DDL®

Testing experts.
Service specialists.

ISO 80369-7: Changing the Standard for Luer Connectors

On October 14, 2016, ISO formally published 80369 Part 7, the long-awaited replacement to everyone's familiar friend, ISO 594, the standard governing dimensions and performance requirements of Luer connectors. The publication caps a monumental change in the fundamental thinking surrounding devices that transfer liquids and gases in healthcare settings. Despite the Technical Committee's desire to disrupt as little as possible surrounding the current practices with Luer connectors, ISO 80369-7 still makes many significant changes.

In this paper, I'll highlight the changes that most significantly affect how one should construct their design verification plan, which are:

- stricter requirements on dimensional and mechanical specifications,
- testing against slip and lock reference connectors,
- modifications to assembly and test procedures, and
- addition of guidance for performance of variable tests.

As should be expected with changes of this magnitude, there are many nuances in the new standard that require some interpretation. At DDL, we have had the opportunity to work with members of the ISO Technical Committee and many industry partners to interpret these changes.

Stricter Requirements on Dimensional and Mechanical Specifications

Prior to the implementation of ISO 80369-7, the ubiquitous use of Luer connectors made it possible for two incompatible devices to be accidentally connected, which could lead to patient injury. The principal goal of ISO 80369 is to reduce the likelihood of these adverse events by introducing unique connector designs for different medical applications whose geometry makes it extremely difficult to make these harmful connections. One consequence of using the geometry of the connectors to preclude misconnections is that the connectors now need to be measured to ensure that they meet the dimensions and tolerances of the prints in the standard. This differs dramatically from ISO 594, where as long as connector performance could be proven against a reference standard, the dimensions of the connector largely did not need to precisely match the standard. This is by far the most burdensome new requirement resulting from the standards change and many of our clients are incredulous to learn that their thread design that has performed adequately must now be changed.

In addition to stricter dimensional requirements, there are also new restrictions on what materials may be used to construct Luer connectors. The elastic modulus of the materials must be greater than 700 MPa when tested in either tension or flexure per standard ASTM methods. Some polymers commonly used as Luer connectors do not meet this requirement, including many polyethylenes.

Testing Against Slip and Lock Reference Connectors – When is it Required?

The separation of ISO 594-1 for slip Luers and 594-2 for locking Luers created a convenient distinction between their separate requirements, but also a lack of clarity about if and when both sets of tests needed to be performed. ISO 80369-7 contains both requirements within the same document, but is still not explicit about when one should invoke the tests against both slip and lock reference connectors. This is an important consideration when qualifying a female locking Luer, as both male slip and locking Luers can easily be connected. The simplest answer is that if a device with a female locking Luer is intended to connect with a specific device that has a male locking Luer, then the female locking Luer only needs to be tested against the male locking reference connector. If the device's use is not as specific, or if it's uncertain, then both sets of requirements are in play.

The table below lists the test requirements for each possible configuration.

Test Piece Type	Reference Connector Type	ISO 80369-7 TEST					
		Fluid Leakage		Stress Cracking	Resistance to Separation from Axial Load	Resistance to Separation from Unscrewing	Resistance to Overriding
Male Locking Luer	Female Locking Luer	X	X	X	X	X	X
Male Slip Luer	Female Slip Luer	X	X	X	X		
Female Locking Luer	Male Locking Luer	X	X	X	X	X	X
	Male Slip Luer	X(*)	X(*,^)	X(*,^)	X(*)		
Female Slip Luer	Male Slip Luer	X	X	X	X		

The tests with a (*) are only required if the female locking Luer under test isn't specifically indicated for use with a male Luer lock device. In addition, the tests with a (^) can be omitted through a worst-case analysis and justification. In our discussions with representatives from the ISO Technical Committee responsible for ISO 80369-7, we were able to conclude that in certain circumstances, a rigorous examination of each test could lead to a determination of a worst-case configuration.

Modifications to Assembly and Test Procedures

One of the critical elements of ISO 594 was a standardization of the torque and axial force used to assemble a test sample to a reference connector. ISO 80369-20, which is the standard that defines how to conduct the test methods, narrows the range of acceptable torque and axial force, utilizes the same assembly values for every test and clarifies the assembly procedure for products with floating or rotatable collars.

The following table outlines the assembly parameters of ISO 594 and 80369.

Test Standard	Test Method	Assembly Parameters	
		Axial Force (N)	Torque (N·m)
ISO 594-1	All	27.5	≤0.1
SO 594-2	Leakage, Separation Force, Unscrewing Torque, Resistance to Overriding	≤27.5	≤0.12
	Ease of Assembly	≤20	≤0.08
	Stress Cracking	≥27.5	≥0.12
ISO 80369-7	Slip Connectors	26.5≤x≤27.5	0.8≤x≤0.10
	Lock Connectors	26.5≤x≤27.5	0.8≤x≤0.12

In addition to changes in the assembly parameters, many of the tests have changed substantially as well; titles and test parameters have been modified, new tests have been added, and the ease of assembly test was eliminated because of its subjectivity. The following table compares and contrasts some of the most significant changes to each test.

The following table outlines the assembly parameters of ISO 594 and 80369.

ISO 594 Test	ISO 80369-7 Test Equivalent	COMMENTS
Liquid Leakage	Leakage by Pressure Decay	This is a new test which utilizes a pressure decay leak tester in order to determine the pressure decay rate of the connection using air as the medium. The fluid leakage requirement in ISO 80369 is satisfied by performing either this test or the falling drop positive pressure liquid leakage test.
	Falling Drop Positive Pressure Liquid Leakage	The ISO 80369 test resembles the ISO 594 test without significant changes to the method.
Air Leakage	Sub-Atmospheric Pressure Air Leakage	Rather than pulling a vacuum using a syringe and monitoring for formation of bubbles, ISO 80369 specifies the vacuum pressure applied to the connectors and the rate of pressure loss is recorded. Use of a pressure decay leak tester is preferred for this test.
	Separation Force	There aren't significant changes to the method; however, the acceptance criterion is more specific in ISO 80369, which specifies that the interface between the connectors should not detach.
Unscrewing Torque	Resistance to Separation from Unscrewing	The ISO 80369 test resembles the ISO 594 test without significant changes to the method.
Ease of Assembly	None	The ease of assembly test was not included in ISO 80369 because the analysis was too dependent upon test operator subjectivity.
Resistance to Overriding	Resistance to Overriding	The ISO 80369 test resembles the ISO 594 test without significant changes to the method.
Stress Cracking	Stress Cracking	The stress cracking preconditioning has not changed significantly; however, the method of detecting cracks has changed. In ISO 594, a visual inspection was performed. In ISO 80369, one the two fluid leakage tests is performed in order to reduce the subjectivity of the test.

Addition of Guidance for Performance of Variable Tests

Annex J in ISO 80369-20 contains specific instructions and guidance on how each test can be modified in order to obtain data of a variable (numerical) type, which may help to reduce the sample size needed in order to achieve the desired confidence intervals. For some tests, e.g. sub-atmospheric pressure air leakage, the change is trivial, only requiring one or two additional calculation steps. For others, like the positive pressure falling drop liquid leakage test, the apparatus used to perform the variable test method requires additional levels of control beyond what is needed to perform the attribute test method. The determination of whether or not to utilize the variable methods is typically made on a case-by-case basis and takes into account the potential extra test method validation work, fixturing and increased cost for tests which require more time and complex equipment to perform.

Closing Caveats

On December 23rd, 2016, the FDA added ISO 80369-7 to its list of recognized consensus standards. The FDA website states that the Agency will continue to accept declaration of conformity to ISO 594 in support of premarket submissions until December 31st, 2019. The FDA has since extended the deadline and will issue a new deadline for conformity when version 2 of ISO 80369-7 is released in 2020. DDL will continue to offer testing to both ISO 594 and 80369 to meet the needs of our customers.

Finally, this paper is intended to give a high-level overview of the differences between ISO 594 and 80369-7 and is not intended to be a substitute for a comprehensive understanding of the contents of the standards and how it may affect design and testing. We at DDL always welcome an opportunity to discuss the nuances of the standards in greater detail, so don't hesitate to contact us if you have any lingering questions or would like to discuss an upcoming project.

DDL®
Testing experts.
Service specialists.

REQUEST A QUOTE OR MEET WITH OUR TESTING EXPERTS!

DDL Headquarters
10200 Valley View Road
Eden Prairie, MN 55344
United States (US)
Phone: 952-941-9226
Fax: 952-941-9318

DDL West
9400 Toledo Way
Irvine, CA 92618
United States (US)
Phone: 714-979-1712
Fax: 714-979-1721

DDL – NJ
551 Raritan Center Parkway
Edison, NJ 08837
Phone: 732-346-9200
Fax: 732-346-0295

DDLTesting.com

DDL is a third party testing facility offering full service package product and materials testing in its Eden Prairie, MN and Irvine, CA lab locations. Both facilities are ISO/IEC 17025 accredited and ISTA Certified. The Edison, NJ lab is currently ISO 9001: 2015 and ISTA certified with plans to become ISO 17025 accredited under DDL's quality system in 2020.