Application Note ▪ Medical

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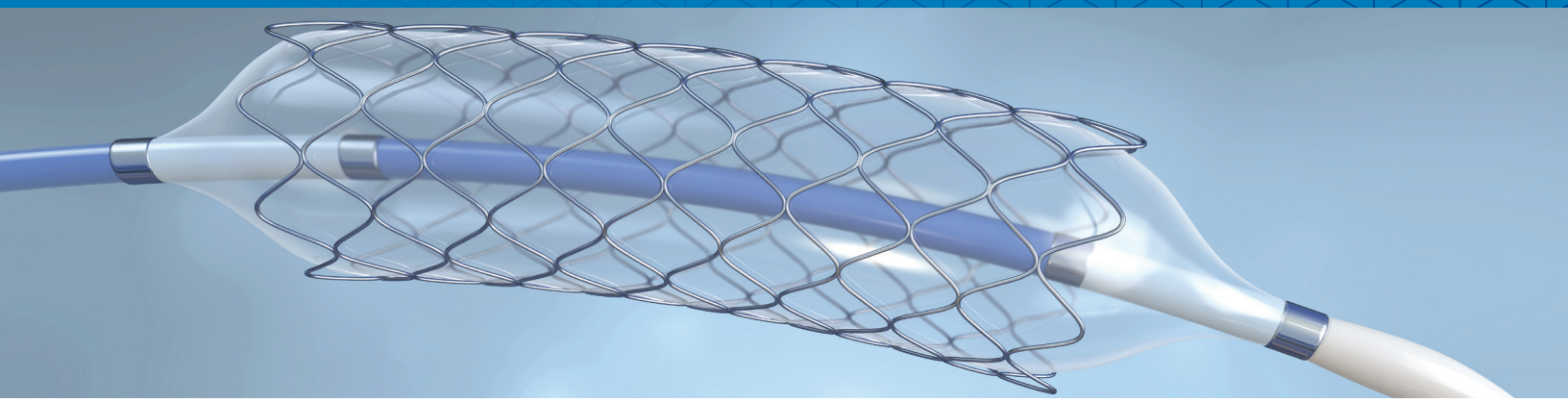
How to Leak Test Non-Compliant Balloon Catheters



Non-compliant balloon catheters are equipped with an inflatable balloon near the distal or outlet of the device. Typically made of polyester/PET or nylon, they are capable of inflating to a specific diameter at relatively high saline or radiopaque solution injection pressures. They are often used for vessel dilation and/or stent delivery.

Test methods vary slightly for non-stented versus stented non-compliant catheters and the same Sentinel Blackbelt or Blackbelt Pro instrument can handle 100% testing in production for both types of testing.

Common Non-Compliant Balloon Catheters

- Angioplasty (PTA & PTCA) catheters
- Dilation (esophageal, sinus, gastric, venous, arterial, biliary) catheters
- Stent delivery catheters
- Heat transfer catheters
- Laser balloon catheters
- Cryogenic catheters
- Drug delivery catheters
- Atherectomy catheters
- Sinuplasty catheters
- Carpal tunnelplasty catheters
- Kyphoplasty catheters

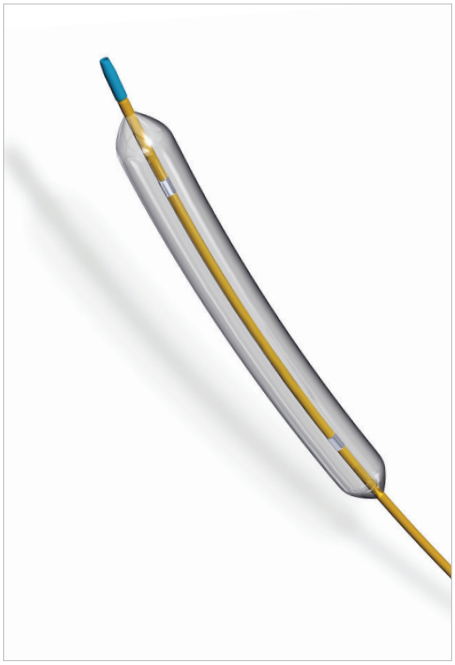
Solution for Leak Testing Non-Compliant Balloon Catheters

Sentinel Blackbelt
Single channel instrument

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

Test Methods: Non-Stented Non-Compliant Balloon Catheters

For Non-Stented Non-Compliant Balloon Catheters, most applications require pressure decay testing using clean, dry nitrogen or compressed air at positive pressures ranging from 150 psig to 450 psig—in some rare cases up to 1000 psig. Standard single-channel Sentinel Blackbelt or multi-channel Blackbelt Pro pressure decay instrumentation can be used for these tests. The typical test method:



SEALING AND PRESSURE DECAY TEST

1. The female luer fitting on the proximal end of the catheter's balloon lumen is mated to the test port on the Sentinel Blackbelt or Blackbelt Pro test instrument. The instrument is supplied with either a standard ISO 80369 metal luer-lock fitting or an optional CTS CO31L Luer Connect on each of its test ports.

CO31L Connect

2. The Start button is pressed by the user and the instrument activates the CTS Luer Connect (if supplied), sealing the female luer fitting on the proximal end of the catheter's balloon lumen. The pressure decay test cycle begins.

PRESSURIZATION OF THE BALLOON

3. The instrument pressurizes the balloon lumen with regulated nitrogen or compressed air, inflating the balloon to the desired test pressure for a defined Fill time. This pressure is measured by the instrument's pressure transducer and compared to min/max limits, enabling it to detect improper pressure supply or gross leaks on the balloon lumen.

STABILIZATION: REDUCING NATURAL PRESSURE LOSS AND FINDING GROSS LEAKS

4. Once the Fill time is completed, 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.

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

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 loss limits to determine whether fine leaks are present.

Using Leak Rate to Standardize 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 balloon diameter 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 balloons with the same leak.

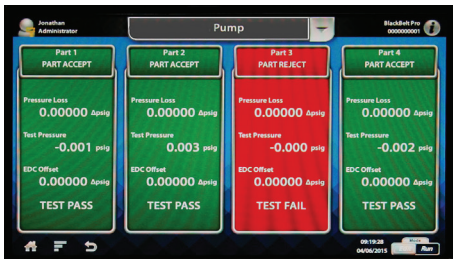
The advantage is that once the user defines a target reject leak rate in sccm, they can often apply the same leak rate criteria to an entire family of similar products having differing internal volumes. Executing a simple program calibration teaches the instrument the typical decay of a known non-leaking 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.

EXHAUST AND END OF TEST

6. At the end of the Test, the pressure trapped inside the balloon is vented to atmosphere using a defined Exhaust time.

Some users want to perform a dimensional measurement of the balloon diameter following the pressure decay leak test using laser micrometers, calipers or similar tools. The Sentinel Blackbelt and Blackbelt Pro have the capability to retain pressure inside the balloon at the completion of the test cycle on good parts, rather than venting it to atmosphere. After dimensions are verified by the operator, they may simply depress the Stop/Reset button on the instrument to vent the part and safely remove the catheter from the test port.

7. Following Exhaust, the final variable test result data is displayed on the instrument and highly visible indicators make it obvious to the operator which parts 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.



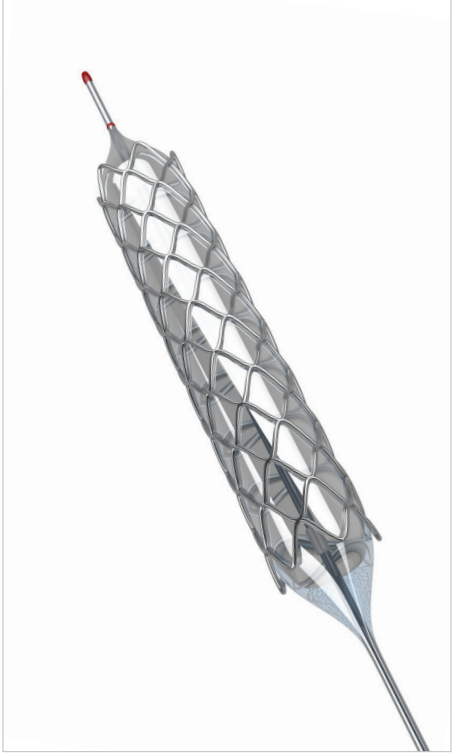
Pass/fail display on Blackbelt Pro instrument

Ensuring Failed Parts Are Properly Handled

Using the CTS CO31 Luer Connects driven by the Sentinel Blackbelt or Blackbelt Pro, 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.

Test Methods: Stented Non-Compliant Balloon Catheters

For stented non-compliant balloon catheters, most applications require using either vacuum or very low positive pressures between -12 psig to +10 psig to prevent deforming the stent during the test.



The procedure for this test is the same as for non-stented parts; however, in many cases the Sentinel Blackbelt or Blackbelt Pro instrument is equipped with an internal Venturi vacuum generator as the source for the test if vacuum decay testing is required.

The instrument measures vacuum min/max limits through the process and vacuum decay during the Test time. As Sentinel Blackbelt and Blackbelt Pro use absolute pressure transducers capable of measuring both pressure and vacuum on each test channel, the same instrument is often capable of executing both pre-stent or and post-stent testing 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 & 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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