

How to Test Vascular Access Sheaths for Leaks and Blockages



Vascular access sheaths, also known as sheath introducers or introducer sheaths, are commonly used in catheter-based, minimally invasive procedures. The device acts as a hemostasis (blood-blocking) access port where catheters and guidewires may be placed/threaded into the patient's vasculature with minimal blood loss.

The proximal end of the sheath typically has a molded and slit elastomer aperture that self-seals around catheters and guidewires after they are placed inside the patient.

The majority have a flush port mated to the side of the device which is a manual stopcock attached to a tube mated to the side of the sheath. It allows the clinician to connect a saline-filled syringe to the stopcock, open the stopcock and use the syringe to both expel any air from the interior of the sheath prior to placement into the patient or to expel blood back into the vasculature just prior to removal of the sheath from the patient near the conclusion of the procedure.

Tests are conducted to inspect for leaks and potential blockages on 100% of parts during production.

Solutions for Leak and Blockage Testing of Vascular Access Sheaths



Sentinel Blackbelt

Single channel instrument



Sentinel Blackbelt Pro

Multi-channel instrument
with features that support 21 CFR
Part 11 and EU Annex 11

Test Method

The standard leak test to test these types of sheaths uses dry compressed air pressure or vacuum decay at pressures ranging from -400 mmHg to +400 mmHg (-7.7 to +7.7 psig). The single-channel Sentinel Blackbelt or multi-channel Blackbelt Pro pressure/vacuum decay instrumentation are designed for this purpose.

The potential exists for the adhesive bond between the flush port tube and either the stopcock or the sheath to be completely or near-completely blocked should excess adhesive be applied. As such, most manufacturers execute a basic "inverted-limit" pressure decay test to verify patency from the interior of the sheath all the way out through the stopcock.

Here is how the leak test is typically performed.

SEALING THE SHEATH

1. The distal/outlet end of the sheath is placed inside a standard CTS CO31 Connect which is designed to seal radially around the OD of the sheath's distal tip.



CTS CO31 Connect

2. The stopcock on the flush port is left in the closed position, sealing the port from atmosphere. The Start button is pressed to activate the Connect(s) sealing the distal end(s) radially, mating it to the instrument's test port. The pressure decay test cycle begins.

PRESSURIZATION OF THE SHEATH

3. The instrument pressurizes the distal end of Sheath through the CO31 Connect with regulated compressed air to the desired test pressure for a user-defined Fill time. This pressure is measured by the instrument's pressure transducer and compared to min/max limits to detect improper pressure supply or gross leaks on the sheath.

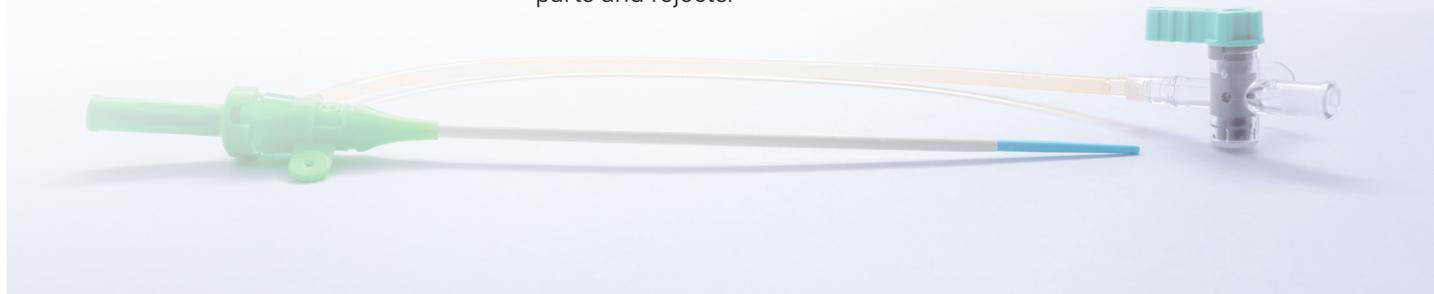
STABILIZATION: FINDING GROSS LEAKS

4. Following Fill, the isolation valve inside the instrument closes, trapping pressure inside the part for a user-selected 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 sheath.

TEST: DETECTING FINE LEAKS

5. 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 Sheath Variations

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

- Once the Test timer expires, the pressure trapped inside the sheath is vented to atmosphere using a defined Exhaust time. The Test sequence typically pauses at this point, awaiting the operator to manually rotate the stopcock to the vented position where the flush port is now open to atmosphere. To automate this process, CTS can build a pneumatically rotating custom nest to rotate the stopcock from closed to open positions. This system is entirely controlled by optional internal valving and user test programming within the Sentinel Blackbelt or Blackbelt Pro instrument and removes the need for manual intervention beyond the initial placement of the stopcock into this nest.
- The operator again presses Start on the instrument to begin the inverted-limit pressure decay flush port blockage test cycle. This step is eliminated if using the pneumatically rotating nest option as the instrument will automatically manage the sequence.

FLUSH PORT BLOCKAGE TEST

- The sheath is again charged with pressure during the Fill time, typically at the same pressure as for the leak test. The Stabilize time is set to a bare minimum value of 0.05 seconds to minimize pressure losses through good (unblocked) parts.

- After the Stabilize timer expires, the pressure transducer is tared and the resulting loss/decay over a fixed time is recorded and compared to min/max pressure loss limits to determine whether or not the flush port has a total or nearly total blockage during the Test time. Test time is also short, generally between 0.1 and 1.0 seconds to permit intentional loss of between 50-80% of the initial starting pressure seen during Fill time when testing unblocked parts. At the end of the Test, the pressure trapped inside the sheath is vented to atmosphere during the Exhaust time. The variable test result data is then displayed along with highly visible pass/fail indicators on the instrument to allow the operator to disconnect from the Sentinel instrument and properly move the parts down the production line or into reject containers.

Ensuring Failed Parts Are Properly Handled

If using the CTS CO31 Connect controlled by the Sentinel Blackbelt or Blackbelt Pro, the test program can be set to leave failed sheaths 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 with passed sheaths.



Pass/fail display on Blackbelt Pro instrument

Vacuum Leak Verification: Optional Test

For some sheaths the manufacturer needs to challenge the silicone seal on the proximal end of the sheath for leaks under negative pressure (vacuum). This requires the use of vacuum between -12 psig to -0.1 psig and the test is typically executed either just before or immediately following the positive pressure decay leak test.

This test is the same as the leak test detailed previously though the Sentinel Blackbelt or Blackbelt Pro is normally equipped with an internal Venturi vacuum generator as the source for the test if vacuum decay is required.

The Sentinel instrument measures vacuum min/max limits throughout the process and measures the vacuum decay during the Test time. As the both the Blackbelt and Blackbelt Pro use absolute pressure transducers capable of measuring both pressure and vacuum on each test channel, often the same instrument can execute both positive pressure and vacuum tested if needed.

Total test cycle time required is dependent upon many factors, however most critically:

- 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 and 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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