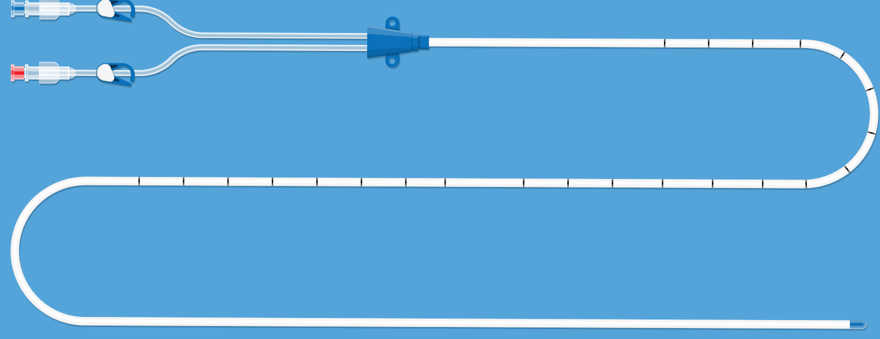
Application Note ▪ Medical

Your Global Leak and Function Test Solution Experts

How to Test Multi-Lumen Catheters for Leaks and Blockages



Multi-lumen catheters are used in a multitude of minimally invasive clinical procedures.

This type of catheter has a single tube with multiple internal pathways/lumens (tubes within a tube) isolated from one another. It permits external access of media to each lumen individually, typically without cross-contact with any other pathway inside the catheter. Often these are used for exchange of blood or to permit drug/solution delivery within the vasculature of the patient

Most catheters are tested after final assembly: they are tipped and have skived holes cut radially on the outside diameter of the multi-lumen shaft at the distal end of the catheter. Others are tested prior to finishing when untipped and before any skived holes have been cut.

Leak testing either configuration requires a two-step process to first find leaks and then determine whether there are blockages. This application note provides an example of a test process to achieve 100% testing of parts in production.

Solutions for Leak Testing Multi-Lumen Catheters

Sentinel Blackbelt

Single channel, multiple sequential test port instrument

CO31 (OD) and CO31L (Luer) Connects

Common Multi-Lumen Catheters

- Central venous (CVC) catheters
- Peripherally inserted central (PICC) catheters
- Hemodialysis catheters
- Cardiac pacing catheters
- Angiography (contrast media delivery) catheters
- Anesthesia catheters
- Sampling catheters
- Diagnostic (oximetry, volume, ejection fraction, hemodynamic pressure) catheters

Test Methods

The most common test method is dry compressed air or nitrogen pressure decay leak testing and either mass flow or pressure decay for blockage. The single-channel Sentinel Blackbelt with 2, 3 or 4 sequential ports are designed for this purpose. Most multi-lumen catheters require testing at pressures ranging from 5 psig to 200 psig.

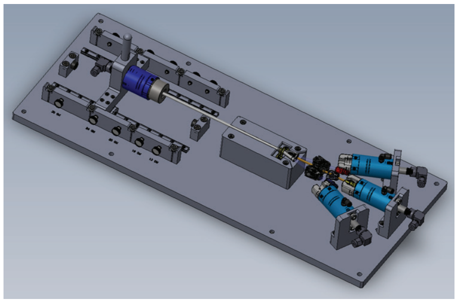
SEALING THE CATHETER FOR TEST

1. Each of the female luer fittings on the catheter's proximal/inlet end is mated to a separate sequential test port on the Sentinel Blackbelt test instrument. The instrument is supplied with either a standard ISO 80369 metal luer-lock fitting or optional CTS CO31L Luer Connect on each test port.

2. For a finished catheter (tipped and skived holes cut), the distal/outlet end of the catheter is placed inside a custom CTS CO31 Connect which is designed to radially seal off all the skived holes simultaneously, isolating each lumen from one another and atmosphere.

   For untipped catheters without skived holes cut, the test process is the same. However, the operator typically utilizes a hemostat or similar tool to manually clamp the distal tip of the unfinished catheter to isolate each of the lumens from one another during the leak test.

3. The Start button is pressed by the user and the instrument activates the CTS Connects (if supplied), sealing the distal end radially and/or each of the female luer fittings on the proximal end of the catheter.



CTS designed 3-lumen CVC Catheter fixture

PRESSURIZATION OF THE LUMEN

4. As the pressure decay leak test cycle begins the instrument pressurizes one lumen only with regulated compressed air or nitrogen for a user-defined Fill time. All lumens not currently under test are vented to the atmosphere. The pressure is measured by the instrument's pressure transducer and compared to min/max limits, enabling detection of improper pressure supply or gross leaks on the lumen.

STABILIZATION: REDUCING NATURAL PRESSURE LOSS AND FINDING GROSS LEAKS

5. Once the Fill timer expires, the isolation valve inside the instrument closes, trapping pressure inside the lumen for a user-defined Stabilize time. This time is intended to minimize the natural pressure loss of even non-leaking parts due to expansion or creep, adiabatic thermal effect and potentially absorption, increasing the separation of the final measured pressure loss/decay between good parts and rejects.

   The pressure is also measured by the instrument's pressure transducer and compared to min/max limits to detect slightly smaller but still gross leaks on the lumen being tested.

TEST: DETECTING FINE LEAKS

6. After the Stabilize timer expires, the pressure transducer is tared, and the resulting pressure loss/decay is recorded over a user-defined Test time and compared to min/max pressure limits to determine whether fine leaks are present.

Using Leak Rate to Simplify Testing across Catheter Variations

Many manufacturers opt to convert the basic pressure decay/loss value to a leak rate in standard cubic centimeters per minute (sccm). Because pure pressure loss values are dependent upon the volume under test, similarly constructed catheters which have different pressurized volumes (due to differences in catheter French size or length) will yield different pressure losses even if they are leaking at the same rate. With a fixed leak rate, larger volumes have lower pressure decay/loss values vs. smaller volume lumens with the same leak.

The advantage is that once the user defines a target reject leak rate in sccm, they can often apply the same leak rate criteria to an entire family of similar products having differing internal volumes. Executing a simple program calibration teaches the instrument the typical decay of a known non-leaking part alone and then repeated with the same non-leaking part but with a fixed leak standard added. The learning process allows the instrument to accurately convert any future resulting pressure loss to a true leak rate in sccm and make testing parts with unique volumes to have matching reject criteria.

7. Once the Test timer expires, the pressure trapped inside the lumen is vented to the atmosphere using a user-defined Exhaust time. The full test cycle is then repeated for each untested lumen mated to a different sequential port until all have been individually tested. These sequential tests inspect for both lumen-to-exterior and lumen-to-lumen leakage. Once all tests are complete, the instrument releases the distal Connect, allowing all lumens to vent to atmosphere on the distal end of the catheter to permit Blockage testing.

   For untipped catheters without skived holes cut, the test sequence pauses prior to the blockage test to allow the operator time to manually release the hemostat or other clamping device from the distal tip of the catheter.

INSPECTING FOR BLOCKAGES WITH MASS FLOW

8. Using the same method as in the pressure decay test, the instrument pressurizes one lumen. Once the Fill timer expires, the mass flow transducer inside the instrument is introduced to the circuit, and the flow through that lumen is permitted to reach a stable value. The final flow value is recorded and compared to min/max flow limits to determine if some degree of blockage is present.

Option for Blockage Testing without Mass Flow

A lower cost option for detection of only complete or near-complete blockage can be done by performing a rapid pressure decay test and inspecting for some minimum loss in a user-defined Test time.

In this process the lumen is again charged with pressure during the Fill time, typically the same as for the leak test. Stabilize time is set to a bare minimum value (0.05 seconds) to minimize pressure losses through good, unblocked parts. After stabilization, the pressure transducer is tared and the resulting pressure loss/decay over a fixed time is recorded and compared to min/max pressure loss limits to determine whether or not the lumen has a total or nearly total blockage during the test time.

Test time is short, typically between 0.1 and 1.0 seconds to permit an intentional loss of between 50% to 80% of the initial starting pressure seen during Fill time when testing unblocked parts. Once the test is done, the pressure in the lumen is vented to the atmosphere.

9. The test is repeated on each lumen mated to a different sequential test port until all been tested for blockages. After Exhaust, the final variable test result data is displayed on the instrument. Highly visible indicators on the display and front panel make it obvious to the operator which lumens have passed or failed, allowing them to disconnect from the Sentinel instrument and properly move the catheters down the production line or into reject containers.

Ensuring Failed Parts Are Properly Handled

Using the CTS C031 Luer Connects driven by the Sentinel Blackbelt, the test program can be set to leave failed catheters sealed by the Connect, forcing the user to either press a reset button or use a security key or password to release the failed part. This method of forcing the operator to break rhythm limits the risk of failed parts being inadvertently placed for downstream operations.

Total test cycle time is dependent upon different factors, most importantly:

- Reject limit selected
- Volume of the pressurized/evacuated area of the part under test
- Temperature stability of part and testing environment
- Dimensional stability of the part while under test
- Repeatability requirements defined by the user
- Accuracy, precision & resolution of the instrument executing the test

Contact CTS to discuss your test application

Contact us for more information on our industry leading medical device leak testing systems, catheter testing solutions, medical bag testing and pressure decay testing, or **request a quote today**.

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Your Global Leak and Function Test Solution Experts

CINCINNATI TEST SYSTEMS Corporate Headquarters – 10100 Progress Way, Harrison, OH 45030
Phone (513) 367-6699 | International (513) 202-5100 | cincinnati-test.com