Quickseal® Aseptic Disconnections

Validation Guide

Simplifying Progress

SARTORIUS

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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 times 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

Thermoplastic Elastomer	
St. Gobain	C-Flex®
AdvantaPure	AdvantaFlex®
Sartorius	Tuflux® TPE

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 fluid management systems. Wherever possible, Sartorius refers to our supplier's product validation documentation. Supplier documentation is available on 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 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 and review
- Document control
- Records control and retention
- Corrective and preventive action internal auditing
- Personnel training and competency
- Customer notification and recall

1.5 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 ISO 11137.

1.6 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: clean-rooms and associated controlled environments
  - Classification of air cleanliness by particle concentration
- Bioburden and sterility
  - ISO 14698: clean-rooms 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

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
Sartorius	Tuflux® TPE	Yes	Yes	Yes	Yes	No	No

2. Production and Quality

2.1 Personnel

Sartorius 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 ensure 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 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 and Qualification

Suppliers are carefully selected according to internal standards and applicable regulations. Typical requirements for suppliers are the following (non-exhaustive list):

- Quality control system
- Quality assurance system
- Facility and clean-room controls
- Product | component lot traceability system
- Change notification procedures

Suppliers are evaluated and approved according to internal standards.

2.3.2 Component and 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 (non-exhaustive list):

- USP Class VI and | or ISO 10993 conformity
- TSE | BSE statement
- EP conformity (if applicable)
- Change notification statement
- Reach compliance
- Bisphenol A free

Beyond these requirements, Sartorius 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 on arrival at Sartorius against approved control specifications. Typical testing requirements applied at incoming quality inspection
are (non-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' inventory and quality management system, 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 clean-room) 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 clean-room with a schedule of LpH®, Vesphene® and Spor-Klenz® takes place as per our clean-room management and cleaning procedures.

Viable organisms are measured quarterly to monitor the effectiveness of the clean-room management and cleaning procedures and to be compliant to EU GMPs and ISO 14698. 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 clean-room reduces and controls 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 (e.g. tubing) are received into our Class 7 clean-room per incoming inspection and testing procedures.

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

3.4 Traceability and Batch Control

Sartorius 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 sub-assemblies. Sub-assemblies are built from components or sub-assemblies. Components are parts that are purchased or manufactured by Sartorius. Each component and sub-assembly has a unique part number. All components and sub-assemblies are assigned a unique lot number on 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 sub-assembly list to execute the designated procedure. Operators fill in batch records including recording lot numbers of components and sub-assemblies. This data is also entered into the traceability system.

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

3.5 In-Process and 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.

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, therefore 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 five year shelf-life. Sartorius' inventory management procedures ensure the tubing is converted into Quickseal® assembly within two years of receipt.

Thus, non-irradiated Quickseal® assemblies have a shelf-life of three 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 three years.

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

4.3 Quickseal® Product Sizes

Tube Size (outer diameter)						
Inches	¼	⅜	7⁄16	⅝	¾	1⅛
mm	≈ 6.4	≈ 9.6	≈ 11.1	≈ 15.9	≈ 19.0	≈ 28.6

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

4.4 Properties

4.4.1 Disconnection Qualification

Sartorius performed an 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	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	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

4.4.2 Pressure Test

The purpose of the pressure test is to check the clamping tightness after the tubing disconnection when the tube is filled with liquid.

The test is passed if no water leak appears during pressure testing (0.5 bar and 1 bar are applied for 1 minute).

	Aging	Gamma Irradiation	Autoclave (2 × 134 °C, 30 min)	Pass | Fail
Platinum-cured silicone	No	No	No	Pass
Platinum-cured silicone	No	50 kGy	Yes	Pass
Platinum-cured silicone	Six months (after disconnect) ambient temp	50 kGy	Yes	Pass
Platinum-cured silicone	Six months (after disconnect) 5.7 °C	50 kGy	Yes	Pass
Platinum-cured silicone	12 months uncut + six months after disconnect (accelerated)	50 kGy	Yes	Pass
Platinum-cured silicone	36 months uncut + six months after disconnect (accelerated)	50 kGy	Yes	Pass
C-Flex® TPE	No	No	No	Pass
C-Flex® TPE	No	50 kGy	No	Pass
C-Flex® TPE	Six months (after disconnect) ambient temp	50 kGy	No	Pass
C-Flex® TPE	Six months (after disconnect) 5.7 °C	50 kGy	No	Pass
C-Flex® TPE	12 months uncut + six months after disconnect (accelerated)	50 kGy	No	Pass
C-Flex® TPE	36 months uncut + six months after disconnect (accelerated)	50 kGy	No	Pass

4.4.3 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.

Acceptance criteria: F > 40 N except for ⅛" × ¼" Tubing F > 15 N

	Aging	Gamma Irradiation	Autoclave (2 × 134 °C, 30 min)	Pass | Fail
Platinum-cured silicone	No	No	No	Pass
Platinum-cured silicone	No	50 kGy	Yes	Pass
Platinum-cured silicone	Six months (after disconnect) ambient temp	50 kGy	Yes	Pass
Platinum-cured silicone	Six months (after disconnect) 5.7 °C	50 kGy	Yes	Pass
Platinum-cured silicone	12 months uncut + six months after disconnect (accelerated)	50 kGy	Yes	Pass
Platinum-cured silicone	36 months uncut + six months after disconnect (accelerated)	50 kGy	Yes	Pass
C-Flex® TPE	No	No	No	Pass
C-Flex® TPE	No	50 kGy	No	Pass
C-Flex® TPE	Six months (after disconnect) ambient temp	50 kGy	No	Pass
C-Flex® TPE	Six months (after disconnect) 5.7 °C	50 kGy	No	Pass
C-Flex® TPE	12 months uncut + six months after disconnect (accelerated)	50 kGy	No	Pass
C-Flex® TPE	36 months uncut + six months after disconnect (accelerated)	50 kGy	No	Pass

4.4.4 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 seven 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 Seven Days at 32 °C ± 2 °C
Platinum-cured silicone	No	None	No growth Negative control pass
Platinum-cured silicone	No	Bacteria injected into assemblies (concentration 6.4×10^3)	Positive growth Positive control pass
Platinum-cured silicone	No	Immersed into bacterial solution (concentration 6.4×10^9)	No growth Test passed
Platinum-cured silicone	Six months	None	No growth Negative control pass
Platinum-cured silicone	Six months	Bacteria injected into assemblies (concentration 6.4×10^3)	Positive growth Positive control pass
Platinum-cured silicone	Six months	Immersed into bacterial solution (concentration 6.4×10^9)	No growth Test passed
C-Flex® TPE	No	None	No growth Negative Control pass
C-Flex® TPE	No	Bacteria injected into assemblies (concentration 6.4×10^3)	Positive growth Positive control pass
C-Flex® TPE	No	Immersed into bacterial solution (concentration 6.4×10^9)	No growth Test passed
C-Flex® TPE	Six months	None	No growth Negative control pass
C-Flex® TPE	Six months	Bacteria injected into assemblies (concentration 6.4×10^3)	Positive growth Positive control pass
C-Flex® TPE	Six months	Immersed into bacterial solution (concentration 6.4×10^9)	No growth Test passed

4.4.5 Freezing Validation

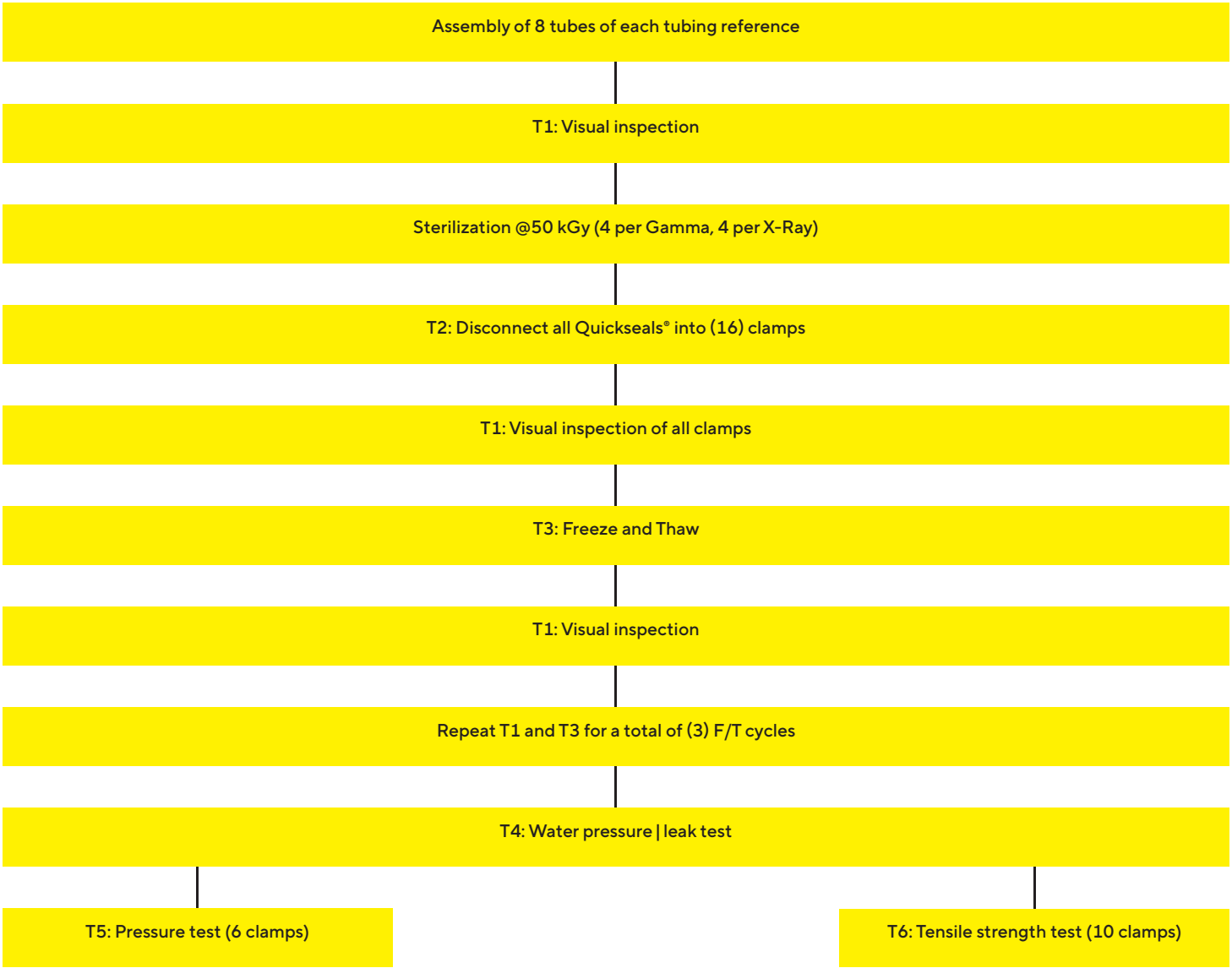
Sartorius performed three freeze and thaw cycles to align with the latest testing methodology performed on finished Celsius® products.

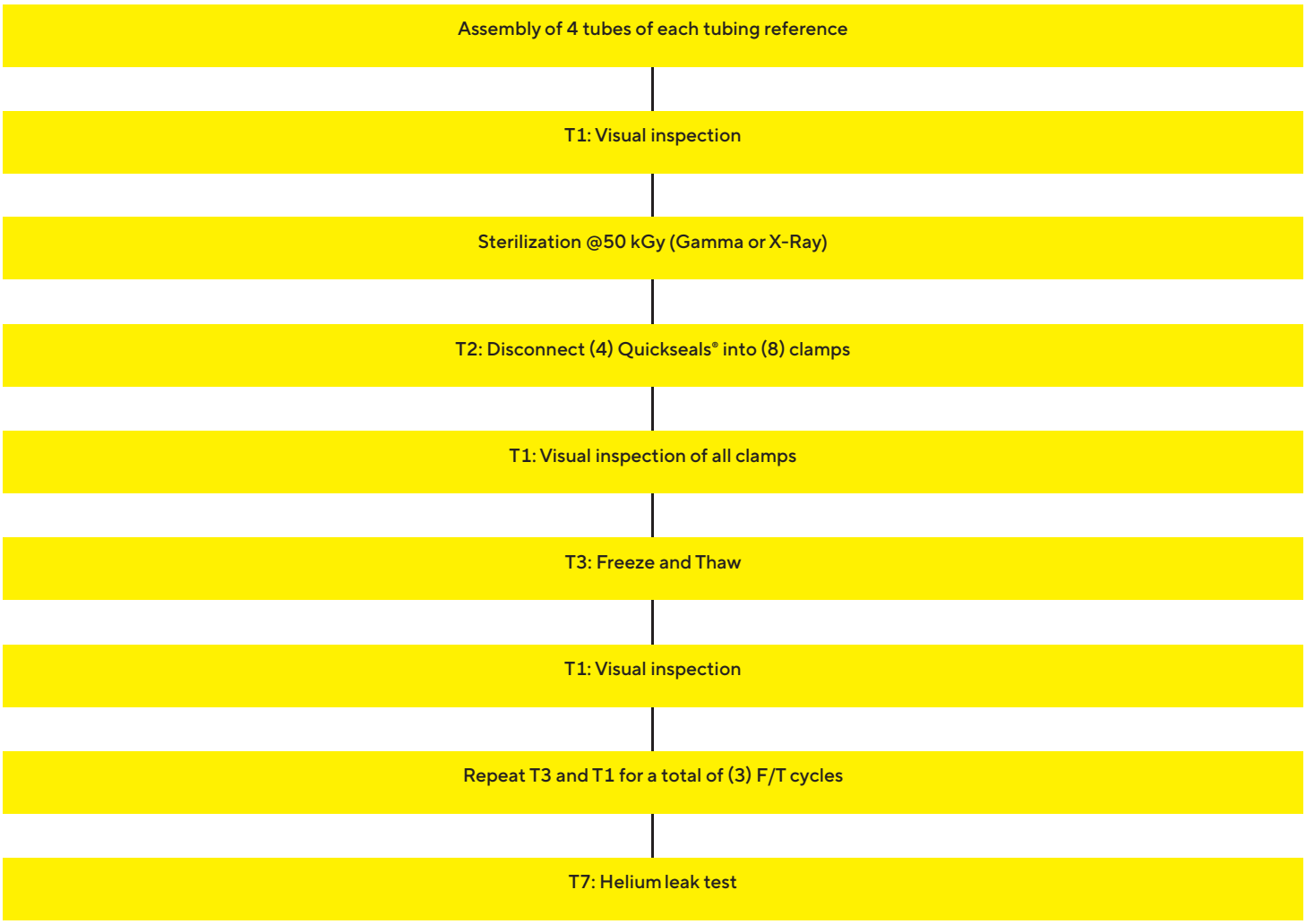
Tested tubes

- **Tested Material**
  - Pharma® 50 Silicone
  - C-Flex® 374 TPE
  - Tuflux® TPE

- **Tested Diameters**
  - 1/8" × 1/4"
  - 1/4" × 3/8"
  - 3/8" × 5/8"

Tests sequence for each tubing reference




Assembly of 4 tubes of each tubing reference
T1: Visual inspection
Sterilization @50 kGy (Gamma or X-Ray)
T2: Disconnect (4) Quickseals® into (8) clamps
T1: Visual inspection of all clamps
T3: Freeze and Thaw
T1: Visual inspection
Repeat T3 and T1 for a total of (3) F/T cycles
T7: Helium leak test

Tests parameters and acceptance criteria

Visual inspection
Visual inspection of the Quickseal®.

Acceptance criteria
No damage on the Quickseal®. No disassembling.
No damage on the tube. No obvious leak path.

Freeze-thaw cycle
Samples protected in a protective pouch frozen at -85 °C in a lab freezer for at least 24 hours. The samples will then be directly thawed in a water bath at +45 °C for about 2 minutes. Three freeze and thaw cycles will be performed in this testing to align with the latest testing methodology performed on finished Celsius® products. Allow product to return to room temperature and be fully dried of moisture before initiating another freezing cycle (to prevent ice formation).

Acceptance criteria
No damage on the Quickseal®. No disassembling. No damage on the tube. No obvious leak path.

Water leak test
Test the assembly with pressurized water starting at 0.5 bar during 1 min, then 1 bar during 1 min.

Acceptance criteria
No water leak (at 1 bar during 1 min).

Pressure test
The purpose of the pressure test is to check the clamping tightness after the tubing disconnection when the tube is filled with liquid.

Acceptance criteria
The test is passed if no water leak appears during pressure testing (0.5 bar and 1 bar are applied for 1 minute).

Tensile strength
Measure the tensile strength resistance of the tubing assembly. Traction Speed was 500 mm/min

Acceptance criteria
F > 40 N except for ⅛'' × ¼'' Tubing F > 15 N

Helium leak test
Measure the seal integrity using helium leak (detection up to 2 microns).

Tests results
All tested tubes resist to 3 cycles of freeze and thaw.

5. Leachables and Extractables

Leachables and 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)	Both jaws: 420 SS Cutter guard assembly: 304 SS
Weight	4 lbs | 2.2 kg
Width	2" | 60 mm
Depth	4.25" | 108 mm
Length	14.75" | 375 mm
Sound	< 80 dB at one meter
Vibration	< 2.5 m/s²
Cutting time	Four 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)	Body: 420 SS Jaws: Carbide inserts
Weight	4 lbs | 2.2 kg
Width	0.5" | 13 mm
Depth	1.125" | 27 mm
Length	8.125" | 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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