Solving a Catheter Seal Integrity Challenge with Autocouple Devices

Joe Pustka

Finding the best connections between parts to be leak tested and leak detection equipment is an inherent challenge to leak test system designs. Flat pad surface seals have a potential to mask leakage by holding parts together with leaking seams.

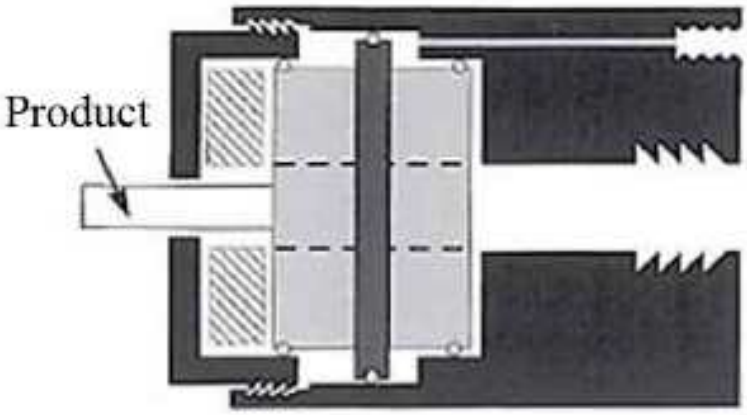
Autocouplers come in an unlimited variety of geometries, all having in common that they affect a seal with a mechanical squeeze process.

Autocouplers that seal catheters at the distal end are a good example of best practice sealing devices for several reasons:

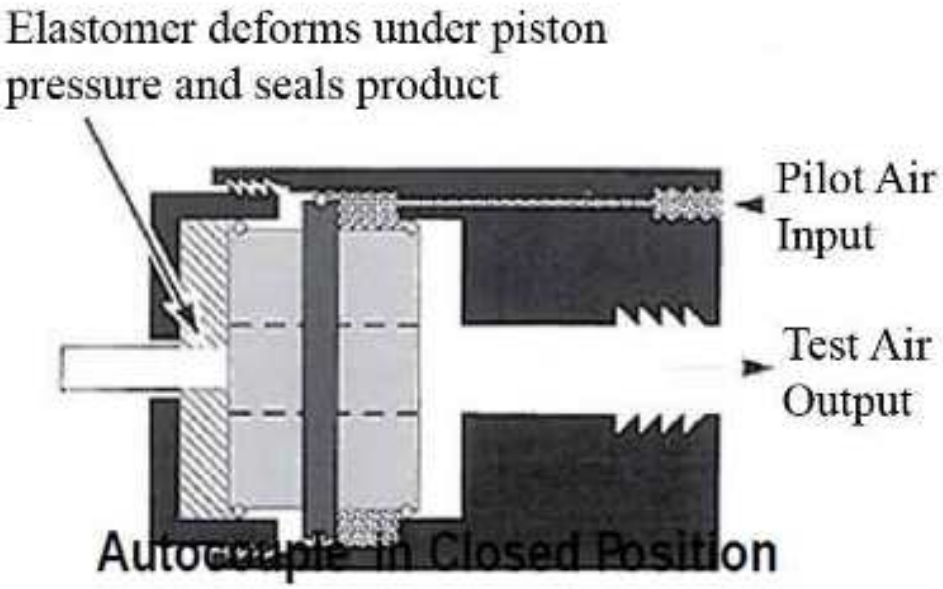
- Operators do not have to twist on and off to make connections between the catheter and the tester. This makes the testing more ergonomic, consistent, and fast.
- Because autocouple seals are activated by air pressure, the leak test

instrumentation can easily control the clamping.
- Diverse sizes and configurations of autocouples are available for both inside and outside sealing.

How an Autocouple Seal Works
The coupling time (i.e., the delay interval before fill and after test time) is input via the leak detector's setup screen. This latches the coupling valve between test intervals to maintain clamp pressure. A separate regulator controls the pilot air supplied to the seal. When the start button is pressed, coupling time begins and clamp pressure is applied to the seal before fill time begins. In this way, test parts are secure before filling with test air. At the conclusion of the test time, clamp pressure stays on for the coupling interval, during which air vents from the product.



Autocouple In Open Position



Autocouple In Closed Position

The sketch showing the autocouple in open and closed position illustrates how the autocouple device works. In this example, a hollow metal piston is inside a hollow chamber. The piston has O-rings at each end and in the center to isolate pilot and test air. Seal material, such as neoprene or urethane, is formed into the shape of a

thick washer. The catheter is inserted through the hole in the seal.

When pilot air is supplied to the autocouple, the piston is forced against the one-piece seal. The elastomeric seal deforms under pressure and presses against the product to generate a leak-tight closure. Clamping is regulated by the level of pilot air delivered to the autocouple.

In this catheter example, the autocouple device is an “outside diameter” model. One could also use inside diameter clamping, as well as clamp around square, hexagonal, or other shapes. Although catheters generally do not present this challenge, an autocouple sealing solution can also be applied to rough or irregular surfaces.

When required, the autocouple device disassembles quickly for seal and O-ring replacement by backing out a set screw and unscrewing the nose from the body section.

Is the autocouple device a unique fixture for leak testing catheters? Absolutely not. Autocouples operated in this manner are usually the sealing fixture of choice for leak testing any product that is relatively small (i.e., under six inches in diameter) and fairly uniform. Any medical device or product that is like a catheter in that it has small diameter, smooth wall tubing is a natural fit for this type sealing fixture. Other devices and parts that are usually good fits for autocouples used for sealing include ones that have: threaded and smooth pipe; internal and external threads; barbed plastic and metal fittings; expanded or flared end fittings; smooth holes in metal or plastic; threaded holes in metal or plastic; and medical luer and luer-lock fittings.

Autocouple fixtures for seal integrity can be used with the full gamut of leak detectors—from pressure decay, differential pressure decay, mass flow, or tracer gas leak testing. They can and are used with leak detectors with built-in circuits that automatically switch leak tests from one side of a part to another or with leak detection equipment optimized for multiple test pressure requirements. They are not the usual seal integrity fixtures recommended for leak detection equipment including high flow valves capable of filling large volumes quickly.

Buyers Beware

Leak detector manufacturers that do not include detailed consideration and specifications for test fixtures as part of their response to your leak detector RFP are not giving your application the detailed consideration it requires. Fixture design consideration should always be incorporated into up-front quotes. A long track record of developing leak testing solutions for medical device applications of all kinds enables experienced providers of leak test systems to quickly specify best-match fixtures for an application. In most cases, detailed specifications for leak detection equipment, including recommended fixtures, should only take 48 hours.

Joe Pustka is the Medical Device Leak Testing Technical Support Manager for Uson *[1], which first developed high accuracy leak testing methods for NASA, and since 1963 has been at the forefront of* leak detection *[2], leak testing, and non-destructive testing for the medical device and medical packaging industries, among*

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