How to Leak Test Multi-Lumen Catheters

A new series of guides to tackling specific manufacturing problems.

In recent years there has been a great deal of development of more complex medical devices, many of which have a diagnostic function. Multi-lumen catheters are employed in these devices in applications such as measurement of cardiac output, blood flow, electrolytes and blood gases. Multi-lumen catheters typically have an outside diameter of 3 or 4 mm and may contain up to seven channels. Lumens will normally transmit a fluid or contain a signal carrier, be it an electrical wire or an optical fibre. The fluid lumens need to have a luer connection bonded in place. An electrical or other connection will be required for other types of lumen, but there is still the potential for a leak.

One of the challenges in production is to ensure product safety. This requires leak testing of the joints in each lumen to verify that

- none of the lumens are occluded
- the correct connections have been made to each lumen
- there is no cross-talk between lumens.

The product application is often sufficiently critical to require that every catheter be tested.

Test method

In-house investigation has found the best way to carry out these tests is with electronic pressure decay air testing, which avoids the need to introduce fluids into the clean-room environment. The sensitivity of this method is sufficient for most requirements and the equipment is relatively simple. Pressures of up to 30 bar can be safely employed in the clean room. Alternative test methods include helium gas testing and mass spectroscopy for greater sensitivity, mass flow transducers for quantitative flow measurement, and water injection or observation underwater for lower capital cost.

Points to consider

Air-pressure leak testing is not a rapid process, however, because each lumen has only a small volume, and providing extremely sensitive pressure transducers are used, the test time for each lumen may be only a few seconds. Tooling design can give further time reductions by utilising rapid connection systems for the luers and a process that requires connections to be made only once. An operator can also use the test cycle time to load the next catheter onto a second set of tooling. If a fault condition is found, the test programme should be set to abort immediately to ensure that no time is wasted on unnecessary testing cycles.

The procedure

The requirement is for a leak-test system that can keep pace with production. Connect each lumen to an individual channel on a leak-test machine. Insert the patient end of the catheter into seal tooling. A multi-channel leak-test machine can then apply air pressure to each lumen individually. The sophistication arises in the need to apply pressure to lumens individually and consecutively whilst monitoring the other lumens for pressure changes. This involves the use of several pressure transducers and a software control system.

The seal is a vital part of the system. The catheter is inserted through a hole into a manifold tube. The tube contains rubber rings that seal onto the catheter. A longitudinal compression of the rubber results in an axial expansion, which can seal onto the catheter. A seal is usually required between each eye on the catheter to separate them for signal analysis. The rubber seals may be compressed by a cylinder operated from the leak tester.

Recommended reading

EN ISO 10555, Intravascular Catheters, Parts 1–5.
EN ISO 1618, Catheters other than Intravascular Catheters — Test Method for Common Properties.
EN ISO 1617, Sterile Drainage Catheters and Accessory Devices for Single Use.

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