



*providing world-class leak test and assembly verification solutions*

## SHEATH INTRODUCER LEAK & BLOCKAGE TESTING

### Problem:

The customer needed to perform 100% testing of sheath introducers for both leakage and blockage. They had been passing each part through a sequence of three stations of simple variable area flowmeter with a visual marked band indicating the pass fail limit in series with the part. The first station tested with positive pressure for blockages in the side/flush-port due to excessive or improperly applied solvent bonding of the side-port tubing to its and the sheath it was mated to. The next station performed a leak test using positive pressure with the side-port closed to test the connected side-port tubing and primarily the split silicone fluid barrier on the proximal end of the introducer. The final station performed another leak test using vacuum (also with side-port closed) to again test the side-port tubing and split silicone barrier. The customer was unhappy with:

- **Operator subjectivity**
- **Risk of inaccuracy** of analog flowmeter
- **Lack of sensitivity** of analog flowmeter
- **Lack of consistency** of operator and flowmeter
- **No quantitative results**

### Test Requirement:

Occlusion test with side-port valve open for blockage at 6.1 psig followed by pressure decay leak test with side-port valve closed to 2.0 sccm @ 6.1 psig followed by vacuum decay leak test with side-port valve closed to 2.0 sccm @ -6.1 psig.

### CTS Solution:

CTS utilized the Sentinel Blackbelt test instrument with both 0-30 psig positive pressure and 0-15 psiv vacuum (internal venturi) operation to perform the three required tests sequentially on a single instrument semi-automatically. A Parent program with three child programs (Occlusion linked to Pressure Decay linked to Vacuum Decay) performed each test in sequence without operator involvement beyond manual load and unload of the Sheath Introducers. The system utilized an NIST traceable leak standard which allows calibration of each test to a known volumetric flow rate (sccm), forcing agreement of the test result on each production line using the same test part and compensating for any differences in volume from test system to test system. A single pass/fail result was generated for each Introducer tested as well as quantitative results in back-pressure (for blockage test) and pressure change over time as well as volumetric flow in sccm (for leak tests), allowing historical trending.

### Other Features of this Application:

The operator would load the distal end of the sheath into a CTS OD Connect mated to the instrument test port which remained sealed the entire test cycle. The operator also inserted the side-port valve into a second special CTS Connect which was used to open and close the side-port valve between blockage and leak tests automatically by activation/deactivation commands issued by the Blackbelt instrument (open position for Occlusion test and closed for Pressure Decay and Vacuum Decay tests). If the part passes all three tests, 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 same technology is often used in testing:**  
Catheter Introducers, Hemo-Dialysis/Vascular Access Introducers, Trocars and other devices needing pressure and vacuum testing.