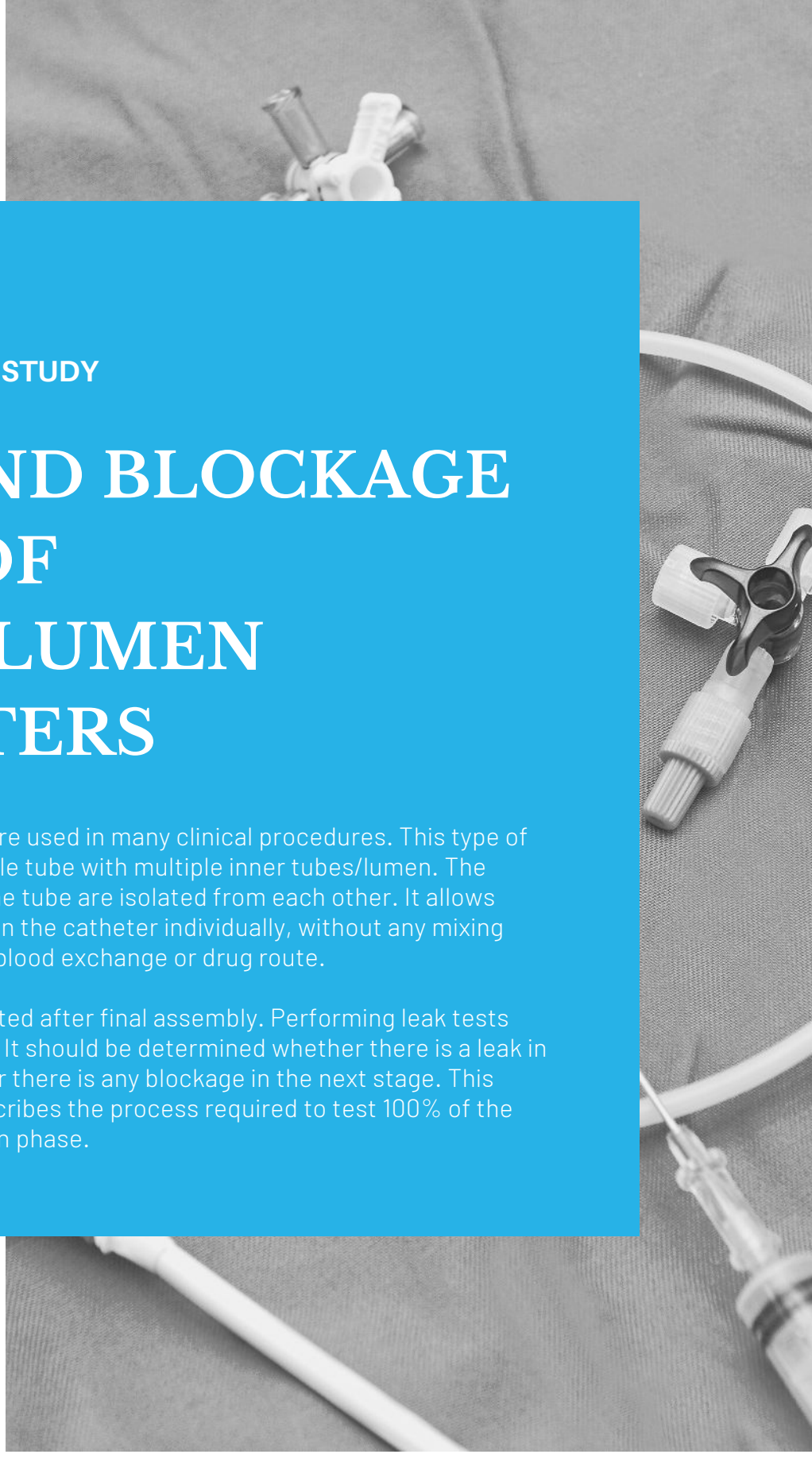


AUGUST 2022 | **CASE STUDY**

LEAK AND BLOCKAGE TESTS OF MULTI-LUMEN CATHETERS

Multi-lumen catheters are used in many clinical procedures. This type of catheter consists of a single tube with multiple inner tubes/lumen. The tubes and lumens inside the tube are isolated from each other. It allows access to the lumens within the catheter individually, without any mixing inside. It can be used as a blood exchange or drug route.

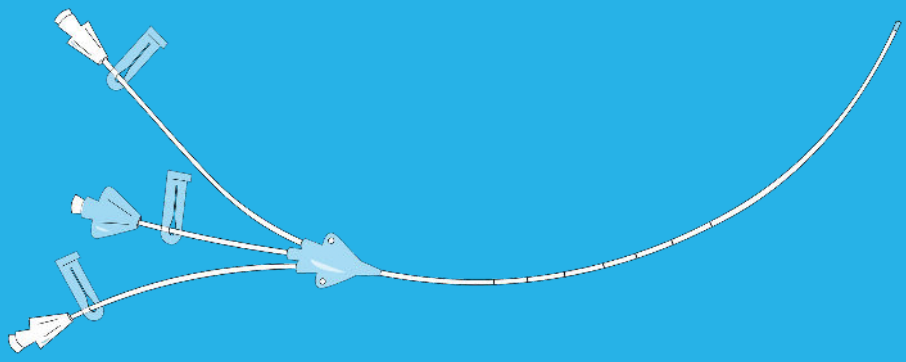
Catheters should be tested after final assembly. Performing leak tests requires a 2-step process. It should be determined whether there is a leak in the first stage and whether there is any blockage in the next stage. This application document describes the process required to test 100% of the parts during the production phase.

ADLEMA

ADVANCED LEAK TESTING MACHINES

Multi-Lumen Catheters

- Central Venous Catheter
- Porta Catheter
- ERCP Catheter
- Dual Lumen PICC Catheter
- Anesthesia Catheter
- Cardiac Catheter
- Epidural and Spinal Catheter
- Diagnostic Catheter



TEST METHODS

The most common test methods for leak tests are the differential pressure decay test with compressed dry air and Helium test equipment. Flow analysis or pressure decay methods can be used for blockage testing. The pressure required for leak testing of most catheters is between 0.36 mBar and 14.3 mBar.

ADLEMA BT4000

1 SEALING THE CATHETER FOR TEST

All female luer connections on the catheter are connected in isolation to the sequential test ports on the Adlema BT4000 series leak testing device. With the Adlema CZ series quick-connectors, all inlets of the catheter are sealed before the test.

The distal/outlet end from a finished catheter is placed inside the Adlema sealing station. All skived holes are closed simultaneously and isolating each lumen from one another and the atmosphere.

2 PRESSURIZATION OF THE LUMEN

Since the leak test works with the pressure decay method, the lumens are pressurized before starting the test.
Adlema BT4000 series leak testing device is measured with a pressure transmitter, in this way, it is checked whether the appropriate pressure is given and whether there are large leaks in the product.

3 STABILIZATION

After the product is pressurized, the valves are closed and the pressure is trapped inside. The stabilization time varies from application to application and is adjusted in consultation with Adlema. The purpose of the stabilization period is to separate the pressure differences that may occur due to possible leakage from the pressure differences that occur due to natural causes. The causes of pressure differences due to natural causes may be the expansion of the product or temperature change, and these pressure changes should be excluded from the parameters that indicate the product is OK or NOK. At this stage, the pressure is measured via the pressure transmitter in the Adlema BT4000 series, and compared with the max/min parameters entered before the test, large leaks can be detected.

4 TEST: DETECTING FINE LEAKS

After the stabilization period is over, the product pressure is measured by the differential method. The measured values are recorded and the maximum leakage rate entered in the test parameters is automatically compared with the maximum total leakage parameters during the test. It is automatically decided whether the part is OK or NOK.

5 POST-TEST

When the test period is over, the remaining air in the lumens is discharged through the Adlema BT4000 series. The test cycle starts again by pressing the start button for the untested catheter. In order to test the leak between the lumens during the test, a leak test is performed on the lumens one by one. In order to test the leak between the inside and outside of the catheter, the air is supplied to all the lumens at the same time and the leak test is performed.

Using Leak Rate to Simplify Testing across Catheter Variations

For manufacturers producing different size catheters, it is reasonable to perform the leak test using the max leakage rate parameter (cc/min). Because the total pressure change during the test depends on the tested volume.
Similarly, when the sizes or lengths of the catheters are different, the amount of stretching is also different. As a result, the total pressure decay may be different even if 2 different catheters leak at the same rate. As a result, it would be a logical method to determine a fixed maximum leakage rate parameter that is valid for all catheters, instead of specifying a separate maximum pressure decay value for all produced catheters. It is advantageous for the user to use the max leakage rate parameter (cc/min). The leakage rate parameter can be applied to an entire product group. After examining the NOK and OK samples and entering the selected maximum leak rate parameter to the device, all of the leaked products can be detected on the production line.

Inspecting for Blockages with Mass Flow

It works in a similar way to pressure testing. When a single lumen is pressurized, it monitors the velocity of the flow in the lumen with high precision. The flow rate will be lower in blocked products. Adlema BT4000 series leak testing devices automatically decide whether the lumen is blocked.

Inspecting for Blockages with Pressure Decay Method

In this method, which is more cost-effective but with lower resolution compared to flow analysis, the product will be pressurized the same as for the leak tests. Since there will be a fixed-size hole at the exit of the tested solid product, it is expected that the product pressure will equalize to the atmospheric pressure within the specified time. In blocked products, this period is longer when the part equalizes to atmospheric pressure. In fully clogged products, the product pressure is not equal to atmospheric pressure. According to the parameters decided before the test, it is decided automatically whether the product is blocked or not.