



providing world-class leak test and assembly verification solutions

MEDICAL MULTI-LUMEN CATHETER FLOW & LEAK TESTING

Application:

A medical device manufacturer had a new project requiring 100% testing of several French sizes of Triple-Lumen Catheters. The Catheter's distal end was tipped and skive holes were cut for each lumen. Each lumen needed to be independently tested for degree of blockage as well as leakage from lumen to lumen and lumen to exterior of the Catheter. Each lumen had different sized paths and therefore had unique blockage pass/fail limits as well as volumes under test during leak testing. The manufacturer needed help establishing a test methodology and desired that the operator only be used to load an untested Catheter and remove a tested Catheter at the end of the cycle and have no involvement in the actual pass/fail decision making process or recording of data from each test.

Test Requirement:

Blockage Test of Each Lumen: TBD

Leak Test : 2.0 sccm @ 25.0 psig

CTS Solution:

CTS performed testing in their applications lab with the customer and their Catheters and attempted both Occlusion and Mass Flow test types. Because of the capability mass flow testing has to grade the size of the opening (not simply verify open/blocked states), the customer elected to mass flow test each Catheter lumen independently at 1.5 psig with unique pass/fail limits for each lumen and then air pressure decay each lumen isolated from one another at 25.0 psig to a leak rate of 2.0 sccm on all lumens regardless of volume. CTS utilized a Sentinel Blackbelt leak test instrument with 3-sequential test ports (up to 4 available), 0-30 psig pressure range and 0-3000 sccm mass flow capability to complete all tests in single combination test sequence of mass flow followed by pressure decay – Leak Rate. Blackbelt used separate regulators for leak & flow tests. The operator attached the female luer fittings from the proximal end of each lumen to the appropriate port on the front of the Blackbelt and placed the distal end of the catheter into a special CTS Connect designed to not only seal the distal end of the catheter but to independently isolate each skived hole/lumen from one another when the Connect seal was activated. They then pressed the green Start button to begin the test cycle. At test start, the distal end of the catheter including all skived holes remained vented to atmosphere as the Connect was left deactivated. The Blackbelt performed independent mass flow testing on each lumen in a pre-determined sequence to grade the degree of blockage of each and fail if any were excessively blocked. Provided all lumens passed flow testing, Blackbelt would then activate the distal end Connect and sequentially leak test each lumen independently while venting all other lumens that were not under test. This way, the leak test could detect any cross-lumen leakage as well as leakage to the outside of the catheter. Only if all flow and leak tests passed would the instrument indicate a final Accept result. If any step failed, the customer elected to have Blackbelt activate and leave active the distal Connect seal, preventing the operator from removing the part from the Connect until an authorized supervisor performed a security key reset. The data from the last 5000 test results was automatically stored in onboard memory however the customer chose to also send data from each test immediately upon completion using Ethernet communication to another computer on the network running SPC software.



This same technology is often used in testing:

Angiography Catheters, Central Venous Catheters (CVC), Hemo-Dialysis Catheters, Heat Exchange Catheters, Oxymetry Catheters, Pacing Catheters, Peripherally Inserted Central Catheters (PICC), Pulmonary Arterial Catheters and many others, .

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