raw material internally.

For raw materials, the internal qualification will include physical performance of the component made with this raw material.

For components, the qualification will be centered on the testing of the assembly of the new component with other components that will be attached.

**2.3.3 Incoming Quality Controls**

All raw materials, components and sub-contracted products are inspected upon arrival at Sartorius Stedim Biotech against approved control specifications. Typical testing requirements applied at incoming quality inspection are (not exhaustive list):

- Supplier documentation controls (Certificates)
- Packaging identification and integrity
- Visual inspection
- Dimensional check

Only approved materials will be allowed to be used in production of QUICKSEAL® aseptic disconnect. Approved materials are recorded in Sartorius Stedim Biotech's inventory and quality management system and labeled with an internal lot number and designated internal part number and released for use.

# 3. Production

### 3.1 Equipment Qualification

All equipment used in production goes through qualification that includes Installation Qualification, Operational Qualification and Performance Qualification. This qualification effort is carried out by a multidisciplinary team and follows the rules described in the corresponding procedure in our Quality System.

Equipment undergoes its applicable calibration schedule according to the calibration plan described in our Quality System.

### 3.2 Production Environment

Product manufacturing occurs in an ISO 7 (Class 100,000 cleanroom) per ISO 14644-1 and in accordance with the key principles of cGMPs.

Contact us for further details or precise questions about our quality and operating systems or to schedule an on-site audit.

#### 3.2.1 Viable Organism Control and Monitoring

In addition to line clearance and weekly cleaning of equipment and work surfaces, monthly cleaning of the cleanroom with a schedule of LpH®, Vesphene® and Spor-Klenz® occurs per our Cleanroom Management and Cleaning procedures.

Viable organisms are measured quarterly to monitor the effectiveness of the cleanroom Management and Cleaning procedures and to be compliant to EU GMPs and ISO14698. As of the drafting of this document, viable monitoring is up-to-date:

Air Viables < 100 CFU
Surface Viables < 25 CFU
Wall Viables < 5 CFU

#### 3.2.2 Non-viable Control and Monitoring

Line clearance, weekly cleaning of equipment and work surfaces and monthly cleaning of the cleanroom reduce and control non-viable particles.

Non-viable readings are recorded weekly to ensure 0.5 $\mu m/m^3$ and 5.0 $\mu m/m^3$ particles are within the ISO Class 7 acceptance criteria, per ISO 14644-1.

### 3.3 Material Receipt

Components received at New Oxford arrive in two forms; double-bagged and clean or bulk-packed. Double-bagged and clean materials (tubing, for example) are received into our Class 7 cleanroom per incoming inspection and testing procedures.

Bulk-packed items are cleaned and transferred into the cleanroom per incoming inspection and testing procedures.

## 3.4 Traceability & Batch Control

Sartorius Stedim Biotech has a process and maintains an effective traceability system which can be used in the event of product, component or manufacturing issue to alert impacted customers.

Generally, all finished assemblies are composed of components and subassemblies. Subassemblies are built from components or subassemblies. Components are parts that are purchased or manufactured by Sartorius Stedim. Each component and subassembly has a unique part number. All components and subassemblies are assigned a unique lot number upon receipt or manufacture|assembly. The lot number is recorded in batch records and maintained in our traceability system.

Batch records provide the operators all the necessary instructions and component and subassembly list to execute the designated procedure. Operators fill in batch records including recording lot number of components and subassemblies. This data is also entered into the traceability system.

The traceability system and batch record system links all manufacturing steps, components and subassemblies to the final assembly, allowing for complete backward and forward traceability of every assembled product.

## 3.5 In-Process & Product Release Controls

Quality controls are performed at various stages during the manufacturing process. Some of these controls are listed below. Other specific controls dependent on the specific application of the products may be performed but are not listed.

- Product conformity against technical drawing or specifications
- Visual inspection (particles or contamination, correctness assembly, etc.)
- Product packaging controls
- Product labeling controls

After production, every batch of finished products is released by Quality Assurance before it can be shipped. The release will be documented in the batch record and in the traceability system.

The system for product release is constructed in such a way that only batches that have been released by quality can have the corresponding shipping and billing documents.

A Certificate of Release is issued for each batch of finished product that is shipped from Sartorius Stedim Biotech.

# 4. QUICKSEAL® Product Properties

## 4.1 QUICKSEAL® Structure

QUICKSEAL® aseptic disconnect is an aluminum (3003) collar bonded to a length of elastomeric tubing. The tubing runs continuously through the QUICKSEAL® collar for an uninterrupted fluid-pathway. A QUICKSEAL® cutting tool cuts and compresses the collar, squeezing the walls of the tubing together to create a mechanical seal. The cut collar maintains compression of the tubing to retain the closure.

QUICKSEAL® aseptic disconnect is commercially available on a variety of platinum-cured silicone and thermoplastic elastomer (TPE) tubing.

### 4.1.1 Silicone QUICKSEAL®

The QUICKSEAL® collar is bonded to the tubing using a platinum-curable liquid silicone. The liquid silicone undergoes a crosslinking or vulcanization reaction which produces a three dimensional network of silicone chains which are rendered insoluble, intractable, and infusible. A heat cycle accelerates curing between the collar and the tubing, as is the case of silicone.

The composition of the liquid silicone adhesive is:

- 99.95 wt % Elastosil® LR3003/50 A,B platinum-cured silicone
- 0.05 wt % multifunctional silane coupling agent

The silane coupling agent achieves adhesion between the silicone tubing and the aluminum collar. This compound has dual functionality: silanol groups and vinyl groups.

The methoxy groups hydrolyze to form silanol groups which react with hydroxyl groups on the surface of the aluminum, thus attaching the adhesive to the aluminum, as well as hydroxyl groups on the silicone tubing, thus covalently attaching to the tubing. This hydrolysis reaction occurs above 125 °C and occurs when the aluminum collar is attached to the silicone tubing.

The second functionality of the silane coupling agent is that of a double bond which hydrosilylates into the vulcanizing adhesive along with the vinyl groups which are on the ends of the base polymer. Thus, the silane coupling agent reacts to all three materials: the aluminum collar, the silicone tubing, and to the adhesive itself.

### 4.1.2 TPE QUICKSEAL®

The QUICKSEAL® collar is bonded to the TPE tubing using a thermoplastic tie layer. The tie layer has block copolymer composition which microphase separates into functional domains:

- For adhesion with the backbone of the block copolymer of the TPE (eg. Styrene isobutylene styrene).
- For adhesion to the oxide functionality of the aluminum QUICKSEAL® collar.

The heat cycle applied during QUICKSEAL® manufacture melts the tie layer to fuse together the TPE tubing and the aluminum collar, creating a durable bond without solvent based adhesives.

## 4.2 QUICKSEAL® Shelf-Life

### 4.2.1 Non-Irradiated QUICKSEAL®

Section 4.1 describes the structure of QUICKSEAL® and demonstrates that the addition of the QUICKSEAL® collar makes no significant change to the tubing material.

As such, the QUICKSEAL® assembly carries the remaining shelf-life of the tubing material. Tube materials described in this validation guide arrive at Sartorius' site with 5 year shelf-life. Sartorius' inventory management procedures ensure the tubing is converted into QUICKSEAL® asembly within 2 years of receipt.

Thus, non-irradiated QUICKSEAL® assemblies have a shelf-life of 3 years.

### 4.2.2 Gamma Irradiated QUICKSEAL®

Section 4.4 describes the validation testing of critical performance attributes of QUICKSEAL® after gamma irradiation (50 kGy) and aging to 3 years.

All critical attributes were met. Shelf-life of QUICKSEAL® assemblies after irradiation to 50 kGy is 3 years.

## 4.3 QUICKSEAL® Product Sizes

| Tube Size (outer diameter) | Inches | 1/8 | 3/16 | 1/4 | 3/8 | 7/16 | 1/2 | 5/8 | 3/4 | 1 | 1 1/8 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | mm | ≈ 3.2 | ≈ 4.8 | ≈ 6.4 | ≈ 9.6 | ≈ 11.1 | ≈ 12.7 | ≈ 15.9 | ≈ 19.0 | ≈ 25.4 | ≈ 28.6 |

## 4.4 QUICKSEAL® Collar Dimensions

| | | QUICKSEAL® | QUICKSEAL® |
|---|---|---|---|
| | **Tube Size (o.d.)** | **Collar Size (o.d.)** | **Collar Length** |
| **1/4" QUICKSEAL®** | 1/4" | 0.281" | 1.500" |
| **3/8" QUICKSEAL®** | 3/8" | 0.435" | 2.000" |
| **7/16" QUICKSEAL®** | 7/16" | 0.498" | 2.125" |
| **1/2" QUICKSEAL®** | 1/2" | 0.573" | 2.250" |
| **5/8" QUICKSEAL®** | 5/8" | 0.700" | 2.500" |
| **3/4" QUICKSEAL®** | 3/4" | 0.835" | 3.000" |
| **1" QUICKSEAL®** | 1" | 1.091" | 3.500" |
| **1 1/8" QUICKSEAL®** | 1 1/8" | 1.220" | 4.000" |

## 4.5 Properties

### 4.5.1 Disconnection Qualification

Sartorius performed evaluation of the disconnection of QUICKSEAL® under various conditions. All assemblies were filled with water and installed to a rig so that pressure in the tubing could be controlled. The cut collar was inspected for water leaks during disconnection and blotted on absorbent paper after disconnection.

Passing results achieved if no leaks are noted and no moisture is observed on absorbent paper.

| | Aging | Gamma Irradiation | Autoclave (2 × 134 °C, 30 min) | Pressure at Disconnection [bar] | Pass\|Fail |
|---|---|---|---|---|---|
| **Platinum-Cured Silicone** | No | No | No | Ambient, 0.5, 1.0, 1.5, 2.0 | Pass |
| **Platinum-Cured Silicone** | No | 50 kGy | Yes | Ambient, 0.5, 1.0, 1.5, 2.0 | Pass |
| **Platinum-Cured Silicone** | 12 months | 50 kGy | Yes | Ambient, 0.5, 1.0, 1.5, 2.0 | Pass |
| **Platinum-Cured Silicone** | 18 months | 50kGy | Yes | Ambient, 0.5, 1.0, 1.5, 2.0 | Pass |
| **C-Flex® TPE** | No | No | No | Ambient, 0.5, 1.0, 1.5, 2.0 | Pass |
| **C-Flex® TPE** | No | 50 kGy | No | Ambient, 0.5, 1.0, 1.5, 2.0 | Pass |
| **C-Flex® TPE** | 12 months | 50 kGy | No | Ambient, 0.5, 1.0, 1.5, 2.0 | Pass |
| **C-Flex® TPE** | 18 months | 50 kGy | No | Ambient, 0.5, 1.0, 1.5, 2.0 | Pass |

### 4.5.2 Push-Pull Test

Sartorius performed evaluation of the disconnected of QUICKSEAL® under various conditions. All assemblies were filled with water and disconnection was performed. The tubing assembly with cut collar was manipulated by hand including bending the tubing and pushing and pulling at the cut collar. Pressure was increased and manipulations repeated.

Passing results achieved if no leaks were observed.

| | Aging | Gamma Irradiation | Autoclave (2 × 134 °C, 30 min) | Pressure at Push\|Pull [bar] | Pass\|Fail |
|---|---|---|---|---|---|
| **Platinum-Cured Silicone** | No | No | No | Ambient, 0.5, 1.0, 1.5, 2.0 | Pass |
| **Platinum-Cured Silicone** | No | 50 kGy | Yes | Ambient, 0.5, 1.0, 1.5, 2.0 | Pass |
| **Platinum-Cured Silicone** | 6 months (after disconnect) Ambient Temp | 50 kGy | Yes | Ambient, 0.5, 1.0, 1.5, 2.0 | Pass |
| **Platinum-Cured Silicone** | 6 months (after disconnect) 5.7 °C | 50 kGy | Yes | Ambient, 0.5, 1.0, 1.5, 2.0 | Pass |
| **Platinum-Cured Silicone** | 12 months uncut + 6 months after disconnect (accelerated) | 50 kGy | Yes | Ambient, 0.5, 1.0, 1.5, 2.0 | Pass |
| **Platinum-Cured Silicone** | 36 months uncut + 6 months after disconnect (accelerated) | 50 kGy | Yes | Ambient, 0.5, 1.0, 1.5, 2.0 | Pass |
| **C-Flex® TPE** | No | No | No | Ambient, 0.5, 1.0, 1.5, 2.0 | Pass |
| **C-Flex® TPE** | No | 50 kGy | No | Ambient, 0.5, 1.0, 1.5, 2.0 | Pass |
| **C-Flex® TPE** | 6 months (after disconnect) Ambient Temp | 50 kGy | No | Ambient, 0.5, 1.0, 1.5, 2.0 | Pass |
| **C-Flex® TPE** | 6 months (after disconnect) 5.7 °C | 50 kGy | No | Ambient, 0.5, 1.0, 1.5, 2.0 | Pass |
| **C-Flex® TPE** | 12 months uncut + 6 months after disconnect (accelerated) | 50 kGy | No | Ambient, 0.5, 1.0, 1.5, 2.0 | Pass |
| **C-Flex® TPE** | 36 months uncut + 6 months after disconnect (accelerated) | 50 kGy | No | Ambient, 0.5, 1.0, 1.5, 2.0 | Pass |

### 4.5.3 Burst Testing

Sartorius performed burst testing on QUICKSEAL® aseptic disconnect after certain conditions. All assemblies were filled with water and disconnection was performed. Pressure in the tubing assembly with cut collar was increased by 0.5 bar increments until failure.

| | Aging | Gamma Irradiation | Autoclave (2 × 134 °C, 30 min) | Burst Pressure [bar] |
|---|---|---|---|---|
| **Platinum-Cured Silicone** | No | No | No | 5.5 |
| **Platinum-Cured Silicone** | No | 50 kGy | Yes | 5.5 |
| **Platinum-Cured Silicone** | 6 months (after disconnect) Ambient Temp | 50 kGy | Yes | 5.5 |
| **Platinum-Cured Silicone** | 6 months (after disconnect) 5.7 °C | 50 kGy | Yes | 5.5 |
| **Platinum-Cured Silicone** | 12 months uncut + 6 months after disconnect (accelerated) | 50 kGy | Yes | 5.5 |
| **Platinum-Cured Silicone** | 36 months uncut + 6 months after disconnect (accelerated) | 50 kGy | Yes | 5.5 |
| **C-Flex® TPE** | No | No | No | 5.5 |
| **C-Flex® TPE** | No | 50 kGy | No | 4.0 |
| **C-Flex® TPE** | 6 months (after disconnect) Ambient Temp | 50 kGy | No | 3.5 |
| **C-Flex® TPE** | 6 months (after disconnect) 5.7 °C | 50 kGy | No | 4.0 |
| **C-Flex® TPE** | 12 months uncut + 6 months after disconnect (accelerated) | 50 kGy | No | 4.0 |
| **C-Flex® TPE** | 36 months uncut + 6 months after disconnect (accelerated) | 50 kGy | No | 4.0 |

### 4.5.4 Tensile Strength Test

Sartorius performed Tensile Strength Test on QUICKSEAL® aseptic disconnect after certain conditions. The force to pull the collar off the tubing was measured. Traction speed was 500 mm/min. Passing results achived when force > 40N.

| | Aging | Gamma Irradiation | Autoclave (2 × 134 °C, 30 min) | Average Force [N] |
|---|---|---|---|---|
| **Platinum-Cured Silicone** | No | No | No | 134.5 |
| **Platinum-Cured Silicone** | No | 50 kGy | Yes | 124.6 |
| **Platinum-Cured Silicone** | 6 months (after disconnect) Ambient Temp | 50 kGy | Yes | 109.3 |
| **Platinum-Cured Silicone** | 6 months (after disconnect) 5.7 °C | 50 kGy | Yes | 132.4 |
| **Platinum-Cured Silicone** | 12 months uncut + 6 months after disconnect (accelerated) | 50 kGy | Yes | 100.6 |
| **Platinum-Cured Silicone** | 36 months uncut + 6 months after disconnect (accelerated) | 50 kGy | Yes | 118.0 |
| **C-Flex® TPE** | No | No | No | 87.6 |
| **C-Flex® TPE** | No | 50 kGy | No | 69.0 |
| **C-FLEX® TPE** | 6 months (after disconnect) Ambient Temp | 50 kGy | No | 73.6 |
| **C-Flex® TPE** | 6 months (after disconnect) 5.7 °C | 50 kGy | No | 74.9 |
| **C-FLEX® TPE** | 12 months uncut + 6 months after disconnect (accelerated) | 50 kGy | No | 75.6 |
| **C-Flex® TPE** | 36 months uncut + 6 months after disconnect (accelerated) | 50 kGy | No | 62.1 |

### 4.5.5 Bacterial Challenge Testing|Container Closure

Sartorius performed Bacterial Challenge Test on QUICKSEAL® aseptic disconnect after certain conditions.

QUICKSEAL® test articles were assembled to connect two Flexboy® bags to each other and gamma irradiated to 50 kGy. The assemblies were filled with Casein Peptone Soybean Digest Broth and incubated for 7 days at 32 °C ± 2 °C. All assemblies showed no signs of contamination so the QUICKSEAL® collars were cut.

Bacteria used in the tests was *Bacillus atrophaeus* (ATCC 9372). Tests for inhibition demonstrated that the QUICKSEAL® assembly does not inhibit growth of *Bacillus atrophaeus.*

| | Aging | Bacterial Challenge | Observation after Incubation 7 days at 32 °C ± 2 °C |
|---|---|---|---|
| **Platinum-Cured Silicone** | No | None | No Growth<br>Negative Control Pass |
| **Platinum-Cured Silicone** | No | Bacteria Injected into Assemblies (concentration $6.4 \times 10^3$) | Positive Growth<br>Positive Control Pass |
| **Platinum-Cured Silicone** | No | Immersed into bacterial solution (concentration $6.4 \times 10^9$) | No Growth<br>Test Passed |
| **Platinum-Cured Silicone** | 6 months | None | No Growth<br>Negative Control Pass |
| **Platinum-Cured Silicone** | 6 months | Bacteria Injected into Assemblies (concentration $6.4 \times 10^3$) | Positive Growth<br>Positive Control Pass |
| **Platinum-Cured Silicone** | 6 months | Immersed into bacterial solution (concentration $6.4 \times 10^9$) | No Growth<br>Test Passed |
| **C-Flex® TPE** | No | None | No Growth<br>Negative Control Pass |
| **C-Flex® TPE** | No | Bacteria Injected into Assemblies (concentration $6.4 \times 10^3$) | Positive Growth<br>Positive Control Pass |
| **C-Flex® TPE** | No | Immersed into bacterial solution (concentration $6.4 \times 10^9$) | No Growth<br>Test Passed |
| **C-Flex® TPE** | 6 months | None | No Growth<br>Negative Control Pass |
| **C-Flex® TPE** | 6 months | Bacteria Injected into Assemblies (concentration $6.4 \times 10^3$) | Positive Growth<br>Positive Control Pass |
| **C-Flex® TPE** | 6 months | Immersed into bacterial solution (concentration $6.4 \times 10^9$) | No Growth<br>Test Passed |

### 4.5.6 Low Temperature Bacterial Challenge Testing|Container Closure

Sartorius performed Bacterial Challenge Test on QUICKSEAL® aseptic disconnect with an freeze|thaw cycle.

Platinum-cured silicone and C-Flex® tubes with QUICKSEAL® collars were filled with sterile medium supportive of bacterial growth. The collars were cut and the samples were placed in a freezer at -60 °C to -100 °C for 48 hours. The samples were thawed and then immersed tubes into a bacterial solution (*Brevundimonas diminuta*). During immersion the system is cycled between positive 15 psig and negative 10 psig.

Fluid from the sealed tubing is plated, in triplicate, on soybean casein digest agar (SCDA) and incubated for 7 days at 30 °C ± 2 °C and observed for growth of organisms as indicated by colony forming units (CFU).

All test articles were negative for growth indicating the cut QUICKSEAL® may be frozen. Care should be taken when handling components at or below their glass transition temperatures.

Positive Controls were positive for growth.

Negative Controls were negative for growth.

# 5. Leachables & Extractables

Leachables & Extractables are compounds that have the potential to or will actually leach from the materials of the fluid handling system into the solution.

A risk assessment is advised to determine the extent of leachable and extractable studies are required. Considerations should include; the production stage, exposure time and temperature, exposure surface area, material familiarity and the process fluid pH and polarity.

Testing requirements for items of low risk may be adequately met by USP <87> and USP <88>, which are extractable studies. These studies do not identify or quantify compounds leaching the materials. Instead, these studies measure biologic and cytotoxic effects of leachables from the materials under the defined extraction parameters.

The fluid contact surface of QUICKSEAL® assemblies is the tubing to which it is attached. All tubing materials offered with QUICKSEAL® pass USP <87> and USP <88 >testing. Confidential information about leachable and extractable studies may be available from our component manufacturers.

Sartorius' Confidence® Services is available to perform customized and confidential extractable and leachable studies on polymer-based process components.

# 6. QUICKSEAL® Cutting Tools

Sartorius offers two cutting tools to complete the disconnection and create the seal with QUICKSEAL®.

## 6.1 Large Diameter QUICKSEAL® Cutting Tool

| Large Diameter Cutting Tool | |
|---|---|
| Tube Size\|QUICKSEAL® Cut Range Outer Diameter | ≤ 1.125" (≈ 28.6 mm) |
| Materials of Construction (Cutting Head) | 304 Stainless Steel |
| Weight | 4 lbs<br>2.2 kg |
| Width | 2"<br>60 mm |
| Depth | 4.25"<br>108 mm |
| Length | 14.75"<br>375 mm |
| Sound | < 80 dB at 1 Meter |
| Vibration | < 2.5 $m/s^2$ |
| Cutting Time | 4 Seconds |
| Closing Speed | 6 mm/second |
| Cuts Per Charge | ≈ 300 |
| Battery Voltage | 18 V, Lithium Ion |
| Charging Time | 20 minutes |

## 6.2 Small Diameter QUICKSEAL® Cutting Tool

| Small Diameter Cutting Tool | |
|---|---|
| Tube Size\|QUICKSEAL® Cut Range Outer Diameter | ≤ 0.25" (≈ 6.4 mm) |
| Materials of Construction (Cutting Head) | 304 Stainless Steel |
| Weight | 4 lbs<br>2.2 kg |
| Width | 0.5"<br>13 mm |
| Depth | 1.125"<br>27 mm |
| Length | 8.125"<br>206 mm |

# 7. QUICKSEAL® Protective Caps

The QUICKSEAL® protective caps can be installed after collars are cut. The caps are made from silicone so are very flexible, durable and have a wide temperature range.

## 7.1 Installation

Installation is simple:

- Grasp the cap near the open end between index finger and thumb
- Squeeze the cap until the opening is wide enough for the cut QUICKSEAL® collar
- Insert the QUICKSEAL® collar and release

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