PRODUCT SHOWCASE: ZwickRoell Luer Lock Testing System

REVISIONS TO ISO 80369

With a new series of ISO 80369 standards for Luer lock testing pending release, the industry will soon face changes to the design of these small-bore tubing connectors worldwide. The existing standards, ISO 594-1 and ISO 594-2, published in the 1980s, have become insufficient due to the rising risk of inadvertent misconnection by healthcare providers, which has resulted in patients suffering injury and even death.

To address the need for dimensionally unique connectors for different applications, an initiative was started by the European Committee for Standardization (CEN) in the late 1990s, which resulted in the first version of ISO 80369 in 2015.

Yet, this version of ISO 80369 makes complete compliance with device requirements difficult, most notably in the tolerance of the thread pitch, which is too tight for any supplier to measure. These issues were recognised and a new version of ISO 80369, sent for review in October 2019, is pending release after a typical approval process of 12 months. The ISO 80369 standard is valid for different application types, going by section (Table 1).

ISO 80369 Annex	Scope of Application
-1	General requirements
-2	Connectors for breathing systems and driving gases applications
-3	Connectors for enteral applications
-4	Connectors for urethral and urological applications
-5	Connectors for limb cuff inflation applications
-6	Connectors for neuraxial applications
-7	Connectors for intravascular or hypodermic applications
-20	Common test methods

Table 1: Scope of the relevant sections of ISO 80369 to Luer lock testing.

The general requirements for small-bore connectors for liquids and gases in healthcare applications are covered in Section 1. Sections 2-7 describe the detailed mechanical and leakage tests for the various applications. Section 20 and its annexes describe the common test methods used to evaluate performance requirements.

THE NEED FOR A RELIABLE TESTING SOLUTION TO ENSURE DATA INTEGRITY

Historically, assembly, mechanical test sequences and tests for leakage and pressure have been performed separately. This meant companies needed a separate testing solution for each set of tests, often having to source them from two different vendors. With multiple systems and users in play, obtaining reliable test results was a challenge.

Recently, manufacturers of connector systems, as well as pharmaceutical companies and their contract partners, have turned to ZwickRoell for a comprehensive testing system that minimises errors and improves data integrity and repeatability. ZwickRoell has developed a solution based on the single-column zwickiLine testing machine, which features a superimposed torsion drive to handle the assembly process

ENVIRONMENTAL PROTECTION, SUSTAINABILITY AND SOCIAL RESPONSIBILITY AT ZWICKROELL

Thinking and acting sustainably is of fundamental importance for a future-oriented company. ZwickRoell is committed to harmonising economic success, environmental protection and social responsibility for people in need.

Since 2014, all the company's production has been CO_2 neutral. In 2019, ZwickRoell offset more than five tons of CO_2 emissions. The company proudly supports underprivileged youth in India through its local training academy. In its annual ZwickRoell Runs the World charity challenge, employees and customers run together for a good cause. To date, this event has raised over €100,000 (£92,464) for charitable purposes.

ZwickRoell is also leading the way in terms of machines and processes. The company modernises its own machines, as well as those of other manufacturers, to extend their time in operation and achieve better ecological balance.

of the connectors. The solution also includes an integrated air pressure system with the capability to handle both positive and sub-atmospheric pressures.

The zwickiLine testing machine controls all process parameters, including the integrated air pressure system, allowing the system to perform the complete test method, from assembly to the mechanical and leakage test, required by ISO 80369 Annex 20 (Figure 1). This ultimately saves time and money in an area of healthcare that is critical to the safety of patients.

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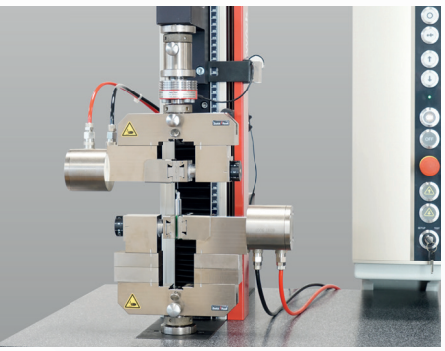
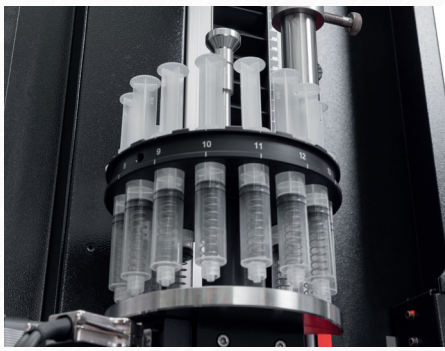
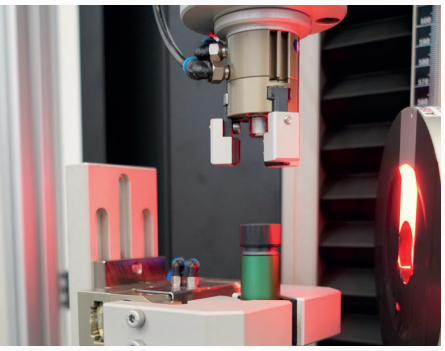
Figure 1: Luer lock testing in accordance with ISO 80369, as performed on a zwickiLine testing machine with testXpert testing software. The zwickiLine fulfills the requirements set out by the US FDA in 21 CFR Part 11.

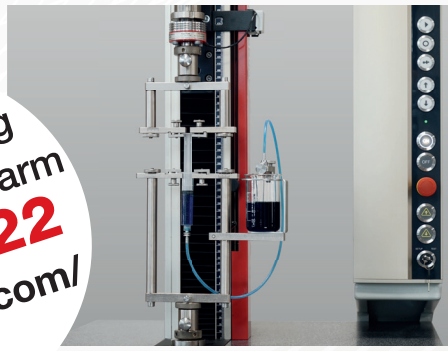
Testing systems

for the medical and pharmaceutical industry









Virtual Testing Forum MedPharm
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- Manual, semi-automatic and fully automated testing solutions for therapy systems (needles, (pre-filled) syringes, insulin pens, auto injectors)
- Traceable and tamper-proof test results in accordance with FDA 21 CFR Part 11
- ZwickRoell supports customers with DQ, IQ and OQ services

What is your testing challenge?

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