

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

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

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

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	Resistance to Separation from Axial Load	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.