

## NON-COMPLIANT BALLOON CATHETER TESTING

### Problem:

The customer needed to perform 100% testing of a high variety of their PTCA (coronary angioplasty) balloon catheters for leakage. They had been pressurizing the non-compliant balloons to over 450 psig in purified water and having the operator observe the part for bubbles leaving the balloon area. The customer was unhappy with:

- Operator subjectivity
- No quantitative results
- Limited leak locations tested
- Long drying times and bio-burden risk after testing

### Test requirement:

Pressure Decay leak test each part at 450 psig with leak rate detection of 0.5 sccm.

### CTS Solution:

CTS utilized their Sentinel Blackbelt leak test instrument with 0-500 psig operation perform the leak test on the entire part at 450 psig. As the system sees the entire volume under test, any leaking area from the part inlet (luer fitting) to balloon is tested for leakage using pressure decay. The system was set up to utilize a leak standard which allows calibration of the instrument to a known volumetric flow rate (sccm) at a rate matching their bubble allowance. Each test generates a quantified result in both pressure loss over time as well as volumetric flow in sccm.

### Other Features of this Application:

This customer also wished to make dimensional measurements of the balloon following the completion of the test. Their Blackbelt instrument is equipped with a Retain Part Pressure feature that allows pressure to be trapped within the balloon at the end of the cycle, giving the operator unlimited time to make all required dimensional measurements prior to releasing the part from the instrument.

The instrument was also installed with CTS Luer Connect to automatically seal the inlet port of the PTCA Catheter and mate it to the test port of the instrument. If the part passes the leak test, the Connect automatically releases the part to the operator. If the test fails, the part is securely held in the Connect and requires a reset action of some kind (operator pressing the Stop button or requiring a key reset) to unlock the part. This action is used to prevent the inadvertent placement of the failed part into the passed-part area.



**This same technology is often used in testing:**  
 PTA , Urinary, & Urethral Dilation Catheters  
 Esophageal & Endotracheal Dilation Catheters  
 Gastrointestinal & Biliary Dilation Catheters  
 Ablation Catheter Cooling Lines  
 Stent Delivery Catheters